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

Study Period: Controlled Treatment Period

	rhNGF 10 µg/ml (N=7)			rhNGF 20 µg/ml (N=7)			Vehicle Control (N=4)			Total (N=18)		
	N*	n	%	N*	n	%	N*	n	%	N*	n	%
Any Adverse Events	8	3	(42.9%)	28	5	(71.4%)	11	4	(100.0%)	47	12	(66.7%)
Adverse Events Leading to Discontinuation of Study Treatment	1	1	(14.3%)	1	1	(14.3%)	2	2	(50.0%)	4	4	(22.2%)
Treatment-Related Adverse Events	4	1	(14.3%)	12	3	(42.9%)	1	1	(25.0%)	17	5	(27.8%)
Any Serious Adverse Events	1	1	(14.3%)	0	0		1	1	(25.0%)	2	2	(11.1%)
Serious Treatment-Related Adverse Events	0	0		0	0		0	0		0	0	
Adverse Events Leading to Death	0	0		0	0		0	0		0	0	

N* = Number of Events Reported, n = Number of Patients, % = Percentage of Patients.
Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Uncontrolled Treatment Period and Follow-Up Period.
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.
The data presented in this Table are contained in Listing 16.2.7.1a

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtaeovr.sas Executed: 19OCT2015, 09:42

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

Study Period: Uncontrolled Treatment Period

	rhNGF 10 µg/ml (N=0)			rhNGF 20 µg/ml (N=0)			Total (N=0)		
	N*	n	%	N*	n	%	N*	n	%

No data for this study period

N* = Number of Events Reported, n = Number of Patients, % = Percentage of Patients.
Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Uncontrolled Treatment Period and Follow-Up Period.
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.
The data presented in this Table are contained in Listing 16.2.7.1a

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtaeovr.sas Executed: 19OCT2015, 09:42

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

Study Period: Follow-Up Period

	rhNGF 10 µg/ml (N=7)			rhNGF 20 µg/ml (N=7)			Vehicle Control (N=4)			Total (N=18)		
	N*	n	%	N*	n	%	N*	n	%	N*	n	%
Any Adverse Events	5	4	(57.1%)	12	2	(28.6%)	5	2	(50.0%)	22	8	(44.4%)
Adverse Events Leading to Discontinuation of Study Treatment	0	0		0	0		0	0		0	0	
Treatment-Related Adverse Events	0	0		0	0		0	0		0	0	
Any Serious Adverse Events	2	2	(28.6%)	1	1	(14.3%)	3	2	(50.0%)	6	5	(27.8%)
Serious Treatment-Related Adverse Events	0	0		0	0		0	0		0	0	
Adverse Events Leading to Death	0	0		0	0		0	0		0	0	

N* = Number of Events Reported, n = Number of Patients, % = Percentage of Patients.
Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Uncontrolled Treatment Period and Follow-Up Period.
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.
The data presented in this Table are contained in Listing 16.2.7.1a

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtaeovr.sas Executed: 19OCT2015, 09:42