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TABLE T14.1-1.1 DISPOSITION OF PATIENTS: SCREENING FAILURES
SUMMARY OF ALL PATIENTS

Number of patients screened	131
Number of screening failures	11

Cross-reference: Listing 16.2.1-2.1
Program (Date\Time): \Tables\Tab_T14_1-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

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TABLE T14.1-1.2 DISPOSITION OF PATIENTS
RANDOMIZED POPULATION

	TRAVOPROST PR N=58	TRAVATAN N=62
Screening Visit – Visit 1		
Number of patients	58	62
Randomization Visit – Visit 2		
Number of patients	58	62
2 Weeks Visit – Visit 3		
Number of patients	53	59
4 Weeks Visit – Visit 4		
Number of patients	50	58
6 Weeks Visit – Visit 5		
Number of patients	50	56
8 Weeks Visit – Visit 6		
Number of patients	49	56
12 Weeks Final Visit – Visit 7		
Number of patients	55	58
Number of patients who completed	49	56
Number of patients who discontinued	9	6

Cross-reference: Listing 16.2.1-1
Program (Date\Time): \Tables\Tab_T14_1-1_2.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.1-2 PRIMARY REASONS FOR DISCONTINUATION FROM THE STUDY
RANDOMIZED POPULATION

	TRAVOPROST PR N=58		TRAVATAN N=62	
Number of patients who completed the study	49	(84.5%)	56	(90.3%)
Number of patients who discontinued	9	(15.5%)	6	(9.7%)
Reasons for discontinuation				
Adverse event	5	(8.6%)	3	(4.8%)
Consent withdrawn	2	(3.4%)	0	(0.0%)
Lack of efficacy	1	(1.7%)	2	(3.2%)
Lost to follow up	1	(1.7%)	0	(0.0%)
Non compliant with requests of the study	0	(0.0%)	1	(1.6%)

Note 1: Patients discontinued prior to randomization are not presented in this table.
Note 2: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.1-2.2
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LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.1-3.1 SUMMARY OF MAJOR PROTOCOL VIOLATIONS
RANDOMIZED POPULATION

	TRAVOPROST PR N=58		TRAVATAN N=62	
Number of patients with at least one major protocol violation	4	(6.9%)	1	(1.6%)
Time windows between visits not respected	1	(1.7%)	0	(0.0%)
Violation of Inclusion Criterion no. 3: IOP > 21 mmHg at Randomization visit	3	(5.2%)	1	(1.6%)

Note 1: Patients can have more than one major protocol violation.
Note 2: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.2-1.1
Program (Date\Time): \Tables\Tab_T14_1-2.sas (19JUN2014\10:06) SAS Version: 9.2

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TABLE T14.1-3.2 SUMMARY OF MINOR PROTOCOL VIOLATIONS
RANDOMIZED POPULATION

	TRAVOPROST PR N=58		TRAVATAN N=62	
Number of patients with at least one minor protocol violation	9	(15.5%)	6	(9.7%)
Number of days between visit and laboratory test not respected	1	(1.7%)	3	(4.8%)
Time windows between visits not respected	8	(13.8%)	3	(4.8%)

Note 1: Patients can have more than one minor protocol violation.
Note 2: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.2-1.2
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TABLE T14.1-4 POPULATIONS FOR ANALYSIS
RANDOMIZED POPULATION

	TRAVOPROST PR N=58	TRAVATAN N=62
Randomized population [1]	58	62
Intent-to-treat population [2]	54	59
Per protocol population [3]	46	55
Safety population [4]	58	62

[1] The randomized population consists of all randomized patients.
[2] The Intent-to-treat population includes all randomized patients who instilled at least one dose of study medication and with at least one available post-baseline efficacy evaluation.
[3] The Per protocol population includes all patients from ITT population who completed the study, meeting all inclusion/exclusion criteria and without any major protocol violations.
[4] The Safety population consists of all randomized patients who took at least one dose of study medication.

Cross-reference: Listing 16.2.3
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TABLE T14.1-5 PATIENT RECRUITMENT BY CENTRE
RANDOMIZED POPULATION

	TRAVOPROST PR N=58	TRAVATAN N=62
Centre: 01		
Randomized population [1]	9	9
Intent-to-treat population [2]	9	9
Per protocol population [3]	6	8
Safety population [4]	9	9
Centre: 02		
Randomized population [1]	2	2
Intent-to-treat population [2]	2	1
Per protocol population [3]	2	1
Safety population [4]	2	2
Centre: 03		
Randomized population [1]	8	9
Intent-to-treat population [2]	7	7
Per protocol population [3]	6	7
Safety population [4]	8	9

[1] The randomized population consists of all randomized patients.
[2] The Intent-to-treat population includes all randomized patients who instilled at least one dose of study medication and with at least one available post-baseline efficacy evaluation.
[3] The Per protocol population includes all patients from ITT population who completed the study, meeting all inclusion/exclusion criteria and without any major protocol violations.
[4] The Safety population consists of all randomized patients who took at least one dose of study medication.

Cross-reference: Listing 16.2.3
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TABLE T14.1-5 PATIENT RECRUITMENT BY CENTRE (Continued)
RANDOMIZED POPULATION

	TRAVOPROST PR N=58	TRAVATAN N=62
Centre: 04		
Randomized population [1]	4	5
Intent-to-treat population [2]	3	5
Per protocol population [3]	1	4
Safety population [4]	4	5
Centre: 05		
Randomized population [1]	10	14
Intent-to-treat population [2]	10	14
Per protocol population [3]	10	13
Safety population [4]	10	14
Centre: 06		
Randomized population [1]	5	4
Intent-to-treat population [2]	4	4
Per protocol population [3]	3	3
Safety population [4]	5	4

[1] The randomized population consists of all randomized patients.
[2] The Intent-to-treat population includes all randomized patients who instilled at least one dose of study medication and with at least one available post-baseline efficacy evaluation.
[3] The Per protocol population includes all patients from ITT population who completed the study, meeting all inclusion/exclusion criteria and without any major protocol violations.
[4] The Safety population consists of all randomized patients who took at least one dose of study medication.

Cross-reference: Listing 16.2.3
Program (Date\Time): \Tables\Tab_T14_1-2.sas (19JUN2014\10:06) SAS Version: 9.2

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TABLE T14.1-5 PATIENT RECRUITMENT BY CENTRE (Continued)
RANDOMIZED POPULATION

	TRAVOPROST PR N=58	TRAVATAN N=62
Centre: 07		
Randomized population [1]	12	11
Intent-to-treat population [2]	12	11
Per protocol population [3]	12	11
Safety population [4]	12	11
Centre: 08		
Randomized population [1]	8	8
Intent-to-treat population [2]	7	8
Per protocol population [3]	6	8
Safety population [4]	8	8

[1] The randomized population consists of all randomized patients.
[2] The Intent-to-treat population includes all randomized patients who instilled at least one dose of study medication and with at least one available post-baseline efficacy evaluation.
[3] The Per protocol population includes all patients from ITT population who completed the study, meeting all inclusion/exclusion criteria and without any major protocol violations.
[4] The Safety population consists of all randomized patients who took at least one dose of study medication.

Cross-reference: Listing 16.2.3
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TABLE T14.1-6 DEMOGRAPHIC CHARACTERISTICS
INTENT-TO-TREAT POPULATION

	TRAVOPROST PR N=54	TRAVATAN N=59
Age (years)		
n	54	59
Mean (SD)	63.2 (11.9)	66.3 (9.3)
Median	64.5	68.0
Range	32 ;88	44 ;80
Sex		
Male	30 (55.6%)	23 (39.0%)
Female	24 (44.4%)	36 (61.0%)
Race		
White	53 (98.1%)	58 (98.3%)
Other	1 (1.9%)	1 (1.7%)
Height (cm)		
n	54	59
Mean (SD)	166.9 (9.6)	165.5 (8.1)
Median	168.0	165.0
Range	146 ;190	150 ;181

Note 1: If the date of birth is specified, age has been calculated using the following rules: if the month of Screening Visit is greater than month of birth or month of Screening Visit is equal to month of birth and day of Screening Visit is greater than or equal to day of birth, then age has been calculated as year(date of Screening Visit) – year(date of birth), otherwise age has been calculated as year(date of Screening Visit) – year(date of birth) + 1.
Note 2: Percentages are calculated on the number of patients (N).
Note 3: BMI has been calculated as [weight (kg)/(height (m))²].

Cross-reference: Listing 16.2.4-1
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TABLE T14.1-6 DEMOGRAPHIC CHARACTERISTICS (Continued)
INTENT-TO-TREAT POPULATION

	TRAVOPROST PR N=54	TRAVATAN N=59
Weight (kg)		
n	54	59
Mean (SD)	74.2 (15.7)	70.7 (14.3)
Median	73.0	70.0
Range	47 ;120	48 ;140
BMI (kg/m²)		
n	54	59
Mean (SD)	26.5 (4.4)	25.7 (4.4)
Median	25.5	25.1
Range	19 ;44	19 ;47

Note 1: If the date of birth is specified, age has been calculated using the following rules: if the month of Screening Visit is greater than month of birth or month of Screening Visit is equal to month of birth and day of Screening Visit is greater than or equal to day of birth, then age has been calculated as year(date of Screening Visit) – year(date of birth), otherwise age has been calculated as year(date of Screening Visit) – year(date of birth) + 1.
Note 2: Percentages are calculated on the number of patients (N).
Note 3: BMI has been calculated as [weight (kg)/(height (m))²].

Cross-reference: Listing 16.2.4-1
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TABLE T14.1-7 STUDY DISEASE ASSESSMENT
INTENT-TO-TREAT POPULATION

	TRAVOPROST PR N=54	TRAVATAN N=59
Disease		
Primary Open-Angle Glaucoma	40 (74.1%)	46 (78.0%)
Ocular Hypertension	14 (25.9%)	13 (22.0%)
Type of disease		
Mono-lateral	7 (13.0%)	8 (13.6%)
Bilateral	47 (87.0%)	51 (86.4%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-2
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TABLE T14.1-8.1 MEDICAL HISTORY
INTENT-TO-TREAT POPULATION

	TRAVOPROST PR N=54		TRAVATAN N=59	
Number of patients with at least one medical condition	25	(46.3%)	30	(50.8%)
EENT (Eyes, Ears, Nose, Throat)				
Normal	44	(81.5%)	49	(83.1%)
Abnormal	10	(18.5%)	10	(16.9%)
Respiratory				
Normal	50	(92.6%)	54	(91.5%)
Abnormal	4	(7.4%)	5	(8.5%)
Cardiovascular				
Normal	52	(96.3%)	56	(94.9%)
Abnormal	2	(3.7%)	3	(5.1%)
Gastrointestinal				
Normal	45	(83.3%)	48	(81.4%)
Abnormal	9	(16.7%)	11	(18.6%)
Hepatic				
Normal	51	(94.4%)	54	(91.5%)
Abnormal	3	(5.6%)	5	(8.5%)

Note 1: Medical conditions not ongoing at Screening visit are presented in this table.
Note 2: Patients can have more than one medical condition.
Note 3: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-5.1
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TABLE T14.1-8.1 MEDICAL HISTORY (Continued)
INTENT-TO-TREAT POPULATION

	TRAVOPROST PR N=54		TRAVATAN N=59	
Renal				
Normal	52	(96.3%)	58	(98.3%)
Abnormal	2	(3.7%)	1	(1.7%)
Genito-urinary				
Normal	48	(88.9%)	50	(84.7%)
Abnormal	6	(11.1%)	9	(15.0%)
Neurological				
Normal	51	(94.4%)	52	(88.1%)
Abnormal	3	(5.6%)	7	(11.9%)
Hematopoietic and lymphatic				
Normal	54	(100.0%)	58	(98.3%)
Abnormal	0	(0.0%)	1	(1.7%)
Endocrine and metabolic				
Normal	54	(100.0%)	56	(94.9%)
Abnormal	0	(0.0%)	3	(5.1%)
Musculoskeletal				
Normal	52	(96.3%)	55	(93.2%)
Abnormal	2	(3.7%)	4	(6.8%)

Note 1: Medical conditions not ongoing at Screening visit are presented in this table.
Note 2: Patients can have more than one medical condition.
Note 3: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-5.1
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TABLE T14.1-8.1 MEDICAL HISTORY (Continued)
INTENT-TO-TREAT POPULATION

	TRAVOPROST PR N=54		TRAVATAN N=59	
Immunological				
Normal	54	(100.0%)	59	(100.0%)
Dermatological				
Normal	53	(98.1%)	59	(100.0%)
Abnormal	1	(1.9%)	0	(0.0%)
Psychiatric/psycological				
Normal	54	(100.0%)	59	(100.0%)
Other				
Normal	51	(94.4%)	49	(83.1%)
Abnormal	3	(5.6%)	10	(16.9%)

Note 1: Medical conditions not ongoing at Screening visit are presented in this table.
Note 2: Patients can have more than one medical condition.
Note 3: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-5.1
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TABLE T14.1-8.2 CONCOMITANT DISEASES
INTENT-TO-TREAT POPULATION

	TRAVOPROST PR N=54		TRAVATAN N=59	
Number of patients with at least one medical condition	46	(85.2%)	51	(86.4%)
EENT (Eyes, Ears, Nose, Throat)				
Normal	30	(55.6%)	36	(61.0%)
Abnormal	24	(44.4%)	23	(39.0%)
Respiratory				
Normal	53	(98.1%)	56	(94.9%)
Abnormal	1	(1.9%)	3	(5.1%)
Cardiovascular				
Normal	27	(50.0%)	25	(42.4%)
Abnormal	27	(50.0%)	34	(57.6%)
Gastrointestinal				
Normal	49	(90.7%)	46	(78.0%)
Abnormal	5	(9.3%)	13	(22.0%)
Hepatic				
Normal	51	(94.4%)	55	(93.2%)
Abnormal	3	(5.6%)	4	(6.8%)

Note 1: Medical conditions ongoing at Screening visit are presented in this table.
Note 2: Patients can have more than one concomitant disease.
Note 3: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-5.2
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TABLE T14.1-8.2 CONCOMITANT DISEASES (Continued)
INTENT-TO-TREAT POPULATION

	TRAVOPROST PR N=54		TRAVATAN N=59	
Renal				
Normal	52	(96.3%)	58	(98.3%)
Abnormal	2	(3.7%)	1	(1.7%)
Genito-urinary				
Normal	53	(98.1%)	51	(86.4%)
Abnormal	1	(1.9%)	8	(13.6%)
Neurological				
Normal	49	(90.7%)	53	(89.8%)
Abnormal	5	(9.3%)	6	(10.2%)
Hematopoietic and lymphatic				
Normal	52	(96.3%)	55	(93.2%)
Abnormal	2	(3.7%)	4	(6.8%)
Endocrine and metabolic				
Normal	35	(64.8%)	30	(50.8%)
Abnormal	19	(35.2%)	29	(49.2%)
Musculoskeletal				
Normal	43	(79.6%)	49	(83.1%)
Abnormal	11	(20.4%)	10	(16.9%)

Note 1: Medical conditions ongoing at Screening visit are presented in this table.
Note 2: Patients can have more than one concomitant disease.
Note 3: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-5.2
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TABLE T14.1-8.2 CONCOMITANT DISEASES (Continued)
INTENT-TO-TREAT POPULATION

	TRAVOPROST PR N=54		TRAVATAN N=59	
Immunological				
Normal	51	(94.4%)	56	(94.9%)
Abnormal	3	(5.6%)	3	(5.1%)
Dermatological				
Normal	51	(94.4%)	55	(93.2%)
Abnormal	3	(5.6%)	4	(6.8%)
Psychiatric/psycological				
Normal	50	(92.6%)	49	(83.1%)
Abnormal	4	(7.4%)	10	(16.9%)
Other				
Normal	48	(88.9%)	49	(83.1%)
Abnormal	6	(11.1%)	10	(16.9%)

Note 1: Medical conditions ongoing at Screening visit are presented in this table.
Note 2: Patients can have more than one concomitant disease.
Note 3: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-5.2
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TABLE T14.1-9.1 PRIOR MEDICATIONS
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Number of patients with at least one medication	16 (29.6%)	12 (20.3%)
Musculo-skeletal system, M	0 (0.0%)	1 (1.7%)
Propionic acid derivatives, M01AE	0 (0.0%)	1 (1.7%)
Ibuprofen	0 (0.0%)	1 (1.7%)
Sensory organs, S	16 (29.6%)	10 (16.9%)
Beta blocking agents, S01ED	10 (18.5%)	6 (10.2%)
Azarga	0 (0.0%)	1 (1.7%)
Carteolol hydrochloride	1 (1.9%)	0 (0.0%)
Combigan	1 (1.9%)	1 (1.7%)
Cosopt	0 (0.0%)	1 (1.7%)
Timolol	1 (1.9%)	0 (0.0%)
Timolol maleate	6 (11.1%)	2 (3.4%)
Vistagan	1 (1.9%)	0 (0.0%)
Xalacar-t	1 (1.9%)	0 (0.0%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
Note 2: Medications with start date < date of first randomised drug instillation and stop date < date of first randomised drug instillation are presented in this table.
Note 3: Patients can have more than one prior therapy.
Note 4: Patients are only counted once per treatment for each row.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.5
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TABLE T14.1-9.1 PRIOR MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Xalacom	0 (0.0%)	1 (1.7%)
Carbonic anhydrase inhibitors, S01EC	1 (1.9%)	2 (3.4%)
Brinzolamide	1 (1.9%)	1 (1.7%)
Dorzolamide hydrochloride	0 (0.0%)	1 (1.7%)
Prostaglandin analogues, S01EE	6 (11.1%)	2 (3.4%)
Bimatoprost	3 (5.6%)	1 (1.7%)
Latanoprost	2 (3.7%)	1 (1.7%)
Tafluprost	1 (1.9%)	0 (0.0%)
Systemic hormonal preparations, excl. sex hormones, H	0 (0.0%)	1 (1.7%)
Thyroid hormones, H03AA	0 (0.0%)	1 (1.7%)
Levothyroxine sodium	0 (0.0%)	1 (1.7%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
Note 2: Medications with start date < date of first randomised drug instillation and stop date < date of first randomised drug instillation are presented in this table.
Note 3: Patients can have more than one prior therapy.
Note 4: Patients are only counted once per treatment for each row.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.5
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS
INTENT-TO-TREAT POPULATION (Continued)

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Number of patients with at least one medication	45 (83.3%)	50 (84.7%)
Alimentary tract and metabolism, A	17 (31.5%)	18 (30.5%)
Aminosalicylic acid and similar agents, A07EC	1 (1.9%)	0 (0.0%)
Mesalazine	1 (1.9%)	0 (0.0%)
Antibiotics, A07AA	0 (0.0%)	3 (5.1%)
Rifaximin	0 (0.0%)	3 (5.1%)
Ascorbic acid (vitamin c), plain, A11GA	1 (1.9%)	0 (0.0%)
Ascorbic acid	1 (1.9%)	0 (0.0%)
Biguanides, A10BA	4 (7.4%)	6 (10.2%)
Metformin	3 (5.6%)	3 (5.1%)
Metformin hydrochloride	1 (1.9%)	3 (5.1%)
Bile acid preparations, A05AA	0 (0.0%)	1 (1.7%)
Ursodeoxycholic acid	0 (0.0%)	1 (1.7%)
Calcium, A12AA	2 (3.7%)	2 (3.4%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
Note 2: Medications with start date < date of first randomised drug instillation and stop date >= date of first randomised drug instillation or ongoing are presented in this table.
Note 3: Patients can have more than one concomitant medication.
Note 4: Patients are only counted once per treatment for each row.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.5
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Cacit	0 (0.0%)	1 (1.7%)
Calcium carbonate	2 (3.7%)	1 (1.7%)
Calcium, combinations with other drugs, A12AX	0 (0.0%)	1 (1.7%)
Lekovit ca	0 (0.0%)	1 (1.7%)
Combinations and complexes of aluminium, calcium a, A02AD	0 (0.0%)	1 (1.7%)
Magaldrate	0 (0.0%)	1 (1.7%)
Combinations of vitamins, A11JA	0 (0.0%)	2 (3.4%)
Berocca plus	0 (0.0%)	1 (1.7%)
Vitamin c and e	0 (0.0%)	1 (1.7%)
Insulins and analogues for injection, fast-acting, A10AB	2 (3.7%)	1 (1.7%)
Insulin aspart	1 (1.9%)	0 (0.0%)
Insulin glulisine	1 (1.9%)	0 (0.0%)
Insulin lispro	0 (0.0%)	1 (1.7%)
Insulins and analogues for injection, long-acting, A10AE	3 (5.6%)	0 (0.0%)
Insulin detemir	1 (1.9%)	0 (0.0%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
Note 2: Medications with start date < date of first randomised drug instillation and stop date >= date of first randomised drug instillation or ongoing are presented in this table.
Note 3: Patients can have more than one concomitant medication.
Note 4: Patients are only counted once per treatment for each row.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.5
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Insulin glargine	2 (3.7%)	0 (0.0%)
Other blood glucose lowering drugs, excl. insulins, A10BX	1 (1.9%)	0 (0.0%)
Repaglinide	1 (1.9%)	0 (0.0%)
Other plain vitamin preparations, A11HA	0 (0.0%)	1 (1.7%)
Pyridoxine hydrochloride	0 (0.0%)	1 (1.7%)
Propulsives, A03FA	1 (1.9%)	1 (1.7%)
Domperidone	1 (1.9%)	1 (1.7%)
Proton pump inhibitors, A02BC	4 (7.4%)	6 (10.2%)
Esomeprazole magnesium	0 (0.0%)	1 (1.7%)
Omeprazole	4 (7.4%)	3 (5.1%)
Pantoprazole	0 (0.0%)	1 (1.7%)
Pantoprazole sodium	0 (0.0%)	1 (1.7%)
Sulfonamides, urea derivatives, A10BB	0 (0.0%)	2 (3.4%)
Gliclazide	0 (0.0%)	1 (1.7%)
Glimepiride	0 (0.0%)	1 (1.7%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Vitamin d and analogues, A11CC	2 (3.7%)	2 (3.4%)
Calcitriol	0 (0.0%)	1 (1.7%)
Colecalciferol	2 (3.7%)	1 (1.7%)
Vitamins, other combinations, A11JC	0 (0.0%)	1 (1.7%)
Vitamins, other combinations	0 (0.0%)	1 (1.7%)
Not coded	4 (7.4%)	0 (0.0%)
Alimentary tract and metabolism	3 (5.6%)	0 (0.0%)
Other vitamin products, combinations	1 (1.9%)	0 (0.0%)
Antiinfectives for systemic use, J	2 (3.7%)	7 (11.9%)
Combinations of penicillins, incl. beta-lactamase, J01CR	0 (0.0%)	2 (3.4%)
Augmentin	0 (0.0%)	2 (3.4%)
Fluoroquinolones, J01MA	1 (1.9%)	3 (5.1%)
Ciprofloxacin	0 (0.0%)	1 (1.7%)
Ciprofloxacin hydrochloride	1 (1.9%)	0 (0.0%)
Levofloxacin	0 (0.0%)	2 (3.4%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Influenza vaccines, J07BB	1 (1.9%)	1 (1.7%)
Influenza vaccine	1 (1.9%)	1 (1.7%)
Penicillins with extended spectrum, J01CA	0 (0.0%)	1 (1.7%)
Amoxicillin trihydrate	0 (0.0%)	1 (1.7%)
Pneumococcal vaccines, J07AL	0 (0.0%)	1 (1.7%)
Pneumococcal vaccine	0 (0.0%)	1 (1.7%)
Third-generation cephalosporins, J01DD	0 (0.0%)	1 (1.7%)
Ceftibuten	0 (0.0%)	1 (1.7%)
Antineoplastic and immunomodulating agents, L	1 (1.9%)	1 (1.7%)
Enzyme inhibitors, L02BG	1 (1.9%)	1 (1.7%)
Anastrozole	1 (1.9%)	0 (0.0%)
Letrozole	0 (0.0%)	1 (1.7%)
Blood and blood forming organs, B	12 (22.2%)	13 (22.0%)
Folic acid and derivatives, B03BB	1 (1.9%)	1 (1.7%)
Folic acid	1 (1.9%)	1 (1.7%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Other antithrombotic agents, B01AX	1 (1.9%)	1 (1.7%)
Coumarin	1 (1.9%)	1 (1.7%)
Platelet aggregation inhibitors excl. heparin, B01AC	11 (20.4%)	11 (18.6%)
Acetylsalicylate lysine	2 (3.7%)	0 (0.0%)
Acetylsalicylic acid	8 (14.8%)	9 (15.3%)
Cilostazol	0 (0.0%)	1 (1.7%)
Clopidogrel	1 (1.9%)	0 (0.0%)
Ticlopidine hydrochloride	2 (3.7%)	2 (3.4%)
Vitamin k antagonists, B01AA	0 (0.0%)	1 (1.7%)
Acenocoumarol	0 (0.0%)	1 (1.7%)
Cardiovascular system, C	34 (63.0%)	39 (66.1%)
Ace inhibitors and diuretics, C09BA	1 (1.9%)	1 (1.7%)
Delapride	0 (0.0%)	1 (1.7%)
Zestoretic	1 (1.9%)	0 (0.0%)
Ace inhibitors, plain, C09AA	8 (14.8%)	9 (15.3%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
Note 2: Medications with start date < date of first randomised drug instillation and stop date >= date of first randomised drug instillation or ongoing are presented in this table.
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Ace inhibitors	1 (1.9%)	0 (0.0%)
Enalapril	0 (0.0%)	1 (1.7%)
Enalapril maleate	0 (0.0%)	2 (3.4%)
Perindopril	1 (1.9%)	0 (0.0%)
Ramipril	5 (9.3%)	5 (8.5%)
Zofenopril	1 (1.9%)	0 (0.0%)
Zofenopril calcium	0 (0.0%)	1 (1.7%)
Alpha-adrenoreceptor antagonists, C02CA	2 (3.7%)	0 (0.0%)
Doxazosin mesilate	2 (3.7%)	0 (0.0%)
Angiotensin II antagonists and diuretics, C09DA	4 (7.4%)	6 (10.2%)
Benicar hct	0 (0.0%)	1 (1.7%)
Blopress plus	1 (1.9%)	2 (3.4%)
Co-diovan	0 (0.0%)	2 (3.4%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Hyzaar	2 (3.7%)	1 (1.7%)
Pritorplus	1 (1.9%)	0 (0.0%)
Angiotensin II antagonists, plain, C09CA	8 (14.8%)	6 (10.2%)
Candesartan cilexetil	0 (0.0%)	1 (1.7%)
Losartan potassium	1 (1.9%)	2 (3.4%)
Olmesartan medoxomil	4 (7.4%)	1 (1.7%)
Telmisartan	0 (0.0%)	1 (1.7%)
Valsartan	3 (5.6%)	1 (1.7%)
Antiarrhythmics, class III, C01BD	0 (0.0%)	1 (1.7%)
Amiodarone hydrochloride	0 (0.0%)	1 (1.7%)
Antiarrhythmics, class ic, C01BC	0 (0.0%)	1 (1.7%)
Propafenone hydrochloride	0 (0.0%)	1 (1.7%)
Beta blocking agents, non-selective, C07AA	1 (1.9%)	0 (0.0%)
Propranolol hydrochloride	1 (1.9%)	0 (0.0%)
Beta blocking agents, selective, C07AB	5 (9.3%)	8 (13.6%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Atenolol	1 (1.9%)	1 (1.7%)
Bisoprolol fumarate	0 (0.0%)	2 (3.4%)
Metoprolol tartrate	1 (1.9%)	0 (0.0%)
Nebivolol hydrochloride	3 (5.6%)	5 (8.5%)
Beta blocking agents, selective, and thiazides, C07BB	0 (0.0%)	1 (1.7%)
Biselect	0 (0.0%)	1 (1.7%)
Digitalis glycosides, C01AA	0 (0.0%)	1 (1.7%)
Digoxin	0 (0.0%)	1 (1.7%)
Dihydropyridine derivatives, C08CA	7 (13.0%)	6 (10.2%)
Amlodipine	0 (0.0%)	1 (1.7%)
Amlodipine besilate	4 (7.4%)	4 (6.8%)
Felodipine	1 (1.9%)	0 (0.0%)
Lacidipine	1 (1.9%)	0 (0.0%)
Lercanidipine	1 (1.9%)	0 (0.0%)
Nifedipine	0 (0.0%)	1 (1.7%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Nitrendipine	0 (0.0%)	1 (1.7%)
Fibrates, C10AB	0 (0.0%)	1 (1.7%)
Fenofibrate	0 (0.0%)	1 (1.7%)
Hmg coa reductase inhibitors in combination with o, C10BA	3 (5.6%)	0 (0.0%)
Inegy	3 (5.6%)	0 (0.0%)
Hmg coa reductase inhibitors, C10AA	9 (16.7%)	18 (30.5%)
Atorvastatin calcium	3 (5.6%)	5 (8.5%)
Fluvastatin sodium	0 (0.0%)	1 (1.7%)
Lovastatin	0 (0.0%)	1 (1.7%)
Pravastatin sodium	1 (1.9%)	1 (1.7%)
Rosuvastatin calcium	1 (1.9%)	5 (8.5%)
Simvastatin	4 (7.4%)	5 (8.5%)
Imidazoline receptor agonists, C02AC	1 (1.9%)	0 (0.0%)
Clonidine	1 (1.9%)	0 (0.0%)
Low-ceiling diuretics and potassium-sparing agents, C03EA	2 (3.7%)	2 (3.4%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
Note 2: Medications with start date < date of first randomised drug instillation and stop date >= date of first randomised drug instillation or ongoing are presented in this table.
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Moduretic	2 (3.7%)	2 (3.4%)
Other lipid modifying agents, C10AX	1 (1.9%)	1 (1.7%)
Omega-3 triglycerides	1 (1.9%)	1 (1.7%)
Phenylalkylamine derivatives, C08DA	1 (1.9%)	1 (1.7%)
Verapamil	1 (1.9%)	0 (0.0%)
Verapamil hydrochloride	0 (0.0%)	1 (1.7%)
Sulfonamides, plain, C03CA	2 (3.7%)	4 (6.8%)
Furosemide	2 (3.7%)	4 (6.8%)
Thiazides, plain, C03AA	0 (0.0%)	1 (1.7%)
Hydrochlorothiazide	0 (0.0%)	1 (1.7%)
Dermatologicals, D	1 (1.9%)	2 (3.4%)
Corticosteroids, potent (group III), D07AC	1 (1.9%)	1 (1.7%)
Betamethasone sodium phosphate	1 (1.9%)	0 (0.0%)

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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Betamethasone valerate	0 (0.0%)	1 (1.7%)
Other antipsoriatics for topical use, D05AX	0 (0.0%)	1 (1.7%)
Daivobet	0 (0.0%)	1 (1.7%)
Genito urinary system and sex hormones, G	1 (1.9%)	4 (6.8%)
Alpha-adrenoreceptor antagonists, G04CA	1 (1.9%)	2 (3.4%)
Tamsulosin hydrochloride	1 (1.9%)	2 (3.4%)
Drugs used in erectile dysfunction, G04BE	0 (0.0%)	1 (1.7%)
Tadalafil	0 (0.0%)	1 (1.7%)
Natural and semisynthetic estrogens, plain, G03CA	0 (0.0%)	1 (1.7%)
Promestriene	0 (0.0%)	1 (1.7%)
Musculo-skeletal system, M	5 (9.3%)	11 (18.6%)
Acetic acid derivatives and related substances, M01AB	1 (1.9%)	3 (5.1%)
Aceclofenac	0 (0.0%)	1 (1.7%)
Diclofenac	0 (0.0%)	2 (3.4%)

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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Diclofenac sodium	1 (1.9%)	0 (0.0%)
Bisphosphonates, M05BA	1 (1.9%)	1 (1.7%)
Alendronate sodium	1 (1.9%)	0 (0.0%)
Neridronic acid	0 (0.0%)	1 (1.7%)
Coxibs, M01AH	0 (0.0%)	1 (1.7%)
Celecoxib	0 (0.0%)	1 (1.7%)
Etoricoxib	0 (0.0%)	1 (1.7%)
Other antiinflammatory and antirheumatic agents, n, M01AX	1 (1.9%)	2 (3.4%)
Morniflumate	0 (0.0%)	1 (1.7%)
Nimesulide	1 (1.9%)	1 (1.7%)
Other drugs affecting bone structure and mineraliz, M05BX	0 (0.0%)	1 (1.7%)
Strontium ranelate	0 (0.0%)	1 (1.7%)
Oxicams, M01AC	1 (1.9%)	0 (0.0%)
Piroxicam	1 (1.9%)	0 (0.0%)
Preparations inhibiting uric acid production, M04AA	1 (1.9%)	1 (1.7%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Allopurinol	1 (1.9%)	1 (1.7%)
Propionic acid derivatives, M01AE	1 (1.9%)	4 (6.8%)
Ibuprofen	1 (1.9%)	3 (5.1%)
Naproxen sodium	0 (0.0%)	1 (1.7%)
Nervous system, N	10 (18.5%)	11 (18.6%)
Anilides, N02BE	0 (0.0%)	1 (1.7%)
Paracetamol	0 (0.0%)	1 (1.7%)
Antivertigo preparations, N07CA	1 (1.9%)	0 (0.0%)
Antivertigo preparations	1 (1.9%)	0 (0.0%)
Benzodiazepine derivatives, N05BA	0 (0.0%)	7 (11.9%)
Alprazolam	0 (0.0%)	3 (5.1%)
Bromazepam	0 (0.0%)	2 (3.4%)
Delorazepam	0 (0.0%)	1 (1.7%)
Diazepam	0 (0.0%)	1 (1.7%)
Benzodiazepine derivatives, N05CD	1 (1.9%)	0 (0.0%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Triazolam	1 (1.9%)	0 (0.0%)
Benzodiazepine related drugs, N05CF	1 (1.9%)	1 (1.7%)
Zolpidem	1 (1.9%)	0 (0.0%)
Zolpidem tartrate	0 (0.0%)	1 (1.7%)
Butyrophenone derivatives, N05AD	1 (1.9%)	0 (0.0%)
Haloperidol decanoate	1 (1.9%)	0 (0.0%)
Natural opium alkaloids, N02AA	0 (0.0%)	1 (1.7%)
Panadeine co	0 (0.0%)	1 (1.7%)
Other antiepileptics, N03AX	1 (1.9%)	0 (0.0%)
Pregabalin	1 (1.9%)	0 (0.0%)
Other local anesthetics, N01BX	1 (1.9%)	0 (0.0%)
Capsaicin	1 (1.9%)	0 (0.0%)
Other opioids, N02AX	1 (1.9%)	0 (0.0%)
Tapentadol	1 (1.9%)	0 (0.0%)
Other psychostimulants and nootropics, N06BX	1 (1.9%)	0 (0.0%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
Note 2: Medications with start date < date of first randomised drug instillation and stop date >= date of first randomised drug instillation or ongoing are presented in this table.
Note 3: Patients can have more than one concomitant medication.
Note 4: Patients are only counted once per treatment for each row.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.5
Program (Date\Time): \Tables\Tab_T14_1-2.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Acetylcarnitine hydrochloride	1 (1.9%)	0 (0.0%)
Salicylic acid and derivatives, N02BA	2 (3.7%)	1 (1.7%)
Acetylsalicylic acid	2 (3.7%)	1 (1.7%)
Selective serotonin reuptake inhibitors, N06AB	2 (3.7%)	3 (5.1%)
Escitalopram oxalate	1 (1.9%)	0 (0.0%)
Fluoxetine	1 (1.9%)	0 (0.0%)
Paroxetine hydrochloride	0 (0.0%)	3 (5.1%)
Respiratory system, R	0 (0.0%)	6 (10.2%)
Adrenergics and other drugs for obstructive airway, R03AK	0 (0.0%)	2 (3.4%)
Breva	0 (0.0%)	1 (1.7%)
Budesonide w/formoterol fumarate	0 (0.0%)	1 (1.7%)
Glucocorticoids, R03BA	0 (0.0%)	2 (3.4%)
Beclometasone dipropionate	0 (0.0%)	2 (3.4%)
Flunisolide	0 (0.0%)	1 (1.7%)
Mucolytics, R05CB	0 (0.0%)	1 (1.7%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
Note 2: Medications with start date < date of first randomised drug instillation and stop date >= date of first randomised drug instillation or ongoing are presented in this table.
Note 3: Patients can have more than one concomitant medication.
Note 4: Patients are only counted once per treatment for each row.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.5
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LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Acetylcysteine	0 (0.0%)	1 (1.7%)
Ambroxol hydrochloride	0 (0.0%)	1 (1.7%)
Opium alkaloids and derivatives, R05DA	0 (0.0%)	1 (1.7%)
Cardiazol-paracodina	0 (0.0%)	1 (1.7%)
Other cough suppressants, R05DB	0 (0.0%)	1 (1.7%)
Levodropropizine	0 (0.0%)	1 (1.7%)
Piperazine derivatives, R06AE	0 (0.0%)	1 (1.7%)
Cetirizine hydrochloride	0 (0.0%)	1 (1.7%)
Sensory organs, S	1 (1.9%)	2 (3.4%)
Antibiotics, S01AA	0 (0.0%)	1 (1.7%)
Netilmicin sulfate	0 (0.0%)	1 (1.7%)
Antiinfectives, S02AA	0 (0.0%)	1 (1.7%)
Ofloxacin	0 (0.0%)	1 (1.7%)
Corticosteroids and antiinfectives in combination, S01CA	1 (1.9%)	0 (0.0%)
Betabioptal	1 (1.9%)	0 (0.0%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
Note 2: Medications with start date < date of first randomised drug instillation and stop date >= date of first randomised drug instillation or ongoing are presented in this table.
Note 3: Patients can have more than one concomitant medication.
Note 4: Patients are only counted once per treatment for each row.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.5
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TABLE T14.1-9.2 CONCOMITANT MEDICATIONS (Continued)
INTENT-TO-TREAT POPULATION

Anatomical Main Group Chemical Subgroup Preferred Name	TRAVOPROST PR N=54	TRAVATAN N=59
Viscoelastic substances, S01KA	0 (0.0%)	1 (1.7%)
Hyaluronic acid	0 (0.0%)	1 (1.7%)
Systemic hormonal preparations, excl. sex hormones, H	6 (11.1%)	10 (16.9%)
Glucocorticoids, H02AB	1 (1.9%)	0 (0.0%)
Prednisone	1 (1.9%)	0 (0.0%)
Thyroid hormones, H03AA	5 (9.3%)	10 (16.9%)
Levothyroxine sodium	5 (9.3%)	10 (16.9%)
Not coded	1 (1.9%)	0 (0.0%)
Not coded	1 (1.9%)	0 (0.0%)
Not coded	1 (1.9%)	0 (0.0%)

Note 1: Medications have been coded using WHO Drug Dictionary, 2011Q1 (1st Quarter of 2011). Anatomical Main Group, Chemical Subgroup and Preferred Name are presented.
Note 2: Medications with start date < date of first randomised drug instillation and stop date >= date of first randomised drug instillation or ongoing are presented in this table.
Note 3: Patients can have more than one concomitant medication.
Note 4: Patients are only counted once per treatment for each row.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.5
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LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.2-1.1 IOP (MMHG) AT EACH VISIT AND CHANGE AND PERCENT CHANGE FROM BASELINE TO END OF TREATMENT
INTENT-TO-TREAT POPULATION

	Visit 1 Screening	Visit 2 Baseline	Visit 3 2 Weeks	Visit 4 4 Weeks	Visit 5 6 Weeks	Visit 6 8 Weeks	Visit 7 12 Weeks
TRAVOPROST PR (N=54)							
IOP (mmHg) measured at 9.00							
n	54	54	52	50	50	49	52
Mean (SD)	18.38 (3.97)	22.82 (1.85)	15.07 (2.91)	14.92 (2.53)	14.50 (2.69)	14.42 (2.13)	14.92 (3.4
Median	18.00	22.17	14.33	14.00	14.17	14.00	14.67
Range	10.0 ;25.0	17.0 ;30.0	10.0 ;25.7	11.3 ;22.0	10.0 ;26.7	10.7 ;18.3	10.0 ;33.3
Mean change from baseline							
n			52	50	50	49	52
Mean change (SD)			-7.79 (3.02)	-7.86 (2.50)	-8.28 (3.04)	-8.39 (2.32)	-7.83 (4.2
Range			-15.0 ;4.0	-13.0 ;0.3	-13.0 ;5.0	-13.0 ;-4.0	-20.0 ;11.7
Mean percent change from baseline							
n			52	50	50	49	52
Mean change (SD)			-33.92 (12.50)	-34.43 (10.45)	-36.06 (12.62)	-36.63 (9.06)	-33.76 (17.
Range			-54.5 ;18.5	-50.7 ;1.5	-56.5 ;23.1	-50.7 ;-18.2	-66.7 ;53.8
IOP (mmHg) measured at 13.00							
n		54					51
Mean (SD)		22.41 (2.23)					14.67 (3.5
Median		22.00					14.67
Range		16.3 ;32.0					10.0 ;34.3

Note 1: For IOP values recorded at 9.00, 13.00 and 17.00 the mean value of the three measurements detected at each time point is considered in this table.

Cross-reference: Listing 16.2.6
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

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TABLE T14.2-1.1 IOP (MMHG) AT EACH VISIT AND CHANGE AND PERCENT CHANGE FROM BASELINE TO END OF TREATMENT (Continued)
INTENT-TO-TREAT POPULATION

	Visit 1 Screening	Visit 2 Baseline	Visit 3 2 Weeks	Visit 4 4 Weeks	Visit 5 6 Weeks	Visit 6 8 Weeks	Visit 7 12 Weeks
IOP (mmHg) measured at 17.00							
n		54					51
Mean (SD)		22.60 (2.21)					14.73 (3.6
Median		22.17					14.67
Range		16.0 ;29.0					10.0 ;33.3
IOP (mmHg) - mean value of measurements at 9.00, 13.00 and 17.00							
n		54					52
Mean (SD)		22.61 (1.87)					14.74 (3.3
Median		22.39					14.67
Range		18.7 ;30.3					10.0 ;33.7
Mean change from baseline							
n							52
Mean change (SD)							-7.79 (3.5
Range							-15.7 ;9.8
Mean percent change from baseline							
n							52
Mean change (SD)							-34.40 (14.
Range							-53.1 ;40.9

Note 1: For IOP values recorded at 9.00, 13.00 and 17.00 the mean value of the three measurements detected at each time point is considered in this table.

Cross-reference: Listing 16.2.6
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LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.2-1.1 IOP (MMHG) AT EACH VISIT AND CHANGE AND PERCENT CHANGE FROM BASELINE TO END OF TREATMENT (Continued)
INTENT-TO-TREAT POPULATION

	Visit 1 Screening	Visit 2 Baseline	Visit 3 2 Weeks	Visit 4 4 Weeks	Visit 5 6 Weeks	Visit 6 8 Weeks	Visit 7 12 Weeks
TRAVATAN (N=59)							
IOP (mmHg) measured at 9.00							
n	59	59	59	58	56	55	56
Mean (SD)	19.15 (4.61)	23.40 (3.13)	15.07 (3.27)	14.59 (3.20)	14.63 (2.45)	14.78 (2.61)	14.30 (2.9
Median	20.00	23.00	14.67	14.00	14.75	14.33	14.00
Range	10.0 ;34.7	13.7 ;35.0	10.3 ;32.0	7.3 ;26.3	9.0 ;21.0	8.7 ;22.0	8.7 ;22.0
Mean change from baseline							
n			59	58	56	55	56
Mean change (SD)			-8.33 (3.34)	-8.61 (3.49)	-8.60 (2.91)	-8.44 (3.27)	-8.93 (3.8
Range			-22.0 ;-2.0	-17.0 ;2.3	-16.0 ;0.0	-16.7 ;0.0	-19.0 ;3.0
Mean percent change from baseline							
n			59	58	56	55	56
Mean change (SD)			-35.33 (11.19)	-36.81 (13.21)	-36.57 (10.91)	-35.78 (12.03)	-37.70 (15.
Range			-64.7 ;-7.7	-69.0 ;9.7	-62.0 ;0.0	-61.0 ;0.0	-60.6 ;22.0
IOP (mmHg) measured at 13.00							
n		59					55
Mean (SD)		23.12 (3.10)					14.00 (3.1
Median		22.33					13.00
Range		17.3 ;35.0					8.7 ;23.0

Note 1: For IOP values recorded at 9.00, 13.00 and 17.00 the mean value of the three measurements detected at each time point is considered in this table.

Cross-reference: Listing 16.2.6
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TABLE T14.2-1.1 IOP (MMHG) AT EACH VISIT AND CHANGE AND PERCENT CHANGE FROM BASELINE TO END OF TREATMENT (Continued)
INTENT-TO-TREAT POPULATION

	Visit 1 Screening	Visit 2 Baseline	Visit 3 2 Weeks	Visit 4 4 Weeks	Visit 5 6 Weeks	Visit 6 8 Weeks	Visit 7 12 Weeks
IOP (mmHg) measured at 17.00							
n		59					55
Mean (SD)		22.60 (3.04)					13.92 (2.8
Median		22.33					13.33
Range		16.0 ;32.0					8.2 ;20.7
IOP (mmHg) - mean value of measurements at 9.00, 13.00 and 17.00							
n		59					56
Mean (SD)		23.04 (2.92)					14.06 (2.7
Median		22.33					13.31
Range		16.1 ;34.0					8.9 ;20.4
Mean change from baseline							
n							56
Mean change (SD)							-8.84 (3.0
Range							-15.4 ;-2.3
Mean percent change from baseline							
n							56
Mean change (SD)							-38.26 (11.
Range							-59.8 ;-11.

Note 1: For IOP values recorded at 9.00, 13.00 and 17.00 the mean value of the three measurements detected at each time point is considered in this table.

Cross-reference: Listing 16.2.6
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TABLE T14.2-1.2 PRIMARY EFFICACY ANALYSIS: CHANGE IN IOP (MMHG) FROM BASELINE TO END OF TREATMENT
ANALYSIS OF COVARIANCE
INTENT-TO-TREAT POPULATION

Number of patients			
TRAVOPROST PR	54		
TRAVATAN	59		
Number of patients considered in the model			
TRAVOPROST PR	52		
TRAVATAN	56		
p-value for fixed effects			
Treatment	0.156		
Baseline	<0.001		
Adjusted means		95% confidence interval	p-value
TRAVOPROST PR	-7.911	-8.722 ,-7.099	
TRAVATAN	-8.725	-9.507 ,-7.943	
Treatments difference: Travoprost PR and Travatan	0.814	-0.315 ,1.943	0.156 Equivalence not declared

Note 1: Analysis is based on an ANCOVA model with change in IOP from baseline to end of treatment as dependent variable, treatment as factor and baseline as covariate.
Note 2: The mean of IOP measured at 9.00, 13.00 and 17.00 has been considered in the analysis.

Cross-reference: Listing 16.2.6
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TABLE T14.2-1.3 SECONDARY EFFICACY ANALYSIS: PERCENT CHANGE IN IOP (MMHG) FROM BASELINE TO END OF TREATMENT
ANALYSIS OF COVARIANCE
INTENT-TO-TREAT POPULATION

Number of patients			
TRAVOPROST PR	54		
TRAVATAN	59		
Number of patients considered in the model			
TRAVOPROST PR	52		
TRAVATAN	56		
p-value for fixed effects			
Treatment	0.166		
Baseline	0.040		
Adjusted means		95% confidence interval	p-value
TRAVOPROST PR	-34.611	-38.139 ,-31.084	
TRAVATAN	-38.061	-41.460 ,-34.663	
Treatments difference: Travoprost PR and Travatan	3.450	-1.456 ,8.356	0.166

Note 1: Analysis is based on an ANCOVA model with percent change in IOP from baseline to end of treatment as dependent variable, treatment as factor and baseline as covariate.
Note 2: The mean of IOP measured at 9.00, 13.00 and 17.00 has been considered in the analysis.

Cross-reference: Listing 16.2.6
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LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.2-2.1 IOP (MMHG) AT EACH VISIT AND CHANGE AND PERCENT CHANGE FROM BASELINE TO END OF TREATMENT
PER PROTOCOL POPULATION

	Visit 1 Screening	Visit 2 Baseline	Visit 3 2 Weeks	Visit 4 4 Weeks	Visit 5 6 Weeks	Visit 6 8 Weeks	Visit 7 12 Weeks
TRAVOPROST PR (N=46)							
IOP (mmHg) measured at 9.00							
n	46	46	46	46	46	46	46
Mean (SD)	18.11 (4.07)	22.99 (1.71)	14.72 (2.32)	14.91 (2.35)	14.30 (2.12)	14.46 (2.11)	14.45 (2.2
Median	18.00	22.33	14.00	14.17	14.17	14.00	14.17
Range	10.0 ;25.0	21.3 ;30.0	10.0 ;20.0	11.3 ;21.0	10.0 ;19.0	11.0 ;18.3	10.0 ;20.0
Mean change from baseline							
n			46	46	46	46	46
Mean change (SD)			-8.26 (2.45)	-8.08 (2.25)	-8.69 (2.28)	-8.53 (2.32)	-8.54 (3.0
Range			-15.0 ;-3.0	-13.0 ;-1.0	-13.0 ;-3.0	-13.0 ;-4.0	-20.0 ;-3.3
Mean percent change from baseline							
n			46	46	46	46	46
Mean change (SD)			-35.84 (9.75)	-35.13 (9.40)	-37.68 (9.01)	-36.96 (9.17)	-36.75 (11.
Range			-54.5 ;-13.6	-50.7 ;-4.5	-56.5 ;-13.6	-50.7 ;-18.2	-66.7 ;-15.
IOP (mmHg) measured at 13.00							
n		46					46
Mean (SD)		22.36 (2.35)					14.20 (2.2
Median		22.00					14.17
Range		16.3 ;32.0					10.0 ;20.0

Note 1: For IOP values recorded at 9.00, 13.00 and 17.00 the mean value of the three measurements detected at time point is considered in this ta

Cross-reference: Listing 16.2.6
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TABLE T14.2-2.1 IOP (MMHG) AT EACH VISIT AND CHANGE AND PERCENT CHANGE FROM BASELINE TO END OF TREATMENT (Continued)
PER PROTOCOL POPULATION

	Visit 1 Screening	Visit 2 Baseline	Visit 3 2 Weeks	Visit 4 4 Weeks	Visit 5 6 Weeks	Visit 6 8 Weeks	Visit 7 12 Weeks
IOP (mmHg) measured at 17.00							
n		46					46
Mean (SD)		22.43 (2.20)					14.40 (2.5
Median		22.17					14.67
Range		16.0 ;29.0					10.0 ;20.7
IOP (mmHg) - mean value of measurements at 9.00, 13.00 and 17.00							
n		46					46
Mean (SD)		22.59 (1.91)					14.35 (2.0
Median		22.39					14.67
Range		18.7 ;30.3					10.0 ;20.2
Mean change from baseline							
n							46
Mean change (SD)							-8.25 (2.5
Range							-15.7 ;-3.4
Mean percent change from baseline							
n							46
Mean change (SD)							-36.24 (9.6
Range							-53.1 ;-14.

Note 1: For IOP values recorded at 9.00, 13.00 and 17.00 the mean value of the three measurements detected at time point is considered in this ta

Cross-reference: Listing 16.2.6
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TABLE T14.2-2.1 IOP (MMHG) AT EACH VISIT AND CHANGE AND PERCENT CHANGE FROM BASELINE TO END OF TREATMENT (Continued)
PER PROTOCOL POPULATION

	Visit 1 Screening	Visit 2 Baseline	Visit 3 2 Weeks	Visit 4 4 Weeks	Visit 5 6 Weeks	Visit 6 8 Weeks	Visit 7 12 Weeks
TRAVATAN (N=55)							
IOP (mmHg) measured at 9.00							
n	55	55	55	55	55	53	55
Mean (SD)	18.93 (4.15)	23.41 (2.52)	14.82 (2.39)	14.57 (3.17)	14.65 (2.47)	14.84 (2.65)	14.26 (2.9
Median	20.00	23.00	14.50	14.00	14.83	14.67	14.00
Range	10.0 ;27.7	21.3 ;35.0	10.7 ;21.3	7.3 ;26.3	9.0 ;21.0	8.7 ;22.0	8.7 ;22.0
Mean change from baseline							
n			55	55	55	53	55
Mean change (SD)			-8.59 (3.28)	-8.84 (3.42)	-8.76 (2.68)	-8.59 (3.12)	-9.15 (3.4
Range			-22.0 ;-2.0	-17.0 ;2.3	-16.0 ;-2.7	-16.7 ;-2.0	-19.0 ;-1.7
Mean percent change from baseline							
n			55	55	55	53	55
Mean change (SD)			-36.24 (10.76)	-37.56 (13.05)	-37.23 (9.80)	-36.36 (11.17)	-38.79 (12.
Range			-64.7 ;-8.7	-69.0 ;9.7	-62.0 ;-11.6	-61.0 ;-8.3	-60.6 ;-7.0
IOP (mmHg) measured at 13.00							
n		55					54
Mean (SD)		23.10 (2.91)					14.04 (3.1
Median		22.33					13.00
Range		19.0 ;35.0					8.7 ;23.0

Note 1: For IOP values recorded at 9.00, 13.00 and 17.00 the mean value of the three measurements detected at time point is considered in this ta

Cross-reference: Listing 16.2.6
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TABLE T14.2-2.1 IOP (MMHG) AT EACH VISIT AND CHANGE AND PERCENT CHANGE FROM BASELINE TO END OF TREATMENT (Continued)
PER PROTOCOL POPULATION

	Visit 1 Screening	Visit 2 Baseline	Visit 3 2 Weeks	Visit 4 4 Weeks	Visit 5 6 Weeks	Visit 6 8 Weeks	Visit 7 12 Weeks
IOP (mmHg) measured at 17.00							
n		55					54
Mean (SD)		22.55 (2.79)					13.96 (2.8
Median		22.33					13.33
Range		16.0 ;32.0					8.2 ;20.7
IOP (mmHg) - mean value of measurements at 9.00, 13.00 and 17.00							
n		55					55
Mean (SD)		23.02 (2.55)					14.07 (2.7
Median		22.33					13.28
Range		19.7 ;34.0					8.9 ;20.4
Mean change from baseline							
n							55
Mean change (SD)							-8.95 (2.9
Range							-15.4 ;-2.3
Mean percent change from baseline							
n							55
Mean change (SD)							-38.65 (11.
Range							-59.8 ;-11.

Note 1: For IOP values recorded at 9.00, 13.00 and 17.00 the mean value of the three measurements detected at time point is considered in this ta

Cross-reference: Listing 16.2.6
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TABLE T14.2-2.2 PRIMARY EFFICACY ANALYSIS: CHANGE IN IOP (MMHG) FROM BASELINE TO END OF TREATMENT
ANALYSIS OF COVARIANCE
PER PROTOCOL POPULATION

Number of patients				
TRAVOPROST PR	46			
TRAVATAN	55			
Number of patients considered in the model				
TRAVOPROST PR	46			
TRAVATAN	55			
p-value for fixed effects				
Treatment	0.375			
Baseline	<0.001			
Adjusted means		95% confidence interval	p-value	
TRAVOPROST PR	-8.400	-9.094 ,-7.706		
TRAVATAN	-8.823	-9.457 ,-8.189		
Treatments difference: Travoprost PR and Travatan	0.423	-0.519 ,1.365	0.375	Equivalence declared

Note 1: Analysis is based on an ANCOVA model with change in IOP from baseline to end of treatment as dependent variable, treatment as factor and baseline as covariate.
Note 2: The mean of IOP measured at 9.00, 13.00 and 17.00 has been considered in the analysis.

Cross-reference: Listing 16.2.6
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TABLE T14.3-1 EXTENT OF EXPOSURE
SAFETY POPULATION

	TRAVOPROST PR N=58	TRAVATAN N=62
Extent of exposure (days)		
n	58	62
Mean (SD)	73.6 (24.7)	79.3 (19.6)
Median	83.0	84.0
Range	7 ;96	5 ;100

Note 1: The extent of exposure (days) has been calculated using the following formula: Extent of exposure (days)=(Date of last randomised drug instillation – Date of first randomised drug instillation)+1. If the patient discontinued the study: Extent of exposure (days)=(Date of discontinuation – Date of first randomised drug instillation).

Cross-reference: Listing 16.2.1-1
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.1-1.1 SUMMARY OF PRE-TREATMENT ADVERSE EVENTS
SAFETY POPULATION

	TRAVOPROST PR N=58	TRAVATAN N=62
Number of AEs	1	1
Number of patients with AEs	1 (1.7%)	1 (1.6%)
Number of SAEs	0	0
Number of patients with SAEs	0 (0.0%)	0 (0.0%)
Number of ADRs	1	1
Number of patients with ADRs	1 (1.7%)	1 (1.6%)
Number of serious ADRs	0	0
Number of patients with serious ADRs	0 (0.0%)	0 (0.0%)
Number of severe AEs	0	0
Number of patients with severe AEs	0 (0.0%)	0 (0.0%)
Number of AEs leading to discontinuation	0	0
Number of patients with AEs leading to discontinuation	0 (0.0%)	0 (0.0%)

Note 1: Adverse events with date of informed consent signature <= AE onset date < date of first randomised drug instillation are presented in this table.
Note 2: SAE = Serious Adverse Event, ADR = Adverse Drug Reaction.
Note 3: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-7
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.1-1.2 SUMMARY OF TREATMENT-EMERGENT ADVERSE EVENTS
SAFETY POPULATION

	TRAVOPROST PR N=58	TRAVATAN N=62	
Number of AEs	57	73	
Number of patients with AEs	22 (37.9%)	27 (43.5%)	
Chi-square test, p-value			0.532
Number of SAEs	1	1	
Number of patients with SAEs	1 (1.7%)	1 (1.6%)	
Fisher Exact test, p-value			1.000
Number of ADRs	38	41	
Number of patients with ADRs	19 (32.8%)	22 (35.5%)	
Chi-square test, p-value			0.753
Number of serious ADRs	0	0	
Number of patients with serious ADRs	0 (0.0%)	0 (0.0%)	
Number of severe AEs	9	1	
Number of patients with severe AEs	5 (8.6%)	1 (1.6%)	
Fisher Exact test, p-value			0.106
Number of AEs leading to discontinuation	14	5	
Number of patients with AEs leading to discontinuation	5 (8.6%)	3 (4.8%)	
Fisher Exact test, p-value			0.481

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: SAE = Serious Adverse Event, ADR = Adverse Drug Reaction.
Note 3: Percentages are calculated on the number of patients (N).
Note 4: Differences between groups have been evaluated using chi-square test or, if more than 20% of the cells in a contingency table have expected counts less than 5, Fisher's exact test.

Cross-reference: Listing 16.2.7-7
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.1-2 TREATMENT-EMERGENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58		TRAVATAN N=62	
	Number (%) of Patients	Number of Events	Number (%) of Patients	Number of Events
Any TEAE	22 (37.9%)	57	27 (43.5%)	73
Cardiac disorders	1 (1.7%)	1	0 (0.0%)	0
Heart valve incompetence	1 (1.7%)	1	0 (0.0%)	0
Congenital, familial and genetic disorders	1 (1.7%)	1	0 (0.0%)	0
Hydrocele	1 (1.7%)	1	0 (0.0%)	0
Ear and labyrinth disorders	1 (1.7%)	1	0 (0.0%)	0
Vertigo	1 (1.7%)	1	0 (0.0%)	0
Eye disorders	16 (27.6%)	26	17 (27.4%)	25
Abnormal sensation in eye	0 (0.0%)	0	1 (1.6%)	1
Chalazion	1 (1.7%)	1	0 (0.0%)	0
Conjunctival hyperaemia	6 (10.3%)	6	5 (8.1%)	5
Conjunctivitis	0 (0.0%)	0	1 (1.6%)	2
Dry eye	1 (1.7%)	2	2 (3.2%)	2
Eye irritation	4 (6.9%)	4	7 (11.3%)	7

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 4: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-7
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.1-2 TREATMENT-EMERGENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (Continued)
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58		TRAVATAN N=62	
	Number (%) of Patients	Number of Events	Number (%) of Patients	Number of Events
Eye pruritus	1 (1.7%)	1	3 (4.8%)	3
Eye swelling	0 (0.0%)	0	1 (1.6%)	1
Eyelid oedema	2 (3.4%)	2	0 (0.0%)	0
Eyelid ptosis	1 (1.7%)	1	0 (0.0%)	0
Foreign body sensation in eyes	0 (0.0%)	0	1 (1.6%)	1
Glare	1 (1.7%)	1	0 (0.0%)	0
Ocular hyperaemia	3 (5.2%)	3	2 (3.2%)	2
Photopsia	1 (1.7%)	1	1 (1.6%)	1
Retinal vein occlusion	1 (1.7%)	1	0 (0.0%)	0
Vision blurred	2 (3.4%)	2	0 (0.0%)	0
Vitreous floaters	1 (1.7%)	1	0 (0.0%)	0
Gastrointestinal disorders	1 (1.7%)	1	4 (6.5%)	4
Abdominal pain upper	0 (0.0%)	0	1 (1.6%)	1
Dry mouth	0 (0.0%)	0	1 (1.6%)	1
Nausea	1 (1.7%)	1	0 (0.0%)	0

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 4: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-7
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.1-2 TREATMENT-EMERGENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (Continued)
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58		TRAVATAN N=62	
	Number (%) of Patients	Number of Events	Number (%) of Patients	Number of Events
Odynophagia	0 (0.0%)	0	1 (1.6%)	1
Toothache	0 (0.0%)	0	1 (1.6%)	1
General disorders and administration site conditions	1 (1.7%)	1	4 (6.5%)	4
Chest pain	0 (0.0%)	0	1 (1.6%)	1
Fatigue	0 (0.0%)	0	2 (3.2%)	2
Sensation of foreign body	0 (0.0%)	0	1 (1.6%)	1
Swelling	1 (1.7%)	1	0 (0.0%)	0
Infections and infestations	2 (3.4%)	2	9 (14.5%)	14
Bronchitis	0 (0.0%)	0	1 (1.6%)	1
Cystitis	0 (0.0%)	0	1 (1.6%)	3
Ear infection	0 (0.0%)	0	3 (4.8%)	3
Gastroenteritis viral	0 (0.0%)	0	1 (1.6%)	1
Influenza	0 (0.0%)	0	1 (1.6%)	2
Nasopharyngitis	2 (3.4%)	2	3 (4.8%)	3
Tooth abscess	0 (0.0%)	0	1 (1.6%)	1

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 4: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-7
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LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.1-2 TREATMENT-EMERGENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (Continued)
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58		TRAVATAN N=62	
	Number (%) of Patients	Number of Events	Number (%) of Patients	Number of Events
Injury, poisoning and procedural complications	0 (0.0%)	0	1 (1.6%)	1
Femur fracture	0 (0.0%)	0	1 (1.6%)	1
Investigations	1 (1.7%)	1	0 (0.0%)	0
Heart rate increased	1 (1.7%)	1	0 (0.0%)	0
Musculoskeletal and connective tissue disorders	2 (3.4%)	6	5 (8.1%)	6
Arthralgia	1 (1.7%)	1	2 (3.2%)	2
Back pain	1 (1.7%)	1	0 (0.0%)	0
Musculoskeletal pain	1 (1.7%)	2	0 (0.0%)	0
Myalgia	0 (0.0%)	0	1 (1.6%)	1
Neck pain	1 (1.7%)	2	2 (3.2%)	2
Pain in extremity	0 (0.0%)	0	1 (1.6%)	1
Nervous system disorders	2 (3.4%)	2	3 (4.8%)	3
Headache	2 (3.4%)	2	2 (3.2%)	2
Tremor	0 (0.0%)	0	1 (1.6%)	1
Psychiatric disorders	0 (0.0%)	0	2 (3.2%)	2

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 4: Percentages are calculated on the number of patients (N).
Cross-reference: Listing 16.2.7-7
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TABLE T14.3.1-2 TREATMENT-EMERGENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (Continued)
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58		TRAVATAN N=62	
	Number (%) of Patients	Number of Events	Number (%) of Patients	Number of Events
Anxiety disorder	0 (0.0%)	0	1 (1.6%)	1
Insomnia	0 (0.0%)	0	1 (1.6%)	1
Reproductive system and breast disorders	1 (1.7%)	1	0 (0.0%)	0
Prostatitis	1 (1.7%)	1	0 (0.0%)	0
Respiratory, thoracic and mediastinal disorders	2 (3.4%)	2	4 (6.5%)	4
Cough	0 (0.0%)	0	1 (1.6%)	1
Dyspnoea	2 (3.4%)	2	0 (0.0%)	0
Oropharyngeal pain	0 (0.0%)	0	3 (4.8%)	3
Skin and subcutaneous tissue disorders	4 (6.9%)	6	3 (4.8%)	5
Alopecia	0 (0.0%)	0	1 (1.6%)	1
Eczema	1 (1.7%)	1	1 (1.6%)	1
Erythema	1 (1.7%)	1	0 (0.0%)	0
Madarosis	0 (0.0%)	0	1 (1.6%)	1
Pruritus	2 (3.4%)	2	1 (1.6%)	1
Rash	1 (1.7%)	1	0 (0.0%)	0

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 4: Percentages are calculated on the number of patients (N).
Cross-reference: Listing 16.2.7-7
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LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.1-2 TREATMENT-EMERGENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (Continued)
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58 Number (%) of Patients	TRAVOPROST PR N=58 Number of Events	TRAVATAN N=62 Number (%) of Patients	TRAVATAN N=62 Number of Events
Rash pruritic	1 (1.7%)	1	0 (0.0%)	0
Skin hyperpigmentation	0 (0.0%)	0	1 (1.6%)	1
Surgical and medical procedures	1 (1.7%)	1	2 (3.2%)	2
Astringent therapy	0 (0.0%)	0	1 (1.6%)	1
Skin neoplasm excision	0 (0.0%)	0	1 (1.6%)	1
Uterine polypectomy	1 (1.7%)	1	0 (0.0%)	0
Vascular disorders	4 (6.9%)	5	3 (4.8%)	3
Hyperaemia	2 (3.4%)	3	3 (4.8%)	3
Hypertension	2 (3.4%)	2	0 (0.0%)	0

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 4: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-7
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TABLE T14.3.1-3 SERIOUS TREATMENT-EMERGENT ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58		TRAVATAN N=62	
	Number (%) of Patients	Number of Events	Number (%) of Patients	Number of Events
Any Serious TEAE	1 (1.7%)	1	1 (1.6%)	1
Eye disorders	1 (1.7%)	1	0 (0.0%)	0
Eyelid ptosis	1 (1.7%)	1	0 (0.0%)	0
Injury, poisoning and procedural complications	0 (0.0%)	0	1 (1.6%)	1
Femur fracture	0 (0.0%)	0	1 (1.6%)	1

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: A serious adverse event is an adverse event judged as serious.
Note 4: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-7
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LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.1-4 TREATMENT-EMERGENT ADVERSE DRUG REACTIONS BY SYSTEM ORGAN CLASS AND PREFERRED TERM
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58			TRAVATAN N=62		
	Number (%) of Patients		Number of Events	Number (%) of Patients		Number of Events
Any ADR	19	(32.8%)	38	22	(35.5%)	41
Ear and labyrinth disorders	1	(1.7%)	1	0	(0.0%)	0
Vertigo	1	(1.7%)	1	0	(0.0%)	0
Eye disorders	14	(24.1%)	20	16	(25.8%)	23
Abnormal sensation in eye	0	(0.0%)	0	1	(1.6%)	1
Chalazion	1	(1.7%)	1	0	(0.0%)	0
Conjunctival hyperaemia	6	(10.3%)	6	5	(8.1%)	5
Dry eye	1	(1.7%)	2	2	(3.2%)	2
Eye irritation	3	(5.2%)	3	7	(11.3%)	7
Eye pruritus	1	(1.7%)	1	3	(4.8%)	3
Eye swelling	0	(0.0%)	0	1	(1.6%)	1
Eyelid oedema	2	(3.4%)	2	0	(0.0%)	0
Foreign body sensation in eyes	0	(0.0%)	0	1	(1.6%)	1

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: An adverse drug reaction is an adverse event judged as related to the study medication.
Note 4: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-7
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TABLE T14.3.1-4 TREATMENT-EMERGENT ADVERSE DRUG REACTIONS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (Continued)
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58		TRAVATAN N=62	
	Number (%) of Patients	Number of Events	Number (%) of Patients	Number of Events
Ocular hyperaemia	3 (5.2%)	3	2 (3.2%)	2
Photopsia	0 (0.0%)	0	1 (1.6%)	1
Retinal vein occlusion	1 (1.7%)	1	0 (0.0%)	0
Vision blurred	1 (1.7%)	1	0 (0.0%)	0
Gastrointestinal disorders	0 (0.0%)	0	2 (3.2%)	2
Dry mouth	0 (0.0%)	0	1 (1.6%)	1
Odynophagia	0 (0.0%)	0	1 (1.6%)	1
General disorders and administration site conditions	1 (1.7%)	1	2 (3.2%)	2
Fatigue	0 (0.0%)	0	1 (1.6%)	1
Sensation of foreign body	0 (0.0%)	0	1 (1.6%)	1
Swelling	1 (1.7%)	1	0 (0.0%)	0
Infections and infestations	0 (0.0%)	0	1 (1.6%)	1
Gastroenteritis viral	0 (0.0%)	0	1 (1.6%)	1
Investigations	1 (1.7%)	1	0 (0.0%)	0

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: An adverse drug reaction is an adverse event judged as related to the study medication.
Note 4: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 5: Percentages are calculated on the number of patients (N).
Cross-reference: Listing 16.2.7-7
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LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.1-4 TREATMENT-EMERGENT ADVERSE DRUG REACTIONS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (Continued)
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58		TRAVATAN N=62	
	Number (%) of Patients	Number of Events	Number (%) of Patients	Number of Events
Heart rate increased	1 (1.7%)	1	0 (0.0%)	0
Musculoskeletal and connective tissue disorders	0 (0.0%)	0	2 (3.2%)	2
Myalgia	0 (0.0%)	0	1 (1.6%)	1
Neck pain	0 (0.0%)	0	1 (1.6%)	1
Nervous system disorders	2 (3.4%)	2	1 (1.6%)	1
Headache	2 (3.4%)	2	0 (0.0%)	0
Tremor	0 (0.0%)	0	1 (1.6%)	1
Psychiatric disorders	0 (0.0%)	0	1 (1.6%)	1
Insomnia	0 (0.0%)	0	1 (1.6%)	1
Respiratory, thoracic and mediastinal disorders	2 (3.4%)	2	1 (1.6%)	1
Cough	0 (0.0%)	0	1 (1.6%)	1
Dyspnoea	2 (3.4%)	2	0 (0.0%)	0
Skin and subcutaneous tissue disorders	4 (6.9%)	6	3 (4.8%)	5
Alopecia	0 (0.0%)	0	1 (1.6%)	1

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: An adverse drug reaction is an adverse event judged as related to the study medication.
Note 4: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 5: Percentages are calculated on the number of patients (N).
Cross-reference: Listing 16.2.7-7
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TABLE T14.3.1-4 TREATMENT-EMERGENT ADVERSE DRUG REACTIONS BY SYSTEM ORGAN CLASS AND PREFERRED TERM (Continued)
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58 Number (%) of Patients	TRAVOPROST PR N=58 Number of Events	TRAVATAN N=62 Number (%) of Patients	TRAVATAN N=62 Number of Events
Eczema	1 (1.7%)	1	1 (1.6%)	1
Erythema	1 (1.7%)	1	0 (0.0%)	0
Madarosis	0 (0.0%)	0	1 (1.6%)	1
Pruritus	2 (3.4%)	2	1 (1.6%)	1
Rash	1 (1.7%)	1	0 (0.0%)	0
Rash pruritic	1 (1.7%)	1	0 (0.0%)	0
Skin hyperpigmentation	0 (0.0%)	0	1 (1.6%)	1
Vascular disorders	4 (6.9%)	5	3 (4.8%)	3
Hyperaemia	2 (3.4%)	3	3 (4.8%)	3
Hypertension	2 (3.4%)	2	0 (0.0%)	0

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: An adverse drug reaction is an adverse event judged as related to the study medication.
Note 4: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-7
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LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.1-5 SERIOUS TREATMENT-EMERGENT ADVERSE DRUG REACTIONS BY SYSTEM ORGAN CLASS AND PREFERRED TERM
SAFETY POPULATION

There are no data that fit the criteria for this summary

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: A serious adverse drug reaction is a serious adverse event judged as related to the study medication.
Note 4: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-7
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TABLE T14.3.1-6 TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO DISCONTINUATION BY SYSTEM ORGAN CLASS AND PREFERRED TERM
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58		TRAVATAN N=62	
	Number (%) of Patients	Number of Events	Number (%) of Patients	Number of Events
Any TEAE leading to discontinuation	5 (8.6%)	14	3 (4.8%)	5
Eye disorders	3 (5.2%)	5	1 (1.6%)	1
Conjunctival hyperaemia	3 (5.2%)	3	0 (0.0%)	0
Eye swelling	0 (0.0%)	0	1 (1.6%)	1
Eyelid oedema	2 (3.4%)	2	0 (0.0%)	0
General disorders and administration site conditions	1 (1.7%)	1	0 (0.0%)	0
Swelling	1 (1.7%)	1	0 (0.0%)	0
Injury, poisoning and procedural complications	0 (0.0%)	0	1 (1.6%)	1
Femur fracture	0 (0.0%)	0	1 (1.6%)	1
Investigations	1 (1.7%)	1	0 (0.0%)	0
Heart rate increased	1 (1.7%)	1	0 (0.0%)	0
Musculoskeletal and connective tissue disorders	0 (0.0%)	0	1 (1.6%)	1
Myalgia	0 (0.0%)	0	1 (1.6%)	1

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: An adverse event leading to discontinuation is an adverse event with action taken with the study medication = "Study drug permanently discontinued".
Note 4: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 5: Percentages are calculated on the number of patients (N).
Cross-reference: Listing 16.2.7-7
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.1-6 TREATMENT-EMERGENT ADVERSE EVENTS LEADING TO DISCONTINUATION BY SYSTEM ORGAN CLASS AND PREFERRED TERM (Continued)
SAFETY POPULATION

System Organ Class Preferred Term	TRAVOPROST PR N=58		TRAVATAN N=62	
	Number (%) of Patients	Number of Events	Number (%) of Patients	Number of Events
Nervous system disorders	2 (3.4%)	2	1 (1.6%)	1
Headache	2 (3.4%)	2	0 (0.0%)	0
Tremor	0 (0.0%)	0	1 (1.6%)	1
Psychiatric disorders	0 (0.0%)	0	1 (1.6%)	1
Insomnia	0 (0.0%)	0	1 (1.6%)	1
Respiratory, thoracic and mediastinal disorders	2 (3.4%)	2	0 (0.0%)	0
Dyspnoea	2 (3.4%)	2	0 (0.0%)	0
Skin and subcutaneous tissue disorders	1 (1.7%)	2	0 (0.0%)	0
Erythema	1 (1.7%)	1	0 (0.0%)	0
Pruritus	1 (1.7%)	1	0 (0.0%)	0
Vascular disorders	1 (1.7%)	1	0 (0.0%)	0
Hyperaemia	1 (1.7%)	1	0 (0.0%)	0

Note 1: Adverse events with AE onset date >= date of first randomised drug instillation are presented in this table.
Note 2: Adverse events have been coded using the MedDRA dictionary (version 14.0). System Organ Class and Preferred Term are presented.
Note 3: An adverse event leading to discontinuation is an adverse event with action taken with the study medication = "Study drug permanently discontinued".
Note 4: Patients are only counted once per treatment for each row in the column 'Number (%) of patients'.
Note 5: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-7
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-1 PHYSICAL EXAMINATION: SHIFT TABLE FROM BASELINE TO END OF TREATMENT
SAFETY POPULATION

VISIT 2 Baseline	VISIT 7 End of treatment: Normal	Abnormal	Missing	Overall
TRAVOPROST PR (N=58)				
Eyes, ears, nose				
Normal	42 (72.4%)	4 (6.9%)	5 (8.6%)	51 (87.9%)
Abnormal	1 (1.7%)	6 (10.3%)	0 (0.0%)	7 (12.1%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	43 (74.1%)	10 (17.2%)	5 (8.6%)	58 (100.0%)
Mouth and throat				
Normal	51 (87.9%)	1 (1.7%)	5 (8.6%)	57 (98.3%)
Abnormal	0 (0.0%)	1 (1.7%)	0 (0.0%)	1 (1.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	51 (87.9%)	2 (3.4%)	5 (8.6%)	58 (100.0%)
Neck				
Normal	53 (91.4%)	0 (0.0%)	5 (8.6%)	58 (100.0%)
Abnormal	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	53 (91.4%)	0 (0.0%)	5 (8.6%)	58 (100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-4
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-1 PHYSICAL EXAMINATION: SHIFT TABLE FROM BASELINE TO END OF TREATMENT (Continued)
SAFETY POPULATION

	VISIT 7 End of treatment			
VISIT 2 Baseline	Normal	Abnormal	Missing	Overall
Chest				
Normal	52 (89.7%)	0 (0.0%)	5 (8.6%)	57 (98.3%)
Abnormal	0 (0.0%)	1 (1.7%)	0 (0.0%)	1 (1.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	52 (89.7%)	1 (1.7%)	5 (8.6%)	58 (100.0%)
Heart				
Normal	52 (89.7%)	0 (0.0%)	5 (8.6%)	57 (98.3%)
Abnormal	0 (0.0%)	1 (1.7%)	0 (0.0%)	1 (1.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	52 (89.7%)	1 (1.7%)	5 (8.6%)	58 (100.0%)
Abdomen				
Normal	51 (87.9%)	0 (0.0%)	5 (8.6%)	56 (96.6%)
Abnormal	0 (0.0%)	2 (3.4%)	0 (0.0%)	2 (3.4%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	51 (87.9%)	2 (3.4%)	5 (8.6%)	58 (100.0%)
Neurological				
Normal	53 (91.4%)	0 (0.0%)	5 (8.6%)	58 (100.0%)
Abnormal	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	53 (91.4%)	0 (0.0%)	5 (8.6%)	58 (100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-4
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-1 PHYSICAL EXAMINATION: SHIFT TABLE FROM BASELINE TO END OF TREATMENT (Continued)
SAFETY POPULATION

	VISIT 7 End of treatment							
VISIT 2 Baseline	Normal		Abnormal		Missing		Overall	
Skin								
Normal	52	(89.7%)	0	(0.0%)	5	(8.6%)	57	(98.3%)
Abnormal	0	(0.0%)	1	(1.7%)	0	(0.0%)	1	(1.7%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	52	(89.7%)	1	(1.7%)	5	(8.6%)	58	(100.0%)
Lymph nodes								
Normal	53	(91.4%)	0	(0.0%)	5	(8.6%)	58	(100.0%)
Abnormal	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	53	(91.4%)	0	(0.0%)	5	(8.6%)	58	(100.0%)
Limbs								
Normal	53	(91.4%)	0	(0.0%)	5	(8.6%)	58	(100.0%)
Abnormal	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	53	(91.4%)	0	(0.0%)	5	(8.6%)	58	(100.0%)
Other								
Normal	38	(65.5%)	0	(0.0%)	5	(8.6%)	43	(74.1%)
Abnormal	1	(1.7%)	0	(0.0%)	0	(0.0%)	1	(1.7%)
Missing	1	(1.7%)	0	(0.0%)	13	(22.4%)	14	(24.1%)
Overall	40	(69.0%)	0	(0.0%)	18	(31.0%)	58	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-4
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-1 PHYSICAL EXAMINATION: SHIFT TABLE FROM BASELINE TO END OF TREATMENT (Continued)
SAFETY POPULATION

VISIT 2 Baseline	VISIT 7 End of treatment: Normal	Abnormal	Missing	Overall
TRAVATAN (N=62)				
Eyes, ears, nose				
Normal	52 (83.9%)	0 (0.0%)	5 (8.1%)	57 (91.9%)
Abnormal	1 (1.6%)	4 (6.5%)	0 (0.0%)	5 (8.1%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	53 (85.5%)	4 (6.5%)	5 (8.1%)	62 (100.0%)
Mouth and throat				
Normal	57 (91.9%)	0 (0.0%)	5 (8.1%)	62 (100.0%)
Abnormal	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	57 (91.9%)	0 (0.0%)	5 (8.1%)	62 (100.0%)
Neck				
Normal	56 (90.3%)	0 (0.0%)	5 (8.1%)	61 (98.4%)
Abnormal	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (1.6%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	56 (90.3%)	1 (1.6%)	5 (8.1%)	62 (100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-4
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-1 PHYSICAL EXAMINATION: SHIFT TABLE FROM BASELINE TO END OF TREATMENT (Continued)
SAFETY POPULATION

	VISIT 7 End of treatment							
VISIT 2 Baseline	Normal		Abnormal		Missing		Overall	
Chest								
Normal	56	(90.3%)	0	(0.0%)	5	(8.1%)	61	(98.4%)
Abnormal	0	(0.0%)	1	(1.6%)	0	(0.0%)	1	(1.6%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	56	(90.3%)	1	(1.6%)	5	(8.1%)	62	(100.0%)
Heart								
Normal	55	(88.7%)	0	(0.0%)	5	(8.1%)	60	(96.8%)
Abnormal	0	(0.0%)	2	(3.2%)	0	(0.0%)	2	(3.2%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	55	(88.7%)	2	(3.2%)	5	(8.1%)	62	(100.0%)
Abdomen								
Normal	54	(87.1%)	0	(0.0%)	5	(8.1%)	59	(95.2%)
Abnormal	1	(1.6%)	2	(3.2%)	0	(0.0%)	3	(4.8%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	55	(88.7%)	2	(3.2%)	5	(8.1%)	62	(100.0%)
Neurological								
Normal	56	(90.3%)	0	(0.0%)	5	(8.1%)	61	(98.4%)
Abnormal	0	(0.0%)	1	(1.6%)	0	(0.0%)	1	(1.6%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	56	(90.3%)	1	(1.6%)	5	(8.1%)	62	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-4
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-1 PHYSICAL EXAMINATION: SHIFT TABLE FROM BASELINE TO END OF TREATMENT (Continued)
SAFETY POPULATION

	VISIT 7 End of treatment			
VISIT 2 Baseline	Normal	Abnormal	Missing	Overall
Skin				
Normal	54 (87.1%)	1 (1.6%)	5 (8.1%)	60 (96.8%)
Abnormal	1 (1.6%)	1 (1.6%)	0 (0.0%)	2 (3.2%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	55 (88.7%)	2 (3.2%)	5 (8.1%)	62 (100.0%)
Lymph nodes				
Normal	56 (90.3%)	0 (0.0%)	5 (8.1%)	61 (98.4%)
Abnormal	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	57 (91.9%)	0 (0.0%)	5 (8.1%)	62 (100.0%)
Limbs				
Normal	56 (90.3%)	1 (1.6%)	5 (8.1%)	62 (100.0%)
Abnormal	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	56 (90.3%)	1 (1.6%)	5 (8.1%)	62 (100.0%)
Other				
Normal	45 (72.6%)	0 (0.0%)	4 (6.5%)	49 (79.0%)
Abnormal	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	13 (21.0%)	13 (21.0%)
Overall	45 (72.6%)	0 (0.0%)	17 (27.4%)	62 (100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.4-4
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-2.1 VITAL SIGNS: SYSTOLIC BLOOD PRESSURE (MMHG) DURING THE STUDY AND CHANGE FROM BASELINE
SAFETY POPULATION

	Visit 1 Screening	Visit 2 Baseline	Visit 3 2 Weeks	Visit 4 4 Weeks	Visit 5 6 Weeks	Visit 6 8 Weeks	Visit 7 12 Weeks
TRAVOPROST PR (N=58)							
Systolic blood pressure (mmHg)							
n	58	58	52	50	50	49	54
Mean (SD)	132.1 (11.6)	132.4 (12.5)	132.1 (17.4)	132.9 (14.2)	133.0 (15.2)	128.9 (14.0)	130.9 (12.7)
Median	130.0	130.0	130.0	130.0	130.0	130.0	130.0
Range	110 ;170	110 ;170	100 ;200	110 ;180	110 ;180	99 ;170	105 ;170
Mean change from baseline							
n			52	50	50	49	54
Mean change (SD)			-0.6 (14.9)	-0.2 (12.5)	-0.2 (9.5)	-4.2 (10.6)	-1.6 (11.8)
Range			-40 ;50	-30 ;35	-20 ;30	-40 ;20	-28 ;25
TRAVATAN (N=62)							
Systolic blood pressure (mmHg)							
n	62	62	59	58	56	56	56
Mean (SD)	129.9 (12.7)	129.3 (12.4)	131.5 (13.3)	131.4 (12.1)	131.0 (14.0)	132.4 (12.7)	129.4 (11.2)
Median	130.0	130.0	130.0	130.0	130.0	130.0	130.0
Range	105 ;180	100 ;160	100 ;155	106 ;160	105 ;170	110 ;170	110 ;155
Mean change from baseline							
n			59	58	56	56	56
Mean change (SD)			1.4 (9.7)	1.1 (10.6)	0.7 (12.5)	1.6 (12.5)	-0.9 (11.9)
Range			-30 ;20	-30 ;25	-22 ;40	-35 ;30	-30 ;30

Cross-reference: Listing 16.2.7-5
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-2.2 VITAL SIGNS: DIASTOLIC BLOOD PRESSURE (MMHG) DURING THE STUDY AND CHANGE FROM BASELINE
SAFETY POPULATION

	Visit 1 Screening	Visit 2 Baseline	Visit 3 2 Weeks	Visit 4 4 Weeks	Visit 5 6 Weeks	Visit 6 8 Weeks	Visit 7 12 Weeks
TRAVOPROST PR (N=58)							
Diastolic blood pressure (mmHg)							
n	58	58	52	50	50	49	54
Mean (SD)	79.1 (9.4)	79.9 (9.6)	83.1 (9.3)	81.5 (8.2)	82.5 (8.5)	81.2 (7.1)	80.4 (8.0)
Median	80.0	80.0	80.0	80.0	80.0	80.0	80.0
Range	60 ;100	60 ;105	60 ;110	60 ;100	70 ;100	66 ;100	60 ;95
Mean change from baseline							
n			52	50	50	49	54
Mean change (SD)			3.0 (9.9)	1.1 (11.0)	2.1 (8.6)	0.8 (9.3)	0.0 (10.0)
Range			-20 ;40	-30 ;20	-15 ;30	-25 ;20	-20 ;20
TRAVATAN (N=62)							
Diastolic blood pressure (mmHg)							
n	62	62	59	58	56	56	56
Mean (SD)	79.4 (9.1)	80.0 (9.3)	82.0 (7.8)	82.6 (9.8)	81.0 (8.5)	82.4 (7.3)	79.1 (7.6)
Median	80.0	80.0	80.0	80.0	80.0	80.0	80.0
Range	60 ;100	50 ;110	60 ;100	58 ;110	60 ;110	60 ;105	60 ;90
Mean change from baseline							
n			59	58	56	56	56
Mean change (SD)			1.7 (9.2)	2.2 (10.8)	0.7 (9.7)	1.7 (8.9)	-1.2 (11.8)
Range			-30 ;30	-30 ;40	-20 ;20	-20 ;25	-40 ;30

Cross-reference: Listing 16.2.7-5
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-2.3 VITAL SIGNS: HEART RATE (BPM) DURING THE STUDY AND CHANGE FROM BASELINE
SAFETY POPULATION

	Visit 1 Screening	Visit 2 Baseline	Visit 3 2 Weeks	Visit 4 4 Weeks	Visit 5 6 Weeks	Visit 6 8 Weeks	Visit 7 12 Weeks
TRAVOPROST PR (N=58)							
Heart rate (bpm)							
n	58	58	52	50	50	49	54
Mean (SD)	71.0 (8.5)	71.9 (7.7)	73.1 (8.0)	73.6 (8.8)	71.7 (9.3)	74.4 (9.8)	74.9 (9.0)
Median	70.0	70.0	71.0	70.0	70.0	70.0	75.5
Range	56 ;90	58 ;88	56 ;104	58 ;93	58 ;110	60 ;108	60 ;104
Mean change from baseline							
n			52	50	50	49	54
Mean change (SD)			1.7 (8.6)	2.2 (7.4)	0.4 (9.8)	2.8 (8.8)	3.4 (9.5)
Range			-18 ;24	-15 ;18	-24 ;29	-16 ;28	-14 ;24
TRAVATAN (N=62)							
Heart rate (bpm)							
n	62	62	59	58	56	56	56
Mean (SD)	70.5 (9.3)	70.4 (8.2)	71.9 (11.1)	73.6 (9.5)	73.1 (10.4)	73.0 (9.0)	71.7 (10.8)
Median	70.0	70.0	70.0	71.0	70.0	70.0	70.0
Range	48 ;104	48 ;90	42 ;104	56 ;96	50 ;104	53 ;100	55 ;104
Mean change from baseline							
n			59	58	56	56	56
Mean change (SD)			1.4 (8.5)	3.2 (7.5)	3.0 (8.2)	2.8 (8.1)	1.8 (10.2)
Range			-26 ;20	-18 ;22	-15 ;23	-18 ;17	-28 ;24

Cross-reference: Listing 16.2.7-5
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-3.1 LABORATORY TESTS: SHIFT TABLE OF GLUCOSE FROM SCREENING TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment						
VISIT 1 Screening	Low CS	Low CI	Normal	High CI	High CS	Missing	Overall
TRAVOPROST PR (N=58)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Normal	0 (0.0%)	2 (3.4%)	32 (55.2%)	5 (8.6%)	0 (0.0%)	7 (12.1%)	46 (79.3%)
High CI	0 (0.0%)	0 (0.0%)	4 (6.9%)	2 (3.4%)	0 (0.0%)	1 (1.7%)	7 (12.1%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.4%)	0 (0.0%)	2 (3.4%)
Missing	0 (0.0%)	0 (0.0%)	1 (1.7%)	2 (3.4%)	0 (0.0%)	0 (0.0%)	3 (5.2%)
Overall	0 (0.0%)	2 (3.4%)	37 (63.8%)	9 (15.5%)	2 (3.4%)	8 (13.8%)	58 (100.0%)
TRAVATAN (N=62)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	1 (1.6%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
Normal	0 (0.0%)	1 (1.6%)	41 (66.1%)	3 (4.8%)	0 (0.0%)	3 (4.8%)	48 (77.4%)
High CI	0 (0.0%)	0 (0.0%)	1 (1.6%)	4 (6.5%)	1 (1.6%)	2 (3.2%)	8 (12.9%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.2%)	0 (0.0%)	2 (3.2%)
Missing	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
Overall	0 (0.0%)	2 (3.2%)	44 (71.0%)	8 (12.9%)	3 (4.8%)	5 (8.1%)	62 (100.0%)

Note 1: CS=Clinically Significant; CI=Clinically insignificant.
Note 2: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-6
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-3.2 LABORATORY TESTS: SHIFT TABLE OF CREATININE FROM SCREENING TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment						
VISIT 1 Screening	Low CS	Low CI	Normal	High CI	High CS	Missing	Overall
TRAVOPROST PR (N=58)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
Normal	0 (0.0%)	0 (0.0%)	36 (62.1%)	3 (5.2%)	0 (0.0%)	7 (12.1%)	46 (79.3%)
High CI	0 (0.0%)	0 (0.0%)	3 (5.2%)	3 (5.2%)	0 (0.0%)	1 (1.7%)	7 (12.1%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
Missing	0 (0.0%)	0 (0.0%)	3 (5.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (5.2%)
Overall	0 (0.0%)	0 (0.0%)	43 (74.1%)	7 (12.1%)	0 (0.0%)	8 (13.8%)	58 (100.0%)
TRAVATAN (N=62)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	1 (1.6%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)	3 (4.8%)
Normal	0 (0.0%)	1 (1.6%)	45 (72.6%)	0 (0.0%)	0 (0.0%)	7 (11.3%)	53 (85.5%)
High CI	0 (0.0%)	0 (0.0%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (1.6%)
Missing	0 (0.0%)	0 (0.0%)	2 (3.2%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	3 (4.8%)
Overall	0 (0.0%)	2 (3.2%)	50 (80.6%)	1 (1.6%)	1 (1.6%)	8 (12.9%)	62 (100.0%)

Note 1: CS=Clinically Significant; CI=Clinically insignificant.
Note 2: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-6
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-3.3 LABORATORY TESTS: SHIFT TABLE OF BUN FROM SCREENING TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment						
VISIT 1 Screening	Low CS	Low CI	Normal	High CI	High CS	Missing	Overall
TRAVOPROST PR (N=58)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Normal	1 (1.7%)	0 (0.0%)	38 (65.5%)	4 (6.9%)	0 (0.0%)	5 (8.6%)	48 (82.8%)
High CI	0 (0.0%)	0 (0.0%)	4 (6.9%)	1 (1.7%)	0 (0.0%)	2 (3.4%)	7 (12.1%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	1 (1.7%)	2 (3.4%)	0 (0.0%)	0 (0.0%)	3 (5.2%)
Overall	1 (1.7%)	0 (0.0%)	43 (74.1%)	7 (12.1%)	0 (0.0%)	7 (12.1%)	58 (100.0%)
TRAVATAN (N=62)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Normal	0 (0.0%)	0 (0.0%)	47 (75.8%)	1 (1.6%)	0 (0.0%)	5 (8.1%)	53 (85.5%)
High CI	0 (0.0%)	0 (0.0%)	2 (3.2%)	3 (4.8%)	0 (0.0%)	0 (0.0%)	5 (8.1%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (1.6%)
Missing	0 (0.0%)	0 (0.0%)	3 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (4.8%)
Overall	0 (0.0%)	0 (0.0%)	52 (83.9%)	4 (6.5%)	1 (1.6%)	5 (8.1%)	62 (100.0%)

Note 1: CS=Clinically Significant; CI=Clinically insignificant.
Note 2: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-6
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-3.4 LABORATORY TESTS: SHIFT TABLE OF AST FROM SCREENING TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment						
VISIT 1 Screening	Low CS	Low CI	Normal	High CI	High CS	Missing	Overall
TRAVOPROST PR (N=58)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Normal	0 (0.0%)	0 (0.0%)	47 (81.0%)	0 (0.0%)	0 (0.0%)	5 (8.6%)	52 (89.7%)
High CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	1 (1.7%)	2 (3.4%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	1 (1.7%)
Missing	0 (0.0%)	0 (0.0%)	2 (3.4%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	3 (5.2%)
Overall	0 (0.0%)	0 (0.0%)	49 (84.5%)	2 (3.4%)	0 (0.0%)	7 (12.1%)	58 (100.0%)
TRAVATAN (N=62)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Normal	0 (0.0%)	0 (0.0%)	54 (87.1%)	0 (0.0%)	0 (0.0%)	5 (8.1%)	59 (95.2%)
High CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
Overall	0 (0.0%)	0 (0.0%)	56 (90.3%)	1 (1.6%)	0 (0.0%)	5 (8.1%)	62 (100.0%)

Note 1: CS=Clinically Significant; CI=Clinically insignificant.
Note 2: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-6
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-3.5 LABORATORY TESTS: SHIFT TABLE OF ALT FROM SCREENING TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment						
VISIT 1 Screening	Low CS	Low CI	Normal	High CI	High CS	Missing	Overall
TRAVOPROST PR (N=58)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Normal	0 (0.0%)	0 (0.0%)	46 (79.3%)	0 (0.0%)	0 (0.0%)	6 (10.3%)	52 (89.7%)
High CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	1 (1.7%)	2 (3.4%)
Missing	0 (0.0%)	0 (0.0%)	3 (5.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (5.2%)
Overall	0 (0.0%)	0 (0.0%)	49 (84.5%)	1 (1.7%)	1 (1.7%)	7 (12.1%)	58 (100.0%)
TRAVATAN (N=62)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Normal	0 (0.0%)	0 (0.0%)	49 (79.0%)	2 (3.2%)	0 (0.0%)	5 (8.1%)	56 (90.3%)
High CI	0 (0.0%)	0 (0.0%)	3 (4.8%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	4 (6.5%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
Overall	0 (0.0%)	0 (0.0%)	54 (87.1%)	3 (4.8%)	0 (0.0%)	5 (8.1%)	62 (100.0%)

Note 1: CS=Clinically Significant; CI=Clinically insignificant.
Note 2: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-6
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-3.6 LABORATORY TESTS: SHIFT TABLE OF NA+ FROM SCREENING TO END OF TREATMENT
SAFETY POPULATION

VISIT 1 Screening	VISIT 7 End of treatment: Low CS	Low CI	Normal	High CI	High CS	Missing	Overall
TRAVOPROST PR (N=58)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	2 (3.4%)
Normal	0 (0.0%)	0 (0.0%)	46 (79.3%)	0 (0.0%)	0 (0.0%)	6 (10.3%)	52 (89.7%)
High CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	3 (5.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (5.2%)
Overall	0 (0.0%)	0 (0.0%)	50 (86.2%)	1 (1.7%)	0 (0.0%)	7 (12.1%)	58 (100.0%)
TRAVATAN (N=62)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (1.6%)
Normal	0 (0.0%)	0 (0.0%)	51 (82.3%)	1 (1.6%)	0 (0.0%)	3 (4.8%)	55 (88.7%)
High CI	0 (0.0%)	0 (0.0%)	3 (4.8%)	0 (0.0%)	0 (0.0%)	1 (1.6%)	4 (6.5%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
Overall	0 (0.0%)	0 (0.0%)	56 (90.3%)	1 (1.6%)	0 (0.0%)	5 (8.1%)	62 (100.0%)

Note 1: CS=Clinically Significant; CI=Clinically insignificant.
Note 2: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-6
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-3.7 LABORATORY TESTS: SHIFT TABLE OF K+ FROM SCREENING TO END OF TREATMENT
SAFETY POPULATION

VISIT 1 Screening	VISIT 7 End of treatment: Low CS	Low CI	Normal	High CI	High CS	Missing	Overall
TRAVOPROST PR (N=58)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Normal	0 (0.0%)	1 (1.7%)	41 (70.7%)	5 (8.6%)	0 (0.0%)	8 (13.8%)	55 (94.8%)
High CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	2 (3.4%)	3 (5.2%)
Overall	0 (0.0%)	1 (1.7%)	41 (70.7%)	6 (10.3%)	0 (0.0%)	10 (17.2%)	58 (100.0%)
TRAVATAN (N=62)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Normal	0 (0.0%)	0 (0.0%)	50 (80.6%)	2 (3.2%)	0 (0.0%)	5 (8.1%)	57 (91.9%)
High CI	0 (0.0%)	0 (0.0%)	2 (3.2%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	3 (4.8%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (1.6%)	2 (3.2%)
Overall	0 (0.0%)	0 (0.0%)	52 (83.9%)	4 (6.5%)	0 (0.0%)	6 (9.7%)	62 (100.0%)

Note 1: CS=Clinically Significant; CI=Clinically insignificant.
Note 2: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-6
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-3.8 LABORATORY TESTS: SHIFT TABLE OF URIC ACID FROM SCREENING TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment						
VISIT 1 Screening	Low CS	Low CI	Normal	High CI	High CS	Missing	Overall
TRAVOPROST PR (N=58)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Normal	0 (0.0%)	0 (0.0%)	35 (60.3%)	3 (5.2%)	0 (0.0%)	9 (15.5%)	47 (81.0%)
High CI	0 (0.0%)	0 (0.0%)	2 (3.4%)	3 (5.2%)	0 (0.0%)	3 (5.2%)	8 (13.8%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	3 (5.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (5.2%)
Overall	0 (0.0%)	0 (0.0%)	40 (69.0%)	6 (10.3%)	0 (0.0%)	12 (20.7%)	58 (100.0%)
TRAVATAN (N=62)							
Low CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Low CI	0 (0.0%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
Normal	0 (0.0%)	3 (4.8%)	39 (62.9%)	2 (3.2%)	0 (0.0%)	10 (16.1%)	54 (87.1%)
High CI	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	4 (6.5%)
High CS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
Overall	0 (0.0%)	5 (8.1%)	42 (67.7%)	5 (8.1%)	0 (0.0%)	10 (16.1%)	62 (100.0%)

Note 1: CS=Clinically Significant; CI=Clinically insignificant.
Note 2: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-6
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-4.1 LOCAL TOLERABILITY: FREQUENCY TABLE OF VISUAL ACUITY AT BASELINE AND END OF TREATMENT
SAFETY POPULATION

VISUAL ACUITY AT V2	TREATMENT		
Frequency	TRAVOPROST PR (%)	TRAVATAN® (%)	Total
10/10	26 (48.83)	19 (30.65)	45
11/10	1 (1.72)	0 (0.00)	1
2/10	0 (0.00)	1 (1.61)	1
20/100	1 (1.72)	0 (0.00)	1
20/13	0 (0.00)	1 (1.61)	1
20/16	4 (6.90)	4 (6.45)	8
20/20	10 (17.24)	14 (22.58)	24
20/25	1 (1.72)	1 (1.61)	2
20/28	0 (0.00)	1 (1.61)	1
20/32	1 (1.72)	1 (1.61)	2
20/40	0 (0.00)	2 (3.23)	2
20/80	1 (1.72)	0 (0.00)	1
4/10	0 (0.00)	1 (1.61)	1
5/10	2 (3.45)	2 (3.23)	4
6/10	3 (5.17)	1 (1.61)	4
7/10	1 (1.72)	1 (1.61)	2
8/10	3 (5.17)	6 (9.68)	9
9/10	4 (6.90)	7 (11.29)	11
Total	58	62	120

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-1

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-4.1 LOCAL TOLERABILITY: FREQUENCY TABLE OF VISUAL ACUITY AT BASELINE AND END OF TREATMENT (continued)
SAFETY POPULATION

VISUAL ACUITY AT V7	TREATMENT		
Frequency	TRAVOPROST PR (%)	TRAVATAN® (%)	Total
10/10	19 (32.76)	21 (33.87)	40
20/13	1 (1.72)	0 (0.00)	1
20/16	4 (6.90)	3 (4.84)	7
20/20	10 (17.24)	13 (20.97)	23
20/25	0 (0.00)	3 (4.84)	3
20/30	1 (1.72)	0 (0.00)	1
20/32	1 (1.72)	1 (1.61)	2
20/40	0 (0.00)	1 (1.61)	1
20/50	0 (0.00)	1 (1.61)	1
2/10	1 (1.72)	0 (0.00)	1
4/10	0 (0.00)	1 (1.61)	1
5/10	2 (3.45)	1 (1.61)	3
6/10	4 (6.90)	1 (1.61)	5
7/10	1 (1.72)	2 (3.23)	3
8/10	7 (12.07)	5 (8.06)	12
9/10	2 (3.45)	4 (6.45)	6
Missing	5 (8.62)	5 (8.06)	10
Total	58	62	120

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-1

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-4.2 LOCAL TOLERABILITY: SHIFT TABLE OF CONJUNCTIVAL HYPEREMIA FROM BASELINE TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment											
VISIT 2 Bseline	None or trace		Mild		Moderate		Severe		Missing		Overall	
TRAVOPROST PR (N=58)												
None or trace	13	(22.4%)	10	(17.2%)	4	(6.9%)	1	(1.7%)	4	(6.9%)	32	(55.2%)
Mild	2	(3.4%)	7	(12.1%)	7	(12.1%)	0	(0.0%)	4	(6.9%)	20	(34.5%)
Moderate	0	(0.0%)	2	(3.4%)	4	(6.9%)	0	(0.0%)	0	(0.0%)	6	(10.3%)
Severe	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	15	(25.9%)	19	(32.8%)	15	(25.9%)	1	(1.7%)	8	(13.8%)	58	(100.0%)
TRAVATAN (N=62)												
None or trace	11	(17.7%)	10	(16.1%)	5	(8.1%)	0	(0.0%)	3	(4.8%)	29	(46.8%)
Mild	2	(3.2%)	12	(19.4%)	8	(12.9%)	2	(3.2%)	4	(6.5%)	28	(45.2%)
Moderate	0	(0.0%)	3	(4.8%)	2	(3.2%)	0	(0.0%)	0	(0.0%)	5	(8.1%)
Severe	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	13	(21.0%)	25	(40.3%)	15	(24.2%)	2	(3.2%)	7	(11.3%)	62	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-1
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-5 LOCAL TOLERABILITY: LIDS EXAMINATIONS - SHIFT TABLE FROM BASELINE TO END OF TREATMENT
SAFETY POPULATION

VISIT 2 Baseline	VISIT 7 End of treatment: Normal	Abnormal	Missing	Overall
TRAVOPROST PR (N=58)				
Skin				
Normal	50 (86.2%)	1 (1.7%)	3 (5.2%)	54 (93.1%)
Abnormal	2 (3.4%)	0 (0.0%)	2 (3.4%)	4 (6.9%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	52 (89.7%)	1 (1.7%)	5 (8.6%)	58 (100.0%)
Margin of upper lids				
Normal	48 (82.8%)	2 (3.4%)	5 (8.6%)	55 (94.8%)
Abnormal	0 (0.0%)	3 (5.2%)	0 (0.0%)	3 (5.2%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	48 (82.8%)	5 (8.6%)	5 (8.6%)	58 (100.0%)
Margin of lower lids				
Normal	49 (84.5%)	1 (1.7%)	5 (8.6%)	55 (94.8%)
Abnormal	1 (1.7%)	2 (3.4%)	0 (0.0%)	3 (5.2%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	50 (86.2%)	3 (5.2%)	5 (8.6%)	58 (100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-1
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-5 LOCAL TOLERABILITY: LIDS EXAMINATIONS - SHIFT TABLE FROM BASELINE TO END OF TREATMENT (Continued)
SAFETY POPULATION

	VISIT 7 End of treatment							
VISIT 2 Baseline	Normal		Abnormal		Missing		Overall	
TRAVATAN (N=62)								
Skin								
Normal	53	(85.5%)	1	(1.6%)	3	(4.8%)	57	(91.9%)
Abnormal	0	(0.0%)	3	(4.8%)	2	(3.2%)	5	(8.1%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	53	(85.5%)	4	(6.5%)	5	(8.1%)	62	(100.0%)
Margin of upper lids								
Normal	51	(82.3%)	2	(3.2%)	4	(6.5%)	57	(91.9%)
Abnormal	1	(1.6%)	3	(4.8%)	1	(1.6%)	5	(8.1%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	52	(83.9%)	5	(8.1%)	5	(8.1%)	62	(100.0%)
Margin of lower lids								
Normal	53	(85.5%)	0	(0.0%)	4	(6.5%)	57	(91.9%)
Abnormal	1	(1.6%)	3	(4.8%)	1	(1.6%)	5	(8.1%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	54	(87.1%)	3	(4.8%)	5	(8.1%)	62	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-1
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-6 LOCAL TOLERABILITY: SLIT LAMP EXAMINATIONS - SHIFT TABLE
FROM BASELINE TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment							
VISIT 2 Baseline	Normal		Abnormal		Missing		Overall	
TRAVOPROST PR (N=58)								
Conjunctiva								
Normal	28	(48.3%)	10	(17.2%)	2	(3.4%)	40	(69.0%)
Abnormal	2	(3.4%)	13	(22.4%)	3	(5.2%)	18	(31.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	30	(51.7%)	23	(39.7%)	5	(8.6%)	58	(100.0%)
Palpebra								
Normal	49	(84.5%)	2	(3.4%)	4	(6.9%)	55	(94.8%)
Abnormal	0	(0.0%)	2	(3.4%)	1	(1.7%)	3	(5.2%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	49	(84.5%)	4	(6.9%)	5	(8.6%)	58	(100.0%)
Bulbus								
Normal	53	(91.4%)	0	(0.0%)	5	(8.6%)	58	(100.0%)
Abnormal	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	53	(91.4%)	0	(0.0%)	5	(8.6%)	58	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-2
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-6 LOCAL TOLERABILITY: SLIT LAMP EXAMINATIONS - SHIFT TABLE
FROM BASELINE TO END OF TREATMENT (Continued)
SAFETY POPULATION

VISIT 2 Baseline	VISIT 7 End of treatment: Normal	Abnormal	Missing	Overall
Cornea				
Normal	50 (86.2%)	0 (0.0%)	5 (8.6%)	55 (94.8%)
Abnormal	0 (0.0%)	3 (5.2%)	0 (0.0%)	3 (5.2%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	50 (86.2%)	3 (5.2%)	5 (8.6%)	58 (100.0%)
Iris				
Normal	51 (87.9%)	0 (0.0%)	4 (6.9%)	55 (94.8%)
Abnormal	0 (0.0%)	2 (3.4%)	1 (1.7%)	3 (5.2%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	51 (87.9%)	2 (3.4%)	5 (8.6%)	58 (100.0%)
Len				
Normal	36 (62.1%)	0 (0.0%)	2 (3.4%)	38 (65.5%)
Abnormal	0 (0.0%)	17 (29.3%)	3 (5.2%)	20 (34.5%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	36 (62.1%)	17 (29.3%)	5 (8.6%)	58 (100.0%)
Vitreous membrane				
Normal	52 (89.7%)	0 (0.0%)	5 (8.6%)	57 (98.3%)
Abnormal	0 (0.0%)	1 (1.7%)	0 (0.0%)	1 (1.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	52 (89.7%)	1 (1.7%)	5 (8.6%)	58 (100.0%)

Note 1: Percentages are calculated on the number of patients (N).
Cross-reference: Listing 16.2.7-2
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-6 LOCAL TOLERABILITY: SLIT LAMP EXAMINATIONS - SHIFT TABLE
FROM BASELINE TO END OF TREATMENT (Continued)
SAFETY POPULATION

	VISIT 7 End of treatment							
VISIT 2 Baseline	Normal		Abnormal		Missing		Overall	
Anterior chamber,cells								
Normal	53	(91.4%)	0	(0.0%)	5	(8.6%)	58	(100.0%)
Abnormal	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	53	(91.4%)	0	(0.0%)	5	(8.6%)	58	(100.0%)
Anterior chamber,flare								
Normal	53	(91.4%)	0	(0.0%)	5	(8.6%)	58	(100.0%)
Abnormal	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	53	(91.4%)	0	(0.0%)	5	(8.6%)	58	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-2
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-6 LOCAL TOLERABILITY: SLIT LAMP EXAMINATIONS - SHIFT TABLE
FROM BASELINE TO END OF TREATMENT (Continued)
SAFETY POPULATION

	VISIT 7 End of treatment							
VISIT 2 Baseline	Normal		Abnormal		Missing		Overall	
TRAVATAN (N=62)								
Conjunctiva								
Normal	23	(37.1%)	14	(22.6%)	4	(6.5%)	41	(66.1%)
Abnormal	2	(3.2%)	18	(29.0%)	1	(1.6%)	21	(33.9%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	25	(40.3%)	32	(51.6%)	5	(8.1%)	62	(100.0%)
Palpebra								
Normal	51	(82.3%)	1	(1.6%)	4	(6.5%)	56	(90.3%)
Abnormal	0	(0.0%)	5	(8.1%)	1	(1.6%)	6	(9.7%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	51	(82.3%)	6	(9.7%)	5	(8.1%)	62	(100.0%)
Bulbus								
Normal	56	(90.3%)	0	(0.0%)	5	(8.1%)	61	(98.4%)
Abnormal	0	(0.0%)	1	(1.6%)	0	(0.0%)	1	(1.6%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	56	(90.3%)	1	(1.6%)	5	(8.1%)	62	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).
Cross-reference: Listing 16.2.7-2
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-6 LOCAL TOLERABILITY: SLIT LAMP EXAMINATIONS - SHIFT TABLE FROM BASELINE TO END OF TREATMENT (Continued)- SAFETY POPULATION

	VISIT 7 - End of treatment							
VISIT 2 Baseline	Normal		Abnormal		Missing		Overall	
Cornea								
Normal	51	(82.3%)	0	(0.0%)	4	(6.5%)	55	(88.7%)
Abnormal	2	(3.2%)	4	(6.5%)	1	(1.6%)	7	(11.3%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	53	(85.5%)	4	(6.5%)	5	(8.1%)	62	(100.0%)
Iris								
Normal	55	(88.7%)	0	(0.0%)	4	(6.5%)	59	(95.2%)
Abnormal	0	(0.0%)	2	(3.2%)	1	(1.6%)	3	(4.8%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	55	(88.7%)	2	(3.2%)	5	(8.1%)	62	(100.0%)
Len								
Normal	27	(43.5%)	2	(3.2%)	3	(4.8%)	32	(51.6%)
Abnormal	1	(1.6%)	27	(43.5%)	2	(3.2%)	30	(48.4%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	28	(45.2%)	29	(46.8%)	5	(8.1%)	62	(100.0%)
Vitreous membrane								
Normal	55	(88.7%)	1	(1.6%)	5	(8.1%)	61	(98.4%)
Abnormal	1	(1.6%)	0	(0.0%)	0	(0.0%)	1	(1.6%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	56	(90.3%)	1	(1.6%)	5	(8.1%)	62	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).
Cross-reference: Listing 16.2.7-2
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-6 LOCAL TOLERABILITY: SLIT LAMP EXAMINATIONS - SHIFT TABLE
FROM BASELINE TO END OF TREATMENT (Continued)- SAFETY POPULATION

VISIT 2 Baseline	VISIT 7 - End of treatment: Normal	Abnormal	Missing	Overall
Vitreous membrane				
Normal	55 (88.7%)	1 (1.6%)	5 (8.1%)	61 (98.4%)
Abnormal	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	56 (90.3%)	1 (1.6%)	5 (8.1%)	62 (100.0%)
Anterior chamber,flare				
Normal	57 (91.9%)	0 (0.0%)	5 (8.1%)	62 (100.0%)
Abnormal	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	57 (91.9%)	0 (0.0%)	5 (8.1%)	62 (100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-2
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-7 LOCAL TOLERABILITY: SHIFT TABLE OF ANTERIOR CHAMBER ANGLE FROM BASELINE TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment						
VISIT 2 Bseline	0	10 or less	20	35-20	45-35	Missing	Overall
TRAVOPROST PR (N=58)							
0	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
10 or less	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
20	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
35-20	0 (0.0%)	0 (0.0%)	0 (0.0%)	20 (34.5%)	4 (6.9%)	3 (5.2%)	27 (46.6%)
45-35	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	17 (29.3%)	3 (5.2%)	21 (36.2%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (15.5%)	9 (15.5%)
Overall	0 (0.0%)	0 (0.0%)	1 (1.7%)	21 (36.2%)	21 (36.2%)	15 (25.9%)	58 (100.0%)
TRAVATAN (N=62)							
0	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
10 or less	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
20	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
35-20	0 (0.0%)	0 (0.0%)	0 (0.0%)	20 (32.3%)	1 (1.6%)	3 (4.8%)	24 (38.7%)
45-35	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.2%)	25 (40.3%)	2 (3.2%)	29 (46.8%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (14.5%)	9 (14.5%)
Overall	0 (0.0%)	0 (0.0%)	0 (0.0%)	22 (35.5%)	26 (41.9%)	14 (22.6%)	62 (100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-3
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-8 LOCAL TOLERABILITY: SHIFT TABLE OF VISUAL FIELD FROM BASELINE TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment							
VISIT 2 Bseline	Normal		Abnormal		Missing		Overall	
TRAVOPROST PR (N=58)								
Normal	28	(48.3%)	4	(6.9%)	6	(10.3%)	38	(65.5%)
Abnormal	1	(1.7%)	17	(29.3%)	2	(3.4%)	20	(34.5%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	29	(50.0%)	21	(36.2%)	8	(13.8%)	58	(100.0%)
TRAVATAN (N=62)								
Normal	28	(45.2%)	1	(1.6%)	2	(3.2%)	31	(50.0%)
Abnormal	5	(8.1%)	21	(33.9%)	5	(8.1%)	31	(50.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Overall	33	(53.2%)	22	(35.5%)	7	(11.3%)	62	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-3
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-9.1 LOCAL TOLERABILITY: LENS OPACITIES - SHIFT TABLE OF CORTICAL CATARACT FROM BASELINE TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment											
VISIT 2 Baseline	Ctr		C1		C2		C3		C4		Missing		Overall	
TRAVOPROST PR (N=58)												
Ctr	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
C1	0	(0.0%)	25	(43.1%)	1	(1.7%)	0	(0.0%)	0	(0.0%)	5	(8.6%)	31	(53.4%)
C2	0	(0.0%)	1	(1.7%)	11	(19.0%)	0	(0.0%)	0	(0.0%)	1	(1.7%)	13	(22.4%)
C3	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.7%)	0	(0.0%)	0	(0.0%)	1	(1.7%)
C4	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.7%)	0	(0.0%)	1	(1.7%)
Missing	0	(0.0%)	1	(1.7%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	11	(19.0%)	12	(20.7%)
Overall	0	(0.0%)	27	(46.6%)	12	(20.7%)	1	(1.7%)	1	(1.7%)	17	(29.3%)	58	(100.0%)
TRAVATAN (N=62)												
Ctr	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
C1	0	(0.0%)	25	(40.3%)	2	(3.2%)	1	(1.6%)	0	(0.0%)	4	(6.5%)	32	(51.6%)
C2	0	(0.0%)	2	(3.2%)	11	(17.7%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	13	(21.0%)
C3	0	(0.0%)	0	(0.0%)	0	(0.0%)	3	(4.8%)	0	(0.0%)	2	(3.2%)	5	(8.1%)
C4	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	12	(19.4%)	12	(19.4%)
Overall	0	(0.0%)	27	(43.5%)	13	(21.0%)	4	(6.5%)	0	(0.0%)	18	(29.0%)	62	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-4
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-9.2 LOCAL TOLERABILITY: LENS OPACITIES - SHIFT TABLE OF NUCLEAR COLOR FROM BASELINE TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment													
VISIT 2 Baseline	NC1		NC2		NC3		NC4		NC5		NC6		Missing		Overall	
TRAVOPROST PR (N=58)																
NC1	15	(25.9%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	4	(6.9%)	19	(32.8%)
NC2	0	(0.0%)	10	(17.2%)	2	(3.4%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.7%)	13	(22.4%)
NC3	0	(0.0%)	0	(0.0%)	4	(6.9%)	1	(1.7%)	0	(0.0%)	0	(0.0%)	1	(1.7%)	6	(10.3%)
NC4	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(3.4%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(3.4%)
NC5	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
NC6	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	1	(1.7%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	17	(29.3%)	18	(31.0%)
Overall	15	(25.9%)	10	(17.2%)	7	(12.1%)	3	(5.2%)	0	(0.0%)	0	(0.0%)	23	(39.7%)	58	(100.0%)
TRAVATAN (N=62)																
NC1	11	(17.7%)	3	(4.8%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.6%)	15	(24.2%)
NC2	0	(0.0%)	18	(29.0%)	0	(0.0%)	1	(1.6%)	0	(0.0%)	0	(0.0%)	4	(6.5%)	23	(37.1%)
NC3	0	(0.0%)	0	(0.0%)	6	(9.7%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.6%)	7	(11.3%)
NC4	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.6%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.6%)
NC5	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.6%)	0	(0.0%)	0	(0.0%)	1	(1.6%)
NC6	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	15	(24.2%)	15	(24.2%)
Overall	11	(17.7%)	21	(33.9%)	6	(9.7%)	2	(3.2%)	1	(1.6%)	0	(0.0%)	21	(33.9%)	62	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-4
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-9.3 LOCAL TOLERABILITY: LENS OPACITIES - SHIFT TABLE OF NUCLEAR OPALESCENCE FROM BASELINE TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment													
VISIT 2 Baseline	NO1		NO2		NO3		NO4		NO5		NO6		Missing		Overall	
TRAVOPROST PR (N=58)																
NO1	14	(24.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	3	(5.2%)	17	(29.3%)
NO2	0	(0.0%)	10	(17.2%)	3	(5.2%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	3	(5.2%)	16	(27.6%)
NO3	0	(0.0%)	0	(0.0%)	4	(6.9%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	4	(6.9%)
NO4	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(3.4%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(3.4%)
NO5	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	1	(1.7%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	18	(31.0%)	19	(32.8%)
Overall	14	(24.1%)	10	(17.2%)	8	(13.8%)	2	(3.4%)	0	(0.0%)	0	(0.0%)	24	(41.4%)	58	(100.0%)
TRAVATAN (N=62)																
NO1	14	(22.6%)	2	(3.2%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.6%)	17	(27.4%)
NO2	0	(0.0%)	11	(17.7%)	2	(3.2%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	4	(6.5%)	17	(27.4%)
NO3	0	(0.0%)	2	(3.2%)	4	(6.5%)	1	(1.6%)	0	(0.0%)	0	(0.0%)	1	(1.6%)	8	(12.9%)
NO4	0	(0.0%)	0	(0.0%)	1	(1.6%)	1	(1.6%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(3.2%)
NO5	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.6%)	0	(0.0%)	0	(0.0%)	1	(1.6%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	17	(27.4%)	17	(27.4%)
Overall	14	(22.6%)	15	(24.2%)	7	(11.3%)	2	(3.2%)	1	(1.6%)	0	(0.0%)	23	(37.1%)	62	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-4
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-9.4 LOCAL TOLERABILITY: LENS OPACITIES - SHIFT TABLE OF POSTERIOR SUBCAPSULAR CATARACT FROM BASELINE TO END OF TREATMENT
SAFETY POPULATION

	VISIT 7 End of treatment											
VISIT 2 Baseline	P1		P2		P3		P4		P5		Missing		Overall	
TRAVOPROST PR (N=58)												
P1	27	(46.6%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	5	(8.6%)	32	(55.2%)
P2	0	(0.0%)	4	(6.9%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.7%)	5	(8.6%)
P3	0	(0.0%)	0	(0.0%)	1	(1.7%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.7%)
P4	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
P5	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.7%)	0	(0.0%)	19	(32.8%)	20	(34.5%)
Overall	27	(46.6%)	4	(6.9%)	1	(1.7%)	1	(1.7%)	0	(0.0%)	25	(43.1%)	58	(100.0%)
TRAVATAN (N=62)												
P1	31	(50.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	4	(6.5%)	35	(56.5%)
P2	0	(0.0%)	6	(9.7%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	1	(1.6%)	7	(11.3%)
P3	0	(0.0%)	1	(1.6%)	1	(1.6%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(3.2%)
P4	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
P5	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Missing	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	18	(29.0%)	18	(29.0%)
Overall	31	(50.0%)	7	(11.3%)	1	(1.6%)	0	(0.0%)	0	(0.0%)	23	(37.1%)	62	(100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-4
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-10 LOCAL TOLERABILITY: RETINA AND OPTIC DISC EXAMINATION - SHIFT TABLE FROM BASELINE TO END OF TREATMENT
SAFETY POPULATION

VISIT 2 Baseline	VISIT 7 End of treatment: Normal	Abnormal	Missing	Overall
TRAVOPROST PR (N=58)				
Retina				
Normal	42 (72.4%)	1 (1.7%)	4 (6.9%)	47 (81.0%)
Abnormal	0 (0.0%)	9 (15.5%)	2 (3.4%)	11 (19.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	42 (72.4%)	10 (17.2%)	6 (10.3%)	58 (100.0%)
Optic disk				
Normal	27 (46.6%)	0 (0.0%)	4 (6.9%)	31 (53.4%)
Abnormal	0 (0.0%)	25 (43.1%)	2 (3.4%)	27 (46.6%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	27 (46.6%)	25 (43.1%)	6 (10.3%)	58 (100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-4
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2

LIST OF TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

TABLE T14.3.4-10 LOCAL TOLERABILITY: RETINA AND OPTIC DISC EXAMINATION -
SHIFT TABLE FROM BASELINE TO END OF TREATMENT (Continued)
SAFETY POPULATION

VISIT 2 Baseline	VISIT 7 End of treatment: Normal	Abnormal	Missing	Overall
TRAVATAN (N=62)				
Retina				
Normal	38 (61.3%)	1 (1.6%)	6 (9.7%)	45 (72.6%)
Abnormal	1 (1.6%)	16 (25.8%)	0 (0.0%)	17 (27.4%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	39 (62.9%)	17 (27.4%)	6 (9.7%)	62 (100.0%)
Optic disk				
Normal	29 (46.8%)	0 (0.0%)	2 (3.2%)	31 (50.0%)
Abnormal	4 (6.5%)	23 (37.1%)	4 (6.5%)	31 (50.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	33 (53.2%)	23 (37.1%)	6 (9.7%)	62 (100.0%)

Note 1: Percentages are calculated on the number of patients (N).

Cross-reference: Listing 16.2.7-4
Program (Date\Time): \Tables\Tab_T14_2-1_1.sas (19JUN2014\10:06) SAS Version: 9.2