

**MortalityTimeToEvent\_DS001.sas: Mortality Time to Event Validation Program  
SAFETY Population, Actural Treatment, Last Disposition Date as censor date  
Overall survival Analysis By treatment**

Overall Survival	NIC.15		Placebo	
	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 surviva				
Quantile	NIC.15		Placebo	
	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

	Demographic Subgroup	NIC.15 N=N_nic		Placebo N=N_Placebo		NIC .15 vs Placebo	
		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, . )

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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)