Statistical Analysis Plan

SPONSOR:	Viridian Therapeutics, Inc.
PROTOCOL TITLE:	An open-label study for participants who are non-responders at the end of treatment assessment on the VRDN-001-101 and VRDN-001-301 pivotal studies
PROTOCOL VERSION:	Version 4.1, Amendment date: 24MAR2025
STUDY CODE:	VRDN-001-302
VERSION:	V1.0
DATE:	21MAY2025

SIGNATURE PAGE

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Viridian Therapeutics, Inc.

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1. List of Abbreviations and Definition of Terms

Abbreviation	Term
ADA	anti-drug antibodies
AE	adverse events
ATC	Anatomical Therapeutic Chemical
CAS	clinical activity score
DSMB	data safety monitoring board
ECG	electrocardiogram
EOM	extraocular muscle
EXI	exophthalmometer imputation
GO-QoL	Graves' Orbitopathy-Quality of Life
IMP	investigational medicinal product
IOP	intraocular pressure
ITT	intent-to-treat
IV	intravenous
mITT	modified intent-io-treat
OC	observed cases
PP	per-protocol
PT	preferred term
SAE	serious adverse events
SAP	statistical analysis plan
SOC	system organ class
TEAE	treatment-emergent adverse events
TEAESI	TEAE of special interest
TED	thyroid eye disease
VA	visual acuity
VAS	visual analogue scale
WOCF	worst observation carried forward

2. Introduction

This Statistical Analysis Plan (SAP) was written for the clinical study VRDN-001-302. The SAP was based on version 4.1 of the protocol dated 24-MAR-2025.

This plan may be modified until time of final database lock. Any deviations from the analysis plan will be documented as such in the study report.

2.1 Changes from Protocol

If there are any changes pertaining to statistical considerations between the SAP and the protocol, the SAP will take precedence.

3. Study Objectives and Endpoints

3.1 Study Objectives and Endpoints

The objectives of this study are as follows:

- To provide open-label access of VRDN-001 to participants who were previously nonresponders at 3 weeks post the fifth IV infusion in the VRDN-001-101 and VRDN-001-301 pivotal studies.
- To assess the safety and efficacy of VRDN-001 in participants who were previously treated with VRDN-001 or placebo.

3.1.1 Primary Efficacy Endpoint

For the primary and the key secondary endpoints, the method of measurement for proptosis is MRI/CT unless stated otherwise.

3.1.1.1 USA, Canada, and China

The primary efficacy endpoint is Proptosis Responder Rate in the most proptotic eye (ie, reduction of proptosis of ≥ 2 mm from baseline [without a corresponding increase of ≥ 2 mm in the other eye]) as measured by exophthalmometer at 3 weeks post the fifth IV infusion (ie, Week 15).

3.1.1.2 Australia, Israel, European Union, Turkey and United Kingdom

The primary efficacy endpoint is Overall Responder Rate comprising Proptosis Responder Rate (assessed using MRI/CT derived proptosis evaluation results as per Protocol Section 10.3.1) in the most proptotic eye (ie reduction of proptosis of ≥ 2 mm from baseline [without a corresponding increase of ≥ 2 mm in the other eye]) at 3 weeks post the fifth IV infusion (ie Week 15) and Clinical Activity Responder Rate in the most proptotic eye (ie, no worsening in Clinical Activity Score (CAS) from baseline [without a corresponding increase of ≥2 points in the other eye]) at 3 weeks post the fifth IV infusion (ie, Week 15).

3.1.2 Key Secondary Endpoints

3.1.2.1 USA, Canada, and China

The key secondary endpoints are as follows:

- Change from baseline in proptosis in the most proptotic eye as measured by exophthalmometer at Week 15
- Proptosis Responder Rate in the most proptotic eye at Week 15
- Change from baseline in proptosis in the most proptotic eye at Week 15
- Clinical Activity Responder Rate in the most proptotic eye as measured by exophthalmometer at Week 15
- Overall Responder Rate comprised of Proptosis Responder Rate in the most proptotic eye as measured by exophthalmometer at Week 15 and Clinical Activity Responder Rate in the most proptotic eye as measured by exophthalmometer at Week 15
- Diplopia Responder Rate (ie, reduction in Gorman Subjective Diplopia Score of ≥1 from baseline for participants with baseline Gorman Subjective Diplopia Score >0) at Week 15
- Diplopia Resolution Rate (ie, reduction in Gorman Subjective Diplopia Score to 0 from baseline for participants with baseline Gorman Subjective Diplopia Score >0) at Week 15

3.1.2.3 Australia, Israel, European Union, Turkey and United Kingdom

The key secondary efficacy endpoints are as follows:

- Change from Baseline in proptosis in the most proptotic eye at Week 15
- Proptosis Responder Rate in the most proptotic eye as measured by exophthalmometer at Week 15
- Change from baseline in proptosis in the most proptotic eye as measured by exophthalmometer at Week 15
- Diplopia Responder Rate (ie, reduction in Gorman Subjective Diplopia Score of ≥1 from baseline for participants with baseline Gorman Subjective Diplopia Score >0) at Week 15
- Diplopia Resolution Rate (ie, reduction in Gorman Subjective Diplopia Score to 0 from baseline for participants with baseline Gorman Subjective Diplopia Score >0) at Week 15

3.1.3 Exploratory Endpoints

The exploratory efficacy endpoints are as follows.

Exploratory Endpoints for USA, Canada and China will include:

- Proptosis Responder Rate in the most proptotic eye by visit

- Durability of Proptosis Response in the most proptotic eye at Week 24
- Proptosis Responder Rate in the other eye (ie, reduction of proptosis of ≥ 2 mm from baseline) by visit
- Time to First Proptosis Response in the most proptotic eye
- Clinical Activity Responder Rate in the most proptotic eye by visit
- Clinical Activity Responder Rate in the other eye by visit
- Overall Responder Rate in the most proptotic eye by visit
- Overall Responder Rate in the other eye by visit
- Diplopia Responder Rate by visit
- Diplopia Resolution Rate by visit
- Change from baseline in CAS in the most proptotic eye at Week 15 for those with a baseline CAS ≥3
- Change from baseline in CAS in the other eye at Week 15 for those with a baseline CAS ≥3
- Proportion of participants with a CAS of zero or one in the most proptotic eye at Week 15 for those with a baseline CAS ≥3
- Proportion of participants with a CAS of zero or one in the other eye at Week 15 for those with a baseline CAS ≥3
- Proptosis responder rate in the most proptotic eye in participants with baseline CAS of 0 or 1 by visit
- Proptosis responder rate in the other eye in participants with baseline CAS of 0 or 1 by visit
- Proptosis responder rate in the most proptotic eye in participants with baseline CAS of 0, 1, or 2 by visit
- Proptosis responder rate in the other eye in participants with baseline CAS of 0, 1, or 2 by visit
- Proptosis responder rate in the most proptotic eye in participants with baseline CAS of ≥3 by visit
- Proptosis responder rate in the other eye in participants with baseline CAS of ≥3 by visit
- Change from baseline in the most proptotic eye and other eye where applicable in the following parameters by visit:
    - Proptosis
    - CAS
    - Extraocular muscle volume
    - Orbital fat volume
    - Manual measurement of lid retraction
    - Graves' Orbitopathy-Quality of Life (GO-QoL) combined score
    - GO-QoL activity subscale
    - GO-QoL appearance subscale
    - Visual Acuity (VA)
    - Gorman Subjective Diplopia Score
    - EQ-5D-5L QoL questionnaire
- VRDN-001, IGF-1 and anti-drug antibodies (ADA) at various timepoints pre- and post-IV infusions as described in Appendix 1 of the protocol

Exploratory Endpoints for Australia, Israel, Turkey, EU and UK all regions will include:

- Proptosis Responder Rate in the most proptotic eye at Week 24 (12 weeks post fifth IV infusion)
- Proptosis Responder Rate in the other eye (ie, reduction of proptosis of ≥2 mm from baseline) at Weeks 15 and 24
- Durability of Proptosis Response in the most proptotic eye at Week 24
- Time to First Proptosis Response in the most proptotic eye
- Clinical Activity Responder Rate in the most proptotic eye at Week 24
- Clinical Activity Responder Rate in the other eye at Weeks 15 and 24
- Overall Responder Rate in the most proptotic eye at Week 24
- Overall Responder Rate in the other eye at Weeks 15 and 24
- Diplopia Responder Rate at Week 24
- Diplopia Resolution Rate at Week 24
- Change from baseline in the most proptotic eye and other eye where applicable in the following parameters at Weeks 15 and 24:
    - Proptosis
    - CAS
    - Extraocular muscle volume
    - Orbital fat volume
    - Manual measurement of lid retraction
    - Graves' Orbitopathy-Quality of Life (GO-QoL) combined score
    - GO-QoL activity subscale
    - GO-QoL appearance subscale
    - EQ-5D-5L QoL questionnaire
    - Visual Acuity (VA)
    - Gorman Subjective Diplopia Score

- VRDN-001, IGF-1 and anti-drug antibodies (ADA) at various timepoints pre- and post-IV infusions as described in Appendix 1

3.2 [redacted]

[redacted]

4. Overall Study Design

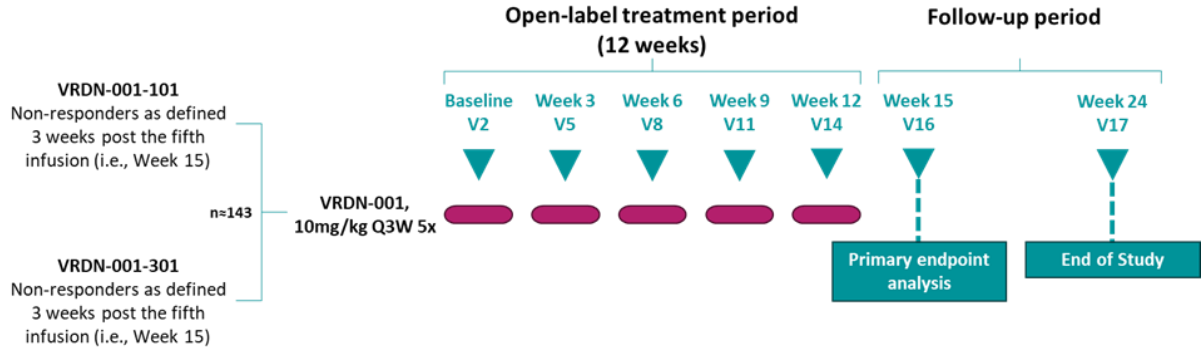
This study is an open-label evaluation of safety and efficacy of VRDN-001 in participants who were found to be nonresponders in either the VRDN-001-101 or VRDN-001-301 pivotal studies. Participants to be enrolled from the VRDN-001-101 pivotal portion of the study will have been either randomized (1:1:1) to 5 active IV infusions or 8 active IV infusions versus placebo, or randomized (2:1) to 5 active IV infusions versus placebo depending on the version of the VRDN-001-101 protocol under which a participant was randomized. Participants to be enrolled from VRDN-001-301 study will have been randomized (2:1) to 5 active IV infusions versus placebo. In both studies participants will have received IV infusions at 3-week intervals and all participants will have received a total of 5 to 8 IV infusions to maintain masking.

The intent of this study is to provide open-label access to VRDN-001 for those participants who received placebo in either the VRDN-001-101 or VRDN-001-301 pivotal studies, as well as evaluate safety and efficacy outcomes in these participants. However, in order to maintain the integrity of the masking in the pivotal studies, all participants will be offered open-label treatment with 5 IV infusions of VRDN-001 at 3-week intervals if they are determined to be nonresponders in either VRDN-001-101 or VRDN-001-301. Therefore, it is likely that there will be some participants included in this study (where permitted by local health authorities) who had previously received 5 to 8 IV infusions of VRDN-001 and were found to be nonresponders in the pivotal studies. Furthermore, in some countries, per local health authority requirements, participants may be unmasked prior to the decision to enroll in this open-label treatment study.

Participants will undergo safety assessments, including audiometry, prior to the first IV infusion on this study as outlined in Appendix 1 of the protocol.

The Day-1/Day 1 visit(s) are to be conducted within 4 weeks of the 3 week post the fifth IV infusion assessment (ie, Week 15) in either the VRDN-001-101 or VRDN-001-301 pivotal studies. More than 4 weeks may be allowed between the completion of the 3 week post the fifth IV infusion assessment (ie, Week 15) in the pivotal studies and the Day-1/Day 1 visit of this study with prior written approval by the Sponsor.

The overall study schematic below presents a graphical representation of some important study milestones.



4.1 Sample Size

The study is expected to include approximately 143 participants.

5. General Analysis Definitions

Data collected for this clinical study will be analyzed with SAS (Version 9.4 or higher) for all endpoints described in this SAP.

Descriptive statistics will be tabulated as follows:

- Categorical data will be summarized in contingency tables presenting frequencies and percentages.

- Continuous data will be summarized using number of non-missing values (n), mean, standard deviation, median, minimum and maximum values. First and third quartiles may be added in case of well-known asymmetric distribution.
- Time to event data will be summarized using the Kaplan-Meier method. The 25th, 50th, 75th percentile and the corresponding 95% confidence interval will be reported as applicable.

Analyses and endpoints will be displayed by treatment group.

The safety analyses will be presented by treatment group as well.

Listings with individual values will be provided for much of the data presented in the tables. These listings will be sorted by participant identification number.

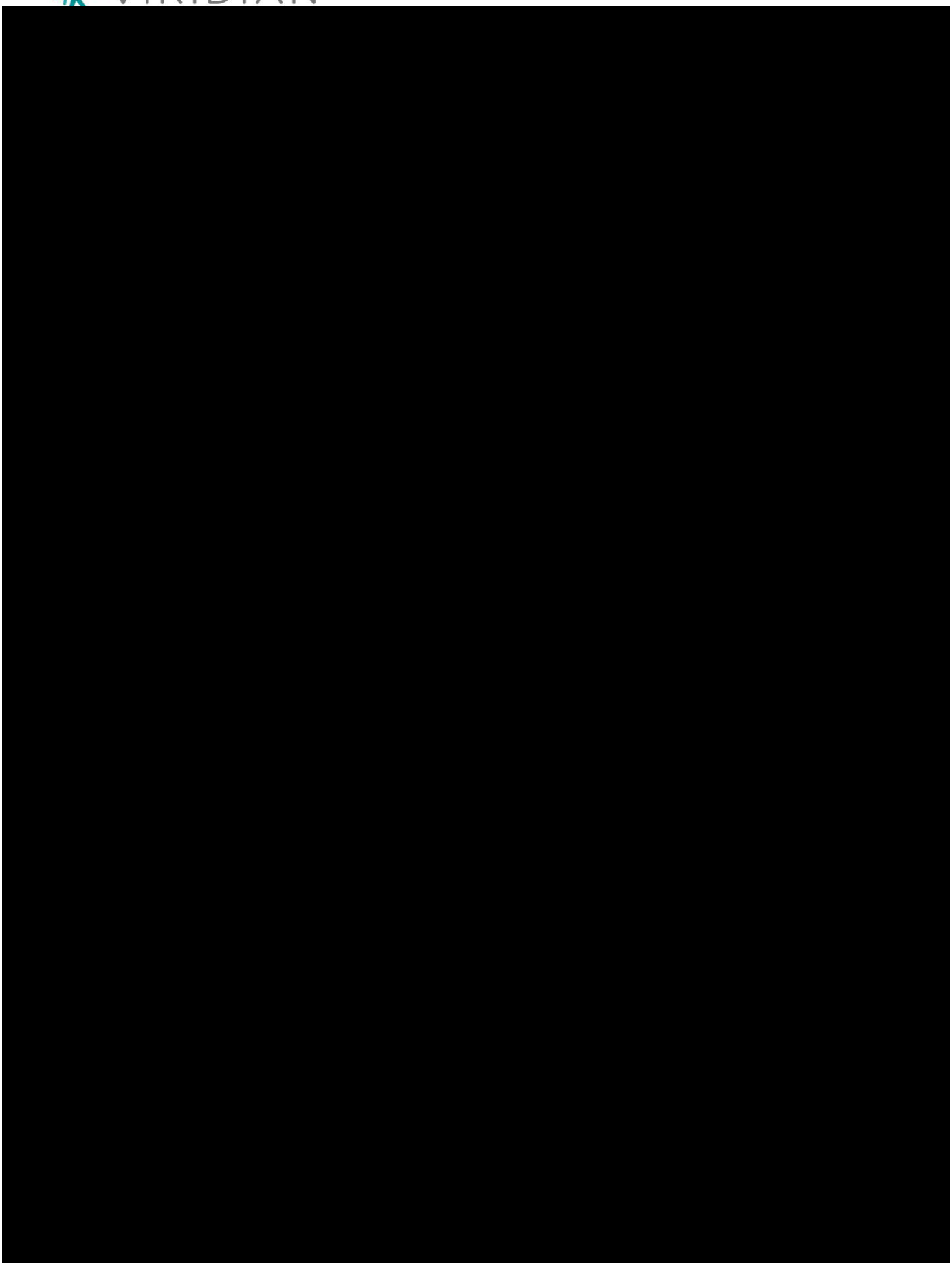
5.1 Study Period and Visit Window Definitions

5.1.1 Study Periods

Screening period will be defined as the period before the start date of study medication. The open-label treatment period will occur from baseline to Week 12, and the follow-up period will occur from Week 15 until Week 24.

5.1.2 [redacted]

[redacted]



5.2 Planned Analyses

5.2.1 Data Safety Monitoring Board

An independent Data Safety Monitoring Board (DSMB) will review the safety and limited efficacy data at 6-month intervals during the study. Interim ad hoc DSMB meetings may be conducted as needed to monitor clinical safety and determine if any required changes to study design should be implemented. The details of the meeting are outlined in the DSMB Charter.

5.2.2 Week 15 Primary Analysis

There will be a primary efficacy database lock and subsequent analysis when all participants complete the Week 15 assessment or have early discontinuation. The analyses will include the following but are not limited to:

- Demographic and Baseline Characteristics
- Medical History
- Ophthalmic History
- Disposition
- All primary, secondary and exploratory endpoints through Week 15
- Treatment-emergent AE (TEAE) through Week 15
- Safety data through Week 15

Due to the nature of an ongoing study at the time of the Week 15 analysis, the database and external data will contain data beyond Week 15 for some subjects at the time of the database lock for the Week 15 Analysis. Only data occurring prior or on the Week 15 visit will be included in the Week 15 Analyses.

Additional analyses including data beyond the Week 15 visit may be produced at the time of the Week 15 Primary Analysis.

5.2.3 Week 24 Follow-up Analysis

A second database lock will occur when all participants complete their final study visit at Week 24 or discontinue. All analyses specified in this SAP will be performed.

5.3 Definition of Populations

5.3.1 Enrolled Population

The Enrolled population includes all subjects that signed the informed consent.

5.3.2 Intent-To-Treat Population

The Intent-to-Treat (ITT) population will include all participants who sign informed consent for this study, irrespective of whether study medication was administered or not. This dataset will be used to report participant disposition and for the efficacy endpoints.

5.3.3 Modified Intent-To-Treat Population

The Modified Intent-to-Treat (ITT) population will include all participants who received at least one IV infusion treatment. This population will be utilized as the primary analysis population and for all endpoints other than safety.

5.3.4 Safety Population

The Safety population will comprise all participants in the ITT population who received at least one dose of study medication. This dataset will be employed to analyze the safety endpoints. Participants will be analyzed according to the study medication received for all safety analyses.

5.3.5 Per-Protocol Population

The Per-Protocol (PP) population will comprise participants in the mITT population who did not have selected major protocol violations, which strongly confound the efficacy results, during the treatment period. This population will only be utilized as a sensitivity analysis for the primary and key secondary efficacy endpoints. Major protocol violations may include, but are not limited to:

- Did not meet the inclusion/exclusion criteria
- Received prohibited concomitant medications

The PP population will be finalized prior to the Week 15 analysis for the primary and secondary endpoints.

5.4 Subgroup Definitions

The primary and key secondary endpoints will be summarized descriptively according to the following subgroups for the mITT population:

- Age: 18 to 34, 35 to 65, >65 years
- Sex: Male, Female
- Race: Black, Asian, White, Other
- Country: United States, Rest of World
- Randomization Stratification: <23 mm and ≥23 mm
- Steroid use during the Treatment period (Y/N)
- Tobacco use

5.5 Treatment Assignment and Treatment Arms

Treatment columns will include the following. If a participant is a rollover from the VRDN-001-101 study, they are considered an active TED participant. If they are a rollover from the VRDN-001-301 study, they are considered a chronic TED participant.

- VRDN/VRDN Active TED
- VRDN/VRDN Chronic TED
- Total VRDN/VRDN
- Placebo/VRDN Active TED
- Placebo/VRDN Chronic TED
- Total Placebo/VRDN
- Total overall

5.6 Calculated Variables

- For events that occur after the first administration of study medication, relative day will be calculated as (date of XXX -date of first administration of study medication) +1. For events that occur before the first administration of study medication, relative day will be calculated as (date of XXX - date of first administration of study medication).
- Study day 1 is defined as the day of the first administration of study medication.
- Baseline is defined as the last non-missing assessment prior to the first administration of study medication. Assessments completed on the date of study medication administration are assumed to take place before the administration, unless specified otherwise in the protocol.

Change from baseline is defined as the post-baseline value – baseline value.

Percent change from baseline is defined as 100*(post-baseline value – baseline value)/baseline value. If the baseline value is 0 and the post-baseline value is 0, the change from baseline and the percent change from baseline are both 0. If the baseline value is 0 and the post-baseline value is not 0, the change from baseline is the same as the post-baseline value and the percent change from baseline will be missing.

Body Mass Index (BMI) = weight in kg / (height in m)^2.

Age is collected in the clinical database.

When calculating time in months utilize 30.4375 as the denominator.

When calculating time in years utilize 365.25 as the denominator.

XXX can be any reference time point of interest (eg, start of adverse event [AE]) in calculation of the associated duration.

5.7 Partial Dates

Partial or missing dates in general will not be imputed.

For the calculation of the time (in months) from XXX to date of IMP or randomization, the following imputation rules will be applied when the date of XXX is incomplete:

If the day is missing: first day of the month

If the day and month are missing: first day of January.

If the day and month are missing and if the year is the same as the year of IMP: leave missing.

In order to evaluate if an AE is treatment emergent or not, and to evaluate if a medication or procedure is concomitant or not, the following rules will be applied in case of incomplete or missing dates:

If end date is missing and the outcome is “Recovered/Resolved”, the end date will be set to the last contact date.

If end date is incomplete and the outcome of “Recovered/Resolved”:

- if the day is missing and month/year is same as the last contact date then use last contact date, else the end date will be imputed with the last day of the month;
- if the day and month are missing: the end date will be imputed with minimum of (31 December of the year, last contact date, date of death).

If start date is missing:

- if end date is before the start date of IMP administration, the start date will remain missing (medical history).
- if end date is after or on the date of IMP administration or the medication/AE is ongoing (or end date is missing), the start date will be imputed by the date of IMP administration.

If start date is incomplete:

- if end date is before the date of IMP administration, the start date will remain incomplete.
- if end date is after or on the date of IMP administration or the medication/history is ongoing (or end date is missing), the start date will be imputed as follows: if the day is missing, the start date will be imputed with minimum of (the last day of the month, end date of medication/AE if available); if the day and month are missing: the start date will be imputed with minimum of (31 December of the year, end date of medication/AE if available).

However, the original date variable will not be imputed and only a temporary variable will be created in order to perform the evaluation. The temporary variable will not be used in any other calculation and will not be listed. In patient data listings, the documented date as recorded in the clinical database (ie, without imputation), will be reported (eg, XXMAR2014 in case of day missing, but month and year available). The imputation will only occur for the final analysis.

5.8 [redacted]

5.9 Changes from the Protocol

If there are any discrepancies between the protocol and SAP, the text in the SAP will take precedence. In particular, substantial changes are noted in the table below.

Protocol	SAP	Rationale
Section 10.3 of the protocol states: The most proptotic eye for a given assessment modality will remain the same as that identified at baseline (last assessment performed prior to the Day 1 IV infusion) on the VRDN-001-101 or VRDN-001-301 study.	Section 8 of the SAP includes text that states: The most proptotic eye in study VRDN-001-302 is determined by the last assessment performed prior to the Day 1 IV infusion in study VRDN-001-302 by the given assessment modality.	Since baseline for all analyses in VRDN-001-302 (except those described in section 8.5 of the SAP) is defined as the last measurement prior to Day 1 IV infusion in study VRDN-001-302, the most proptotic eye will also be based on this baseline. The most proptotic eye determination for analyses described in section 8.5 of the SAP will be based on baseline values from the parent study (VRDN-001-101 or VRDN-001-301).

6. Study Participants

6.1 Disposition of Participants

The number and percentage of participants in each population, along with number and percentage of participants who discontinue the treatment and study along with the primary reasons will be tabulated.

The number of screen failures and the reasons for screen failure will be summarized.

6.2 Protocol Deviations

The major protocol deviations will be summarized for the ITT population and mITT. The summary will include the number and percentage of subjects with at least one major protocol deviation along with the number of events. Additionally, the number, percentage, and number of events for each major deviation category will be presented. Details of all protocol deviations will be listed by participant and indicating category of protocol deviation.

Protocol deviations will be defined as major or minor by the Sponsor prior to the Week 15 and Week 24 database locks.

It is possible that new protocol deviations will be discovered, or existing ones modified during the final Week 24 database lock. Therefore, a comparison on the protocol deviations will be reviewed and the impact to the PP population will be examined. If deemed necessary, the PP population may be regenerated with the updated population. Any updates to the PP population will be documented in the study report.

6.3 Inclusion and Exclusion Criteria

A listing of all inclusion and exclusion criteria not met will be provided for the Enrolled population.

7. Demographic and Other Baseline Characteristics

Participant demographics and baseline characteristics will be summarized for the ITT, mITT and safety populations. The variables to be summarized are as following:

Age (years)

Age groups (18 to 34, 35 to 65, >65)

Actual stratification (baseline proptosis) in most proptotic eye (>=23mm, <23mm) by both modalities

Sex (Male, Female)

Race (Asian, Black, White, Other)

Ethnicity (Hispanic or Latino, Not Hispanic or Latino)

Study Eye (OD, OS)

Country (United States, Rest of World)

Initial TED onset (months) from study start date

Audiometry: PTA (db), PTA >25 Y/N

Gorman Subjective Diplopia Grade

Diplopia status

Baseline CAS for both OD and OS

Baseline Proptosis value (by Hertel and MRI/CT)

Height

Weight

BMI

Tobacco use

Duration of TED (number of months between onset of TED symptoms and Day 1) groups (<=15 months, >15 months)

7.1 Medical History

All relevant general medical histories, including Graves' disease, will be collected on the "Medical History" eCRF page and will be used for the analysis of medical history and ophthalmic histories. Procedures and surgeries are reported on a separate eCRF page and will be summarized separately.

Medical history will be summarized by system organ class (SOC) and preferred term (PT), for the ITT population. Number and percentage will be displayed for SOC and PT; including number and percentage of all participants with at least one medical history event. Participants will be counted only once at each level of reporting. The summary table will be sorted alphabetically by SOC and PT by descending overall frequency. The Medical Dictionary for Regulatory Activities (MedDRA) dictionary will be utilized for coding. The study data management plan will specify the version. The version will be included in the footnote of the appropriate output.

A listing of medical history will be provided.

7.2 Ophthalmic History

Clinically significant ophthalmic history events will be collected using box 5 on the "Medical History" eCRF page.

Ophthalmic history events will be summarized by SOC and PT for the ITT population. Number and percentage will be displayed for SOC and PT; including number and percentage of all participants with at least one ophthalmic history event. Participants will be counted only once at each level of reporting. Summary tables will be sorted alphabetically by SOC and PT by descending overall frequency. MedDRA dictionary will be utilized for coding. The study data management plan will specify the version. The version will be included in the footnote of the appropriate output and listings.

An indicator for ophthalmic history events will be included in the medical history listing.

7.3 Prior and Concomitant Medication

Prior and concomitant medications will be collected on the "Prior and Concomitant Medications" eCRF page.

Prior medications are defined as medications that start before study day 1.

Concomitant medications are defined as medications that are administered on or after the first day of study medication.

Medications that start before study day 1 and continue after will be reported as both prior and concomitant.

Prior and concomitant medications will be classified according to World Health Organization Drug Dictionary. The version of the dictionary will be specified in the data management plan and will be included in the footnote of the appropriate output.

Prior and concomitant medications will be summarized separately. The number and percentage of participants receiving a medication will be summarized by anatomical main group (1st level of the Anatomical Therapeutic Chemical [ATC] classification) and chemical subgroup (4th level of the ATC classification) for the ITT population. Participants will be counted only once at each level of reporting. Summary tables will be sorted alphabetically by ATC Level 1 and ATC level 4 by descending overall frequency.

A listing of all medications will be provided.

7.4 Prior and Concomitant Procedures and Surgeries

Concomitant procedures will be collected on the "Concomitant Procedures" eCRF page.

Prior procedures and surgeries are defined as procedures and surgeries that start before study day 1.

Concomitant procedures and surgeries are defined as procedures and surgeries that start on or after the first day of Study medication.

Procedures and surgeries that start before study day 1 and continue after will be reported as both prior and concomitant.

Prior and concomitant procedures and surgeries will be classified according to MedDRA. The version of the dictionary will be specified in the data management plan and will be included in the footnote of the appropriate output.

Prior and concomitant procedures and surgeries will be summarized separately. Prior and concomitant procedures and surgeries will be summarized SOC and PT, for the ITT population. Number and percentage will be displayed for SOC and PT; including number and percentage of all participants with at least one event. Participants will be counted only once at each level of reporting. Summary tables will be sorted alphabetically by SOC and PT by descending overall frequency.

The data will be presented in a listing.

8. Efficacy

8.1 Efficacy Assessments and Derived Endpoints

Measurement of Proptosis with Exophthalmometer

Proptosis (distance between the lateral orbital rim and the most anterior position of the cornea in millimeters (mm)) will be measured using an exophthalmometer. Three independent measurements will be performed at each visit for each eye where proptosis is assessed. The average of the three measurements is recorded in the database.

Proptosis Responder in the most proptotic eye is defined as a reduction of proptosis of ≥2 mm from baseline in the most proptotic eye (without a corresponding increase of ≥2 mm in the other eye).

Proptosis Responder in the other eye is defined as a reduction of proptosis of ≥2 mm from baseline in the other eye (without a corresponding increase of ≥2 mm in the most proptotic eye).

Durability of Proptosis Response in the most proptotic eye at Week 24 is defined as achieving a response at Week 15 and Week 24.

Time to first Proptosis Response in the most proptotic eye is defined as (date of first proptosis response-date of first administration of study medication) +1. If a participant does not achieve proptosis response in the most proptotic eye by their Week 15 assessment, they will be censored at their last proptosis assessment during the treatment period.

Clinical Activity Score (CAS)

The CAS is based on seven components: spontaneous retrobulbar pain, pain on attempted eye movements (upward, side to-side, and downward gazes), conjunctival redness, redness of the eyelids, chemosis, swelling of the caruncle or plica and swelling of the eyelids. Each component is scored as present or absent (scored as 1 or 0, respectively), and the CAS is given as the sum of the scores (range, 0 to 7, with higher scores indicating greater level of inflammation).

Subjective Assessment of Diplopia (Gorman Subjective Diplopia Score)

Changes in diplopia grade will be assessed using the Gorman subjective diplopia score (range, 0 to 3), which includes four categories: no diplopia (absent, scored as 0), diplopia in the primary position of gaze when the patient is tired or awakening (intermittent, scored as 1), diplopia at extremes of gaze (inconstant, scored as 2), and continuous diplopia in the primary or reading position (constant, scored as 3).

Diplopia Resolution is defined as a reduction in Gorman Subjective Diplopia Score to 0 from baseline for participants with baseline Gorman Subjective Diplopia Score >0.

Diplopia Responder Rate is defined as a reduction in Gorman Subjective Diplopia Score of ≥1 from baseline for participants with baseline Gorman Subjective Diplopia Score >0.

Measurement of Proptosis by Orbital MRI/CT

Measurements of proptosis will be conducted by the central imaging reading center using MRI/CT of the orbits acquired without contrast. Measurements are conducted by two independent readers with adjudication if difference between primary readers in proptosis measurement exceeds 5% (calculated as the difference divided by the larger measurement). For analysis the average of 2 (or 3 if adjudicated) measurements will be used. Details for acquisition will be outlined in the imaging user manuals provided by the central imaging

reading center. Images will be taken at baseline and the measurements compared at various post-treatment timepoints.

For the purpose of the analysis if the modality of the post-baseline measurement is different than the baseline modality, the post-baseline value will be considered as missing.

Measurement of Extraocular Muscle Volume and Orbital Fat Volume by MRI/CT

Three-dimensional volumetric calculation of extraocular muscle (EOM) will be conducted by the central imaging reading center using MRI/CT of the orbits acquired without contrast. Details for acquisition will be outlined in the imaging user manuals provided by the central imaging reading center. Images will be taken at baseline and the volumes compared at various post-treatment timepoints.

Three-dimensional volumetric calculation of orbital fat will be conducted by the central imaging reading center using MRI/CT of the orbits acquired without contrast. Details for acquisition will be outlined in the imaging user manuals provided by the central imaging reading center. Images will be taken at baseline and the volumes compared at various post-treatment timepoints.

Graves' Orbitopathy - Quality of Life Measurement (GO-QoL)

The questionnaire has two self-assessment subscales: one covering the impact of visual function on daily activities, and the other assessing the impact of self-perceived appearance.

Each subscale has 8 questions which are scored 1-3 and the total raw score is then mathematically transformed to a 0-100 scale, where 0 represents the most negative impact on quality of life, and 100 represents no impact. The combined score takes raw scores from both subscales and again transforms them to a single 0-100 scale. The transformed score is defined as:

Transformed score = ((sum of each score – number of completed items) /(2 × number of completed items)) X 100.

EUROQOL QUESTIONNAIRE VERSION (EQ-5D-5L)

The EQ-5D-5L is an established and validated quality of life assessment, which will be used to evaluate participants' quality of life throughout the study. The EQ-5D-5L is a 5-level that consists of the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state.

The EQ VAS records the patient's self-rated health on a vertical visual analogue scale, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'.

The EQ-5D-5L index will be produced using the United States value[1] set from the EUROQOL website (https://euroqol.org/).

Visual Acuity (VA)

VA will be measured with either Snellen Eye Charts, or equivalent and using a participant's distance prescription glasses or contact lenses, as applicable. Pinhole acuity is acceptable in place of formal refraction if up to date or accurate refractions are not available. This assessment should be conducted prior to dilation of the eyes.

The change from baseline of visual acuity will be assessed by the visual acuity line and will be defined as (Post-baseline logMAR- Baseline logMAR). Where logMAR=-1*$\log_{10}$ (Snellen fraction).

Manual Measurement of Lid Retraction

Lid retraction will be recorded in mm by measuring the lid aperture along the midline of the pupil with the participant looking in the primary position while sitting relaxed and with distant fixation (midpupil to upper lid margin distance, MPLD). A change in lid retraction of 2 mm or greater is considered clinically meaningful.

8.1.1 Efficacy Analysis Procedure

The most proptotic eye in study VRDN-001-302 is determined by the last assessment performed prior to the Day 1 IV infusion in study VRDN-001-302 by the given assessment modality (ie, endpoints assessed by MRI/CT will use most proptotic eye by MRI/CT and endpoints assessed by exophthalmometer will use most proptotic eye by exophthalmometer measurement). If the baseline of MRI/CT is missing then the most proptotic eye will be determined by exophthalmometer measurement. If both eyes are equally proptotic then the eye with the worse VA will be selected. If proptosis and VA are the same for both eyes, then the right eye will be selected as the most proptotic eye.

All analyses for primary and secondary efficacy endpoints will be repeated for the other eye following similar definitions.

No formal statistical testing will be conducted, and endpoints will instead be summarized descriptively.

Key secondary endpoints which include proptosis will be assessed using MRI/CT derived proptosis evaluation results unless otherwise specified within the endpoint.

The following analyses will be conducted for the primary and key secondary endpoints:

Analysis	Population
USA, Canada, China Primary Analysis of Primary Endpoint	mITT
USA, Canada, China Sensitivity Analysis of the Primary Endpoint	ITT PP
Australia, Israel, European Union, Turkey, United Kingdom Primary Analysis of Primary Endpoint	mITT
Australia, Israel, European Union, Turkey, United Kingdom Sensitivity Analysis of the Primary Endpoint	ITT PP
USA, Canada, China Primary Analysis of Key Secondary Endpoints	mITT
USA, Canada, China Sensitivity Analysis Key Secondary Endpoints	ITT PP
Australia, Israel, European Union, Turkey, United Kingdom Primary Analysis of Key Secondary Endpoint	mITT
Australia, Israel, European Union, Turkey, United Kingdom	ITT

8.2 [redacted]

[redacted]

8.3 [redacted]

[redacted]

8.4 Exploratory Endpoints

The analysis for the Week 15 exploratory endpoints will only include data up to and including Week 15. The exploratory endpoints after Week 15 will include all available data.

8.4.1 Exploratory Endpoints in all regions

Proptosis related exploratory endpoints will be assessed by both exophthalmometer and MRI/CT measurement in the most proptotic and other eye as determined by the corresponding measurement modality, except time to first proptosis response which will only be assessed by exophthalmometer. Other exploratory endpoints involving assessments by eye will be analyzed for most proptotic eye and other eye as determined by exophthalmometer and for most proptotic eye and other eye as determined by MRI/CT.

The exploratory endpoints listed in Section 3.1.3 will be summarized descriptively. No statistical testing will be done in this study.

8.5 Additional Analyses

A secondary baseline analysis will be presented for selected efficacy endpoints using the baseline values from parent study VRDN-001-101 or VRDN-001-301. In this analysis, the

most proptotic eye (with respect to each measurement modality) will be determined by the baseline assessment from the parent study. The analyses will include:

- Proptosis responder rate by both modalities across all visits
- Mean change from baseline in proptosis by both modalities across all visits
- Overall responder rate by both modalities across all visits
- Diplopia responder rate across all visits
- Diplopia resolution rate across all visits

Additional analyses may be presented as needed.

9. Safety Evaluation

All safety analyses will be performed on the Safety population unless specified differently.

Safety assessments will be analyzed according to the analysis visits and by right or left eye if applicable. Both safety and tolerability will be evaluated by assessing the incidence of AEs and the incidence of Serious Adverse Events (SAEs).

9.1 Extent of Exposure

Exposure will be summarized for the mITT population by number of doses received as well as the average duration between doses. For the number of doses received, the highest number of doses will be determined for each participant. The table will summarize the number of participants who received that number as the highest number of doses.

The number of participants who had a dose interruption will also be summarized.

All exposure data will be presented in a listing.

9.2 Adverse Events

AEs and SAEs will be reported from the time the participant signs the informed consent to the time the participant completes the study.

AEs will be coded using MedDRA. The dictionary versions are specified in the data management plan and will be included in the footnote for appropriate outputs. AEs will be analysed in terms of their type, incidence, severity/toxicity grade and relationship to the study treatment.

A TEAE will be defined as an AE occurring on or after the day of the first administration of study medication. Furthermore, TEAE through Week 15 is defined as a TEAE occurring on or after the day of the first dose of study medication through the Week 15 visit (inclusive). A follow-up period TEAE is any TEAE that occurred the day after the Week 15 visit through the end of the study.

Related AEs are defined as events with a relationship to study medication equal to ‘related’ or with missing relationship.

The safety analysis in this section will summarize TEAEs through Week 15 and overall employing discrete summaries at the participant- and event-level by SOC and PT. Participants will only be counted once at each level of summary.

An overall summary table will present the number and percentage of participants with at least one category of AE, for TEAEs through Week 15, and overall.

In addition, tabulations of the number and percentage of participants who experienced TEAEs as well as severity of the events will be presented by SOC and PT. Participants will only be counted once for each preferred term. In case a participant experienced the same event more than once, the worst severity will be presented. A summary of total number of AEs will also be presented for each SOC.

The following tabulations will be presented for the Week 15 TEAEs:

- TEAEs
- Treatment-related TEAEs
- TEAEs leading to discontinuation of study medication
- Serious TEAEs
- Treatment-related TEAEs leading to discontinuation of study medication
- TEAEs leading to death
- Treatment-related TEAEs leading to death
- Serious TEAE related to study medication
- TEAEs of interest (TEAEI)
- TEAEs by the maximum severity grade
- Treatment-related TEAEs by the maximum severity grade

The following tabulations will be presented for all TEAEs:

- TEAEs
- Treatment-related TEAEs
- TEAEs leading to discontinuation of study medication
- Serious TEAEs
- Treatment-related TEAEs leading to discontinuation of study medication
- TEAEs leading to death
- Treatment-related TEAEs leading to death
- Serious TEAE related to study medication
- TEAEs of interest (TEAEI)
- TEAEs by the maximum severity grade
- Treatment-related TEAEs by the maximum severity grade

An additional summary describing the onset of TEAEI will be provided. The TEAEI are defined as below. They will be identified via standard MedDRA query (SMQ) or PT as has been prespecified.

The summary of the number of infusions prior to the onset of an adverse event of interest will be provided. If the TEAEI occurs on the day of an infusion that infusion will be considered. In other words, if a participant reported hyperglycaemia after three infusions, the onset will be considered 3 infusions. If there are multiple TEAEI the TEAEI with the least number of infusions prior to onset will be used for the analysis.

All deaths, SAEs and TEAEs leading to discontinuation will be listed.

9.3 Clinical Laboratory

Parameters from the following laboratory categories will be summarised descriptively and by analysis visit for the observed and change from baseline: serum chemistry and lipid panel, haematology (including HbA1c), coagulation and urinalysis.

Shift tables of NCI-CTCAE grade at baseline versus worst post-baseline NCI-CTCAE grade, end of treatment, end of study by CTCAE term will be produced for all gradable parameters. For the laboratory parameters that cannot be graded, shift tables will be displayed for normal, low and high.

All NCI-CTCAE grade 3/4 laboratory values will be listed by participant, parameter and date. Abnormal values will be listed for laboratory values that cannot be graded.

Other laboratory parameters will be listed, as appropriate. These will include FSH test (females only), HIV 1/2, HCV, HBV, and pregnancy test (serum and urine) results (females only).

9.4 Vital Signs

Vital signs include body temperature (°C), respiratory rate (breaths/min), heart rate (beats/min), systolic and diastolic blood pressure (mmHg), height (cm), weight (kg) and BMI (kg/m^2). Descriptive statistics of observed values and change from baseline by analysis visit and time point will be presented.

A summary of abnormal vital signs will be presented. The criteria for identifying abnormal vital signs are presented below.

Parameter	Abnormal Criteria
Systolic blood pressure	• ≥180 mmHg and increase from baseline of ≥20 mmHg • ≤90 mmHg and decrease from baseline of ≥20 mmHg • Decrease from baseline ≥20 mmHg
Diastolic blood pressure	• ≥105 mmHg and increase from baseline of ≥15 mmHg • ≤50 mmHg and decrease from baseline of ≥15 mmHg • Decrease from baseline ≥10 mmHg
Heart rate	• ≥150 beats/min and increase from baseline ≥15 beats/min • ≤50 beats/min and decrease from baseline ≥15 beats/min

Weight	• Increase from baseline ≥7% • Decrease from baseline ≥7%

A listing of vital signs data will be provided.

9.5 ECG

ECG results will be tabulated by analysis visit as "normal", "abnormal, not clinically significant" or "abnormal, clinically significant". A shift from baseline table will also be presented. Shift tables at baseline versus worst post-baseline assessment, end of treatment and end of study will be produced.

A listing of ECG test results will be provided.

9.6 Physical Findings

A listing of physical examination data will be provided.

9.7 [redacted]

[redacted]

[redacted]

9.8 Ophthalmic Variables

9.8.1 Slit Lamp Biomicroscopy

The results (normal/abnormal not clinically significant/ abnormal clinically significant, unless otherwise specified) of the following ophthalmic variables will be summarized by eye and analysis visit.

- Motility (Abnormal, Normal)
- Lids / Lacrimal / Lashes (Abnormal, Normal)
- Conjunctiva / Sclera (Abnormal, Normal)
- Cornea (Abnormal, Normal)
- Corneal Staining (0,1+,2+3+,4+)
- Anterior Chamber (Abnormal, Normal)
- Anterior Vitreous (Abnormal, Normal)
- AC Cells (0, 0.5+, 1+, 2+, 3+, 4+)
- AC Flare (0, 0.5+, 1+, 2+, 3+, 4+)
- Iris/Anterior Chamber (Abnormal, Normal)
- Pupils (Abnormal, Normal)
- Lens Status (Aphakic, Pseudo-phakic, Phakic)
- Lens Phakic Grade by type (Nuclear, Cortical, Posterior subcapsular): (0,1,2,3,4)

9.8.2 Fundoscopy

The results (normal/abnormal, abnormal specify) for the following variables will be summarized by eye and analysis visit.

9.8.3 Intraocular Pressure

Intraocular Pressure (IOP) will be summarized by visit. An additional tabular summary of the percentage of subjects in categories of IOP (<15 mmHg, 15 to <20 mmHg, 20 to <25 mmHg, 25 to <30 mmHg, ≥30 mmHg) will be presented by analysis visit.

9.8.4 Manual Measurement of Lid Retraction

Observed and change from baseline will be summarized by analysis visit. An additional tabular summary of the percentage of subjects in categories of change from baseline (<2 mm, ≥2 mm) will be presented by analysis visit.

10. Reference

Craig B, Rand K. Choice Defines QALYs. A US Valuation of the EQ-5D-5L Med Care 2018;00: 000–000

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Signer Events	Signature	Timestamp
[redacted] Viridian Therapeutics Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Pre-selected Style Signature ID: [redacted] Using IP Address: [redacted] With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 5/21/2025 5:40:19 AM Viewed: 5/21/2025 12:18:34 PM Signed: 5/21/2025 12:25:29 PM
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[redacted] [redacted] Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Pre-selected Style Signature ID: [redacted] Using IP Address: [redacted] With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 5/21/2025 5:40:20 AM Viewed: 5/21/2025 9:38:21 AM Signed: 5/21/2025 9:39:08 AM
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[redacted] [redacted] Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Pre-selected Style Signature ID: [redacted] Using IP Address: [redacted] With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 5/21/2025 5:40:19 AM Viewed: 5/21/2025 5:40:41 AM Signed: 5/21/2025 5:41:09 AM
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[redacted] [redacted] [redacted] Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Pre-selected Style Signature ID: [redacted] Using IP Address: [redacted] With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 5/21/2025 5:40:20 AM Viewed: 5/21/2025 11:51:37 PM Signed: 5/21/2025 11:52:42 PM
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Envelope Sent	Hashed/Encrypted	5/21/2025 5:40:20 AM
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