# P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:23:14 First Dose M/F: NA / NA Lab: BAT

C Number:	C61994A
Lock Date:	04/07/1992
Cage Range:	All
Date Range:	All
Reasons For Removal:	All
Removal Date Range:	All
Treatment Groups:	All
Study Gender:	Both
PWG Approval Date	04/27/1994

# P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:23:14 First Dose M/F: NA / NA Lab: BAT

# Male MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

					INDI	VIDUAL SU	RVIVAL IIN	IES (DAYS)					
DOSE = \	/EHICLE C	ONTROL											
TOTAL 30	)		UNCEN	ISORED DE	ATHS 0	CENSO	RED DEATH	HS 0	TERMIN	IAL 30			
UNCENS	ORED DEA	TH DAYS											
none													
CENSOR	ED DEATH	DAYS											
none													
DOSE = 1	PA 5 CO	MPLETE											
TOTAL 30	)		UNCEN	ISORED DE	ATHS 0	CENSO	RED DEATH	IS 0	TERMIN	IAL 30			
UNCENS	ORED DEA	TH DAYS											
none													
CENSOR	ED DEATH	DAYS											
none													
DOSE = N	/INNG 100/	ACETONE											
TOTAL 30	)		UNCEN	ISORED DE	ATHS 0	CENSO	RED DEATH	IS 0	TERMIN	IAL 30			
UNCENS	ORED DEA	TH DAYS											
none													
CENSOR	ED DEATH	DAYS											
none													
DOSE = N	/INNG100/	COMPLETE											
TOTAL 30	)		UNCEN	ISORED DE	ATHS 14	CENSO	RED DEATH	HS 0	TERMIN	IAL 16			
UNCENS	ORED DEA	TH DAYS											
245	258	282	282	282	293	304	318	330	330	330	343	343	353
CENSOR	ED DEATH	DAYS											
none													

(A) FIRST TERMINAL SACRIFICE

(B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

# P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

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CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:23:14 First Dose M/F: NA / NA Lab: BAT

# Male MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

						IDUAL SUI	RVIVAL IIN	IES (DAYS)					
DOSE = N	1NNG 100/T	PA 5											
TOTAL 30	)		UNCEN	SORED DE/	ATHS 1	CENSO	RED DEATH	HS 0	TERMIN	IAL 29			
UNCENS	ORED DEAT	TH DAYS											
343													
CENSOR	ED DEATH	DAYS											
none													
DOSE = N	INNG 500/A	CETONE											
TOTAL 30	)		UNCEN	SORED DE	ATHS 1	CENSO	RED DEATH	HS 0	TERMIN	IAL 29			
UNCENS	ORED DEAT	TH DAYS											
266													
CENSOR	ED DEATH	DAYS											
none													
DOSE = N	INNG1000//	ACETONE											
TOTAL 30	)		UNCEN	SORED DE	ATHS 2	CENSO	RED DEATH	HS 0	TERMIN	IAL 28			
UNCENS	ORED DEAT	TH DAYS											
212	318												
CENSOR	ED DEATH	DAYS											
none													
DOSE = N	INNG1000/7	ГРА 5											
TOTAL 30			UNCEN	SORED DE/	ATHS 14	CENSO	RED DEATH	HS 0	TERMIN	IAL 16			
UNCENS	ORED DEAT	TH DAYS											
165	195	227	227	227	266	266	268	282	304	318	318	343	349
CENSOR	ED DEATH	DAYS											
none													

(A) FIRST TERMINAL SACRIFICE

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

# P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

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CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:23:14 First Dose M/F: NA / NA Lab: BAT

# Male MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

	INDIV	IDUAL SURVIVAL TIMES (DAYS)	
DOSE = BPO 20 COMPLETE			
TOTAL 30	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 30
UNCENSORED DEATH DAYS			
none			
CENSORED DEATH DAYS			
none			
DOSE = MNNG 100/BPO 20			
TOTAL 30	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 30
UNCENSORED DEATH DAYS			
none			
CENSORED DEATH DAYS			
none			
DOSE = MNNG 500/BPO 20			
TOTAL 30	UNCENSORED DEATHS 1	CENSORED DEATHS 0	TERMINAL 29
UNCENSORED DEATH DAYS			
343			
CENSORED DEATH DAYS			
none			
DOSE = MNNG1000/BPO 20			
TOTAL 30	UNCENSORED DEATHS 2	CENSORED DEATHS 0	TERMINAL 28
UNCENSORED DEATH DAYS			
290 290			
CENSORED DEATH DAYS			
none			

(A) FIRST TERMINAL SACRIFICE

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

### P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

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#### CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:23:14 First Dose M/F: NA / NA Lab: BAT

#### Male MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

#### KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE					TIME	(DAYS)				
	37	74	111	148	185	222	259	296	333	363(A)
VEHICLE CONTROL	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
TPA 5 COMPLETE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
MNNG 100/ACETONE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
MNNG100/COMPLETE	100.0	100.0	100.0	100.0	100.0	100.0	93.3	80.0	63.3	53.3
MNNG 100/TPA 5	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.7
MNNG 500/ACETONE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.7	96.7	96.7
MNNG1000/ACETONE	100.0	100.0	100.0	100.0	100.0	96.7	96.7	96.7	93.3	93.3
MNNG1000/TPA 5	100.0	100.0	100.0	100.0	96.7	93.3	83.3	70.0	60.0	53.3
BPO 20 COMPLETE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
MNNG 100/BPO 20	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
MNNG 500/BPO 20	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.7
MNNG1000/BPO 20	100.0	100.0	100.0	100.0	100.0	100.0	100.0	93.3	93.3	93.3

(A) FIRST TERMINAL SACRIFICE

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

# P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

#### CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:23:14 First Dose M/F: NA / NA Lab: BAT

#### Male MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

### SURVIVAL SUMMARY STATISTICS

DOSE	VEHICLE CONTROL	TPA 5 COMPLETE	MNNG 100/ACETONE	MNNG100/COMPLETE
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	53.3%
(KAPLAN-MEIER)				
SIGNIFICANCE (B)	P=0.005N			P=0.000
(LIFE TABLE)				
MEAN DAY OF NATURAL DEATHS (C)				306.6
(STANDARD ERROR)	(.)	(.)	(.)	(9.0)
MEAN LIFE SPAN (D)	363.0	363.0	363.0	336.7
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(6.6)

(A) FIRST TERMINAL SACRIFICE

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

## P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

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#### CAS Number: INIT/PROM

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#### Male MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

### SURVIVAL SUMMARY STATISTICS

DOSE	MNNG 100/TPA 5	MNNG 500/ACETONE	MNNG1000/ACETONE	MNNG1000/TPA 5
SURVIVAL AT END OF STUDY	96.7%	96.7%	93.3%	53.3%
(KAPLAN-MEIER)				
SIGNIFICANCE (B)	P=1.000	P=1.000	P=0.472	P=0.000
(LIFE TABLE)				
MEAN DAY OF NATURAL DEATHS (C)	343.0	266.0	265.0	268.2
(STANDARD ERROR)	(.)	(.)	(53.0)	(14.8)
MEAN LIFE SPAN (D)	362.3	359.8	356.5	318.8
(STANDARD ERROR)	(0.7)	(3.2)	(5.2)	(11.1)

(A) FIRST TERMINAL SACRIFICE

(B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

## P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

#### CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:23:14 First Dose M/F: NA / NA Lab: BAT

#### Male MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

### SURVIVAL SUMMARY STATISTICS

DOSE	<b>BPO 20 COMPLETE</b>	MNNG 100/BPO 20	MNNG 500/BPO 20	MNNG1000/BPO 20
SURVIVAL AT END OF STUDY	100.0%	100.0%	96.7%	93.3%
(KAPLAN-MEIER)				
SIGNIFICANCE (B)			P=1.000	P=0.476
(LIFE TABLE)				
MEAN DAY OF NATURAL DEATHS (C)			343.0	290.0
(STANDARD ERROR)	(.)	(.)	(.)	(.)
MEAN LIFE SPAN (D)	363.0	363.0	362.3	358.1
(STANDARD ERROR)	(0.0)	(0.0)	(0.7)	(3.4)

(A) FIRST TERMINAL SACRIFICE

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

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CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:23:14 First Dose M/F: NA / NA Lab: BAT

# Female MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

					IND	VIDUAL SU	RVIVAL TIN	IES (DAYS)						
DOSE =	VEHICLE (	CONTROL												
TOTAL	30		UNCEN	SORED DE	ATHS 0	CENSO	RED DEAT	HS 0	TERMI	NAL 30				
UNCEN	SORED DE	ATH DAYS												
none														
CENSO	RED DEATH	H DAYS												
none														
DOSE =	TPA 5 CO	MPLETE												
TOTAL :	30		UNCEN	SORED DE	ATHS 0	CENSO	RED DEAT	HS 0	TERMI	VAL 30				
UNCEN	SORED DE	ATH DAYS												
none														
CENSO	RED DEATH	H DAYS												
none														
DOSE =	MNNG 100	ACETONE												
TOTAL :	30		UNCEN	SORED DE	ATHS 0	CENSO	RED DEAT	HS 0	TERMI	VAL 30				
UNCEN	SORED DE	ATH DAYS												
none														
CENSO	RED DEATH	H DAYS												
none														
DOSE =	MNNG100/	COMPLETE												
TOTAL 3	30		UNCEN	SORED DE	ATHS 17	CENSO	RED DEATI	HS 0	TERMI	VAL 13				
UNCEN	SORED DE	ATH DAYS												
189	268	268	281	281	282	290	308	308	311	318	318	330	336	
339	343	343												
CENSO	RED DEATH	H DAYS												
none														

(A) FIRST TERMINAL SACRIFICE

(B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

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CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:23:14 First Dose M/F: NA / NA Lab: BAT

# Female MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

					IND	VIDUAL SU	RVIVAL TIMES (DA	YS)	
DOSE =	MNNG 100/	/TPA 5							
TOTAL 30	D		UNCEN	SORED DE	ATHS 0	CENSO	RED DEATHS 1	TERMINAL 29	
UNCENS	ORED DE	ATH DAYS							
none									
CENSOR	ED DEATH	I DAYS							
77									
DOSE = I	MNNG 500/	ACETONE							
TOTAL 30	D		UNCEN	SORED DE	ATHS 0	CENSO	RED DEATHS 0	TERMINAL 30	
UNCENS	ORED DE	ATH DAYS							
none									
CENSOR	ED DEATH	I DAYS							
none									
DOSE = I	MNNG1000	ACETONE							
TOTAL 30	D		UNCEN	SORED DE	ATHS 7	CENSO	RED DEATHS 0	TERMINAL 23	
UNCENS	ORED DE	ATH DAYS							
177	177	245	282	298	304	349			
CENSOR	ED DEATH	I DAYS							
none									
DOSE = I	MNNG1000	/TPA 5							
TOTAL 30	D		UNCEN	SORED DE	ATHS 8	CENSO	RED DEATHS 0	TERMINAL 22	
UNCENS	ORED DEA	ATH DAYS							
12	170	212	268	282	290	330	338		
CENSOR	ED DEATH	I DAYS							
none									

(A) FIRST TERMINAL SACRIFICE

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

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# Female MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

	IND	IVIDUAL SURVIVAL TIMES (DAYS	5)	
DOSE = BPO 20 COMPLETE				
TOTAL 30	UNCENSORED DEATHS 1	CENSORED DEATHS 0	TERMINAL 29	
UNCENSORED DEATH DAYS				
315				
CENSORED DEATH DAYS				
none				
DOSE = MNNG 100/BPO 20				
TOTAL 30	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 30	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = MNNG 500/BPO 20				
TOTAL 30	UNCENSORED DEATHS 2	CENSORED DEATHS 1	TERMINAL 27	
UNCENSORED DEATH DAYS				
248 353				
CENSORED DEATH DAYS				
306				
DOSE = MNNG1000/BPO 20				
TOTAL 30	UNCENSORED DEATHS 5	CENSORED DEATHS 0	TERMINAL 25	
UNCENSORED DEATH DAYS				
134 227 254	258 343			
CENSORED DEATH DAYS				
none				

(A) FIRST TERMINAL SACRIFICE

(B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

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# Female MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

#### KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE					TIME	(DAYS)				
	37	74	111	148	185	222	259	296	333	363(A)
VEHICLE CONTROL	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
TPA 5 COMPLETE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
MNNG 100/ACETONE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
MNNG100/COMPLETE	100.0	100.0	100.0	100.0	100.0	96.7	96.7	76.7	56.7	43.3
MNNG 100/TPA 5	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
MNNG 500/ACETONE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
MNNG1000/ACETONE	100.0	100.0	100.0	100.0	93.3	93.3	90.0	86.7	80.0	76.7
MNNG1000/TPA 5	96.7	96.7	96.7	96.7	93.3	90.0	90.0	80.0	76.7	73.3
BPO 20 COMPLETE	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.7	96.7
MNNG 100/BPO 20	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
MNNG 500/BPO 20	100.0	100.0	100.0	100.0	100.0	100.0	96.7	96.7	96.7	93.2
MNNG1000/BPO 20	100.0	100.0	100.0	96.7	96.7	96.7	86.7	86.7	86.7	83.3

(A) FIRST TERMINAL SACRIFICE

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

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#### Female MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

### SURVIVAL SUMMARY STATISTICS

DOSE	VEHICLE CONTROL	TPA 5 COMPLETE	MNNG 100/ACETONE	MNNG100/COMPLETE
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	43.3%
(KAPLAN-MEIER)				
SIGNIFICANCE (B)	P=0.133N			P=0.000
(LIFE TABLE)				
MEAN DAY OF NATURAL DEATHS (C)				300.8
(STANDARD ERROR)	(.)	(.)	(.)	(9.4)
MEAN LIFE SPAN (D)	363.0	363.0	363.0	327.7
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(7.8)

(A) FIRST TERMINAL SACRIFICE

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

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# Female MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

## SURVIVAL SUMMARY STATISTICS

DOSE	MNNG 100/TPA 5	MNNG 500/ACETONE	MNNG1000/ACETONE	MNNG1000/TPA 5	
SURVIVAL AT END OF STUDY	100.0%	100.0%	76.7%	73.3%	
(KAPLAN-MEIER)					
SIGNIFICANCE (B)			P=0.016	P=0.008	
(LIFE TABLE)					
MEAN DAY OF NATURAL DEATHS (C)			261.7	237.8	
(STANDARD ERROR)	(.)	(.)	(24.8)	(37.9)	
MEAN LIFE SPAN (D)	353.5	363.0	339.4	329.6	
(STANDARD ERROR)	(9.5)	(0.0)	(9.6)	(14.1)	

(A) FIRST TERMINAL SACRIFICE

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

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#### Female MOUSE FIRST TERMINAL SACRIFICE AT 363 DAYS

### SURVIVAL SUMMARY STATISTICS

DOSE	BPO 20 COMPLETE	MNNG 100/BPO 20	MNNG 500/BPO 20	MNNG1000/BPO 20
SURVIVAL AT END OF STUDY	96.7%	100.0%	93.2%	83.3%
(KAPLAN-MEIER)				
SIGNIFICANCE (B)	P=1.000		P=0.464	P=0.062
(LIFE TABLE)				
MEAN DAY OF NATURAL DEATHS (C)	315.0		300.5	243.2
(STANDARD ERROR)	(.)	(.)	(52.5)	(33.5)
MEAN LIFE SPAN (D)	361.4	363.0	356.9	343.0
(STANDARD ERROR)	(1.6)	(0.0)	(4.2)	(9.7)

(A) FIRST TERMINAL SACRIFICE

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

# P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

CAS Number: INIT/PROM

\*\* END OF REPORT \*\*

Date Report Requested: 10/21/2014 Time Report Requested: 06:23:14 First Dose M/F: NA / NA Lab: BAT

(A) FIRST TERMINAL SACRIFICE

(B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE