

MortalityTimeToEvent_DS001.sas: Mortality Time to Event Validation Program
SAFETY Population, Actual Treatment, Last Disposition Date as censor date
Overall survival Analysis By treatment

	NIC.15		Placebo	
Overall Survival	Count	%	Count	%
DEATH	80	17.90	81	17.80
CENSORED	367	82.10	374	82.20
COMPLETED	356	79.64	363	79.78
LOST TO FOLLOW-UP	11	2.46	11	2.42

Kaplan-Meier estimate of overall survival				
	NIC.15		Placebo	
Quantile	Estimate	CI	Estimate	CI
25	55.000	(37,66.0)	55.000	(37,81.0)
50	91.000	(70, .)	112.000	(82, .)
75		(., .)	125.000	(118, .)

Unstratified Analysis		
Description	HazardRatio	95 % CI
TRT01P NIC .15 vs Placebo	1.006	(0.739, 1.371)

Test	Pr > Chi-Square
Log-Rank	0.9677

		NIC.15 N=N_nic		Placebo N=N_Placebo		NIC .15 vs Placebo	
	Demographic Subgroup	Event Counts	Subgroup Counts	Event Counts	Subgroup Counts	Hazard Ratio	Confidence Interval
Race	ASIAN	2	8	2	7	1.080	(0.151, 7.716)
	BLACK OR AF	17	78	13	60	1.209	(0.573, 2.549)
	OTHER	2	21	2	29	1.344	(0.189, 9.543)
	WHITE	59	340	64	359	0.932	(0.654, 1.328)
agegrp	0<=Age<=39	16	113	10	107	1.748	(0.790, 3.867)
	39<Age<=64	44	266	51	285	0.910	(0.607, 1.362)
	Age>64	20	68	20	63	0.840	(0.450, 1.567)
countr	USA	80	447	81	455	1.006	(0.739, 1.371)
sex	F	52	281	56	297	1.022	(0.700, 1.491)
	M	28	166	25	158	1.091	(0.627, 1.897)
siteid	01	5	25	4	26	1.000	(0.257, 3.895)
	02	1	16	2	16	0.537	(0.048, 5.952)
	03	1	11	1	12	67878667	(0.000, .)
	04	4	14	2	12	1.119	(0.196, 6.403)
	05	1	2	2	2	1.414	(0.085,23.573)
	06	2	3	1	4	4.109E8	(0.000, .)
	07	2	3	0	2	1.8619E8	(0.000, .)
	08	3	12	6	11	0.259	(0.052, 1.287)
	09	9	20	4	20	2.592	(0.696, 9.654)
	10	4	9	1	8	3.813	(0.388,37.473)
	12	3	9	4	7	0.864	(0.174, 4.295)
	14	4	37	3	38	1.917	(0.340,10.806)
	16	0	19	1	20	0.000	(0.000, .)

MortalityTimeToEvent_DS001.sas: Mortality Time to Event Validation Program
SAFETY Popluation, Actural Treatment, Last Disposition Date as censor date
Overall survival Analysis By treatment

		NIC.15 N=N_nic		Placebo N=N_Placebo		NIC .15 vs Placebo	
	Demographic Subgroup	Event Counts	Subgroup Counts	Event Counts	Subgroup Counts	Hazard Ratio	Confidence Interval
	17	3	8	2	10	2.167	(0.361,13.004)
	18	1	11	0	11	80429755	(0.000, .)
	19	0	3	2	5	0.000	(0.000, .)
	20	0	9	3	9	0.000	(0.000, .)
	21	0	4	2	6	0.000	(0.000, .)
	22	1	11	4	12	0.241	(0.027, 2.174)
	23	5	15	2	14	1.076	(0.172, 6.717)
	24	1	11	1	10	1.005	(0.063,16.124)
	25	3	8	3	7	2.017	(0.304,13.404)
	26	1	4	0	4	1.000	(1.000, 1.000)
	27	0	12	3	12	0.000	(0.000, .)
	28	5	36	4	38	1.234	(0.331, 4.605)
	29	0	6	3	6	0.000	(0.000, .)
	30	0	3	0	2	1.000	(1.000, 1.000)
	31	1	1	1	3	5.2819E8	(0.000, .)
	32	6	23	3	22	2.464	(0.603,10.075)
	33	1	5	1	4	0.000	(0.000, .)
	34	1	3	1	4	3.0251E8	(0.000, .)
	35	1	4	0	4	1.575E12	(0.000, .)
	36	0	3	0	3	1.000	(1.000, 1.000)
	37	1	6	1	7	0.000	(0.000, .)
	39	2	8	1	9	2.000	(0.181,22.053)
	40	2	18	3	20	0.847	(0.140, 5.127)
	42	2	10	1	10	2.072	(0.188,22.866)
	44	2	19	5	19	0.391	(0.076, 2.019)
	45	1	10	0	10	1.2816E8	(0.000, .)
	46	1	16	4	16	0.298	(0.031, 2.870)