STATISTICAL ANALYSIS PLAN

Protocol: LT4032-301

European Trial Number: 2017-000846-23

Efficacy and safety assessment of T4032 (unpreserved bimatoprost 0.01%) *versus* Lumigan® 0.01% in ocular hypertensive or glaucomatous patients

Phase III, international, multicentre, randomised, 2 parallel groups, investigator-masked, 3-months treatment duration

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APPROVALS

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ABBREVIATIONS

AE	Adverse Event
ANCOVA	Analysis of Covariance
ATC	Anatomic Therapeutic Chemical
BCVA	Best-Corrected Visual Acuity
CI	Confidence Interval
CFS	Corneal Fluorescein Staining
CMH	Cochran-Mantel-Haenszel
COVID	Coronavirus Disease
e-CRF	Electronic Case Report Form
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
IOP	Intra Ocular Pressure
ITT	Intent-To-Treat
IWRS	Interactive Web Response System
LOCF	Last Observation Carried Forward
MedDRA	Medicinal Dictionary for Regulatory Activities
m-ITT	modified Intent-To-Treat
MMRM	Mixed Model for Repeated Measures
PP	Per Protocol
PT	Preferred Term
Q1	First quartile
Q3	Third quartile
REML	Restricted Maximum Likelihood
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
WHO-DD	World Health Organisation-Drug Dictionary

INTRODUCTION

This Statistical Analysis Plan (SAP) describes the statistical analyses to be performed on study T4032-301, contains the definition of analysis sets and protocol deviations, defines derived data, and specifies the methodology for analysing primary and secondary efficacy endpoints and safety endpoints.

This SAP is based on:

1. Study Protocol final version 3.0 dated on 05-JUL-2019 and addendum version 1.0 dated on 05-JUN-2020
2. Electronic-Case Report Form (e-CRF) final version 2.0 dated on 31-MAR-2019

The analyses closely follow the ICH guidelines for industry on topic E3 - Structure and Content of Clinical Study Reports and E9 - Statistical Principles for Clinical Trials.

1 DESCRIPTION OF THE STUDY

1.1 Study objectives

1.1.1 Primary objective

The primary objective of the study is to demonstrate the non-inferiority of T4032 unpreserved eye drops compared to Lumigan® 0.01% in terms of efficacy.

1.1.2 Secondary objective(s)

The secondary objectives of this study are to evaluate the safety and efficacy of T4032 versus Lumigan® 0.01%.

1.2 Study design

1.2.1 Description

This is a phase III, international, multicentre, randomised, two parallel groups, investigator-masked, 3-month treatment duration. It was planned to randomise 400 patients. Considering a screen failure rate of about 40%, 668 patients were planned to be selected in order to have 400 randomised patients.

1.2.2 Schedule of assessments and study procedures

All patients are expected to attend 4 visits at the investigator centre during the course of the study followed by a phone call:

- Visit #1: Day -42 or Day -49 ±3 days (Screening Visit) (respectively before or after Clinical Study Protocol amendement 1 – 05JUL2019)
- Visit #2: Day 1 (Randomisation Visit)
- Visit #3: Week 6 (Day 42±3 days)
- Visit #4: Week 12 (Day 84±7 days) (Final Visit)
- Follow-up phone call: Week 16 (Day 112±7 days)

FLOW CHART: Schedule of visits and procedures

	Visit# 1 Screening Visit *Day -42 or Day -49* (±3 days)*	**14 or7 days before visit#2***	**Visit# 2 Randomisation Visit** *Day 1*		**Visit# 3** *Day 42 (±3 days) Week 6*		**Visit# 4 Final Visit or premature discontinuation visit** *Day 84 (±7 days) Week 12*		**Follow-up Phone call** *Day 112 (±7 days) Week 16*
	First ophthalmologist investigator		**First ophthalmologist investigator**	**Second investigator**	**First ophthalmologist investigator (the same as Day 1)**	**Second investigator**	**First ophthalmologist investigator (the same as Day 1)**	**Second investigator**	
Informed consent	X								
Demography	X								
History of glaucoma or ocular hypertension	X								
Ocular medical and surgical history (other than the studied disease)	X								
Systemic medical and surgical history	X								
Previous and concomitant ocular/non ocular treatments	X		X			X		X	X[11]
Ocular symptoms throughout the day [1]	X			X		X		X	
Ocular symptoms upon instillation [1]						X		X	
Far Best Corrected Visual Acuity (BCVA)	X		X				X		
Intra-Ocular Pressure (IOP) assessment [2]	X		X		X		X		
Fundus examination	X[3]						X[4]		
Central corneal thickness measurement	X[3]								
Automated visual field	X[3]						X[4]		
Slit lamp examination [6]	X		X		X		X		
Corneal fluorescein staining (Oxford grading scheme)	X		X		X		X		
Conjunctival hyperaemia (McMonnies scale)	X		X		X		X		
Pregnancy test [7]	X		X			X		X	
Adverse event (AE)			X	X	X	X	X	X	X
Verification of inclusion and exclusion criteria / Patient status	X		X						
Run-in treatment (Azopt®) dispensation [8]	X								
Run-in treatment /Wash-out compliance				X					

Wash-out[5]

Randomisation (IWRS)				X					
Investigational Medical Product (IMP) dispensation (9)				X		X			
IMP (T4032 or Lumigan®) compliance						X		X	
Efficacy assessment by the investigator (10)			X		X		X		
Ocular tolerance assessment by the investigator (10)			X		X		X		
Ocular tolerance assessment by the patient (10)			X			X		X	

*Respectively before or after Clinical Study Protocol amendement 1 – 05JUL2019

In case of premature discontinuation during the run-in/wash-out period or patient non-eligibility at visit#2, the investigator must perform the evaluations described for the randomization visit (visit #2) except to IOP measurements at 10:00 and 16:00, pregnancy test, randomization and IMP dispensation.

All the ocular assessments have to be performed in both eyes.

(1) Ocular symptoms (irritation/burning, stinging, itching, tearing, eye dryness feeling, foreign body sensation), scored using 0-3 scale, will be collected by the investigator /delegate.

(2) At Screening Visit, one IOP measurement should be performed at 08:00 (± 30 minutes). At Day 1, Day 42/Week 6 and Day 84/Week 12, IOP should be measured at three time points: 08:00, 10:00 and 16:00 (each ± 30 minutes) with a.m. measurements of IOP at least 2 hours apart. IOP measurements should be done at the same hours (± 30 min) than Day 1, by the same investigator and using the same technique (Goldmann applanation tonometer) for all visits.

(3) To be performed if fundus examination / central corneal thickness measurement / automated visual field not done within the previous 12 months and/or results dating from the last 12 months not available.

(4) To be performed only if the IOP is not stable at the Week 12 visit or if the ophthalmologist judges that it is necessary.

(5) Azopt® must be stopped for 2 weeks before the Randomisation Visit.

(6) Slit lamp examination: Score of each ocular sign (blepharitis, eyelid oedema, iris pigmentation modification, abnormal eyelashes aspect, folliculo-papillary conjunctivitis or other ocular abnormality) will be recorded in each eye using 0-3 scale.

(7) Urinary test to be done for childbearing potential women.

(8) Run-in treatment (Azopt®) will be instilled by the patient one drop in each eye twice a day (morning and evening) for 5 weeks.

(9) One drop of IP (T4032 or Lumigan®) will be instilled by the patient in each eye once daily at 20:00 (± 1 hour) for 12 weeks.

(10) Efficacy and ocular tolerance will be assessed by the investigator and the patient as very satisfactory, satisfactory, not very satisfactory, or unsatisfactory.

(11) In case of AE, all treatments of the follow-up period will be collected.

1.3 Study endpoints

1.3.1 Primary efficacy endpoint

The primary efficacy endpoint is the change in Intra-Ocular Pressure (IOP) from baseline (Day 1) to Week 12 at three time points (08:00, 10:00 and 16:00) in the worse eye.

The worse eye is defined as the eligible eye with the highest IOP at baseline at 08:00. In case of no IOP difference between both eyes, the right eye will be considered the worse eye.

1.3.2 Secondary efficacy endpoints

The secondary efficacy endpoints are:

- Change in IOP from baseline to Week 12 at three time points (08:00, 10:00 and 16:00) in the contralateral eye
- Change in IOP from baseline to Week 6 at three time points (08:00, 10:00 and 16:00) in the worse eye and in the contralateral eye
- Efficacy assessed by the investigator at Week 6 and Week 12

1.3.3 Safety endpoints

Safety and tolerability endpoints are:

- Conjunctival hyperaemia on McMonnies scale in each eye at Week 6 and Week 12
- Change from baseline of conjunctival hyperaemia on McMonnies scale in three classes (improvement, no change, worsening) at Week 6 and Week 12
- Score of each ocular symptom throughout the day and the sum of these scores
- Score of each ocular symptom upon instillation and the sum of these scores
- Score of each ocular sign
- Corneal fluorescein staining (CFS) on Oxford scale
- Far Best Corrected Visual Acuity expressed in LogMar
- Ocular tolerance assessed by the investigator
- Ocular tolerance assessed by the patient
- Ocular and systemic adverse events (AEs) by System Organ Class (SOC) and Preferred Term (PT)

1.4 Study treatments

1.4.1 Treatment groups

Run-in treatment/wash out

There is one run-in treatment with the following dose regimen:

- Azopt®: a preserved brinzolamide 10mg/ml eye drops suspension in 5 mL multi-dose container. It is a white to off-white suspension

During the run-in period, the patient should instill one drop in each eye twice a day, morning and evening for 5 weeks. The Azopt® treatment must be stopped 2 weeks or 1 week before the randomisation visit (respectively before or after Clinical Study Protocol amendement 1 – 05JUL2019).

Treatment period

There are two groups of treatment with the following dose regimen:

- T4032: a preservative-free bimatoprost 0.01% eye drops gel in single-dose container. It is a sterile, colourless and opalescent gel

- Lumigan® 0.01%: a preserved bimatoprost 0.1 mg/ml eye drops solution in 3 mL multi-dose container. It is a colourless solution

At the randomisation visit, the patient was randomly assigned to receive T4032 or Lumigan® 0,01%. The patient should instil one drop once daily at 20:00 (±1 hour) in the conjunctival sac of each eye for 12 weeks.

1.4.2 Randomisation

1.4.2.1 Randomisation procedure

The randomisation code list stratified by site was generated by Aixial. Patients were randomised on a 1:1 basis to T4032 or Lumigan® 0.01%. The investigational medicinal product (IMP) (T4032 or Lumigan®) was allocated to the patients according to randomisation using an interactive web response system (IWRS).

1.4.2.2 Masking

This is an investigator-masked clinical study. The first ophthalmologist investigator should therefore remain masked to the IMP, and not dispense or receive the returned medication from the patients.

Masking is achieved by providing the two IMPs (T4032 and Lumigan® 0.01%) in identical cardboard containers and by identifying each IMP by an IMP number.

The code should not be broken except:

- in case of medical emergency (where knowledge of the IMP received would affect the treatment of the emergency)
- or when it is a regulatory requirement

If an emergency code breaking becomes necessary, the investigator should notify the Sponsor before code breaking. The investigator and/or pharmacist are responsible for accessing the IWRS to obtain the code of the IMP (T4032 or Lumigan®) allocated to the patient. When a code is broken, the date, time and reason must be recorded in the patient's source documentation as well as in the e-CRF, and in any associated Serious AE (SAE) report. The IMP code should not be disclosed in these documents.

During the SAE assessment procedure by the Global Drug Safety & Medical Information Department, the code might be broken for reporting purposes. The relevant THEA, Contract Research Organisation, and investigator staff remains unaware of the identification of the IMP (T4032 or Lumigan®).

The overall randomisation list will only be broken for data analysis after database lock

1.5 Sample size considerations

The sample size determination was based on the primary efficacy endpoint, *i.e.,* the change in IOP at the three time points (08:00, 10:00, 16:00) after 12 weeks of treatment, in the worse eye.

Non-inferiority of T4032 *versus* Lumigan® 0.01% will be tested with a non-inferiority margin of 1.5 mmHg. Non-inferiority will be concluded if it is achieved for each of the three time points 08:00, 10:00 and 16:00.

The evaluation will be based upon a two-sided 95% confidence interval (CI) on the difference in mean change in IOP after 12 weeks of treatment.

With data available for 180 patients in each arm, there is more than 90% power to show that the T4032 unpreserved eye drops is non-inferior to Lumigan® 0.01% preserved eye drops. The hypothesis was based on the 1.5 mmHg margin, assuming no difference between the two groups (average difference of 0 mmHg), and a standard deviation of 3 mmHg and correlation between time-points of 0.7 on the primary efficacy variable.

Evaluable patients are defined as randomised patients having received at least one dose of IMP (T4032 or Lumigan®) and with at least one post-randomisation efficacy assessment.

Accounting for a 10% dropout/non-evaluable rate, 400 initially treated patients were expected to be randomised.

The sample size of 400 randomised patients is also justified to collect enough safety data. Number of screened patients depends on the screen failure rate and was estimated at 668 patients.

At the end of the recruitment period, 723 patients were screened and 485 patients were randomised.

2 ANALYSIS SETS

The following analysis sets will be considered.

2.1 Safety set and Azopt® Safety Set

The Safety set will include all enrolled patients, having received at least one dose of IMP (T4032 or Lumigan®) and considered as-treated. Safety endpoints will be analysed on the Safety set.

The Azopt® Safety set will include all enrolled patients, having received at least one dose of Azopt®.

Note: Enrolled patients will be patients who have signed the informed consent and for whom the screening visit has been recorded in the e-CRF.

2.2 Intent-to-treat set

The Intent-to-Treat (ITT) set will include all randomised patients and considered as-randomised (*i.e.,* according to the randomisation at Day 1). The ITT set will be considered as a secondary population and will be used for sensitivity analyses for the primary efficacy endpoint.

2.3 Modified intent-to-treat set

The modified ITT (m-ITT) set will include all randomised patients having received at least one dose of IMP (T4032 or Lumigan®), with at least one baseline and one post randomisation efficacy assessment and considered as-randomised (*i.e.,* according to the randomisation at Day 1). The m-ITT set will be the primary population for efficacy analysis.

2.4 Per-protocol set

The Per-protocol (PP) set will include all m-ITT patients without any major protocol violation. Deviations from the protocol, including violations of inclusion/exclusion criteria will be detailed in a separate document and assessed as “minor” or “major” in cooperation with the Sponsor during a blind review meeting prior to the database lock. The PP set will be considered as a secondary population.

3 GENERAL CONSIDERATIONS FOR DATA ANALYSES

Statistical analyses will be performed by the Biostatistics unit of AIXIAL. Analyses will be conducted with SAS® software, version 9.4 (SAS Institute, North Caroline, USA).

Continuous data will be described in summary tables presenting, for each treatment group (and for the overall population for baseline descriptions), the number of non-missing observations (n), mean, standard deviation (SD), median, lower quartile (Q1), upper quartile (Q3), minimum and maximum, and 95% CI of the mean/median.

Categorical data will be described in summary tables presenting, for each treatment group (and for the overall population for baseline descriptions), the number of non-missing observations (n), count and percentage of each modality, and 95% CI.

95% CI of a proportion will be calculated using the scoring method of Wilson without continuity correction:

Lower Limit = $\frac{2np + z^2 - z\sqrt{z^2 + 4npq}}{2\left(n + z^2\right)}$ Upper Limit = $\frac{2np + z^2 + z\sqrt{z^2 + 4npq}}{2\left(n + z^2\right)}$

with n = number of non-missing observations
p = percentage
q = 1 – p
z = 1.96 for two-sided 95%CI

Except for minimum and maximum, descriptive statistics will be presented with one more decimal than the recorded value.

For all variables, the number of missing values will also be reported in the tables, but they will not be counted for the percentage calculation (categorical data).

Variables recorded for each eye will be described separately for the worse eye and for the other eye (if applicable).

An eye is eligible if inclusion and exclusion (ophthalmological criteria) are respected at screening visit and baseline.

The worse eye is defined as the eligible eye with the highest IOP at baseline at 08:00. In case of no IOP difference between both eyes, the right eye will be considered the worse eye.

Quantitative parameters will be compared between groups using Mixed Model for Repeated Measures (MMRM) or Analysis of Covariance (ANCOVA) model. Assumptions underlying the MMRM (respectively ANCOVA for the sensitivity analyses) will be checked:

- A histogram of residuals will be plotted to check the assumption of normality
- The underlying assumptions of normality of residuals for mixed model will also be checked by using Skewness and Kurtosis statistics
- Normal probability plot and QQ-plot will be performed to check the assumption of normality
- Residuals will be plotted against predicted values to check the assumption of heteroscedasticity
- Plots of residuals and studentised residuals will be performed to detect outliers. Cook’s distance will also be computed. If any outliers are detected, then main model will be performed with and then without them
- For ANCOVA models, Levene's test will also be performed to check the homogeneity of variances

For each model (MMRM or ANCOVA), if there is a strong violation of normality assumption (or violation of homogeneity of variances for ANCOVA), in addition to the initial model, a rank transformation will be done, and the model will be applied to ranks.

The acceptable risk of error for the statistical tests will be set at 5%, except for treatment by covariates interactions. For those interactions, the level of significance will be set at 7%.

For ordered qualitative variables, treatment groups will be compared using Cochran-Mantel-Haenszel (CMH) test stratified by country, with modified ridit scores and “row mean score differ” option.

Tables and Listings will be provided in separated documents except the listing of Deaths, Other Serious adverse events, discontinuations due to adverse events and other adverse events of special interest (see Section 7.10.3).

All individual data will be described in the listings 16.2, by treatment and by patient as follows: discontinued patients, protocol deviations, patients excluded from the efficacy analysis, demographic data, compliance, individual efficacy response data, adverse event listings, listing of individual laboratory measurements.

All individual data of eCRF will be described in the listing 16.4, by patient.

3.1 Display of analysis results

The following labelling for treatment groups will be used in statistical tables: “T4032” and “Lumigan”.

3.2 Interim analyses

No interim analysis will be performed.

3.3 Centre effect management

For efficacy analysis, centre effect will not be tested, but country effect will be tested (Section 6.1.3).

3.4 Subgroup analyses

No subgroup analysis is planned except in case of statistically significant and qualitative treatment by covariate interaction.

3.5 Other strata and covariates

Country, wash-out duration factor and possible impact of COVID-19 pandemic will be included in all models as covariate, and CMH test used for ordered qualitative variables will be stratified by country.

Baseline value will be included in all MMRM and ANCOVA as covariate:

- For analyses on the change from baseline in IOP, baseline IOP will be included as covariate in MMRM and ANCOVA
- For analysis on the change from baseline in total symptoms score throughout the day, corresponding baseline value will be included as covariate in MMRM

3.6 Multiple comparisons and multiplicity

There is a single primary efficacy endpoint in the study (change from baseline in IOP at Week 12 in the worse eye) and non-inferiority will be achieved if the non-inferiority margin of 1.5 mmHg is met at each of the time point assessments: 08:00, 10:00 and 16:00. Other efficacy measures are defined as of secondary importance. Consequently, comparisons between T4032 and Lumigan® 0.01% will be performed at a two-sided significance level of 5% and no adjustment of the type I error rate will be made.

4 DATA HANDLING CONVENTIONS

4.1 Visit windows

All data will be organised and analysed according to the actual observed visits.

Moreover, for IOP, the recorded value should be allocated to the most appropriate time point.

Time point	Interval of time point
08:00	Until 09:00
10:00	From 9:01 to 13:00
16:00	From 13:01

If more than one record occurs within the same timepoint then the following rule should be applied: the closest non-missing result to the scheduled timepoint should be used. To be noted as the record not used will be reclassified in another timepoint if it occurs within 30min of interval of timepoint.

4.2 Premature discontinuation and missing data

A patient who prematurely discontinues from the study should have, if possible, a premature discontinuation visit with the assessment planned on the final visit. This visit should take place as soon as possible after the patient stops taking the IMP.

For patients who prematurely discontinue from the study during the COVID-19 outbreak, the premature discontinuation visit was requested by visit on site if possible, else by phone.

For these patients who prematurely discontinue from the study, evaluations performed during the premature withdrawal visit will be considered as the first unobserved scheduled visit whatever their actual dates. If the premature withdrawal visit occurs after the discontinuation of the treatment, evaluations will be reviewed during the blind review meeting prior to the database lock to confirm their use thereof.

Otherwise, missing data will not be replaced, except for sensitivity analysis of the primary endpoint (see Section 6.1.2). Based on the Last Observation Carried Forward (LOCF) method, missing values at Week 12 will be replaced by the post-randomisation last available value. For the primary efficacy endpoint, a sensitivity analysis considering the post-randomisation last available value will be performed for the contralateral eye (see Section 6.2.1).

4.3 Derived and transformed data

Following derived data used for analyses will be calculated.

4.3.1 Country Grouping

The patients from the following country will be pooled into one group: Canada, Hungary, Mauritius, and UK, as outsiders Countries.
After this grouping, if the model fails to converge due to low numbers of patients per treatment arm by grouping countries, other grouping should be reconsidered and explained in the footnote.

4.3.2 Baseline

Baseline will be defined for each assessment as an evaluation before the first instillation of the IMP:

- For IOP, the value recorded at 08:00 at Day 1, respectively at 10:00 and at 16:00, will be the baseline for analysis of IOP at 08:00, respectively at 10:00 and at 16:00
- For visual field, fundoscopy and corneal thickness, the value recorded at screening visit will be the baseline
- For others parameters, the value recorded at Day 1, will be the baseline for analysis

4.3.3 Possible impact of COVID-19 pandemic

To investigate the biais of recruitment before and after the recruitment interruption, patients will be classified with or without possible impact of COVID-19 pandemic based on their screening visit date respectively up to and including 18-MARS-2020, or after the 18-MAR-2020.

4.3.4 Time from diagnosis

Time from diagnosis (months) will be calculated as:
(Date of randomisation visit (Day 1) – Date of diagnosis) / 365.25 x 12.
If the day is missing and month is present the 15th day of the month will be used. If year is present and day and month are missing, the time to diagnosis will be calculated as (Year of randomisation visit (Day 1) – Year of diagnosis) x 12.

4.3.5 Wash-out duration

Wash-out duration (days) will be calculated as (Date of randomisation visit – Date of last Azopt® instillation).

4.3.6 Duration of Azopt®

Duration of Azopt® (days) will be calculated as (Date of last instillation – Date of first instillation) + 1. If the day or the month is missing for one of the dates, the duration of Azopt® will be missing.

4.3.7 Duration of T4032 or Lumigan®

Duration of T4032/Lumigan® (days) will be calculated as (Date of last instillation at Week 12 or premature discontinuation visit – Date of first instillation at Day 1) + 1. If the day or the month is missing for one of the dates, the duration of T4032/Lumigan® will be missing.
Note: This duration is also called time of exposure.

4.3.8 Compliance of Azopt®

Compliance of Azopt® will be calculated for the worse eye and the contralateral eye separately.

Compliance of* Azopt® *(%)

Compliance of Azopt® will be calculated for each eye as follows:
(Actual number of instillations of Azopt®) / (Theoretical number of instillations of Azopt®) x 100 with:

- Theoretical number of instillations of Azopt® = (Date of randomisation visit – 8 or – 15 (respectively before or after Clinical Study Protocol amendement 1 – 05JUL2019 based on the recorded information on the e-CRF) – Date of screening visit + 1) *2, (*2: as patients should instil one drop twice a day in each eye)
- Maximum number of instillations of Azopt® = (Date of last instillation – Date of first instillation + 1) *2, as patients should instil one drop twice a day in each eye
- Actual number of instillations:
  - If no change in Azopt® instillation is recorded in the e-CRF, the actual number of instillations will be considered as equal to the maximum number of instillations
  - If changes in Azopt® instillation are recorded in the e-CRF, the actual number of instillations will be equal to:

    (Date of last instillation – Date of first instillation + 1) *2

    – [(∑ Number of days with number of instillations per day in the corresponding eye=0 x 2)

    + ∑ Number of days with number of instillations per day in the corresponding eye=1)]

    + ∑ Number of days x (Number of instillations per day in the corresponding eye when number of instillations is >2 -2)

4.3.9 Compliance of T4032 or Lumigan®

Compliance will be calculated for the worse eye and the contralateral eye separately. For the calculation, the premature discontinuation is taken into account (reclassification of visits).

Compliance (%) from Day 1 to Week 6

Compliance from Day 1 to Week 6 will be calculated for each eye as follows:
(Actual number of instillations from Day 1 to Week 6) / (Theoretical number of instillations from Day 1 to Week 6) x 100 with:

- Theoretical number of instillations = (Date of Visit V3 – Date of randomisation visit), as patients should instil one drop of IMP once daily in each eye
- Maximum number of instillations = (Date of last instillation* – Date of first instillation + 1), as patients should instil one drop of IMP once daily in each eye
- Actual number of instillations:
  - If no change in the IMP instillation is recorded from Day 1 to Week 6 in the e-CRF, the actual number of instillations will be considered as equal to the maximum number of instillations
  - If changes in the IMP instillation are recorded from Day 1 to Week 6 in the e-CRF, the actual number of instillations will be equal to: Date of last instillation* – Date of first instillation + 1 – ∑ Number of days with number of instillations per day in the corresponding eye=0 + ∑ Number of days x (-1 + Number of instillations per day in the corresponding eye when number of instillations is >1)

Compliance (%) from Week 6 to Week 12

Compliance from Week 6 to Week 12 will be calculated for each eye, for patients not withdrawn before Week 6 as follows:
((Actual number of instillations from Week 6 to Week 12) / (Theoretical number of instillations from Week 6 to Week 12)) x 100 with:

- Theoretical number of instillations = (Date of Visit V4 – Date of V3), as patients should instil one drop of IMP once daily in each eye
- Maximum number of instillations = (Date of last instillation* – Date of first instillation + 1), as patients should instil one drop of IMP once daily in each eye
- Actual number of instillations:
  - If no change in the IMP instillation is recorded from Week 6 to Week 12 in the e-CRF, the actual number of instillations will be considered as equal to the maximum number of instillations
  - If changes in the IMP instillation are recorded from Week 6 to Week 12 in the e-CRF, the actual number of instillations will be equal to: Date of last instillation* – Date of first instillation + 1 – ∑ Number of days with number of instillations per day in the corresponding eye=0 + ∑ Number of days x (-1 + Number of instillations per day in the corresponding eye when number of instillations is >1)

Compliance (%) from Day 1 to Week 12

Compliance from Day 1 to Week 12 will be calculated for each eye as follows:
((Actual number of instillations from Day 1 to Week 6 + Actual number of instillations from Week 6 to Week 12) / (Theoretical number of instillations from Day 1 to Week 6 + Theoretical number of instillations from Week 6 to Week 12)) x 100.

For patients withdrawn before Week 6, actual and theoretical numbers of instillations from Week 6 to Week 12 will not be considered for the calculation.

Individual data regarding changes in the study product instillation will be examined during a blind review meeting before database lock. In case of missing data (missing date(s), missing number of days or missing number of instillations per day), rules for calculation will be decided on a case by case basis.

* If the date of the last instillation is on/after the date of the Visit, the last date of instillation will be replaced by the day before the date of the Visit. In this case, the date of the Visit will be assumed as

the date of the first instillation for the subsequent treatment period, if applicable (I.e., for Compliance from Week 6 to Week 12).

4.3.10 Change from baseline

Change from baseline will be calculated as the difference:
Assessment at the visit – Assessment at baseline.

4.3.11 Change from baseline in classes

Change from baseline in classes will be defined as detailed below:

In four classes:

- Improvement (Decrease of score from baseline): Change from baseline <0
- Absence stable: Change from baseline = 0 and absence of symptoms
- Presence stable: Change from baseline = 0 and presence of symptoms
- Worsening (Increase of score from baseline): Change from baseline >0

In three classes compared to 0:

- Improvement (Decrease of score from baseline): Change from baseline <0
- No change: Change from baseline = 0
- Worsening (Increase of score from baseline): Change from baseline >0

In three classes compared to -1/1:

- Improvement of more than 1 point: Change from baseline <-1
- No significant change: Change from baseline ≥-1 and ≤1
- Worsening of more than 1 point: Change from baseline >1

4.3.12 IOP value

The IOP value will be calculated for each eye as follows:

- If the first 2 readings differ by 2 mmHg or less, the mean IOP will be the average of the first 2 readings, regardless of the third reading
- If the first 2 readings differ by more than 2 mmHg and the third reading is recorded, the mean IOP will be the average of the 3 readings
- If the first 2 readings differ by more than 2 mmHg and the third reading is not recorded, the mean IOP will be the average of the first 2 readings
- If only one reading is recorded, this single reading will be used for assessment of the mean IOP

4.3.13 Mean diurnal IOP

Mean diurnal IOP will be calculated as the mean of the IOP value at 08:00, 10:00 and 16:00. If any individual IOP is missing, the mean diurnal IOP will also be missing.

Change from baseline of mean diurnal IOP will be calculated as defined in Section 4.3.10.

4.3.14 Total score of subjective ocular symptoms throughout the day

The total score of subjective ocular symptoms throughout the day (ranging from 0 to 18) will be calculated by adding the individual scores of the 6 following symptoms: irritation/burning, stinging, itching, tearing, eye dryness feeling, foreign body sensation. If any individual score is missing, the total score will also be missing.

4.3.15 Total score of subjective ocular symptoms upon instillation

The total score of subjective ocular symptoms upon instillation (ranging from 0 to 18) will be calculated by adding the individual scores of the 6 following symptoms: irritation/burning, stinging, itching, tearing, eye dryness feeling, foreign body sensation. If any individual score is missing, the total score will also be missing.

4.3.16 Far best corrected visual acuity

Far best corrected visual acuity will be calculated in Log Mar as: Log_{10} (10/ Visual acuity) with Visual acuity expressed in /10 unit.

4.3.17 AE time to occurence

Time to occurence (days) of an AE will be calculated as follows: Date of onset – Date of IMP first instillation.

4.3.18 AE duration

Duration (days) of an AE will be calculated as follows: (Date of recovery – Date of onset) + 1.

5 DESCRIPTION OF THE STUDY POPULATION

5.1 Disposition of patients

The number of enrolled patients will be presented overall. The number (%) of patients included in Azopt® Safety set will be presented overall. The number (%) of patients included in each other analysis set (Safety, ITT, m-ITT and PP) will be presented by treatment group and overall. It will also be presented by possible impact of COVID-19 pandemic classes.

The number (%) of patients by country will be presented by treatment group and overall, for each analysis set. The number (%) of patients by country will be also presented for patients who prematurely discontinued the study for COVID-19 crisis and by possible impact of COVID-19 pandemic classes for the Safety set.

The number (%) of patients per visit as considered in the analysis will be described by treatment group and overall for the Safety set, for the ITT set (if it differs from the Safety set) for the m-ITT set and for PP. It will also be described by possible impact of COVID-19 pandemic classes for each population.

A listing of patients with populations, treatment group (planned group and actual group), worse eye of the enrolled patients and possible impact of COVID-19 pandemic classes and a listing of visits and visits as considered in the analysis (see Sections 4.1 and 4.2) will be produced for the Safety set.

The number (%) of patients who prematurely discontinued the study and the primary reason for discontinuation will be presented by treatment group and overall for the Safety set, ITT set (if it differs from the Safety set) and m-ITT set. A listing will be produced presenting the patients who prematurely discontinued the study with the detailed reason for discontinuation. The number (%) of patients by country will be also presented for patients who prematurely discontinued the study and for those who prematurely discontinued for COVID-19 crisis.

The number (%) of patients with at least one major deviation, the number (%) of patients with only minor deviations (without major deviations) and the number (%) of patients with minor deviations (including those with major deviations) will be presented by treatment group and overall for the m-ITT set. The reasons for deviation will also be described for the m-ITT set and an individual patient data listing with all minor/major deviations will be provided. This description will also be performed possible impact of COVID-19 pandemic classes.

A listing of patients excluded from the Azopt® Safety, Safety, ITT, m-ITT and PP sets, presenting the reason for exclusion, will be produced on the enrolled patients' population.

5.2 Demographic and baseline characteristics

The demographic and baseline characteristics of the patients will be described overall and by treatment group for the m-ITT set, Safety set, ITT set (if it differs from the Safety set) and PP set.

The following characteristics will be summarised:

- Demographic characteristics:
  - Age (years) as continuous and in classes (<65, ≥65 years old)
  - Gender
  - Gender by age class (<65, ≥65 years old)
- Medical history (*)
  - Ocular medical history other than the studied disease
  - Systemic medical history
- Surgical history (*)
  - Ocular surgical history related to another disease than the studied one
  - Systemic surgical history

(*) Diagnoses (for medical history) and surgical procedures (for surgical history) will be coded using the Medicinal Dictionary for Regulatory Activities (MedDRA) version the most recent possible at the database lock. Number (%) of patients will be presented by SOC and PT by treatment group and overall.

- Ocular treatments (**)
  - Previous ocular treatments
  - Concomitant ocular treatments
- Non-ocular treatments (**)
  - Previous non-ocular treatments
  - Concomitant non-ocular treatments

(**) All previous and concomitant ocular and non-ocular treatments will be coded using the World Health Organisation-Drug Dictionary (WHO-DD version Q1 2018). Treatments will be summarised according to the Anatomical therapeutic chemical (ATC) class (level 2 and level 4) of the WHO-DD dictionary by treatment group and overall. A previous treatment will be defined as a treatment stopped prior to (or the same day as) the first instillation of T4032 or Lumigan®. A concomitant treatment will be defined as a treatment i) started after (or the same day as) the first instillation of the T4032/ Lumigan®, ii) started prior to and continued after the first instillation of the T4032/ Lumigan®. If the classification is not possible due to partial start/end date(s) of treatment, the treatment will be considered as concomitant.

- History of glaucoma or ocular hypertension:
  - Diagnosis in the worse and contralateral eye (Ocular hypertension / Primary Open Angle Glaucoma / Secondary Open Angle Glaucoma: Exfoliation Glaucoma / Secondary Open Angle Glaucoma: Pigmentary Glaucoma)
  - Time from diagnosis in the worse and contralateral eye (months)
  - Previous treatment (Bimatoprost/Latanoprost/Tafluprost/Travoprost/Other)
  - Surgical history related to the glaucoma or ocular hypertension in the worse and contralateral eye (by SOC and PT)
- Results of the automated visual field (Normal/Abnormal; If abnormal, clinically significant [Yes/No]) for the worse and the contralateral eyes
- Central corneal thickness measurement (µm) for the worse and contralateral eye as continuous and in classes (<555, ≥555 µm)
- Fundus examination (listing)
- IOP data during run-in period: Descriptive statistics will be performed on IOP at 08:00, for the worse and contralateral eye, at each assessment time (i.e., screened visit and randomisation visit). Change from screening to randomisation will be described. The descriptions will also be performed depending on the wash-out duration (≤8 days, >8 days).

Data regarding contraception status and pregnancy test results (for women) will be presented in an individual data listing (Section 16.2).

In addition, the following data will be described for the Safety set:

- Number of patients and cumulative time of exposure (in days)
- Number of patients and cumulative time of exposure (in days) by age group (<65 years old, ≥65 and <75 years old, ≥75 and <85 years old, ≥85 years old) and gender
- Number of patients and cumumative time of exposure (in days) by IMP exposure in classes (<1 month, ≥1 and <3 months, ≥3 months)

Demographics characteristics, history of glaucoma or ocular hypertension, automated visual field, central corneal thickness measurement, IOP data during run-in period, baseline values of IOP will be also presented for patients who prematurely discontinued the study for COVID-19 crisis for the Safety set, by possible impact of COVID-19 pandemic classes for m-ITT, Safety and PP sets and according to the following groups: Patients from ITT set included in m-ITT set versus Patients from ITT set not included in m-ITT set.

Baseline values of the efficacy and safety endpoints will be provided in statistical tables with assessments at Week 6 (if applicable) and Week 12 (see Sections 6 and 7).

5.3 Treatment exposure and compliance

The following data on the use of Azopt® will be summarised overall for the Azopt® Safety set and by treatment group for the m-ITT set:

- Duration of Azopt® (days)
- Frequency distribution of patients with any absence or modification of Azopt® instillation (Yes/No) from the first to the last instillation

The following data on the use of Azopt® will be summarised by treatment group for the m-ITT set:

- Compliance (%) for each eye from the first to the last instillation, as continuous variable and in categories (<80%, ≥80% and ≤120%, >120%)

Details of data relative to Azopt® instillation and modification of Azopt® instillation will be provided in individual data listing.

The following data on the use of the IMP T4032 or Lumigan® will be summarised overall and by treatment group for the Safety and m-ITT sets and it will also be summarised by possible impact of COVID-19 pandemic classes:

- Duration of treatment (days)
- Frequency distribution of patients with any absence or modification of instillation (Yes/No) from the first to the last instillation, between Day 1 and Week 6, Week 6 and Week 12, Day 1 and Week 12
- Frequency distribution of patients with any instillation time modifications (Yes/No) from the first to the last instillation, Day 1 and Week 6, Week 6 and Week 12, Day 1 and Week 12
- Compliance (%) for the worse and contralateral eye from the first to the last instillation, from Day 1 and Week 6, Week 6 and Week 12, Day 1 and Week 12, as continuous variable and in categories (<80%, ≥80% and ≤120%, >120%)

Details of data relative to IMP instillation, absence of instillations and instillation time modifications will be provided in individual data listings.

6 EFFICACY ANALYSIS

The primary efficacy endpoint will be primarily analysed on the m-ITT set. Sensitivity analyses will be performed on the ITT and PP sets. Secondary efficacy endpoints will be analysed on the m-ITT set and on PP set.

For efficacy variables, descriptions will be given by treatment group at each assessment time. Change from baseline will also be presented.

Of note, for analyses on change from baseline in IOP at 10:00 (respectively at 16:00) in the worse eye and in the contralateral eye, the baseline IOP is the IOP recorded at 10:00 (respectively at 16:00) at Day 1, before the first instillation.

6.1 Primary efficacy endpoint

The primary efficacy endpoint is the change from baseline in IOP (average of the 2 or 3 recorded values - see the calculation in Section 4.3.12) at Week 12 at the three time points (08:00, 10:00 and 16:00) in the worse eye (see the definition for the worse eye in Section 3).

Inferential analyses of the primary endpoint will aim to assess the non-inferiority of T4032 to Lumigan® 0.01%. The non-inferiority testing will be performed on the basis of a 95% CI for the difference between the two treatment groups in the change from baseline in IOP.

Descriptive statistics will be performed on IOP at 08:00, 10:00 and 16:00 for the worse eye at each assessment time (*i.e.,* baseline, Week 6 and Week 12). Change from baseline to Week 6 and change from baseline to Week 12 will be described as well. These descriptions will also be performed by country and by possible impact of COVID-19 pandemic classes.

6.1.1 Main analysis of the primary efficacy endpoint

The non-inferiority of T4032 to Lumigan® 0.01% on the change from baseline in IOP will be primarily tested using a MMRM approach. Three independent models will be performed, one for each time point (*i.e.,* at 08:00, 10:00 and 16:00). Each model will include as fixed factors, treatment, scheduled visit time point (Week 6 and Week 12), baseline IOP, wash-out duration, country as covariates, treatment by visit interaction, baseline IOP by visit interaction, and patient as random factor. The Restricted Maximum Likelihood (REML) estimation approach will be used, and the default covariance structure will be unstructured. Consistent with MMRM model fitting, no explicit imputation of missing assessments for a given visit time point will be performed. The 95% CI for treatment effect (difference T4032 - Lumigan® 0.01%) will be estimated at Week 12 in this model. Non-inferiority will be achieved if the upper bound of the 95% CI for the difference between treatment groups (T4032 - Lumigan® 0.01%) is lower than the margin of +1.5 mmHg for each of the three time points 08:00, 10:00 and 16:00.

The syntax with SAS using the MIXED procedure is detailed in Appendix 1.

6.1.2 Sensitivity analyses of the primary efficacy endpoint

Whilst patients who have missing data at Week 12 but who have an earlier recorded value (*i.e.,* Week 6) will be included in the MMRM primary analysis, the interpretability of the results from the primary model will depend on the missing data satisfying the Missing at Random. To support the validity of the conclusions drawn from this analysis, sensitivity analyses will be performed to explore the dropout pattern and its possible impact on treatment comparisons.

1) Missing values at Week 12 at 08:00, respectively at 10:00 and at 16:00, will be replaced by the post-randomisation last available value (*i.e.,* the Week 6-based IOP, if available) at 08:00, respectively at 10:00 and at 16:00, *i.e.,* based on LOCF method. The change from baseline in IOP at Week 12 will be analysed using an ANCOVA including treatment, baseline IOP, wash-out duration and country. Three independent ANCOVA will be performed, one for each time point (*i.e.,* at 08:00, 10:00 and 16:00). The adjusted mean treatment differences (T4032 - Lumigan® 0.01%) and their corresponding 95% CI will be estimated in these models to test the non-inferiority hypothesis.

2) The same analyses as the ones planned on the post-randomisation last available value will be performed on the observed value at Week 12 (*i.e.,* missing values at Week 12 will not be replaced). The change from baseline in IOP recorded at Week 12 will be analysed using an ANCOVA including treatment (T4032/Lumigan®), baseline IOP, wash-out duration and country. Three independent ANCOVA will be performed, one for each time point (*i.e.,* at 08:00, 10:00 and 16:00). The adjusted mean treatment differences (T4032 - Lumigan® 0.01%) and their corresponding 95% CI will be estimated in these models to test the non-inferiority hypothesis.

The syntax with SAS using the MIXED procedure is detailed in Appendix 1.

The primary analysis (*i.e.,* based on the MMRM approach) and the same sensitivity analyses presented here above will be performed in the ITT and PP sets.

6.1.3 Supporting analyses to check the validity of the main and sensitivity analyses

Possible treatment by covariate (baseline IOP, wash-out duration and country) interaction will be investigated in the separated MMRM models (resp. in the ANCOVA models for the sensitivity analysis) including the additional interaction term of interest for the m-ITT set.

The tests for interactions will be interpreted at the 7% level of significance.

The adjusted mean difference between treatment groups will be computed. If the p-value is lower than 7% and the interaction is qualitative, then the main model will be performed by covariate in classes.

The syntax with SAS using the MIXED procedure is detailed in Appendix 1.

6.1.4 Exploratory analysis of the primary efficacy endpoint

Possible covariate effect (Possible impact of COVID-19 pandemic) will be investigated in the MMRM model (resp. in the ANCOVA model for the sensitivity analysis). Covariate of interest and covariate by treatment interaction will be added to the main model on the m-ITT set.

The tests for interactions will be interpreted at the 7% level of significance.

The adjusted mean difference between treatment groups will be computed. If the p-value is lower than 7% and the interaction is qualitative, then the main model will be performed by inclusion period.

The impact of circadian rhythm will also be assessed by using time factor within the model, as patient nested in time, i.e. the model will include as fixed factors, treatment, scheduled visit time point (Week 6 and Week 12), time (8:00, 10:00 and 16:00), wash-out duration, country as covariates, treatment by visit interaction, treatment by time interaction, and patient nested in time. The adjusted mean treatment differences (T4032 - Lumigan® 0.01%) and their corresponding 95% CI will be estimated at each time at Week 12.

The syntax with SAS using the MIXED procedure is detailed in Appendix 1.

6.2 Secondary efficacy endpoints

Secondary efficacy endpoints will be analysed on the m-ITT set and on PP set.

6.2.1 Change from baseline in IOP

Descriptive statistics will be performed on IOP at 08:00,10:00 and 16:00 for the contralateral eye at each assessment time (*i.e.,* baseline, Week 6 and Week 12). Change from baseline to Week 6 and change from baseline to Week 12 will be described as well. These descriptions will also be performed by country and by possible impact of COVID-19 pandemic classes.

Using the same MMRM as for the main analysis of the primary efficacy endpoint, 95% CI of the adjusted mean difference between treatment groups will be estimated for:

- Change from baseline in IOP at Week 12 at 08:00, 10:00 and 16:00 in the contralateral eye
- Change from baseline in IOP at Week 6 at 08:00, 10:00 and 16:00 in the worse eye and in the contralateral eye

As for the primary endpoint, sensitivity analyses based on ANCOVA: using i) the LOCF method and ii) observed value at Week 12 will be performed for the contralateral eye. The 95% CI of the adjusted mean difference between treatment groups in the change from baseline to Week 12 in IOP will be provided.

ANCOVA on the change from baseline in IOP at Week 6 will also be performed for the worse eye and for the contralateral eye. The 95% CI of the adjusted mean difference between treatment groups will be provided.

The exploratory analysis on the impact of circadian rhythm will also be assessed at Week 6 by using the same model described in Section 6.1.4 for this parameter.

6.2.2 Other analyses on IOP

Frequency distribution of patients with IOP <18 mmHg and IOP ≥18 mmHg will be described by treatment group at each assessment time (Baseline [Day 1] at 08:00, 10:00 and 16:00, Week 6 at 08:00, 10:00 and 16:00 and Week 12 at 08:00, 10:00 and 16:00), separately for the worse eye and the contralateral eye.

Descriptive statistics will be performed on IOP at 08:00, 10:00 and 16:00 and on changes from baseline for the worse eye and for the contralateral eye at each assessment time (*i.e.,* baseline, Week 6 and Week 12), depending on the History of glaucoma or ocular hypertension.

Descriptive statistics will be performed on the mean diurnal IOP at baseline, Week 6 and Week 12. Change from baseline to Week 6 and change from baseline to Week 12 will be described.

6.2.3 Global assessment of efficacy by the investigator

Global judgment of efficacy by investigator will be assessed on a 4-point ordinal scale (Very satisfactory, Satisfactory, Not very satisfactory, Unsatisfactory).

Assessment of Azopt® efficacy will be presented by frequency distribution for each modality and frequency distribution after regrouping ‘very satisfactory’ with ‘satisfactory’, and ‘not very satisfactory’ with ‘unsatisfactory’.

Assessment of LT4032 or Lumigan® efficacy will be presented by frequency distribution for each modality and frequency distribution after regrouping ‘very satisfactory’ with ‘satisfactory’, and ‘not very satisfactory’ with ‘unsatisfactory’, at Week 6 and Week 12. After regrouping in 2 classes, comparison of treatment groups at Week 6 and Week 12 will be performed using a CMH test stratified by country.

7 SAFETY ANALYSIS

Safety endpoints will be analysed on the Safety set, by treatment group except when specify on the Azopt® Safety set overall.

7.1 Conjunctival hyperaemia – Slit lamp examination

Conjunctival hyperaemia assessed for each eye using the McMonnies photographic 6-point ordinal scale from 0 to 5 will be presented by frequency distribution at each assessment time (screening, baseline [Day 1], Week 6 and Week 12), for the worse eye and contralateral eye. Comparison between treatment groups will be performed at Week 6 and at Week 12, using a CMH test with modified ridit scores stratified by country, separately for the worse eye and for the contralateral eye.

In addition, frequency distribution of change from baseline will be presented for conjunctival hyperaemia at Week 6 and Week 12 for the worse eye and contralateral eye. The following categories will be defined and presented: i) improvement (*i.e.,* decrease of symptom score from baseline), absence stable, presence stable, worsening (*i.e.,* increase of symptom score from baseline), ii) improvement, no change, worsening, iii) improvement of more than 1 point (*i.e.,* change from baseline <-1, no significant change (*i.e.,* change from baseline ≥-1 and ≤1), worsening of more than 1 point (*i.e.,* change from baseline >1). Comparison of changes from baseline in 3 classes (improvement, no change, worsening) for conjunctival hyperaemia between treatment groups will be performed at Week 6 and Week 12, using a CMH test with modified ridit scores stratified by country, separately for the worse eye and for the contralateral eye.

7.2 Subjective ocular symptoms throughout the day

Subjective ocular symptoms throughout the day (irritation/burning, stinging, itching, tearing, eye dryness feeling, foreign body sensation) will be assessed using a 4-point ordinal scale from 0 to 3, 0 indicating no symptom and 3 indicating very disturbing symptom.

Frequency distribution of each symptom will be presented at screening, baseline (Day 1), Week 6 and Week 12. Comparison between treatment groups will be performed for each symptom at Week 6 and at Week 12 using a CMH test with modified ridit scores stratified by country.

The total score of the 6 symptoms, ranging from 0 to 18, will be calculated and presented for screening, baseline (Day 1), Week 6 and Week 12. Change in total score from baseline will also be described at Week 6 and Week 12. Comparison of the change from baseline in total score between treatment groups will be performed at Week 6 and Week 12 using an MMRM model. The model will include as fixed factors, treatment, scheduled visit time point (Week 6 and Week 12), baseline, wash-out duration and country, treatment by visit interaction and patient as random factor.

Data relative to other symptoms will be provided in individual data listing. Other symptoms will be coded using MedDRA dictionary version the most recent possible at the database lock.

Note: If the patient did not feel any ocular symptom throughout the day, each symptom will be scored 0.

7.3 Subjective ocular symptoms upon instillation

Subjective ocular symptoms upon instillation (irritation/burning, stinging, itching, tearing, eye dryness feeling, foreign body sensation) will be assessed using a 4-point ordinal scale from 0 to 3, 0 indicating no symptom and 3 indicating very disturbing symptom.

Frequency distribution of each symptom will be presented at Week 6 and Week 12. Comparison of each symptom between treatment groups, separately for Week 6 and Week 12 will be performed using a CMH test with modified ridit scores stratified by country.

The total score of the 6 symptoms, ranging from 0 to 18, will be calculated and presented for Week 6 and Week 12.

Comparison of the total score between treatment will be performed at Week 6 and Week 12 using an MMRM model. The model will include as fixed factors, treatment, scheduled visit time point (Week 6 and Week 12), country, wash-out duration treatment by visit interaction and patient as random factor.

Data relative to other symptoms will be provided in individual data listing. Other symptoms will be coded using MedDRA dictionary version the most recent possible at the database lock.

Note: If the patient did not feel any ocular symptom upon instillation, each symptom will be scored 0.

7.4 Ocular signs – Slit lamp examination

Each ocular sign (blepharitis, eyelid oedema, iris hyperpigmentation, abnormal eyelashes aspect, folliculo-papillary conjunctivitis) assessed for each eye on a 4-point ordinal scale from 0 to 3, 0 indicating absence and 3 indicating severe sign.

Frequency distribution of each ocular sign will be presented at screening, baseline (Day 1), Week 6 and Week 12, on the worse eye and the contralateral eye. Comparison between treatment groups will be performed for each ocular sign, at Week 6 and at Week 12, using a CMH test with modified ridit scores stratified by country, separately for the worse eye and for the contralateral eye.

Data relative to other ocular abnormalities will be provided in individual data listing. Other ocular abnormalities will be coded using MedDRA dictionary version the most recent possible at the database lock.

7.5 Corneal staining according to Oxford grading scheme

The Oxford 0-5 grading scheme assesses the staining of the corneal area.

The CFS score (ranging from 0 to 5) will be calculated and frequency distribution will be presented at screening, baseline (Day 1), Week 6 and Week 12, for the worse eye and for the contralateral eye. Comparison of the CFS score between treatment groups will be performed at Week 6 and at Week 12 using a CMH test with modified ridit scores stratified by country, separately for the worse eye and for the contralateral eye.

7.6 Far best corrected visual acuity

Far best corrected visual acuity in LogMar will be summarised at screening, baseline (Day 1) and Week 12 using usual descriptive statistics for continuous variable, for the worse eye and for the contralateral eye.

Frequency distribution in classes (*i.e.,* values from 1/10 to 10/10, including NA category, with non-integer numbers rounded to the nearest integer) will also be presented.

7.7 Automated visual field and Funduscopy

Visual field and the funduscopy at Week 12 will be listed also including screening results and IOP values at each visit (Section 16.2).

7.8 Ocular tolerance by the investigator

Ocular tolerance by the investigator will be assessed on a 4-point ordinal scale (Very satisfactory/Satisfactory/Not very satisfactory/Unsatisfactory).

Assessment of Azopt® ocular tolerance by the investigator at Visit 2 will be presented by frequency distribution for each modality and frequency distribution after regrouping 'very satisfactory' with 'satisfactory', and 'not very satisfactory' with 'unsatisfactory', on Azopt® Safety set, overall.

Assessment of LT4032 or Lumigan® ocular tolerance by the investigator will be presented by frequency distribution for each modality and frequency distribution after regrouping 'very satisfactory' with 'satisfactory', and 'not very satisfactory' with 'unsatisfactory'. After regrouping in 2 classes, comparison of treatment groups at Week 6 and Week 12 will be performed using a CMH stratified by country.

7.9 Ocular tolerance by the patient

Ocular tolerance by the patient will be assessed on a 4-point ordinal scale (Very satisfactory/Satisfactory/Not very satisfactory/Unsatisfactory).

Assessment of Azopt® ocular tolerance at Visit 2 by the patient will be presented by frequency distribution for each modality and frequency distribution after regrouping 'very satisfactory' with 'satisfactory', and 'not very satisfactory' with 'unsatisfactory', on Azopt® Safety set, overall.

Assessment of LT4032 or Lumigan® ocular tolerance by the patient will be presented by frequency distribution for each modality and frequency distribution after regrouping 'very satisfactory' with 'satisfactory', and 'not very satisfactory' with 'unsatisfactory'. After regrouping in 2 classes, comparison of treatment groups at Week 6 and Week 12 will be performed using a CMH stratified.

7.10 Ocular and systemic adverse events

All AEs reported during the study will be coded with MedDRA version the most recent possible at the database lock.

Ocular and systemic AEs will be analysed separately on the basis of the localisation as recorded by the investigator in the CRF.

Summary tables will be produced for treatment-emergent AEs (TEAEs).

TEAEs for Azopt® are AEs that occurred the same day or after the first Azopt® instillation and until the day of the first IMP (LT4032 or Lumigan®).

TEAEs for LT4032 or Lumigan® are AEs that occurred the same day or after the first IMP (LT4032 or Lumigan®) instillation and before or the day of the maximal date between last IMP instillation and Visit 4 (Week 12).

AEs that occurred the day of the first Azopt® instillation will be reviewed during a blind review meeting to decide if they have to be considered as a TEAE for Azopt® or not. AEs that occurred the day of the first IMP instillation will be reviewed during a blind review meeting to decide if they have to be considered as a TEAE for LT4032 or Lumigan® or a TEAE for Azopt®.

7.10.1 Summary of TEAEs

Separate summaries of treatment-emergent ocular and systemic AEs will be produced by treatment group presenting the number and percentages of patients experiencing at least one:

- AE,
- SAE,
- IMP-related AE (*i.e.,* related or missing relationship with the IMP),
- AE leading to premature study IMP withdrawal.

This table will be presented overall on the Azopt® safety set for TEAE for Azopt® and by treatment group on the Safety set for TEAE for LT4032 or Lumigan®

7.10.2 Details of AEs

Separate descriptions of treatment-emergent ocular and systemic AEs for Azopt® will be produced overall on Azopt® Safety set:

- Number and percentage of patients experiencing at least one TEAE, as well as the number of TEAEs, by SOC and PT. The same summary table will be produced for SAEs (if any), and AEs related to Azopt® and AEs leading to premature IMP drug withdrawal

Separate descriptions of treatment-emergent ocular and systemic AEs for LT4032 or Lumigan® will be produced by treatment group on the Safety set.

- Number and percentage of patients experiencing at least one TEAEs as well as the number of TEAEs by SOC and PT. The same summary table will be produced for SAEs, IMP-related AEs, IMP-related SAEs and AEs leading to premature IMP drug withdrawal
- Number and percentage of patients experiencing at least one TEAEs as well as the number of TEAEs by SOC, PT and severity
- Number and percentage of patients experiencing at least one TEAEs as well as the number of TEAEs by SOC, PT and relationship with IMP
- Number and percentage of patients with TEAEs by SOC, PT and maximal severity
- Number of patients with TEAEs by SOC, PT and strongest relationship

Summary of treatment-emergent non serious AEs (ocular or systemic) will be produced by treatment group, for LT4032 or Lumigan® presenting the number and percentages of patients experiencing:

- at least one non serious AE
- at least one non serious AE when percentages by PT is >=5% for one group,

as well as the number of these TEAEs by SOC and PT

7.10.3 Individual listing of AEs

Patient data listings of AEs (ocular and systemic together) will be produced:

- for non emergent AEs on enrolled patients
- for TEAE, serious TEAE, drug related TEAE and TEAE leading to premature IMP drug withdrawal, separetly TEAE for Azopt and TEAE for T4032 or Lumigan®
- for Post-treatment AE, ie. after the day of the maximal date between last IMP instillation and Visit 4 (Week 12)

Patient data listings of COVID-19 AEs (PT: COVID-19, Coronavirus infection) will also be produced.

The following variables will be presented:

- Treatment group
- Patient's identifier
- Worse eye (Right Eye/Left eye)
- Gender
- Age at baseline (Day 1)
- Diagnosis (Verbatim)
- SOC
- PT
- Localisation
- Date / time of occurence
- Time to occurence (days) from the date of the first IMP instillation
- Date / time of recovery/date of death, if any
- Duration (days)
- Outcome

- Frequency and details
- Severity
- Action taken regarding the IMP
- Requirement for therapy adjustment/modification
- Requirement for surgical/medical procedure,
- Seriousness,
- Relationship with T4032/Lumigan® in the investigator's opinion,
- Relationship with Azopt® in the investigator's opinion,
- Relationship with protocol procedure.

Listings will be sorted by treatment group, patient's identifier and date of onset.

Listing of Deaths, Other Serious adverse events, discontinuations due to adverse events and other adverse events of special interest will be also provided for narratives.

Discontinuations due to adverse events include drug related AE leading to premature IMP drug OR study withdrawal (ie drug related AE with action taken = drug withdrawn OR End of study with premature discontinuation due to this AE).

8 CHANGES FROM PROTOCOL

Changes from protocol are the following:

- Regarding Safety set (Section 2.1), due to Azopt® is an IMP, Azopt® Safety Set has been added.
- Baseline definition has been completed (Section 4.3.2).
- Regarding IOPs:
  - Descriptions during the run-in period have been added (Section 5.2)
  - Descriptions during the treatment period depending on the History of glaucoma or ocular hypertension (Section 6.2.2) have been added
  - Descriptions of the mean diurnal IOP have been added (Section 6.2.2)
  - Exploratory analysis of impact of circadian rhythm on IOP have been added (Sections 6.1.4 and 6.2.1)
- Regarding COVID-19 crisis, some analyses have been added to explore the consequence on this trial:
  - Descriptions of disposition of patients (Section 5.1) and demographic and baseline characteristics (Section 5.2) for patients who prematurely discontinued the study for COVID-19 crisis and by possible impact of COVID-19 pandemic classes have been added
  - Descriptions of demographic and baseline characteristics (Section 5.2) according to the following groups have been added: Patients from ITT set included in m-ITT set versus Patients from ITT set not included in m-ITT set
  - Descriptive statistics of IOP (Section 6.1) and exploratory analysis (Section 6.1.4) on possible impact of COVID-19 pandemic classes have been added
  - Listing of patients with COVID-19 AE (Section 7.10.3)
- Regarding secondary efficacy endpoints (Section 6.2), they will be performed on PP
- Regarding subjective ocular symptoms throughout the day (Section 7.2) and subjective ocular symptoms upon instillation (Section 7.3), due to data are repeated at Week 6 and Week 12, ANCOVA models at Week 6 and Week 12 have been replaced by MMRM models
- Regarding adverse events (Section 7.10):
  - Due to a follow-up visit is performed and Azopt® is an IMP, the period of emergence for each product has been reviewed
  - Description of treatment emergent non serious AEs for LT4032 or Lumigan® have been added
  - Necessary listings of AEs have been modified

9 VALIDATION OF STATISTICAL PROGRAMMING

Validation of statistical programming will be performed in agreement with Aixial SOP.

Logs of all programs used for analysis and data preparation will be checked for errors and unexpected warnings.

Double programming of ITT population, worse/contralateral eye, derivation and analyses regarding primary endpoint (i.e., IOP) will be performed by the lead statistician. Double programming of all derived will be also performed by a third party. A third party will review all statistical outputs (tables, figures) and results from statistical tests/models, as well as SAS code of all statistical programs. This includes macros programs developed for the study.

Any undocumented updating of study data in statistical programs instead of change in clinical database (or source data) is not allowed. Specifically, this refers to the cases where patients or the data are added/changed using a statistical program rather than updating the database. This kind of hard coding is usually proposed to correct deficiencies (missing values, wrong values, and wrong measurement units) in the database when these errors are detected after database lock.

No hard coding is done in any programs used for the creation of analysis data sets, tables, listings, or analyses that are intended for external reporting after database lock (i.e., clinical study reports, publications, abstracts, etc.).

This policy ensures integrity of clinical data, since no changes are made to the study data without appropriate documentation from the investigator sites and appropriate audit trails within the clinical trial database.

10 REFERENCES

[1] ICH guidelines - E9: Statistical Principles for Clinical Trials, Adopted in EU by CPMP, March 1998, issued as CPMP/ICH/363/96

[2] ICH guidelines - E3: Structure and Content of Clinical Study Reports, Adopted in EU by CPMP, December 95, issued as CPMP/ICH/137/95

APPENDIX 1. SAS SYNTAX FOR STATISTICAL MODELS PROGRAMMING

1. Main analysis of the primary efficacy endpoint (Section 6.1.1)

Mixed Model for Repeated Measures (MMRM)

The syntax with SAS using the MIXED procedure will be:

```
Proc mixed data = … method = REML;
      Class patient treatment visit country;
      Model changeIOP = treatment visit baselineIOP washoutdur country
      treatment*visit baselineIOP*visit / ddfm = satterth solution alpha=0.05;
      Repeated visit / type = UN subject = patient;
      Lsmeans treatment*visit / pdiff cl;
      Estimate "Week 12 – Diff T4032 – Lumigan" treatment 1 -1
      treatment*visit 0 1 0 -1 / cl;
      Estimate "Week 6 – Diff T4032 – Lumigan" treatment 1 -1
      treatment*visit 1 0 -1 0 / cl;
Run;
```

2. Sensitivity analyses of the primary efficacy endpoint (Section 6.1.2)

ANCOVA considering the post-randomisation last available value (LOCF)

The syntax with SAS using the MIXED procedure will be:

```
Proc mixed data = … ;
      Class treatment country;
      Model last_changeIOP = treatment baselineIOP washoutdur country / solution
      ddfm=satterth;
      LSmeans treatment / pdiff cl;
      Estimate "Week 12 – Diff T4032 – Lumigan " treatment 1 -1 / cl;
Run;
```

ANCOVA considering the observed value

The syntax with SAS using the MIXED procedure will be:

```
Proc mixed data = … ;
      Class treatment country;
      Model changeIOP_W12 = treatment baselineIOP washoutdur country/ solution
      ddfm=satterth;
      LSmeans treatment / pdiff cl;
      Estimate "Week 12 – Diff T4032 – Lumigan" treatment 1 -1 / cl;
Run;
```

3. Supporting analyses to check the validity of the main analysis (Section 6.1.3)

3.1. Investigation of treatment by baseline IOP interaction

The syntax with SAS using the MIXED procedure will be:

```
Proc mixed data = … method = REML;
      Class patient treatment visit country;
      Model changeIOP = treatment visit baselineIOP washoutdur country
      treatment*visit baselineIOP*visit treatment*baselineIOP / ddfm = satterth
      solution alpha=0.07;
      Repeated visit / type = UN subject = patient;
      LSmeans treatment*visit / pdiff cl;
Run;
```

3.2. Investigation of treatment by wash-out duration interaction

The syntax with SAS using the MIXED procedure will be:

```
Proc mixed data = … method = REML;
      Class patient treatment visit country;
      Model changeIOP = treatment visit baselineIOP washoutdur country
      treatment*visit baselineIOP*visit treatment*washoutdur / ddfm = satterth
      solution alpha=0.07;
      Repeated visit / type = UN subject = patient;
      LSmeans treatment*visit / pdiff cl;
Run;
```

3.3. Investigation of treatment by country interaction

The syntax with SAS using the MIXED procedure will be:

```
Proc mixed data = … method = REML;
      Class patient treatment visit country;
      Model changeIOP = treatment visit baselineIOP washoutdur country
      treatment*visit baselineIOP*visit treatment*country / ddfm = satterth
      solution alpha=0.07;
      Repeated visit / type = UN subject = patient;
      LSmeans treatment*visit / pdiff cl slice = ;
Run;
```

3.4. Supporting analyses to check the validity of the ANCOVA

For the treatment by baseline IOP interaction, the syntax with SAS using the MIXED procedure will be:

```
Proc mixed data = … ;
      Class treatment country;
      Model last_changeIOP = treatment baselineIOP washoutdur country
      treatment*baselineIOP / solution ddfm=satterth alpha=0.07;
      LSmeans treatment*visit / pdiff cl;
Run;
```

For the treatment by washout duration interaction, the syntax with SAS using the MIXED procedure will be:

```
Proc mixed data = … ;
      Class treatment country;
      Model last_changeIOP = treatment baselineIOP washoutdur country
      treatment*washoutdur / solution ddfm=satterth alpha=0.07;
      LSmeans treatment*visit / pdiff cl;
Run;
```

For the treatment by country interaction, the syntax with SAS using the MIXED procedure will be:

```
Proc mixed data = … ;
      Class treatment country;
      Model last_changeIOP = treatment baselineIOP washoutdur country
      treatment*country / solution ddfm=satterth alpha=0.07;
      LSmeans treatment*visit / pdiff cl;
Run;
```

4. Exploratory analyses of the primary efficacy endpoint analysis (Section 6.1.4)

For treatment by possible impact of COVID-19 pandemic interaction for MMRM, the syntax with SAS using the MIXED procedure will be:

```
Proc mixed data = … method = REML;
      Class patient treatment visit country impactcovid;
      Model changeIOP = treatment visit baselineIOP washoutdur country impactcovid
      treatment*visit baselineIOP*visit treatment*impactcovid / ddfm = satterth
      solution alpha=0.07;
      Repeated visit / type = UN subject = patient;
      LSmeans treatment*visit / pdiff cl;
Run;
```

For treatment by possible impact of COVID-19 pandemic interaction for ANCOVA, the syntax with SAS using the MIXED procedure will be:

```
Proc mixed data = … ;
      Class treatment country impactcovid;
      Model last_changeIOP = treatment baselineIOP washoutdur country impactcovid
      treatment*impactcovid / solution ddfm=satterth alpha=0.07;
      LSmeans treatment*visit / pdiff cl;
Run;
```

For the impact of circadian rhythm, the syntax with SAS using the MIXED procedure will be:

```
Proc mixed data= … covtest method=REML;
      Class patient treatment time visit country;
      Model changeIOP = treatment time visit country washoutdur treatment*time
      treatment*visit / solution;
      Repeated visit / subject= patient(time) type=unstructured;

      Estimate 'Week 12 8am – Diff T4032 – Lumigan' treatment 1 -1
      treatment*time 0 0 1 0 0 -1 treatment*visit 0 1 0 -1 / cl;
      Estimate 'Week 12 10am – Diff T4032 – Lumigan' treatment 1 -1
      treatment*time 1 0 0 -1 0 0 treatment*visit 0 1 0 -1 / cl;
      Estimate 'Week 12 4pm – Diff T4032 – Lumigan' treatment 1 -1
      treatment*time 0 1 0 0 -1 0 treatment*visit 0 1 0 -1 / cl;
      Estimate 'Week 6 8am – Diff T4032 – Lumigan' treatment 1 -1
      treatment*time 0 0 1 0 0 -1 treatment*visit 1 0 -1 0 / cl;
      Estimate 'Week 6 10am – Diff T4032 – Lumigan' treatment 1 -1
      treatment*time 1 0 0 -1 0 0 treatment*visit 1 0 -1 0 / cl;
      Estimate 'Week 6 4pm – Diff T4032 – Lumigan' treatment 1 -1
      treatment*time 0 1 0 0 -1 0 treatment*visit 1 0 -1 0 / cl;

      Estimate 'Week 12 8am - T4032' intercept 1 treatment 1 0
      time 0 0 1 visit 0 1 treatment*time 0 0 1 0 0 0
      treatment*visit 0 1 0 0 washoutdur xxx*/ cl;
      Estimate 'Week 12 10am – T4032' intercept 1 treatment 1 0
      time 1 0 0 visit 0 1 treatment*time 1 0 0 0 0 0
      treatment*visit 0 1 0 0 washoutdur xxx*/ cl;
      Estimate 'Week 12 4pm – T4032' intercept 1 treatment 1 0
      time 0 1 0 visit 0 1 treatment*time 0 1 0 0 0 0
      treatment*visit 0 1 0 0 washoutdur xxx*/ cl;
      Estimate 'Week 12 8am - Lumigan' intercept 1 treatment 0 1
      time 0 0 1 visit 0 1 treatment*time 0 0 0 0 0 1
      treatment*visit 0 0 0 1 washoutdur xxx*/ cl;
      Estimate 'Week 12 10am – Lumigan' intercept 1 treatment 0 1
      time 1 0 0 visit 0 1 treatment*time 0 0 0 1 0 0
      treatment*visit 0 0 0 1 washoutdur xxx*/ cl;
      Estimate 'Week 12 4pm – Lumigan' intercept 1 treatment 0 1
      time 0 1 0 visit 0 1 treatment*time 0 0 0 0 1 0
      treatment*visit 0 0 0 1 washoutdur xxx*/ cl;
```

```
      Estimate 'Week 6 8am - T4032' intercept 1 treatment 1 0
      time 0 0 1 visit 1 0 treatment*time 0 0 1 0 0 0
      treatment*visit 1 0 0 0 washoutdur xxx*/ cl;
      Estimate 'Week 6 10am – T4032' intercept 1 treatment 1 0
      time 1 0 0 visit 1 0 treatment*time 1 0 0 0 0 0
      treatment*visit 1 0 0 0 washoutdur xxx*/ cl;
      Estimate 'Week 6 4pm – T4032' intercept 1 treatment 1 0
      time 0 1 0 visit 1 0 treatment*time 0 1 0 0 0 0
      treatment*visit 1 0 0 0 washoutdur xxx*/ cl;
      Estimate 'Week 6 8am - Lumigan' intercept 1 treatment 0 1
      time 0 0 1 visit 1 0 treatment*time 0 0 0 0 0 1
      treatment*visit 0 0 1 0 washoutdur xxx*/ cl;
      Estimate 'Week 6 10am – Lumigan' intercept 1 treatment 0 1
      time 1 0 0 visit 1 0 treatment*time 0 0 0 1 0 0
      treatment*visit 0 0 1 0 washoutdur xxx*/ cl;
      Estimate 'Week 6 4pm – Lumigan' intercept 1 treatment 0 1
      time 0 1 0 visit 1 0 treatment*time 0 0 0 0 1 0
      treatment*visit 0 0 1 0 washoutdur xxx*/ cl;

run;
```

** xxx= Mean of washout duration values in the population*

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5 Safety analyses

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1. Disposition of patients

Study: LT4032-301 Page X / N
Population: Enrolled patients

Table 1.1 – Number of patients in each analysis set – Enrolled patients

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Enrolled patients			xx
Azopt Safety set			xx (xx.x%)
Safety set	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Intent-To-Treat set (ITT set)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
m-ITT set	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Per-protocol set (PP set)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Enrolled patients

Table 1.2 – Number of patients in each analysis set – With possible impact of COVID-19 pandemic – Enrolled patients
Same as Table 1.1

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Enrolled patients

Table 1.3 – Number of patients in each analysis set – Without possible impact of COVID-19 pandemic – Enrolled patients
Same as Table 1.1

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Enrolled patients

Listing 1.1 – Disposition of patients – Enrolled patients

Planned group	Actual group	Patient number	Worse Eye	Possible impact of COVID-19 pandemic		Azopt Safety set	Safety set	ITT Set	m-ITT Set	PP Set

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Enrolled patients

Table 1.4 – Number of enrolled patients by country – Enrolled patients

	Total (N=XX)
Belgium	xx (xx.x%)
Canada	xx (xx.x%)
Czech Republic	xx (xx.x%)
Estonia	xx (xx.x%)
France	xx (xx.x%)
Germany	xx (xx.x%)
Greece	xx (xx.x%)
Italy	xx (xx.x%)
Latvia	xx (xx.x%)
Lithuania	xx (xx.x%)
Mauritius	xx (xx.x%)
Poland	xx (xx.x%)
Russian	xx (xx.x%)
Slovakia	xx (xx.x%)
Spain	xx (xx.x%)
Ukraine	xx (xx.x%)
United Kingdom	xx (xx.x%)

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Azopt Safety Set

Table 1.5 – Number of patients by country – Azopt Safety Set
Same as Table 1.4

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 1.6 – Number of patients by country – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Belgium	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Canada	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Czech Republic	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Estonia	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
France	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Germany	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Greece	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Italy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Latvia	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lithuania	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mauritius	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Poland	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Russian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Slovakia	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Spain	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ukraine	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
United Kingdom	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 1.7 – Number of patients by country – For patients who prematurely discontinued the study for COVID-19 crisis – Safety set

Same as Table 1.6

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 1.8 – Number of patients by country – With possible impact of COVID-19 pandemic – Safety set
Same as Table 1.6

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 1.9 – Number of patients by country – Without possible impact of COVID-19 pandemic – Safety set
Same as Table 1.6

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: ITT set

Table 1.10 – Number of patients by country – ITT set
Same as Table 1.6 (if the ITT set differs from the Safety set)

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 1.11 – Number of patients by country – m-ITT set
Same as Table 1.6

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: PP set

Table 1.12 – Number of patients by country – PP set
Same as Table 1.6

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 1.13 – Number of patients at each visit as considered in the analysis – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Visit 1 - Screening visit – Day -42 or Day-49*	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Visit 2 - Randomisation visit – Day 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Visit 3 - Day 42 - Week 6	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Visit 4 - Day 84 - Week 12	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Follow-up phone call - Day 112 - Week 16	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
*Respectively before or after Clinical Study Protocol amendment 1 - 05JUL2019			

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 1.14 – Number of patients at each visit as considered in the analysis – With possible impact of COVID-19 pandemic – Safety set
Same as Table 1.13

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 1.15 – Number of patients at each visit as considered in the analysis – Without possible impact of COVID-19 pandemic – Safety set
Same as Table 1.13

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: ITT set

Table 1.16 – Number of patients at each visit as considered in the analysis – ITT set
Same as Table 1.13 (if the ITT set differs from the Safety set)

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: ITT set

Table 1.17 – Number of patients at each visit as considered in the analysis – With possible impact of COVID-19 pandemic – ITT set
Same as Table 1.13 (if the ITT set differs from the Safety set)

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: ITT set

Table 1.18 – Number of patients at each visit as considered in the analysis – Without possible impact of COVID-19 pandemic – ITT set
Same as Table 1.13 (if the ITT set differs from the Safety set)

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 1.19 – Number of patients at each visit as considered in the analysis – m-ITT set
Same as Table 1.13

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 1.20 – Number of patients at each visit as considered in the analysis – With possible impact of COVID-19 pandemic – m-ITT set
Same as Table 1.13

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 1.21 – Number of patients at each visit as considered in the analysis – Without possible impact of COVID-19 pandemic – m-ITT set

Same as Table 1.13

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 1.22 – Number of patients at each visit as considered in the analysis – PP set

Same as Table 1.13

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 1.23 – Number of patients at each visit as considered in the analysis – With possible impact of COVID-19 pandemic – PP set

Same as Table 1.13

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 1.24 – Number of patients at each visit as considered in the analysis – Without possible impact of COVID-19 pandemic – PP set

Same as Table 1.13

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
Population: Safety Set

Listing 1.2 – Visit as considered in the analysis – Safety set

Planned group	Actual group	Patient number	Possible impact of COVID-19 pandemic	Visit		Date of Visit	Time interval between Visit and Day 1 (days)*	Last instillation date	Analysis Visit
									Visit xx
*Time interval = Date of Visit – Date of randomization visit									

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
Population: Safety set

Table 1.25 – Premature study discontinuation – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Has the patient completed the study?			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Yes)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (No)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx
If yes, country			
n	xx	xx	xx
Belgium	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Canada	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing data	xx	xx	xx
Reason for discontinuation			
n	xx	xx	xx
Screen failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Adverse event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lack of efficacy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Patient's request	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
COVID-19 crisis	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing data	xx	xx	xx
If COVID-19 crisis, country			
n	xx	xx	xx
Belgium	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Canada	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing data	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: ITT set

Table 1.26 – Premature study discontinuation – ITT set
Same as Table 1.25 (if the ITT set differs from the Safety set)

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 1.27 – Premature study discontinuation – m-ITT set
Same as Table 1.25

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Listing 1.3 – Listing of premature study discontinuations – Safety set

Planned group	Actual group	Patient number	Possible impact of COVID-19 pandemic	Safety set	ITT Set	mITT Set	Date of discontinuation	Primary reason for discontinuation	Detail regarding reason for discontinuation

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 1.28 – Protocol deviations – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)		Total (N=XX)
At least one major deviation	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
Deviation 1	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
Deviation 2	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
…				
At least one minor deviation*	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
Deviation 1	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
Deviation 2	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
…				
Only minor deviation	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
Deviation 1	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
Deviation 2	xx (xx.x%)	xx (xx.x%)		xx (xx.x%)
…				
* includes major deviations				

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 1.29 – Protocol deviations – With possible impact of COVID-19 pandemic – m-ITT set
Same as Table 1.28

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 1.30 – Protocol deviations – Without possible impact of COVID-19 pandemic – m-ITT set
Same as Table 1.28

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Listing 1.4 – Listing of protocol deviations – m-ITT set

Planned group	Actual group	Patient number	Possible impact of COVID-19 pandemic	Deviation number	Class of deviation	Deviation term	Description

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Enrolled patients

Listing 1.5 – Listing of patients excluded from Azopt Safety, Safety, ITT, m-ITT, and PP sets – Enrolled patients

Planned group	Actual group	Patient number	Azopt Safety set		Safety set		ITT set	m-ITT set	PP Set	Reason for exclusion for ITT, m-ITT and/or PP sets
			Patient in Azopt Safety set	Reason for exclusion	Patient in Safety set	Reason for exclusion				
			Yes / No		Yes / No		Yes/No	Yes/No	Yes/No	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

2. Demographics and baseline characteristics

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.1 – Demographic characteristics – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Age (years)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx	xx ; xx
Missing data	xx	xx	xx
Age (years) in classes			
n	xx	xx	xx
< 65	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (< 65)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
>= 65	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (>= 65)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx
Gender			
n	xx	xx	xx
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Female)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Male)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx
Gender of patients <65 years old			
n	xx	xx	xx
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Female)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Male)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Gender of patients >=65 years old			
n	xx	xx	xx
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Female)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Male)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
Population: m-ITT set
Page X / N

Table 2.2 – Ocular medical history other than the studied disease by SOC and PT – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Patients having at least one ocular medical history other than the studied disease	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT 1_1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT 1_2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
SOC 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT 2_1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.3 – Ocular surgical history related to another disease than the studied one by SOC and PT – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Patients having at least one ocular surgical history related to another disease than the studied one	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT 1_1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT 1_2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
SOC 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT 2_1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.4 – Systemic medical history by SOC and PT – m-ITT set
Same as Table 2.2

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.5 – Systemic surgical history by SOC and PT – m-ITT set
Same as Table 2.3

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.6 – Previous ocular treatments by WHO-Drug ATC2 and ATC4 – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Any previous ocular treatment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC class 2_1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC class 4_1_1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC class 4_1_2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
ATC class 2_2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC class 4_2_1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ATC class 4_2_2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.7 – Concomitant ocular treatments by WHO-Drug ATC2 and ATC4 – m-ITT set
Same as Table 2.6

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.8 – Previous non-ocular treatments by WHO-Drug ATC2 and ATC4 – m-ITT set
Same as Table 2.6

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.9 – Concomitant non-ocular treatments by WHO-Drug ATC2 and ATC4 – m-ITT set
Same as Table 2.6

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.10 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Diagnosis			
n	xx	xx	xx
Ocular hypertension	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Ocular hypertension)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Primary open angle glaucoma	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Primary open angle glaucoma)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Secondary open angle glaucoma: Exfoliation Glaucoma	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Secondary open angle glaucoma: Exfoliation Glaucoma)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Secondary open angle glaucoma: Pigmentary Glaucoma	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Secondary open angle glaucoma: Pigmentary Glaucoma)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx
Time between diagnosis (months) and randomisation visit			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx	xx ; xx
Missing data	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.11 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye – m-ITT set
Same as Table 2.10

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
Population: m-ITT set

Table 2.12 – History of glaucoma or ocular hypertension – Previous treatment – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Previous treatment			
n	xx	xx	xx
Bimatoprost	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Bimatoprost)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Latanoprost	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Latanoprost)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Tafluprost	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Tafluprost)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Travoprost	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Travoprost)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Other)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx
Treated for at least 6 months			

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.13 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse eye - m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Patients having at least one surgical history related to the studied disease	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT 1_1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT 1_2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
SOC 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT 2_1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.14 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral eye - m-ITT set

Same as Table 2.13

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.15 – Automated visual field at screening visit – Worse eye – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Result			
n	xx	xx	xx
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Normal)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Abnormal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Abnormal)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx
If abnormal, clinically significant			
n	xx	xx	xx
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (Yes)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (No)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.16 – Automated visual field at screening visit – Contralateral eye – m-ITT set
Same as Table 2.15

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.17 – Central corneal thickness measurement (µm) at screening visit – Worse eye – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Corneal thickness measurement (µm)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx	xx ; xx
Missing data	xx	xx	xx
Corneal thickness measurement (µm) in classes			
n	xx	xx	xx
< 555 µm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (< 555 µm)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
>= 555 µm	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
95% CI (>= 555 µm)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.18 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – m-ITT set

Same as Table 2.17

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.19 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Screening			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx	xx ; xx
Missing data	xx	xx	xx
Randomisation – Day 1			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx	xx ; xx
Missing data	xx	xx	xx
Change from screening to randomisation – Day 1			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx	xx ; xx
Missing data	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.20 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration <= 8 days – Worse eye – m-ITT set
Same as Table 2.19

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas

Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.21 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration > 8 days – Worse eye – m-ITT set
Same as Table 2.19

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.22 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – m-ITT set
Same as Table 2.19

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.23 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration <= 8 days – Contralateral eye – m-ITT set
Same as Table 2.19

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 2.24 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration > 8 days – Contralateral eye – m-ITT set
Same as Table 2.19

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Following Tables related to Demographics and Baseline Characteristics will be repeated on the m-ITT set according to the possible impact of COVID-19 pandemic classes:

Table 2.25 – Demographic characteristics –With possible impact of COVID-19 pandemic – m-ITT set
Table 2.26 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – With possible impact of COVID-19 pandemic – m-ITT set
Table 2.27 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye – With possible impact of COVID-19 pandemic – m-ITT set
Table 2.28 – History of glaucoma or ocular hypertension – Previous treatment – With possible impact of COVID-19 pandemic – m-ITT set
Table 2.29 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse Eye – With possible impact of COVID-19 pandemic – m-ITT set
Table 2.30 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral Eye – With possible impact of COVID-19 pandemic – m-ITT set
Table 2.31 – Automated visual field at screening visit – Worse eye – With possible impact of COVID-19 pandemic – m-ITT set
Table 2.32 – Automated visual field at screening visit – Contralateral eye – With possible impact of COVID-19 pandemic – m-ITT set
Table 2.33 – Central corneal thickness measurement (µm) at screening visit – Worse eye – With possible impact of COVID-19 pandemic – m-ITT set
Table 2.34 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – With possible impact of COVID-19 pandemic – m-ITT set
Table 2.35 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – With possible impact of COVID-19 pandemic – m-ITT set
Table 2.36 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – With possible impact of COVID-19 pandemic – m-ITT set

Table 2.37 – Demographic characteristics –Without possible impact of COVID-19 pandemic – m-ITT set
Table 2.38 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – Without possible impact of COVID-19 pandemic – m-ITT set
Table 2.39 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye – Without possible impact of COVID-19 pandemic – m-ITT set
Table 2.40 – History of glaucoma or ocular hypertension – Previous treatment – Without possible impact of COVID-19 pandemic – m-ITT set
Table 2.41 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse Eye – Without possible impact of COVID-19 pandemic – m-ITT set
Table 2.42 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral Eye – Without possible impact of COVID-19 pandemic – m-ITT set
Table 2.43 – Automated visual field at screening visit – Worse eye – Without possible impact of COVID-19 pandemic – m-ITT set
Table 2.44 – Automated visual field at screening visit – Contralateral eye – Without possible impact of COVID-19 pandemic – m-ITT set
Table 2.45 – Central corneal thickness measurement (µm) at screening visit – Worse eye – Without possible impact of COVID-19 pandemic – m-ITT set
Table 2.46 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – Without possible impact of COVID-19 pandemic – m-ITT set
Table 2.47 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – Without possible impact of COVID-19 pandemic – m-ITT set
Table 2.48 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – Without possible impact of COVID-19 pandemic – m-ITT set

Same as Table 2.1 to 2.24

All Tables related to Demographics and Baseline Characteristics will be repeated on the Safety set:

Table 2.49 – Demographic characteristics – Safety Set
Table 2.50 – Ocular medical history other than the studied disease by system organ class and preferred term– Safety set
Table 2.51 – Ocular surgical history related to another disease than the studied one by system organ class and preferred term – Safety set
Table 2.52 – Systemic medical history by system organ class and preferred term – Safety set
Table 2.53 – Systemic surgical history by system organ class and preferred term – Safety set
Table 2.54 – Previous ocular treatments by WHO-Drug ATC2 and ATC4 – Safety set
Table 2.55 – Concomitant ocular treatments by WHO-Drug ATC2 and ATC4 – Safety set
Table 2.56 – Previous non-ocular treatments by WHO-Drug ATC2 and ATC4 – Safety set
Table 2.57 – Concomitant non-ocular treatments by WHO-Drug ATC2 and ATC4 – Safety set
Table 2.58 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – Safety set
Table 2.59 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye - Safety set
Table 2.60 – History of glaucoma or ocular hypertension – Previous treatment – Safety set
Table 2.61 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse Eye – Safety set
Table 2.62 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral Eye – Safety set
Table 2.63 – Automated visual field at screening visit – Worse eye – Safety set
Table 2.64 – Automated visual field at screening visit – Contralateral eye – Safety set
Table 2.65 – Central corneal thickness measurement (µm) at screening visit – Worse eye – Safety set
Table 2.66 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – Safety set
Table 2.67 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – Safety set
Table 2.68 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration <= 8 days – Worse eye – Safety set
Table 2.69 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration > 8 days – Worse eye – Safety set
Table 2.70 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – Safety set
Table 2.71 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration <= 8 days – Contralateral eye – Safety set
Table 2.72 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration > 8 days – Contralateral eye – Safety set

Same as Table 2.1 to 2.24

Study: LT4032-301 Page X / N
Population: m-ITT set

Listing 2.1 – Fundus examination at screening visit – Safety set

Planned group	Actual group	Patient number	Possible impact of COVID-19 pandemic	ITT Set	m-ITT Set	PP Set	Date of fundus examination	Abnormality	Eye

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 2.73 – Number of Patients and cumulative time of exposure (in days) – Safety set

	T4032		Lumigan	
	Patients	Person time	Patients	Person time
Total person time	xx	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 2.74 – Number of Patients and cumulative time of exposure (in days) by age group and gender – Safety set

	Patient				Person time			
	T4032		Lumigan		T4032		Lumigan	
Age group	Male	Female	Male	Female	Male	Female	Male	Female
< 65 years	xx	xx	xx	xx	xx	xx	xx	xx
>= 65 years and < 75 years	xx	xx	xx	xx	xx	xx	xx	xx
>= 75 years and < 85 years	xx	xx	xx	xx	xx	xx	xx	xx
Total	xx	xx	xx	xx	xx	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 2.75 – Number of Patients and cumulative time of exposure (in days) by exposure in classes – Safety set

	T4032		Lumigan	
Duration of exposure	Patients	Person time	Patients	Person time
< 1 months	xx	xx	xx	xx
>= 1 months and < 3 months	xx	xx	xx	xx
>= 3 months	xx	xx	xx	xx
Total	xx	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Following Tables related to Demographics and Baseline Characteristics will be repeated on the Safety set for patients who prematurely discontinued the study for COVID-19 crisis:

Table 2.76 – Demographic characteristics –For patients who prematurely discontinued the study for COVID-19 crisis – Safety set
Table 2.77 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – For patients who prematurely discontinued the study for COVID-19 crisis – Safety set
Table 2.78 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye – For patients who prematurely discontinued the study for COVID-19 crisis – Safety set
Table 2.79 – History of glaucoma or ocular hypertension – Previous treatment – For patients who prematurely discontinued the study for COVID-19 crisis – Safety set
Table 2.80 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse Eye – For patients who prematurely discontinued the study for COVID-19 crisis – Safety set
Table 2.81 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral Eye – For patients who prematurely discontinued the study for COVID-19 crisis – Safety set
Table 2.82 – Automated visual field at screening visit – Worse eye – For patients who prematurely discontinued the study for COVID-19 crisis – Safety set
Table 2.83 – Automated visual field at screening visit – Contralateral eye – For patients who prematurely discontinued the study for COVID-19 crisis – Safety set
Table 2.84 – Central corneal thickness measurement (µm) at screening visit – Worse eye – For patients who prematurely discontinued the study for Covid-19 crisis – Safety set
Table 2.85 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – For patients who prematurely discontinued the study for Covid-19 crisis – Safety set
Table 2.86 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – For patients who prematurely discontinued the study for COVID-19 crisis – Safety set
Table 2.87 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – For patients who prematurely discontinued the study for COVID-19 crisis – Safety set

Same as Table 2.1 to 2.24

Study: LT4032-301
Page X / N
Population: Safety set

Table 2.88 – Summary of baseline IOP (mmHg) – Worse eye – For patients who prematurely discontinued the study for COVID-19 crisis – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
08:00			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx	xx ; xx
Missing data	xx	xx	xx
10:00			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx	xx ; xx
Missing data	xx	xx	xx
16:00			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx	xx ; xx
Missing data	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
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Population: Safety set

Table 2.89 – Summary of baseline IOP (mmHg) – Contralateral eye – For patients who prematurely discontinued the study for COVID-19 crisis – Safety set
Same as Table 2.88

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas

Date and time program was run: JJMMMYYYY HH:MM

Following Tables related to Demographics and Baseline Characteristics will be repeated on the Safety set according to the possible impact of COVID-19 pandemic classes:

Table 2.90 – Demographic characteristics –With possible impact of COVID-19 pandemic – Safety set
Table 2.91 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – With possible impact of COVID-19 pandemic – Safety set
Table 2.92 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye – With possible impact of COVID-19 pandemic – Safety set
Table 2.93 – History of glaucoma or ocular hypertension – Previous treatment – With possible impact of COVID-19 pandemic – Safety set
Table 2.94 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse Eye – With possible impact of COVID-19 pandemic – Safety set
Table 2.95 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral Eye – With possible impact of COVID-19 pandemic – Safety set
Table 2.96 – Automated visual field at screening visit – Worse eye – With possible impact of COVID-19 pandemic – Safety set
Table 2.97 – Automated visual field at screening visit – Contralateral eye – With possible impact of COVID-19 pandemic – Safety set
Table 2.98 – Central corneal thickness measurement (µm) at screening visit – Worse eye – With possible impact of COVID-19 pandemic – Safety set
Table 2.99 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – With possible impact of COVID-19 pandemic – Safety set
Table 2.100 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – With possible impact of COVID-19 pandemic – Safety set
Table 2.101 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – With possible impact of COVID-19 pandemic – Safety set
Table 2.102 – Summary of baseline IOP (mmHg) – Worse eye – With possible impact of COVID-19 pandemic – Safety set
Table 2.103 – Summary of baseline IOP (mmHg) – Contralateral eye – With possible impact of COVID-19 pandemic – Safety set

Table 2.104 – Demographic characteristics –Without possible impact of COVID-19 pandemic – Safety set
Table 2.105 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – Without possible impact of COVID-19 pandemic – Safety set
Table 2.106 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye – Without possible impact of COVID-19 pandemic – Safety set
Table 2.107 – History of glaucoma or ocular hypertension – Previous treatment – Without possible impact of COVID-19 pandemic – Safety set
Table 2.108 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse Eye – Without possible impact of COVID-19 pandemic – Safety set
Table 2.109 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral Eye – Without possible impact of COVID-19 pandemic – Safety set
Table 2.110 – Automated visual field at screening visit – Worse eye – Without possible impact of COVID-19 pandemic – Safety set
Table 2.111 – Automated visual field at screening visit – Contralateral eye – Without possible impact of COVID-19 pandemic – Safety set
Table 2.112 – Central corneal thickness measurement (µm) at screening visit – Worse eye – Without possible impact of COVID-19 pandemic – Safety set
Table 2.113 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – Without possible impact of COVID-19 pandemic – Safety set
Table 2.114 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – Without possible impact of COVID-19 pandemic – Safety set
Table 2.115 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – Without possible impact of COVID-19 pandemic – Safety set
Table 2.116 – Summary of baseline IOP (mmHg) – Worse eye – Without possible impact of COVID-19 pandemic – Safety set
Table 2.117 – Summary of baseline IOP (mmHg) – Contralateral eye – Without possible impact of COVID-19 pandemic – Safety set

Same as Table 2.76 to 2.89

All Tables related to Demographics and Baseline Characteristics will be repeated on the ITT set if it differs from the Safety set:

Table 2.118 – Demographic characteristics – ITT Set
Table 2.119 – Ocular medical history other than the studied disease by system organ class and preferred term– ITT set
Table 2.120 – Ocular surgical history related to another disease than the studied one by system organ class and preferred term – ITT set
Table 2.121 – Systemic medical history by system organ class and preferred term – ITT set
Table 2.122 – Systemic surgical history by system organ class and preferred term – ITT set
Table 2.123 – Previous ocular treatments by WHO-Drug ATC2 and ATC4 – ITT set
Table 2.124 – Concomitant ocular treatments by WHO-Drug ATC2 and ATC4 – ITT set
Table 2.125 – Previous non-ocular treatments by WHO-Drug ATC2 and ATC4 – ITT set
Table 2.126 – Concomitant non-ocular treatments by WHO-Drug ATC2 and ATC4 – ITT set
Table 2.127 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – ITT set
Table 2.128 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye - ITT set
Table 2.129 – History of glaucoma or ocular hypertension – Previous treatment - ITT set
Table 2.130 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse Eye – ITT set
Table 2.131 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral Eye – ITT set
Table 2.132 – Automated visual field at screening visit – Worse eye – ITT set
Table 2.133 – Automated visual field at screening visit – Contralateral eye – ITT set
Table 2.134 – Central corneal thickness measurement (µm) at screening visit – Worse eye – ITT set
Table 2.135 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – ITT set
Table 2.136– Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – ITT set
Table 2.137 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration <= 8 days – Worse eye – ITT set
Table 2.138 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration > 8 days – Worse eye – ITT set
Table 2.139 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – ITT set
Table 2.140 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration <= 8 days – Contralateral eye – ITT set
Table 2.141 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration > 8 days – Contralateral eye – ITT set

Same as Table 2.1 to 2.24

Following Tables related to Demographics and Baseline Characteristics will be repeated on the ITT set for patients included in m-ITT set and for patients not included in m-ITT set:

Table 2.142 – Demographic characteristics –Patients included in m-ITT set – ITT set
Table 2.143 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – Patients included in m-ITT set – ITT set
Table 2.144 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye – Patients included in m-ITT set – ITT set
Table 2.145 – History of glaucoma or ocular hypertension – Previous treatment – Patients included in m-ITT set – ITT set
Table 2.146 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse Eye – Patients included in m-ITT set – ITT set
Table 2.147 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral Eye – Patients included in m-ITT set – ITT set
Table 2.148 – Automated visual field at screening visit – Worse eye – Patients included in m-ITT set – ITT set
Table 2.149 – Automated visual field at screening visit – Contralateral eye – Patients included in m-ITT set – ITT set
Table 2.150 – Central corneal thickness measurement (µm) at screening visit – Worse eye – Patients included in m-ITT set – ITT set
Table 2.151 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – Patients included in m-ITT set – ITT set
Table 2.152 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – Patients included in m-ITT set – ITT set
Table 2.153 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – Patients included in m-ITT set – ITT set
Table 2.154 – Summary of baseline IOP (mmHg) – Worse eye – Patients included in m-ITT set – ITT set
Table 2.155 – Summary of baseline IOP (mmHg) – Contralateral eye – Patients included in m-ITT set – ITT set

Table 2.156 – Demographic characteristics –Patients not included in m-ITT set – ITT set
Table 2.157 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – Patients not included in m-ITT set – ITT set
Table 2.158 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye – Patients not included in m-ITT set – ITT set
Table 2.159 – History of glaucoma or ocular hypertension – Previous treatment – Patients not included in m-ITT set – ITT set
Table 2.160 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse Eye – Patients not included in m-ITT set – ITT set
Table 2.161 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral Eye – Patients not included in m-ITT set – ITT set
Table 2.162 – Automated visual field at screening visit – Worse eye – Patients not included in m-ITT set – ITT set
Table 2.163 – Automated visual field at screening visit – Contralateral eye – Patients not included in m-ITT set – ITT set
Table 2.164 – Central corneal thickness measurement (µm) at screening visit – Worse eye – Patients not included in m-ITT set – ITT set
Table 2.165 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – Patients not included in m-ITT set – ITT set
Table 2.166 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – Patients not included in m-ITT set – ITT set
Table 2.167 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – Patients not included in m-ITT set – ITT set
Table 2.168 – Summary of baseline IOP (mmHg) – Worse eye – Patients not included in m-ITT set – ITT set
Table 2.169 – Summary of baseline IOP (mmHg) – Contralateral eye – Patients not included in m-ITT set – ITT set

Same as Table 2.76 to 2.89

All Tables related to Demographics and Baseline Characteristics will be repeated on the PP set.

Table 2.170 – Demographic characteristics – PP Set
Table 2.171 – Ocular medical history other than the studied disease by system organ class and preferred term– PP set
Table 2.172 – Ocular surgical history related to another disease than the studied one by system organ class and preferred term – PP set
Table 2.173 – Systemic medical history by system organ class and preferred term – PP set
Table 2.174 – Systemic surgical history by system organ class and preferred term – PP set
Table 2.175 – Previous ocular treatments by WHO-Drug ATC2 and ATC4 – PP set
Table 2.176 – Concomitant ocular treatments by WHO-Drug ATC2 and ATC4 – PP set
Table 2.177 – Previous non-ocular treatments by WHO-Drug ATC2 and ATC4 – PP set
Table 2.178 – Concomitant non-ocular treatments by WHO-Drug ATC2 and ATC4 – PP set
Table 2.179 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – PP set
Table 2.180 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye - PP set
Table 2.181 – History of glaucoma or ocular hypertension – Previous treatment –- PP set
Table 2.182 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse Eye – PP set
Table 2.183 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral Eye – PP set
Table 2.184 – Automated visual field at screening visit – Worse eye – PP set
Table 2.185 – Automated visual field at screening visit – Contralateral eye – PP set
Table 2.186 – Central corneal thickness measurement (µm) at screening visit – Worse eye – PP set
Table 2.187 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – PP set
Table 2.188– Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – PP set
Table 2.189 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration <= 8 days – Worse eye – PP set
Table 2.190 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration > 8 days – Worse eye – PP set
Table 2.191 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – PP set
Table 2.192 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration <= 8 days – Contralateral eye – PP set
Table 2.193 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Wash-out duration > 8 days – Contralateral eye – PP set

Same as Table 2.1 to 2.24

Following Tables related to Demographics and Baseline Characteristics will be repeated on the PP set according to the possible impact of COVID-19 pandemic classes:

Table 2.194 – Demographic characteristics –With possible impact of COVID-19 pandemic – PP set
Table 2.195 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – With possible impact of COVID-19 pandemic – PP set
Table 2.196 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye – With possible impact of COVID-19 pandemic – PP set
Table 2.197 – History of glaucoma or ocular hypertension – Previous treatment – With possible impact of COVID-19 pandemic – PP set
Table 2.198 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse Eye – With possible impact of COVID-19 pandemic – PP set
Table 2.199 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral Eye – With possible impact of COVID-19 pandemic – PP set
Table 2.200 – Automated visual field at screening visit – Worse eye – With possible impact of COVID-19 pandemic – PP set
Table 2.201 – Automated visual field at screening visit – Contralateral eye – With possible impact of COVID-19 pandemic – PP set
Table 2.202 – Central corneal thickness measurement (µm) at screening visit – Worse eye – With possible impact of COVID-19 pandemic – PP set
Table 2.203 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – With possible impact of COVID-19 pandemic – PP set
Table 2.204 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – With possible impact of COVID-19 pandemic – PP set
Table 2.205 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – With possible impact of COVID-19 pandemic – PP set

Table 2.206 – Demographic characteristics –Without possible impact of COVID-19 pandemic – PP set
Table 2.207 – History of glaucoma or ocular hypertension – Diagnosis – Worse eye – Without possible impact of COVID-19 pandemic – PP set
Table 2.208 – History of glaucoma or ocular hypertension – Diagnosis – Contralateral eye – Without possible impact of COVID-19 pandemic – PP set
Table 2.209 – History of glaucoma or ocular hypertension – Previous treatment – Without possible impact of COVID-19 pandemic – PP set
Table 2.210 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Worse Eye – Without possible impact of COVID-19 pandemic – PP set
Table 2.211 – Surgical history of glaucoma and ocular hypertension by system organ class and preferred term – Contralateral Eye – Without possible impact of COVID-19 pandemic – PP set
Table 2.212 – Automated visual field at screening visit – Worse eye – Without possible impact of COVID-19 pandemic – PP set
Table 2.213 – Automated visual field at screening visit – Contralateral eye – Without possible impact of COVID-19 pandemic – PP set
Table 2.214 – Central corneal thickness measurement (µm) at screening visit – Worse eye – Without possible impact of COVID-19 pandemic – PP set
Table 2.215 – Central corneal thickness measurement (µm) at screening visit – Contralateral eye – Without possible impact of COVID-19 pandemic – PP set
Table 2.216 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Worse eye – Without possible impact of COVID-19 pandemic – PP set
Table 2.217 – Summary of IOP (mmHg) and Change from screening in IOP at 08:00 – Contralateral eye – Without possible impact of COVID-19 pandemic – PP set

Same as Table 2.1 to 2.24

3. Treatment exposure and compliance

Study: LT4032-301
Population: Azopt Safety set

Table 3.1 – Azopt exposure – Azopt Safety set

	Total (N=XX)
Duration of Azopt (days)	
n	xx
Mean (SD)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]
Median	xx.x
Q1 ; Q3	xx.x
Median	xx.x
Min. ; Max.	xx ; xx
Missing data	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Azopt Safety set

Table 3.2 – Changes in the Azopt instillations – Azopt Safety set

	Total (N=XX)
Absence or Modification of instillations	
n	xx
Yes	xx.x (xx.x)
95% CI (Yes)	[xx.x%;xx.x%]
No	xx.x (xx.x)
95% CI (No)	[xx.x%;xx.x%]
Missing data	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Azopt Safety set

Listing 3.1 – Listing of data relative to Azopt instillations modifications – Azopt Safety set

Actual group	Planned group	Patient number	Azopt Safety set	m-ITT set	Date of first / last instillation	Absence or Modification of instillations	Start date / end date	Number of days	Number of instillation / day	
									Worse eye	Contralateral eye
						Yes				

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

All Tables related to Azopt Exposure will be repeated by treatment group on the m-ITT set:

Table 3.3 – Azopt exposure – m-ITT set
Table 3.4 – Changes in the Azopt instillations – m-ITT set
Same as Table 3.1 to 3.2

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 3.5 – Compliance of Azopt (%) – Worse eye – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Compliance (%)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx	xx ; xx
Missing data	xx	xx	xx
Compliance (%) in classes			
n	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
< 80%	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (< 80%)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
≥ 80% - ≤ 120%	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (≥ 80% - ≤ 120%)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
> 120%	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (> 120%)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 3.6 – Compliance of Azopt (%) – Contralateral eye– m-ITT set
Same as Table 3.5

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
Population: Safety set

Table 3.7 – Treatment exposure – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Duration of treatment (days)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx	xx ; xx
Missing data	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 3.8 – Changes in the IMP instillation (between the first and the last instillation) – From Day 1 to Week 6 – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Absence of instillation			
n	xx	xx	xx
Yes	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (Yes)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
No	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (No)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx
Instillation time modification			
n	xx	xx	xx
Yes	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (Yes)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
No	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (No)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 3.9 – Changes in the IMP instillations (between the first and the last instillation) – From Week 6 to Week 12 – Safety set
Same as Table 3.8

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 3.10 – Changes in the IMP instillations (between the first and the last instillation) – From Day 1 to Week 12 - Safety set
Same as Table 3.8

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 3.11 – Compliance (%) – Worse eye – From Day 1 to Week 6 – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	Total (N=XX)
Compliance (%)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx	xx ; xx
Missing data	xx	xx	xx
Compliance (%) in classes			
n	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
< 80%	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (< 80%)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
≥ 80% - ≤ 120%	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (≥ 80% - ≤ 120%)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
> 120%	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI (> 120%)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 3.12 – Compliance (%) – Worse eye – From Week 6 to Week 12 – Safety set
Same as Table 3.11

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 3.13 – Compliance (%) – Worse eye – From Day 1 to Week 12 – Safety set
Same as Table 3.11

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 3.14 – Compliance (%) – Contralateral eye – From Day 1 toWeek 6 - Safety set
Same as Table 3.11

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 3.15 – Compliance (%) – Contralateral eye – From Week 6 to Week 12 – Safety set
Same as Table 3.11

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 3.16 – Compliance (%) – Contralateral eye – From Day 1 to Week 12 – Safety set
Same as Table 3.11

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Listing 3.2 – Listing of data relative to IMP instillations modifications – Safety set

Actual group	Planned group	Patient number	Possible impact of COVID-19 pandemic	m-ITT set	Visit	Date of first / last instillation	Absence of instillations	Modification start date / end date	Number of days	Number of instillations / day	
										Worse eye	Contralateral eye
					Week 6 / Week 12		Yes				

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Listing 3.3 – Listing of data relative to IMP instillation time modifications – Safety set

Actual group	Planned group	Patient number	Possible impact of COVID-19 pandemic	m-ITT set	Visit	Date of first / last instillation	Time modifications	Modification start date / end date	Number of days	Time of instillation	
										Worse eye	Contralateral eye
					Week 6 / Week 12		Yes				

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Following Tables related to Demographics and Baseline Characteristics will be repeated on the Safety set according to the possible impact of COVID-19 pandemic classes:

Table 3.17 – Treatment exposure – With possible impact of COVID-19 pandemic – Safety set
Table 3.18 – Changes in the IMP instillations (between the first and the last instillation) – From Day 1 to Week 6 – With possible impact of COVID-19 pandemic – Safety set
Table 3.19 – Changes in the IMP instillations (between the first and the last instillation) – From Week 6 to Week 12 – With possible impact of COVID-19 pandemic – Safety set
Table 3.20 – Changes in the IMP instillations (between the first and the last instillation) – From Day 1 to Week 12 – With possible impact of COVID-19 pandemic – Safety set
Table 3.21 – Compliance (%) – Worse eye – From Day 1 to Week 6 – With possible impact of COVID-19 pandemic – Safety set
Table 3.22 – Compliance (%) – Worse eye – From Week 6 to Week 12 – With possible impact of COVID-19 pandemic – Safety set
Table 3.23 – Compliance (%) – Worse eye – From Day 1 to Week 12 – With possible impact of COVID-19 pandemic – Safety set
Table 3.24 – Compliance (%) – Contralateral eye – From Day 1 toWeek 6 – With possible impact of COVID-19 pandemic – Safety set
Table 3.25 – Compliance (%) – Contralateral eye – From Week 6 to Week 12 – With possible impact of COVID-19 pandemic – Safety set
Table 3.26 – Compliance (%) – Contralateral eye – From Day 1 to Week 12 – With possible impact of COVID-19 pandemic – Safety set

Table 3.27 – Treatment exposure – Without possible impact of COVID-19 pandemic – Safety set
Table 3.28 – Changes in the IMP instillations (between the first and the last instillation) – From Day 1 to Week 6 – Without possible impact of COVID-19 pandemic – Safety set
Table 3.29 – Changes in the IMP instillations (between the first and the last instillation) – From Week 6 to Week 12 – Without possible impact of COVID-19 pandemic – Safety set
Table 3.30 – Changes in the IMP instillations (between the first and the last instillation) – From Day 1 to Week 12 – Without possible impact of COVID-19 pandemic – Safety set
Table 3.31 – Compliance (%) – Worse eye – From Day 1 to Week 6 – Without possible impact of COVID-19 pandemic – Safety set
Table 3.32 – Compliance (%) – Worse eye – From Week 6 to Week 12 – Without possible impact of COVID-19 pandemic – Safety set
Table 3.33 – Compliance (%) – Worse eye – From Day 1 to Week 12 – Without possible impact of COVID-19 pandemic – Safety set
Table 3.34 – Compliance (%) – Contralateral eye – From Day 1 toWeek 6 – Without possible impact of COVID-19 pandemic – Safety set
Table 3.35 – Compliance (%) – Contralateral eye – From Week 6 to Week 12 – Without possible impact of COVID-19 pandemic – Safety set
Table 3.36 – Compliance (%) – Contralateral eye – From Day 1 to Week 12 – Without possible impact of COVID-19 pandemic – Safety set

Same as Table 3.7 to 3.16

All Tables related to Treatment Exposure and Compliance will be repeated on the m-ITT set:

Table 3.37 – Treatment exposure – m-ITT set
Table 3.38 – Changes in the IMP instillations (between the first and the last instillation) – From Day 1 to Week 6 – m-ITT set
Table 3.39 – Changes in the IMP instillations (between the first and the last instillation) – From Week 6 to Week 12 – m-ITT set
Table 3.40 – Changes in the IMP instillations (between the first and the last instillation) – From Day 1 to Week 12 – m-ITT set
Table 3.41 – Compliance (%) – Worse eye – From Day 1 to Week 6 – m-ITT set
Table 3.42 – Compliance (%) – Worse eye – From Week 6 to Week 12 – m-ITT set
Table 3.43 – Compliance (%) – Worse eye – From Day 1 to Week 12 – m-ITT set
Table 3.44 – Compliance (%) – Contralateral eye – From Day 1 toWeek 6 – m-ITT set
Table 3.45 – Compliance (%) – Contralateral eye – From Week 6 to Week 12 – m-ITT set
Table 3.46 – Compliance (%) – Contralateral eye – From Day 1 to Week 12 – m-ITT set

Same as Table 3.7 to 3.16

Following Tables related to Demographics and Baseline Characteristics will be repeated on the m-ITT set according to the possible impact of COVID-19 pandemic classes:

Table 3.47 – Treatment exposure – With possible impact of COVID-19 pandemic – m-ITT set
Table 3.48 – Changes in the IMP instillations (between the first and the last instillation) – From Day 1 to Week 6 – With possible impact of COVID-19 pandemic – m-ITT set
Table 3.49 – Changes in the IMP instillations (between the first and the last instillation) – From Week 6 to Week 12 – With possible impact of COVID-19 pandemic – m-ITT set
Table 3.50 – Changes in the IMP instillations (between the first and the last instillation) – From Day 1 to Week 12 – With possible impact of COVID-19 pandemic – m-ITT set
Table 3.51 – Compliance (%) – Worse eye – From Day 1 to Week 6 – With possible impact of COVID-19 pandemic – m-ITT set
Table 3.52 – Compliance (%) – Worse eye – From Week 6 to Week 12 – With possible impact of COVID-19 pandemic – m-ITT set
Table 3.53 – Compliance (%) – Worse eye – From Day 1 to Week 12 – With possible impact of COVID-19 pandemic – m-ITT set
Table 3.54 – Compliance (%) – Contralateral eye – From Day 1 toWeek 6 – With possible impact of COVID-19 pandemic – m-ITT set
Table 3.55 – Compliance (%) – Contralateral eye – From Week 6 to Week 12 – With possible impact of COVID-19 pandemic – m-ITT set
Table 3.56 – Compliance (%) – Contralateral eye – From Day 1 to Week 12 – With possible impact of COVID-19 pandemic – m-ITT set

Table 3.57 – Treatment exposure – Without possible impact of COVID-19 pandemic – m-ITT set
Table 3.58 – Changes in the IMP instillations (between the first and the last instillation) – From Day 1 to Week 6 – Without possible impact of COVID-19 pandemic – m-ITT set
Table 3.59 – Changes in the IMP instillations (between the first and the last instillation) – From Week 6 to Week 12 – Without possible impact of COVID-19 pandemic – m-ITT set
Table 3.60 – Changes in the IMP instillations (between the first and the last instillation) – From Day 1 to Week 12 – Without possible impact of COVID-19 pandemic – m-ITT set
Table 3.61 – Compliance (%) – Worse eye – From Day 1 to Week 6 – Without possible impact of COVID-19 pandemic – m-ITT set
Table 3.62 – Compliance (%) – Worse eye – From Week 6 to Week 12 – Without possible impact of COVID-19 pandemic – m-ITT set
Table 3.63 – Compliance (%) – Worse eye – From Day 1 to Week 12 – Without possible impact of COVID-19 pandemic – m-ITT set
Table 3.64 – Compliance (%) – Contralateral eye – From Day 1 toWeek 6 – Without possible impact of COVID-19 pandemic – m-ITT set
Table 3.65 – Compliance (%) – Contralateral eye – From Week 6 to Week 12 – Without possible impact of COVID-19 pandemic – m-ITT set
Table 3.66 – Compliance (%) – Contralateral eye – From Day 1 to Week 12 – Without possible impact of COVID-19 pandemic – m-ITT set

Same as Table 3.7 to 3.16

4. Efficacy analysis

Primary efficacy endpoint

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 4.1 – Summary of IOP (mmHg) and Change from baseline in IOP – Worse eye – m-ITT set

				Parameter at each visit					Change from Baseline				
Variable	Treatment group	N	Visit	n	Mean (SD)	Median	Min ; Max	95% CI (Mean)	n	Mean (SD)	Median	Min ; Max	95% CI (Mean)
IOP (mmHg) at (*)	T4032	XX	Baseline	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]					
			Week 6	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]
			Week 12	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]
			Week 12 (LOCF)	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]
	Lumigan	XX	Baseline	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]					
			Week 6	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]
			Week 12	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]
			Week 12 (LOCF)	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]

(LOCF) Last observation carried forward

(*) at 08:00, 10:00 and 16:00

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.2 – Summary of IOP (mmHg) and Change from baseline in IOP – Worse eye – ITT set
Table 4.3 – Summary of IOP (mmHg) and Change from baseline in IOP – Worse eye – PP set

Table 4.4 – Summary of IOP (mmHg) and Change from baseline in IOP – Worse eye – (*) – m-ITT set
Table 4.5 – Summary of IOP (mmHg) and Change from baseline in IOP – Worse eye – (*) – ITT set
Table 4.6 – Summary of IOP (mmHg) and Change from baseline in IOP – Worse eye – (*) – PP set
(*) Country: Belgium, Canada, Czech Republic, Estonia, France, Germany, Greece, Italy, Latvia, Lithuania, Mauritius, Poland, Russian, Slovakia, Spain, Ukraine, United Kingdom
Possible impact of COVID-19 pandemic: With impact of of COVID-19 pandemic, Without of COVID-19 pandemic

Same as Table 4.1

Study: LT4032-301
Population: m-ITT set
Page X / N

Table 4.7 – Primary analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 – MMRM analysis – Worse eye – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Visit	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Treatment x Visit Interaction	0.xxx	
Baseline IOP x Visit Interaction	0.xxx	
Non-inferiority will be achieved if the upper bound of the 95% CI for the difference between treatment groups (T4032 – Lumigan 0.01%) is lower than the margin of +1.5 mmHg for each of the three time points 08:00, 10:00 and 16:00.		

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.8 – Primary analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 – MMRM analysis – Worse eye – m-ITT set
Table 4.9 – Primary analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 – MMRM analysis – Worse eye – m-ITT set

Table 4.10 –Analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 – MMRM analysis – Worse eye – ITT set
Table 4.11 –Analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 – MMRM analysis – Worse eye – ITT set
Table 4.12 –Analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 – MMRM analysis – Worse eye – ITT set

Table 4.13 –Analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 – MMRM analysis – Worse eye – PP set
Table 4.14 –Analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 – MMRM analysis – Worse eye – PP set
Table 4.15 –Analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 – MMRM analysis – Worse eye – PP set

Same as Table 4.7

Study: LT4032-301
Population: m-ITT set
Page X / N

Table 4.16 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (LOCF) – ANCOVA – Worse eye – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12 (LOCF)		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95%CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.17 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (LOCF) – ANCOVA – Worse eye – m-ITT set
Table 4.18 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (LOCF) – ANCOVA – Worse eye – m-ITT set

Table 4.19 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (LOCF) – ANCOVA – Worse eye – ITT set
Table 4.20 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (LOCF) – ANCOVA – Worse eye – ITT set
Table 4.21 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (LOCF) – ANCOVA – Worse eye – ITT set

Table 4.22 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (LOCF) – ANCOVA – Worse eye – PP set
Table 4.23 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (LOCF) – ANCOVA – Worse eye – PP set
Table 4.24 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (LOCF) – ANCOVA – Worse eye – PP set

Same as Table 4.16

Study: LT4032-301
Population: m-ITT set
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Table 4.25 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (Observed) – ANCOVA – Worse eye – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12 (Observed)		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95%CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.26 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (Observed) – ANCOVA – Worse eye – m-ITT set
Table 4.27 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (Observed) – ANCOVA – Worse eye – m-ITT set

Table 4.28 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (Observed) – ANCOVA – Worse eye – ITT set
Table 4.29 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (Observed) – ANCOVA – Worse eye – ITT set
Table 4.30 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (Observed) – ANCOVA – Worse eye – ITT set

Table 4.31 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (Observed) – ANCOVA – Worse eye – PP set
Table 4.32 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (Observed) – ANCOVA – Worse eye – PP set
Table 4.33 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (Observed) – ANCOVA – Worse eye – PP set

Same as Table 4.25

Study: LT4032-301
Population: m-ITT set
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Table 4.34 – Supporting analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 – MMRM analysis – Worse eye – Investigation of 'Treatment by Baseline IOP' interaction – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Visit	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country		
Treatment x Visit Interaction	0.xxx	
Baseline IOP x Visit Interaction	0.xxx	
Treatment x Baseline IOP Interaction	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.35 – Supporting analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 – MMRM analysis – Worse eye – Investigation of 'Treatment by Baseline IOP' interaction – m-ITT set
Table 4.36 – Supporting analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 – MMRM analysis – Worse eye – Investigation of 'Treatment by Baseline IOP' interaction – m-ITT set

Same as Table 4.34

Study: LT4032-301
Population: m-ITT set
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Table 4.37 – Supporting analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 – MMRM analysis – Worse eye – Investigation of 'Treatment by Wash-out duration' interaction – m-ITT set

	T4032 (N=XX)	T4030b (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Visit	0.xxx	
Baseline IOP	0.xxx	
Wash-out Duration	0.xxx	
Country	0.xxx	
Treatment x Visit Interaction	0.xxx	
Baseline IOP x Visit Interaction	0.xxx	
Treatment x Wash-out duration	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.38 – Supporting analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 – MMRM analysis – Worse eye – Investigation of 'Treatment by Wash-out duration' interaction – m-ITT set

Table 4.39 – Supporting analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 – MMRM analysis – Worse eye – Investigation of 'Treatment by Wash-out duration' interaction – m-ITT set

Same as Table 4.37

Study: LT4032-301
Population: m-ITT set
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Table 4.40 – Supporting analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 – MMRM analysis – Worse eye – Investigation of 'Treatment by Country' interaction – m-ITT set

	T4032 (N=XX)	T4030b (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Visit	0.xxx	
Baseline IOP	0.xxx	
Wash-out Duration	0.xxx	
Country	0.xxx	
Treatment x Visit Interaction	0.xxx	
Baseline IOP x Visit Interaction	0.xxx	
Treatment x Country	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Note for programming:
If the p value of the interaction term is lower than 7%, qualitative interaction will be graphically investigated.
If the interaction is qualitative, then the primary model will be performed by modality of the covariate.

Table 4.41 – Supporting analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 – MMRM analysis – Worse eye – Investigation of 'Treatment by Country' interaction – m-ITT set
Table 4.42 – Supporting analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 – MMRM analysis – Worse eye – Investigation of 'Treatment by Country' interaction – m-ITT set

Same as Table 4.40

Study: LT4032-301
Population: m-ITT set
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Table 4.43 – Supporting analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (LOCF) – ANCOVA – Worse eye – Investigation of 'Treatment by Baseline IOP' interaction – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12 (LOCF)		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95%CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Treatment x Baseline IOP Interaction	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.44 – Supporting analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (LOCF) – ANCOVA – Worse eye – Investigation of 'Treatment by Baseline IOP' interaction – m-ITT set

Table 4.45 – Supporting analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (LOCF) – ANCOVA – Worse eye – Investigation of 'Treatment by Baseline IOP' interaction – m-ITT set

Same as Table 4.43

Study: LT4032-301
Population: m-ITT set
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Table 4.46 – Supporting analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (LOCF) – ANCOVA – Worse eye – Investigation of 'Treatment by Wash-out duration' interaction – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12 (LOCF)		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95%CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Treatment x Wash-out duration	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.47 – Supporting analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (LOCF) – ANCOVA – Worse eye – Investigation of 'Treatment by Wash-out duration' interaction – m-ITT set

Table 4.48 – Supporting analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (LOCF) – ANCOVA – Worse eye – Investigation of 'Treatment by Wash-out duration' interaction – m-ITT set

Same as Table 4.46

Study: LT4032-301
Population: m-ITT set
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Table 4.49 – Supporting analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (LOCF) – ANCOVA – Worse eye – Investigation of 'Treatment by Country' interaction – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12 (LOCF)		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95%CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Treatment x Country	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Note for programming:
If the p value of the interaction term is lower than 7%, qualitative interaction will be graphically investigated.
If the interaction is qualitative, then the primary model will be performed by modality of the covariate.

Table 4.50 – Supporting analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (LOCF) – ANCOVA – Worse eye – Investigation of 'Treatment by Country' interaction – m-ITT set
Table 4.51 – Supporting analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (LOCF) – ANCOVA – Worse eye – Investigation of 'Treatment by Country' interaction – m-ITT set

Same as Table 4.49

Study: LT4032-301
Population: m-ITT set
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Table 4.52 – Supporting analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (observed) – ANCOVA – Worse eye – Investigation of 'Treatment by Baseline IOP' interaction – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12 (Observed)		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95%CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Treatment x Baseline IOP Interaction	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.53 – Supporting analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (observed) – ANCOVA – Worse eye – Investigation of 'Treatment by Baseline IOP' interaction – m-ITT set

Table 4.54 – Supporting analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (observed) – ANCOVA – Worse eye – Investigation of 'Treatment by Baseline IOP' interaction – m-ITT set

Same as Table 4.52

Study: LT4032-301
Population: m-ITT set
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Table 4.55 – Supporting analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (observed) – ANCOVA – Worse eye – Investigation of 'Treatment by Wash-out duration' interaction – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12 (Observed)		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95%CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Treatment x Wash-out duration Interaction	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.56 – Supporting analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (observed) – ANCOVA – Worse eye – Investigation of 'Treatment by Wash-out duration' interaction – m-ITT set

Table 4.57 – Supporting analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (observed) – ANCOVA – Worse eye – Investigation of 'Treatment by Wash-out duration' interaction – m-ITT set

Same as Table 4.55

Study: LT4032-301
Population: m-ITT set
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Table 4.58 – Supporting analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (observed) – ANCOVA – Worse eye – Investigation of 'Treatment by Country' interaction – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12 (Observed)		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95%CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Treatment x Country Interaction	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.59 – Supporting analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (observed) – ANCOVA – Worse eye – Investigation of 'Treatment by Country' interaction – m-ITT set
Table 4.60 – Supporting analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (observed) – ANCOVA – Worse eye – Investigation of 'Treatment by Country' interaction – m-ITT set

Same as Table 4.58

Study: LT4032-301
Population: m-ITT set
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Table 4.61 – Exploratory analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 – MMRM analysis – Worse eye – Investigation of 'Treatment by Possible impact of COVID-19 pandemic' interaction – m-ITT set

	T4032 (N=XX)	T4030b (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Visit	0.xxx	
Baseline IOP	0.xxx	
Wash-out Duration	0.xxx	
Country	0.xxx	
Possible impact of COVID-19 pandemic	0.xxx	
Treatment x Visit Interaction	0.xxx	
Baseline IOP x Visit Interaction	0.xxx	
Treatment x Possible impact of COVID-19 pandemic	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Note for programming:
If the p value of the interaction term is lower than 7%, qualitative interaction will be graphically investigated.
If the interaction is qualitative, then the primary model will be performed by modality of the covariate.

Table 4.62 – Exploratory analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 – MMRM analysis – Worse eye – Investigation of 'Treatment by Possible impact of COVID-19 pandemic' interaction – m-ITT set

Table 4.63 – Exploratory analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 – MMRM analysis – Worse eye – Investigation of 'Treatment by Possible impact of COVID-19 pandemic' interaction – m-ITT set

Same as Table 4.61

Study: LT4032-301
Population: m-ITT set
Page X / N

Table 4.64 – Exploratory analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (LOCF) – ANCOVA – Worse eye – Investigation of 'Treatment by possible impact of COVID-19 pandemic' interaction – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12 (LOCF)		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95%CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Possible impact of COVID-19 pandemic	0.xxx	
Treatment x Possible impact of COVID-19 pandemic	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Note for programming:
If the p value of the interaction term is lower than 7%, qualitative interaction will be graphically investigated.
If the interaction is qualitative, then the primary model will be performed by modality of the covariate.

Table 4.65 – Exploratory analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (LOCF) – ANCOVA – Worse eye – Investigation of 'Treatment by Possible impact of COVID-19 pandemic' interaction – m-ITT set

Table 4.66 – Supporting analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (LOCF) – ANCOVA – Worse eye – Investigation of 'Treatment by Possible impact of COVID-19 pandemic' interaction – m-ITT set

Same as Table 4.64

Study: LT4032-301
Population: m-ITT set
Page X / N

Table 4.67 – Exploratory analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (observed) – ANCOVA – Worse eye – Investigation of 'Treatment by Possible impact of COVID-19 pandemic' interaction –
m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12 (Observed)		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95%CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Possible impact of COVID-19 pandemic	0.xxx	
Treatment x Possible impact of COVID-19 pandemic	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Note for programming:
If the p value of the interaction term is lower than 7%, qualitative interaction will be graphically investigated.
If the interaction is qualitative, then the primary model will be performed by modality of the covariate.

Table 4.68 – Exploratory analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (observed) – ANCOVA – Worse eye – Investigation of 'Treatment by Possible impact of COVID-19 pandemic' interaction – m-ITT set
Table 4.69 – Exploratory analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (observed) – ANCOVA – Worse eye – Investigation of 'Treatment by Possible impact of COVID-19 pandemic' interaction – m-ITT set

Same as Table 4.67

Study: LT4032-301
Population: m-ITT set
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Table 4.70 – Exploratory analysis of the change from baseline in IOP (mmHg) at Week 12 – Worse eye – Impact of circadian rhythm – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 12		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Change from baseline at 10:00 at Week 12		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Change from baseline at 16:00 at Week 12		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Visit	0.xxx	
Time	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Treatment x Visit Interaction	0.xxx	
Teatment x Time Interaction	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Secondary efficacy endpoints

Table 4.71 – Summary of IOP (mmHg) and Change from baseline in IOP – Contralateral eye – m-ITT set
Table 4.72 – Summary of IOP (mmHg) and Change from baseline in IOP – Contralateral eye – PP set
Table 4.73 – Summary of IOP (mmHg) and Change from baseline in IOP – Contralateral eye – (*) – m-ITT set
Table 4.74 – Summary of IOP (mmHg) and Change from baseline in IOP – Contralateral eye – (*) – PP set

(*) Country: Belgium, Canada, Czech Republic, Estonia, France, Germany, Greece, Italy, Latvia, Lithuania, Mauritius, Poland, Russian, Slovakia, Spain, Ukraine, United Kingdom
Possible impact of COVID-19 pandemic: With impact of of COVID-19 pandemic, Without of COVID-19 pandemic

Same as Table 4.1

Table 4.75 –Analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 – MMRM analysis – Contralateral eye – m-ITT set
Table 4.76 –Analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 – MMRM analysis – Contralateral eye – m-ITT set
Table 4.77 –Analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 – MMRM analysis – Contralateral eye – m-ITT set

Table 4.78 –Analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 – MMRM analysis – Contralateral eye – PP set
Table 4.79 –Analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 – MMRM analysis – Contralateral eye – PP set
Table 4.80 –Analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 – MMRM analysis – Contralateral eye – PP set

Same as Table 4.7

Table 4.81 –Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (LOCF) – ANCOVA – Contralateral eye – m-ITT set
Table 4.82 –Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (LOCF) – ANCOVA – Contralateral eye – m-ITT set
Table 4.83 –Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (LOCF) – ANCOVA – Contralateral eye – m-ITT set

Table 4.84 –Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (LOCF) – ANCOVA – Contralateral eye – PP set
Table 4.85 –Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (LOCF) – ANCOVA – Contralateral eye – PP set
Table 4.86 –Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (LOCF) – ANCOVA – Contralateral eye – PP set

Same table 4.16

Table 4.87 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (Observed) – ANCOVA – Contralateral eye – m-ITT set
Table 4.88 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (Observed) – ANCOVA – Contralateral eye – m-ITT set
Table 4.89 –Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (Observed) – ANCOVA – Contralateral eye – m-ITT set

Table 4.90 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 12 (Observed) – ANCOVA – Contralateral eye – PP set
Table 4.91 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 12 (Observed) – ANCOVA – Contralateral eye – PP set
Table 4.92 –Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 12 (Observed) – ANCOVA – Contralateral eye – PP set

Same as Table 4.25

Study: LT4032-301
Population: m-ITT set
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Table 4.93 – Analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 6 – MMRM analysis – Worse eye – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 6		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Visit	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Treatment x Visit Interaction	0.xxx	
Baseline IOP x Visit Interaction	0.xxx	
Using the MMRM model presented in Table 4.7		

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.94 –Analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 6 – MMRM analysis – Worse eye – m-ITT set
Table 4.95 –Analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 6 – MMRM analysis – Worse eye – m-ITT set

Table 4.96 –Analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 6 – MMRM analysis – Worse eye – PP set
Table 4.97 –Analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 6 – MMRM analysis – Worse eye – PP set
Table 4.98 –Analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 6 – MMRM analysis – Worse eye – PP set

Table 4.99 –Analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 6 – MMRM analysis – Contralateral eye – m-ITT set
Table 4.100 –Analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 6 – MMRM analysis – Contralateral eye – m-ITT set
Table 4.101 –Analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 6 – MMRM analysis – Contralateral eye – m-ITT set

Table 4.102 –Analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 6 – MMRM analysis – Contralateral eye – PP set
Table 4.103 –Analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 6 – MMRM analysis – Contralateral eye – PP set
Table 4.104 –Analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 6 – MMRM analysis – Contralateral eye – PP set

Same as Table 4.93

Study: LT4032-301
Population: m-ITT set
Page X / N

Table 4.105 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 6 (observed) – ANCOVA – Worse eye – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 6 (observed)		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95%CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Baseline IOP	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.106 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 6 (observed) – ANCOVA – Worse eye – m-ITT set
Table 4.107 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 6 (observed) – ANCOVA – Worse eye – m-ITT set

Table 4.108 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 6 (observed) – ANCOVA – Worse eye – PP set
Table 4.109 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 6 (observed) – ANCOVA – Worse eye – PP set
Table 4.110 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 6 (observed) – ANCOVA – Worse eye – PP set

Table 4.111 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 6 (observed) – ANCOVA – Contralateral eye – m-ITT set
Table 4.112 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 6 (observed) – ANCOVA – Contralateral eye – m-ITT set
Table 4.113 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 6 (observed) – ANCOVA – Contralateral eye – m-ITT set

Table 4.114 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 08:00 at Week 6 (observed) – ANCOVA – Contralateral eye – PP set
Table 4.115 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 10:00 at Week 6 (observed) – ANCOVA – Contralateral eye – PP set
Table 4.116 – Sensitivity analysis of the change from baseline in IOP (mmHg) at 16:00 at Week 6 (observed) – ANCOVA – Contralateral eye – PP set

Same as Table 4.103

Study: LT4032-301
Population: m-ITT set

Table 4.117 – Exploratory analysis of the change from baseline in IOP (mmHg) at Week 6 – Worse eye – Impact of circadian rhythm – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline at 08:00 at Week 6		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Change from baseline at 10:00 at Week 6		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Change from baseline at 16:00 at Week 6		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Visit	0.xxx	
Time	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Treatment x Visit Interaction	0.xxx	
Teatment x Time Interaction	0.xxx	
Using the same model presented in Table 4.70		

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
Population: m-ITT set

Table 4.118 – Summary of IOP (in classes) – Worse eye – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)
IOP at (*)		
n	xx	xx
< 18 mmHg	xx.x (xx.x)	xx.x (xx.x)
95% CI (< 18 mmHg)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
>= 18 mmHg	xx.x (xx.x)	xx.x (xx.x)
95% CI (>= 18 mmHg)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx

(*) Baseline [Day 1], Week 6 and Week 12 at 08:00, 10:00 and 16:00

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.119 – Summary of IOP (in classes) – Worse eye – PP set

Table 4.120 – Summary of IOP (in classes) – Contralateral eye – m-ITT set
Table 4.121 – Summary of IOP (in classes) – Contralateral eye – PP set

Same as Table 4.118

Table 4.122 – Summary of IOP (mmHg) and Change from baseline in IOP – Worse eye – Patients with history of glaucoma – m-ITT set
Table 4.123 – Summary of IOP (mmHg) and Change from baseline in IOP – Worse eye – Patients with history of ocular hypertension – m-ITT set

Table 4.124 – Summary of IOP (mmHg) and Change from baseline in IOP – Worse eye – Patients with history of glaucoma – PP set
Table 4.125 – Summary of IOP (mmHg) and Change from baseline in IOP – Worse eye – Patients with history of ocular hypertension – PP set

Table 4.126 – Summary of IOP (mmHg) and Change from baseline in IOP – Contralateral eye – Patients with history of glaucoma – m-ITT set
Table 4.127 – Summary of IOP (mmHg) and Change from baseline in IOP – Contralateral eye – Patients with history of ocular hypertension – m-ITT set

Table 4.128 – Summary of IOP (mmHg) and Change from baseline in IOP – Contralateral eye – Patients with history of glaucoma – PP set
Table 4.129 – Summary of IOP (mmHg) and Change from baseline in IOP – Contralateral eye – Patients with history of ocular hypertension – PP set

Same as Table 4.1

Study: LT4032-301
Population: m-ITT set

Table 4.130 – Summary of IOP (mmHg) and Change from baseline in IOP – Mean diurnal IOP – Worse Eye – m-ITT set

				Parameter at each visit					Change from Baseline				
Variable	Treatment group	N	Visit	n	Mean (SD)	Median	Min ; Max	95% CI (Mean)	n	Mean (SD)	Median	Min ; Max	95% CI (Mean)
IOP (mmHg)	T4032	XX	Baseline	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]					
			Week 6	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]
			Week 12	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]
	Lumigan	XX	Baseline	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]					
			Week 6	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]
			Week 12	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 4.131 – Summary of IOP (mmHg) and Change from baseline in IOP – Mean diurnal IOP – Worse Eye – PP set

Table 4.132 – Summary of IOP (mmHg) and Change from baseline in IOP – Mean diurnal IOP – Contralateral Eye – m-ITT set
Table 4.133 – Summary of IOP (mmHg) and Change from baseline in IOP – Mean diurnal IOP – Contralateral Eye – PP set

Same as Table 130

Study: LT4032-301 Page X / N
Population: m-ITT Set

Table 4.134 – Global assessment of Azopt efficacy by the investigator – m-ITT Set

	T4032 (N=XX)	Lumigan (N=XX)
Global judgment of Azopt efficacy		
n	xx	xx
Very satisfactory	xx (xx.x%)	xx (xx.x%)
95% CI (Very satisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Satisfactory	xx (xx.x%)	xx (xx.x%)
95% CI (Satisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Not very satisfactory	xx (xx.x%)	xx (xx.x%)
95% CI (Not very satisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Unsatisfactory	xx (xx.x%)	xx (xx.x%)
95% CI (Unsatisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx
Global judgment of Azopt efficacy (grouping)		
n	xx	xx
Very satisfactory + Satisfactory	xx (xx.x%)	xx (xx.x%)
95% CI (Very satisfactory + Satisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Not very satisfactory + Unsatisfactory	xx (xx.x%)	xx (xx.x%)
95% CI (Not very satisfactory + Unsatisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: PP set

Table 4.135 – Global assessment of Azopt efficacy by the investigator – PP set
Same as Table 134

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: m-ITT set

Table 4.136 – Global assessment of efficacy by the investigator – m-ITT set

	T4032 (N=XX)	Lumigan (N=XX)	p-value
Time (*)			
Global judgment of the efficacy			
n	xx	xx	
Very satisfactory	xx (xx.x%)	xx (xx.x%)	
95% CI (Very satisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Satisfactory	xx (xx.x%)	xx (xx.x%)	
95% CI (Satisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Not very satisfactory	xx (xx.x%)	xx (xx.x%)	
95% CI (Not very satisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Unsatisfactory	xx (xx.x%)	xx (xx.x%)	
95% CI (Unsatisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Missing data	xx	xx	
Global judgment of the efficacy (grouping)			0.xxx (CMH)
n	xx	xx	
Very satisfactory + Satisfactory	xx (xx.x%)	xx (xx.x%)	
95% CI (Very satisfactory + Satisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Not very satisfactory + Unsatisfactory	xx (xx.x%)	xx (xx.x%)	
95% CI (Not very satisfactory + Unsatisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Missing data	xx	xx	
CMH : Cochran-Mantel-Haenszel stratified by country			

(*) Week 6 / Week 12

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: PP set

Table 4.137 – Global assessment of efficacy by the investigator – PP set
Same as Table 136

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

5. Safety analysis

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.1 – Conjunctival hyperaemia using slit lamp examination – Worse eye – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	p-value (**)
(*)			0.xxx (CMH)
n	xx	xx	
0	xx (xx.x%)	xx (xx.x%)	
95% CI (0)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
1	xx (xx.x%)	xx (xx.x%)	
95% CI (1)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
2	xx (xx.x%)	xx (xx.x%)	
95% CI (2)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
3	xx (xx.x%)	xx (xx.x%)	
95% CI (3)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
4	xx (xx.x%)	xx (xx.x%)	
95% CI (4)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
5	xx (xx.x%)	xx (xx.x%)	
95% CI (5)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Missing data	xx (xx.x%)	xx (xx.x%)	
(CMH) Cochran Mantel Haenszel test with modified ridit scores			

(*) Screening / Baseline – Day 1/Week 6 / Week 12
(**) p-value for Week 6 and Week 12

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
Population: Safety set

Table 5.2 – Conjunctival hyperaemia using slit lamp examination – Change from baseline (in classes) – Worse eye – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	p-value
(*)			
Change from baseline			
n	xx	xx	
…	xx (xx.x%)	xx (xx.x%)	
-1	xx (xx.x%)	xx (xx.x%)	
0	xx (xx.x%)	xx (xx.x%)	
1	xx (xx.x%)	xx (xx.x%)	
…	xx (xx.x%)	xx (xx.x%)	
Missing data	xx (xx.x%)	xx (xx.x%)	
Change from baseline			
n	xx	xx	
Improvement	xx (xx.x%)	xx (xx.x%)	
95% CI (Improvement)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Absence stable	xx (xx.x%)	xx (xx.x%)	
95% CI (Absence stable)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Presence stable	xx (xx.x%)	xx (xx.x%)	
95% CI (Presence stable)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Worsening	xx (xx.x%)	xx (xx.x%)	
95% CI (Worsening)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Missing data	xx (xx.x%)	xx (xx.x%)	
Change from baseline			0.xxx (CMH)
n	xx	xx	
Improvement	xx (xx.x%)	xx (xx.x%)	
95% CI (Improvement)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
No change	xx (xx.x%)	xx (xx.x%)	
95% CI (No change)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Worsening	xx (xx.x%)	xx (xx.x%)	
95% CI (Worsening)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Missing data	xx (xx.x%)	xx (xx.x%)	
Change from baseline			
n	xx	xx	
Improvement of more than 1 point	xx (xx.x%)	xx (xx.x%)	
95% CI (Improvement of more than 1 point)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
No significant change (change between -1 and 1).	xx (xx.x%)	xx (xx.x%)	
95% CI (No significant change (change between -1 and 1))	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Worsening of more than 1 point	xx (xx.x%)	xx (xx.x%)	
95% CI (Worsening of more than 1 point)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Missing data	xx (xx.x%)	xx (xx.x%)	
(CMH) Cochran Mantel Haenszel test with modified ridit scores			

(*) Week 6 / Week 12

Name of SAS program: P:\ THEA\LT2347\Analyse\Pgm*nom_du_programme*.sas

Date and time program was run: JJMMMYYYY HH:MM
Study: LT4032-301 Page X / N
Population: Safety set

Table 5.3 – Conjunctival hyperaemia using slit lamp examination – Contralateral eye – Safety set
Same as Table 5.1

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.4 – Conjunctival hyperaemia using slit lamp examination – Change from baseline (in classes) – Contralateral eye – Safety set
Same as Table 5.2

Name of SAS program: P:\ THEA\LT2347\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
Population: Safety set

Table 5.5 – Subjective ocular symptoms throughout the day – *Symptom* (*) – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	p-value (***)
(**)			0.xxx (CMH)
n	xx	xx	
0: Absent	xx (xx.x%)	xx (xx.x%)	
95% CI (0)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
1: Present but not disturbing	xx (xx.x%)	xx (xx.x%)	
95% CI (1)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
2: Disturbing	xx (xx.x%)	xx (xx.x%)	
95% CI (2)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
3: Very distressing	xx (xx.x%)	xx (xx.x%)	
95% CI (3)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Missing data	xx (xx.x%)	xx (xx.x%)	
(CMH) Cochran Mantel Haenszel test with modified ridit scores			

(*) Irritation-burning / Stinging / Itching / Tearing / Eye dryness feeling / Foreign body sensation
(**) Screening / Baseline – Day 1 / Week 6 / Week 12
(***) p-alue for Week 6 and Week 12

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.6 – Total score of subjective ocular symptoms throughout the day – Safety set

				Parameter at each visit					Change from Baseline				
Variable	Treatment group	N	Visit	n	Mean (SD)	Median	Min ; Max	95% CI (Mean)	n	Mean (SD)	Median	Min ; Max	95% CI (Mean)
Total score	T4032	XX	Screening	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]					
			Baseline	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]					
			Week 6	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]
			Week 12	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]
	Lumigan	XX	Screening	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]					
			Baseline	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]					
			Week 6	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]
			Week 12	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]	XX	XX.X (X.X)	XX.X	XX ; XX	[XX.X;XX.X]
Total score ranges from 0 (no symptom) to 18 (very disturbing symptoms)													

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
Population: Safety set

Table 5.7 – Analysis of the change from baseline in total score of subjective ocular symptoms throughout the day – MMRM analysis– Safety set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Change from baseline in total score at Week 6		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Change from baseline in total score at Week 12		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Visit	0.xxx	
Baseline value	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Treatment x Visit Interaction	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Listing 5.1 – Listing of data relative to other ocular symptoms throughout the day – Safety set

Actual group	Patient number	Assessment time	Other symptoms (SOC / PT)	Severity
		Screening Baseline – Day 1 Week 6 Week 12		
0 = Absent, 1 = Present but not disturbing, 2 = Disturbing, 3 = Very distressing				

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm\nom_du_programme.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.8 – Subjective ocular symptoms upon instillation – *Symptom* (*) – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	p-value
(**)			0.xxx (CMH)
n	xx	xx	
0: Absent	xx (xx.x%)	xx (xx.x%)	
95% CI (0)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
1: Present but not disturbing	xx (xx.x%)	xx (xx.x%)	
95% CI (1)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
2: Disturbing	xx (xx.x%)	xx (xx.x%)	
95% CI (2)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
3: Very distressing	xx (xx.x%)	xx (xx.x%)	
95% CI (3)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Missing data	xx (xx.x%)	xx (xx.x%)	
(CMH) Cochran Mantel Haenszel test with modified ridit scores			

(*) Irritation-burning / Stinging / Itching / Tearing / Eye dryness feeling / Foreign body sensation
(**) Week 6 / Week 12

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm\nom_du_programme.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
Population: Safety set

Table 5.9 – Total score of subjective ocular symptoms upon instillation – Safety set

	T4032 (N=XX)	Lumigan (N=XX)
Week 6		
n	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx
Missing data	xx	xx
Week 12		
n	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx
Missing data	xx	xx
Total score ranges from 0 (no symptom) to 18 (very disturbing symptoms)		

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
Population: Safety set

Table 5.10 – Analysis of total score of subjective ocular symptoms upon instillation at week 6 - MMRM analysis – Safety set

	T4032 (N=XX)	Lumigan (N=XX)
Number of patients in the model	xx	xx
Total Score at Week 6		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Total Score at Week 12		
Adjusted mean (SE)	xx.x (xx.x)	xx.x (xx.x)
Adjusted mean difference (T4032 vs Lumigan) (SE)	xx.x (xx.x)	
95% CI of adjusted mean difference	[xx.x ; xx.x]	
p-value	0.xxx	
Type III test of fixed effects (p-value)		
Treatment	0.xxx	
Visit	0.xxx	
Wash-out duration	0.xxx	
Country	0.xxx	
Treatment x Visit Interaction	0.xxx	

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Listing 5.2 – Listing of data relative to other ocular symptoms upon instillation – Safety set

Actual group	Patient number	Assessment time	Other symptoms (SOC / PT)	Severity
		Week 6 Week 12		
0 = Absent, 1 = Present but not disturbing, 2 = Disturbing, 3 = Very distressing				

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm\nom_du_programme.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.11 – Ocular signs using slit lamp examination - *Sign* (*) – Worse eye – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	p-value (***)
(**)			0.xxx (CMH)
n	xx	xx	
0: None	xx (xx.x%)	xx (xx.x%)	
95% CI (0)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
1: Mild	xx (xx.x%)	xx (xx.x%)	
95% CI (1)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
2: Moderate	xx (xx.x%)	xx (xx.x%)	
95% CI (2)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
3: Severe	xx (xx.x%)	xx (xx.x%)	
95% CI (3)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
0: None	xx (xx.x%)	xx (xx.x%)	
Missing data	xx (xx.x%)	xx (xx.x%)	
(CMH) Cochran Mantel Haenszel test with modified ridit scores			

(*) Blepharitis / Eyelid oedema / Abnormal eyelashes aspect / Folliculo-papillary conjunctivitis / Iris pigmentation
(**) Screening / Baseline – Day 1 / Week 6 / Week 12
(***) p-value for Week 6 and Week 12

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.12 – Ocular signs using slit lamp examination - *Sign* (*) – Contralateral eye – Safety set
Same as Table 5.11

(*) Blepharitis / Eyelid oedema / Abnormal eyelashes aspect / Folliculo-papillary conjunctivitis / Iris pigmentation
Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Listing 5.3 – Listing of data relative to other ocular abnormalities – Safety set

Actual group	Patient number	Worse Eye	Assessment time	Other symptoms (SOC / PT)	Severity	
					Worse eye	Contralateral eye
			Screening Baseline Week 6 Week 12			
0 = Absent, 1 = Present but not disturbing, 2 = Disturbing, 3 = Very distressing						

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm\nom_du_programme.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.13 – Corneal staining according to Oxford grading scheme – Worse eye – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	p-value(**)
(*)			0.xxx (CMH)
n	xx	xx	
Grade 0	xx (xx.x%)	xx (xx.x%)	
95% CI (Grade 0)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Grade 1	xx (xx.x%)	xx (xx.x%)	
95% CI (Grade 1)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Grade 2	xx (xx.x%)	xx (xx.x%)	
95% CI (Grade 2)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Grade 3	xx (xx.x%)	xx (xx.x%)	
95% CI (Grade 3)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Grade 4	xx (xx.x%)	xx (xx.x%)	
95% CI (Grade 4)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Grade 5	xx (xx.x%)	xx (xx.x%)	
95% CI (Grade 5)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Missing data	xx (xx.x%)	xx (xx.x%)	
(CMH) Cochran Mantel Haenszel test with modified ridit scores			

(*) Screening / Baseline – Day 1 / Week 6 / Week 12
(**) p-value for Week 6 and Week 12
Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm\nom_du_programme.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.14 – Corneal staining according to Oxford grading scheme – Contralateral eye – Safety set
Same as Table 5.13

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm\nom_du_programme.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.15 – Far best corrected visual acuity – Worse eye – Safety set

	T4032 (N=XX)	Lumigan (N=XX)
(*) (LogMar)		
n	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
95% CI (mean)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Median	xx.x	xx.x
Q1 ; Q3	xx.x	xx.x
Min. ; Max.	xx ; xx	xx ; xx
Missing data	xx	xx
(*) (in classes)		
n	xx	xx
1/10	xx (xx.x%)	xx (xx.x%)
95% CI (1/10)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
…	xx (xx.x%)	xx (xx.x%)
10/10	xx (xx.x%)	xx (xx.x%)
95% CI (10/10)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
NA	xx (xx.x%)	xx (xx.x%)
95% CI (NA)	[xx.x%;xx.x%]	[xx.x%;xx.x%]
Missing data	xx	xx

(*) Screening / Baseline – Day 1 / Week 12

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.16 – Far best corrected visual acuity – Contralateral eye – Safety set
Same as Table 5.15

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Azopt Safety Set

Table 5.17 – Azopt Ocular tolerance by the investigator – Azopt Safety Set

	Total (N=XX)
Global judgment of the Azopt ocular tolerance	
n	xx
Very satisfactory	xx (xx.x%)
95% CI (Very satisfactory)	[xx.x%;xx.x%]
Satisfactory	xx (xx.x%)
95% CI (Satisfactory)	[xx.x%;xx.x%]
Not very satisfactory	xx (xx.x%)
95% CI (Not very satisfactory)	[xx.x%;xx.x%]
Unsatisfactory	xx (xx.x%)
95% CI (Unsatisfactory)	[xx.x%;xx.x%]
Missing data	xx
Global judgment of the Azopt ocular tolerance (grouping)	
n	xx
Very satisfactory + Satisfactory	xx (xx.x%)
95% CI (Very satisfactory + Satisfactory)	[xx.x%;xx.x%]
Not very satisfactory + Unsatisfactory	xx (xx.x%)
95% CI (Not very satisfactory + Unsatisfactory)	[xx.x%;xx.x%]
Missing data	xx

Study: LT4032-301 Page X / N
Population: Azopt Safety Set

Table 5.18 – Azopt Ocular tolerance by the patient – Azopt Safety Set
Same as Table 5.17

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.19 – T4032 or Lumigan Ocular tolerance by the investigator – Safety set

	T4032 (N=XX)	Lumigan (N=XX)	p-value
Time (*)			
Global judgment of the safety			
n	xx	xx	
Very satisfactory	xx (xx.x%)	xx (xx.x%)	
95% CI (Very satisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Satisfactory	xx (xx.x%)	xx (xx.x%)	
95% CI (Satisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Not very satisfactory	xx (xx.x%)	xx (xx.x%)	
95% CI (Not very satisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Unsatisfactory	xx (xx.x%)	xx (xx.x%)	
95% CI (Unsatisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Missing data	xx	xx	
Global judgment of the safety (grouping)			0.xxx (CMH)
n	xx	xx	
Very satisfactory + Satisfactory	xx (xx.x%)	xx (xx.x%)	
95% CI (Very satisfactory + Satisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Not very satisfactory + Unsatisfactory	xx (xx.x%)	xx (xx.x%)	
95% CI (Not very satisfactory + Unsatisfactory)	[xx.x%;xx.x%]	[xx.x%;xx.x%]	
Missing data	xx	xx	
(CMH) Cochran Mantel Haenszel test			

(*) Week 6 / Week 12

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.20 – T4032 or Lumigan Ocular tolerance by the patient – Safety set
Same as Table 5.19

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Azopt Safety set

Table 5.21 – Overview of ocular treatment-emergent adverse events for Azopt – Azopt Safety set

	Total (N=XX)
Any TEAE	xx (xx.x%)
Any serious TEAE	xx (xx.x%)
Any IMP-related TEAE	xx (xx.x%)
Any TEAE leading to premature IMP withdrawal	xx (xx.x%)

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.22 – Overview of ocular treatment-emergent adverse events for T4032 or Lumigan – Safety set

	T4032 (N=XX)	Lumigan (N=XX)
Any TEAE	xx (xx.x%)	xx (xx.x%)
Any serious TEAE	xx (xx.x%)	xx (xx.x%)
Any IMP-related TEAE	xx (xx.x%)	xx (xx.x%)
Any TEAE leading to premature IMP withdrawal	xx (xx.x%)	xx (xx.x%)

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Azopt Safety set

Table 5.23 – Summary of treatment-emergent ocular AEs for Azopt per SOC and PT – Azopt Safety set

	Total (N=XX)	
	Nb of AEs	Nb (%) of patients
At least one (*)	xx	x (xx.x%)
Body system 1	xx	xx (xx.x%)
Preferred term 1	xx	xx (xx.x%)
Preferred term 2	xx	xx (xx.x%)
…		
Preferred term n	xx	xx (xx.x%)
Body system 2	xx	xx (xx.x%)
Preferred term 1	xx	xx (xx.x%)
Preferred term 2	xx	xx (xx.x%)
…		
Preferred term n	xx	xx (xx.x%)
….		
Body system n	xx	xx (xx.x%)
Preferred term 1	xx	xx (xx.x%)
Preferred term 2	xx	xx (xx.x%)
…		
Preferred term n	xx	xx (xx.x%)

(*) TEAE / Serious TEAE / IMP-related TEAE / TEAE leading to premature study drug withdrawal

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 5.24 – Summary of treatment-emergent ocular SAEs for Azopt per SOC and PT – Azopt Safety set
Table 5.25 – Summary of treatment-emergent ocular IMP-related AEs for Azopt per SOC and PT – Azopt Safety set
Table 5.26 – Summary of treatment-emergent ocular AEs for Azopt leading to premature IMP drug withdrawal per SOC and PT – Azopt Safety set

Same as Table 5.23

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.27 – Summary of treatment-emergent ocular AEs for LT4032 or Lumigan per SOC and PT – Safety set

	T4032 (N=XX)		Lumigan (N=XX)	
	Nb of AEs	Nb (%) of patients	Nb of AEs	Nb (%) of patients
At least one (*)	xx	x (xx.x%)	xx	x (xx.x%)
Body system 1	xx	xx (xx.x%)	xx	xx (xx.x%)
Preferred term 1	xx	xx (xx.x%)	xx	xx (xx.x%)
Preferred term 2	xx	xx (xx.x%)	xx	xx (xx.x%)
…				
Preferred term n	xx	xx (xx.x%)	xx	xx (xx.x%)
Body system 2	xx	xx (xx.x%)	xx	xx (xx.x%)
Preferred term 1	xx	xx (xx.x%)	xx	xx (xx.x%)
Preferred term 2	xx	xx (xx.x%)	xx	xx (xx.x%)
…				
Preferred term n	xx	xx (xx.x%)	xx	xx (xx.x%)
….				
Body system n	xx	xx (xx.x%)	xx	xx (xx.x%)
Preferred term 1	xx	xx (xx.x%)	xx	xx (xx.x%)
Preferred term 2	xx	xx (xx.x%)	xx	xx (xx.x%)
…				
Preferred term n	xx	xx (xx.x%)	xx	xx (xx.x%)
Nb of AEs: Number of adverse events – Each AE is counted once per System Organ Class / Preferred Term *Nb (%) of patients: Number (%) of patients with at least one AE - Each patient is counted once per Preferred Term then per System Organ Class*				

(*) TEAE / Serious TEAE / IMP-related TEAE / IMP-related Serious TEAE / TEAE leading to premature study drug withdrawal

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Table 5.28 – Summary of treatment-emergent ocular SAEs for LT4032 or Lumigan per SOC and PT – Safety set

Table 5.29 – Summary of treatment-emergent ocular IMP-related AEs for LT4032 or Lumigan per SOC and PT – Safety set

Table 5.30 – Summary of treatment-emergent ocular IMP-related SAEs for LT4032 or Lumigan per SOC and PT – Safety set

Table 5.31 – Summary of treatment-emergent ocular AEs for LT4032 or Lumigan leading to premature IMP drug withdrawal per SOC and PT – Safety set

Same as Table 5.27

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.32 – Summary of treatment-emergent ocular AEs for LT4032 or Lumigan per SOC, PT and severity – Safety set

	T4032 (N=XX)		Lumigan (N=XX)	
	Nb of AEs	Nb (%) of patients	Nb of AEs	Nb (%) of patients
At least one AE	xx	x (xx.x%)	xx	x (xx.x%)
Body system 1	xx	xx (xx.x%)	xx	xx (xx.x%)
Mild	xx	xx (xx.x%)	xx	xx (xx.x%)
Moderate	xx	xx (xx.x%)	xx	xx (xx.x%)
Severe	xx	xx (xx.x%)	xx	xx (xx.x%)
Preferred term 1	xx	xx (xx.x%)	xx	xx (xx.x%)
Mild	xx	xx (xx.x%)	xx	xx (xx.x%)
Moderate	xx	xx (xx.x%)	xx	xx (xx.x%)
Severe	xx	xx (xx.x%)	xx	xx (xx.x%)
…				
Preferred term n	xx	xx (xx.x%)	xx	xx (xx.x%)
Mild	xx	xx (xx.x%)	xx	xx (xx.x%)
Moderate	xx	xx (xx.x%)	xx	xx (xx.x%)
Severe	xx	xx (xx.x%)	xx	xx (xx.x%)
….				
Body system n	xx	xx (xx.x%)	xx	xx (xx.x%)
Mild	xx	xx (xx.x%)	xx	xx (xx.x%)
Moderate	xx	xx (xx.x%)	xx	xx (xx.x%)
Severe	xx	xx (xx.x%)	xx	xx (xx.x%)
Preferred term 1	xx	xx (xx.x%)	xx	xx (xx.x%)
Mild	xx	xx (xx.x%)	xx	xx (xx.x%)
Moderate	xx	xx (xx.x%)	xx	xx (xx.x%)
Severe	xx	xx (xx.x%)	xx	xx (xx.x%)
…				
Preferred term n	xx	xx (xx.x%)	xx	xx (xx.x%)
Mild	xx	xx (xx.x%)	xx	xx (xx.x%)
Moderate	xx	xx (xx.x%)	xx	xx (xx.x%)
Severe	xx	xx (xx.x%)	xx	xx (xx.x%)

Nb of AEs: Number of adverse events – Each AE is counted once per System Organ Class / Preferred Term
Nb (%) of patients: Number (%) of patients with at least one AE - Each patient is counted once per Preferred Term then per System Organ Class

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Safety set

Table 5.33 – Summary of treatment-emergent ocular AEs for LT4032 or Lumigan per SOC, PT and relationship with the IMP – Safety set

	T4032 (N=XX)		Lumigan (N=XX)	
	Nb of AEs	Nb (%) of patients	Nb of AEs	Nb (%) of patients
At least one AE	xx	x (xx.x%)	xx	x (xx.x%)
Body system 1	xx	xx (xx.x%)	xx	xx (xx.x%)
Related	xx	xx (xx.x%)	xx	xx (xx.x%)
Not related	xx	xx (xx.x%)	xx	xx (xx.x%)
Preferred term 1	xx	xx (xx.x%)	xx	xx (xx.x%)
Related	xx	xx (xx.x%)	xx	xx (xx.x%)
Not related	xx	xx (xx.x%)	xx	xx (xx.x%)
…				
Preferred term n	xx	xx (xx.x%)	xx	xx (xx.x%)
Related	xx	xx (xx.x%)	xx	xx (xx.x%)
Not related	xx	xx (xx.x%)	xx	xx (xx.x%)
….				
Body system n	xx	xx (xx.x%)	xx	xx (xx.x%)
Related	xx	xx (xx.x%)	xx	xx (xx.x%)
Not related	xx	xx (xx.x%)	xx	xx (xx.x%)
Preferred term 1	xx	xx (xx.x%)	xx	xx (xx.x%)
Related	xx	xx (xx.x%)	xx	xx (xx.x%)
Not related	xx	xx (xx.x%)	xx	xx (xx.x%)
…				
Preferred term n	xx	xx (xx.x%)	xx	xx (xx.x%)
Related	xx	xx (xx.x%)	xx	xx (xx.x%)
Not related	xx	xx (xx.x%)	xx	xx (xx.x%)

Nb of AEs: Number of adverse events – Each AE is counted once per System Organ Class / Preferred Term
Nb (%) of patients: Number (%) of patients with at least one AE - Each patient is counted once per Preferred Term then per System Organ Class

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4030-201 Page X / N
Population: Safety set

Table 5.34 – Summary of treatment-emergent ocular AEs for T4032 per SOC, PT and maximal severity – Safety set

	Mild	Moderate	Severe
	Nb (%) of patients	Nb (%) of patients	Nb (%) of patients
Body system 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred term 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
Preferred term n	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Body system 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred term 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
Preferred term n	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
….			
Body system n	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred term 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred term 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…			
Preferred term n	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Nb (%) of patients: Number (%) of patients with at least one AE - Each patient is counted once per Preferred Term then per System Organ Class			

Name of SAS program: B:\THEA\LT4030-201\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4030-201 Page X / N
Population: Safety set

Table 5.35 – Summary of treatment-emergent ocular AEs for Lumigan per SOC, PT and maximal severity –Safety set
Same as Table 5.34

Name of SAS program: B:\THEA\LT4030-201\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4030-201 Page X / N
Population: Safety set

Table 5.36 – Summary of treatment-emergent ocular AEs for T4032 per SOC, PT and strongest relationship –Safety set

	Not related	Related
	Nb (%) of patients	Nb (%) of patients
Body system 1	xx (xx.x%)	xx (xx.x%)
Preferred term 1	xx (xx.x%)	xx (xx.x%)
Preferred term 2	xx (xx.x%)	xx (xx.x%)
…		
Preferred term n	xx (xx.x%)	xx (xx.x%)
Body system 2	xx (xx.x%)	xx (xx.x%)
Preferred term 1	xx (xx.x%)	xx (xx.x%)
Preferred term 2	xx (xx.x%)	xx (xx.x%)
…		
Preferred term n	xx (xx.x%)	xx (xx.x%)
….		
Body system n	xx (xx.x%)	xx (xx.x%)
Preferred term 1	xx (xx.x%)	xx (xx.x%)
Preferred term 2	xx (xx.x%)	xx (xx.x%)
…		
Preferred term n	xx (xx.x%)	xx (xx.x%)
Nb (%) of patients: Number (%) of patients with at least one AE - Each patient is counted once per Preferred Term then per System Organ Class		

Name of SAS program: B:\THEA\LT4030-201\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4030-201 Page X / N
Population: Safety set

Table 5.37 – Summary of treatment-emergent ocular AEs for Lumigan per SOC, PT and strongest relationship –Safety set
Same as Table 5.36

Name of SAS program: B:\THEA\LT4030-201\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301
Population: Safety set
Page X / N

Table 5.38 – Overview of systemic treatment-emergent adverse events for Azopt – Azopt Safety set
Table 5.39 – Overview of systemic treatment-emergent adverse events for LT4032 or Lumigan – Safety set

Table 5.40 – Summary of treatment-emergent systemic AEs for Azopt per SOC and PT – Azopt Safety set
Table 5.41 – Summary of treatment-emergent systemic SAEs for Azopt per SOC and PT – Azopt Safety set
Table 5.42 – Summary of treatment-emergent systemic IMP-related AEs for Azopt per SOC and PT – Azopt Safety set
Table 5.43 – Summary of treatment-emergent systemic AEs for Azopt leading to premature IMP drug withdrawal per SOC and PT – Azopt Safety set

Table 5.44 – Summary of treatment-emergent systemic AEs for LT4032 or Lumigan per SOC and PT – Safety set
Table 5.45 – Summary of treatment-emergent systemic SAEs for LT4032 or Lumigan per SOC and PT – Safety set
Table 5.46 – Summary of treatment-emergent systemic IMP-related AEs for LT4032 or Lumigan per SOC and PT – Safety set
Table 5.47 – Summary of treatment-emergent systemic IMP-related SAEs for LT4032 or Lumigan per SOC and PT – Safety set
Table 5. 48 – Summary of treatment-emergent systemic AEs for LT4032 or Lumigan leading to premature study drug withdrawal per SOC and PT – Safety set

Table 5.49 – Summary of treatment-emergent systemic AEs for LT4032 or Lumigan per SOC, PT and severity – Safety set
Table 5.50 – Summary of treatment-emergent systemic AEs for LT4032 or Lumigan per SOC, PT and relationship with the IMP – Safety set
Table 5.51 – Summary of treatment-emergent systemic AEs for T4032 per SOC, PT and maximal severity –Safety set
Table 5.52 – Summary of treatment-emergent systemic AEs for Lumigan per SOC, PT and maximal severity –Safety set
Table 5.53 – Summary of treatment-emergent systemic AEs for T4032 per SOC, PT and strongest relationship –Safety set
Table 5.54 – Summary of treatment-emergent systemic AEs for Lumigan per SOC, PT and strongest relationship –Safety set

Same as Tables 5.23 to 5.37

Table 5.55 – Summary of treatment-emergent non-serious AEs for LT4032 or Lumigan per SOC and PT – Safety set
Table 5.56 – Summary of treatment-emergent non-serious AEs for LT4032 or Lumigan per SOC and PT with PT is ≥5% for one group – Safety set

Same as Table 5.27

Study: LT4032-301
Population: Enrolled patients

Page X / N

Listing 5.6 – Listing of Non emergent AEs – Enrolled patients

Actual group	Patient's identifier – Gender – Age at baseline	Worse Eye	Diagnosis (verbatim)	SOC / PT	Localisation	Date-Time of occurence / Date-Time of recovery or death	Time to occu-rence (days)	AE duration (days)	Outcome	Frequency and details	Severity	Action taken regarding the IMP	Requirement for therapy adaptation / modification	Requirement for surgical / medical procedure	Serious ness	Relationship with IMP / with procedure

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Listing 5.7 – Listing of treatment-emergent AEs for Azopt – Azopt Safety Set
Listing 5.8 – Listing of treatment-emergent SAEs for Azopt – Azopt Safety Set
Listing 5.9 – Listing of treatment-emergent IMP-related AEs for Azopt – Azopt Safety Set
Listing 5.10 – Listing of treatment-emergent systemic AEs for Azopt leading to premature IMP drug withdrawal – Azopt Safety Set

Listing 5.11 – Listing of treatment-emergent AEs for T4032 or Lumigan – Safety Set
Listing 5.12 – Listing of treatment-emergent SAEs for T4032 or Lumigan – Safety Set
Listing 5.13 – Listing of treatment-emergent IMP-related AEs for T4032 or Lumigan – Safety Set
Listing 5.14 – Listing of treatment-emergent systemic AEs for T4032 or Lumigan leading to premature IMP drug withdrawal – Safety Set
Listing 5.15 – Listing of AEs for T4032 or Lumigan occur after the day of the maximal date between last IMP instillation and Visit 4 (Week 12) –Safety Set

Same as Listing 5.6

Study: LT4032-301 Page X / N
Population: Enrolled patients

Listing 5.16 – Listings of COVID-19 AEs – Enrolled patients

Actual group	Patient's identifier – Gender – Age at baseline	Worse Eye	Diagnosis (verbatim)	SOC / PT	Localisation	Date-Time of occurence / Date-Time of recovery or death	Time to occu-rence (days)	Treatment-emergence	AE duration (days)	Outcome	Frequency and details	Severity	Action taken regarding the IMP	Requirement for therapy adaptation / modification	Requirement for surgical / medical procedure	Serious ness	Relationship with IMP / with procedure
								No / TEAE Azopt / TEAE T4032 or Lumigan / Post AE									

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM

Study: LT4032-301 Page X / N
Population: Enrolled patients

Listing 5.17 – Listings of Deaths, Other Serious adverse events, discontinuations due to adverse events and other adverse events of special interest (for narratives)– Enrolled patients

Same as Table 5.16

Name of SAS program: B:\THEA\LT4032-301\Analyse\Pgm*nom_du_programme*.sas
Date and time program was run: JJMMMYYYY HH:MM