Statistical Analysis Plan

jCyte, Inc.

Protocol JC-01

A Prospective, Multicenter, Open-Label, Single-Arm Study of the Safety and Tolerability of a Single, Intravitreal Injection of Human Retinal Progenitor Cells (jCell) in Adult Subjects with Retinitis Pigmentosa (RP)

Protocol Version: Amendment 6 (July 07, 2016)

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Version	Date
Final V1.0	**19 Jul2017**
Final V2.0	**08Nov2017**

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.

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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
cm	Centimeter(s)
CRF	Case Report Form
CS	Clinically Significant
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
DDT	Dictionary Derived Term
ECG	Electrocardiogram
E-ETDRS	Electronic Early Treatment for Diabetic Retinopathy Study
ERG	Electroretinogram
EZ	Ellipsoid Zone
hRPC	Human Retinal Progenitor Cells
ICH	International Conference on Harmonization
in	Inch(es)
ITT	Intent-to-Treat
kg	kilogram(s)
msec	Millisecond
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)
PT	Preferred Term
QTc	Corrected QT Interval
QTcB	Corrected QT Interval According to Bazett's formula
QTcF	Corrected QT Interval According to Fridericia's formula

LIST OF ABBREVIATIONS (continued)

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-25	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	All subjects who enroll in the study and who provide any post-screening data
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 with an onset time after the initial dose of study drug.

1. INTRODUCTION

This document outlines the statistical methods to be implemented during the analyses of data collected within the scope of jCyte Protocol JC-01 [A Prospective, Multicenter, Open-Label, Single -Arm Study of the Safety and Tolerability of a Single, 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).

2. STUDY OBJECTIVES

2.1 Primary Objective

The primary objective is to evaluate the safety and tolerability of jCell injection in adult subjects with non-syndromic RP.

2.2 Secondary Objective

The secondary objectives of the study are to monitor ocular function over a 12 month period following a single injection of hRPC (jCell) to evaluate the potential therapeutic response in subjects with RP.

3. STUDY DESIGN AND PLAN

This is a prospective, multicenter, open-label, single-arm, Phase I/II trial of human retinal progenitor cells (jCell) for the treatment of retinitis pigmentosa (RP). Study subjects will be screened for eligibility, informed consent obtained, baseline studies of primary and exploratory endpoints performed. Then the subjects will be treated with one of four doses of jCell, with initially enrolled subjects receiving the lowest dose.

Cohort 1: BCVA no better than 20/200 and no worse than Hand Motions

The first four subjects in Cohort 1 will receive an intravitreal injection of 0.5×10^6 hRPC (50 µL volume) into the eye with the worst visual acuity; only one eye will be injected. Subjects will be monitored closely following injection for 60 minutes prior to being released home on the day of treatment, based on intraocular pressure <30mm Hg and vital signs returned to pre-injection. Subjects will be treated with ophthalmic corticosteroid eye drops to minimize any inflammation from injection for up to 14 days (including tapering schedule). There will be a minimum four week interval between the

treatment of the first and second subjects in this cohort to confirm no serious injection related AEs have occurred for subject #1 prior to treatment of subject #2. Subsequent cohort 1 subjects at the same dose level will be spaced at least one week apart (subjects 2, 3 and 4). All subjects will receive injection of cells into the eye with the poorest visual acuity. Following at least one week of safety observations for the last study subject at the lower dose level, safety and tolerability data will be reviewed by the DSMB.

Assuming no unexpected safety issues, an additional 4 subjects will be enrolled in Cohort 1 and treated at the second dose level, 1.0 x 10^6 hRPC. Treatment will be similar to the first four subjects, i.e. intravitreal injection under topical anesthesia with treatment of the first two subjects separated by at least 4 weeks and subsequent subjects in this cohort (subject 6, 7 and 8) spaced at least one week apart. Following at least one week of safety observation for the last Cohort 1 subject, safety and tolerability data will be reviewed by the DSMB prior to initiation of Cohort 2.

Following completion of DSMB review of the first 8 subjects in Cohort 1 (dose levels 0.5 x 10^6 and 1x 10^6 hRPC), an additional three subjects may be enrolled into Cohort 1 and treated at the third dose level, 2 x 10^6 hRPC (50µL volume). Treatment will be administered as described above for the first two dose levels, with all subjects spaced at least a week apart. Following at least one week of safety observations for the last study subject at the 2 x 10^6 hRPC dose level, safety and tolerability data will be reviewed by the DSMB. Assuming no unexpected safety issues and with DSMB recommendation, an additional 3 subjects may be enrolled into Cohort 1 for treatment at the highest dose level, 3.0 x 10^6 hRPC (50 µL volume). Treatment will be administered as described above for the first two dose levels, with all subjects spaced at least a week apart.

Cohort 2: BCVA no better than 20/40 and no worse than 20/200

The first four subjects in Cohort 2 will receive an intravitreal injection of 0.5 x 10^6 hRPC into the eye with the worst visual acuity; only one eye will be injected. Subjects will be monitored closely following injection for 60 minutes prior to being released home on the day of treatment, based on intraocular pressure <30mm Hg and vital signs returned to pre-injection. Subjects will be treated with ophthalmic corticosteroid eye drops to minimize any inflammation from injection for up to 14 days (including tapering schedule). Assuming no unexpected safety issues in the low dose group, an additional 4 subjects will be enrolled in Cohort 2 and treated at the second dose level, 1.0 x 10^6 hRPC.

Once the first two dose levels are completed in Cohort 2, and following the review of safety data from Cohort 1 subjects who were treated at the third dose level (2.0 x 10^6 hRPC), three additional subjects may be enrolled into Cohort 2 and treated at the 2 x 10^6

hRPC dose level. Following this and assuming no unexpected safety issues in the Cohort 1 subjects at the 3 x 10^6 dose level, three additional subjects may be enrolled into Cohort 2 and treated at this highest dose level.

Assuming safety and tolerability data from all dose levels in Cohort 1 are acceptable, there will be no minimum interval between treatment of subjects in Cohort 2.

If ≥2 subjects develop the same CTCAE grade 3 adverse events or 1 subject develops a CTCAE grade 4 adverse events, the study will be suspended until the DSMB reviews the events and makes a determination whether to continue. If a Grade 3 or worse event is clearly attributable to a non-treatment event and therefore not a suspected adverse reaction, the event will not be considered for the purposes of stopping.

The schedule of observations and assessments during the study are summarized in Table 2 of the study protocol.

4. DETERMINATION OF SAMPLE SIZE

The sample size for this study was not based on any formal statistical considerations.

5. GENERAL ANALYSIS CONSIDERATIONS

The statistical analyses will be reported using summary tables and listings (TLs). The International Conference on Harmonization (ICH) numbering convention will be used for all TLs. 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 cohort and dose level. Baseline summaries will also include a total summary column. Unless otherwise noted, 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.

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 received any amount of study drug.

The following subject population will be used for efficacy analyses:

- Intent-to-Treat (ITT) population will include all subjects enrolled and who provide any post-screening data. Subjects in the clinical database will be considered to be enrolled in the study.

7. STUDY POPULATION

7.1 Subject Disposition

Subject disposition information will be summarized for all subjects by cohort and dose level. 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 cohort, 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) will be summarized for each treatment by primary System organ class and dictionary-derived term by using MedDRA 18.1. These summaries will present the number and percentage of subjects per each OMH. Subjects may have more than one OMH per System Organ Class (SOC) and Dictionary Derived Term (DDT). At each level of subject summarization, a subject is counted once if he/she reported one or more OMH at that level. Each summary will be ordered by descending order of incidence of SOC and DDT within each SOC.

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, 2015).

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 letter missed using E-ETDRS will be recorded for each eye and recorded on the Best Corrected Visual Acuity (BCVA) case report form.

- Electroretinogram (ERG): For each eye, A-wave Amplitude, B-wave Amplitude, Time from Flash Onset to A-wave Trough and Time from Flash Onset B-wave peak will be measured under the following conditions:
  - Dark adapted 0.01 ERG (rod response)
  - Dark adapted 3.0 ERG (rod-cone response)
  - Light adapted 3.0 ERG (single flash cone response)
  - Light adapted 3.0 flicker ERG

  In addition, an overall assessment of Normal or Abnormal will be recorded for each condition. For those assessments of Abnormal, whether the assessment was Clinically Significant will also be reported. If Clinically Significant value is not reported in the follow-up visit, then the value will be imputed based on the value of previous visit, consistent with CRF completion guidelines. For example, if abnormal change from previous visit is “NO” then imputed value will be value from the previous visit.

- Optical Coherence Tomography (OCT): for assessment of OCT, the central subfield thickness reported on the Optical Coherence Tomography case report

form will be used. Also information recorded at each visit as to whether Cystoid macular edema (CME) was present and if so, did it involve the foveal center will also be considered.

- Fluorescein Angiography: information regarding active leakage (Yes/No) and ischemia (Yes/No) will be collected for each eye for each Fluorescein Angiography performed.

- Autofluorescence: an overall assessment of Normal or Abnormal will be recorded for each eye for each fundus auto fluorescence imaging performed. For those assessments of Abnormal, whether the assessment was Clinically Significant will also be reported. If Clinically Significant value is not reported in the follow-up visit, then the value will be imputed based on the value of previous visit, consistent with CRF completion guidelines. For example, if abnormal change from previous visit is "NO" then imputed value will be value from the previous visit.

- Visual Field Test: an overall assessment of Normal or Abnormal will be recorded for each eye for each visual field examination performed. For those assessments of Abnormal, whether the assessment was Clinically Significant will also be reported. In addition, information regarding Mean Deviation, Fixation Loss, False Positives and False Negatives will also be recorded. If Clinically Significant value is not reported in the follow-up visit, then the value will be imputed based on the value of previous visit, consistent with CRF completion guidelines. For example, if abnormal change from previous visit is "NO" then imputed value will be value from the previous visit.

8.2 Baseline Values

Unless otherwise noted, baseline is defined as the value obtained at 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.

8.3 Handling of Dropouts or Missing Data

No imputations will be made for missing values. Summaries will be based on observed data only.

8.4 Interim Analysis and Data Monitoring

There are no planned interim analyses for this study.

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

Since this is an exploratory study, no formal hypothesis testing will be done. Descriptive statistics will be used to tabulate and summarize study outcomes. The baseline results of clinical examinations of the non-injected (non-study) eye serve as controls for the injected (study) eye. Results of clinical testing of the non-injected eye will also be described. 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 cohort and dose level using summary statistics.

9.1 Best Corrected Visual Acuity (BCVA)

For BCVA, summary statistics of the total number of letters correct (Letters correct=100-letters missed) will be generated at each time point for each cohort. 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 individual subjects who have number scores, the same formula for letters correct will be used to calculate each time point (letters correct = 100-letters missed). 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. summarized (i) proportion of treated eyes with ≥5, ≥10 and ≥15 letter

improvements at any timepoint in the study same for untreated eyes at month 3,6,9 and 12 or Early Termination.

In addition, change in BCVA from baseline will be summarized for each dose level combining cohorts 1 and 2 at month 3,6,9 and 12 or early termination. Difference of mean change in BCVA between treated eye and non-treated eye from baseline will be summarized at month 3,6,9 and 12 or early termination. Furthermore, proportion of ≥5, ≥10 and ≥15 letter improvements will be summarized for each dose level combining cohorts 1 and 2 at month 3,6,9 and 12 or early termination.

9.2 Electroretinogram (ERG)

Electroretinogram (ERG) results will be summarized using both continuous and categorical methods. Descriptive statistics by eye (Study, Non-Study) of A-wave Amplitude, B-wave Amplitude, Time from Flash Onset to A-wave Trough and Time from Flash Onset B-wave peak endpoints will be calculated for each time point and condition specified in Section 8.1. Summaries of change from baseline will be presented in a similar fashion. In addition, count and percentages of overall ERG assessments of the following categories will be shown for each time point, eye (Study, Non-Study) and condition specified in Section 8.1:

- Normal
- Abnormal, Not Clinically Significant (NCS)
- Abnormal, Clinically Significant (CS)

9.3 Visual Field Examination

From the visual field examination, whether the results are Normal, Abnormal NCS and Abnormal CS will be summarized with counts and percentages at each time point for both study eye and non- study eye.

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 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 were there any AEs observed, were the subject's vital signs comparable to pre-treatment of study drug injection, was the subject's IOP measurement less than 30 mm post treatment of study drug injection and was the subject 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 18.1).

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 one or more events. 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

one or more events. 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 , serum chemistry and coagulation laboratory parameters will be summarized using descriptive statistics at baseline, Day 7, Day 28, Month 3, Month 6, and Month 12/Early Term. Change from baseline in the laboratory parameters will also be presented, Unless otherwise noted, 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.

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 and ECG interpretation 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. 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.

10.5 Physical Examination

Physical examination results will be included in data listings only.

10.6 Electrocardiogram

ECG parameters will be presented in a listing..

10.7 Ophthalmic AEs

10.7.1 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, subjects will be tabulated by the categories of Normal and Abnormal NCS and Abnormal CS. Results will be presented for each of subjects' eyes (study eye and non-study eye) at all time points.

If Clinically Significant value is not reported in the follow-up visit, then the value will be imputed based on the value of previous visit, consistent with CRF completion guidelines. For example, if abnormal change from previous visit is "NO" then imputed value will be value from the previous visit.

10.7.2 Intraocular Pressure (IOP)

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

10.7.3 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. If Clinically Significant value is not reported in the follow-up visit, then the value will be imputed based on the value of previous visit, consistent with CRF completion guidelines. For example, if abnormal change from previous visit is "NO" then imputed value will be value from the previous visit.

10.7.4 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. If Clinically Significant value is not reported in the follow-up visit, then the value will be imputed based on the value of previous visit, consistent with CRF completion guidelines. For example, if abnormal change from previous visit is "NO" then imputed value will be value from the previous visit.

10.7.5 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).

10.7.6 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.

10.7.7 Fluorescein Angiography

For fluorescein angiography analysis, the number of subjects whose eyes (both study and non-study eye) have active leakage or show signs of ischemia at each time point will be shown by frequency and corresponding percentages.

10.7.8 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, Abnormal CS

11. REFERENCES

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

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.

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 whose counts are zero will be displayed for the sake of completeness. For example, if none of the subjects discontinue due to “lost to follow-up,” this reason will be included in the table with a count of 0. Categories with zero counts will not have zero percentages 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 a SAS date (e.g., 29AUG2001) 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 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.

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Appendix C: Table Layouts

Table 14.1.1
Subject Disposition
All Enrolled Subjects

	Cohort 1				Cohort 2				
	0.5×10^6 hRPC	1.0×10^6 hRPC	2.0×10^6 hRPC	3.0×10^6 hRPC	0.5×10^6 hRPC	1.0×10^6 hRPC	2.0×10^6 hRPC	3.0×10^6 hRPC	Total [1]
Subjects Enrolled	N	N	N	N	N	N	N	N	N
ITT Population [2]	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Safety Population [3]	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Primary Reason for Discontinuation									
Completed Study	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Adverse Event	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Lack of Efficacy	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Lost to Follow Up	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Non-Compliance with Study Treatment	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Physician Decision	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pregnancy	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Progressive Disease	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Protocol Deviation	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Recovery	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Study Terminated by Sponsor	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Withdrawn by Subject	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Death	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
[2] All enrolled subjects who provide any post-screening data.
[3] Received any amount of jCyte treatment.
Note: Percentages based on Subjects Enrolled.
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Programmer Note: only shows primary reason for Discontinuation that has results.

Table 14.1.2
Demographic and Baseline Characteristics
Safety/ITT Population

	Cohort 1				Cohort 2				
	0.5 x 10^6 hRPC (N=)	1.0 x 10^6 hRPC (N=)	2.0 x 10^6 hRPC (N=)	3.0 x 10^6 hRPC (N=)	0.5 x 10^6 hRPC (N=)	1.0 x 10^6 hRPC (N=)	2.0 x 10^6 hRPC (N=)	3.0 x 10^6 hRPC (N=)	Total [1] (N=)
Age (years) [2]									
n	n	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Sex									
Male	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Ethnicity									
Hispanic or Latino	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Not Hispanic or Latino	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Race									
American Indian or Alaska Native	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Asian	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Black or African American	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Native Hawaiian or Other Pacific Islander	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
White	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Multiple Races Checked	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
[2] Age determined by comparing date of birth to date of informed consent.
[3] 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.
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Table 14.1.2
Demographics and Baseline Characteristics
Safety/ITT Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	…..	0.5 x 10^6 hRPC (N=)	….	Total [1] (N=)
Study Eye					
OD (Right)	n (%)	n (%)	n (%)	n (%)	n (%)
OS (Left)	n (%)	n (%)	n (%)	n (%)	n (%)
Height (cm) [3]					
n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Weight (kg) [3]					
n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

[1] Total includes both Cohorts 1 and 2.
[2] Age determined by comparing date of birth to date of informed consent.
[3] 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.
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Programmer note: For the subsequent tables, use Table 14.1.2 to determine which columns to include.

Table 14.1.3
Ocular Medical History
Safety/ITT Population

Ocular System Organ Class// Dictionary Derived Term	Cohort 1		Cohort 2		Total [1]
	0.5 x 10^6 hRPC (N=)	…	0.5 x 10^6 hRPC (N=)	….	(N=)
Congenital, Familial and Genetic Disorders Dictionary Derived Term					
Eye Disorders Dictionary Derived Term	n (%)	n (%)	n (%)	n (%)	n (%)
Nervous System Disorders Dictionary Derived Term	n (%)	n (%)	n (%)	n (%)	n (%)
Surgical Medical Procedures Dictionary Derived Term	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
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Programmer Note: add all SOC and PT terms from xmh1 dataset..
Programmer Note:sort table by Alphabetical SOC order.

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

	Cohort 1		Cohort 2		
	0.5×10^6 hRPC (N=)	……	0.5×10^6 hRPC (N=)	…..	Total [1] (N=)
Baseline [2]					
n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 1					
n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 1 Change from Baseline					
n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 2					
n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
…	…	…	…	…	…

[1] Total includes both Cohorts 1 and 2.
[2] 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.
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Programmer Note: Continue table for Visits: Day 3, Day 7, Day14, Day 21, Day 28, Month 2, Month 3, Month 4, Month 5, Month 6, Month 9, Month 12 or Early Term.
Programmer Note: Table 14.2.1.2 will contain the same information for the Non-Study Eye
.

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

	Cohort 1		Cohort 2		
	0.5×10^6 hRPC (N=)	……	0.5×10^6 hRPC (N=)	…..	Total [1] (N=)
Proportion of Subjects with Specified increase in letters correct for any Post Baseline Assessment	(n=)	(n=)	(n=)	(n=)	(n=)
>=5 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
>=10 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
>=15 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
Proportion of Subjects with Specified increase in letters correct at Month 3	(n=)	(n=)	(n=)	(n=)	(n=)
>=5 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
>=10 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
>=15 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
Proportion of Subjects with Specified increase in letters correct at Month 6	(n=)	(n=)	(n=)	(n=)	(n=)
>=5 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
>=10 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
>=15 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
Proportion of Subjects with Specified increase in letters correct at Month 9	(n=)	(n=)	(n=)	(n=)	(n=)
>=5 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
>=10 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
>=15 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
Proportion of Subjects with Specified increase in letters correct at Month 12 or Eartly Termination	(n=)	(n=)	(n=)	(n=)	(n=)
>=5 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
>=10 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)
>=15 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
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Programmer Note: Table 14.2.1.4 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 14.2.1.5
Best Corrected Visual Acuity (ETDRS): Study Eye vs Non-Study Eye
Number of Letters correct
ITT Population

	0.5 x 10^6 hRPC		1.0 x 10^6 hRPC		2.0 x 10^6 hRPC		3.0x 10^6 hRPC	
	Study Eye (N=)	Non-Study Eye (N=)	Study Eye (N=)	Non-Study Eye (N=)	Study Eye (N=)	Non-Study Eye (N=)	Study Eye (N=)	Non-Study Eye (N=)
Baseline [1]								
n	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Month 3								
n	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Month 3 Change from Baseline								
n	n	n	n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Difference between Study Eye Vs Non-Study Eye								
n		n		n		n		n
Mean (SD)		xx.x (xx.x)		xx.x (xx.x)		xx.x (xx.x)		xx.x (xx.x)
Median		xx.x		xx.x		xx.x		xx.x
Min, Max		xx, xx		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 last non-missing value recorded prior to the first dose of study drug.
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Programmer Note: Continue table for Visits: Month 3,Month 6, Month 9, Month 12 or Early Term.

Table 14.2.1.6
Categorical Analysis of Best Corrected Visual Acuity (ETDRS): Study Eye vs Non-Study Eye
Number of Letters correct
ITT Population

	0.5 x 10^6 hRPC		1.0 x 10^6 hRPC		2.0 x 10^6 hRPC		3.0 x 10^6 hRPC	
	Study Eye (N=)	Non-Study Eye (N=)	Study Eye (N=)	Non-Study Eye (N=)	Study Eye (N=)	Non-Study Eye (N=)	Study Eye (N=)	Non-Study Eye (N=)
Proportion of Subjects with Specified increase in letters correct for any Post Baseline Assessment	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)
>=5 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
>=10 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
>=15 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Proportion of Subjects with Specified increase in letters correct at Month 3	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)
>=5 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
>=10 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
>=15 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Proportion of Subjects with Specified increase in letters correct at Month 6	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)
>=5 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
>=10 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
>=15 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Proportion of Subjects with Specified increase in letters correct at Month 9	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)
>=5 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
>=10 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
>=15 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Proportion of Subjects with Specified increase in letters correct at Month 12 or Early Termination	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)	(n=)
>=5 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
>=10 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
>=15 Letters Increase	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

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Programmer Note: Denominators used for percentage calculation to be based on number of results reported for that particular time point..

Table 14.2.2.1
Electroretinogram (ERG) - Study Eye
Categorical Analysis
ITT Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	……	0.5 x 10^6 hRPC (N=)	…..	Total [1] (N=)
Dark Adapted 0.01 ERG (rod response)					
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Month 6	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Month 12/ Early Termination	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Dark Adapted 3.0 ERG (rod-cone response)					
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Month 6	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Month 12/ Early Termination	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
[2] 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 Light Adapted 3.0 ERG (single flash cone response), Light Adapted 3.0 Flicker ERG

Programmer Note: Denominators used for percentage calculation to be based on number of results reported for that perticular time point..
Programmer Note: Table 14.2.2.2 will contain the same information for the Non-Study Eye.

Table 14.2.3
Visual Field Examination by Eye
Categorical Analysis
ITT Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	……	0.5 x 10^6 hRPC (N=)	…….	Total [1] (N=)
Study Eye					
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Month 6	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Month 12/Early Termination	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Non-Study Eye					
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Month 6	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Month 12/Early Termination	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
[2] 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: Denominators used for percentage calculation to be based on number of results reported for that perticular time point..

Table 14.3.1
Study Drug Administration
Safety Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	……	0.5 x 10^6 hRPC (N=)	…..	Total [1] (N=)
Eye Drug Injected into:					
OD (Right)	n (%)	n (%)	n (%)	n (%)	n (%)
OS (Left)	n (%)	n (%)	n (%)	n (%)	n (%)
Total Dose Administered?					
Yes	n (%)	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)	n (%)
Any Dose interruptions?					
Yes	n (%)	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)	n (%)
Were any Adverse Events observed?					
Yes	n (%)	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)	n (%)
Subject Vital Signs comparable to pre injection levels?					
Yes	n (%)	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)	n (%)
Subject IOP < 30mm post treatment of injection?					
Yes	n (%)	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)	n (%)
Subject Prescribed Topical Treatment after Study Drug					
Yes	n (%)	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
path\t_program.sas date time

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

System Organ Class / Preferred Term	Cohort 1				Cohort2					
	0.5 x 10^6 hRPC (N=)		……. (N=)		0.5 x 10^6 hRPC (N=)		……. (N=)		Total [1] (N=)	
	Subjects	Events	Subjects	Events	Subjects	Events	Subjects	Events	Subjects	Events
Subjects Reporting at Least One TEAE	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
System Organ Class 1	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 1	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 2	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
…										
System Organ Class 2	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 1	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 2	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
…										

[1] Total includes both Cohorts 1 and 2.
Note: At each level of summation (overall, system organ class, preferred term), subjects reporting more than one 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 14.3.1.2
TEAEs by System Organ Class, Preferred Term and Maximum Severity
Safety Population

System Organ Class / Preferred Term	Cohort 1 0.5 x 10^6 hRPC (N=)				…….			
	Mild	Moderate	Severe	Life Threatening	Mild	Moderate	Severe	Life Threatening
Subjects Reporting at Least One TEAE	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
System Organ Class 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
.								
.								
System Organ Class 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 2	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.
path\t_program.sas date time

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	Cohort 2											
	0.5 x 10^6 hRPC (N=)				…….				Total [1] (N=)			
	Mild	Moderate	Severe	Life Threatening	Mild	Moderate	Severe	Life Threatening	Mild	Moderate	Severe	Life Threatening
Subjects Reporting at Least One TEAE	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 (%)
Preferred Term 1	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 (%)
.												
.												
System Organ Class 2	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 (%)
Preferred Term 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
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.
path\t_program.sas date time

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	Cohort 1				Cohort2					
	0.5 x 10^6 hRPC (N=)		……. (N=)		0.5 x 10^6 hRPC (N=)		……. (N=)		Total [1] (N=)	
	Subjects	Events	Subjects	Events	Subjects	Events	Subjects	Events	Subjects	Events
Subjects Reporting at Least One Related TEAE	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
System Organ Class 1	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 1	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 2	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
…										
System Organ Class 2	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 1	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 2	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
…										

[1] Total includes both Cohorts 1 and 2.
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	Cohort 1				Cohort2					
	0.5 x 10^6 hRPC (N=)		……. (N=)		0.5 x 10^6 hRPC (N=)		……. (N=)		Total [1] (N=)	
	Subjects	Events	Subjects	Events	Subjects	Events	Subjects	Events	Subjects	Events
Subjects Reporting at Least One Serious TEAE	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
System Organ Class 1	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 1	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 2	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
…										
System Organ Class 2	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 1	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
Preferred Term 2	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx	n (%)	xx
…										

[1] Total includes both Cohorts 1 and 2.
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	Cohort 1		Cohort 2		Total [1]
		0.5 x 10^6 hRPC (N=)	….……	0.5 x 10^6 hRPC (N=)	……	(N=)
Hemoglobin (g/dL),	Baseline [2]					
	n	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Day 7					
	N	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Day 7 Change from Baseline					
	N	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Day 28					
	n	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	…	…	…	…	…	…

[1] Total includes both Cohorts 1 and 2.
[2] Baseline is defined as the last non-missing value prior to 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 Term.
Programmer Note: Table will include the following hematology parameters: Hemoglobin (g/dL), Hematocrit (%), Platelet Count(x 10^3/uL), Red cell Count (x 10^6/uL), White cell Count(x 10^3/uL), Percent Neutrophil(%)s, Percent Lymphocytes(%)s, Percent Monocyte(%),, Percent Eosinophil(%),, Percent Basophils(%), Neutrophil(x 10^3/uL)*s, Lymphocytes*(x 10^3/uL)*, Eosionophil*(x 10^3/uL) *and Basophils*(x 10^3/uL).

Table 14.3.4.2
Chemistry
Safety Population

Laboratory Parameter	Time Point	Cohort 1 0.5 x 10^6 hRPC (N=)	….	Cohort 2 0.5 x 10^6 hRPC (N=)	…..	Total [1] (N=)
ALT (SGPT) (U/L)	Baseline [2]					
	n	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Day 7					
	N	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Day 7 Change from Baseline					
	N	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Day 28					
	n	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	…	…	…	…	…	…

[1] Total includes both Cohorts 1 and 2.
[2] 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: Day 28, Month 3, Month 6, Month 12/Early Term.
Programmer Note: Table will include the following serum 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), Bicarbonate (mmol/L), Blood Urea Nitrogen (mgdL), Creatinine (mg/dL), Creatinine (mg/dL), Total Protein (g/dL), Albumin (g/dL), Calcium(mg/dL), Phosphate (mg/dL) and Glucose (mg/dL).

Table 14.3.4.3
Coagulation
Safety Population

Laboratory Parameter	Time Point	Cohort 1		Cohort 2		
		0.5 x 10^6 hRPC (N=)	….	0.5 x 10^6 hRPC (N=)	…..	Total [1] (N=)
Prothrombin Time (PT) (Sec)	Baseline [2]					
	n	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Day 7					
	N	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Day 7 Change from Baseline					
	N	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Day 28					
	n	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	…	…	…	…	…	…

[1] Total includes both Cohorts 1 and 2.
[2] 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: Day 28, Month 3, Month 6, Month 12/Early Term.
Programmer Note: Table will include the following Coagulation parameters: Partial Thromboplastin Time (PTT) (sec) and INR.

Table 14.3.4.4
Vital Signs
Safety Population

Vital Sign	Time Point	Cohort 1 0.5 x 10^6 hRPC (N=)	Cohort 1 ……	Cohort 2 0.5 x 10^6 hRPC (N=)	Cohort 2 …….	Total [1] (N=)
Systolic BP (mmHg)	Baseline [2]					
	n	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Day 0 15 min Post-Injection					
	N	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Day 0 15 min Post-Injection Change from Baseline					
	N	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	Day 2					
	n	n	n	n	n	n
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
	…	…	…	…	…	…

Source: xxx
[1] Total includes both Cohorts 1 and 2.
[2] 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: Table will include the following vital signs: systolic BP (mmHg), diastolic BP (mmHg), Heart Rate (bpm), Respiration (Breaths/min) and Temperature(C).

Programmer Note: Continue table for Visits: Day 0- 60 min post injection, Day 1, Day 2, Day 3, Day 7, Day 14, Day 21, Day 28, Month 2, Month 3, Month 4, Month 5, Month 6, Month 9, Month 12/Early Term.

Table 14.3.4.5
12-Lead Electrocardiogram – Overall Interpretation
Safety Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	……	0.5 x 10^6 hRPC (N=)	……	Total [1] (N=)
Baseline [2]					
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1					
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
[2] 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: Denominators used for percentage calculation to be based on number of results reported for that Perticular time point..

Table 14.3.4.6.1
Slit Lamp Examination: Study Eye
Safety Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	……	0.5 x 10^6 hRPC (N=)	……	Total [1] (N=)
Eyelids					
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Day 2	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Day 3	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Day 7	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)

…

[1] Total includes both Cohorts 1 and 2.
[2] 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.
[3] Subject may be counted more than one row.
ath\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 21, Day 28, Month 2, Month 3, Month 4, Month 5, Month 6, Month 9, Month 12/Early Term.
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 Perticular time point..

Programmer Note: Table can be modified to align with information collected on the CRF.

Table 14.3.4.6.1
Slit Lamp Examination: Study Eye
Safety Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	……	0.5 x 10^6 hRPC (N=)	……	Total [1] (N=)
Lens Status					
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
Aphakic	n (%)	n (%)	n (%)	n (%)	n (%)
Psedophakic	n (%)	n (%)	n (%)	n (%)	n (%)
Phakic	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1	(n=)	(n=)	(n=)	(n=)	(n=)
Aphakic	n (%)	n (%)	n (%)	n (%)	n (%)
Psedophakic	n (%)	n (%)	n (%)	n (%)	n (%)
Phakic	n (%)	n (%)	n (%)	n (%)	n (%)
Cataract Type [3]					
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
Nuclear	n (%)	n (%)	n (%)	n (%)	n (%)
Cortical	n (%)	n (%)	n (%)	n (%)	n (%)
Posterior Subcapsular	n (%)	n (%)	n (%)	n (%)	n (%)
Not Applicable	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1	(n=)	(n=)	(n=)	(n=)	(n=)
Nuclear	n (%)	n (%)	n (%)	n (%)	n (%)
Cortical	n (%)	n (%)	n (%)	n (%)	n (%)
Posterior Subcapsular	n (%)	n (%)	n (%)	n (%)	n (%)
Not Applicable	n (%)	n (%)	n (%)	n (%)	n (%)
Grade					
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
+1	n (%)	n (%)	n (%)	n (%)	n (%)
+2	n (%)	n (%)	n (%)	n (%)	n (%)
+3	n (%)	n (%)	n (%)	n (%)	n (%)
+4	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
[2] 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.
[3] 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: Day1, Day2, Day3, Day7,Day14, Day 21, Day 28, Month 2, Month 3, Month 4, Month 5, Month 6, Month 9, Month 12/Early Term.

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 perticular time point.
Programmer Note: Table can be modified to align with information collected on the CRF.

Table 14.3.4.7
Fundus Photography by Eye
Vitreous Examination
Safety Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	…	0.5 x 10^6 hRPC (N=)	….	Total [1] (N=)
Study Eye					
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
…	…	…	…	…	…
Non-Study Eye					
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
[2] 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: Denominators used for percentage calculation to be based on number of results reported for that particular time point.

Table 14.3.4.8.1
Intraocular Pressure (IOP): Study Eye
Safety Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	…..	0.5 x 10^6 hRPC (N=)	…..	Total [1] (N=)
Baseline [2]					
n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 1					
n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 1 Change from Baseline					
n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Day 2					
n	n	n	n	n	n
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
…	…	…	…	…	…

[1] Total includes both Cohorts 1 and 2.
[2] 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: Day 3, Day 7, Day14, Day 21, Day 28, Month 2, Month 3, Month 4, Month 5, Month 6, Month 9, Month 12/Early Term.
Programmer Note: Table 14.3.4.8.2 will contain the same information for the Non-Study Eye.

Table 14.3.4.9.1
B-Scan: Study Eye
Safety Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	…..	0.5 x 10^6 hRPC (N=)	……	Total [1] (N=)
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Good	n (%)	n (%)	n (%)	n (%)	n (%)
Poor	n (%)	n (%)	n (%)	n (%)	n (%)
Injected Cells Visualized					
Yes	n (%)	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)	n (%)
Not Applicable	n (%)	n (%)	n (%)	n (%)	n (%)
Day 3	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Good	n (%)	n (%)	n (%)	n (%)	n (%)
Poor	n (%)	n (%)	n (%)	n (%)	n (%)
Injected Cells Visualized					
Yes	n (%)	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)	n (%)
Not Applicable	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
[2] Baseline is defined as the value obtained at the baseline visit.
path\t_program.sas date time

Programmer Note: Continue table for Visits: Day 7, Month3, Month 6, Month 12/Early Term.
Programmer Note: Table 14.3.4.9.2 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 14.3.4.10.1
Dilated Fundoscopic Examination: Study Eye
Safety Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	….	0.5 x 10^6 hRPC (N=)	…..	Total [1] (N=)
Vitreous Examination					
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
Mild +1	n (%)	n (%)	n (%)	n (%)	n (%)
Moderate +2	n (%)	n (%)	n (%)	n (%)	n (%)
Severe +3	n (%)	n (%)	n (%)	n (%)	n (%)
Very Severe +4					
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1	(n=)	(n=)	(n=)	(n=)	(n=)
Mild +1	n (%)	n (%)	n (%)	n (%)	n (%)
Moderate +2	n (%)	n (%)	n (%)	n (%)	n (%)
Severe +3	n (%)	n (%)	n (%)	n (%)	n (%)
Very Severe +4					
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Day 2	(n=)	(n=)	(n=)	(n=)	(n=)
Mild +1	n (%)	n (%)	n (%)	n (%)	n (%)
Moderate +2	n (%)	n (%)	n (%)	n (%)	n (%)
Severe +3	n (%)	n (%)	n (%)	n (%)	n (%)
Very Severe +4					
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
[2] 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 Optic Nerve, Macula, and Peripheral Retina Examinations.
Programmer Note: Continue table for Visits: Day 3, Day 7, Day 14, Day 21, Day 28, Month 2, Month 3, Month 4, Month 5, Month 6, Month 9, Month 12/Early Term.

Programmer Note: Table 14.3.4.10.2 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 14.3.4.11
Post Injection Clinical Vitreous Exam: Study Eye
Safety Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	….	0.5 x 10^6 hRPC (N=)	…..	Total [1] (N=)
Day0	(n=)	(n=)	(n=)	(n=)	(n=)
Injected eye examined					
Yes	n (%)	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)	n (%)
Methods of Examination [2]					
Indirect Ophthalmoscopy	n (%)	n (%)	n (%)	n (%)	n (%)
Fundus Exam	n (%)	n (%)	n (%)	n (%)	n (%)
Slit Lamp Exam	n (%)	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)	n (%)
Change from Previous Exam					
Yes	n (%)	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)	n (%)
Appearance					
Cells	n (%)	n (%)	n (%)	n (%)	n (%)
Clumps	n (%)	n (%)	n (%)	n (%)	n (%)
Opacity	n (%)	n (%)	n (%)	n (%)	n (%)
Debris	n (%)	n (%)	n (%)	n (%)	n (%)
Strands	n (%)	n (%)	n (%)	n (%)	n (%)
Inflammation	n (%)	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)	n (%)
Photograph taken					
Yes	n (%)	n (%)	n (%)	n (%)	n (%)
No	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
[2] Subject may be counted more than one row.

path\t_program.sas date time
Programmer Note: Continue table for Visits: Day 1, Day 2, Day 3, Day 7, Day 14, Day 21, Day 28, Month 2, Month 3, Month 4, Month 5, Month 6, Month 9, Month 12/Early Term.
Programmer Note: Denominators used for percentage calculation to be based on number of results reported for that perticular time point.

Table 14.3.4.12.1
Optical Coherence Tomography (OCT): Study Eye
Categorical Analysis
ITT Population

	Cohort 1		Cohort 2		
	0.5×10^6 hRPC (N=)	….	0.5×10^6 hRPC (N=)	….	Total [1] (N=)
Cystoid Macular Edema (CME) present					
Baseline [2]	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Day 28	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Month 3	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Month 6	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Month 9	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Month 12/ Early Termination	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
If CME Present, Involve Foveal Center					
Baseline [2]	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Day 28	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Month 3	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Month 6	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Month 9	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Month 12/ Early Termination	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)

[1] Total includes both Cohorts 1 and 2.
[2] 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 9, Month 12/Early Term.
Programmer Note: Table 14.3.4.12.2 will contain the same information for the Non-Study Eye.

Table 14.3.4.13.1
Fluorescein Angiography: Study Eye
Categorical Analysis
ITT Population

	Cohort 1		Cohort 2		
	0.5×10^6 hRPC (N=)	….	0.5×10^6 hRPC (N=)	….	Total [1] (N=)
Active Leakage					
Baseline [1]	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Month 6	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Month 12/ Early Termination	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Ischemia					
Baseline [1]	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Month 6	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Month 12/ Early Termination	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)

[1] Total includes both Cohorts 1 and 2.
[2] 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 9, Month 12/Early Term.
Programmer Note: for Active Leakage and Ischemia present for "YES"
Programmer Note: Table 14.3.13.2 will contain the same information for the Non-Study Eye.

Table 14.3.4.14.1
Autofluorescence: Study Eye
ITT Population

	Cohort 1		Cohort 2		
	0.5 x 10^6 hRPC (N=)	….	0.5 x 10^6 hRPC (N=)	……	Total [1] (N=)
Baseline [2]	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Month 6	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Month 12/ Early Termination	(n=)	(n=)	(n=)	(n=)	(n=)
Normal	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Not Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)
Abnormal, Clinically Significant	n (%)	n (%)	n (%)	n (%)	n (%)

[1] Total includes both Cohorts 1 and 2.
[2] 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: Denominators used for percentage calculation to be based on number of results reported for that particular time point.
Programmer Note: Table 14.3.4.14.2 will contain the same information for the Non-Study Eye.

Appendix D: Listing Layouts

Listing 16.2.1.1
Subject Disposition

Treatment Group	Subject ID	Safety Population [1]	ITT Population [2]	Information Consent Date	First Drug Administration Date/Time	Completion or Discontinuation Date	Primary Reason for Discontinuation
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Yes/No	Yes/No	Date9.	Date9./time5.	Date9.	xxxxxxxxxxxxxxxxx
…….	……	…..	……				
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Yes/No	Yes/No	Date9.	Date9./time5.	Date9.	xxxxxxxxxxxxxxxxx
…….	…….	…….	…….				

[1] Received any amount of jCell treatment.
[2] All enrolled subjects who provide any post-screening 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

Treatment Group	Subject ID	Deviation Type	Protocol Deviation Category	Description of Protocol Deviation
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	xxxxxx	xxxxxxxxx	xxxxxxxxx
……..	……	…….	………..	……
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	xxxxxx	xxxxxxxxx	xxxxxxxxx
……..	…….	…….	……	……

path\l_program.sas date time

Listing 16.2.2.2
Inclusion/Exclusion Criteria

Treatment Group	Subject ID	All Eligibility Criteria Met?	If Not Met, Inc/Exc Criterion ID Not Met	Protocol Version Date
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Yes/No	Inclusion #/Exclusion#	Date9.
……..	……			
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Yes/No	Inclusion #/Exclusion#	Date9.
……..	…….			

path\l_program.sas date time

Listing 16.2.4.1
Demographic and Baseline Characteristics

Treatment Group	Subject ID	Date of Birth	Age (years)	Sex	If Female, Childbearing Potential?	If YES, Method of Birth Control	Ethnicity	Race	Previously Typed to Determine PR Gene Mutation?	Study Eye	Baseline Height (cm)	Baseline Weight (Kg)
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Date9.	xx	Female	No/Yes	IUD	Hispanic or Latino	White	Yes/No	OD(Right)	xxx	xxx
……..	……											
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Date9.	xx	Male	No/Yes	Oral Contraception	Not Hispanic or Latino	Asian	Yes/No	OS(Left)	xxx	xxx
……..	…….											

path\l_program.sas date time

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

.

Listing 16.2.4.2
Medical History

Treatment Group	Subject ID	Past Diseases or Surgeries?	MH#	Body System	Medical History Condition/Event	Start Date	End Date/Ongoing
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Yes/No	1	xxxxxxxx	xxxxxxxxxxxx	Date9.	Date9./Ongoing
……..	……						
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Yes/No	2	xxxxxxxx	xxxxxxxxxxxx	Date9.	Date9./Ongoing
……..	…….						

path\l_program.sas date time

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

Treatment Group	Subject ID	Ocular Medical History?	Ocular MH #	Eye	Body System	Ocular MH Condition/Diagnosis/Surgery	Date of Diagnosis/Surgery	Date Resolved/Ongoing
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Yes/No	1	OD	xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	Date9.	Date9./Ongoing
……..	……							
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Yes/No	1	OS	xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	Date9.	Date9./Ongoing
……..	…….							

path\l_program.sas date time

Programmer Note: sort by medical history number within each subject.
Programmer Note: If MH marked as Unknown start or end date, then show "Unknown" under Date of Diagnosis/Surgery or Date Resolved columns, respectively.
Programmer Note: If MH marked as Ongoing end date, then show "Ongoing" under Date Resolved column..

Listing 16.2.4.4
Urine Drug Screen

Treatment Group	Subject ID	Visit	Collection Date	Collection Time	Any Test Results Positive?	If YES, Which Tests Were Positive?
Cohort 1 - 0.5 x 10^6 hRPC	xxx-xxx	Screening	Date9.	Time5.	Yes/No	Test Name
Cohort 1 – 1.0 x 10^6 hRPC	xxx-xxx	Screening	Date9.	Time5.	Yes/No	Test Name
…….						
Cohort 2 - 0.5 x 10^6 hRPC	xxx-xxx	Screening	Date9.	Time5.	Yes/No	Test Name
Cohort 2 – 1.0 x 10^6 hRPC	xxx-xxx	Screening	Date9.	Time5.	Yes/No	Test Name
……						

path\l_program.sas date time

Listing 16.2.4.5
Infectious Disease Tests

Treatment Group	Subject ID	Visit	Tested for Hepatitis B: Reason	Hepatitis B Result	Tested for Hepatitis C? Reason	Hepatitis C Result	Tested for HIV? Reason	HIV Result
Cohort 1 - 0.5 x 10^6 hRPC	xxx-xxx	Screening Baseline	Yes No: Reason	Negative/Positive	Yes No: Reason	Negative/Positive	Yes No: Reason	Negative/Positive
……..								
Cohort 2 - 0.5 x 10^6 hRPC	xxx-xxx	Screening Baseline	Yes No: Reason	Negative/Positive	Yes No: Reason	Negative/Positive	Yes No: Reason	Negative/Positive

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Listing 16.2.5.1
Study Drug Administration

Treatment Group	Subject ID (Study Eye)	Visit	Administration Date	Dilation Time	Injection Time	Eye Drug Injected Into	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
Cohort 1 - 0.5 x 10^6 hRPC	Xxxxx (OS)	Day 0	Date 9.	Time5.	Time5.	OS (Left)	Yes	Yes: Reason	No/Yes	No/Yes	No/Yes	No/Yes
Cohort 1 - 1.0 x 10^6 hRPC	Xxxxx (OD)	Day 0	Date9.	Time5.	Time5.	OD (Right)	No: Reason	No	No	No	No	No
……..												
Cohort 2 - 0.5 x 10^6 hRPC	Xxxxx (OS)	Day 0	Date9.	Time5.	Time5.	OS (Left)	Yes	Yes: Reason	No/Yes	No/Yes	No/Yes	No/Yes
Cohort 2 - 1.0 x 10^6 hRPC	Xxxxx (OD)	Day 0	Date9.	Time5.	Time5.	OD (Right)	No: Reason	No	No	No	No	No
……..												

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Programmer Note: If NO marked for administration, include reason in "Administration Date" column.

Listing 16.2.6.1
Best Corrected Visual Acuity (ETDRS)

				OD Visual Acuity		OS Visual Acuity	
Treatment Group	Subject ID	Visit	Assessment Date (Study Day)	Measurement	Total Numbers of Letters Missed	Measurement	Total Numbers of Letters Missed
Cohort 1 - 0.5 x 10^6 hRPC	xxx-xxx	Screening	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Baseline	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Day0	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Day1	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Day2	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Day3	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Day7	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Day14	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Day21	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Day28	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Month2	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Month3	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Month4	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Month6	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Month9	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
		Month12 or Early Termination	Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
Cohort 1 - 1.0 x 10^6 hRPC	xxx-xxx		Not Done: Reason				
……..							
Cohort 2 - 0.5 x 10^6 hRPC	xxx-xxx		Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
Cohort 2 - 1.0 x 10^6 hRPC	xxx-xxx		Date9. (xx)	Xx/xxx	xxx	Xx/xxx	xxx
……..							

path\l_program.sas date time

Programmer Note: If NO marked for testing, include reason in "Assessment Date" column.

Listing 16.2.6.2.1
Electroretinogram
Right Eye (OD)

					Dark Adapted 0.01 ERG (Rod Response)								
Treatment Group	Subject ID	Visit	ERG Prior to Ancillary Testing?	ERG Date (Study Day)	Start Time	Stop Time	A-Wave Amplitude	B-Wave Amplitude	Time from Flash to A-Wave Trough	Time from Flash to B-Wave Peak	Result	If Abnormal, Change from Previous Visit	Abnormality
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Yes/No	Date9. (xx)	Time5.	Time5.					Normal		
		Baseline	Yes/No	Date9. (xx)	Time5.	Time5.					Abnormal CS	Yes/No	xxxxxxxxx
	……	Month6	Yes/No	Not Done: reason	Time5.	Time5.					Abnormal NCS	Yes/No	xxxxxxxxx
……..		Month12											
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Yes/No	Date9. (xx)	Time5.	Time5.					Normal		
		Baseline	Yes/No	Date9. (xx)	Time5.	Time5.					Abnormal NCS	Yes/No	xxxxxxxxx
……..	…….	Month6	Yes/No	Date9. (xx)	Time5.	Time5.					Abnormal CS	Yes/No	xxxxxxxxx
		Month12											
	……												

Note: CS=Clinically Significant, NCS=Not Clinically Significant.
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Programmer Note: If NO marked for testing, include reason in "ERG Date" column.
Programmer Note: Include Description of Abnormality and Clinically Significant information in "Result" column.
Programmer Note: Repeat columns for Dark Adapted 3.0 ERG (Rod Cone Response), Light Adapted 3.0 (Single Rod Cone Response), Light Adapted 3.0 Flicker ERG.
Programmer Note: 16.2.6.2.2 Repeat same for left Eye columns for Dark Adopted 0.01 ERG (rod response), Dark Adapted 3.0 ERG (Rod Cone Response), Light Adapted 3.0 (Single Rod Cone Response), Light Adapted 3.0 Flicker ERG.

Listing 16.2.6.3
Optical Coherence Tomography (OCT)

Treatment Group	Subject ID	Visit	Assessment Date (Study Day)	Cystoid Macular Edema (CME) Present?	IF CME Present, Involve Foveal Center?	OD Central Subfield Thickness (um)	OS Central Subfield Thickness (um)
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9. (xx)	Yes/No	Yes/No	xxx	xxx
		Day 28	Date9. (xx)	Yes/No	Yes/No	xxx	xxx
		Month 3	Date9. (xx)	Yes/No	Yes/No	xxx	xxx
		Month 6	Date9. (xx)	Yes/No	Yes/No	xxx	xxx
		Month 12 or Early Termination	Date9. (xx)	Yes/No	Yes/No	xxx	xxx
……..	……..						
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9. (xx)	Yes/No	Yes/No	xxx	xxx
		Day 28	Date9. (xx)	Yes/No	Yes/No	xxx	xxx
		Month 3	Date9. (xx)	Yes/No	Yes/No	xxx	xxx
		Month 6	Date9. (xx)	Yes/No	Yes/No	xxx	xxx
		Month 12 or Early Termination	Date9. (xx)	Yes/No	Yes/No	xxx	xxx
	……						

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Programmer Note: If NO marked for testing, include reason in "Assessment Date" column.

Listing 16.2.6.4
Fluorescein Angiography

					OD (Right)				OS (Left)			
Treatment Group	Subject ID	Visit	Assessment Date(Study Day)	Imaging Type	Start Time	Active Leakage?	Ischemia?	Other Observations	Start Time	Active Leakage?	Ischemia?	Other Observations
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9. (xx)	Field Imaging	Time5.	Yes/No	Yes/No	xxxxxx	Time5.	Yes/No	Yes/No	xxxxxx
		Month 6	Date9. (xx)	Wide Field Imaging	Time5.	Yes/No	Yes/No	xxxxxx	Time5.	Yes/No	Yes/No	xxxxxx
		Month 12	Date9. (xx)	Other: specify	Time5.	Yes/No	Yes/No	xxxxxxx	Time5.	Yes/No	Yes/No	xxxxxxx
……..	……..											
Cohort 2 - 0.5 x 10^6 hRPC	xxx--	Baseline	Date9. (xx)	Field Imaging	Time5.	Yes/No	Yes/No	xxxxxxx	Time5.	Yes/No	Yes/No	xxxxxxx
		Month 6	Notdone: Reason	Wide Field Imaging	Time5.	Yes/No	Yes/No	xxxxxxxx	Time5.	Yes/No	Yes/No	xxxxxxxx
		Month 12	Date9. (xx)	Other	Time5.	Yes/No	Yes/No	xxxxxxx	Time5.	Yes/No	Yes/No	xxxxxxx
	……											

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Programmer Note: If NO marked for testing, include reason in "Assessment Date" column.

Listing 16.2.6.5
Autofluorescence

Treatment Group	Subject ID	Visit	Assessment Date (Study Day)	Pupils Dilated for Imagining Exam?	Right Eye (OD) Result	Abnormal, Change from Previous Visit?	Left Eye (OS) Result	Abnormal, Change from Previous Visit?
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9. (xx)	Yes/No	Normal		Normal	
		Month 6	Not Done: reason	Yes/No	Abnormal CS: Abnormality	Yes	Abnormal CS:Abnoramlity	Yes
		Month 12 or Early Termination	Date9. (xx)	Yes/No	Abnormal NCS:	No	Abnormal NCS	No
……..	……..							
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9. (xx)	Yes/No	Normal		Normal	
		Month 6	Date9. (xx)	Yes/No	Abnormal CS Abnormality	Not Applicable	Abnormal CS: Abnormality	Not Applicable
		Month 12 or Early Termination	Date9. (xx)	Yes/No	Abnormal NCS	No	Abnormal NCS	No

Note: CS=Clinically Significant, NCS=Not Clinically Significant.
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Programmer Note: If NO marked for testing, include reason in "Assessment Date" column.
Programmer Note: Include Description of Abnormality and Clinically Significant information in "Result" column

Listing 16.2.6.6
Visual Field Examination

							OD (Right)							OS (Left)				
Treatment Group	Subject ID	Visit	Assessment Date (study Day)	Pupil Dialated	Visual Field Technology	Overall Result	Comments	Result	If Abnormal, Change from Baseline	Mean Dev.	Fixation Loss	False Positive	False Negative	Result	If Abnormal, Change from Baseline	Mean Dev.	Fixation Loss	False Positive	False Negative
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9. (xx)	Yes	Goldmann VF		xxxxxxxx	Normal						Normal					
		Month 6	Date9. (xx)		Humphrey 10-2		xxxxxxxx	Abnormal NCS	Yes					Abnormal NCS	No				
		Month 12 or Early Termination	Not Done: Reason																
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9. (xx)	No	Other:		xxxxxxxx	Normal						Normal					
		Month 6	Date9. (xx)		Goldmann VF		xxxxxxxx	Normal						Normal					
		Month 12 or Early Termination	Date9. (xx)		Humphrey 10-2		xxxxxxxx	Normal						Abnormal Cs	Not Applicable				

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

Programmer Note: If NO marked for testing, include reason in "Assessment Date" column.
Programmer Note: Include Description of Abnormality and Clinically Significant information in "Result" column

Listing 16.2.7.1
Adverse Events

Treatment Group	Subject ID	AE#	Verbatim Term // System Organ Class//Preferred Term	Onset Date (Study Day)	Onset Time	End Date (Study Day)	Serious	Severity	Relationship to Study Drug	Treatment of Event	Outcome
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx			Date9.(xx)	Time5.	Date9.(xx)	Yes	Mild	Not Related	None	Recovery/Resolved
				Date9.(xx)	Time5.	Date9.(xx)	No	Moderate	Unlikely Related	Medication	Recovery/Resolved W/Seq
				Date9.(xx)	Time5.	Date9.(xx)	No	Moderate	Possibly Related	Non-Drug Treatment	Recovering/Resolving
				Date9.(xx)		Date9.(xx)	No	Mild	Related	Hospitalization	
				Date9.(xx)		Date9.(xx)	No	Severe	Unlikely Related		
				Date9.(xx)		Date9.(xx)	No	Mild			
……..	……..										
Cohort 2 - 0.5 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

Treatment Group	Subject ID	AE #	Verbatim Term // System Organ Class//Preferred Term	Onset Date (Study Day)	Onset Time	End Date (Study Day)	Severity	Relationship to Study Drug	Treatment of Event	Outcome
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx			Date9.(xx)	Time5.	Date9.(xx)	Mild	Not Related	None	Recovery/Resolved
				Date9.(xx)		Date9.(xx)	Moderate	Unlikely Related	Medication	Recovery/Resolved W/Seq
				Date9.(xx)		Date9.(xx)	Moderate	Possibly Related	Non-Drug Treatment	Recovering/Resolving
				Date9.(xx)		Date9.(xx)	Mild	Related	Hospitalization	
				Date9.(xx)		Date9.(xx)	Severe	Unlikely Related		
				Date9.(xx)		Date9.(xx)	Mild			
……..	……..									
Cohort 2 - 0.5 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

Treatment Group	Subject ID	AE #	Verbatim Term // Preferred Term	Onset Date/Time (Study Day)	End Date (Study Day)	Serious	Severity	Relationship to Study Drug	Treatment of Event	Outcome
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx			Date9.(xx)	Date9.(xx)	Yes	Mild	Related	None	Recovery/Resolved
				Date9.(xx)	Date9.(xx)	No	Moderate	Related	Medication	Recovery/Resolved W/Seq
				Date9.(xx)	Date9.(xx)	No	Moderate	Possibly Related	Non-Drug Treatment	Recovering/Resolving
				Date9.(xx)	Date9.(xx)	No	Mild	Related	Hospitalization	
				Date9.(xx)	Date9.(xx)	Yes	Severe	Related		
				Date9.(xx)	Date9.(xx)	No	Mild			
……..	……..									
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx									

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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

Treatment Group	Subject ID	Visit	Examination Date (Study Day)	Method Used	Change from Prev. Visit	Appearance	Size	Location	Photograph Taken?
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Day 0	Date9.(xx)	Indirect Ophthalmoscopy	Yes/No	Cells	xxxxxx	xxxxxx	Yes/No
		Day 1	Date9.(xx)	Fundus Exam	Yes/No	Clumps	xxxxxx	xxxxxx	Yes/No
		Day 2	Date9.(xx)	Slit Lamp Exam	Yes/No	Opacity	xxxxxx	xxxxxx	Yes/No
		Day 3	Date9.(xx)	Other:	Yes/No	Debris	xxxxxx	xxxxxx	Yes/No
		Day 7	Date9.(xx)	Indirect Ophthalmoscopy	Yes/No	Stands	xxxxxx	xxxxxx	Yes/No
		Day 14	Date9.(xx)	Fundus Exam	Yes/No	Inflammation	xxxxxx	xxxxxx	Yes/No
		Day 21	Not Done: Reason						
		Day 28	Date9.(xx)	Other:	Yes/No	Clumps	xxxxxx	xxxxxx	Yes/No
		Month 2	Date9.(xx)	Indirect Ophthalmoscopy	Yes/No	Opacity	xxxxxx	xxxxxx	Yes/No
		Month 3	Date9.(xx)	Fundus Exam	Yes/No	Debris	xxxxxx	xxxxxx	Yes/No
		Month 4	Date9.(xx)	Slit Lamp Exam	Yes/No	Stands	xxxxxx	xxxxxx	Yes/No
		Month 5	Date9.(xx)	Other:	Yes/No	Inflammation	xxxxxx	xxxxxx	Yes/No
		Month 9	Date9.(xx)	Slit Lamp Exam	Yes/No	Cells	xxxxxx	xxxxxx	Yes/No
		Month 12 or Early Termination	Date9.(xx)	Other:	Yes/No	Other:	xxxxxx	xxxxxx	Yes/No
…….	…….								
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx								
……	……..								

path\l_program.sas date time

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Programmer Note: If NO marked for examination, include reason in "Examination Date" column. Methods used include all applicable Methods.

Listing 16.2.8.1
Hematology
Part 1 of 2

Treatment Group	Subject ID	Visit	Collection Date (Study Day)	Collection Time	Hemoglobin (g/dL)	Hematocrit (%)	Platelet Count (x 10^3/uL)	Red Cell Count (x 10^6/uL)	White Cell Count (x 10^3/uL)
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9. (xx)	Time5.					
		Baseline	Date9. (xx)	Time5.					
		Day 7	Date9. (xx)	Time5.					
		Day 28	Date9. (xx)	Time5.					
		Month 3	Date9. (xx)	Time5.					
		Month 6	Date9. (xx)	Time5.					
		Month 12 or Early Termination	Date9. (xx)	Time5.					
…….	….								
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx								

Listing 16.2.8.1
Hematology
Part 2 of 2

Treatment Group	Subject ID	Visit	Collection Date/Time	Neutrophils (%)	Lymphocytes (%)	Monocytes (%)	Eosinophils (%)	Basophils (%)	Neutrophils (x 10^3/uL)	Lymphocytes (x 10^3/uL)	Monocytes (x 10^3/uL)	Eosiophils (x 10^3/uL)	Basophils (x 10^3/uL)

Note: L=Low and H=High, CS=Clinically Significant
. path\l_program.sas date time

Programmer Note: If NO marked for examination, include reason in "Examination Date" column.

Listing 16.2.8.2
Chemistry
Part 1 of 2

Treatment Group	Subject ID	Visit	Collection Date (Study Day)	Collection Time	Bilirubin (mg/dL)	Sodium (mmol/L))	Potassium (mmol/L)	Chloride (mmol/L)	Bicarbonate (mmol/L)	ALT (U/L)	AST (U/L)	Alkaline Phosphatase (U/L)
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9. (xx)	Time5.								
		Baseline	Date9. (xx)	Time5.								
		Day 7	Date9. (xx)	Time5.								
		Day 28	Date9. (xx)	Time5.								
		Month 3	Not Done: Reason									
		Month 6	Date9. (xx)	Time5.								
		Month 12 or Early Termination	Date9. (xx)	Time5.								
…….	….											
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx											

Listing 16.2.8.2
Chemistry
Part 2 of 2

Treatment Group	Subject ID	Visit	Collection Date (Study Day)	Collection Time	BUN (mg/dL)	Creatinine (mg/dL)	Total Protein (g/dL)	Albumin (g/dL)	Calcium (mg/dL)	Phosphate (mg/dL)	Glucose (mg/dL)
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9. (xx)	Time5.							

Note: L=Low and H=High, CS=Clinically Significant.
path\l_program.sas date time

Programmer Note: If NO marked for examination, include reason in "Examination Date" column.

Listing 16.2.8.3
Coagulation

Treatment Group	Subject ID	Visit	Collection Date/ (Study Day)	Collection Time	PT (sec)	PTT (sec)	INR	Coagulation Results Abnormal?/if Yes: Abnormatlity
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9. (xx)	Time5.				Yes: NCS
		Baseline	Date9. (xx)	Time5.				
		Day 7	Date9. (xx)	Time5.				No
		Day 28	Date9. (xx)	Time5.				Yes: CS
		Month 3	Date9. (xx)	Time5.				
		Month 6	Date9. (xx)	Time5.				
		Month 12 or Early Termination	Date9. (xx)	Time5.				
…….	….							
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx							
…….								

Note: CS=Clinically Significant.
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Programmer Note: Include Clinically Significant information in "Coagulation Results Abnormal?" column.
Programmer Note: If NO marked for examination, include reason in "Examination Date" column.

Listing 16.2.8.4
Urinalysis
Part 1 of 2

Treatment Group	Subject ID	Visit	Collection Date (Study Day)	Collection Time	Specific Gravity	pH	Glucose	Bilirubin	Ketone	Blood	Protein	Urobilinogen
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9. (xx)	Time5.			Negative	Negative	Negative	Negative	Negative	Negative
		Baseline	Date9. (xx)	Time5.			positive	positive	positive	positive	positive	positive
		Month 3	Date9. (xx)	Time5.			Negative	Negative	Negative	Negative	Negative	Negative
		Month 6	Not Done, Reason:									
		Month 12 or Early Termination	Date9. (xx)	Time5.			positive	positive	positive	positive	positive	positive
…….	….											
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx											

Listing 16.2.8.4
Microscopic Exam
Part 2 of 2

				Microscopic Exam					
Treatment Group	Subject ID	Visit	Collection Date (Study Day)	Collection Time	WBC (/hpf)	RBC (/hpf)	Epithelial Cells	Bacteria	Other
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9. (xx)	Time5.			Absent/Present	Absent/Present	

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Programmer Note: If NO marked for examination, include reason in "Examination Date" column.

Listing 16.2.8.5
Clinically Significant Lab Values
Part 1 of 2

Treatment Group	Subject ID	Visit	Collection Date (Study Day)	Collection Time	Lab Category	Lab Test	Value
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9. (xx)	Time5.	Hematology	Hemoglobin	
		Baseline	Date9. (xx)	Time5.		Hematocrit	
		Month 3	Date9. (xx)	Time5.			
		Month 6	Not Done, Reason:				
		Month 12 or Early Termination	Date9. (xx)	Time5.			
…….	….						
Cohort 2 - 0.5 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 16.2.8.6
Vital Signs

Treatment Group	Subject ID	Visit	Measurement Date (Study Day)	Measurement Time	Time Point	SBP/DBP (mmHg)	Heart Rate (beats/min)	Respiration Rate (breaths/min)	Temperature (C)	Weight (Kg)	Height (cm)
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9.(xx	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Baseline	Date9.(xx	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Day 0	Date9.(xx)	Time5.	15 min Pre-Injection	Xxx/xxx	xxx	xxx	xxx	xxx	xxx
			Date9.(xx)	Time5.	15 min Post-Injection	Xxx/xxx	xxx	xxx	xxx	xxx	xxx
			Date9.(xx)	Time5.	60 min Post-Injection	Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Day 1	Date9.(xx)	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Day 2	Date9.(xx)	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Day 3	Date9.(xx)	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Day 7	Date9.(xx)	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Day 14	Date9.(xx)	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Day 21	Date9.(xx)	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Day 28	Not Done: Reason								
		Month 2	Date9.(xx)	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Month 3	Date9.(xx)	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Month 4	Date9.(xx)	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Month 5	Date9.(xx)	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Month 9	Date9.(xx)	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
		Month 12 or Early Termination	Date9.(xx)	Time5.		Xxx/xxx	xxx	xxx	xxx	xxx	xxx
……	……..										
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Day 0	Date9.(xx)	Time5.							

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Programmer Note: If NO marked for examination, include reason in "Examination Date" column.

Listing 16.2.8.7.1
12-Lead Electrocardiogram

Treatment Group	Subject ID	Visit	ECG Date (Study Day)	ECG Time	Subject Position	Interpretation	Heart Rate (bpm)	RR (msec)	PR (msec)	QRS (msec)	QT (msec)	QTcB (msec)	QTcF (msec)
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9.(xx	Time5.	Sitting	Normal	xx	xxxx	xxx	xx	xxx	xx.xx	xxx.xx
		Baseline	Date9.(xx	Time5.	Standing	Abnormal CS	xx	xxxx	xxx	xx	xxx	xx.xx	xxx.xx
		Day 0	Date9.(xx)	Time5.	Supine	Normal	xx	xxxx	xxx	xx	xxx	xx.xx	xxx.xx
		Day 1	Date9.(xx)	Time5.	Prone	Abnormal	xx	xxxx	xxx	xx	xxx	xx.xx	xxx.xx
……..													
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9.(xx	Time5.	Sitting	Normal	xx	xxxx	xxx	xx	xxx	xx.xx	xxx.xx
		Baseline	Date9.(xx	Time5.	Standing	Abnormal NCS	xx	xxxx	xxx	xx	xxx	xx.xx	xxx.xx
		Day 0	Date9.(xx)	Time5.	Supine	Normal	xx	xxxx	xxx	xx	xxx	xx.xx	xxx.xx
		Day 1	Date9.(xx)	Time5.	Prone	Abnormal NCS	xx	xxxx	xxx	xx	xxx	xx.xx	xxx.xx
…….													

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

Programmer Note: If NO marked for ECG, include reason in "ECG Date/Time" column.

Listing 16.2.8.7.2
Clinically Significant 12-Lead Electrocardiogram Interpretation

Treatment Group	Subject ID	Visit	ECG Date (Study Day)	ECG Time	Subject Position	Interpretation
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9.(xx	Time5.	Sitting	AbNormal CS
		Baseline	Date9.(xx	Time5.	Standing	Abnormal CS
		Day 1	Date9.(xx)	Time5.	Prone	Abnormal CS
……..						
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9.(xx	Time5.	Sitting	AbNormal CS
		Baseline	Date9.(xx	Time5.	Standing	Abnormal CS
		Day 0	Date9.(xx)	Time5.	Supine	AbNormal CS
		Day 1	Date9.(xx)	Time5.	Prone	Abnormal CS
…….						

Note: CS=Clinically Significant.
path\l_program.sas date time

Programmer Note: If NO marked for ECG, include reason in "ECG Date/Time" column.

Listing 16.2.8.8
Physical Examination

Treatment Group	Subject ID	Visit	Examination Date (Study Day)	Were There Any Abnormal Findings on the Physical Exam?	Any Changes in Vision or Light Perception Since Baseline?	Any Changes in Vision or Light Perception since Prior Physical Examination
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9. (xx)	Yes/No		
		Baseline	Not Done : Reason	Yes/No		
		Day 1	Date9. (xx)	Yes/No	Yes:Change/No	No
		Day 7	Date9. (xx)	Yes/No		No
		Day 28	Date9. (xx)	Yes/No		No
		Month 3	Date9. (xx)	Yes/No		No
		Month 6	Date9. (xx)	Yes/No		Yes: Changes
		Month 12 or Early Termination	Date9. (xx)	Yes/No		Yes: Changes
…….	……					
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx					

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Programmer Note: If NO marked for examination, include reason in "Examination Date" column.

Listing 16.2.8.9
Prior and Concomitant Medications

Treatment Group	Subject ID	CM #	Verbatim Term // Preferred Drug Name	Start Date (Study Day)	Stop Date (Study Day)	Dose	Units	Dose Form	Route	Frequency	Indication
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	1	Xxxxxxxxxxxx // xxxxxxxxxxx	Date9.(xx)	Date9.(xx)	xxx	mg	Tablet	Oral	Daily	MH#, AE#, injection procedure
		2	Xxxxxxxxxxxx // xxxxxxxxxxx	Date9.(xx)	Ongoing	xxx	ug	Capsule	Oral	As Needed	
		3	Xxxxxxxxxxxx // xxxxxxxxxxx	Date9.(xx)	Date9.(xx)	xx	ml	Suspension	Oral	Daily	
		4	Xxxxxxxxxxxx // xxxxxxxxxxx	Date9.(xx)	Ongoing	xxx	g	Ointment	Oral	Daily	
		5	Xxxxxxxxxxxx // xxxxxxxxxxx	Date9.(xx)	Ongoing	xx	Tablets	Tablet	Oral	Daily	
		6	Xxxxxxxxxxxx // xxxxxxxxxxx	Date9.(xx)	Date9.(xx)	xxx	Capsules	Capsule	Oral	Daily	
		7	Xxxxxxxxxxxx // xxxxxxxxxxx	Date9.(xx)	Ongoing	xxx	Puff	Aerosol	Oral	2X a Day	
		8	Xxxxxxxxxxxx // xxxxxxxxxxx	Date9.(xx)	Date9.(xx)	xxx	mg	Powder	Oral	Every Month	
…….	……. …										
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx										

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Programmer Note: sort by CM # within each subject.

Listing 16.2.8.10
Pregnancy Test

Treatment Group	Subject ID	Visit	Urine Pregnancy Collection Date (Study Day)	Result	If Positive, Was a Serum Test Performed?	If Serum Test Performed, Result
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9. (xx)	Positive/Negative	Yes/No	Positive/Negative
		Baseline	Date9. (xx)	Positive/Negative	Yes/No	Positive/Negative
		Month 12 or Early Termination	Date9. (xx)	Positive/Negative	Yes/No	Positive/Negative
…….	……					
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx		Not Done: Reason			

path\l_program.sas date time

Programmer Note: If NO marked for urine collection, include reason in "Urine Pregnancy Collection Date" column.

Listing 16.2.8.11
PRA and DRA Antibody Test Results Received

Treatment Group	Subject ID	Visit	Collection Date (Study Day)	Sample Collected
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9. (xx)	Yes/No
		Day 14	Date9. (xx)	Yes/No
		Day 28	Date9. (xx)	Yes/No
		Month 12 or Early Termination	Date9. (xx)	
…….	…….			
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx			

path\l_program.sas date time

Programmer Note: If a panel/donor reactive antibody sample was not collected, please display "Not Done" and the reason in the "Collection Date/Time" column.

Listing 16.2.8.12
HLA Antibody Testing

Treatment Group	Subject ID	Visit	Collection Date (Study Day)	Result	Other HLA Antibody Testing Results/Reason
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening Baseline	Date9. (xx)	xxxxxx	
……..	…….				
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Screening Baseline	Date9. (xx) Date9. (xx)	xxxxxx xxxxxx	

path\l_program.sas date time

Programmer Note: If a HLA antibody testing sample was not collected, please display "Not Done" and the reason in the "Collection Date" column.

Listing 16.2.8.13
RP Gene Mutation Received

Treatment Group	Subject ID	Collection Date (Study Day)	Sample Collected
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Date9. (xx) Date9. (xx) Date9. (xx)	
……..	…….		
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx		

path\l_program.sas date time

Programmer Note: For Other Row, show either Subject or Related under HLAA Typing Result column

Listing 16.2.8.14.1
Slit Lamp Exam (OD)
Part 1 of 2

Treatment Group	Subject ID	Visit	Exam Date (Study Day)	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?
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Baseline	Not Done: Reason	Abnormal CS	Yes	Abnormal CS	Yes	Abnormal CS	Yes	Abnormal CS	Yes	Abnormal CS	Yes
		Day 1	Date9.(xx)	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No
		Day 2	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Day 3	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Day 7	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Day 14	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Day 21	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
.		Day 28	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Month 2	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Month 3	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Month 4	Date9.(xx)	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No
		Month 5	Date9.(xx)	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No
		Month 6	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Month 9	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Month 12 or Early Termination	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx												

Note: CS=Clinically Significant, NCS=Not Clinically Significant.
path\l_program.sas date time
Programmer Note: If Slit Lamp Exam was not performed on left eye, please display "Not Done" and the reason in the "Exam Date" column.

Listing 16.2.8.14.1
Slit Lamp Exam (OD)
Part 1 of 2

Treatment Group	Subject ID	Visit	Exam Date (Study Day)	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	Clinically Significant Change from Baseline
Cohort 1 - 0.5 x 10^6 hRPC	xxx--	Screening	Date9.(xx)	0		Normal		Aphakic	Nuclear	+1	Yes/No	Finding : Abnoraml CS	Yes/No
		Baseline	Not Done: Reason	+1	Yes	Abnormal CS	Yes	Psedophakic	Cortical	+2	Yes/No		
		Day 1	Date9.(xx)	+1	No	Abnormal NCS	No	Phakic	Posterior	+3	Yes/No		
		Day 2	Date9.(xx)	+2		Normal		Aphakic	Not Applicable	+4	Yes/No		
		Day 3	Date9.(xx)	+3		Normal		Psedophakic	Nuclear	+1	Yes/No		
		Day 7	Date9.(xx)	+4		Normal		Phakic	Cortical	+2	Yes/No		
		Day 14	Date9.(xx)	+1		Normal		Aphakic	Posterior	+3	Yes/No		
		Day 21	Date9.(xx)	+4		Normal		Psedophakic	Nuclear	+4	Yes/No		
.		Day 28	Date9.(xx)	+1		Normal		Phakic	Cortical	+1	Yes/No		
		Month 2	Date9.(xx)	+4		Normal		Aphakic	Posterior	+2	Yes/No		
		Month 3	Date9.(xx)	+1		Normal		Psedophakic	Nuclear	+3	Yes/No		
		Month 4	Date9.(xx)	+3	No	Abnormal NCS	No	Phakic	Cortical	+4	Yes/No		
		Month 5	Date9.(xx)	+1	No	Abnormal NCS	No	Aphakic	Posterior	+1	Yes/No		
		Month 6	Date9.(xx)	+4		Normal		Psedophakic	Nuclear	+2	Yes/No		
		Month 9	Date9.(xx)	+3		Normal		Phakic	Cortical	+3	Yes/No		
		Month 12 or Early Termination	Date9.(xx)	+1		Normal		Aphakic	Posterior	+4	Yes/No		
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx												

Note: CS=Clinically Significant, NCS=Not Clinically Significant.
path\l_program.sas date time
Programmer Note: If Slit Lamp Exam was not performed on left eye, please display "Not Done" and the reason in the "Exam Date" column.
Programmer Note: Listing 16.2.8.14.2 will contain the same information for the other eye (OD).

Listing 16.2.8.14.2
Slit Lamp Exam (OS)
Part 2 of 2

Treatment Group	Subject ID	Visit	Exam Date (Study Day)	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?
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Baseline	Not Done: Reason	Abnormal CS	Yes	Abnormal CS	Yes	Abnormal CS	Yes	Abnormal CS	Yes	Abnormal CS	Yes
		Day 1	Date9.(xx)	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No
		Day 2	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Day 3	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Day 7	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Day 14	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Day 21	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
.		Day 28	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Month 2	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Month 3	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Month 4	Date9.(xx)	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No
		Month 5	Date9.(xx)	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No	Abnormal NCS	No
		Month 6	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Month 9	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
		Month 12 or Early Termination	Date9.(xx)	Normal		Normal		Normal		Normal		Normal	
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx												

Note: CS=Clinically Significant, NCS=Not Clinically Significant..
path\l_program.sas date time
Programmer Note: If Slit Lamp Exam was not performed on left eye, please display "Not Done" and the reason in the "Exam Date" column.
Programmer Note: Listing 16.2.8.14.2 will contain the same information for the other eye (OS).

Listing 16.2.8.14.2
Slit Lamp Exam (OS)
Part 2 of 2

Treatment Group	Subject ID	Visit	Exam Date (Study Day)	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	Clinically Significant Change from Baseline
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9.(xx)	0		Normal		Aphakic	Nuclear	+1	Yes/No	Finding : Abnoraml CS	Yes/No
		Baseline	Not Done: Reason	+1	Yes	Abnormal CS	Yes	Psedophakic	Cortical	+2	Yes/No		
		Day 1	Date9.(xx)	+1	No	Abnormal NCS	No	Phakic	Posterior	+3	Yes/No		
		Day 2	Date9.(xx)	+2		Normal		Aphakic	Not Applicable	+4	Yes/No		
		Day 3	Date9.(xx)	+3		Normal		Psedophakic	Nuclear	+1	Yes/No		
		Day 7	Date9.(xx)	+4		Normal		Phakic	Cortical	+2	Yes/No		
		Day 14	Date9.(xx)	+1		Normal		Aphakic	Posterior	+3	Yes/No		
		Day 21	Date9.(xx)	+4		Normal		Psedophakic	Nuclear	+4	Yes/No		
.		Day 28	Date9.(xx)	+1		Normal		Phakic	Cortical	+1	Yes/No		
		Month 2	Date9.(xx)	+4		Normal		Aphakic	Posterior	+2	Yes/No		
		Month 3	Date9.(xx)	+1		Normal		Psedophakic	Nuclear	+3	Yes/No		
		Month 4	Date9.(xx)	+3	No	Abnormal NCS	No	Phakic	Cortical	+4	Yes/No		
		Month 5	Date9.(xx)	+1	No	Abnormal NCS	No	Aphakic	Posterior	+1	Yes/No		
		Month 6	Date9.(xx)	+4		Normal		Psedophakic	Nuclear	+2	Yes/No		
		Month 9	Date9.(xx)	+3		Normal		Phakic	Cortical	+3	Yes/No		
		Month 12 or Early Termination	Date9.(xx)	+1		Normal		Aphakic	Posterior	+4	Yes/No		
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx												

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

Programmer Note: If Slit Lamp Exam was not performed on left eye, please display "Not Done" and the reason in the "Exam Date" column.

Listing 16.2.8.15
Fundus Photography

				OD		OS	
Treatment Group	Subject ID	Visit	Date Performed (Study Day)	Results	If Right Eye Abnormal – Change from Previous Visit	Results	If Left Eye Abnormal – Change from Previous Visit
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9.(xx)	Normal		Normal	
	xxx-xxx	Baseline	Not Done: Reason				
	xxx-xxx	Baseline	Date9.(xx)	Abnormal CS: Abnormality	Yes	Abnormal CS:Abnormality	Yes
	xxx-xxx	Baseline	Date9.(xx)	Abnormal NCS	Yes	Abnormal NCS	Yes
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Date9.(xx)				

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

path\l_program.sas date time

Programmer Note: If Fundus Photography was not performed, please display "Not Done" and the reason in the "Date Performed" column.

Listing 16.2.8.16
Intraocular Pressure (IOP)

Treatment Group	Subject ID	Visit	Measurement Date (Study Day)	Measurement Time	Was a Tonopen Used?	If No, Specify Device Used	OD (Right) Mean IOP (mmHg)	OS (Left) Mean IOP (mmHg)
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Day 0	Not done: Reason					
		Day1	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Day 2	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Day 3	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Day 7	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Day 14	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Day 21	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Day 28	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Month 2	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Month 3	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Month 4	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Month 5	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Month 6	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Month 9	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
		Month 12 or Early Termination	Date9.(xx)	Time5.	Yes/No	xxxxxxxxx	xx	xx
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9.(xx)					

path\l_program.sas date time

Programmer Note If an IOP measurement was not completed, please display "Not Done" and the reason in the "Measurement Date/Time" column.

Listing 16.2.8.17
B-Scan

					Study Eye		Right Eye (OD)				Left Eye (OS)			
Treatment Group	Subject ID	Visit	Measurement Date (Study Day)	Time	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
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9.(xx)	Time5.	Yes: Description/ No/NA	Yes/No/NA	Normal	Yes/No/NA	Retinal Detachment	Good/Poor	Normal	Yes/No/NA	Retinal Detachment	Good/Poor
		Day 3	Not done: Reason											
		Day 7	Date9.(xx)	Time5.	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 3	Date9.(xx)	Time5.	Yes/No/NA	Yes/No/NA	Abnormal NCS	Yes/No/NA		Good/Poor	Abnormal NCS	Yes/No/NA		Good/Poor
		Month 6	Date9.(xx)	Time5.	Yes/No/NA	Yes/No/NA	Normal	Yes/No/NA		Good/Poor	Normal	Yes/No/NA		Good/Poor
		Month 12 or Early Termination	Date9.(xx)	Time5.	Yes/No/NA	Yes/No/NA	Normal	Yes/No/NA		Good/Poor	Normal	Yes/No/NA		Good/Poor
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Baseline	Date9.(xx)	Time5.	Yes/No/NA	Yes/No/NA	Normal	Yes/No/NA		Good/Poor	Normal	Yes/No/NA		Good/Poor
		Day 3	Not done: Reason											
		Day 7	Date9.(xx)	Time5.	Yes/No/NA	Yes/No/NA	Abnormal CS:Abnormality	Yes/No/NA		Good/Poor	Abnormal CS:Abnormality	Yes/No/NA		Good/Poor
		Month 3	Date9.(xx)	Time5.	Yes/No/NA	Yes/No/NA	Abnormal NCS	Yes/No/NA		Good/Poor	Abnormal NCS	Yes/No/NA		Good/Poor
		Month 6	Date9.(xx)	Time5.	Yes/No/NA	Yes/No/NA	Normal	Yes/No/NA		Good/Poor	Normal	Yes/No/NA		Good/Poor
		Month 12 or Early Termination	Date9.(xx)	Time5.	Yes/No/NA	Yes/No/NA	Normal	Yes/No/NA		Good/Poor	Normal	Yes/No/NA		Good/Poor

Note: CS=Clinically Significant, NCS=Not Clinically Significant.
path\l_program.sas date time
Programmer Note :If B-Scan measurement was not completed, please display "Not Done" and the reason in the "Measurement Date/Time" column.
Programmer Note Include description of abnormality and Clinically Significant information in "B-Scan Result" column.

Listing 16.2.8.18
Dilated Funduscopic Examination
Part 1 of 4

					OD (Right)						
Treatment Group	Subject ID	Visit	Time of Dilator Administration	Examination Date (Study Day)	Time of Examination	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
Cohort 1 - 0.5×10^6 hRPC	xxx--xxx	Screening	Time5.	Date9. (xx)	Time5.	Normal		Mild	Normal		Mild
		Baseline	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
	……	Day 1	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Severe	Abnormal CS: Abnormality	Yes	Severe
……..		Day 2	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Very Server	Abnormal NCS	No	Very Server
		Day 3	Time5.	Date9. (xx)	Time5.	Normal		Mild	Normal		Mild
		Day 7	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
		Day 14	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
		Day 21	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Moderate	Abnormal NCS	No	Moderate
		Day 28	Time5.	Date9. (xx)	Time5.	Not Done		Mild	Not Done		Mild
		Month 2	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
		Month 3	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
		Month 4	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Not Done	Abnormal NCS	No	Not Done
		Month 5	Time5.	Date9. (xx)	Time5.	Normal		Mild	Normal		Mild
		Month 6	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
	……	Month 9	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
……..		Month 12 or Early Termination	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Moderate	Abnormal NCS	No	Moderate
Cohort 2 - 0.5×10^6 hRPC	xxx--xxx										

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: If dilated funduscopic examination was not performed, please display “Not Done” and the reason in the “Examination Date/Time” column

Listing 16.2.8.18
Dilated Funduscopic Examination
Part 2 of 4

					OD (Right)						
Treatment Group	Subject ID	Visit	Time of Dilator Administration	Examination Date (Study Day)	Time of Examination	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
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Time5.	Date9. (xx)	Time5.	Normal		Mild	Normal		Mild
		Baseline	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
	……	Day 1	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Severe	Abnormal CS: Abnormality	Yes	Severe
……..		Day 2	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Very Server	Abnormal NCS	No	Very Server
		Day 3	Time5.	Date9. (xx)	Time5.	Normal		Mild	Normal		Mild
		Day 7	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
		Day 14	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
		Day 21	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Moderate	Abnormal NCS	No	Moderate
		Day 28	Time5.	Date9. (xx)	Time5.	Not Done		Mild	Not Done		Mild
		Month 2	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
		Month 3	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
		Month 4	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Not Done	Abnormal NCS	No	Not Done
		Month 5	Time5.	Date9. (xx)	Time5.	Normal		Mild	Normal		Mild
		Month 6	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
		Month 9	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
.		Month 12 or Early Termination	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Moderate	Abnormal NCS	No	Moderate
……	…..	……									
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx										

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: If dilated funduscopic examination was not performed, please display “Not Done” and the reason in the “Examination Date/Time” column

Listing 16.2.8.18
Dilated Funduscopic Examination
Part 3 of 4

						OS(Left)					
Treatment Group	Subject ID	Visit	Time of Dilator Administration	Examination Date (Study Day)	Time of Examination	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
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Time5.	Date9. (xx)	Time5.	Normal		Mild	Normal		Mild
		Baseline	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
	……	Day 1	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Severe	Abnormal CS: Abnormality	Yes	Severe
……..		Day 2	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Very Server	Abnormal NCS	No	Very Server
		Day 3	Time5.	Date9. (xx)	Time5.	Normal		Mild	Normal		Mild
		Day 7	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
		Day 14	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
		Day 21	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Moderate	Abnormal NCS	No	Moderate
		Day 28	Time5.	Date9. (xx)	Time5.	Not Done		Mild	Not Done		Mild
		Month 2	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
		Month 3	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
		Month 4	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Not Done	Abnormal NCS	No	Not Done
		Month 5	Time5.	Date9. (xx)	Time5.	Normal		Mild	Normal		Mild
		Month 6	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
	……	Month 9	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
……..		Month 12 or Early Termination	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Moderate	Abnormal NCS	No	Moderate
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx										

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 Cohort #, subject ID, examination date (include unscheduled visits in the date sequence), and examination time.
Programmer Note: If dilated funduscopic examination was not performed, please display “Not Done” and the reason in the “Examination Date/Time” column

Listing 16.2.8.18
Dilated Funduscopic Examination
Part 4 of 4

					OS (Left)							
Treatment Group	Subject ID	Visit	Time of Dilator Administration	Examination Date (Study Day)	Time of Examination	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
Cohort 1 - 0.5 x 10^6 hRPC	xxx--xxx	Screening	Time5.	Date9. (xx)	Time5.	Normal		Mild	Normal		Mild
		Baseline	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
	……	Day 1	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Severe	Abnormal CS: Abnormality	Yes	Severe
……..		Day 2	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Very Server	Abnormal NCS	No	Very Server
		Day 3	Time5.	Date9. (xx)	Time5.	Normal		Mild	Normal		Mild
		Day 7	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
		Day 14	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
		Day 21	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Moderate	Abnormal NCS	No	Moderate
		Day 28	Time5.	Date9. (xx)	Time5.	Not Done		Mild	Not Done		Mild
		Month 2	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
		Month 3	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
		Month 4	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Not Done	Abnormal NCS	No	Not Done
		Month 5	Time5.	Date9. (xx)	Time5.	Normal		Mild	Normal		Mild
		Month 6	Time5.	Date9. (xx)	Time5.	Not Done		Moderate	Not Done		Moderate
		Month 9	Time5.	Date9. (xx)	Time5.	Abnormal CS: Abnormality	Yes	Mild	Abnormal CS: Abnormality	Yes	Mild
.		Month 12 or Early Termination	Time5.	Date9. (xx)	Time5.	Abnormal NCS	No	Moderate	Abnormal NCS	No	Moderate
……	…..	……									
Cohort 2 - 0.5 x 10^6 hRPC	xxx--xxx										

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 Cohort #, subject ID, examination date (include unscheduled visits in the date sequence), and examination time.
Programmer Note: If dilated funduscopic examination was not performed, please display “Not Done” and the reason in the “Examination Date/Time” column

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