Table 14.3.1.1c Summary of Adverse Events by Treatment and Overall
(Safety Population)

Study Period: Follow-Up Period

	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	77	22	(35.5%)	65	21	(32.3%)	21	11	(37.9%)	163	54	(34.6%)
Adverse Events Leading to Discontinuation of Study Treatment	1	1	(1.6%)	5	2	(3.1%)	1	1	(3.4%)	7	4	(2.6%)
Treatment-Related Adverse Events	1	1	(1.6%)	0	0		2	1	(3.4%)	3	2	(1.3%)
Any Serious Adverse Events	23	10	(16.1%)	10	8	(12.3%)	5	4	(13.8%)	38	22	(14.1%)
Serious Treatment-Related Adverse Events	0	0		0	0		0	0		0	0	
Adverse Events Leading to Death	7	4	(6.5%)	1	1	(1.5%)	1	1	(3.4%)	9	6	(3.8%)

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.
Treatment-Related Adverse Events are those events having a relationship to study treatment recorded as Possible, Probable or Highly Probable.
Events are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.
Note: Patient 312006 was allocated to Vehicle Control in the Controlled Treatment Period and is categorised as such in this table, but received an unscheduled course of rhNGF 20 µg/ml, which was discontinued due to the AE, Herpes simplex ophthalmic, during follow-up.
Patient 350002 was allocated to Vehicle Control in the Controlled Treatment Period and is categorised as such in this table; however, the treatment-related AEs 'Dry eye' and 'Eye lid pain' occurred during follow-up, while the patient was being treated with an unscheduled course of rhNGF 10 µg/ml.
The data presented in this Table are contained in Listing 16.2.7.1c