NOVARTIS

Clinical Development

RFB002/ranibizumab / NCT01972789

A Phase IV, randomised, controlled, single masked study investigating the efficacy and safety of ranibizumab "inject and extend" using an intensive retinal fluid retreatment regimen compared to a relaxed retinal fluid retreatment regimen in patients with wet age-related macular degeneration (AMD).

Project standard In-text and Post-text and appendix deliverables

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By my signature, I confirm that this deliverables document has been reviewed by Novartis Australia, and has been approved for use on the CRFB002AAU15 study:

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Table of contents

General guidance

1.1 General guidance on shells in this document

1.1.1 Document headers

The following header will be used for all Section 14 and Section 16 tables, listings and figures outlined in this document: CRFB002AAU15/RFB002/Ranibizumab.

1.1.2 Presentation of table numbering and titles within this document

In order to facilitate the inclusion of a table of contents for all output, the format of the number and title for each layout should be in the Novstyle format “Non-TOC Heading” and therefore does not exactly match the layout that is intended for the final deliverable.

In practice, the numbering and title for all Section 14 and Section 16 tables and listings defined in this document will be of the following formats respectively:

```
Table XX.X-X.X
Title Title Title Title Title Title
Analysis set

Listing XX.X-X.X
Title Title Title Title Title Title
Analysis set
```

1.2 General strategies of data presentation

1.2.1 Treatment group labels and ordering

The following treatment labels will be used for all tables, listings and figures in the order provided here:

- Intensive
- Relaxed
- Total (*where applicable*)

1.2.2 Missing treatment columns

All treatment columns should be presented as long as data is available for at least one treatment group. When information is not available for any treatment groups then “No observations available” will be used to reflect that observations are not available for a specific table/figure/listing.

In the case where treatment columns are automatically dropped due to lack of events/data etc. output the following footnote will be added:

```
Note: Treatment groups which do not contribute events are not displayed.
```

1.2.3 Order of entries in listings

All listings should be sorted by treatment group, site, patient, visit date/event date (in the case of multiple observations per visit date/event date, the observations should be sorted alphabetically within visit date/event date).

1.2.4 Decimal places

Decimal places for demographic, background and duration of exposure variables will be as follows:

- 3 decimal places for p-values; if p-value is less than 0.001, display <0.001.
- 2 decimal places for standard errors and standard deviations.
- 1 decimal place for means and medians.
- 1 decimal place for min and max.
- 1 decimal place for percentages.
- If percentage = 100, no decimal is required.

Decimal places for efficacy and other safety summary tables and listings will be as follows:

- p-value: 3 decimal places; if p-value is less than 0.001, display <0.001.
- Standard errors and standard deviations: data precision + 2 decimal places
- Means and medians: data precision + 1 decimal place
- Minimums and maximums: same as data precision
- Percentages: 1 decimal place
- If percentage = 100, no decimal is required.

Please ignore current examples of precision in shells.

1.2.5 Baseline Definition

For statistical purposes, baseline will be defined as the last available non-missing value collected just prior to the start of treatment in the study eye.

Overall table of contents for IIS outputs

2 Shells and specifications

2.1 Shells and specifications for Sections 10, 11 and 12 of a standard CSR (Text tables and figures)

Section 10 Study patients

PATIENT DISPOSITION

Table 10-1 Patient disposition – n (%) of patients

Randomised Set

n(%)	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
All Enrolled	x (xx.x)	x (xx.x)	x (xx.x)
Number of Subjects Started Treatment	x (xx.x)	x (xx.x)	x (xx.x)
Number of Subjects Completed Treatment	x (xx.x)	x (xx.x)	x (xx.x)
Number of Subjects Discontinued Early	x (xx.x)	x (xx.x)	x (xx.x)
Primary Reason for Early Discontinuation			
Adverse Event	x (xx.x)	x (xx.x)	x (xx.x)
Subject withdrew consent	x (xx.x)	x (xx.x)	x (xx.x)
Lost to follow-up	x (xx.x)	x (xx.x)	x (xx.x)
Site administrative problems	x (xx.x)	x (xx.x)	x (xx.x)
Death	x (xx.x)	x (xx.x)	x (xx.x)
Protocol deviation	x (xx.x)	x (xx.x)	x (xx.x)
Physician’s decision	x (xx.x)	x (xx.x)	x (xx.x)

Source: Table 14.1-1

PROTOCOL DEVIATIONS

Table 10-2 Protocol Deviations – n (%) of patients and total counts

Full Analysis Set

Population n (%)	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Subjects with at least one protocol deviation	x (xx.x)	x (xx.x)	x (xx.x)
Number of deviations	x	x	x
Type of Deviation			
I (inclusion criteria)	x (xx.x)	x (xx.x)	x (xx.x)
E (Exclusion criteria)	x (xx.x)	x (xx.x)	x (xx.x)
M (Medication)	x (xx.x)	x (xx.x)	x (xx.x)
O (other)	x (xx.x)	x (xx.x)	x (xx.x)

Source: Table 14.1-3

Section 11 Efficacy

ANALYSIS SETS

Table 11.1-1 Analysis sets – n (%) of patients

Randomised Set

Population n(%)	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Randomised Set	x (xx.x)	x (xx.x)	x (xx.x)
Full Analysis Set	x (xx.x)	x (xx.x)	x (xx.x)
Safety Set	x (xx.x)	x (xx.x)	x (xx.x)
Per-Protocol Set*	x (xx.x)	x (xx.x)	x (xx.x)

* Includes all patients who contributed at least one data point to per-protocol analyses. Individual data points or visits may have been excluded from per-protocol analyses based on protocol deviation assessments.

Source: Table 14.1-7

Note to Programmer: Table needs to include all analysis sets used in the output. This includes any derived analysis sets used for sensitivity analyses

DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Table 11.2-1 Demographic summary by treatment group

Randomised Set

		Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Study Eye				
	Left	x (xx.x)	x (xx.x)	x (xx.x)
	Right	x (xx.x)	x (xx.x)	x (xx.x)
Age (years)*				
	n	x	x	x
	Mean	x.x	x.x	x.x
	Median	x.x	x.x	x.x
	SD	x.x	x.x	x.x
	Minimum	x	x	x
	Maximum	x	x	x
Gender n(%)				
	Female	x (xx.x)	x (xx.x)	x (xx.x)
	Male	x (xx.x)	x (xx.x)	x (xx.x)
Predominate Race n(%)				
	Caucasian: Afghan, Caucasian, Egypt, Egyptian, El Salvadore, Greek, Hispanic, Israeli, Italian, Maltese, Middle East, Middle Eastern, South American, Turkish, Yugoslavian	x (xx.x)	x (xx.x)	x (xx.x)

		Intensive (N=X)	Relaxed (N=X)	Total (N=X)
	Black African	x (xx.x)	x (xx.x)	x (xx.x)
	Asian: Asian and Indian	x (xx.x)	x (xx.x)	x (xx.x)
	Aboriginal and Torres Strait Islander	x (xx.x)	x (xx.x)	x (xx.x)
	Pacific Islander	x (xx.x)	x (xx.x)	x (xx.x)
	Not Sure	x (xx.x)	x (xx.x)	x (xx.x)
Ethnicity n(%)				
	Anglo Saxon	x (xx.x)	x (xx.x)	x (xx.x)
	Northern European	x (xx.x)	x (xx.x)	x (xx.x)
	Southern European	x (xx.x)	x (xx.x)	x (xx.x)
	Asian Indian	x (xx.x)	x (xx.x)	x (xx.x)
	Other	x (xx.x)	x (xx.x)	x (xx.x)
	Not Sure	x (xx.x)	x (xx.x)	x (xx.x)
Do you have a family history of AMD?				
	Yes	x (xx.x)	x (xx.x)	x (xx.x)
	No	x (xx.x)	x (xx.x)	x (xx.x)
Is there any history of arterial thromboembolic events?				
	Yes	x (xx.x)	x (xx.x)	x (xx.x)
	No	x (xx.x)	x (xx.x)	x (xx.x)
Has the participant ever smoked cigarettes, pipes or cigars?				
	Yes	x (xx.x)	x (xx.x)	x (xx.x)
	No	x (xx.x)	x (xx.x)	x (xx.x)

*Age calculated at date of informed consent
SD: Standard Deviation
Source: Table 14.1-6

Table 11.2-2 Baseline Medical History Questions by treatment group

Randomised Set

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Medical history/Current medical conditions to be reported*	x (xx.x)	x (xx.x)	x (xx.x)

* Refer to Table 14.1-9 and 14.1-10 for further details
Source: Table 14.1-7

Table 11.2-3 Medical History - Arterial Thomboembolic Events

Randomised Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
Arterial Thomboembolic Events (ATEs)*	xx.x	x	xx.x	x	xx.x	x
Nonfatal myocardial infarction	xx.x	x	xx.x	x	xx.x	x
Nonfatal stroke	xx.x	x	xx.x	x	xx.x	x

* ATEs defined as nonfatal myocardial infarction, nonfatal stroke, vascular death and death of unknown cause
AE: Adverse Event
Note: Some patients may have experienced multiple events

Table 11.2-4 Baseline AMD characteristics (STUDY EYE) by treatment group

Randomised Set

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Was any treatment ever given to the fellow eye prior to Screening?			
No	x (xx.x)	x (xx.x)	x (xx.x)
Yes	x (xx.x)	x (xx.x)	x (xx.x)
Lucentis	x (xx.x)	x (xx.x)	x (xx.x)
Eylea	x (xx.x)	x (xx.x)	x (xx.x)
Visudyne	x (xx.x)	x (xx.x)	x (xx.x)
Avastin	x (xx.x)	x (xx.x)	x (xx.x)
Steroids	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)
Total BCVA Score (ETDRS letters)			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x
Visual Acuity - Categorical (20/40)			
>=70 letters	x (xx.x)	x (xx.x)	x (xx.x)
<70 letters	x (xx.x)	x (xx.x)	x (xx.x)

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Central Subfield Foveal Thickness (µm)*			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x
Central Subfield Volume (mm^3)*			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x
Area of Lesion (mm^2)*			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x
Intra-Retinal Fluid Status			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can’t Grade	x (xx.x)	x (xx.x)	x (xx.x)

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Intra-Retinal Fluid Status*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Intra-Retinal Fluid Centre Involvement*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Intra-Retinal Cysts*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Intra-Retinal Cysts Centre Involvement*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Sub-Retinal Fluid Status			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Sub-Retinal Fluid Status*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Sub-Retinal Fluid Centre Involvement*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Sub-Retinal Fluid at Centrepoint*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Sub-Retinal Fluid Height at Centrepoint			
<=200µm	x (xx.x)	x (xx.x)	x (xx.x)
>200 µm	x (xx.x)	x (xx.x)	x (xx.x)
Not Applicable	x (xx.x)	x (xx.x)	x (xx.x)
Sub-Retinal Fluid Height at Centrepoint*			
<=200µm	x (xx.x)	x (xx.x)	x (xx.x)
>200 µm	x (xx.x)	x (xx.x)	x (xx.x)
Not Applicable	x (xx.x)	x (xx.x)	x (xx.x)
Morphologic Changes*			
Epiretinal Membrane	x (xx.x)	x (xx.x)	x (xx.x)
Vitreoretinal Traction	x (xx.x)	x (xx.x)	x (xx.x)
Macular Hole	x (xx.x)	x (xx.x)	x (xx.x)
Atrophy	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Area of CNV (mm^2)*			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x
CNV Complex (lesion)			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Definite	x (xx.x)	x (xx.x)	x (xx.x)
Questionable	x (xx.x)	x (xx.x)	x (xx.x)
……	x (xx.x)	x (xx.x)	x (xx.x)
CNV Complex (lesion)*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Definite	x (xx.x)	x (xx.x)	x (xx.x)
Questionable	x (xx.x)	x (xx.x)	x (xx.x)
……	x (xx.x)	x (xx.x)	x (xx.x)
CNV Complex (lesion) Location			
Subfoveal	x (xx.x)	x (xx.x)	x (xx.x)
Juxtafoveal	x (xx.x)	x (xx.x)	x (xx.x)
Juxtafoveal with centre involvement	x (xx.x)	x (xx.x)	x (xx.x)
Extrafoveal	x (xx.x)	x (xx.x)	x (xx.x)
Extrafoveal with centre involvement	x (xx.x)	x (xx.x)	x (xx.x)
Can't grade	x (xx.x)	x (xx.x)	x (xx.x)

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
CNV Location			
Subfoveal	x (xx.x)	x (xx.x)	x (xx.x)
Juxtafoveal	x (xx.x)	x (xx.x)	x (xx.x)
Extrafoveal	x (xx.x)	x (xx.x)	x (xx.x)
Can't grade	x (xx.x)	x (xx.x)	x (xx.x)
CNV Location*			
Subfoveal	x (xx.x)	x (xx.x)	x (xx.x)
Juxtafoveal	x (xx.x)	x (xx.x)	x (xx.x)
Juxtafoveal with centre involvement	x (xx.x)	x (xx.x)	x (xx.x)
Extrafoveal	x (xx.x)	x (xx.x)	x (xx.x)
Extrafoveal with centre involvement	x (xx.x)	x (xx.x)	x (xx.x)
Can't grade	x (xx.x)	x (xx.x)	x (xx.x)
CNV Secondary to …..*			
AMD	x (xx.x)	x (xx.x)	x (xx.x)
Angioid Streaks	x (xx.x)	x (xx.x)	x (xx.x)
Idiopathic	x (xx.x)	x (xx.x)	x (xx.x)
Pathologic Myopia	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)
Type of CNV*			
Predominantly classic	x (xx.x)	x (xx.x)	x (xx.x)
Occult	x (xx.x)	x (xx.x)	x (xx.x)
Fibrovascular PED	x (xx.x)	x (xx.x)	x (xx.x)
Serous PED	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
CNV Leakage*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Lesion Components*			
Blood	x (xx.x)	x (xx.x)	x (xx.x)
CNV	x (xx.x)	x (xx.x)	x (xx.x)
Serous PED	x (xx.x)	x (xx.x)	x (xx.x)
RPE Tear	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Geographic Atrophy (Status)*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Definite	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Not Applicable	x (xx.x)	x (xx.x)	x (xx.x)
Geographic Atrophy Location*			
Central Subfield	x (xx.x)	x (xx.x)	x (xx.x)
Inner Subfield	x (xx.x)	x (xx.x)	x (xx.x)
Outer Subfield	x (xx.x)	x (xx.x)	x (xx.x)
Geographic Atrophy Area (mm^2)*			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Haemorrhage*			
Yes	x (xx.x)	x (xx.x)	x (xx.x)
No	x (xx.x)	x (xx.x)	x (xx.x)
Haemorrhage Location*			
Central Subfield	x (xx.x)	x (xx.x)	x (xx.x)
Inner Subfield	x (xx.x)	x (xx.x)	x (xx.x)
Outer Subfield	x (xx.x)	x (xx.x)	x (xx.x)
Retinal Abnormality*			
Drusen	x (xx.x)	x (xx.x)	x (xx.x)
Atrophy	x (xx.x)	x (xx.x)	x (xx.x)
Fibrosis	x (xx.x)	x (xx.x)	x (xx.x)
PED	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)
Retinal Abnormality Location*			
Central	x (xx.x)	x (xx.x)	x (xx.x)
Periphery	x (xx.x)	x (xx.x)	x (xx.x)

* Source: [redacted]
Source: Table 14.1-8

Note to Programmer: Footnote is to appear on all pages

ANALYSIS OF EFFICACY

Table 11.4-1.1 Mean absolute change in BCVA from baseline to months 2, 12 and 24

Full analysis set

Visit	Statistic	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
		Actual Value	Absolute Change from Baseline*	Actual Value	Absolute Change from Baseline	Actual Value	Absolute Change from Baseline
Baseline	n	x	-	x	-	x	-
	Mean (SD)	x.x (x.x)	-	x.x (x.x)	-	x.x (x.x)	-
	Min; Max	x;x	-	x;x	-	x;x	-
Month 2	n	x	x	x	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x	x;x	x;x	x;x
Month 12	n	x	x	x	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x	x;x	x;x	x;x
Month 24	n	x	x	x	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x	x;x	x;x	x;x

*Baseline: The last available non-missing value collected just prior to the start of treatment in the study eye
SD: Standard Deviation
Source: Table 14.2-1

Table 11.4-1.2 Mean absolute change in BCVA from baseline to months 2, 12 and 24

Per Protocol Set

Visit	Statistic	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
		Actual Value	Absolute Change from Baseline*	Actual Value	Absolute Change from Baseline	Actual Value	Absolute Change from Baseline
Baseline	n	x	-	x	-	x	-
	Mean (SD)	x.x (x.x)	-	x.x (x.x)	-	x.x (x.x)	-
	Min; Max	x;x	-	x;x	-	x;x	-
Month 2	n	x	x	x	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x	x;x	x;x	x;x
Month 12	n	x	x	x	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x	x;x	x;x	x;x
Month 24	n	x	x	x	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x	x;x	x;x	x;x

*Baseline: The last available non-missing value collected just prior to the start of treatment in the study eye
SD: Standard Deviation
Source: Table 14.2-1

Table 11.4-2 Mean change in Central Retinal Thickness from baseline to months 2, 12 and 24 (STUDY EYE)

Full Analysis Set

Visit	Statistic	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
		Actual Value	Absolute Change from Baseline*	Actual Value	Absolute Change from Baseline	Actual Value	Absolute Change from Baseline
Baseline	n	x	-	x	-	x	-
	Mean (SD)	x.x (x.x)	-	x.x (x.x)	-	x.x (x.x)	-
	Min; Max	x;x	-	x;x	-	x;x	-
Month 2	n	x	-	x	-	x	-
	Mean (SD)	x.x (x.x)	-	x.x (x.x)	-	x.x (x.x)	-
	Min; Max	x;x	-	x;x	-	x;x	-
Month 12	n	x	-	x	-	x	-
	Mean (SD)	x.x (x.x)	-	x.x (x.x)	-	x.x (x.x)	-
	Min; Max	x;x	-	x;x	-	x;x	-
Month 24	n	x	-	x	-	x	-
	Mean (SD)	x.x (x.x)	-	x.x (x.x)	-	x.x (x.x)	-
	Min; Max	x;x	-	x;x	-	x;x	-

*Baseline: The last available non-missing value collected just prior to the start of treatment in the study eye
SD: Standard Deviation
NOTE: Data based on Central Reading Center data
Source: Table 14.2-5

Table 11.4-3 Number of Injections from baseline to month 12 and 24

Full Analysis Set

Visit		Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Number of Injections (First Year)	n	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x
Number of Injections (Second Year)	n	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x
Number of Injections (Total)	n	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x
Exposure (year)	n	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x
Injections per year*		xx	xx	xx

* Injections per year = Total number of injections / total exposure to treatment (years)

Source: Table 14.2-8

Section 12 Safety evaluation

EXTENT OF EXPOSURE

Table 12.1-1 Overall exposure

Safety Set

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Duration of Exposure (days)*			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x

SD: Standard Deviation

*Duration of Exposure = Date of first treatment to date of End of Treatment + 1

Source: Table 14.3-2

Table 12.1-2 Treatment Frequency and Intervals at 12 and 24 months

Safety set

Visit	Interval n (%)	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Month 12	4 weeks	x (xx.x)	x (xx.x)	x (xx.x)
	6 weeks	x (xx.x)	x (xx.x)	x (xx.x)
	8 weeks	x (xx.x)	x (xx.x)	x (xx.x)
	10 weeks	x (xx.x)	x (xx.x)	x (xx.x)
	12 weeks	x (xx.x)	x (xx.x)	x (xx.x)
Month 24	4 weeks	x (xx.x)	x (xx.x)	x (xx.x)
	6 weeks	x (xx.x)	x (xx.x)	x (xx.x)
	8 weeks	x (xx.x)	x (xx.x)	x (xx.x)
	10 weeks	x (xx.x)	x (xx.x)	x (xx.x)
	12 weeks	x (xx.x)	x (xx.x)	x (xx.x)

Source: Table 14.3-1

Note to Programmer: This table counts what interval schedule each patient is on at the static timepoints of Month 12 and Month 24. Knowing the Month 12 date, look at the injection visit immediately prior to that date and use the Interval Decision value. If the patient's injection visit was held at the same time as the Month 12 visit then use the Interval leading up to the visit rather than the Injection Decision.

ADVERSE EVENTS

Table 12.2-1 Number (%) of patients with AEs by primary system organ class

Safety set

System Organ Class (SOC) Preferred Term (PT)	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x)	x	x (xx.x)	x	x (xx.x)	x
SOC1	x (xx.x)	x	x (xx.x)	x	x (xx.x)	x
PT1	x (xx.x)	x	x (xx.x)	x	x (xx.x)	x
PT2	x (xx.x)	x	x (xx.x)	x	x (xx.x)	x
….	….	….	….	….	….	….
PTx	x (xx.x)	x	x (xx.x)	x	x (xx.x)	x
SOC2	x (xx.x)	x	x (xx.x)	x	x (xx.x)	x
PT1	x (xx.x)	x	x (xx.x)	x	x (xx.x)	x
PT2	x (xx.x)	x	x (xx.x)	x	x (xx.x)	x
….	….	….	….	….	….	….
PTx	x (xx.x)	x	x (xx.x)	x	x (xx.x)	x
……..						

AE: Adverse Event

A patient with multiple occurrences of an AE under one treatment is counted only once in the AE category for that treatment.

A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

Source: Table 14.3.1-1

DEATHS, OTHER SERIOUS ADVERSE EVENTS, AND OTHER SIGNIFICANT ADVERSE EVENTS

None

LABORATORY EVALUATIONS

None

LIVER TOXICITY

None

VITAL SIGNS, PHYSICAL FINDING, OTHER OBSERVATION RELATED TO SAFETY

None

2.2 Shells and specifications for Sections 14 and 16 of a standard CSR

Section 14 – Tables, figures referred to but not included in the text

Section 14.1 – Demographic data

Figures (Section 14.1)

No Output

Tables (Section 14.1)

Table 14.1-1 Patient disposition, by treatment

Randomised Set

Disposition Reason	Intensive (N=X) n (%)	Relaxed (N=X) n (%)	Total (N=X) n (%)
All Enrolled	x (xx.x)	x (xx.x)	x (xx.x)
Number of Subjects Started Treatment	x (xx.x)	x (xx.x)	x (xx.x)
Number of Subjects Completed Treatment	x (xx.x)	x (xx.x)	x (xx.x)
Number of Subjects Terminated Early	x (xx.x)	x (xx.x)	x (xx.x)
Primary Reason for Termination			
Adverse Event	x (xx.x)	x (xx.x)	x (xx.x)
Subject withdrew consent	x (xx.x)	x (xx.x)	x (xx.x)
Lost to follow-up	x (xx.x)	x (xx.x)	x (xx.x)
Site administrative problems	x (xx.x)	x (xx.x)	x (xx.x)
Death	x (xx.x)	x (xx.x)	x (xx.x)
Protocol deviation	x (xx.x)	x (xx.x)	x (xx.x)
Physician’s decision	x (xx.x)	x (xx.x)	x (xx.x)

Table 14.1-2 Screening phase subject disposition

Randomised Set

Disposition Reason	Total (N=X) n (%)
Completed Screening phase	x (xx.x)
Discontinued prior to screening phase completion	x (xx.x)
Primary Reason for Termination	
Adverse Event	x (xx.x)
Lost to follow-up	x (xx.x)
Physician's decision	x (xx.x)
Screen failure	x (xx.x)
Study terminated by Sponsor	x (xx.x)
Technical problems	x (xx.x)
Subject/guardian decision	x (xx.x)
Death	x (xx.x)

Note: Percentage is out of total number screened

Table 14.1-3 Protocol deviations, by treatment

Full Analysis Set

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Subjects with at least one protocol deviation	x (xx.x)	x (xx.x)	x (xx.x)
Number of deviations	x	x	x
Category 1	x (xx.x)	x (xx.x)	x (xx.x)
Category 2	x (xx.x)	x (xx.x)	x (xx.x)
Category 3	x (xx.x)	x (xx.x)	x (xx.x)
Category 4	x (xx.x)	x (xx.x)	x (xx.x)
Category ***n***	x (xx.x)	x (xx.x)	x (xx.x)

Note: Patients with multiple occurrences of a protocol deviation category are counted only once in the protocol deviation category.

Note: Patients may have protocol deviations in more than one protocol deviation category.

Table 14.1-4 Protocol deviations leading to exclusion from analysis sets

Full Analysis Set

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Excluded from Full Analysis Set (FAS)	x (xx.x)	x (xx.x)	x (xx.x)
Total	x (xx.x)	x (xx.x)	x (xx.x)
Category 1	x (xx.x)	x (xx.x)	x (xx.x)
PD term 1			
PD term 2			
….			
Category 2	x (xx.x)	x (xx.x)	x (xx.x)
PD term 1			
PD term 2			
….			
Category 3	x (xx.x)	x (xx.x)	x (xx.x)
PD term 1			
PD term 2			
….			
Category 4	x (xx.x)	x (xx.x)	x (xx.x)
PD term 1			
PD term 2			
….			
Category ***n***			
….			
Excluded from …… Set			
….			

Note: Patients with multiple occurrences of a protocol deviation category are counted only once for that specific protocol deviation criterion.

Note: Patients may have multiple protocol deviations.

Table 14.1-5 Out of Window visits

Full Analysis Set

		Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Number of days earlier than planned	1 - 7 days	x (xx.x)	x (xx.x)	x (xx.x)
	8 – 14 days	x (xx.x)	x (xx.x)	x (xx.x)
	15 - 28 days	x (xx.x)	x (xx.x)	x (xx.x)
	29 - 42 days	x (xx.x)	x (xx.x)	x (xx.x)
	>42 days	x (xx.x)	x (xx.x)	x (xx.x)
Number of days later than planned	1 - 7 days	x (xx.x)	x (xx.x)	x (xx.x)
	8 – 14 days	x (xx.x)	x (xx.x)	x (xx.x)
	15 - 28 days	x (xx.x)	x (xx.x)	x (xx.x)
	29 - 42 days	x (xx.x)	x (xx.x)	x (xx.x)
	>42 days	x (xx.x)	x (xx.x)	x (xx.x)

Table 14.1-6 Under and Over Treatment due to treatment interval error

Full Analysis Set

		Intensive (N=X)	**Relaxed (N=X)**	**Total (N=X)**
Under-Treated at least once	n(%)	x (xx.x)	x (xx.x)	x (xx.x)
Number of Times Under-Treated	n	x	x	x
	Mean	x.x	x.x	x.x
	Median	x.x	x.x	x.x
	SD	x.x	x.x	x.x
	Minimum	x	x	x
	Maximum	x	x	x
Over-Treated at least once	n(%)	x (xx.x)	x (xx.x)	x (xx.x)
Number of Times Over-Treated	n	x	x	x
	Mean	x.x	x.x	x.x
	Median	x.x	x.x	x.x
	SD	x.x	x.x	x.x
	Minimum	x	x	x
	Maximum	x	x	X

SD: Standard Deviation

Table 14.1-7 Analysis sets, by treatment

All Enrolled

Analysis Set	Intensive (N=X) n (%)	Relaxed (N=X) n (%)	Total (N=X) n (%)
Randomized Set	x (xx.x)	x (xx.x)	x (xx.x)
Full Analysis Set	x (xx.x)	x (xx.x)	x (xx.x)
Safety Set	x (xx.x)	x (xx.x)	x (xx.x)
Per-Protocol Set*	x (xx.x)	x (xx.x)	x (xx.x)

Note: Percentages are based on the number of patients in the Randomized set.

* Includes all patients who contributed at least one data point to per-protocol analyses. Individual data points or visits may have been excluded from per-protocol analyses based on protocol deviation assessments.

Randomized Set: The Randomised Population will consist of all randomised patients.
Full Analysis Set (FAS): The Full Analysis Set (FAS) compromises all subjects randomised and whom have at least one post-baseline efficacy value for the primary endpoint.
Safety Set: The Safety Set will consist of all patients who received at least one application of study treatment and had at least one post-baseline safety assessment. The statement that a patient had no adverse events also constitutes a safety assessment.
Per-Protocol Set: The Per-Protocol Set (PPS) will consist of all patients in the FAS who followed the treatment regimen as randomised and completed the study without clinically significant protocol deviations. Clinically significant protocol deviations will be identified and documented prior to the database lock. Refer to “Protocol Deviations” study document for further details.

Note to Programmer: Table needs to include all analysis sets used in the output. This includes any derived analysis sets used for sensitivity analyses

Table 14.1-8 Randomisation by Site

All Enrolled

Site	Intensive (N=X) n (%)	Relaxed (N=X) n (%)	P Value	Total (N=X) n (%)
			x.xxxx	
Site A	x (xx.x)	x (xx.x)		x (xx.x)
Site B	x (xx.x)	x (xx.x)		x (xx.x)
Site C	x (xx.x)	x (xx.x)		x (xx.x)
Site D	x (xx.x)	x (xx.x)		x (xx.x)

Table 14.1-9 Demographics, by treatment

Randomised Set

		Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Study Eye				
	Left	x (xx.x)	x (xx.x)	x (xx.x)
	Right	x (xx.x)	x (xx.x)	x (xx.x)
Age (years)*				
	n	x	x	x
	Mean	x.x	x.x	x.x
	Median	x.x	x.x	x.x
	SD	x.x	x.x	x.x
	Minimum	x	x	x
	Maximum	x	x	x
Gender n(%)				
	Female	x (xx.x)	x (xx.x)	x (xx.x)
	Male	x (xx.x)	x (xx.x)	x (xx.x)
Predominate Race n(%)				
	Caucasian: Afghan, Caucasian, Egypt, Egyptian, El Salvadore, Greek, Hispanic, Israeli, Italian, Maltese, Middle East, Middle Eastern, South American, Turkish, Yugoslavian	x (xx.x)	x (xx.x)	x (xx.x)
	Black African	x (xx.x)	x (xx.x)	x (xx.x)
	Asian: Asian and Indian	x (xx.x)	x (xx.x)	x (xx.x)
	Aboriginal and Torres Strait Islander	x (xx.x)	x (xx.x)	x (xx.x)
	Pacific Islander	x (xx.x)	x (xx.x)	x (xx.x)
	Not Sure	x (xx.x)	x (xx.x)	x (xx.x)
Ethnicity n(%)				
	Anglo Saxon	x (xx.x)	x (xx.x)	x (xx.x)
	Northern European	x (xx.x)	x (xx.x)	x (xx.x)
	Southern European	x (xx.x)	x (xx.x)	x (xx.x)

Asian Indian	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)
Not Sure	x (xx.x)	x (xx.x)	x (xx.x)
Do you have a family history of AMD?			
Yes	x (xx.x)	x (xx.x)	x (xx.x)
No	x (xx.x)	x (xx.x)	x (xx.x)
Is there any history of arterial thromboembolic events?			
Yes	x (xx.x)	x (xx.x)	x (xx.x)
No	x (xx.x)	x (xx.x)	x (xx.x)
Has the participant ever smoked cigarettes, pipes or cigars?			
Yes	x (xx.x)	x (xx.x)	x (xx.x)
No	x (xx.x)	x (xx.x)	x (xx.x)

*Age calculated at date of informed consent
SD: Standard Deviation

Table 14.1-10 Baseline characteristics by Treatment Group

Randomised Set

	Intensive (N=X)	Relaxed (N=X)	P Value	Total (N=X)
Age (years)*				
-			x.xxxx	
n	xxx	xxx		xxx
Mean	xx.x	xx.x		xx.x
Median	xx.x	xx.x		xx.x
SD	x.x	x.x		x.x
Minimum	xx	xx		xx
Maximum	xx	xx		xx
Gender				
-			x.xxxx	
Female	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Male	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Race				
-			0.5840	
AFGHAN	1 (0.4%)			xxx (xx.x%)
……	1 (0.4%)			xxx (xx.x%)
Race (Grouped)				
-			x.xxxx	
Caucasian: Afghan, Caucasian, Egypt, Egyptian, El Salvadore, Greek, Hispanic, Israeli, Italian, Maltese, Middle East, Middle Eastern, South American, Turkish, Yugoslavian	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Black African	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Asian: Asian and Indian	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Aboriginal and Torres Strait Islander	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Pacific Islander	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Not Sure	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)

	Intensive (N=X)	Relaxed (N=X)	P Value	Total (N=X)
Ethnicity				
-			x.xxxx	
ABORIGINAL	xxx (xx.x%)			xxx (xx.x%)
……				
WELSH	xxx (xx.x%)			xxx (xx.x%)
Family history of AMD				
-			x.xxxx	
No	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Yes	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
History of arterial thromboembolic events				
-			0.2342	
No	216 (85.7%)	86 (90.5%)		302 (87.0%)
Yes	36 (14.3%)	9 (9.5%)		45 (13.0%)
Smoking History				
-			0.2612	
Current smoker	24 (9.5%)	8 (8.4%)		32 (9.2%)
Never smoked	108 (42.9%)	50 (52.6%)		158 (45.5%)
Smoked in the past	120 (47.6%)	37 (38.9%)		157 (45.2%)
Smoking History (Grouped)				
-			0.7516	
Current smoker	24 (9.5%)	8 (8.4%)		32 (9.2%)
Non-Smoker	228 (90.5%)	87 (91.6%)		315 (90.8%)
Previous exposure of non-study eye				
-			0.0246	
No	183 (72.6%)	80 (84.2%)		263 (75.8%)
Yes	69 (27.4%)	15 (15.8%)		84 (24.2%)
Previous exposure - treatment				
-			0.3904	
Avastin	10 (14.5%)	3 (20.0%)		13 (15.5%)
Eylea	15 (21.7%)	5 (33.3%)		20 (23.8%)
Lucentis	50 (72.5%)	7 (46.7%)		57 (67.9%)
Visudyne	7 (10.1%)			7 (8.3%)
Other	2 (2.9%)			2 (2.4%)

	Intensive (N=X)	Relaxed (N=X)	P Value	Total (N=X)
Study Eye				
-			0.0149	
Left eye	109 (43.3%)	55 (57.9%)		164 (47.3%)
Right eye	143 (56.7%)	40 (42.1%)		183 (52.7%)
Best Corrective Visual Acuity				
-			0.2503	
n	252	95		347
Mean	63.8	61.8		63.2
Median	67.0	63.0		66.0
SD	13.7	14.7		14.0
Minimum	23	23		23
Maximum	90	85		90
BCVA (Categorical)				
-			0.1910	
<70	145 (57.5%)	62 (65.3%)		207 (59.7%)
>=70	107 (42.5%)	33 (34.7%)		140 (40.3%)
Central Subfield Foveal Thickness				
-			0.4227	
n	252	95		347
Mean	445.0	461.6		449.5
Median	405.0	409.0		406.0
SD	175.6	162.6		172.1
Minimum	169	256		169
Maximum	1309	1123		1309
Central Subfield Foveal Volume				
-			0.3304	
n	252	95		347
Mean	0.4	0.4		0.4
Median	0.3	0.3		0.3
SD	0.2	0.3		0.2
Minimum	0	0		0
Maximum	3	3		3
Intraretinal Fluid				
-			0.7260	
Absent	159 (63.1%)	58 (61.1%)		217 (62.5%)
Present	93 (36.9%)	37 (38.9%)		130 (37.5%)

	Intensive (N=X)	Relaxed (N=X)	P Value	Total (N=X)
Intraretinal Fluid - Center Involvement				
-			0.6946	
Absent	8 (3.2%)	4 (4.2%)		12 (3.5%)
Present	85 (33.7%)	33 (34.7%)		118 (34.0%)
Intraretinal Cysts				
-			0.8995	
Absent	108 (42.9%)	40 (42.1%)		148 (42.7%)
Definite	144 (57.1%)	55 (57.9%)		199 (57.3%)
Intraretinal Cysts - Center Involvement				
-			0.3667	
Absent	8 (3.2%)	5 (5.3%)		13 (3.7%)
Definite	136 (54.0%)	50 (52.6%)		186 (53.6%)
Any Subretinal Fluid				
-			0.0341	
Absent	51 (20.2%)	10 (10.5%)		61 (17.6%)
Present	201 (79.8%)	85 (89.5%)		286 (82.4%)
Any Subretinal Fluid - Center Involvement				
-			0.1079	
Absent	18 (7.1%)	3 (3.2%)		21 (6.1%)
Present	183 (72.6%)	82 (86.3%)		265 (76.4%)
Morphological Changes				
-			0.3693	
Absent	176 (69.8%)	71 (74.7%)		247 (71.2%)
Definite	76 (30.2%)	24 (25.3%)		100 (28.8%)
Morphological Change - Epiretinal Membrane				
-			0.4748	
No	48 (19.0%)	13 (13.7%)		61 (17.6%)
Yes	29 (11.5%)	11 (11.6%)		40 (11.5%)

	Intensive (N=X)	Relaxed (N=X)	P Value	Total (N=X)
No Intraretinal Fluid or Cysts (derived)				
-			0.7266	
IRF or IR Cyst or both (IRF and Cyst)	154 (61.1%)	60 (63.2%)		214 (61.7%)
No IRF nor IR Cyst	98 (38.9%)	35 (36.8%)		133 (38.3%)
Morphological Change - Vitreo-Retinal Traction				
-			0.7219	
No	38 (15.1%)	13 (13.7%)		51 (14.7%)
Yes	38 (15.1%)	11 (11.6%)		49 (14.1%)
Morphological Change - Macular Hole				
-			-	
No	76 (30.2%)	24 (25.3%)		100 (28.8%)
Morphological Change - Atrophy				
-			0.0990	
No	36 (14.3%)	16 (16.8%)		52 (15.0%)
Yes	40 (15.9%)	8 (8.4%)		48 (13.8%)
Morphological Change - Other				
-			0.5722	
No	75 (29.8%)	24 (25.3%)		99 (28.5%)
Yes	1 (0.4%)			1 (0.3%)
Subfoveal Fluid Center Point				
-			0.7931	
Absent	27 (10.7%)	7 (7.4%)		34 (9.8%)
Not Applicable	10 (4.0%)	2 (2.1%)		12 (3.5%)
Present	17 (6.7%)	6 (6.3%)		23 (6.6%)
Subfoveal Fluid - Height at Center Point				
-			0.2698	
<=200um	14 (5.6%)	6 (6.3%)		20 (5.8%)
>200um	3 (1.2%)			3 (0.9%)
Evidence of CNV Complex				
-			0.0460	
Absent	9 (3.6%)			9 (2.6%)
Can't Grade	1 (0.4%)			1 (0.3%)
Definite	232 (92.1%)	95 (100.0%)		327 (94.2%)
Questionable	10 (4.0%)			10 (2.9%)

	Intensive (N=X)	Relaxed (N=X)	P Value	Total (N=X)
Location of CNV Complex, by centre involvement* (derived)				
-			-	
CNV Leakage				
-			0.1795	
Absent	2 (0.8%)			2 (0.6%)
Can't Grade	1 (0.4%)	1 (1.1%)		2 (0.6%)
Definite	230 (91.3%)	94 (98.9%)		324 (93.4%)
Questionable	9 (3.6%)			9 (2.6%)
Area of CNV				
-			0.1179	
n	228	92		320
Mean	5.589	4.688		5.330
Median	4.045	3.500		3.715
SD	4.899	3.954		4.659
Minimum	0.30	0.43		0.30
Maximum	30.09	22.72		30.09
CNV Location				
-			0.2412	
Can't Grade	3 (1.2%)	1 (1.1%)		4 (1.2%)
Extrafoveal	16 (6.3%)	3 (3.2%)		19 (5.5%)
Juxtafoveal	23 (9.1%)	9 (9.5%)		32 (9.2%)
No CNV complex	10 (4.0%)			10 (2.9%)
Subfoveal	200 (79.4%)	82 (86.3%)		282 (81.3%)
CNV Location, by centre involvement* (derived)				
-			0.3611	
Can't Grade	3 (1.2%)	1 (1.1%)		4 (1.2%)
Extrafoveal	x (x.x%)	x (x.x%)		x (x.x%)
Extrafoveal with centre involvement	16 (6.3%)	3 (3.2%)		19 (5.5%)
Juxtafoveal	2 (0.8%)	2 (2.1%)		4 (1.2%)
Juxtafoveal with centre involvement	21 (8.3%)	7 (7.4%)		28 (8.1%)
No CNV complex	2 (0.8%)			2 (0.6%)
Subfoveal	200 (79.4%)	82 (86.3%)		282 (81.3%)

	Intensive (N=X)	Relaxed (N=X)	P Value	Total (N=X)
Type of CNV				
-			0.5981	
Can't Grade	7 (2.8%)	1 (1.1%)		8 (2.3%)
Occult (fibrovascular PED)	178 (70.6%)	72 (75.8%)		250 (72.0%)
Occult (late leakage)	4 (1.6%)			4 (1.2%)
Occult with serious PED	10 (4.0%)	6 (6.3%)		16 (4.6%)
Other	5 (2.0%)	1 (1.1%)		6 (1.7%)
Predominant classic	38 (15.1%)	15 (15.8%)		53 (15.3%)
Type of CNV (Grouping 1)				
-			0.6981	
Can't Grade	7 (2.8%)	1 (1.1%)		8 (2.3%)
Occult	192 (76.2%)	78 (82.1%)		270 (77.8%)
Other	5 (2.0%)	1 (1.1%)		6 (1.7%)
Predominant classic	38 (15.1%)	15 (15.8%)		53 (15.3%)
Type of CNV (Grouping 2)				
-			0.6069	
Can't Grade	7 (2.8%)	1 (1.1%)		8 (2.3%)
Other	197 (78.2%)	79 (83.2%)		276 (79.5%)
Predominant classic	38 (15.1%)	15 (15.8%)		53 (15.3%)
Type of CNV (Grouping 3)				
-			0.5005	
Can't Grade	7 (2.8%)	1 (1.1%)		8 (2.3%)
Non-PED	47 (18.7%)	16 (16.8%)		63 (18.2%)
PED	188 (74.6%)	78 (82.1%)		266 (76.7%)
CNV Center Involvement				
-			0.1731	
Absent	6 (2.4%)			6 (1.7%)
Definite	231 (91.7%)	91 (95.8%)		322 (92.8%)
Questionable	3 (1.2%)			3 (0.9%)
Lesion Components - CNV				
-			-	
CNV	239 (94.8%)	95 (100.0%)		334 (96.3%)
Lesion Components - Blood				
-			0.8264	
Blood	95 (37.7%)	39 (41.1%)		134 (38.6%)
No	144 (57.1%)	56 (58.9%)		200 (57.6%)

	Intensive (N=X)	Relaxed (N=X)	P Value	Total (N=X)
Lesion Components - Serious PED				
-			0.6364	
No	227 (90.1%)	89 (93.7%)		316 (91.1%)
Serious PED	12 (4.8%)	6 (6.3%)		18 (5.2%)
Lesion Components - RPE rip/tear				
-			-	
No	239 (94.8%)	95 (100.0%)		334 (96.3%)
Lesion Components - Can't Grade				
-			0.0240	
Can't Grade	13 (5.2%)			13 (3.7%)
No	239 (94.8%)	95 (100.0%)		334 (96.3%)
Lesion Components - Others				
-			0.7288	
No	178 (70.6%)	69 (72.6%)		247 (71.2%)
Others	61 (24.2%)	26 (27.4%)		87 (25.1%)
Area of Lesion				
-			0.3695	
n	232	94		326
Mean	6.332	5.724		6.157
Median	4.400	4.000		4.335
SD	5.642	5.259		5.533
Minimum	0.30	0.43		0.30
Maximum	35.06	25.15		35.06
Geographic Atrophy				
-			0.0064	
Absent	203 (80.6%)	88 (92.6%)		291 (83.9%)
Definite	49 (19.4%)	7 (7.4%)		56 (16.1%)
Location of Geographic Atrophy - Central Subfield				
-			0.9125	
No	34 (13.5%)	5 (5.3%)		39 (11.2%)
Yes	15 (6.0%)	2 (2.1%)		17 (4.9%)
Location of Geographic Atrophy - Inner Subfield				
-			0.2850	
No	7 (2.8%)			7 (2.0%)
Yes	42 (16.7%)	7 (7.4%)		49 (14.1%)

	Intensive (N=X)	Relaxed (N=X)	P Value	Total (N=X)
Location of Geographic Atrophy - Other Subfield				
-			0.2795	
No	17 (6.7%)	1 (1.1%)		18 (5.2%)
Yes	32 (12.7%)	6 (6.3%)		38 (11.0%)
Location of Geographic Atrophy - Can't Grade				
-			-	
No	49 (19.4%)	7 (7.4%)		56 (16.1%)
Geographic Atrophy - Area				
-			0.7834	
n	46	7		53
Mean	3.207	2.617		3.129
Median	1.470	0.850		1.440
SD	5.397	4.123		5.216
Minimum	0.06	0.33		0.06
Maximum	30.69	11.69		30.69
Retinal Abnormalities				
-			0.4664	
Absent	3 (1.2%)			3 (0.9%)
Definite	248 (98.4%)	95 (100.0%)		343 (98.8%)
Not Applicable	1 (0.4%)			1 (0.3%)
Retinal Abnormalities - Drusen				
-			0.9035	
No	3 (1.2%)	1 (1.1%)		4 (1.2%)
Yes	245 (97.2%)	94 (98.9%)		339 (97.7%)
Retinal Abnormalities - Atrophy				
-			0.0076	
No	208 (82.5%)	90 (94.7%)		298 (85.9%)
Yes	40 (15.9%)	5 (5.3%)		45 (13.0%)
Retinal Abnormalities - Fibrosis				
-			0.9937	
No	235 (93.3%)	90 (94.7%)		325 (93.7%)
Yes	13 (5.2%)	5 (5.3%)		18 (5.2%)
Retinal Abnormalities - Hemorrhage (old format CF data)				
-			0.9897	
No	146 (57.9%)	56 (58.9%)		202 (58.2%)
Yes	102 (40.5%)	39 (41.1%)		141 (40.6%)

	Intensive (N=X)	Relaxed (N=X)	P Value	Total (N=X)
Retinal Abnormalities - PED				
-			0.6179	
No	238 (94.4%)	90 (94.7%)		328 (94.5%)
Yes	10 (4.0%)	5 (5.3%)		15 (4.3%)
Retinal Abnormalities - Other				
-			0.5250	
No	158 (62.7%)	57 (60.0%)		215 (62.0%)
Yes	90 (35.7%)	38 (40.0%)		128 (36.9%)
Retinal Abnormalities Location Central				
-			0.2937	
No	2 (0.8%)	3 (3.2%)		5 (1.4%)
Yes	3 (1.2%)	1 (1.1%)		1 (0.3%)
Retinal Abnormalities Location Peripheral				
-			0.2937	
No	2 (0.8%)	3 (3.2%)		5 (1.4%)
Yes	3 (1.2%)	1 (1.1%)		1 (0.3%)
Hemorrhage (new format CF data)				
-			0.7765	
Absent	148 (58.7%)	54 (56.8%)		202 (58.2%)
Definite	103 (40.9%)	41 (43.2%)		144 (41.5%)
Not Applicable	1 (0.4%)			1 (0.3%)
Hemorrhage Location Central Subfield				
-			0.0730	
No	5 (2.0%)	2 (2.1%)		4 (1.2%)
Yes		2 (2.1%)		2 (0.6%)
Hemorrhage Location Inner Subfield				
-			0.2937	
No	2 (0.8%)	3 (3.2%)		4 (1.2%)
Yes	3 (1.2%)	1 (1.1%)		2 (0.6%)
Hemorrhage Location Outer Subfield				
-			0.6353	
No	3 (1.2%)	3 (3.2%)		5 (1.4%)
Yes	2 (0.8%)	1 (1.1%)		1 (0.3%)

	Intensive (N=X)	Relaxed (N=X)	P Value	Total (N=X)
CNV Location (CRF DATA)				
-			0.2168	
Juxtafoveal	4 (1.6%)			4 (1.2%)
Subfoveal	248 (98.4%)	95 (100.0%)		343 (98.8%)
Extrafoveal	xx (x.x%)	xx (x.x%)		xx (x.x%)
IRF (CRF DATA)				
-			0.4505	
Absent	60 (23.8%)	19 (20.0%)		79 (22.8%)
Present	192 (76.2%)	76 (80.0%)		268 (77.2%)
Can’t Grade	xx (x.x%)	xx (x.x%)		xx (x.x%)
SRF (CRF DATA)				
-			0.0258	
Absent	62 (24.6%)	13 (13.7%)		75 (21.6%)
Can't grade		1 (1.1%)		1 (0.3%)
Present	190 (75.4%)	81 (85.3%)		271 (78.1%)

*: Centre involvement is concluded when 'Intraretinal Fluid - Center Involvement'='Present', 'Intraretinal Cysts - Center Involvement'='Definite' or 'Any Subretinal Fluid - Center Involvement'='Present'.

Table 14.1-11 Baseline characteristics by genotyping status

Randomised Set

	Genotype Sample (N=X)	NO Genotype Sample (N=X)	P Value	Total (N=X)
Age (years)*				
-			x.xxxx	
n	xxx	xxx		xxx
Mean	xx.x	xx.x		xx.x
Median	xx.x	xx.x		xx.x
SD	x.x	x.x		x.x
Minimum	xx	xx		xx
Maximum	xx	xx		xx
Gender				
-			x.xxxx	
Female	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Male	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Race				
-			0.5840	
AFGHAN	1 (0.4%)			xxx (xx.x%)
……	1 (0.4%)			xxx (xx.x%)
Race (Grouped)				
-			x.xxxx	
Caucasian: Afghan, Caucasian, Egypt, Egyptian, El Salvadore, Greek, Hispanic, Israeli, Italian, Maltese, Middle East, Middle Eastern, South American, Turkish, Yugoslavian	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Black African	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Asian: Asian and Indian	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Aboriginal and Torres Strait Islander	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Pacific Islander	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Not Sure	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Ethnicity				
-			x.xxxx	
ABORIGINAL	xxx (xx.x%)			xxx (xx.x%)
……				
WELSH	xxx (xx.x%)			xxx (xx.x%)

	Genotype Sample (N=X)	NO Genotype Sample (N=X)	P Value	Total (N=X)
Family history of AMD				
-			x.xxxx	
No	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
Yes	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)
History of arterial thromboembolic events				
-			0.2342	
No	216 (85.7%)	86 (90.5%)		302 (87.0%)
Yes	36 (14.3%)	9 (9.5%)		45 (13.0%)
Smoking History				
-			0.2612	
Current smoker	24 (9.5%)	8 (8.4%)		32 (9.2%)
Never smoked	108 (42.9%)	50 (52.6%)		158 (45.5%)
Smoked in the past	120 (47.6%)	37 (38.9%)		157 (45.2%)
Smoking History (Grouped)				
-			0.7516	
Current smoker	24 (9.5%)	8 (8.4%)		32 (9.2%)
Non-Smoker	228 (90.5%)	87 (91.6%)		315 (90.8%)
Previous exposure of non-study eye				
-			0.0246	
No	183 (72.6%)	80 (84.2%)		263 (75.8%)
Yes	69 (27.4%)	15 (15.8%)		84 (24.2%)
Previous exposure - treatment				
-			0.3904	
Avastin	10 (14.5%)	3 (20.0%)		13 (15.5%)
Eylea	15 (21.7%)	5 (33.3%)		20 (23.8%)
Lucentis	50 (72.5%)	7 (46.7%)		57 (67.9%)
Visudyne	7 (10.1%)			7 (8.3%)
Other	2 (2.9%)			2 (2.4%)
Study Eye				
-			0.0149	
Left eye	109 (43.3%)	55 (57.9%)		164 (47.3%)
Right eye	143 (56.7%)	40 (42.1%)		183 (52.7%)

	Genotype Sample (N=X)	NO Genotype Sample (N=X)	P Value	Total (N=X)
Best Corrective Visual Acuity				
-			0.2503	
n	252	95		347
Mean	63.8	61.8		63.2
Median	67.0	63.0		66.0
SD	13.7	14.7		14.0
Minimum	23	23		23
Maximum	90	85		90
BCVA (Categorical)				
-			0.1910	
<70	145 (57.5%)	62 (65.3%)		207 (59.7%)
>=70	107 (42.5%)	33 (34.7%)		140 (40.3%)
Central Subfield Foveal Thickness				
-			0.4227	
n	252	95		347
Mean	445.0	461.6		449.5
Median	405.0	409.0		406.0
SD	175.6	162.6		172.1
Minimum	169	256		169
Maximum	1309	1123		1309
Central Subfield Foveal Volume				
-			0.3304	
n	252	95		347
Mean	0.4	0.4		0.4
Median	0.3	0.3		0.3
SD	0.2	0.3		0.2
Minimum	0	0		0
Maximum	3	3		3
Intraretinal Fluid				
-			0.7260	
Absent	159 (63.1%)	58 (61.1%)		217 (62.5%)
Present	93 (36.9%)	37 (38.9%)		130 (37.5%)
Intraretinal Fluid - Center Involvement				
-			0.6946	
Absent	8 (3.2%)	4 (4.2%)		12 (3.5%)
Present	85 (33.7%)	33 (34.7%)		118 (34.0%)

	Genotype Sample (N=X)	NO Genotype Sample (N=X)	P Value	Total (N=X)
Intraretinal Cysts				
-			0.8995	
Absent	108 (42.9%)	40 (42.1%)		148 (42.7%)
Definite	144 (57.1%)	55 (57.9%)		199 (57.3%)
Intraretinal Cysts - Center Involvement				
-			0.3667	
Absent	8 (3.2%)	5 (5.3%)		13 (3.7%)
Definite	136 (54.0%)	50 (52.6%)		186 (53.6%)
Any Subretinal Fluid				
-			0.0341	
Absent	51 (20.2%)	10 (10.5%)		61 (17.6%)
Present	201 (79.8%)	85 (89.5%)		286 (82.4%)
Any Subretinal Fluid - Center Involvement				
-			0.1079	
Absent	18 (7.1%)	3 (3.2%)		21 (6.1%)
Present	183 (72.6%)	82 (86.3%)		265 (76.4%)
Morphological Changes				
-			0.3693	
Absent	176 (69.8%)	71 (74.7%)		247 (71.2%)
Definite	76 (30.2%)	24 (25.3%)		100 (28.8%)
Morphological Change - Epiretinal Membrane				
-			0.4748	
No	48 (19.0%)	13 (13.7%)		61 (17.6%)
Yes	29 (11.5%)	11 (11.6%)		40 (11.5%)
No Intraretinal Fluid or Cysts (derived)				
-			0.7266	
IRF or IR Cyst or both (IRF and Cyst)	154 (61.1%)	60 (63.2%)		214 (61.7%)
No IRF nor IR Cyst	98 (38.9%)	35 (36.8%)		133 (38.3%)

	Genotype Sample (N=X)	NO Genotype Sample (N=X)	P Value	Total (N=X)
Morphological Change - Vitreo-Retinal Traction				
-			0.7219	
No	38 (15.1%)	13 (13.7%)		51 (14.7%)
Yes	38 (15.1%)	11 (11.6%)		49 (14.1%)
Morphological Change - Macular Hole				
-			-	
No	76 (30.2%)	24 (25.3%)		100 (28.8%)
Morphological Change - Atrophy				
-			0.0990	
No	36 (14.3%)	16 (16.8%)		52 (15.0%)
Yes	40 (15.9%)	8 (8.4%)		48 (13.8%)
Morphological Change - Other				
-			0.5722	
No	75 (29.8%)	24 (25.3%)		99 (28.5%)
Yes	1 (0.4%)			1 (0.3%)
Subfoveal Fluid Center Point				
-			0.7931	
Absent	27 (10.7%)	7 (7.4%)		34 (9.8%)
Not Applicable	10 (4.0%)	2 (2.1%)		12 (3.5%)
Present	17 (6.7%)	6 (6.3%)		23 (6.6%)
Subfoveal Fluid - Height at Center Point				
-			0.2698	
<=200um	14 (5.6%)	6 (6.3%)		20 (5.8%)
>200um	3 (1.2%)			3 (0.9%)
Evidence of CNV Complex				
-			0.0460	
Absent	9 (3.6%)			9 (2.6%)
Can't Grade	1 (0.4%)			1 (0.3%)
Definite	232 (92.1%)	95 (100.0%)		327 (94.2%)
Questionable	10 (4.0%)			10 (2.9%)
Location of CNV Complex, by centre involvement* (derived)				
-			-	

	Genotype Sample (N=X)	NO Genotype Sample (N=X)	P Value	Total (N=X)
CNV Leakage				
-			0.1795	
Absent	2 (0.8%)			2 (0.6%)
Can't Grade	1 (0.4%)	1 (1.1%)		2 (0.6%)
Definite	230 (91.3%)	94 (98.9%)		324 (93.4%)
Questionable	9 (3.6%)			9 (2.6%)
Area of CNV				
-			0.1179	
n	228	92		320
Mean	5.589	4.688		5.330
Median	4.045	3.500		3.715
SD	4.899	3.954		4.659
Minimum	0.30	0.43		0.30
Maximum	30.09	22.72		30.09
CNV Location				
-			0.2412	
Can't Grade	3 (1.2%)	1 (1.1%)		4 (1.2%)
Extrafoveal	16 (6.3%)	3 (3.2%)		19 (5.5%)
Juxtafoveal	23 (9.1%)	9 (9.5%)		32 (9.2%)
No CNV complex	10 (4.0%)			10 (2.9%)
Subfoveal	200 (79.4%)	82 (86.3%)		282 (81.3%)
CNV Location, by centre involvement* (derived)				
-			0.3611	
Can't Grade	3 (1.2%)	1 (1.1%)		4 (1.2%)
Extrafoveal	x (xx.x%)	x (xx.x%)		x (xx.x%)
Extrafoveal with centre involvement	16 (6.3%)	3 (3.2%)		19 (5.5%)
Juxtafoveal	2 (0.8%)	2 (2.1%)		4 (1.2%)
Juxtafoveal with centre involvement	21 (8.3%)	7 (7.4%)		28 (8.1%)
No CNV complex	2 (0.8%)			2 (0.6%)
Subfoveal	200 (79.4%)	82 (86.3%)		282 (81.3%)
Type of CNV				
-			0.5981	
Can't Grade	7 (2.8%)	1 (1.1%)		8 (2.3%)
Occult (fibrovascular PED)	178 (70.6%)	72 (75.8%)		250 (72.0%)
Occult (late leakage)	4 (1.6%)			4 (1.2%)
Occult with serious PED	10 (4.0%)	6 (6.3%)		16 (4.6%)
Other	5 (2.0%)	1 (1.1%)		6 (1.7%)
Predominant classic	38 (15.1%)	15 (15.8%)		53 (15.3%)

	Genotype Sample (N=X)	NO Genotype Sample (N=X)	P Value	Total (N=X)
Type of CNV (Grouping 1)				
-			0.6981	
Can't Grade	7 (2.8%)	1 (1.1%)		8 (2.3%)
Occult	192 (76.2%)	78 (82.1%)		270 (77.8%)
Other	5 (2.0%)	1 (1.1%)		6 (1.7%)
Predominant classic	38 (15.1%)	15 (15.8%)		53 (15.3%)
Type of CNV (Grouping 2)				
-			0.6069	
Can't Grade	7 (2.8%)	1 (1.1%)		8 (2.3%)
Other	197 (78.2%)	79 (83.2%)		276 (79.5%)
Predominant classic	38 (15.1%)	15 (15.8%)		53 (15.3%)
Type of CNV (Grouping 3)				
-			0.5005	
Can't Grade	7 (2.8%)	1 (1.1%)		8 (2.3%)
Non-PED	47 (18.7%)	16 (16.8%)		63 (18.2%)
PED	188 (74.6%)	78 (82.1%)		266 (76.7%)
CNV Center Involvement				
-			0.1731	
Absent	6 (2.4%)			6 (1.7%)
Definite	231 (91.7%)	91 (95.8%)		322 (92.8%)
Questionable	3 (1.2%)			3 (0.9%)
Lesion Components - CNV				
-			-	
CNV	239 (94.8%)	95 (100.0%)		334 (96.3%)
Lesion Components - Blood				
-			0.8264	
Blood	95 (37.7%)	39 (41.1%)		134 (38.6%)
No	144 (57.1%)	56 (58.9%)		200 (57.6%)
Lesion Components - Serious PED				
-			0.6364	
No	227 (90.1%)	89 (93.7%)		316 (91.1%)
Serious PED	12 (4.8%)	6 (6.3%)		18 (5.2%)
Lesion Components - RPE rip/tear				
-			-	
No	239 (94.8%)	95 (100.0%)		334 (96.3%)

	Genotype Sample (N=X)	NO Genotype Sample (N=X)	P Value	Total (N=X)
Lesion Components - Can't Grade				
-			0.0240	
Can't Grade	13 (5.2%)			13 (3.7%)
No	239 (94.8%)	95 (100.0%)		334 (96.3%)
Lesion Components - Others				
-			0.7288	
No	178 (70.6%)	69 (72.6%)		247 (71.2%)
Others	61 (24.2%)	26 (27.4%)		87 (25.1%)
Area of Lesion				
-			0.3695	
n	232	94		326
Mean	6.332	5.724		6.157
Median	4.400	4.000		4.335
SD	5.642	5.259		5.533
Minimum	0.30	0.43		0.30
Maximum	35.06	25.15		35.06
Geographic Atrophy				
-			0.0064	
Absent	203 (80.6%)	88 (92.6%)		291 (83.9%)
Definite	49 (19.4%)	7 (7.4%)		56 (16.1%)
Location of Geographic Atrophy - Central Subfield				
-			0.9125	
No	34 (13.5%)	5 (5.3%)		39 (11.2%)
Yes	15 (6.0%)	2 (2.1%)		17 (4.9%)
Location of Geographic Atrophy - Inner Subfield				
-			0.2850	
No	7 (2.8%)			7 (2.0%)
Yes	42 (16.7%)	7 (7.4%)		49 (14.1%)
Location of Geographic Atrophy - Other Subfield				
-			0.2795	
No	17 (6.7%)	1 (1.1%)		18 (5.2%)
Yes	32 (12.7%)	6 (6.3%)		38 (11.0%)
Location of Geographic Atrophy - Can't Grade				
-			-	
No	49 (19.4%)	7 (7.4%)		56 (16.1%)

	Genotype Sample (N=X)	NO Genotype Sample (N=X)	P Value	Total (N=X)
Geographic Atrophy - Area				
-			0.7834	
n	46	7		53
Mean	3.207	2.617		3.129
Median	1.470	0.850		1.440
SD	5.397	4.123		5.216
Minimum	0.06	0.33		0.06
Maximum	30.69	11.69		30.69
Retinal Abnormalities				
-			0.4664	
Absent	3 (1.2%)			3 (0.9%)
Definite	248 (98.4%)	95 (100.0%)		343 (98.8%)
Not Applicable	1 (0.4%)			1 (0.3%)
Retinal Abnormalities - Drusen				
-			0.9035	
No	3 (1.2%)	1 (1.1%)		4 (1.2%)
Yes	245 (97.2%)	94 (98.9%)		339 (97.7%)
Retinal Abnormalities - Atrophy				
-			0.0076	
No	208 (82.5%)	90 (94.7%)		298 (85.9%)
Yes	40 (15.9%)	5 (5.3%)		45 (13.0%)
Retinal Abnormalities - Fibrosis				
-			0.9937	
No	235 (93.3%)	90 (94.7%)		325 (93.7%)
Yes	13 (5.2%)	5 (5.3%)		18 (5.2%)
Retinal Abnormalities - Hemorrhage (old format CF data)				
-			0.9897	
No	146 (57.9%)	56 (58.9%)		202 (58.2%)
Yes	102 (40.5%)	39 (41.1%)		141 (40.6%)
Retinal Abnormalities - PED				
-			0.6179	
No	238 (94.4%)	90 (94.7%)		328 (94.5%)
Yes	10 (4.0%)	5 (5.3%)		15 (4.3%)

	Genotype Sample (N=X)	NO Genotype Sample (N=X)	P Value	Total (N=X)
Retinal Abnormalities - Other				
-			0.5250	
No	158 (62.7%)	57 (60.0%)		215 (62.0%)
Yes	90 (35.7%)	38 (40.0%)		128 (36.9%)
Retinal Abnormalities Location Central				
-			0.2937	
No	2 (0.8%)	3 (3.2%)		5 (1.4%)
Yes	3 (1.2%)	1 (1.1%)		1 (0.3%)
Retinal Abnormalities Location Peripheral				
-			0.2937	
No	2 (0.8%)	3 (3.2%)		5 (1.4%)
Yes	3 (1.2%)	1 (1.1%)		1 (0.3%)
Hemorrhage (new format CF data)				
-			0.7765	
Absent	148 (58.7%)	54 (56.8%)		202 (58.2%)
Definite	103 (40.9%)	41 (43.2%)		144 (41.5%)
Not Applicable	1 (0.4%)			1 (0.3%)
Hemorrhage Location Central Subfield				
-			0.0730	
No	5 (2.0%)	2 (2.1%)		4 (1.2%)
Yes		2 (2.1%)		2 (0.6%)
Hemorrhage Location Inner Subfield				
-			0.2937	
No	2 (0.8%)	3 (3.2%)		4 (1.2%)
Yes	3 (1.2%)	1 (1.1%)		2 (0.6%)
Hemorrhage Location Outer Subfield				
-			0.6353	
No	3 (1.2%)	3 (3.2%)		5 (1.4%)
Yes	2 (0.8%)	1 (1.1%)		1 (0.3%)
CNV Location (CRF DATA)				
-			0.2168	
Juxtafoveal	4 (1.6%)			4 (1.2%)
Subfoveal	248 (98.4%)	95 (100.0%)		343 (98.8%)
Extrafoveal	xx (x.x%)	xx (x.x%)		xx (x.x%)

	Genotype Sample (N=X)	NO Genotype Sample (N=X)	P Value	Total (N=X)
IRF (CRF DATA)				
-			0.4505	
Absent	60 (23.8%)	19 (20.0%)		79 (22.8%)
Present	192 (76.2%)	76 (80.0%)		268 (77.2%)
Can’t Grade	xx (x.x%)	xx (x.x%)		xx (x.x%)
SRF (CRF DATA)				
-			0.0258	
Absent	62 (24.6%)	13 (13.7%)		75 (21.6%)
Can't grade		1 (1.1%)		1 (0.3%)
Present	190 (75.4%)	81 (85.3%)		271 (78.1%)

*: Centre involvement is concluded when 'Intraretinal Fluid - Center Involvement'='Present', 'Intraretinal Cysts - Center Involvement'='Definite' or 'Any Subretinal Fluid - Center Involvement'='Present'.

Table 14.1-12 Baseline Medical History Questions by treatment group

Randomised Set

	Intensive (N=X) n (%)	Relaxed (N=X) n (%)	Total (N=X) n (%)
Are there any relevant Medical history/Current medical conditions to be reported?*			
Yes	x (xx.x)	x (xx.x)	x (xx.x)
No	x (xx.x)	x (xx.x)	x (xx.x)

Table 14.1-13 Medical History, by primary system organ class, preferred terms and treatment

Randomised Set

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr (%) of Subjects	Nr (%) of Subjects
All Body Systems	x (xx.x)	x (xx.x)	x (xx.x)
SOC1	x (xx.x)	x (xx.x)	x (xx.x)
PT1	x (xx.x)	x (xx.x)	x (xx.x)
PT2	x (xx.x)	x (xx.x)	x (xx.x)
….	….	….	….
PTx	x (xx.x)	x (xx.x)	x (xx.x)
SOC2	x (xx.x)	x (xx.x)	x (xx.x)
PT1	x (xx.x)	x (xx.x)	x (xx.x)
PT2	x (xx.x)	x (xx.x)	x (xx.x)
….	….	….	….
PTx	x (xx.x)	x (xx.x)	x (xx.x)
……..			

Table 14.1-14 Ocular Medical History, by primary system organ class, preferred terms

Randomised Set

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr (%) of Subjects	Nr (%) of Subjects
Eye disorders	x (xx.x)	x (xx.x)	x (xx.x)
PT1	x (xx.x)	x (xx.x)	x (xx.x)
PT2	x (xx.x)	x (xx.x)	x (xx.x)
….	….	….	….
PTx	x (xx.x)	x (xx.x)	x (xx.x)

Table 14.1-15 Medical History - Arterial Thomboembolic Events

Randomised Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
Arterial Thomboembolic Events (ATEs)*	xx.x	x	xx.x	x	xx.x	x
Nonfatal myocardial infarction	xx.x	x	xx.x	x	xx.x	x
Nonfatal stroke	xx.x	x	xx.x	x	xx.x	x

* ATEs defined as nonfatal myocardial infarction, nonfatal stroke, vascular death and death of unknown cause
AE: Adverse Event
Note: Some patients may have experienced multiple events

Table 14.1-16 Baseline AMD characteristics (STUDY EYE) by treatment group

Randomised Set

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Was any treatment ever given to the fellow eye prior to Screening?			
No	x (xx.x)	x (xx.x)	x (xx.x)
Yes	x (xx.x)	x (xx.x)	x (xx.x)
Lucentis	x (xx.x)	x (xx.x)	x (xx.x)
Eylea	x (xx.x)	x (xx.x)	x (xx.x)
Visudyne	x (xx.x)	x (xx.x)	x (xx.x)
Avastin	x (xx.x)	x (xx.x)	x (xx.x)
Steroids	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)
Total BCVA Score (ETDRS letters)			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x
Visual Acuity - Categorical (20/40)			
>=70 letters	x (xx.x)	x (xx.x)	x (xx.x)
<70 letters	x (xx.x)	x (xx.x)	x (xx.x)

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Central Subfield Foveal Thickness (µm)*			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x
Central Subfield Volume (mm^3)*			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x
Area of Lesion (mm^2)*			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x
Intra-Retinal Fluid Status			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Intra-Retinal Fluid Status*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Intra-Retinal Fluid Centre Involvement*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Intra-Retinal Cysts*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Intra-Retinal Cysts Centre Involvement*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Sub-Retinal Fluid Status			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Sub-Retinal Fluid Status*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Sub-Retinal Fluid Centre Involvement*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Sub-Retinal Fluid at Centrepoint*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Sub-Retinal Fluid Height at Centrepoint			
<=200µm	x (xx.x)	x (xx.x)	x (xx.x)
>200 µm	x (xx.x)	x (xx.x)	x (xx.x)
Not Applicable	x (xx.x)	x (xx.x)	x (xx.x)
Sub-Retinal Fluid Height at Centrepoint*			
<=200µm	x (xx.x)	x (xx.x)	x (xx.x)
>200 µm	x (xx.x)	x (xx.x)	x (xx.x)
Not Applicable	x (xx.x)	x (xx.x)	x (xx.x)
Morphologic Changes*			
Epiretinal Membrane	x (xx.x)	x (xx.x)	x (xx.x)
Vitreoretinal Traction	x (xx.x)	x (xx.x)	x (xx.x)
Macular Hole	x (xx.x)	x (xx.x)	x (xx.x)
Atrophy	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Area of CNV (mm^2)*			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x
CNV Complex (lesion)			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Definite	x (xx.x)	x (xx.x)	x (xx.x)
Questionable	x (xx.x)	x (xx.x)	x (xx.x)
……	x (xx.x)	x (xx.x)	x (xx.x)
CNV Complex (lesion)*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Definite	x (xx.x)	x (xx.x)	x (xx.x)
Questionable	x (xx.x)	x (xx.x)	x (xx.x)
……	x (xx.x)	x (xx.x)	x (xx.x)
CNV Complex (lesion) Location			
Subfoveal	x (xx.x)	x (xx.x)	x (xx.x)
Juxtafoveal	x (xx.x)	x (xx.x)	x (xx.x)
Juxtafoveal with centre involvement	x (xx.x)	x (xx.x)	x (xx.x)
Extrafoveal	x (xx.x)	x (xx.x)	x (xx.x)
Extrafoveal with centre involvement	x (xx.x)	x (xx.x)	x (xx.x)
Can’t grade	x (xx.x)	x (xx.x)	x (xx.x)

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
CNV Location			
Subfoveal	x (xx.x)	x (xx.x)	x (xx.x)
Juxtafoveal	x (xx.x)	x (xx.x)	x (xx.x)
Extrafoveal	x (xx.x)	x (xx.x)	x (xx.x)
Can't grade	x (xx.x)	x (xx.x)	x (xx.x)
CNV Location*			
Subfoveal	x (xx.x)	x (xx.x)	x (xx.x)
Juxtafoveal	x (xx.x)	x (xx.x)	x (xx.x)
Juxtafoveal with centre involvement	x (xx.x)	x (xx.x)	x (xx.x)
Extrafoveal	x (xx.x)	x (xx.x)	x (xx.x)
Extrafoveal with centre involvement	x (xx.x)	x (xx.x)	x (xx.x)
Can't grade	x (xx.x)	x (xx.x)	x (xx.x)
CNV Secondary to …..*			
AMD	x (xx.x)	x (xx.x)	x (xx.x)
Angioid Streaks	x (xx.x)	x (xx.x)	x (xx.x)
Idiopathic	x (xx.x)	x (xx.x)	x (xx.x)
Pathologic Myopia	x (xx.x)	x (xx.x)	x (xx.x)
Macular telangiectasis	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)
Type of CNV*			
Predominantly classic	x (xx.x)	x (xx.x)	x (xx.x)
Occult	x (xx.x)	x (xx.x)	x (xx.x)
Fibrovascular PED	x (xx.x)	x (xx.x)	x (xx.x)
Serous PED	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
CNV Leakage*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Present	x (xx.x)	x (xx.x)	x (xx.x)
Lesion Components*			
Blood	x (xx.x)	x (xx.x)	x (xx.x)
CNV	x (xx.x)	x (xx.x)	x (xx.x)
Serous PED	x (xx.x)	x (xx.x)	x (xx.x)
RPE Tear	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Geographic Atrophy (Status)*			
Absent	x (xx.x)	x (xx.x)	x (xx.x)
Definite	x (xx.x)	x (xx.x)	x (xx.x)
Can't Grade	x (xx.x)	x (xx.x)	x (xx.x)
Not Applicable	x (xx.x)	x (xx.x)	x (xx.x)
Geographic Atrophy Location*			
Central Subfield	x (xx.x)	x (xx.x)	x (xx.x)
Inner Subfield	x (xx.x)	x (xx.x)	x (xx.x)
Outer Subfield	x (xx.x)	x (xx.x)	x (xx.x)
Geographic Atrophy Area (mm^2)*			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Haemorrhage*			
Yes	x (xx.x)	x (xx.x)	x (xx.x)
No	x (xx.x)	x (xx.x)	x (xx.x)
Haemorrhage Location*			
Central Subfield	x (xx.x)	x (xx.x)	x (xx.x)
Inner Subfield	x (xx.x)	x (xx.x)	x (xx.x)
Outer Subfield	x (xx.x)	x (xx.x)	x (xx.x)
Retinal Abnormality*			
Drusen	x (xx.x)	x (xx.x)	x (xx.x)
Atrophy	x (xx.x)	x (xx.x)	x (xx.x)
Fibrosis	x (xx.x)	x (xx.x)	x (xx.x)
PED	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)
Retinal Abnormality Location*			
Central	x (xx.x)	x (xx.x)	x (xx.x)
Periphery	x (xx.x)	x (xx.x)	x (xx.x)

* Source: [redacted]
Note: Geographic Atrophy not assessed by all sites.

Table 14.1-17 Baseline AMD characteristics (FELLOW EYE) by treatment group

Randomised Set

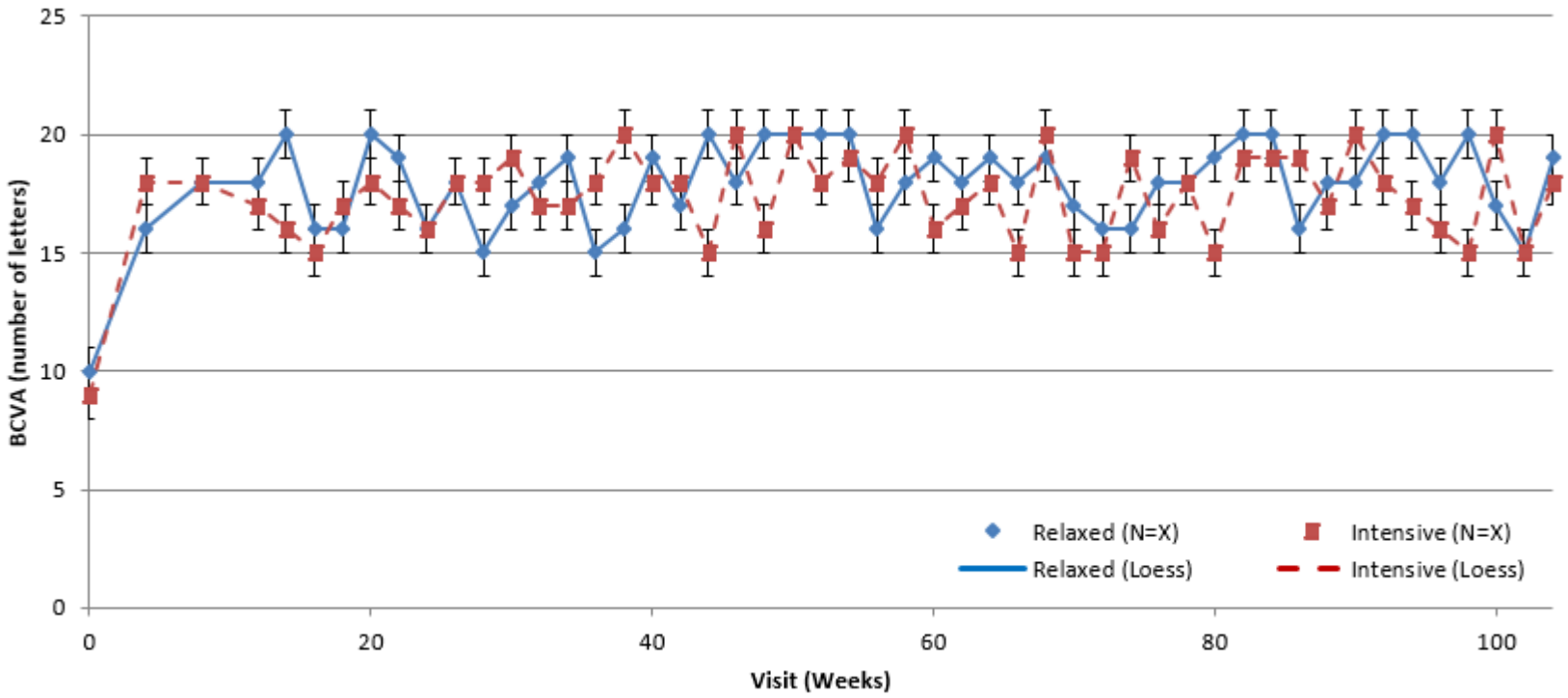
	Intensive (N=X) n (%)	Relaxed (N=X) n (%)	Total (N=X) n (%)
Fellow Eye			
Left	x (xx.x)	x (xx.x)	x (xx.x)
Right	x (xx.x)	x (xx.x)	x (xx.x)
Was any treatment ever given to the fellow eye prior to Screening?			
No	x (xx.x)	x (xx.x)	x (xx.x)
Yes	x (xx.x)	x (xx.x)	x (xx.x)
Lucentis	x (xx.x)	x (xx.x)	x (xx.x)
Eylea	x (xx.x)	x (xx.x)	x (xx.x)
Visudyne	x (xx.x)	x (xx.x)	x (xx.x)
Avastin	x (xx.x)	x (xx.x)	x (xx.x)
Steroids	x (xx.x)	x (xx.x)	x (xx.x)
Other	x (xx.x)	x (xx.x)	x (xx.x)

Section 14.2 – Efficacy and other non-safety data (e.g. PK, PK/PD, health economics, QoL)

Figures (Section 14.2)

Figure 14.2-1 Absolute BCVA over time by treatment

Full Analysis Set



Note: Locally weighted scatterplot smooth (loess) curves

Figure 14.2-2 Absolute change in BCVA over time by treatment

Per Protocol Set

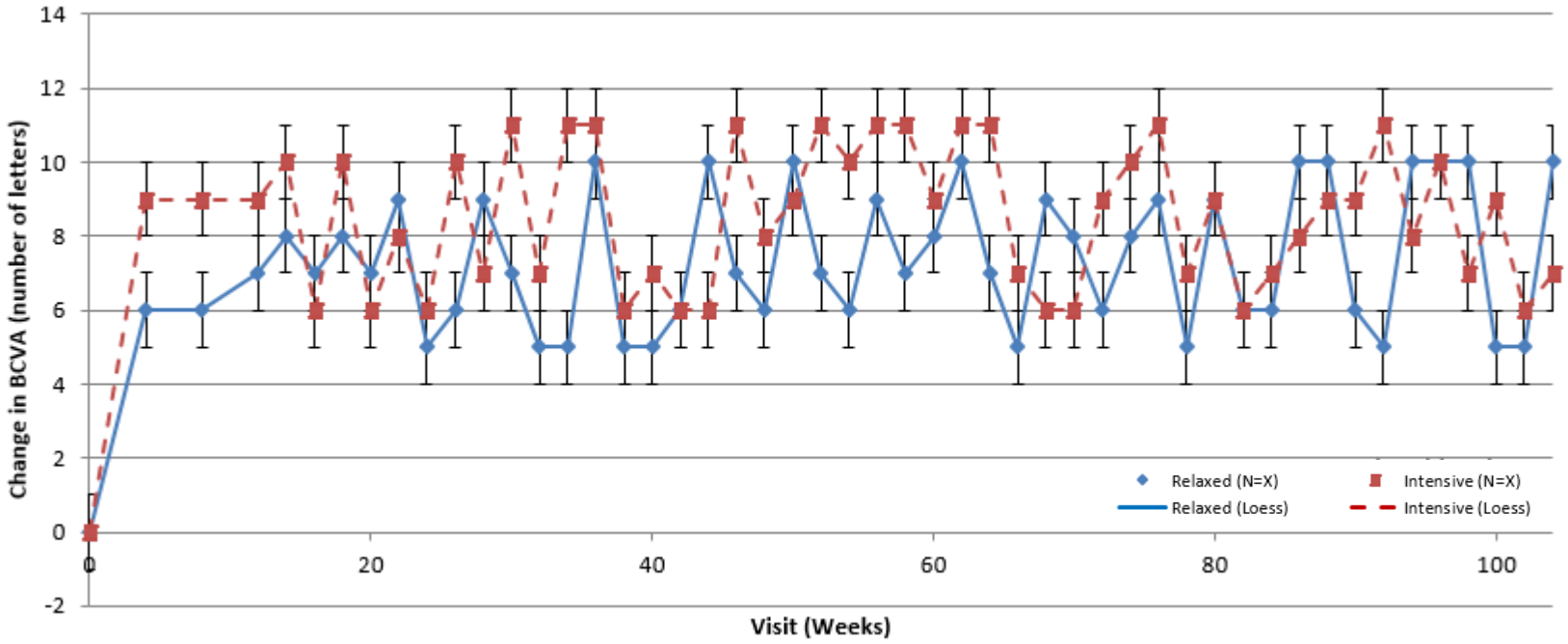


Figure 14.2-3 Visual Acuity over time, stratified by baseline acuity

Full Analysis Set

Example:

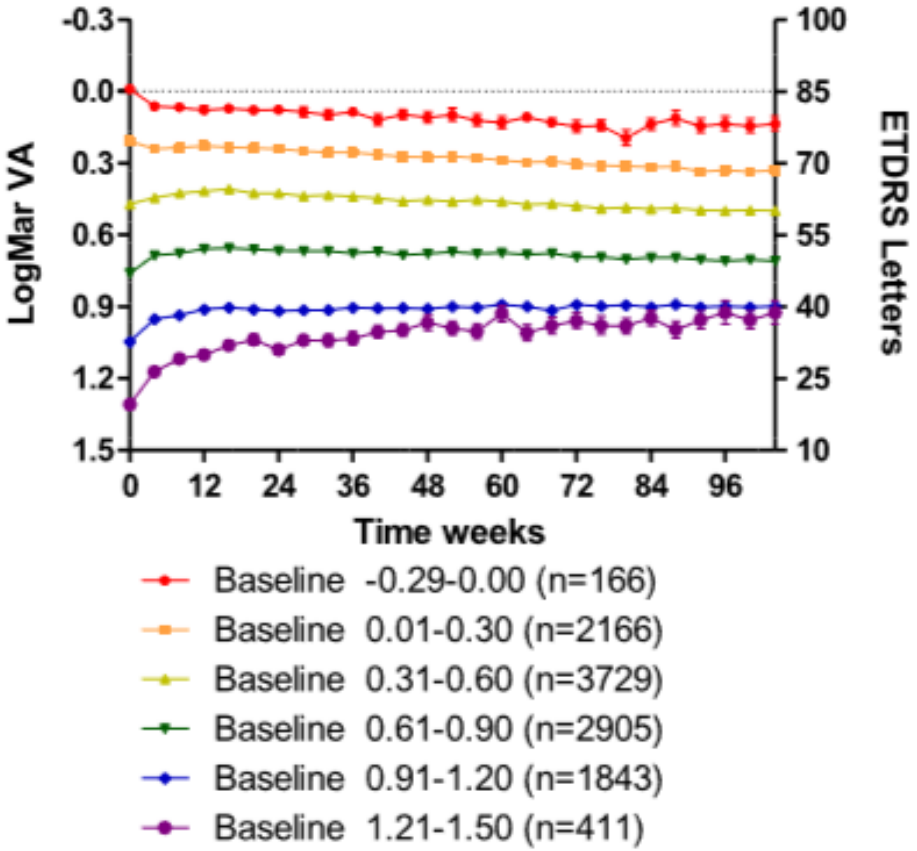


Figure 14.2-4 Visual Acuity over time, stratified by baseline acuity

Per Protocol Set

Example:

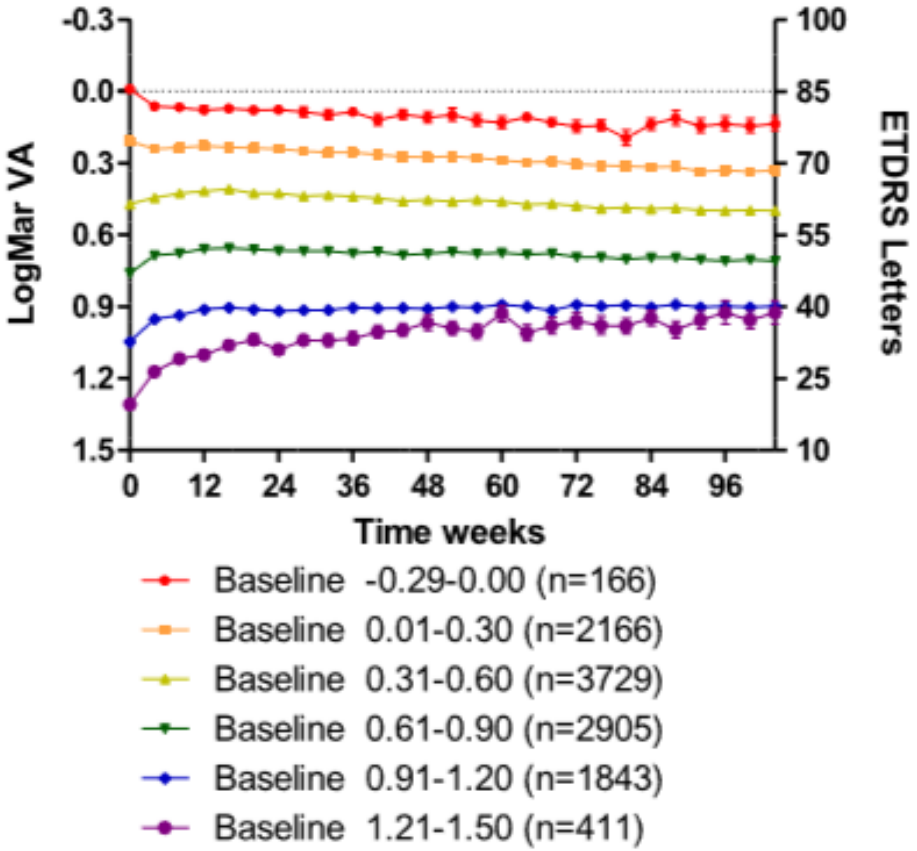


Figure 14.2-5 Change in BCVA from baseline stratified by visual acuity

Full Analysis Set

Example:

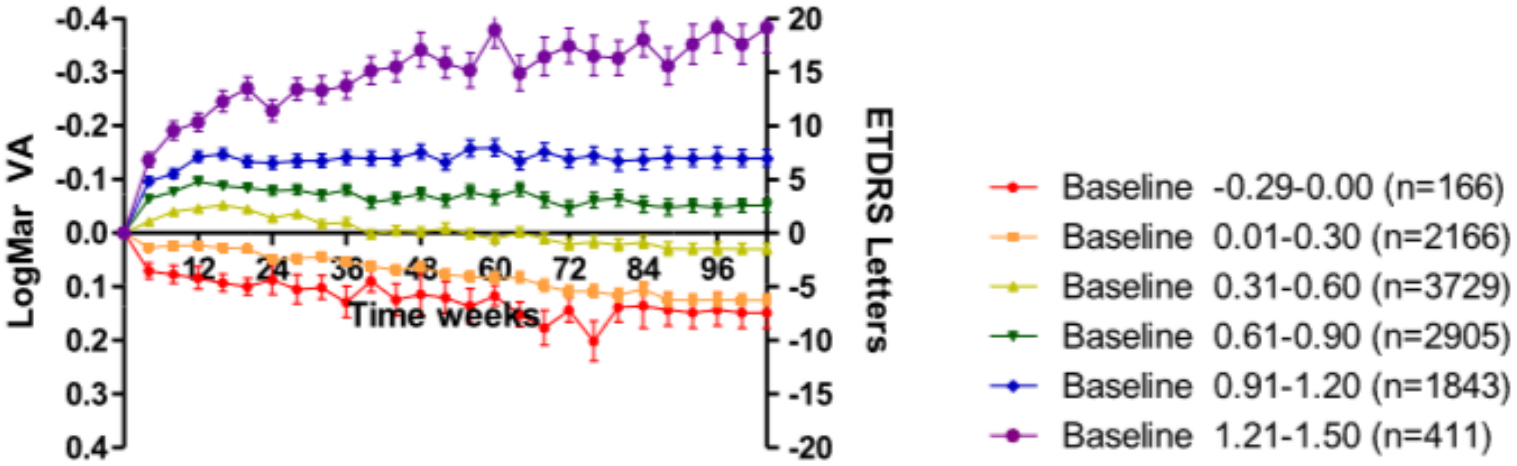


Figure 14.2-6 Change in BCVA from baseline stratified by visual acuity

Per Protocol Set

Example:

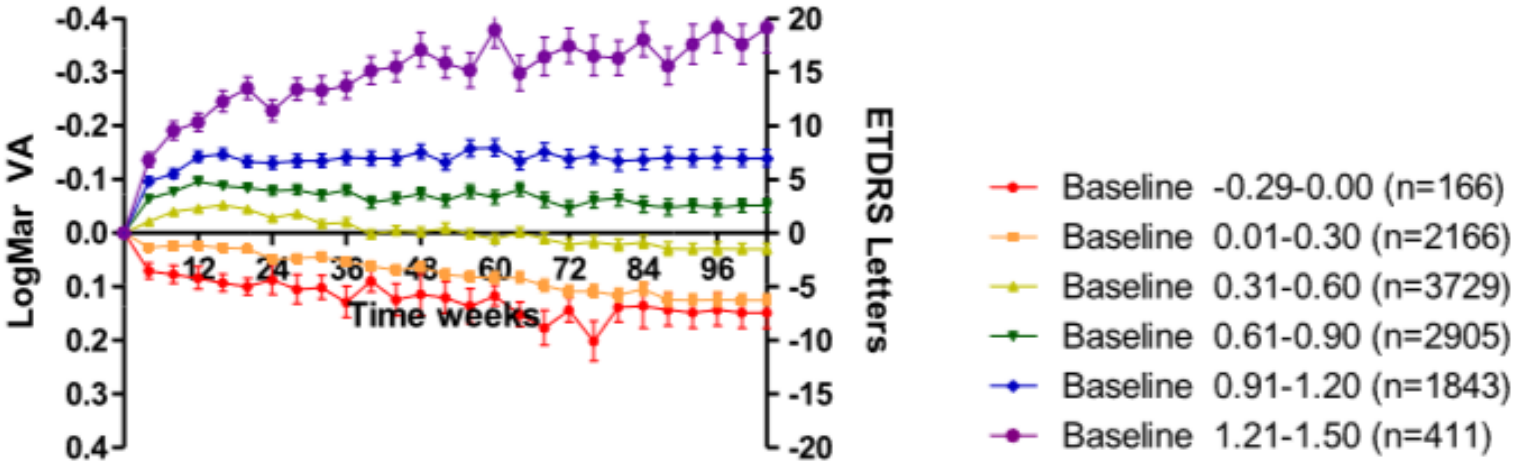


Figure 14.2-7 Proportion of Patients with >= 15 letter increase in BCVA from baseline, over time by treatment

Full Analysis Set

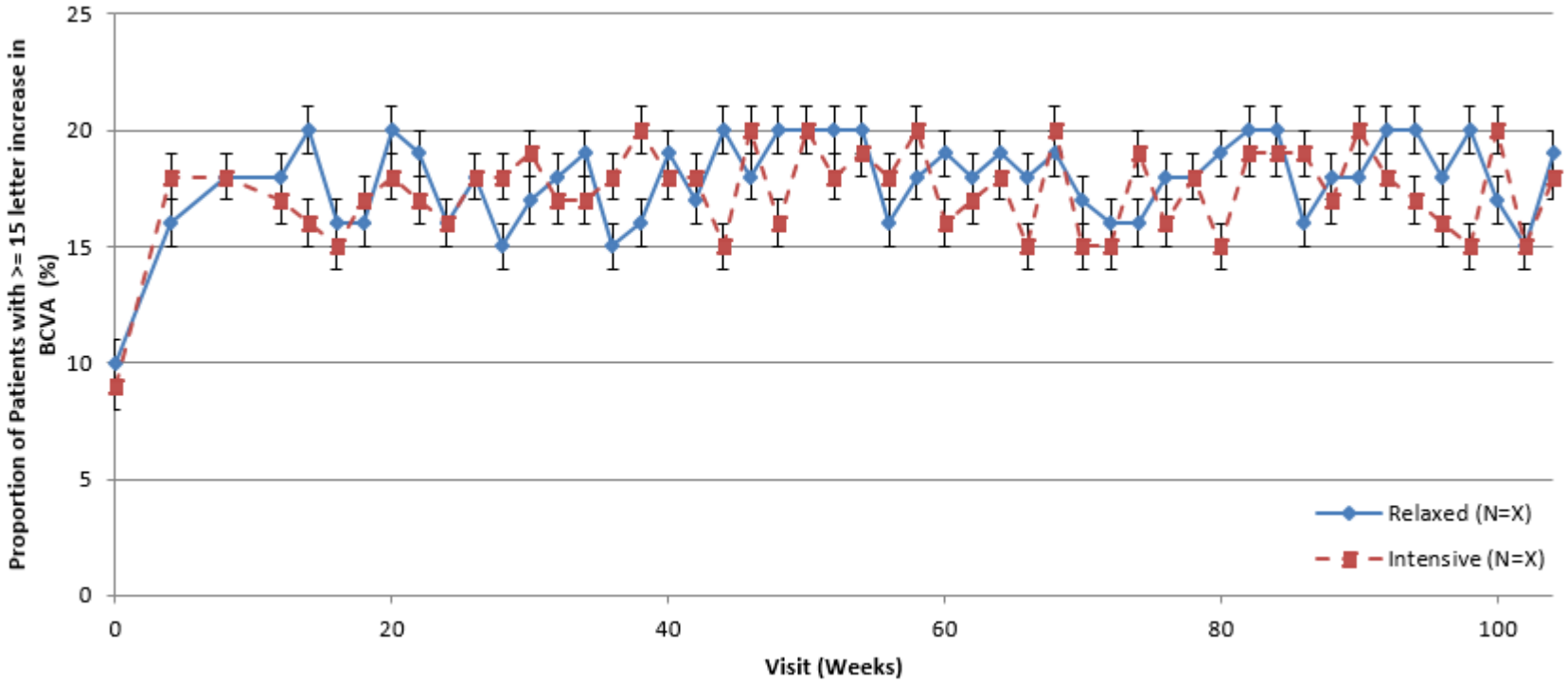


Figure 14.2-8 Proportion of Patients with >= 15 letter increase in BCVA from baseline at Month 12 and 24

Full Analysis Set

Bar graph with p-values

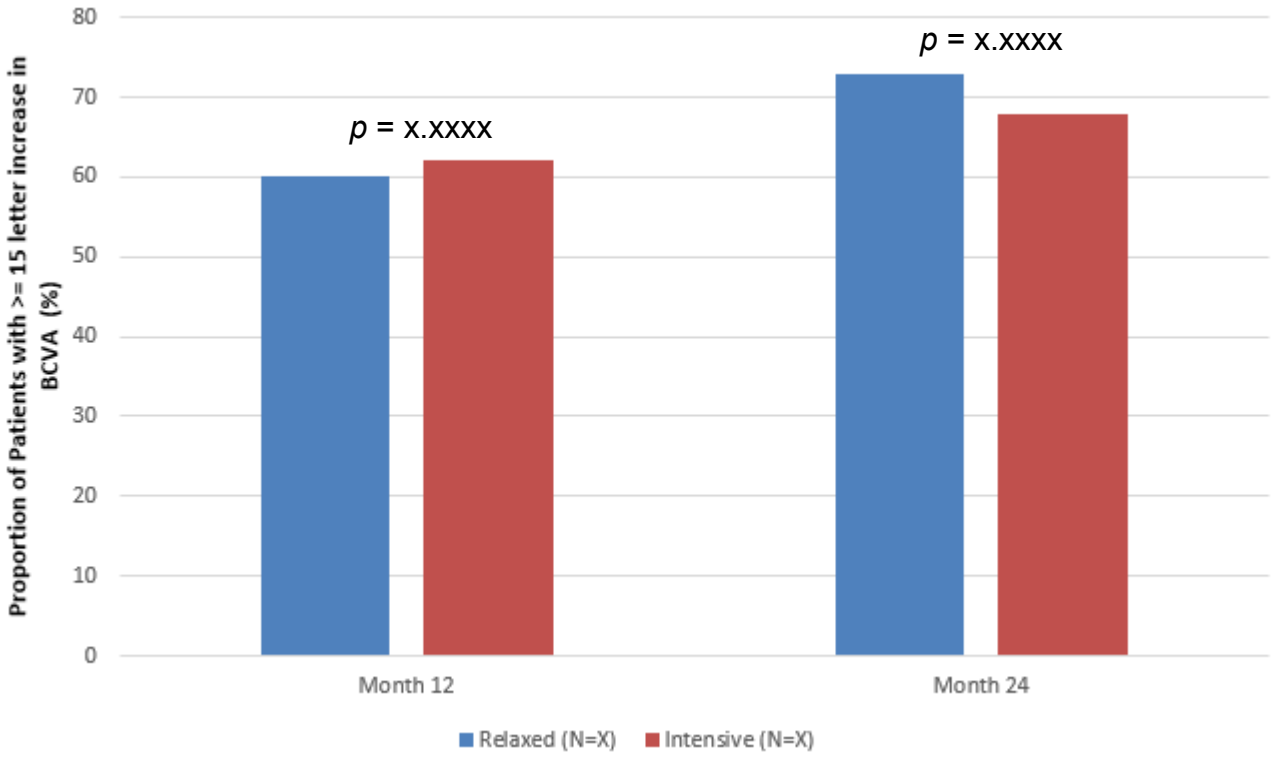


Figure 14.2-9 Proportion of patients achieving >=6/12 vision, over time by treatment

Full Analysis Set

Time series graph as per Figure 14.2-7.

Figure 14.2-10 Proportion of of patients achieving >=6/12 vision at Month 12 and 24

Full Analysis Set

Column graph as per Figure 14.2-8.

Figure 14.2-11 Proportion of patients showing worse than 6/60 vision, over time by treatment

Full Analysis Set

Time series graph as per Figure 14.2-7.

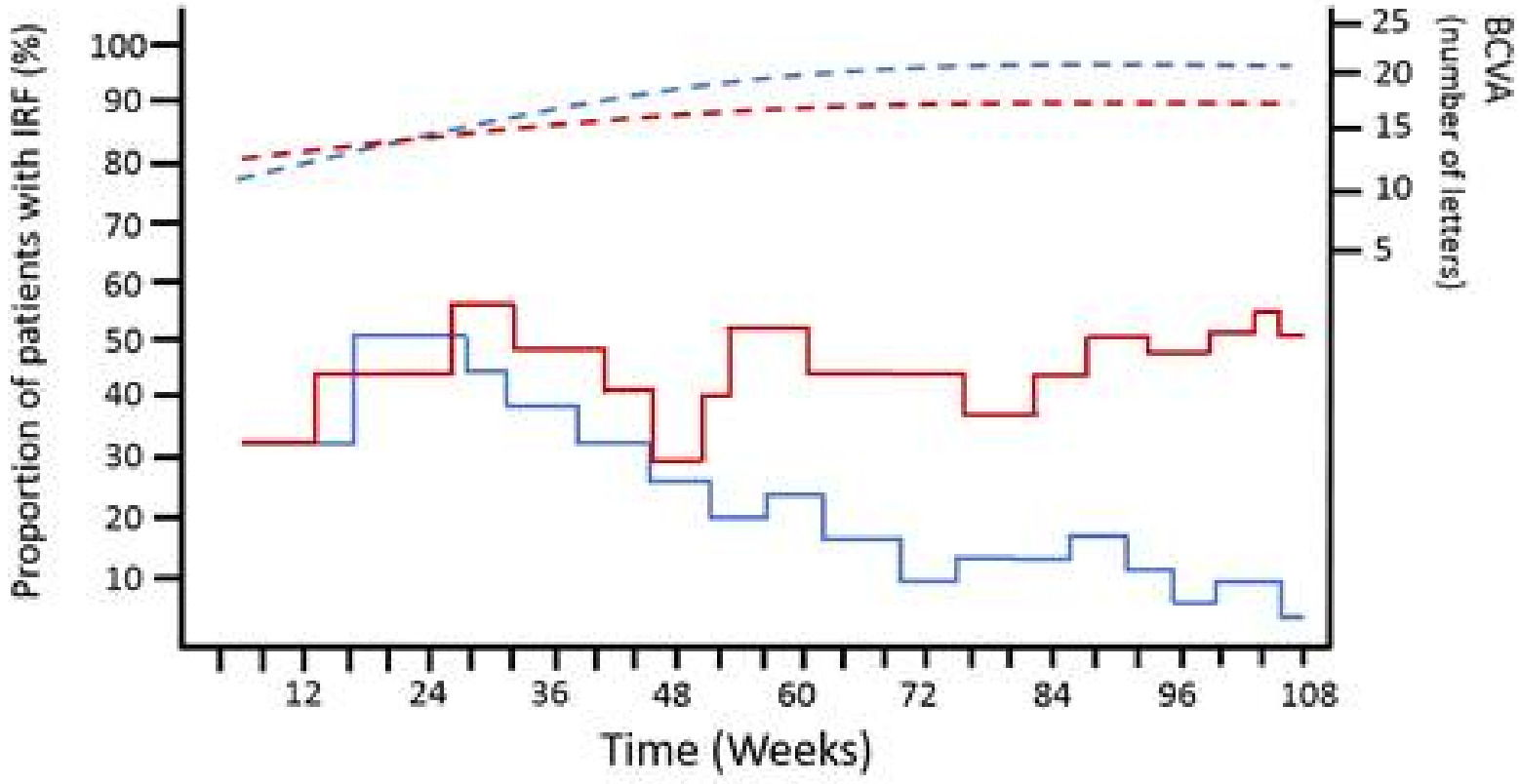
Figure 14.2-12 Proportion of of patients showing worse than 6/60 vision at Month 12 and 24

Full Analysis Set

Column graph as per Figure 14.2-8.

Figure 14.2-13 Proportion of patients with IRF and BCVA, over time by treatment

Full Analysis Set



Note to Programmer: "IRF" refers to IRF and IRC (cysts) grouped together

Figure 14.2-14 Proportion of patients with SRF and BCVA, over time by treatment

Full Analysis Set

As per Figure 14.2-13.

Figure 14.2-15 Proportion of patients with IRF and SRF, and BCVA, over time by treatment

Full Analysis Set

As per Figure 14.2-13.

Note to Programmer: “IRF” refers to IRF and IRC (cysts) grouped together

Figure 14.2-16 Proportion of patients with neither IRF or SRF, and BCVA, over time by treatment

Full Analysis Set

Note to Programmer: “IRF” refers to IRF and IRC (cysts) grouped together

Figure 14.2-17 Proportion of patients with Geographic Atrophy and BCVA, over time by treatment

Full Analysis Set

As per Figure 14.2-13.

Figure 14.2-18 Proportion of Patients with IRF over time by treatment

Full Analysis Set

Time series graph as per Figure 14.2-7.

Note to Programmer: “IRF” refers to IRF and IRC (cysts) grouped together

Figure 14.2-19 Proportion of Patients with SRF over time by treatment

Full Analysis Set

Time series graph as per Figure 14.2-7.

Figure 14.2-20 Proportion of Patients with IRF and SRF over time by treatment

Full Analysis Set

Time series graph as per Figure 14.2-7.

Note to Programmer: “IRF” refers to IRF and IRC (cysts) grouped together

Figure 14.2-21 Proportion of Patients with neither IRF or SRF over time by treatment

Full Analysis Set

Time series graph as per Figure 14.2-7.

Note to Programmer: “IRF” refers to IRF and IRC (cysts) grouped together

Figure 14.2-22 Proportion of Patients with Geographic Atrophy over time by treatment

Full Analysis Set

Time series graph as per Figure 14.2-7.

Figure 14.2-23 Change in geographic atrophy area from baseline over time by treatment

Full Analysis Set

Time series graph as per Figure 14.2-5.

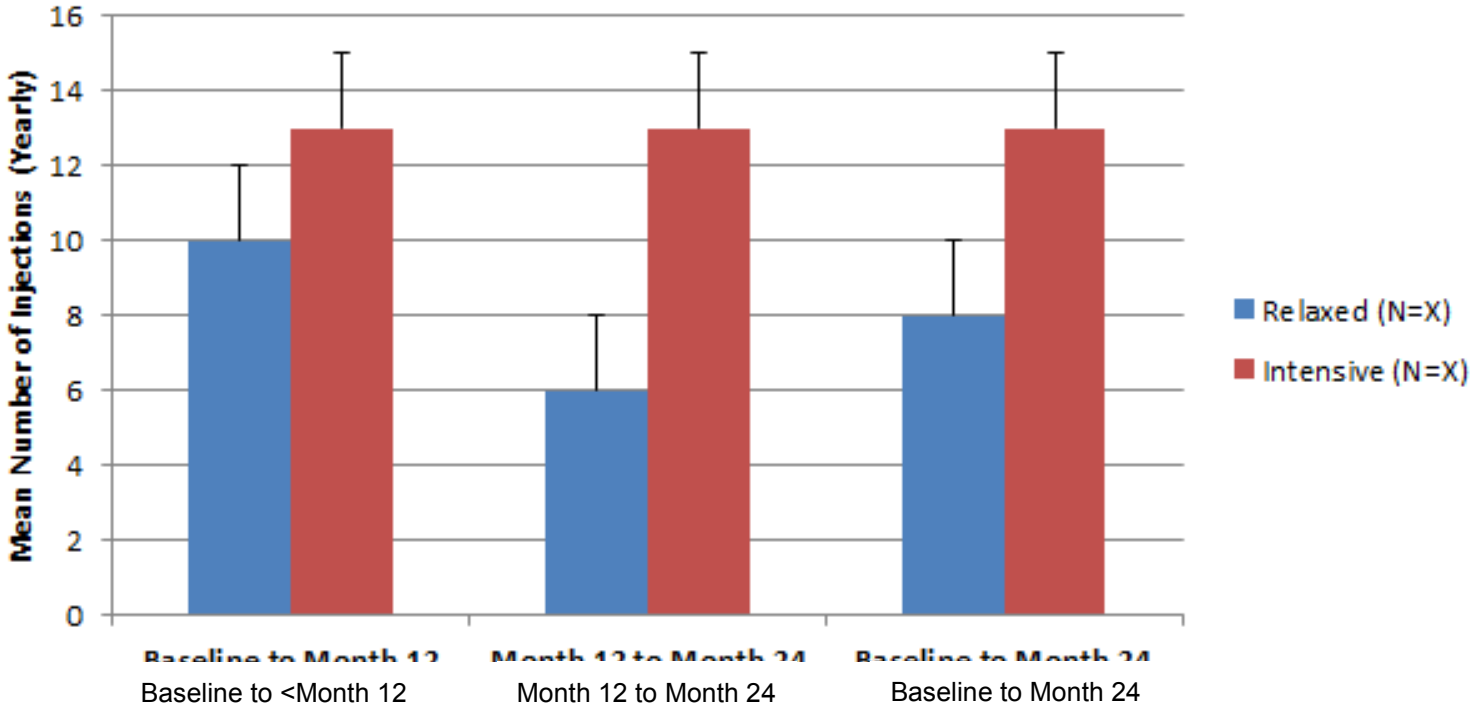
Figure 14.2-24 Change in Central Subfield Foveal Thickness from baseline, over time by treatment

Full Analysis Set

Time series graph as per Figure 14.2-5.

Figure 14.2-25 Number of injections by treatment at 12 and 24 months

Full Analysis Set



Tables (Section 14.2)

Table 14.2-1 Visual Acuity – Summary and Change from Baseline

Full Analysis Set and Per-Protocol Set

Visit	Statistic	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
		Actual Value	Absolute Change from Baseline*	Actual Value	Absolute Change from Baseline	Actual Value	Absolute Change from Baseline
Screening	n	x	-	x	-	x	-
	Mean	x.x	-	x.x	-	x.x	-
	Median	x.x	-	x.x	-	x.x	-
	SD	x.x	-	x.x	-	x.x	-
	Minimum	x	-	x	-	x	-
	Maximum	x	-	x	-	x	-
Baseline*	n	x	-	x	-	x	-
	Mean	x.x	-	x.x	-	x.x	-
	Median	x.x	-	x.x	-	x.x	-
	SD	x.x	-	x.x	-	x.x	-
	Minimum	x	-	x	-	x	-
	Maximum	x	-	x	-	x	-
Week *n*	…….						

Continued through to Month 24

*Baseline: The last available non-missing value collected just prior to the start of treatment in the study eye
SD: Standard Deviation

Table 14.2-2 Visual Acuity – Mixed Model Analysis

Full Analysis Set

	Random Effects Mixed Model*				Treatment Effects	
	Num d.f.	Den d.f.	F-stat	p-value	Intensive (N=X)	Relaxed (N=X)
Baseline Effect	x	xx	x.xx	x.xxxx		
Treatment	x	xx	x.xx	x.xxxx		
Visit	x	xx	x.xx	x.xxxx		
*Treatment*Visit*	x	xx	x.xx	x.xxxx		
Least Squares Means						
Month *2 (95% CI)*					x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
Month *12 (95% CI)*					x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
Month *24 (95% CI)*					x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
Treatment Effect						
Month *2*, Treatment Effect (95%CI)					x.xx (x.xx,x.xx)	
Month *2*, p-value					x.xxxx	
Month *12*, Treatment Effect (95%CI)					x.xx (x.xx,x.xx)	
Month *12*, p-value					x.xxxx	
Month *24*, Treatment Effect (95%CI)					x.xx (x.xx,x.xx)	
Month 24, p-value					x.xxxx	

*Mixed Model: Change from Baseline (BCVA) = Baseline (BCVA) + Treatment + Visit (weeks) + Treatment * Visit + Subject (random effect)
CI: Confidence Interval;

Note to Programmer: The above table is an example only. Output to be updated to reflect aspects of the final model as appropriate.

Table 14.2-3 Visual Acuity – Mixed Model Analysis

Per Protocol Set

	Mixed Model*				Treatment Effects	
	Num d.f.	Den d.f.	F-stat	p-value	Intensive (N=X)	Relaxed (N=X)
Treatment Main Effects	x	xx	x.xx	x.xxxx		
Visits	x	xx	x.xx	x.xxxx		
Baseline Effect	x	xx	x.xx	x.xxxx		
Class variable	x	xx	x.xx	x.xxxx		
*Treatment * Visit*	x	xx	x.xx	x.xxxx		
Least Squares Means						
Month *2 (95% CI)*					x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
Month *12 (95% CI)*					x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
Month *24 (95% CI)*					x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
Treatment Effect						
Month *2*, Treatment Effect (95%CI)					x.xx (x.xx,x.xx)	
Month *2*, p-value					x.xxxx	
Month *12*, Treatment Effect (95%CI)					x.xx (x.xx,x.xx)	
Month *12*, p-value					x.xxxx	
Month *24*, Treatment Effect (95%CI)					x.xx (x.xx,x.xx)	
Month 24, p-value					x.xxxx	

*Mixed Model: Change from Baseline (BCVA) = Baseline (BCVA) + Treatment + Visit (weeks) + Treatment * Visit + Subject (random effect)
CI: Confidence Interval

Note to Programmer: The above table is an example only. Output to be updated to reflect aspects of the final model as appropriate.

Table 14.2-4 Proportion of Patients with >=15 letters change from baseline – Logistic Regression

Full Analysis Set

		Intensive (N=X)		Relaxed (N=X)
Letters change from baseline to Month 12				
>= 15 letters	YES	xx (xx.x%)		xx (xx.x%)
	NO	xx (xx.x%)		xx (xx.x%)
Odds Ratio*				
Odds Ratio (95% CI)			x.xx (x.xx,x.xx)	
p-value			x.xxxx	
Letters change from baseline to Month 24				
>= 15 letters	YES	xx (xx.x%)		xx (xx.x%)
	NO	xx (xx.x%)		xx (xx.x%)
Odds Ratio*				
Odds Ratio (95% CI)			x.xx (x.xx,x.xx)	
p-value			x.xxxx	

*Logistic regression model includes treatment as factor and baseline BCVA as covariate

Table 14.2-4 Proportion of Patients with less than 15 letters lost change from baseline – Logistic Regression

Full Analysis Set

		Intensive (N=X)		Relaxed (N=X)
Letters change from baseline to Month 12				
<15 letters lost	YES	xx (xx.x%)		xx (xx.x%)
	NO	xx (xx.x%)		xx (xx.x%)
Odds Ratio*				
Odds Ratio (95% CI)			x.xx (x.xx,x.xx)	
p-value			x.xxxx	
Letters change from baseline to Month 24				
<15 letters lost	YES	xx (xx.x%)		xx (xx.x%)
	NO	xx (xx.x%)		xx (xx.x%)
Odds Ratio*				
Odds Ratio (95% CI)			x.xx (x.xx,x.xx)	
p-value			x.xxxx	

*Logistic regression model includes treatment as factor and baseline BCVA as covariate

Table 14.2-5 Proportion of Patients who achieve >=6/12 visual acuity – Logistic Regression

Full Analysis Set

	Intensive (N=X)		Relaxed (N=X)
Baseline			
>= 6/12 visual acuity	xx (xx.x%)		xx (xx.x%)
<6/12 visual acuity	xx (xx.x%)		xx (xx.x%)
Month 12			
>= 6/12 visual acuity	xx (xx.x%)		xx (xx.x%)
<6/12 visual acuity	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	
Month 24			
>= 6/12 visual acuity	xx (xx.x%)		xx (xx.x%)
<6/12 visual acuity	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	

*Logistic regression model includes treatment as factor and baseline BCVA as covariate

Table 14.2-6 Proportion of Patients who achieve <=6/60 visual acuity – Logistic Regression

Full Analysis Set

	Intensive (N=X)		Relaxed (N=X)
Baseline			
<= 6/60 visual acuity	xx (xx.x%)		xx (xx.x%)
>6/60 visual acuity	xx (xx.x%)		xx (xx.x%)
Month 2			
<= 6/60 visual acuity	xx (xx.x%)		xx (xx.x%)
>6/60 visual acuity	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	
Month 12			
<= 6/60 visual acuity	xx (xx.x%)		xx (xx.x%)
>6/60 visual acuity	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	
Month 24			
<= 6/60 visual acuity	xx (xx.x%)		xx (xx.x%)
>6/60 visual acuity	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	

*Logistic regression model includes treatment as factor and baseline BCVA as covariate

Table 14.2-7 Interval Decision Summary Table

Full Analysis Set

Visit	Interval Decision*	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Week 8				
	Loss in VA	x (xx.x)	x (xx.x)	x (xx.x)
	Haemorrhage	x (xx.x)	x (xx.x)	x (xx.x)
	IRF/SRF	x (xx.x)	x (xx.x)	x (xx.x)
	Loss in VA AND Haemorrhage	x (xx.x)	x (xx.x)	x (xx.x)
	Loss in VA AND IRF/SRF	x (xx.x)	x (xx.x)	x (xx.x)
	Loss in VA AND Haemorrhage AND IRF/SRF	x (xx.x)	x (xx.x)	x (xx.x)
	Haemorrhage AND IRF/SRF	x (xx.x)	x (xx.x)	x (xx.x)
Week n	…….			

*Interval Decisions:

Loss in VA: A loss of VA of >=5 letters or more than the best VA recorded since treatment started (Where VA loss is considered, by the investigator, to be due to disease activity);

Haemorrhage: New retinal haemorrhage;

IRF/SRF: Intensive Arm: The presence of any intra-retinal fluid or sub-retinal fluid on OCT
Relaxed Arm: The presence of any intra-retinal fluid or sub-retinal fluid >200 µm in height at foveal centre?

Table 14.2-8 Number of Injections

Visit		Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Number of Injections	n	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x
Exposure (year)	n	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x
Injections per year*		xx	xx	xx

* Injections per year = Total number of injections / total exposure to treatment (years)

Visit		Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Number of Injections	n	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x
Exposure (year)	n	x	x	x
	Mean (SD)	x.x (x.x)	x.x (x.x)	x.x (x.x)
	Min; Max	x;x	x;x	x;x
Injections per year*		xx	xx	xx

* Injections per year = Total number of injections / total exposure to treatment (years)

Table 14.2-9 Number of Injections from Baseline to Months 12 and 24 – Negative Binomial Regression

Full Analysis Set

	Negative Binomial Regression*				Treatment Effects	
	Estimate	Standard Error	Chi-square	p-value	Intensive (N=X)	Relaxed (N=X)
Parameter Estimates						
Intercept	x.xx	x.xxxx	x.xx	x.xxxx		
Treatment	x.xx	x.xxxx	x.xx	x.xxxx		
Disperson						
Least Squares Means						
Least Squares Means (95% CI)					x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
Treatment Effect						
Treatment Effect (95% CI)					x.xx (x.xx, x.xx)	
p-value					x.xxx	

* number of injections will be the outcome variable, and treatment and BL BCVA as a predictor. The logarithm of length of time (year) each subject is in the study up to their 24 month visit will be used as an offset variable.

Table 14.2-10 Treatment Interval Summary (Based on Interval Decision)

Full Analysis Set and Per-Protocol Set

Statistic	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x

SD: Standard Deviation

Average treatment interval for each group - need to average it out for patient then average out for the treatment arm

Table 14.2-11 Treatment Interval Summary (Based on Actual Intervals between Visits)

Full Analysis Set and Per-Protocol Set

Statistic	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x

SD: Standard Deviation

Average treatment interval for each group - need to average it out for patient then average out for the treatment arm

Table 14.2-12 Treatment Interval Visit Summary (Based on Interval Decision)

Full Analysis Set

Visit	Interval	Intensive (N=x)	Relaxed (N=x)	Total (N=x)
Week 4	4 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
Week 8	4 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
Week 12	4 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	6 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	8 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	10 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	12 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
Week ***n***	4 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	6 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	8 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	10 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	12 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)

Table 14.2-13 Treatment Interval Visit Summary (Based on Actual Intervals between Visits)

Full Analysis Set

Visit	Interval	Intensive (N=x)	Relaxed (N=x)	Total (N=x)
Week 4	4 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
Week 8	4 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
Week 12	4 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	6 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	8 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	10 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	12 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
Week ***n***	4 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	6 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	8 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	10 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)
	12 Weeks	x (xx.x%)	x (xx.x%)	x (xx.x%)

Table 14.2-14 Breakpoint Set Interval - Summary

Full Analysis Set

Visit	Interval	Intensive (N=x)	Relaxed (N=x)	Total (N=x)
Week 52	4 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	6 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	8 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	10 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	12 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	Has not reached breakpoint	x (x.xx%)	x (x.xx%)	x (x.xx%)
Week 104	4 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	6 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	8 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	10 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	12 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	Has not reached breakpoint	x (x.xx%)	x (x.xx%)	x (x.xx%)

Note to Programmer: Use assigned interval (Interval Decision)

Table 14.2-15 Post-Breakpoint Maximum Inteval - Summary

Full Analysis Set

Visit	Interval	Intensive (N=x)	Relaxed (N=x)	Total (N=x)
Week 52	4 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	6 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	8 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	10 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	Has not reached breakpoint	x (x.xx%)	x (x.xx%)	x (x.xx%)
Week 104	4 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	6 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	8 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	10 Weeks	x (x.xx%)	x (x.xx%)	x (x.xx%)
	Has not reached breakpoint	x (x.xx%)	x (x.xx%)	x (x.xx%)

Note to Programmer: Use assigned interval (Interval Decision)

Table 14.2-16 Time to Breakpoint - Summary

Full Analysis Set

	Intensive (N=x)	Relaxed (N=x)	Total (N=x)
Time to Meet Breakpoint Criteria (weeks)			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x

SD: Standard Deviation

Table 14.2-17 Time to Breakpoint – Survival Analysis

Full Analysis Set

	Intensive (N=x)	Relaxed (N=x)	Total (N=x)
Total Subjects	x	x	X
Event n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Censored n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Time to Events (Weeks)			
25 Percentile (95% CI)	x (xx,xx)	x (xx,xx)	x (xx,xx)
Median (95% CI)	x (xx,xx)	x (xx,xx)	x (xx,xx)
75 Percentile (95% CI)	x (xx,xx)	x (xx,xx)	x (xx,xx)
Range	xx;xx	xx;xx	xx;xx

***Table 14.2-18 Geographic Atrophy Area – Summary and Change from Baseline* (Central Reading Center Data)**

Full Analysis Set

Visit	Statistic	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
		Actual Value	Absolute Change from Baseline*	Actual Value	Absolute Change from Baseline	Actual Value	Absolute Change from Baseline
Screening	n	x	-	x	-	x	-
	Mean	x.x	-	x.x	-	x.x	-
	Median	x.x	-	x.x	-	x.x	-
	SD	x.x	-	x.x	-	x.x	-
	Minimum	x	-	x	-	x	-
	Maximum	x	-	x	-	x	-
Baseline*	n	x	-	x	-	x	-
	Mean	x.x	-	x.x	-	x.x	-
	Median	x.x	-	x.x	-	x.x	-
	SD	x.x	-	x.x	-	x.x	-
	Minimum	x	-	x	-	x	-
	Maximum	x	-	x	-	x	-
Week *n*	…….						

Continued through to Month 24

*Baseline: The last available non-missing value collected just prior to the start of treatment in the study eye
SD: Standard Deviation

Table 14.2-19 Geographic Atrophy – Categorical Summary

Full Analysis Set

Visit		Intensive	Relaxed	Total
Baseline*	Present	x (xx.x%)	x (xx.x%)	x (xx.x%)
	Absent	x (xx.x%)	x (xx.x%)	x (xx.x%)
Week *4*	Present	x (xx.x%)	x (xx.x%)	x (xx.x%)
	Absent	x (xx.x%)	x (xx.x%)	x (xx.x%)
Week 8	Present	x (xx.x%)	x (xx.x%)	x (xx.x%)
	Absent	x (xx.x%)	x (xx.x%)	x (xx.x%)
Week *n*	Present	x (xx.x%)	x (xx.x%)	x (xx.x%)
	Absent	x (xx.x%)	x (xx.x%)	x (xx.x%)

*Baseline: The last available non-missing value collected just prior to the start of treatment in the study eye
SD: Standard Deviation

Table 14.2-20 Geographic Atrophy – Survival Analysis

Full Analysis Set

	Intensive (N=x)	Relaxed (N=x)	Total (N=x)
Total Subjects	x	x	X
Event n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Censored n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Time to Events (Weeks)			
25 Percentile (95% CI)	x (xx,xx)	x (xx,xx)	x (xx,xx)
Median (95% CI)	x (xx,xx)	x (xx,xx)	x (xx,xx)
75 Percentile (95% CI)	x (xx,xx)	x (xx,xx)	x (xx,xx)
Range	xx;xx	xx;xx	xx;xx

	Intensive (N=x)	Relaxed (N=x)	Total (N=x)
Total Subjects	x	x	X
Event n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Censored n(%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
Time to Events (Weeks)			
25 Percentile (95% CI)	x (xx,xx)	x (xx,xx)	x (xx,xx)
Median (95% CI)	x (xx,xx)	x (xx,xx)	x (xx,xx)
75 Percentile (95% CI)	x (xx,xx)	x (xx,xx)	x (xx,xx)
Range	xx;xx	xx;xx	xx;xx

Table 14.2-21 Geographic Atrophy – Mixed Model Analysis

Full Analysis Set

	Mixed Model*				Treatment Effects	
	Num d.f.	Den d.f.	F-stat	p-value	Intensive (N=X)	Relaxed (N=X)
Treatment Main Effects	x	xx	x.xx	x.xxxx		
Visits	x	xx	x.xx	x.xxxx		
Baseline Effect	x	xx	x.xx	x.xxxx		
Class variable	x	xx	x.xx	x.xxxx		
Class variable	x	xx	x.xx	x.xxxx		
Least Squares Means						
Month *2*					x.xx (x.xx)	x.xx (x.xx)
Month *12*					x.xx (x.xx)	x.xx (x.xx)
Month *24*					x.xx (x.xx)	x.xx (x.xx)
Treatment Effect						
Month *2*, Treatment Effect (95%CI)						x.xx (x.xx,x.xx)
Month *2*, p-value						x.xxxx
Month *12*, Treatment Effect (95%CI)						x.xx (x.xx,x.xx)
Month *12*, p-value						x.xxxx
Month *24*, Treatment Effect (95%CI)						x.xx (x.xx,x.xx)
Month 24, p-value						x.xxxx

*Mixed Model: Change from Baseline (Geographic Atrophy Area) = Baseline (Geographic Atrophy Area) + Treatment + Visit (weeks)
CI: Confidence Interval; SE: Standard Error

Note to Programmer: The above table is an example only. Output to be updated to reflect aspects of the final model as appropriate.

Table 14.2-22 Geographic Atrophy – Mixed Model Analysis

Per Protocol Set

	Mixed Model*				Treatment Effects	
	Num d.f.	Den d.f.	F-stat	p-value	Intensive (N=X)	Relaxed (N=X)
Treatment Main Effects	x	xx	x.xx	x.xxxx		
Visits	x	xx	x.xx	x.xxxx		
Baseline Effect	x	xx	x.xx	x.xxxx		
Class variable	x	xx	x.xx	x.xxxx		
Class variable	x	xx	x.xx	x.xxxx		
Least Squares Means						
Month *2*					x.xx (x.xx)	x.xx (x.xx)
Month *12*					x.xx (x.xx)	x.xx (x.xx)
Month *24*					x.xx (x.xx)	x.xx (x.xx)
Treatment Effect						
Month *2*, Treatment Effect (95%CI)						x.xx (x.xx,x.xx)
Month *2*, p-value						x.xxxx
Month *12*, Treatment Effect (95%CI)						x.xx (x.xx,x.xx)
Month *12*, p-value						x.xxxx
Month *24*, Treatment Effect (95%CI)						x.xx (x.xx,x.xx)
Month 24, p-value						x.xxxx

*Mixed Model: Change from Baseline (Geographic Atrophy Area) = Baseline (Geographic Atrophy Area) + Treatment + Visit (weeks)
CI: Confidence Interval; SE: Standard Error

Note to Programmer: The above table is an example only. Output to be updated to reflect aspects of the final model as appropriate.

Table 14.2-23 Proportion of Patients with Geographic Atrophy from Baseline to Month 24 – Logistic Regression

Full Analysis Set

	Intensive (N=X)		Relaxed (N=X)
Status of Geographic Atrophy			
Baseline			
Absent	xx (xx.x%)		xx (xx.x%)
Present	xx (xx.x%)		xx (xx.x%)
Month 24			
Absent	xx (xx.x%)		xx (xx.x%)
Present	xx (xx.x%)		xx (xx.x%)
Newly developed geographic atrophy only	xx (xx.x%)		xx (xx.x%)
Odds Ratios*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	

*Logistic regression model (proportion of newly developed geographic atrophy at Month 24) includes treatment as factor

Table 14.2-24 Proportion of Patients showing intra-retinal / sub-retinal fluid, by visit

Full Analysis Set

		Intensive (N=X) n (%)	Relaxed (N=X) n (%)	**p-value (Logistic Regression)**	**Total (N=X) n (%)**
Screening	Intra-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	No Intra-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	Intra-retinal Fluid – Center Involvement	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	No Intra-retinal Fluid – Center Involvement	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	Sub-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	No Sub-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	No Intra-retinal Fluid or Sub-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	Intra-retinal Fluid OR Sub-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	Intra-retinal Fluid AND Sub-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
Baseline	Intra-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	No Intra-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	Intra-retinal Fluid – Center Involvement	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	No Intra-retinal Fluid – Center Involvement	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	Sub-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	No Sub-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	No Intra-retinal Fluid or Sub-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	Intra-retinal Fluid OR Sub-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	Intra-retinal Fluid AND Sub-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
Week *n*	Intra-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	No Intra-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	Sub-retinal Fluid	x (xx.x)	x (xx.x)	x.xxx	x (xx.x)
	.....				

Table 14.2-25 Proportion of patients with SRF at baseline who never resolve their SRF (irrespective of their IRF) – Logistic Regression

Full Analysis Set

	Intensive (N=X)		Relaxed (N=X)
Month 2	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	
Month 12	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	
Month 24	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	

*Logistic regression model includes treatment as factor and baseline BCVA as covariate

Table 14.2-26 Proportion of patients with IRF at baseline who never resolve their IRF (irrespective of their SRF) – Logistic Regression

Full Analysis Set

	Intensive (N=X)		Relaxed (N=X)
Month 2	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	
Month 12	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	
Month 24	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	

*Logistic regression model includes treatment as factor and baseline BCVA as covariate

Table 14.2-27 Proportion of patients with IRF and SRF at baseline who never resolve either their IRF or SRF – Logistic Regression

Full Analysis Set

	Intensive (N=X)		Relaxed (N=X)
Month 2	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	
Month 12	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	
Month 24	xx (xx.x%)		xx (xx.x%)
Odds Ratio*			
Odds Ratio (95% CI)		x.xx (x.xx,x.xx)	
p-value		x.xxxx	

*Logistic regression model includes treatment as factor and baseline BCVA as covariate

Table 14.2-28 Intra-Retinal and Sub-Retinal Fluid – Generalized Estimating Equation

Full Analysis Set

	Generalised Estimating Equation*				Treatment Effects	
	Odds Ratio	95% CI Lower	95% CI Upper	p-value	Intensive (N=X)	Relaxed (N=X)
Intra-Retinal Fluid						
Parameter Estimates						
Visit	x.xx	x.xx	x.xx	x.xxxx		
Least Squares Means						
Month *n*					x.xx (x.xx)	x.xx (x.xx)
Month *n*					x.xx (x.xx)	x.xx (x.xx)
Sub-Retinal Fluid						
Parameter Estimates						
Intercept	x.xx	x.xx	x.xx	x.xxxx		
Treatment	x.xx	x.xx	x.xx	x.xxxx		
Month	x.xx	x.xx	x.xx	x.xxxx		
Least Squares Means						
Month *n*					x.xx (x.xx)	x.xx (x.xx)
Month *n*					x.xx (x.xx)	x.xx (x.xx)

*Generalised Estimating Equation (GEE)

Table 14.2-29 Central Retinal Thickness – Summary and Change from Baseline, by treatment

Full Analysis Set

Visit	Statistic	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
		Actual Value	Absolute Change from Baseline*	Actual Value	Absolute Change from Baseline	Actual Value	Absolute Change from Baseline
Screening	n	x	-	x	-	x	-
	Mean	x.x	-	x.x	-	x.x	-
	Median	x.x	-	x.x	-	x.x	-
	SD	x.x	-	x.x	-	x.x	-
	Minimum	x	-	x	-	x	-
	Maximum	x	-	x	-	x	-
Baseline	n	x	-	x	-	x	-
	Mean	x.x	-	x.x	-	x.x	-
	Median	x.x	-	x.x	-	x.x	-
	SD	x.x	-	x.x	-	x.x	-
	Minimum	x	-	x	-	x	-
	Maximum	x	-	x	-	x	-
Week *n*	…….						

Continued through to Month 24

*Baseline: The last available non-missing value collected just prior to the start of treatment in the study eye
SD: Standard Deviation

Table 14.2-30 Central Retinal Thickness – Mixed Model Analysis

Full Analysis Set

	Random effect Mixed Model *				Treatment Effects	
	Num d.f.	Den d.f.	F-stat	p-value	**Intensive (N=X)**	**Relaxed (N=X)**
Treatment Main Effects	x	xx	x.xx	x.xxxx		
Visits	x	xx	x.xx	x.xxxx		
Baseline Effect	x	xx	x.xx	x.xxxx		
Class variable	x	xx	x.xx	x.xxxx		
Class variable	x	xx	x.xx	x.xxxx		
Least Squares Means						
Month 2 (95%CI)					x.xx (x.xx,x.xx)	x.xx (x.xx,x.xx)
Month *12* (95%CI)					x.xx (x.xx,x.xx)	x.xx (x.xx,x.xx)
Month *24* (95%CI)						
Treatment Effect						
Month *2*, Treatment Effect (95%CI)						x.xx (x.xx,x.xx)
Month *2*, p-value						x.xxxx
Month *12*, Treatment Effect (95%CI)						x.xx (x.xx,x.xx)
Month *12*, p-value						x.xxxx
Month *24*, Treatment Effect (95%CI)						x.xx (x.xx,x.xx)
Month *24*, p-value						x.xxxx

*Mixed Model: Change from Baseline (CRT) = Baseline (CRT) + Treatment + Visit (weeks) + Treatment * Visit + Subject (random effect)
CI: Confidence Interval; CRT: Central Retinal Thickness; SE: Standard Error

Table 14.2-31 Genotyping by Treatment

Full Analysis Set

	Intensive (N=X)	Relaxed (N=X)	P Value	Total (N=X)
rsXXXXXXXX				
-			x.xxxx	
GG	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
GT	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
TT	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
rsXXXXXXXX				
-			x.xxxx	
CC	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
CT	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
TT	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
rsXXXXXXXX				
-			x.xxxx	
CC	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
CT	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
……..				

* Fisher Analysis

Table 14.2-32 Genotyping by Race

Full Analysis Set

	Asian (N=X)	Caucasian (N=X)	P Value*	Total (N=X)
rsXXXXXXXX				
-			x.xxxx	
GG	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
GT	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
TT	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
rsXXXXXXXX				
-			x.xxxx	
CC	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
CT	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
TT	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
rsXXXXXXXX				
-			x.xxxx	
CC	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
CT	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
……..				

* Fisher Analysis

Listings (Section 14.2)

Not applicable.

Section 14.3 – Safety data

Tables (Section 14.3)

Table 14.3-1 Number (%) of patients receiving each dose and regimen of study medication by treatment and visit

Safety Set

Visit	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Baseline	x (xx.x)	x (xx.x)	x (xx.x)
Week 4	x (xx.x)	x (xx.x)	x (xx.x)
Week 8	x (xx.x)	x (xx.x)	x (xx.x)
Week *n*	x (xx.x)	x (xx.x)	x (xx.x)
Week *n*	x (xx.x)	x (xx.x)	x (xx.x)
Week *n*	x (xx.x)	x (xx.x)	x (xx.x)
Week *n*	x (xx.x)	x (xx.x)	x (xx.x)
Week *n*	x (xx.x)	x (xx.x)	x (xx.x)
Week *n*	x (xx.x)	x (xx.x)	x (xx.x)
Week *n*	x (xx.x)	x (xx.x)	x (xx.x)
Week *n*	x (xx.x)	x (xx.x)	x (xx.x)
Week *n*	x (xx.x)	x (xx.x)	x (xx.x)
Month *n*	x (xx.x)	x (xx.x)	x (xx.x)
Month *n*	x (xx.x)	x (xx.x)	x (xx.x)
Month 24	x (xx.x)	x (xx.x)	x (xx.x)

Table 14.3-2 Duration of exposure to study drug, by treatment

Safety Set

	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Duration of Exposure (days)*			
n	x	x	x
Mean	x.x	x.x	x.x
Median	x.x	x.x	x.x
SD	x.x	x.x	x.x
Minimum	x	x	x
Maximum	x	x	x

SD: Standard Deviation

*Duration of Exposure = Date of first treatment to date of End of Treatment

Table 14.3-3 Medications and significant non-drug therapies taken prior to the start of study drug by ATC class, preferred term and treatment

Safety Set

Anatomic Therapeutic Classification (ATC) Preferred Term (PT)	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Any ATC Class with medication/surgery	x (xx.x)	x (xx.x)	x (xx.x)
Nr of concomitant medications reported	x	x	x
ATC1	x (xx.x)	x (xx.x)	x (xx.x)
PT1	x (xx.x)	x (xx.x)	x (xx.x)
PT2	x (xx.x)	x (xx.x)	x (xx.x)
….	….	….	….
PTx	x (xx.x)	x (xx.x)	x (xx.x)
ATC1	x (xx.x)	x (xx.x)	x (xx.x)
PT1	x (xx.x)	x (xx.x)	x (xx.x)
PT2	x (xx.x)	x (xx.x)	x (xx.x)
….	….	….	….
PTx	x (xx.x)	x (xx.x)	x (xx.x)
…….			

Note: Patients who take the same medication (in terms of the preferred term) more than once will be counted only once for that medication.

Table 14.3-4 Forbidden concomitant medications and significant non-drug therapies after start of study drug by ATC class, preferred term and treatment

Safety Set

Anatomic Therapeutic Classification (ATC) Preferred Term (PT)	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Any ATC Class with medication/surgery	x (xx.x)	x (xx.x)	x (xx.x)
Nr of concomitant medications reported	x	x	x
ATC1	x (xx.x)	x (xx.x)	x (xx.x)
PT1	x (xx.x)	x (xx.x)	x (xx.x)
PT2	x (xx.x)	x (xx.x)	x (xx.x)
….	….	….	….
PTx	x (xx.x)	x (xx.x)	x (xx.x)
ATC1	x (xx.x)	x (xx.x)	x (xx.x)
PT1	x (xx.x)	x (xx.x)	x (xx.x)
PT2	x (xx.x)	x (xx.x)	x (xx.x)
….	….	….	….
PTx	x (xx.x)	x (xx.x)	x (xx.x)
…….			

Note: Patients who take the same medication (in terms of the preferred term) more than once will be counted only once for that medication.

Table 14.3-5 Vital signs by visit and treatment

Safety Set

Visit	Statistic	Intensive (N=X)	Relaxed (N=X)	Total (N=X)
Systolic Blood Pressure (SBP) (mmHg)				
Screening	n	x	x	x
	Mean	x.x	x.x	x.x
	Median	x.x	x.x	x.x
	SD	x.x	x.x	x.x
	Minimum	x	x	x
	Maximum	x	x	x
Baseline	n	x	x	x
	Mean	x.x	x.x	x.x
	Median	x.x	x.x	x.x
	SD	x.x	x.x	x.x
	Minimum	x	x	x
	Maximum	x	x	x
Diastolic Blood Pressure (DBP) (mmHg)				
……				

*Baseline: The last available non-missing value collected just prior to the start of treatment in the study eye
SD: Standard Deviation

Table 14.3-6 Ophthalmic Examination – Intraocular Pressure (IOP) by treatment

Safety Set

Visit	Statistic	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
		Actual Value	Absolute Change from Baseline*	Actual Value	Absolute Change from Baseline	Actual Value	Absolute Change from Baseline
Screening	n	x	-	x	-	x	-
	Mean	x.x	-	x.x	-	x.x	-
	Median	x.x	-	x.x	-	x.x	-
	SD	x.x	-	x.x	-	x.x	-
	Minimum	x	-	x	-	x	-
	Maximum	x	-	x	-	x	-
Baseline	n	x	-	x	-	x	-
	Mean	x.x	-	x.x	-	x.x	-
	Median	x.x	-	x.x	-	x.x	-
	SD	x.x	-	x.x	-	x.x	-
	Minimum	x	-	x	-	x	-
	Maximum	x	-	x	-	x	-
Week *n*	…….						

Continued through to Month 24

*Baseline: The last available non-missing value collected just prior to the start of treatment in the study eye
SD: Standard Deviation

Listings (Section 14.3)

Listing 14.3-1 Patients with notably abnormal vital signs

Safety Set

Subject Number	Visit	Were Vital Signs Performed?	Date of Vital Signs Assessment (YYYY-MM-DD)	Systolic Blood Pressure (mmHg)*	Diastolic Blood Pressure (mmHg)*
XXX-XX	ABCD	Yes/No	YYYY-MM-DD	XXXH	XXXH
	ABCD	Yes/No	YYYY-MM-DD	XXXH	XXXH
	ABCD	Yes/No	YYYY-MM-DD	XXXL	XXXL
	ABCD	Yes/No	YYYY-MM-DD	XXXL	XXXL
……..					
XXX-XX	ABCD	Yes/No	YYYY-MM-DD	XXXH	XXXH
	ABCD	Yes/No	YYYY-MM-DD	XXXH	XXXH
	ABCD	Yes/No	YYYY-MM-DD	XXXL	XXXL
	ABCD	Yes/No	YYYY-MM-DD	XXXL	XXXL
……..					

*Flags: H=High (Systolic - >180 and increase from baseline of >20, Diastolic - >105 and increase from baseline of >15)
L=Low (Systolic - <90 and decrease from baseline of >20, Diastolic - <50 and decrease from baseline of >15)

Section 14.3.1 – Displays of adverse events

Figures (Section 14.3.1)

No Output

Tables (Section 14.3.1)

Table 14.3.1-1 Incidence of adverse events, regardless of study drug relationship, by primary system organ class, preferred term and treatment

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-2 Incidence of ocular adverse events, regardless of study drug relationship, by primary system organ class, preferred term and treatment

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Ocular	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-3 Incidence of adverse events, regardless of study drug relationship by primary system organ class, preferred term, maximum severity and treatment

Safety Set

	Intensive (N=X)			Relaxed (N=X)			Total (N=X)		
System Organ Class (SOC) Preferred Term (PT)	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)
All Body Systems	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
SOC1	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PT1	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PT2	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
….	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PTx	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
SOC2	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PT1	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PT2	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
….	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PTx	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

Note: Subjects are counted once at maximum severity within each sub grouping.

Table 14.3.1-4 Incidence of ocular adverse events, regardless of study drug relationship by primary system organ class, preferred term, maximum severity and treatment

Safety Set

	Intensive (N=X)			Relaxed (N=X)			Total (N=X)		
System Organ Class (SOC) Preferred Term (PT)	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)
All Body Systems	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
SOC1	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PT1	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PT2	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
….	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PTx	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
SOC2	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PT1	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PT2	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
….	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PTx	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

Note: Subjects are counted once at maximum severity within each sub grouping.

Table 14.3.1-5 Incidence of adverse events, by primary system organ class, preferred term, maximum relationship to study drug and treatment

Safety Set

System Organ Class (SOC) Preferred Term (PT)	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
	Not Suspected	Suspected	Not Suspected	Suspected	Not Related	Related*
All Body Systems	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
SOC1	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PT1	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PT2	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
….	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PTx	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
SOC2	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PT1	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PT2	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
….	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)
PTx	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)	x (xx.x%)

*Related: includes possibly, probably and definitely related
Note: Percentages are based on the number of subjects in each group.

Table 14.3.1-6 Incidence of adverse events suspected to be related to study drug, by primary system organ class, preferred term and treatment

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-7 Incidence of ocular adverse events suspected to be related to study drug, by primary system organ class, preferred term and treatment

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-8 Incidence of serious adverse events, regardless of study drug relationship, by primary system organ class, preferred term and treatment

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-9 Incidence of ocular serious adverse events, regardless of study drug relationship, by primary system organ class, preferred term and treatment

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-10 Incidence of adverse events leading to treatment withdrawal, regardless of study drug relationship, by primary system organ class, preferred term and treatment

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-11 Incidence of ocular adverse events leading to treatment withdrawal, regardless of study drug relationship, by primary system organ class, preferred term and treatment

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-12 Incidence of adverse events leading to study drug interruption, regardless of study drug relationship, by primary system organ class, preferred term and treatment

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-13 Incidence of ocular adverse events leading to study drug interruption, regardless of study drug relationship, by primary system organ class, preferred term and treatment

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-14 Incidence of adverse events requiring significant additional therapy, regardless of study drug relationship, by primary system organ class, preferred term and treatment

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-15 Incidence of ocular adverse events requiring significant additional therapy, regardless of study drug relationship, by primary system organ class, preferred term and treatment

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-16 Deaths, by primary system organ class, preferred term and treatment

Safety Set

Principal Cause of Death	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
System Organ Class (SOC) Preferred Term (PT)	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
All Body Systems	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
SOC2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT1	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
PT2	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
….	….	….	….	….	….	….
PTx	x (xx.x%)	x	x (xx.x%)	x	x (xx.x%)	x
……..						

AE: Adverse Event
Note: Multiple records from the same subject are only counted once within the same category

Table 14.3.1-17 Arterial Thomboembolic Events

Safety Set

	Intensive (N=X)		Relaxed (N=X)		Total (N=X)	
	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs	Nr (%) of Subjects	Nr of AEs
Arterial Thomboembolic Events (ATEs)*	xx.x	x	xx.x	x	xx.x	x
Nonfatal myocardial infarction	xx.x	x	xx.x	x	xx.x	x
Nonfatal stroke	xx.x	x	xx.x	x	xx.x	x
Vascular death and death of unknown cause	xx.x	x	xx.x	x	xx.x	x

* ATEs defined as nonfatal myocardial infarction, nonfatal stroke, vascular death and death of unknown cause
AE: Adverse Event
Note: Some patients may have experienced multiple events

Section 14.3.2 – Listings of deaths, other serious and significant adverse events

Listings (Section 14.3.2)

Listing 14.3.2-1 Deaths, by treatment

Safety Set

Site / Subject Number	Age	Sex	Race	Date of Last Dose (YYYY-MM-DD)	Date of Death (YYYY-MM-DD)	Study Day*	Principal cause reported
XXX / XXX-XX	XX	Male	Caucasian	YYYY-MM-DD	YYYY-MM-DD	XX	ABCD
XXX / XXX-XX	XX	Female	Asian	YYYY-MM-DD	YYYY-MM-DD	XX	ABCD
XXX / XXX-XX	XX	XX	XX	YYYY-MM-DD	YYYY-MM-DD	XX	ABCD
XXX / XXX-XX	XX	XX	XX	YYYY-MM-DD	YYYY-MM-DD	XX	ABCD
XXX / XXX-XX	XX	XX	XX	YYYY-MM-DD	YYYY-MM-DD	XX	ABCD
XXX / XXX-XX	XX	XX	XX	YYYY-MM-DD	YYYY-MM-DD	XX	ABCD
XXX / XXX-XX	XX	XX	XX	YYYY-MM-DD	YYYY-MM-DD	XX	ABCD
XXX / XXX-XX	XX	XX	XX	YYYY-MM-DD	YYYY-MM-DD	XX	ABCD
…….							

*Relative to the first day of treatment (Baseline)

Listing 14.3.2-2 Serious adverse events, by treatment

Safety Set

Site / Subject Number	Age / Sex / Race	Adverse Event (REPORTED/ Preferred / System Organ Class)	Start Date (YYYY-MM-DD) / Study day	End Date (YYYY-MM-DD) / Study day	Duration (Days)	Severity	Relationship to Study Medication	Action Taken
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mild	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mod	susp	X
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Sev	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mild	susp	X
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mod	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Sev	susp	X
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mild	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mod	susp	X
…….								

Severity: Mild=Mild, Mod=Moderate, Sev=Severe

Relationship to study drug: Not susp=Not suspected, Susp=Suspected

Action taken: 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this AE
3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/Prolonged hospitalization

Note: Study day is relative to the first day of treatment (Baseline)

Listing 14.3.2-3 Adverse events causing study drug discontinuation by treatment

Safety Set

Site / Subject Number	Age / Sex / Race	Adverse Event (REPORTED/ Preferred / System Organ Class)	Start Date (YYYY-MM-DD) / Study day	End Date (YYYY-MM-DD) / Study day	Duration (Days)	Severity	Relationship to Study Medication	Action Taken
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mild	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mod	susp	X
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Sev	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mild	susp	X
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mod	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Sev	susp	X
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mild	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mod	susp	X
…….								

Severity: Mild=Mild, Mod=Moderate, Sev=Severe

Relationship to study drug: Not susp=Not suspected, Susp=Suspected

Action taken: 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this AE
3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/Prolonged hospitalization

Note: Study day is relative to the first day of treatment (Baseline)

Listing 14.3.2-4 Adverse events requiring interruption by treatment

Safety Set

Site / Subject Number	Age / Sex / Race	Adverse Event (REPORTED/ Preferred / System Organ Class)	Start Date (YYYY-MM-DD) / Study day	End Date (YYYY-MM-DD) / Study day	Duration (Days)	Severity	Relationship to Study Medication	Action Taken
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mild	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mod	susp	X
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Sev	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mild	susp	X
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mod	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Sev	susp	X
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mild	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD	YYYY-MM-DD	XX	Mod	susp	X
…….								

Severity: Mild=Mild, Mod=Moderate, Sev=Severe

Relationship to study drug: Not susp=Not suspected, Susp=Suspected

Action taken: 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this AE
3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/Prolonged hospitalization

Note: Study day is relative to the first day of treatment (Baseline)

Listing 14.3.2-5 Adverse events requiring significant additional therapy

Safety Set

Site / Subject Number	Age / Sex / Race	Adverse Event (REPORTED/ Preferred / System Organ Class)	Start Date (YYYY-MM-DD) / Study day	End Date (YYYY-MM-DD) / Study day	Duration (Days)	Severity	Relationship to Study Medication	Action Taken
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD / X	YYYY-MM-DD / X	XX	Mild	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD / X	YYYY-MM-DD / X	XX	Mod	susp	X
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD / X	YYYY-MM-DD / X	XX	Sev	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD / X	YYYY-MM-DD / X	XX	Mild	susp	X
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD / X	YYYY-MM-DD / X	XX	Mod	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD / X	YYYY-MM-DD / X	XX	Sev	susp	X
XXX / XXX-XX	55/M/Ca	ABCD / abcd / abcd	YYYY-MM-DD / X	YYYY-MM-DD / X	XX	Mild	Not susp	X
XXX / XXX-XX	76/F/As	ABCD / abcd / abcd	YYYY-MM-DD / X	YYYY-MM-DD / X	XX	Mod	susp	X
…….								

Severity: Mild=Mild, Mod=Moderate, Sev=Severe

Relationship to study drug: Not susp=Not suspected, Susp=Suspected

Action taken: 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this AE
3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/Prolonged hospitalization

Note: Study day is relative to the first day of treatment (Baseline)

Section 14.3.3 – Narratives of deaths, other serious and significant adverse events (non Biometric deliverables)

No output

Section 14.3.4 – Abnormal laboratory value listings

Listings (Section 14.3.4)

No output

Listings (Section 16.1.7)

Listing 16.1.7-1 Randomized allocation to treatment

All Enrolled

Site	Subject Number	Age / Sex / Race	Randomisation Number	Treatment	Randomisation Date (YYYY-MM-DD) / Study Day
XXX	XXX-XX	55/M/Ca	XXXX	Intensive	YYYY-MM-DD / X
XXX	XXX-XX	76/F/As	XXXX	Relaxed	YYYY-MM-DD / X
XXX	XXX-XX	55/M/Ca	XXXX	Relaxed	YYYY-MM-DD / X
XXX	XXX-XX	76/F/As	XXXX	Intensive	YYYY-MM-DD / X
XXX	XXX-XX	55/M/Ca	XXXX	Intensive	YYYY-MM-DD / X
XXX	XXX-XX	76/F/As	XXXX	Intensive	YYYY-MM-DD / X
XXX	XXX-XX	55/M/Ca	XXXX	Relaxed	YYYY-MM-DD / X
XXX	XXX-XX	76/F/As	XXXX	Relaxed	YYYY-MM-DD / X
…….					

Note: Study day is relative to the first day of treatment (Baseline)

Section 16.1.9 – Documentation of statistical methods

Tables (Section 16.1.9)

No output

Section 16.2 – Patient data listings

Section 16.2.1 – Discontinued patients

Listing 16.2.1-1 Study phase completion by treatment

Full Analysis Set

Site / Subject Number	Age / Sex / Race	Study phase	Last known date on study drug (YYYY-MM-DD) / Study Day	Completed	Primary reason	Was treatment code revealed	Date Revealed
XXX / XXX-XX	55/M/Ca	Comparative	YYYY-MM-DD / X	Yes	-	No	-
XXX / XXX-XX	76/F/As	Comparative	YYYY-MM-DD / X	Yes	-	No	-
XXX / XXX-XX	55/M/Ca	Comparative	YYYY-MM-DD / X	No	Abcd	No	-
XXX / XXX-XX	76/F/As	Comparative	YYYY-MM-DD / X	Yes	-	No	-
XXX / XXX-XX	55/M/Ca	Comparative	YYYY-MM-DD / X	Yes	-	No	-
XXX / XXX-XX	76/F/As	Comparative	YYYY-MM-DD / X	Yes	-	No	-
XXX / XXX-XX	55/M/Ca	Comparative	YYYY-MM-DD / X	Yes	-	No	-
XXX / XXX-XX	76/F/As	Comparative	YYYY-MM-DD / X	Yes	-	No	-
…….							

Note: Study day is relative to the first day of treatment (Baseline)

Listing 16.2.1-2 Screened subjects discontinued from study prior to randomization

All subjects

Site / Subject Number	Age / Sex / Race	Date of Discontinuation (YYYY-MM-DD)	Primary reason for discontinuation
XXX / XXX-XX	55/M/Ca	YYYY-MM-DD	Adverse Event
XXX / XXX-XX	76/F/As	YYYY-MM-DD	Lost to follow-up
XXX / XXX-XX	55/M/Ca	YYYY-MM-DD	Physician decision
XXX / XXX-XX	76/F/As	YYYY-MM-DD	Pregnancy
XXX / XXX-XX	55/M/Ca	YYYY-MM-DD	Screen failure
XXX / XXX-XX	76/F/As	YYYY-MM-DD	Study terminated by sponsor
XXX / XXX-XX	55/M/Ca	YYYY-MM-DD	Technical problems
XXX / XXX-XX	76/F/As	YYYY-MM-DD	Subject/guardian decision
XXX / XXX-XX	55/M/Ca	YYYY-MM-DD	Death
…….			

Section 16.2.2 – Protocol deviations

Listing 16.2.2-1.1 Protocol deviations by treatment

Full Analysis Set

Subject Number	Any Protocol Deviation?	Type of Deviation	Date of Deviation (YYYY-MM-DD)	Visit	Specify Deviation Details
Intensive					
XXX-XX	Yes	Inclusion criteria	YYYY-MM-DD	-	ABCD
XXX-XX	Yes	Exclusion criteria	YYYY-MM-DD	ABCD	ABCD
XXX-XX	Yes	Discontinuation of Treatment	YYYY-MM-DD	ABCD	ABCD
XXX-XX	Yes	Medication (includes excluded meds)	YYYY-MM-DD	ABCD	ABCD
XXX-XX	Yes	Others	YYYY-MM-DD	ABCD	ABCD
XXX-XX	No	-	-	-	-
Relaxed					
XXX-XX	Yes	Exclusion criteria	YYYY-MM-DD	-	ABCD
XXX-XX	Yes	Discontinuation of Treatment	YYYY-MM-DD	ABCD	ABCD
XXX-XX	Yes	Medication (includes excluded meds)	YYYY-MM-DD	ABCD	ABCD

Section 16.2.3 – Patients excluded from the efficacy analysis

Listing 16.2.3-1 Patients excluded from Per-Protocol efficacy analysis by treatment

Full Analysis Set

Subject Number	Reason for Exclusion from Per-Protocol Efficacy Analysis
Intensive	
XXX-XX	xxxxxxxxxxxxxxxx
XXX-XX	xxxxxxxxxxxxxxxx
XXX-XX	xxxxxxxxxxxxxxxx
XXX-XX	xxxxxxxxxxxxxxxx
XXX-XX	xxxxxxxxxxxxxxxx
XXX-XX	xxxxxxxxxxxxxxxx
Relaxed	
XXX-XX	xxxxxxxxxxxxxxxx
XXX-XX	xxxxxxxxxxxxxxxx
XXX-XX	xxxxxxxxxxxxxxxx

Section 16.2.4 – Demographic data

Listing 16.2.4-1 Patient Disposition

Randomised Set

Subject Number	Informed Consent Date (YYYY-MM-DD)	Did the patient complete the study?	Date of Withdrawal (YYYY-MM-DD)	Date of Completion (YYYY-MM-DD)	Reason for Treatment Termination
Intensive					
XXX-XX	YYYY-MM-DD	Yes	YYYY-MM-DD	YYYY-MM-DD	ABCD
XXX-XX	YYYY-MM-DD	No	YYYY-MM-DD	-	ABCD
XXX-XX	YYYY-MM-DD	Yes	YYYY-MM-DD	YYYY-MM-DD	ABCD
XXX-XX	YYYY-MM-DD	Yes	YYYY-MM-DD	YYYY-MM-DD	ABCD
Relaxed					
XXX-XX	YYYY-MM-DD	Yes	YYYY-MM-DD	YYYY-MM-DD	ABCD
XXX-XX	YYYY-MM-DD	No	YYYY-MM-DD	YYYY-MM-DD	ABCD
XXX-XX	YYYY-MM-DD	Yes	YYYY-MM-DD	YYYY-MM-DD	ABCD
XXX-XX	YYYY-MM-DD	Yes	YYYY-MM-DD	YYYY-MM-DD	ABCD

Listing 16.2.4-2 Eligibility Criteria

Randomised Set

Subject Number	Has the patient met all Inclusion Criteria?	Has the patient met all Exclusion Criteria?
Intensive		
XXX-XX	Yes	Yes
XXX-XX	No: Inc 1	No: Exc 1
XXX-XX	Yes	Yes
XXX-XX	No: Inc 2	No: Exc 2
Relaxed		
XXX-XX	Yes	Yes
XXX-XX	No: Inc 3	No: Exc 3
XXX-XX	Yes	Yes
XXX-XX	No: Inc 4	No: Exc 4

Listing 16.2.4-3 Patient demographics by treatment

Randomised Set

Subject Number	Gender	Child-bearing Potential	Date of Birth	Age*	Predominant Race	Ethnicity
Intensive						
XXX-XX	Female	Able to bear children	YYYY-MM-DD	XX	Caucasian	Anglo Saxon
XXX-XX	Male	-	YYYY-MM-DD	XX	Black African	Northern European
XXX-XX	Female	Post Menopausal	YYYY-MM-DD	XX	Asian	Southern European
XXX-XX	Female	Sterile - of child bearing age	YYYY-MM-DD	XX	Caucasian	Asian Indian
XXX-XX	Male	-	YYYY-MM-DD	XX	Other: xxxxxx	Other: xxxxxx
…….						
Relaxed						
XXX-XX	Female		YYYY-MM-DD	XX	Caucasian	Anglo Saxon
XXX-XX	Male		YYYY-MM-DD	XX	Black African	Northern European
XXX-XX	Female		YYYY-MM-DD	XX	Asian	Southern European
XXX-XX	Female		YYYY-MM-DD	XX	Caucasian	Asian Indian
XXX-XX	Male		YYYY-MM-DD	XX	Black African	Other: xxxxxx
…….						

Listing 16.2.4-4 Patient demographic questions by treatment

Randomised Set

Subject Number	Family History of AMD	Is yes, was it a first degree relative?	Ever smoked cigarettes, pipes or cigars	If the participant smoked in the past, when did the participant stop smoking?
Intensive				
XXX-XX	Yes	Yes	Never smoked	-
XXX-XX	Yes	No	Smoked in the past	One year ago or less
XXX-XX	Yes	Yes	Current smoker	-
XXX-XX	Yes	No	Never smoked	-
XXX-XX	Yes	Yes	Smoked in the past	More than one year ago
…….				
Relaxed				
XXX-XX	No	-	Never smoked	-
XXX-XX	No	-	Smoked in the past	One year ago or less
XXX-XX	No	-	Current smoker	-
XXX-XX	No	-	Never smoked	-
XXX-XX	No	-	Smoked in the past	More than one year ago
…….				

Listing 16.2.4-5 Relevant medical history and current medical conditions by treatment

Randomised Set

Subject Number	MH No	History Condition (REPORTED / Preferred / System Organ Class)	Site	Date of Diagnosis (YYYY-MM-DD)	Ongoing?
Intensive					
XXX-XX	1	ABCD / Acbd / Acbd	Left eye	YYYY-MM-DD	Yes/No
	2	ABCD / Acbd / Acbd	Non-ocular	YYYY-MM-DD	Yes/No
	3	ABCD / Acbd / Acbd	Right eye	YYYY-MM-DD	Yes/No
	4	ABCD / Acbd / Acbd	Non-ocular	YYYY-MM-DD	Yes/No
XXX-XX	1	ABCD / Acbd / Acbd	Both eyes	YYYY-MM-DD	Yes/No
……					
Relaxed					
XXX-XX	1	ABCD / Acbd / Acbd	Left eye	YYYY-MM-DD	Yes/No
	2	ABCD / Acbd / Acbd	Non-ocular	YYYY-MM-DD	Yes/No
	3	ABCD / Acbd / Acbd	Right eye	YYYY-MM-DD	Yes/No
	4	ABCD / Acbd / Acbd	Non-ocular	YYYY-MM-DD	Yes/No
XXX-XX	1	ABCD / Acbd / Acbd	Both eyes	YYYY-MM-DD	Yes/No
……					

NK: Not Known; MH No: Medical History Number

Listing 16.2.4-6 AMD Treatment History (STUDY eye)

Randomised Set

Subject Number	FELLOW Eye	Was any treatment ever given to the fellow eye prior to Screening?	Treatment	Dose	Start date of treatment (YYYY-MM-DD)	Stop date of treatment (YYYY-MM-DD)	Ongoing
Intensive							
XXX-XX	Left	Yes	Lucentis	XX unit	YYYY-MM-DD	YYYY-MM-DD	-
XXX-XX	Right	Yes	Eylea	XX unit	YYYY-MM-DD	-	Yes
XXX-XX	Left	Yes	Visudyne	XX unit	YYYY-MM-DD	YYYY-MM-DD	-
			Avastin	XX unit	YYYY-MM-DD	YYYY-MM-DD	-
XXX-XX	Left	No	-	-	-	-	-
……							
Relaxed							
XXX-XX	Left	Yes	Lucentis	XX unit	YYYY-MM-DD	YYYY-MM-DD	-
XXX-XX	Right	Yes	Eylea	XX unit	YYYY-MM-DD	-	Yes
XXX-XX	Left	Yes	Steroids	XX unit	YYYY-MM-DD	YYYY-MM-DD	-
			Other	XX unit	YYYY-MM-DD	YYYY-MM-DD	-
XXX-XX	Left	No	-	-	-	-	-
……							

NK: Not Known; MH No: Medical History Number

Listing 16.2.4-7 AMD Treatment History (FELLOW eye)

Randomised Set

Subject Number	FELLOW Eye	Was any treatment ever given to the fellow eye prior to Screening?	Treatment	Dose	Start date of treatment (YYYY-MM-DD)	Stop date of treatment (YYYY-MM-DD)	Ongoing
Intensive							
XXX-XX	Left	Yes	Lucentis	XX unit	YYYY-MM-DD	YYYY-MM-DD	-
XXX-XX	Right	Yes	Eylea	XX unit	YYYY-MM-DD	-	Yes
XXX-XX	Left	Yes	Visudyne	XX unit	YYYY-MM-DD	YYYY-MM-DD	-
			Avastin	XX unit	YYYY-MM-DD	YYYY-MM-DD	-
XXX-XX	Left	No	-	-	-	-	-
……							
Relaxed							
XXX-XX	Left	Yes	Lucentis	XX unit	YYYY-MM-DD	YYYY-MM-DD	-
XXX-XX	Right	Yes	Eylea	XX unit	YYYY-MM-DD	-	Yes
XXX-XX	Left	Yes	Steroids	XX unit	YYYY-MM-DD	YYYY-MM-DD	-
			Other	XX unit	YYYY-MM-DD	YYYY-MM-DD	-
XXX-XX	Left	No	-	-	-	-	-
……							

NK: Not Known; MH No: Medical History Number

Listing 16.2.4-8 AMD Treatment at Baseline

Randomised Set

Subject Number	Treatment at Baseline	EYE	Date of diagnosis of active CNV due to wet AMD (YYYY-MM-DD)	Type of CNV Location	CNV classification
Intensive					
XXX-XX	Two treatment naïve eyes	STUDY – Right	YYYY-MM-DD	Subfoveal	Occult
		FELLOW - Left	YYYY-MM-DD	Juxtafoveal	Predominantly classic
XXX-XX	One eye (fellow eye) being treated with ranibizumab	STUDY – Right	YYYY-MM-DD	Extrafoveal	Minimally classic
		FELLOW - Left	YYYY-MM-DD	Note evaluable	PCV
XXX-XX	One eye (fellow eye) being treated with anti-VEGF other than ranibizumab	STUDY – Right	YYYY-MM-DD	Subfoveal	RAP
		FELLOW - Left	YYYY-MM-DD	Juxtafoveal	Note evaluable
XXX-XX	Two treatment naïve eyes	STUDY – Right	YYYY-MM-DD	Extrafoveal	Occult
		FELLOW - Left	YYYY-MM-DD	Note evaluable	Predominantly classic
……					
Relaxed					
XXX-XX	Two treatment naïve eyes	STUDY – Right	YYYY-MM-DD	Subfoveal	Occult
		FELLOW - Left	YYYY-MM-DD	Juxtafoveal	Predominantly classic
XXX-XX	One eye (fellow eye) being treated with ranibizumab	STUDY – Right	YYYY-MM-DD	Extrafoveal	Minimally classic
		FELLOW - Left	YYYY-MM-DD	Note evaluable	PCV
……					

NK: Not Known; MH No: Medical History Number

Section 16.2.5 Compliance and/or drug concentration data

Listing 16.2.5-1 Dose administration record by treatment (STUDY eye)

Safety Set

Subject Number	Visit	Was Study Drug Administered?	Date of dosing (YYYY-MM-DD)	Total dose administered (mg)	STUDY eye treated	Batch number
XXX-XX	Baseline	Yes	YYYY-MM-DD	XX	Left eye	XXXXXXX
	Week *n*	Yes	YYYY-MM-DD	XX	Left eye	Not available
	……					
XXX-XX	Baseline	Yes	YYYY-MM-DD	XX	Right eye	XXXXXXX
	Week *n*	No: xxxxxxx	-	-	-	
	……					

Listing 16.2.5-2 Dose administration record by treatment (FELLOW eye)

Safety Set

Subject Number	Visit	Was treatment for FELLOW eye given?	FELLOW eye treated	Date of dosing (YYYY-MM-DD)	Treatment for wet AMD to fellow eye	Total dose administered
XXX-XX	Baseline	Yes	Left eye	YYYY-MM-DD	xxxxxxxxxxxx	XX units
	Week *n*	Yes	Left eye	YYYY-MM-DD	Not xxxxxxxxxxxx	XX units
	……					
XXX-XX	Baseline	Yes	Right eye	YYYY-MM-DD	xxxxxxxxxxxx	XX units
	Week *n*	No	-	-		-
	……					

Listing 16.2.5-3 Medications and significant non-drug therapies prior to start of study drug by treatment

Randomised Set

Subject Number	CM No	Concomitant Medication (REPORTED / Preferred)	Reason
Intensive			
XXX-XX	1	ABCD / Acbd	xxxxxxxxxxxxxxx
	2	ABCD / Acbd	xxxxxxxxxxxxxxx
	3	ABCD / Acbd	xxxxxxxxxxxxxxx
	4	ABCD / Acbd	xxxxxxxxxxxxxxx
XXX-XX	1	ABCD / Acbd	xxxxxxxxxxxxxxx
……			
Relaxed			
XXX-XX	1	ABCD / Acbd	xxxxxxxxxxxxxxx
	2	ABCD / Acbd	xxxxxxxxxxxxxxx
	3	ABCD / Acbd	xxxxxxxxxxxxxxx
	4	ABCD / Acbd	xxxxxxxxxxxxxxx
XXX-XX	1	ABCD / Acbd	xxxxxxxxxxxxxxx
……			

Listing 16.2.5-4 Medications and significant non-drug therapies after start of study drug by treatment

Full Analysis Set

Subject Number	CM No	Concomitant Medication (REPORTED / Preferred)	Start Date (YYYY-MM-DD)	Stop Date (YYYY-MM-DD)	Reason
Intensive					
XXX-XX	1	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	2	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	3	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	4	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
XXX-XX	1	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
.....					
Relaxed					
XXX-XX	1	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	2	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	3	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	4	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
XXX-XX	1	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
.....					

Listing 16.2.5-5 Medications and significant non-drug therapies after start of study drug by treatment (STUDY EYE)

Full Analysis Set

Subject Number	CM No	Concomitant Medication (REPORTED / Preferred)	Start Date (YYYY-MM-DD)	Stop Date (YYYY-MM-DD)	Reason
Intensive					
XXX-XX	1	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	2	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	3	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	4	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
XXX-XX	1	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
.....					
Relaxed					
XXX-XX	1	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	2	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	3	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	4	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
XXX-XX	1	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
.....					

NOTE: Includes all ocular medications administered to the STUDY eye only.

Listing 16.2.5-6 Medications and significant non-drug therapies after start of study drug by treatment (FELLOW EYE)

Full Analysis Set

Subject Number	CM No	Concomitant Medication (REPORTED / Preferred)	Start Date (YYYY-MM-DD)	Stop Date (YYYY-MM-DD)	Reason
Intensive					
XXX-XX	1	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	2	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	3	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	4	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
XXX-XX	1	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
.....					
Relaxed					
XXX-XX	1	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	2	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	3	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
	4	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
XXX-XX	1	ABCD / Acbd	YYYY-MM-DD	YYYY-MM-DD	xxxxxxxxxxxxxxx
.....					

NOTE: Includes all ocular medications administered to the FELLOW eye only.

Section 16.2.6 – Individual efficacy response data and other non-safety data

Listing 16.2.6-1 CF/FA/AF by treatment (STUDY EYE) (CRF Data)

Full Analysis Set

Subject Number	Visit	STUDY eye assessed	Was CF Performed?	Date CF performed (YYYY-MM-DD)	Was FA Performed?	Date FA performed (YYYY-MM-DD)	Presence of Retinal Haemorrhage	Was AF Performed?	Date AF performed (YYYY-MM-DD)
Intensive									
XXX-XX	ABCD	Left	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	Yes	Yes	YYYY-MM-DD
	ABCD	Left	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	No	Yes	YYYY-MM-DD
	ABCD	Left	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	Evaluable	Yes	YYYY-MM-DD
	ABCD	Left	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	Yes	Yes	YYYY-MM-DD
……..									
XXX-XX	ABCD	Right	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	Yes	Yes	YYYY-MM-DD
	ABCD	Right	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	No	Yes	YYYY-MM-DD
	ABCD	Right	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	Evaluable	Yes	YYYY-MM-DD
	ABCD	Right	No	YYYY-MM-DD	No	YYYY-MM-DD	Yes	No	YYYY-MM-DD
……..									
Relaxed									
……..									

AF: Autofluorescence, CF: Colour Fundus Photography, FA: Fluorescein Angiography

Listing 16.2.6-2 CF/FA/AF by treatment (FELLOW EYE)

Full Analysis Set

Subject Number	Visit	FELLOW eye assessed	Was CF Performed?	Date CF performed (YYYY-MM-DD)	Was FA Performed?	Date FA performed (YYYY-MM-DD)	Presence of Retinal Haemorrhage	Was AF Performed?	Date AF performed (YYYY-MM-DD)
Intensive									
XXX-XX	ABCD	Left	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	Yes	Yes	YYYY-MM-DD
	ABCD	Left	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	No	Yes	YYYY-MM-DD
	ABCD	Left	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	Evaluable	Yes	YYYY-MM-DD
	ABCD	Left	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	Yes	Yes	YYYY-MM-DD
……..									
XXX-XX	ABCD	Right	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	Yes	Yes	YYYY-MM-DD
	ABCD	Right	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	No	Yes	YYYY-MM-DD
	ABCD	Right	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	Evaluable	Yes	YYYY-MM-DD
	ABCD	Right	No	YYYY-MM-DD	No	YYYY-MM-DD	Yes	No	YYYY-MM-DD
……..									
Relaxed									
……..									

AF: Autofluorescence, CF: Colour Fundus Photography, FA: Fluorescein Angiography

Listing 16.2.6-3 Fluorescein Angiography Assessments by treatment (STUDY EYE) (Central Reading Center Data)

Full Analysis Set

Subject Number	Visit	STUDY eye assessed	Parameter	Result
Intensive				
XXX-XX	ABCD	Left	Lesion leakage present	Yes
			Lesions components*	CNV, blood
			Type of lesion	Occult
			Location of lesion	Subfoveal
			CNV present	Yes
			CNV Location	Subfoveal
			CNV leakage present	Yes
			Area of lesion (mm2)	xx
			Area of CNV (mm2)	xx
			Geographic Atrophy present	Yes
……..			Location of Geographic Atrophy	Outer Subfield
			Total area of Geographic Atrophy within ETDRS grid	xx
Relaxed				
……..				

Listing 16.2.6-4 Colour Fundus Assessments by treatment (STUDY EYE) (Central Reading Center Data)

Full Analysis Set

Subject Number	Visit	STUDY eye assessed	Parameter	Result
Intensive				
XXX-XX	ABCD	Left	Haemorrhage present	Yes
			Haemorrhage location	Central subfield
			Retinal Abnormalities present	Yes: Drusen
			Retinal Abnormalities Location	Central
			Retinal Abnormalities Type	Inflammation
	……..			
……..				
Relaxed				
……..				

Listing 16.2.6-5 Visual Acuity by Treatment (STUDY EYE)

Full Analysis Set and Per-Protocol

Subject Number	Visit	Was VA Performed?	Date VA performed (YYYY-MM-DD)	Was Refraction Performed?	STUDY Eye Assessed	EDTRS chart used for 3 metres lane?	Total BCVA score
Intensive							
XXX-XX	ABCD	Yes	YYYY-MM-DD	Yes/No	Left eye	Yes/No	XX
	ABCD	Yes	YYYY-MM-DD	Yes/No	Left eye	Yes/No	XX
	ABCD	Yes	YYYY-MM-DD	Yes/No	Left eye	Yes/No	XX
	ABCD	Yes	YYYY-MM-DD	Yes/No	Left eye	Yes/No	XX
……..							
XXX-XX	ABCD	Yes	YYYY-MM-DD	Yes/No	Right eye	Yes/No	XX
	ABCD	Yes	YYYY-MM-DD	Yes/No	Right eye	Yes/No	XX
	ABCD	Yes	YYYY-MM-DD	Yes/No	Right eye	Yes/No	XX
	ABCD	Not Done: specify	-	-	-	-	-
……..							
Relaxed							
……..							

VA: Visual Acuity, BCVA: Best Corrective Visual Acuity

Listing 16.2.6-6 Visual Acuity by Treatment (FELLOW EYE)

Full Analysis Set

Subject Number	Visit	Was VA Performed?	Date VA performed (YYYY-MM-DD)	Was Refraction Performed?	FELLOW Eye Assessed	EDTRS chart used for 3 metres lane?	Total BCVA score
Intensive							
XXX-XX	ABCD	Yes	YYYY-MM-DD	Yes/No	Left eye	Yes/No	XX
	ABCD	Yes	YYYY-MM-DD	Yes/No	Left eye	Yes/No	XX
	ABCD	Yes	YYYY-MM-DD	Yes/No	Left eye	Yes/No	XX
	ABCD	Yes	YYYY-MM-DD	Yes/No	Left eye	Yes/No	XX
……..							
XXX-XX	ABCD	Yes	YYYY-MM-DD	Yes/No	Right eye	Yes/No	XX
	ABCD	Yes	YYYY-MM-DD	Yes/No	Right eye	Yes/No	XX
	ABCD	Yes	YYYY-MM-DD	Yes/No	Right eye	Yes/No	XX
	ABCD	Not Done: specify	-	-	-	-	-
……..							
Relaxed							
……..							

VA: Visual Acuity, BCVA: Best Corrective Visual Acuity

Listing 16.2.6-7 Optical Coherence Tomography (OCT) by Treatment (STUDY EYE) (CRF Data)

Full Analysis Set

Subject Number	Visit	Was OCT Performed?	Date OCT performed (YYYY-MM-DD)	STUDY Eye	Type of OCT (Including subtype if high definition/spectral domain OCT)	Presence of intra-retinal fluid	Compared to previous intra-retinal assessment	Presence of sub-retinal fluid	Compared to previous sub-retinal assessment	>200µm height or SRF at foveal centre
Intensive										
XXX-XX	ABCD	Yes	YYYY-MM-DD	Left eye	Other: Time domain	Present	-	Present	-	Yes
	ABCD	Yes	YYYY-MM-DD	Left eye	Other: Time domain	Present	No change	Present	No change	No
	ABCD	Yes	YYYY-MM-DD	Left eye	Other: Time domain	Absence	Improved	Absence	Improved	Yes
	ABCD	Yes	YYYY-MM-DD	Left eye	Other: Time domain	Present	Worse	Present	Worse	No
……..										
Relaxed										
XXX-XX	ABCD	Yes	YYYY-MM-DD	Right eye	High definition / spectral domain: Cirrus	Present	-	Present	-	Yes
	ABCD	Yes	YYYY-MM-DD	Right eye	High definition / spectral domain: Cirrus	Absent	Improved	Absent	Improved	No
	ABCD	Yes	YYYY-MM-DD	Right eye	High definition / spectral domain: Cirrus	Can't grade	-	Can't grade	-	Yes
	ABCD	Not Done: specify	-	-	-	-	-	-	-	-
……..										

OCT: Optical Coherence Tomography, SRF: Sub-retinal fluid

Listing 16.2.6-8 Optical Coherence Tomography (OCT) by Treatment (FELLOW EYE) (CRF Data)

Full Analysis Set

Subject Number	Visit	Was OCT Performed?	Date OCT performed (YYYY-MM-DD)	FELLOW Eye	Type of OCT (Including subtype if high definition/spectral domain OCT)	Presence of intra-retinal fluid	Compared to previous intra-retinal assessment	Presence of sub-retinal fluid	Compared to previous sub-retinal assessment	>200µm height or SRF at foveal centre
Intensive										
XXX-XX	ABCD	Yes	YYYY-MM-DD	Left eye	Other: Time domain	Present	-	Present	-	Yes
	ABCD	Yes	YYYY-MM-DD	Left eye	Other: Time domain	Present	No change	Present	No change	No
	ABCD	Yes	YYYY-MM-DD	Left eye	Other: Time domain	Absence	Improved	Absence	Improved	Yes
	ABCD	Yes	YYYY-MM-DD	Left eye	Other: Time domain	Present	Worse	Present	Worse	No
……..										
Relaxed										
XXX-XX	ABCD	Yes	YYYY-MM-DD	Right eye	High definition / spectral domain: Cirrus	Present	-	Present	-	Yes
	ABCD	Yes	YYYY-MM-DD	Right eye	High definition / spectral domain: Cirrus	Absent	Improved	Absent	Improved	No
	ABCD	Yes	YYYY-MM-DD	Right eye	High definition / spectral domain: Cirrus	Can't grade	-	Can't grade	-	Yes
	ABCD	Not Done: specify	-	-	-	-	-	-	-	-
……..										

OCT: Optical Coherence Tomography, SRF: Sub-retinal fluid

Listing 16.2.6-9 Optical Coherence Tomography (OCT) by treatment (STUDY EYE) (Central Reading Center Data)

Full Analysis Set

Subject Number	Visit	STUDY eye assessed	Parameter	Result	Comments
Intensive					
XXX-XX	ABCD	Left	Central Subfield Foveal Thickness	xx	ABCD
			Central Subfield Volume	xx	
			Cysts Present?	Yes	
			Cyst(s) involving central macula	Yes	
			Cysts: Thickness at Center Point	xx	
			Vitreomacular traction present	Yes	
	……..		Subretinal fluid (within 6x6mm scan) present	Yes	
			Intraretinal fluid present	No	
			Vitreoretinal Abnormalities	No	
			Type of OCT	HD	
			GA Measurement*	xx	
			Subfoveal SRF (at centrepoint) present**	Yes	
……..					
Relaxed					
……..					

* Where allowable by imaging equipment at site

** For the relaxed arm, if “Yes”, height “> 200um” or “= or <200um”

Listing 16.2.6-10 Genotyping Sampling

Full Analysis Set

Subject Number	Consent provided for genotyping sample collection?	Date of consent specific to genotyping (YYYY-MM-DD)	Was genotyping sample taken?	Date genotyping sample collected (YYYY-MM-DD)	Sample Number
Intensive					
XXX-XX	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	XXXXXX
XXX-XX	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	XXXXXX
XXX-XX	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	XXXXXX
XXX-XX	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	XXXXXX
XXX-XX	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	XXXXXX
XXX-XX	Yes	YYYY-MM-DD	No	-	-
XXX-XX	Yes	YYYY-MM-DD	Yes	YYYY-MM-DD	XXXXXX
……..					
Relaxed					
……..					

Listing 16.2.6-11 Genotyping SNPs

Full Analysis Set

Subject Number	rsXXXXXXXXX	rsXXXXXXXXX	rsXXXXXXXXX	rsXXXXXXXXX	rsXXXXXXXXX	rsXXXXXXXXX	rsXXXXXXXXX	rsXXXXXXXXX	rsXXXXXXXXX
Intensive									
XXX-XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
XXX-XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
XXX-XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
XXX-XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
XXX-XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
XXX-XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
XXX-XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
……..									
Relaxed									
……..									

Section 16.2.7 – Adverse event listings

Listing 16.2.7-1 Adverse events

Safety Set

Subject Number	AE No	Adverse Event (REPORTED / Preferred / System Organ Class)	Start Date (YYYY-MM-DD) / Study Day	Stop Date (YYYY-MM-DD) / Study Day	Duration (Days)	Site	Severity	Action Taken	Relation to Study Drug
Intensive									
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Left	Mild	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Right	Mod	ABCD	Not susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Both	Sev	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Non-Ocular	Mild	ABCD	Not susp
Intensive									
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Left	Mild	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Right	Mod	ABCD	Not susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Both	Sev	ABCD	Susp

NK: Not Known; AE No = Adverse Number
Severity: Mild=Mild, Mod=Moderate, Sev=Severe
Relationship to study drug: Not susp=Not suspected, Susp=Suspected
Action taken: 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this AE
3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/Prolonged hospitalization
Note: Day is relative to the first day of treatment (day 1)

Listing 16.2.7-2 Ocular adverse events

Safety Set

Subject Number	AE No	Adverse Event (REPORTED / Preferred / System Organ Class)	Start Date (YYYY-MM-DD) / Study Day	Stop Date (YYYY-MM-DD) / Study Day	Duration	Site	Severity	Action Taken	Relation to Study Drug
Intensive									
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Left	Mild	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Right	Mod	ABCD	Not susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Both	Sev	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Non-Ocular	Mild	ABCD	Not susp
Intensive									
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Left	Mild	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Right	Mod	ABCD	Not susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Both	Sev	ABCD	Susp

NK: Not Known; AE No = Adverse Number

Severity: Mild=Mild, Mod=Moderate, Sev=Severe

Relationship to study drug: Not susp=Not suspected, Susp=Suspected

Action taken: 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this AE
3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/Prolonged hospitalization

Note: Day is relative to the first day of treatment (day 1)

Listing 16.2.7-3 Adverse events suspect to be related to study drug and/or ocular injection

Safety Set

Subject Number	AE No	Adverse Event (REPORTED / Preferred / System Organ Class)	Start Date (YYYY-MM-DD) / Study Day	Stop Date (YYYY-MM-DD) / Study Day	Duration	Site	Severity	Action Taken
Intensive								
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Left	Mild	ABCD
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Right	Mod	ABCD
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Both	Sev	ABCD
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Non-Ocular	Mild	ABCD
Intensive								
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Left	Mild	ABCD
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Right	Mod	ABCD
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Both	Sev	ABCD

NK: Not Known; AE No = Adverse Number

Severity: Mild=Mild, Mod=Moderate, Sev=Severe

Action taken: 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this AE
3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/Prolonged hospitalization

Note: Day is relative to the first day of treatment (day 1)

Listing 16.2.7-4 Serious adverse events

Safety Set

Subject Number	AE No	Adverse Event (REPORTED / Preferred / System Organ Class)	Start Date (YYYY-MM-DD) / Study Day	Stop Date (YYYY-MM-DD) / Study Day	Duration	Site	Severity	Action Taken	Relation to Study Drug
Intensive									
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Left	Mild	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Right	Mod	ABCD	Not susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Both	Sev	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Non-Ocular	Mild	ABCD	Not susp
Intensive									
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Left	Mild	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Right	Mod	ABCD	Not susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Both	Sev	ABCD	Susp

NK: Not Known; AE No = Adverse Number

Severity: Mild=Mild, Mod=Moderate, Sev=Severe

Relationship to study drug: Not susp=Not suspected, Susp=Suspected

Action taken: 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this AE
3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/Prolonged hospitalization

Note: Day is relative to the first day of treatment (day 1)

Listing 16.2.7-5 Adverse events leading to treatment withdrawal

Safety Set

Subject Number	AE No	Adverse Event (REPORTED / Preferred / System Organ Class)	Start Date (YYYY-MM-DD) / Study Day	Stop Date (YYYY-MM-DD) / Study Day	Duration	Site	Severity	Action Taken	Relation to Study Drug
Intensive									
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Left	Mild	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Right	Mod	ABCD	Not susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Both	Sev	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Non-Ocular	Mild	ABCD	Not susp
Intensive									
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Left	Mild	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Right	Mod	ABCD	Not susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Both	Sev	ABCD	Susp

NK: Not Known; AE No = Adverse Number

Severity: Mild=Mild, Mod=Moderate, Sev=Severe

Relationship to study drug: Not susp=Not suspected, Susp=Suspected

Action taken: 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this AE
3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/Prolonged hospitalization

Note: Day is relative to the first day of treatment (day 1)

Listing 16.2.7-6 Adverse events leading to treatment interruption

Safety Set

Subject Number	AE No	Adverse Event (REPORTED / Preferred / System Organ Class)	Start Date (YYYY-MM-DD) / Study Day	Stop Date (YYYY-MM-DD) / Study Day	Duration	Site	Severity	Action Taken	Relation to Study Drug
Intensive									
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Left	Mild	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Right	Mod	ABCD	Not susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Both	Sev	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Non-Ocular	Mild	ABCD	Not susp
Intensive									
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Left	Mild	ABCD	Susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Right	Mod	ABCD	Not susp
XXX-XX	X	ABCD	YYYY-MM-DD / X	YYYY-MM-DD / X	X	Both	Sev	ABCD	Susp

NK: Not Known; AE No = Adverse Number

Severity: Mild=Mild, Mod=Moderate, Sev=Severe

Relationship to study drug: Not susp=Not suspected, Susp=Suspected

Action taken: 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this AE
3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/Prolonged hospitalization

Note: Day is relative to the first day of treatment (day 1)

Section 16.2.8 – Laboratory measurements

No output

Section 16.2.9 – Vital signs, physical findings and other observations related to safety listings

Listing 16.2.9-1 Vital signs by treatment

Safety Set

Subject Number	Visit	Were Vital Signs Performed?	Date of Vital Signs Assessment (YYYY-MM-DD)	Systolic Blood Pressure (mmHg)*	Diastolic Blood Pressure (mmHg)*
XXX-XX	ABCD	Yes/No	YYYY-MM-DD	XXXH	XXX
	ABCD	Yes/No	YYYY-MM-DD	XXX	XXX
	ABCD	Yes/No	YYYY-MM-DD	XXXL	XXX
	ABCD	Yes/No	YYYY-MM-DD	XXX	XXX
……..					
XXX-XX	ABCD	Yes/No	YYYY-MM-DD	XXX	XXX
	ABCD	Yes/No	YYYY-MM-DD	XXX	XXX
	ABCD	Yes/No	YYYY-MM-DD	XXX	XXX
	ABCD	Yes/No	YYYY-MM-DD	XXX	XXX
……..					

*Flags: H=High (Systolic - >180 and increase from baseline of >20, Diastolic - >105 and increase from baseline of >15)
L=Low (Systolic - <90 and decrease from baseline of >20, Diastolic - <50 and decrease from baseline of >15)

Listing 16.2.9-2 Ophthalmic Examinations by treatment (STUDY EYE)

Safety Set

Subject Number	Visit	Was OE Performed?	Date OE performed (YYYY-MM-DD)	STUDY Eye assessed	IOP (mmHg)	Examination	Result
XXX-XX	Screening	Yes	YYYY-MM-DD	Left eye	XX	Cornea	Normal
						Iris	Abnormal
						Vitreous	Abnormal
						Disc	Normal
						Retina other than AMD	Abnormal
						Lens	Phakic
	Baseline	Yes	YYYY-MM-DD	Left eye	XX	Changes since previous assessment?	Yes: xxxxxxxx
						Cornea	Normal
						Iris	Abnormal
						Vitreous	Abnormal
						Disc	Normal
						Retina other than AMD	Abnormal
						Lens	Aphakic
						AREDS – Nuclear Sclerosis	<2
						AREDS – Cortical	>2
						AREDS – PSC	>2
	Week *n*	Yes	YYYY-MM-DD	Left eye	XX	…….	…….
	Week *n*	Yes	YYYY-MM-DD	Left eye	XX	…….	…….
…….							
XXX-XX	……..						
…….							

OE: Ophthalmic Examination, IOP: Intra Ocular Pressure

Listing 16.2.9-3 Ophthalmic Examinations by treatment (FELLOW EYE)

Safety Set

Subject Number	Visit	Was OE Performed?	Date OE performed (YYYY-MM-DD)	FELLOW Eye assessed	IOP (mmHg)	Examination	Result
XXX-XX	Screening	Yes	YYYY-MM-DD	Left eye	XX	Cornea	Normal
						Iris	Not done
						Vitreous	Abnormal
						Disc	Normal
						Retina other than AMD	Abnormal
						Lens	Normal
	Baseline	Yes	YYYY-MM-DD	Left eye	XX	Changes since previous assessment?	Yes: xxxxxxxx
						Cornea	Normal
						Iris	Not done
						Vitreous	Abnormal
						Disc	Normal
						Retina other than AMD	Abnormal
						Lens	Normal
						AREDS – Nuclear Sclerosis	<2
						AREDS – Cortical	>2
						AREDS – PSC	>2
	Week *n*	Yes	YYYY-MM-DD	Left eye	XX	…….	…….
	Week *n*	Yes	YYYY-MM-DD	Left eye	XX	…….	…….
…….							
XXX-XX	……..						
…….							

OE: Ophthalmic Examination, IOP: Intra Ocular Pressure

Listing 16.2.9-4 Pregnancy test data by treatment

Safety Set

Subject Number	Was pregnancy test done?	Type of sample taken	Date of sample (YYYY-MM-DD)	Result of Test
Intensive				
XXX-XX	Yes	Urine sample	YYYY-MM-DD	Negative
XXX-XX	Yes	Serum sample	YYYY-MM-DD	Negative
XXX-XX	Yes	Urine sample	YYYY-MM-DD	Negative
XXX-XX	Yes	Serum sample	YYYY-MM-DD	Negative
……..				
Relaxed				
XXX-XX	Yes	Urine sample	YYYY-MM-DD	Negative
XXX-XX	Yes	Serum sample	YYYY-MM-DD	Negative
XXX-XX	Yes	Urine sample	YYYY-MM-DD	Negative
XXX-XX	No	-	-	-
……..				

*Flags: H=High (Systolic - >180 and increase from baseline of >20, Diastolic - >105 and increase from baseline of >15)
L=Low (Systolic - <90 and decrease from baseline of >20, Diastolic - <50 and decrease from baseline of >15)

Section 16.2.10 – Listing of subject numbers who reported at least one safety event of special interest by event and treatment

No output

Section 16.2.11 – Case retrieval strategy listing

No output