Table 14.3.1.5c Summary of Treatment-Related 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	1	1	(1.6%)	0	0		2	1	(3.4%)	3	2	(1.3%)
Eye disorders	0	0		0	0		2	1	(3.4%)	2	1	(0.6%)
Dry eye	0	0		0	0		1	1	(3.4%)	1	1	(0.6%)
Eyelid pain	0	0		0	0		1	1	(3.4%)	1	1	(0.6%)
General disorders and administration site conditions	1	1	(1.6%)	0	0		0	0		1	1	(0.6%)
Disease progression	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.
Treatment-Related Adverse Events are those events having a relationship to study treatment recorded as Possible, Probable or Highly Probable.
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.
Note: Patient 350002 was allocated to Vehicle Control in the Controlled Treatment Period and is categorised as such in this table; however, the 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 16.2.7.2c