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

Study Period: Controlled Treatment Period

Body System MedDRA Preferred Term	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	1	1	(14.3%)	0	0		1	1	(25.0%)	2	2	(11.1%)
General disorders and administration site conditions	1	1	(14.3%)	0	0		1	1	(25.0%)	2	2	(11.1%)
Disease progression	1	1	(14.3%)	0	0		1	1	(25.0%)	2	2	(11.1%)

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.
Body system and preferred terms are sorted by descending frequency of patient count in the Total column.
The data presented in this Table are contained in Listing 14.3.2.1a

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtae.sas Executed: 16OCT2015, 09:42

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

Study Period: Uncontrolled Treatment Period

Body System MedDRA Preferred Term	rhNGF 10 µg/ml (N=0)			rhNGF 20 µg/ml (N=0)			Total (N=0)		
	N*	n	%	N*	n	%	N*	n	%
Any Adverse Events	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.
Body system and preferred terms are sorted by descending frequency of patient count in the Total column.
The data presented in this Table are contained in Listing 14.3.2.1a

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtae.sas Executed: 16OCT2015, 09:42

Table 14.3.1.6a 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=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	2	2	(28.6%)	1	1	(14.3%)	3	2	(50.0%)	6	5	(27.8%)
Cardiac disorders	0	0		1	1	(14.3%)	0	0		1	1	(5.6%)
Myocardial infarction	0	0		1	1	(14.3%)	0	0		1	1	(5.6%)
Eye disorders	1	1	(14.3%)	0	0		0	0		1	1	(5.6%)
Visual acuity reduced	1	1	(14.3%)	0	0		0	0		1	1	(5.6%)
General disorders and administration site conditions	1	1	(14.3%)	0	0		0	0		1	1	(5.6%)
Disease progression	1	1	(14.3%)	0	0		0	0		1	1	(5.6%)
Injury, poisoning and procedural complications	0	0		0	0		1	1	(25.0%)	1	1	(5.6%)
Femur fracture	0	0		0	0		1	1	(25.0%)	1	1	(5.6%)
Renal and urinary disorders	0	0		0	0		1	1	(25.0%)	1	1	(5.6%)
Renal failure	0	0		0	0		1	1	(25.0%)	1	1	(5.6%)

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.
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 14.3.2.1a

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtae.sas Executed: 16OCT2015, 09:42

Table 14.3.1.6a 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=7)			rhNGF 20 µg/ml (N=7)			Vehicle Control (N=4)			Total (N=18)		
	N*	n	%	N*	n	%	N*	n	%	N*	n	%
Respiratory, thoracic and mediastinal disorders	0	0		0	0		1	1	(25.0%)	1	1	(5.6%)
Pulmonary oedema	0	0		0	0		1	1	(25.0%)	1	1	(5.6%)

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.
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 14.3.2.1a

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtae.sas Executed: 16OCT2015, 09:42