表 2.7.4.7-1. 101390002LT:発現時期別有害事象の発現例数（安全性解析対象集団）

Preferred Term (PT)	1 - 30 days (N=260)	31 – 90 days (N=245)	91 - 180 days (N=197)	181 - 270 days (N=161)	271 - 360 days (N=142)	>= 361 days (N=68)
Abdominal discomfort	0	0	0	1 (0.6%)	0	0
Abdominal distension	0	0	1 (0.5%)	0	0	0
Abdominal pain	0	0	1 (0.5%)	0	0	0
Abdominal pain upper	0	0	0	0	1 (0.7%)	0
Abnormal sensation in eye	2 (0.8%)	0	0	0	0	0
Adenoviral conjunctivitis	0	0	1 (0.5%)	1 (0.6%)	0	0
Alopecia areata	0	0	0	1 (0.6%)	0	0
Amaurosis fugax	0	0	0	1 (0.6%)	0	0
Anaemia	0	0	1 (0.5%)	0	0	0
Anterior chamber inflammation	0	1 (0.4%)	0	0	0	0
Arthralgia	0	1 (0.4%)	2 (1.0%)	0	1 (0.7%)	0
Arthropod bite	0	2 (0.8%)	0	0	0	0
Asthenopia	0	0	1 (0.5%)	0	0	0
Back pain	1 (0.4%)	1 (0.4%)	1 (0.5%)	0	0	0
Blepharitis	2 (0.8%)	5 (2.0%)	5 (2.5%)	3 (1.9%)	2 (1.4%)	0
Blepharitis allergic	0	0	3 (1.5%)	3 (1.9%)	0	0
Blood pressure increased	0	0	1 (0.5%)	0	0	0
Blood uric acid increased	0	0	1 (0.5%)	0	0	0
Burning sensation	1 (0.4%)	0	0	0	0	0
COVID-19	2 (0.8%)	0	1 (0.5%)	2 (1.2%)	2 (1.4%)	0
Cardiac failure congestive	0	1 (0.4%)	0	0	0	0
Cataract	0	3 (1.2%)	0	1 (0.6%)	0	0
Chronic sinusitis	0	0	0	0	1 (0.7%)	0
Ciliary hyperaemia	0	1 (0.4%)	0	0	0	0
Conjunctival cyst	1 (0.4%)	0	0	0	0	0
Conjunctival deposit	1 (0.4%)	0	1 (0.5%)	0	0	0
Conjunctival follicles	0	1 (0.4%)	0	0	0	0
Conjunctival haemorrhage	9 (3.5%)	22 (9.0%)	14 (7.1%)	2 (1.2%)	4 (2.8%)	1 (1.5%)
Conjunctival hyperaemia	127 (48.8%)	21 (8.6%)	10 (5.1%)	4 (2.5%)	1 (0.7%)	0
Conjunctival oedema	1 (0.4%)	0	0	0	1 (0.7%)	0
Conjunctivitis	0	2 (0.8%)	4 (2.0%)	2 (1.2%)	1 (0.7%)	0
Conjunctivitis allergic	3 (1.2%)	31 (12.7%)	23 (11.7%)	12 (7.5%)	5 (3.5%)	1 (1.5%)
Conjunctivitis bacterial	0	4 (1.6%)	0	1 (0.6%)	0	0
Constipation	1 (0.4%)	0	0	0	0	0
Contusion	0	2 (0.8%)	0	0	0	0
Cornea verticillata	8 (3.1%)	41 (16.7%)	36 (18.3%)	19 (11.8%)	6 (4.2%)	0
Corneal degeneration	0	0	0	1 (0.6%)	0	0
Corneal disorder	1 (0.4%)	0	0	0	1 (0.7%)	0
Corneal erosion	1 (0.4%)	1 (0.4%)	0	1 (0.6%)	0	0
Corneal oedema	0	2 (0.8%)	0	0	0	0
Corneal opacity	2 (0.8%)	1 (0.4%)	0	0	1 (0.7%)	0
Coronavirus infection	0	1 (0.4%)	2 (1.0%)	1 (0.6%)	1 (0.7%)	0
Cough	0	1 (0.4%)	0	0	0	0
Cough variant asthma	0	1 (0.4%)	0	1 (0.6%)	0	0
Cystitis	0	0	1 (0.5%)	0	1 (0.7%)	0
Dental caries	1 (0.4%)	0	1 (0.5%)	0	1 (0.7%)	0
Dermal cyst	0	1 (0.4%)	0	0	0	0
Dermatitis	0	0	1 (0.5%)	1 (0.6%)	0	0
Dermatitis contact	0	2 (0.8%)	0	0	0	0
Diabetes mellitus	0	0	1 (0.5%)	0	0	1 (1.5%)
Diabetic retinopathy	0	0	0	1 (0.6%)	0	0
Dizziness	0	1 (0.4%)	0	0	1 (0.7%)	0
Dry eye	0	3 (1.2%)	0	4 (2.5%)	1 (0.7%)	0

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Preferred Term (PT)	1 - 30 days (N=260)	31 – 90 days (N=245)	91 - 180 days (N=197)	181 - 270 days (N=161)	271 - 360 days (N=142)	>= 361 days (N=68)
Dry skin	0	0	0	2 (1.2%)	0	0
Dyspnoea	0	0	1 (0.5%)	0	0	0
Eczema	0	0	1 (0.5%)	0	0	0
Eczema eyelids	0	3 (1.2%)	2 (1.0%)	1 (0.6%)	1 (0.7%)	0
Enterocele	0	0	1 (0.5%)	0	0	0
Erythema of eyelid	1 (0.4%)	0	0	0	0	0
Eye discharge	1 (0.4%)	1 (0.4%)	1 (0.5%)	0	0	0
Eye irritation	26 (10.0%)	0	0	0	0	0
Eye pain	2 (0.8%)	4 (1.6%)	1 (0.5%)	0	0	0
Eye pruritus	5 (1.9%)	6 (2.4%)	5 (2.5%)	0	0	0
Eyelids pruritus	4 (1.5%)	1 (0.4%)	1 (0.5%)	0	0	0
Faeces soft	0	1 (0.4%)	0	0	0	0
Foot fracture	0	1 (0.4%)	0	0	0	0
Foreign body sensation in eyes	1 (0.4%)	0	0	0	0	0
Gastritis	1 (0.4%)	0	0	0	0	0
Gastroenteritis	0	1 (0.4%)	0	0	0	0
Gingivitis	0	0	0	1 (0.6%)	0	0
Hand fracture	0	1 (0.4%)	0	0	0	0
Headache	0	1 (0.4%)	1 (0.5%)	0	1 (0.7%)	0
Helicobacter gastritis	0	0	1 (0.5%)	0	0	0
Herpes zoster	0	0	1 (0.5%)	0	0	0
Hordeolum	0	0	1 (0.5%)	1 (0.6%)	2 (1.4%)	1 (1.5%)
Hyperaemia	1 (0.4%)	0	0	0	0	0
Hyperuricaemia	0	0	0	0	1 (0.7%)	0
Immunisation reaction	4 (1.5%)	6 (2.4%)	7 (3.6%)	3 (1.9%)	0	0
Infected dermal cyst	1 (0.4%)	0	0	0	0	0
Influenza	0	0	1 (0.5%)	0	1 (0.7%)	0
Injection site pain	0	1 (0.4%)	0	0	0	0
Instillation site discomfort	1 (0.4%)	0	0	0	0	0
Instillation site pain	6 (2.3%)	0	0	0	0	0
Intervertebral disc protrusion	0	0	0	1 (0.6%)	0	0
Intraocular pressure increased	0	1 (0.4%)	1 (0.5%)	1 (0.6%)	1 (0.7%)	0
Iron deficiency anaemia	0	0	0	1 (0.6%)	0	0
Irritable bowel syndrome	0	0	0	0	1 (0.7%)	0
Keratitis	0	1 (0.4%)	1 (0.5%)	0	0	0
Lacrimation increased	6 (2.3%)	2 (0.8%)	4 (2.0%)	1 (0.6%)	2 (1.4%)	0
Lipoma	0	0	0	0	1 (0.7%)	0
Loss of visual contrast sensitivity	0	2 (0.8%)	3 (1.5%)	0	0	0
Lymphangiectasia	0	0	1 (0.5%)	0	0	0
Lymphoma	0	0	0	1 (0.6%)	0	0
Madarosis	0	0	0	1 (0.6%)	0	0
Meibomian gland dysfunction	0	0	0	1 (0.6%)	0	0
Meibomianitis	0	1 (0.4%)	0	0	0	0
Muscle strain	0	1 (0.4%)	0	0	0	0
Nasopharyngitis	1 (0.4%)	3 (1.2%)	4 (2.0%)	3 (1.9%)	1 (0.7%)	0
Nausea	0	1 (0.4%)	1 (0.5%)	0	0	1 (1.5%)
Neck pain	1 (0.4%)	0	0	0	0	0
Noninfective gingivitis	0	0	0	1 (0.6%)	0	0
Ocular discomfort	0	0	0	1 (0.6%)	0	0
Oropharyngeal pain	0	0	1 (0.5%)	0	1 (0.7%)	0
Osteoarthritis	0	1 (0.4%)	1 (0.5%)	0	0	0
Osteoporosis	1 (0.4%)	0	1 (0.5%)	0	0	0
Otitis externa	1 (0.4%)	0	0	0	0	0
Pain in extremity	0	0	0	1 (0.6%)	0	0
Palpitations	0	0	1 (0.5%)	0	0	0

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Preferred Term (PT)	1 - 30 days (N=260)	31 – 90 days (N=245)	91 - 180 days (N=197)	181 - 270 days (N=161)	271 - 360 days (N=142)	>= 361 days (N=68)
Periarthritis	0	0	0	1 (0.6%)	0	0
Periodontal disease	0	0	1 (0.5%)	0	0	0
Photophobia	0	0	1 (0.5%)	0	0	0
Pneumonia aspiration	0	1 (0.4%)	0	0	0	0
Presbyopia	1 (0.4%)	0	0	0	0	0
Proteinuria	0	0	0	1 (0.6%)	0	0
Pruritus	0	0	1 (0.5%)	0	0	0
Punctate keratitis	4 (1.5%)	3 (1.2%)	2 (1.0%)	2 (1.2%)	3 (2.1%)	0
Purulence	0	0	1 (0.5%)	0	0	0
Pyrexia	0	4 (1.6%)	2 (1.0%)	1 (0.6%)	1 (0.7%)	0
Radius fracture	0	1 (0.4%)	0	0	0	0
Retinal exudates	0	1 (0.4%)	0	0	0	0
Rhinitis allergic	0	1 (0.4%)	2 (1.0%)	0	0	0
Rib fracture	0	1 (0.4%)	0	0	0	0
Seasonal allergy	1 (0.4%)	1 (0.4%)	0	1 (0.6%)	0	0
Seborrhoeic dermatitis	0	0	1 (0.5%)	0	0	0
Sinusitis	0	1 (0.4%)	0	0	0	0
Skin fissures	0	0	0	1 (0.6%)	0	0
Skin papilloma	0	0	1 (0.5%)	0	0	0
Spinal compression fracture	1 (0.4%)	0	0	0	0	0
Spinal osteoarthritis	0	0	0	0	1 (0.7%)	0
Stomatitis	0	0	1 (0.5%)	0	0	0
Subdural haematoma	0	1 (0.4%)	0	0	0	0
Sudden hearing loss	2 (0.8%)	0	0	0	0	0
Tenosynovitis	0	1 (0.4%)	0	0	1 (0.7%)	0
Tension headache	0	1 (0.4%)	0	0	0	0
Tinea pedis	1 (0.4%)	0	1 (0.5%)	0	0	0
Tinnitus	0	0	1 (0.5%)	0	0	0
Traumatic subarachnoid haemorrhage	0	1 (0.4%)	0	0	0	0
Trichiasis	0	1 (0.4%)	0	0	0	0
Ulcerative keratitis	0	1 (0.4%)	0	0	0	0
Urinary tract infection	1 (0.4%)	0	1 (0.5%)	0	0	0
Urticaria	1 (0.4%)	0	0	0	0	0
Uveitis	0	1 (0.4%)	0	0	1 (0.7%)	0
Vertigo	0	0	0	0	0	1 (1.5%)
Vertigo positional	1 (0.4%)	0	0	0	0	0
Vision blurred	7 (2.7%)	5 (2.0%)	12 (6.1%)	0	1 (0.7%)	0
Visual acuity reduced	4 (1.5%)	5 (2.0%)	3 (1.5%)	9 (5.6%)	1 (0.7%)	1 (1.5%)
Visual field defect	0	1 (0.4%)	0	2 (1.2%)	0	0
White blood cell count increased	0	1 (0.4%)	0	0	0	0

An event reported on the AE eCRF was considered as a TEAE except for "Cornea Verticillata" if the date of onset of the event was on or after the treatment start date up to and including 30 days after the treatment end date.

Note: N in the headers represents the total number of subjects who took an investigational product in period in each treatment group for the population being analyzed. Any subject who experienced multiple adverse events within a SOC or preferred term is counted only once at onset for that SOC or preferred term. Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 27.1.

Source: 添付資料 5.3.5.2-1 Table 14.3.1.4.5

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表 2.7.4.7-2. 101390002LT:死亡例一覧

Subject	Treatment	Adverse event reported (SOC/Preferred Term)	Onset / stop date (Days *)	Serious/Severity/ Causality	Action taken to study drug	Outcome
3920167-08	0.02% STN1013900 (15<=IOP<22 mmHg)	ASPIRATION PNEUMONIA (Infections and infestations / Pneumonia aspiration)	20[redacted]- [redacted] (50)/ 202[redacted]- [redacted] (60)	Y / SEVERE / NOT RELATED	DRUG WITHDRAWN	FATAL

Note: MedDRA Version: 27.1

* From treatment start date

Source: 添付資料 5.3.5.2-1 Listing 16.2.7.2.1

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表 2.7.4.7-3. AR-13324-CS305: 死亡以外の重篤な有害事象発現症例一覧

Subject ID/ Randomized Trt.	Verbatim Adverse Event/ System Organ Class (SOC)/ Preferred Term (PT)	Loc	Onset Date & Time (Study Day) [1]/ Resolution Date & Time (Study Day)* [1]	Was Event Serious?/ Reason for Seriousness [2]	Severity	Relationship/ Withdrawn from Study due to AE?	Action Taken with Study Drug [3]/ Other Action Taken [4]	Frequency/ Outcome [5]
307-016/ Ripasudil 0.4% BID	PNEUMONIA/ Infections and infestations/ Pneumonia	NA	20[redacted] (20)/ 20[redacted] (74)	Yes/3	Moderate	Not Related/ Yes	2/ 3, 5	Continuous/ 3
321-006/ Ripasudil 0.4% BID	ERYTHEMA MULTIFORME EXUDATIVUM/ Skin and subcutaneous tissue disorders/ Erythema multiforme	NA	20[redacted] (71)/ 20[redacted] (74)	Yes/1	Moderate	Unlikely Related/ No	1/ 1	Intermittent/ 1

Abbreviations: AE = Adverse Event; BID = Twice per Day; Loc = Location; NA = Not Available; OD = Right Eye; OS = Left Eye; OTC = Over the Counter; OU = Both Eyes; QD = Once per Day; RX = Prescription; UNK = Unknown.
Note: Adverse Events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 23.1. Time is given on a 24-hour clock.
[1] Study day is based on treatment start date.
[2] 1 = Death; 2 = Life-threatening; 3 = In-subject hospitalization or prolongation of existing hospitalization; 4 = Persistent or significant disability/incapacity; 5 = Congenital anomaly or birth defect; 6 = Important medical event.
[3] 1 = None; 2 = Investigational product discontinued; 3 = Investigational Product Interrupted, Date Restarted.
[4] 1 = None; 2 = Non-Drug Therapy; 3 = New OTC or RX Drug Added; 4 = Hospitalized < 24 hours; 5 = Hospitalized >= 24 Hours.
[5] 1 = Fatal; 2 = Not Recovered/Not Resolved; 3 = Recovered/Resolved; 4 = Recovered/Resolved with Sequelae; 5 = Recovering/Resolving; 6 = Unknown/Lost to Follow-up.
* Indicates not a Treatment-Emergent Adverse Event.

Source: 添付資料 5.3.5.1-3 Listing 16.2.7.2

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表 2.7.4.7-4. 101390002LT:死亡以外の重篤な有害事象発現症例一覧

Subject	Treatment	Adverse event reported	SAE Start Date Admission Date Discharge Date	Improve/ Reappear
3920013-01	0.02% STN1013900 + 0.005% Latanoprost	MALIGNANT LYMPHOMA	20[redacted] / 20[redacted]	/ NA / NA
3920015-09	0.02% STN1013900 + 0.005% Latanoprost	URINARY TRACT INFECTION	20[redacted] / 20[redacted]	/ NA / NA
3920046-03	0.02% STN1013900 (15<=IOP<22 mmHg)	LEFT UPPER ARM LIPOMA	20[redacted] / 20[redacted]	/ NA / NA
3920080-12	0.02% STN1013900 + 0.005% Latanoprost	ACUTE SUBDURAL HAEMATOMA	20[redacted] / 20[redacted]	/ NA / NA
		TRAUMATIC SUBARACHNOID HAEMORRHAGE	20[redacted] / 20[redacted]	/ NA / NA
3920117-10	0.02% STN1013900 (22<=IOP<35 mmHg)	CARDIAC FAILURE CONGESTIVE	20[redacted] / 20[redacted]	/ NA / NA
3920151-01	0.02% STN1013900 + 0.5% Timolol	CHRONIC SINUSITIS	20[redacted] / 20[redacted]	/ NA / NA
3920168-05	0.02% STN1013900 (22<=IOP<35 mmHg)	WORSENING OF ENTEROCELE	20[redacted] / 20[redacted]	/ NA / NA

Source: 添付資料 5.3.5.2-1 Listing 16.2.7.4

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表 2.7.4.7-5. 101390002LT:Visit 3（ベースライン）、OBS Visit 1、OBS Visit Final における VFQ-25 質問票（7-subscale composite ）の平均値及び Visit 3 からの平均変化量

	0.02% STN1013900 (15<=IOP<22 mmHg) (N=34)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=26)		0.02% STN1013900 + 0.005% Latanoprost (N=23)		0.02% STN1013900 + 0.5% Timolol (N=27)		All subjects (N=110)	
Parameter Visit Statistic	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline
Overall Composite Score (Combo 7)										
V3: Qualification 2 (Day 1)										
n	34	N/A	26	N/A	23	N/A	27	N/A	110	N/A
Mean	84.04	N/A	87.82	N/A	87.20	N/A	85.70	N/A	86.00	N/A
(SD)	(10.642)		(7.495)		(8.336)		(8.603)		(9.009)	
Median	84.55	N/A	89.10	N/A	89.40	N/A	87.60	N/A	87.90	N/A
Min, Max	55.1, 100.0	N/A	69.5, 99.1	N/A	63.4, 97.1	N/A	66.1, 97.1	N/A	55.1, 100.0	N/A
OBS V1										
n	34	34	26	26	23	23	27	27	110	110
Mean	81.33	-2.71	87.12	-0.70	86.82	-0.38	85.26	-0.43	84.81	-1.19
(SD)	(12.199)	(7.353)	(9.021)	(5.984)	(8.227)	(4.480)	(10.143)	(6.654)	(10.386)	(6.344)
Median	83.85	-1.20	89.55	-0.35	88.50	-1.20	85.80	0.30	87.75	-1.20
Min, Max	47.5, 97.1	-33.1, 8.0	61.5, 100.0	-12.5, 15.3	65.6, 97.1	-9.7, 8.6	64.2, 97.1	-19.2, 12.5	47.5, 100.0	-33.1, 15.3
OBS Final										
n	34	34	26	26	23	23	27	27	110	110
Mean	83.72	-0.31	86.83	-0.98	85.18	-2.02	86.01	0.32	85.33	-0.67
(SD)	(10.614)	(5.847)	(6.765)	(5.282)	(10.065)	(6.920)	(9.283)	(7.570)	(9.331)	(6.385)
Median	85.35	0.00	87.60	-1.20	88.60	-1.30	87.30	0.10	87.30	-0.45
Min, Max	53.2, 97.1	-14.3, 16.1	77.5, 99.1	-10.1, 13.1	61.8, 97.1	-20.0, 11.0	63.9, 97.1	-25.2, 13.6	53.2, 99.1	-25.2, 16.1

Abbreviations: OBS = Observational Study; N/A = Not Applicable, Combo 7 = 7-subscale composite score.

Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Higher scores indicate better vision-specific health-related quality of life. Overall composite score is the average of all sub-scale scores except for the general health item.

Overall Composite Score (Combo 7): Mean of General Vision, Near Activities, Distance Activities, Social Functioning, Mental Health, Role Difficulties and Dependency

Source : 添付資料 5.3.5.2-1 Table 14.3.4.2.1

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表 2.7.4.7-6. 101390002LT:OBS Visit 1、OBS Visit Final における VFQ-25 質問票（7-subscale composite ）の平均値及び OBS Visit 1 からの平均変化量

	0.02% STN1013900 (15<=IOP<22 mmHg) (N=34)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=26)		0.02% STN1013900 + 0.005% Latanoprost (N=23)		0.02% STN1013900 + 0.5% Timolol (N=27)		All subjects (N=110)	
Parameter Visit Statistic	Observed	Change from OBS V1	Observed	Change from OBS V1	Observed	Change from OBS V1	Observed	Change from OBS V1	Observed	Change from OBS V1
Overall Composite Score (Combo 7)										
OBS V1										
n	34	N/A	26	N/A	23	N/A	27	N/A	110	N/A
Mean	81.33	N/A	87.12	N/A	86.82	N/A	85.26	N/A	84.81	N/A
(SD)	(12.199)		(9.021)		(8.227)		(10.143)		(10.386)	
Median	83.85	N/A	89.55	N/A	88.50	N/A	85.80	N/A	87.75	N/A
Min, Max	47.5, 97.1	N/A	61.5, 100.0	N/A	65.6, 97.1	N/A	64.2, 97.1	N/A	47.5, 100.0	N/A
OBS Final										
n	34	34	26	26	23	23	27	27	110	110
Mean	83.72	2.40	86.83	-0.28	85.18	-1.63	86.01	0.75	85.33	0.52
(SD)	(10.614)	(8.736)	(6.765)	(5.478)	(10.065)	(6.061)	(9.283)	(5.126)	(9.331)	(6.776)
Median	85.35	2.25	87.60	-1.45	88.60	0.00	87.30	0.90	87.30	0.65
Min, Max	53.2, 97.1	-14.6, 37.2	77.5, 99.1	-8.3, 17.5	61.8, 97.1	-17.6, 9.0	63.9, 97.1	-10.4, 8.9	53.2, 99.1	-17.6, 37.2

Abbreviations: OBS = Observational Study; N/A = Not Applicable, Combo 7 = 7-subscale composite score.

Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Higher scores indicate better vision-specific health-related quality of life. Overall composite score is the average of all sub-scale scores except for the general health item.

Overall Composite Score (Combo 7): Mean of General Vision, Near Activities, Distance Activities, Social Functioning, Mental Health, Role Difficulties and Dependency

Source : 添付資料 5.3.5.2-1 Table 14.3.4.2.2

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表 2.7.4.7-7. 101390002LT:最高矯正視力の平均値及び Visit 3（ベースライン）からの平均変化量

Visit / Statistic	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67) Observed	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67) Change from Baseline	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52) Observed	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52) Change from Baseline	0.02% STN1013900 + 0.005% Latanoprost (N=44) Observed	0.02% STN1013900 + 0.005% Latanoprost (N=44) Change from Baseline	0.02% STN1013900 + 0.5% Timolol (N=52) Observed	0.02% STN1013900 + 0.5% Timolol (N=52) Change from Baseline	All Subjects (N=215) Observed	All Subjects (N=215) Change from Baseline
V3: Qualification 2 (Day 1)										
n	67	N/A	52	N/A	44	N/A	52	N/A	215	N/A
Mean (SD)	1.15 (0.249)	N/A	1.12 (0.232)	N/A	1.21 (0.328)	N/A	1.09 (0.249)	N/A	1.14 (0.265)	N/A
Median	1.20	N/A	1.20	N/A	1.20	N/A	1.00	N/A	1.20	N/A
Min, Max	0.4, 1.5	N/A	0.5, 1.5	N/A	0.6, 2.0	N/A	0.4, 1.5	N/A	0.4, 2.0	N/A
OBS V1										
n	67	67	52	52	44	44	52	52	215	215
Mean (SD)	1.04 (0.276)	-0.11 (0.180)	1.08 (0.251)	-0.04 (0.156)	1.08 (0.258)	-0.12 (0.237)	1.01 (0.275)	-0.08 (0.187)	1.05 (0.266)	-0.09 (0.191)
Median	1.00	-0.10	1.20	0.00	1.00	0.00	1.00	0.00	1.00	0.00
Min, Max	0.4, 1.5	-0.6, 0.3	0.4, 1.5	-0.4, 0.4	0.5, 1.5	-0.5, 0.3	0.3, 1.5	-0.6, 0.5	0.3, 1.5	-0.6, 0.5
OBS V2										
n	66	66	52	52	44	44	50	50	212	212
Mean (SD)	1.02 (0.282)	-0.13 (0.180)	1.08 (0.284)	-0.04 (0.200)	1.07 (0.312)	-0.14 (0.299)	0.99 (0.253)	-0.11 (0.172)	1.04 (0.283)	-0.10 (0.215)
Median	1.00	-0.10	1.20	0.00	1.00	0.00	1.00	0.00	1.00	0.00
Min, Max	0.4, 1.5	-0.6, 0.3	0.5, 1.5	-0.6, 0.5	0.4, 2.0	-0.9, 0.3	0.3, 1.5	-0.5, 0.2	0.3, 2.0	-0.9, 0.5
OBS V3										
n	66	66	52	52	43	43	46	46	207	207
Mean (SD)	0.99 (0.267)	-0.16 (0.161)	1.05 (0.252)	-0.06 (0.150)	1.06 (0.268)	-0.16 (0.309)	1.03 (0.260)	-0.08 (0.145)	1.03 (0.262)	-0.12 (0.199)
Median	1.00	-0.20	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00
Min, Max	0.3, 1.5	-0.6, 0.2	0.4, 1.5	-0.5, 0.4	0.5, 1.5	-1.0, 0.3	0.3, 1.5	-0.4, 0.2	0.3, 1.5	-1.0, 0.4
OBS V4										
n	64	64	50	50	41	41	46	46	201	201
Mean (SD)	1.04 (0.256)	-0.12 (0.136)	1.06 (0.260)	-0.06 (0.153)	1.11 (0.284)	-0.11 (0.266)	1.05 (0.273)	-0.06 (0.136)	1.06 (0.266)	-0.09 (0.175)
Median	1.00	-0.10	1.20	0.00	1.20	0.00	1.00	0.00	1.00	0.00
Min, Max	0.5, 1.5	-0.4, 0.1	0.4, 1.5	-0.4, 0.4	0.6, 2.0	-0.8, 0.3	0.3, 1.5	-0.5, 0.2	0.3, 2.0	-0.8, 0.4
OBS V5										
n	60	60	46	46	37	37	38	38	181	181
Mean (SD)	1.04 (0.274)	-0.13 (0.202)	1.01 (0.272)	-0.10 (0.135)	1.03 (0.255)	-0.19 (0.306)	1.08 (0.203)	-0.04 (0.164)	1.04 (0.255)	-0.12 (0.212)
Median	1.00	-0.15	1.00	0.00	1.00	-0.10	1.20	0.00	1.00	0.00
Min, Max	0.3, 1.5	-0.9, 0.5	0.4, 1.5	-0.5, 0.2	0.4, 1.5	-1.0, 0.3	0.5, 1.5	-0.5, 0.2	0.3, 1.5	-1.0, 0.5
OBS V6										
n	46	46	40	40	32	32	34	34	152	152
Mean (SD)	1.06 (0.296)	-0.11 (0.239)	1.05 (0.274)	-0.07 (0.158)	1.03 (0.362)	-0.22 (0.245)	1.11 (0.189)	-0.01 (0.188)	1.06 (0.285)	-0.10 (0.220)
Median	1.00	-0.10	1.00	0.00	1.00	-0.20	1.20	0.00	1.00	-0.05

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Visit	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Statistic	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline
Min, Max	0.4, 1.5	-0.8, 0.3	0.4, 1.5	-0.4, 0.3	0.2, 2.0	-0.8, 0.2	0.6, 1.5	-0.5, 0.3	0.2, 2.0	-0.8, 0.3
OBS V7										
n	38	38	28	28	26	26	28	28	120	120
Mean (SD)	1.04	-0.11	0.99	-0.05	1.14	-0.15	1.15	0.02	1.08	-0.07
	(0.263)	(0.191)	(0.277)	(0.184)	(0.377)	(0.263)	(0.171)	(0.183)	(0.282)	(0.212)
Median	1.00	-0.15	1.00	-0.05	1.20	0.00	1.20	0.00	1.20	0.00
Min, Max	0.4, 1.5	-0.5, 0.3	0.3, 1.5	-0.3, 0.4	0.2, 2.0	-0.8, 0.2	0.8, 1.5	-0.3, 0.5	0.2, 2.0	-0.8, 0.5
OBS V8										
n	36	36	14	14	20	20	22	22	92	92
Mean (SD)	1.08	-0.09	0.89	-0.09	1.00	-0.21	1.11	-0.00	1.04	-0.09
	(0.237)	(0.168)	(0.183)	(0.169)	(0.356)	(0.283)	(0.121)	(0.184)	(0.249)	(0.210)
Median	1.20	0.00	0.95	-0.10	1.00	-0.10	1.20	0.00	1.00	0.00
Min, Max	0.4, 1.5	-0.4, 0.3	0.5, 1.2	-0.4, 0.2	0.4, 2.0	-1.0, 0.1	0.9, 1.2	-0.3, 0.3	0.4, 2.0	-1.0, 0.3
OBS V9										
n	28	28	10	10	18	18	16	16	72	72
Mean (SD)	1.04	-0.10	0.93	-0.08	1.14	-0.11	1.11	-0.03	1.07	-0.08
	(0.282)	(0.208)	(0.206)	(0.253)	(0.391)	(0.183)	(0.163)	(0.144)	(0.288)	(0.195)
Median	1.00	0.00	0.95	-0.15	1.20	-0.10	1.20	0.00	1.00	0.00
Min, Max	0.4, 1.5	-0.5, 0.3	0.5, 1.2	-0.4, 0.4	0.5, 2.0	-0.3, 0.3	0.9, 1.5	-0.3, 0.2	0.4, 2.0	-0.5, 0.4
OBS V10										
n	22	22	6	6	8	8	6	6	42	42
Mean (SD)	1.03	-0.11	0.95	-0.03	1.01	-0.05	1.07	0.03	1.02	-0.07
	(0.282)	(0.219)	(0.251)	(0.186)	(0.210)	(0.141)	(0.103)	(0.082)	(0.241)	(0.189)
Median	1.00	-0.15	1.00	0.00	1.05	-0.05	1.00	0.00	1.00	0.00
Min, Max	0.3, 1.5	-0.5, 0.3	0.6, 1.2	-0.3, 0.2	0.7, 1.2	-0.3, 0.2	1.0, 1.2	0.0, 0.2	0.3, 1.5	-0.5, 0.3
OBS V11										
n	16	16	6	6	6	6	2	2	30	30
Mean (SD)	1.03	-0.11	0.95	-0.03	0.88	-0.23	1.10	0.10	0.99	-0.11
	(0.246)	(0.175)	(0.197)	(0.186)	(0.349)	(0.207)	(0.141)	(0.141)	(0.253)	(0.193)
Median	1.00	-0.15	1.00	0.00	0.90	-0.25	1.10	0.10	1.00	-0.05
Min, Max	0.6, 1.5	-0.3, 0.2	0.6, 1.2	-0.3, 0.2	0.5, 1.2	-0.5, 0.0	1.0, 1.2	0.0, 0.2	0.5, 1.5	-0.5, 0.2
OBS V12										
n	6	6	2	2	2	2			10	10
Mean (SD)	1.10	0.03	0.95	0.10	1.20	0.00			1.09	0.04
	(0.167)	(0.082)	(0.071)	(0.000)	(0.000)	(0.000)			(0.152)	(0.070)
Median	1.20	0.00	0.95	0.10	1.20	0.00			1.20	0.00
Min, Max	0.8, 1.2	0.0, 0.2	0.9, 1.0	0.1, 0.1	1.2, 1.2	0.0, 0.0			0.8, 1.2	0.0, 0.2
OBS V13										
n	6	6							6	6
Mean (SD)	1.10	0.03							1.10	0.03
	(0.167)	(0.082)							(0.167)	(0.082)
Median	1.20	0.00							1.20	0.00
Min, Max	0.8, 1.2	0.0, 0.2							0.8, 1.2	0.0, 0.2

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Visit Statistic	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67) Observed	Change from Baseline	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52) Observed	Change from Baseline	0.02% STN1013900 + 0.005% Latanoprost (N=44) Observed	Change from Baseline	0.02% STN1013900 + 0.5% Timolol (N=52) Observed	Change from Baseline	All Subjects (N=215) Observed	Change from Baseline
OBS Final										
n	67	67	52	52	44	44	52	52	215	215
Mean (SD)	1.08 (0.243)	-0.07 (0.168)	1.07 (0.282)	-0.05 (0.167)	1.17 (0.280)	-0.04 (0.277)	1.06 (0.254)	-0.03 (0.167)	1.09 (0.265)	-0.05 (0.194)
Median	1.20	0.00	1.20	0.00	1.20	0.00	1.00	0.00	1.20	0.00
Min, Max	0.4, 1.5	-0.5, 0.3	0.3, 1.5	-0.4, 0.3	0.6, 2.0	-0.8, 0.4	0.4, 1.5	-0.3, 0.3	0.3, 2.0	-0.8, 0.4

Abbreviations: OBS = Observational Study; N/A = Not Applicable.

Note: N in the headers represents the total number of eyes with Cornea Verticillata in each treatment group for the population being analyzed. For each OBS visit, if n=0, no summary statistics are displayed

Source : 添付資料 5.3.5.2-1 Table 14.3.4.3.1.1

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表 2.7.4.7-8. 101390002LT:最高矯正視力の平均値及び OBS Visit 1 からの平均変化量

Visit / Statistic	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67) Observed	Change from OBS V1	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52) Observed	Change from OBS V1	0.02% STN1013900 + 0.005% Latanoprost (N=44) Observed	Change from OBS V1	0.02% STN1013900 + 0.5% Timolol (N=52) Observed	Change from OBS V1	All Subjects (N=215) Observed	Change from OBS V1
OBS V1										
n	67	N/A	52	N/A	44	N/A	52	N/A	215	N/A
Mean (SD)	1.04 (0.276)	N/A	1.08 (0.251)	N/A	1.08 (0.258)	N/A	1.01 (0.275)	N/A	1.05 (0.266)	N/A
Median	1.00	N/A	1.20	N/A	1.00	N/A	1.00	N/A	1.00	N/A
Min, Max	0.4, 1.5	N/A	0.4, 1.5	N/A	0.5, 1.5	N/A	0.3, 1.5	N/A	0.3, 1.5	N/A
OBS V2										
n	66	66	52	52	44	44	50	50	212	212
Mean (SD)	1.02 (0.282)	-0.01 (0.172)	1.08 (0.284)	0.00 (0.158)	1.07 (0.312)	-0.02 (0.215)	0.99 (0.253)	-0.03 (0.157)	1.04 (0.283)	-0.01 (0.174)
Median	1.00	0.00	1.20	0.00	1.00	0.00	1.00	0.00	1.00	0.00
Min, Max	0.4, 1.5	-0.5, 0.3	0.5, 1.5	-0.6, 0.3	0.4, 2.0	-0.4, 0.5	0.3, 1.5	-0.5, 0.3	0.3, 2.0	-0.6, 0.5
OBS V3										
n	66	66	52	52	43	43	46	46	207	207
Mean (SD)	0.99 (0.267)	-0.04 (0.206)	1.05 (0.252)	-0.02 (0.166)	1.06 (0.268)	-0.03 (0.164)	1.03 (0.260)	-0.00 (0.165)	1.03 (0.262)	-0.02 (0.179)
Median	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00
Min, Max	0.3, 1.5	-0.6, 0.6	0.4, 1.5	-0.4, 0.3	0.5, 1.5	-0.5, 0.3	0.3, 1.5	-0.5, 0.3	0.3, 1.5	-0.6, 0.6
OBS V4										
n	64	64	50	50	41	41	46	46	201	201
Mean (SD)	1.04 (0.256)	0.00 (0.200)	1.06 (0.260)	-0.02 (0.193)	1.11 (0.284)	0.02 (0.192)	1.05 (0.273)	0.02 (0.170)	1.06 (0.266)	0.00 (0.189)
Median	1.00	0.00	1.20	0.00	1.20	0.00	1.00	0.00	1.00	0.00
Min, Max	0.5, 1.5	-0.5, 0.6	0.4, 1.5	-0.4, 0.5	0.6, 2.0	-0.3, 0.5	0.3, 1.5	-0.3, 0.4	0.3, 2.0	-0.5, 0.6
OBS V5										
n	60	60	46	46	37	37	38	38	181	181
Mean (SD)	1.04 (0.274)	-0.02 (0.234)	1.01 (0.272)	-0.07 (0.152)	1.03 (0.255)	-0.07 (0.163)	1.08 (0.203)	0.02 (0.186)	1.04 (0.255)	-0.03 (0.194)
Median	1.00	0.00	1.00	0.00	1.00	0.00	1.20	0.00	1.00	0.00
Min, Max	0.3, 1.5	-0.7, 0.5	0.4, 1.5	-0.5, 0.3	0.4, 1.5	-0.5, 0.2	0.5, 1.5	-0.3, 0.6	0.3, 1.5	-0.7, 0.6
OBS V6										
n	46	46	40	40	32	32	34	34	152	152
Mean (SD)	1.06 (0.296)	0.00 (0.227)	1.05 (0.274)	-0.04 (0.193)	1.03 (0.362)	-0.06 (0.179)	1.11 (0.189)	0.04 (0.201)	1.06 (0.285)	-0.02 (0.204)
Median	1.00	0.00	1.00	0.00	1.00	0.00	1.20	0.00	1.00	0.00
Min, Max	0.4, 1.5	-0.6, 0.5	0.4, 1.5	-0.4, 0.5	0.2, 2.0	-0.4, 0.5	0.6, 1.5	-0.5, 0.6	0.2, 2.0	-0.6, 0.6
OBS V7										
n	38	38	28	28	26	26	28	28	120	120
Mean (SD)	1.04 (0.263)	0.01 (0.176)	0.99 (0.277)	-0.04 (0.189)	1.14 (0.377)	0.06 (0.269)	1.15 (0.171)	0.09 (0.196)	1.08 (0.282)	0.03 (0.209)
Median	1.00	0.00	1.00	0.00	1.20	0.00	1.20	0.00	1.20	0.00
Min, Max	0.4, 1.5	-0.3, 0.5	0.3, 1.5	-0.6, 0.3	0.2, 2.0	-0.4, 0.5	0.8, 1.5	-0.3, 0.6	0.2, 2.0	-0.6, 0.6

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Visit / Statistic	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67) Observed	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67) Change from OBS V1	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52) Observed	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52) Change from OBS V1	0.02% STN1013900 + 0.005% Latanoprost (N=44) Observed	0.02% STN1013900 + 0.005% Latanoprost (N=44) Change from OBS V1	0.02% STN1013900 + 0.5% Timolol (N=52) Observed	0.02% STN1013900 + 0.5% Timolol (N=52) Change from OBS V1	All Subjects (N=215) Observed	All Subjects (N=215) Change from OBS V1
OBS V8										
n	36	36	14	14	20	20	22	22	92	92
Mean (SD)	1.08	0.04	0.89	-0.11	1.00	-0.01	1.11	0.06	1.04	0.01
	(0.237)	(0.209)	(0.183)	(0.127)	(0.356)	(0.267)	(0.121)	(0.206)	(0.249)	(0.216)
Median	1.20	0.00	0.95	-0.15	1.00	0.00	1.20	0.00	1.00	0.00
Min, Max	0.4, 1.5	-0.3, 0.5	0.5, 1.2	-0.3, 0.1	0.4, 2.0	-0.5, 0.5	0.9, 1.2	-0.3, 0.6	0.4, 2.0	-0.5, 0.6
OBS V9										
n	28	28	10	10	18	18	16	16	72	72
Mean (SD)	1.04	0.00	0.93	-0.09	1.14	0.13	1.11	0.03	1.07	0.03
	(0.282)	(0.157)	(0.206)	(0.213)	(0.391)	(0.252)	(0.163)	(0.224)	(0.288)	(0.215)
Median	1.00	0.00	0.95	-0.05	1.20	0.10	1.20	0.00	1.00	0.00
Min, Max	0.4, 1.5	-0.4, 0.3	0.5, 1.2	-0.5, 0.2	0.5, 2.0	-0.2, 0.5	0.9, 1.5	-0.3, 0.6	0.4, 2.0	-0.5, 0.6
OBS V10										
n	22	22	6	6	8	8	6	6	42	42
Mean (SD)	1.03	0.02	0.95	0.03	1.01	0.14	1.07	0.00	1.02	0.04
	(0.282)	(0.216)	(0.251)	(0.103)	(0.210)	(0.256)	(0.103)	(0.110)	(0.241)	(0.200)
Median	1.00	0.00	1.00	0.00	1.05	0.20	1.00	0.00	1.00	0.00
Min, Max	0.3, 1.5	-0.5, 0.3	0.6, 1.2	-0.1, 0.2	0.7, 1.2	-0.3, 0.6	1.0, 1.2	-0.2, 0.1	0.3, 1.5	-0.5, 0.6
OBS V11										
n	16	16	6	6	6	6	2	2	30	30
Mean (SD)	1.03	0.01	0.95	0.03	0.88	0.05	1.10	0.05	0.99	0.03
	(0.246)	(0.167)	(0.197)	(0.103)	(0.349)	(0.138)	(0.141)	(0.071)	(0.253)	(0.141)
Median	1.00	0.00	1.00	0.00	0.90	0.05	1.10	0.05	1.00	0.00
Min, Max	0.6, 1.5	-0.4, 0.2	0.6, 1.2	-0.1, 0.2	0.5, 1.2	-0.1, 0.2	1.0, 1.2	0.0, 0.1	0.5, 1.5	-0.4, 0.2
OBS V12										
n	6	6	2	2	2	2			10	10
Mean (SD)	1.10	0.10	0.95	0.00	1.20	0.20			1.09	0.10
	(0.167)	(0.110)	(0.071)	(0.141)	(0.000)	(0.000)			(0.152)	(0.115)
Median	1.20	0.10	0.95	0.00	1.20	0.20			1.20	0.15
Min, Max	0.8, 1.2	0.0, 0.2	0.9, 1.0	-0.1, 0.1	1.2, 1.2	0.2, 0.2			0.8, 1.2	-0.1, 0.2
OBS V13										
n	6	6							6	6
Mean (SD)	1.10	0.10							1.10	0.10
	(0.167)	(0.110)							(0.167)	(0.110)
Median	1.20	0.10							1.20	0.10
Min, Max	0.8, 1.2	0.0, 0.2							0.8, 1.2	0.0, 0.2
OBS Final										
n	67	67	52	52	44	44	52	52	215	215
Mean (SD)	1.08	0.04	1.07	-0.01	1.17	0.08	1.06	0.05	1.09	0.04
	(0.243)	(0.192)	(0.282)	(0.181)	(0.280)	(0.220)	(0.254)	(0.210)	(0.265)	(0.201)
Median	1.20	0.00	1.20	0.00	1.20	0.00	1.00	0.00	1.20	0.00
Min, Max	0.4, 1.5	-0.5, 0.4	0.3, 1.5	-0.3, 0.5	0.6, 2.0	-0.3, 0.6	0.4, 1.5	-0.6, 0.6	0.3, 2.0	-0.6, 0.6

Abbreviations: OBS = Observational Study; N/A = Not Applicable.

Note: N in the headers represents the total number of eyes with Cornea Verticillata in each treatment group for the population being analyzed. For each OBS visit, if n=0, no summary statistics are displayed
Source : 添付資料 5.3.5.2-1 Table 14.3.4.3.2.1

表 2.7.4.7-9. 101390002LT:「渦巻き角膜 (Cornea verticillata) 」の消失／安定後の最終来院時点の 215 眼について、Visit 3（ベースライン）から LogMAR 視力で 0.3 以上悪化した割合

Visit	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)	0.02% STN1013900 + 0.005% Latanoprost (N=44)	0.02% STN1013900 + 0.5% Timolol (N=52)	All Subjects (N=215)
OBS Final					
m	67	52	44	52	215
Better	0	0	0	0	0
Same	67 (100.0%)	52 (100.0%)	44 (100.0%)	52 (100.0%)	215 (100.0%)
Worse	0	0	0	0	0

Abbreviations: OBS = Observational Study.

Note: N in the headers represents the total number of eyes with Cornea Verticillata in each treatment group for the population being analyzed. Percentages are based on the number of eyes (m) in a given treatment group with non-missing values in the population being analyzed. better (logMAR <= -0.3), same (-0.3 < logMAR < 0.3), worse (0.3 <= logMAR)

Source : 添付資料 5.3.5.2-1 Table 14.3.4.3.3.1

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表 2.7.4.7-10. 101390002LT:コントラスト感度検査の平均値及び Visit 3（ベースライン） からの平均変化量

	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Parameter Visit Statistic	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline
Spatial Frequency 3 cycles/degree										
V3: Qualification 2 (Day 1)										
n	67	N/A	52	N/A	44	N/A	52	N/A	215	N/A
Mean (SD)	1.691 (0.2275)	N/A	1.646 (0.2291)	N/A	1.626 (0.2461)	N/A	1.677 (0.2484)	N/A	1.664 (0.2366)	N/A
Median	1.780	N/A	1.630	N/A	1.630	N/A	1.780	N/A	1.630	N/A
Min, Max	1.00, 2.08	N/A	1.17, 2.08	N/A	1.17, 2.08	N/A	1.00, 2.08	N/A	1.00, 2.08	N/A
OBS V1										
n	65	65	52	52	44	44	52	52	213	213
Mean (SD)	1.610 (0.2959)	-0.087 (0.2545)	1.620 (0.3052)	-0.026 (0.2963)	1.645 (0.2650)	0.019 (0.2628)	1.599 (0.3276)	-0.078 (0.2833)	1.617 (0.2986)	-0.048 (0.2752)
Median	1.630	-0.150	1.630	0.000	1.630	0.000	1.630	0.000	1.630	0.000
Min, Max	0.70, 2.08	-0.74, 0.63	0.70, 2.08	-0.93, 0.45	1.00, 2.08	-0.59, 0.44	0.70, 2.08	-1.08, 0.61	0.70, 2.08	-1.08, 0.63
OBS V2										
n	14	14	10	10	8	8	10	10	42	42
Mean (SD)	1.739 (0.1785)	-0.053 (0.2774)	1.797 (0.2142)	0.074 (0.2333)	1.760 (0.2967)	-0.003 (0.2132)	1.723 (0.2894)	0.073 (0.2242)	1.753 (0.2332)	0.017 (0.2418)
Median	1.705	-0.145	1.780	0.000	1.780	0.000	1.705	0.000	1.780	0.000
Min, Max	1.49, 2.08	-0.45, 0.44	1.49, 2.08	-0.15, 0.44	1.17, 2.08	-0.46, 0.29	1.34, 2.08	-0.30, 0.44	1.17, 2.08	-0.46, 0.44
OBS V3										
n	10	10	12	12	6	6	8	8	36	36
Mean (SD)	1.587 (0.2240)	-0.209 (0.3228)	1.697 (0.2917)	0.001 (0.2679)	1.855 (0.2068)	0.048 (0.0749)	1.726 (0.2956)	0.018 (0.3131)	1.699 (0.2667)	-0.046 (0.2838)
Median	1.630	-0.220	1.705	0.000	1.855	0.000	1.705	0.000	1.630	0.000
Min, Max	1.17, 1.93	-0.61, 0.30	1.34, 2.08	-0.44, 0.45	1.63, 2.08	0.00, 0.15	1.34, 2.08	-0.45, 0.44	1.17, 2.08	-0.61, 0.45
OBS V4										
n	18	18	8	8	6	6	8	8	40	40
Mean (SD)	1.666 (0.2261)	-0.124 (0.2484)	1.855 (0.1389)	0.074 (0.1937)	1.855 (0.1837)	-0.002 (0.1320)	1.893 (0.1747)	0.093 (0.2246)	1.777 (0.2149)	-0.023 (0.2331)
Median	1.705	-0.150	1.855	0.075	1.780	0.000	1.855	0.000	1.780	0.000
Min, Max	1.17, 2.08	-0.61, 0.45	1.63, 2.08	-0.15, 0.44	1.63, 2.08	-0.15, 0.15	1.63, 2.08	-0.15, 0.45	1.17, 2.08	-0.61, 0.45
Spatial Frequency 3 cycles/degree										
OBS V5										
n	12	12	8	8	6	6	8	8	34	34
Mean (SD)	1.708 (0.2228)	-0.049 (0.2905)	1.893 (0.1747)	0.111 (0.2731)	1.855 (0.1837)	0.122 (0.1427)	1.728 (0.3155)	0.019 (0.2463)	1.782 (0.2365)	0.035 (0.2556)
Median	1.705	0.000	1.855	0.075	1.780	0.075	1.780	-0.150	1.780	0.000
Min, Max	1.34, 2.08	-0.59, 0.30	1.63, 2.08	-0.30, 0.45	1.63, 2.08	0.00, 0.29	1.34, 2.08	-0.15, 0.45	1.34, 2.08	-0.59, 0.45
OBS V6										
n	12	12	8	8	2	2	6	6	28	28
Mean (SD)	1.781 (0.1794)	0.024 (0.1973)	1.835 (0.3025)	0.054 (0.3311)	1.930 (0.0000)	0.370 (0.0990)	1.905 (0.1475)	0.098 (0.1192)	1.834 (0.2096)	0.073 (0.2348)
Median	1.780	0.000	1.855	0.075	1.930	0.370	1.855	0.075	1.780	0.070
Min, Max	1.49, 2.08	-0.30, 0.30	1.17, 2.08	-0.61, 0.44	1.93, 1.93	0.30, 0.44	1.78, 2.08	0.00, 0.29	1.17, 2.08	-0.61, 0.44
OBS V7										
n	4	4	4	4	2	2	6	6	16	16

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Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Visit		Change from		Change from		Change from		Change from		Change from
Statistic	Observed	Baseline	Observed	Baseline	Observed	Baseline	Observed	Baseline	Observed	Baseline
Mean (SD)	1.783	-0.110	1.708	0.075	1.855	0.295	1.905	0.098	1.819	0.065
	(0.3634)	(0.2200)	(0.2570)	(0.3515)	(0.1061)	(0.2051)	(0.1475)	(0.2936)	(0.2333)	(0.2857)
Median	1.855	0.000	1.630	0.070	1.855	0.295	1.855	0.145	1.780	0.000
Min, Max	1.34, 2.08	-0.44, 0.00	1.49, 2.08	-0.29, 0.45	1.78, 1.93	0.15, 0.44	1.78, 2.08	-0.30, 0.45	1.34, 2.08	-0.44, 0.45
OBS V8										
n	6	6	4	4	4	4	2	2	16	16
Mean (SD)	1.782	0.000	1.968	0.335	1.820	0.223	2.005	-0.075	1.866	0.130
	(0.2486)	(0.4609)	(0.1436)	(0.2528)	(0.3277)	(0.2570)	(0.1061)	(0.1061)	(0.2360)	(0.3513)
Median	1.705	-0.070	2.005	0.375	1.930	0.220	2.005	-0.075	1.930	0.075
Min, Max	1.49, 2.08	-0.45, 0.59	1.78, 2.08	0.00, 0.59	1.34, 2.08	0.00, 0.45	1.93, 2.08	-0.15, 0.00	1.34, 2.08	-0.45, 0.59
OBS V9										
n	4	4	4	4	2	2	2	2	12	12
Mean (SD)	1.743	-0.078	1.968	0.335	1.855	0.295	1.560	0.145	1.806	0.159
	(0.0750)	(0.2570)	(0.1436)	(0.2528)	(0.1061)	(0.2051)	(0.0990)	(0.0071)	(0.1774)	(0.2725)
Median	1.780	-0.080	2.005	0.375	1.855	0.295	1.560	0.145	1.780	0.150
Min, Max	1.63, 1.78	-0.30, 0.15	1.78, 2.08	0.00, 0.59	1.78, 1.93	0.15, 0.44	1.49, 1.63	0.14, 0.15	1.49, 2.08	-0.30, 0.59
Spatial Frequency 3 cycles/degree										
OBS V10										
n	4	4	2	2					6	6
Mean (SD)	1.745	-0.075	1.930	0.370					1.807	0.073
	(0.2528)	(0.3501)	(0.2121)	(0.5233)					(0.2376)	(0.4256)
Median	1.705	0.070	1.930	0.370					1.780	0.070
Min, Max	1.49, 2.08	-0.59, 0.15	1.78, 2.08	0.00, 0.74					1.49, 2.08	-0.59, 0.74
OBS V11										
n	4	4	2	2					6	6
Mean (SD)	1.708	-0.113	1.855	0.295					1.757	0.023
	(0.1898)	(0.4071)	(0.1061)	(0.4172)					(0.1722)	(0.4225)
Median	1.705	-0.080	1.855	0.295					1.780	0.070
Min, Max	1.49, 1.93	-0.59, 0.30	1.78, 1.93	0.00, 0.59					1.49, 1.93	-0.59, 0.59
OBS V12										
n	2	2	2	2					4	4
Mean (SD)	1.630	0.070	1.635	0.075					1.633	0.073
	(0.0000)	(0.0990)	(0.2051)	(0.5162)					(0.1184)	(0.3035)
Median	1.630	0.070	1.635	0.075					1.630	0.070
Min, Max	1.63, 1.63	0.00, 0.14	1.49, 1.78	-0.29, 0.44					1.49, 1.78	-0.29, 0.44
OBS V13										
n	4	4							4	4
Mean (SD)	1.745	0.185							1.745	0.185
	(0.1841)	(0.2469)							(0.1841)	(0.2469)
Median	1.780	0.220							1.780	0.220
Min, Max	1.49, 1.93	-0.14, 0.44							1.49, 1.93	-0.14, 0.44
OBS Final										
n	67	67	52	52	44	44	52	52	215	215
Mean (SD)	1.673	-0.018	1.743	0.097	1.689	0.063	1.583	-0.094	1.672	0.008
	(0.2943)	(0.2627)	(0.2584)	(0.3365)	(0.2657)	(0.2543)	(0.2275)	(0.2358)	(0.2690)	(0.2824)
Median	1.780	0.000	1.780	0.150	1.705	0.070	1.630	-0.140	1.780	0.000
Min, Max	0.70, 2.08	-0.59, 0.45	1.00, 2.08	-0.93, 0.76	1.00, 2.08	-0.61, 0.45	1.00, 2.08	-0.76, 0.29	0.70, 2.08	-0.93, 0.76
Spatial Frequency 6 cycles/degree										
V3: Qualification 2 (Day 1)										
n	67	N/A	52	N/A	44	N/A	52	N/A	215	N/A

	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Parameter Visit Statistic	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline
Mean (SD)	1.807 (0.2490)	N/A	1.776 (0.2528)	N/A	1.774 (0.2876)	N/A	1.710 (0.3123)	N/A	1.769 (0.2748)	N/A
Median	1.840	N/A	1.700	N/A	1.840	N/A	1.700	N/A	1.840	N/A
Min, Max	1.21, 2.29	N/A	1.21, 2.29	N/A	0.91, 2.29	N/A	0.91, 2.29	N/A	0.91, 2.29	N/A
OBS V1										
n	65	65	52	52	44	44	52	52	213	213
Mean (SD)	1.722 (0.3423)	-0.095 (0.2962)	1.793 (0.3345)	0.017 (0.2610)	1.718 (0.2929)	-0.056 (0.2822)	1.735 (0.3519)	0.024 (0.2399)	1.742 (0.3322)	-0.030 (0.2749)
Median	1.840	0.000	1.840	0.000	1.700	0.000	1.840	0.000	1.840	0.000
Min, Max	0.61, 2.29	-0.93, 0.45	0.91, 2.29	-0.63, 0.59	0.91, 2.14	-0.79, 0.46	0.91, 2.29	-0.64, 0.44	0.61, 2.29	-0.93, 0.59
OBS V2										
n	14	14	10	10	8	8	10	10	42	42
Mean (SD)	1.821 (0.2183)	-0.074 (0.3279)	1.873 (0.2284)	-0.029 (0.2716)	2.048 (0.2367)	0.093 (0.2499)	1.764 (0.4085)	0.001 (0.1975)	1.863 (0.2871)	-0.014 (0.2703)
Median	1.840	-0.140	1.840	0.000	2.140	0.000	1.770	0.000	1.840	0.000
Min, Max	1.38, 2.14	-0.46, 0.59	1.55, 2.14	-0.44, 0.46	1.55, 2.29	-0.15, 0.59	0.91, 2.14	-0.44, 0.30	0.91, 2.29	-0.46, 0.59
OBS V3										
n	10	10	12	12	6	6	8	8	36	36
Mean (SD)	1.828 (0.1280)	-0.074 (0.2623)	1.915 (0.3561)	0.088 (0.1180)	2.090 (0.1225)	0.073 (0.2242)	1.860 (0.1662)	-0.018 (0.2189)	1.908 (0.2445)	0.017 (0.2091)
Median	1.840	-0.070	1.990	0.145	2.065	0.075	1.840	0.000	1.840	0.000
Min, Max	1.70, 2.14	-0.45, 0.30	1.21, 2.29	-0.15, 0.29	1.99, 2.29	-0.15, 0.44	1.55, 2.14	-0.30, 0.29	1.21, 2.29	-0.45, 0.44
OBS V4										
n	18	18	8	8	6	6	8	8	40	40
Mean (SD)	1.851 (0.2475)	-0.098 (0.3004)	1.936 (0.2079)	-0.035 (0.2633)	2.140 (0.0949)	0.173 (0.2882)	1.936 (0.1743)	-0.018 (0.1994)	1.929 (0.2252)	-0.029 (0.2795)
Median	1.840	-0.145	1.915	0.000	2.140	0.075	1.990	-0.140	1.990	0.000
Min, Max	1.38, 2.29	-0.46, 0.59	1.70, 2.29	-0.44, 0.46	1.99, 2.29	-0.15, 0.59	1.70, 2.14	-0.15, 0.30	1.38, 2.29	-0.46, 0.59
Spatial Frequency 6 cycles/degree										
OBS V5										
n	12	12	8	8	6	6	8	8	34	34
Mean (SD)	1.830 (0.2946)	-0.062 (0.3135)	2.121 (0.1689)	0.150 (0.1997)	1.965 (0.1475)	-0.002 (0.1866)	1.974 (0.2551)	0.096 (0.1963)	1.956 (0.2541)	0.036 (0.2499)
Median	1.840	0.000	2.140	0.145	1.915	-0.075	2.065	0.150	1.990	0.070
Min, Max	1.38, 2.29	-0.46, 0.45	1.84, 2.29	0.00, 0.61	1.84, 2.14	-0.15, 0.29	1.55, 2.29	-0.15, 0.45	1.38, 2.29	-0.46, 0.61
OBS V6										
n	12	12	8	8	2	2	6	6	28	28
Mean (SD)	1.956 (0.2276)	0.064 (0.2904)	1.938 (0.3533)	-0.034 (0.2965)	2.140 (0.0000)	0.445 (0.2051)	2.115 (0.1754)	0.173 (0.1458)	1.998 (0.2561)	0.087 (0.2799)
Median	1.990	0.000	1.990	0.075	2.140	0.445	2.140	0.220	2.065	0.150
Min, Max	1.70, 2.29	-0.30, 0.59	1.55, 2.29	-0.59, 0.30	2.14, 2.14	0.30, 0.59	1.84, 2.29	0.00, 0.30	1.55, 2.29	-0.59, 0.59
OBS V7										
n	4	4	4	4	2	2	6	6	16	16
Mean (SD)	1.733 (0.1384)	-0.258 (0.0718)	1.920 (0.3515)	0.080 (0.0927)	2.140 (0.2121)	0.445 (0.0071)	2.140 (0.1643)	0.198 (0.1537)	1.983 (0.2674)	0.086 (0.2536)
Median	1.770	-0.290	1.920	0.075	2.140	0.445	2.140	0.295	2.065	0.075
Min, Max	1.55, 1.84	-0.30, -0.15	1.55, 2.29	0.00, 0.17	1.99, 2.29	0.44, 0.45	1.84, 2.29	0.00, 0.30	1.55, 2.29	-0.30, 0.45
OBS V8										
n	6	6	4	4	4	4	2	2	16	16
Mean (SD)	1.992 (0.2474)	0.052 (0.2015)	1.955 (0.2211)	0.115 (0.1518)	2.105 (0.2791)	0.483 (0.2513)	2.065 (0.1061)	-0.150 (0.0000)	2.020 (0.2240)	0.150 (0.2765)

Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Visit		Change from		Change from		Change from		Change from		Change from
Statistic	Observed	Baseline	Observed	Baseline	Observed	Baseline	Observed	Baseline	Observed	Baseline
Median	2.140	0.075	1.990	0.070	2.215	0.520	2.065	-0.150	2.140	0.145
Min, Max	1.55, 2.14	-0.29, 0.30	1.70, 2.14	0.00, 0.32	1.70, 2.29	0.15, 0.74	1.99, 2.14	-0.15, -0.15	1.55, 2.29	-0.29, 0.74
OBS V9										
n	4	4	4	4	2	2	2	2	12	12
Mean (SD)	2.065	0.113	2.253	0.413	2.140	0.445	1.845	0.160	2.103	0.276
	(0.0866)	(0.1436)	(0.0750)	(0.3110)	(0.2121)	(0.4172)	(0.2051)	(0.6364)	(0.1803)	(0.3298)
Median	2.065	0.075	2.290	0.370	2.140	0.445	1.845	0.160	2.140	0.150
Min, Max	1.99, 2.14	0.00, 0.30	2.14, 2.29	0.15, 0.76	1.99, 2.29	0.15, 0.74	1.70, 1.99	-0.29, 0.61	1.70, 2.29	-0.29, 0.76
Spatial Frequency 6 cycles/degree										
OBS V10										
n	4	4	2	2					6	6
Mean (SD)	2.103	0.150	2.215	0.675					2.140	0.325
	(0.0750)	(0.1732)	(0.1061)	(0.1202)					(0.0949)	(0.3072)
Median	2.140	0.150	2.215	0.675					2.140	0.300
Min, Max	1.99, 2.14	0.00, 0.30	2.14, 2.29	0.59, 0.76					1.99, 2.29	0.00, 0.76
OBS V11										
n	4	4	2	2					6	6
Mean (SD)	2.178	0.225	2.290	0.750					2.215	0.400
	(0.1436)	(0.0866)	(0.0000)	(0.2263)					(0.1255)	(0.2971)
Median	2.215	0.225	2.290	0.750					2.290	0.300
Min, Max	1.99, 2.29	0.15, 0.30	2.29, 2.29	0.59, 0.91					1.99, 2.29	0.15, 0.91
OBS V12										
n	2	2	2	2					4	4
Mean (SD)	1.990	0.150	1.770	0.230					1.880	0.190
	(0.0000)	(0.0000)	(0.0990)	(0.1273)					(0.1393)	(0.0868)
Median	1.990	0.150	1.770	0.230					1.915	0.150
Min, Max	1.99, 1.99	0.15, 0.15	1.70, 1.84	0.14, 0.32					1.70, 1.99	0.14, 0.32
OBS V13										
n	4	4							4	4
Mean (SD)	2.028	0.188							2.028	0.188
	(0.0750)	(0.0750)							(0.0750)	(0.0750)
Median	1.990	0.150							1.990	0.150
Min, Max	1.99, 2.14	0.15, 0.30							1.99, 2.14	0.15, 0.30
OBS Final										
n	67	67	52	52	44	44	52	52	215	215
Mean (SD)	1.837	0.030	1.838	0.063	1.865	0.091	1.742	0.032	1.820	0.051
	(0.3209)	(0.2839)	(0.2918)	(0.2613)	(0.3019)	(0.2763)	(0.2548)	(0.2267)	(0.2965)	(0.2632)
Median	1.840	0.000	1.840	0.000	1.840	0.070	1.840	0.000	1.840	0.000
Min, Max	0.91, 2.29	-0.79, 0.59	1.21, 2.29	-0.61, 0.59	1.21, 2.29	-0.59, 0.74	0.91, 2.29	-0.44, 0.93	0.91, 2.29	-0.79, 0.93
Spatial Frequency 12 cycles/degree										
V3: Qualification 2 (Day 1)										
n	67	N/A	52	N/A	44	N/A	52	N/A	215	N/A
Mean (SD)	1.426 (0.3133)	N/A	1.416 (0.2872)	N/A	1.443 (0.3007)	N/A	1.393 (0.3379)	N/A	1.419 (0.3092)	N/A
Median	1.400	N/A	1.400	N/A	1.540	N/A	1.470	N/A	1.400	N/A
Min, Max	0.61, 1.99	N/A	0.61, 1.99	N/A	0.91, 1.99	N/A	0.61, 1.99	N/A	0.61, 1.99	N/A
OBS V1										
n	65	65	52	52	44	44	52	52	213	213
Mean (SD)	1.335	-0.098	1.399	-0.017	1.367	-0.076	1.348	-0.045	1.361	-0.061
	(0.4394)	(0.3994)	(0.3861)	(0.3328)	(0.3755)	(0.3214)	(0.3933)	(0.3129)	(0.4007)	(0.3469)

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Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Visit		Change from		Change from		Change from		Change from		Change from
Statistic	Observed	Baseline	Observed	Baseline	Observed	Baseline	Observed	Baseline	Observed	Baseline
Median	1.400	0.000	1.400	0.000	1.400	-0.070	1.400	0.000	1.400	0.000
Min, Max	0.31, 1.99	-1.23, 1.08	0.61, 1.99	-0.79, 0.61	0.61, 1.99	-0.78, 0.93	0.61, 1.99	-0.78, 0.93	0.31, 1.99	-1.23, 1.08
OBS V2										
n	14	14	10	10	8	8	10	10	42	42
Mean (SD)	1.446	-0.077	1.560	0.093	1.766	0.038	1.431	-0.035	1.530	-0.005
	(0.2398)	(0.2899)	(0.2452)	(0.1710)	(0.2383)	(0.2063)	(0.4840)	(0.2468)	(0.3293)	(0.2416)
Median	1.470	-0.145	1.470	0.070	1.840	0.000	1.400	-0.070	1.540	0.000
Min, Max	1.08, 1.84	-0.59, 0.30	1.25, 1.99	-0.15, 0.49	1.40, 1.99	-0.15, 0.45	0.61, 1.99	-0.34, 0.45	0.61, 1.99	-0.59, 0.49
OBS V3										
n	10	10	12	12	6	6	8	8	36	36
Mean (SD)	1.539	0.024	1.538	0.097	1.840	0.048	1.520	-0.043	1.585	0.038
	(0.1761)	(0.2418)	(0.4250)	(0.3605)	(0.1897)	(0.2040)	(0.3648)	(0.3974)	(0.3316)	(0.3101)
Median	1.540	0.070	1.615	0.155	1.915	0.070	1.540	-0.170	1.540	0.070
Min, Max	1.08, 1.69	-0.32, 0.29	0.61, 1.99	-0.79, 0.59	1.54, 1.99	-0.30, 0.30	1.08, 1.99	-0.45, 0.59	0.61, 1.99	-0.79, 0.59
OBS V4										
n	18	18	8	8	6	6	8	8	40	40
Mean (SD)	1.514	-0.047	1.710	0.208	1.742	0.050	1.601	-0.054	1.605	0.017
	(0.2974)	(0.3622)	(0.2565)	(0.2114)	(0.2421)	(0.1991)	(0.3151)	(0.3783)	(0.2909)	(0.3263)
Median	1.540	0.000	1.765	0.225	1.765	0.000	1.545	-0.220	1.690	0.000
Min, Max	0.91, 1.99	-0.93, 0.59	1.25, 1.99	-0.15, 0.44	1.40, 1.99	-0.14, 0.44	1.25, 1.99	-0.44, 0.59	0.91, 1.99	-0.93, 0.59
Spatial Frequency 12 cycles/degree										
OBS V5										
n	12	12	8	8	6	6	8	8	34	34
Mean (SD)	1.454	-0.053	1.841	0.339	1.765	0.098	1.614	0.051	1.638	0.090
	(0.3280)	(0.4354)	(0.2091)	(0.1764)	(0.2068)	(0.1778)	(0.3900)	(0.3029)	(0.3305)	(0.3419)
Median	1.470	0.000	1.915	0.300	1.765	0.000	1.765	0.075	1.690	0.075
Min, Max	0.61, 1.84	-1.23, 0.59	1.40, 1.99	0.00, 0.59	1.54, 1.99	0.00, 0.44	0.91, 1.99	-0.34, 0.45	0.61, 1.99	-1.23, 0.59
OBS V6										
n	12	12	8	8	2	2	6	6	28	28
Mean (SD)	1.448	-0.060	1.544	0.041	1.915	0.445	1.715	0.097	1.566	0.039
	(0.3133)	(0.3591)	(0.2619)	(0.2519)	(0.1061)	(0.2051)	(0.1754)	(0.2011)	(0.2902)	(0.3088)
Median	1.540	0.000	1.540	0.070	1.915	0.445	1.690	0.070	1.540	0.070
Min, Max	0.91, 1.84	-0.76, 0.30	1.25, 1.99	-0.44, 0.34	1.84, 1.99	0.30, 0.59	1.54, 1.99	-0.15, 0.44	0.91, 1.99	-0.76, 0.59
OBS V7										
n	4	4	4	4	2	2	6	6	16	16
Mean (SD)	1.575	-0.043	1.508	0.195	1.990	0.520	1.865	0.247	1.719	0.196
	(0.3590)	(0.3150)	(0.1384)	(0.2690)	(0.0000)	(0.0990)	(0.1994)	(0.2754)	(0.2804)	(0.3007)
Median	1.690	-0.075	1.470	0.220	1.990	0.520	1.990	0.220	1.765	0.220
Min, Max	1.08, 1.84	-0.32, 0.30	1.40, 1.69	-0.15, 0.49	1.99, 1.99	0.45, 0.59	1.54, 1.99	0.00, 0.59	1.08, 1.99	-0.32, 0.59
OBS V8										
n	6	6	4	4	4	4	2	2	16	16
Mean (SD)	1.618	0.050	1.578	0.265	1.840	0.493	1.915	-0.075	1.701	0.199
	(0.1788)	(0.2739)	(0.0750)	(0.2706)	(0.1732)	(0.2654)	(0.1061)	(0.1061)	(0.1913)	(0.3123)
Median	1.690	0.075	1.540	0.215	1.840	0.520	1.915	-0.075	1.690	0.150
Min, Max	1.40, 1.84	-0.44, 0.30	1.54, 1.69	0.00, 0.63	1.69, 1.99	0.15, 0.78	1.84, 1.99	-0.15, 0.00	1.40, 1.99	-0.44, 0.78
OBS V9										
n	4	4	4	4	2	2	2	2	12	12
Mean (SD)	1.803	0.260	1.765	0.453	1.765	0.295	1.400	0.005	1.717	0.288
	(0.2250)	(0.1463)	(0.2598)	(0.2799)	(0.1061)	(0.0071)	(0.0000)	(0.2051)	(0.2354)	(0.2361)
Median	1.840	0.225	1.765	0.465	1.765	0.295	1.400	0.005	1.690	0.295
Min, Max	1.54, 1.99	0.14, 0.45	1.54, 1.99	0.14, 0.74	1.69, 1.84	0.29, 0.30	1.40, 1.40	-0.14, 0.15	1.40, 1.99	-0.14, 0.74

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Parameter / Visit / Statistic	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67) Observed	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67) Change from Baseline	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52) Observed	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52) Change from Baseline	0.02% STN1013900 + 0.005% Latanoprost (N=44) Observed	0.02% STN1013900 + 0.005% Latanoprost (N=44) Change from Baseline	0.02% STN1013900 + 0.5% Timolol (N=52) Observed	0.02% STN1013900 + 0.5% Timolol (N=52) Change from Baseline	All Subjects (N=215) Observed	All Subjects (N=215) Change from Baseline
Spatial Frequency 12 cycles/degree										
OBS V10										
n	4	4	2	2					6	6
Mean (SD)	1.915 (0.0866)	0.373 (0.1898)	1.470 (0.0990)	0.315 (0.2475)					1.767 (0.2434)	0.353 (0.1864)
Median	1.915	0.375	1.470	0.315					1.840	0.375
Min, Max	1.84, 1.99	0.15, 0.59	1.40, 1.54	0.14, 0.49					1.40, 1.99	0.14, 0.59
OBS V11										
n	4	4	2	2					6	6
Mean (SD)	1.728 (0.1887)	0.185 (0.2548)	1.840 (0.2121)	0.685 (0.5586)					1.765 (0.1837)	0.352 (0.4099)
Median	1.690	0.220	1.840	0.685					1.690	0.290
Min, Max	1.54, 1.99	-0.15, 0.45	1.69, 1.99	0.29, 1.08					1.54, 1.99	-0.15, 1.08
OBS V12										
n	2	2	2	2					4	4
Mean (SD)	1.545 (0.2051)	0.075 (0.1061)	1.620 (0.3111)	0.465 (0.6576)					1.583 (0.2195)	0.270 (0.4456)
Median	1.545	0.075	1.620	0.465					1.545	0.075
Min, Max	1.40, 1.69	0.00, 0.15	1.40, 1.84	0.00, 0.93					1.40, 1.84	0.00, 0.93
OBS V13										
n	4	4							4	4
Mean (SD)	1.618 (0.1898)	0.148 (0.1704)							1.618 (0.1898)	0.148 (0.1704)
Median	1.615	0.145							1.615	0.145
Min, Max	1.40, 1.84	0.00, 0.30							1.40, 1.84	0.00, 0.30
OBS Final										
n	67	67	52	52	44	44	52	52	215	215
Mean (SD)	1.450 (0.3591)	0.024 (0.3411)	1.443 (0.3784)	0.028 (0.3486)	1.491 (0.4024)	0.048 (0.3491)	1.391 (0.3382)	-0.002 (0.3449)	1.443 (0.3672)	0.024 (0.3435)
Median	1.540	0.000	1.400	0.000	1.400	0.000	1.400	0.000	1.400	0.000
Min, Max	0.61, 1.99	-0.64, 0.93	0.31, 1.99	-0.94, 0.78	0.61, 1.99	-0.78, 0.63	0.61, 1.99	-0.63, 1.23	0.31, 1.99	-0.94, 1.23
Spatial Frequency 18 cycles/degree										
V3: Qualification 2 (Day 1)										
n	67	N/A	52	N/A	44	N/A	52	N/A	215	N/A
Mean (SD)	0.872 (0.3506)	N/A	0.904 (0.3301)	N/A	0.984 (0.3331)	N/A	0.921 (0.3707)	N/A	0.915 (0.3472)	N/A
Median	0.960	N/A	0.960	N/A	0.960	N/A	0.960	N/A	0.960	N/A
Min, Max	0.17, 1.40	N/A	0.17, 1.55	N/A	0.01, 1.55	N/A	0.17, 1.55	N/A	0.01, 1.55	N/A
OBS V1										
n	65	65	52	52	44	44	52	52	213	213
Mean (SD)	0.871 (0.4091)	-0.009 (0.3976)	0.927 (0.4295)	0.023 (0.3889)	0.982 (0.3352)	-0.002 (0.3417)	0.865 (0.3818)	-0.055 (0.3345)	0.906 (0.3935)	-0.011 (0.3681)
Median	0.960	0.000	0.960	0.000	0.960	0.000	0.810	0.000	0.960	0.000
Min, Max	0.01, 1.55	-0.93, 1.08	0.17, 1.55	-1.08, 1.23	0.17, 1.55	-1.08, 0.80	0.17, 1.55	-1.08, 0.64	0.01, 1.55	-1.08, 1.23
OBS V2										
n	14	14	10	10	8	8	10	10	42	42
Mean (SD)	0.911 (0.3980)	-0.125 (0.3529)	1.133 (0.1945)	0.140 (0.2838)	1.345 (0.2085)	0.129 (0.3010)	1.018 (0.5307)	-0.033 (0.3099)	1.072 (0.3908)	0.008 (0.3275)
Median	1.100	0.000	1.100	0.070	1.325	0.075	1.030	0.000	1.100	0.000
Min, Max	0.17, 1.40	-0.93, 0.30	0.96, 1.55	-0.30, 0.63	0.96, 1.55	-0.30, 0.59	0.17, 1.55	-0.49, 0.47	0.17, 1.55	-0.93, 0.63

Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Visit		Change from		Change from		Change from		Change from		Change from
Statistic	Observed	Baseline	Observed	Baseline	Observed	Baseline	Observed	Baseline	Observed	Baseline
OBS V3										
n	10	10	12	12	6	6	8	8	36	36
Mean (SD)	1.025	-0.043	1.134	0.124	1.475	0.222	1.069	-0.085	1.146	0.048
	(0.2294)	(0.2248)	(0.4009)	(0.4061)	(0.1255)	(0.2024)	(0.2924)	(0.4511)	(0.3279)	(0.3535)
Median	1.100	0.000	1.250	0.000	1.550	0.225	0.960	-0.220	1.175	0.000
Min, Max	0.64, 1.25	-0.46, 0.29	0.47, 1.55	-0.46, 0.93	1.25, 1.55	0.00, 0.44	0.81, 1.55	-0.59, 0.64	0.47, 1.55	-0.59, 0.93
OBS V4										
n	18	18	8	8	6	6	8	8	40	40
Mean (SD)	1.139	0.056	1.251	0.210	1.253	0.122	1.158	-0.188	1.183	0.048
	(0.3104)	(0.2454)	(0.2249)	(0.2596)	(0.2804)	(0.2362)	(0.3104)	(0.3107)	(0.2849)	(0.2836)
Median	1.100	0.000	1.175	0.075	1.250	0.000	1.175	-0.220	1.100	0.000
Min, Max	0.47, 1.55	-0.63, 0.45	0.96, 1.55	0.00, 0.63	0.96, 1.55	0.00, 0.59	0.64, 1.55	-0.76, 0.30	0.47, 1.55	-0.76, 0.63
Spatial Frequency 18 cycles/degree										
OBS V5										
n	12	12	8	8	6	6	8	8	34	34
Mean (SD)	1.049	-0.001	1.271	0.230	1.302	0.098	1.174	0.020	1.175	0.076
	(0.3649)	(0.3921)	(0.2788)	(0.2244)	(0.2421)	(0.2555)	(0.4061)	(0.4339)	(0.3401)	(0.3471)
Median	1.100	0.070	1.250	0.150	1.325	0.075	1.250	-0.070	1.250	0.145
Min, Max	0.17, 1.55	-0.93, 0.59	0.81, 1.55	-0.14, 0.59	0.96, 1.55	-0.29, 0.44	0.47, 1.55	-0.49, 0.93	0.17, 1.55	-0.93, 0.93
OBS V6										
n	12	12	8	8	2	2	6	6	28	28
Mean (SD)	1.026	-0.024	1.100	0.059	1.475	0.590	1.177	-0.150	1.111	0.016
	(0.3406)	(0.2146)	(0.2553)	(0.3655)	(0.1061)	(0.2121)	(0.2031)	(0.1342)	(0.2937)	(0.3003)
Median	1.100	0.000	1.100	0.070	1.475	0.590	1.250	-0.150	1.100	0.000
Min, Max	0.17, 1.55	-0.30, 0.29	0.64, 1.55	-0.46, 0.63	1.40, 1.55	0.44, 0.74	0.81, 1.40	-0.30, 0.00	0.17, 1.55	-0.46, 0.74
OBS V7										
n	4	4	4	4	2	2	6	6	16	16
Mean (SD)	0.785	-0.233	1.213	0.305	1.475	0.590	1.328	0.002	1.182	0.093
	(0.5507)	(0.3244)	(0.2250)	(0.2869)	(0.1061)	(0.0000)	(0.3467)	(0.1625)	(0.4170)	(0.3505)
Median	0.860	-0.225	1.100	0.295	1.475	0.590	1.550	0.000	1.250	0.000
Min, Max	0.17, 1.25	-0.63, 0.15	1.10, 1.55	0.00, 0.63	1.40, 1.55	0.59, 0.59	0.81, 1.55	-0.15, 0.30	0.17, 1.55	-0.63, 0.63
OBS V8										
n	6	6	4	4	4	4	2	2	16	16
Mean (SD)	1.100	0.055	1.400	0.493	1.363	0.368	1.550	0.000	1.297	0.236
	(0.2706)	(0.1819)	(0.1225)	(0.3231)	(0.2250)	(0.1898)	(0.0000)	(0.0000)	(0.2561)	(0.2860)
Median	1.175	0.075	1.400	0.445	1.400	0.365	1.550	0.000	1.325	0.160
Min, Max	0.64, 1.40	-0.15, 0.30	1.25, 1.55	0.15, 0.93	1.10, 1.55	0.15, 0.59	1.55, 1.55	0.00, 0.00	0.64, 1.55	-0.15, 0.93
OBS V9										
n	4	4	4	4	2	2	2	2	12	12
Mean (SD)	1.400	0.225	1.363	0.455	1.325	0.440	1.100	0.465	1.325	0.378
	(0.2121)	(0.1936)	(0.2250)	(0.2175)	(0.1061)	(0.0000)	(0.0000)	(0.6576)	(0.1971)	(0.2742)
Median	1.475	0.225	1.400	0.520	1.325	0.440	1.100	0.465	1.325	0.440
Min, Max	1.10, 1.55	0.00, 0.45	1.10, 1.55	0.15, 0.63	1.25, 1.40	0.44, 0.44	1.10, 1.10	0.00, 0.93	1.10, 1.55	0.00, 0.93
Spatial Frequency 18 cycles/degree										
OBS V10										
n	4	4	2	2					6	6
Mean (SD)	1.325	0.150	1.475	0.690					1.375	0.330
	(0.2598)	(0.3674)	(0.1061)	(0.3394)					(0.2208)	(0.4264)
Median	1.325	0.225	1.475	0.690					1.475	0.450
Min, Max	1.10, 1.55	-0.30, 0.45	1.40, 1.55	0.45, 0.93					1.10, 1.55	-0.30, 0.93

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Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Visit		Change from		Change from		Change from		Change from		Change from
Statistic	Observed	Baseline	Observed	Baseline	Observed	Baseline	Observed	Baseline	Observed	Baseline
OBS V11										
n	4	4	2	2					6	6
Mean (SD)	1.288	0.113	1.180	0.395					1.252	0.207
	(0.1436)	(0.1436)	(0.3111)	(0.1344)					(0.1866)	(0.1930)
Median	1.325	0.075	1.180	0.395					1.325	0.225
Min, Max	1.10, 1.40	0.00, 0.30	0.96, 1.40	0.30, 0.49					0.96, 1.40	0.00, 0.49
OBS V12										
n	2	2	2	2					4	4
Mean (SD)	1.325	0.225	1.550	0.765					1.438	0.495
	(0.1061)	(0.1061)	(0.0000)	(0.4455)					(0.1436)	(0.4088)
Median	1.325	0.225	1.550	0.765					1.475	0.375
Min, Max	1.25, 1.40	0.15, 0.30	1.55, 1.55	0.45, 1.08					1.25, 1.55	0.15, 1.08
OBS V13										
n	4	4							4	4
Mean (SD)	1.250	0.220							1.250	0.220
	(0.1225)	(0.1885)							(0.1225)	(0.1885)
Median	1.250	0.220							1.250	0.220
Min, Max	1.10, 1.40	0.00, 0.44							1.10, 1.40	0.00, 0.44
OBS Final										
n	67	67	52	52	44	44	52	52	215	215
Mean (SD)	0.923	0.051	0.963	0.058	1.091	0.107	0.938	0.017	0.971	0.056
	(0.4140)	(0.3541)	(0.3611)	(0.3915)	(0.3677)	(0.3116)	(0.3322)	(0.3248)	(0.3760)	(0.3475)
Median	0.960	0.150	0.960	0.075	1.100	0.000	0.960	0.000	0.960	0.000
Min, Max	0.01, 1.55	-0.93, 0.79	0.01, 1.55	-1.38, 0.93	0.17, 1.55	-0.47, 0.76	0.17, 1.55	-0.79, 0.93	0.01, 1.55	-1.38, 0.93

Abbreviations: OBS = Observational Study; N/A = Not Applicable.

Note: N in the headers represents the total number of eyes with Cornea Verticillata in each treatment group for the population being analyzed. For each OBS visit, if n=0, no summary statistics are displayed

Source : 添付資料 5.3.5.2-1 Table 14.3.4.4.1

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表 2.7.4.7-11. 101390002LT:コントラスト感度検査の平均値及び OBS Visit 1 からの平均変化量

Parameter / Visit / Statistic	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67) Observed	Change from OBS V1	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52) Observed	Change from OBS V1	0.02% STN1013900 + 0.005% Latanoprost (N=44) Observed	Change from OBS V1	0.02% STN1013900 + 0.5% Timolol (N=52) Observed	Change from OBS V1	All Subjects (N=215) Observed	Change from OBS V1
Spatial Frequency 3 cycles/degree										
OBS V1										
n	65	N/A	52	N/A	44	N/A	52	N/A	213	N/A
Mean (SD)	1.610 (0.2959)	N/A	1.620 (0.3052)	N/A	1.645 (0.2650)	N/A	1.599 (0.3276)	N/A	1.617 (0.2986)	N/A
Median	1.630	N/A	1.630	N/A	1.630	N/A	1.630	N/A	1.630	N/A
Min, Max	0.70, 2.08	N/A	0.70, 2.08	N/A	1.00, 2.08	N/A	0.70, 2.08	N/A	0.70, 2.08	N/A
OBS V2										
n	14	14	10	10	8	8	10	10	42	42
Mean (SD)	1.739 (0.1785)	0.053 (0.1722)	1.797 (0.2142)	0.014 (0.2345)	1.760 (0.2967)	0.016 (0.1919)	1.723 (0.2894)	0.029 (0.2304)	1.753 (0.2332)	0.031 (0.1992)
Median	1.705	0.000	1.780	0.000	1.780	0.000	1.705	0.000	1.780	0.000
Min, Max	1.49, 2.08	-0.30, 0.30	1.49, 2.08	-0.30, 0.44	1.17, 2.08	-0.32, 0.30	1.34, 2.08	-0.30, 0.44	1.17, 2.08	-0.32, 0.44
OBS V3										
n	10	10	12	12	6	6	8	8	36	36
Mean (SD)	1.587 (0.2240)	-0.046 (0.2637)	1.697 (0.2917)	-0.061 (0.1932)	1.855 (0.2068)	0.075 (0.1255)	1.726 (0.2956)	-0.038 (0.2863)	1.699 (0.2667)	-0.029 (0.2249)
Median	1.630	0.000	1.705	-0.070	1.855	0.000	1.705	0.000	1.630	0.000
Min, Max	1.17, 1.93	-0.59, 0.30	1.34, 2.08	-0.30, 0.30	1.63, 2.08	0.00, 0.30	1.34, 2.08	-0.45, 0.30	1.17, 2.08	-0.59, 0.30
OBS V4										
n	18	18	8	8	6	6	8	8	40	40
Mean (SD)	1.666 (0.2261)	-0.034 (0.2444)	1.855 (0.1389)	-0.001 (0.2240)	1.855 (0.1837)	0.173 (0.1722)	1.893 (0.1747)	0.038 (0.1061)	1.777 (0.2149)	0.018 (0.2144)
Median	1.705	0.000	1.855	0.000	1.780	0.150	1.855	0.000	1.780	0.000
Min, Max	1.17, 2.08	-0.45, 0.45	1.63, 2.08	-0.30, 0.44	1.63, 2.08	0.00, 0.44	1.63, 2.08	-0.15, 0.15	1.17, 2.08	-0.45, 0.45
OBS V5										
n	12	12	8	8	6	6	8	8	34	34
Mean (SD)	1.708 (0.2228)	0.038 (0.2632)	1.893 (0.1747)	0.036 (0.2489)	1.855 (0.1837)	0.075 (0.1573)	1.728 (0.3155)	-0.036 (0.1726)	1.782 (0.2365)	0.026 (0.2185)
Median	1.705	0.000	1.855	0.150	1.780	0.075	1.780	-0.075	1.780	0.000
Min, Max	1.34, 2.08	-0.45, 0.45	1.63, 2.08	-0.30, 0.30	1.63, 2.08	-0.15, 0.30	1.34, 2.08	-0.29, 0.15	1.34, 2.08	-0.45, 0.45
Spatial Frequency 3 cycles/degree										
OBS V6										
n	12	12	8	8	2	2	6	6	28	28
Mean (SD)	1.781 (0.1794)	0.111 (0.1579)	1.835 (0.3025)	-0.021 (0.1283)	1.930 (0.0000)	0.300 (0.0000)	1.905 (0.1475)	0.000 (0.0949)	1.834 (0.2096)	0.063 (0.1558)
Median	1.780	0.140	1.855	0.000	1.930	0.300	1.855	0.000	1.780	0.000
Min, Max	1.49, 2.08	-0.15, 0.45	1.17, 2.08	-0.17, 0.15	1.93, 1.93	0.30, 0.30	1.78, 2.08	-0.15, 0.15	1.17, 2.08	-0.17, 0.45
OBS V7										
n	4	4	4	4	2	2	6	6	16	16
Mean (SD)	1.783 (0.3634)	0.110 (0.2557)	1.708 (0.2570)	0.038 (0.2562)	1.855 (0.1061)	0.225 (0.1061)	1.905 (0.1475)	0.000 (0.1897)	1.819 (0.2333)	0.065 (0.2117)
Median	1.855	0.070	1.630	0.075	1.855	0.225	1.855	0.075	1.780	0.145
Min, Max	1.34, 2.08	-0.15, 0.45	1.49, 2.08	-0.30, 0.30	1.78, 1.93	0.15, 0.30	1.78, 2.08	-0.30, 0.15	1.34, 2.08	-0.30, 0.45
OBS V8										
n	6	6	4	4	4	4	2	2	16	16

Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Visit		Change from		Change from		Change from		Change from		Change from
Statistic	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1
Mean	1.782	0.123	1.968	0.298	1.820	0.115	2.005	-0.075	1.866 (0.2360)	0.140
(SD)	(0.2486)	(0.3465)	(0.1436)	(0.1184)	(0.3277)	(0.3897)	(0.1061)	(0.1061)		(0.2950)
Median	1.705	0.145	2.005	0.300	1.930	0.225	2.005	-0.075	1.930	0.220
Min, Max	1.49, 2.08	-0.45, 0.45	1.78, 2.08	0.15, 0.44	1.34, 2.08	-0.44, 0.45	1.93, 2.08	-0.15, 0.00	1.34, 2.08	-0.45, 0.45
OBS V9										
n	4	4	4	4	2	2	2	2	12	12
Mean	1.743	0.000	1.968	0.298	1.855	0.225	1.560	0.220	1.806 (0.1774)	0.173
(SD)	(0.0750)	(0.2121)	(0.1436)	(0.1184)	(0.1061)	(0.1061)	(0.0990)	(0.0990)		(0.1882)
Median	1.780	0.075	2.005	0.300	1.855	0.225	1.560	0.220	1.780	0.150
Min, Max	1.63, 1.78	-0.30, 0.15	1.78, 2.08	0.15, 0.44	1.78, 1.93	0.15, 0.30	1.49, 1.63	0.15, 0.29	1.49, 2.08	-0.30, 0.44
OBS V10										
n	4	4	2	2					6	6
Mean	1.745	0.003	1.930	0.445					1.807 (0.2376)	0.150
(SD)	(0.2528)	(0.4371)	(0.2121)	(0.0071)						(0.4085)
Median	1.705	0.075	1.930	0.445					1.780	0.295
Min, Max	1.49, 2.08	-0.59, 0.45	1.78, 2.08	0.44, 0.45					1.49, 2.08	-0.59, 0.45
Spatial Frequency 3 cycles/degree										
OBS V11										
n	4	4	2	2					6	6
Mean	1.708	-0.035	1.855	0.370					1.757	0.100
(SD)	(0.1898)	(0.2548)	(0.1061)	(0.0990)					(0.1722)	(0.2909)
Median	1.705	-0.070	1.855	0.370					1.780	0.150
Min, Max	1.49, 1.93	-0.30, 0.30	1.78, 1.93	0.30, 0.44					1.49, 1.93	-0.30, 0.44
OBS V12										
n	2	2	2	2					4	4
Mean	1.630	0.000	1.635	0.150					1.633	0.075
(SD)	(0.0000)	(0.0000)	(0.2051)	(0.0000)					(0.1184)	(0.0866)
Median	1.630	0.000	1.635	0.150					1.630	0.075
Min, Max	1.63, 1.63	0.00, 0.00	1.49, 1.78	0.15, 0.15					1.49, 1.78	0.00, 0.15
OBS V13										
n	4	4							4	4
Mean	1.745	0.003							1.745	0.003
(SD)	(0.1841)	(0.2702)							(0.1841)	(0.2702)
Median	1.780	0.000							1.780	0.000
Min, Max	1.49, 1.93	-0.29, 0.30							1.49, 1.93	-0.29, 0.30
OBS Final										
n	67	65	52	52	44	44	52	52	215	213
Mean	1.673	0.069	1.743	0.123	1.689	0.044	1.583	-0.016	1.672	0.056
(SD)	(0.2943)	(0.2520)	(0.2584)	(0.3432)	(0.2657)	(0.2582)	(0.2275)	(0.2911)	(0.2690)	(0.2896)
Median	1.780	0.140	1.780	0.070	1.705	0.000	1.630	0.000	1.780	0.000
Min, Max	0.70, 2.08	-0.74, 0.46	1.00, 2.08	-0.93, 1.08	1.00, 2.08	-0.76, 0.46	1.00, 2.08	-0.91, 0.59	0.70, 2.08	-0.93, 1.08
Spatial Frequency 6 cycles/degree										
OBS V1										
n	65	N/A	52	N/A	44	N/A	52	N/A	213	N/A
Mean	1.722	N/A	1.793	N/A	1.718	N/A	1.735	N/A	1.742	N/A
(SD)	(0.3423)		(0.3345)		(0.2929)		(0.3519)		(0.3322)	
Median	1.840	N/A	1.840	N/A	1.700	N/A	1.840	N/A	1.840	N/A
Min, Max	0.61, 2.29	N/A	0.91, 2.29	N/A	0.91, 2.14	N/A	0.91, 2.29	N/A	0.61, 2.29	N/A

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Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Visit		Change from		Change from		Change from		Change from		Change from
Statistic	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1
Spatial Frequency 6 cycles/degree										
OBS V2										
n	14	14	10	10	8	8	10	10	42	42
Mean	1.821	0.009	1.873	-0.089	2.048	0.133	1.764	-0.029	1.863	0.000
(SD)	(0.2183)	(0.2286)	(0.2284)	(0.2663)	(0.2367)	(0.0968)	(0.4085)	(0.1258)	(0.2871)	(0.2069)
Median	1.840	0.000	1.840	-0.150	2.140	0.150	1.770	0.000	1.840	0.000
Min, Max	1.38, 2.14	-0.59, 0.30	1.55, 2.14	-0.45, 0.46	1.55, 2.29	0.00, 0.30	0.91, 2.14	-0.32, 0.17	0.91, 2.29	-0.59, 0.46
OBS V3										
n	10	10	12	12	6	6	8	8	36	36
Mean	1.828	0.073	1.915	0.038	2.090	0.050	1.860	-0.055	1.908	0.029
(SD)	(0.1280)	(0.1998)	(0.3561)	(0.1591)	(0.1225)	(0.1225)	(0.1662)	(0.2427)	(0.2445)	(0.1855)
Median	1.840	0.000	1.990	0.070	2.065	0.075	1.840	-0.075	1.840	0.000
Min, Max	1.70, 2.14	-0.15, 0.59	1.21, 2.29	-0.15, 0.30	1.99, 2.29	-0.15, 0.15	1.55, 2.14	-0.30, 0.46	1.21, 2.29	-0.30, 0.59
OBS V4										
n	18	18	8	8	6	6	8	8	40	40
Mean	1.851	0.082	1.936	-0.110	2.140	0.297	1.936	-0.091	1.929	0.041
(SD)	(0.2475)	(0.2188)	(0.2079)	(0.3192)	(0.0949)	(0.2079)	(0.1743)	(0.1749)	(0.2252)	(0.2632)
Median	1.840	0.000	1.915	-0.150	2.140	0.300	1.990	-0.070	1.990	0.000
Min, Max	1.38, 2.29	-0.17, 0.45	1.70, 2.29	-0.45, 0.46	1.99, 2.29	0.00, 0.59	1.70, 2.14	-0.44, 0.15	1.38, 2.29	-0.45, 0.59
OBS V5										
n	12	12	8	8	6	6	8	8	34	34
Mean	1.830	0.061	2.121	0.075	1.965	-0.050	1.974	0.059	1.956	0.044
(SD)	(0.2946)	(0.3327)	(0.1689)	(0.2801)	(0.1475)	(0.1549)	(0.2551)	(0.1968)	(0.2541)	(0.2596)
Median	1.840	0.000	2.140	0.145	1.915	0.000	2.065	0.000	1.990	0.000
Min, Max	1.38, 2.29	-0.46, 0.74	1.84, 2.29	-0.30, 0.61	1.84, 2.14	-0.30, 0.15	1.55, 2.29	-0.15, 0.46	1.38, 2.29	-0.46, 0.74
OBS V6										
n	12	12	8	8	2	2	6	6	28	28
Mean	1.956	0.187	1.938	-0.109	2.140	0.225	2.115	0.075	1.998	0.081
(SD)	(0.2276)	(0.2434)	(0.3533)	(0.2866)	(0.0000)	(0.1061)	(0.1754)	(0.1573)	(0.2561)	(0.2600)
Median	1.990	0.220	1.990	-0.075	2.140	0.225	2.140	0.075	2.065	0.150
Min, Max	1.70, 2.29	-0.29, 0.59	1.55, 2.29	-0.59, 0.17	2.14, 2.14	0.15, 0.30	1.84, 2.29	-0.15, 0.30	1.55, 2.29	-0.59, 0.59
Spatial Frequency 6 cycles/degree										
OBS V7										
n	4	4	4	4	2	2	6	6	16	16
Mean	1.733	0.035	1.920	0.043	2.140	0.225	2.140	0.100	1.983	0.085
(SD)	(0.1384)	(0.0700)	(0.3515)	(0.1491)	(0.2121)	(0.1061)	(0.1643)	(0.1225)	(0.2674)	(0.1226)
Median	1.770	0.000	1.920	0.075	2.140	0.225	2.140	0.075	2.065	0.070
Min, Max	1.55, 1.84	0.00, 0.14	1.55, 2.29	-0.15, 0.17	1.99, 2.29	0.15, 0.30	1.84, 2.29	0.00, 0.30	1.55, 2.29	-0.15, 0.30
OBS V8										
n	6	6	4	4	4	4	2	2	16	16
Mean	1.992	0.222	1.955	0.078	2.105	0.335	2.065	-0.075	2.020	0.177
(SD)	(0.2474)	(0.2429)	(0.2211)	(0.2004)	(0.2791)	(0.2528)	(0.1061)	(0.1061)	(0.2240)	(0.2445)
Median	2.140	0.300	1.990	0.070	2.215	0.375	2.065	-0.075	2.140	0.220
Min, Max	1.55, 2.14	-0.15, 0.44	1.70, 2.14	-0.15, 0.32	1.70, 2.29	0.00, 0.59	1.99, 2.14	-0.15, 0.00	1.55, 2.29	-0.15, 0.59
OBS V9										
n	4	4	4	4	2	2	2	2	12	12
Mean	2.065	0.223	2.253	0.375	2.140	0.225	1.845	0.305	2.103	0.288
(SD)	(0.0866)	(0.0838)	(0.0750)	(0.3586)	(0.2121)	(0.3182)	(0.2051)	(0.0212)	(0.1803)	(0.2265)

Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Visit		Change from		Change from		Change from		Change from		Change from
Statistic	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1
Median	2.065	0.220	2.290	0.370	2.140	0.225	1.845	0.305	2.140	0.290
Min, Max	1.99, 2.14	0.15, 0.30	2.14, 2.29	0.00, 0.76	1.99, 2.29	0.00, 0.45	1.70, 1.99	0.29, 0.32	1.70, 2.29	0.00, 0.76
OBS V10										
n	4	4	2	2					6	6
Mean	2.103	0.260	2.215	0.675					2.140	0.398
(SD)	(0.0750)	(0.0735)	(0.1061)	(0.1202)					(0.0949)	(0.2282)
Median	2.140	0.295	2.215	0.675					2.140	0.300
Min, Max	1.99, 2.14	0.15, 0.30	2.14, 2.29	0.59, 0.76					1.99, 2.29	0.15, 0.76
OBS V11										
n	4	4	2	2					6	6
Mean	2.178	0.335	2.290	0.750					2.215	0.473
(SD)	(0.1436)	(0.2528)	(0.0000)	(0.2263)					(0.1255)	(0.3074)
Median	2.215	0.375	2.290	0.750					2.290	0.520
Min, Max	1.99, 2.29	0.00, 0.59	2.29, 2.29	0.59, 0.91					1.99, 2.29	0.00, 0.91
Spatial Frequency 6 cycles/degree										
OBS V12										
n	2	2	2	2					4	4
Mean	1.990	0.075	1.770	0.230					1.880 (0.1393)	0.153
(SD)	(0.0000)	(0.1061)	(0.0990)	(0.1273)						(0.1310)
Median	1.990	0.075	1.770	0.230					1.915	0.145
Min, Max	1.99, 1.99	0.00, 0.15	1.70, 1.84	0.14, 0.32					1.70, 1.99	0.00, 0.32
OBS V13										
n	4	4							4	4
Mean	2.028	0.150							2.028 (0.0750)	0.150
(SD)	(0.0750)	(0.0000)								(0.0000)
Median	1.990	0.150							1.990	0.150
Min, Max	1.99, 2.14	0.15, 0.15							1.99, 2.14	0.15, 0.15
OBS Final										
n	67	65	52	52	44	44	52	52	215	213
Mean	1.837	0.126	1.838	0.045	1.865	0.147	1.742	0.007	1.820 (0.2965)	0.082
(SD)	(0.3209)	(0.3148)	(0.2918)	(0.3125)	(0.3019)	(0.2248)	(0.2548)	(0.2659)		(0.2895)
Median	1.840	0.140	1.840	0.000	1.840	0.145	1.840	0.000	1.840	0.000
Min, Max	0.91, 2.29	-0.79, 0.79	1.21, 2.29	-0.59, 1.08	1.21, 2.29	-0.46, 0.59	0.91, 2.29	-0.45, 0.93	0.91, 2.29	-0.79, 1.08
Spatial Frequency 12 cycles/degree										
OBS V1										
n	65	N/A	52	N/A	44	N/A	52	N/A	213	N/A
Mean	1.335	N/A	1.399	N/A	1.367	N/A	1.348	N/A	1.361 (0.4007)	N/A
(SD)	(0.4394)		(0.3861)		(0.3755)		(0.3933)			
Median	1.400	N/A	1.400	N/A	1.400	N/A	1.400	N/A	1.400	N/A
Min, Max	0.31, 1.99	N/A	0.61, 1.99	N/A	0.61, 1.99	N/A	0.61, 1.99	N/A	0.31, 1.99	N/A
OBS V2										
n	14	14	10	10	8	8	10	10	42	42
Mean	1.446	0.089	1.560	-0.021	1.766	0.076	1.431	-0.120	1.530 (0.3293)	0.010
(SD)	(0.2398)	(0.2872)	(0.2452)	(0.4444)	(0.2383)	(0.1429)	(0.4840)	(0.1956)		(0.2978)
Median	1.470	0.140	1.470	-0.075	1.840	0.070	1.400	-0.070	1.540	0.000
Min, Max	1.08, 1.84	-0.44, 0.49	1.25, 1.99	-0.59, 0.93	1.40, 1.99	-0.15, 0.32	0.61, 1.99	-0.49, 0.17	0.61, 1.99	-0.59, 0.93
Spatial Frequency 12 cycles/degree										
OBS V3										
n	10	10	12	12	6	6	8	8	36	36

	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Parameter		Change from		Change from		Change from		Change from		Change from
Visit Statistic	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1
Mean	1.539	0.174	1.538	0.080	1.840	0.023	1.520	-0.170	1.585 (0.3316)	0.041
(SD)	(0.1761)	(0.2092)	(0.4250)	(0.2517)	(0.1897)	(0.1740)	(0.3648)	(0.2338)		(0.2495)
Median	1.540	0.215	1.615	0.070	1.915	0.070	1.540	-0.145	1.540	0.070
Min, Max	1.08, 1.69	-0.30, 0.46	0.61, 1.99	-0.30, 0.64	1.54, 1.99	-0.30, 0.15	1.08, 1.99	-0.45, 0.15	0.61, 1.99	-0.45, 0.64
OBS V4										
n	18	18	8	8	6	6	8	8	40	40
Mean	1.514	0.053	1.710	0.065	1.742	0.228	1.601	-0.148	1.605	0.042
(SD)	(0.2974)	(0.2743)	(0.2565)	(0.3972)	(0.2421)	(0.3596)	(0.3151)	(0.1358)	(0.2909)	(0.3064)
Median	1.540	0.000	1.765	-0.075	1.765	0.150	1.545	-0.150	1.690	0.000
Min, Max	0.91, 1.99	-0.45, 0.59	1.25, 1.99	-0.30, 0.93	1.40, 1.99	-0.30, 0.78	1.25, 1.99	-0.30, 0.00	0.91, 1.99	-0.45, 0.93
OBS V5										
n	12	12	8	8	6	6	8	8	34	34
Mean	1.454	-0.015	1.841	0.196	1.765	0.073	1.614	-0.076	1.638	0.036
(SD)	(0.3280)	(0.4006)	(0.2091)	(0.4042)	(0.2068)	(0.2242)	(0.3900)	(0.2529)	(0.3305)	(0.3461)
Median	1.470	0.000	1.915	0.000	1.765	0.075	1.765	-0.075	1.690	0.000
Min, Max	0.61, 1.84	-0.64, 0.61	1.40, 1.99	-0.15, 1.08	1.54, 1.99	-0.15, 0.44	0.91, 1.99	-0.49, 0.32	0.61, 1.99	-0.64, 1.08
OBS V6										
n	12	12	8	8	2	2	6	6	28	28
Mean	1.448	-0.022	1.544	-0.101	1.915	0.295	1.715	-0.102	1.566	-0.039
(SD)	(0.3133)	(0.4457)	(0.2619)	(0.4665)	(0.1061)	(0.4172)	(0.1754)	(0.2596)	(0.2902)	(0.4083)
Median	1.540	0.140	1.540	-0.225	1.915	0.295	1.690	-0.075	1.540	0.000
Min, Max	0.91, 1.84	-1.08, 0.61	1.25, 1.99	-0.59, 0.79	1.84, 1.99	0.00, 0.59	1.54, 1.99	-0.45, 0.29	0.91, 1.99	-1.08, 0.79
OBS V7										
n	4	4	4	4	2	2	6	6	16	16
Mean	1.575	0.183	1.508	0.208	1.990	0.370	1.865	0.048	1.719 (0.2804)	0.162
(SD)	(0.3590)	(0.2195)	(0.1384)	(0.7113)	(0.0000)	(0.3111)	(0.1994)	(0.1184)		(0.3654)
Median	1.690	0.145	1.470	0.095	1.990	0.370	1.990	0.000	1.765	0.000
Min, Max	1.08, 1.84	0.00, 0.44	1.40, 1.69	-0.44, 1.08	1.99, 1.99	0.15, 0.59	1.54, 1.99	0.00, 0.29	1.08, 1.99	-0.44, 1.08
Spatial Frequency 12 cycles/degree										
OBS V8										
n	6	6	4	4	4	4	2	2	16	16
Mean	1.618	0.223	1.578	0.278	1.840	0.368	1.915	-0.075	1.701 (0.1913)	0.236
(SD)	(0.1788)	(0.1248)	(0.0750)	(0.5962)	(0.1732)	(0.1898)	(0.1061)	(0.1061)		(0.3198)
Median	1.690	0.290	1.540	0.240	1.840	0.365	1.915	-0.075	1.690	0.290
Min, Max	1.40, 1.84	0.00, 0.32	1.54, 1.69	-0.30, 0.93	1.69, 1.99	0.15, 0.59	1.84, 1.99	-0.15, 0.00	1.40, 1.99	-0.30, 0.93
OBS V9										
n	4	4	4	4	2	2	2	2	12	12
Mean	1.803	0.293	1.765	0.465	1.765	0.145	1.400	0.090	1.717 (0.2354)	0.292
(SD)	(0.2250)	(0.2098)	(0.2598)	(0.3838)	(0.1061)	(0.2051)	(0.0000)	(0.3253)		(0.2964)
Median	1.840	0.220	1.765	0.390	1.765	0.145	1.400	0.090	1.690	0.220
Min, Max	1.54, 1.99	0.14, 0.59	1.54, 1.99	0.15, 0.93	1.69, 1.84	0.00, 0.29	1.40, 1.40	-0.14, 0.32	1.40, 1.99	-0.14, 0.93
OBS V10										
n	4	4	2	2					6	6
Mean	1.915	0.405	1.470	0.710					1.767 (0.2434)	0.507
(SD)	(0.0866)	(0.1841)	(0.0990)	(0.3111)						(0.2540)
Median	1.915	0.440	1.470	0.710					1.840	0.465
Min, Max	1.84, 1.99	0.15, 0.59	1.40, 1.54	0.49, 0.93					1.40, 1.99	0.15, 0.93
OBS V11										
n	4	4	2	2					6	6
Mean	1.728	0.218	1.840	1.080					1.765 (0.1837)	0.505
(SD)	(0.1887)	(0.0838)	(0.2121)	(0.0000)						(0.4501)

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Parameter Visit Statistic	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67) Observed	Change from OBS V1	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52) Observed	Change from OBS V1	0.02% STN1013900 + 0.005% Latanoprost (N=44) Observed	Change from OBS V1	0.02% STN1013900 + 0.5% Timolol (N=52) Observed	Change from OBS V1	All Subjects (N=215) Observed	Change from OBS V1
Median	1.690	0.220	1.840	1.080					1.690	0.290
Min, Max	1.54, 1.99	0.14, 0.29	1.69, 1.99	1.08, 1.08					1.54, 1.99	0.14, 1.08
OBS V12										
n	2	2	2	2					4	4
Mean (SD)	1.545 (0.2051)	0.145 (0.2051)	1.620 (0.3111)	0.860 (0.0990)					1.583 (0.2195)	0.503 (0.4332)
Median	1.545	0.145	1.620	0.860					1.545	0.540
Min, Max	1.40, 1.69	0.00, 0.29	1.40, 1.84	0.79, 0.93					1.40, 1.84	0.00, 0.93
Spatial Frequency 12 cycles/degree										
OBS V13										
n	4	4							4	4
Mean	1.618	-0.078							1.618	-0.078
(SD)	(0.1898)	(0.5178)							(0.1898)	(0.5178)
Median	1.615	-0.080							1.615	-0.080
Min, Max	1.40, 1.84	-0.59, 0.44							1.40, 1.84	-0.59, 0.44
OBS Final										
n	67	65	52	52	44	44	52	52	215	213
Mean	1.450	0.129	1.443	0.044	1.491	0.124	1.391	0.043	1.443	0.086
(SD)	(0.3591)	(0.3652)	(0.3784)	(0.3533)	(0.4024)	(0.2809)	(0.3382)	(0.2946)	(0.3672)	(0.3300)
Median	1.540	0.140	1.400	0.000	1.400	0.150	1.400	0.000	1.400	0.000
Min, Max	0.61, 1.99	-0.61, 0.94	0.31, 1.99	-0.77, 0.78	0.61, 1.99	-0.59, 0.91	0.61, 1.99	-0.64, 0.79	0.31, 1.99	-0.77, 0.94
Spatial Frequency 18 cycles/degree										
OBS V1										
n	65	N/A	52	N/A	44	N/A	52	N/A	213	N/A
Mean (SD)	0.871 (0.4091)	N/A	0.927 (0.4295)	N/A	0.982 (0.3352)	N/A	0.865 (0.3818)	N/A	0.906 (0.3935)	N/A
Median	0.960	N/A	0.960	N/A	0.960	N/A	0.810	N/A	0.960	N/A
Min, Max	0.01, 1.55	N/A	0.17, 1.55	N/A	0.17, 1.55	N/A	0.17, 1.55	N/A	0.01, 1.55	N/A
OBS V2										
n	14	14	10	10	8	8	10	10	42	42
Mean	0.911	0.000	1.133	-0.025	1.345	0.055	1.018	-0.032	1.072	-0.003
(SD)	(0.3980)	(0.2543)	(0.1945)	(0.4724)	(0.2085)	(0.2096)	(0.5307)	(0.2092)	(0.3908)	(0.2959)
Median	1.100	0.000	1.100	-0.075	1.325	0.075	1.030	0.000	1.100	0.000
Min, Max	0.17, 1.40	-0.59, 0.46	0.96, 1.55	-0.59, 0.93	0.96, 1.55	-0.30, 0.30	0.17, 1.55	-0.49, 0.17	0.17, 1.55	-0.59, 0.93
OBS V3										
n	10	10	12	12	6	6	8	8	36	36
Mean	1.025	0.048	1.134	0.116	1.475	0.098	1.069	-0.084	1.146	0.050
(SD)	(0.2294)	(0.2733)	(0.4009)	(0.5317)	(0.1255)	(0.1524)	(0.2924)	(0.3157)	(0.3279)	(0.3705)
Median	1.100	0.000	1.250	0.000	1.550	0.000	0.960	-0.075	1.175	0.000
Min, Max	0.64, 1.25	-0.29, 0.61	0.47, 1.55	-0.45, 1.23	1.25, 1.55	0.00, 0.30	0.81, 1.55	-0.59, 0.34	0.47, 1.55	-0.59, 1.23
Spatial Frequency 18 cycles/degree										
OBS V4										
n	18	18	8	8	6	6	8	8	40	40
Mean	1.139	0.131	1.251	0.004	1.253	0.130	1.158	-0.131	1.183	0.053
(SD)	(0.3104)	(0.2347)	(0.2249)	(0.4523)	(0.2804)	(0.2782)	(0.3104)	(0.1702)	(0.2849)	(0.2949)
Median	1.100	0.070	1.175	-0.075	1.250	0.160	1.175	-0.075	1.100	0.000
Min, Max	0.47, 1.55	-0.17, 0.59	0.96, 1.55	-0.59, 0.93	0.96, 1.55	-0.30, 0.44	0.64, 1.55	-0.46, 0.00	0.47, 1.55	-0.59, 0.93
OBS V5										
n	12	12	8	8	6	6	8	8	34	34

Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Visit		Change from		Change from		Change from		Change from		Change from
Statistic	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1
Mean	1.049	0.114	1.271	0.024	1.302	0.048	1.174	0.021	1.175	0.059
(SD)	(0.3649)	(0.4118)	(0.2788)	(0.2946)	(0.2421)	(0.1478)	(0.4061)	(0.3774)	(0.3401)	(0.3320)
Median	1.100	0.145	1.250	0.000	1.325	0.000	1.250	0.075	1.250	0.000
Min, Max	0.17, 1.55	-0.47, 0.91	0.81, 1.55	-0.30, 0.64	0.96, 1.55	-0.14, 0.29	0.47, 1.55	-0.49, 0.63	0.17, 1.55	-0.49, 0.91
OBS V6										
n	12	12	8	8	2	2	6	6	28	28
Mean	1.026	0.091	1.100	-0.148	1.475	0.295	1.177	-0.175	1.111	-0.020
(SD)	(0.3406)	(0.2166)	(0.2553)	(0.5423)	(0.1061)	(0.4172)	(0.2031)	(0.1129)	(0.2937)	(0.3566)
Median	1.100	0.140	1.100	-0.225	1.475	0.295	1.250	-0.150	1.100	0.000
Min, Max	0.17, 1.55	-0.30, 0.44	0.64, 1.55	-0.91, 0.93	1.40, 1.55	0.00, 0.59	0.81, 1.40	-0.30, 0.00	0.17, 1.55	-0.91, 0.93
OBS V7										
n	4	4	4	4	2	2	6	6	16	16
Mean	0.785	-0.118	1.213	0.268	1.475	0.295	1.328	-0.023	1.182	0.066
(SD)	(0.5507)	(0.1457)	(0.2250)	(0.5643)	(0.1061)	(0.2051)	(0.3467)	(0.1722)	(0.4170)	(0.3326)
Median	0.860	-0.085	1.100	0.295	1.475	0.295	1.550	0.000	1.250	0.000
Min, Max	0.17, 1.25	-0.30, 0.00	1.10, 1.55	-0.45, 0.93	1.40, 1.55	0.15, 0.44	0.81, 1.55	-0.29, 0.15	0.17, 1.55	-0.45, 0.93
OBS V8										
n	6	6	4	4	4	4	2	2	16	16
Mean	1.100	0.107	1.400	0.455	1.363	0.258	1.550	0.075	1.297	0.228
(SD)	(0.2706)	(0.1616)	(0.1225)	(0.5747)	(0.2250)	(0.2513)	(0.0000)	(0.1061)	(0.2561)	(0.3334)
Median	1.175	0.150	1.400	0.370	1.400	0.220	1.550	0.075	1.325	0.150
Min, Max	0.64, 1.40	-0.15, 0.32	1.25, 1.55	-0.15, 1.23	1.10, 1.55	0.00, 0.59	1.55, 1.55	0.00, 0.15	0.64, 1.55	-0.15, 1.23
Spatial Frequency 18 cycles/degree										
OBS V9										
n	4	4	4	4	2	2	2	2	12	12
Mean	1.400	0.188	1.363	0.418	1.325	0.145	1.100	0.545	1.325	0.317
(SD)	(0.2121)	(0.1436)	(0.2250)	(0.3878)	(0.1061)	(0.2051)	(0.0000)	(0.1202)	(0.1971)	(0.2764)
Median	1.475	0.225	1.400	0.370	1.325	0.145	1.100	0.545	1.325	0.300
Min, Max	1.10, 1.55	0.00, 0.30	1.10, 1.55	0.00, 0.93	1.25, 1.40	0.00, 0.29	1.10, 1.10	0.46, 0.63	1.10, 1.55	0.00, 0.93
OBS V10										
n	4	4	2	2					6	6
Mean	1.325	0.113	1.475	0.985					1.375	0.403
(SD)	(0.2598)	(0.3092)	(0.1061)	(0.3465)					(0.2208)	(0.5333)
Median	1.325	0.075	1.475	0.985					1.475	0.375
Min, Max	1.10, 1.55	-0.15, 0.45	1.40, 1.55	0.74, 1.23					1.10, 1.55	-0.15, 1.23
OBS V11										
n	4	4	2	2					6	6
Mean	1.288	0.075	1.180	0.690					1.252	0.280
(SD)	(0.1436)	(0.0866)	(0.3111)	(0.1414)					(0.1866)	(0.3307)
Median	1.325	0.075	1.180	0.690					1.325	0.150
Min, Max	1.10, 1.40	0.00, 0.15	0.96, 1.40	0.59, 0.79					0.96, 1.40	0.00, 0.79
OBS V12										
n	2	2	2	2					4	4
Mean	1.325	0.150	1.550	1.060					1.438 (0.1436)	0.605
(SD)	(0.1061)	(0.0000)	(0.0000)	(0.4525)						(0.5868)
Median	1.325	0.150	1.550	1.060					1.475	0.445
Min, Max	1.25, 1.40	0.15, 0.15	1.55, 1.55	0.74, 1.38					1.25, 1.55	0.15, 1.38
OBS V13										
n	4	4							4	4
Mean	1.250	0.300							1.250 (0.1225)	0.300
(SD)	(0.1225)	(0.3900)								(0.3900)

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	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
Parameter		Change from		Change from				Change from		Change from
Visit						Change from				
Statistic	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1	Observed	OBS V1
Median	1.250	0.295							1.250	0.295
Min, Max	1.10, 1.40	-0.15, 0.76							1.10, 1.40	-0.15, 0.76
Spatial Frequency 18 cycles/degree										
OBS Final										
n	67	65	52	52	44	44	52	52	215	213
Mean	0.923	0.061	0.963	0.036	1.091	0.109	0.938	0.073	0.971 (0.3760)	0.068
(SD)	(0.4140)	(0.3660)	(0.3611)	(0.4116)	(0.3677)	(0.2587)	(0.3322)	(0.3149)		(0.3453)
Median	0.960	0.000	0.960	0.000	1.100	0.000	0.960	0.000	0.960	0.000
Min, Max	0.01, 1.55	-0.79, 0.91	0.01, 1.55	-1.08, 0.91	0.17, 1.55	-0.47, 0.79	0.17, 1.55	-0.61, 0.79	0.01, 1.55	-1.08, 0.91

Abbreviations: OBS = Observational Study; N/A = Not Applicable.

Note: N in the headers represents the total number of eyes with Cornea Verticillata in each treatment group for the population being analyzed. For each OBS visit, if n=0, no summary statistics are displayed

Source : 添付資料 5.3.5.2-1 Table 14.3.4.4.2

Confidential

表 2.7.4.7-12. 101390002LT: 「渦巻き角膜 (Cornea verticillata) 」の消失／安定後の最終来院時点の 215 眼について、Visit 3（ベースライン）からコントラスト感度検査で LogMAR 視力で 0.3 以上悪化した割合

Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)	0.02% STN1013900 + 0.005% Latanoprost (N=44)	0.02% STN1013900 + 0.5% Timolol (N=52)	All Subjects (N=215)
Spatial Frequency 3 cycles/degree					
m	67	52	44	52	215
Better	5 (7.5%)	9 (17.3%)	6 (13.6%)	0	20 (9.3%)
Same	52 (77.6%)	39 (75.0%)	35 (79.5%)	46 (88.5%)	172 (80.0%)
Worse	10 (14.9%)	4 (7.7%)	3 (6.8%)	6 (11.5%)	23 (10.7%)
Spatial Frequency 6 cycles/degree					
m	67	52	44	52	215
Better	6 (9.0%)	7 (13.5%)	8 (18.2%)	3 (5.8%)	24 (11.2%)
Same	55 (82.1%)	42 (80.8%)	32 (72.7%)	48 (92.3%)	177 (82.3%)
Worse	6 (9.0%)	3 (5.8%)	4 (9.1%)	1 (1.9%)	14 (6.5%)
Spatial Frequency 12 cycles/degree					
m	67	52	44	52	215
Better	10 (14.9%)	8 (15.4%)	11 (25.0%)	6 (11.5%)	35 (16.3%)
Same	45 (67.2%)	36 (69.2%)	27 (61.4%)	38 (73.1%)	146 (67.9%)
Worse	12 (17.9%)	8 (15.4%)	6 (13.6%)	8 (15.4%)	34 (15.8%)
Spatial Frequency 18 cycles/degree					
m	67	52	44	52	215
Better	12 (17.9%)	13 (25.0%)	12 (27.3%)	9 (17.3%)	46 (21.4%)
Same	46 (68.7%)	34 (65.4%)	27 (61.4%)	36 (69.2%)	143 (66.5%)
Worse	9 (13.4%)	5 (9.6%)	5 (11.4%)	7 (13.5%)	26 (12.1%)

Abbreviations: OBS = Observational Study.

Note: N in the headers represents the total number of eyes with Cornea Verticillata in each treatment group for the population being analyzed. Percentages are based on the number of eyes (m) in a given treatment group with non-missing values in the population being analyzed. better (0.3 < log CS), same (-0.3 <= log CS <= 0.3), worse (log CS < -0.3)

Source : 添付資料 5.3.5.2-1 Table 14.3.4.4.3.2

Confidential

表 2.7.4.7-13. 101390002LT:「渦巻き角膜 (Cornea verticillata) 」のグレード分類の平均及び OBS Visit 1 からの平均変化量

	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)		0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)		0.02% STN1013900 + 0.005% Latanoprost (N=44)		0.02% STN1013900 + 0.5% Timolol (N=52)		All Subjects (N=215)	
OBS Visit Statistic	Observed	Change from OBS V1	Observed	Change from OBS V1	Observed	Change from OBS V1	Observed	Change from OBS V1	Observed	Change from OBS V1
OBS V1										
n	67	N/A	52	N/A	44	N/A	52	N/A	215	N/A
Mean (SD)	1.6 (0.92)	N/A	1.6 (0.75)	N/A	1.7 (0.67)	N/A	1.5 (0.70)	N/A	1.6 (0.78)	N/A
Median	1.0	N/A	1.0	N/A	2.0	N/A	1.0	N/A	2.0	N/A
Min, Max	0, 4	N/A	0, 3	N/A	0, 3	N/A	0, 3	N/A	0, 4	N/A
OBS V2										
n	66	66	52	52	44	44	50	50	212	212
Mean (SD)	1.9 (0.96)	0.3 (0.58)	1.8 (0.74)	0.2 (0.50)	1.9 (0.93)	0.2 (1.04)	1.6 (0.70)	0.1 (0.54)	1.8 (0.85)	0.2 (0.68)
Median	2.0	0.0	2.0	0.0	2.0	0.0	1.0	0.0	2.0	0.0
Min, Max	0, 4	-1, 2	1, 4	-1, 2	1, 4	-2, 3	1, 3	-1, 2	0, 4	-2, 3
OBS V3										
n	66	66	52	52	43	43	46	46	207	207
Mean (SD)	2.0 (0.99)	0.4 (0.68)	1.7 (0.82)	0.1 (0.66)	2.0 (0.90)	0.3 (1.08)	1.6 (0.77)	0.1 (0.65)	1.8 (0.89)	0.2 (0.77)
Median	2.0	0.0	2.0	0.0	2.0	0.0	1.0	0.0	2.0	0.0
Min, Max	0, 4	-1, 2	1, 4	-1, 2	1, 4	-2, 3	1, 3	-1, 2	0, 4	-2, 3
OBS V4										
n	64	64	50	50	41	41	46	46	201	201
Mean (SD)	2.0 (1.02)	0.4 (0.83)	1.6 (0.78)	-0.0 (0.68)	2.0 (0.91)	0.3 (1.09)	1.7 (0.82)	0.1 (0.78)	1.8 (0.91)	0.2 (0.86)
Median	2.0	0.0	1.0	0.0	2.0	0.0	1.0	0.0	2.0	0.0
Min, Max	0, 4	-2, 2	0, 4	-2, 2	1, 4	-2, 3	1, 3	-1, 2	0, 4	-2, 3
OBS V5										
n	60	60	46	46	37	37	38	38	181	181
Mean (SD)	2.0 (1.05)	0.4 (1.03)	1.6 (0.95)	0.0 (0.79)	2.1 (1.03)	0.5 (1.17)	1.8 (0.79)	0.2 (0.92)	1.9 (0.98)	0.3 (0.99)
Median	2.0	0.0	1.0	0.0	2.0	0.0	2.0	0.0	2.0	0.0
Min, Max	0, 4	-2, 3	0, 4	-2, 2	0, 4	-2, 3	1, 3	-1, 3	0, 4	-2, 3
OBS V6										
n	46	46	40	40	32	32	34	34	152	152
Mean (SD)	2.0 (1.14)	0.5 (1.17)	1.6 (1.06)	-0.1 (1.00)	2.2 (1.17)	0.5 (1.16)	1.8 (0.90)	0.2 (1.05)	1.9 (1.09)	0.3 (1.11)
Median	2.0	0.0	1.0	0.0	2.0	0.0	2.0	0.0	2.0	0.0
Min, Max	0, 4	-3, 3	0, 4	-2, 2	0, 4	-2, 3	0, 3	-2, 3	0, 4	-3, 3
OBS V7										
n	38	38	28	28	26	26	28	28	120	120
Mean (SD)	2.1 (1.21)	0.6 (1.28)	1.6 (1.17)	-0.2 (1.12)	2.2 (1.05)	0.4 (1.06)	1.9 (0.77)	0.4 (0.95)	2.0 (1.09)	0.3 (1.15)
Median	2.0	1.0	1.0	0.0	2.0	0.0	2.0	0.0	2.0	0.0
Min, Max	0, 4	-3, 3	0, 4	-2, 2	1, 4	-1, 2	1, 3	-2, 3	0, 4	-3, 3
OBS V8										
n	36	36	14	14	20	20	20	20	90	90
Mean (SD)	1.7 (0.81)	0.3 (0.81)	1.9 (1.10)	-0.1 (1.07)	2.0 (1.19)	0.2 (0.89)	1.5 (0.60)	-0.1 (0.51)	1.7 (0.92)	0.1 (0.82)

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OBS Visit Statistic	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67) Observed	Change from OBS V1	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52) Observed	Change from OBS V1	0.02% STN1013900 + 0.005% Latanoprost (N=44) Observed	Change from OBS V1	0.02% STN1013900 + 0.5% Timolol (N=52) Observed	Change from OBS V1	All Subjects (N=215) Observed	Change from OBS V1
Median	2.0	0.0	2.0	0.0	1.5	0.0	1.0	0.0	2.0	0.0
Min, Max	0, 3	-1, 2	0, 4	-2, 1	0, 4	-1, 2	1, 3	-1, 1	0, 4	-2, 2
OBS V9										
n	28	28	10	10	18	18	16	16	72	72
Mean (SD)	1.6 (0.79)	0.0 (1.00)	1.6 (0.52)	-0.7 (1.16)	1.1 (0.58)	-0.6 (0.78)	1.0 (0.52)	-0.6 (0.50)	1.3 (0.69)	-0.4 (0.93)
Median	2.0	0.0	2.0	-1.0	1.0	0.0	1.0	-1.0	1.0	0.0
Min, Max	0, 3	-2, 2	1, 2	-2, 1	0, 2	-2, 0	0, 2	-1, 0	0, 3	-2, 2
OBS V10										
n	22	22	6	6	8	8	6	6	42	42
Mean (SD)	1.4 (0.66)	-0.2 (1.15)	1.7 (0.52)	-0.2 (1.17)	0.9 (0.35)	-1.3 (0.89)	0.8 (0.41)	-1.3 (0.52)	1.2 (0.62)	-0.6 (1.13)
Median	1.0	-0.5	2.0	0.0	1.0	-1.0	1.0	-1.0	1.0	-1.0
Min, Max	0, 3	-2, 2	1, 2	-2, 1	0, 1	-3, 0	0, 1	-2, -1	0, 3	-3, 2
OBS V11										
n	16	16	6	6	6	6	2	2	30	30
Mean (SD)	1.4 (0.72)	-0.4 (1.26)	1.3 (0.52)	-0.5 (0.84)	0.8 (0.41)	-1.5 (0.84)	1.0 (0.00)	-1.0 (0.00)	1.2 (0.63)	-0.7 (1.12)
Median	1.5	-0.5	1.0	0.0	1.0	-1.0	1.0	-1.0	1.0	-1.0
Min, Max	0, 2	-3, 2	1, 2	-2, 0	0, 1	-3, -1	1, 1	-1, -1	0, 2	-3, 2
OBS V12										
n	6	6	2	2	2	2			10	10
Mean (SD)	1.5 (0.84)	-1.0 (1.67)	2.0 (0.00)	0.0 (0.00)	0.5 (0.71)	-1.5 (0.71)			1.4 (0.84)	-0.9 (1.37)
Median	2.0	-1.5	2.0	0.0	0.5	-1.5			2.0	-1.0
Min, Max	0, 2	-3, 1	2, 2	0, 0	0, 1	-2, -1			0, 2	-3, 1
OBS V13										
n	6	6							6	6
Mean (SD)	1.2 (0.75)	-1.3 (1.21)							1.2 (0.75)	-1.3 (1.21)
Median	1.0	-1.5							1.0	-1.5
Min, Max	0, 2	-3, 0							0, 2	-3, 0
OBS Final										
n	67	67	52	52	44	44	52	52	215	215
Mean (SD)	0.2 (0.51)	-1.4 (0.92)	0.3 (0.68)	-1.3 (0.93)	0.4 (0.54)	-1.3 (0.93)	0.4 (0.69)	-1.1 (1.08)	0.3 (0.61)	-1.3 (0.96)
Median	0.0	-1.0	0.0	-1.0	0.0	-1.0	0.0	-1.0	0.0	-1.0
Min, Max	0, 2	-3, 0	0, 2	-3, 1	0, 2	-3, 1	0, 2	-3, 2	0, 2	-3, 2

Abbreviations: OBS = Observational Study; N/A = Not Applicable.

Note: N in the headers represents the total number of eyes with Cornea Verticillata in each treatment group for the population being analyzed. Percentages are based on the number of eyes (m) in a given treatment group with non-missing values in the population being analyzed.

Source : 添付資料 5.3.5.2-1 Table 14.3.4.5.1

Confidential

表 2.7.4.7-14. 101390002LT:「渦巻き角膜 (Cornea verticillata) 」の視軸への関与の有無

OBS Visit	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)	0.02% STN1013900 + 0.005% Latanoprost (N=44)	0.02% STN1013900 + 0.5% Timolol (N=52)	All Subjects (N=215)
OBS V1					
m	67	52	44	52	215
No	44 (65.7%)	41 (78.8%)	34 (77.3%)	41 (78.8%)	160 (74.4%)
Yes	23 (34.3%)	11 (21.2%)	10 (22.7%)	11 (21.2%)	55 (25.6%)
OBS V2					
m	66	52	44	50	212
No	34 (51.5%)	33 (63.5%)	35 (79.5%)	37 (74.0%)	139 (65.6%)
Yes	32 (48.5%)	19 (36.5%)	9 (20.5%)	13 (26.0%)	73 (34.4%)
OBS V3					
m	66	52	43	46	207
No	29 (43.9%)	33 (63.5%)	29 (67.4%)	34 (73.9%)	125 (60.4%)
Yes	37 (56.1%)	19 (36.5%)	14 (32.6%)	12 (26.1%)	82 (39.6%)
OBS V4					
m	64	50	41	46	201
No	29 (45.3%)	30 (60.0%)	29 (70.7%)	33 (71.7%)	121 (60.2%)
Yes	35 (54.7%)	20 (40.0%)	12 (29.3%)	13 (28.3%)	80 (39.8%)
OBS V5					
m	60	46	37	38	181
No	30 (50.0%)	25 (54.3%)	23 (62.2%)	22 (57.9%)	100 (55.2%)
Yes	30 (50.0%)	21 (45.7%)	14 (37.8%)	16 (42.1%)	81 (44.8%)
OBS V6					
m	46	40	32	34	152
No	19 (41.3%)	23 (57.5%)	20 (62.5%)	19 (55.9%)	81 (53.3%)
Yes	27 (58.7%)	17 (42.5%)	12 (37.5%)	15 (44.1%)	71 (46.7%)
OBS V7					
m	38	28	26	28	120
No	20 (52.6%)	16 (57.1%)	16 (61.5%)	16 (57.1%)	68 (56.7%)
Yes	18 (47.4%)	12 (42.9%)	10 (38.5%)	12 (42.9%)	52 (43.3%)
OBS V8					
m	36	14	20	20	90
No	22 (61.1%)	8 (57.1%)	12 (60.0%)	19 (95.0%)	61 (67.8%)
Yes	14 (38.9%)	6 (42.9%)	8 (40.0%)	1 (5.0%)	29 (32.2%)
OBS V9					
m	28	10	18	16	72
No	16 (57.1%)	6 (60.0%)	16 (88.9%)	15 (93.8%)	53 (73.6%)
Yes	12 (42.9%)	4 (40.0%)	2 (11.1%)	1 (6.3%)	19 (26.4%)
OBS V10					
m	22	6	8	6	42
No	13 (59.1%)	4 (66.7%)	8 (100.0%)	5 (83.3%)	30 (71.4%)
Yes	9 (40.9%)	2 (33.3%)	0	1 (16.7%)	12 (28.6%)
OBS V11					
m	16	6	6	2	30
No	9 (56.3%)	4 (66.7%)	6 (100.0%)	2 (100.0%)	21 (70.0%)
Yes	7 (43.8%)	2 (33.3%)	0	0	9 (30.0%)
OBS V12					
m	6	2	2	0	10
No	2 (33.3%)	0	2 (100.0%)	0	4 (40.0%)
Yes	4 (66.7%)	2 (100.0%)	0	0	6 (60.0%)

OBS Visit	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)	0.02% STN1013900 + 0.005% Latanoprost (N=44)	0.02% STN1013900 + 0.5% Timolol (N=52)	All Subjects (N=215)
OBS V13					
m	6	0	0	0	6
No	2 (33.3%)	0	0	0	2 (33.3%)
Yes	4 (66.7%)	0	0	0	4 (66.7%)
OBS Final					
m	67	52	44	52	215
No	60 (89.6%)	45 (86.5%)	42 (95.5%)	48 (92.3%)	195 (90.7%)
Yes	7 (10.4%)	7 (13.5%)	2 (4.5%)	4 (7.7%)	20 (9.3%)

Abbreviations: OBS = Observational Study.

Note: N in the headers represents the total number of eyes with Cornea Verticillata in each treatment group for the population being analyzed. Percentages are based on the number of eyes (m) in a given treatment group with non-missing values in the population being analyzed.

Source : 添付資料 5.3.5.2-1 Table 14.3.4.5.4

Confidential

表 2.7.4.7-15. 101390002LT:「渦巻き角膜 (Cornea verticillata) 」の深さ

OBS Visit Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)	0.02% STN1013900 + 0.005% Latanoprost (N=44)	0.02% STN1013900 + 0.5% Timolol (N=52)	All Subjects (N=215)
OBS V1					
m	67	52	44	52	215
Epithelium	61 (91.0%)	47 (90.4%)	43 (97.7%)	46 (88.5%)	197 (91.6%)
Superficial stroma	0	2 (3.8%)	0	2 (3.8%)	4 (1.9%)
Epithelium, Superficial stroma	0	2 (3.8%)	0	2 (3.8%)	4 (1.9%)
OBS V2					
m	66	52	44	50	212
Epithelium	62 (93.9%)	48 (92.3%)	42 (95.5%)	45 (90.0%)	197 (92.9%)
Superficial stroma	0	2 (3.8%)	0	2 (4.0%)	4 (1.9%)
Epithelium, Superficial stroma	2 (3.0%)	2 (3.8%)	2 (4.5%)	3 (6.0%)	9 (4.2%)
OBS V3					
m	66	52	43	46	207
Epithelium	62 (93.9%)	48 (92.3%)	39 (90.7%)	41 (89.1%)	190 (91.8%)
Superficial stroma	0	2 (3.8%)	0	2 (4.3%)	4 (1.9%)
Epithelium, Superficial stroma	2 (3.0%)	2 (3.8%)	4 (9.3%)	3 (6.5%)	11 (5.3%)
OBS V4					
m	64	50	41	46	201
Epithelium	61 (95.3%)	45 (90.0%)	37 (90.2%)	41 (89.1%)	184 (91.5%)
Superficial stroma	0	2 (4.0%)	0	2 (4.3%)	4 (2.0%)
Epithelium, Superficial stroma	2 (3.1%)	2 (4.0%)	4 (9.8%)	3 (6.5%)	11 (5.5%)
OBS V5					
m	60	46	37	38	181
Epithelium	54 (90.0%)	42 (91.3%)	34 (91.9%)	36 (94.7%)	166 (91.7%)
Superficial stroma	1 (1.7%)	2 (4.3%)	0	0	3 (1.7%)
Epithelium, Superficial stroma	2 (3.3%)	0	2 (5.4%)	2 (5.3%)	6 (3.3%)
OBS V6					
m	46	40	32	34	152
Epithelium	39 (84.8%)	34 (85.0%)	28 (87.5%)	30 (88.2%)	131 (86.2%)
Superficial stroma	0	2 (5.0%)	0	0	2 (1.3%)
Epithelium, Superficial stroma	4 (8.7%)	0	2 (6.3%)	2 (5.9%)	8 (5.3%)
OBS V7					
m	38	28	26	28	120
Epithelium	32 (84.2%)	23 (82.1%)	25 (96.2%)	26 (92.9%)	106 (88.3%)
Superficial stroma	0	2 (7.1%)	0	0	2 (1.7%)
Epithelium, Superficial stroma	4 (10.5%)	0	1 (3.8%)	2 (7.1%)	7 (5.8%)
OBS V8					
m	36	14	20	20	90
Epithelium	33 (91.7%)	13 (92.9%)	18 (90.0%)	20 (100.0%)	84 (93.3%)
Epithelium, Superficial stroma	2 (5.6%)	0	1 (5.0%)	0	3 (3.3%)
OBS V9					
m	28	10	18	16	72
Epithelium	26 (92.9%)	10 (100.0%)	15 (83.3%)	14 (87.5%)	65 (90.3%)

OBS Visit Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)	0.02% STN1013900 + 0.005% Latanoprost (N=44)	0.02% STN1013900 + 0.5% Timolol (N=52)	All Subjects (N=215)
Epithelium, Superficial stroma	0	0	1 (5.6%)	0	1 (1.4%)
OBS V10					
m	22	6	8	6	42
Epithelium	19 (86.4%)	6 (100.0%)	7 (87.5%)	5 (83.3%)	37 (88.1%)
Epithelium, Superficial stroma	2 (9.1%)	0	0	0	2 (4.8%)
OBS V11					
m	16	6	6	2	30
Epithelium	12 (75.0%)	6 (100.0%)	5 (83.3%)	2 (100.0%)	25 (83.3%)
Epithelium, Superficial stroma	2 (12.5%)	0	0	0	2 (6.7%)
OBS V12					
m	6	2	2	0	10
Epithelium	5 (83.3%)	2 (100.0%)	1 (50.0%)	0	8 (80.0%)
OBS V13					
m	6	0	0	0	6
Epithelium	5 (83.3%)	0	0	0	5 (83.3%)
OBS Final					
m	67	52	44	52	215
Epithelium	9 (13.4%)	12 (23.1%)	16 (36.4%)	14 (26.9%)	51 (23.7%)
Epithelium, Superficial stroma	2 (3.0%)	0	0	0	2 (0.9%)

Abbreviations: OBS = Observational Study.

Note: N in the headers represents the total number of eyes with Cornea Verticillata in each treatment group for the population being analyzed. Percentages are based on the number of eyes (m) in a given treatment group with non-missing values in the population being analyzed.

Source : 添付資料 5.3.5.2-1 Table 14.3.4.6.1

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表 2.7.4.7-16. 101390002LT:「渦巻き角膜 (Cornea verticillata) 」の幅

OBS Visit Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)	0.02% STN1013900 + 0.005% Latanoprost (N=44)	0.02% STN1013900 + 0.5% Timolol (N=52)	All Subjects (N=215)
OBS V1					
m	67	52	44	52	215
Central	7 (10.4%)	5 (9.6%)	2 (4.5%)	3 (5.8%)	17 (7.9%)
Mid-peripheral	32 (47.8%)	26 (50.0%)	14 (31.8%)	24 (46.2%)	96 (44.7%)
Peripheral	2 (3.0%)	4 (7.7%)	2 (4.5%)	3 (5.8%)	11 (5.1%)
Central, Mid-peripheral	7 (10.4%)	10 (19.2%)	8 (18.2%)	7 (13.5%)	32 (14.9%)
Mid-peripheral, Peripheral	3 (4.5%)	4 (7.7%)	9 (20.5%)	7 (13.5%)	23 (10.7%)
Central, Mid-peripheral, Peripheral	10 (14.9%)	2 (3.8%)	8 (18.2%)	6 (11.5%)	26 (12.1%)
OBS V2					
m	66	52	44	50	212
Central	9 (13.6%)	3 (5.8%)	2 (4.5%)	2 (4.0%)	16 (7.5%)
Mid-peripheral	25 (37.9%)	21 (40.4%)	18 (40.9%)	21 (42.0%)	85 (40.1%)
Peripheral	3 (4.5%)	5 (9.6%)	2 (4.5%)	2 (4.0%)	12 (5.7%)
Central, Mid-peripheral	9 (13.6%)	6 (11.5%)	5 (11.4%)	9 (18.0%)	29 (13.7%)
Mid-peripheral, Peripheral	1 (1.5%)	7 (13.5%)	9 (20.5%)	10 (20.0%)	27 (12.7%)
Central, Mid-peripheral, Peripheral	17 (25.8%)	10 (19.2%)	8 (18.2%)	6 (12.0%)	41 (19.3%)
OBS V3					
m	66	52	43	46	207
Central	7 (10.6%)	2 (3.8%)	0	4 (8.7%)	13 (6.3%)
Mid-peripheral	20 (30.3%)	22 (42.3%)	15 (34.9%)	17 (37.0%)	74 (35.7%)
Peripheral	3 (4.5%)	4 (7.7%)	3 (7.0%)	2 (4.3%)	12 (5.8%)
Central, Mid-peripheral	10 (15.2%)	6 (11.5%)	7 (16.3%)	6 (13.0%)	29 (14.0%)
Mid-peripheral, Peripheral	2 (3.0%)	8 (15.4%)	7 (16.3%)	11 (23.9%)	28 (13.5%)
OBS V3					
Central, Mid-peripheral, Peripheral	22 (33.3%)	10 (19.2%)	11 (25.6%)	6 (13.0%)	49 (23.7%)
OBS V4					
m	64	50	41	46	201
Central	7 (10.9%)	4 (8.0%)	0	2 (4.3%)	13 (6.5%)
Mid-peripheral	18 (28.1%)	18 (36.0%)	18 (43.9%)	15 (32.6%)	69 (34.3%)
Peripheral	4 (6.3%)	6 (12.0%)	2 (4.9%)	7 (15.2%)	19 (9.5%)
Central, Mid-peripheral	8 (12.5%)	7 (14.0%)	6 (14.6%)	8 (17.4%)	29 (14.4%)
Mid-peripheral, Peripheral	2 (3.1%)	4 (8.0%)	5 (12.2%)	7 (15.2%)	18 (9.0%)
Central, Mid-peripheral, Peripheral	24 (37.5%)	10 (20.0%)	10 (24.4%)	7 (15.2%)	51 (25.4%)
OBS V5					
m	60	46	37	38	181
Central	5 (8.3%)	4 (8.7%)	0	5 (13.2%)	14 (7.7%)
Mid-peripheral	14 (23.3%)	16 (34.8%)	15 (40.5%)	11 (28.9%)	56 (30.9%)
Peripheral	5 (8.3%)	4 (8.7%)	0	3 (7.9%)	12 (6.6%)
Central, Mid-peripheral	7 (11.7%)	8 (17.4%)	6 (16.2%)	5 (13.2%)	26 (14.4%)
Mid-peripheral, Peripheral	5 (8.3%)	3 (6.5%)	7 (18.9%)	2 (5.3%)	17 (9.4%)
Central, Mid-peripheral, Peripheral	21 (35.0%)	9 (19.6%)	8 (21.6%)	12 (31.6%)	50 (27.6%)
OBS V6					
m	46	40	32	34	152
Central	5 (10.9%)	2 (5.0%)	0	4 (11.8%)	11 (7.2%)
Mid-peripheral	8 (17.4%)	10 (25.0%)	13 (40.6%)	11 (32.4%)	42 (27.6%)

OBS Visit Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)	0.02% STN1013900 + 0.005% Latanoprost (N=44)	0.02% STN1013900 + 0.5% Timolol (N=52)	All Subjects (N=215)
Peripheral	3 (6.5%)	3 (7.5%)	0	0	6 (3.9%)
Central, Mid-peripheral	6 (13.0%)	9 (22.5%)	5 (15.6%)	4 (11.8%)	24 (15.8%)
OBS V6					
Mid-peripheral, Peripheral	4 (8.7%)	5 (12.5%)	4 (12.5%)	1 (2.9%)	14 (9.2%)
Central, Mid-peripheral, Peripheral	17 (37.0%)	7 (17.5%)	8 (25.0%)	12 (35.3%)	44 (28.9%)
OBS V7					
m	38	28	26	28	120
Central	6 (15.8%)	2 (7.1%)	2 (7.7%)	4 (14.3%)	14 (11.7%)
Mid-peripheral	6 (15.8%)	6 (21.4%)	14 (53.8%)	9 (32.1%)	35 (29.2%)
Peripheral	3 (7.9%)	4 (14.3%)	0	0	7 (5.8%)
Central, Mid-peripheral	4 (10.5%)	8 (28.6%)	0	4 (14.3%)	16 (13.3%)
Mid-peripheral, Peripheral	4 (10.5%)	1 (3.6%)	0	1 (3.6%)	6 (5.0%)
Central, Mid-peripheral, Peripheral	13 (34.2%)	4 (14.3%)	10 (38.5%)	10 (35.7%)	37 (30.8%)
OBS V8					
m	36	14	20	20	90
Central	6 (16.7%)	2 (14.3%)	2 (10.0%)	2 (10.0%)	12 (13.3%)
Mid-peripheral	7 (19.4%)	3 (21.4%)	9 (45.0%)	11 (55.0%)	30 (33.3%)
Peripheral	2 (5.6%)	2 (14.3%)	0	1 (5.0%)	5 (5.6%)
Central, Mid-peripheral	4 (11.1%)	2 (14.3%)	0	4 (20.0%)	10 (11.1%)
Mid-peripheral, Peripheral	4 (11.1%)	0	0	1 (5.0%)	5 (5.6%)
Central, Mid-peripheral, Peripheral	12 (33.3%)	4 (28.6%)	8 (40.0%)	1 (5.0%)	25 (27.8%)
OBS V9					
m	28	10	18	16	72
Central	2 (7.1%)	2 (20.0%)	2 (11.1%)	1 (6.3%)	7 (9.7%)
Mid-peripheral	3 (10.7%)	2 (20.0%)	7 (38.9%)	8 (50.0%)	20 (27.8%)
Peripheral	2 (7.1%)	2 (20.0%)	0	2 (12.5%)	6 (8.3%)
OBS V9					
Central, Mid-peripheral	4 (14.3%)	0	3 (16.7%)	3 (18.8%)	10 (13.9%)
Mid-peripheral, Peripheral	4 (14.3%)	0	0	0	4 (5.6%)
Central, Mid-peripheral, Peripheral	11 (39.3%)	4 (40.0%)	4 (22.2%)	0	19 (26.4%)
OBS V10					
m	22	6	8	6	42
Mid-peripheral	5 (22.7%)	0	4 (50.0%)	3 (50.0%)	12 (28.6%)
Peripheral	4 (18.2%)	2 (33.3%)	0	1 (16.7%)	7 (16.7%)
Central, Mid-peripheral	4 (18.2%)	2 (33.3%)	3 (37.5%)	1 (16.7%)	10 (23.8%)
Mid-peripheral, Peripheral	1 (4.5%)	0	0	0	1 (2.4%)
Central, Mid-peripheral, Peripheral	7 (31.8%)	2 (33.3%)	0	0	9 (21.4%)
OBS V11					
m	16	6	6	2	30
Central	1 (6.3%)	0	1 (16.7%)	0	2 (6.7%)
Mid-peripheral	3 (18.8%)	0	2 (33.3%)	2 (100.0%)	7 (23.3%)
Peripheral	2 (12.5%)	2 (33.3%)	0	0	4 (13.3%)
Central, Mid-peripheral	2 (12.5%)	2 (33.3%)	2 (33.3%)	0	6 (20.0%)
Central, Mid-peripheral, Peripheral	6 (37.5%)	2 (33.3%)	0	0	8 (26.7%)
OBS V12					
m	6	2	2	0	10
Central	1 (16.7%)	0	0	0	1 (10.0%)

OBS Visit Parameter	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)	0.02% STN1013900 (22<=IOP<35 mmHg) (N=52)	0.02% STN1013900 + 0.005% Latanoprost (N=44)	0.02% STN1013900 + 0.5% Timolol (N=52)	All Subjects (N=215)
Mid-peripheral	1 (16.7%)	0	1 (50.0%)	0	2 (20.0%)
Central, Mid-peripheral	2 (33.3%)	0	0	0	2 (20.0%)
Central, Mid-peripheral, Peripheral	1 (16.7%)	2 (100.0%)	0	0	3 (30.0%)
OBS V13					
m	6	0	0	0	6
Central	1 (16.7%)	0	0	0	1 (16.7%)
Mid-peripheral	1 (16.7%)	0	0	0	1 (16.7%)
Central, Mid-peripheral	1 (16.7%)	0	0	0	1 (16.7%)
Central, Mid-peripheral, Peripheral	2 (33.3%)	0	0	0	2 (33.3%)
OBS Final					
m	67	52	44	52	215
Central	1 (1.5%)	1 (1.9%)	2 (4.5%)	0	4 (1.9%)
Mid-peripheral	2 (3.0%)	1 (1.9%)	9 (20.5%)	8 (15.4%)	20 (9.3%)
Peripheral	2 (3.0%)	0	1 (2.3%)	1 (1.9%)	4 (1.9%)
Central, Mid-peripheral	2 (3.0%)	2 (3.8%)	0	0	4 (1.9%)
Mid-peripheral, Peripheral	0	2 (3.8%)	2 (4.5%)	1 (1.9%)	5 (2.3%)
Central, Mid-peripheral, Peripheral	4 (6.0%)	6 (11.5%)	2 (4.5%)	4 (7.7%)	16 (7.4%)

Abbreviations: OBS = Observational Study.

Note: N in the headers represents the total number of eyes with Cornea Verticillata in each treatment group for the population being analyzed. Percentages are based on the number of eyes (m) in a given treatment group with non-missing values in the population being analyzed.

Source : 添付資料 5.3.5.2-1 Table 14.3.4.6.2

表 2.7.4.7-17. 101390002LT:「アレルギー及び炎症関連の眼障害」に関連した投与群別の TEAE の発現割合

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)	0.02% STN1013900 (22<=IOP<35 mmHg) (N=62)	0.02% STN1013900 + 0.005% Latanoprost (N=65)	0.02% STN1013900 + 0.5% Timolol (N=66)	All Subjects (N=260)
Number of Subjects with Any TEAE	43 (64.2%)	38 (61.3%)	22 (33.8%)	22 (33.3%)	125 (48.1%)
EYE DISORDERS	40 (59.7%)	36 (58.1%)	22 (33.8%)	20 (30.3%)	118 (45.4%)
Blepharitis	5 (7.5%)	9 (14.5%)	1 (1.5%)	2 (3.0%)	17 (6.5%)
Blepharitis allergic	2 (3.0%)	1 (1.6%)	2 (3.1%)	1 (1.5%)	6 (2.3%)
Conjunctival oedema	1 (1.5%)	1 (1.6%)	0	0	2 (0.8%)
Conjunctivitis allergic	28 (41.8%)	20 (32.3%)	16 (24.6%)	11 (16.7%)	75 (28.8%)
Eczema eyelids	1 (1.5%)	1 (1.6%)	4 (6.2%)	1 (1.5%)	7 (2.7%)
Erythema of eyelid	0	0	0	1 (1.5%)	1 (0.4%)
Eye pruritus	5 (7.5%)	5 (8.1%)	2 (3.1%)	4 (6.1%)	16 (6.2%)
Eyelids pruritus	1 (1.5%)	3 (4.8%)	0	2 (3.0%)	6 (2.3%)
Keratitis	1 (1.5%)	0	1 (1.5%)	0	2 (0.8%)
Punctate keratitis	5 (7.5%)	3 (4.8%)	3 (4.6%)	3 (4.5%)	14 (5.4%)
INFECTIONS AND INFESTATIONS	4 (6.0%)	3 (4.8%)	0	2 (3.0%)	9 (3.5%)
Conjunctivitis	4 (6.0%)	3 (4.8%)	0	2 (3.0%)	9 (3.5%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (1.5%)	0	0	1 (1.5%)	2 (0.8%)
Dermatitis contact	1 (1.5%)	0	0	1 (1.5%)	2 (0.8%)

Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Percentages are based on N in each treatment group unless otherwise noted. Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 27.1. Subjects experiencing more than one TEAE within a given SOC or PT are counted once within that SOC or PT. SOCs and PTs within SOCs are listed in alphabetical order.
Source : 添付資料 5.3.5.2-1 Table 14.3.1.5.1

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表 2.7.4.7-18. 101390002LT:「アレルギー及び炎症関連の眼障害」に関連した投与群別の中止に至った TEAE の発現割合

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)	0.02% STN1013900 (22<=IOP<35 mmHg) (N=62)	0.02% STN1013900 + 0.005% Latanoprost (N=65)	0.02% STN1013900 + 0.5% Timolol (N=66)	All Subjects (N=260)
Number of Subjects with Any TEAE	15 (22.4%)	15 (24.2%)	13 (20.0%)	6 (9.1%)	49 (18.8%)
EYE DISORDERS	15 (22.4%)	14 (22.6%)	13 (20.0%)	6 (9.1%)	48 (18.5%)
Blepharitis	2 (3.0%)	2 (3.2%)	0	0	4 (1.5%)
Blepharitis allergic	1 (1.5%)	1 (1.6%)	1 (1.5%)	1 (1.5%)	4 (1.5%)
Conjunctival oedema	0	1 (1.6%)	0	0	1 (0.4%)
Conjunctivitis allergic	14 (20.9%)	10 (16.1%)	13 (20.0%)	5 (7.6%)	42 (16.2%)
Eye pruritus	0	0	1 (1.5%)	1 (1.5%)	2 (0.8%)
Eyelids pruritus	0	1 (1.6%)	0	0	1 (0.4%)
INFECTIONS AND INFESTATIONS	0	1 (1.6%)	0	0	1 (0.4%)
Conjunctivitis	0	1 (1.6%)	0	0	1 (0.4%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (1.5%)	0	0	0	1 (0.4%)
Dermatitis contact	1 (1.5%)	0	0	0	1 (0.4%)

An event reported on the AE eCRF was considered as a TEAE except for "Cornea Verticillata" if the date of onset of the event was on or after the treatment start date up to and including 30 days after the treatment end date.
Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Percentages are based on N in each treatment group unless otherwise noted. Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 27.1. Subjects experiencing more than one TEAE within a given SOC or PT are counted once within that SOC or PT. SOCs and PTs within SOCs are listed in alphabetical order.
Source : 添付資料 5.3.5.2-1 Table 14.3.1.5.3

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表 2.7.4.7-19. 101390002LT:「アレルギー及び炎症関連の眼障害」に関連した投与群別の因果関係が否定できない TEAE

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (15<=IOP<22 mmHg) (N=67)	0.02% STN1013900 (22<=IOP<35 mmHg) (N=62)	0.02% STN1013900 + 0.005% Latanoprost (N=65)	0.02% STN1013900 + 0.5% Timolol (N=66)	All Subjects (N=260)
Number of Subjects with Any TEAE	37 (55.2%)	30 (48.4%)	18 (27.7%)	19 (28.8%)	104 (40.0%)
EYE DISORDERS	35 (52.2%)	28 (45.2%)	18 (27.7%)	18 (27.3%)	99 (38.1%)
Blepharitis	5 (7.5%)	5 (8.1%)	1 (1.5%)	0	11 (4.2%)
Blepharitis allergic	2 (3.0%)	1 (1.6%)	2 (3.1%)	1 (1.5%)	6 (2.3%)
Conjunctival oedema	0	1 (1.6%)	0	0	1 (0.4%)
Conjunctivitis allergic	27 (40.3%)	16 (25.8%)	13 (20.0%)	9 (13.6%)	65 (25.0%)
Eczema eyelids	0	1 (1.6%)	2 (3.1%)	1 (1.5%)	4 (1.5%)
Erythema of eyelid	0	0	0	1 (1.5%)	1 (0.4%)
Eye pruritus	4 (6.0%)	5 (8.1%)	2 (3.1%)	4 (6.1%)	15 (5.8%)
Eyelids pruritus	1 (1.5%)	3 (4.8%)	0	2 (3.0%)	6 (2.3%)
Keratitis	1 (1.5%)	0	1 (1.5%)	0	2 (0.8%)
Punctate keratitis	2 (3.0%)	2 (3.2%)	1 (1.5%)	3 (4.5%)	8 (3.1%)
INFECTIONS AND INFESTATIONS	3 (4.5%)	2 (3.2%)	0	2 (3.0%)	7 (2.7%)
Conjunctivitis	3 (4.5%)	2 (3.2%)	0	2 (3.0%)	7 (2.7%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (1.5%)	0	0	0	1 (0.4%)
Dermatitis contact	1 (1.5%)	0	0	0	1 (0.4%)

Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Percentages are based on N in each treatment group unless otherwise noted. Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 27.1. Subjects experiencing more than one TEAE within a given SOC or PT are counted once within that SOC or PT. SOCs and PTs within SOCs are listed in alphabetical order.
Treatment-related includes "Possibly Related" and "Related" TEAEs.
Source : 添付資料 5.3.5.2-1 Table 14.3.1.5.2

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表 2.7.4.7-20. 併合解析 2: 男女別の有害事象一覧（男性）

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=128)	0.02% STN1013900 + 0.005% Latanoprost (N=80)	0.02% STN1013900 + 0.5% Timolol (N=29)
Number of Subjects with Any TEAE	89 (69.5%)	54 (67.5%)	26 (89.7%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.8%)	0	0
Iron deficiency anaemia	1 (0.8%)	0	0
CARDIAC DISORDERS	2 (1.6%)	0	0
Cardiac failure congestive	1 (0.8%)	0	0
Palpitations	1 (0.8%)	0	0
EAR AND LABYRINTH DISORDERS	0	1 (1.3%)	1 (3.4%)
Sudden hearing loss	0	1 (1.3%)	1 (3.4%)
EYE DISORDERS	86 (67.2%)	50 (62.5%)	26 (89.7%)
Abnormal sensation in eye	1 (0.8%)	0	0
Accommodation disorder	1 (0.8%)	0	0
Anterior chamber inflammation	1 (0.8%)	0	0
Asthenopia	1 (0.8%)	1 (1.3%)	0
Blepharitis	6 (4.7%)	1 (1.3%)	1 (3.4%)
Blepharitis allergic	0	1 (1.3%)	0
Cataract	1 (0.8%)	1 (1.3%)	0
Conjunctival deposit	0	0	1 (3.4%)
Conjunctival haemorrhage	10 (7.8%)	3 (3.8%)	3 (10.3%)
Conjunctival hyperaemia	57 (44.5%)	36 (45.0%)	20 (69.0%)
Conjunctival oedema	1 (0.8%)	0	0
Conjunctivitis allergic	18 (14.1%)	9 (11.3%)	4 (13.8%)
Cornea verticillata	26 (20.3%)	15 (18.8%)	13 (44.8%)
Corneal degeneration	1 (0.8%)	0	0
Corneal disorder	0	0	1 (3.4%)
Corneal erosion	1 (0.8%)	0	1 (3.4%)
Corneal opacity	1 (0.8%)	1 (1.3%)	0
Diabetic retinopathy	1 (0.8%)	0	0
Dry eye	2 (1.6%)	1 (1.3%)	1 (3.4%)
Eczema eyelids	1 (0.8%)	3 (3.8%)	0
Eye discharge	1 (0.8%)	0	0
Eye irritation	9 (7.0%)	3 (3.8%)	3 (10.3%)
Eye pain	1 (0.8%)	0	2 (6.9%)
Eye pruritus	4 (3.1%)	2 (2.5%)	1 (3.4%)
Eyelids pruritus	2 (1.6%)	0	2 (6.9%)
Lacrimation increased	3 (2.3%)	2 (2.5%)	1 (3.4%)
Loss of visual contrast sensitivity	0	1 (1.3%)	0
Meibomianitis	1 (0.8%)	0	0
Ocular discomfort	1 (0.8%)	0	0
Optic disc haemorrhage	0	1 (1.3%)	0
Punctate keratitis	2 (1.6%)	2 (2.5%)	1 (3.4%)
Ulcerative keratitis	0	1 (1.3%)	0
Vision blurred	5 (3.9%)	6 (7.5%)	4 (13.8%)
Visual acuity reduced	3 (2.3%)	3 (3.8%)	2 (6.9%)
Visual field defect	0	1 (1.3%)	0
GASTROINTESTINAL DISORDERS	3 (2.3%)	3 (3.8%)	1 (3.4%)
Abdominal discomfort	0	1 (1.3%)	0
Abdominal distension	0	1 (1.3%)	0
Dental caries	1 (0.8%)	1 (1.3%)	0
Enterocele	1 (0.8%)	0	0
Faeces soft	0	0	1 (3.4%)
Nausea	1 (0.8%)	0	0
Periodontal disease	1 (0.8%)	0	0
Stomatitis	1 (0.8%)	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	5 (3.9%)	1 (1.3%)	2 (6.9%)
Instillation site discomfort	0	0	1 (3.4%)
Instillation site irritation	1 (0.8%)	0	0
Instillation site pain	2 (1.6%)	0	1 (3.4%)
Pyrexia	2 (1.6%)	1 (1.3%)	0
IMMUNE SYSTEM DISORDERS	1 (0.8%)	0	0
Seasonal allergy	1 (0.8%)	0	0
INFECTIONS AND INFESTATIONS	14 (10.9%)	6 (7.5%)	6 (20.7%)
COVID-19	2 (1.6%)	2 (2.5%)	1 (3.4%)
Chronic sinusitis	0	0	1 (3.4%)

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SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=128)	0.02% STN1013900 + 0.005% Latanoprost (N=80)	0.02% STN1013900 + 0.5% Timolol (N=29)
Conjunctivitis	4 (3.1%)	1 (1.3%)	2 (6.9%)
Conjunctivitis bacterial	1 (0.8%)	0	0
Coronavirus infection	1 (0.8%)	1 (1.3%)	0
Gastroenteritis	1 (0.8%)	0	0
Gingivitis	1 (0.8%)	0	0
Herpes zoster	1 (0.8%)	0	0
Hordeolum	1 (0.8%)	0	1 (3.4%)
Infected dermal cyst	1 (0.8%)	0	0
Nasopharyngitis	3 (2.3%)	2 (2.5%)	1 (3.4%)
Pneumonia aspiration	1 (0.8%)	0	0
Urinary tract infection	1 (0.8%)	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (1.6%)	3 (3.8%)	5 (17.2%)
Contusion	0	1 (1.3%)	0
Immunisation reaction	1 (0.8%)	2 (2.5%)	5 (17.2%)
Radius fracture	1 (0.8%)	0	0
Subdural haematoma	0	1 (1.3%)	0
Traumatic subarachnoid haemorrhage	0	1 (1.3%)	0
INVESTIGATIONS	3 (2.3%)	1 (1.3%)	0
Blood uric acid increased	1 (0.8%)	0	0
Intraocular pressure increased	2 (1.6%)	1 (1.3%)	0
METABOLISM AND NUTRITION DISORDERS	1 (0.8%)	0	1 (3.4%)
Diabetes mellitus	1 (0.8%)	0	0
Hyperuricaemia	0	0	1 (3.4%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (3.1%)	2 (2.5%)	0
Arthralgia	1 (0.8%)	1 (1.3%)	0
Back pain	1 (0.8%)	1 (1.3%)	0
Pain in extremity	1 (0.8%)	0	0
Periarthritis	1 (0.8%)	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.8%)	0	0
Skin papilloma	1 (0.8%)	0	0
NERVOUS SYSTEM DISORDERS	1 (0.8%)	0	1 (3.4%)
Burning sensation	0	0	1 (3.4%)
Headache	1 (0.8%)	0	0
PSYCHIATRIC DISORDERS	0	1 (1.3%)	0
Insomnia	0	1 (1.3%)	0
RENAL AND URINARY DISORDERS	1 (0.8%)	0	0
Proteinuria	1 (0.8%)	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (2.3%)	0	0
Dyspnoea	1 (0.8%)	0	0
Oropharyngeal pain	1 (0.8%)	0	0
Rhinitis allergic	1 (0.8%)	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.8%)	2 (2.5%)	1 (3.4%)
Dermal cyst	0	1 (1.3%)	0
Dermatitis	1 (0.8%)	1 (1.3%)	0
Dermatitis contact	0	0	1 (3.4%)

Abbreviations: TEAE = Treatment-Emergent Adverse Event

Studies: AR-13324-CS208 (0.02% STN1013900), AR-13324-CS305 (0.02% STN1013900), 101390001LT (0.02% STN1013900 + 0.005% Latanoprost) and 101390002LT (0.02% STN1013900 (Group 1 and 2), 0.02% STN1013900 + 0.005% Latanoprost, 0.02% STN1013900 + 0.5% Timolol)

Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Percentages are based on N in each treatment group unless otherwise noted. Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 27.1. Subjects experiencing more than one TEAE within a given SOC or PT are counted once within that SOC or PT. SOCs and PTs within SOCs are listed in alphabetical order.

Source: 添付資料 5.3.5.3-2 Table 4.2.1.1

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表 2.7.4.7-21. 併合解析 2: 男女別の有害事象一覧（女性）

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=177)	0.02% STN1013900 + 0.005% Latanoprost (N=107)	0.02% STN1013900 + 0.5% Timolol (N=37)
Number of Subjects with Any TEAE	136 (76.8%)	88 (82.2%)	34 (91.9%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	1 (0.9%)	0
Anaemia	0	1 (0.9%)	0
EAR AND LABYRINTH DISORDERS	1 (0.6%)	0	2 (5.4%)
Tinnitus	0	0	1 (2.7%)
Vertigo	1 (0.6%)	0	0
Vertigo positional	0	0	1 (2.7%)
EYE DISORDERS	130 (73.4%)	85 (79.4%)	31 (83.8%)
Abnormal sensation in eye	2 (1.1%)	1 (0.9%)	0
Amaurosis fugax	1 (0.6%)	0	0
Blepharitis	9 (5.1%)	2 (1.9%)	1 (2.7%)
Blepharitis allergic	3 (1.7%)	1 (0.9%)	1 (2.7%)
Cataract	1 (0.6%)	0	1 (2.7%)
Chalazion	0	1 (0.9%)	0
Ciliary hyperaemia	1 (0.6%)	0	0
Conjunctival cyst	0	1 (0.9%)	0
Conjunctival deposit	1 (0.6%)	0	0
Conjunctival follicles	1 (0.6%)	0	0
Conjunctival haemorrhage	28 (15.8%)	12 (11.2%)	8 (21.6%)
Conjunctival hyperaemia	109 (61.6%)	74 (69.2%)	19 (51.4%)
Conjunctival oedema	3 (1.7%)	0	0
Conjunctivitis allergic	31 (17.5%)	7 (6.5%)	7 (18.9%)
Cornea verticillata	36 (20.3%)	17 (15.9%)	14 (37.8%)
Corneal disorder	0	1 (0.9%)	0
Corneal erosion	0	0	1 (2.7%)
Corneal oedema	0	1 (0.9%)	1 (2.7%)
Corneal opacity	1 (0.6%)	1 (0.9%)	0
Dry eye	3 (1.7%)	1 (0.9%)	1 (2.7%)
Eczema eyelids	1 (0.6%)	1 (0.9%)	1 (2.7%)
Erythema of eyelid	0	1 (0.9%)	1 (2.7%)
Eye discharge	5 (2.8%)	3 (2.8%)	0
Eye irritation	14 (7.9%)	11 (10.3%)	5 (13.5%)
Eye pain	3 (1.7%)	2 (1.9%)	2 (5.4%)
Eye pruritus	8 (4.5%)	8 (7.5%)	3 (8.1%)
Eyelid myokymia	0	1 (0.9%)	0
Eyelid oedema	1 (0.6%)	0	0
Eyelids pruritus	2 (1.1%)	0	0
Foreign body sensation in eyes	0	3 (2.8%)	1 (2.7%)
Keratitis	1 (0.6%)	1 (0.9%)	0
Lacrimation increased	7 (4.0%)	1 (0.9%)	2 (5.4%)
Loss of visual contrast sensitivity	2 (1.1%)	0	2 (5.4%)
Meibomian gland dysfunction	1 (0.6%)	0	0
Ocular hyperaemia	0	2 (1.9%)	0
Photophobia	2 (1.1%)	1 (0.9%)	0
Presbyopia	0	0	1 (2.7%)
Punctate keratitis	8 (4.5%)	3 (2.8%)	2 (5.4%)
Retinal exudates	0	1 (0.9%)	0
Swelling of eyelid	1 (0.6%)	0	0
Trichiasis	1 (0.6%)	0	0
Uveitis	0	1 (0.9%)	1 (2.7%)
Vision blurred	12 (6.8%)	5 (4.7%)	2 (5.4%)
Visual acuity reduced	14 (7.9%)	3 (2.8%)	3 (8.1%)
Visual field defect	1 (0.6%)	1 (0.9%)	0
GASTROINTESTINAL DISORDERS	7 (4.0%)	2 (1.9%)	3 (8.1%)
Abdominal discomfort	2 (1.1%)	0	0
Abdominal pain	1 (0.6%)	0	0
Abdominal pain upper	0	0	1 (2.7%)
Constipation	0	0	1 (2.7%)
Dental caries	0	1 (0.9%)	0
Gastritis	1 (0.6%)	0	0
Irritable bowel syndrome	1 (0.6%)	0	0
Nausea	2 (1.1%)	1 (0.9%)	0
Noninfective gingivitis	0	0	1 (2.7%)

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SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=177)	0.02% STN1013900 + 0.005% Latanoprost (N=107)	0.02% STN1013900 + 0.5% Timolol (N=37)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	6 (3.4%)	4 (3.7%)	2 (5.4%)
Fatigue	0	1 (0.9%)	0
Injection site pain	1 (0.6%)	0	0
Instillation site pain	4 (2.3%)	0	1 (2.7%)
Pyrexia	1 (0.6%)	3 (2.8%)	1 (2.7%)
IMMUNE SYSTEM DISORDERS	2 (1.1%)	0	0
Seasonal allergy	2 (1.1%)	0	0
INFECTIONS AND INFESTATIONS	22 (12.4%)	5 (4.7%)	7 (18.9%)
Adenoviral conjunctivitis	2 (1.1%)	0	0
COVID-19	2 (1.1%)	1 (0.9%)	1 (2.7%)
Conjunctivitis	3 (1.7%)	0	0
Conjunctivitis bacterial	4 (2.3%)	0	0
Coronavirus infection	2 (1.1%)	1 (0.9%)	0
Cystitis	2 (1.1%)	0	1 (2.7%)
Helicobacter gastritis	1 (0.6%)	0	0
Hordeolum	1 (0.6%)	0	2 (5.4%)
Influenza	2 (1.1%)	0	0
Nasopharyngitis	6 (3.4%)	2 (1.9%)	1 (2.7%)
Otitis externa	1 (0.6%)	0	0
Purulence	1 (0.6%)	0	0
Sinusitis	0	0	1 (2.7%)
Tinea pedis	1 (0.6%)	0	1 (2.7%)
Urinary tract infection	0	1 (0.9%)	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	15 (8.5%)	5 (4.7%)	3 (8.1%)
Arthropod bite	1 (0.6%)	0	1 (2.7%)
Contusion	1 (0.6%)	0	0
Corneal abrasion	1 (0.6%)	0	0
Foot fracture	1 (0.6%)	0	0
Hand fracture	1 (0.6%)	0	0
Immunisation reaction	8 (4.5%)	3 (2.8%)	2 (5.4%)
Muscle strain	0	1 (0.9%)	0
Rib fracture	1 (0.6%)	0	0
Spinal compression fracture	0	0	1 (2.7%)
Thermal burn	0	1 (0.9%)	0
Tooth fracture	1 (0.6%)	0	0
INVESTIGATIONS	2 (1.1%)	1 (0.9%)	1 (2.7%)
Blood pressure increased	1 (0.6%)	0	0
Intraocular pressure increased	0	0	1 (2.7%)
White blood cell count increased	0	1 (0.9%)	0
White blood cells urine positive	1 (0.6%)	0	0
METABOLISM AND NUTRITION DISORDERS	0	1 (0.9%)	0
Diabetes mellitus	0	1 (0.9%)	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	8 (4.5%)	1 (0.9%)	3 (8.1%)
Arthralgia	1 (0.6%)	0	1 (2.7%)
Back pain	1 (0.6%)	1 (0.9%)	0
Intervertebral disc protrusion	1 (0.6%)	0	0
Neck pain	1 (0.6%)	0	0
Osteoarthritis	1 (0.6%)	0	1 (2.7%)
Osteoporosis	1 (0.6%)	0	1 (2.7%)
Spinal osteoarthritis	1 (0.6%)	0	0
Tenosynovitis	2 (1.1%)	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.6%)	1 (0.9%)	0
Lipoma	1 (0.6%)	0	0
Lymphoma	0	1 (0.9%)	0
NERVOUS SYSTEM DISORDERS	2 (1.1%)	0	3 (8.1%)
Dizziness	0	0	2 (5.4%)
Headache	1 (0.6%)	0	1 (2.7%)
Tension headache	1 (0.6%)	0	0
RENAL AND URINARY DISORDERS	1 (0.6%)	0	0
Urine abnormality	1 (0.6%)	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.6%)	1 (0.9%)	3 (8.1%)

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=177)	0.02% STN1013900 + 0.005% Latanoprost (N=107)	0.02% STN1013900 + 0.5% Timolol (N=37)
Cough	0	0	1 (2.7%)
Cough variant asthma	1 (0.6%)	1 (0.9%)	0
Oropharyngeal pain	0	0	1 (2.7%)
Rhinitis allergic	0	1 (0.9%)	1 (2.7%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (1.7%)	2 (1.9%)	3 (8.1%)
Alopecia areata	1 (0.6%)	0	0
Dermatitis contact	1 (0.6%)	0	0
Dry skin	1 (0.6%)	0	1 (2.7%)
Eczema	0	0	1 (2.7%)
Madarosis	1 (0.6%)	0	0
Pruritus	0	1 (0.9%)	0
Seborrhoeic dermatitis	0	0	1 (2.7%)
Skin fissures	0	0	1 (2.7%)
Urticaria	0	1 (0.9%)	0
VASCULAR DISORDERS	2 (1.1%)	0	0
Hyperaemia	1 (0.6%)	0	0
Lymphangiectasia	1 (0.6%)	0	0

Abbreviations: TEAE = Treatment-Emergent Adverse Event

Studies: AR-13324-CS208 (0.02% STN1013900), AR-13324-CS305 (0.02% STN1013900), 101390001LT (0.02% STN1013900 + 0.005% Latanoprost) and 101390002LT (0.02% STN1013900 (Group 1 and 2), 0.02% STN1013900 + 0.005% Latanoprost, 0.02% STN1013900 + 0.5% Timolol)

Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Percentages are based on N in each treatment group unless otherwise noted. Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 27.1. Subjects experiencing more than one TEAE within a given SOC or PT are counted once within that SOC or PT. SOCs and PTs within SOCs are listed in alphabetical order.

Source:添付資料 5.3.5.3-2 Table 4.2.1.2

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表 2.7.4.7-22. 併合解析 2: 男女別の副作用一覧（男性）

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=128)	0.02% STN1013900 + 0.005% Latanoprost (N=80)	0.02% STN1013900 + 0.5% Timolol (N=29)
Number of Subjects with Any TEAE	81 (63.3%)	47 (58.8%)	23 (79.3%)
EYE DISORDERS	81 (63.3%)	47 (58.8%)	22 (75.9%)
Accommodation disorder	1 (0.8%)	0	0
Anterior chamber inflammation	1 (0.8%)	0	0
Blepharitis	4 (3.1%)	1 (1.3%)	0
Blepharitis allergic	0	1 (1.3%)	0
Conjunctival haemorrhage	4 (3.1%)	2 (2.5%)	2 (6.9%)
Conjunctival hyperaemia	56 (43.8%)	36 (45.0%)	19 (65.5%)
Conjunctival oedema	1 (0.8%)	0	0
Conjunctivitis allergic	15 (11.7%)	7 (8.8%)	2 (6.9%)
Cornea verticillata	26 (20.3%)	15 (18.8%)	13 (44.8%)
Corneal disorder	0	0	1 (3.4%)
Corneal erosion	1 (0.8%)	0	1 (3.4%)
Corneal opacity	1 (0.8%)	0	0
Dry eye	2 (1.6%)	1 (1.3%)	0
Eczema eyelids	0	2 (2.5%)	0
Eye irritation	9 (7.0%)	3 (3.8%)	3 (10.3%)
Eye pain	1 (0.8%)	0	2 (6.9%)
Eye pruritus	3 (2.3%)	2 (2.5%)	1 (3.4%)
Eyelids pruritus	2 (1.6%)	0	2 (6.9%)
Lacrimation increased	3 (2.3%)	2 (2.5%)	1 (3.4%)
Loss of visual contrast sensitivity	0	1 (1.3%)	0
Punctate keratitis	1 (0.8%)	0	1 (3.4%)
Vision blurred	3 (2.3%)	5 (6.3%)	4 (13.8%)
Visual acuity reduced	2 (1.6%)	2 (2.5%)	2 (6.9%)
GASTROINTESTINAL DISORDERS	1 (0.8%)	0	0
Nausea	1 (0.8%)	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (2.3%)	0	2 (6.9%)
Instillation site discomfort	0	0	1 (3.4%)
Instillation site irritation	1 (0.8%)	0	0
Instillation site pain	2 (1.6%)	0	1 (3.4%)
INFECTIONS AND INFESTATIONS	3 (2.3%)	0	2 (6.9%)
Conjunctivitis	3 (2.3%)	0	2 (6.9%)
INVESTIGATIONS	1 (0.8%)	0	0
Intraocular pressure increased	1 (0.8%)	0	0

Abbreviations: TEAE = Treatment-Emergent Adverse Event

Studies: AR-13324-CS208 (0.02% STN1013900), AR-13324-CS305 (0.02% STN1013900), 101390001LT (0.02% STN1013900 + 0.005% Latanoprost) and 101390002LT (0.02% STN1013900 (Group 1 and 2), 0.02% STN1013900 + 0.005% Latanoprost, 0.02% STN1013900 + 0.5% Timolol)

Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Percentages are based on N in each treatment group unless otherwise noted. Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 27.1. Subjects experiencing more than one TEAE within a given SOC or PT are counted once within that SOC or PT. SOCs and PTs within SOCs are listed in alphabetical order.

Source:添付資料 5.3.5.3-2 Table 4.2.1.3

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表 2.7.4.7-23. 併合解析 2: 男女別の副作用一覧（女性）

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=177)	0.02% STN1013900 + 0.005% Latanoprost (N=107)	0.02% STN1013900 + 0.5% Timolol (N=37)
Number of Subjects with Any TEAE	125 (70.6%)	82 (76.6%)	30 (81.1%)
EYE DISORDERS	124 (70.1%)	82 (76.6%)	30 (81.1%)
Abnormal sensation in eye	2 (1.1%)	1 (0.9%)	0
Blepharitis	7 (4.0%)	2 (1.9%)	0
Blepharitis allergic	3 (1.7%)	1 (0.9%)	1 (2.7%)
Ciliary hyperaemia	1 (0.6%)	0	0
Conjunctival follicles	1 (0.6%)	0	0
Conjunctival haemorrhage	11 (6.2%)	5 (4.7%)	4 (10.8%)
Conjunctival hyperaemia	107 (60.5%)	73 (68.2%)	19 (51.4%)
Conjunctival oedema	1 (0.6%)	0	0
Conjunctivitis allergic	28 (15.8%)	6 (5.6%)	7 (18.9%)
Cornea verticillata	36 (20.3%)	17 (15.9%)	14 (37.8%)
Corneal disorder	0	1 (0.9%)	0
Corneal erosion	0	0	1 (2.7%)
Corneal oedema	0	1 (0.9%)	1 (2.7%)
Corneal opacity	1 (0.6%)	1 (0.9%)	0
Dry eye	1 (0.6%)	0	0
Eczema eyelids	1 (0.6%)	0	1 (2.7%)
Erythema of eyelid	0	1 (0.9%)	1 (2.7%)
Eye discharge	3 (1.7%)	3 (2.8%)	0
Eye irritation	13 (7.3%)	11 (10.3%)	5 (13.5%)
Eye pain	3 (1.7%)	1 (0.9%)	2 (5.4%)
Eye pruritus	7 (4.0%)	7 (6.5%)	3 (8.1%)
Eyelid oedema	1 (0.6%)	0	0
Eyelids pruritus	2 (1.1%)	0	0
Foreign body sensation in eyes	0	1 (0.9%)	1 (2.7%)
Keratitis	1 (0.6%)	1 (0.9%)	0
Lacrimation increased	4 (2.3%)	1 (0.9%)	2 (5.4%)
Loss of visual contrast sensitivity	2 (1.1%)	0	2 (5.4%)
Ocular hyperaemia	0	2 (1.9%)	0
Photophobia	1 (0.6%)	0	0
Presbyopia	0	0	1 (2.7%)
Punctate keratitis	5 (2.8%)	1 (0.9%)	2 (5.4%)
Retinal exudates	0	1 (0.9%)	0
Swelling of eyelid	1 (0.6%)	0	0
Uveitis	0	1 (0.9%)	0
Vision blurred	12 (6.8%)	4 (3.7%)	2 (5.4%)
Visual acuity reduced	12 (6.8%)	1 (0.9%)	3 (8.1%)
GASTROINTESTINAL DISORDERS	1 (0.6%)	0	0
Abdominal discomfort	1 (0.6%)	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (2.3%)	0	1 (2.7%)
Instillation site pain	4 (2.3%)	0	1 (2.7%)
INFECTIONS AND INFESTATIONS	2 (1.1%)	0	0
Conjunctivitis	2 (1.1%)	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (1.1%)	1 (0.9%)	0
Alopecia areata	1 (0.6%)	0	0
Dermatitis contact	1 (0.6%)	0	0
Madarosis	1 (0.6%)	0	0
Pruritus	0	1 (0.9%)	0

Abbreviations: TEAE = Treatment-Emergent Adverse Event

Studies: AR-13324-CS208 (0.02% STN1013900), AR-13324-CS305 (0.02% STN1013900), 101390001LT (0.02% STN1013900 + 0.005% Latanoprost) and 101390002LT (0.02% STN1013900 (Group 1 and 2), 0.02% STN1013900 + 0.005% Latanoprost, 0.02% STN1013900 + 0.5% Timolol)

Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Percentages are based on N in each treatment group unless otherwise noted. Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 27.1. Subjects experiencing more than one TEAE within a given SOC or PT are counted once within that SOC or PT. SOCs and PTs within SOCs are listed in alphabetical order.

Source: 添付資料 5.3.5.3-2 Table 4.2.1.4

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表 2.7.4.7-24. 併合解析 2: 年齢別の有害事象一覧（65 歳未満）

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=144)	0.02% STN1013900 + 0.005% Latanoprost (N=94)	0.02% STN1013900 + 0.5% Timolol (N=31)
Number of Subjects with Any TEAE	110 (76.4%)	78 (83.0%)	30 (96.8%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	1 (1.1%)	0
Anaemia	0	1 (1.1%)	0
EAR AND LABYRINTH DISORDERS	0	0	1 (3.2%)
Tinnitus	0	0	1 (3.2%)
EYE DISORDERS	107 (74.3%)	77 (81.9%)	29 (93.5%)
Abnormal sensation in eye	3 (2.1%)	0	0
Accommodation disorder	1 (0.7%)	0	0
Asthenopia	0	1 (1.1%)	0
Blepharitis	4 (2.8%)	0	0
Blepharitis allergic	1 (0.7%)	2 (2.1%)	0
Cataract	1 (0.7%)	0	0
Ciliary hyperaemia	1 (0.7%)	0	0
Conjunctival follicles	1 (0.7%)	0	0
Conjunctival haemorrhage	21 (14.6%)	8 (8.5%)	4 (12.9%)
Conjunctival hyperaemia	87 (60.4%)	69 (73.4%)	18 (58.1%)
Conjunctival oedema	1 (0.7%)	0	0
Conjunctivitis allergic	24 (16.7%)	11 (11.7%)	4 (12.9%)
Cornea verticillata	23 (16.0%)	20 (21.3%)	13 (41.9%)
Corneal erosion	0	0	1 (3.2%)
Corneal opacity	0	2 (2.1%)	0
Dry eye	3 (2.1%)	1 (1.1%)	2 (6.5%)
Eczema eyelids	0	3 (3.2%)	0
Eye discharge	2 (1.4%)	2 (2.1%)	0
Eye irritation	14 (9.7%)	6 (6.4%)	6 (19.4%)
Eye pain	3 (2.1%)	1 (1.1%)	1 (3.2%)
Eye pruritus	6 (4.2%)	6 (6.4%)	3 (9.7%)
Eyelids pruritus	2 (1.4%)	0	1 (3.2%)
Foreign body sensation in eyes	0	1 (1.1%)	0
Keratitis	1 (0.7%)	1 (1.1%)	0
Lacrimation increased	3 (2.1%)	2 (2.1%)	0
Loss of visual contrast sensitivity	0	1 (1.1%)	0
Meibomianitis	1 (0.7%)	0	0
Ocular discomfort	1 (0.7%)	0	0
Ocular hyperaemia	0	1 (1.1%)	0
Optic disc haemorrhage	0	1 (1.1%)	0
Photophobia	1 (0.7%)	1 (1.1%)	0
Presbyopia	0	0	1 (3.2%)
Punctate keratitis	7 (4.9%)	3 (3.2%)	3 (9.7%)
Retinal exudates	0	1 (1.1%)	0
Swelling of eyelid	1 (0.7%)	0	0
Trichiasis	1 (0.7%)	0	0
Uveitis	0	1 (1.1%)	0
Vision blurred	5 (3.5%)	6 (6.4%)	3 (9.7%)
Visual acuity reduced	6 (4.2%)	4 (4.3%)	1 (3.2%)
Visual field defect	0	1 (1.1%)	0
GASTROINTESTINAL DISORDERS	3 (2.1%)	5 (5.3%)	2 (6.5%)
Abdominal discomfort	0	1 (1.1%)	0
Abdominal distension	0	1 (1.1%)	0
Abdominal pain upper	0	0	1 (3.2%)
Dental caries	1 (0.7%)	2 (2.1%)	0
Faeces soft	0	0	1 (3.2%)
Nausea	2 (1.4%)	1 (1.1%)	0
Periodontal disease	1 (0.7%)	0	0
Stomatitis	1 (0.7%)	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7 (4.9%)	3 (3.2%)	2 (6.5%)
Injection site pain	1 (0.7%)	0	0
Instillation site discomfort	0	0	1 (3.2%)
Instillation site irritation	1 (0.7%)	0	0
Instillation site pain	4 (2.8%)	0	0
Pyrexia	1 (0.7%)	3 (3.2%)	1 (3.2%)
INFECTIONS AND INFESTATIONS	17 (11.8%)	7 (7.4%)	6 (19.4%)
Adenoviral conjunctivitis	2 (1.4%)	0	0

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SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=144)	0.02% STN1013900 + 0.005% Latanoprost (N=94)	0.02% STN1013900 + 0.5% Timolol (N=31)
COVID-19	2 (1.4%)	2 (2.1%)	1 (3.2%)
Chronic sinusitis	0	0	1 (3.2%)
Conjunctivitis	1 (0.7%)	0	1 (3.2%)
Conjunctivitis bacterial	3 (2.1%)	0	0
Coronavirus infection	2 (1.4%)	1 (1.1%)	0
Cystitis	1 (0.7%)	0	0
Gastroenteritis	1 (0.7%)	0	0
Gingivitis	1 (0.7%)	0	0
Helicobacter gastritis	1 (0.7%)	0	0
Hordeolum	1 (0.7%)	0	2 (6.5%)
Infected dermal cyst	1 (0.7%)	0	0
Influenza	1 (0.7%)	0	0
Nasopharyngitis	4 (2.8%)	4 (4.3%)	1 (3.2%)
Purulence	1 (0.7%)	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6 (4.2%)	5 (5.3%)	5 (16.1%)
Foot fracture	1 (0.7%)	0	0
Hand fracture	1 (0.7%)	0	0
Immunisation reaction	3 (2.1%)	4 (4.3%)	5 (16.1%)
Muscle strain	0	1 (1.1%)	0
Tooth fracture	1 (0.7%)	0	0
INVESTIGATIONS	3 (2.1%)	1 (1.1%)	0
Blood uric acid increased	1 (0.7%)	0	0
Intraocular pressure increased	1 (0.7%)	0	0
White blood cell count increased	0	1 (1.1%)	0
White blood cells urine positive	1 (0.7%)	0	0
METABOLISM AND NUTRITION DISORDERS	0	0	1 (3.2%)
Hyperuricaemia	0	0	1 (3.2%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (2.8%)	1 (1.1%)	1 (3.2%)
Arthralgia	0	1 (1.1%)	1 (3.2%)
Back pain	2 (1.4%)	0	0
Neck pain	1 (0.7%)	0	0
Tenosynovitis	1 (0.7%)	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.7%)	0	0
Lipoma	1 (0.7%)	0	0
NERVOUS SYSTEM DISORDERS	2 (1.4%)	0	2 (6.5%)
Burning sensation	0	0	1 (3.2%)
Dizziness	0	0	1 (3.2%)
Headache	1 (0.7%)	0	0
Tension headache	1 (0.7%)	0	0
PSYCHIATRIC DISORDERS	0	1 (1.1%)	0
Insomnia	0	1 (1.1%)	0
RENAL AND URINARY DISORDERS	2 (1.4%)	0	0
Proteinuria	1 (0.7%)	0	0
Urine abnormality	1 (0.7%)	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.7%)	1 (1.1%)	1 (3.2%)
Cough	0	0	1 (3.2%)
Cough variant asthma	0	1 (1.1%)	0
Oropharyngeal pain	1 (0.7%)	0	0
Rhinitis allergic	0	1 (1.1%)	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (1.4%)	0	0
Alopecia areata	1 (0.7%)	0	0
Dry skin	1 (0.7%)	0	0
Madarosis	1 (0.7%)	0	0
VASCULAR DISORDERS	2 (1.4%)	0	0
Hyperaemia	1 (0.7%)	0	0
Lymphangiectasia	1 (0.7%)	0	0

Abbreviations: TEAE = Treatment-Emergent Adverse Event

Studies: AR-13324-CS208 (0.02% STN1013900), AR-13324-CS305 (0.02% STN1013900), 101390001LT (0.02% STN1013900 + 0.005% Latanoprost) and 101390002LT (0.02% STN1013900 (Group 1 and 2), 0.02% STN1013900 + 0.005% Latanoprost, 0.02% STN1013900 + 0.5% Timolol)

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=144)	0.02% STN1013900 + 0.005% Latanoprost (N=94)	0.02% STN1013900 + 0.5% Timolol (N=31)

Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Percentages are based on N in each treatment group unless otherwise noted. Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 27.1. Subjects experiencing more than one TEAE within a given SOC or PT are counted once within that SOC or PT. SOCs and PTs within SOCs are listed in alphabetical order.
Source: 添付資料 5.3.5.3-2 Table 4.2.2.1

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表 2.7.4.7-25. 併合解析 2: 年齢別の有害事象一覧（65 歳以上）

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=161)	0.02% STN1013900 + 0.005% Latanoprost (N=93)	0.02% STN1013900 + 0.5% Timolol (N=35)
Number of Subjects with Any TEAE	115 (71.4%)	64 (68.8%)	30 (85.7%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.6%)	0	0
Iron deficiency anaemia	1 (0.6%)	0	0
CARDIAC DISORDERS	2 (1.2%)	0	0
Cardiac failure congestive	1 (0.6%)	0	0
Palpitations	1 (0.6%)	0	0
EAR AND LABYRINTH DISORDERS	1 (0.6%)	1 (1.1%)	2 (5.7%)
Sudden hearing loss	0	1 (1.1%)	1 (2.9%)
Vertigo	1 (0.6%)	0	0
Vertigo positional	0	0	1 (2.9%)
EYE DISORDERS	109 (67.7%)	58 (62.4%)	28 (80.0%)
Abnormal sensation in eye	0	1 (1.1%)	0
Amaurosis fugax	1 (0.6%)	0	0
Anterior chamber inflammation	1 (0.6%)	0	0
Asthenopia	1 (0.6%)	0	0
Blepharitis	11 (6.8%)	3 (3.2%)	2 (5.7%)
Blepharitis allergic	2 (1.2%)	0	1 (2.9%)
Cataract	1 (0.6%)	1 (1.1%)	1 (2.9%)
Chalazion	0	1 (1.1%)	0
Conjunctival cyst	0	1 (1.1%)	0
Conjunctival deposit	1 (0.6%)	0	1 (2.9%)
Conjunctival haemorrhage	17 (10.6%)	7 (7.5%)	7 (20.0%)
Conjunctival hyperaemia	79 (49.1%)	41 (44.1%)	21 (60.0%)
Conjunctival oedema	3 (1.9%)	0	0
Conjunctivitis allergic	25 (15.5%)	5 (5.4%)	7 (20.0%)
Cornea verticillata	39 (24.2%)	12 (12.9%)	14 (40.0%)
Corneal degeneration	1 (0.6%)	0	0
Corneal disorder	0	1 (1.1%)	1 (2.9%)
Corneal erosion	1 (0.6%)	0	1 (2.9%)
Corneal oedema	0	1 (1.1%)	1 (2.9%)
Corneal opacity	2 (1.2%)	0	0
Diabetic retinopathy	1 (0.6%)	0	0
Dry eye	2 (1.2%)	1 (1.1%)	0
Eczema eyelids	2 (1.2%)	1 (1.1%)	1 (2.9%)
Erythema of eyelid	0	1 (1.1%)	1 (2.9%)
Eye discharge	4 (2.5%)	1 (1.1%)	0
Eye irritation	9 (5.6%)	8 (8.6%)	2 (5.7%)
Eye pain	1 (0.6%)	1 (1.1%)	3 (8.6%)
Eye pruritus	6 (3.7%)	4 (4.3%)	1 (2.9%)
Eyelid myokymia	0	1 (1.1%)	0
Eyelid oedema	1 (0.6%)	0	0
Eyelids pruritus	2 (1.2%)	0	1 (2.9%)
Foreign body sensation in eyes	0	2 (2.2%)	1 (2.9%)
Lacrimation increased	7 (4.3%)	1 (1.1%)	3 (8.6%)
Loss of visual contrast sensitivity	2 (1.2%)	0	2 (5.7%)
Meibomian gland dysfunction	1 (0.6%)	0	0
Ocular hyperaemia	0	1 (1.1%)	0
Photophobia	1 (0.6%)	0	0
Punctate keratitis	3 (1.9%)	2 (2.2%)	0
Ulcerative keratitis	0	1 (1.1%)	0
Uveitis	0	0	1 (2.9%)
Vision blurred	12 (7.5%)	5 (5.4%)	3 (8.6%)
Visual acuity reduced	11 (6.8%)	2 (2.2%)	4 (11.4%)
Visual field defect	1 (0.6%)	1 (1.1%)	0
GASTROINTESTINAL DISORDERS	7 (4.3%)	0	2 (5.7%)
Abdominal discomfort	2 (1.2%)	0	0
Abdominal pain	1 (0.6%)	0	0
Constipation	0	0	1 (2.9%)
Enterocele	1 (0.6%)	0	0
Gastritis	1 (0.6%)	0	0
Irritable bowel syndrome	1 (0.6%)	0	0
Nausea	1 (0.6%)	0	0
Noninfective gingivitis	0	0	1 (2.9%)

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SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=161)	0.02% STN1013900 + 0.005% Latanoprost (N=93)	0.02% STN1013900 + 0.5% Timolol (N=35)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (2.5%)	2 (2.2%)	2 (5.7%)
Fatigue	0	1 (1.1%)	0
Instillation site pain	2 (1.2%)	0	2 (5.7%)
Pyrexia	2 (1.2%)	1 (1.1%)	0
IMMUNE SYSTEM DISORDERS	3 (1.9%)	0	0
Seasonal allergy	3 (1.9%)	0	0
INFECTIONS AND INFESTATIONS	19 (11.8%)	4 (4.3%)	7 (20.0%)
COVID-19	2 (1.2%)	1 (1.1%)	1 (2.9%)
Conjunctivitis	6 (3.7%)	1 (1.1%)	1 (2.9%)
Conjunctivitis bacterial	2 (1.2%)	0	0
Coronavirus infection	1 (0.6%)	1 (1.1%)	0
Cystitis	1 (0.6%)	0	1 (2.9%)
Herpes zoster	1 (0.6%)	0	0
Hordeolum	1 (0.6%)	0	1 (2.9%)
Influenza	1 (0.6%)	0	0
Nasopharyngitis	5 (3.1%)	0	1 (2.9%)
Otitis externa	1 (0.6%)	0	0
Pneumonia aspiration	1 (0.6%)	0	0
Sinusitis	0	0	1 (2.9%)
Tinea pedis	1 (0.6%)	0	1 (2.9%)
Urinary tract infection	1 (0.6%)	1 (1.1%)	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	11 (6.8%)	3 (3.2%)	3 (8.6%)
Arthropod bite	1 (0.6%)	0	1 (2.9%)
Contusion	1 (0.6%)	1 (1.1%)	0
Corneal abrasion	1 (0.6%)	0	0
Immunisation reaction	6 (3.7%)	1 (1.1%)	2 (5.7%)
Radius fracture	1 (0.6%)	0	0
Rib fracture	1 (0.6%)	0	0
Spinal compression fracture	0	0	1 (2.9%)
Subdural haematoma	0	1 (1.1%)	0
Thermal burn	0	1 (1.1%)	0
Traumatic subarachnoid haemorrhage	0	1 (1.1%)	0
INVESTIGATIONS	2 (1.2%)	1 (1.1%)	1 (2.9%)
Blood pressure increased	1 (0.6%)	0	0
Intraocular pressure increased	1 (0.6%)	1 (1.1%)	1 (2.9%)
METABOLISM AND NUTRITION DISORDERS	1 (0.6%)	1 (1.1%)	0
Diabetes mellitus	1 (0.6%)	1 (1.1%)	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	8 (5.0%)	2 (2.2%)	2 (5.7%)
Arthralgia	2 (1.2%)	0	0
Back pain	0	2 (2.2%)	0
Intervertebral disc protrusion	1 (0.6%)	0	0
Osteoarthritis	1 (0.6%)	0	1 (2.9%)
Osteoporosis	1 (0.6%)	0	1 (2.9%)
Pain in extremity	1 (0.6%)	0	0
Periarthritis	1 (0.6%)	0	0
Spinal osteoarthritis	1 (0.6%)	0	0
Tenosynovitis	1 (0.6%)	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.6%)	1 (1.1%)	0
Lymphoma	0	1 (1.1%)	0
Skin papilloma	1 (0.6%)	0	0
NERVOUS SYSTEM DISORDERS	1 (0.6%)	0	2 (5.7%)
Dizziness	0	0	1 (2.9%)
Headache	1 (0.6%)	0	1 (2.9%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (1.9%)	0	2 (5.7%)
Cough variant asthma	1 (0.6%)	0	0
Dyspnoea	1 (0.6%)	0	0
Oropharyngeal pain	0	0	1 (2.9%)
Rhinitis allergic	1 (0.6%)	0	1 (2.9%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (1.2%)	4 (4.3%)	4 (11.4%)
Dermal cyst	0	1 (1.1%)	0
Dermatitis	1 (0.6%)	1 (1.1%)	0

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=161)	0.02% STN1013900 + 0.005% Latanoprost (N=93)	0.02% STN1013900 + 0.5% Timolol (N=35)
Dermatitis contact	1 (0.6%)	0	1 (2.9%)
Dry skin	0	0	1 (2.9%)
Eczema	0	0	1 (2.9%)
Pruritus	0	1 (1.1%)	0
Seborrhoeic dermatitis	0	0	1 (2.9%)
Skin fissures	0	0	1 (2.9%)
Urticaria	0	1 (1.1%)	0

Abbreviations: TEAE = Treatment-Emergent Adverse Event

Studies: AR-13324-CS208 (0.02% STN1013900), AR-13324-CS305 (0.02% STN1013900), 101390001LT (0.02% STN1013900 + 0.005% Latanoprost) and 101390002LT (0.02% STN1013900 (Group 1 and 2), 0.02% STN1013900 + 0.005% Latanoprost, 0.02% STN1013900 + 0.5% Timolol)

Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Percentages are based on N in each treatment group unless otherwise noted. Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 27.1. Subjects experiencing more than one TEAE within a given SOC or PT are counted once within that SOC or PT. SOCs and PTs within SOCs are listed in alphabetical order.

Source: 添付資料 5.3.5.3-2 Table 4.2.2.2

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表 2.7.4.7-26. 併合解析 2: 年齢別の副作用一覧（65 歳未満）

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=144)	0.02% STN1013900 + 0.005% Latanoprost (N=94)	0.02% STN1013900 + 0.5% Timolol (N=31)
Number of Subjects with Any TEAE	104 (72.2%)	76 (80.9%)	27 (87.1%)
EYE DISORDERS	103 (71.5%)	76 (80.9%)	27 (87.1%)
Abnormal sensation in eye	2 (1.4%)	0	0
Accommodation disorder	1 (0.7%)	0	0
Blepharitis	1 (0.7%)	0	0
Blepharitis allergic	1 (0.7%)	2 (2.1%)	0
Ciliary hyperaemia	1 (0.7%)	0	0
Conjunctival follicles	1 (0.7%)	0	0
Conjunctival haemorrhage	8 (5.6%)	4 (4.3%)	1 (3.2%)
Conjunctival hyperaemia	87 (60.4%)	68 (72.3%)	18 (58.1%)
Conjunctivitis allergic	22 (15.3%)	9 (9.6%)	3 (9.7%)
Cornea verticillata	23 (16.0%)	20 (21.3%)	13 (41.9%)
Corneal erosion	0	0	1 (3.2%)
Corneal opacity	0	1 (1.1%)	0
Dry eye	3 (2.1%)	0	0
Eczema eyelids	0	2 (2.1%)	0
Eye discharge	1 (0.7%)	2 (2.1%)	0
Eye irritation	14 (9.7%)	6 (6.4%)	6 (19.4%)
Eye pain	3 (2.1%)	1 (1.1%)	1 (3.2%)
Eye pruritus	6 (4.2%)	6 (6.4%)	3 (9.7%)
Eyelids pruritus	2 (1.4%)	0	1 (3.2%)
Foreign body sensation in eyes	0	1 (1.1%)	0
Keratitis	1 (0.7%)	1 (1.1%)	0
Lacrimation increased	2 (1.4%)	2 (2.1%)	0
Loss of visual contrast sensitivity	0	1 (1.1%)	0
Ocular hyperaemia	0	1 (1.1%)	0
Presbyopia	0	0	1 (3.2%)
Punctate keratitis	4 (2.8%)	0	3 (9.7%)
Retinal exudates	0	1 (1.1%)	0
Swelling of eyelid	1 (0.7%)	0	0
Uveitis	0	1 (1.1%)	0
Vision blurred	5 (3.5%)	6 (6.4%)	3 (9.7%)
Visual acuity reduced	6 (4.2%)	2 (2.1%)	1 (3.2%)
GASTROINTESTINAL DISORDERS	1 (0.7%)	0	0
Nausea	1 (0.7%)	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	5 (3.5%)	0	1 (3.2%)
Instillation site discomfort	0	0	1 (3.2%)
Instillation site irritation	1 (0.7%)	0	0
Instillation site pain	4 (2.8%)	0	0
INFECTIONS AND INFESTATIONS	0	0	1 (3.2%)
Conjunctivitis	0	0	1 (3.2%)
INVESTIGATIONS	1 (0.7%)	0	0
Intraocular pressure increased	1 (0.7%)	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.7%)	0	0
Alopecia areata	1 (0.7%)	0	0
Madarosis	1 (0.7%)	0	0

Abbreviations: TEAE = Treatment-Emergent Adverse Event

Studies: AR-13324-CS208 (0.02% STN1013900), AR-13324-CS305 (0.02% STN1013900), 101390001LT (0.02% STN1013900 + 0.005% Latanoprost) and 101390002LT (0.02% STN1013900 (Group 1 and 2), 0.02% STN1013900 + 0.005% Latanoprost, 0.02% STN1013900 + 0.5% Timolol)

Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Percentages are based on N in each treatment group unless otherwise noted. Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 27.1. Subjects experiencing more than one TEAE within a given SOC or PT are counted once within that SOC or PT. SOCs and PTs within SOCs are listed in alphabetical order.

Source: 添付資料 5.3.5.3-2 Table 4.2.2.3

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表 2.7.4.7-27. 併合解析 2: 年齢別の副作用一覧（65 歳以上）

SYSTEM ORGAN CLASS (SOC) Preferred Term (PT)	0.02% STN1013900 (N=161)	0.02% STN1013900 + 0.005% Latanoprost (N=93)	0.02% STN1013900 + 0.5% Timolol (N=35)
Number of Subjects with Any TEAE	102 (63.4%)	53 (57.0%)	26 (74.3%)
EYE DISORDERS	102 (63.4%)	53 (57.0%)	25 (71.4%)
Abnormal sensation in eye	0	1 (1.1%)	0
Anterior chamber inflammation	1 (0.6%)	0	0
Blepharitis	10 (6.2%)	3 (3.2%)	0
Blepharitis allergic	2 (1.2%)	0	1 (2.9%)
Conjunctival haemorrhage	7 (4.3%)	3 (3.2%)	5 (14.3%)
Conjunctival hyperaemia	76 (47.2%)	41 (44.1%)	20 (57.1%)
Conjunctival oedema	2 (1.2%)	0	0
Conjunctivitis allergic	21 (13.0%)	4 (4.3%)	6 (17.1%)
Cornea verticillata	39 (24.2%)	12 (12.9%)	14 (40.0%)
Corneal disorder	0	1 (1.1%)	1 (2.9%)
Corneal erosion	1 (0.6%)	0	1 (2.9%)
Corneal oedema	0	1 (1.1%)	1 (2.9%)
Corneal opacity	2 (1.2%)	0	0
Dry eye	0	1 (1.1%)	0
Eczema eyelids	1 (0.6%)	0	1 (2.9%)
Erythema of eyelid	0	1 (1.1%)	1 (2.9%)
Eye discharge	2 (1.2%)	1 (1.1%)	0
Eye irritation	8 (5.0%)	8 (8.6%)	2 (5.7%)
Eye pain	1 (0.6%)	0	3 (8.6%)
Eye pruritus	4 (2.5%)	3 (3.2%)	1 (2.9%)
Eyelid oedema	1 (0.6%)	0	0
Eyelids pruritus	2 (1.2%)	0	1 (2.9%)
Foreign body sensation in eyes	0	0	1 (2.9%)
Lacrimation increased	5 (3.1%)	1 (1.1%)	3 (8.6%)
Loss of visual contrast sensitivity	2 (1.2%)	0	2 (5.7%)
Ocular hyperaemia	0	1 (1.1%)	0
Photophobia	1 (0.6%)	0	0
Punctate keratitis	2 (1.2%)	1 (1.1%)	0
Vision blurred	10 (6.2%)	3 (3.2%)	3 (8.6%)
Visual acuity reduced	8 (5.0%)	1 (1.1%)	4 (11.4%)
GASTROINTESTINAL DISORDERS	1 (0.6%)	0	0
Abdominal discomfort	1 (0.6%)	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (1.2%)	0	2 (5.7%)
Instillation site pain	2 (1.2%)	0	2 (5.7%)
INFECTIONS AND INFESTATIONS	5 (3.1%)	0	1 (2.9%)
Conjunctivitis	5 (3.1%)	0	1 (2.9%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.6%)	1 (1.1%)	0
Dermatitis contact	1 (0.6%)	0	0
Pruritus	0	1 (1.1%)	0

Abbreviations: TEAE = Treatment-Emergent Adverse Event

Studies: AR-13324-CS208 (0.02% STN1013900), AR-13324-CS305 (0.02% STN1013900), 101390001LT (0.02% STN1013900 + 0.005% Latanoprost) and 101390002LT (0.02% STN1013900 (Group 1 and 2), 0.02% STN1013900 + 0.005% Latanoprost, 0.02% STN1013900 + 0.5% Timolol)

Note: N in the headers represents the total number of subjects in each treatment group for the population being analyzed. Percentages are based on N in each treatment group unless otherwise noted. Adverse events are coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 27.1. Subjects experiencing more than one TEAE within a given SOC or PT are counted once within that SOC or PT. SOCs and PTs within SOCs are listed in alphabetical order.

Source: 添付資料 5.3.5.3-2 Table 4.2.2.4

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