Table 14.3.1.6c Summary of Serious Adverse Events by System Organ Class, Preferred Term, Treatment and Overall
(Safety Population)

Study Period: Follow-Up Period

Body System MedDRA Preferred Term	rhNGF 10 µg/ml (N=62)			rhNGF 20 µg/ml (N=65)			Vehicle Control (N=29)			Total (N=156)		
	N*	n	%	N*	n	%	N*	n	%	N*	n	%
Any Adverse Events	23	10	(16.1%)	10	8	(12.3%)	5	4	(13.8%)	38	22	(14.1%)
Eye disorders	4	2	(3.2%)	2	2	(3.1%)	2	2	(6.9%)	8	6	(3.8%)
Corneal opacity	1	1	(1.6%)	0	0		1	1	(3.4%)	2	2	(1.3%)
Corneal epithelium defect	0	0		1	1	(1.5%)	0	0		1	1	(0.6%)
Corneal neovascularisation	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Neurotrophic keratopathy	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Ocular vascular disorder	0	0		0	0		1	1	(3.4%)	1	1	(0.6%)
Ulcerative keratitis	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Visual acuity reduced	0	0		1	1	(1.5%)	0	0		1	1	(0.6%)
Cardiac disorders	4	4	(6.5%)	0	0		0	0		4	4	(2.6%)
Arrhythmia	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Cardiac failure	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Coronary artery stenosis	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Myocardial infarction	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)

N* = Number of Events Reported, n = Number of Patients, % = Percentage of Patients.
Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in their Uncontrolled Treatment group in the Follow-Up Period.
All other patients are counted in their Controlled Treatment group.
Percentages are calculated using the population number in each treatment group (N) as the denominator.
Body system and preferred terms are sorted by descending frequency of patient count in the Total column.
Events are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.
The data presented in this Table are contained in Listing 14.3.2.1c

Table 14.3.1.6c Summary of Serious Adverse Events by System Organ Class, Preferred Term, Treatment and Overall
(Safety Population)

Study Period: Follow-Up Period

Body System MedDRA Preferred Term	rhNGF 10 µg/ml (N=62)			rhNGF 20 µg/ml (N=65)			Vehicle Control (N=29)			Total (N=156)		
	N*	n	%	N*	n	%	N*	n	%	N*	n	%
Respiratory, thoracic and mediastinal disorders	2	2	(3.2%)	1	1	(1.5%)	1	1	(3.4%)	4	4	(2.6%)
Respiratory failure	0	0		1	1	(1.5%)	1	1	(3.4%)	2	2	(1.3%)
Dyspnoea	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Epistaxis	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Gastrointestinal disorders	2	2	(3.2%)	0	0		0	0		2	2	(1.3%)
Diverticular perforation	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Nausea	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
General disorders and administration site conditions	1	1	(1.6%)	1	1	(1.5%)	0	0		2	2	(1.3%)
Disease progression	0	0		1	1	(1.5%)	0	0		1	1	(0.6%)
Impaired healing	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Infections and infestations	2	2	(3.2%)	0	0		0	0		2	2	(1.3%)
Corneal abscess	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Herpes ophthalmic	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)

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	N*	n	%	N*	n	%	N*	n	%	N*	n	%
Injury, poisoning and procedural complications	0	0		2	1	(1.5%)	1	1	(3.4%)	3	2	(1.3%)
Clavicle fracture	0	0		1	1	(1.5%)	0	0		1	1	(0.6%)
Fall	0	0		1	1	(1.5%)	0	0		1	1	(0.6%)
Femur fracture	0	0		0	0		1	1	(3.4%)	1	1	(0.6%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0		1	1	(1.5%)	1	1	(3.4%)	2	2	(1.3%)
Neoplasm recurrence	0	0		1	1	(1.5%)	0	0		1	1	(0.6%)
Neurofibroma	0	0		0	0		1	1	(3.4%)	1	1	(0.6%)
Nervous system disorders	0	0		2	2	(3.1%)	0	0		2	2	(1.3%)
Syncope	0	0		1	1	(1.5%)	0	0		1	1	(0.6%)
Visual field defect	0	0		1	1	(1.5%)	0	0		1	1	(0.6%)
Renal and urinary disorders	1	1	(1.6%)	1	1	(1.5%)	0	0		2	2	(1.3%)
Bladder prolapse	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Renal colic	0	0		1	1	(1.5%)	0	0		1	1	(0.6%)

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	N*	n	%	N*	n	%	N*	n	%	N*	n	%
Vascular disorders	4	2	(3.2%)	0	0		0	0		4	2	(1.3%)
Aortic dissection	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Aortic rupture	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Diabetic vascular disorder	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Shock haemorrhagic	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Investigations	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Blood pressure increased	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Metabolism and nutrition disorders	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Decreased appetite	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Reproductive system and breast disorders	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Uterine prolapse	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)

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The data presented in this Table are contained in Listing 14.3.2.1c