Eigene Vorlage

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Niraparib (Zejula)

GlaxoSmithKline GmbH & Co. KG

Separater Anhang 4-G zu Modul 4A

Tabellen und Abbildungen

Stand: 01.02.2021

Inhaltsverzeichnis

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Baseline	Actual	n	356	173
		Mean (StdDev)	1.5 (1.13)	1.6 (1.17)
		Median	1.0	2.0
		Q1, Q3	1.0, 2.0	1.0, 2.0
		Min, Max	0, 4	0, 4
Cycle 2 Day 1	Actual	n	303	156
		Mean (StdDev)	1.5 (1.15)	1.5 (1.06)
		Median	1.0	1.0
		Q1, Q3	1.0, 2.0	1.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	294	153
		Mean (StdDev)	0.1 (1.16)	-0.2 (1.01)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	-1.0, 0.0
		Min, Max	-4, 4	-3, 3
		LS Mean (SE)	0.1 (0.06)	-0.1 (0.08)
		95% CI	0.0, 0.2	-0.3, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.2 (0.10)	
		95% CI	0.0, 0.4	
		p-value	0.0366	
		Corrected Hedges g (95% CI) [2]	0.21 (0.01, 0.40)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 4 Day 1	Actual	n	267	124
		Mean (StdDev)	1.4 (1.14)	1.5 (1.11)
		Median	1.0	1.0
		Q1, Q3	1.0, 2.0	1.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	258	121
		Mean (StdDev)	0.0(1.04)	-0.1 (1.09)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	-1.0, 0.0
		Min, Max	-3, 3	-3, 3
		LS Mean (SE)	0.0 (0.06)	-0.1 (0.09)
		95% CI	-0.1, 0.1	-0.2, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.10)	
		95% CI	-0.1, 0.3	
		p-value	0.5079	
		Corrected Hedges g (95% CI) [2]	0.07 (-0.14, 0.29)	
Cycle 6 Day 1	Actual	n	224	86
		Mean (StdDev)	1.2 (1.11)	1.4 (1.15)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	0.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	217	86
		Mean (StdDev)	-0.2 (1.15)	-0.2 (1.01)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 3	-3, 3
		LS Mean (SE)	-0.2 (0.06)	-0.2 (0.10)
		95% CI	-0.3, 0.0	-0.4, 0.0
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.12)	
		95% CI	-0.2, 0.2	
		p-value	0.9305	
		Corrected Hedges g (95% CI) [2]	-0.01 (-0.26, 0.24)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 8 Day 1	Actual	n	193	56
		Mean (StdDev)	1.1 (1.08)	1.4 (1.05)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	1.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	189	56
		Mean (StdDev)	-0.2 (1.14)	-0.3 (0.99)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 3	-2, 3
		LS Mean (SE)	-0.2 (0.07)	-0.2 (0.11)
		95% CI	-0.4, -0.1	-0.4, 0.0
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.13)	
		95% CI	-0.3, 0.2	
		p-value	0.7203	
		Corrected Hedges g (95% CI) [2]	-0.05 (-0.35, 0.25)	
Cycle 10 Day 1	Actual	n	164	40
		Mean (StdDev)	1.1 (1.06)	1.2 (1.10)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	0.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	160	40
		Mean (StdDev)	-0.3 (1.13)	-0.5 (1.11)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 3	-4, 1
		LS Mean (SE)	-0.3 (0.06)	-0.4 (0.12)
		95% CI	-0.4, -0.2	-0.6, -0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.13)	
		95% CI	-0.2, 0.3	
		p-value	0.6331	
		Corrected Hedges g (95% CI) [2]	0.08 (-0.27, 0.43)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 12 Day 1	Actual	n	150	36
		Mean (StdDev)	1.0 (1.06)	1.4 (1.05)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	1.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	148	36
		Mean (StdDev)	-0.4 (1.14)	-0.4 (0.87)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 3	-3, 1
		LS Mean (SE)	-0.3 (0.06)	-0.3 (0.12)
		95% CI	-0.5, -0.2	-0.5, 0.0
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.14)	
		95% CI	-0.3, 0.2	
		p-value	0.6254	
		Corrected Hedges g (95% CI) [2]	-0.09 (-0.45, 0.28)	
Cycle 14 Day 1	Actual	n	128	26
		Mean (StdDev)	1.0 (1.05)	1.2 (1.07)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	0.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	125	26
		Mean (StdDev)	-0.4 (1.15)	-0.4 (1.02)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 3	-2, 2
		LS Mean (SE)	-0.3 (0.07)	-0.3 (0.14)
		95% CI	-0.5, -0.2	-0.6, 0.0
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.16)	
		95% CI	-0.3, 0.3	
		p-value	0.9625	
		Corrected Hedges g (95% CI) [2]	-0.01 (-0.43, 0.41)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 17 Day 1	Actual	n	89	18
		Mean (StdDev)	0.9 (0.98)	1.1 (1.00)
		Median	1.0	1.0
		Q1, Q3	0.0, 1.0	0.0, 2.0
		Min, Max	0, 4	0, 3
	Change from BL	n	87	18
		Mean (StdDev)	-0.4 (1.05)	-0.5 (1.15)
		Median	0.0	-1.0
		Q1, Q3	-1.0, 0.0	-1.0, 1.0
		Min, Max	-4, 2	-3, 1
		LS Mean (SE)	-0.4 (0.07)	-0.5 (0.16)
		95% CI	-0.5, -0.2	-0.8, -0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.17)	
		95% CI	-0.2, 0.4	
		p-value	0.5843	
		Corrected Hedges g (95% CI) [2]	0.14 (-0.37, 0.64)	
Cycle 20 Day 1	Actual	n	82	13
		Mean (StdDev)	0.9 (0.95)	1.3 (0.95)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	1.0, 2.0
		Min, Max	0, 4	0, 3
	Change from BL	n	81	13
		Mean (StdDev)	-0.5 (1.06)	-0.2 (1.01)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 2	-2, 2
		LS Mean (SE)	-0.5 (0.07)	-0.2 (0.17)
		95% CI	-0.6, -0.3	-0.6, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.19)	
		95% CI	-0.6, 0.1	
		p-value	0.2056	
		Corrected Hedges g (95% CI) [2]	-0.36 (-0.95, 0.23)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 23 Day 1	Actual	n	65	11
		Mean (StdDev)	0.8 (0.93)	1.4 (1.03)
		Median	1.0	1.0
		Q1, Q3	0.0, 1.0	1.0, 2.0
		Min, Max	0, 4	0, 3
	Change from BL	n	64	11
		Mean (StdDev)	-0.5 (1.21)	-0.2 (1.17)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 1.0
		Min, Max	-4, 2	-2, 2
		LS Mean (SE)	-0.5 (0.09)	-0.2 (0.22)
		95% CI	-0.7, -0.3	-0.6, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.24)	
		95% CI	-0.8, 0.1	
		p-value	0.1738	
		Corrected Hedges g (95% CI) [2]	-0.43 (-1.07, 0.21)	
Cycle 26 Day 1	Actual	n	62	10
		Mean (StdDev)	0.9 (0.98)	1.0 (0.82)
		Median	1.0	1.0
		Q1, Q3	0.0, 1.0	0.0, 2.0
		Min, Max	0, 3	0, 2
	Change from BL	n	61	10
		Mean (StdDev)	-0.4 (1.19)	-0.3 (0.82)
		Median	0.0	-0.5
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 2	-1, 1
		LS Mean (SE)	-0.4 (0.09)	-0.5 (0.22)
		95% CI	-0.6, -0.3	-0.9, 0.0
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.23)	
		95% CI	-0.4, 0.5	
		p-value	0.9442	
		Corrected Hedges g (95% CI) [2]	0.02 (-0.65, 0.69)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 29 Day 1	Actual	n	58	8
		Mean (StdDev)	0.8 (0.93)	1.0 (0.76)
		Median	1.0	1.0
		Q1, Q3	0.0, 1.0	0.5, 1.5
		Min, Max	0, 3	0, 2
	Change from BL	n	57	8
		Mean (StdDev)	-0.5 (1.21)	-0.3 (0.89)
		Median	0.0	-0.5
		Q1, Q3	-1.0, 0.0	-1.0, 0.5
		Min, Max	-4, 2	-1, 1
		LS Mean (SE)	-0.5 (0.08)	-0.4 (0.20)
		95% CI	-0.7, -0.3	-0.8, 0.0
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.22)	
		95% CI	-0.6, 0.3	
		p-value	0.5116	
		Corrected Hedges g (95% CI) [2]	-0.23 (-0.97, 0.51)	
Cycle 32 Day 1	Actual	n	46	8
		Mean (StdDev)	0.7 (0.89)	0.8 (0.89)
		Median	1.0	0.5
		Q1, Q3	0.0, 1.0	0.0, 1.5
		Min, Max	0, 4	0, 2
	Change from BL	n	45	8
		Mean (StdDev)	-0.6 (1.21)	-0.5 (0.76)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 2	-2, 0
		LS Mean (SE)	-0.6 (0.09)	-0.6 (0.21)
		95% CI	-0.8, -0.4	-1.1, -0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.23)	
		95% CI	-0.4, 0.5	
		p-value	0.9436	
		Corrected Hedges g (95% CI) [2]	0.03 (-0.73, 0.78)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 35 Day 1	Actual	n	48	7
		Mean (StdDev)	1.0 (0.99)	0.7 (0.76)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	47	7
		Mean (StdDev)	-0.4 (1.09)	-0.9 (0.69)
		Median	0.0	-1.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 2	-2, 0
		LS Mean (SE)	-0.4 (0.09)	-0.6 (0.22)
		95% CI	-0.6, -0.2	-1.1, -0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.2 (0.24)	
		95% CI	-0.2, 0.7	
		p-value	0.3182	
		Corrected Hedges g (95% CI) [2]	0.38 (-0.41, 1.18)	
Cycle 38 Day 1	Actual	n	41	7
		Mean (StdDev)	0.8 (1.02)	0.4 (0.79)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	40	7
		Mean (StdDev)	-0.6 (0.93)	-0.7 (0.76)
		Median	0.0	-1.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 2	-2, 0
		LS Mean (SE)	-0.5 (0.09)	-0.9 (0.20)
		95% CI	-0.7, -0.3	-1.3, -0.5
		Difference from placebo [1]		
		LS Mean (SE)	0.4 (0.21)	
		95% CI	-0.1, 0.8	
		p-value	0.0930	
		Corrected Hedges g (95% CI) [2]	0.66 (-0.15, 1.48)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
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Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 41 Day 1	Actual	n	44	7
		Mean (StdDev)	1.0 (1.15)	1.0 (0.82)
		Median	1.0	1.0
		Q1, Q3	0.0, 1.5	0.0, 2.0
		Min, Max	0, 4	0, 2
	Change from BL	n	43	7
		Mean (StdDev)	-0.3 (1.13)	-0.4 (0.98)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-3, 2	-2, 1
		LS Mean (SE)	-0.3 (0.12)	-0.4 (0.28)
		95% CI	-0.6, -0.1	-1.0, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.31)	
		95% CI	-0.5, 0.7	
		p-value	0.7909	
		Corrected Hedges g (95% CI) [2]	0.10 (-0.69, 0.90)	
Cycle 44 Day 1	Actual	n	35	8
		Mean (StdDev)	0.8 (1.11)	1.0 (0.53)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	1.0, 1.0
		Min, Max	0, 4	0, 2
	Change from BL	n	35	8
		Mean (StdDev)	-0.4 (1.11)	-0.4 (1.06)
		Median	0.0	-1.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 2	-1, 2
		LS Mean (SE)	-0.4 (0.12)	-0.3 (0.24)
		95% CI	-0.6, -0.2	-0.8, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.27)	
		95% CI	-0.6, 0.4	
		p-value	0.7339	
		Corrected Hedges g (95% CI) [2]	-0.13 (-0.90, 0.64)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 47 Day 1	Actual	n	37	5
		Mean (StdDev)	1.2 (1.27)	1.0 (0.71)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	1.0, 1.0
		Min, Max	0, 4	0, 2
	Change from BL	n	37	5
		Mean (StdDev)	-0.1 (0.99)	-0.4 (1.14)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-3, 2	-2, 1
		LS Mean (SE)	0.0 (0.14)	-0.3 (0.37)
		95% CI	-0.3, 0.2	-1.0, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	0.3 (0.40)	
		95% CI	-0.6, 1.1	
		p-value	0.5328	
		Corrected Hedges g (95% CI) [2]	0.28 (-0.65, 1.22)	
Cycle 53 Day 1	Actual	n	30	6
		Mean (StdDev)	0.8 (0.97)	1.5 (0.84)
		Median	0.5	1.0
		Q1, Q3	0.0, 1.0	1.0, 2.0
		Min, Max	0, 4	1, 3
	Change from BL	n	30	6
		Mean (StdDev)	-0.4 (0.90)	-0.2 (0.75)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-3, 1	-1, 1
		LS Mean (SE)	-0.5 (0.10)	0.1 (0.22)
		95% CI	-0.7, -0.3	-0.4, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.25)	
		95% CI	-1.1, -0.1	
		p-value	0.0159	
		Corrected Hedges g (95% CI) [2]	-1.07 (-1.98, -0.16)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 56 Day 1	Actual	n	29	5
		Mean (StdDev)	0.8 (1.02)	1.6 (1.52)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	1.0, 2.0
		Min, Max	0, 3	0, 4
	Change from BL	n	28	5
		Mean (StdDev)	-0.4 (1.14)	-0.2 (1.30)
		Median	0.0	-1.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 1	-1, 2
		LS Mean (SE)	-0.5 (0.11)	0.1 (0.26)
		95% CI	-0.7, -0.3	-0.4, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.29)	
		95% CI	-1.2, 0.0	
		p-value	0.0510	
		Corrected Hedges g (95% CI) [2]	-0.93 (-1.91, 0.04)	
Cycle 59 Day 1	Actual	n	31	6
		Mean (StdDev)	0.8 (1.07)	1.3 (1.03)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	1.0, 2.0
		Min, Max	0, 3	0, 3
	Change from BL	n	30	6
		Mean (StdDev)	-0.3 (1.18)	-0.3 (1.03)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 2	-2, 1
		LS Mean (SE)	-0.3 (0.12)	-0.1 (0.26)
		95% CI	-0.6, -0.1	-0.6, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.29)	
		95% CI	-0.8, 0.3	
		p-value	0.3906	
		Corrected Hedges g (95% CI) [2]	-0.37 (-1.25, 0.51)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 62 Day 1	Actual	n	27	5
		Mean (StdDev)	0.6 (0.88)	1.6 (1.52)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	1.0, 2.0
		Min, Max	0, 3	0, 4
	Change from BL	n	27	5
		Mean (StdDev)	-0.5 (0.94)	0.0 (1.41)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	0.0, 0.0
		Min, Max	-4, 1	-2, 2
		LS Mean (SE)	-0.6 (0.12)	0.2 (0.26)
		95% CI	-0.9, -0.4	-0.4, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.8 (0.29)	
		95% CI	-1.4, -0.2	
		p-value	0.0102	
		Corrected Hedges g (95% CI) [2]	-1.23 (-2.23, -0.23)	
Cycle 65 Day 1	Actual	n	22	5
		Mean (StdDev)	0.7 (1.03)	1.4 (1.14)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	1.0, 2.0
		Min, Max	0, 3	0, 3
	Change from BL	n	22	5
		Mean (StdDev)	-0.5 (1.10)	-0.4 (1.14)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 1	-2, 1
		LS Mean (SE)	-0.5 (0.11)	-0.1 (0.23)
		95% CI	-0.7, -0.3	-0.6, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.25)	
		95% CI	-0.9, 0.2	
		p-value	0.1769	
		Corrected Hedges g (95% CI) [2]	-0.66 (-1.65, 0.33)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 68 Day 1	Actual	n	23	6
		Mean (StdDev)	0.7 (0.93)	1.3 (0.82)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	1.0, 1.0
		Min, Max	0, 3	1, 3
	Change from BL	n	23	6
		Mean (StdDev)	-0.6 (1.16)	-0.3 (0.82)
		Median	0.0	-0.5
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 1	-1, 1
		LS Mean (SE)	-0.7 (0.12)	-0.1 (0.23)
		95% CI	-0.9, -0.4	-0.5, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.26)	
		95% CI	-1.1, -0.1	
		p-value	0.0229	
		Corrected Hedges g (95% CI) [2]	-1.06 (-2.00, -0.12)	
Study Treatment Discontinuation	Actual	n	275	143
		Mean (StdDev)	1.5 (1.18)	1.5 (1.12)
		Median	1.0	1.0
		Q1, Q3	1.0, 2.0	1.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	268	140
		Mean (StdDev)	0.0 (1.28)	-0.2 (1.07)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	-1.0, 0.0
		Min, Max	-4, 4	-4, 2
		LS Mean (SE)	0.0 (0.06)	0.0 (0.08)
		95% CI	-0.1, 0.2	-0.2, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.10)	
		95% CI	-0.1, 0.3	
		p-value	0.4203	
		Corrected Hedges g (95% CI) [2]	0.08 (-0.12, 0.29)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have a lack of energy

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Post Progression	Actual	n	241	124
		Mean (StdDev)	1.6 (1.16)	1.7 (1.17)
		Median	1.0	2.0
		Q1, Q3	1.0, 2.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	235	120
		Mean (StdDev)	0.1 (1.25)	0.0(1.25)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	-1.0, 1.0
		Min, Max	-4, 3	-4, 4
		LS Mean (SE)	0.1 (0.07)	0.1 (0.10)
		95% CI	0.0, 0.2	-0.1, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.12)	
		95% CI	-0.2, 0.2	
		p-value	0.9143	
		Corrected Hedges g (95% CI) [2]	0.01 (-0.21, 0.23)	
Overall	Change from BL	LS Mean (SE)	-0.1 (0.04)	-0.1 (0.06)
		95% CI	-0.2, 0.0	-0.2, 0.0
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.07)	
		95% CI	-0.1, 0.1	
		p-value	0.9908	
		Corrected Hedges g (95% CI) [2]	0.00 (-0.18, 0.18)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Baseline	Actual	n	356	173
		Mean (StdDev)	0.1 (0.32)	0.1 (0.42)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 3
Cycle 2 Day 1	Actual	n	302	156
		Mean (StdDev)	0.2 (0.60)	0.1 (0.37)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 4	0, 2
	Change from BL	n	294	152
		Mean (StdDev)	0.1 (0.62)	0.0(0.49)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 4	-3, 2
		LS Mean (SE)	0.1 (0.03)	0.0 (0.04)
		95% CI	0.1, 0.2	-0.1, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.05)	
		95% CI	0.0, 0.2	
		p-value	0.0220	
		Corrected Hedges g (95% CI) [2]	0.23 (0.03, 0.43)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 4 Day 1	Actual	n	268	125
		Mean (StdDev)	0.1 (0.46)	0.2 (0.52)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 3	0, 3
	Change from BL	n	259	121
		Mean (StdDev)	0.1 (0.51)	0.0 (0.63)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 3	-3, 3
		LS Mean (SE)	0.1 (0.03)	0.1 (0.04)
		95% CI	0.0, 0.1	0.0, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.05)	
		95% CI	-0.1, 0.1	
		p-value	0.9889	
		Corrected Hedges g (95% CI) [2]	0.00 (-0.21, 0.22)	
Cycle 6 Day 1	Actual	n	225	86
		Mean (StdDev)	0.1 (0.47)	0.1 (0.47)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 3	0, 3
	Change from BL	n	218	86
		Mean (StdDev)	0.0 (0.53)	0.0 (0.42)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 3	-2, 2
		LS Mean (SE)	0.0 (0.03)	0.0 (0.05)
		95% CI	0.0, 0.1	-0.1, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.06)	
		95% CI	-0.1, 0.1	
		p-value	0.8652	
		Corrected Hedges g (95% CI) [2]	0.02 (-0.23, 0.27)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 8 Day 1	Actual	n	191	57
		Mean (StdDev)	0.1 (0.53)	0.1 (0.34)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 4	0, 2
	Change from BL	n	187	57
		Mean (StdDev)	0.1 (0.58)	0.0(0.38)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 4	-2, 1
		LS Mean (SE)	0.1 (0.03)	0.0 (0.06)
		95% CI	0.0, 0.1	-0.1, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.07)	
		95% CI	-0.1, 0.2	
		p-value	0.5030	
		Corrected Hedges g (95% CI) [2]	0.10 (-0.20, 0.40)	
Cycle 10 Day 1	Actual	n	162	40
		Mean (StdDev)	0.1 (0.47)	0.1 (0.35)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 4	0, 2
	Change from BL	n	158	40
		Mean (StdDev)	0.0 (0.44)	0.0(0.42)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 4	-2, 1
		LS Mean (SE)	0.0 (0.03)	0.0 (0.06)
		95% CI	0.0, 0.1	-0.1, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.06)	
		95% CI	-0.1, 0.2	
		p-value	0.5712	
		Corrected Hedges g (95% CI) [2]	0.10 (-0.25, 0.45)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 12 Day 1	Actual	n	148	36
		Mean (StdDev)	0.1 (0.44)	0.1 (0.28)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 3	0, 1
	Change from BL	n	146	36
		Mean (StdDev)	0.0 (0.36)	0.0(0.45)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 3	-2, 1
		LS Mean (SE)	0.0 (0.03)	0.0 (0.06)
		95% CI	0.0, 0.1	-0.1, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.07)	
		95% CI	-0.1, 0.2	
		p-value	0.6146	
		Corrected Hedges g (95% CI) [2]	0.09 (-0.27, 0.46)	
Cycle 14 Day 1	Actual	n	128	26
		Mean (StdDev)	0.1 (0.37)	0.1 (0.43)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 3	0, 2
	Change from BL	n	125	26
		Mean (StdDev)	0.0 (0.46)	0.1 (0.27)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 3	0, 1
		LS Mean (SE)	0.0 (0.03)	0.0 (0.07)
		95% CI	-0.1, 0.1	-0.1, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.08)	
		95% CI	-0.2, 0.1	
		p-value	0.6565	
		Corrected Hedges g (95% CI) [2]	-0.09 (-0.52, 0.33)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 17 Day 1	Actual	n	90	18
		Mean (StdDev)	0.1 (0.33)	0.1 (0.24)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 1
	Change from BL	n	88	18
		Mean (StdDev)	0.0 (0.39)	0.1 (0.24)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 2	0, 1
		LS Mean (SE)	0.0 (0.03)	0.0 (0.07)
		95% CI	-0.1, 0.1	-0.1, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.08)	
		95% CI	-0.2, 0.1	
		p-value	0.8863	
		Corrected Hedges g (95% CI) [2]	-0.04 (-0.54, 0.47)	
Cycle 20 Day 1	Actual	n	81	13
		Mean (StdDev)	0.1 (0.32)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 0
	Change from BL	n	80	13
		Mean (StdDev)	0.0 (0.37)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 2	0, 0
		LS Mean (SE)	0.0 (0.03)	0.0 (0.08)
		95% CI	0.0, 0.1	-0.2, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.09)	
		95% CI	-0.1, 0.2	
		p-value	0.5761	
		Corrected Hedges g (95% CI) [2]	0.16 (-0.42, 0.75)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 23 Day 1	Actual	n	65	11
		Mean (StdDev)	0.1 (0.24)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 1	0, 0
	Change from BL	n	64	11
		Mean (StdDev)	0.0 (0.21)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 1	0, 0
		LS Mean (SE)	0.0 (0.03)	0.0 (0.06)
		95% CI	0.0, 0.1	-0.1, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.07)	
		95% CI	-0.1, 0.2	
		p-value	0.4407	
		Corrected Hedges g (95% CI) [2]	0.23 (-0.41, 0.87)	
Cycle 26 Day 1	Actual	n	62	10
		Mean (StdDev)	0.1 (0.48)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 3	0, 0
	Change from BL	n	61	10
		Mean (StdDev)	0.1 (0.44)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-1, 3	0, 0
		LS Mean (SE)	0.1 (0.06)	0.0 (0.14)
		95% CI	0.0, 0.2	-0.3, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.15)	
		95% CI	-0.2, 0.4	
		p-value	0.5979	
		Corrected Hedges g (95% CI) [2]	0.18 (-0.49, 0.85)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 29 Day 1	Actual	n	58	7
		Mean (StdDev)	0.1 (0.41)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 0
	Change from BL	n	57	7
		Mean (StdDev)	0.1 (0.35)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-1, 2	0, 0
		LS Mean (SE)	0.0 (0.04)	0.0 (0.12)
		95% CI	0.0, 0.1	-0.3, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.13)	
		95% CI	-0.2, 0.3	
		p-value	0.6021	
		Corrected Hedges g (95% CI) [2]	0.20 (-0.58, 0.99)	
Cycle 32 Day 1	Actual	n	46	8
		Mean (StdDev)	0.2 (0.66)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 3	0, 0
	Change from BL	n	45	8
		Mean (StdDev)	0.2 (0.77)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 3	0, 0
		LS Mean (SE)	0.1 (0.10)	-0.1 (0.23)
		95% CI	0.0, 0.3	-0.5, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	0.2 (0.25)	
		95% CI	-0.3, 0.7	
		p-value	0.3635	
		Corrected Hedges g (95% CI) [2]	0.35 (-0.41, 1.10)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 35 Day 1	Actual	n	48	7
		Mean (StdDev)	0.0 (0.29)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 0
	Change from BL	n	47	7
		Mean (StdDev)	0.0(0.15)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-1, 0	0, 0
		LS Mean (SE)	0.0 (0.03)	0.0 (0.07)
		95% CI	-0.1, 0.0	-0.2, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.08)	
		95% CI	-0.2, 0.2	
		p-value	0.9842	
		Corrected Hedges g (95% CI) [2]	0.01 (-0.79, 0.80)	
Cycle 38 Day 1	Actual	n	41	8
		Mean (StdDev)	0.1 (0.35)	0.1 (0.35)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 1
	Change from BL	n	40	8
		Mean (StdDev)	0.0 (0.00)	0.1 (0.35)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 0	0, 1
		LS Mean (SE)	0.0 (0.03)	0.1 (0.06)
		95% CI	0.0, 0.1	0.0, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.07)	
		95% CI	-0.3, 0.0	
		p-value	0.1080	
		Corrected Hedges g (95% CI) [2]	-0.62 (-1.39, 0.15)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 41 Day 1	Actual	n	44	7
		Mean (StdDev)	0.2 (0.69)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 4	0, 0
	Change from BL	n	43	7
		Mean (StdDev)	0.1 (0.74)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 4	0, 0
		LS Mean (SE)	0.1 (0.10)	-0.1 (0.24)
		95% CI	-0.1, 0.3	-0.5, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.26)	
		95% CI	-0.4, 0.7	
		p-value	0.5764	
		Corrected Hedges g (95% CI) [2]	0.23 (-0.57, 1.03)	
Cycle 44 Day 1	Actual	n	36	8
		Mean (StdDev)	0.1 (0.40)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 0
	Change from BL	n	36	8
		Mean (StdDev)	0.1 (0.37)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 0
		LS Mean (SE)	0.1 (0.06)	0.0 (0.13)
		95% CI	-0.1, 0.2	-0.3, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.14)	
		95% CI	-0.2, 0.4	
		p-value	0.5726	
		Corrected Hedges g (95% CI) [2]	0.21 (-0.56, 0.98)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 47 Day 1	Actual	n	38	5
		Mean (StdDev)	0.1 (0.23)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 1	0, 0
	Change from BL	n	38	5
		Mean (StdDev)	0.1 (0.23)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 1	0, 0
		LS Mean (SE)	NA	NA
		95% CI	NA	NA
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.11)	
		95% CI	-0.2, 0.3	
		p-value	0.5726	
		Corrected Hedges g (95% CI) [2]	NA	
Cycle 53 Day 1	Actual	n	31	6
		Mean (StdDev)	0.1 (0.25)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 1	0, 0
	Change from BL	n	31	6
		Mean (StdDev)	0.1 (0.25)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 1	0, 0
		LS Mean (SE)	NA	NA
		95% CI	NA	NA
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.10)	
		95% CI	-0.1, 0.3	
		p-value	0.5094	
		Corrected Hedges g (95% CI) [2]	NA	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 56 Day 1	Actual	n	29	5
		Mean (StdDev)	0.1 (0.44)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 0
	Change from BL	n	28	5
		Mean (StdDev)	0.1 (0.45)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 0
		LS Mean (SE)	NA	NA
		95% CI	NA	NA
		Difference from placebo [1]		
		LS Mean (SE)	0.2 (0.20)	
		95% CI	-0.2, 0.6	
		p-value	0.4258	
		Corrected Hedges g (95% CI) [2]	NA	
Cycle 59 Day 1	Actual	n	31	5
		Mean (StdDev)	0.1 (0.36)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 0
	Change from BL	n	30	5
		Mean (StdDev)	0.1 (0.37)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 0
		LS Mean (SE)	NA	NA
		95% CI	NA	NA
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.18)	
		95% CI	-0.3, 0.4	
		p-value	0.9652	
		Corrected Hedges g (95% CI) [2]	NA	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 62 Day 1	Actual	n	27	5
		Mean (StdDev)	0.1 (0.27)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 1	0, 0
	Change from BL	n	27	5
		Mean (StdDev)	0.1 (0.27)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 1	0, 0
		LS Mean (SE)	NA	NA
		95% CI	NA	NA
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.14)	
		95% CI	-0.3, 0.3	
		p-value	0.9287	
		Corrected Hedges g (95% CI) [2]	NA	
Cycle 68 Day 1	Actual	n	23	6
		Mean (StdDev)	0.0 (0.00)	0.2 (0.41)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 0	0, 1
	Change from BL	n	23	6
		Mean (StdDev)	0.0 (0.00)	0.2 (0.41)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 0	0, 1
		LS Mean (SE)	NA	NA
		95% CI	NA	NA
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.09)	
		95% CI	-0.4, 0.0	
		p-value	0.0652	
		Corrected Hedges g (95% CI) [2]	NA	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Study Treatment Discontinuation	Actual	n	274	142
		Mean (StdDev)	0.2 (0.64)	0.2 (0.55)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 4	0, 3
	Change from BL	n	267	139
		Mean (StdDev)	0.1 (0.70)	0.0 (0.64)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 4	-3, 3
		LS Mean (SE)	0.1 (0.04)	0.1 (0.05)
		95% CI	0.1, 0.2	0.0, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.06)	
		95% CI	-0.1, 0.2	
		p-value	0.2728	
		Corrected Hedges g (95% CI) [2]	0.11 (-0.09, 0.32)	
Post Progression	Actual	n	240	123
		Mean (StdDev)	0.2 (0.63)	0.2 (0.55)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 3	0, 3
	Change from BL	n	234	119
		Mean (StdDev)	0.1 (0.70)	0.0 (0.60)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 3	-3, 2
		LS Mean (SE)	0.1 (0.04)	0.1 (0.05)
		95% CI	0.1, 0.2	0.0, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.06)	
		95% CI	0.0, 0.2	
		p-value	0.2318	
		Corrected Hedges g (95% CI) [2]	0.13 (-0.09, 0.36)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have been vomiting

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Overall	Change from BL	LS Mean (SE)	0.1 (0.02)	0.0 (0.03)
		95% CI	0.0, 0.1	0.0, 0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.03)	
		95% CI	0.0, 0.1	
		p-value	0.1891	
		Corrected Hedges g (95% CI) [2]	0.13 (-0.06, 0.31)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Baseline	Actual	n	355	172
		Mean (StdDev)	0.7 (0.93)	0.8 (1.04)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 4
Cycle 2 Day 1	Actual	n	301	155
		Mean (StdDev)	0.7 (0.94)	1.0 (1.11)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	0.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	292	150
		Mean (StdDev)	0.1 (0.96)	0.2 (0.88)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-4, 4	-2, 3
		LS Mean (SE)	0.1 (0.05)	0.2 (0.07)
		95% CI	0.0, 0.2	0.1, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.09)	
		95% CI	-0.3, 0.0	
		p-value	0.0477	
		Corrected Hedges g (95% CI) [2]	-0.20 (-0.40, 0.00)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 4 Day 1	Actual	n	267	125
		Mean (StdDev)	0.7 (0.94)	1.0 (1.04)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	0.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	257	120
		Mean (StdDev)	0.1 (0.93)	0.2 (0.97)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-3, 3	-2, 3
		LS Mean (SE)	0.1 (0.05)	0.3 (0.07)
		95% CI	0.0, 0.2	0.1, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.09)	
		95% CI	-0.4, 0.0	
		p-value	0.0256	
		Corrected Hedges g (95% CI) [2]	-0.25 (-0.46, -0.03)	
Cycle 6 Day 1	Actual	n	226	86
		Mean (StdDev)	0.7 (0.90)	0.9 (1.02)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	0.0, 2.0
		Min, Max	0, 3	0, 3
	Change from BL	n	218	86
		Mean (StdDev)	0.0 (0.95)	0.1 (0.95)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 3	-2, 3
		LS Mean (SE)	0.0 (0.05)	0.2 (0.08)
		95% CI	-0.1, 0.2	0.1, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.10)	
		95% CI	-0.4, 0.0	
		p-value	0.0570	
		Corrected Hedges g (95% CI) [2]	-0.24 (-0.49, 0.01)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 8 Day 1	Actual	n	192	56
		Mean (StdDev)	0.6 (0.84)	1.0 (1.04)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	0.0, 1.5
		Min, Max	0, 4	0, 4
	Change from BL	n	188	56
		Mean (StdDev)	0.0(0.89)	0.2 (0.80)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-4, 4	-2, 2
		LS Mean (SE)	0.0 (0.05)	0.3 (0.09)
		95% CI	-0.1, 0.1	0.1, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.11)	
		95% CI	-0.5, -0.1	
		p-value	0.0045	
		Corrected Hedges g (95% CI) [2]	-0.42 (-0.72, -0.12)	
Cycle 10 Day 1	Actual	n	161	40
		Mean (StdDev)	0.7 (0.99)	1.0 (1.12)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	0.0, 1.5
		Min, Max	0, 4	0, 4
	Change from BL	n	157	40
		Mean (StdDev)	0.1 (1.01)	0.2 (0.82)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 4	-2, 3
		LS Mean (SE)	0.1 (0.06)	0.3 (0.12)
		95% CI	0.0, 0.2	0.1, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.14)	
		95% CI	-0.5, 0.0	
		p-value	0.0953	
		Corrected Hedges g (95% CI) [2]	-0.29 (-0.64, 0.06)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 12 Day 1	Actual	n	148	36
		Mean (StdDev)	0.7 (0.92)	1.0 (0.99)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	0.0, 2.0
		Min, Max	0, 3	0, 3
	Change from BL	n	146	36
		Mean (StdDev)	0.1 (0.85)	0.1 (0.89)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.5
		Min, Max	-2, 2	-2, 2
		LS Mean (SE)	0.1 (0.06)	0.3 (0.11)
		95% CI	0.0, 0.2	0.1, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.13)	
		95% CI	-0.4, 0.1	
		p-value	0.2217	
		Corrected Hedges g (95% CI) [2]	-0.22 (-0.59, 0.14)	
Cycle 14 Day 1	Actual	n	128	26
		Mean (StdDev)	0.7 (0.90)	0.9 (1.09)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 3
	Change from BL	n	125	26
		Mean (StdDev)	0.1 (0.92)	0.1 (0.77)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 3	-1, 2
		LS Mean (SE)	0.2 (0.07)	0.2 (0.14)
		95% CI	0.0, 0.3	-0.1, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.16)	
		95% CI	-0.3, 0.3	
		p-value	0.8923	
		Corrected Hedges g (95% CI) [2]	-0.03 (-0.45, 0.39)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 17 Day 1	Actual	n	89	18
		Mean (StdDev)	0.6 (0.90)	0.7 (0.89)
		Median	0.0	0.5
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 3
	Change from BL	n	87	18
		Mean (StdDev)	0.1 (0.89)	0.0 (0.49)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 4	-1, 1
		LS Mean (SE)	0.1 (0.08)	0.0 (0.17)
		95% CI	0.0, 0.3	-0.3, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.18)	
		95% CI	-0.3, 0.4	
		p-value	0.7303	
		Corrected Hedges g (95% CI) [2]	0.09 (-0.42, 0.59)	
Cycle 20 Day 1	Actual	n	81	13
		Mean (StdDev)	0.6 (0.84)	0.6 (0.77)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	80	13
		Mean (StdDev)	0.0(0.86)	0.0 (0.82)
		Median	0.0	0.0
		Q1, Q3	-0.5, 0.0	0.0, 0.0
		Min, Max	-2, 3	-1, 2
		LS Mean (SE)	0.1 (0.07)	0.1 (0.18)
		95% CI	-0.1, 0.2	-0.3, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.19)	
		95% CI	-0.4, 0.4	
		p-value	0.9276	
		Corrected Hedges g (95% CI) [2]	0.03 (-0.56, 0.61)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 23 Day 1	Actual	n	64	11
		Mean (StdDev)	0.5 (0.83)	0.6 (0.92)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 3	0, 3
	Change from BL	n	63	11
		Mean (StdDev)	0.1 (0.87)	0.0 (0.77)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	-1.0, 1.0
		Min, Max	-2, 3	-1, 1
		LS Mean (SE)	0.1 (0.09)	0.0 (0.20)
		95% CI	0.0, 0.3	-0.3, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.22)	
		95% CI	-0.3, 0.5	
		p-value	0.6445	
		Corrected Hedges g (95% CI) [2]	0.14 (-0.50, 0.78)	
Cycle 26 Day 1	Actual	n	62	10
		Mean (StdDev)	0.5 (0.74)	1.0 (0.94)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	0.0, 2.0
		Min, Max	0, 3	0, 2
	Change from BL	n	61	10
		Mean (StdDev)	0.0(0.85)	0.5 (0.97)
		Median	0.0	1.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 3	-1, 2
		LS Mean (SE)	-0.1 (0.09)	0.5 (0.21)
		95% CI	-0.2, 0.1	0.1, 0.9
		Difference from placebo [1]		
		LS Mean (SE)	-0.5 (0.23)	
		95% CI	-1.0, -0.1	
		p-value	0.0191	
		Corrected Hedges g (95% CI) [2]	-0.78 (-1.46, -0.10)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 29 Day 1	Actual	n	58	8
		Mean (StdDev)	0.6 (0.88)	0.5 (0.76)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	57	8
		Mean (StdDev)	0.2 (0.97)	0.1 (1.13)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	-1.0, 1.0
		Min, Max	-1, 3	-1, 2
		LS Mean (SE)	0.1 (0.09)	0.2 (0.22)
		95% CI	0.0, 0.3	-0.3, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.23)	
		95% CI	-0.5, 0.4	
		p-value	0.8751	
		Corrected Hedges g (95% CI) [2]	-0.06 (-0.80, 0.68)	
Cycle 32 Day 1	Actual	n	45	8
		Mean (StdDev)	0.6 (0.89)	0.3 (0.46)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.5
		Min, Max	0, 3	0, 1
	Change from BL	n	44	8
		Mean (StdDev)	0.1 (0.90)	-0.1 (0.83)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	-1.0, 0.5
		Min, Max	-2, 3	-1, 1
		LS Mean (SE)	0.1 (0.10)	-0.1 (0.23)
		95% CI	-0.2, 0.3	-0.5, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.25)	
		95% CI	-0.4, 0.6	
		p-value	0.6053	
		Corrected Hedges g (95% CI) [2]	0.19 (-0.57, 0.94)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 35 Day 1	Actual	n	48	7
		Mean (StdDev)	0.5 (0.80)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 3	0, 0
	Change from BL	n	47	7
		Mean (StdDev)	0.1 (0.99)	-0.3 (0.49)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	-1.0, 0.0
		Min, Max	-2, 3	-1, 0
		LS Mean (SE)	-0.1 (0.08)	-0.4 (0.20)
		95% CI	-0.2, 0.1	-0.8, 0.0
		Difference from placebo [1]		
		LS Mean (SE)	0.3 (0.21)	
		95% CI	-0.1, 0.8	
		p-value	0.1168	
		Corrected Hedges g (95% CI) [2]	0.59 (-0.21, 1.39)	
Cycle 38 Day 1	Actual	n	41	7
		Mean (StdDev)	0.4 (0.71)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 2	0, 0
	Change from BL	n	40	7
		Mean (StdDev)	-0.1 (0.73)	-0.4 (0.53)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	-1.0, 0.0
		Min, Max	-2, 2	-1, 0
		LS Mean (SE)	0.0 (0.07)	-0.3 (0.16)
		95% CI	-0.2, 0.1	-0.6, 0.0
		Difference from placebo [1]		
		LS Mean (SE)	0.2 (0.17)	
		95% CI	-0.1, 0.6	
		p-value	0.1669	
		Corrected Hedges g (95% CI) [2]	0.54 (-0.27, 1.35)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 41 Day 1	Actual	n	44	7
		Mean (StdDev)	0.7 (0.89)	0.1 (0.38)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 3	0, 1
	Change from BL	n	43	7
		Mean (StdDev)	0.2 (1.10)	-0.3 (0.76)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	-1.0, 0.0
		Min, Max	-2, 3	-1, 1
		LS Mean (SE)	0.2 (0.11)	-0.2 (0.26)
		95% CI	0.0, 0.4	-0.7, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.4 (0.28)	
		95% CI	-0.2, 1.0	
		p-value	0.1612	
		Corrected Hedges g (95% CI) [2]	0.55 (-0.26, 1.35)	
Cycle 44 Day 1	Actual	n	36	8
		Mean (StdDev)	0.4 (0.59)	0.3 (0.46)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.5
		Min, Max	0, 2	0, 1
	Change from BL	n	36	8
		Mean (StdDev)	0.1 (0.58)	-0.1 (0.83)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	-1.0, 0.5
		Min, Max	-1, 1	-1, 1
		LS Mean (SE)	0.0 (0.09)	0.0 (0.17)
		95% CI	-0.1, 0.2	-0.3, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.19)	
		95% CI	-0.3, 0.4	
		p-value	0.8387	
		Corrected Hedges g (95% CI) [2]	0.07 (-0.69, 0.84)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 47 Day 1	Actual	n	37	5
		Mean (StdDev)	0.5 (0.73)	1.0 (0.71)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	1.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	37	5
		Mean (StdDev)	0.1 (0.94)	0.6 (0.89)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 3	0, 2
		LS Mean (SE)	0.0 (0.10)	0.6 (0.24)
		95% CI	-0.2, 0.2	0.1, 1.1
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.25)	
		95% CI	-1.1, -0.1	
		p-value	0.0196	
		Corrected Hedges g (95% CI) [2]	-1.00 (-1.96, -0.04)	
Cycle 53 Day 1	Actual	n	31	6
		Mean (StdDev)	0.7 (0.94)	0.7 (0.82)
		Median	0.0	0.5
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 2
	Change from BL	n	31	6
		Mean (StdDev)	0.3 (1.10)	0.3 (1.03)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	-2, 4	-1, 2
		LS Mean (SE)	0.2 (0.16)	0.3 (0.35)
		95% CI	-0.2, 0.5	-0.4, 1.0
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.38)	
		95% CI	-0.9, 0.6	
		p-value	0.6735	
		Corrected Hedges g (95% CI) [2]	-0.18 (-1.05, 0.70)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 56 Day 1	Actual	n	29	5
		Mean (StdDev)	0.6 (0.83)	0.4 (0.89)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 3	0, 2
	Change from BL	n	28	5
		Mean (StdDev)	0.2 (0.90)	0.0 (1.22)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.5	-1.0, 0.0
		Min, Max	-2, 2	-1, 2
		LS Mean (SE)	0.1 (0.15)	0.1 (0.34)
		95% CI	-0.2, 0.4	-0.6, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.36)	
		95% CI	-0.7, 0.7	
		p-value	0.9871	
		Corrected Hedges g (95% CI) [2]	-0.01 (-0.96, 0.94)	
Cycle 59 Day 1	Actual	n	31	6
		Mean (StdDev)	0.4 (0.81)	0.5 (0.84)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	30	6
		Mean (StdDev)	0.1 (0.94)	0.2 (1.17)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	-1.0, 1.0
		Min, Max	-2, 2	-1, 2
		LS Mean (SE)	0.0 (0.13)	0.1 (0.26)
		95% CI	-0.3, 0.2	-0.4, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.28)	
		95% CI	-0.7, 0.4	
		p-value	0.5710	
		Corrected Hedges g (95% CI) [2]	-0.22 (-1.10, 0.65)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 62 Day 1	Actual	n	27	6
		Mean (StdDev)	0.4 (0.69)	0.7 (1.21)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 2	0, 3
	Change from BL	n	27	6
		Mean (StdDev)	0.0 (0.94)	0.3 (1.51)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	-1.0, 1.0
		Min, Max	-2, 2	-1, 3
		LS Mean (SE)	-0.1 (0.14)	0.3 (0.27)
		95% CI	-0.4, 0.1	-0.3, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.4 (0.30)	
		95% CI	-1.0, 0.2	
		p-value	0.1996	
		Corrected Hedges g (95% CI) [2]	-0.54 (-1.43, 0.36)	
Cycle 65 Day 1	Actual	n	22	5
		Mean (StdDev)	0.1 (0.35)	0.4 (0.55)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 1	0, 1
	Change from BL	n	22	5
		Mean (StdDev)	-0.3 (0.70)	0.0 (1.00)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 1.0
		Min, Max	-2, 1	-1, 1
		LS Mean (SE)	-0.2 (0.08)	-0.1 (0.17)
		95% CI	-0.4, -0.1	-0.4, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.19)	
		95% CI	-0.5, 0.2	
		p-value	0.3470	
		Corrected Hedges g (95% CI) [2]	-0.44 (-1.41, 0.54)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 68 Day 1	Actual	n	23	6
		Mean (StdDev)	0.3 (0.57)	0.7 (0.82)
		Median	0.0	0.5
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 2	0, 2
	Change from BL	n	23	6
		Mean (StdDev)	0.0(0.88)	0.3 (0.82)
		Median	0.0	0.5
		Q1, Q3	-1.0, 0.0	0.0, 1.0
		Min, Max	-2, 2	-1, 1
		LS Mean (SE)	-0.1 (0.12)	0.3 (0.23)
		95% CI	-0.4, 0.1	-0.2, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.4 (0.25)	
		95% CI	-1.0, 0.1	
		p-value	0.0859	
		Corrected Hedges g (95% CI) [2]	-0.75 (-1.67, 0.17)	
Study Treatment Discontinuation	Actual	n	274	143
		Mean (StdDev)	1.1 (1.10)	1.1 (1.12)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	0.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	266	140
		Mean (StdDev)	0.4 (1.14)	0.2 (1.17)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	-4, 4	-3, 4
		LS Mean (SE)	0.4 (0.06)	0.4 (0.08)
		95% CI	0.3, 0.5	0.2, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.10)	
		95% CI	-0.2, 0.2	
		p-value	0.9094	
		Corrected Hedges g (95% CI) [2]	0.01 (-0.19, 0.22)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have pain

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Post Progression	Actual	n	239	123
		Mean (StdDev)	1.0 (1.11)	1.1 (1.14)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	0.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	232	119
		Mean (StdDev)	0.3 (1.16)	0.2 (1.03)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	-3, 4	-3, 3
		LS Mean (SE)	0.4 (0.06)	0.3 (0.09)
		95% CI	0.2, 0.5	0.1, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.11)	
		95% CI	-0.1, 0.3	
		p-value	0.5232	
		Corrected Hedges g (95% CI) [2]	0.07 (-0.15, 0.29)	
Overall	Change from BL	LS Mean (SE)	0.2 (0.03)	0.3 (0.05)
		95% CI	0.1, 0.2	0.2, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.06)	
		95% CI	-0.2, 0.0	
		p-value	0.0468	
		Corrected Hedges g (95% CI) [2]	-0.19 (-0.37, 0.00)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Baseline	Actual	n	356	173
		Mean (StdDev)	0.4 (0.76)	0.3 (0.68)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 4	0, 3
Cycle 2 Day 1	Actual	n	303	154
		Mean (StdDev)	0.8 (1.00)	0.3 (0.66)
		Median	1.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 4	0, 3
	Change from BL	n	295	150
		Mean (StdDev)	0.5 (0.98)	0.0 (0.70)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	-3, 4	-3, 3
		LS Mean (SE)	0.5 (0.05)	0.0 (0.07)
		95% CI	0.4, 0.6	-0.1, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.5 (0.09)	
		95% CI	0.3, 0.7	
		p-value	<0.0001	
		Corrected Hedges g (95% CI) [2]	0.57 (0.37, 0.77)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 4 Day 1	Actual	n	267	124
		Mean (StdDev)	0.6 (0.87)	0.3 (0.75)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 4	0, 3
	Change from BL	n	258	120
		Mean (StdDev)	0.2 (1.01)	0.0 (0.74)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	-3, 4	-2, 3
		LS Mean (SE)	0.3 (0.05)	0.1 (0.07)
		95% CI	0.2, 0.4	-0.1, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.2 (0.09)	
		95% CI	0.1, 0.4	
		p-value	0.0044	
		Corrected Hedges g (95% CI) [2]	0.31 (0.10, 0.53)	
Cycle 6 Day 1	Actual	n	226	86
		Mean (StdDev)	0.5 (0.74)	0.3 (0.76)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 3	0, 3
	Change from BL	n	219	86
		Mean (StdDev)	0.2 (0.90)	0.1 (0.64)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	-4, 3	-2, 3
		LS Mean (SE)	0.2 (0.04)	0.1 (0.07)
		95% CI	0.1, 0.3	0.0, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.08)	
		95% CI	-0.1, 0.3	
		p-value	0.2353	
		Corrected Hedges g (95% CI) [2]	0.15 (-0.10, 0.40)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 8 Day 1	Actual	n	189	56
		Mean (StdDev)	0.4 (0.75)	0.3 (0.75)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 4	0, 4
	Change from BL	n	185	56
		Mean (StdDev)	0.1 (0.94)	-0.1 (0.67)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-4, 4	-2, 2
		LS Mean (SE)	0.2 (0.05)	0.1 (0.08)
		95% CI	0.1, 0.3	-0.1, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.09)	
		95% CI	-0.1, 0.2	
		p-value	0.5092	
		Corrected Hedges g (95% CI) [2]	0.10 (-0.20, 0.40)	
Cycle 10 Day 1	Actual	n	163	40
		Mean (StdDev)	0.4 (0.80)	0.2 (0.58)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 4	0, 3
	Change from BL	n	159	40
		Mean (StdDev)	0.1 (0.96)	0.0 (0.48)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 3	-1, 1
		LS Mean (SE)	0.1 (0.05)	0.1 (0.09)
		95% CI	0.0, 0.2	-0.1, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.11)	
		95% CI	-0.2, 0.2	
		p-value	0.7602	
		Corrected Hedges g (95% CI) [2]	0.05 (-0.29, 0.40)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 12 Day 1	Actual	n	149	36
		Mean (StdDev)	0.4 (0.76)	0.2 (0.48)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 4	0, 2
	Change from BL	n	147	36
		Mean (StdDev)	0.1 (0.81)	0.0(0.56)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 3	-2, 1
		LS Mean (SE)	0.1 (0.05)	0.1 (0.09)
		95% CI	0.0, 0.2	-0.1, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.11)	
		95% CI	-0.2, 0.3	
		p-value	0.6213	
		Corrected Hedges g (95% CI) [2]	0.09 (-0.28, 0.45)	
Cycle 14 Day 1	Actual	n	128	26
		Mean (StdDev)	0.3 (0.67)	0.3 (0.56)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	125	26
		Mean (StdDev)	0.1 (0.74)	0.2 (0.37)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 3	0, 1
		LS Mean (SE)	0.1 (0.05)	0.2 (0.10)
		95% CI	0.0, 0.2	0.0, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.11)	
		95% CI	-0.4, 0.1	
		p-value	0.1665	
		Corrected Hedges g (95% CI) [2]	-0.28 (-0.70, 0.14)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 17 Day 1	Actual	n	89	18
		Mean (StdDev)	0.3 (0.61)	0.2 (0.55)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 3	0, 2
	Change from BL	n	87	18
		Mean (StdDev)	0.0 (0.72)	0.2 (0.62)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 2	-1, 2
		LS Mean (SE)	0.1 (0.05)	0.1 (0.11)
		95% CI	0.0, 0.2	-0.1, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.13)	
		95% CI	-0.3, 0.2	
		p-value	0.5801	
		Corrected Hedges g (95% CI) [2]	-0.14 (-0.65, 0.37)	
Cycle 20 Day 1	Actual	n	82	13
		Mean (StdDev)	0.3 (0.66)	0.2 (0.38)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 4	0, 1
	Change from BL	n	81	13
		Mean (StdDev)	0.0 (0.75)	0.2 (0.38)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 3	0, 1
		LS Mean (SE)	0.1 (0.06)	0.1 (0.15)
		95% CI	-0.1, 0.2	-0.2, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.16)	
		95% CI	-0.3, 0.3	
		p-value	0.9223	
		Corrected Hedges g (95% CI) [2]	-0.03 (-0.61, 0.56)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 23 Day 1	Actual	n	65	11
		Mean (StdDev)	0.3 (0.55)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 0
	Change from BL	n	64	11
		Mean (StdDev)	0.0 (0.60)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 2	0, 0
		LS Mean (SE)	0.1 (0.06)	-0.1 (0.15)
		95% CI	-0.1, 0.2	-0.4, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.16)	
		95% CI	-0.2, 0.4	
		p-value	0.4392	
		Corrected Hedges g (95% CI) [2]	0.24 (-0.40, 0.88)	
Cycle 26 Day 1	Actual	n	62	10
		Mean (StdDev)	0.3 (0.65)	0.2 (0.42)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 3	0, 1
	Change from BL	n	61	10
		Mean (StdDev)	0.1 (0.60)	0.2 (0.42)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 2	0, 1
		LS Mean (SE)	0.1 (0.06)	0.2 (0.14)
		95% CI	0.0, 0.2	-0.1, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.16)	
		95% CI	-0.4, 0.2	
		p-value	0.5770	
		Corrected Hedges g (95% CI) [2]	-0.18 (-0.85, 0.49)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 29 Day 1	Actual	n	57	8
		Mean (StdDev)	0.2 (0.54)	0.1 (0.35)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 1
	Change from BL	n	56	8
		Mean (StdDev)	0.0(0.56)	0.1 (0.35)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 1	0, 1
		LS Mean (SE)	0.0 (0.05)	0.1 (0.13)
		95% CI	-0.1, 0.1	-0.2, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.14)	
		95% CI	-0.3, 0.2	
		p-value	0.6304	
		Corrected Hedges g (95% CI) [2]	-0.17 (-0.91, 0.57)	
Cycle 32 Day 1	Actual	n	46	8
		Mean (StdDev)	0.2 (0.59)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 3	0, 0
	Change from BL	n	45	8
		Mean (StdDev)	0.0 (0.74)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 3	0, 0
		LS Mean (SE)	-0.1 (0.09)	-0.2 (0.21)
		95% CI	-0.2, 0.1	-0.7, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.2 (0.22)	
		95% CI	-0.3, 0.6	
		p-value	0.3984	
		Corrected Hedges g (95% CI) [2]	0.32 (-0.44, 1.07)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 35 Day 1	Actual	n	48	7
		Mean (StdDev)	0.2 (0.50)	0.3 (0.49)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 2	0, 1
	Change from BL	n	47	7
		Mean (StdDev)	0.0 (0.47)	0.3 (0.49)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 1	0, 1
		LS Mean (SE)	0.0 (0.07)	0.1 (0.16)
		95% CI	-0.2, 0.1	-0.2, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.17)	
		95% CI	-0.5, 0.2	
		p-value	0.2930	
		Corrected Hedges g (95% CI) [2]	-0.40 (-1.20, 0.40)	
Cycle 38 Day 1	Actual	n	41	7
		Mean (StdDev)	0.2 (0.56)	0.3 (0.49)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 2	0, 1
	Change from BL	n	40	7
		Mean (StdDev)	0.0 (0.36)	0.3 (0.49)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-1, 1	0, 1
		LS Mean (SE)	0.0 (0.07)	0.3 (0.15)
		95% CI	-0.1, 0.1	0.0, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.16)	
		95% CI	-0.6, 0.0	
		p-value	0.0630	
		Corrected Hedges g (95% CI) [2]	-0.72 (-1.54, 0.09)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 41 Day 1	Actual	n	44	7
		Mean (StdDev)	0.2 (0.52)	0.1 (0.38)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 1
	Change from BL	n	43	7
		Mean (StdDev)	0.0 (0.62)	0.1 (0.38)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 1	0, 1
		LS Mean (SE)	0.0 (0.06)	0.0 (0.14)
		95% CI	-0.2, 0.1	-0.3, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.15)	
		95% CI	-0.3, 0.3	
		p-value	0.9146	
		Corrected Hedges g (95% CI) [2]	-0.04 (-0.84, 0.76)	
Cycle 44 Day 1	Actual	n	36	8
		Mean (StdDev)	0.2 (0.48)	0.1 (0.35)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 1
	Change from BL	n	36	8
		Mean (StdDev)	0.1 (0.37)	0.1 (0.35)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-1, 1	0, 1
		LS Mean (SE)	0.0 (0.06)	0.0 (0.13)
		95% CI	-0.1, 0.2	-0.2, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.14)	
		95% CI	-0.3, 0.3	
		p-value	0.9840	
		Corrected Hedges g (95% CI) [2]	0.01 (-0.76, 0.77)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 47 Day 1	Actual	n	36	5
		Mean (StdDev)	0.2 (0.54)	0.6 (0.89)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 2	0, 2
	Change from BL	n	36	5
		Mean (StdDev)	0.1 (0.50)	0.6 (0.89)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-1, 2	0, 2
		LS Mean (SE)	0.0 (0.09)	0.4 (0.21)
		95% CI	-0.2, 0.2	0.0, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.4 (0.22)	
		95% CI	-0.9, 0.0	
		p-value	0.0503	
		Corrected Hedges g (95% CI) [2]	-0.85 (-1.80, 0.11)	
Cycle 53 Day 1	Actual	n	31	6
		Mean (StdDev)	0.2 (0.67)	0.8 (0.98)
		Median	0.0	0.5
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	0, 3	0, 2
	Change from BL	n	31	6
		Mean (StdDev)	0.1 (0.70)	0.8 (0.98)
		Median	0.0	0.5
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	-1, 3	0, 2
		LS Mean (SE)	-0.1 (0.14)	0.5 (0.31)
		95% CI	-0.3, 0.2	-0.1, 1.1
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.32)	
		95% CI	-1.2, 0.1	
		p-value	0.0741	
		Corrected Hedges g (95% CI) [2]	-0.74 (-1.63, 0.15)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 56 Day 1	Actual	n	29	5
		Mean (StdDev)	0.2 (0.56)	0.2 (0.45)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 1
	Change from BL	n	28	5
		Mean (StdDev)	0.1 (0.60)	0.2 (0.45)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-1, 2	0, 1
		LS Mean (SE)	-0.1 (0.10)	0.0 (0.22)
		95% CI	-0.3, 0.1	-0.5, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.23)	
		95% CI	-0.5, 0.4	
		p-value	0.8762	
		Corrected Hedges g (95% CI) [2]	-0.07 (-1.02, 0.88)	
Cycle 59 Day 1	Actual	n	31	5
		Mean (StdDev)	0.2 (0.45)	0.2 (0.45)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 1
	Change from BL	n	30	5
		Mean (StdDev)	0.0 (0.49)	0.2 (0.45)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-1, 2	0, 1
		LS Mean (SE)	-0.1 (0.08)	0.0 (0.19)
		95% CI	-0.2, 0.1	-0.4, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.20)	
		95% CI	-0.5, 0.3	
		p-value	0.6581	
		Corrected Hedges g (95% CI) [2]	-0.19 (-1.14, 0.76)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 62 Day 1	Actual	n	27	5
		Mean (StdDev)	0.3 (0.61)	0.2 (0.45)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 1
	Change from BL	n	27	5
		Mean (StdDev)	0.1 (0.53)	0.2 (0.45)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-1, 2	0, 1
		LS Mean (SE)	0.1 (0.10)	0.2 (0.23)
		95% CI	-0.1, 0.3	-0.3, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.25)	
		95% CI	-0.6, 0.4	
		p-value	0.7971	
		Corrected Hedges g (95% CI) [2]	-0.12 (-1.07, 0.84)	
Cycle 65 Day 1	Actual	n	22	5
		Mean (StdDev)	0.0 (0.21)	0.4 (0.55)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 1	0, 1
	Change from BL	n	22	5
		Mean (StdDev)	0.0(0.21)	0.4 (0.55)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-1, 0	0, 1
		LS Mean (SE)	-0.1 (0.07)	0.1 (0.15)
		95% CI	-0.3, 0.0	-0.2, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.15)	
		95% CI	-0.6, 0.0	
		p-value	0.0932	
		Corrected Hedges g (95% CI) [2]	-0.72 (-1.71, 0.27)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 68 Day 1	Actual	n	23	6
		Mean (StdDev)	0.1 (0.46)	0.7 (0.82)
		Median	0.0	0.5
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 2	0, 2
	Change from BL	n	23	6
		Mean (StdDev)	0.0(0.37)	0.7 (0.82)
		Median	0.0	0.5
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-1, 1	0, 2
		LS Mean (SE)	-0.1 (0.08)	0.5 (0.16)
		95% CI	-0.3, 0.1	0.2, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.17)	
		95% CI	-0.9, -0.2	
		p-value	0.0013	
		Corrected Hedges g (95% CI) [2]	-1.50 (-2.48, -0.52)	
Study Treatment Discontinuation	Actual	n	274	141
		Mean (StdDev)	0.6 (0.93)	0.4 (0.79)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 3
	Change from BL	n	267	139
		Mean (StdDev)	0.2 (1.04)	0.0 (0.80)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	-3, 4	-2, 3
		LS Mean (SE)	0.2 (0.05)	0.1 (0.07)
		95% CI	0.1, 0.3	0.0, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.2 (0.08)	
		95% CI	0.0, 0.3	
		p-value	0.0504	
		Corrected Hedges g (95% CI) [2]	0.20 (0.00, 0.41)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have nausea

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Post Progression	Actual	n	240	123
		Mean (StdDev)	0.6 (0.90)	0.6 (0.93)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 3
	Change from BL	n	234	119
		Mean (StdDev)	0.2 (1.05)	0.3 (0.73)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	-3, 4	-1, 3
		LS Mean (SE)	0.2 (0.06)	0.3 (0.08)
		95% CI	0.1, 0.4	0.2, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.10)	
		95% CI	-0.3, 0.1	
		p-value	0.4061	
		Corrected Hedges g (95% CI) [2]	-0.09 (-0.31, 0.13)	
Overall	Change from BL	LS Mean (SE)	0.2 (0.03)	0.1 (0.05)
		95% CI	0.2, 0.3	0.0, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.06)	
		95% CI	0.0, 0.2	
		p-value	0.0220	
		Corrected Hedges g (95% CI) [2]	0.22 (0.03, 0.40)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Baseline	Actual	n	355	173
		Mean (StdDev)	0.4 (0.85)	0.3 (0.74)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 4	0, 3
Cycle 2 Day 1	Actual	n	300	153
		Mean (StdDev)	0.5 (0.92)	0.4 (0.77)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 3
	Change from BL	n	291	149
		Mean (StdDev)	0.1 (0.85)	0.0 (0.68)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 3	-3, 3
		LS Mean (SE)	0.1 (0.05)	0.0 (0.06)
		95% CI	0.0, 0.2	-0.1, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.08)	
		95% CI	-0.1, 0.2	
		p-value	0.8304	
		Corrected Hedges g (95% CI) [2]	0.02 (-0.18, 0.22)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 4 Day 1	Actual	n	266	124
		Mean (StdDev)	0.5 (0.87)	0.5 (0.98)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 4
	Change from BL	n	256	120
		Mean (StdDev)	0.1 (0.89)	0.2 (0.92)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 4	-3, 4
		LS Mean (SE)	0.1 (0.05)	0.2 (0.08)
		95% CI	0.0, 0.2	0.0, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.09)	
		95% CI	-0.2, 0.1	
		p-value	0.5392	
		Corrected Hedges g (95% CI) [2]	-0.07 (-0.28, 0.15)	
Cycle 6 Day 1	Actual	n	225	85
		Mean (StdDev)	0.5 (0.89)	0.6 (1.02)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 4
	Change from BL	n	217	85
		Mean (StdDev)	0.1 (0.81)	0.2 (0.97)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 4	-3, 4
		LS Mean (SE)	0.1 (0.05)	0.2 (0.08)
		95% CI	0.0, 0.2	0.1, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.10)	
		95% CI	-0.3, 0.1	
		p-value	0.2242	
		Corrected Hedges g (95% CI) [2]	-0.15 (-0.40, 0.10)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 8 Day 1	Actual	n	191	57
		Mean (StdDev)	0.4 (0.80)	0.5 (0.85)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 3
	Change from BL	n	186	57
		Mean (StdDev)	0.0 (0.81)	0.1 (0.76)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-4, 3	-3, 3
		LS Mean (SE)	0.0 (0.05)	0.2 (0.08)
		95% CI	-0.1, 0.1	0.0, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.10)	
		95% CI	-0.3, 0.0	
		p-value	0.1167	
		Corrected Hedges g (95% CI) [2]	-0.23 (-0.53, 0.07)	
Cycle 10 Day 1	Actual	n	162	39
		Mean (StdDev)	0.4 (0.75)	0.5 (0.85)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 4	0, 4
	Change from BL	n	157	39
		Mean (StdDev)	0.0(0.78)	0.2 (0.77)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-3, 3	-2, 2
		LS Mean (SE)	0.0 (0.05)	0.3 (0.10)
		95% CI	-0.1, 0.1	0.1, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.11)	
		95% CI	-0.6, -0.1	
		p-value	0.0031	
		Corrected Hedges g (95% CI) [2]	-0.51 (-0.86, -0.16)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 12 Day 1	Actual	n	148	36
		Mean (StdDev)	0.5 (0.89)	0.4 (0.64)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 2
	Change from BL	n	145	36
		Mean (StdDev)	0.1 (0.95)	-0.1 (0.95)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 3	-3, 2
		LS Mean (SE)	0.1 (0.06)	0.2 (0.11)
		95% CI	0.0, 0.2	-0.1, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.13)	
		95% CI	-0.3, 0.2	
		p-value	0.6588	
		Corrected Hedges g (95% CI) [2]	-0.08 (-0.44, 0.29)	
Cycle 14 Day 1	Actual	n	127	26
		Mean (StdDev)	0.4 (0.77)	0.5 (0.81)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 4	0, 3
	Change from BL	n	123	26
		Mean (StdDev)	0.0(0.78)	0.1 (0.82)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 2	-2, 2
		LS Mean (SE)	0.0 (0.05)	0.3 (0.11)
		95% CI	-0.1, 0.1	0.1, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.12)	
		95% CI	-0.5, -0.1	
		p-value	0.0106	
		Corrected Hedges g (95% CI) [2]	-0.52 (-0.95, -0.10)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 17 Day 1	Actual	n	90	17
		Mean (StdDev)	0.4 (0.86)	0.6 (0.70)
		Median	0.0	1.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 4	0, 2
	Change from BL	n	87	17
		Mean (StdDev)	0.0 (0.65)	0.2 (0.64)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 2	-1, 1
		LS Mean (SE)	0.1 (0.06)	0.2 (0.12)
		95% CI	0.0, 0.2	0.0, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.13)	
		95% CI	-0.4, 0.1	
		p-value	0.1745	
		Corrected Hedges g (95% CI) [2]	-0.34 (-0.86, 0.18)	
Cycle 20 Day 1	Actual	n	83	13
		Mean (StdDev)	0.4 (0.71)	0.5 (0.66)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	82	13
		Mean (StdDev)	0.0(0.91)	0.1 (0.95)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 3	-2, 2
		LS Mean (SE)	0.1 (0.07)	0.2 (0.15)
		95% CI	-0.1, 0.2	-0.1, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.17)	
		95% CI	-0.4, 0.2	
		p-value	0.5456	
		Corrected Hedges g (95% CI) [2]	-0.17 (-0.76, 0.41)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 23 Day 1	Actual	n	64	11
		Mean (StdDev)	0.4 (0.63)	0.6 (0.67)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 2	0, 2
	Change from BL	n	63	11
		Mean (StdDev)	0.0(0.75)	0.2 (0.60)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-3, 2	-1, 1
		LS Mean (SE)	0.0 (0.06)	0.2 (0.15)
		95% CI	-0.1, 0.2	-0.1, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.16)	
		95% CI	-0.5, 0.2	
		p-value	0.3873	
		Corrected Hedges g (95% CI) [2]	-0.27 (-0.91, 0.37)	
Cycle 26 Day 1	Actual	n	62	10
		Mean (StdDev)	0.5 (0.88)	0.6 (1.07)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 3
	Change from BL	n	61	10
		Mean (StdDev)	0.0 (0.83)	0.4 (0.97)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 3	-1, 2
		LS Mean (SE)	0.1 (0.08)	0.3 (0.20)
		95% CI	-0.1, 0.3	-0.1, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.22)	
		95% CI	-0.6, 0.2	
		p-value	0.3444	
		Corrected Hedges g (95% CI) [2]	-0.31 (-0.98, 0.36)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 29 Day 1	Actual	n	56	7
		Mean (StdDev)	0.5 (0.85)	0.4 (0.53)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 3	0, 1
	Change from BL	n	55	7
		Mean (StdDev)	0.0 (0.96)	0.3 (0.76)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 3	-1, 1
		LS Mean (SE)	0.2 (0.09)	0.2 (0.23)
		95% CI	0.0, 0.3	-0.3, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.25)	
		95% CI	-0.5, 0.5	
		p-value	0.9983	
		Corrected Hedges g (95% CI) [2]	0.00 (-0.79, 0.79)	
Cycle 32 Day 1	Actual	n	46	8
		Mean (StdDev)	0.4 (0.89)	0.6 (0.92)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.5
		Min, Max	0, 4	0, 2
	Change from BL	n	45	8
		Mean (StdDev)	0.0(0.92)	0.5 (0.93)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 3	0, 2
		LS Mean (SE)	0.1 (0.07)	0.4 (0.17)
		95% CI	-0.1, 0.2	0.0, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.18)	
		95% CI	-0.7, 0.1	
		p-value	0.1001	
		Corrected Hedges g (95% CI) [2]	-0.62 (-1.38, 0.14)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 35 Day 1	Actual	n	47	7
		Mean (StdDev)	0.4 (0.75)	0.7 (0.95)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 2.0
		Min, Max	0, 2	0, 2
	Change from BL	n	46	7
		Mean (StdDev)	0.0(0.77)	0.7 (0.95)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	-2, 2	0, 2
		LS Mean (SE)	0.1 (0.07)	0.4 (0.17)
		95% CI	-0.1, 0.2	0.1, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.4 (0.18)	
		95% CI	-0.8, 0.0	
		p-value	0.0346	
		Corrected Hedges g (95% CI) [2]	-0.83 (-1.64, -0.02)	
Cycle 38 Day 1	Actual	n	41	7
		Mean (StdDev)	0.4 (0.83)	0.4 (0.79)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	40	7
		Mean (StdDev)	-0.1 (0.84)	0.3 (0.95)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-3, 2	-1, 2
		LS Mean (SE)	0.0 (0.08)	0.3 (0.19)
		95% CI	-0.1, 0.2	0.0, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.21)	
		95% CI	-0.7, 0.1	
		p-value	0.1278	
		Corrected Hedges g (95% CI) [2]	-0.61 (-1.42, 0.20)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 41 Day 1	Actual	n	44	7
		Mean (StdDev)	0.4 (0.82)	0.9 (0.90)
		Median	0.0	1.0
		Q1, Q3	0.0, 0.5	0.0, 2.0
		Min, Max	0, 3	0, 2
	Change from BL	n	43	7
		Mean (StdDev)	-0.1 (0.88)	0.9 (0.90)
		Median	0.0	1.0
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	-2, 2	0, 2
		LS Mean (SE)	0.0 (0.07)	0.6 (0.16)
		95% CI	-0.1, 0.2	0.3, 0.9
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.17)	
		95% CI	-0.9, -0.3	
		p-value	0.0008	
		Corrected Hedges g (95% CI) [2]	-1.35 (-2.19, -0.51)	
Cycle 44 Day 1	Actual	n	36	8
		Mean (StdDev)	0.4 (0.81)	0.5 (0.76)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	36	8
		Mean (StdDev)	0.0 (0.93)	0.5 (0.76)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 3	0, 2
		LS Mean (SE)	0.1 (0.10)	0.3 (0.22)
		95% CI	-0.1, 0.3	-0.1, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.25)	
		95% CI	-0.7, 0.3	
		p-value	0.4399	
		Corrected Hedges g (95% CI) [2]	-0.30 (-1.07, 0.47)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 47 Day 1	Actual	n	38	5
		Mean (StdDev)	0.4 (0.83)	0.8 (1.30)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 3	0, 3
	Change from BL	n	38	5
		Mean (StdDev)	-0.1 (0.87)	0.8 (1.30)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 2	0, 3
		LS Mean (SE)	0.1 (0.09)	0.7 (0.24)
		95% CI	-0.1, 0.3	0.2, 1.2
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.26)	
		95% CI	-1.1, 0.0	
		p-value	0.0337	
		Corrected Hedges g (95% CI) [2]	-0.98 (-1.94, -0.03)	
Cycle 53 Day 1	Actual	n	31	6
		Mean (StdDev)	0.5 (0.85)	1.3 (1.21)
		Median	0.0	1.5
		Q1, Q3	0.0, 1.0	0.0, 2.0
		Min, Max	0, 3	0, 3
	Change from BL	n	31	6
		Mean (StdDev)	0.0 (0.71)	1.3 (1.21)
		Median	0.0	1.5
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	-2, 2	0, 3
		LS Mean (SE)	0.1 (0.09)	1.1 (0.22)
		95% CI	-0.1, 0.2	0.6, 1.5
		Difference from placebo [1]		
		LS Mean (SE)	-1.0 (0.24)	
		95% CI	-1.5, -0.5	
		p-value	<0.0001	
		Corrected Hedges g (95% CI) [2]	-1.87 (-2.85, -0.90)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 56 Day 1	Actual	n	29	5
		Mean (StdDev)	0.4 (0.87)	1.0 (1.00)
		Median	0.0	1.0
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	0, 3	0, 2
	Change from BL	n	28	5
		Mean (StdDev)	-0.1 (1.02)	1.0 (1.00)
		Median	0.0	1.0
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	-2, 3	0, 2
		LS Mean (SE)	0.1 (0.11)	0.7 (0.25)
		95% CI	-0.2, 0.3	0.2, 1.3
		Difference from placebo [1]		
		LS Mean (SE)	-0.7 (0.28)	
		95% CI	-1.2, -0.1	
		p-value	0.0177	
		Corrected Hedges g (95% CI) [2]	-1.17 (-2.16, -0.18)	
Cycle 59 Day 1	Actual	n	31	6
		Mean (StdDev)	0.4 (0.85)	1.0 (1.10)
		Median	0.0	1.0
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	0, 3	0, 2
	Change from BL	n	30	6
		Mean (StdDev)	0.0 (1.05)	1.0 (1.10)
		Median	0.0	1.0
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	-2, 3	0, 2
		LS Mean (SE)	0.1 (0.11)	0.6 (0.25)
		95% CI	-0.1, 0.3	0.1, 1.1
		Difference from placebo [1]		
		LS Mean (SE)	-0.5 (0.28)	
		95% CI	-1.1, 0.0	
		p-value	0.0523	
		Corrected Hedges g (95% CI) [2]	-0.88 (-1.78, 0.02)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 62 Day 1	Actual	n	27	6
		Mean (StdDev)	0.3 (0.67)	0.8 (0.98)
		Median	0.0	0.5
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	0, 2	0, 2
	Change from BL	n	27	6
		Mean (StdDev)	-0.1 (0.91)	0.8 (0.98)
		Median	0.0	0.5
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	-2, 2	0, 2
		LS Mean (SE)	-0.1 (0.08)	0.5 (0.16)
		95% CI	-0.2, 0.1	0.1, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.5 (0.18)	
		95% CI	-0.9, -0.2	
		p-value	0.0043	
		Corrected Hedges g (95% CI) [2]	-1.33 (-2.27, -0.39)	
Cycle 65 Day 1	Actual	n	22	5
		Mean (StdDev)	0.2 (0.53)	0.8 (0.84)
		Median	0.0	1.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 2	0, 2
	Change from BL	n	22	5
		Mean (StdDev)	-0.2 (0.91)	0.8 (0.84)
		Median	0.0	1.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 2	0, 2
		LS Mean (SE)	0.0 (0.07)	0.6 (0.15)
		95% CI	-0.2, 0.1	0.3, 0.9
		Difference from placebo [1]		
		LS Mean (SE)	-0.7 (0.17)	
		95% CI	-1.0, -0.3	
		p-value	0.0003	
		Corrected Hedges g (95% CI) [2]	-1.87 (-2.96, -0.78)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 68 Day 1	Actual	n	23	6
		Mean (StdDev)	0.3 (0.63)	0.8 (0.98)
		Median	0.0	0.5
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	0, 2	0, 2
	Change from BL	n	23	6
		Mean (StdDev)	-0.2 (0.85)	0.8 (0.98)
		Median	0.0	0.5
		Q1, Q3	0.0, 0.0	0.0, 2.0
		Min, Max	-2, 2	0, 2
		LS Mean (SE)	-0.1 (0.06)	0.5 (0.12)
		95% CI	-0.2, 0.1	0.2, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.14)	
		95% CI	-0.8, -0.3	
		p-value	0.0001	
		Corrected Hedges g (95% CI) [2]	-1.85 (-2.87, -0.83)	
Study Treatment Discontinuation	Actual	n	273	142
		Mean (StdDev)	0.7 (1.10)	0.8 (1.11)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 4
	Change from BL	n	265	139
		Mean (StdDev)	0.3 (1.09)	0.4 (1.09)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	-3, 4	-3, 4
		LS Mean (SE)	0.3 (0.06)	0.4 (0.08)
		95% CI	0.2, 0.4	0.2, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.10)	
		95% CI	-0.3, 0.1	
		p-value	0.3823	
		Corrected Hedges g (95% CI) [2]	-0.09 (-0.30, 0.11)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have swelling in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Post Progression	Actual	n	241	124
		Mean (StdDev)	0.7 (1.12)	0.8 (1.02)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 4
	Change from BL	n	235	120
		Mean (StdDev)	0.3 (1.19)	0.3 (1.01)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	-4, 4	-3, 3
		LS Mean (SE)	0.3 (0.06)	0.3 (0.09)
		95% CI	0.2, 0.5	0.2, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.11)	
		95% CI	-0.2, 0.2	
		p-value	0.8701	
		Corrected Hedges g (95% CI) [2]	0.02 (-0.20, 0.24)	
Overall	Change from BL	LS Mean (SE)	0.1 (0.03)	0.2 (0.05)
		95% CI	0.1, 0.2	0.1, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.06)	
		95% CI	-0.2, 0.0	
		p-value	0.1331	
		Corrected Hedges g (95% CI) [2]	-0.14 (-0.33, 0.04)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Baseline	Actual	n	356	174
		Mean (StdDev)	1.7 (1.23)	1.8 (1.34)
		Median	2.0	2.0
		Q1, Q3	1.0, 3.0	1.0, 3.0
		Min, Max	0, 4	0, 4
Cycle 2 Day 1	Actual	n	303	156
		Mean (StdDev)	1.6 (1.24)	1.7 (1.28)
		Median	1.0	1.0
		Q1, Q3	1.0, 3.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	294	153
		Mean (StdDev)	-0.1 (1.20)	0.0 (1.25)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	-1.0, 1.0
		Min, Max	-4, 3	-4, 4
		LS Mean (SE)	-0.1 (0.06)	0.0 (0.09)
		95% CI	-0.2, 0.0	-0.2, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.11)	
		95% CI	-0.3, 0.1	
		p-value	0.4439	
		Corrected Hedges g (95% CI) [2]	-0.08 (-0.27, 0.12)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 4 Day 1	Actual	n	267	124
		Mean (StdDev)	1.6 (1.29)	1.9 (1.36)
		Median	1.0	2.0
		Q1, Q3	1.0, 3.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	258	121
		Mean (StdDev)	-0.1 (1.24)	0.2 (1.28)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 1.0
		Min, Max	-4, 4	-2, 4
		LS Mean (SE)	-0.1 (0.07)	0.2 (0.10)
		95% CI	-0.3, 0.0	0.0, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.12)	
		95% CI	-0.6, -0.1	
		p-value	0.0083	
		Corrected Hedges g (95% CI) [2]	-0.29 (-0.51, -0.07)	
Cycle 6 Day 1	Actual	n	227	85
		Mean (StdDev)	1.6 (1.32)	2.0 (1.25)
		Median	1.0	2.0
		Q1, Q3	1.0, 3.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	220	85
		Mean (StdDev)	-0.1 (1.20)	0.3 (1.27)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.5	0.0, 1.0
		Min, Max	-4, 4	-2, 4
		LS Mean (SE)	-0.1 (0.07)	0.4 (0.11)
		95% CI	-0.3, 0.0	0.1, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	-0.5 (0.13)	
		95% CI	-0.7, -0.2	
		p-value	0.0004	
		Corrected Hedges g (95% CI) [2]	-0.44 (-0.70, -0.19)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 8 Day 1	Actual	n	191	56
		Mean (StdDev)	1.5 (1.23)	1.6 (1.17)
		Median	1.0	1.5
		Q1, Q3	0.0, 2.0	1.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	186	56
		Mean (StdDev)	-0.3 (1.27)	-0.1 (1.23)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 1.0
		Min, Max	-4, 4	-2, 2
		LS Mean (SE)	-0.2 (0.07)	0.0 (0.12)
		95% CI	-0.3, 0.0	-0.2, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.14)	
		95% CI	-0.5, 0.1	
		p-value	0.1465	
		Corrected Hedges g (95% CI) [2]	-0.21 (-0.51, 0.09)	
Cycle 10 Day 1	Actual	n	163	40
		Mean (StdDev)	1.5 (1.22)	1.7 (1.29)
		Median	1.0	1.0
		Q1, Q3	1.0, 2.0	1.0, 2.5
		Min, Max	0, 4	0, 4
	Change from BL	n	158	40
		Mean (StdDev)	-0.2 (1.30)	-0.1 (1.40)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.5
		Min, Max	-4, 4	-3, 4
		LS Mean (SE)	-0.2 (0.07)	0.1 (0.14)
		95% CI	-0.3, 0.0	-0.1, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.15)	
		95% CI	-0.6, 0.0	
		p-value	0.0498	
		Corrected Hedges g (95% CI) [2]	-0.33 (-0.68, 0.02)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 12 Day 1	Actual	n	149	36
		Mean (StdDev)	1.6 (1.20)	1.7 (1.22)
		Median	1.0	1.0
		Q1, Q3	1.0, 2.0	1.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	146	36
		Mean (StdDev)	-0.3 (1.13)	-0.1 (1.12)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 1.0
		Min, Max	-4, 3	-2, 2
		LS Mean (SE)	-0.1 (0.07)	0.2 (0.14)
		95% CI	-0.3, 0.0	-0.1, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.16)	
		95% CI	-0.6, 0.0	
		p-value	0.0458	
		Corrected Hedges g (95% CI) [2]	-0.36 (-0.72, 0.01)	
Cycle 14 Day 1	Actual	n	128	26
		Mean (StdDev)	1.4 (1.17)	1.8 (1.17)
		Median	1.0	1.5
		Q1, Q3	0.5, 2.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	124	26
		Mean (StdDev)	-0.3 (1.17)	0.2 (1.41)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 1.0
		Min, Max	-4, 2	-2, 4
		LS Mean (SE)	-0.2 (0.07)	0.4 (0.15)
		95% CI	-0.3, 0.0	0.1, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.17)	
		95% CI	-0.9, -0.2	
		p-value	0.0011	
		Corrected Hedges g (95% CI) [2]	-0.67 (-1.10, -0.24)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 17 Day 1	Actual	n	90	18
		Mean (StdDev)	1.4 (1.10)	1.6 (1.20)
		Median	1.0	1.5
		Q1, Q3	1.0, 2.0	1.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	88	18
		Mean (StdDev)	-0.3 (1.19)	-0.2 (1.42)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 1.0
		Min, Max	-4, 3	-2, 3
		LS Mean (SE)	-0.2 (0.08)	0.2 (0.16)
		95% CI	-0.3, 0.0	-0.1, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.4 (0.18)	
		95% CI	-0.7, 0.0	
		p-value	0.0398	
		Corrected Hedges g (95% CI) [2]	-0.51 (-1.02, 0.00)	
Cycle 20 Day 1	Actual	n	83	13
		Mean (StdDev)	1.5 (1.16)	1.8 (1.34)
		Median	1.0	2.0
		Q1, Q3	1.0, 2.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	82	13
		Mean (StdDev)	-0.2 (1.22)	-0.1 (1.55)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 1.0
		Min, Max	-4, 3	-2, 3
		LS Mean (SE)	-0.1 (0.09)	0.5 (0.21)
		95% CI	-0.3, 0.1	0.1, 0.9
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.23)	
		95% CI	-1.1, -0.2	
		p-value	0.0065	
		Corrected Hedges g (95% CI) [2]	-0.78 (-1.37, -0.18)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 23 Day 1	Actual	n	65	11
		Mean (StdDev)	1.4 (1.04)	1.6 (1.29)
		Median	1.0	1.0
		Q1, Q3	1.0, 2.0	1.0, 3.0
		Min, Max	0, 3	0, 4
	Change from BL	n	64	11
		Mean (StdDev)	-0.3 (1.15)	-0.3 (1.42)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-2.0, 0.0
		Min, Max	-4, 3	-2, 2
		LS Mean (SE)	-0.2 (0.10)	0.3 (0.23)
		95% CI	-0.4, 0.0	-0.2, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.4 (0.25)	
		95% CI	-0.9, 0.1	
		p-value	0.0902	
		Corrected Hedges g (95% CI) [2]	-0.54 (-1.18, 0.11)	
Cycle 26 Day 1	Actual	n	62	10
		Mean (StdDev)	1.4 (1.12)	1.6 (1.26)
		Median	1.0	1.0
		Q1, Q3	1.0, 2.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	61	10
		Mean (StdDev)	-0.4 (1.10)	-0.2 (1.23)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 2	-2, 2
		LS Mean (SE)	-0.2 (0.08)	0.2 (0.20)
		95% CI	-0.4, -0.1	-0.2, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	-0.5 (0.21)	
		95% CI	-0.9, 0.0	
		p-value	0.0364	
		Corrected Hedges g (95% CI) [2]	-0.68 (-1.36, 0.00)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 29 Day 1	Actual	n	58	8
		Mean (StdDev)	1.3 (1.07)	1.6 (1.30)
		Median	1.0	1.0
		Q1, Q3	1.0, 2.0	1.0, 2.5
		Min, Max	0, 4	0, 4
	Change from BL	n	57	8
		Mean (StdDev)	-0.5 (1.09)	-0.3 (1.16)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-4, 2	-2, 2
		LS Mean (SE)	-0.3 (0.09)	0.2 (0.21)
		95% CI	-0.4, -0.1	-0.2, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	-0.4 (0.23)	
		95% CI	-0.9, 0.0	
		p-value	0.0588	
		Corrected Hedges g (95% CI) [2]	-0.67 (-1.41, 0.08)	
Cycle 32 Day 1	Actual	n	46	8
		Mean (StdDev)	1.2 (1.20)	2.1 (1.13)
		Median	1.0	2.0
		Q1, Q3	0.0, 2.0	1.0, 3.0
		Min, Max	0, 4	1, 4
	Change from BL	n	45	8
		Mean (StdDev)	-0.5 (1.29)	0.3 (1.39)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-0.5, 1.5
		Min, Max	-4, 4	-2, 2
		LS Mean (SE)	-0.4 (0.11)	0.7 (0.26)
		95% CI	-0.6, -0.2	0.1, 1.2
		Difference from placebo [1]		
		LS Mean (SE)	-1.1 (0.29)	
		95% CI	-1.7, -0.5	
		p-value	0.0003	
		Corrected Hedges g (95% CI) [2]	-1.42 (-2.21, -0.62)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 35 Day 1	Actual	n	48	7
		Mean (StdDev)	1.3 (1.10)	1.6 (1.40)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	47	7
		Mean (StdDev)	-0.5 (1.16)	-0.4 (1.40)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-2.0, 0.0
		Min, Max	-4, 2	-2, 2
		LS Mean (SE)	-0.3 (0.10)	0.2 (0.24)
		95% CI	-0.5, -0.1	-0.3, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.5 (0.26)	
		95% CI	-1.1, 0.0	
		p-value	0.0405	
		Corrected Hedges g (95% CI) [2]	-0.79 (-1.60, 0.02)	
Cycle 38 Day 1	Actual	n	41	7
		Mean (StdDev)	1.2 (1.16)	1.4 (0.53)
		Median	1.0	1.0
		Q1, Q3	1.0, 1.0	1.0, 2.0
		Min, Max	0, 4	1, 2
	Change from BL	n	40	7
		Mean (StdDev)	-0.4 (1.15)	-0.1 (1.07)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 1.0
		Min, Max	-4, 2	-2, 1
		LS Mean (SE)	-0.2 (0.11)	0.3 (0.25)
		95% CI	-0.5, 0.0	-0.2, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.5 (0.27)	
		95% CI	-1.0, 0.0	
		p-value	0.0608	
		Corrected Hedges g (95% CI) [2]	-0.75 (-1.56, 0.07)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 41 Day 1	Actual	n	44	7
		Mean (StdDev)	1.1 (1.15)	1.7 (1.38)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	43	7
		Mean (StdDev)	-0.6 (1.18)	-0.3 (1.50)
		Median	-1.0	0.0
		Q1, Q3	-1.0, 0.0	-2.0, 1.0
		Min, Max	-4, 3	-2, 2
		LS Mean (SE)	-0.4 (0.12)	0.2 (0.28)
		95% CI	-0.7, -0.2	-0.4, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.30)	
		95% CI	-1.2, 0.0	
		p-value	0.0466	
		Corrected Hedges g (95% CI) [2]	-0.79 (-1.60, 0.02)	
Cycle 44 Day 1	Actual	n	36	8
		Mean (StdDev)	1.0 (0.97)	1.5 (1.41)
		Median	1.0	1.0
		Q1, Q3	0.0, 1.0	0.5, 2.5
		Min, Max	0, 4	0, 4
	Change from BL	n	36	8
		Mean (StdDev)	-0.5 (0.97)	-0.5 (1.41)
		Median	-0.5	0.0
		Q1, Q3	-1.0, 0.0	-2.0, 0.0
		Min, Max	-3, 2	-2, 2
		LS Mean (SE)	-0.5 (0.11)	0.1 (0.23)
		95% CI	-0.7, -0.3	-0.3, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.26)	
		95% CI	-1.1, -0.1	
		p-value	0.0199	
		Corrected Hedges g (95% CI) [2]	-0.91 (-1.70, -0.12)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 47 Day 1	Actual	n	38	5
		Mean (StdDev)	1.1 (1.04)	1.2 (1.64)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	0.0, 1.0
		Min, Max	0, 4	0, 4
	Change from BL	n	38	5
		Mean (StdDev)	-0.2 (1.05)	-0.8 (0.84)
		Median	0.0	-1.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-2, 2	-2, 0
		LS Mean (SE)	-0.3 (0.11)	-0.1 (0.27)
		95% CI	-0.5, -0.1	-0.7, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.30)	
		95% CI	-0.7, 0.5	
		p-value	0.6343	
		Corrected Hedges g (95% CI) [2]	-0.20 (-1.14, 0.73)	
Cycle 53 Day 1	Actual	n	31	6
		Mean (StdDev)	1.0 (1.03)	2.3 (1.51)
		Median	1.0	2.0
		Q1, Q3	0.0, 2.0	1.0, 4.0
		Min, Max	0, 4	1, 4
	Change from BL	n	31	6
		Mean (StdDev)	-0.4 (1.12)	0.3 (1.03)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	0.0, 1.0
		Min, Max	-3, 2	-1, 2
		LS Mean (SE)	-0.5 (0.12)	0.7 (0.27)
		95% CI	-0.7, -0.2	0.2, 1.3
		Difference from placebo [1]		
		LS Mean (SE)	-1.2 (0.29)	
		95% CI	-1.8, -0.6	
		p-value	0.0001	
		Corrected Hedges g (95% CI) [2]	-1.74 (-2.70, -0.78)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 56 Day 1	Actual	n	29	5
		Mean (StdDev)	0.9 (1.05)	2.0 (1.41)
		Median	1.0	1.0
		Q1, Q3	0.0, 1.0	1.0, 3.0
		Min, Max	0, 4	1, 4
	Change from BL	n	28	5
		Mean (StdDev)	-0.4 (1.07)	0.0 (1.41)
		Median	-1.0	0.0
		Q1, Q3	-1.0, 0.0	0.0, 0.0
		Min, Max	-2, 2	-2, 2
		LS Mean (SE)	-0.5 (0.11)	0.2 (0.25)
		95% CI	-0.7, -0.3	-0.3, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.7 (0.28)	
		95% CI	-1.2, -0.1	
		p-value	0.0155	
		Corrected Hedges g (95% CI) [2]	-1.13 (-2.12, -0.14)	
Cycle 59 Day 1	Actual	n	31	6
		Mean (StdDev)	1.0 (1.06)	1.8 (1.33)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	1.0, 3.0
		Min, Max	0, 4	1, 4
	Change from BL	n	30	6
		Mean (StdDev)	-0.2 (1.10)	-0.2 (1.33)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-2, 3	-2, 2
		LS Mean (SE)	-0.4 (0.11)	0.2 (0.24)
		95% CI	-0.7, -0.2	-0.2, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.7 (0.27)	
		95% CI	-1.2, -0.1	
		p-value	0.0133	
		Corrected Hedges g (95% CI) [2]	-1.08 (-1.99, -0.16)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 62 Day 1	Actual	n	27	6
		Mean (StdDev)	1.0 (1.13)	1.8 (1.33)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	1.0, 3.0
		Min, Max	0, 4	1, 4
	Change from BL	n	27	6
		Mean (StdDev)	-0.3 (1.21)	-0.2 (1.33)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-3, 2	-2, 2
		LS Mean (SE)	-0.6 (0.12)	0.2 (0.24)
		95% CI	-0.8, -0.3	-0.2, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.8 (0.28)	
		95% CI	-1.4, -0.3	
		p-value	0.0053	
		Corrected Hedges g (95% CI) [2]	-1.25 (-2.19, -0.32)	
Cycle 65 Day 1	Actual	n	22	5
		Mean (StdDev)	1.0 (1.25)	1.6 (1.52)
		Median	1.0	1.0
		Q1, Q3	0.0, 2.0	1.0, 2.0
		Min, Max	0, 4	0, 4
	Change from BL	n	22	5
		Mean (StdDev)	-0.4 (1.18)	-0.6 (0.55)
		Median	-0.5	-1.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-3, 2	-1, 0
		LS Mean (SE)	-0.4 (0.15)	0.1 (0.30)
		95% CI	-0.7, -0.1	-0.5, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.6 (0.34)	
		95% CI	-1.3, 0.1	
		p-value	0.1027	
		Corrected Hedges g (95% CI) [2]	-0.81 (-1.80, 0.19)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 68 Day 1	Actual	n	23	6
		Mean (StdDev)	1.0 (1.04)	2.0 (1.26)
		Median	1.0	1.5
		Q1, Q3	0.0, 2.0	1.0, 3.0
		Min, Max	0, 3	1, 4
	Change from BL	n	23	6
		Mean (StdDev)	-0.5 (1.38)	0.0 (1.10)
		Median	-1.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 0.0
		Min, Max	-3, 3	-1, 2
		LS Mean (SE)	-0.6 (0.15)	0.4 (0.30)
		95% CI	-0.9, -0.3	-0.2, 1.0
		Difference from placebo [1]		
		LS Mean (SE)	-1.0 (0.34)	
		95% CI	-1.7, -0.4	
		p-value	0.0038	
		Corrected Hedges g (95% CI) [2]	-1.39 (-2.36, -0.42)	
Study Treatment Discontinuation	Actual	n	275	141
		Mean (StdDev)	2.2 (1.33)	2.4 (1.24)
		Median	2.0	3.0
		Q1, Q3	1.0, 3.0	2.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	269	139
		Mean (StdDev)	0.4 (1.33)	0.6 (1.30)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 2.0
		Min, Max	-4, 4	-3, 4
		LS Mean (SE)	0.4 (0.07)	0.7 (0.09)
		95% CI	0.3, 0.6	0.5, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.12)	
		95% CI	-0.5, 0.0	
		p-value	0.0474	
		Corrected Hedges g (95% CI) [2]	-0.21 (-0.41, 0.00)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I worry that my condition will get worse

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Post Progression	Actual	n	241	124
		Mean (StdDev)	2.1 (1.23)	2.3 (1.27)
		Median	2.0	2.0
		Q1, Q3	1.0, 3.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	235	121
		Mean (StdDev)	0.3 (1.27)	0.5 (1.31)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	-4, 4	-3, 4
		LS Mean (SE)	0.3 (0.07)	0.5 (0.10)
		95% CI	0.2, 0.4	0.3, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.12)	
		95% CI	-0.4, 0.0	
		p-value	0.0803	
		Corrected Hedges g (95% CI) [2]	-0.20 (-0.42, 0.02)	
Overall	Change from BL	LS Mean (SE)	0.0 (0.05)	0.3 (0.07)
		95% CI	-0.1, 0.1	0.2, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.08)	
		95% CI	-0.5, -0.1	
		p-value	0.0003	
		Corrected Hedges g (95% CI) [2]	-0.35 (-0.53, -0.16)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Baseline	Actual	n	356	174
		Mean (StdDev)	2.4 (1.15)	2.3 (1.26)
		Median	2.0	2.5
		Q1, Q3	2.0, 3.0	2.0, 3.0
		Min, Max	0, 4	0, 4
Cycle 2 Day 1	Actual	n	303	156
		Mean (StdDev)	2.3 (1.20)	2.2 (1.19)
		Median	2.0	2.0
		Q1, Q3	2.0, 3.0	2.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	295	153
		Mean (StdDev)	-0.1 (1.38)	-0.1 (1.54)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 1.0
		Min, Max	-4, 4	-4, 4
		LS Mean (SE)	-0.1 (0.07)	-0.2 (0.10)
		95% CI	-0.2, 0.0	-0.3, 0.0
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.12)	
		95% CI	-0.2, 0.3	
		p-value	0.7154	
		Corrected Hedges g (95% CI) [2]	0.04 (-0.16, 0.23)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 4 Day 1	Actual	n	266	124
		Mean (StdDev)	2.3 (1.19)	2.5 (1.14)
		Median	2.5	3.0
		Q1, Q3	2.0, 3.0	2.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	257	121
		Mean (StdDev)	0.0(1.44)	0.1 (1.54)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	-1.0, 1.0
		Min, Max	-4, 4	-4, 4
		LS Mean (SE)	-0.1 (0.07)	0.0 (0.11)
		95% CI	-0.2, 0.1	-0.2, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.13)	
		95% CI	-0.3, 0.2	
		p-value	0.5324	
		Corrected Hedges g (95% CI) [2]	-0.07 (-0.28, 0.15)	
Cycle 6 Day 1	Actual	n	227	86
		Mean (StdDev)	2.5 (1.27)	2.2 (1.20)
		Median	3.0	2.0
		Q1, Q3	2.0, 4.0	2.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	220	86
		Mean (StdDev)	0.2 (1.47)	-0.2 (1.49)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	-1.0, 1.0
		Min, Max	-4, 4	-4, 4
		LS Mean (SE)	0.1 (0.08)	-0.2 (0.13)
		95% CI	-0.1, 0.3	-0.5, 0.0
		Difference from placebo [1]		
		LS Mean (SE)	0.4 (0.16)	
		95% CI	0.0, 0.7	
		p-value	0.0230	
		Corrected Hedges g (95% CI) [2]	0.29 (0.04, 0.54)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 8 Day 1	Actual	n	192	57
		Mean (StdDev)	2.5 (1.25)	2.5 (1.17)
		Median	3.0	3.0
		Q1, Q3	2.0, 3.0	2.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	187	57
		Mean (StdDev)	0.1 (1.50)	0.1 (1.37)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	-1.0, 1.0
		Min, Max	-4, 4	-3, 4
		LS Mean (SE)	0.1 (0.09)	0.0 (0.16)
		95% CI	-0.1, 0.2	-0.3, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.18)	
		95% CI	-0.3, 0.4	
		p-value	0.9650	
		Corrected Hedges g (95% CI) [2]	0.01 (-0.29, 0.30)	
Cycle 10 Day 1	Actual	n	163	39
		Mean (StdDev)	2.4 (1.38)	2.5 (1.12)
		Median	3.0	3.0
		Q1, Q3	1.0, 3.0	2.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	158	39
		Mean (StdDev)	-0.1 (1.72)	-0.1 (1.46)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	-1.0, 1.0
		Min, Max	-4, 4	-4, 4
		LS Mean (SE)	-0.1 (0.10)	-0.1 (0.19)
		95% CI	-0.3, 0.1	-0.4, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.21)	
		95% CI	-0.5, 0.4	
		p-value	0.8730	
		Corrected Hedges g (95% CI) [2]	-0.03 (-0.38, 0.32)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 12 Day 1	Actual	n	148	36
		Mean (StdDev)	2.5 (1.26)	2.4 (1.16)
		Median	3.0	3.0
		Q1, Q3	2.0, 3.0	2.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	145	36
		Mean (StdDev)	0.1 (1.59)	-0.3 (1.54)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	-1.0, 1.0
		Min, Max	-4, 4	-4, 4
		LS Mean (SE)	0.0 (0.10)	-0.1 (0.19)
		95% CI	-0.2, 0.2	-0.4, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.21)	
		95% CI	-0.3, 0.5	
		p-value	0.6493	
		Corrected Hedges g (95% CI) [2]	0.08 (-0.28, 0.45)	
Cycle 14 Day 1	Actual	n	128	26
		Mean (StdDev)	2.6 (1.32)	2.0 (1.20)
		Median	3.0	2.0
		Q1, Q3	2.0, 4.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	124	26
		Mean (StdDev)	0.1 (1.57)	-0.6 (1.50)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	-2.0, 0.0
		Min, Max	-4, 4	-4, 1
		LS Mean (SE)	0.1 (0.11)	-0.5 (0.24)
		95% CI	-0.1, 0.3	-0.9, 0.0
		Difference from placebo [1]		
		LS Mean (SE)	0.6 (0.26)	
		95% CI	0.1, 1.1	
		p-value	0.0307	
		Corrected Hedges g (95% CI) [2]	0.46 (0.04, 0.89)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 17 Day 1	Actual	n	92	18
		Mean (StdDev)	2.9 (1.09)	2.6 (1.09)
		Median	3.0	3.0
		Q1, Q3	2.0, 4.0	2.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	89	18
		Mean (StdDev)	0.4 (1.47)	0.3 (1.07)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	-4, 4	-2, 2
		LS Mean (SE)	0.4 (0.10)	0.1 (0.23)
		95% CI	0.2, 0.6	-0.4, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	0.4 (0.25)	
		95% CI	-0.1, 0.9	
		p-value	0.1352	
		Corrected Hedges g (95% CI) [2]	0.38 (-0.13, 0.89)	
Cycle 20 Day 1	Actual	n	84	13
		Mean (StdDev)	2.7 (1.30)	2.5 (0.78)
		Median	3.0	3.0
		Q1, Q3	2.0, 4.0	2.0, 3.0
		Min, Max	0, 4	1, 3
	Change from BL	n	82	13
		Mean (StdDev)	0.1 (1.60)	0.2 (0.69)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	0.0, 1.0
		Min, Max	-4, 4	-1, 1
		LS Mean (SE)	0.2 (0.13)	-0.1 (0.31)
		95% CI	-0.1, 0.4	-0.7, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	0.3 (0.34)	
		95% CI	-0.4, 1.0	
		p-value	0.4092	
		Corrected Hedges g (95% CI) [2]	0.24 (-0.34, 0.83)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 23 Day 1	Actual	n	65	11
		Mean (StdDev)	2.7 (1.33)	2.5 (0.93)
		Median	3.0	3.0
		Q1, Q3	2.0, 4.0	2.0, 3.0
		Min, Max	0, 4	1, 4
	Change from BL	n	63	11
		Mean (StdDev)	0.0 (1.47)	0.2 (0.75)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	0.0, 1.0
		Min, Max	-4, 4	-1, 1
		LS Mean (SE)	0.1 (0.14)	-0.1 (0.34)
		95% CI	-0.1, 0.4	-0.7, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	0.2 (0.37)	
		95% CI	-0.5, 0.9	
		p-value	0.5575	
		Corrected Hedges g (95% CI) [2]	0.19 (-0.45, 0.83)	
Cycle 26 Day 1	Actual	n	63	10
		Mean (StdDev)	3.0 (1.10)	2.7 (0.82)
		Median	3.0	3.0
		Q1, Q3	3.0, 4.0	2.0, 3.0
		Min, Max	0, 4	1, 4
	Change from BL	n	61	10
		Mean (StdDev)	0.5 (1.37)	0.2 (0.92)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	-4, 4	-2, 1
		LS Mean (SE)	0.5 (0.12)	0.0 (0.28)
		95% CI	0.2, 0.7	-0.6, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	0.5 (0.31)	
		95% CI	-0.1, 1.1	
		p-value	0.1305	
		Corrected Hedges g (95% CI) [2]	0.51 (-0.17, 1.18)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 29 Day 1	Actual	n	58	8
		Mean (StdDev)	3.1 (1.08)	2.8 (0.89)
		Median	3.0	3.0
		Q1, Q3	3.0, 4.0	2.5, 3.0
		Min, Max	0, 4	1, 4
	Change from BL	n	56	8
		Mean (StdDev)	0.4 (1.76)	0.3 (1.16)
		Median	1.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	-4, 4	-2, 2
		LS Mean (SE)	0.6 (0.13)	0.0 (0.33)
		95% CI	0.3, 0.8	-0.7, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	0.6 (0.35)	
		95% CI	-0.1, 1.3	
		p-value	0.0967	
		Corrected Hedges g (95% CI) [2]	0.62 (-0.13, 1.36)	
Cycle 32 Day 1	Actual	n	47	8
		Mean (StdDev)	2.9 (1.31)	2.8 (1.04)
		Median	3.0	3.0
		Q1, Q3	3.0, 4.0	2.0, 3.5
		Min, Max	0, 4	1, 4
	Change from BL	n	46	8
		Mean (StdDev)	0.4 (1.71)	0.3 (0.89)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.5
		Min, Max	-4, 4	-1, 2
		LS Mean (SE)	0.3 (0.18)	0.0 (0.43)
		95% CI	0.0, 0.7	-0.9, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	0.4 (0.46)	
		95% CI	-0.5, 1.3	
		p-value	0.4091	
		Corrected Hedges g (95% CI) [2]	0.31 (-0.44, 1.07)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 35 Day 1	Actual	n	48	7
		Mean (StdDev)	2.8 (1.32)	2.9 (1.35)
		Median	3.0	3.0
		Q1, Q3	2.0, 4.0	1.0, 4.0
		Min, Max	0, 4	1, 4
	Change from BL	n	47	7
		Mean (StdDev)	0.3 (1.50)	0.4 (1.13)
		Median	0.0	1.0
		Q1, Q3	0.0, 1.0	-1.0, 1.0
		Min, Max	-4, 4	-1, 2
		LS Mean (SE)	0.3 (0.16)	0.2 (0.41)
		95% CI	-0.1, 0.6	-0.6, 1.0
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.44)	
		95% CI	-0.8, 0.9	
		p-value	0.8749	
		Corrected Hedges g (95% CI) [2]	0.06 (-0.73, 0.86)	
Cycle 38 Day 1	Actual	n	43	7
		Mean (StdDev)	2.9 (1.32)	3.0 (0.58)
		Median	3.0	3.0
		Q1, Q3	2.0, 4.0	3.0, 3.0
		Min, Max	0, 4	2, 4
	Change from BL	n	42	7
		Mean (StdDev)	0.5 (1.66)	0.4 (0.53)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	-4, 4	0, 1
		LS Mean (SE)	0.4 (0.13)	0.2 (0.31)
		95% CI	0.2, 0.7	-0.4, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	0.2 (0.34)	
		95% CI	-0.4, 0.9	
		p-value	0.4861	
		Corrected Hedges g (95% CI) [2]	0.28 (-0.52, 1.08)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 41 Day 1	Actual	n	44	7
		Mean (StdDev)	2.7 (1.49)	2.6 (1.13)
		Median	3.0	3.0
		Q1, Q3	2.0, 4.0	3.0, 3.0
		Min, Max	0, 4	0, 3
	Change from BL	n	43	7
		Mean (StdDev)	0.2 (1.99)	0.0 (1.00)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	0.0, 1.0
		Min, Max	-4, 4	-2, 1
		LS Mean (SE)	0.2 (0.18)	-0.2 (0.44)
		95% CI	-0.1, 0.6	-1.1, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	0.4 (0.47)	
		95% CI	-0.5, 1.4	
		p-value	0.3611	
		Corrected Hedges g (95% CI) [2]	0.37 (-0.44, 1.17)	
Cycle 44 Day 1	Actual	n	36	8
		Mean (StdDev)	2.9 (1.45)	2.5 (1.20)
		Median	3.5	3.0
		Q1, Q3	3.0, 4.0	2.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	36	8
		Mean (StdDev)	0.4 (1.76)	0.0 (0.93)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.5
		Min, Max	-4, 4	-2, 1
		LS Mean (SE)	0.4 (0.19)	-0.1 (0.40)
		95% CI	0.0, 0.8	-1.0, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	0.5 (0.44)	
		95% CI	-0.4, 1.4	
		p-value	0.2267	
		Corrected Hedges g (95% CI) [2]	0.47 (-0.30, 1.24)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 47 Day 1	Actual	n	38	5
		Mean (StdDev)	3.0 (1.35)	2.4 (0.89)
		Median	3.5	3.0
		Q1, Q3	2.0, 4.0	2.0, 3.0
		Min, Max	0, 4	1, 3
	Change from BL	n	38	5
		Mean (StdDev)	0.4 (1.97)	-0.2 (1.10)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	0.0, 0.0
		Min, Max	-4, 4	-2, 1
		LS Mean (SE)	0.5 (0.21)	-0.4 (0.56)
		95% CI	0.1, 0.9	-1.5, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	0.9 (0.60)	
		95% CI	-0.3, 2.1	
		p-value	0.1491	
		Corrected Hedges g (95% CI) [2]	0.67 (-0.27, 1.62)	
Cycle 53 Day 1	Actual	n	31	6
		Mean (StdDev)	3.3 (1.06)	2.5 (0.84)
		Median	4.0	3.0
		Q1, Q3	3.0, 4.0	2.0, 3.0
		Min, Max	0, 4	1, 3
	Change from BL	n	31	6
		Mean (StdDev)	0.5 (1.79)	0.0 (0.63)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	-4, 4	-1, 1
		LS Mean (SE)	0.8 (0.16)	-0.2 (0.37)
		95% CI	0.5, 1.1	-1.0, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	1.0 (0.40)	
		95% CI	0.2, 1.8	
		p-value	0.0138	
		Corrected Hedges g (95% CI) [2]	1.11 (0.20, 2.02)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 56 Day 1	Actual	n	30	5
		Mean (StdDev)	2.7 (1.55)	2.8 (1.10)
		Median	3.0	3.0
		Q1, Q3	1.0, 4.0	3.0, 3.0
		Min, Max	0, 4	1, 4
	Change from BL	n	29	5
		Mean (StdDev)	0.1 (2.04)	0.4 (0.89)
		Median	0.0	1.0
		Q1, Q3	-1.0, 1.0	0.0, 1.0
		Min, Max	-4, 4	-1, 1
		LS Mean (SE)	0.4 (0.23)	0.1 (0.54)
		95% CI	-0.1, 0.8	-1.0, 1.2
		Difference from placebo [1]		
		LS Mean (SE)	0.2 (0.58)	
		95% CI	-1.0, 1.4	
		p-value	0.7026	
		Corrected Hedges g (95% CI) [2]	0.18 (-0.77, 1.13)	
Cycle 59 Day 1	Actual	n	31	6
		Mean (StdDev)	2.9 (1.40)	2.7 (0.82)
		Median	3.0	3.0
		Q1, Q3	2.0, 4.0	3.0, 3.0
		Min, Max	0, 4	1, 3
	Change from BL	n	30	6
		Mean (StdDev)	0.2 (1.89)	0.2 (0.75)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	0.0, 1.0
		Min, Max	-4, 4	-1, 1
		LS Mean (SE)	0.4 (0.21)	-0.1 (0.45)
		95% CI	0.0, 0.9	-1.0, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	0.5 (0.49)	
		95% CI	-0.5, 1.5	
		p-value	0.2939	
		Corrected Hedges g (95% CI) [2]	0.46 (-0.43, 1.34)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 62 Day 1	Actual	n	27	6
		Mean (StdDev)	2.9 (1.33)	2.5 (0.84)
		Median	3.0	3.0
		Q1, Q3	3.0, 4.0	2.0, 3.0
		Min, Max	0, 4	1, 3
	Change from BL	n	27	6
		Mean (StdDev)	0.2 (2.04)	0.0 (0.89)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	-1.0, 1.0
		Min, Max	-4, 4	-1, 1
		LS Mean (SE)	0.5 (0.20)	-0.2 (0.42)
		95% CI	0.1, 0.9	-1.1, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	0.7 (0.47)	
		95% CI	-0.2, 1.7	
		p-value	0.1371	
		Corrected Hedges g (95% CI) [2]	0.67 (-0.23, 1.56)	
Cycle 65 Day 1	Actual	n	22	5
		Mean (StdDev)	2.7 (1.52)	2.4 (0.55)
		Median	3.0	2.0
		Q1, Q3	2.0, 4.0	2.0, 3.0
		Min, Max	0, 4	2, 3
	Change from BL	n	22	5
		Mean (StdDev)	-0.1 (1.96)	0.0 (0.71)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	0.0, 0.0
		Min, Max	-4, 4	-1, 1
		LS Mean (SE)	0.2 (0.30)	-0.3 (0.61)
		95% CI	-0.5, 0.8	-1.6, 0.9
		Difference from placebo [1]		
		LS Mean (SE)	0.5 (0.68)	
		95% CI	-0.9, 1.9	
		p-value	0.4951	
		Corrected Hedges g (95% CI) [2]	0.32 (-0.65, 1.30)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 68 Day 1	Actual	n	23	6
		Mean (StdDev)	2.7 (1.40)	2.8 (0.75)
		Median	3.0	3.0
		Q1, Q3	2.0, 4.0	2.0, 3.0
		Min, Max	0, 4	2, 4
	Change from BL	n	23	6
		Mean (StdDev)	-0.4 (1.47)	0.3 (0.52)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	0.0, 1.0
		Min, Max	-4, 2	0, 1
		LS Mean (SE)	0.0 (0.25)	0.1 (0.45)
		95% CI	-0.5, 0.5	-0.9, 1.0
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.51)	
		95% CI	-1.1, 1.0	
		p-value	0.9113	
		Corrected Hedges g (95% CI) [2]	-0.05 (-0.95, 0.85)	
Study Treatment Discontinuation	Actual	n	276	143
		Mean (StdDev)	2.1 (1.29)	2.0 (1.15)
		Median	2.0	2.0
		Q1, Q3	1.0, 3.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	269	141
		Mean (StdDev)	-0.2 (1.61)	-0.2 (1.56)
		Median	0.0	0.0
		Q1, Q3	-1.0, 1.0	-1.0, 1.0
		Min, Max	-4, 4	-4, 4
		LS Mean (SE)	-0.3 (0.07)	-0.4 (0.10)
		95% CI	-0.4, -0.2	-0.5, -0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.12)	
		95% CI	-0.2, 0.3	
		p-value	0.7016	
		Corrected Hedges g (95% CI) [2]	0.04 (-0.16, 0.24)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I am content with the quality of my life

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Post Progression	Actual	n	239	124
		Mean (StdDev)	2.1 (1.26)	2.1 (1.10)
		Median	2.0	2.0
		Q1, Q3	1.0, 3.0	1.0, 3.0
		Min, Max	0, 4	0, 4
	Change from BL	n	233	121
		Mean (StdDev)	-0.2 (1.51)	-0.2 (1.42)
		Median	0.0	0.0
		Q1, Q3	-1.0, 0.0	-1.0, 1.0
		Min, Max	-4, 4	-4, 4
		LS Mean (SE)	-0.3 (0.07)	-0.3 (0.10)
		95% CI	-0.5, -0.2	-0.5, -0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.13)	
		95% CI	-0.3, 0.2	
		p-value	0.7215	
		Corrected Hedges g (95% CI) [2]	-0.04 (-0.26, 0.18)	
Overall	Change from BL	LS Mean (SE)	0.0 (0.04)	-0.2 (0.06)
		95% CI	-0.1, 0.0	-0.3, -0.1
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.07)	
		95% CI	0.0, 0.3	
		p-value	0.0519	
		Corrected Hedges g (95% CI) [2]	0.18 (0.00, 0.37)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Baseline	Actual	n	356	173
		Mean (StdDev)	0.3 (0.64)	0.2 (0.54)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 4	0, 3
Cycle 2 Day 1	Actual	n	303	156
		Mean (StdDev)	0.5 (0.87)	0.3 (0.72)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 4	0, 4
	Change from BL	n	295	152
		Mean (StdDev)	0.2 (0.75)	0.1 (0.65)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 3	-2, 3
		LS Mean (SE)	0.2 (0.04)	0.1 (0.06)
		95% CI	0.1, 0.3	0.0, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.07)	
		95% CI	0.0, 0.2	
		p-value	0.1662	
		Corrected Hedges g (95% CI) [2]	0.14 (-0.06, 0.33)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 4 Day 1	Actual	n	268	124
		Mean (StdDev)	0.5 (0.87)	0.3 (0.72)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 4	0, 3
	Change from BL	n	259	120
		Mean (StdDev)	0.2 (0.82)	0.1 (0.81)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 4	-2, 3
		LS Mean (SE)	0.2 (0.05)	0.1 (0.07)
		95% CI	0.1, 0.3	0.0, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.08)	
		95% CI	-0.1, 0.2	
		p-value	0.2603	
		Corrected Hedges g (95% CI) [2]	0.12 (-0.09, 0.34)	
Cycle 6 Day 1	Actual	n	227	86
		Mean (StdDev)	0.4 (0.77)	0.3 (0.64)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 3
	Change from BL	n	220	86
		Mean (StdDev)	0.1 (0.67)	0.1 (0.64)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 3	-2, 2
		LS Mean (SE)	0.1 (0.04)	0.1 (0.07)
		95% CI	0.1, 0.2	0.0, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.08)	
		95% CI	-0.2, 0.1	
		p-value	0.9597	
		Corrected Hedges g (95% CI) [2]	-0.01 (-0.26, 0.24)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 8 Day 1	Actual	n	192	57
		Mean (StdDev)	0.4 (0.79)	0.3 (0.63)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 4	0, 2
	Change from BL	n	188	57
		Mean (StdDev)	0.1 (0.77)	0.1 (0.70)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 4	-2, 2
		LS Mean (SE)	0.2 (0.05)	0.1 (0.09)
		95% CI	0.1, 0.2	0.0, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.10)	
		95% CI	-0.2, 0.2	
		p-value	0.8387	
		Corrected Hedges g (95% CI) [2]	0.03 (-0.27, 0.33)	
Cycle 10 Day 1	Actual	n	163	40
		Mean (StdDev)	0.3 (0.74)	0.4 (0.63)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	159	40
		Mean (StdDev)	0.1 (0.64)	0.2 (0.75)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 2	-2, 2
		LS Mean (SE)	0.1 (0.05)	0.3 (0.09)
		95% CI	0.1, 0.2	0.1, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.10)	
		95% CI	-0.3, 0.1	
		p-value	0.2729	
		Corrected Hedges g (95% CI) [2]	-0.19 (-0.53, 0.16)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 12 Day 1	Actual	n	149	36
		Mean (StdDev)	0.4 (0.81)	0.2 (0.48)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 4	0, 2
	Change from BL	n	147	36
		Mean (StdDev)	0.1 (0.78)	0.0 (0.63)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 4	-2, 1
		LS Mean (SE)	0.2 (0.05)	0.1 (0.10)
		95% CI	0.1, 0.3	-0.1, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.11)	
		95% CI	-0.1, 0.3	
		p-value	0.4915	
		Corrected Hedges g (95% CI) [2]	0.12 (-0.24, 0.49)	
Cycle 14 Day 1	Actual	n	128	26
		Mean (StdDev)	0.4 (0.82)	0.4 (0.57)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	125	26
		Mean (StdDev)	0.1 (0.64)	0.1 (0.71)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 3	-2, 2
		LS Mean (SE)	0.2 (0.05)	0.3 (0.11)
		95% CI	0.1, 0.3	0.1, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.12)	
		95% CI	-0.3, 0.1	
		p-value	0.4665	
		Corrected Hedges g (95% CI) [2]	-0.15 (-0.57, 0.27)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 17 Day 1	Actual	n	92	18
		Mean (StdDev)	0.5 (0.89)	0.3 (0.59)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 2
	Change from BL	n	90	18
		Mean (StdDev)	0.2 (0.62)	0.2 (0.62)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 3	-1, 2
		LS Mean (SE)	0.3 (0.06)	0.2 (0.13)
		95% CI	0.1, 0.4	-0.1, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.14)	
		95% CI	-0.2, 0.4	
		p-value	0.6167	
		Corrected Hedges g (95% CI) [2]	0.13 (-0.38, 0.63)	
Cycle 20 Day 1	Actual	n	82	13
		Mean (StdDev)	0.4 (0.73)	0.2 (0.55)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 3	0, 2
	Change from BL	n	81	13
		Mean (StdDev)	0.1 (0.51)	-0.1 (0.49)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-1, 3	-1, 1
		LS Mean (SE)	0.2 (0.05)	0.0 (0.11)
		95% CI	0.1, 0.3	-0.2, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.2 (0.12)	
		95% CI	0.0, 0.5	
		p-value	0.0736	
		Corrected Hedges g (95% CI) [2]	0.51 (-0.08, 1.10)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\program\tables\t-pro-visit.sas
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 23 Day 1	Actual	n	65	11
		Mean (StdDev)	0.3 (0.55)	0.5 (0.52)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 2	0, 1
	Change from BL	n	64	11
		Mean (StdDev)	0.0 (0.59)	0.3 (0.47)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 2	0, 1
		LS Mean (SE)	0.1 (0.06)	0.3 (0.13)
		95% CI	0.0, 0.2	0.0, 0.5
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.15)	
		95% CI	-0.4, 0.1	
		p-value	0.3148	
		Corrected Hedges g (95% CI) [2]	-0.32 (-0.96, 0.32)	
Cycle 26 Day 1	Actual	n	63	10
		Mean (StdDev)	0.4 (0.73)	0.7 (1.06)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 3	0, 3
	Change from BL	n	62	10
		Mean (StdDev)	0.1 (0.44)	0.5 (0.97)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-1, 1	-1, 2
		LS Mean (SE)	0.2 (0.06)	0.5 (0.14)
		95% CI	0.1, 0.3	0.2, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.15)	
		95% CI	-0.6, 0.0	
		p-value	0.0285	
		Corrected Hedges g (95% CI) [2]	-0.72 (-1.40, -0.05)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 29 Day 1	Actual	n	58	8
		Mean (StdDev)	0.3 (0.62)	0.5 (1.41)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 4
	Change from BL	n	57	8
		Mean (StdDev)	0.0(0.61)	0.3 (1.16)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 2	-1, 3
		LS Mean (SE)	0.1 (0.07)	0.4 (0.19)
		95% CI	0.0, 0.3	0.0, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.20)	
		95% CI	-0.6, 0.2	
		p-value	0.2452	
		Corrected Hedges g (95% CI) [2]	-0.42 (-1.17, 0.32)	
Cycle 32 Day 1	Actual	n	46	8
		Mean (StdDev)	0.3 (0.79)	0.3 (0.71)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 4	0, 2
	Change from BL	n	45	8
		Mean (StdDev)	0.0 (0.54)	0.0 (0.53)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-1, 2	-1, 1
		LS Mean (SE)	0.1 (0.07)	0.1 (0.15)
		95% CI	0.0, 0.3	-0.2, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.17)	
		95% CI	-0.3, 0.4	
		p-value	0.7513	
		Corrected Hedges g (95% CI) [2]	0.12 (-0.63, 0.87)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 35 Day 1	Actual	n	47	7
		Mean (StdDev)	0.3 (0.63)	0.6 (1.13)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 2	0, 3
	Change from BL	n	46	7
		Mean (StdDev)	0.0(0.58)	0.4 (0.79)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-3, 1	0, 2
		LS Mean (SE)	0.1 (0.08)	0.4 (0.21)
		95% CI	-0.1, 0.3	0.0, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.22)	
		95% CI	-0.7, 0.2	
		p-value	0.1994	
		Corrected Hedges g (95% CI) [2]	-0.51 (-1.31, 0.30)	
Cycle 38 Day 1	Actual	n	41	7
		Mean (StdDev)	0.3 (0.69)	0.0 (0.00)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	0, 2	0, 0
	Change from BL	n	40	7
		Mean (StdDev)	0.0(0.70)	-0.1 (0.38)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-3, 2	-1, 0
		LS Mean (SE)	0.1 (0.08)	0.0 (0.19)
		95% CI	0.0, 0.3	-0.3, 0.4
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.20)	
		95% CI	-0.3, 0.5	
		p-value	0.6359	
		Corrected Hedges g (95% CI) [2]	0.19 (-0.62, 0.99)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 41 Day 1	Actual	n	43	7
		Mean (StdDev)	0.4 (0.91)	0.4 (0.79)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	42	7
		Mean (StdDev)	0.1 (0.73)	0.3 (0.49)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 3	0, 1
		LS Mean (SE)	0.2 (0.10)	0.3 (0.25)
		95% CI	0.0, 0.4	-0.2, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	0.0 (0.27)	
		95% CI	-0.6, 0.5	
		p-value	0.8581	
		Corrected Hedges g (95% CI) [2]	-0.07 (-0.87, 0.73)	
Cycle 44 Day 1	Actual	n	36	8
		Mean (StdDev)	0.4 (0.69)	0.5 (1.07)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.5
		Min, Max	0, 3	0, 3
	Change from BL	n	36	8
		Mean (StdDev)	0.2 (0.64)	0.4 (0.74)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.5
		Min, Max	-1, 3	0, 2
		LS Mean (SE)	0.3 (0.10)	0.4 (0.20)
		95% CI	0.1, 0.5	0.0, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.22)	
		95% CI	-0.5, 0.3	
		p-value	0.6621	
		Corrected Hedges g (95% CI) [2]	-0.17 (-0.93, 0.60)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 47 Day 1	Actual	n	38	5
		Mean (StdDev)	0.3 (0.55)	0.8 (1.30)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 2	0, 3
	Change from BL	n	38	5
		Mean (StdDev)	-0.1 (0.70)	0.6 (0.89)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 2	0, 2
		LS Mean (SE)	0.1 (0.07)	0.5 (0.19)
		95% CI	0.0, 0.2	0.2, 0.9
		Difference from placebo [1]		
		LS Mean (SE)	-0.4 (0.20)	
		95% CI	-0.8, 0.0	
		p-value	0.0362	
		Corrected Hedges g (95% CI) [2]	-0.95 (-1.91, 0.00)	
Cycle 53 Day 1	Actual	n	31	6
		Mean (StdDev)	0.3 (0.65)	0.8 (1.17)
		Median	0.0	0.5
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 2	0, 3
	Change from BL	n	31	6
		Mean (StdDev)	0.0(0.60)	0.7 (0.82)
		Median	0.0	0.5
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-2, 2	0, 2
		LS Mean (SE)	0.1 (0.08)	0.6 (0.18)
		95% CI	-0.1, 0.3	0.3, 1.0
		Difference from placebo [1]		
		LS Mean (SE)	-0.5 (0.19)	
		95% CI	-0.9, -0.1	
		p-value	0.0116	
		Corrected Hedges g (95% CI) [2]	-1.13 (-2.04, -0.22)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 56 Day 1	Actual	n	29	5
		Mean (StdDev)	0.4 (0.69)	0.4 (0.89)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	0, 2	0, 2
	Change from BL	n	28	5
		Mean (StdDev)	0.2 (0.61)	0.2 (0.45)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-1, 2	0, 1
		LS Mean (SE)	0.3 (0.09)	0.2 (0.22)
		95% CI	0.1, 0.5	-0.2, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.24)	
		95% CI	-0.4, 0.6	
		p-value	0.6869	
		Corrected Hedges g (95% CI) [2]	0.19 (-0.76, 1.14)	
Cycle 59 Day 1	Actual	n	31	6
		Mean (StdDev)	0.4 (0.75)	0.7 (1.21)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 3	0, 3
	Change from BL	n	30	6
		Mean (StdDev)	0.2 (0.70)	0.5 (0.84)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-1, 3	0, 2
		LS Mean (SE)	0.2 (0.11)	0.5 (0.25)
		95% CI	0.0, 0.5	-0.1, 1.0
		Difference from placebo [1]		
		LS Mean (SE)	-0.2 (0.28)	
		95% CI	-0.8, 0.3	
		p-value	0.4515	
		Corrected Hedges g (95% CI) [2]	-0.33 (-1.21, 0.55)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 62 Day 1	Actual	n	27	6
		Mean (StdDev)	0.4 (0.69)	0.5 (0.84)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 2	0, 2
	Change from BL	n	27	6
		Mean (StdDev)	0.1 (0.53)	0.3 (0.52)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-1, 2	0, 1
		LS Mean (SE)	0.2 (0.08)	0.3 (0.17)
		95% CI	0.1, 0.4	0.0, 0.6
		Difference from placebo [1]		
		LS Mean (SE)	-0.1 (0.19)	
		95% CI	-0.4, 0.3	
		p-value	0.7044	
		Corrected Hedges g (95% CI) [2]	-0.17 (-1.05, 0.72)	
Cycle 65 Day 1	Actual	n	22	5
		Mean (StdDev)	0.1 (0.35)	0.8 (1.30)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 1	0, 3
	Change from BL	n	22	5
		Mean (StdDev)	0.0 (0.31)	0.6 (0.89)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-1, 1	0, 2
		LS Mean (SE)	0.1 (0.07)	0.5 (0.15)
		95% CI	0.0, 0.3	0.2, 0.8
		Difference from placebo [1]		
		LS Mean (SE)	-0.4 (0.17)	
		95% CI	-0.7, 0.0	
		p-value	0.0388	
		Corrected Hedges g (95% CI) [2]	-1.00 (-2.01, 0.00)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Cycle 68 Day 1	Actual	n	23	6
		Mean (StdDev)	0.3 (0.70)	0.7 (0.82)
		Median	0.0	0.5
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	0, 3	0, 2
	Change from BL	n	23	6
		Mean (StdDev)	0.0 (0.37)	0.5 (0.55)
		Median	0.0	0.5
		Q1, Q3	0.0, 0.0	0.0, 1.0
		Min, Max	-1, 1	0, 1
		LS Mean (SE)	0.1 (0.06)	0.5 (0.13)
		95% CI	0.0, 0.3	0.2, 0.7
		Difference from placebo [1]		
		LS Mean (SE)	-0.3 (0.14)	
		95% CI	-0.6, -0.1	
		p-value	0.0217	
		Corrected Hedges g (95% CI) [2]	-1.07 (-2.01, -0.13)	
Study Treatment Discontinuation	Actual	n	275	142
		Mean (StdDev)	0.5 (0.96)	0.4 (0.79)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 4	0, 3
	Change from BL	n	268	139
		Mean (StdDev)	0.3 (0.90)	0.2 (0.83)
		Median	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0
		Min, Max	-2, 4	-2, 3
		LS Mean (SE)	0.3 (0.05)	0.2 (0.07)
		95% CI	0.2, 0.4	0.1, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.08)	
		95% CI	-0.1, 0.2	
		p-value	0.5033	
		Corrected Hedges g (95% CI) [2]	0.07 (-0.13, 0.27)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Table 2.7.2
Analysis of Functional Assessment of Cancer Therapy - Ovarian Symptom Index (FOSI) Item Responses over Time by Visit

Parameter: I have cramps in my stomach area

Visit	Actual/ Change	Statistic	Niraparib (N=372)	Placebo (N=181)
Post Progression	Actual	n	241	123
		Mean (StdDev)	0.5 (0.86)	0.5 (0.80)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 1.0
		Min, Max	0, 3	0, 4
	Change from BL	n	235	119
		Mean (StdDev)	0.3 (0.91)	0.2 (0.85)
		Median	0.0	0.0
		Q1, Q3	0.0, 1.0	0.0, 0.0
		Min, Max	-3, 3	-2, 3
		LS Mean (SE)	0.3 (0.05)	0.2 (0.07)
		95% CI	0.2, 0.4	0.0, 0.3
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.09)	
		95% CI	-0.1, 0.3	
		p-value	0.1879	
		Corrected Hedges g (95% CI) [2]	0.15 (-0.07, 0.37)	
Overall	Change from BL	LS Mean (SE)	0.2 (0.03)	0.2 (0.04)
		95% CI	0.1, 0.3	0.1, 0.2
		Difference from placebo [1]		
		LS Mean (SE)	0.1 (0.05)	
		95% CI	0.0, 0.2	
		p-value	0.3040	
		Corrected Hedges g (95% CI) [2]	0.10 (-0.09, 0.28)	

[1] Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, visit, and treatment-by-visit interaction as fixed effects, baseline as a continuous covariate along with baseline-by-visit interaction, and subject is a random effect. An Heterogeneous Autoregressive [ARH(1)] covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom. Visit is not included in the model for the 'Overall' section. Visits with fewer than 5 subjects in any treatment arm are not included in the model.
[2] Corrected Hedges g (95% CI) are derived from the LS Means and associated SEs.
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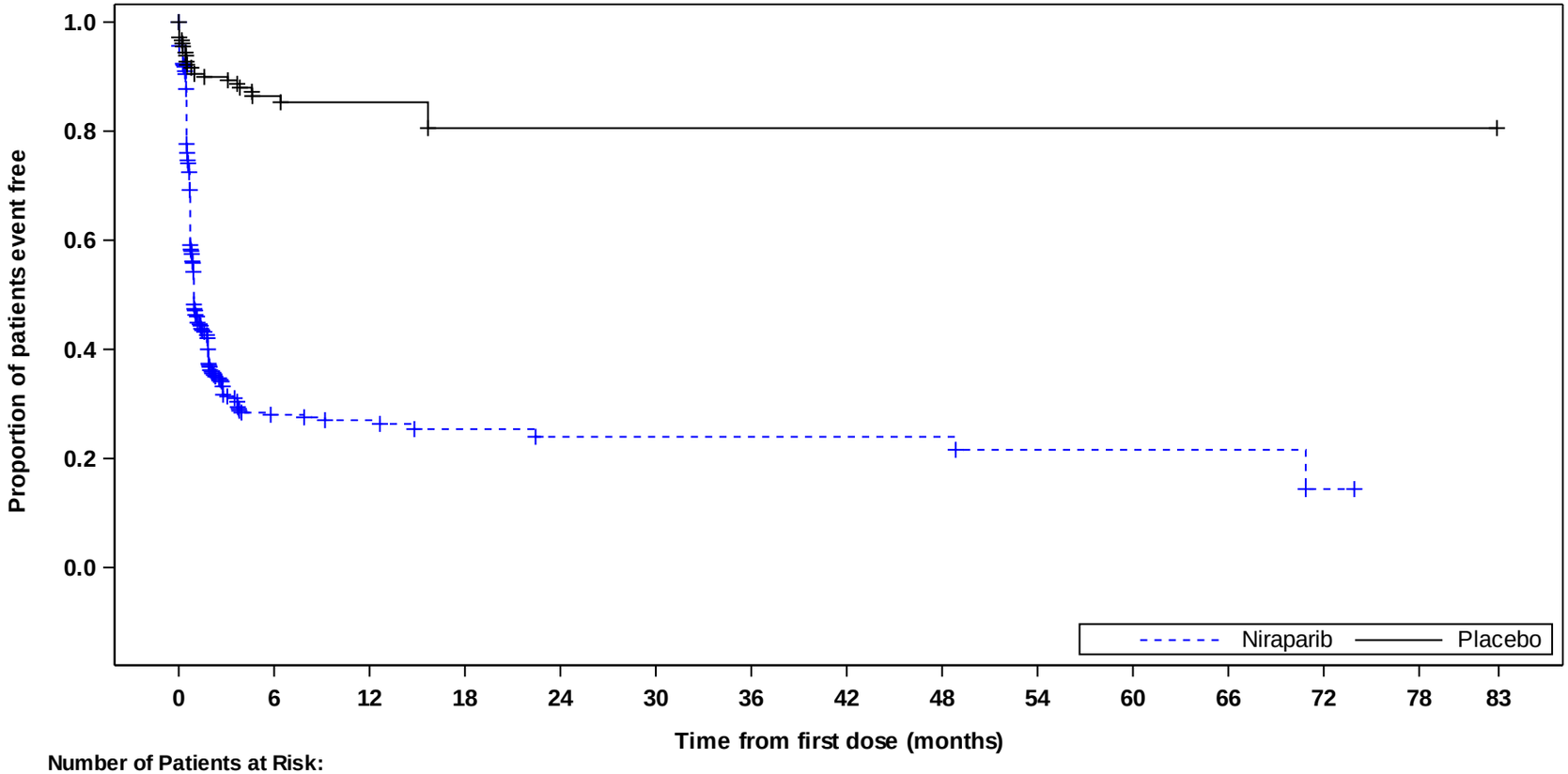
Rundate: 21JAN2021:10:21:18 Data Extraction Date: 01OCT2020

Protocol: PR-30-5011-C Confidential Page 1 of 139
Population: SAF

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders



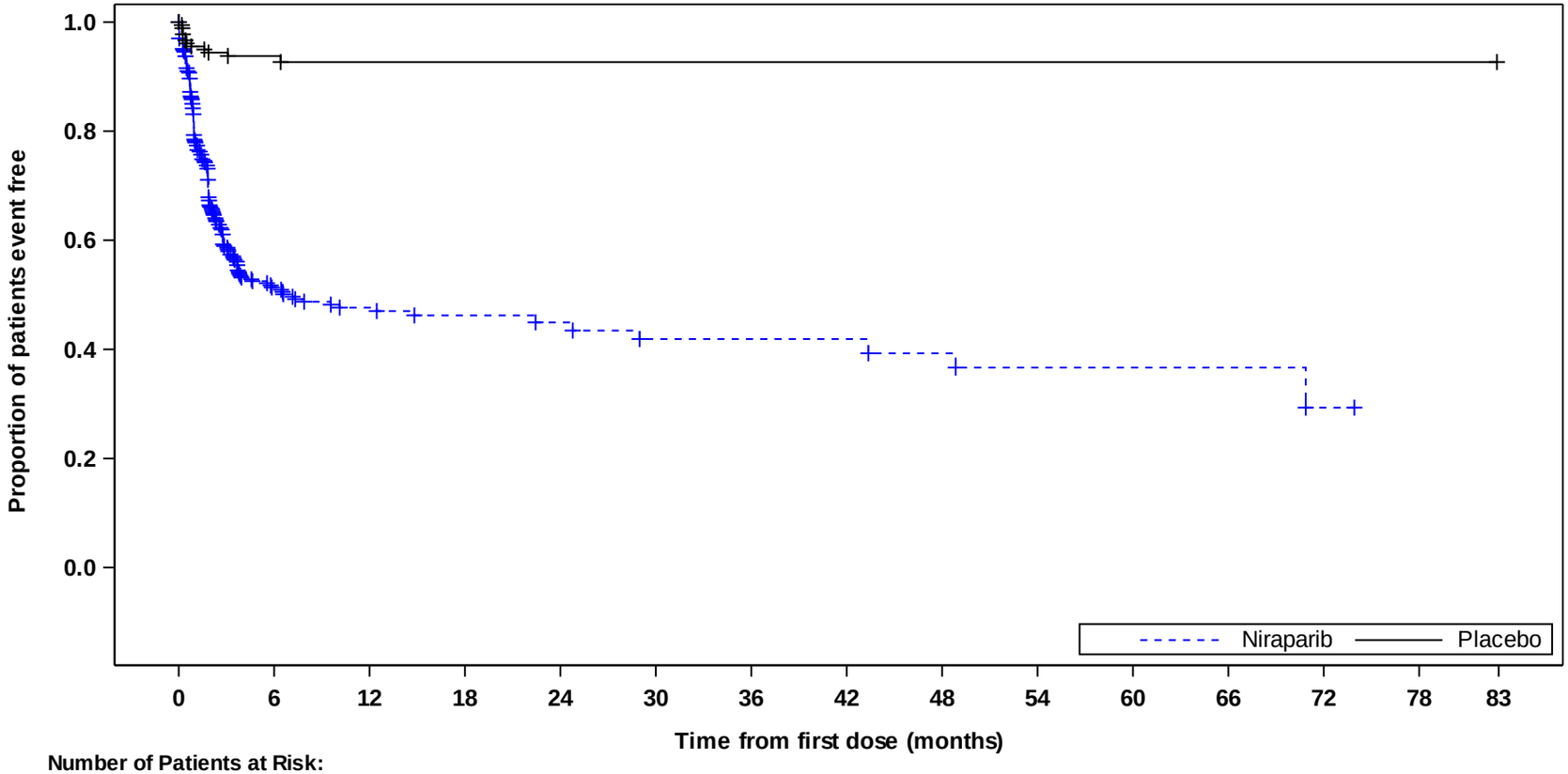
Number of Patients at Risk:

Niraparib	367	69	45	21	14	14	13	10	10	8	7	7	1	0
Placebo	179	79	28	12	8	7	7	6	5	4	4	4	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:06 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Anaemia



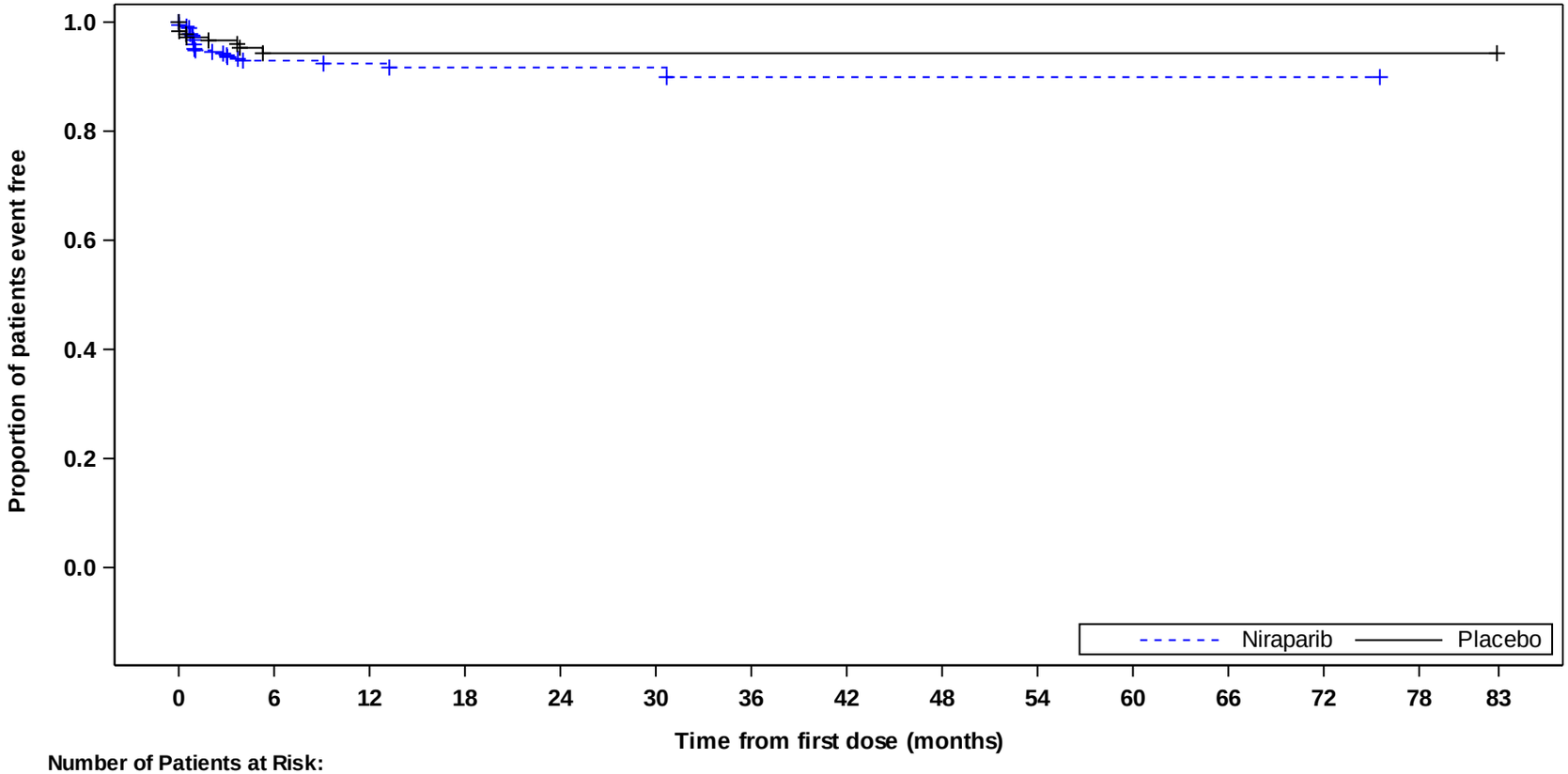
Number of Patients at Risk:

Niraparib	367	128	81	44	30	27	23	17	15	11	10	10	1	0
Placebo	179	87	33	13	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:10 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Leukopenia



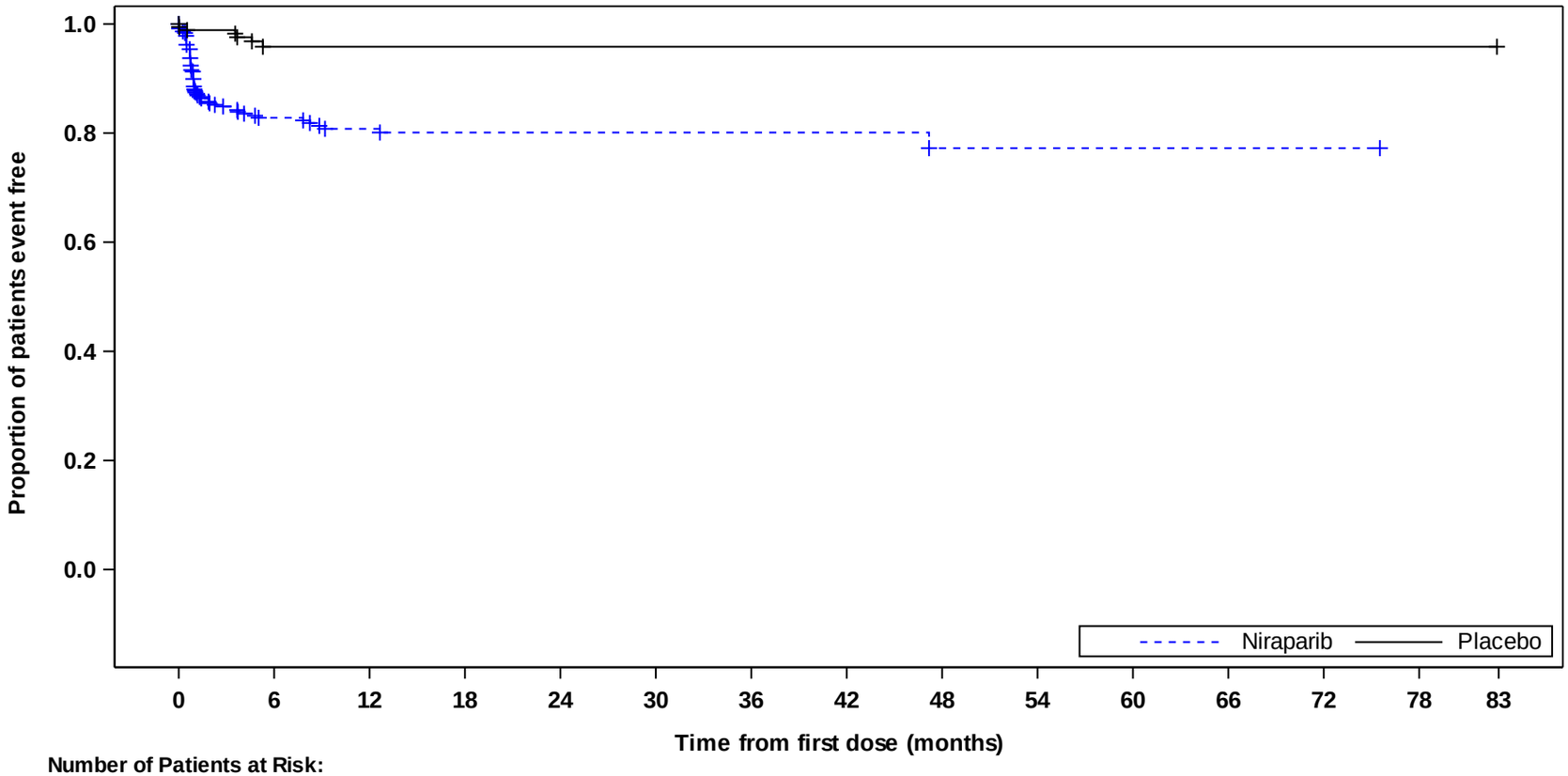
Number of Patients at Risk:

Niraparib	367	230	149	93	64	55	46	36	33	30	26	19	5	0
Placebo	179	85	33	15	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:11 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Neutropenia



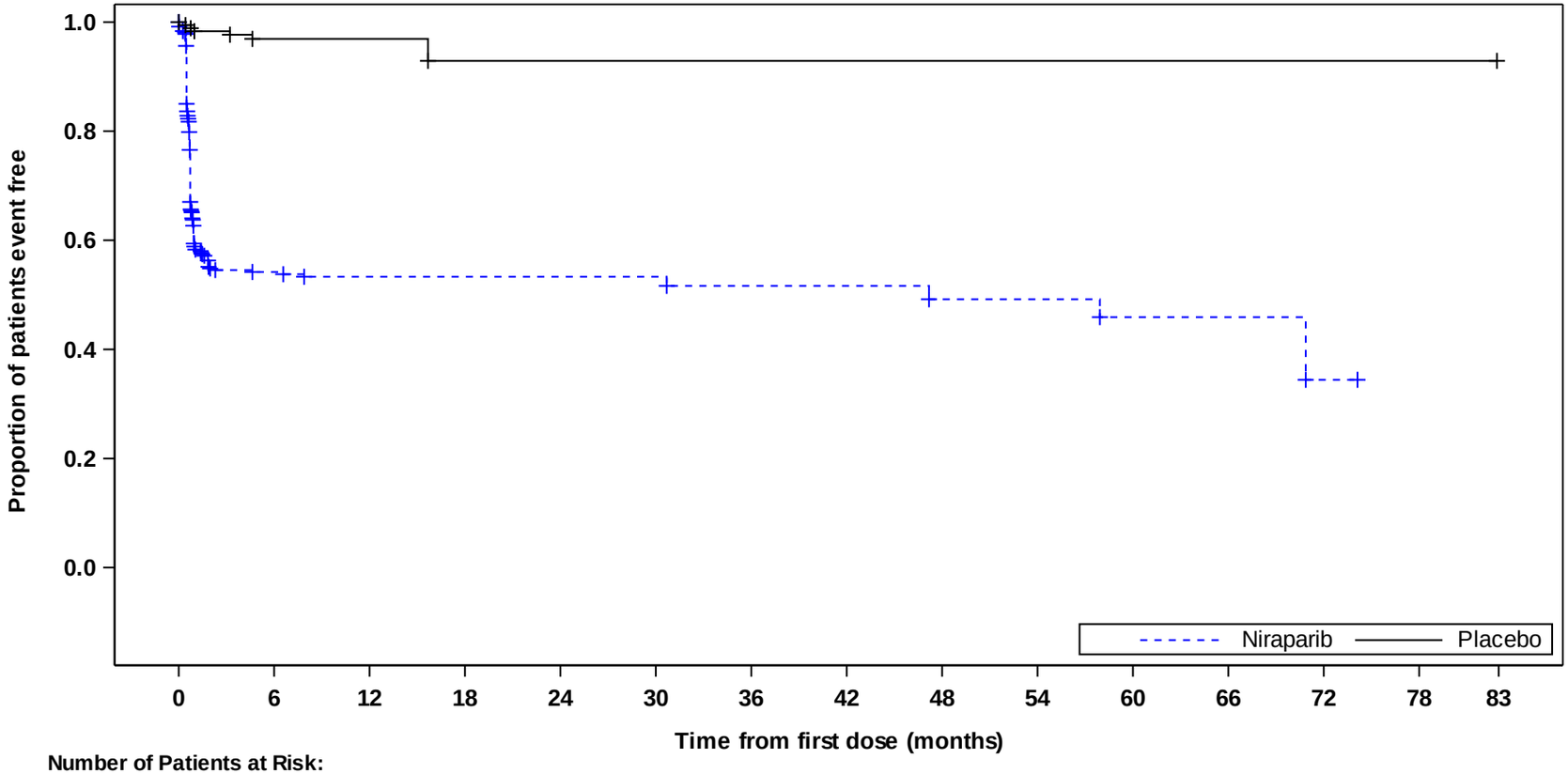
Number of Patients at Risk:

Niraparib	367	204	130	77	51	44	38	30	26	23	21	17	5	0
Placebo	179	88	34	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:12 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia



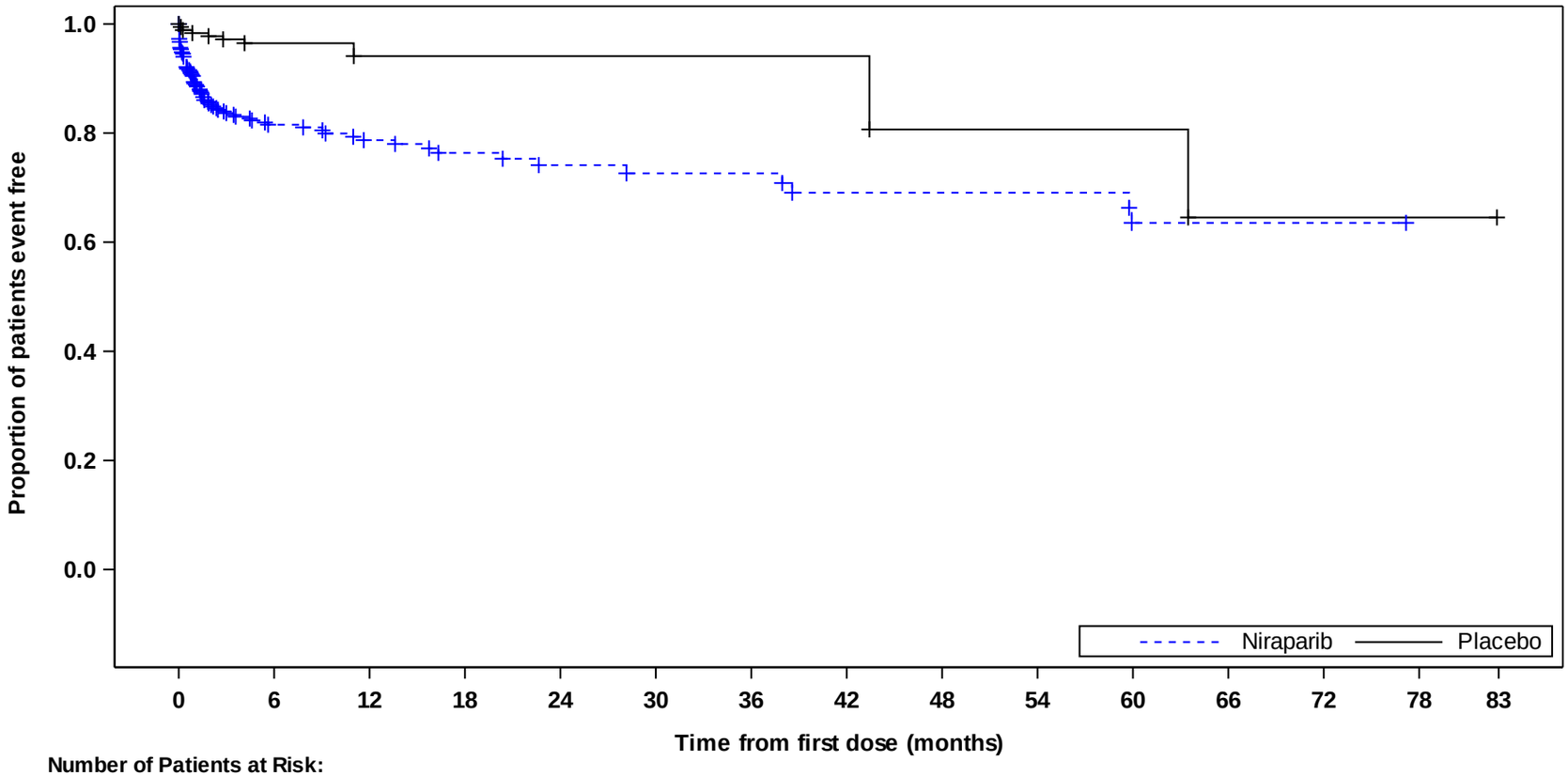
Number of Patients at Risk:

Niraparib	367	134	88	52	37	34	29	21	19	16	12	11	2	0
Placebo	179	91	37	15	9	8	8	7	6	5	5	5	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:13 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Cardiac disorders



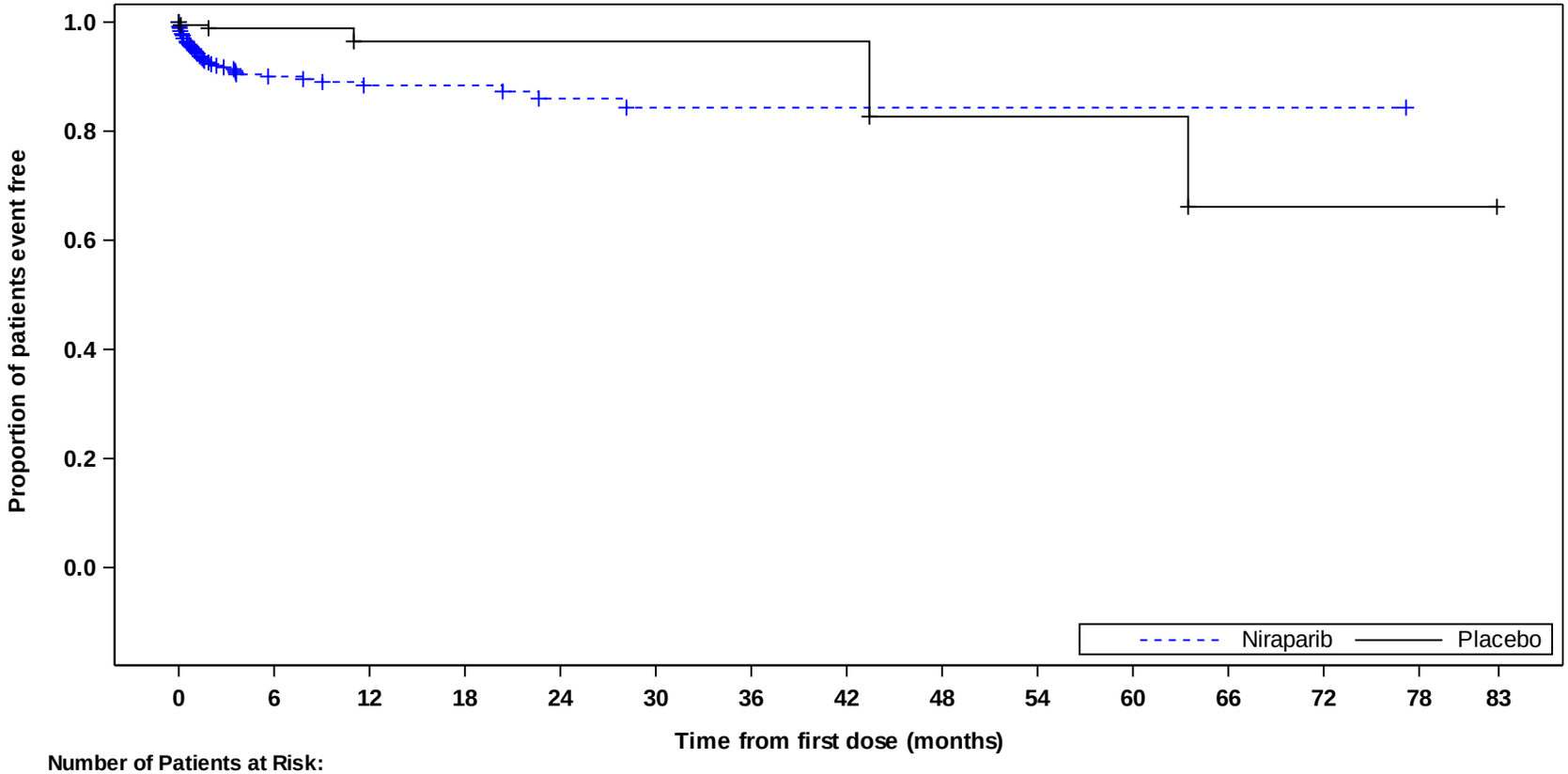
Number of Patients at Risk:

Niraparib	367	197	127	81	59	48	42	34	32	29	23	16	5	0
Placebo	179	90	36	16	10	9	9	8	6	5	5	4	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:14 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Cardiac disorders, PT: Palpitations



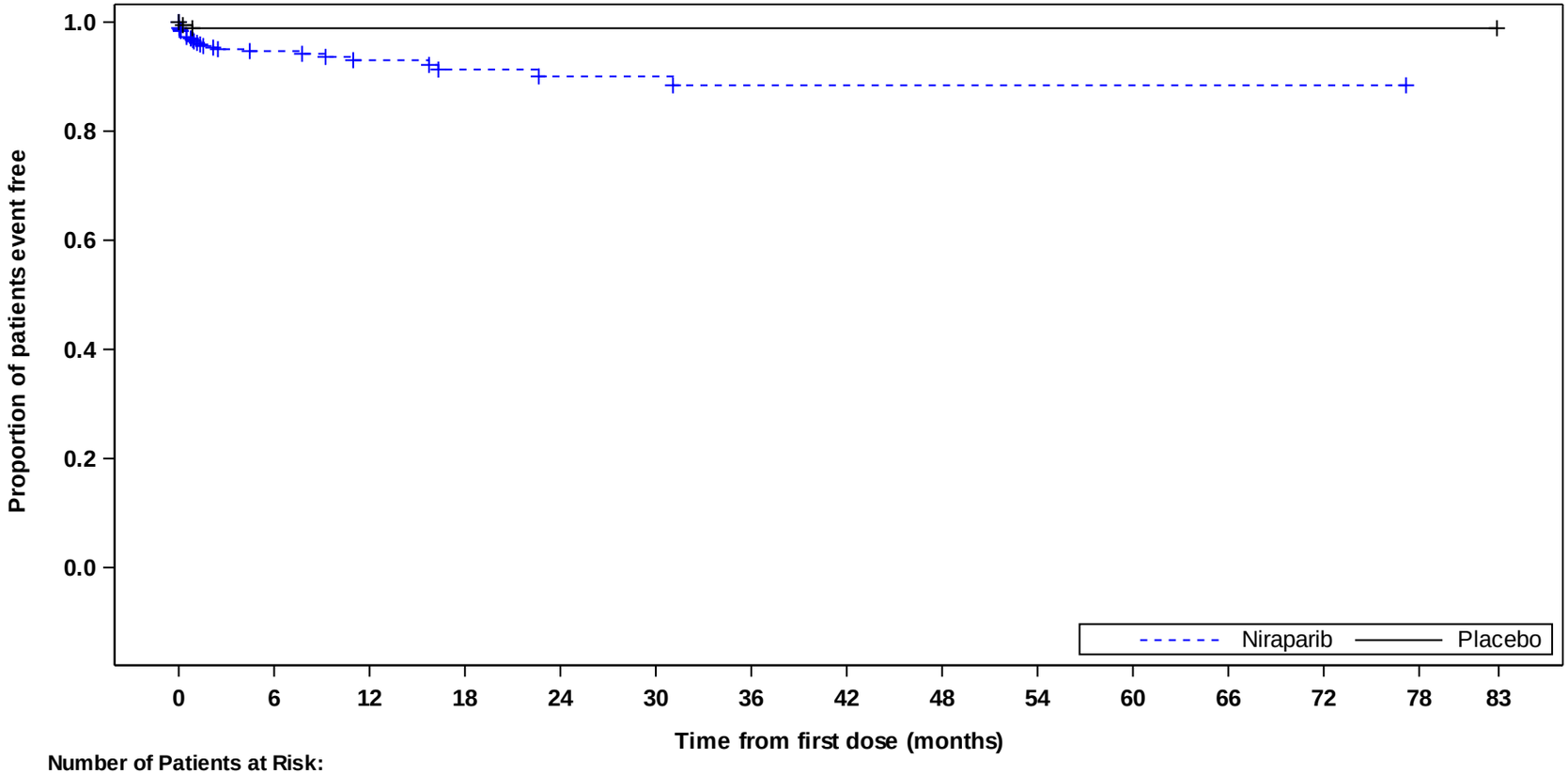
Number of Patients at Risk:

Niraparib	367	222	143	92	62	51	45	38	36	31	27	20	7	0
Placebo	179	92	36	16	10	9	9	8	6	5	5	4	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:15 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Cardiac disorders, PT: Tachycardia



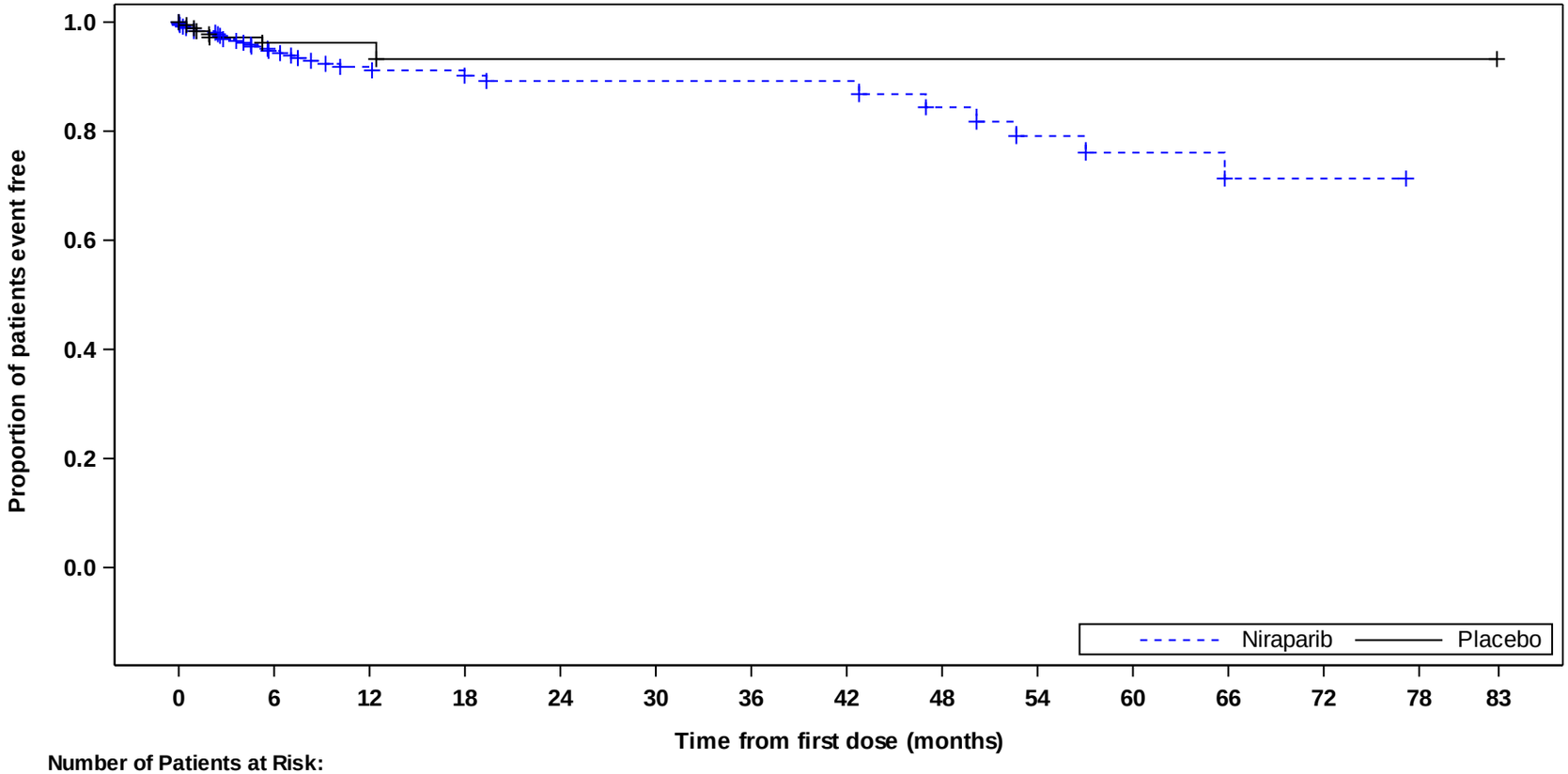
Number of Patients at Risk:

Niraparib	367	230	149	91	68	58	49	40	37	32	28	21	7	0
Placebo	179	91	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:16 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Ear and labyrinth disorders



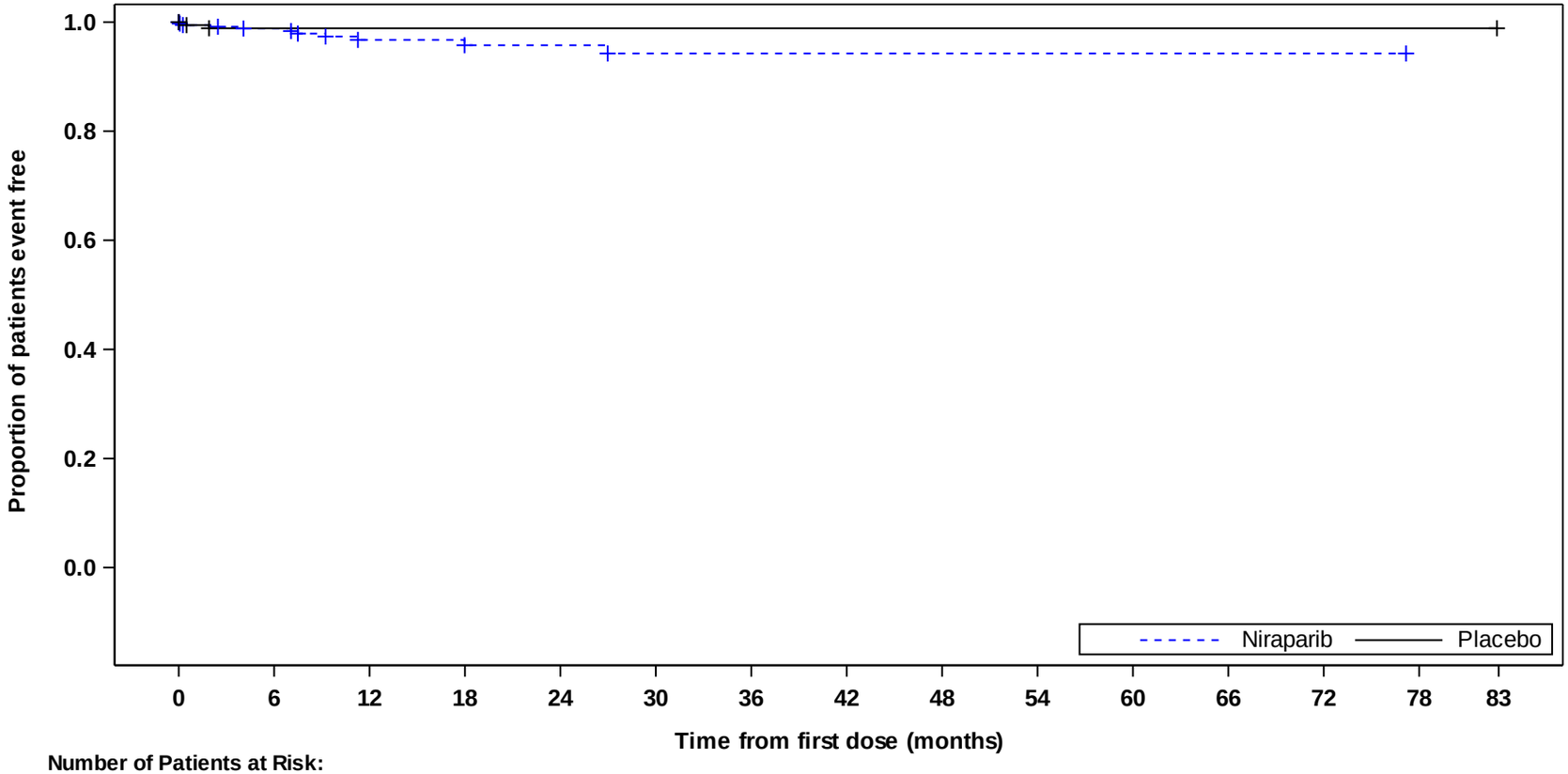
Number of Patients at Risk:

Niraparib	367	234	148	93	64	55	48	38	34	27	22	15	5	0
Placebo	179	89	35	14	9	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:17 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Ear and labyrinth disorders, PT: Tinnitus



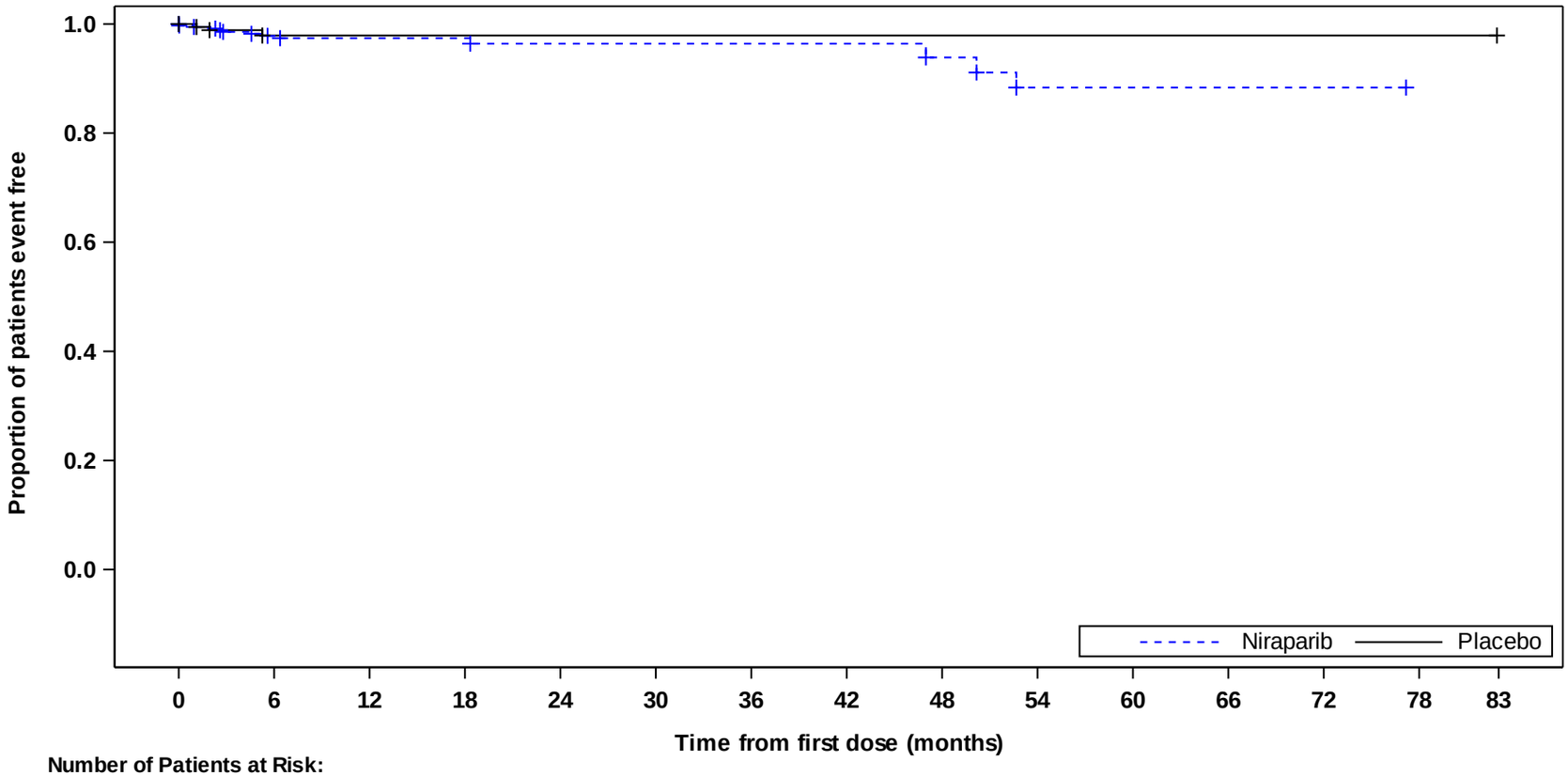
Number of Patients at Risk:

Niraparib	367	245	157	98	70	59	50	40	37	32	27	20	7	0
Placebo	179	91	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:18 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Ear and labyrinth disorders, PT: Vertigo



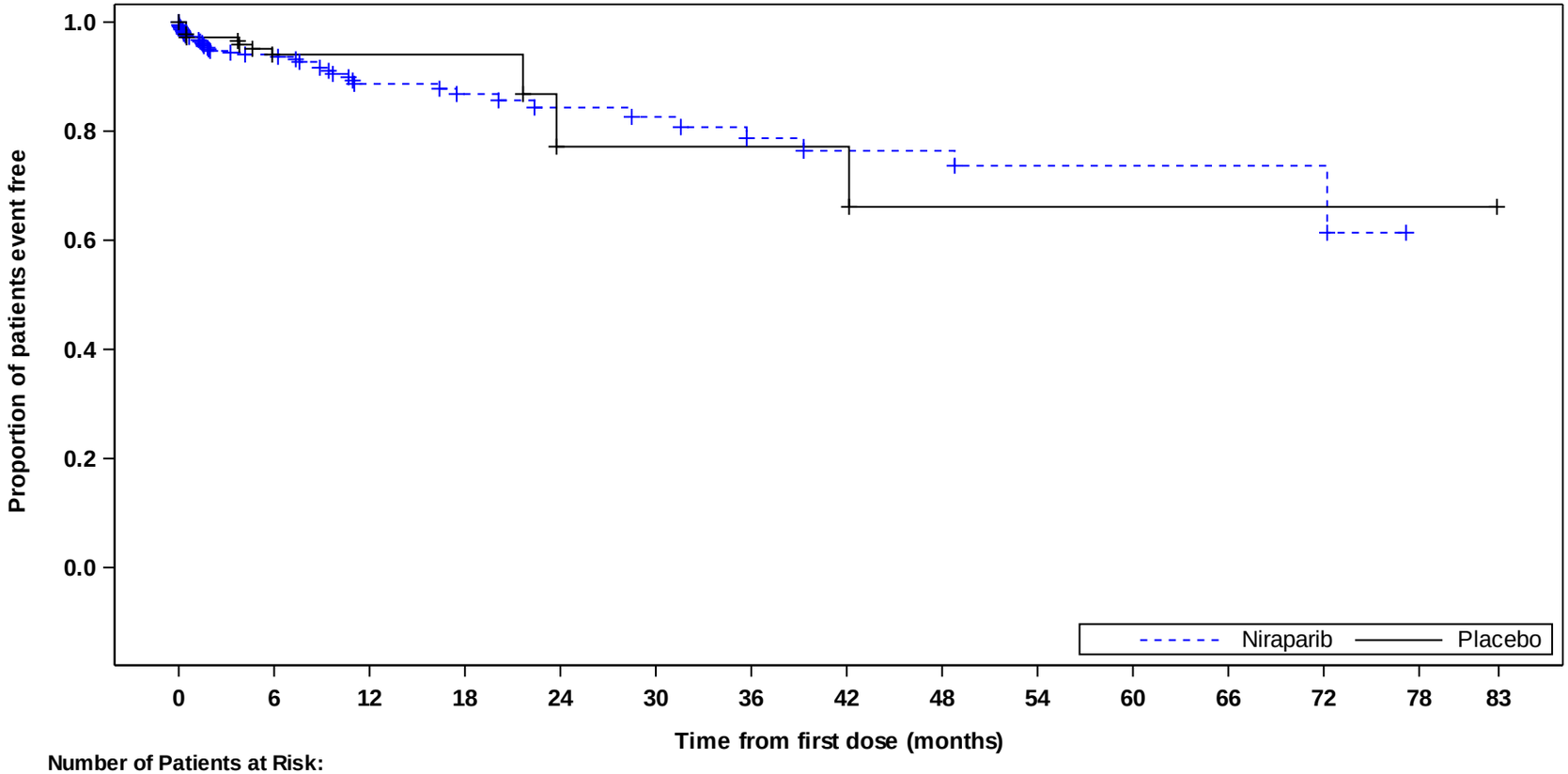
Number of Patients at Risk:

Niraparib	367	240	157	98	68	58	50	40	36	29	25	19	7	0
Placebo	179	90	36	15	9	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:19 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Eye disorders



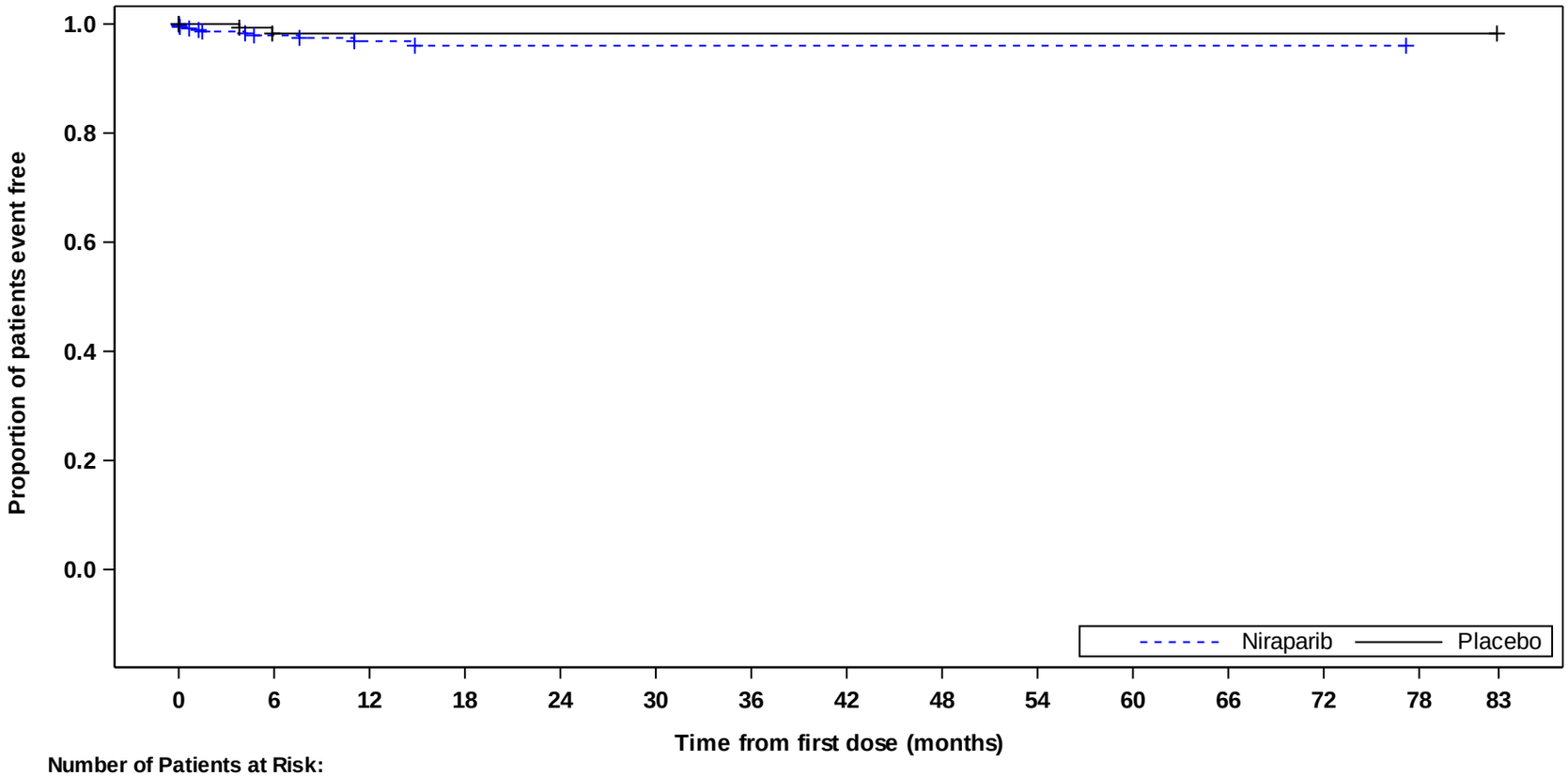
Number of Patients at Risk:

Niraparib	367	231	141	84	59	48	39	30	28	24	20	16	6	0
Placebo	179	86	34	16	8	8	8	7	5	4	4	4	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:20 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Eye disorders, PT: Dry eye



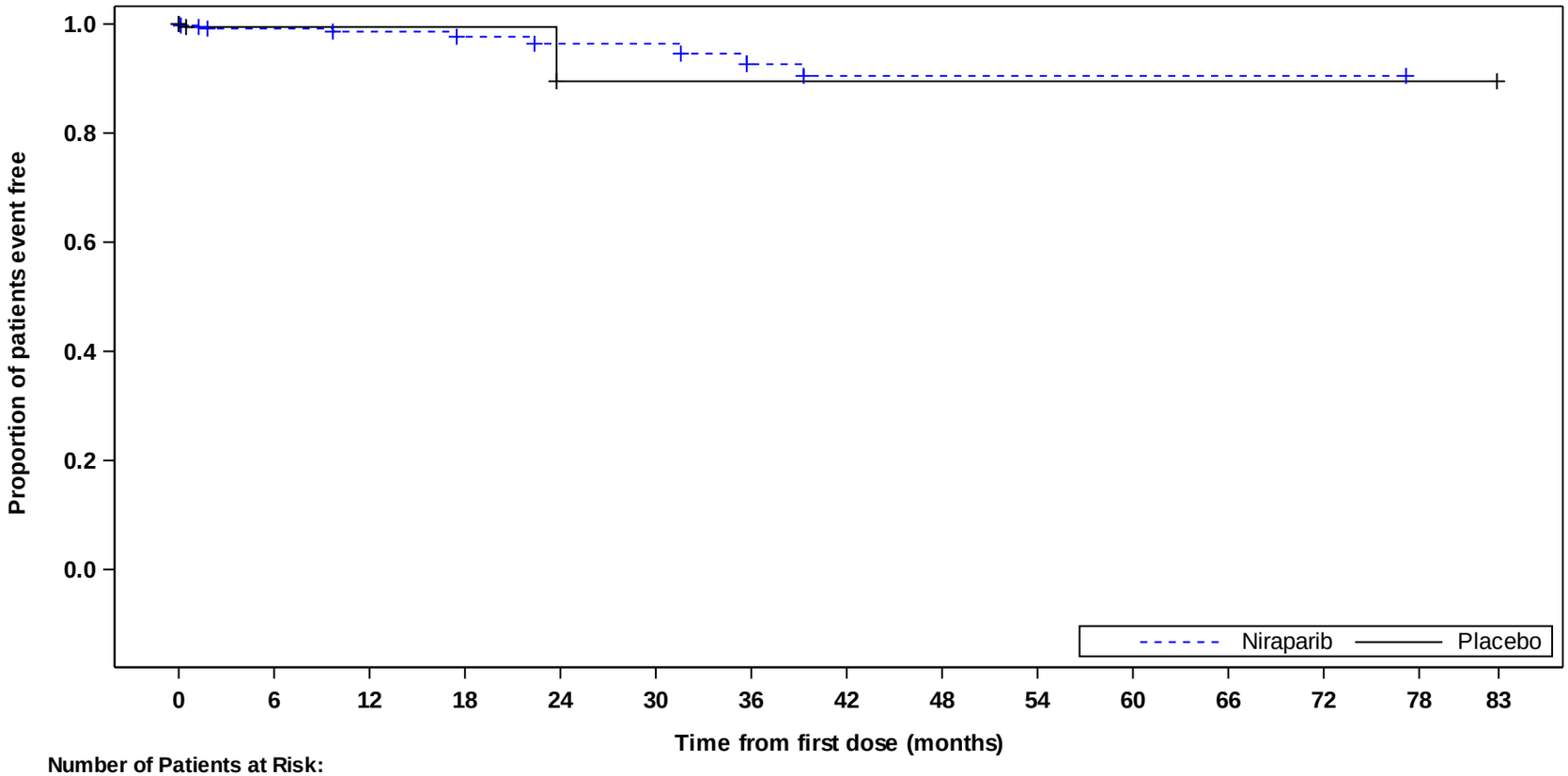
Number of Patients at Risk:

Niraparib	367	242	156	95	67	57	48	39	36	31	26	21	7	0
Placebo	179	90	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:21 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Eye disorders, PT: Vision blurred



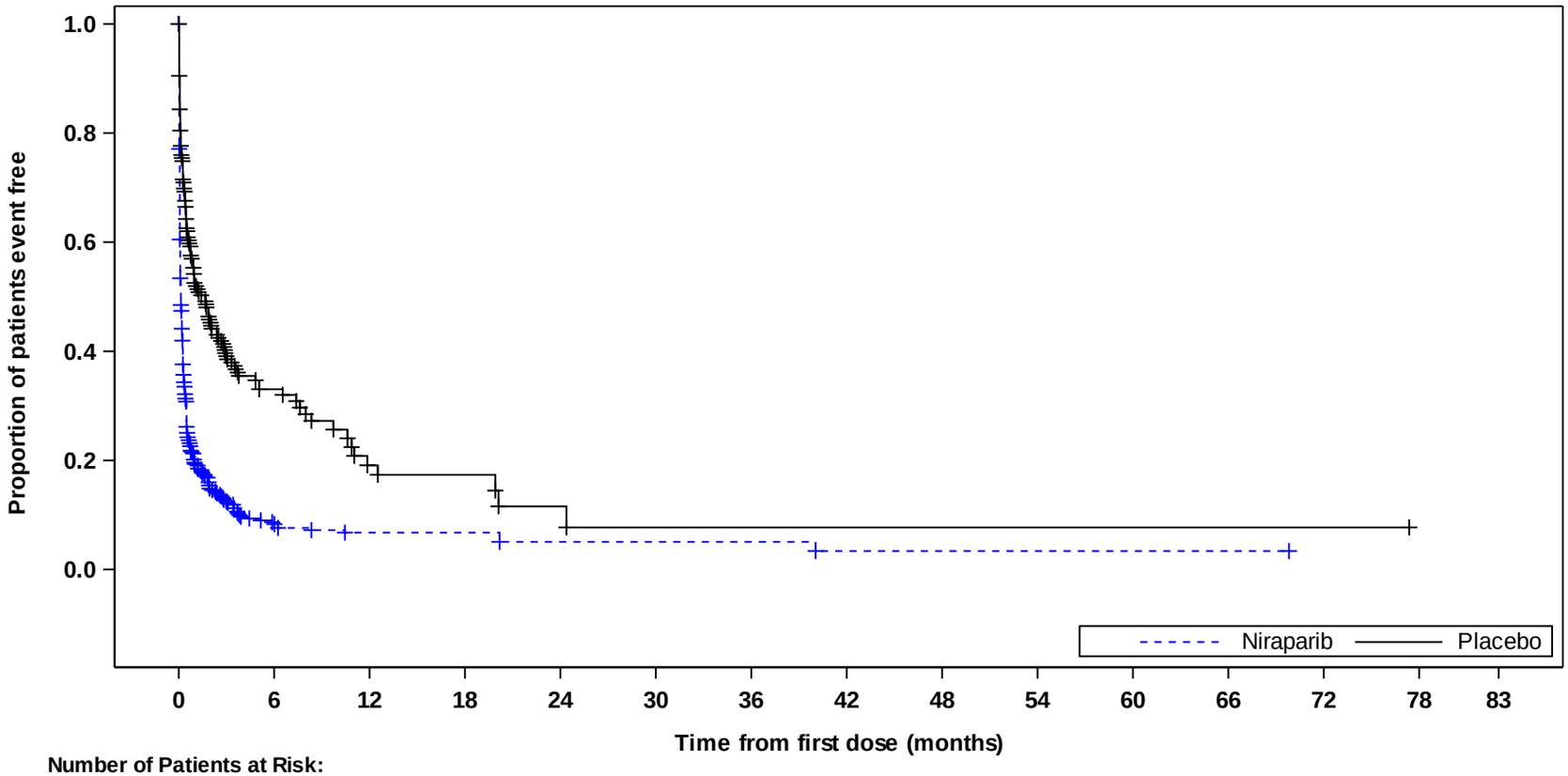
Number of Patients at Risk:

Niraparib	367	245	160	98	68	58	48	38	35	31	26	19	6	0
Placebo	179	92	37	16	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:22 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders



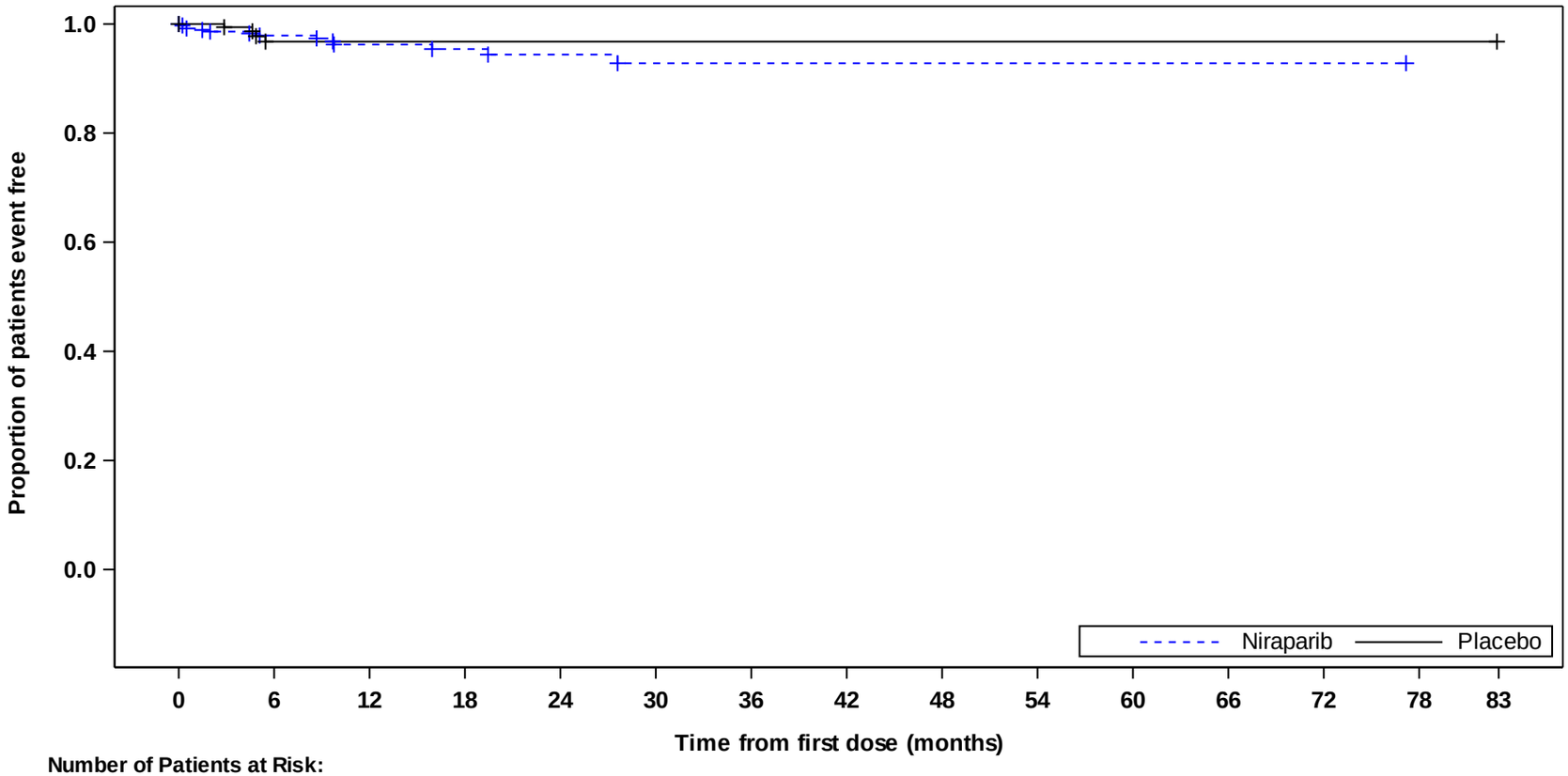
Number of Patients at Risk:

Niraparib	367	25	14	4	3	3	3	2	2	2	2	2	0	
Placebo	179	36	11	7	3	2	2	1	1	1	1	1	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:23 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Abdominal discomfort



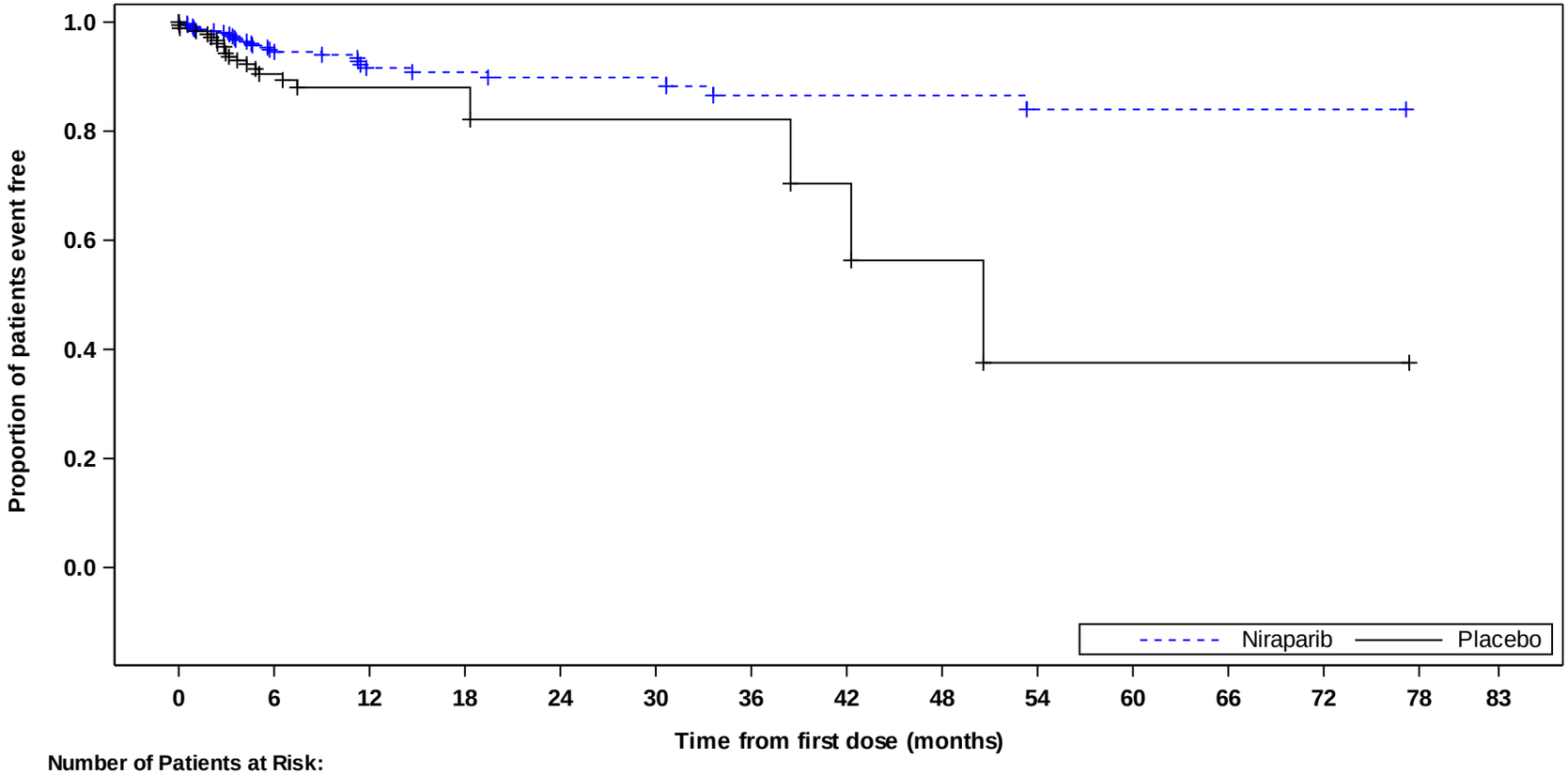
Number of Patients at Risk:

Niraparib	367	242	157	96	68	57	49	39	36	31	26	19	6	0
Placebo	179	89	36	15	9	8	8	7	6	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:23 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Abdominal distension



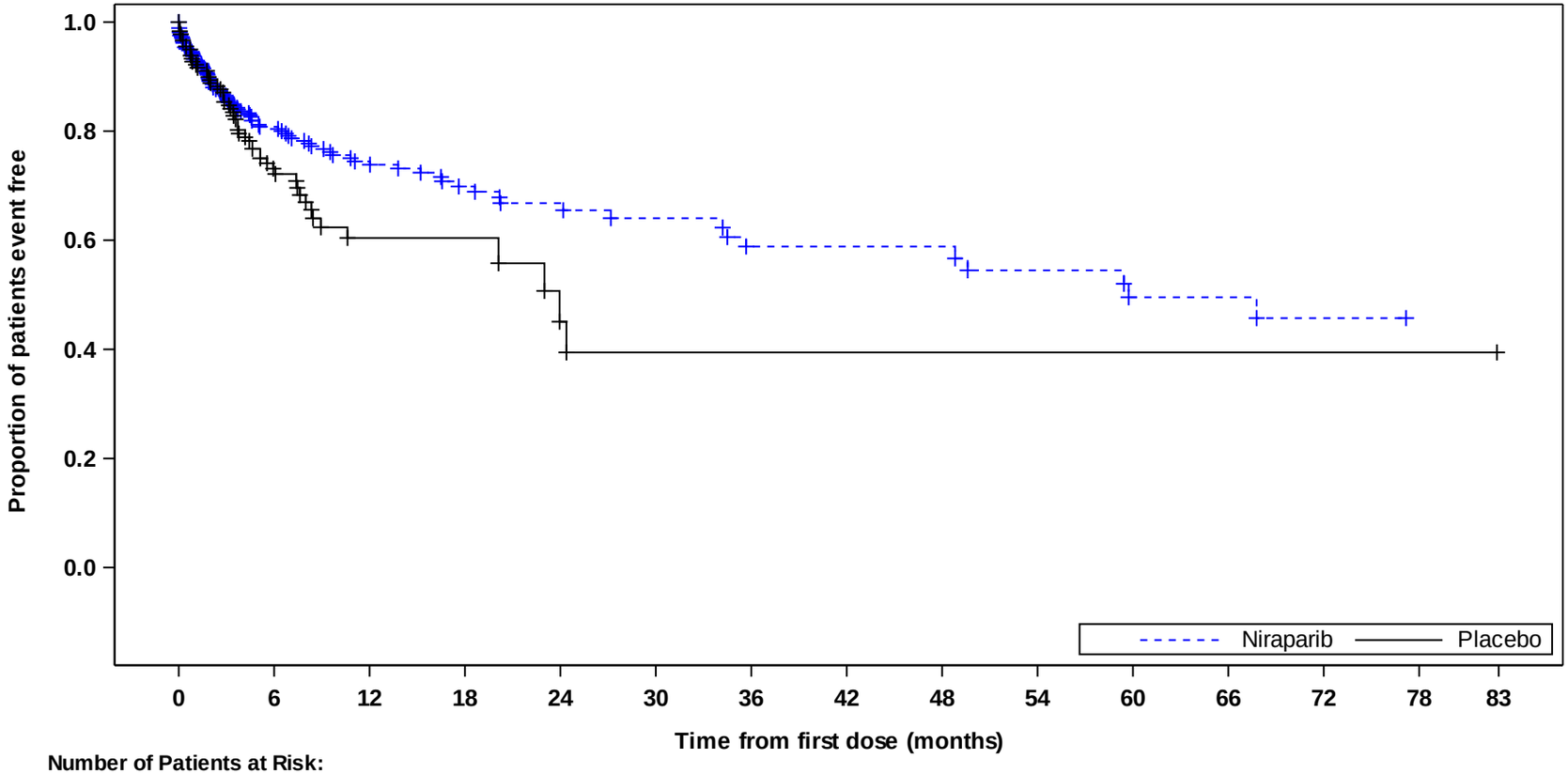
Number of Patients at Risk:

Niraparib	367	236	151	96	68	59	50	40	37	31	27	20	7	0
Placebo	179	88	35	15	8	7	7	5	3	2	2	2	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:24 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Abdominal pain



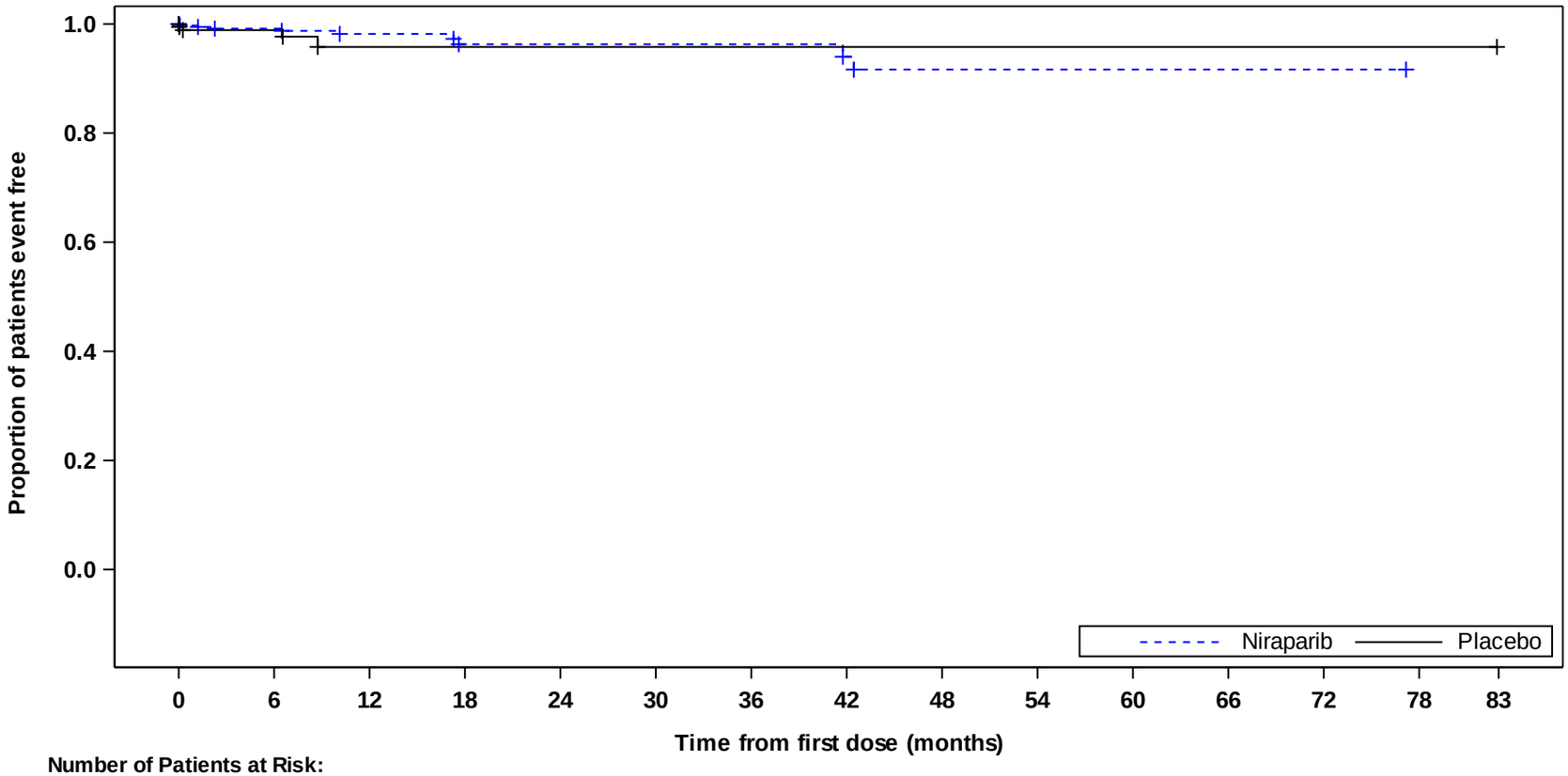
Number of Patients at Risk:

Niraparib	367	204	125	74	51	42	34	28	27	24	20	16	5	0
Placebo	179	74	29	15	8	7	7	6	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:25 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Abdominal pain lower



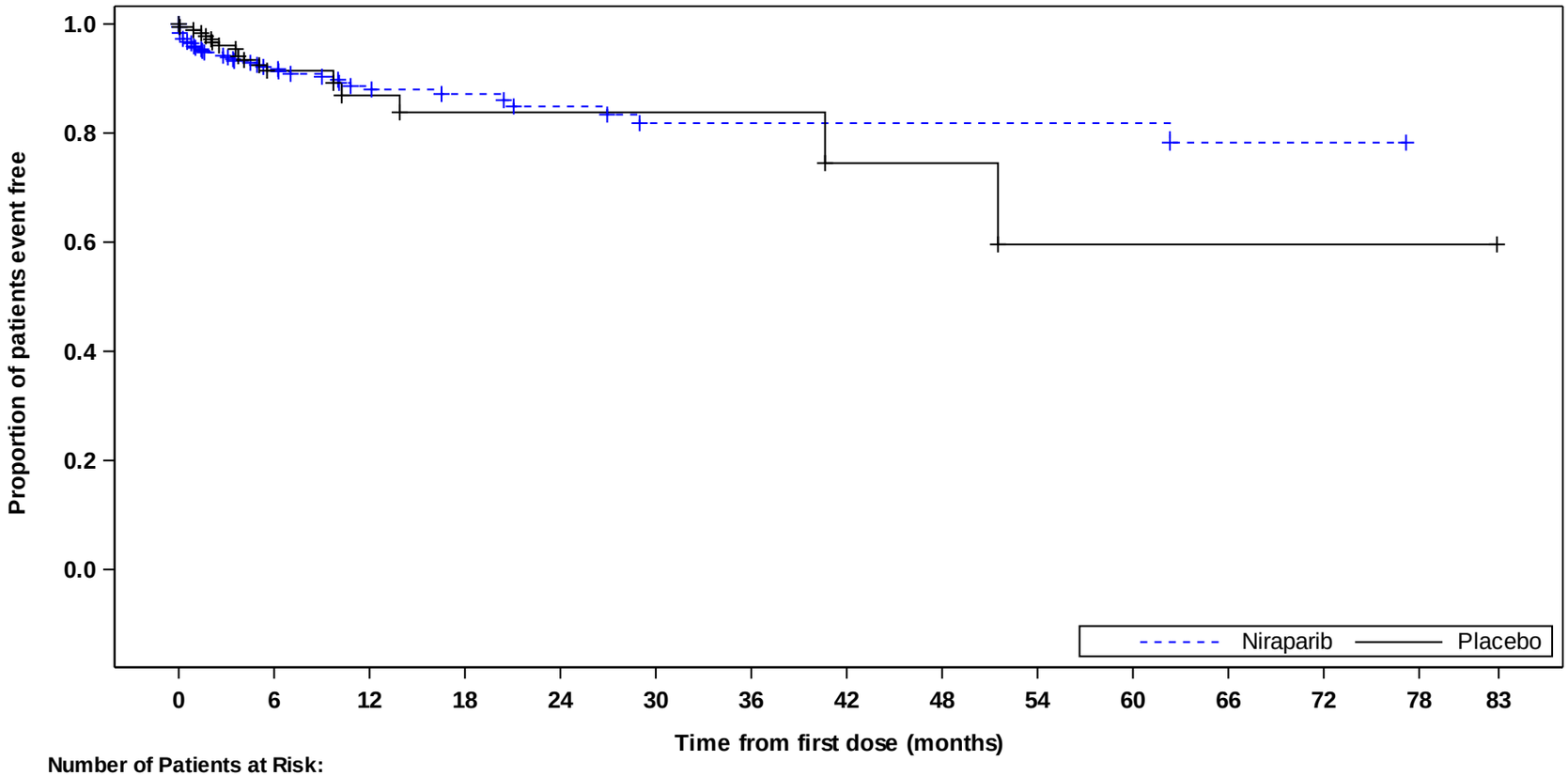
Number of Patients at Risk:

Niraparib	367	245	159	98	70	60	51	40	36	31	26	20	6	0
Placebo	179	92	36	15	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:26 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Abdominal pain upper



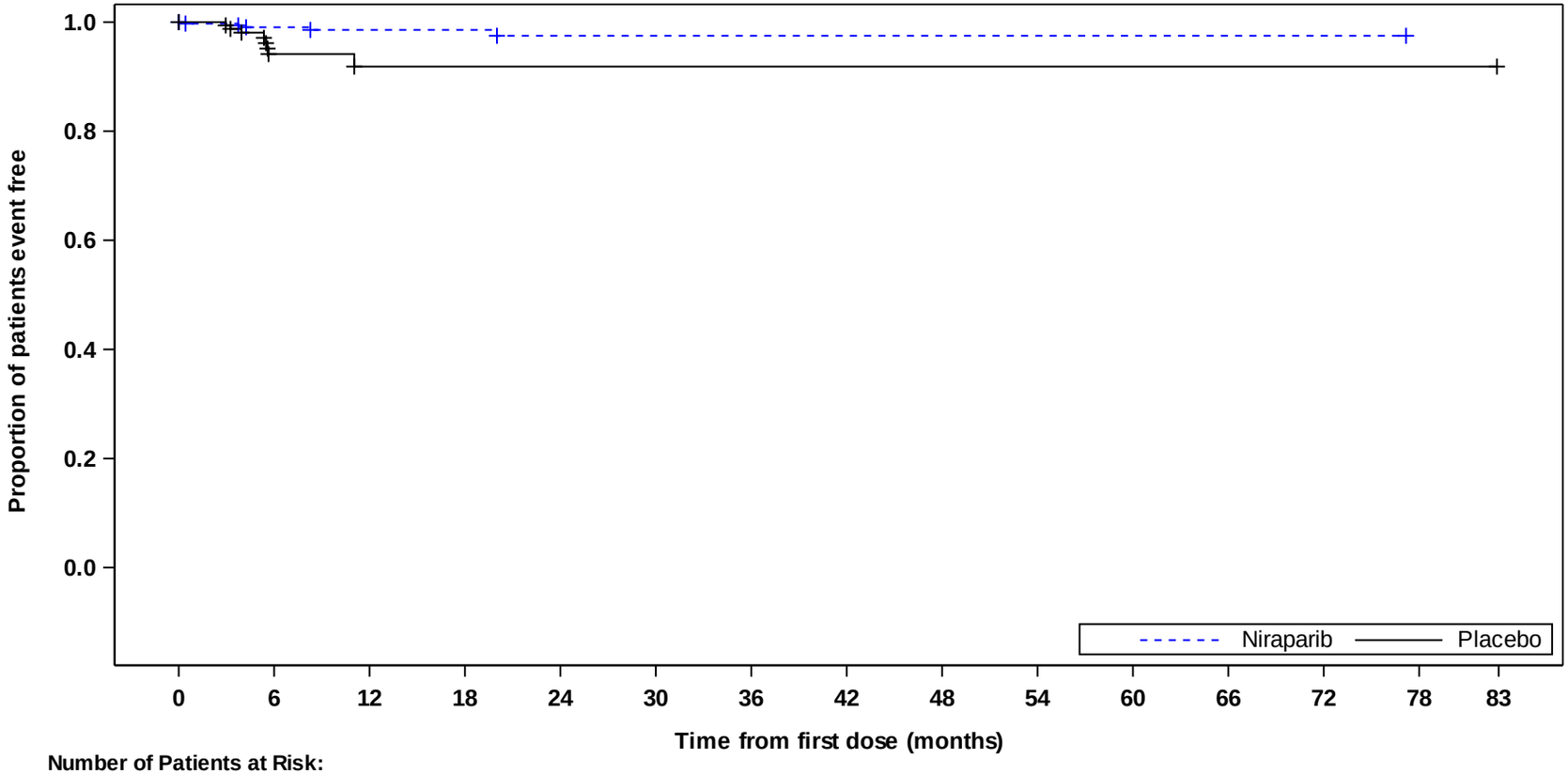
Number of Patients at Risk:

Niraparib	367	229	146	90	63	52	44	35	34	29	24	16	5	0
Placebo	179	84	34	15	9	9	9	7	6	4	4	4	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:27 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Ascites



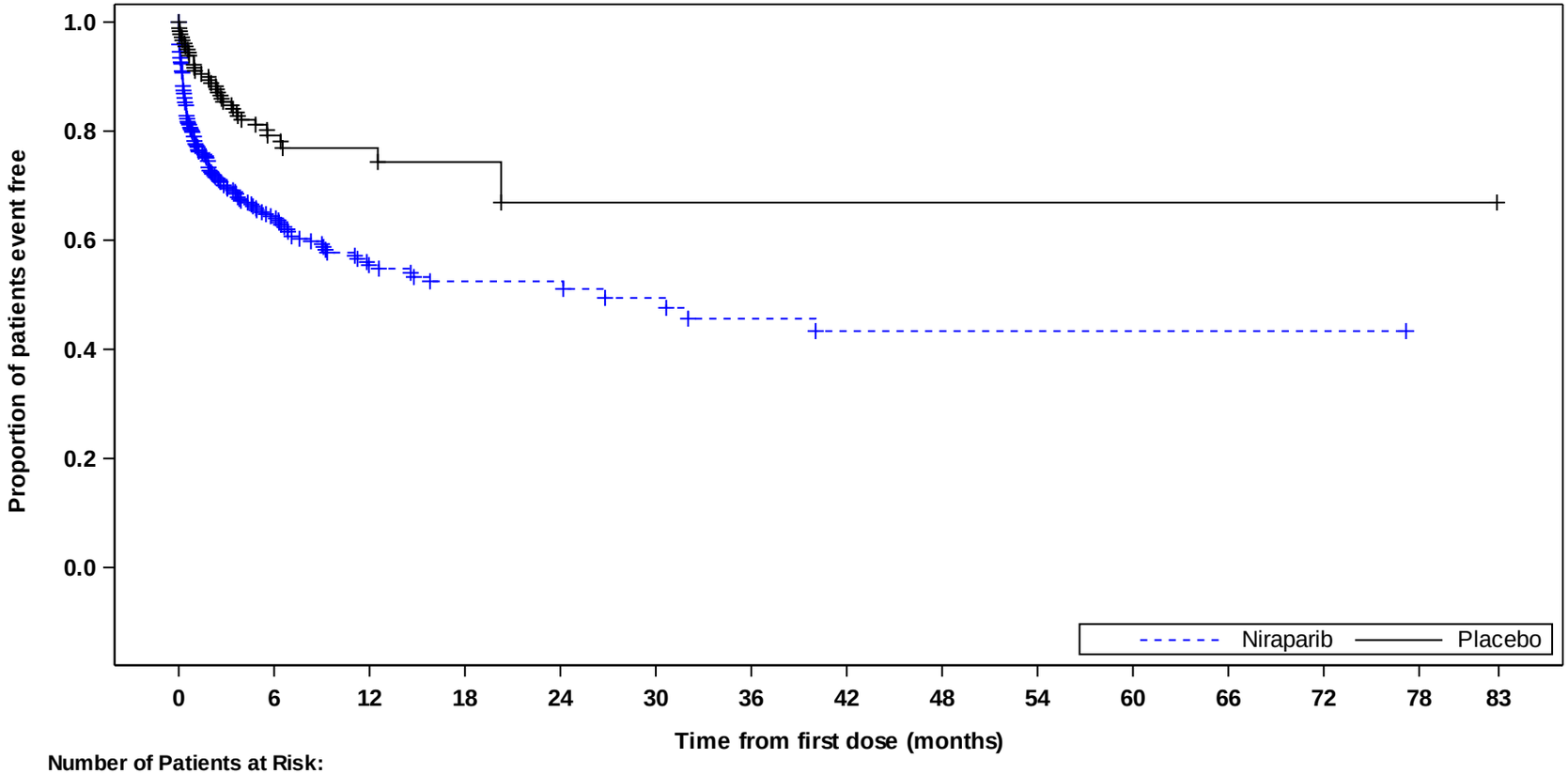
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	88	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:27 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Constipation



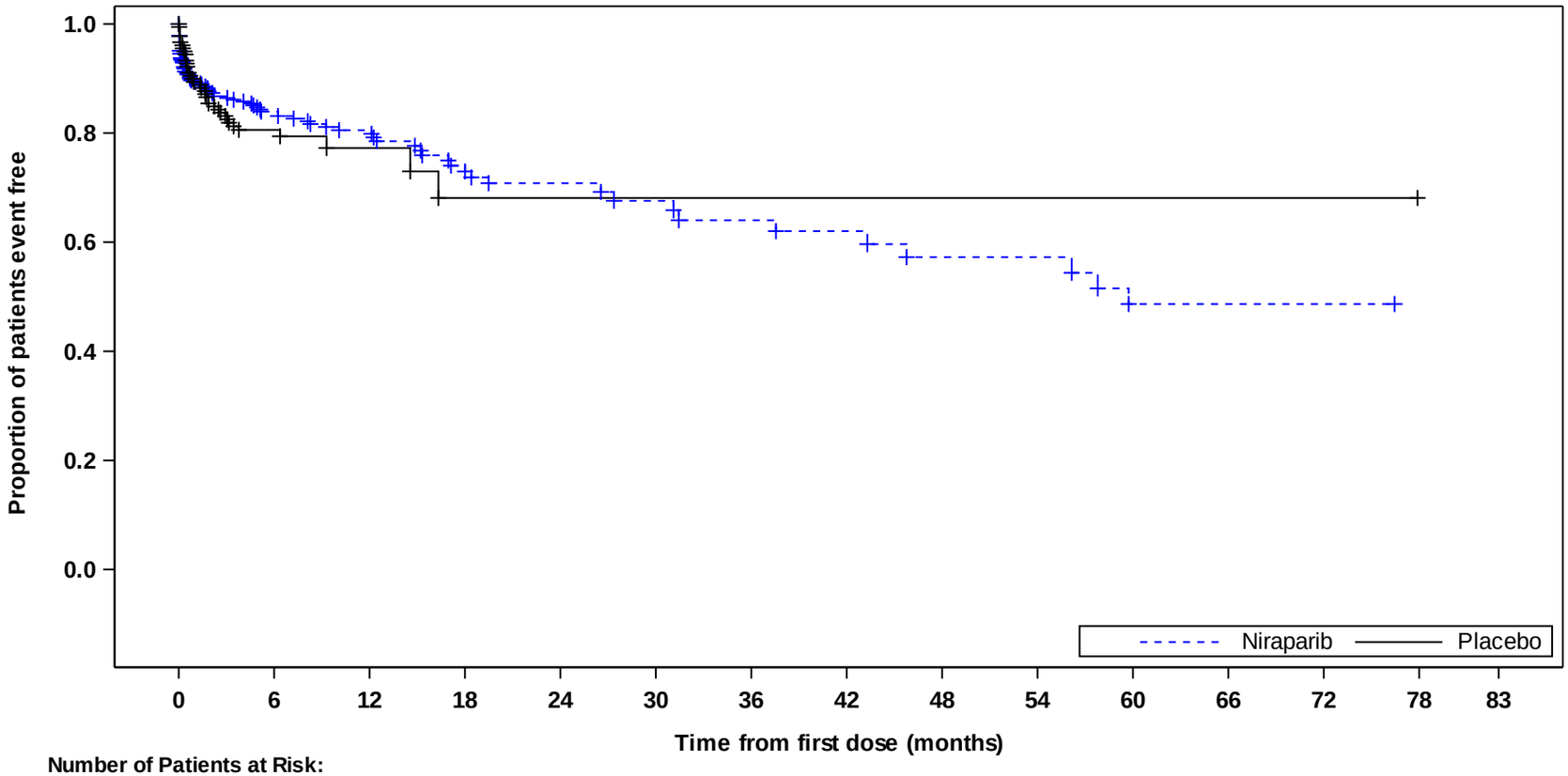
Number of Patients at Risk:

Niraparib	367	166	95	57	38	30	22	18	17	15	14	11	4	0
Placebo	179	74	34	12	6	6	6	5	4	4	4	4	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:28 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Diarrhoea



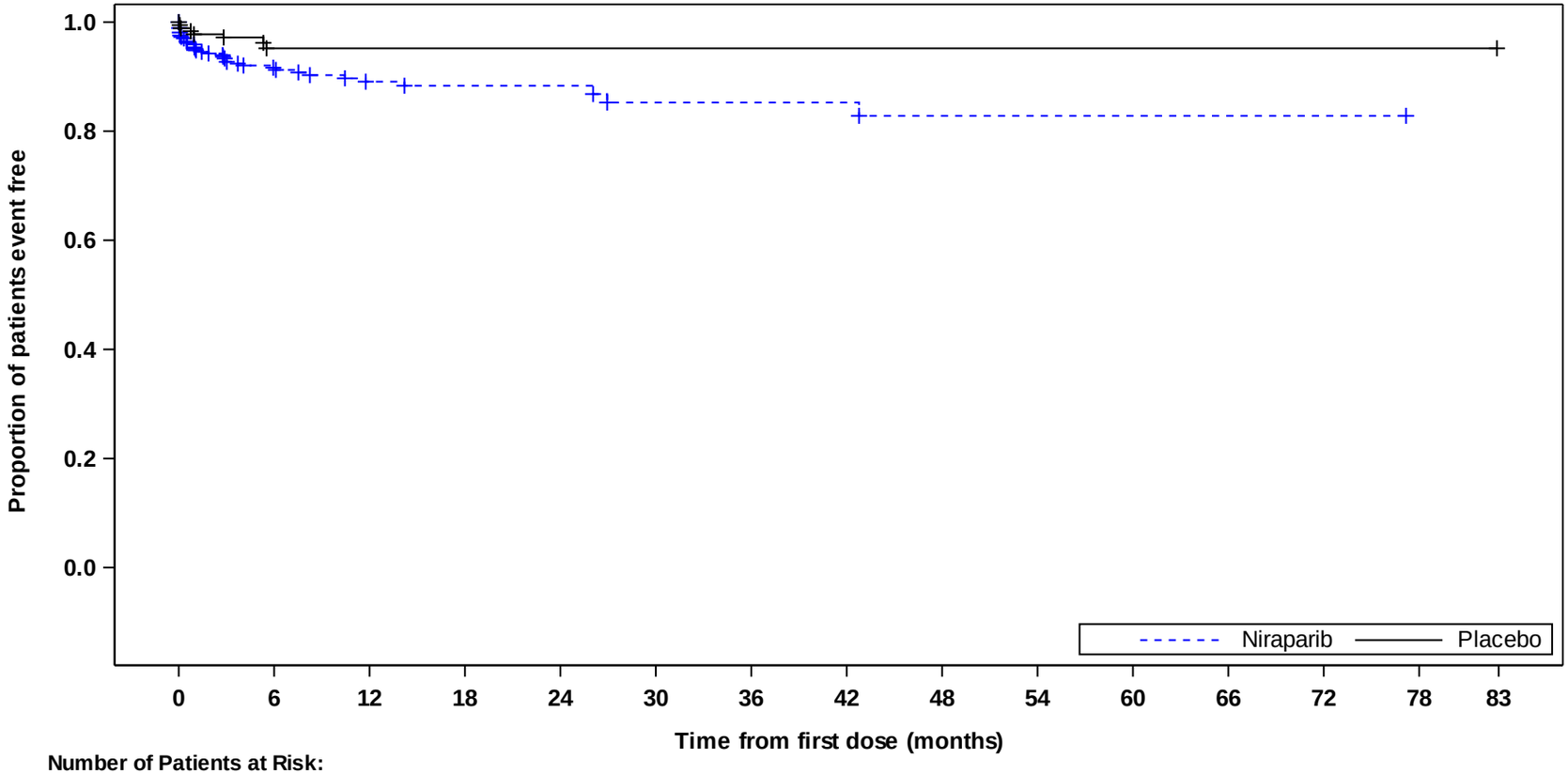
Number of Patients at Risk:

Niraparib	367	208	125	69	47	40	34	27	23	20	17	13	4	0
Placebo	179	72	28	11	5	5	5	4	3	3	3	3	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:29 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Dry mouth



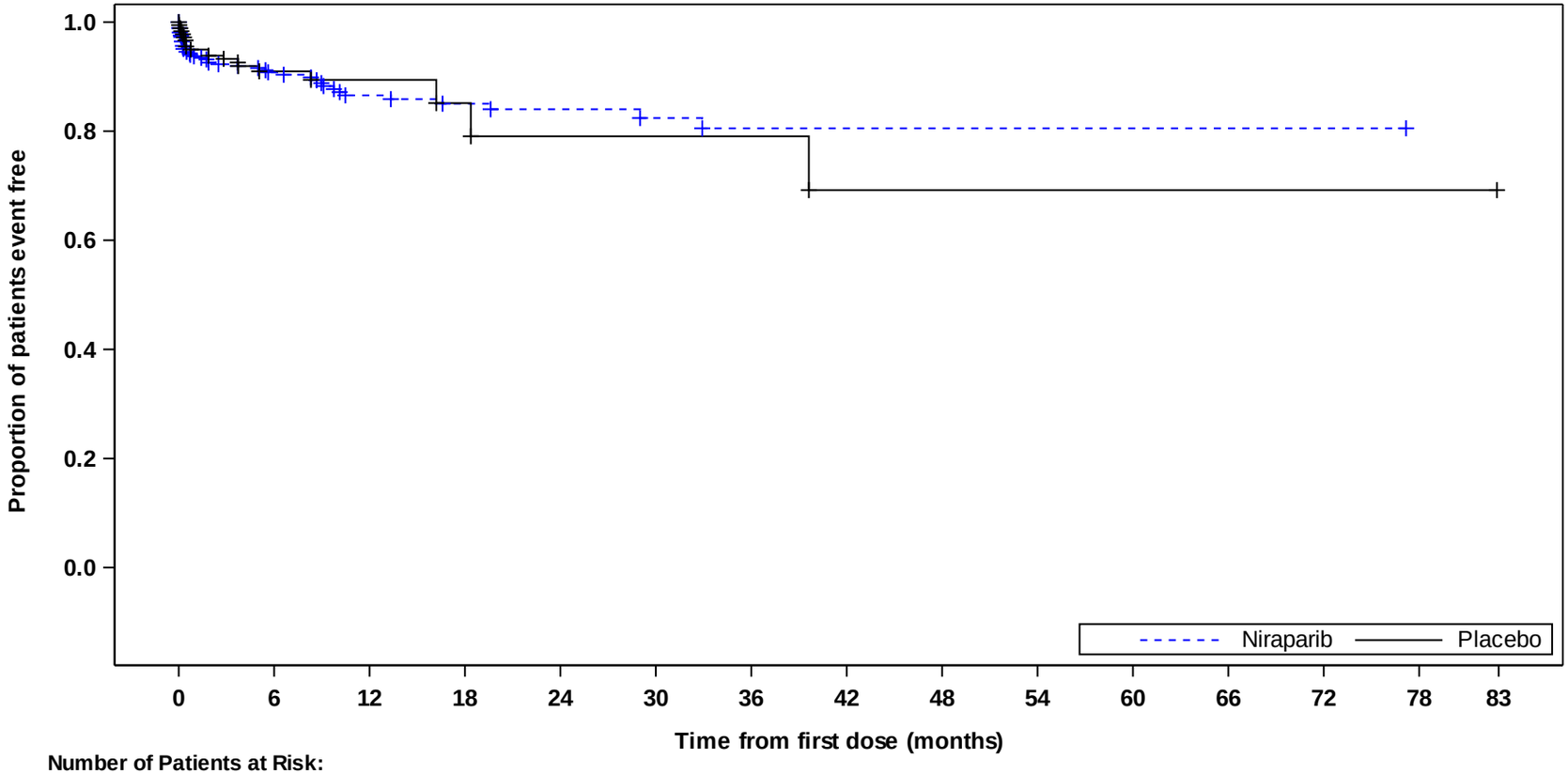
Number of Patients at Risk:

Niraparib	367	226	146	90	63	52	45	36	33	29	24	18	6	0
Placebo	179	86	35	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:30 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Dyspepsia



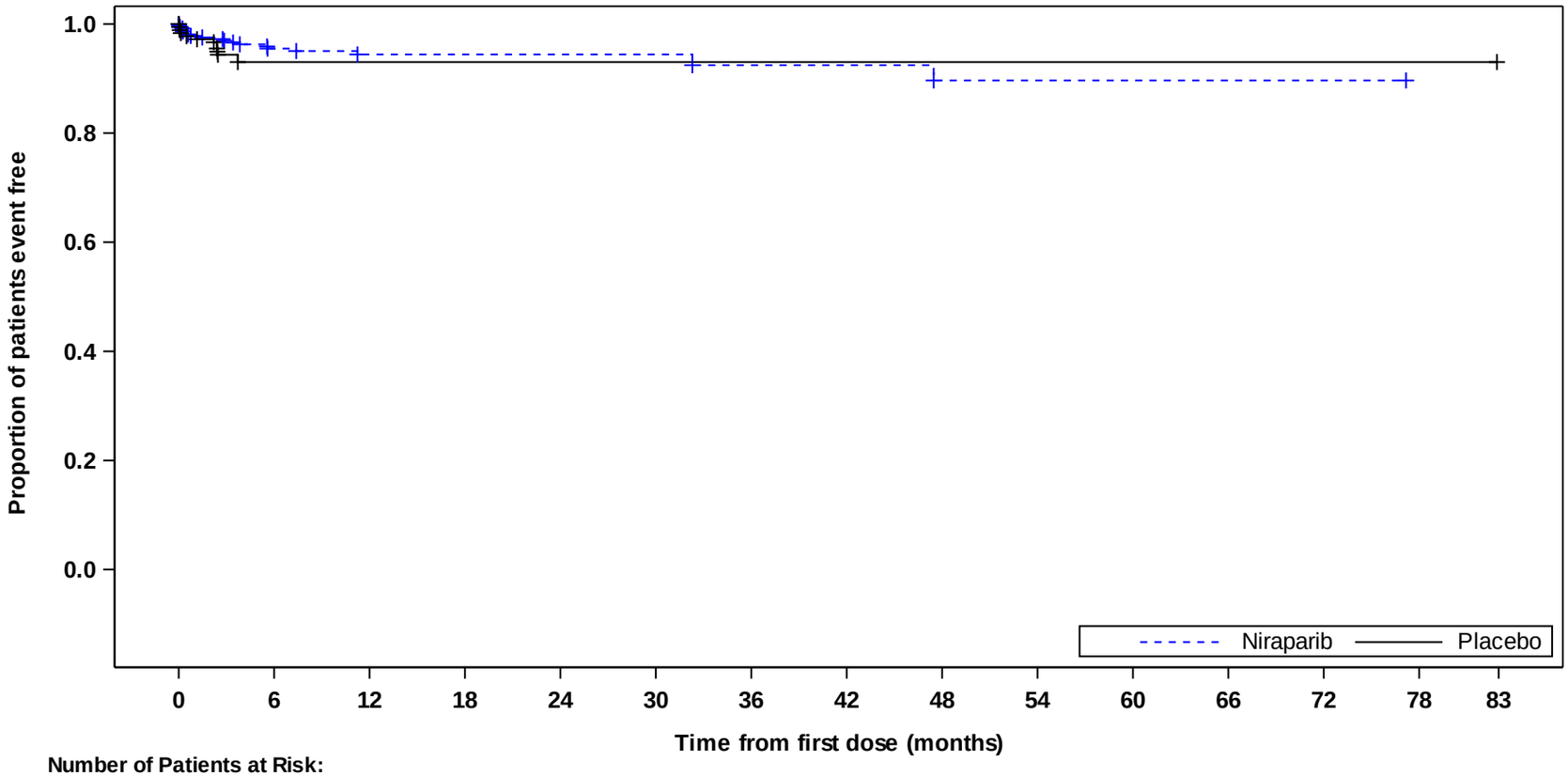
Number of Patients at Risk:

Niraparib	367	223	143	87	59	51	41	33	31	28	24	17	5	0
Placebo	179	85	34	14	8	8	8	6	5	5	5	5	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:31 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Flatulence



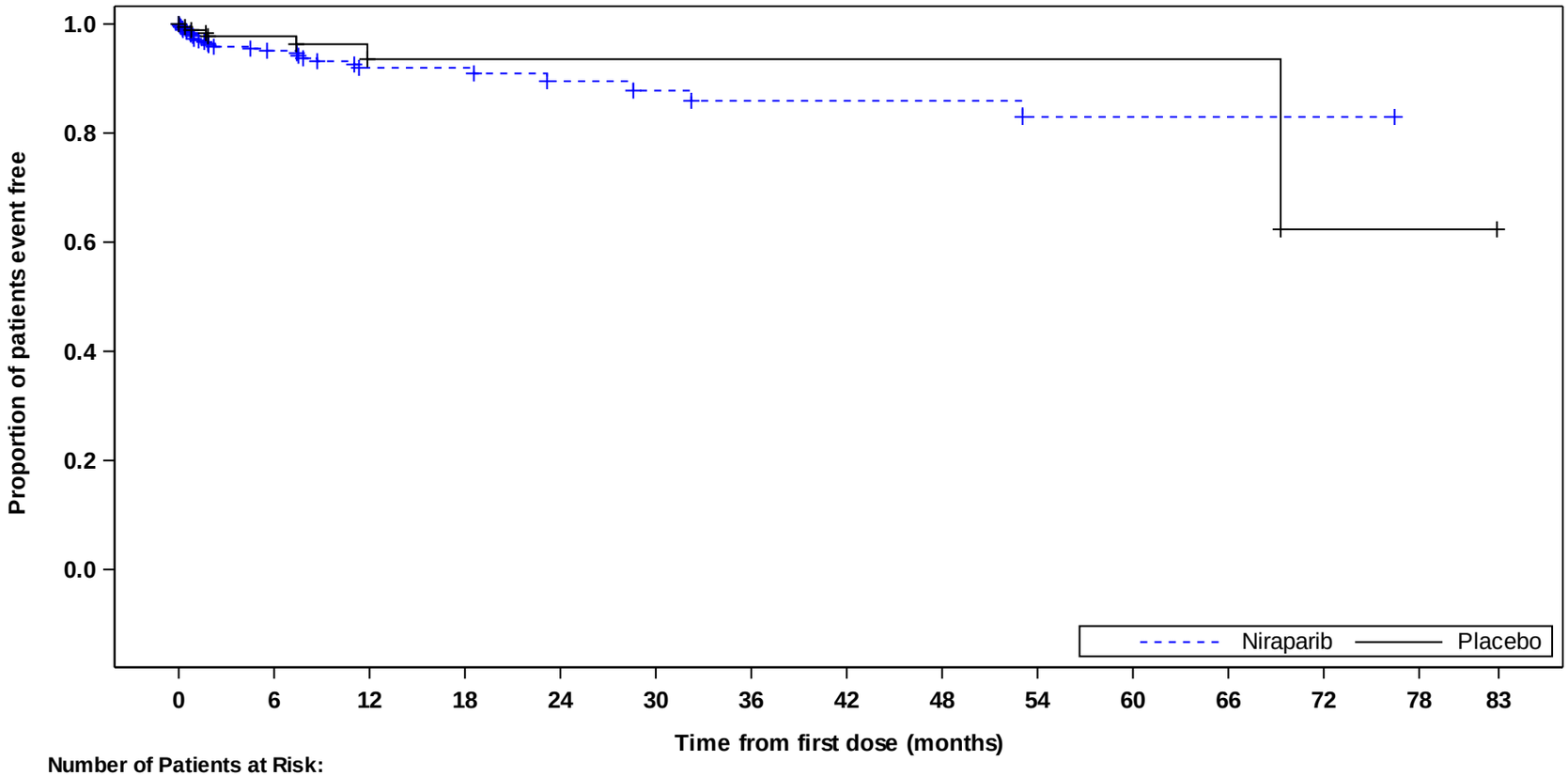
Number of Patients at Risk:

Niraparib	367	234	152	92	63	53	44	35	32	28	23	17	7	0
Placebo	179	85	35	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:32 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease



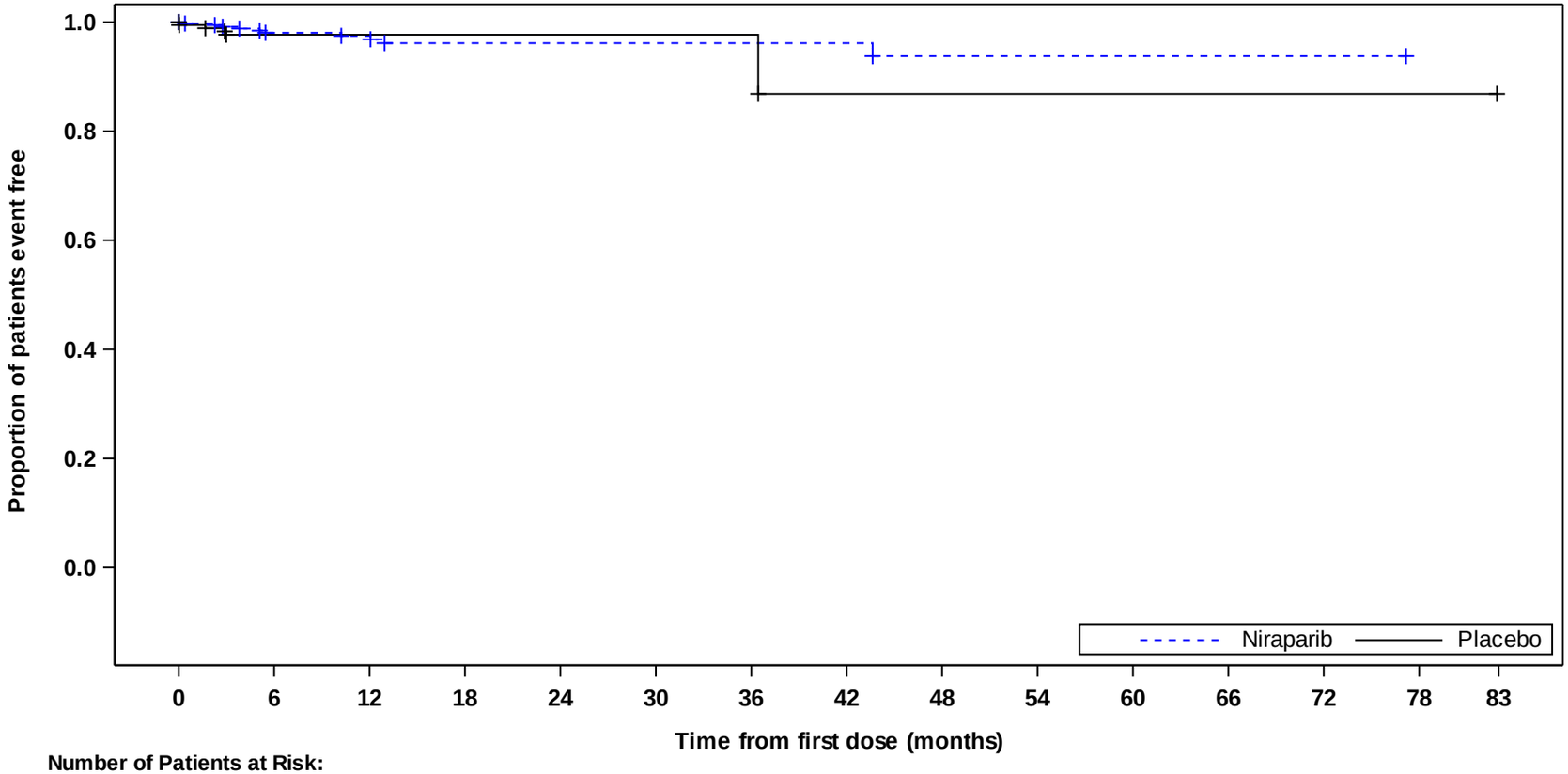
Number of Patients at Risk:

Niraparib	367	238	150	90	61	51	43	33	31	26	22	17	5	0
Placebo	179	91	34	15	10	9	9	8	7	6	6	6	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:33 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Haemorrhoids



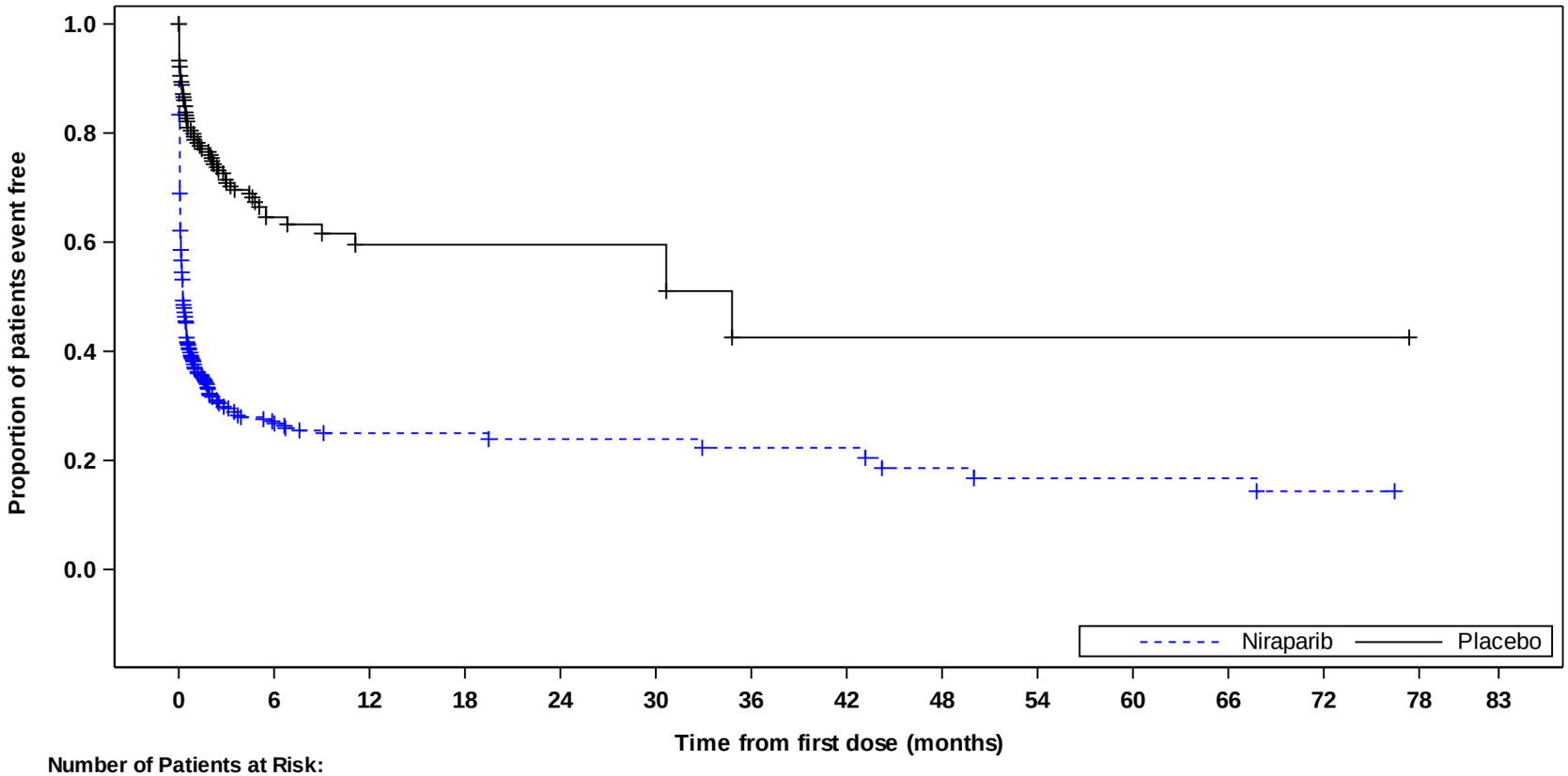
Number of Patients at Risk:

Niraparib	367	242	157	97	69	59	50	41	37	32	27	20	7	0
Placebo	179	89	37	16	10	9	9	7	6	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:34 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Nausea



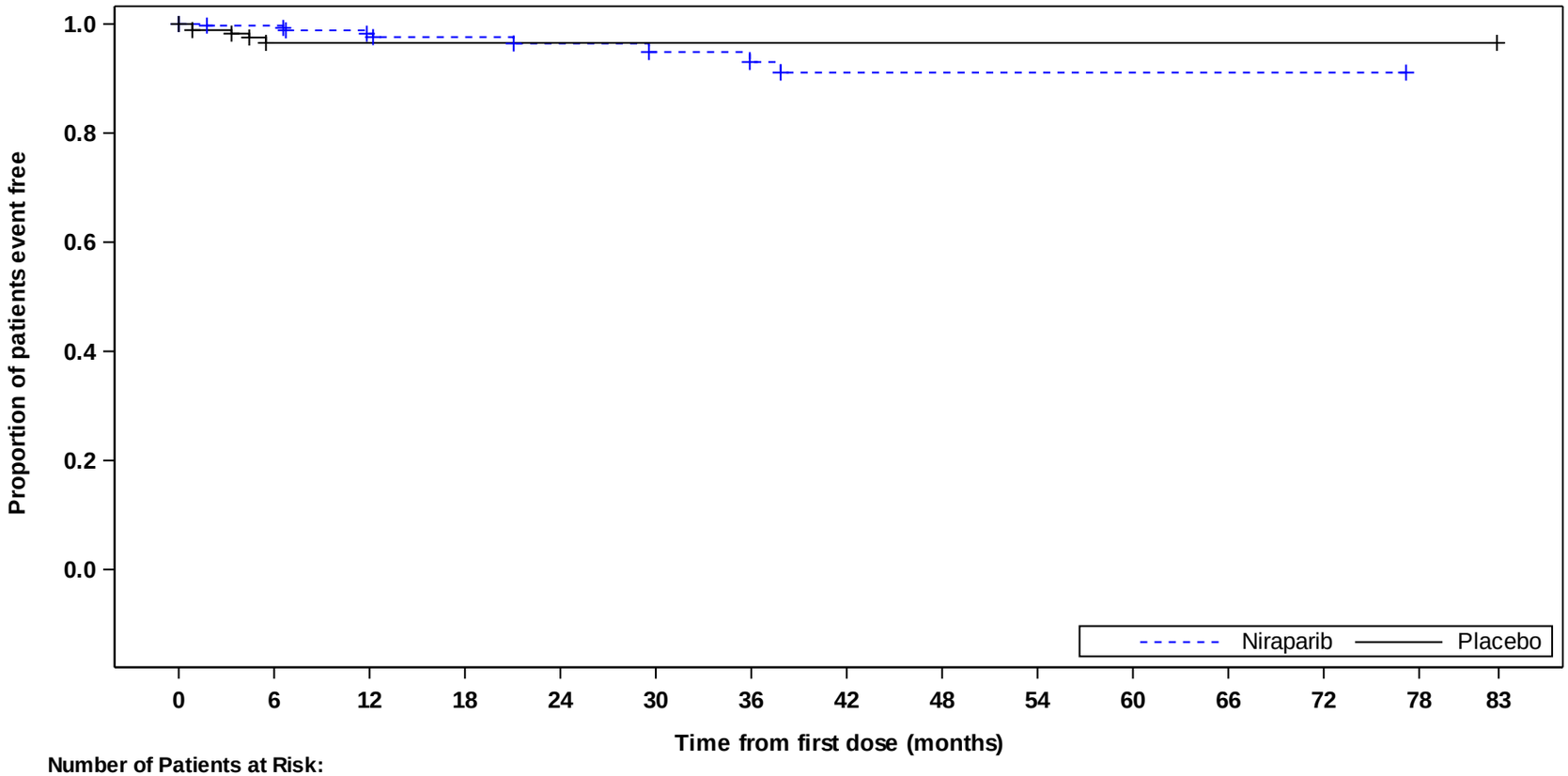
Number of Patients at Risk:

Niraparib	367	69	46	24	17	16	13	12	10	9	9	8	1	0
Placebo	179	61	27	12	8	7	5	4	3	2	2	2	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:35 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Small intestinal obstruction



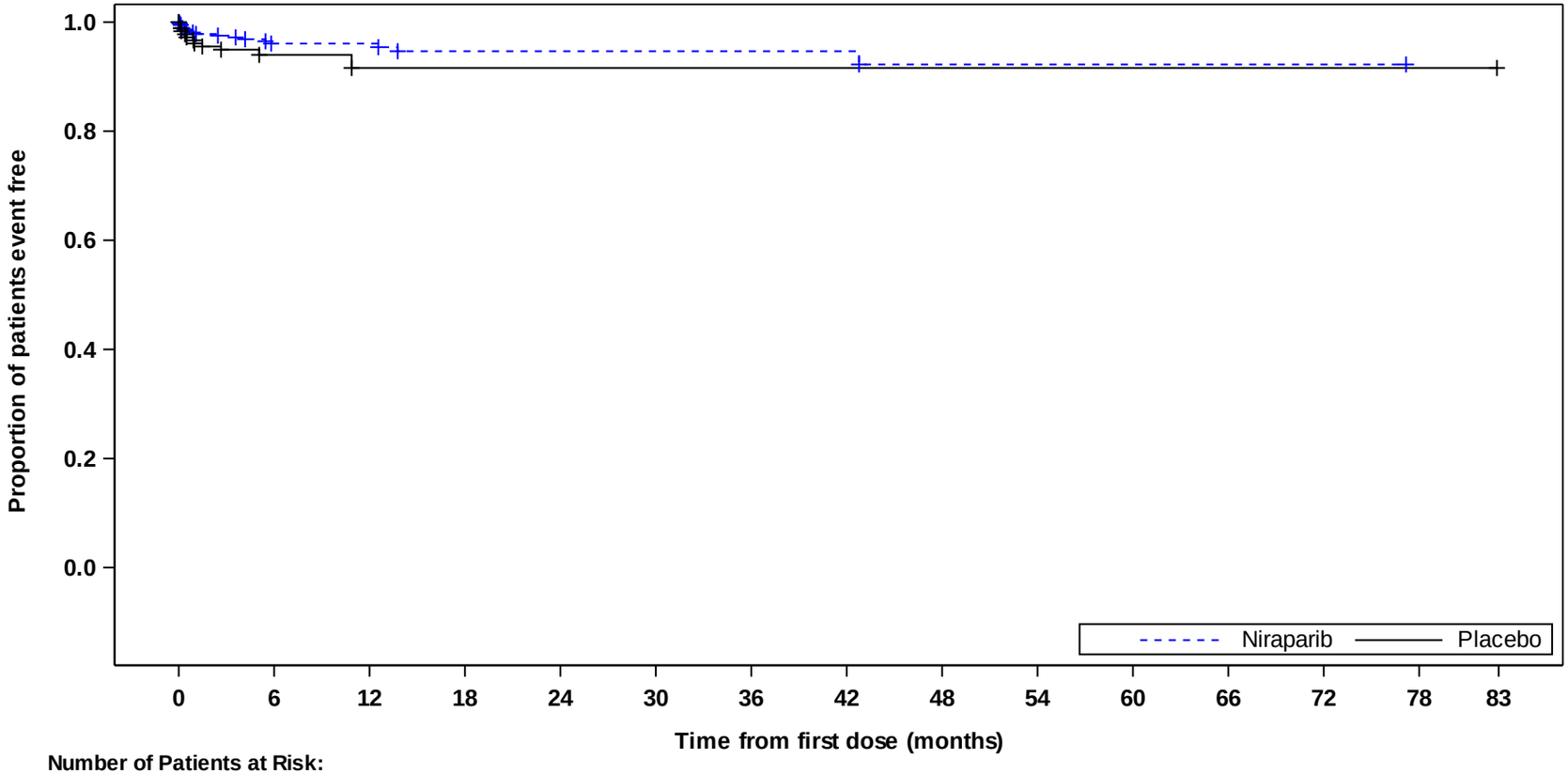
Number of Patients at Risk:

Niraparib	367	247	160	100	71	60	51	40	37	33	29	22	7	0
Placebo	179	89	36	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:36 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Stomatitis



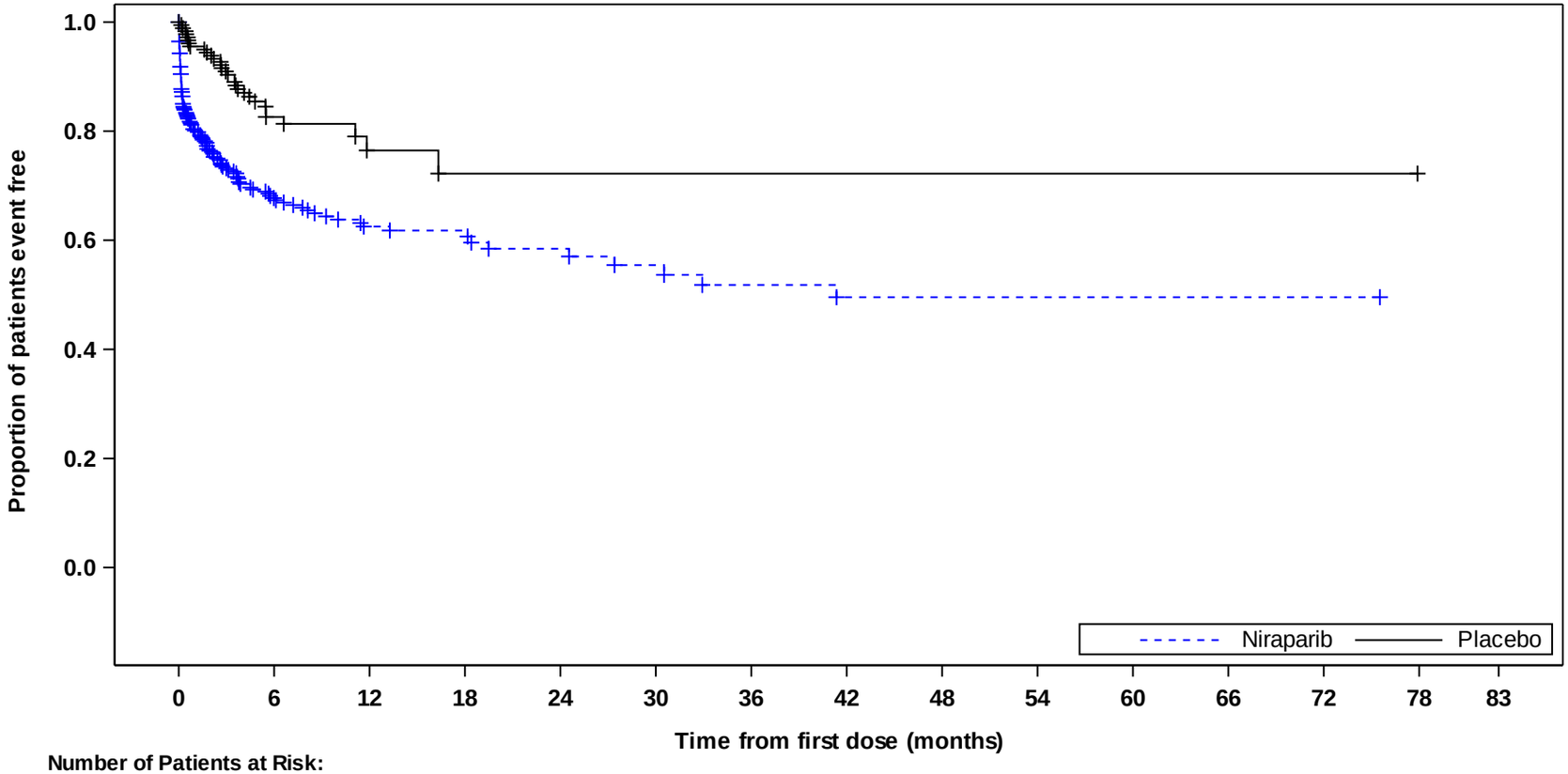
Number of Patients at Risk:

Niraparib	367	237	154	94	68	58	50	40	37	33	28	22	7	0
Placebo	179	86	35	15	9	8	8	7	6	5	5	5	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:37 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Vomiting



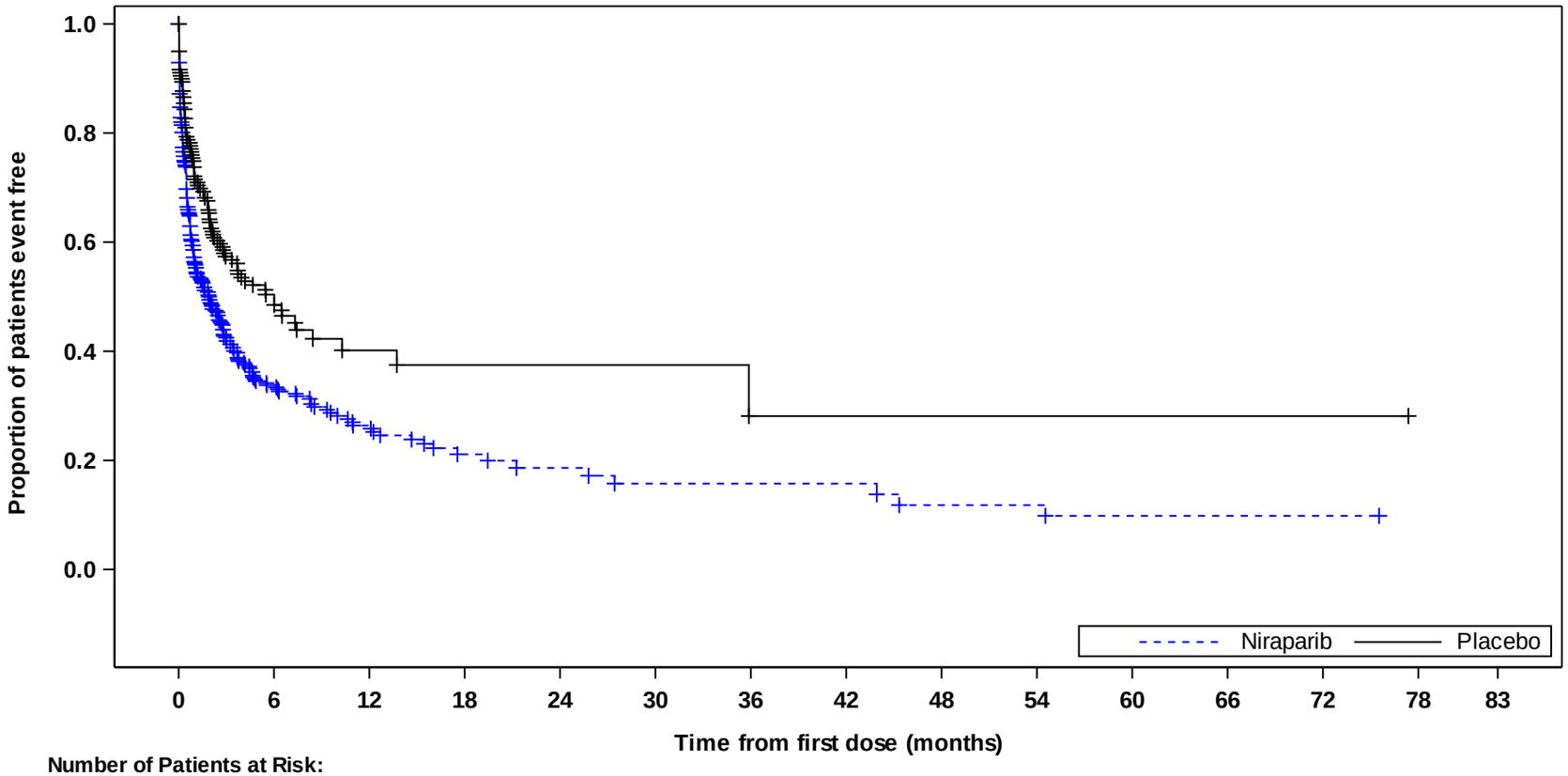
Number of Patients at Risk:

Niraparib	367	169	99	56	41	33	27	21	20	18	18	12	3	0
Placebo	179	78	30	12	7	6	6	5	4	3	3	3	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:38 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions



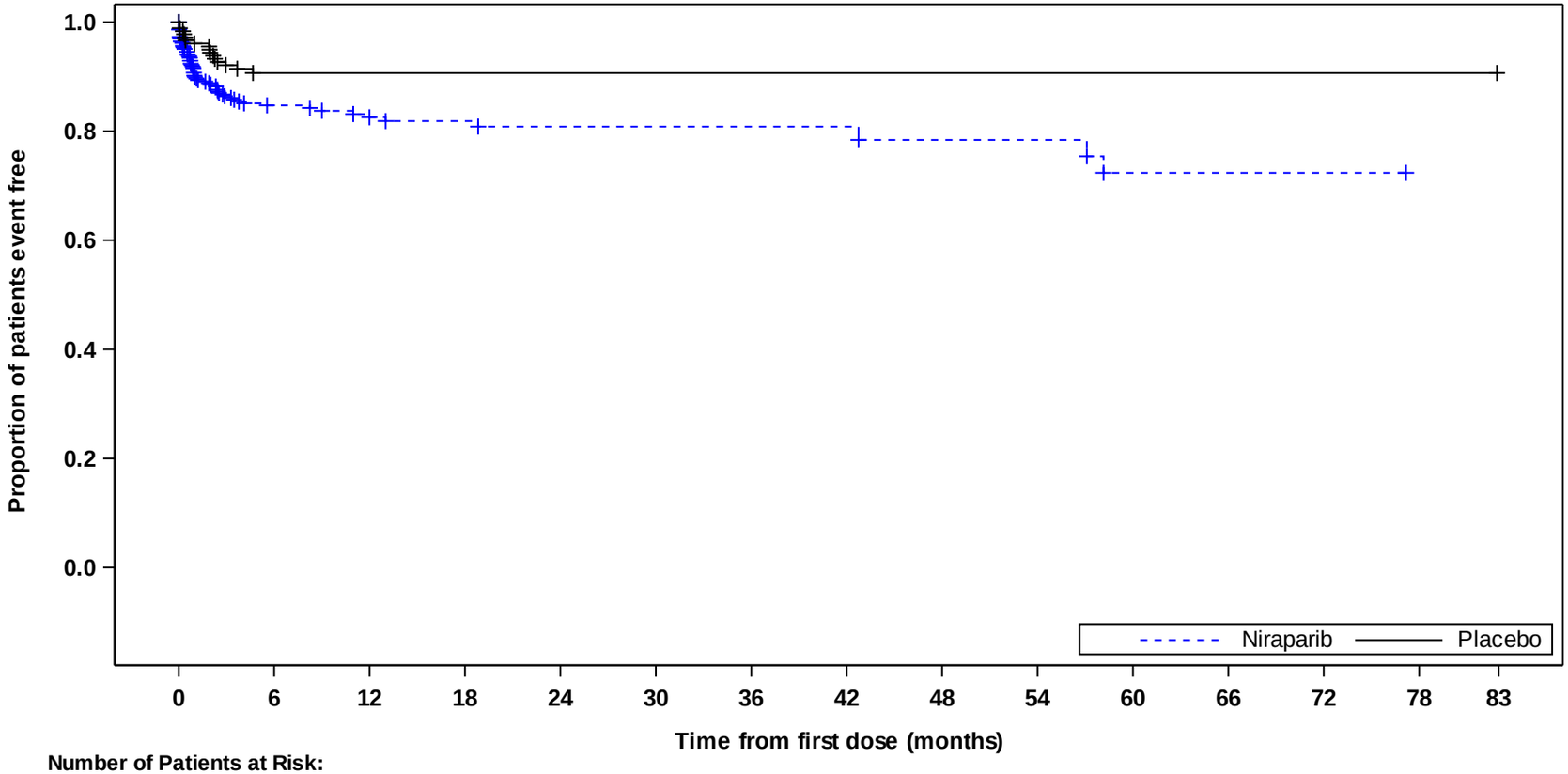
Number of Patients at Risk:

Niraparib	367	88	45	18	13	10	10	8	6	6	5	4	1	0
Placebo	179	53	18	6	4	4	3	2	1	1	1	1	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:39 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions, PT: Asthenia



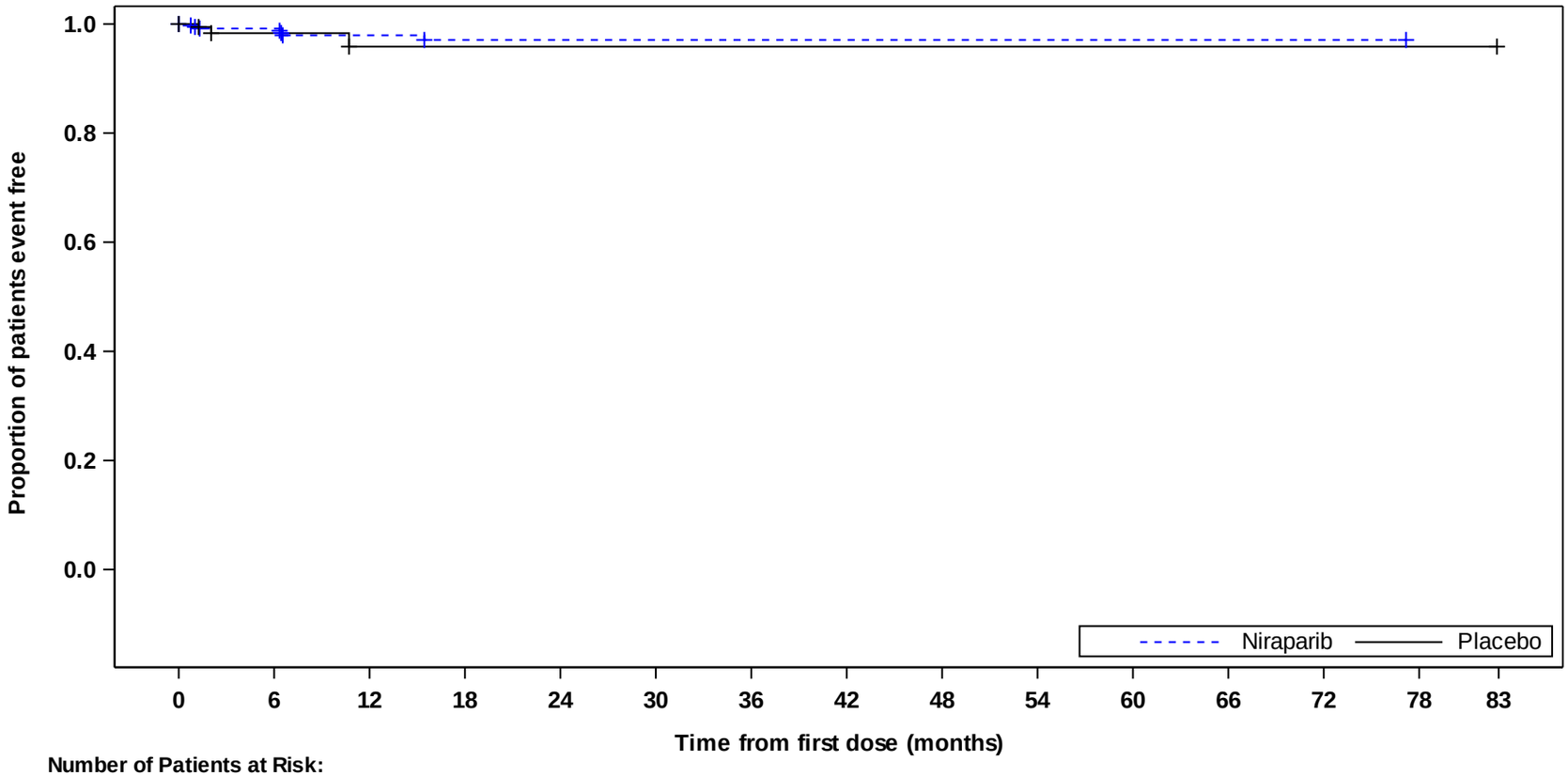
Number of Patients at Risk:

Niraparib	367	215	139	82	56	48	41	33	32	28	22	18	6	0
Placebo	179	86	35	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:39 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions, PT: Chest pain



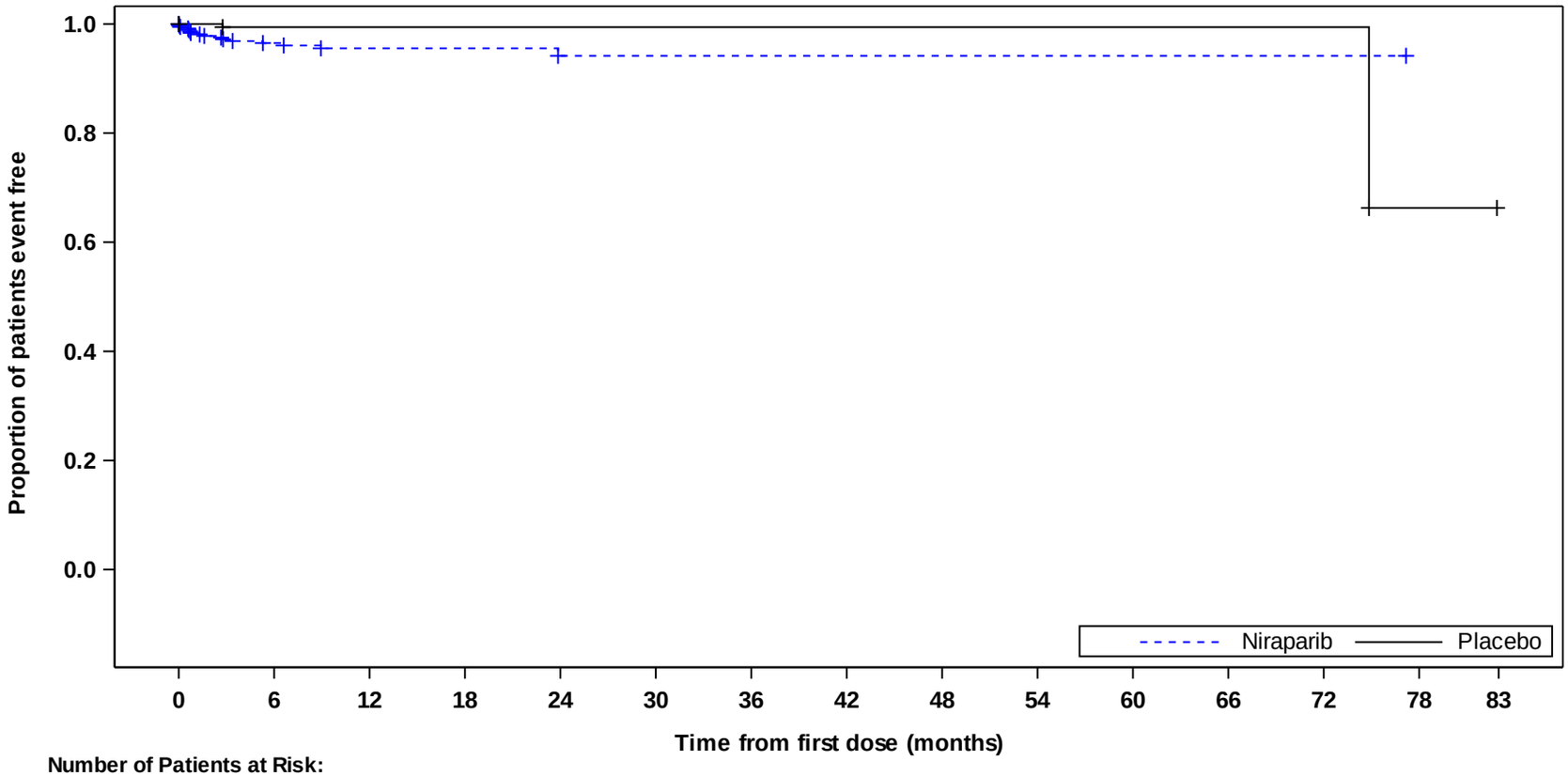
Number of Patients at Risk:

Niraparib	367	244	157	95	69	60	52	42	39	34	29	22	7	0
Placebo	179	90	34	14	9	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:40 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions, PT: Chills



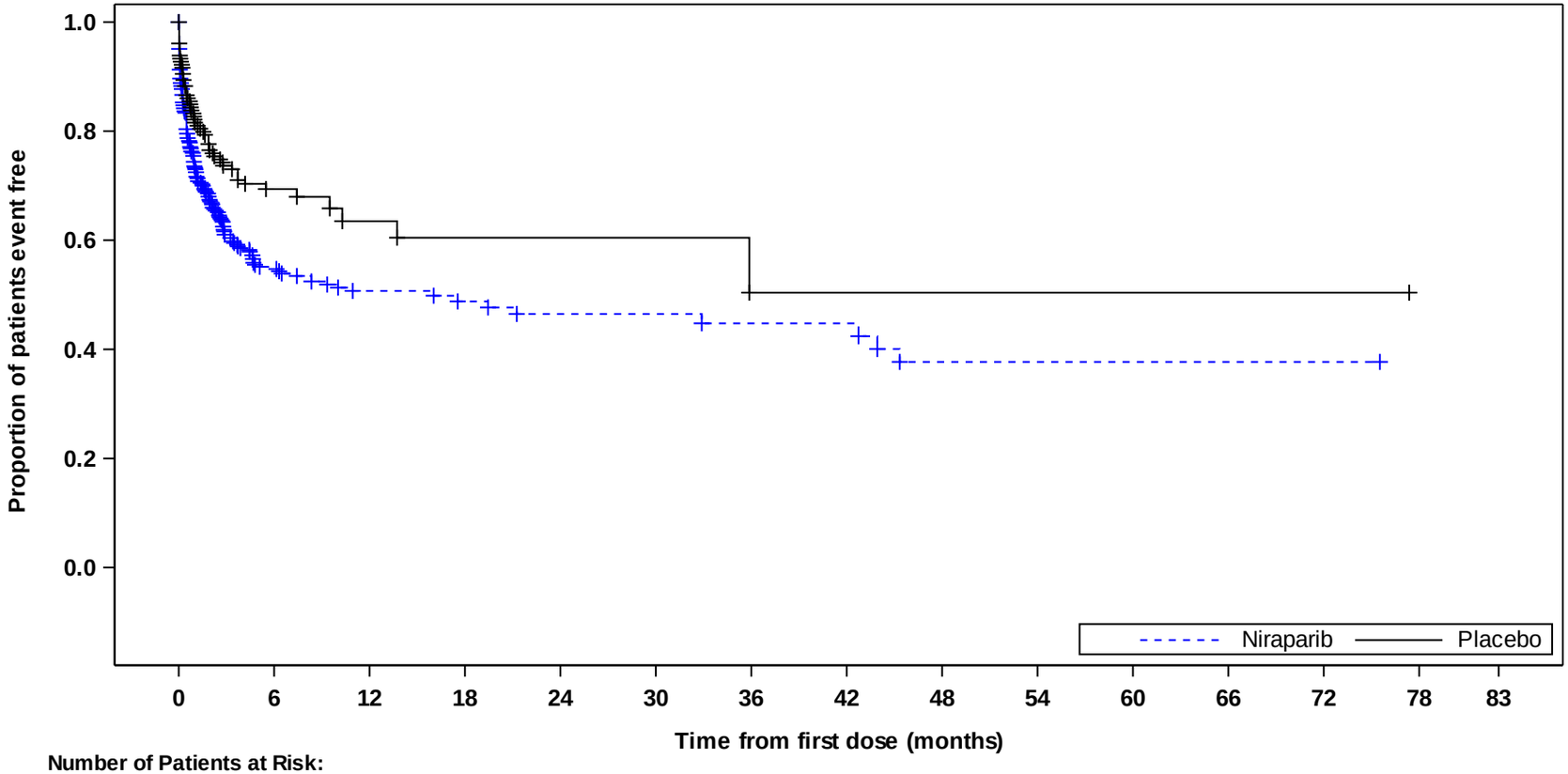
Number of Patients at Risk:

Niraparib	367	240	153	96	68	60	51	41	38	33	28	21	6	0
Placebo	179	91	36	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:41 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions, PT: Fatigue



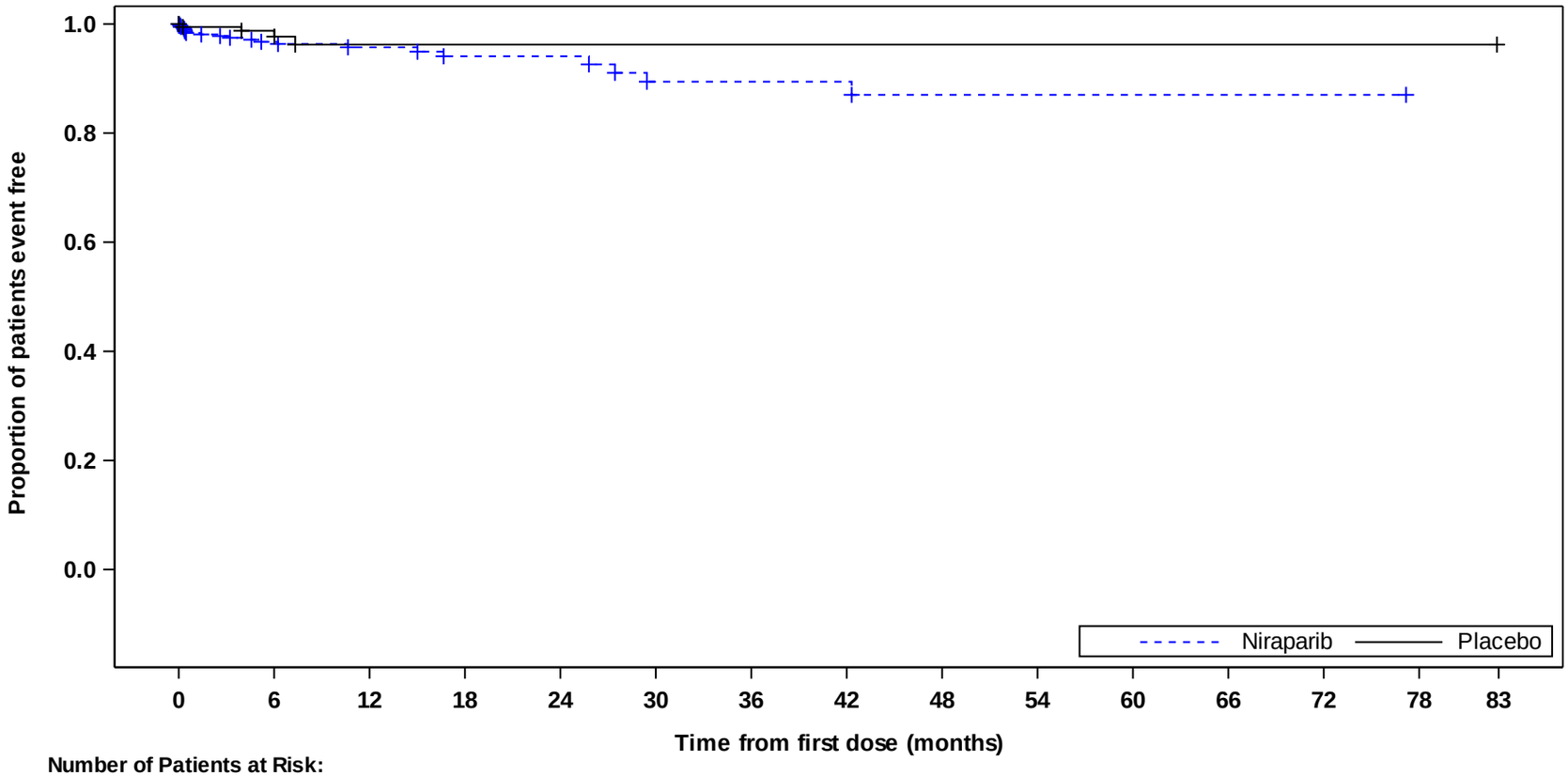
Number of Patients at Risk:

Niraparib	367	136	81	46	34	30	25	19	16	15	14	10	1	0
Placebo	179	65	25	10	6	6	5	4	3	3	3	3	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:42 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions, PT: Influenza like illness



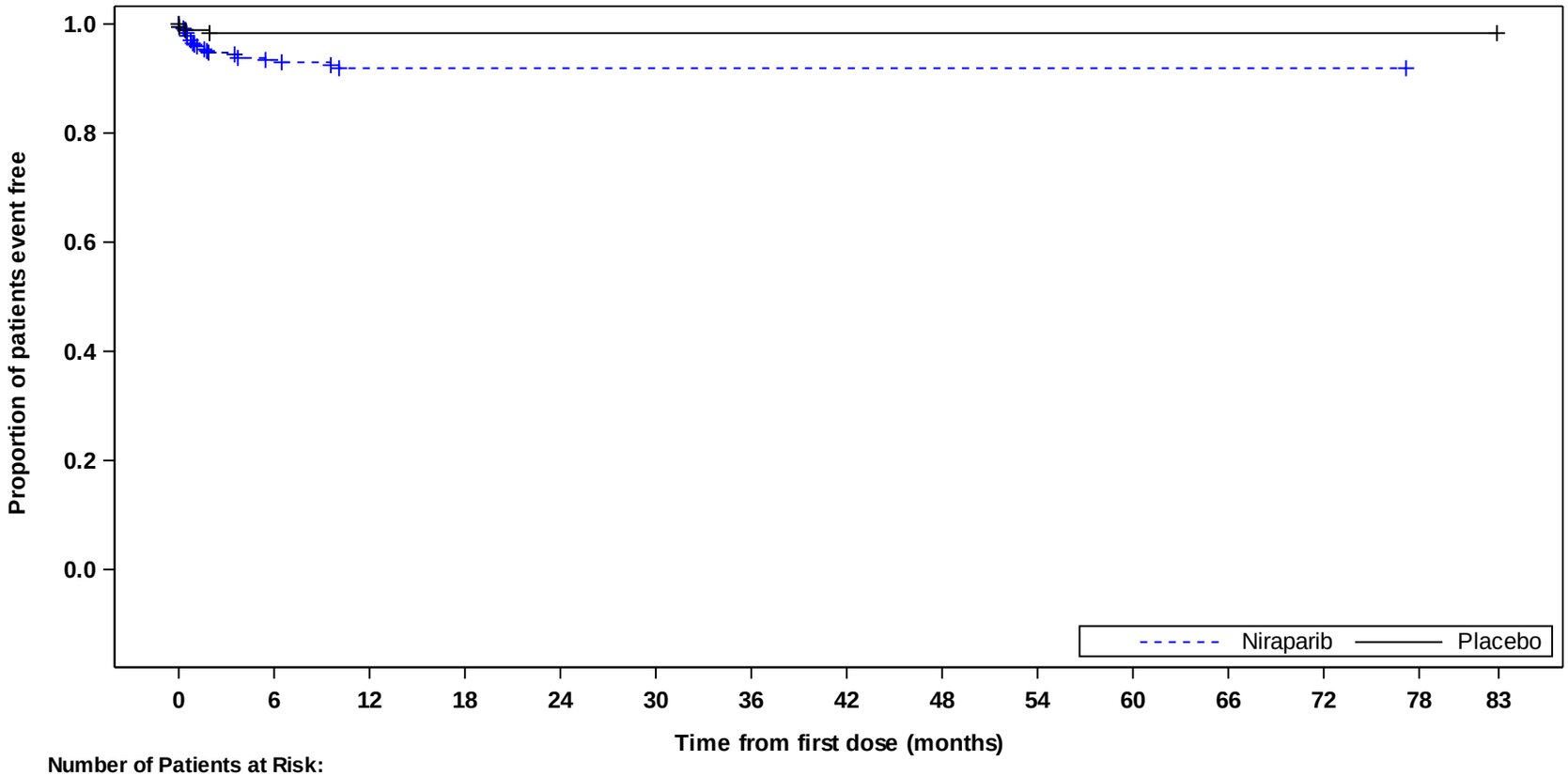
Number of Patients at Risk:

Niraparib	367	240	154	97	68	55	46	37	34	30	26	19	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:43 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions, PT: Mucosal inflammation



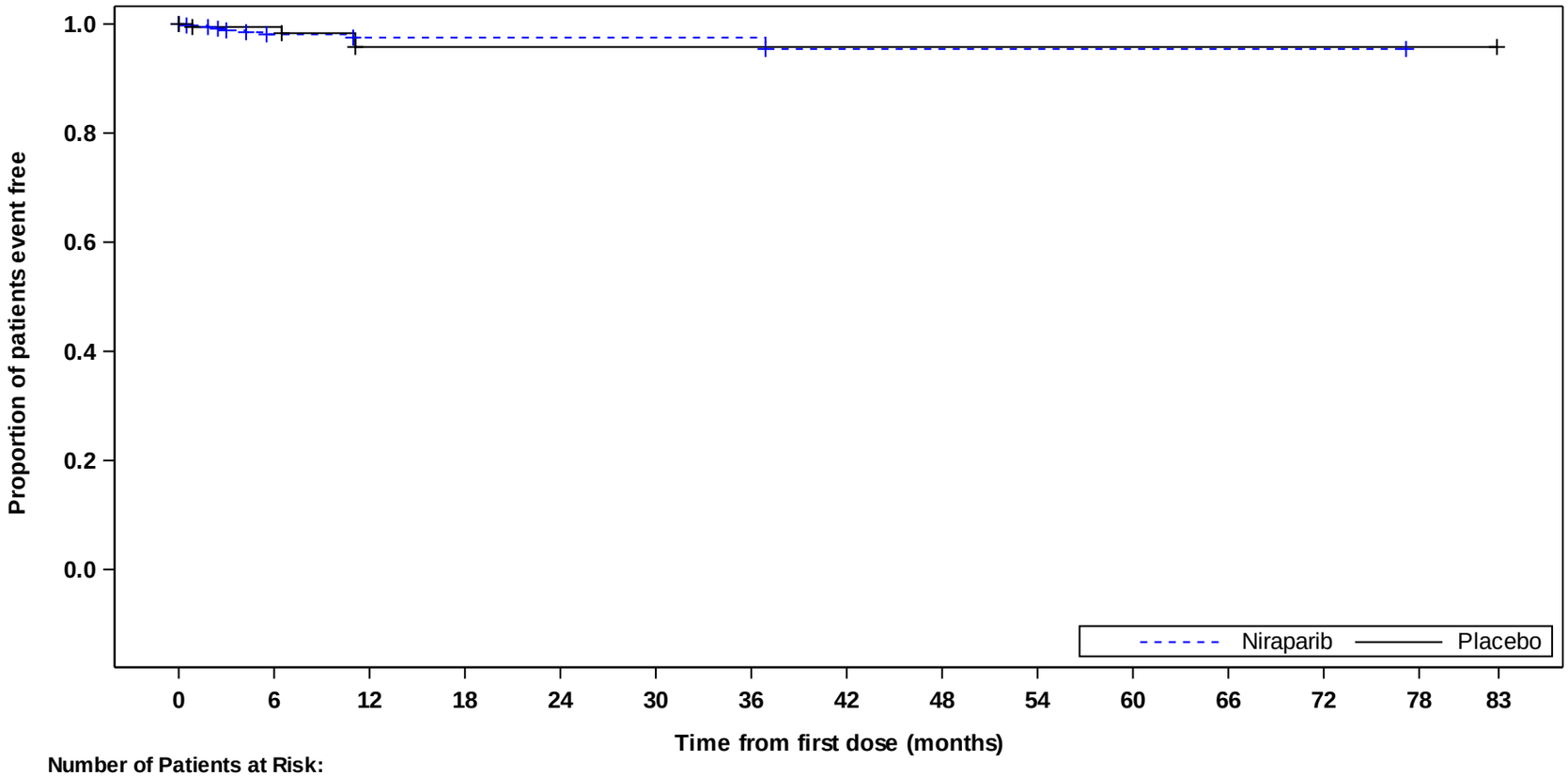
Number of Patients at Risk:

Niraparib	367	230	154	98	69	60	51	41	38	33	28	22	7	0
Placebo	179	90	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:44 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions, PT: Non-cardiac chest pain



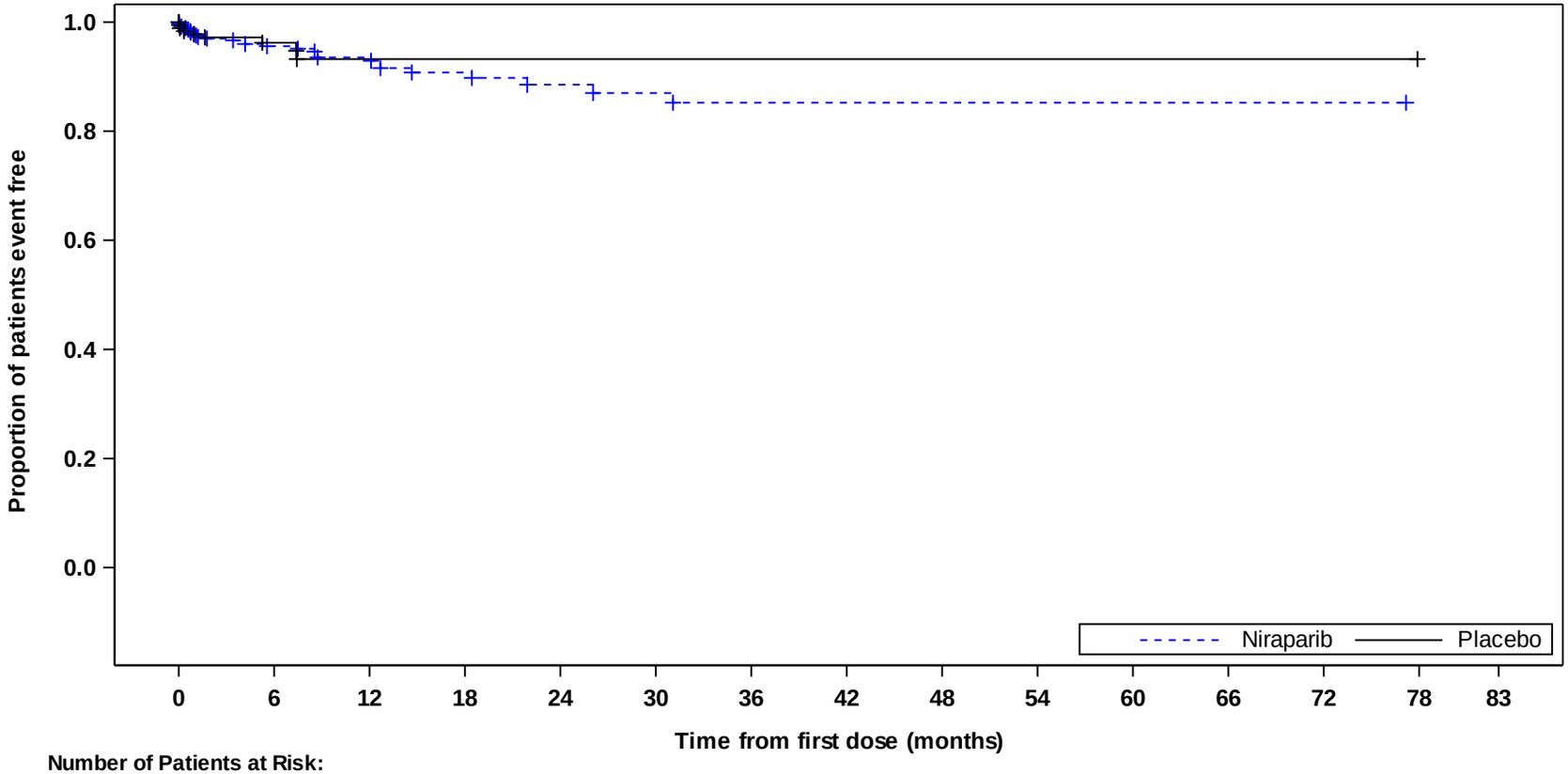
Number of Patients at Risk:

Niraparib	367	243	159	99	69	59	50	39	36	31	26	21	7	0
Placebo	179	92	35	15	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:45 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions, PT: Oedema peripheral



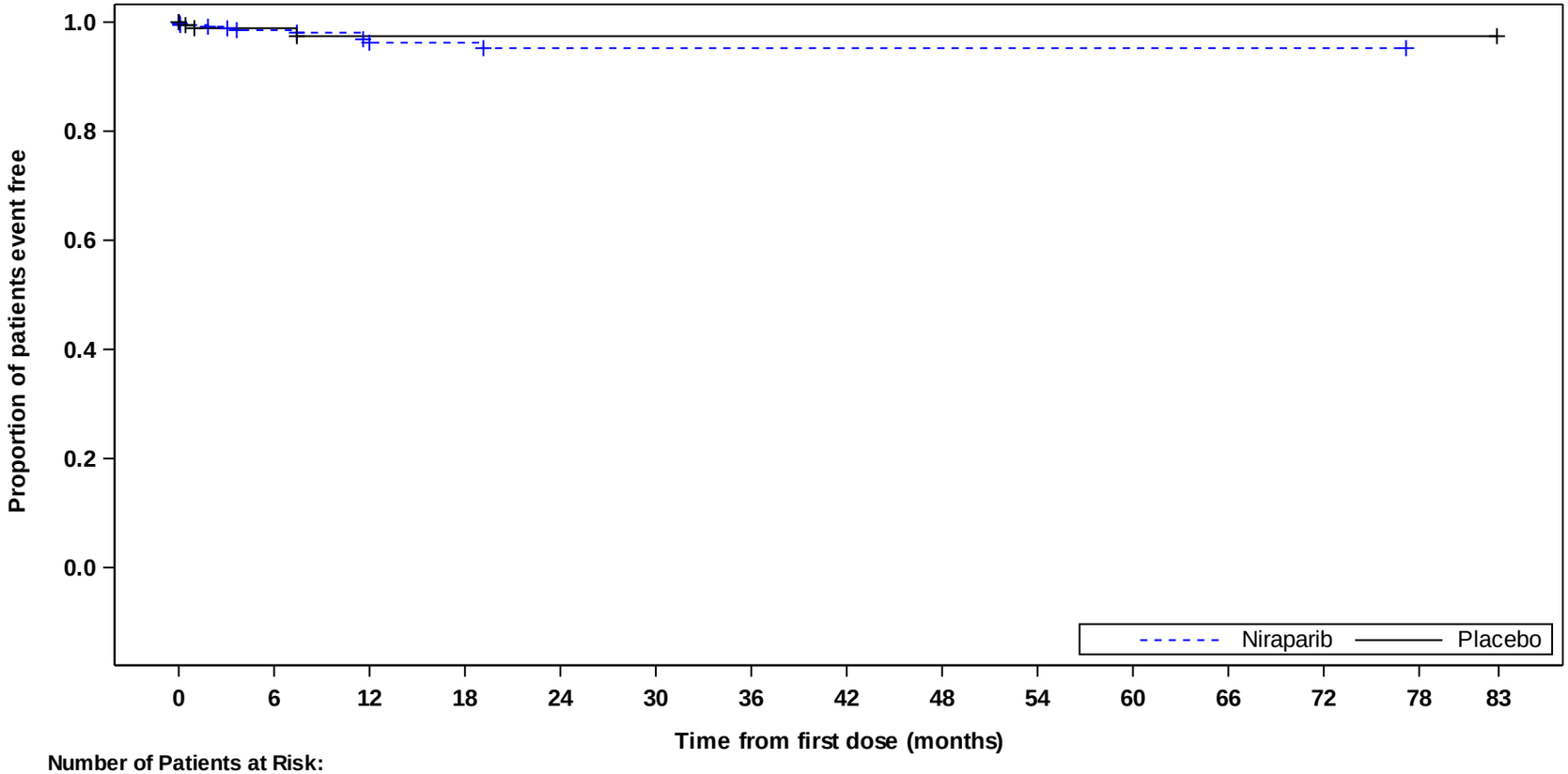
Number of Patients at Risk:

Niraparib	367	236	151	92	63	52	43	34	31	26	24	18	7	0
Placebo	179	88	32	12	7	7	7	6	5	4	4	4	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:46 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions, PT: Pain



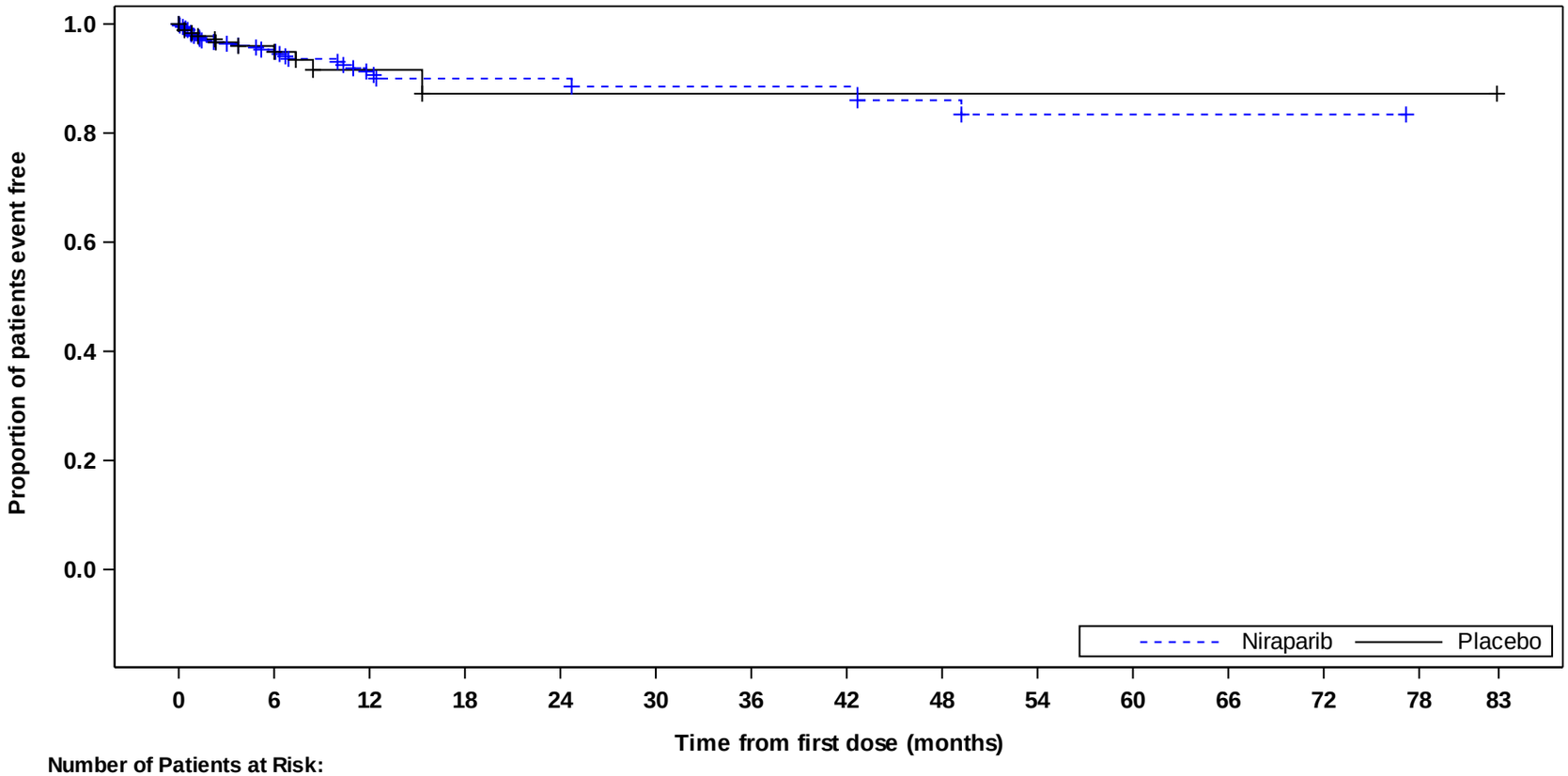
Number of Patients at Risk:

Niraparib	367	244	156	97	67	58	51	41	38	33	28	21	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:47 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions, PT: Pyrexia



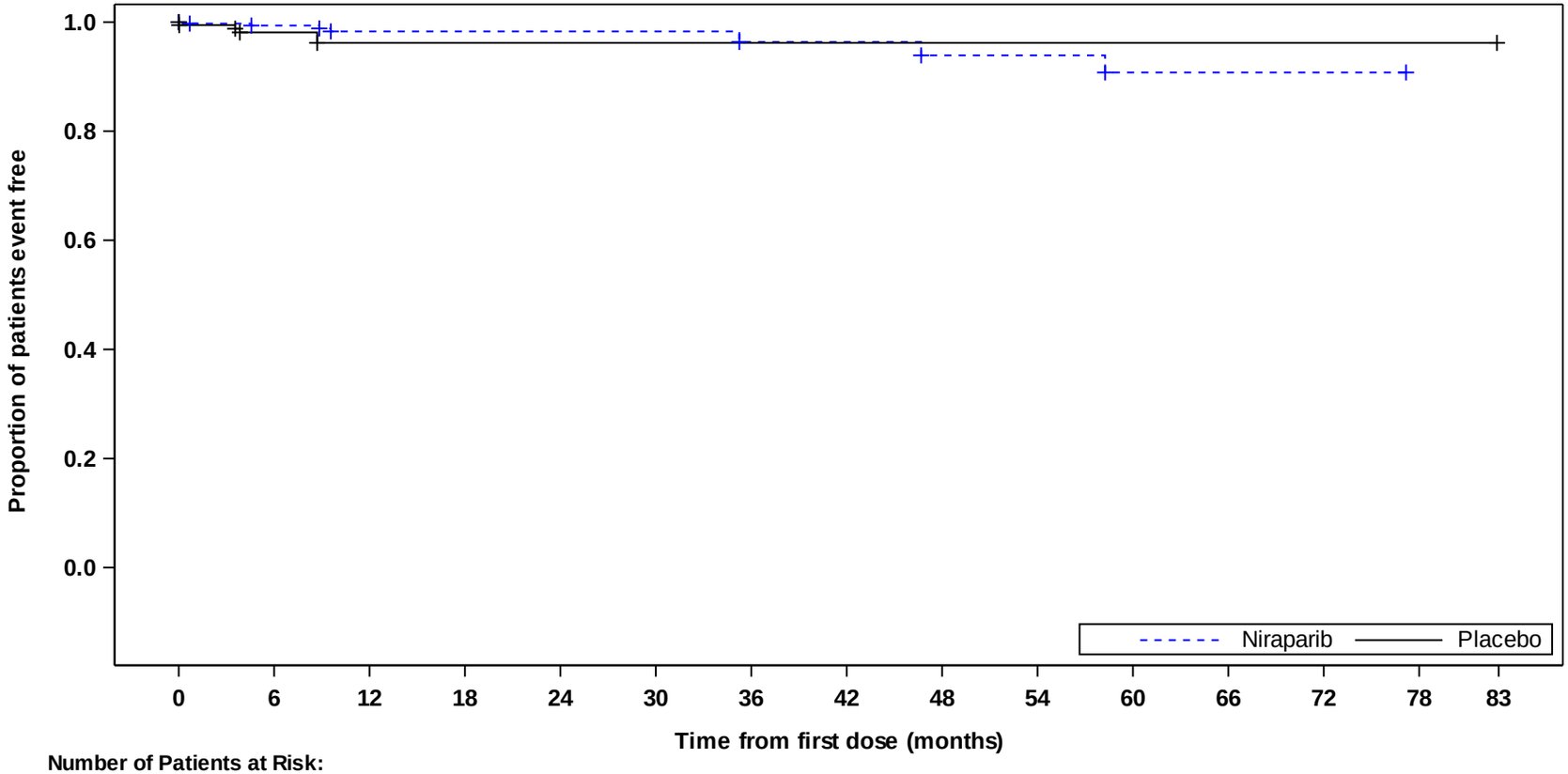
Number of Patients at Risk:

Niraparib	367	235	150	89	62	52	46	36	33	28	24	17	7	0
Placebo	179	88	33	13	8	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:48 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Hepatobiliary disorders



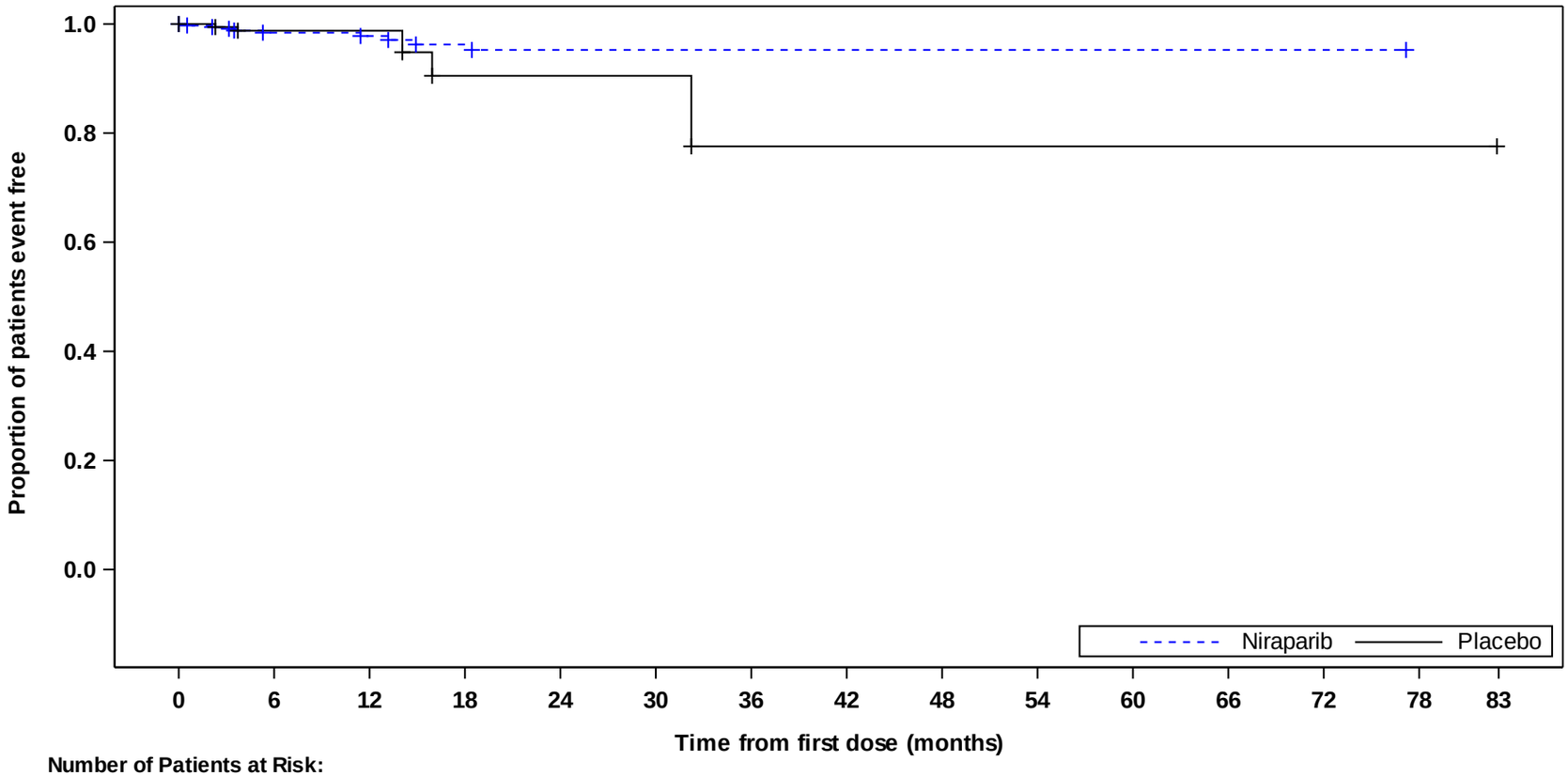
Number of Patients at Risk:

Niraparib	367	245	161	100	70	60	50	41	37	32	26	19	6	0
Placebo	179	90	35	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:48 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Immune system disorders



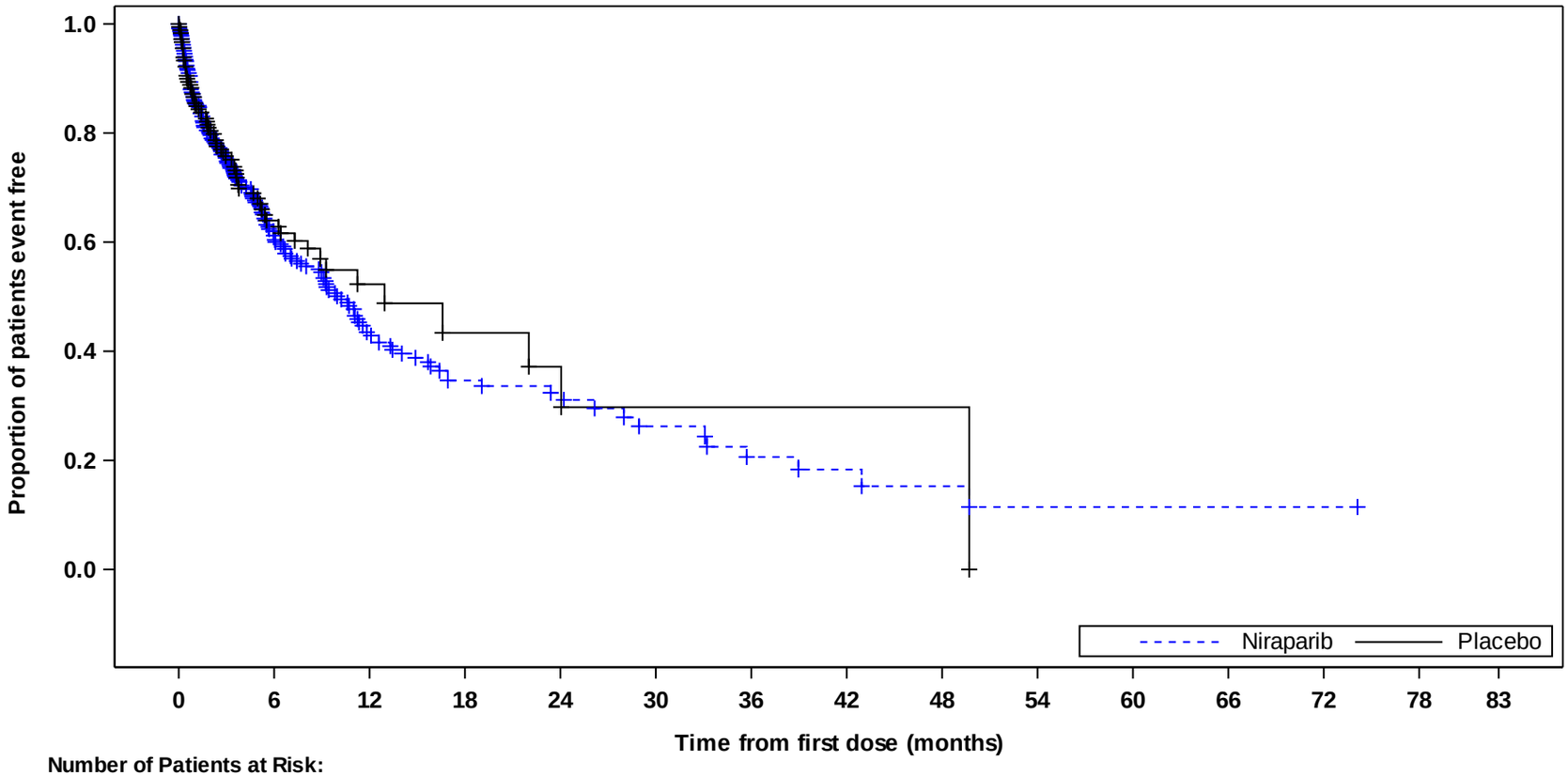
Number of Patients at Risk:

Niraparib	367	242	157	97	68	58	50	40	37	32	27	21	6	0
Placebo	179	91	36	13	8	7	6	5	4	3	3	3	1	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:49 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations



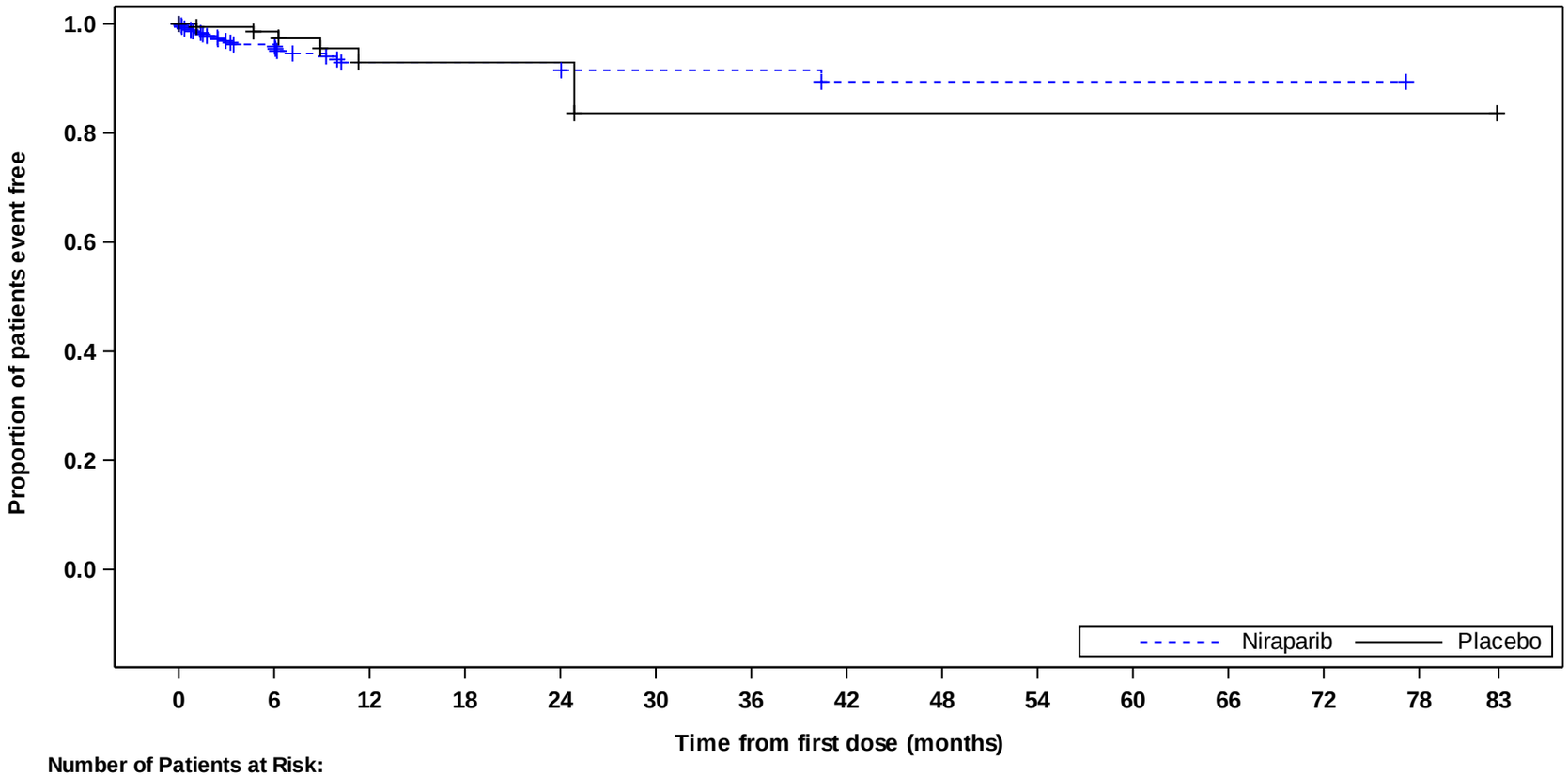
Number of Patients at Risk:

Niraparib	367	154	71	34	25	16	11	6	4	2	2	2	2	0
Placebo	179	56	18	7	5	4	4	3	2	0				

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:50 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Bronchitis



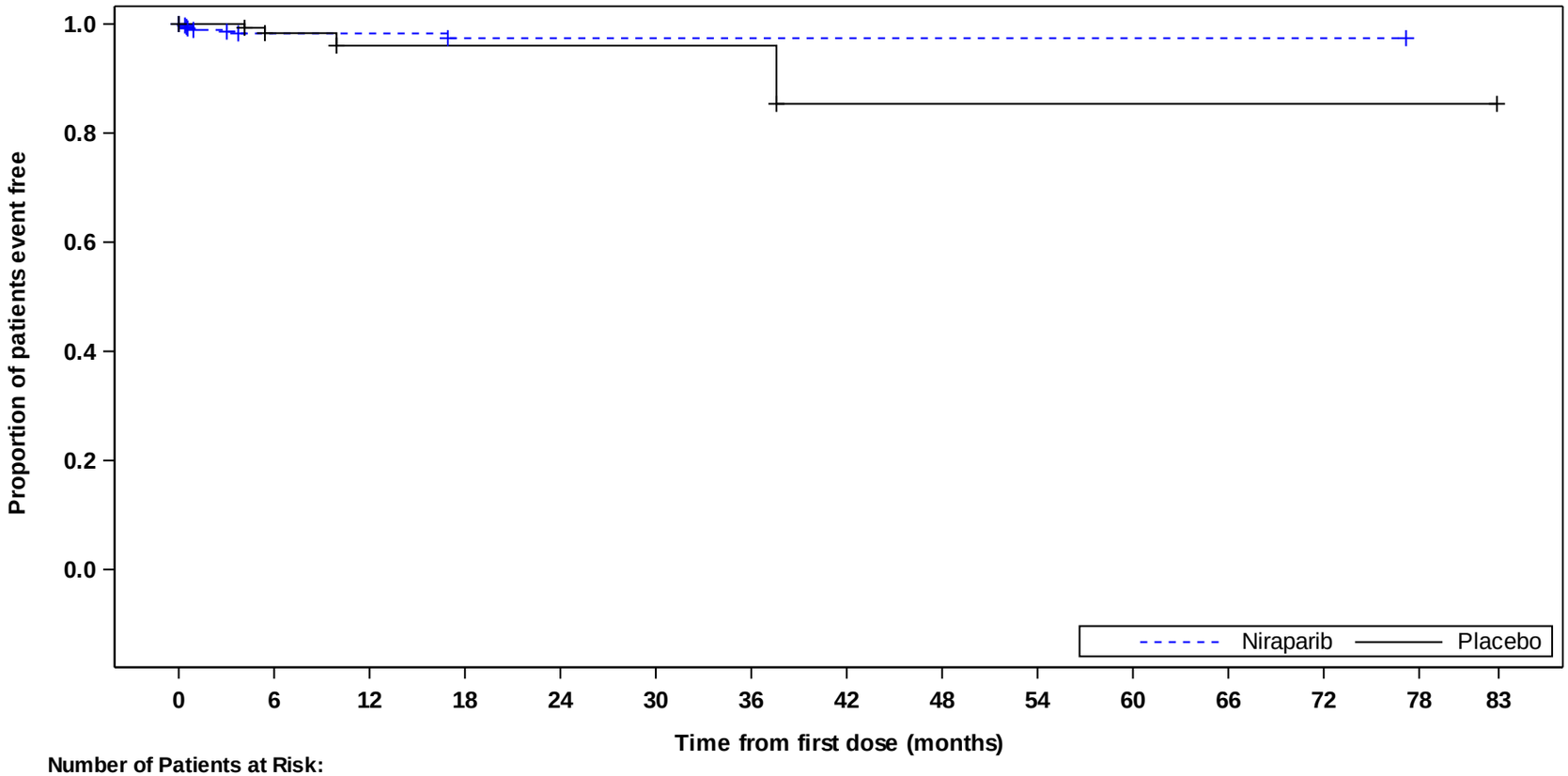
Number of Patients at Risk:

Niraparib	367	238	153	95	66	57	49	39	36	33	28	21	7	0
Placebo	179	90	34	15	10	8	8	7	6	5	5	5	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:51 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Conjunctivitis



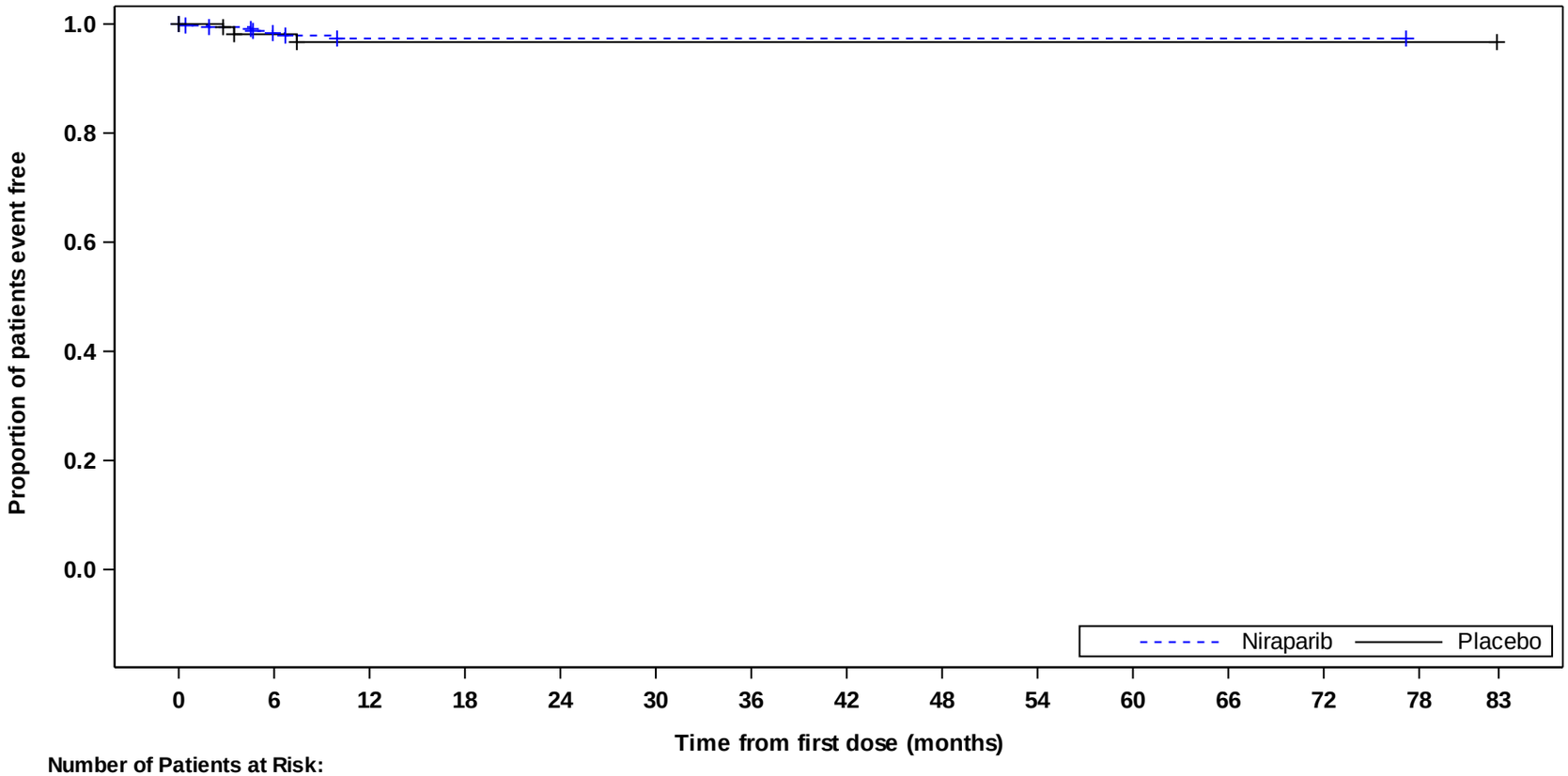
Number of Patients at Risk:

Niraparib	367	243	160	100	70	60	51	42	39	34	29	22	7	0
Placebo	179	90	35	15	10	9	9	7	6	5	5	5	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:52 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Cystitis



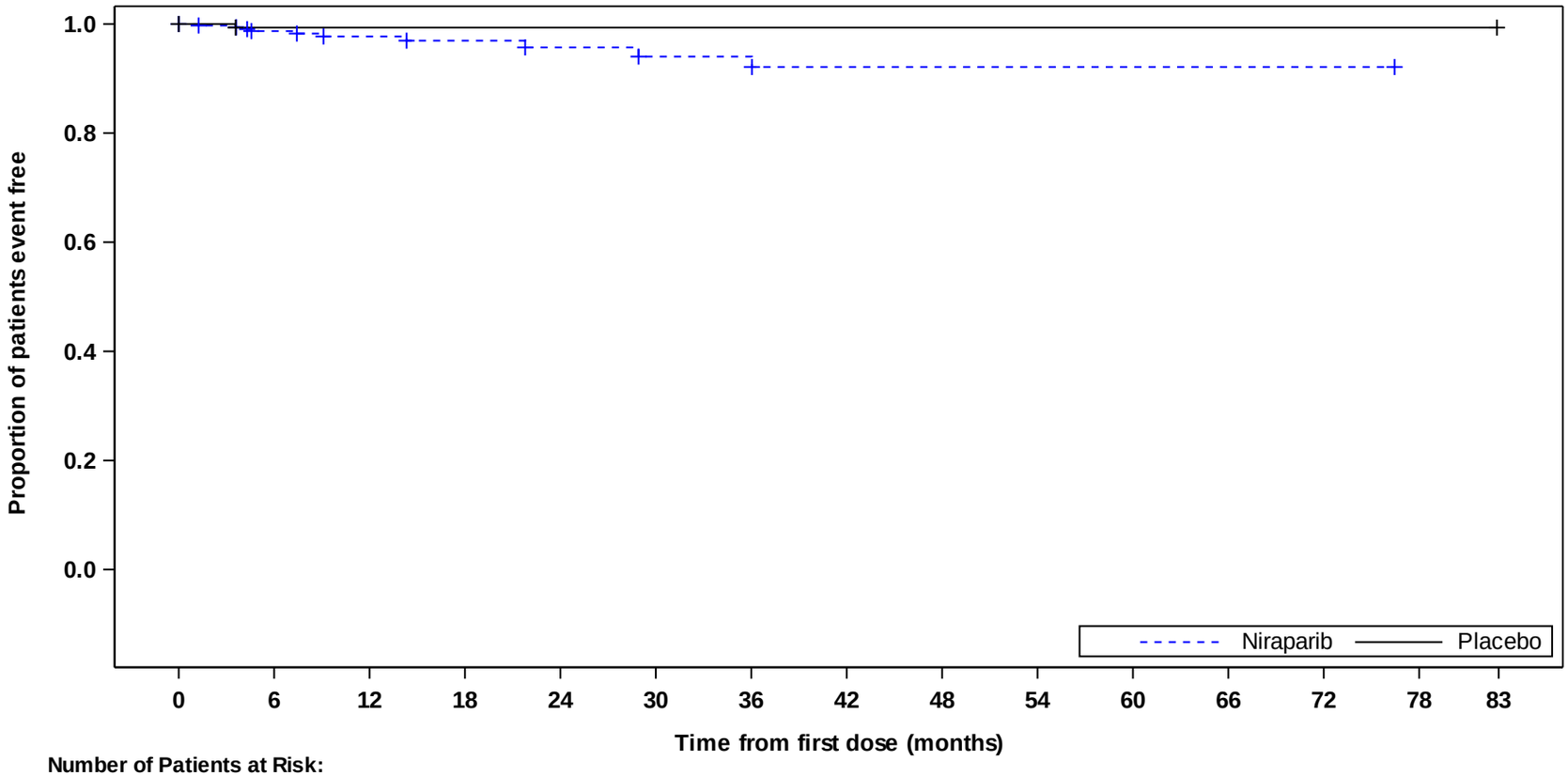
Number of Patients at Risk:

Niraparib	367	242	158	97	69	60	51	41	38	33	28	21	7	0
Placebo	179	90	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:53 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Gastroenteritis



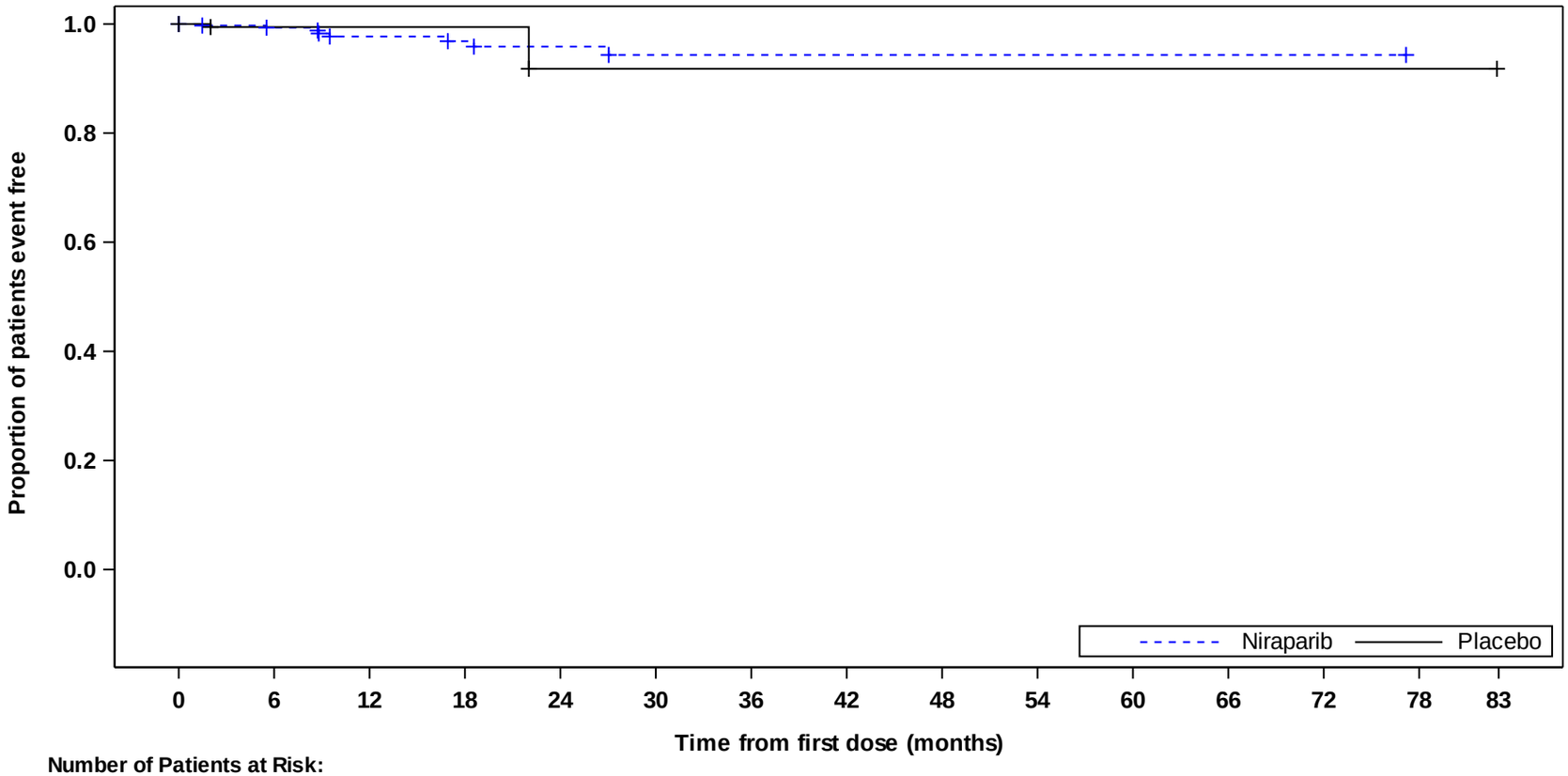
Number of Patients at Risk:

Niraparib	367	244	159	97	66	56	49	38	35	30	25	19	6	0
Placebo	179	91	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:54 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Herpes zoster



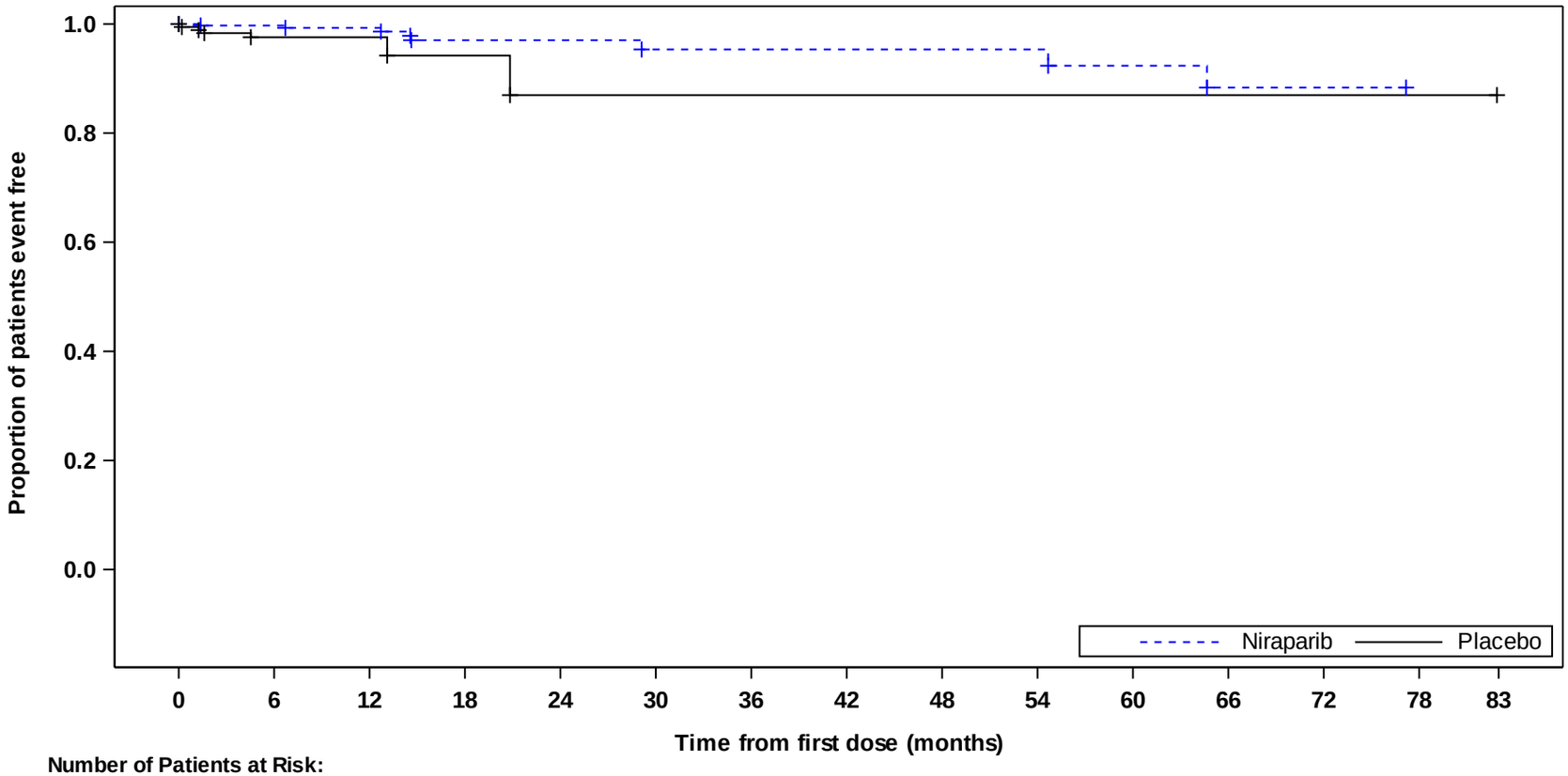
Number of Patients at Risk:

Niraparib	367	245	159	99	70	59	50	40	37	32	28	21	6	0
Placebo	179	92	37	16	9	8	8	7	6	5	5	5	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:54 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Influenza



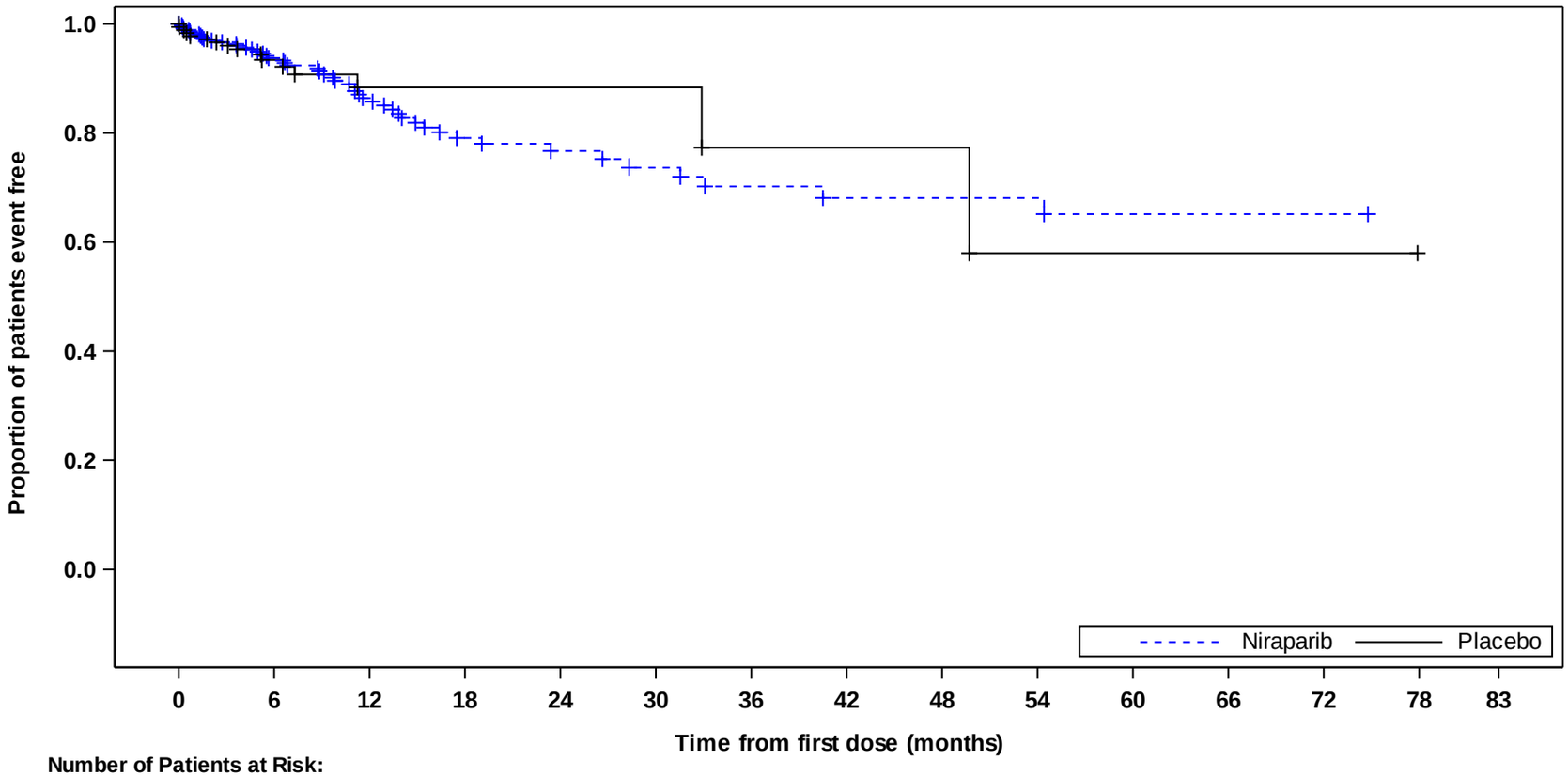
Number of Patients at Risk:

Niraparib	367	246	161	97	67	56	49	40	37	32	26	18	7	0
Placebo	179	89	35	16	9	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:55 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Nasopharyngitis



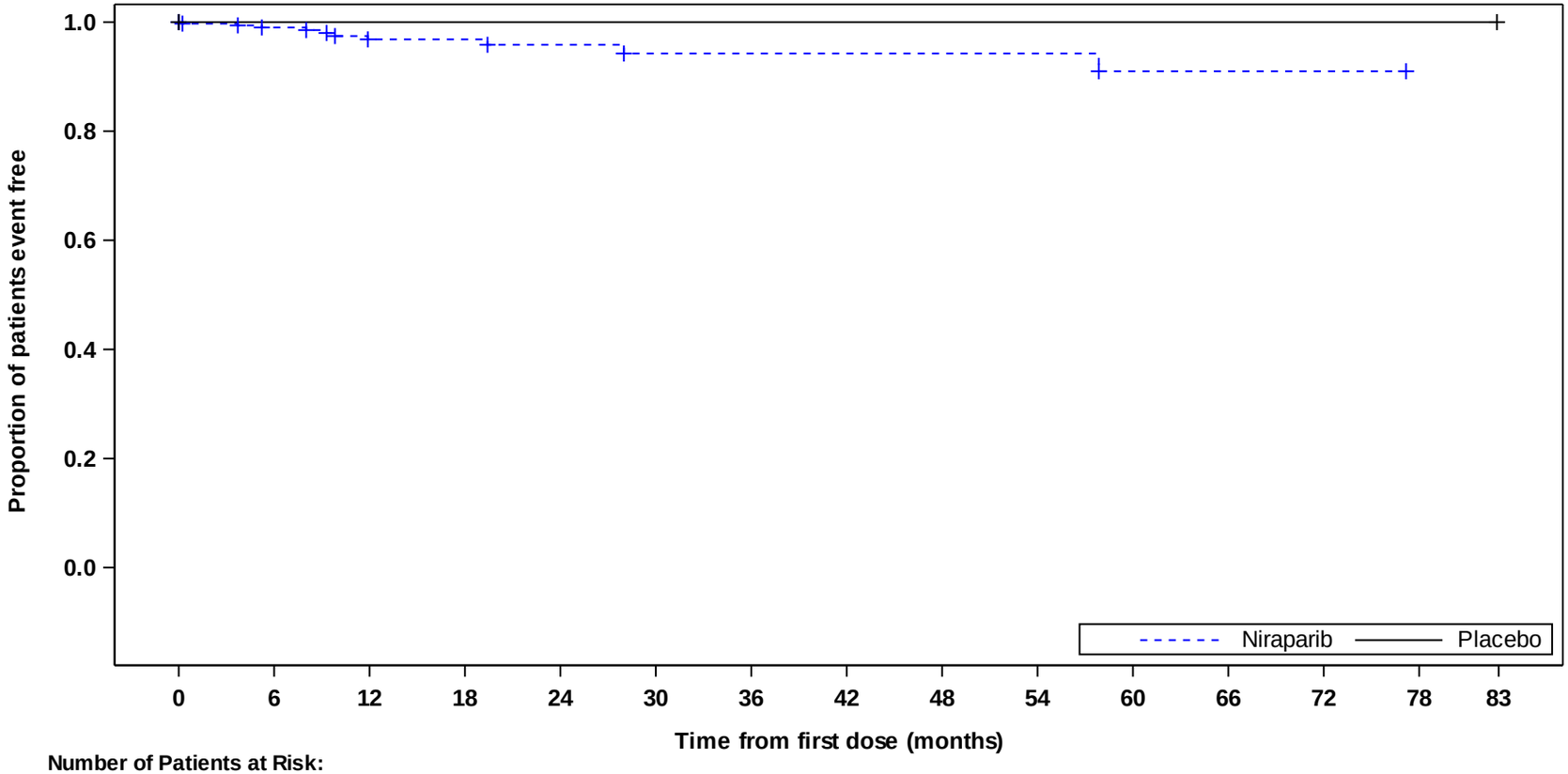
Number of Patients at Risk:

Niraparib	367	228	135	76	56	47	39	29	27	23	17	13	3	0
Placebo	179	85	35	15	9	8	7	6	5	3	3	3	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:56 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Pharyngitis



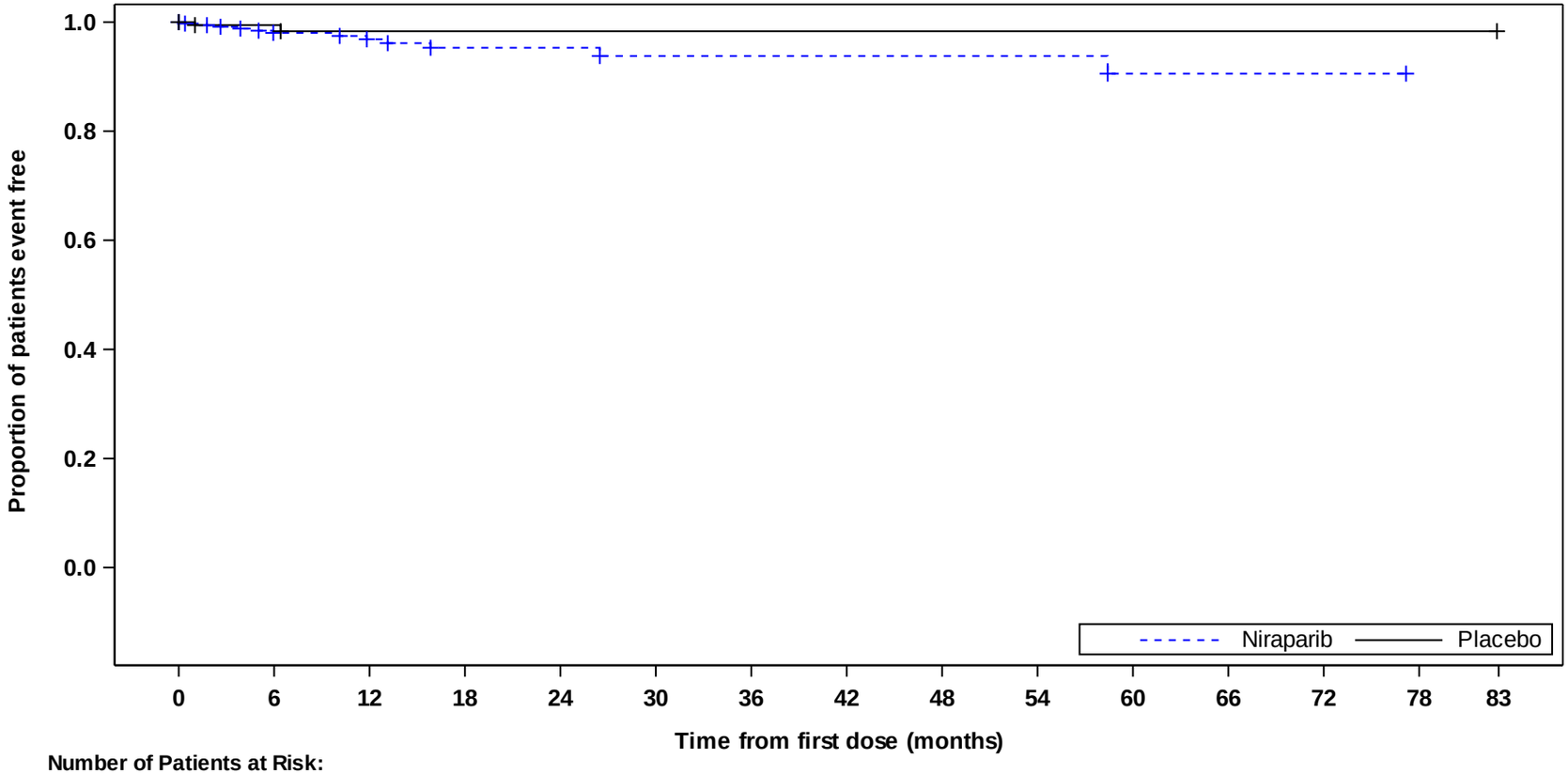
Number of Patients at Risk:

Niraparib	367	246	157	100	69	58	49	39	36	31	25	18	6	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:57 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Pneumonia



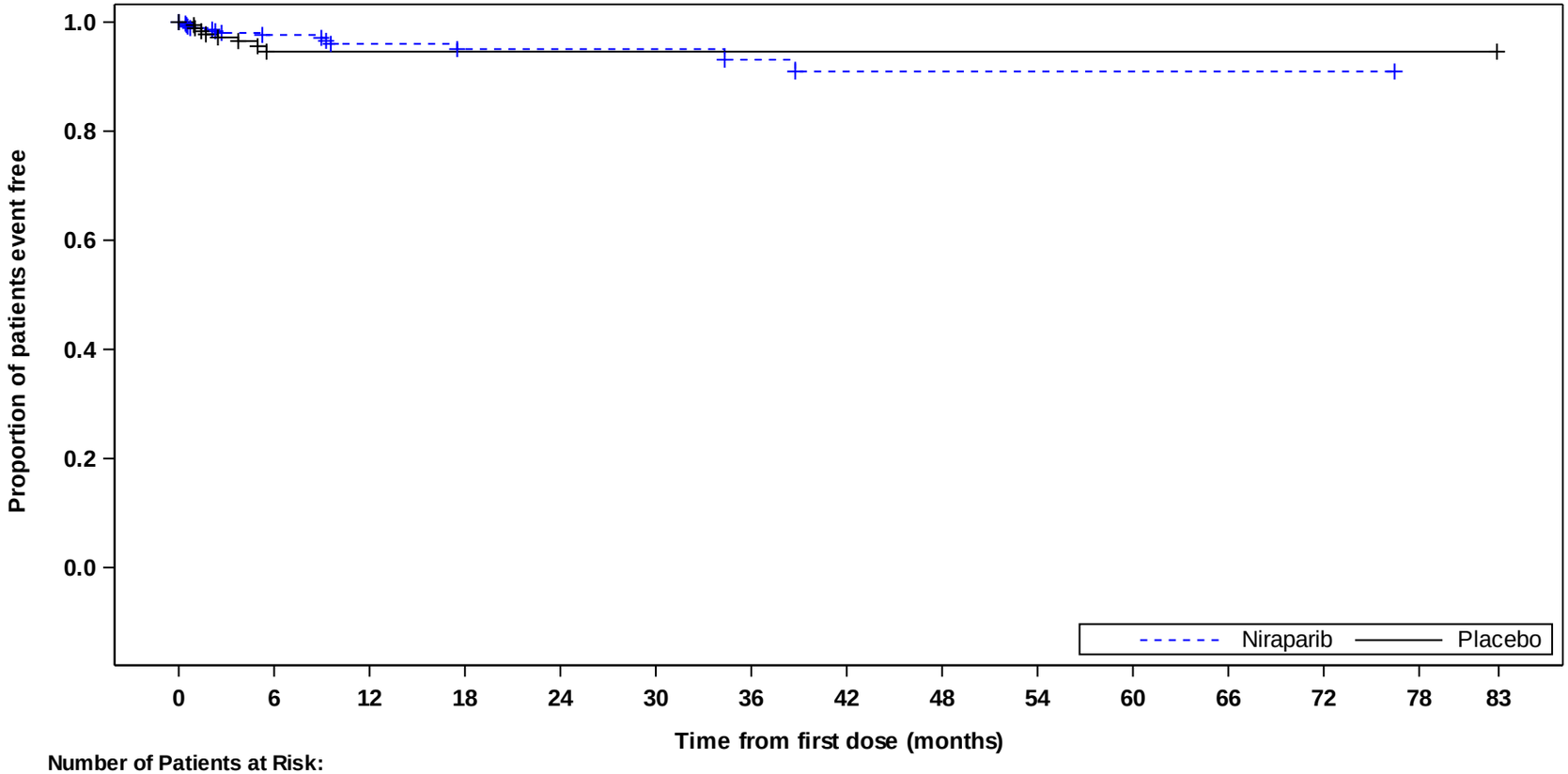
Number of Patients at Risk:

Niraparib	367	242	157	96	69	59	50	40	37	32	27	20	7	0
Placebo	179	92	36	15	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:58 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Rhinitis



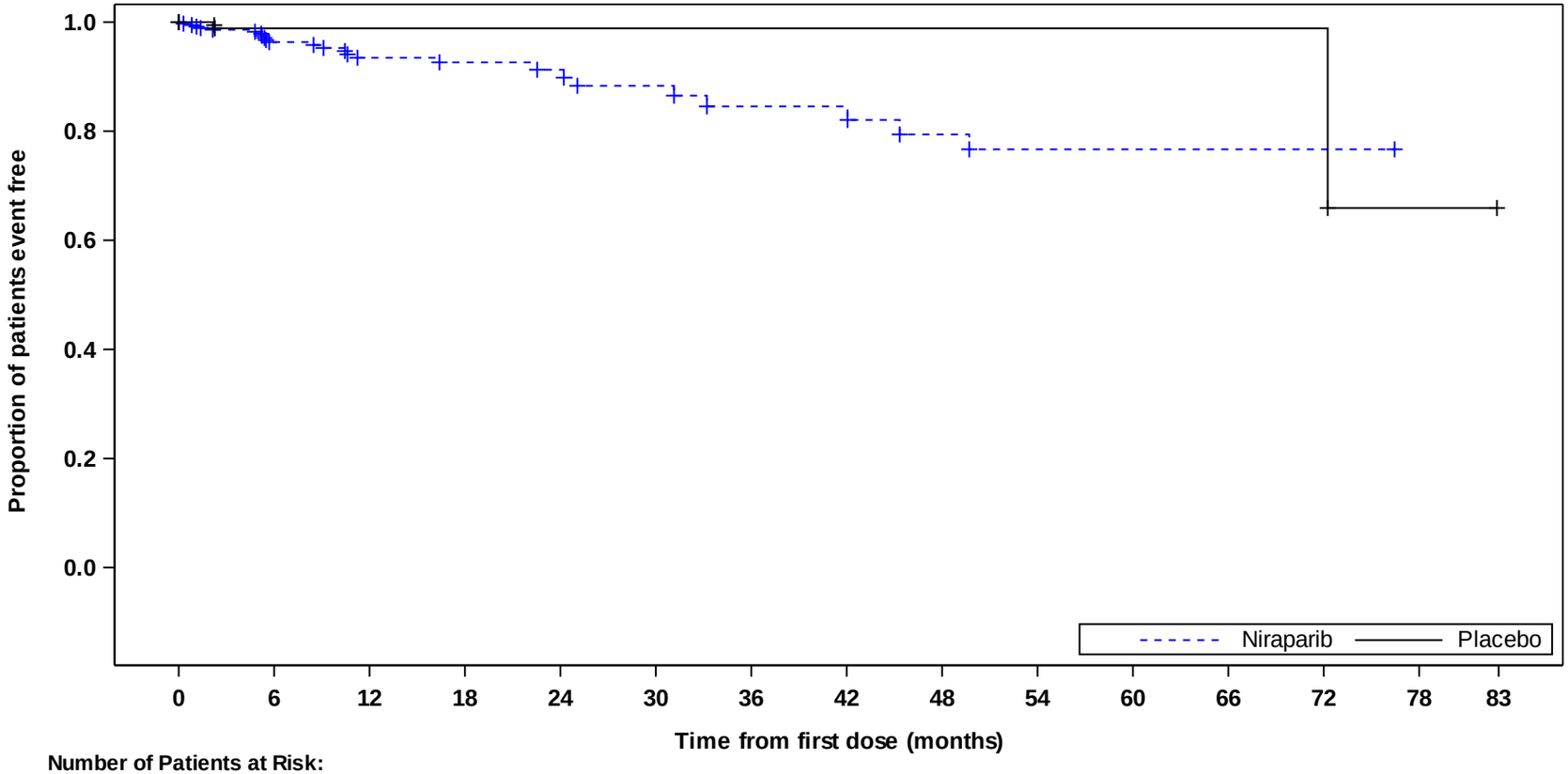
Number of Patients at Risk:

Niraparib	367	241	155	95	67	57	48	37	35	30	25	20	6	0
Placebo	179	86	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:22:59 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Sinusitis



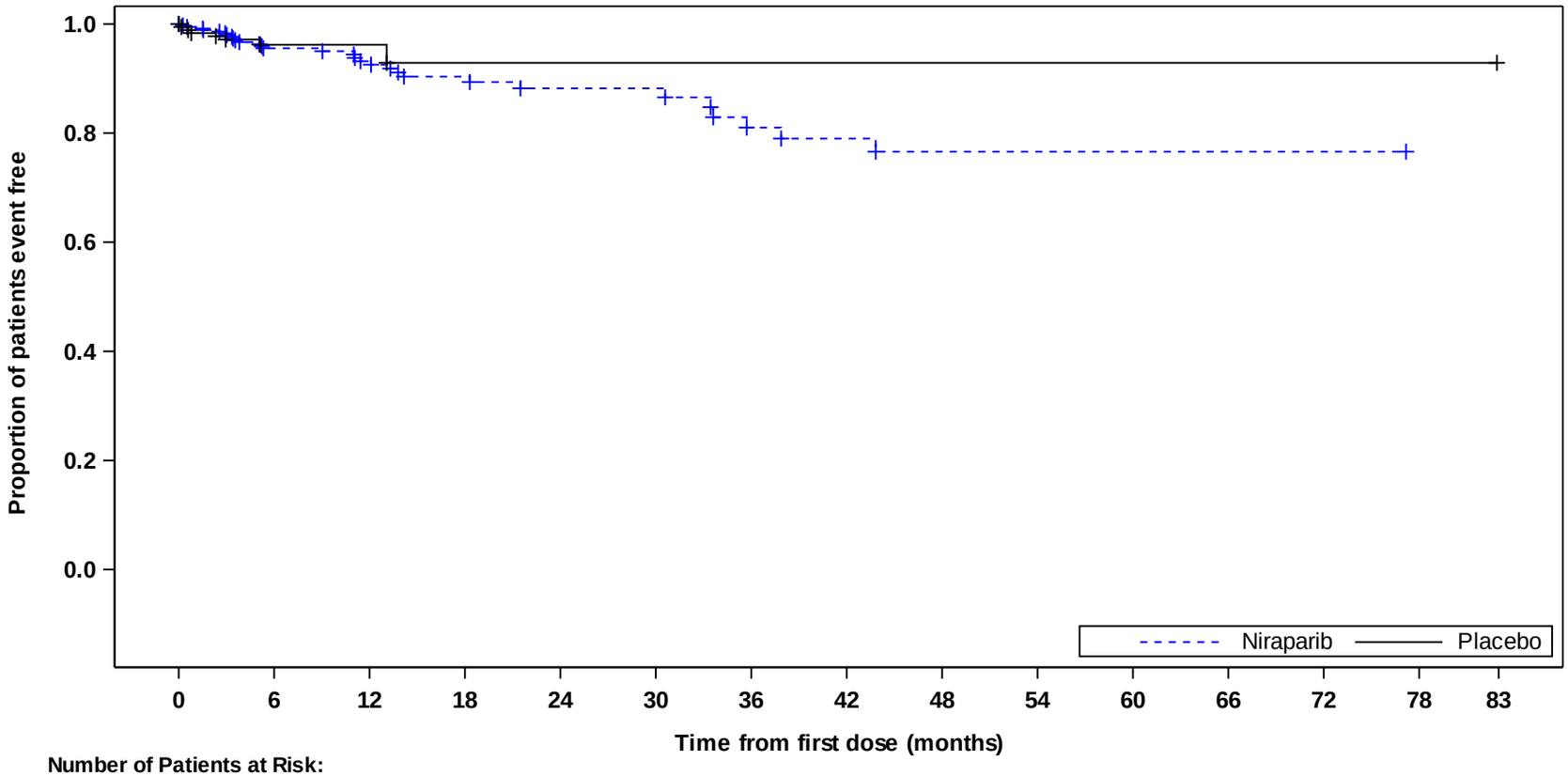
Number of Patients at Risk:

Niraparib	367	238	151	92	63	51	42	34	29	24	22	17	6	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:00 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Upper respiratory tract infection



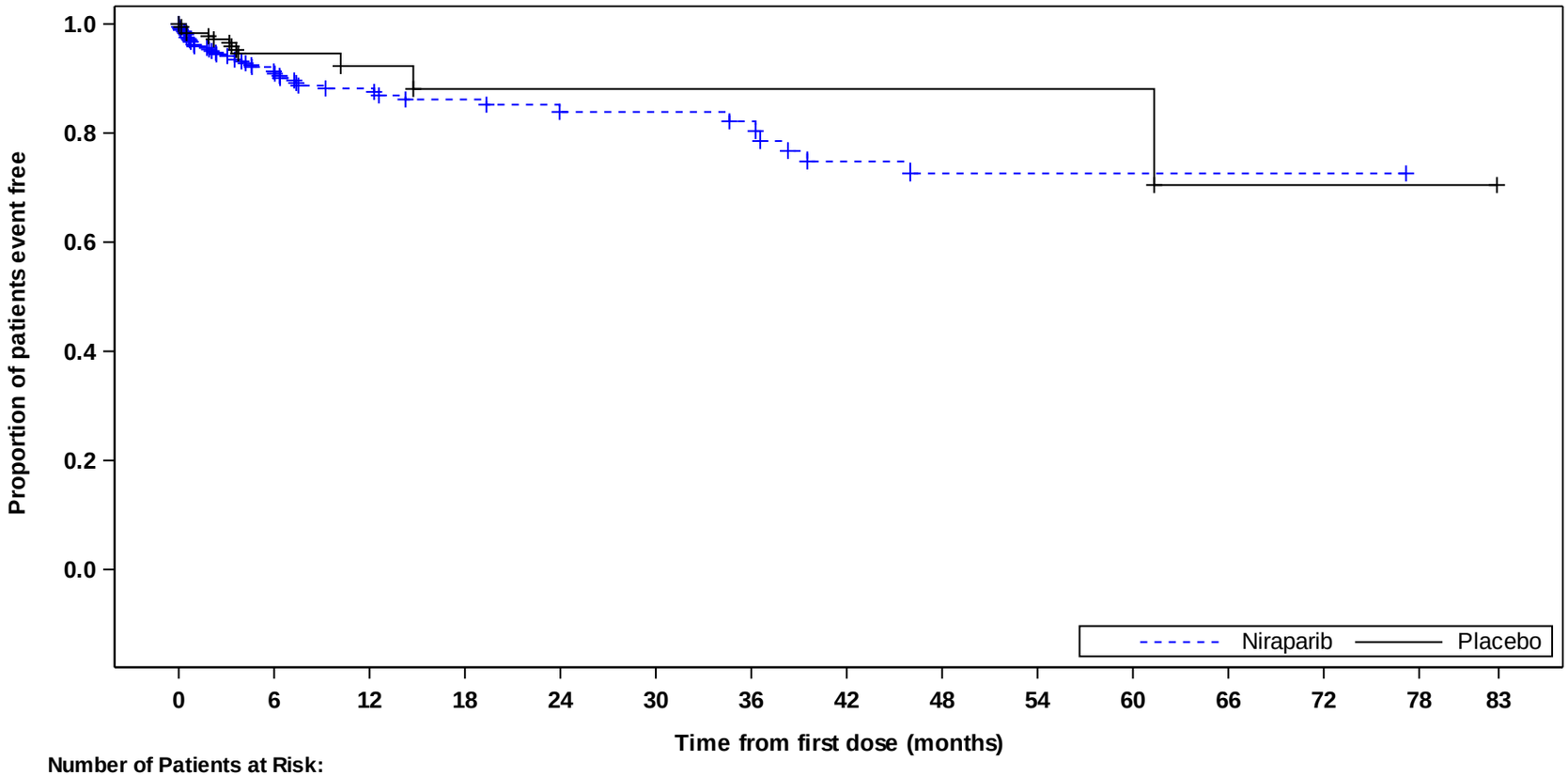
Number of Patients at Risk:

Niraparib	367	236	150	91	65	55	43	34	31	26	23	20	7	0
Placebo	179	89	35	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:01 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations, PT: Urinary tract infection



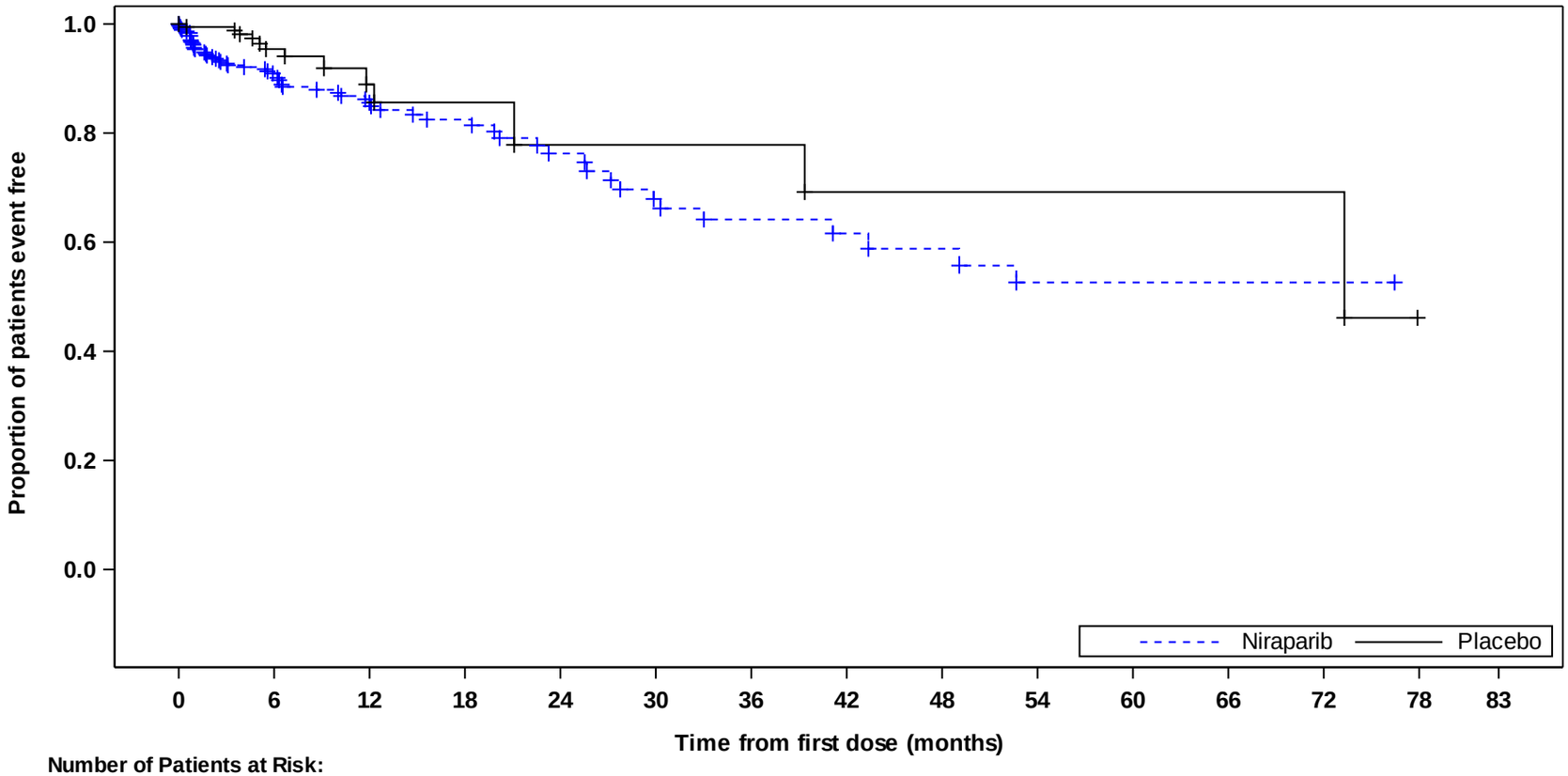
Number of Patients at Risk:

Niraparib	367	226	146	90	63	53	48	35	32	28	25	19	7	0
Placebo	179	87	34	13	8	8	8	7	6	5	5	4	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:02 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Injury, poisoning and procedural complications



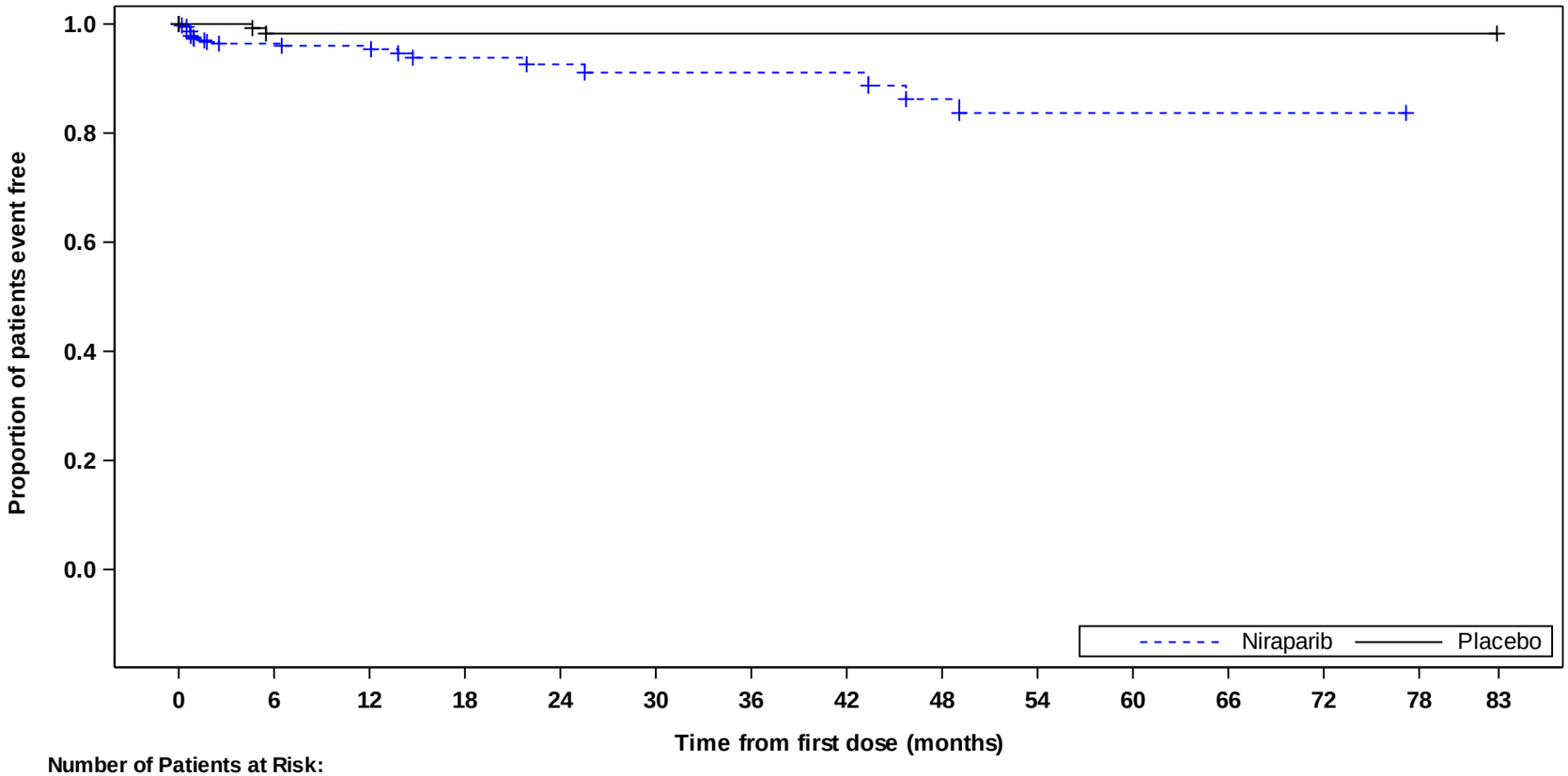
Number of Patients at Risk:

Niraparib	367	226	137	78	51	39	30	23	19	16	15	10	3	0
Placebo	179	87	30	13	9	9	9	7	6	5	5	5	3	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:03 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Injury, poisoning and procedural complications, PT: Contusion



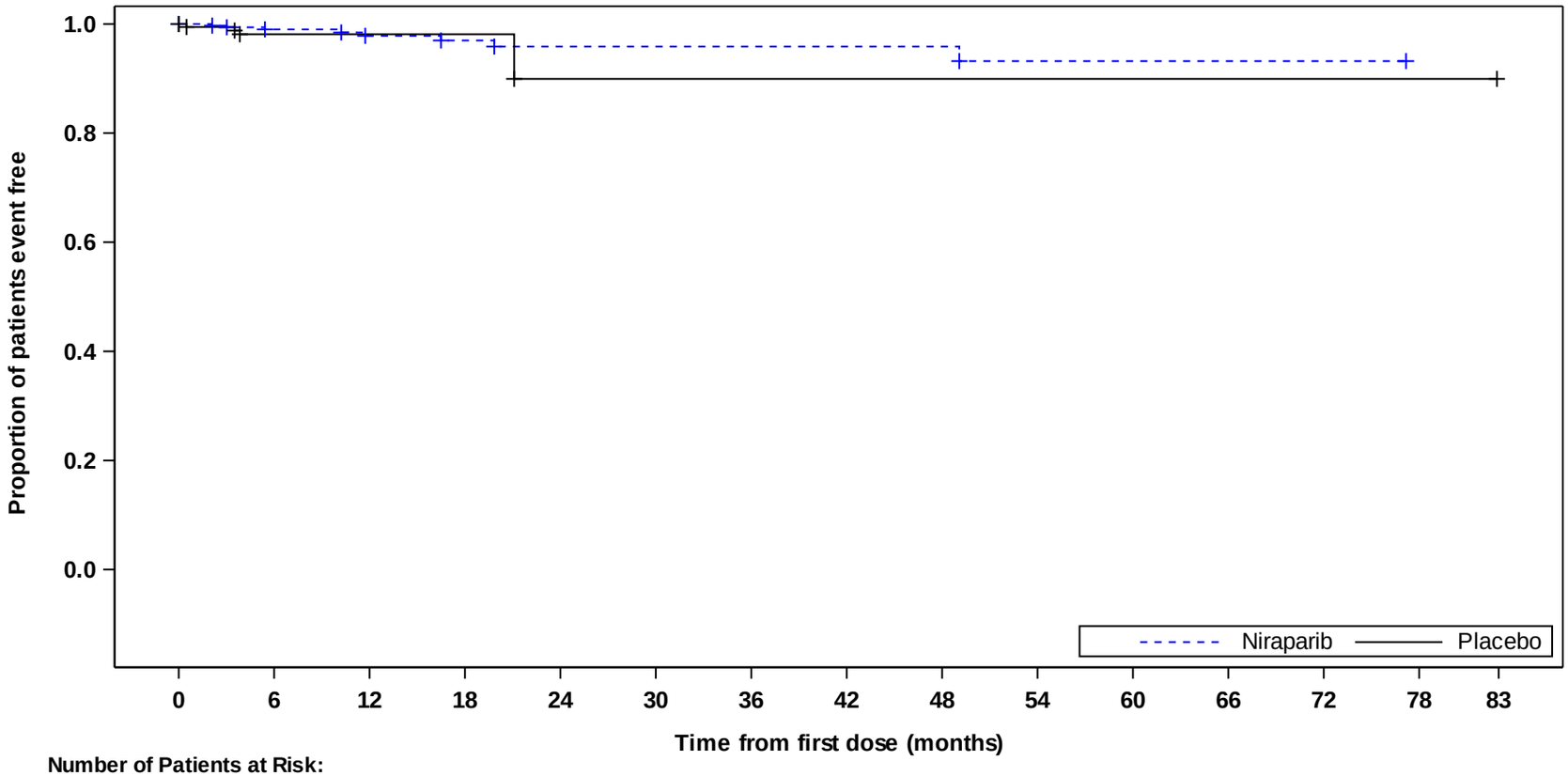
Number of Patients at Risk:

Niraparib	367	239	156	94	66	56	48	39	34	30	27	20	6	0
Placebo	179	90	35	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:04 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Injury, poisoning and procedural complications, PT: Fall



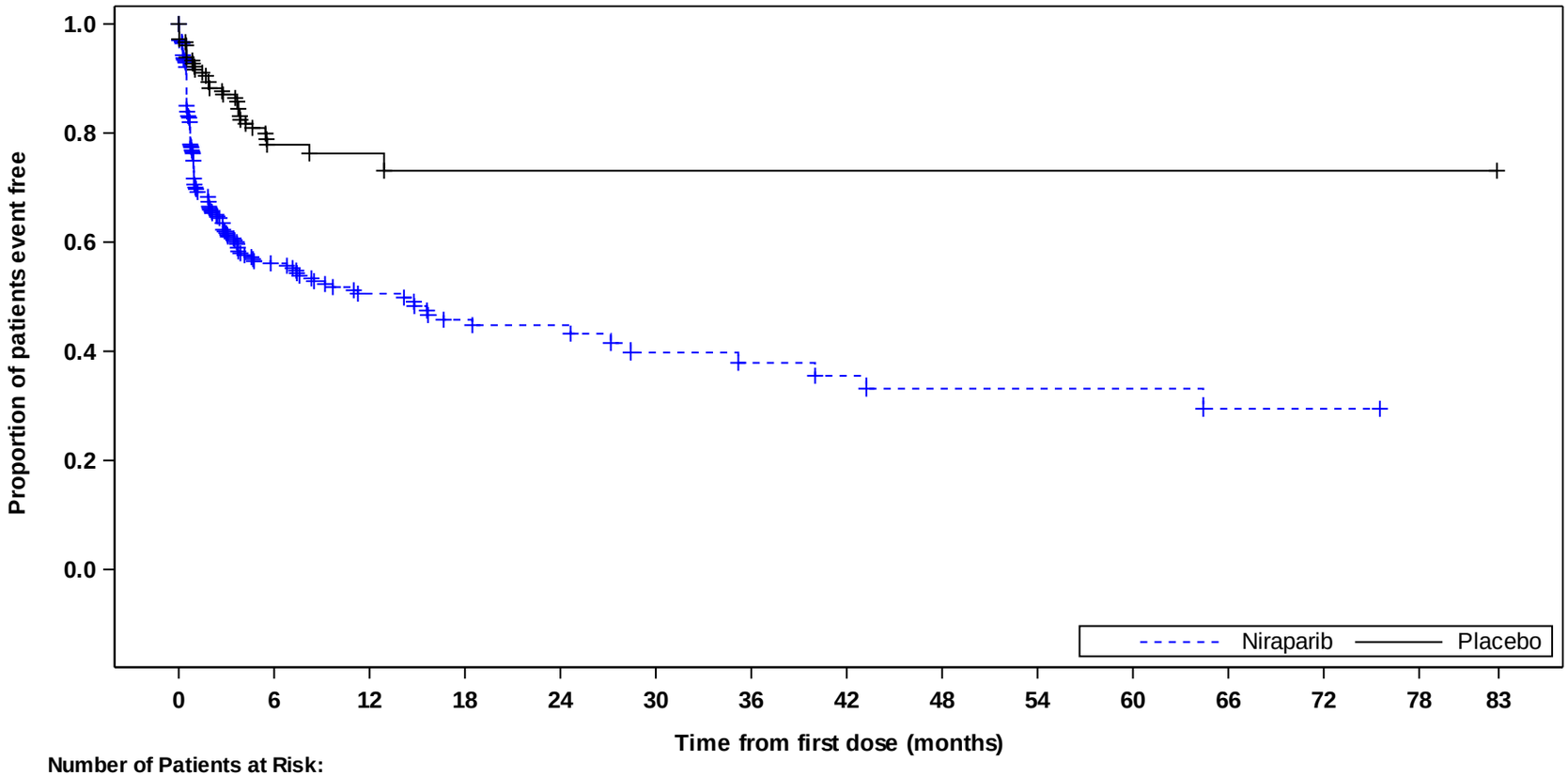
Number of Patients at Risk:

Niraparib	367	244	158	96	65	55	47	39	36	32	29	22	7	0
Placebo	179	90	35	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:05 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations



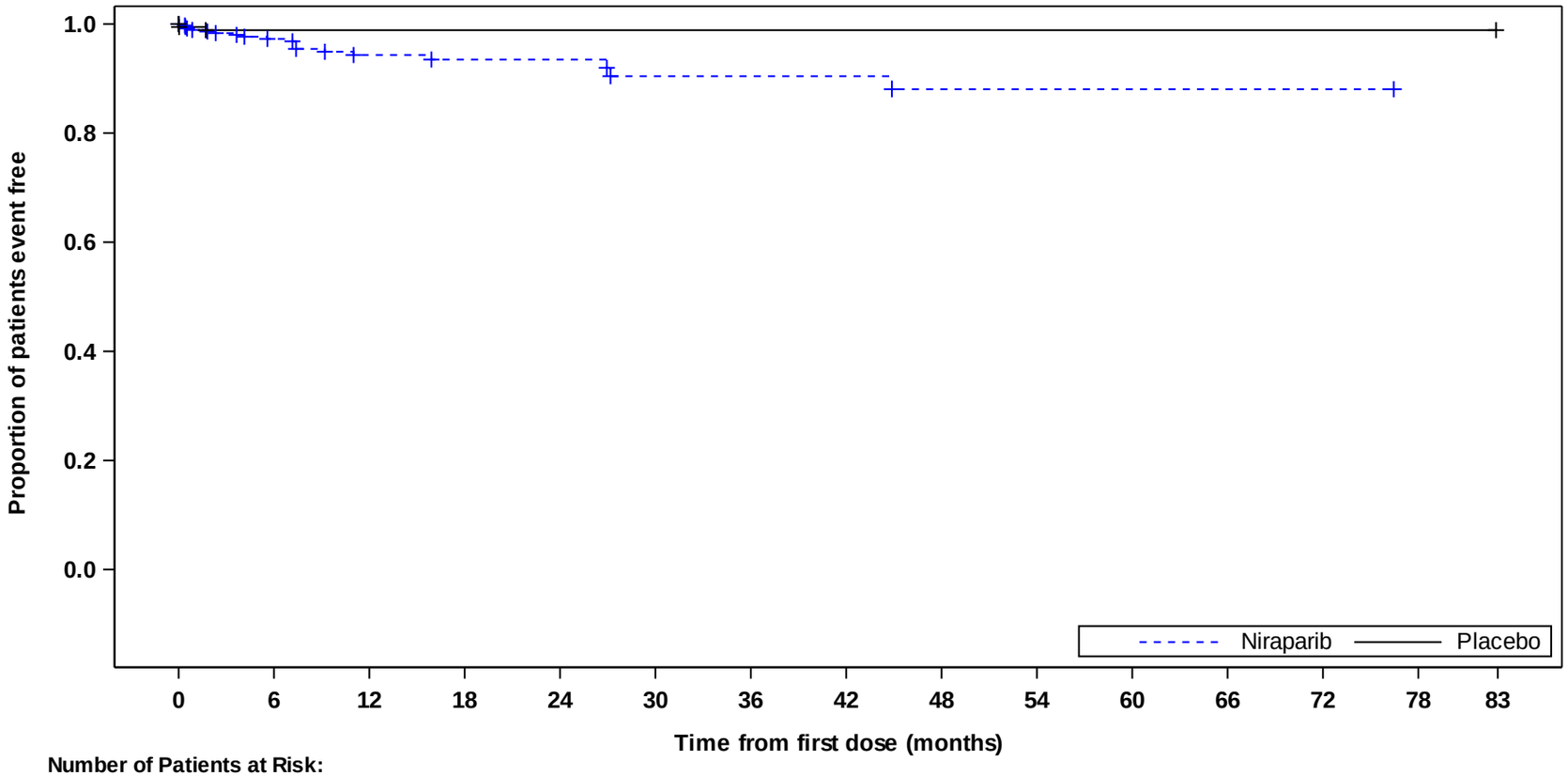
Number of Patients at Risk:

Niraparib	367	138	83	46	29	23	20	15	14	14	12	7	3	0
Placebo	179	69	27	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:06 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Alanine aminotransferase increased



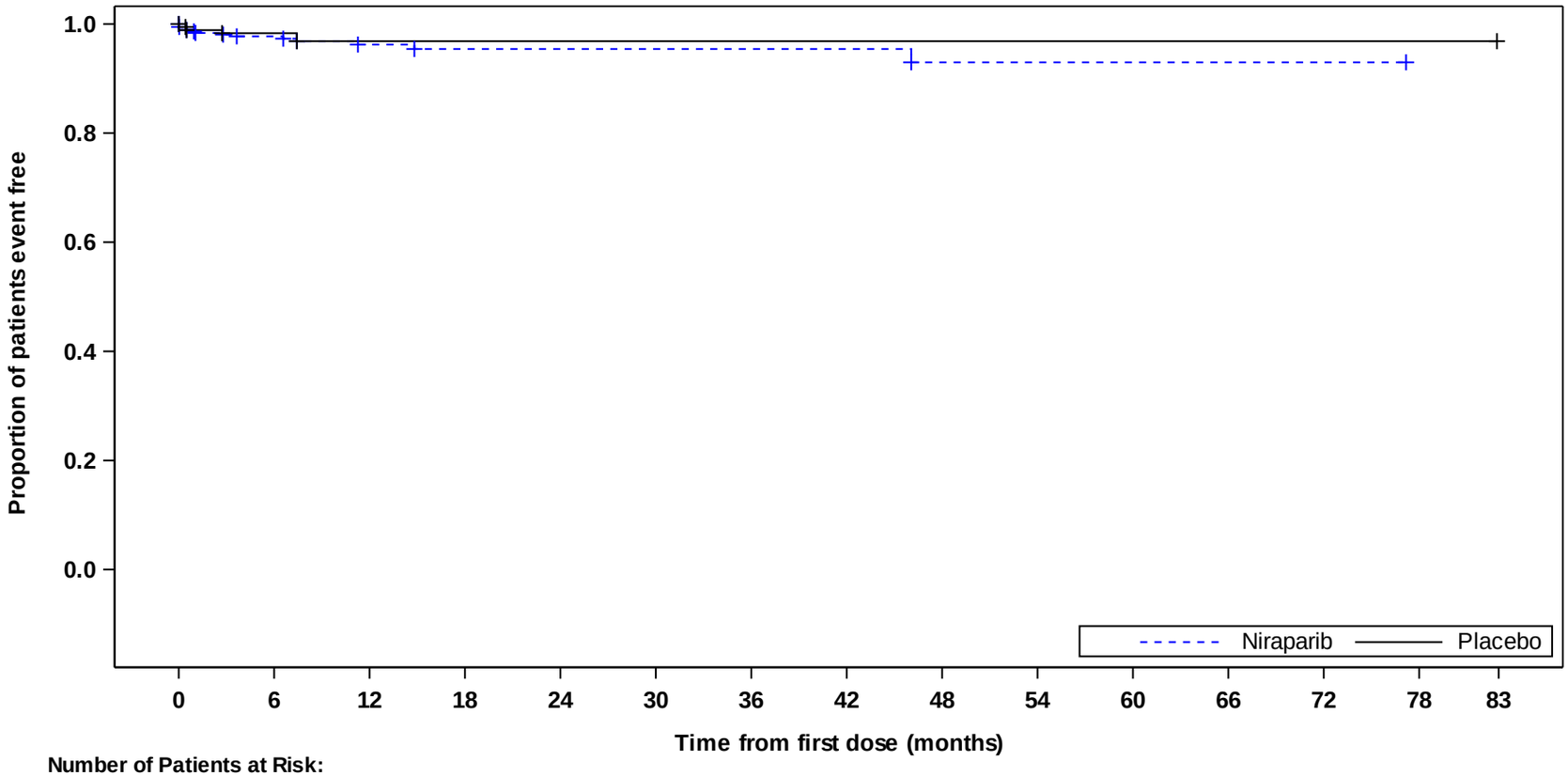
Number of Patients at Risk:

Niraparib	367	242	156	96	67	57	50	40	36	31	26	19	5	0
Placebo	179	91	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:07 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Amylase increased



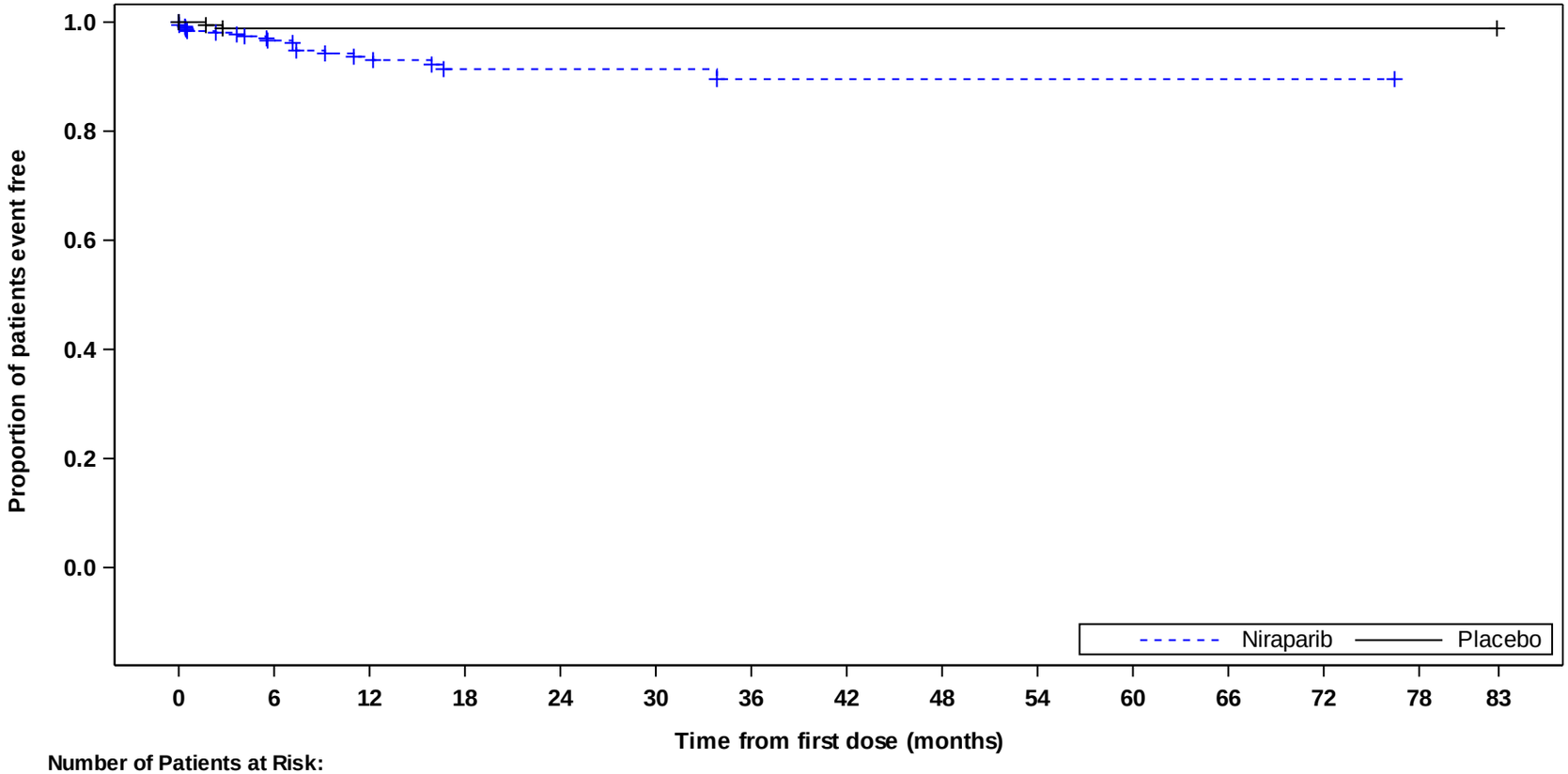
Number of Patients at Risk:

Niraparib	367	241	156	96	67	58	49	41	37	32	27	20	7	0
Placebo	179	91	35	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:08 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Aspartate aminotransferase increased



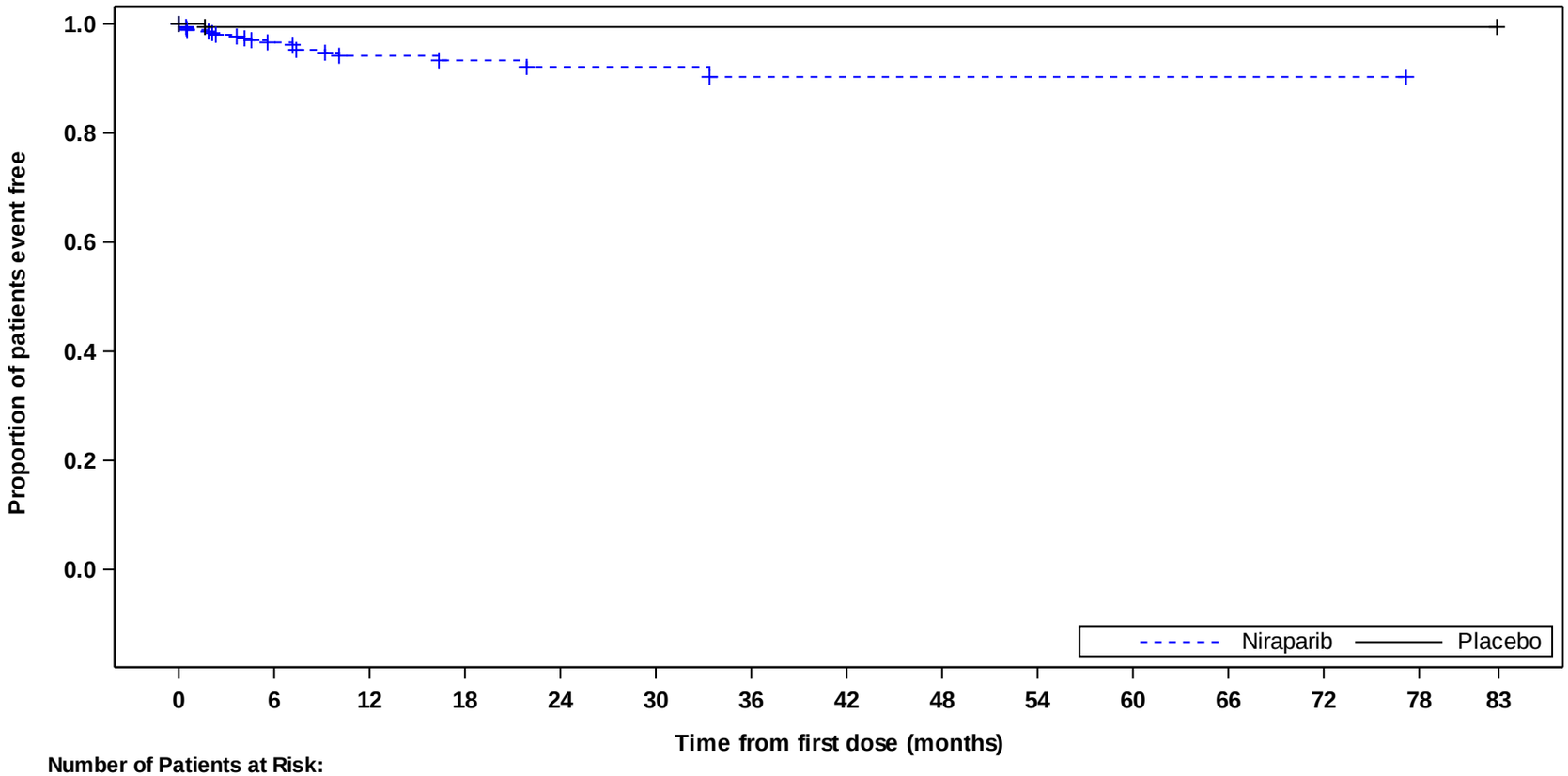
Number of Patients at Risk:

Niraparib	367	240	154	95	66	58	48	39	36	31	26	19	5	0
Placebo	179	91	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:08 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Blood alkaline phosphatase increased



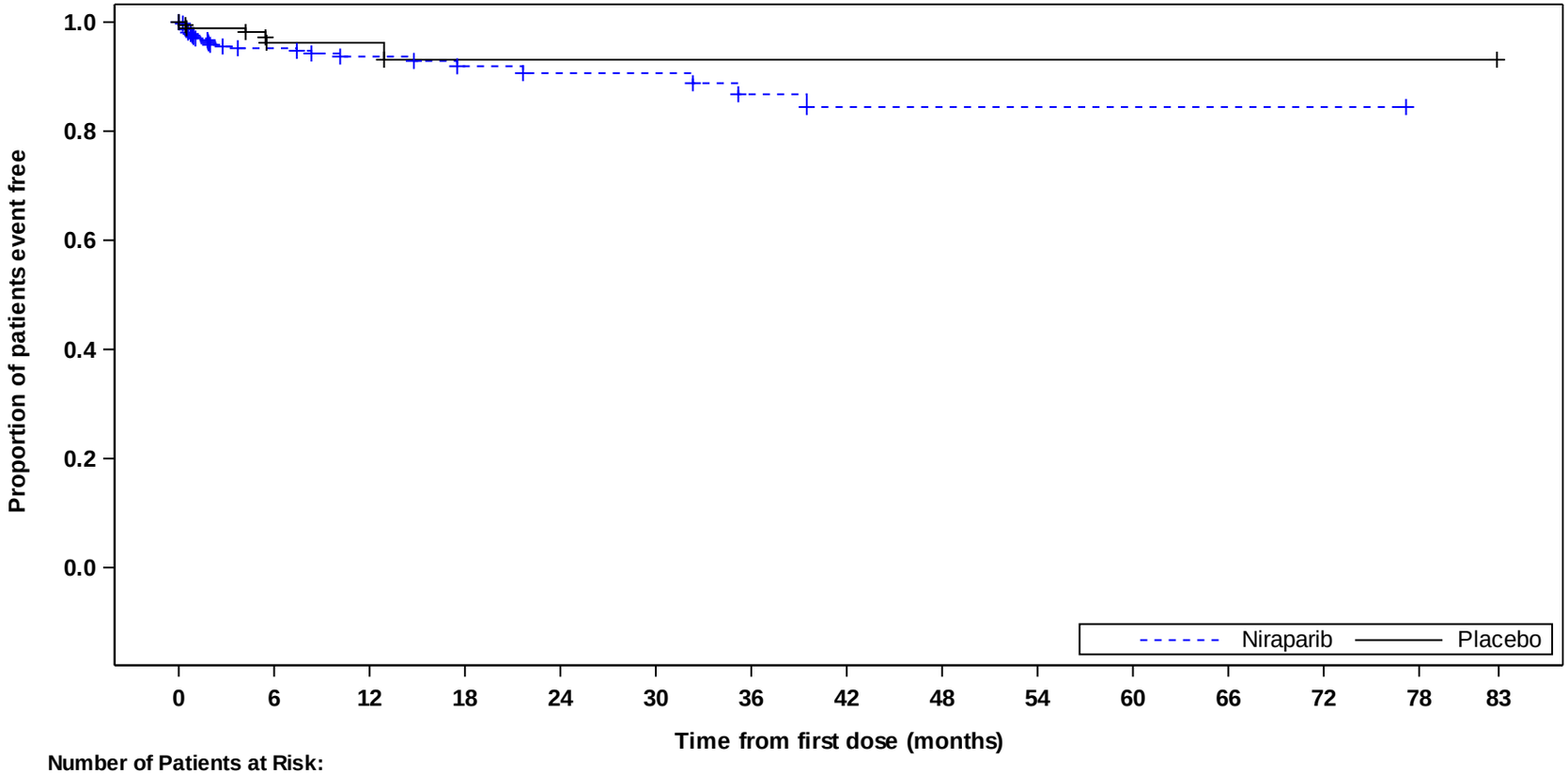
Number of Patients at Risk:

Niraparib	367	240	155	95	67	57	47	37	35	31	26	19	6	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:10 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Blood creatinine increased



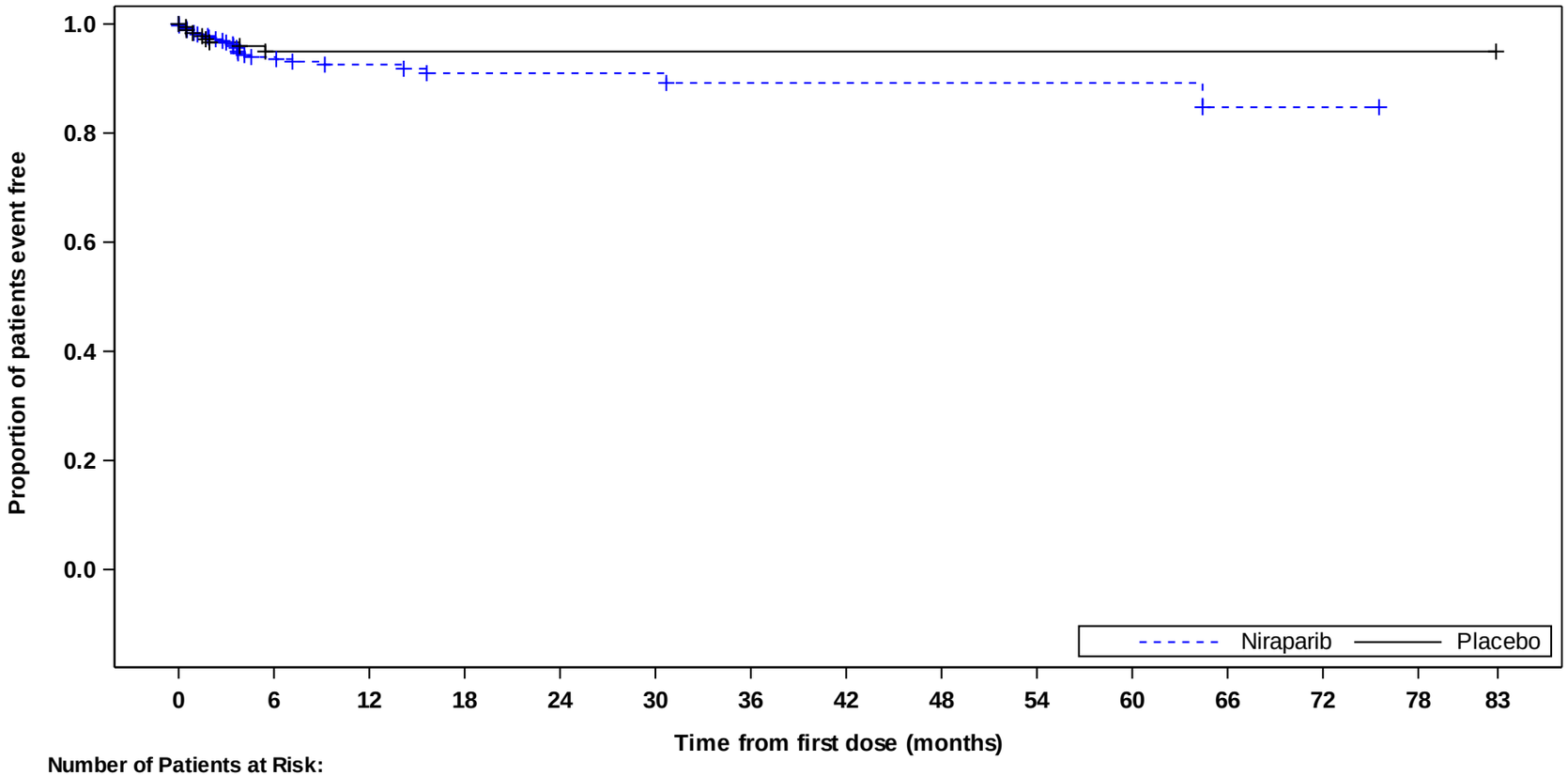
Number of Patients at Risk:

Niraparib	367	235	152	90	61	52	43	33	31	28	25	19	7	0
Placebo	179	89	35	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:10 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Gamma-glutamyltransferase increased



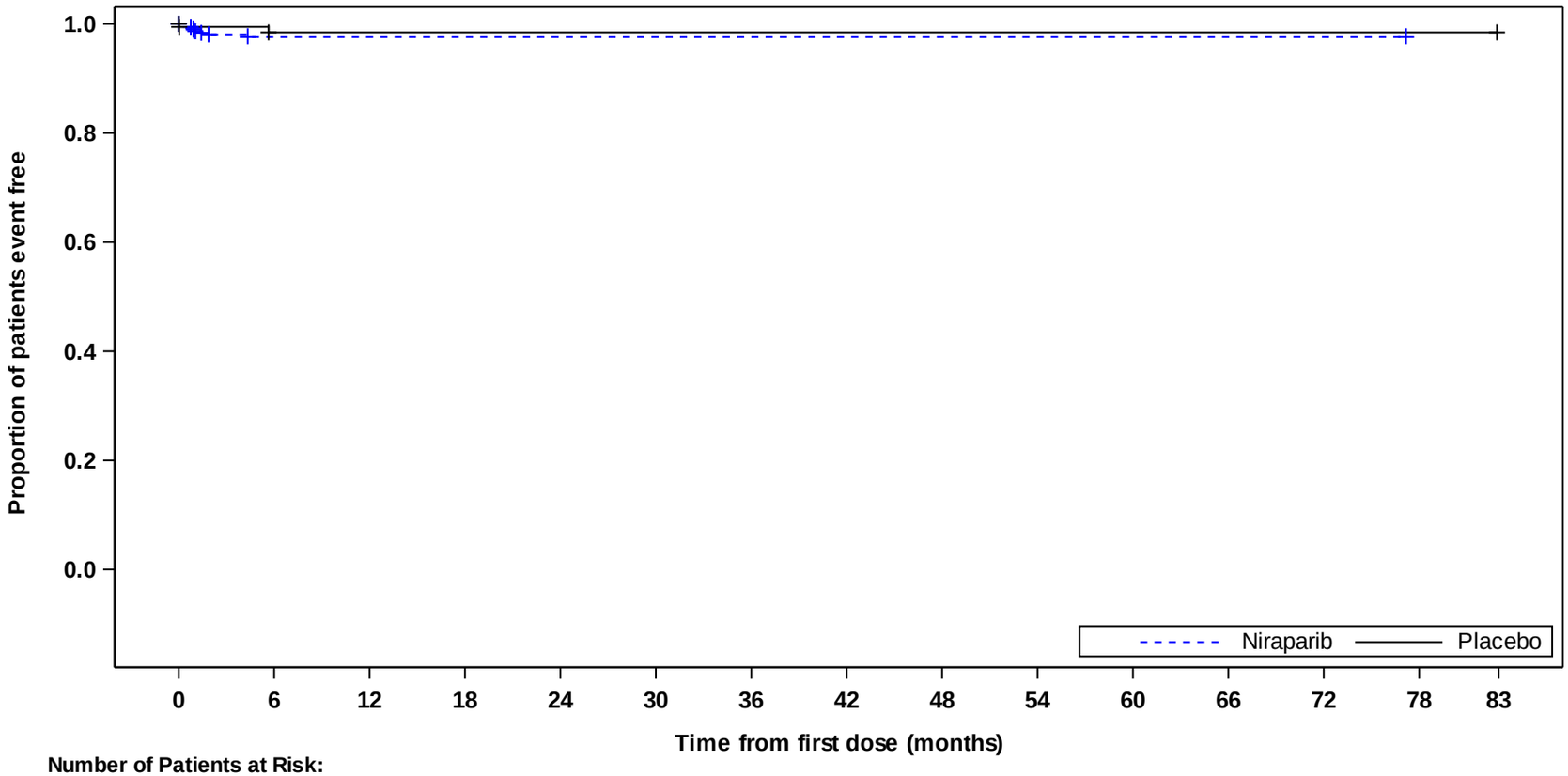
Number of Patients at Risk:

Niraparib	367	234	153	93	63	53	44	35	32	28	23	16	3	0
Placebo	179	86	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:11 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Lymphocyte count decreased



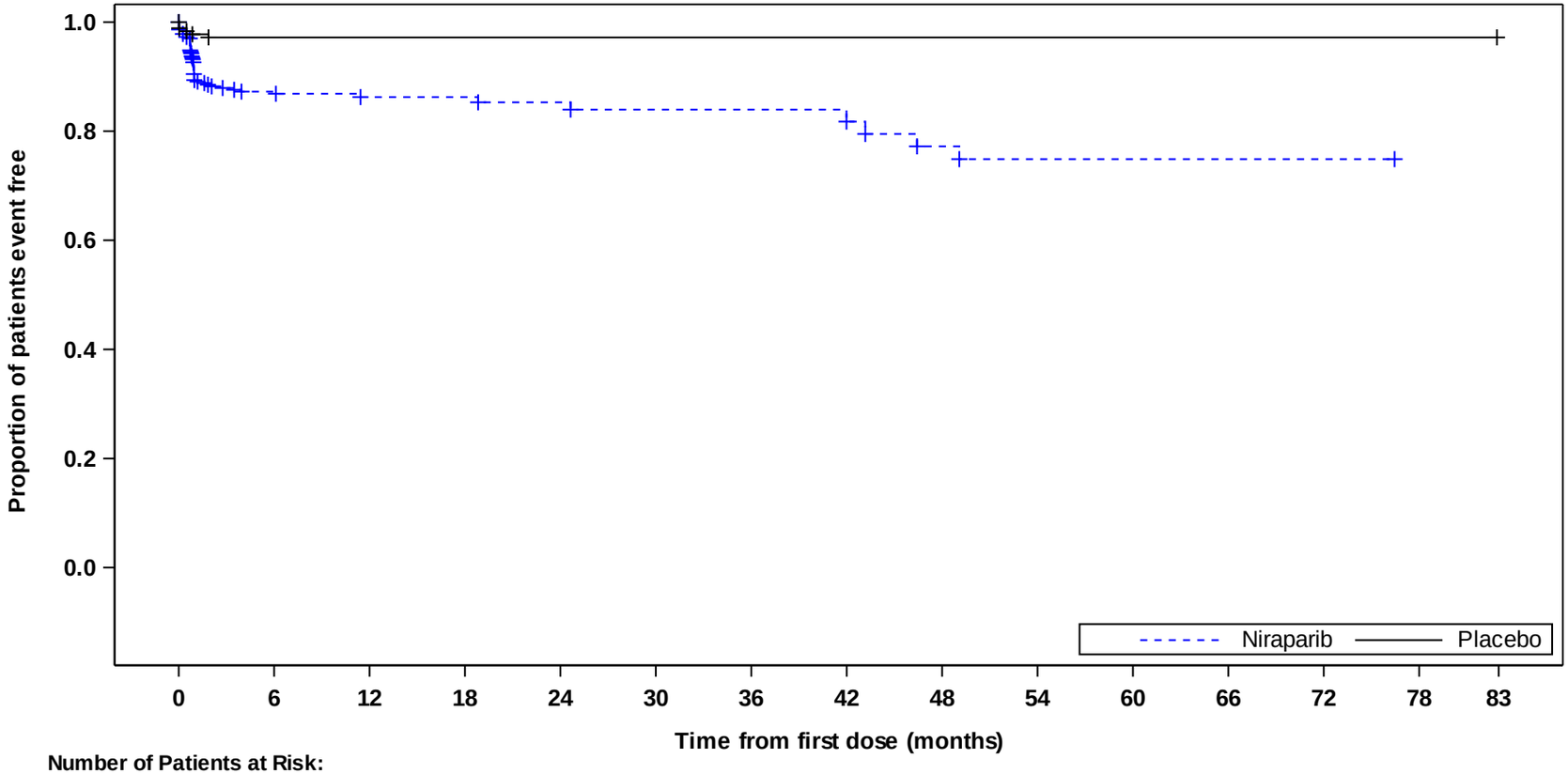
Number of Patients at Risk:

Niraparib	367	243	160	99	70	60	51	41	39	34	29	22	7	0
Placebo	179	91	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:12 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Neutrophil count decreased



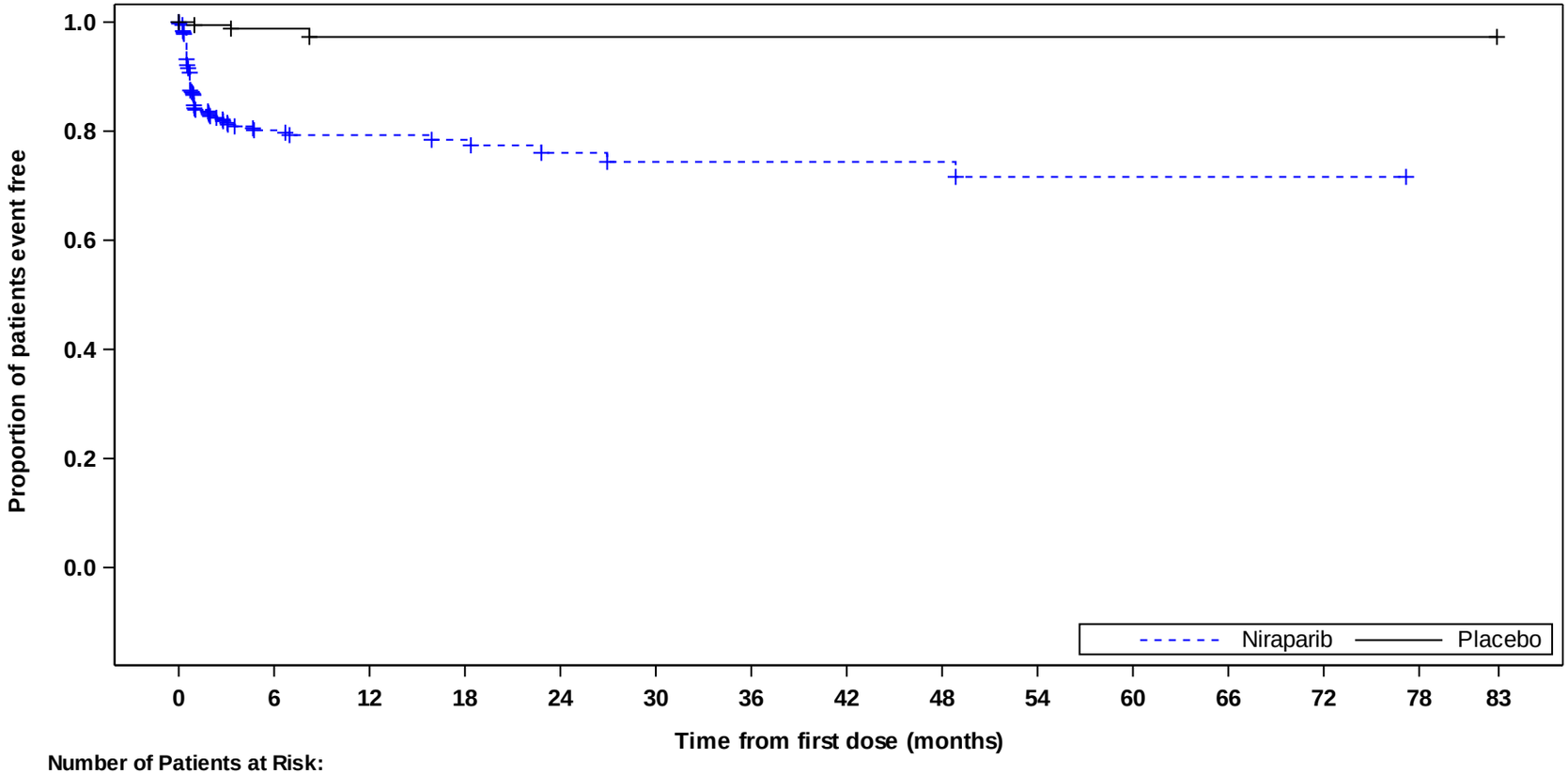
Number of Patients at Risk:

Niraparib	367	218	142	90	64	55	47	37	33	29	24	19	5	0
Placebo	179	88	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:13 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Platelet count decreased



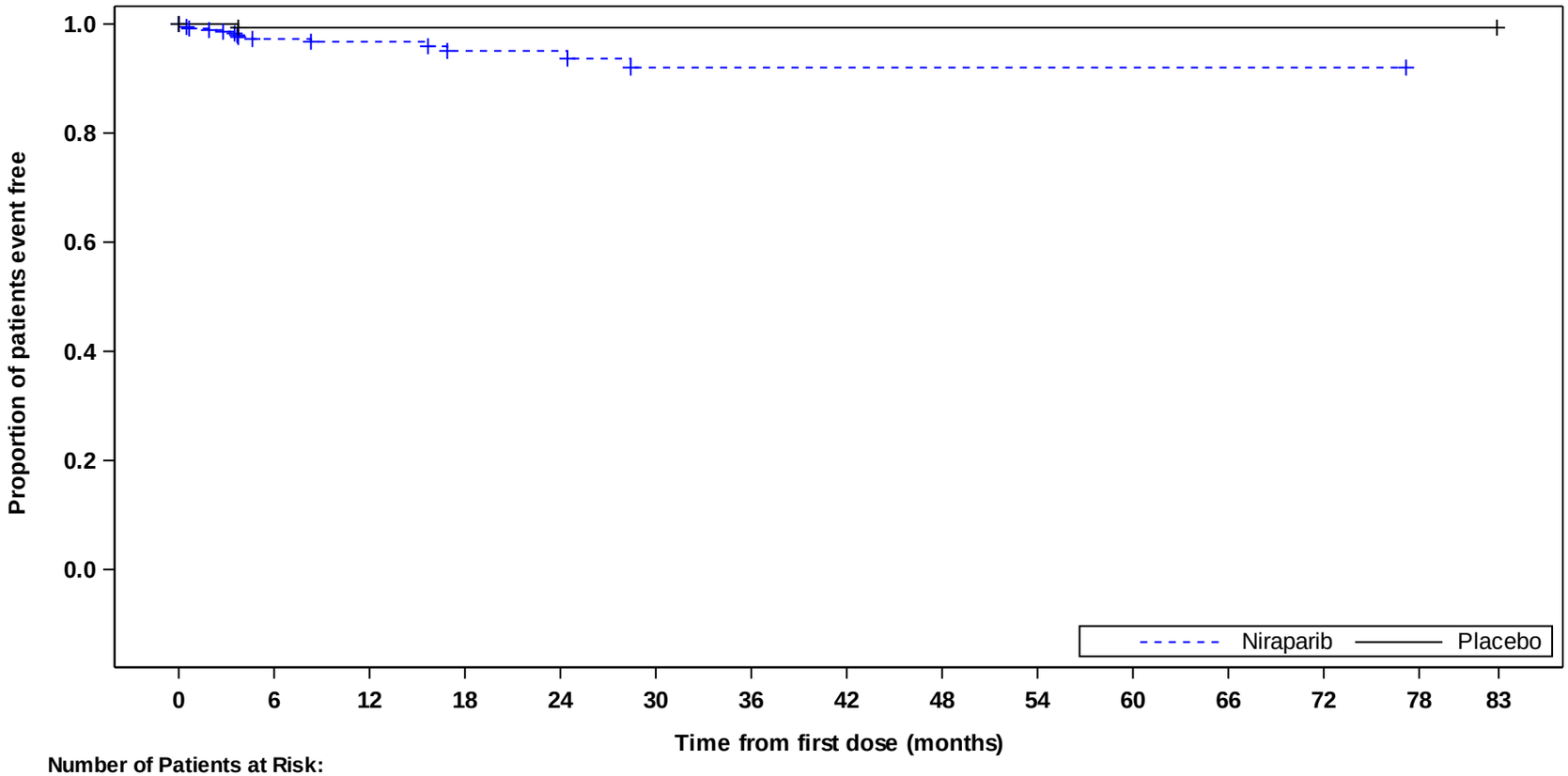
Number of Patients at Risk:

Niraparib	367	200	130	77	52	43	36	28	27	25	22	17	6	0
Placebo	179	91	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:14 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Weight decreased



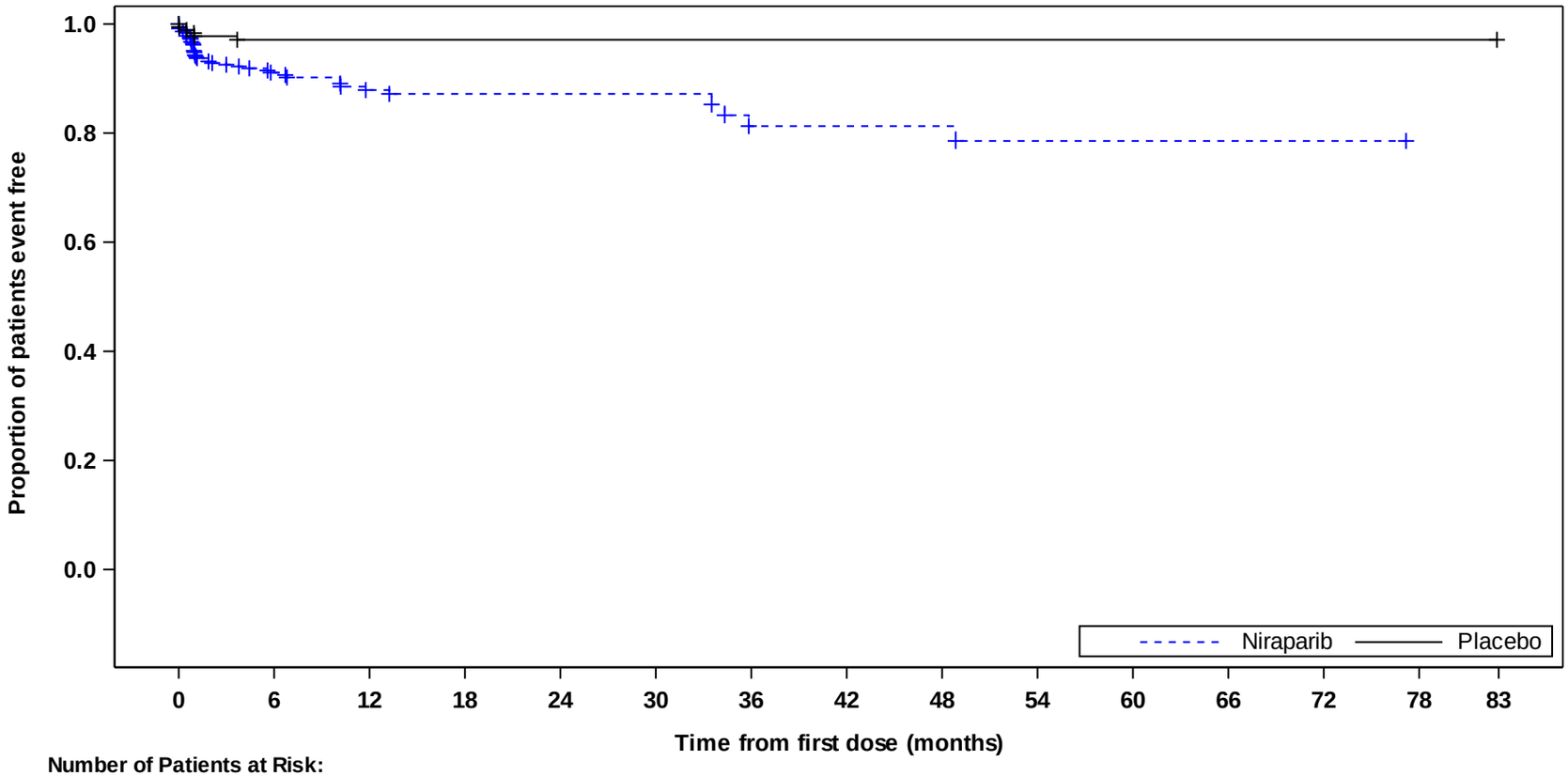
Number of Patients at Risk:

Niraparib	367	239	154	98	68	56	48	39	37	33	28	21	7	0
Placebo	179	91	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:15 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: White blood cell count decreased



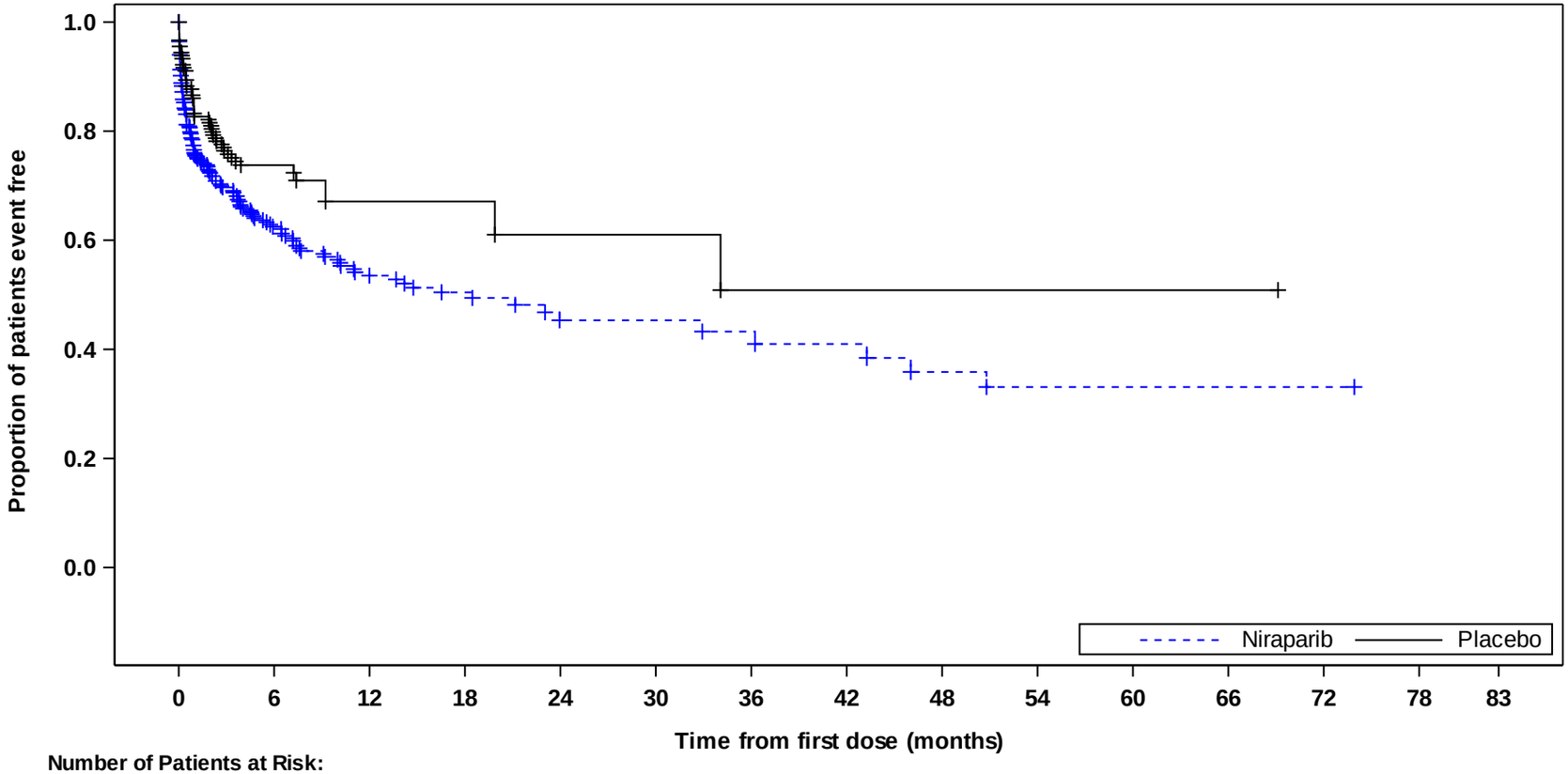
Number of Patients at Risk:

Niraparib	367	225	141	87	59	51	41	32	30	26	21	16	5	0
Placebo	179	89	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:16 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Metabolism and nutrition disorders



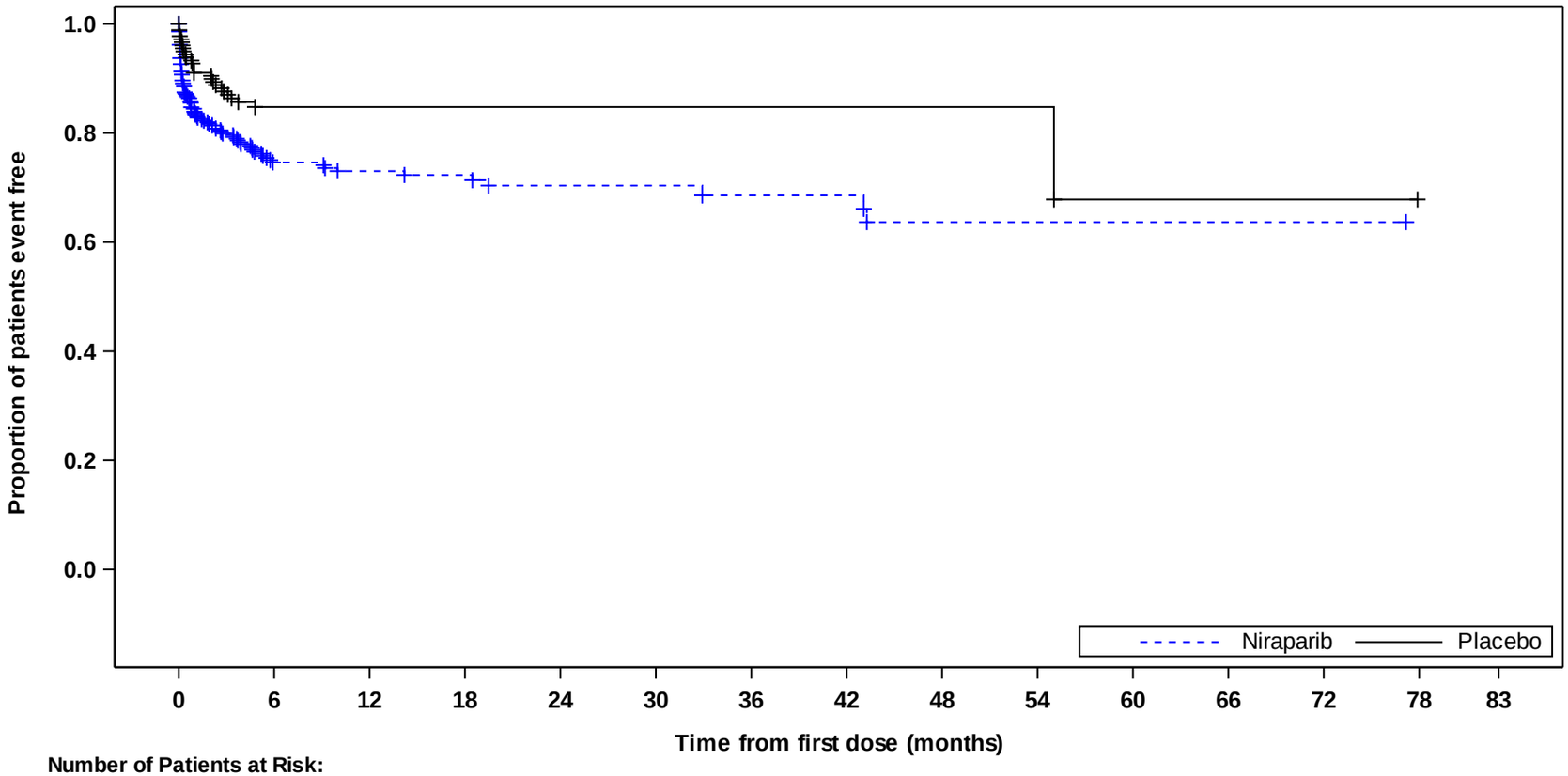
Number of Patients at Risk:

Niraparib	367	152	89	50	31	26	20	16	13	10	8	7	1	0
Placebo	179	66	24	12	7	6	5	4	3	2	2	2	0	

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:17 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Metabolism and nutrition disorders, PT: Decreased appetite



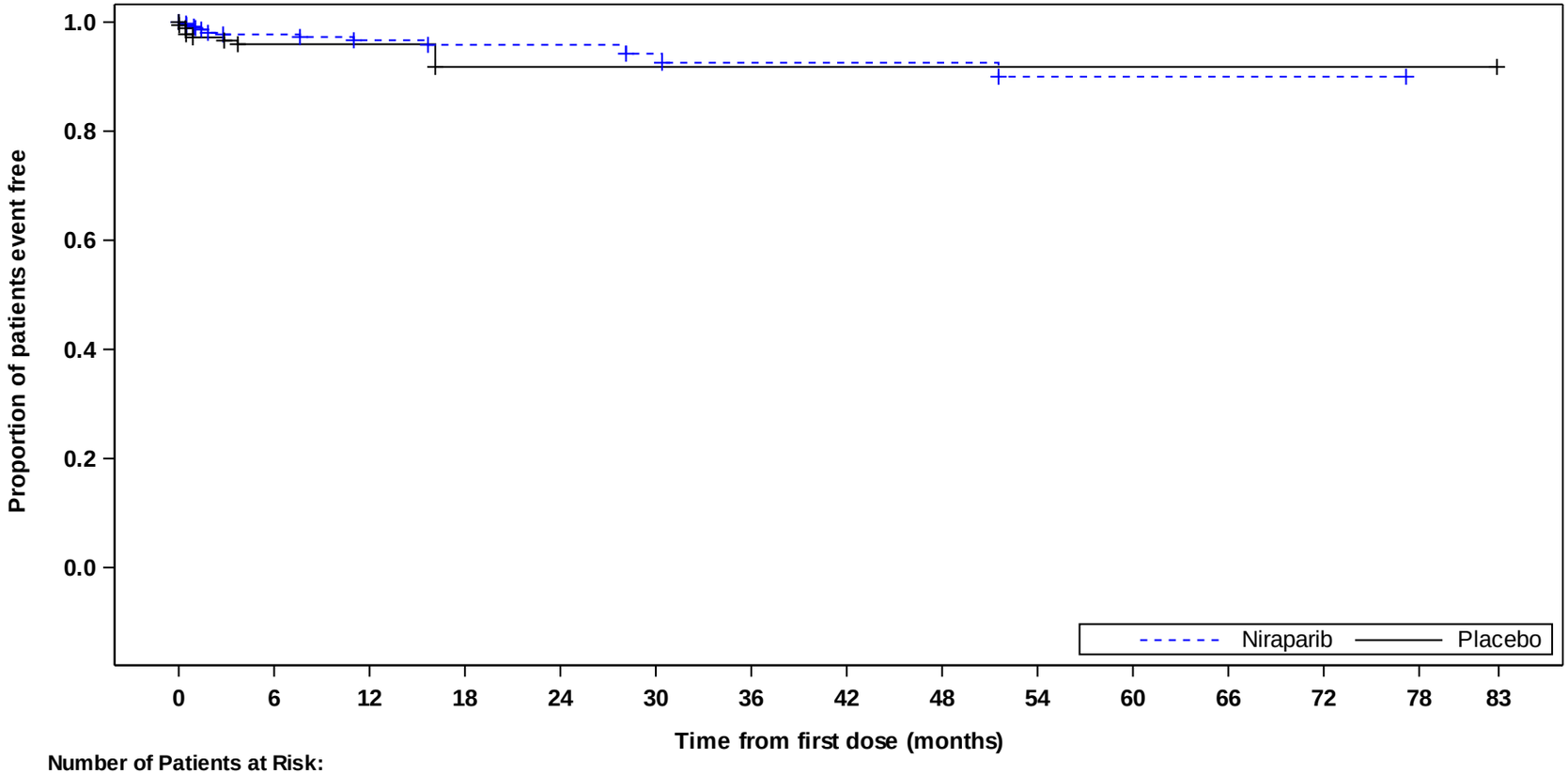
Number of Patients at Risk:

Niraparib	367	183	123	77	53	44	36	28	25	21	19	15	4	0
Placebo	179	77	32	14	9	8	8	7	6	5	4	4	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:18 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Metabolism and nutrition disorders, PT: Hyperglycaemia



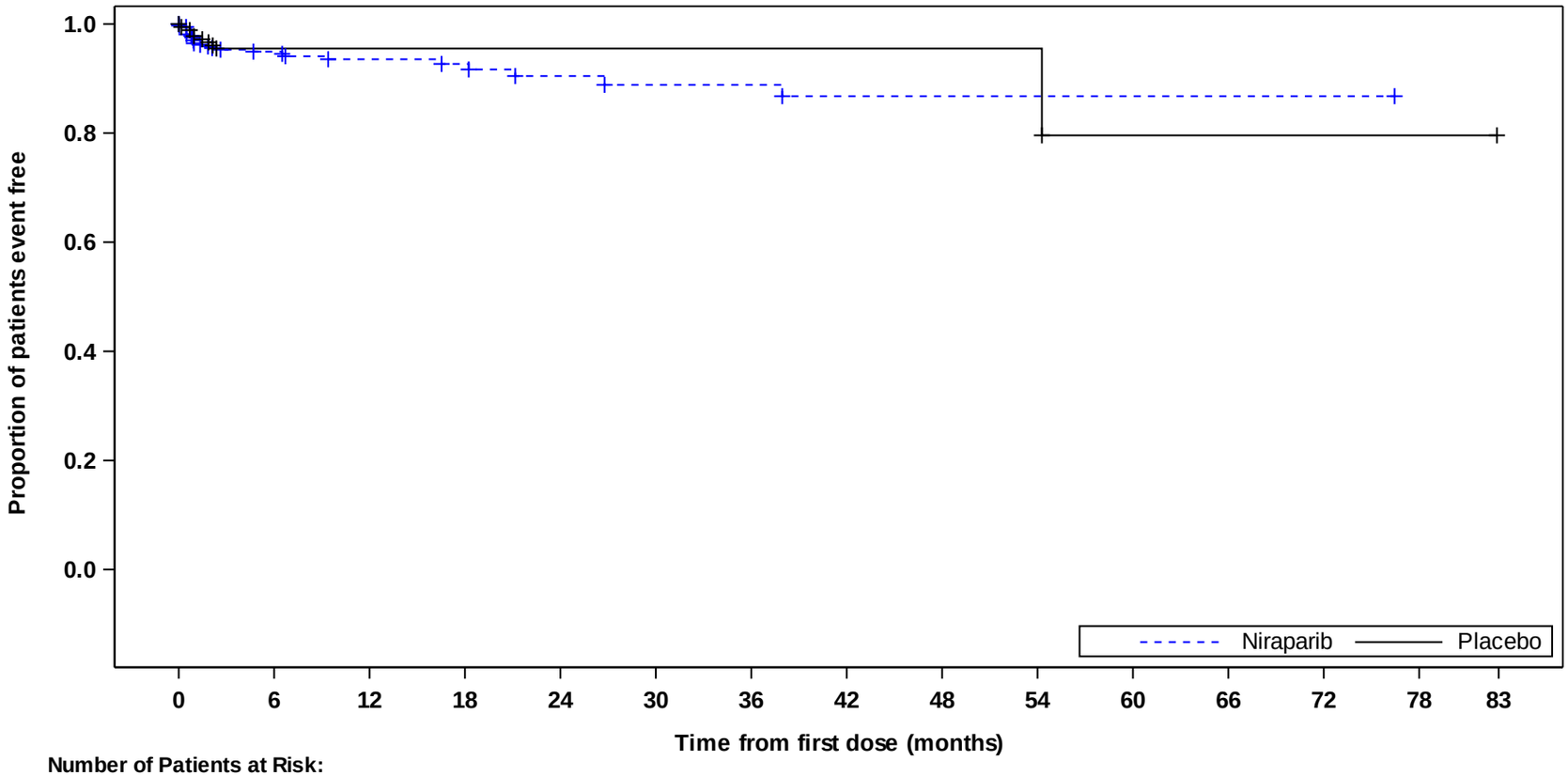
Number of Patients at Risk:

Niraparib	367	241	156	97	68	58	48	39	37	32	27	21	7	0
Placebo	179	89	35	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:19 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Metabolism and nutrition disorders, PT: Hypokalaemia



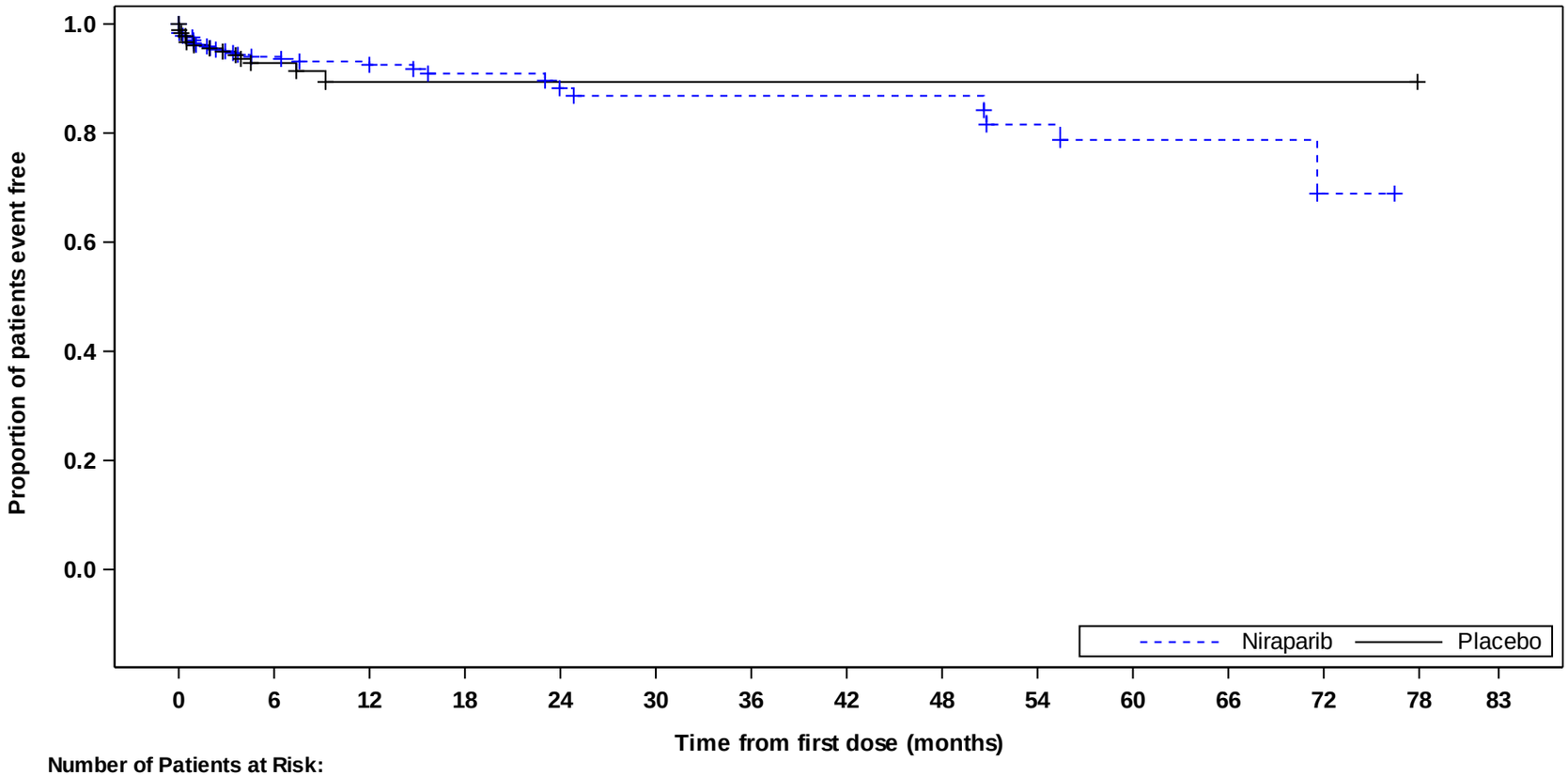
Number of Patients at Risk:

Niraparib	367	234	152	93	63	53	45	37	34	30	26	19	6	0
Placebo	179	88	36	16	10	9	9	8	7	6	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:20 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Metabolism and nutrition disorders, PT: Hypomagnesaemia



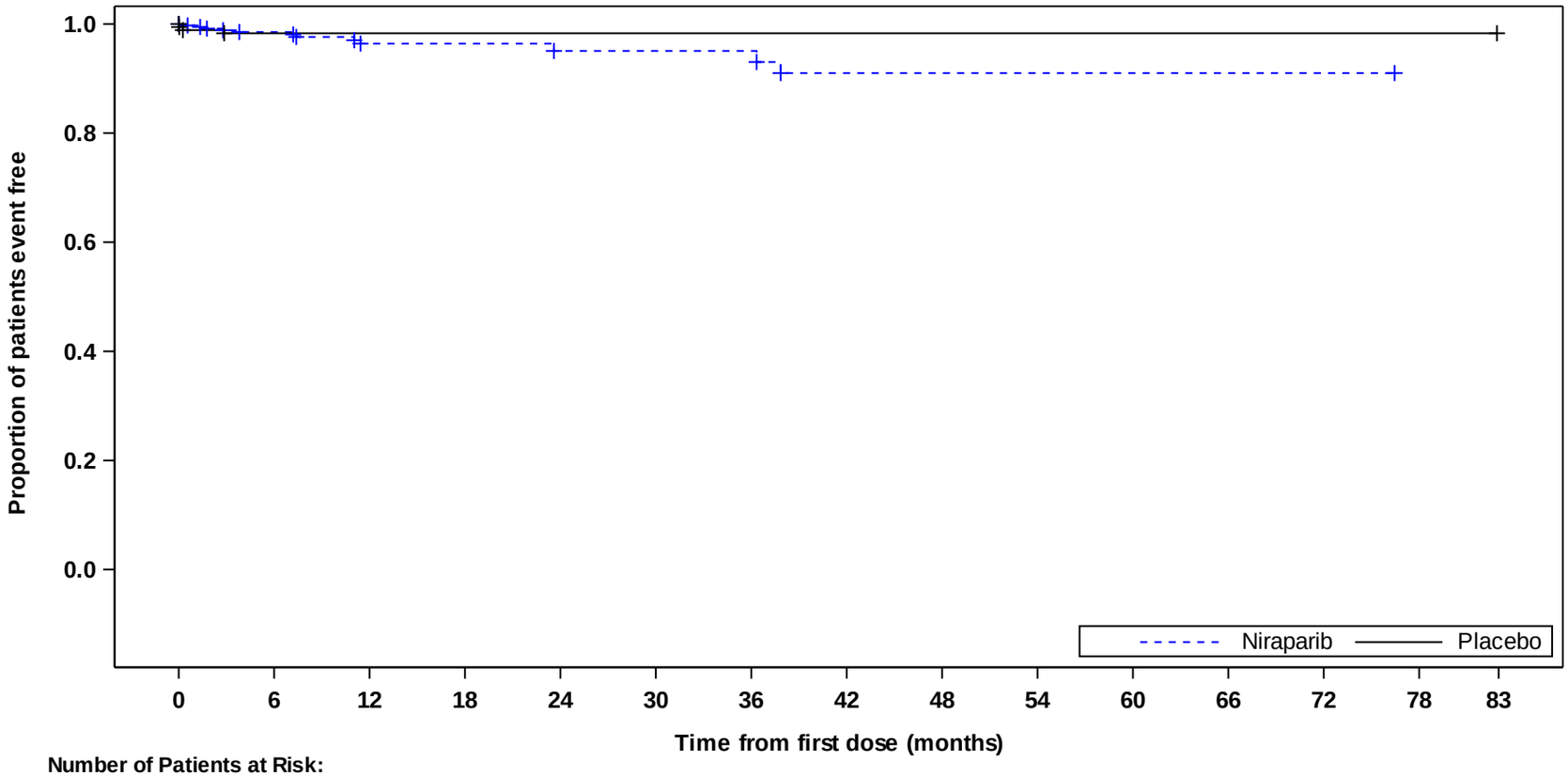
Number of Patients at Risk:

Niraparib	367	234	152	94	64	54	46	38	35	29	25	21	5	0
Placebo	179	83	33	15	9	8	8	7	6	5	5	5	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:21 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Metabolism and nutrition disorders, PT: Hyponatraemia



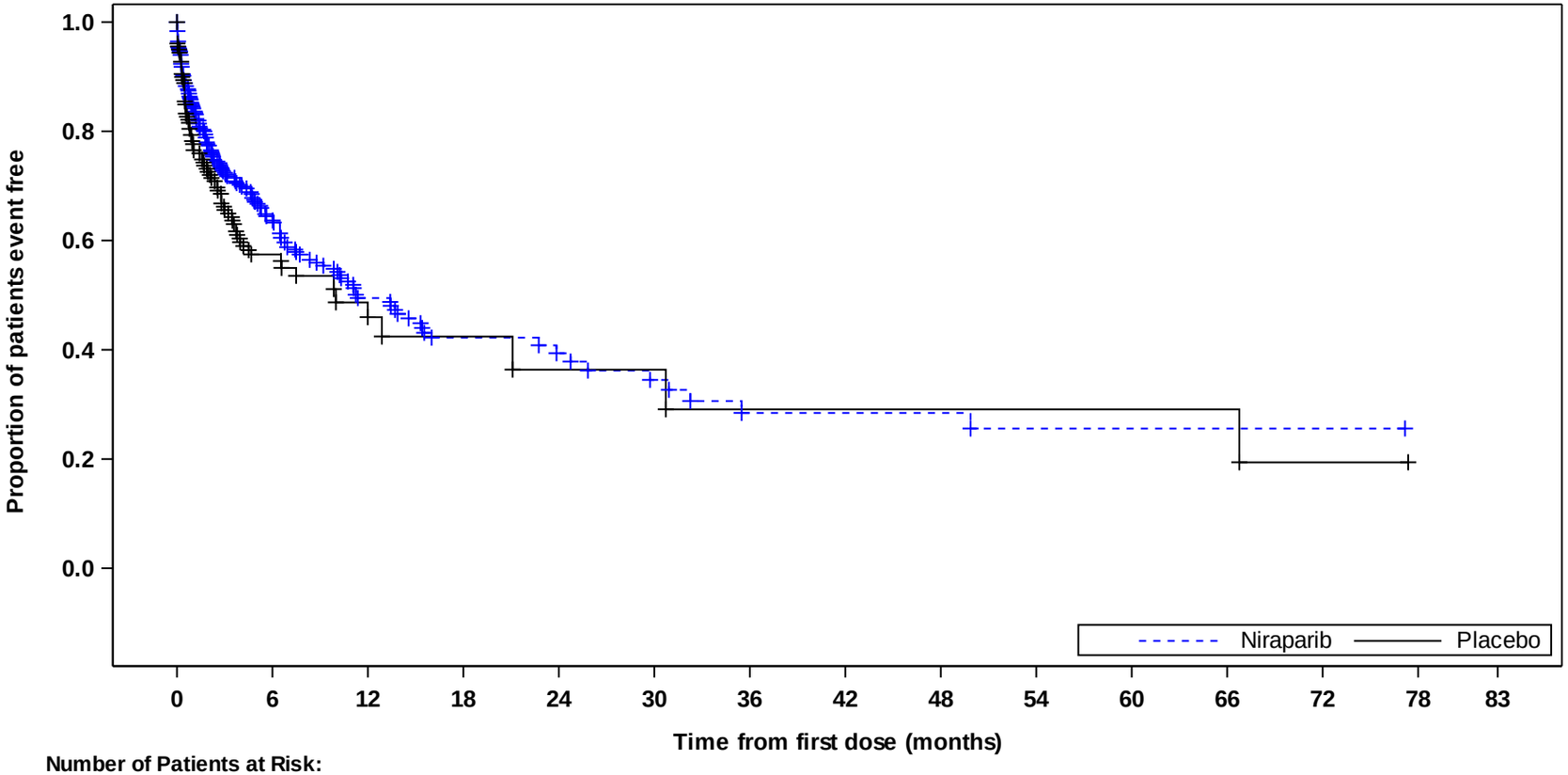
Number of Patients at Risk:

Niraparib	367	245	157	97	68	58	50	38	36	32	27	21	6	0
Placebo	179	91	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:22 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Musculoskeletal and connective tissue disorders



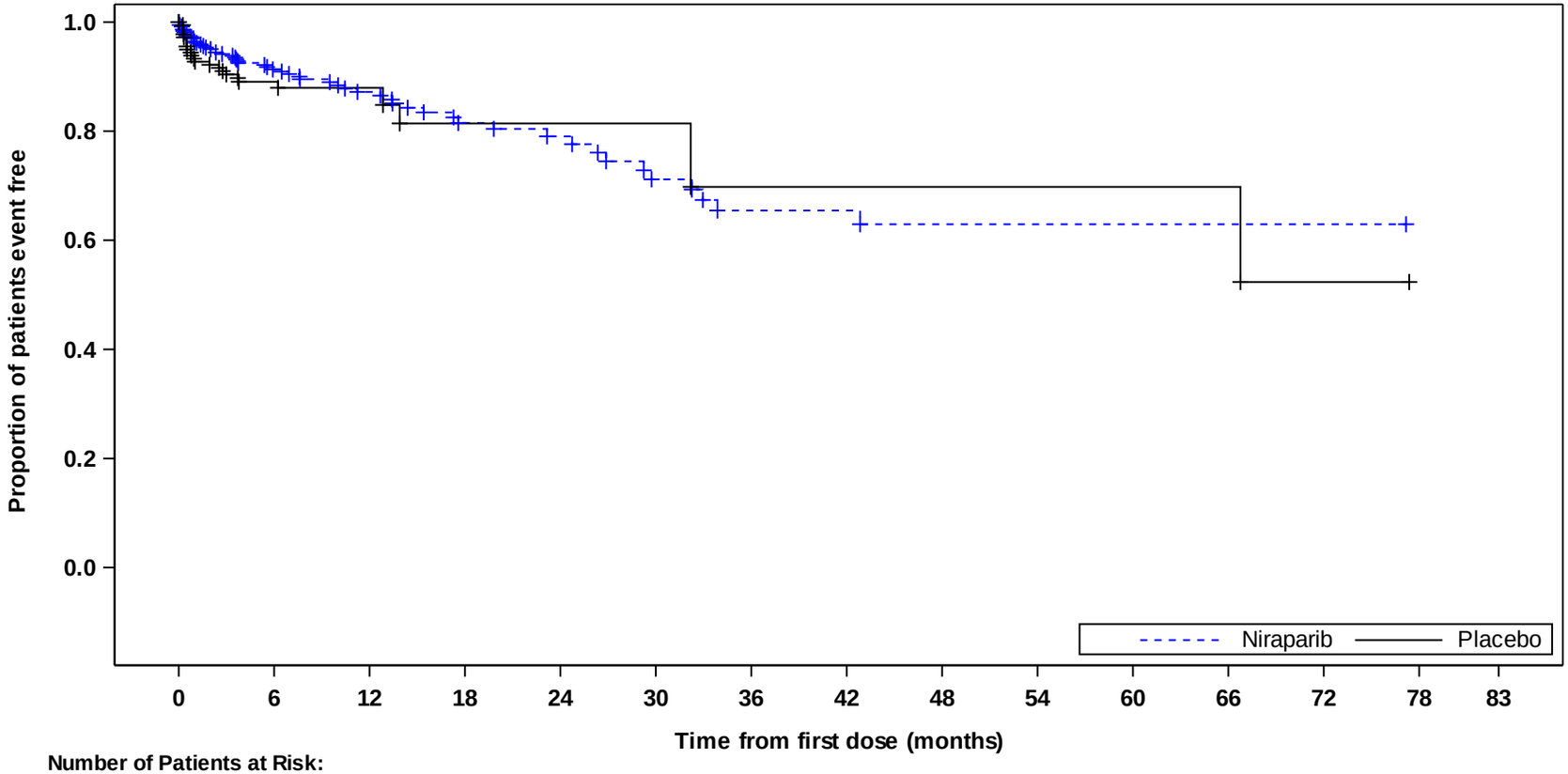
Number of Patients at Risk:

Niraparib	367	165	81	39	26	20	13	11	10	9	9	7	3	0
Placebo	179	50	17	7	5	5	4	3	3	3	3	3	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:23 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia



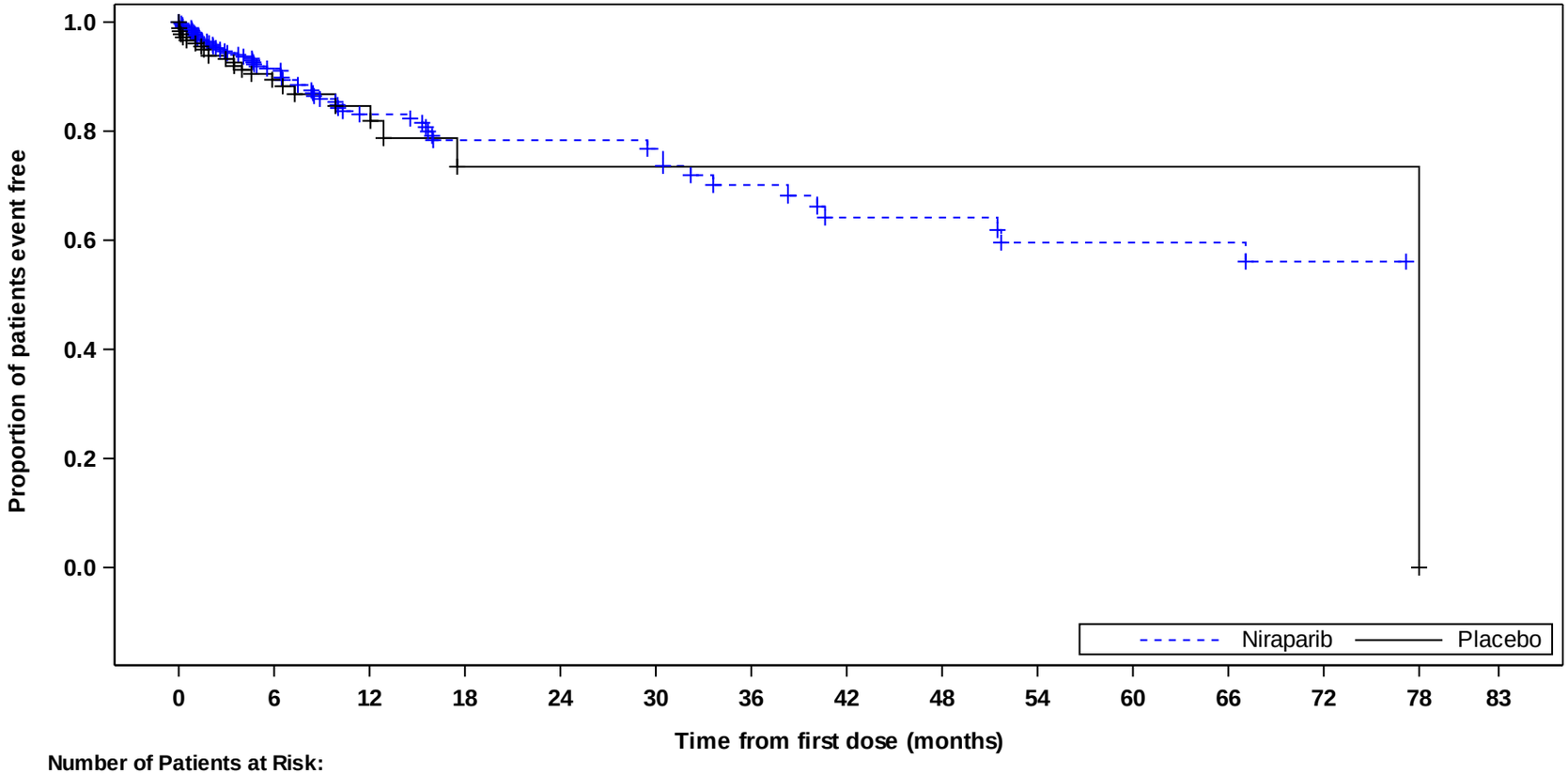
Number of Patients at Risk:

Niraparib	367	224	139	80	55	43	33	26	23	20	18	16	6	0
Placebo	179	80	32	13	8	7	6	5	4	4	4	4	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:24 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Musculoskeletal and connective tissue disorders, PT: Back pain



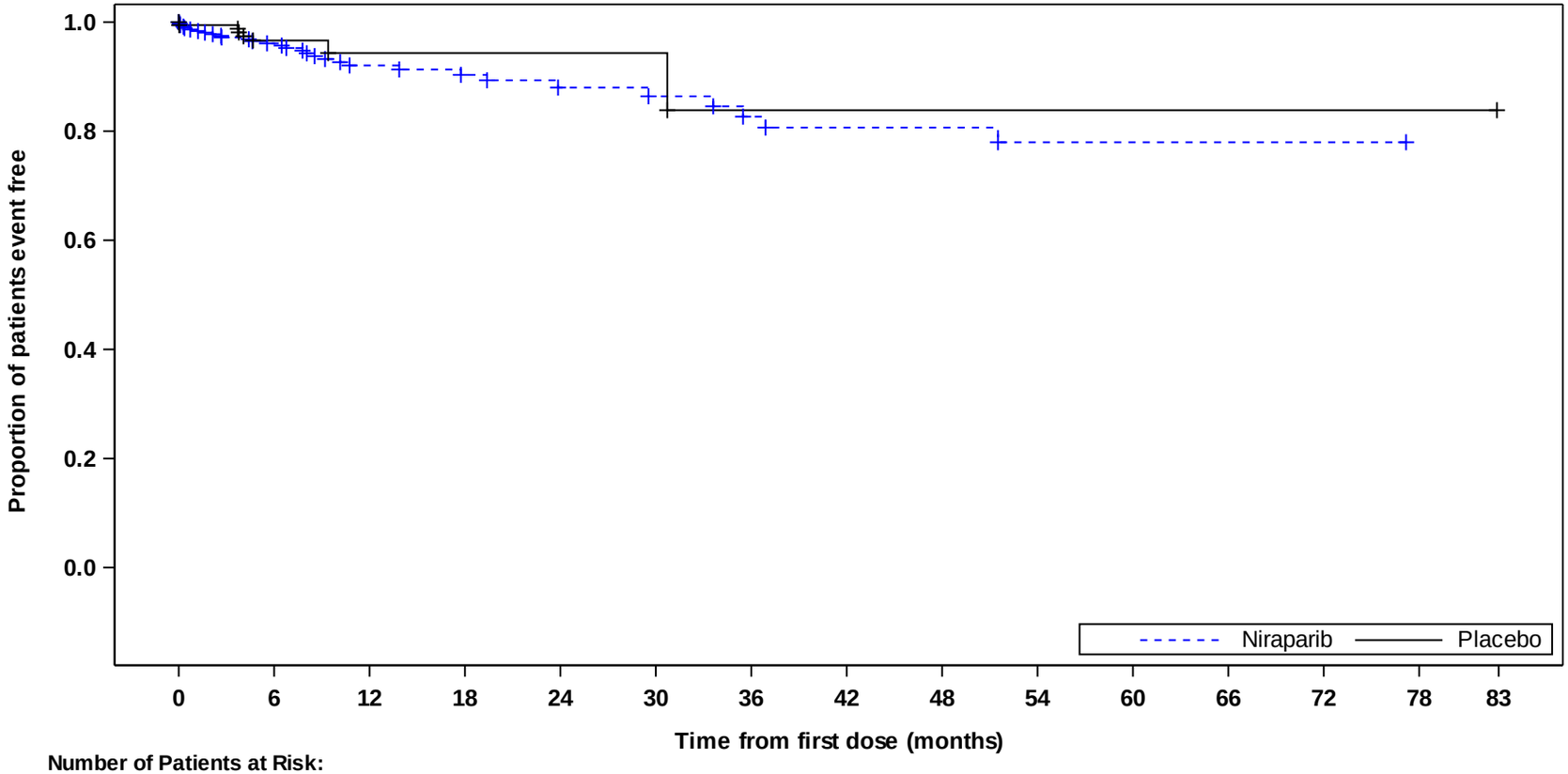
Number of Patients at Risk:

Niraparib	367	225	139	84	58	49	38	30	28	23	21	18	7	0
Placebo	179	81	32	12	7	7	7	6	6	6	6	6	3	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:24 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Musculoskeletal and connective tissue disorders, PT: Muscle spasms



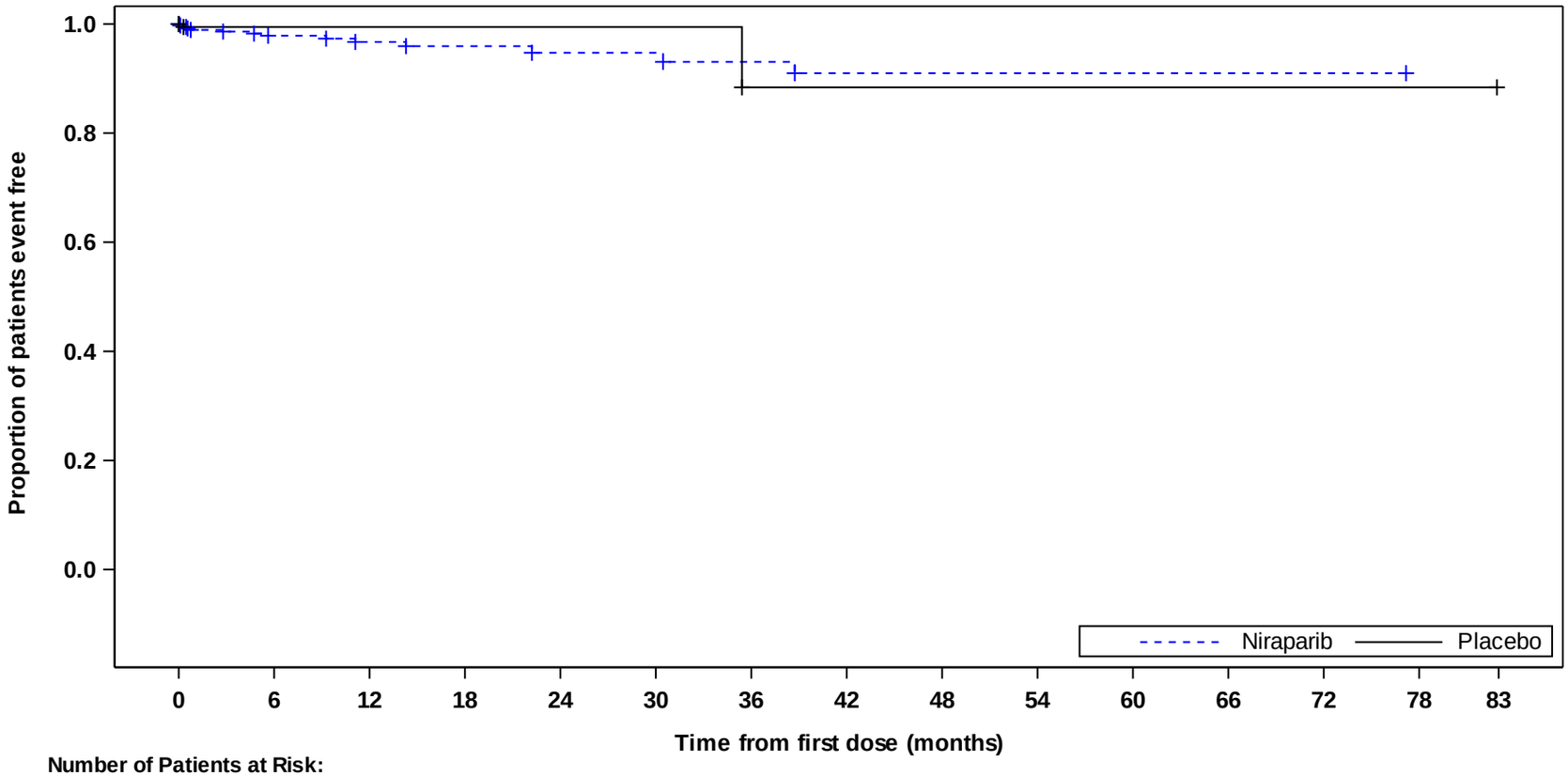
Number of Patients at Risk:

Niraparib	367	239	150	91	65	54	44	33	31	26	21	16	5	0
Placebo	179	87	34	15	9	9	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:25 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Musculoskeletal and connective tissue disorders, PT: Muscular weakness



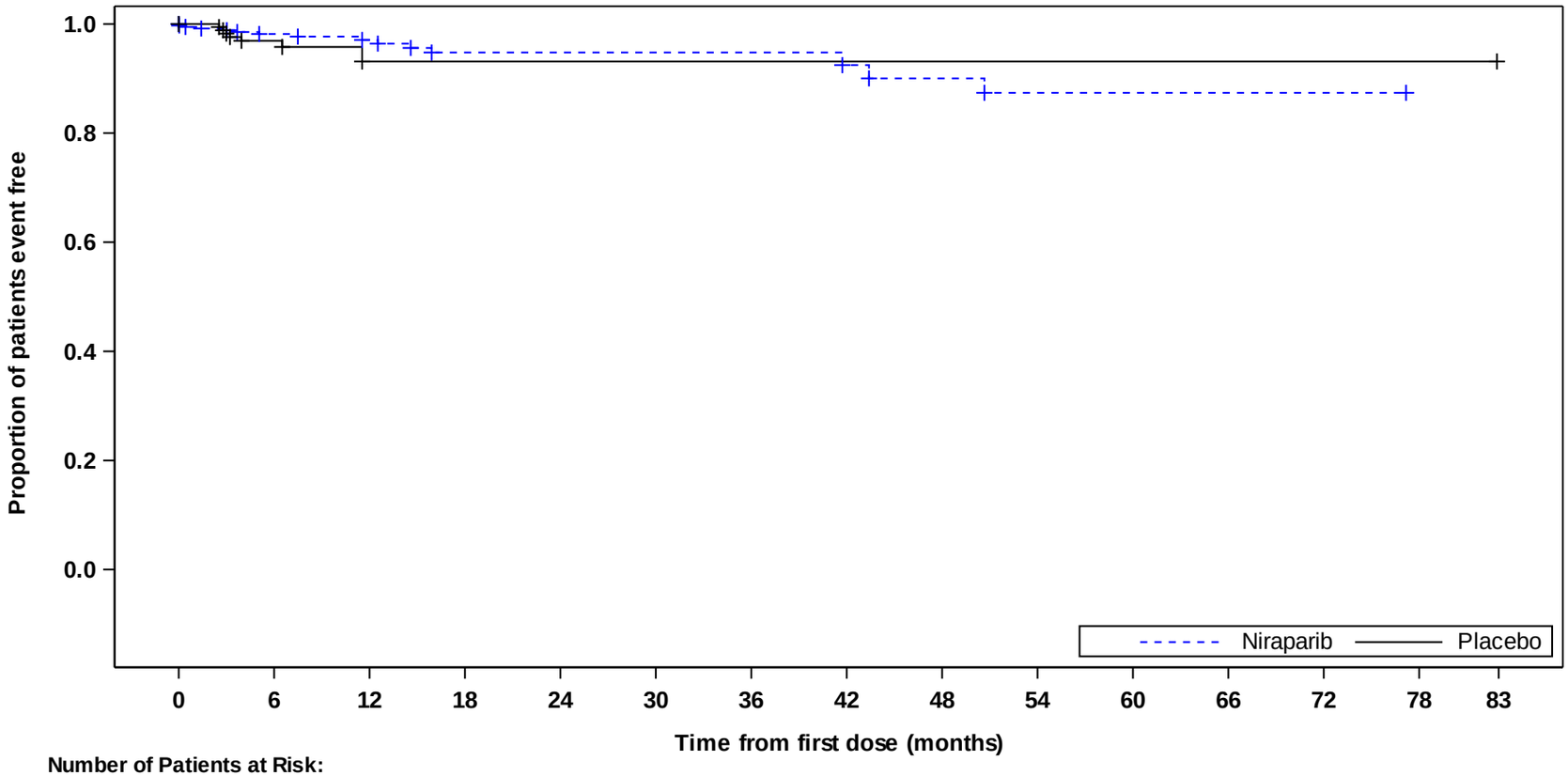
Number of Patients at Risk:

Niraparib	367	242	158	98	68	58	49	40	37	33	28	21	6	0
Placebo	179	92	37	16	10	9	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:26 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Musculoskeletal and connective tissue disorders, PT: Musculoskeletal chest pain



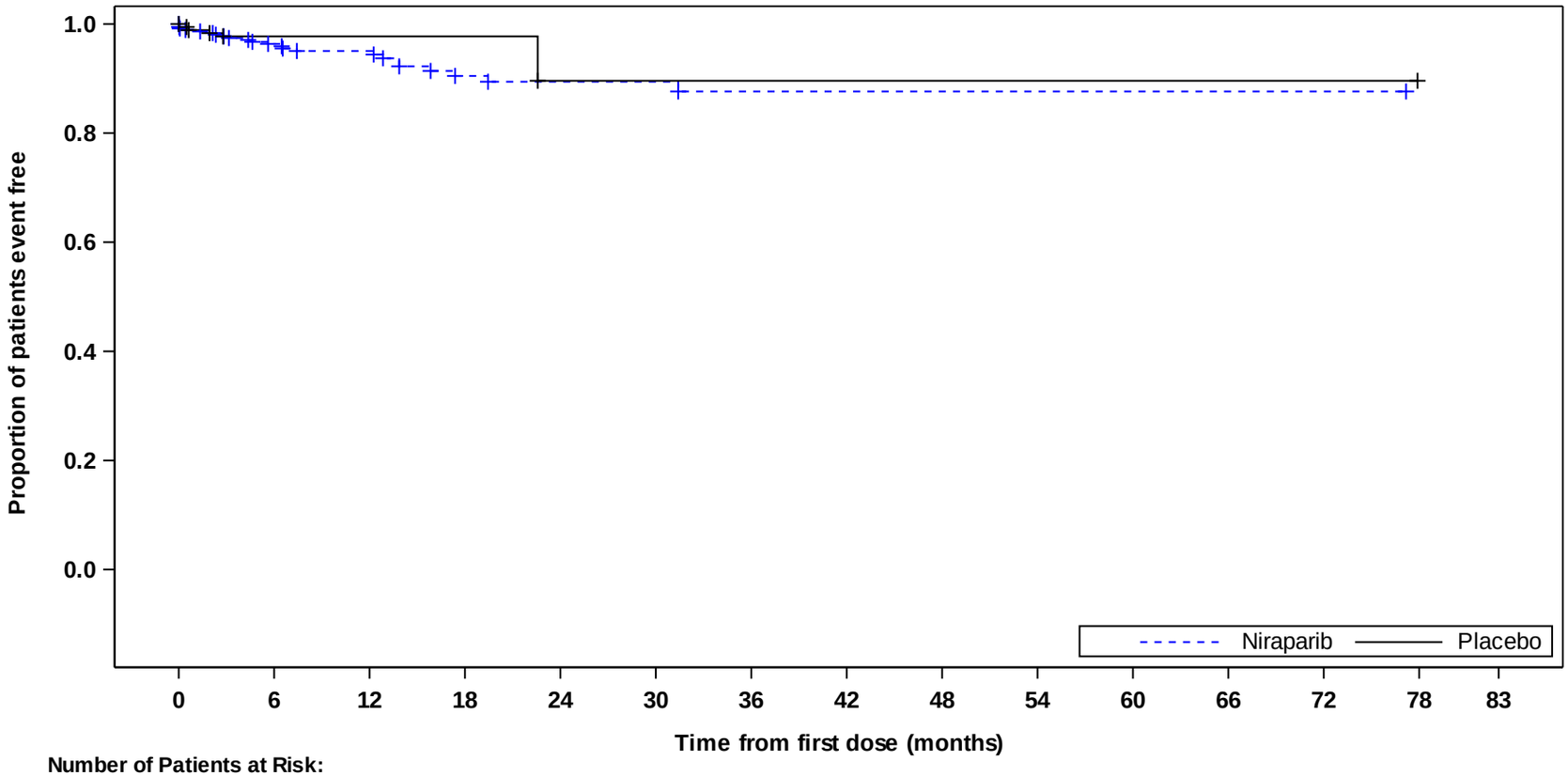
Number of Patients at Risk:

Niraparib	367	243	157	95	68	58	49	39	35	30	26	19	7	0
Placebo	179	91	34	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:27 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Musculoskeletal and connective tissue disorders, PT: Musculoskeletal pain



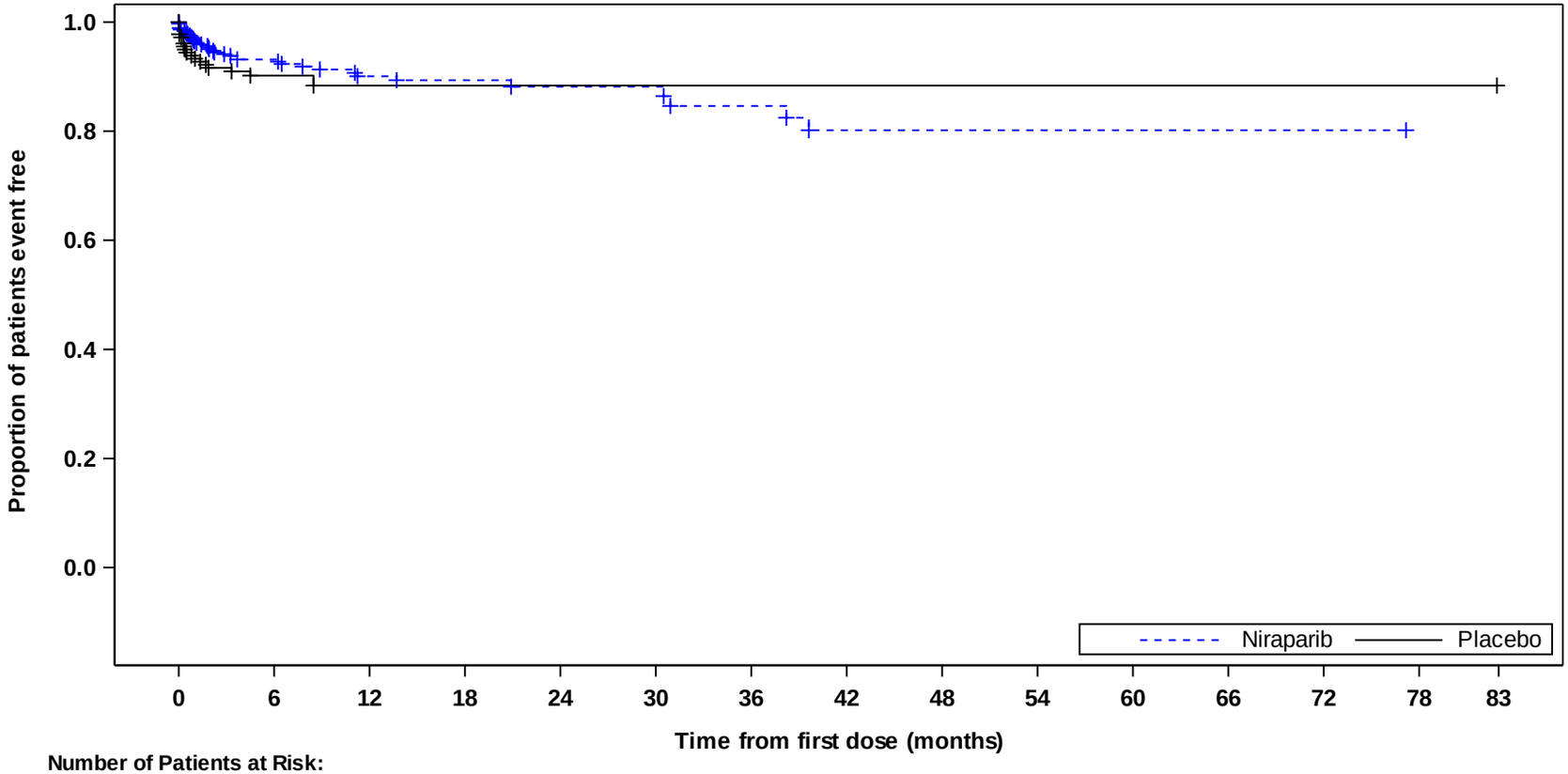
Number of Patients at Risk:

Niraparib	367	237	154	89	64	54	45	37	35	31	26	20	7	0
Placebo	179	88	36	15	9	8	8	7	6	5	5	5	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:28 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia



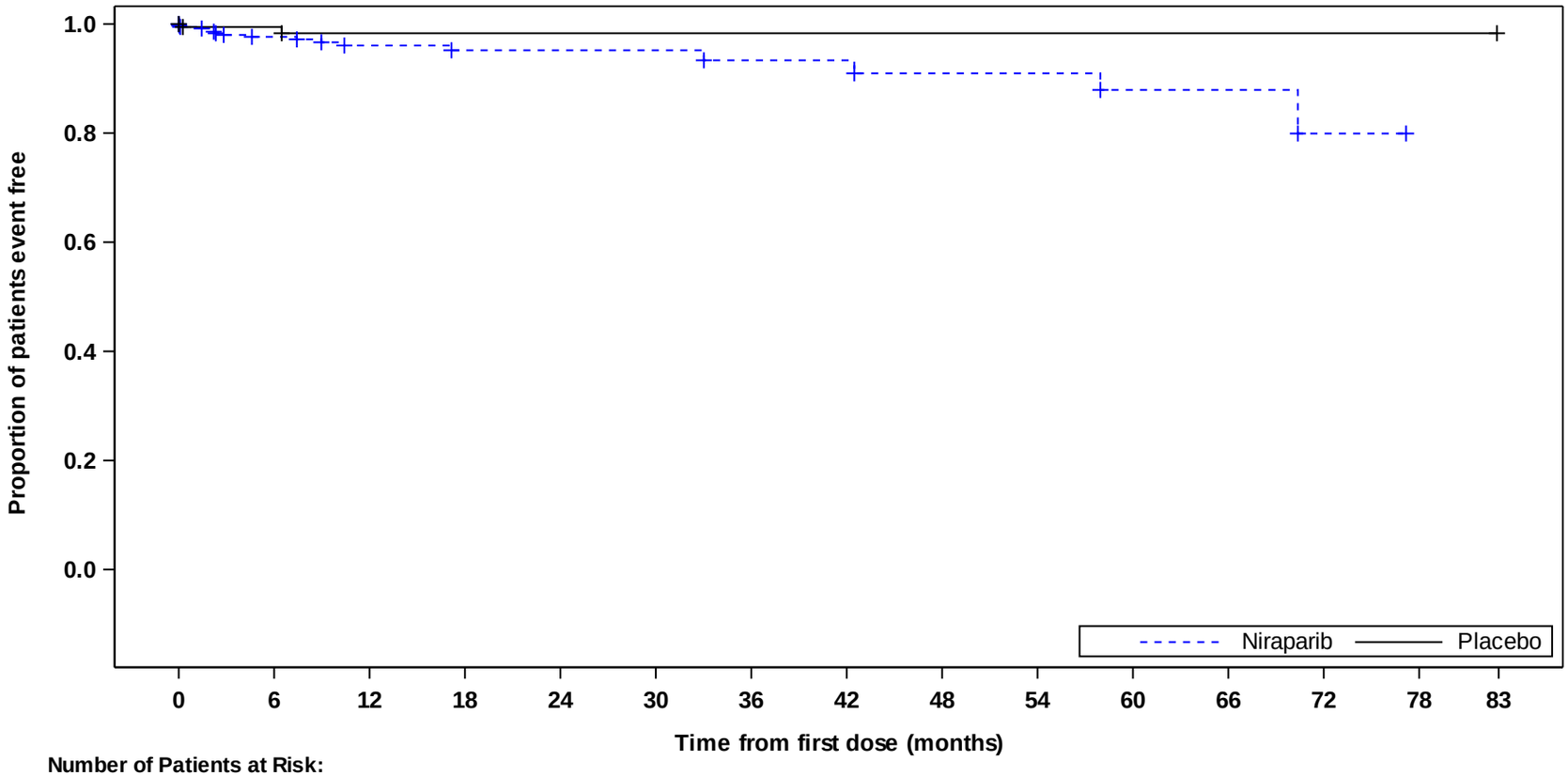
Number of Patients at Risk:

Niraparib	367	228	144	87	61	52	42	34	32	28	24	18	6	0
Placebo	179	83	33	15	9	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:29 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Musculoskeletal and connective tissue disorders, PT: Neck pain



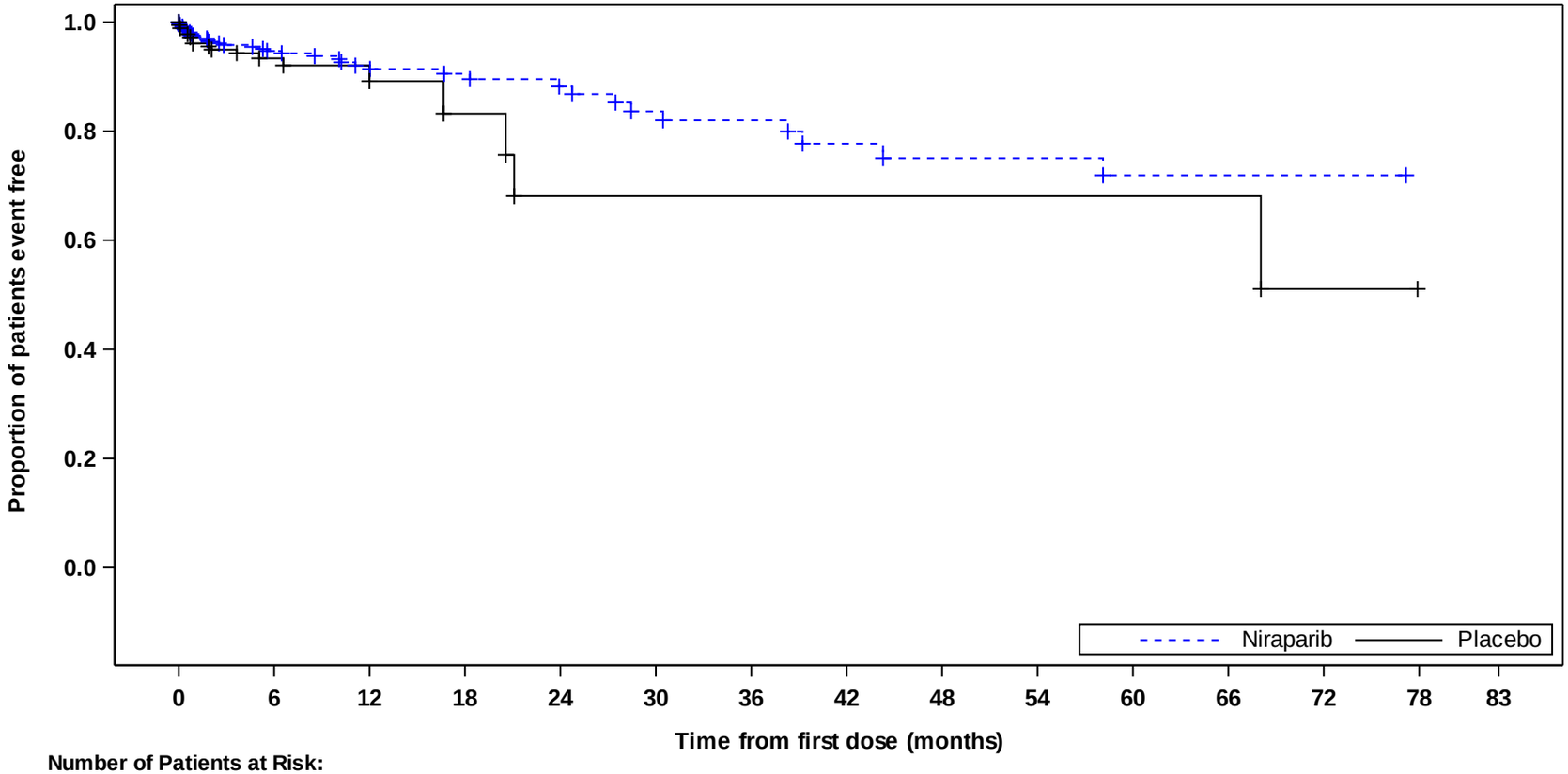
Number of Patients at Risk:

Niraparib	367	240	155	97	69	59	49	40	36	32	27	21	6	0
Placebo	179	91	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:30 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Musculoskeletal and connective tissue disorders, PT: Pain in extremity



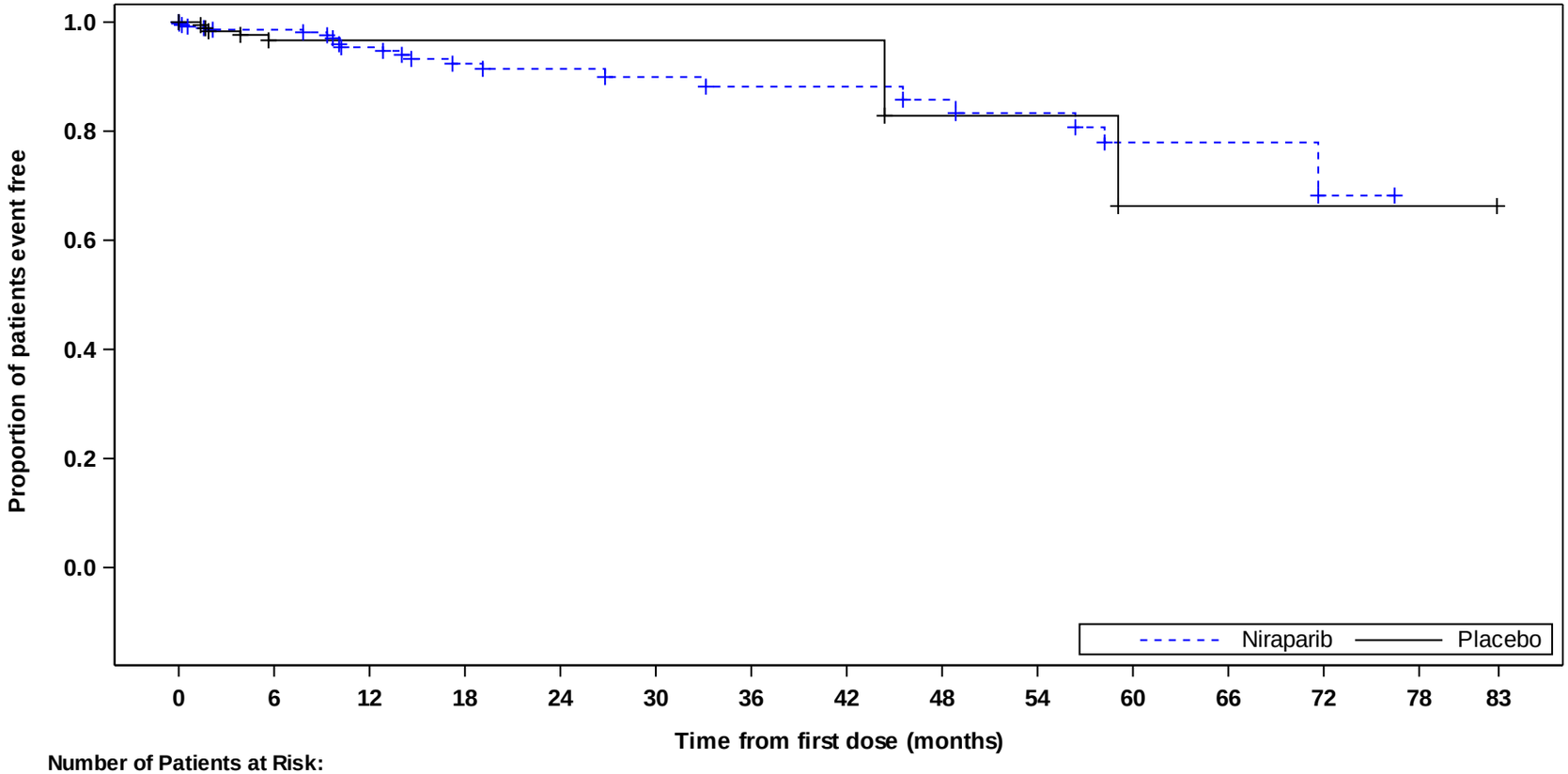
Number of Patients at Risk:

Niraparib	367	236	149	93	64	52	42	31	27	25	21	17	7	0
Placebo	179	85	31	12	7	6	6	5	4	4	4	4	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:32 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)



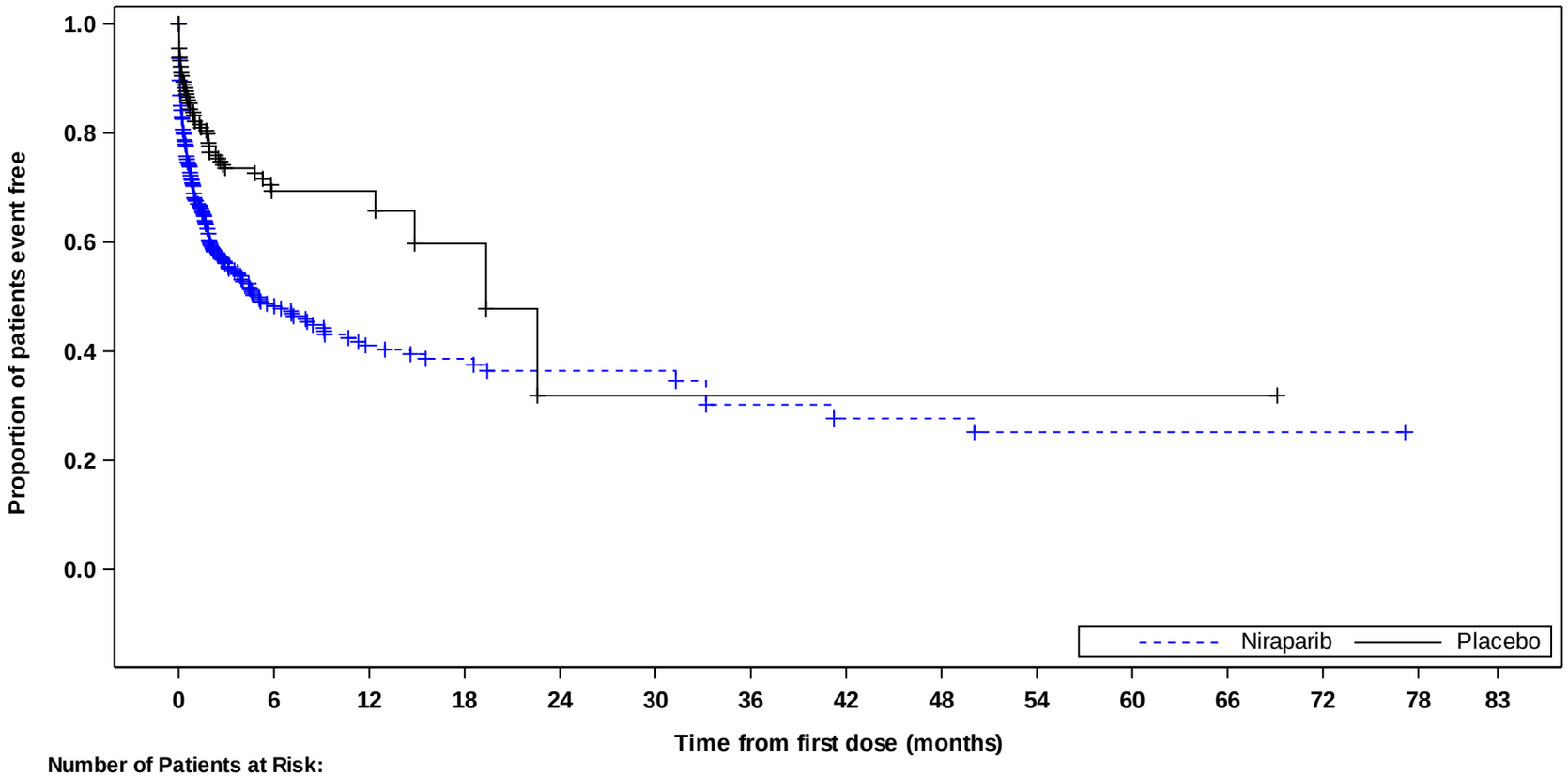
Number of Patients at Risk:

Niraparib	367	245	159	98	68	58	49	39	35	32	26	19	5	0
Placebo	179	91	36	16	10	9	9	8	6	5	4	4	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:33 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Nervous system disorders



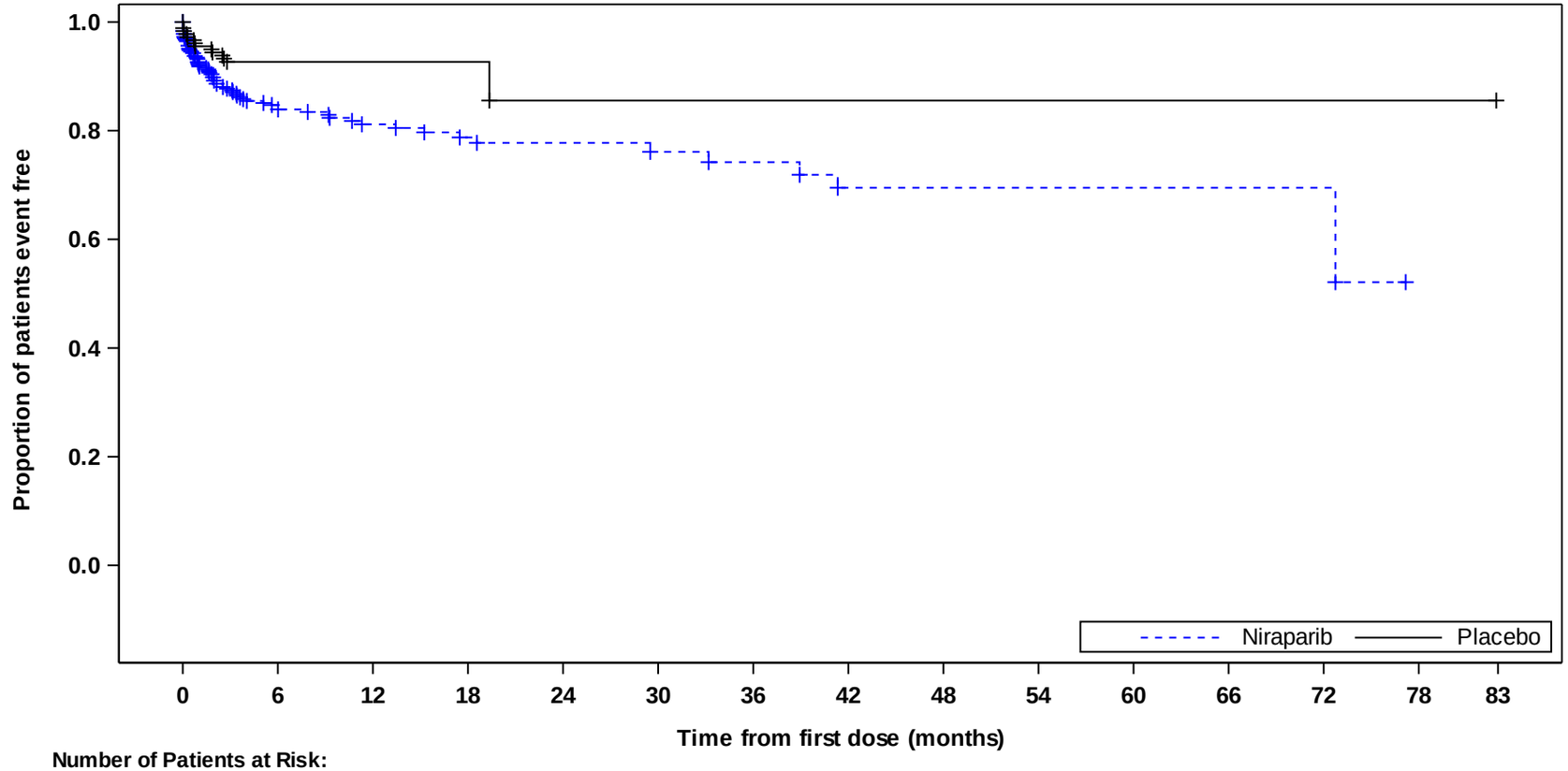
Number of Patients at Risk:

Niraparib	367	113	59	36	25	22	14	11	11	10	9	7	2	0
Placebo	179	58	22	6	2	2	2	1	1	1	1	1	0	

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:33 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Nervous system disorders, PT: Dizziness



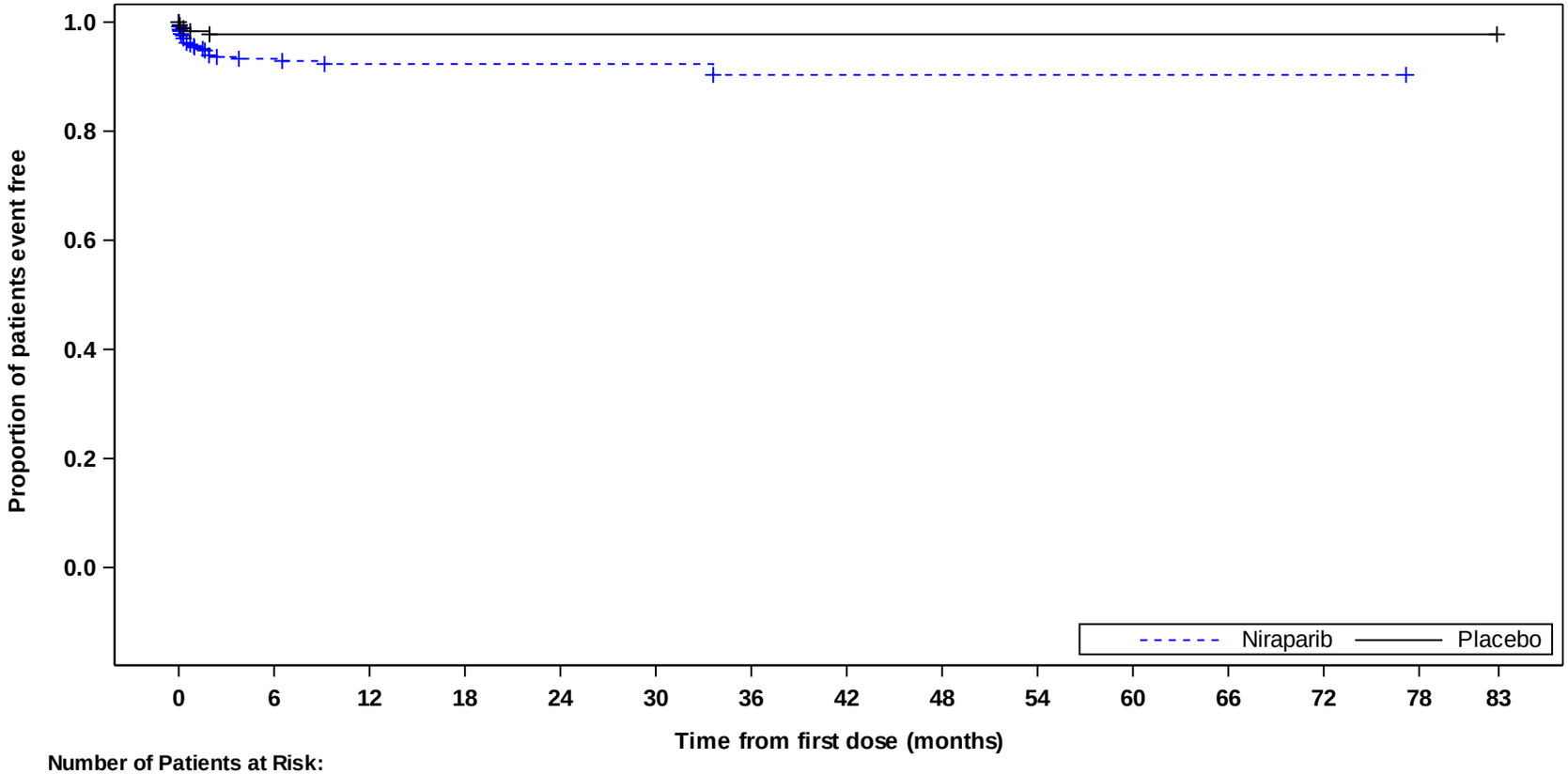
Number of Patients at Risk:

Niraparib	367	211	134	80	54	46	37	27	24	21	18	15	4	0
Placebo	179	84	34	15	8	7	7	6	5	4	4	4	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:34 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Nervous system disorders, PT: Dysgeusia



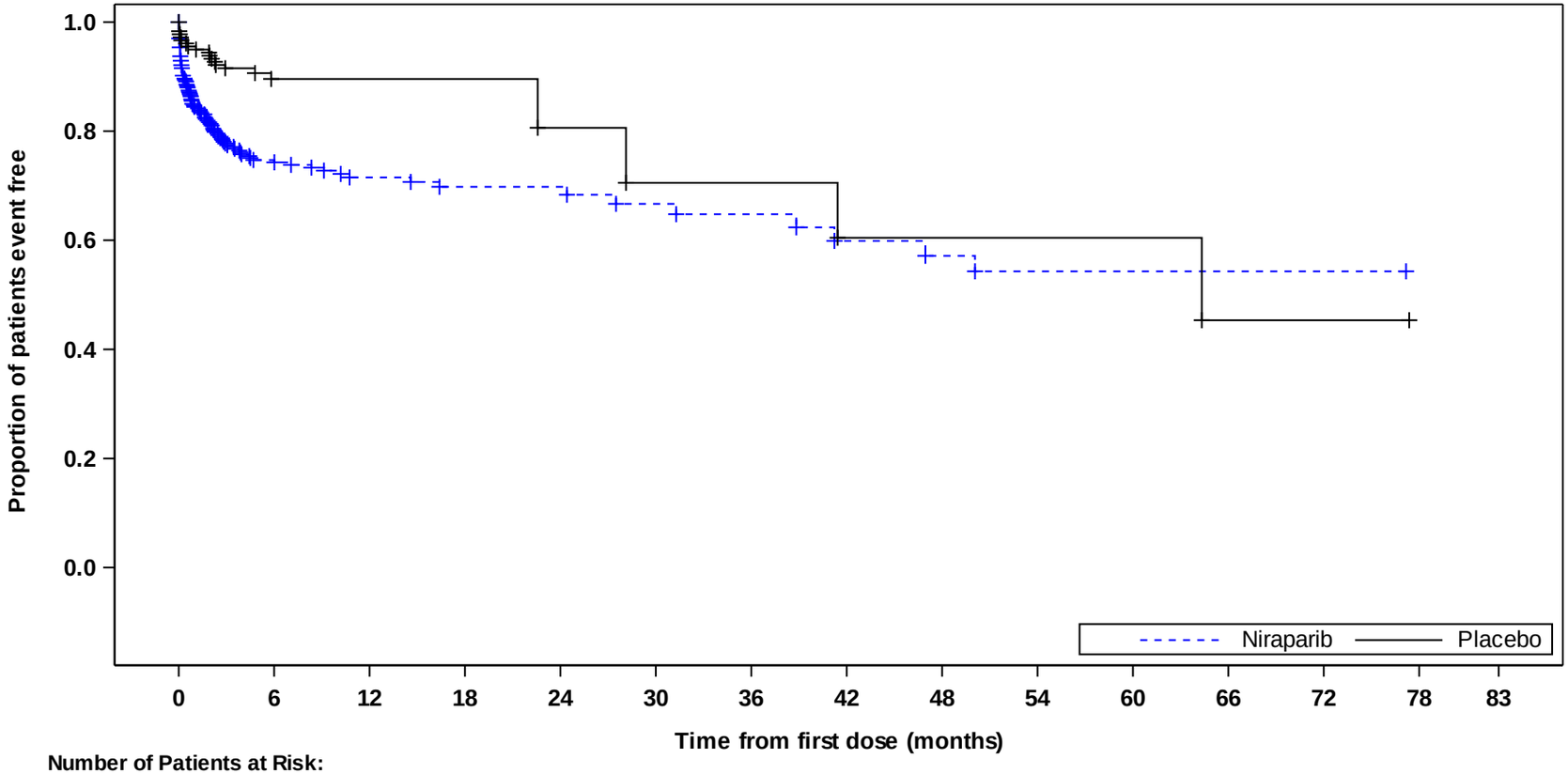
Number of Patients at Risk:

Niraparib	367	226	147	88	63	54	44	37	35	32	27	21	7	0
Placebo	179	90	36	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:35 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Nervous system disorders, PT: Headache



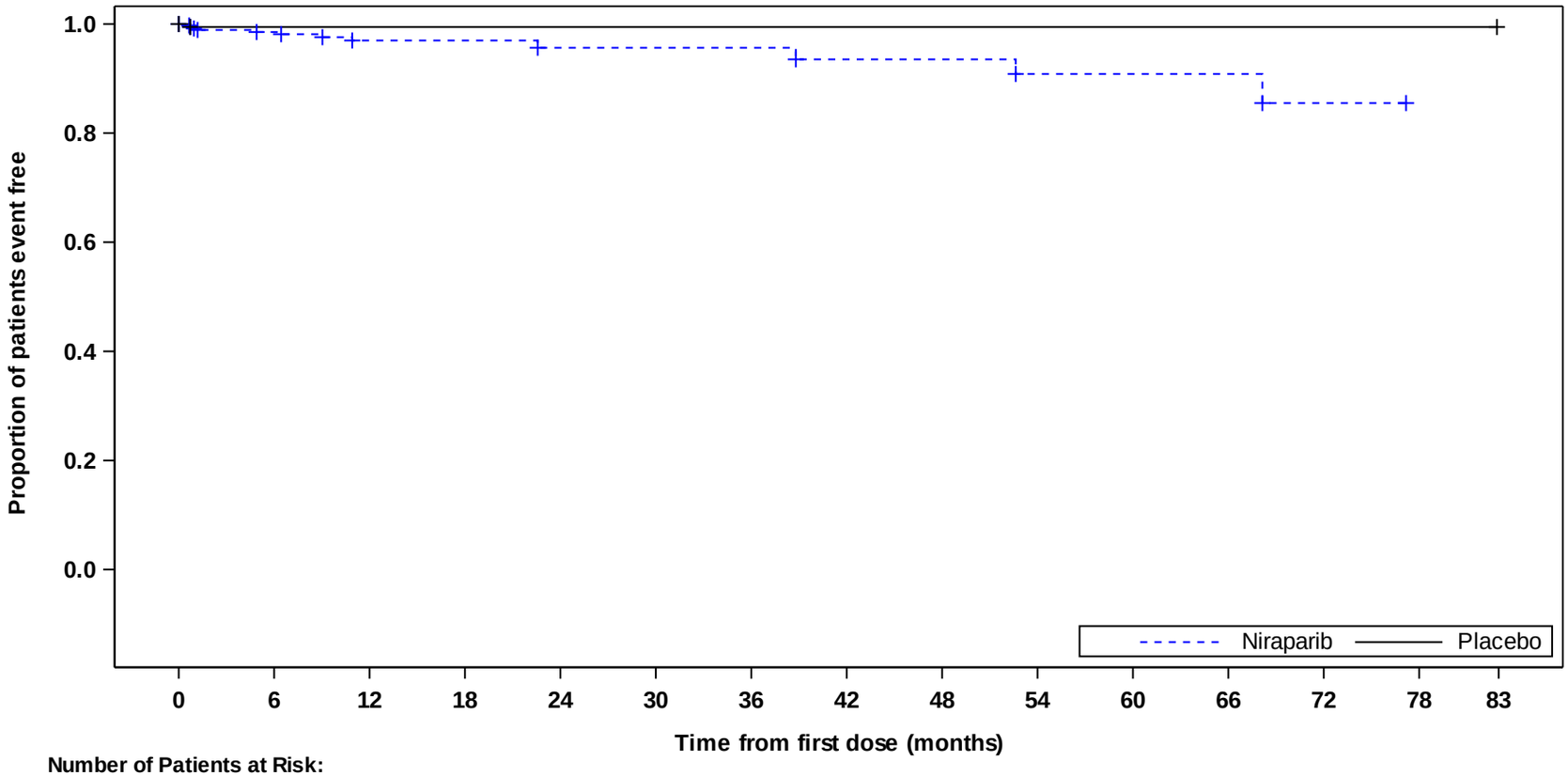
Number of Patients at Risk:

Niraparib	367	178	109	65	48	39	31	23	21	18	14	11	4	0
Placebo	179	79	32	14	8	7	7	5	4	4	4	3	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:36 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Nervous system disorders, PT: Hypoaesthesia



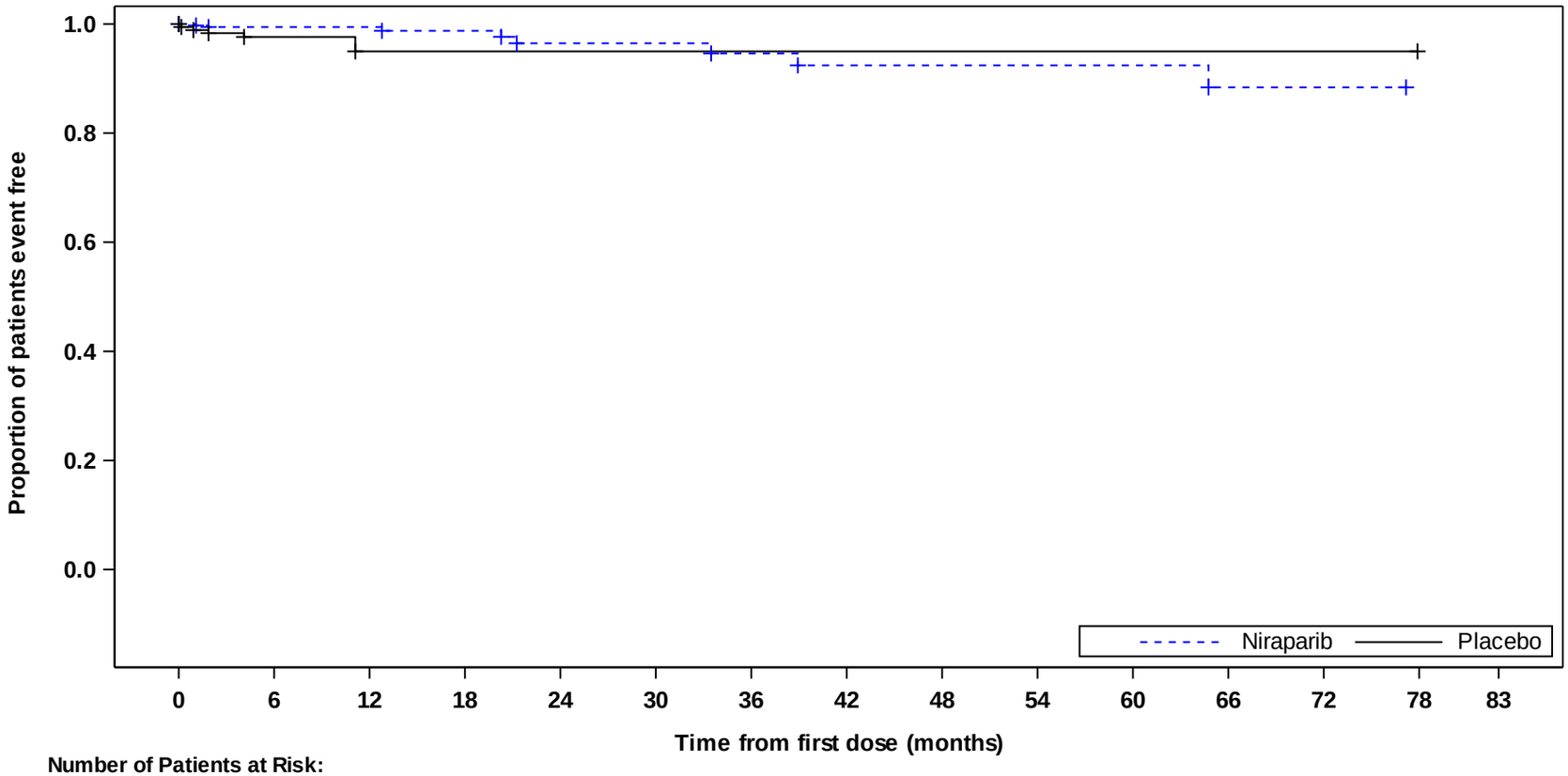
Number of Patients at Risk:

Niraparib	367	242	156	98	68	59	50	39	36	32	27	20	6	0
Placebo	179	91	36	15	9	8	8	7	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:37 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Nervous system disorders, PT: Migraine



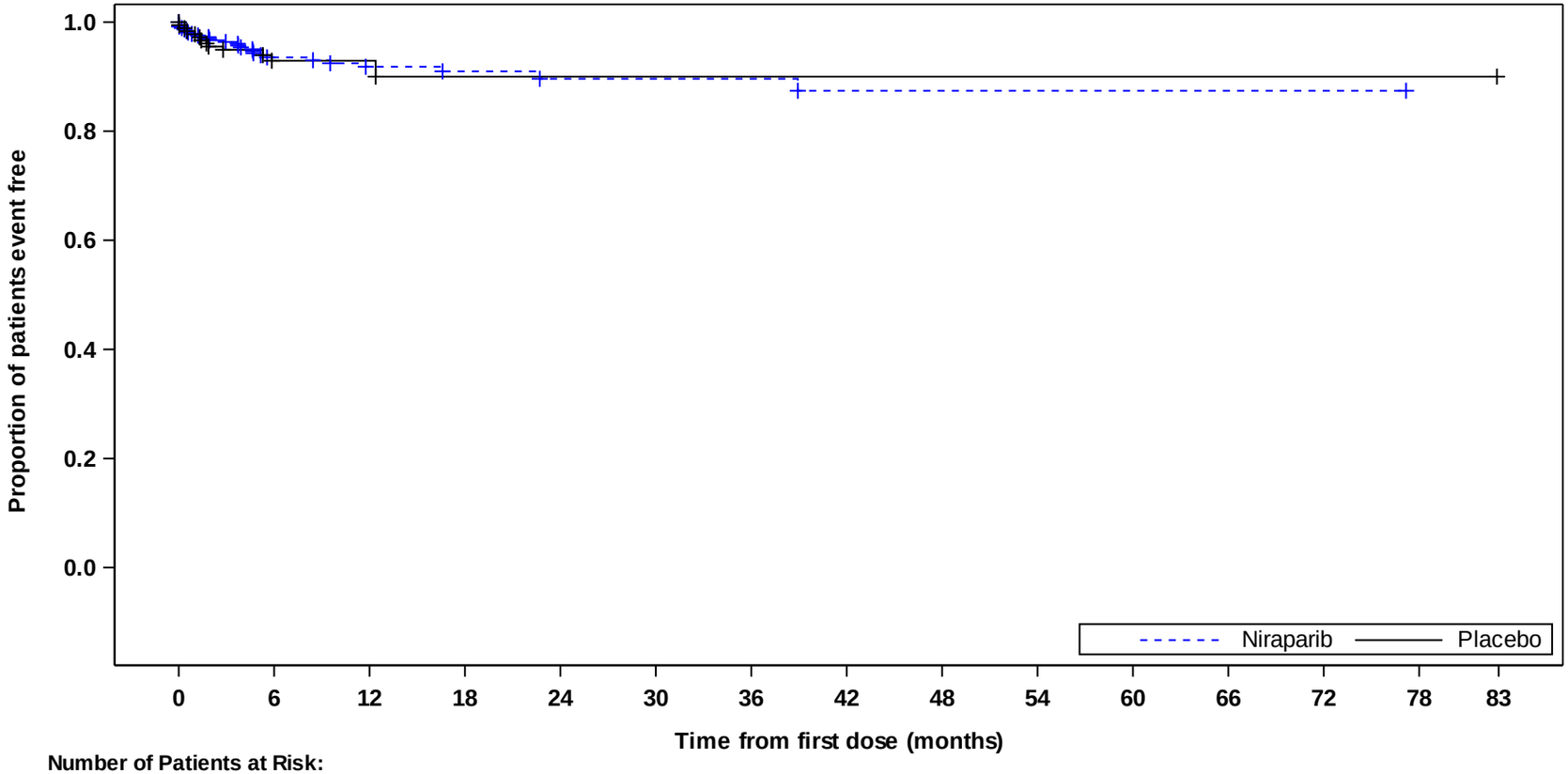
Number of Patients at Risk:

Niraparib	367	245	160	100	69	59	49	38	35	30	26	19	6	0
Placebo	179	89	33	14	8	8	8	7	6	5	5	5	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:38 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Nervous system disorders, PT: Neuropathy peripheral



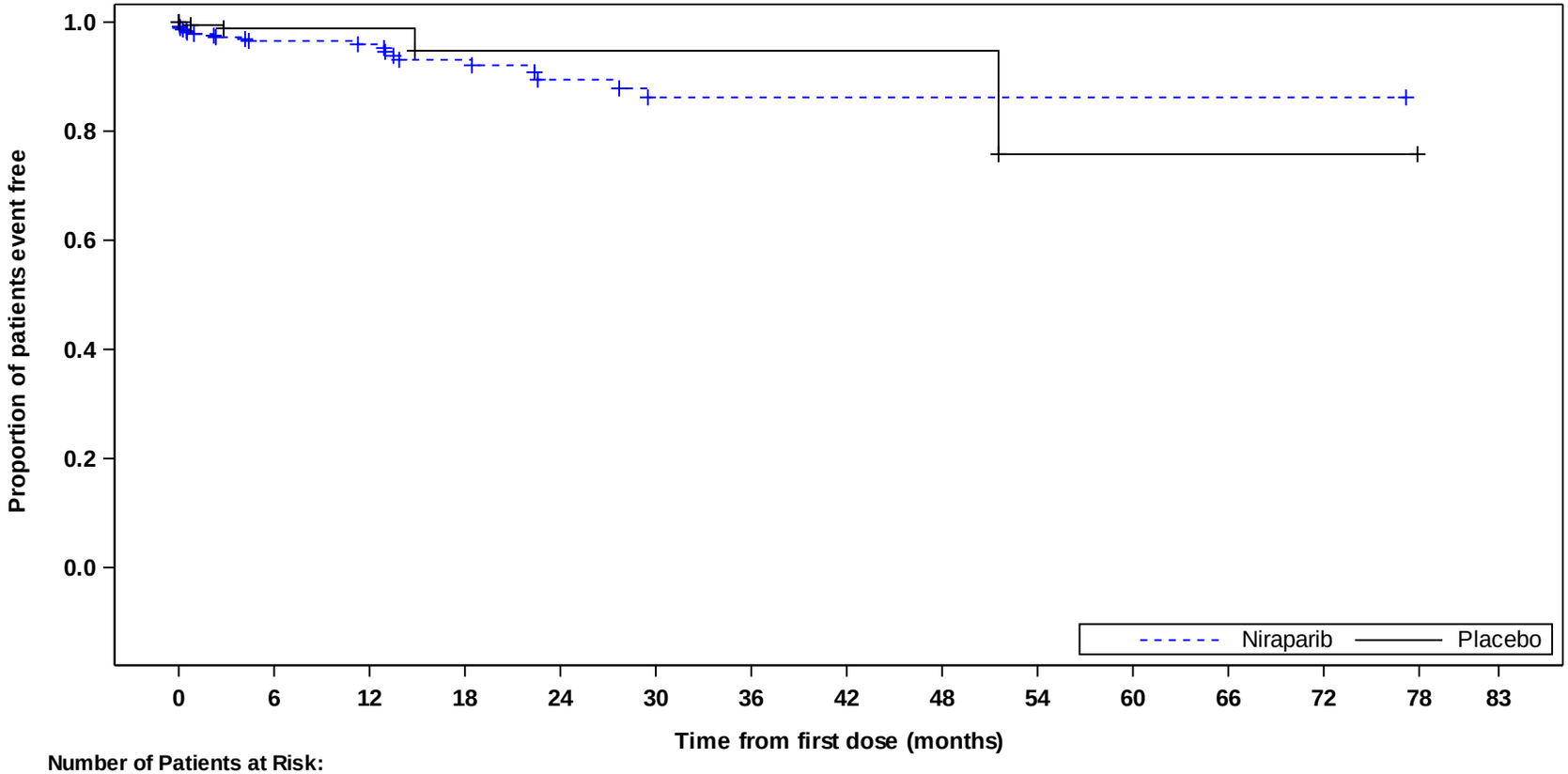
Number of Patients at Risk:

Niraparib	367	229	146	90	63	53	44	37	36	31	27	21	7	0
Placebo	179	85	35	14	9	8	8	7	6	5	5	5	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:39 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Nervous system disorders, PT: Paraesthesia



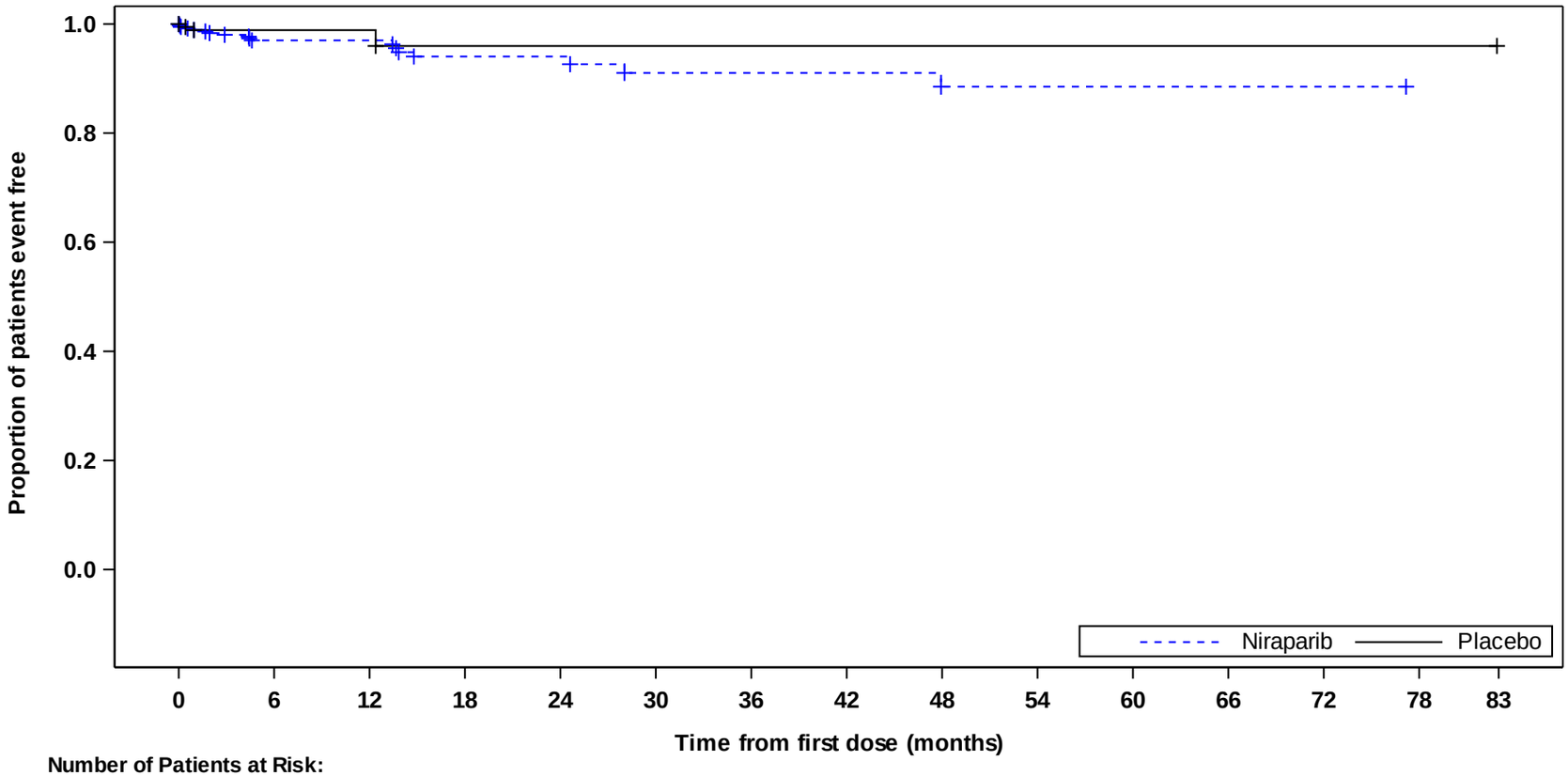
Number of Patients at Risk:

Niraparib	367	238	155	93	64	52	44	35	32	28	23	17	6	0
Placebo	179	90	36	15	9	8	8	7	6	4	4	4	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:40 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Nervous system disorders, PT: Peripheral sensory neuropathy



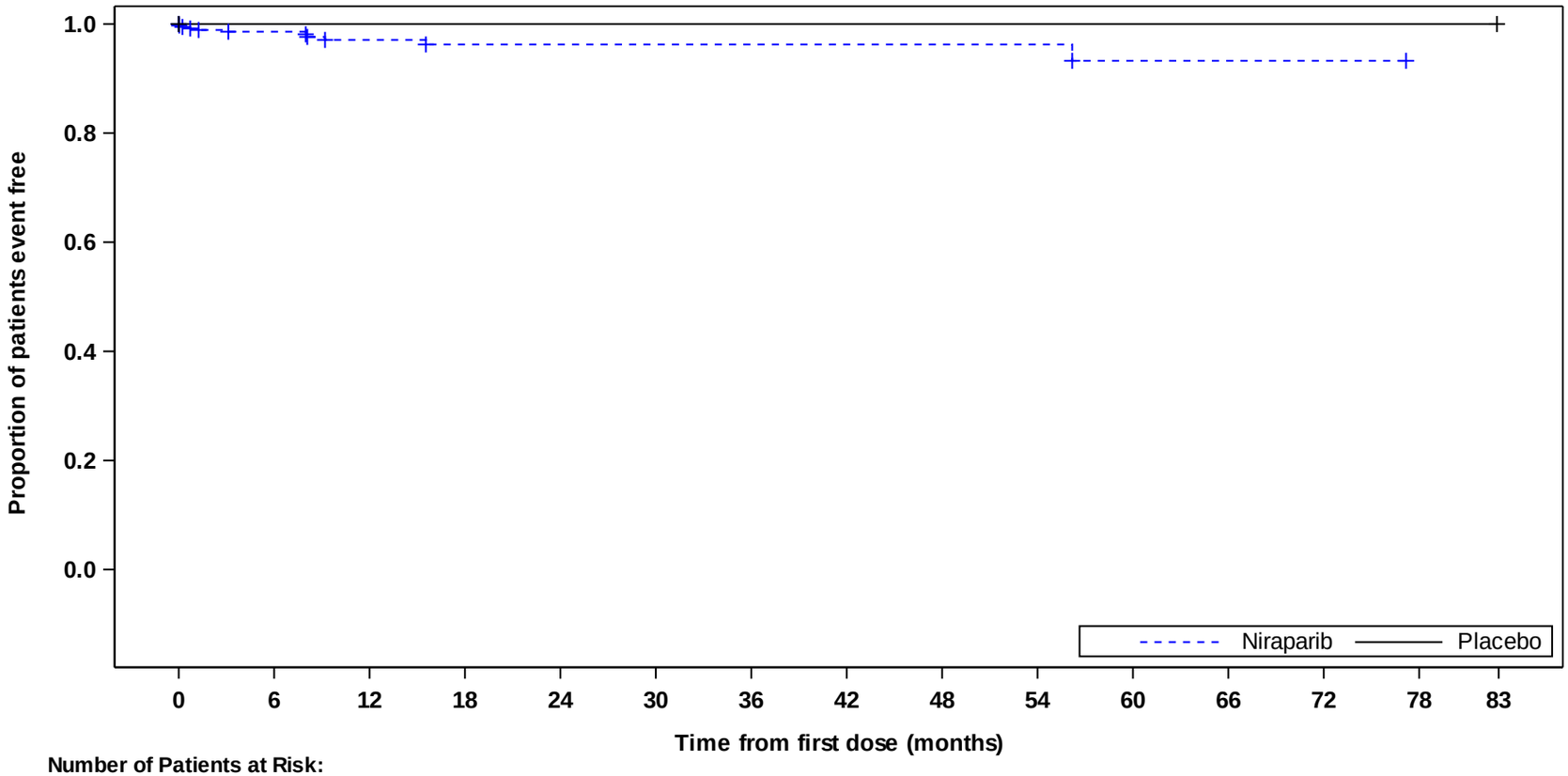
Number of Patients at Risk:

Niraparib	367	241	158	96	67	56	48	39	35	30	27	20	7	0
Placebo	179	92	37	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:41 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Nervous system disorders, PT: Sciatica



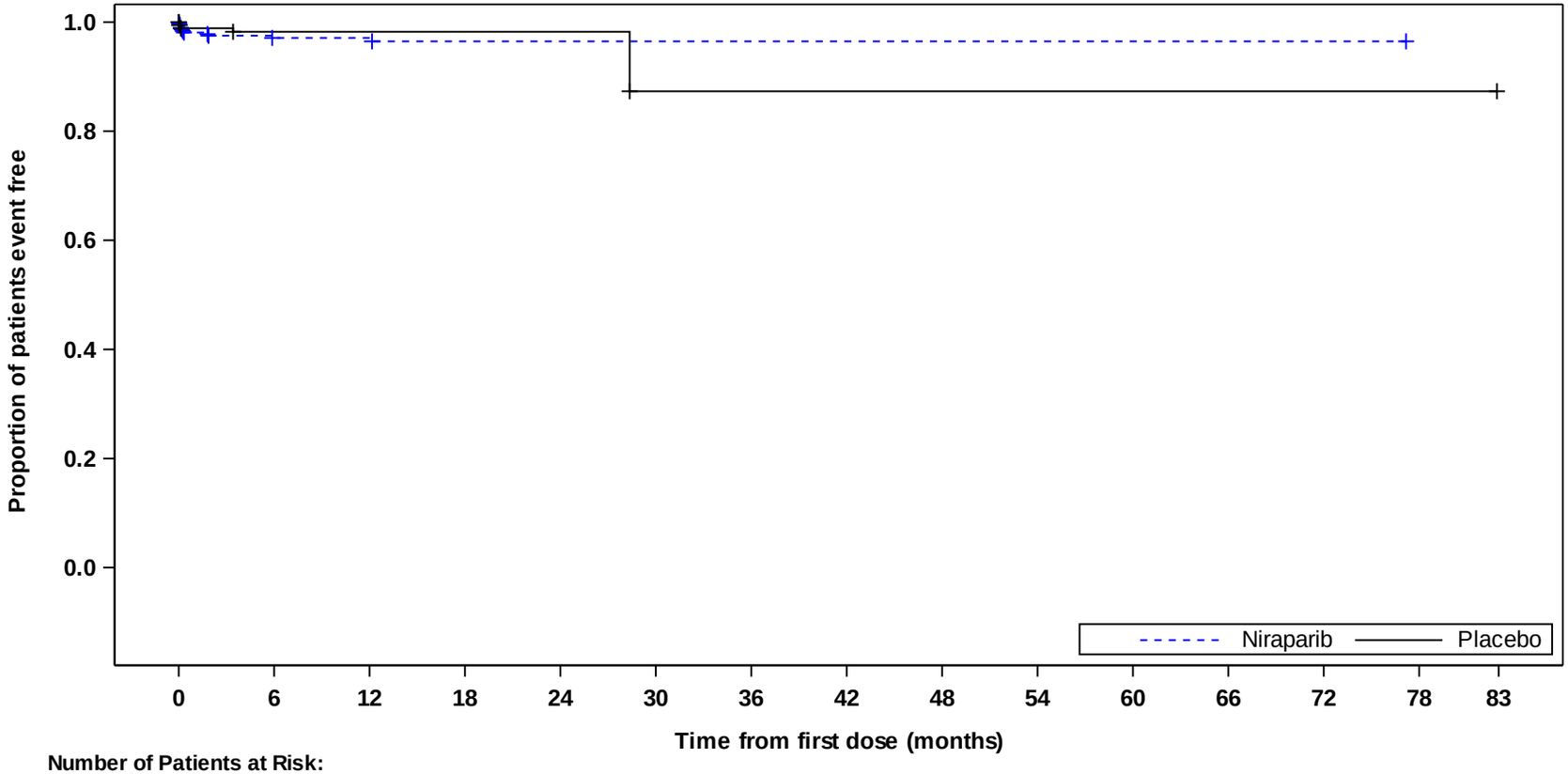
Number of Patients at Risk:

Niraparib	367	244	157	97	67	58	49	39	37	32	27	21	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:42 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Nervous system disorders, PT: Taste disorder



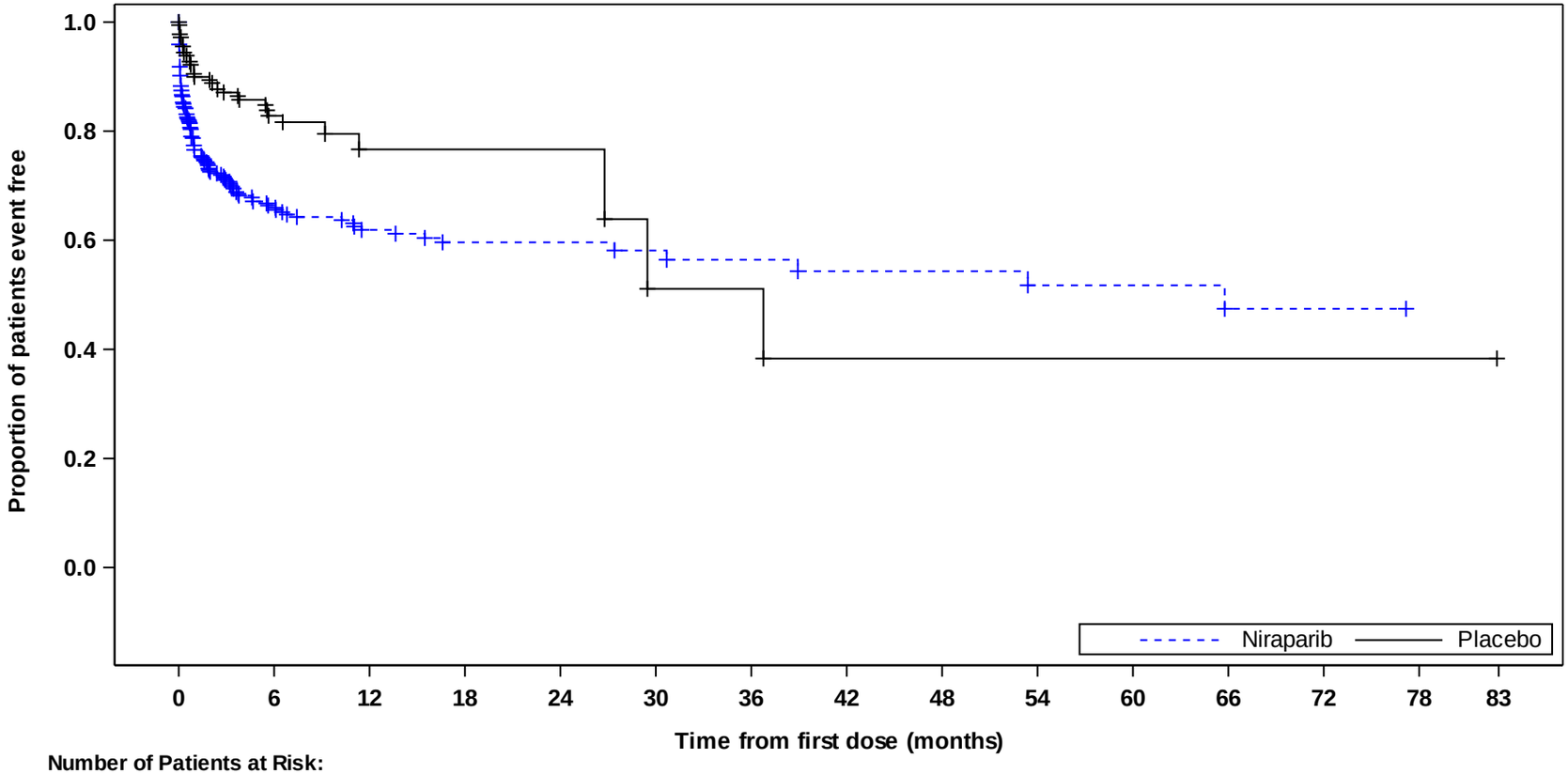
Number of Patients at Risk:

Niraparib	367	239	157	96	68	61	52	42	39	34	29	22	7	0
Placebo	179	91	37	16	10	8	8	7	6	5	5	5	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:43 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Psychiatric disorders



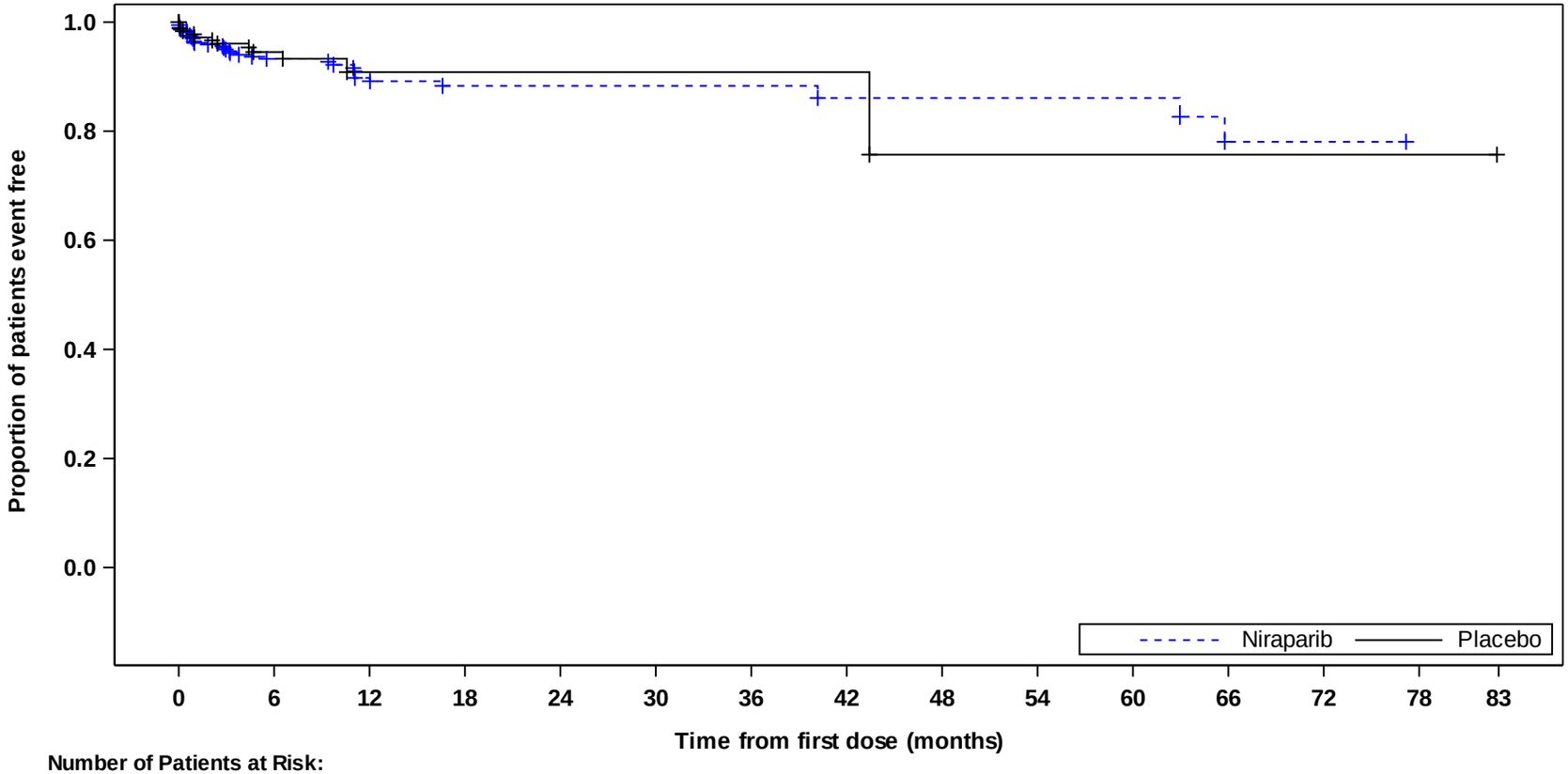
Number of Patients at Risk:

Niraparib	367	165	103	63	45	37	30	24	22	19	15	11	5	0
Placebo	179	79	27	11	7	4	4	3	2	2	2	2	1	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:44 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Psychiatric disorders, PT: Anxiety



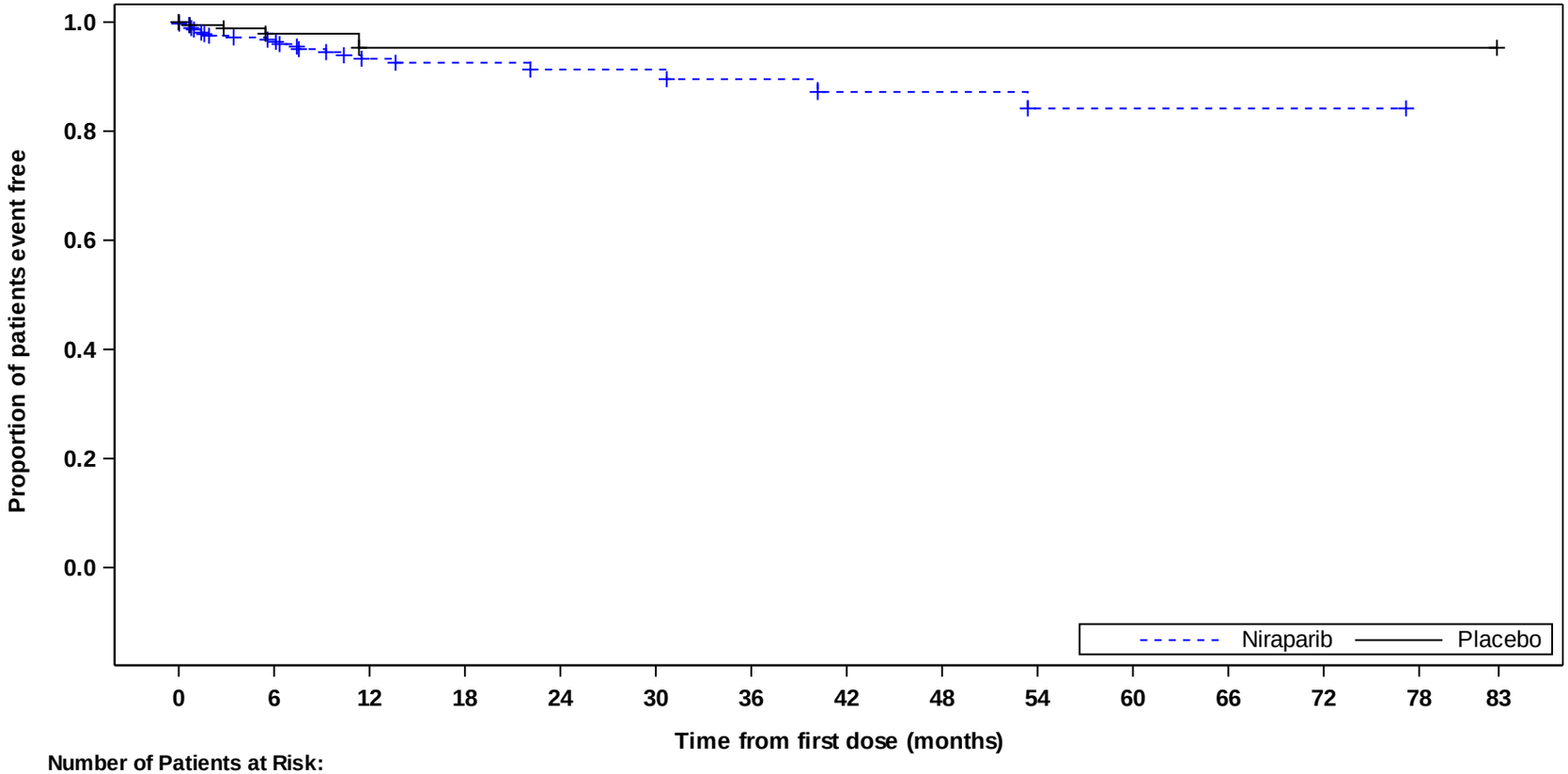
Number of Patients at Risk:

Niraparib	367	229	147	88	61	53	44	36	33	30	26	17	6	0
Placebo	179	87	33	13	9	8	8	7	5	4	4	4	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:45 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Psychiatric disorders, PT: Depression



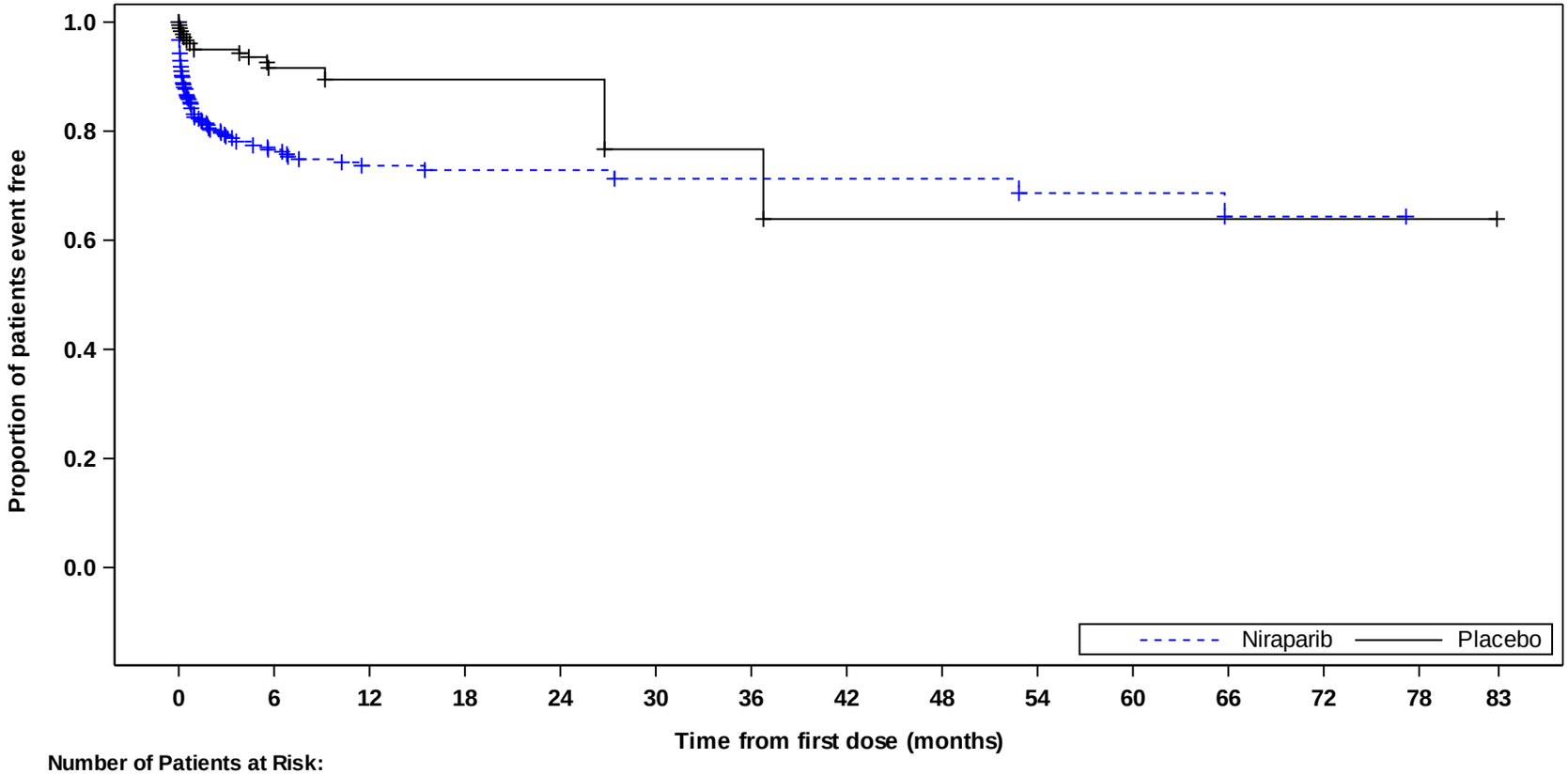
Number of Patients at Risk:

Niraparib	367	239	149	92	64	55	45	34	31	26	22	18	7	0
Placebo	179	90	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:46 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Psychiatric disorders, PT: Insomnia



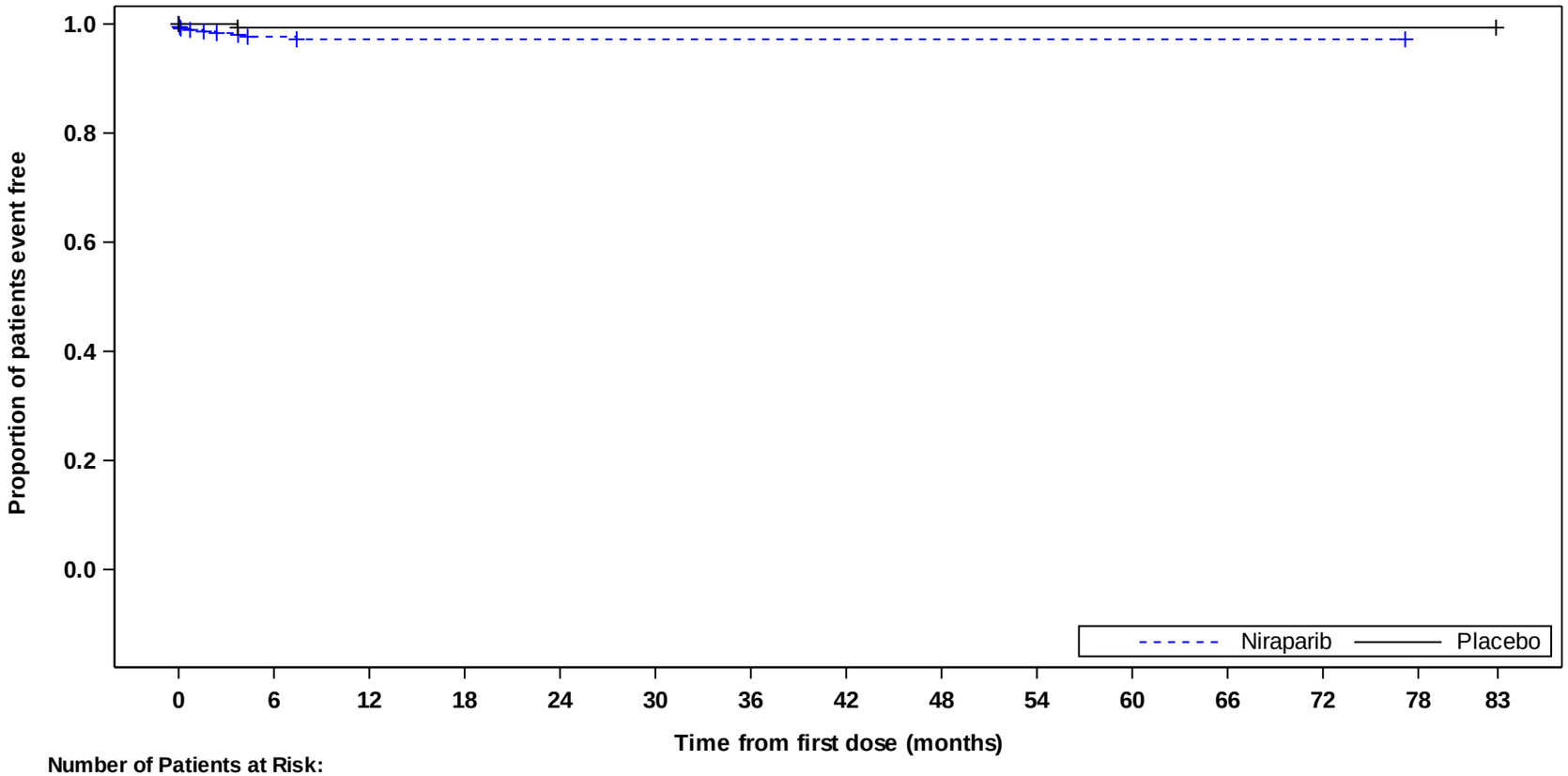
Number of Patients at Risk:

Niraparib	367	191	120	75	53	43	37	31	28	24	20	15	5	0
Placebo	179	85	32	14	8	6	6	4	3	2	2	2	1	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:47 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Psychiatric disorders, PT: Sleep disorder



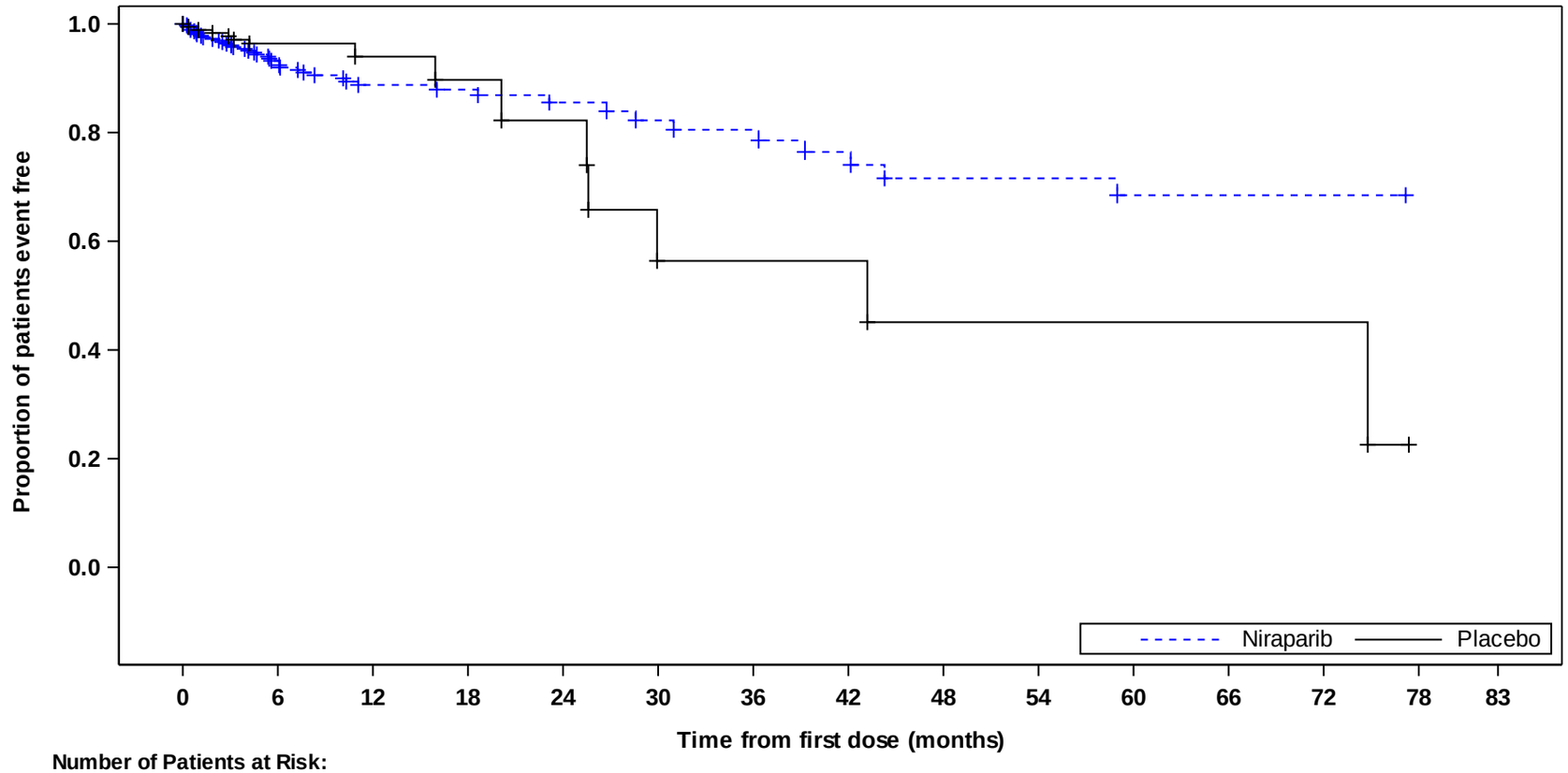
Number of Patients at Risk:

Niraparib	367	239	156	98	70	60	51	41	38	33	28	21	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:48 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Renal and urinary disorders



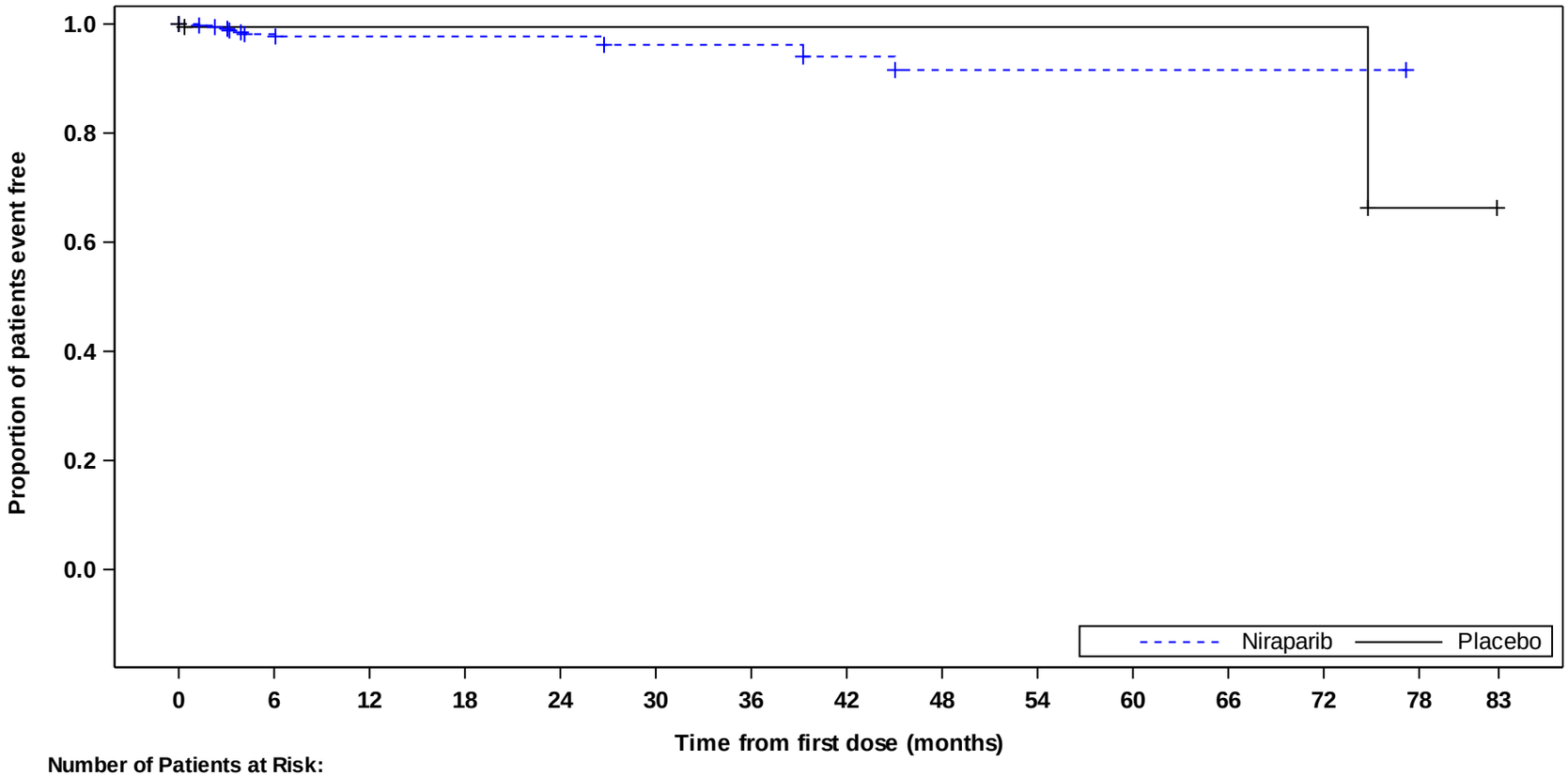
Number of Patients at Risk:

Niraparib	367	230	140	87	60	49	43	32	28	24	22	16	7	0
Placebo	179	90	35	15	10	6	6	5	3	3	3	3	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:49 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Renal and urinary disorders, PT: Dysuria



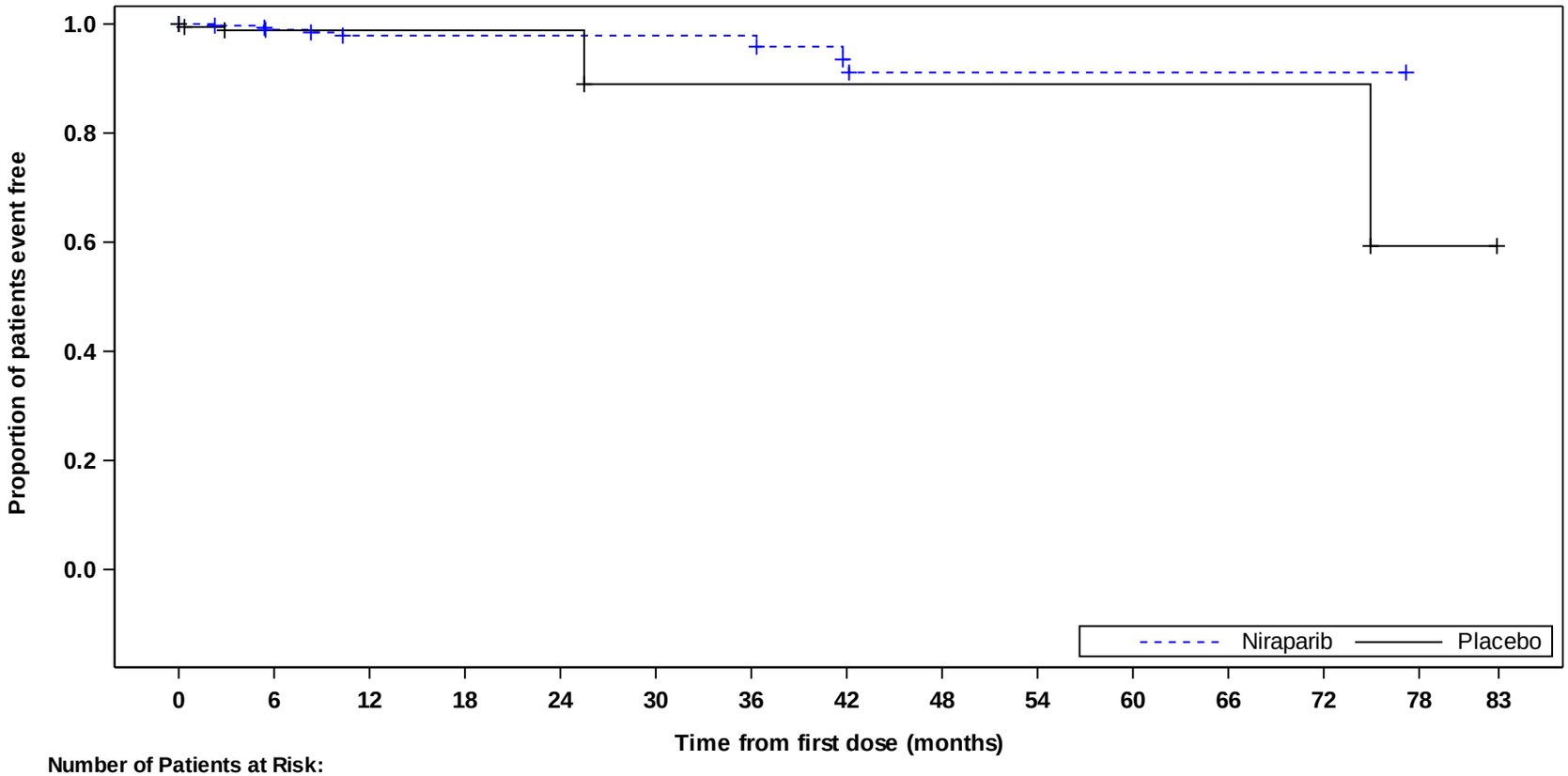
Number of Patients at Risk:

Niraparib	367	242	158	98	70	59	51	40	36	31	27	20	7	0
Placebo	179	91	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:50 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Renal and urinary disorders, PT: Pollakiuria



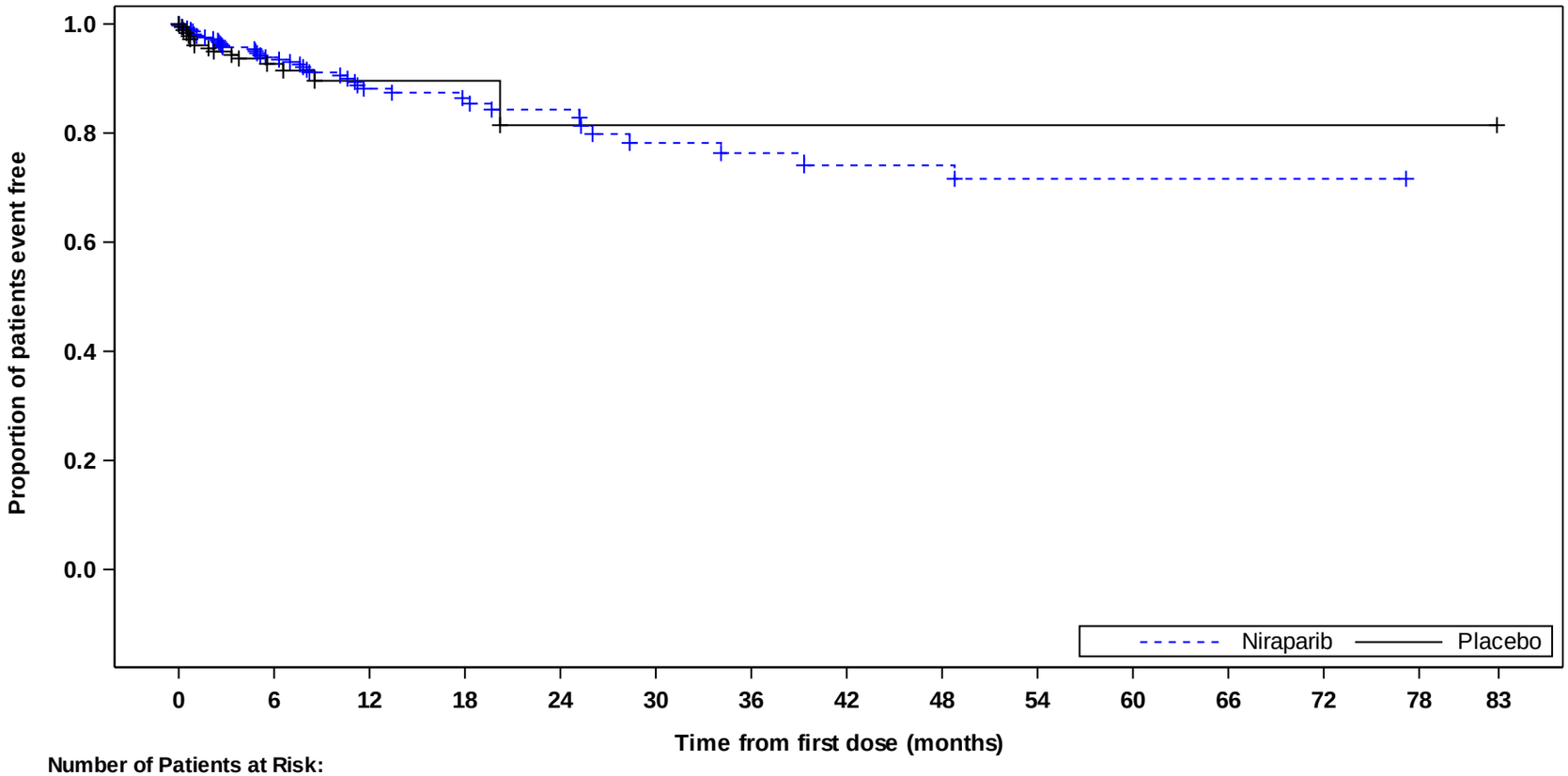
Number of Patients at Risk:

Niraparib	367	245	158	99	69	59	51	39	36	31	27	20	7	0
Placebo	179	90	36	16	10	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:51 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Reproductive system and breast disorders



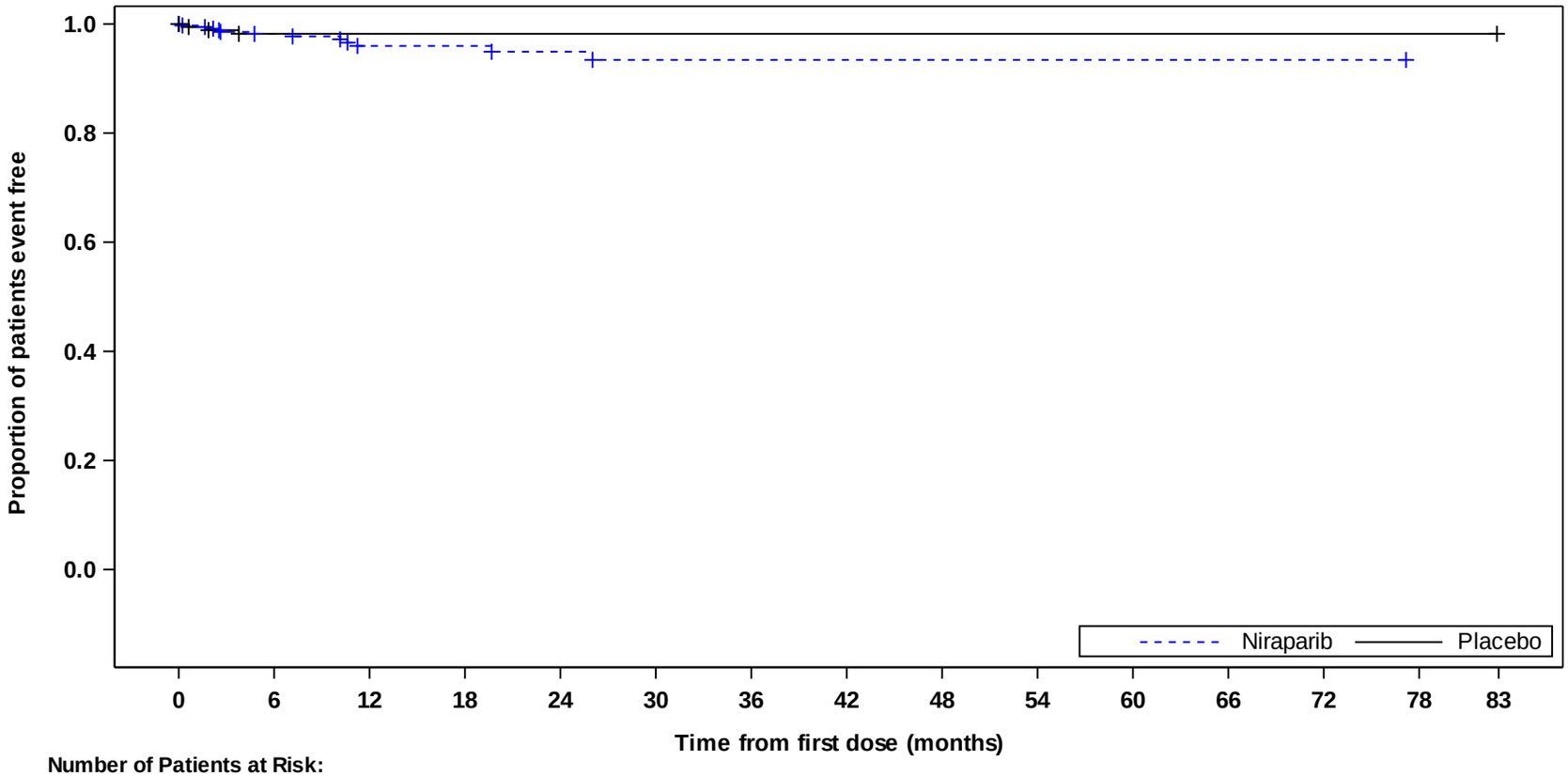
Number of Patients at Risk:

Niraparib	367	233	143	86	60	48	40	32	30	25	21	16	6	0
Placebo	179	87	32	13	7	6	6	5	4	4	4	4	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:52 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Reproductive system and breast disorders, PT: Pelvic pain



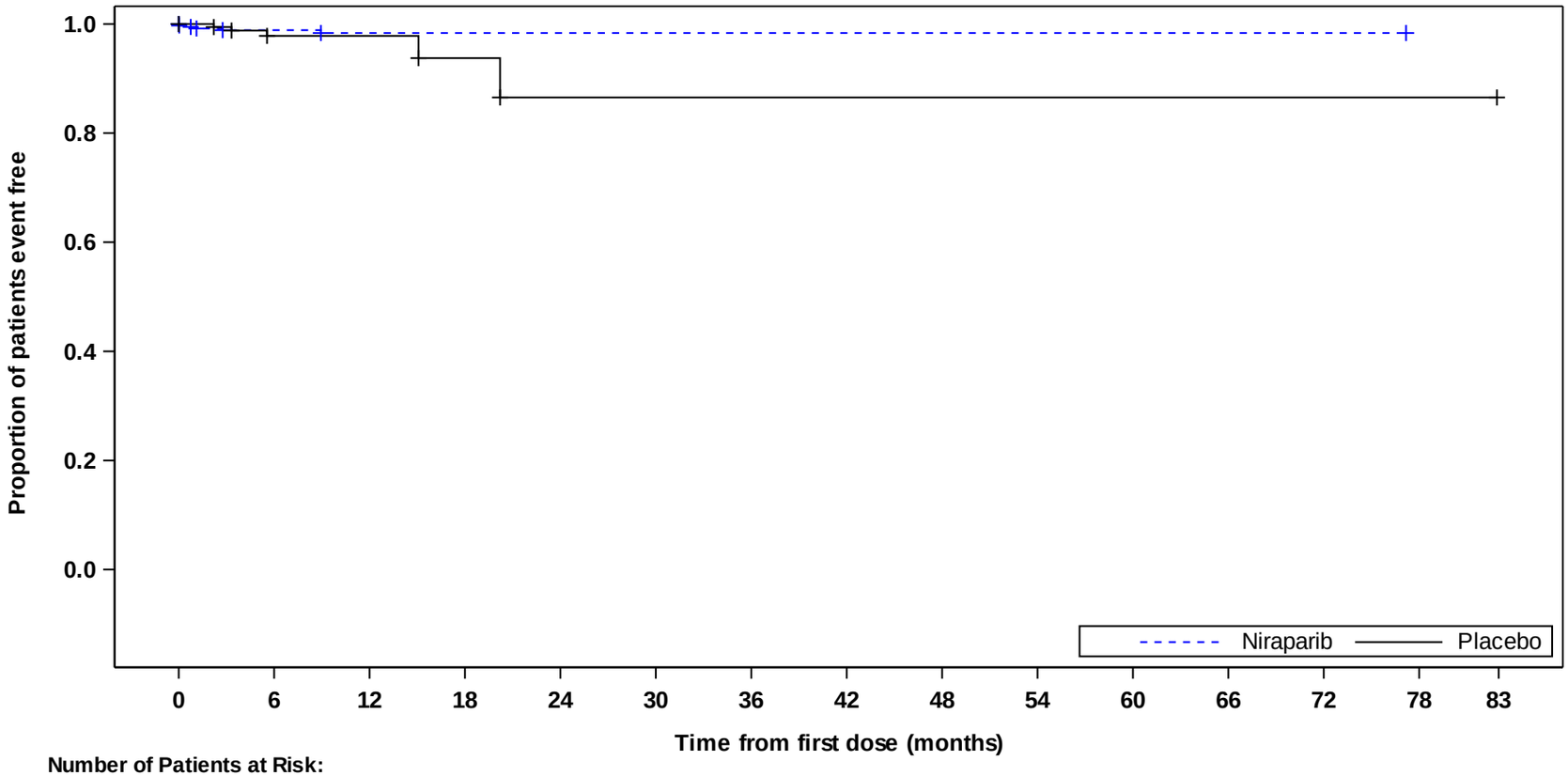
Number of Patients at Risk:

Niraparib	367	244	157	97	67	58	50	41	38	33	28	21	7	0
Placebo	179	91	36	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:53 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Reproductive system and breast disorders, PT: Vaginal haemorrhage



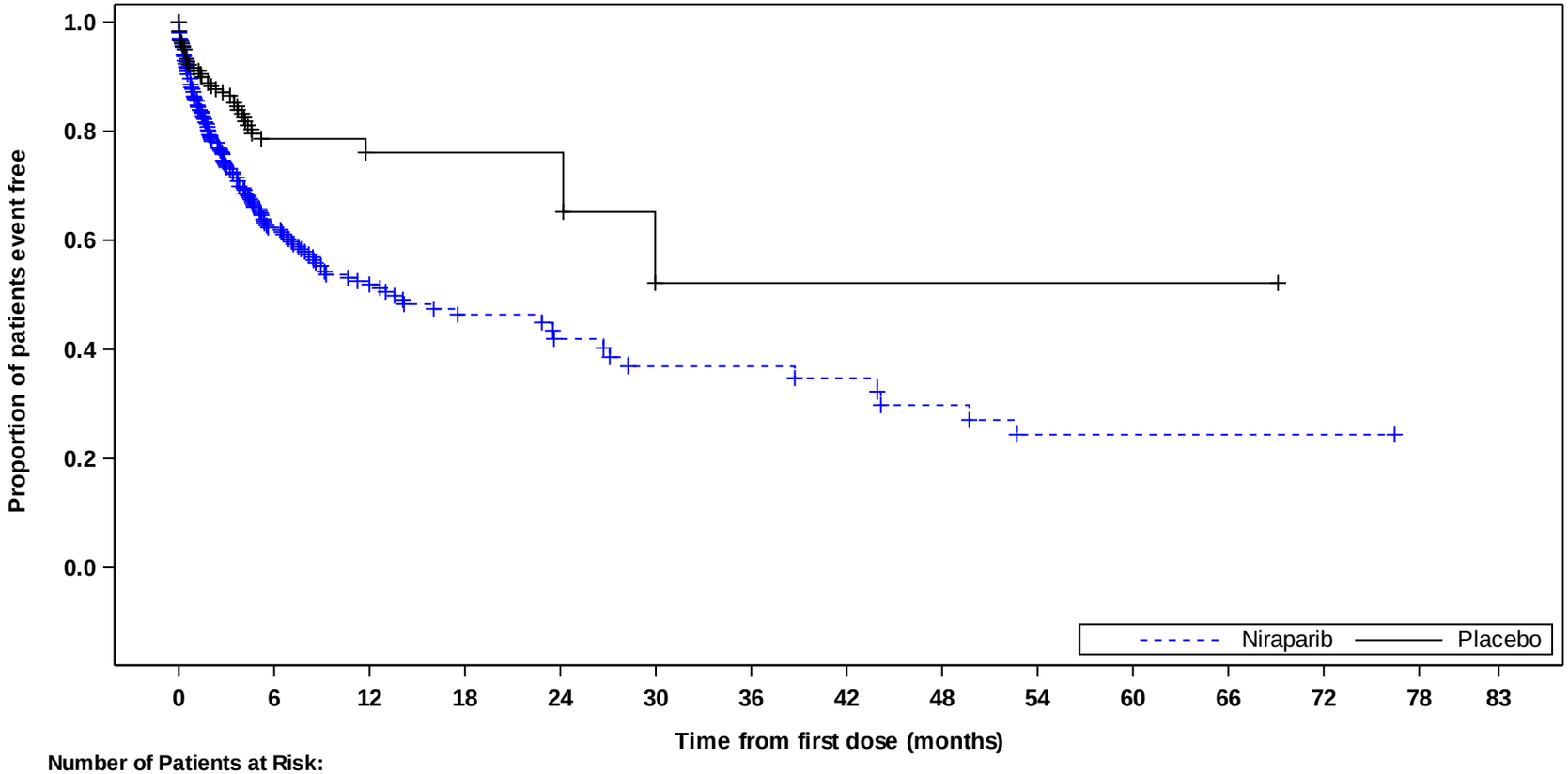
Number of Patients at Risk:

Niraparib	367	246	161	100	70	60	51	41	38	33	28	21	7	0
Placebo	179	91	37	16	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:54 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders



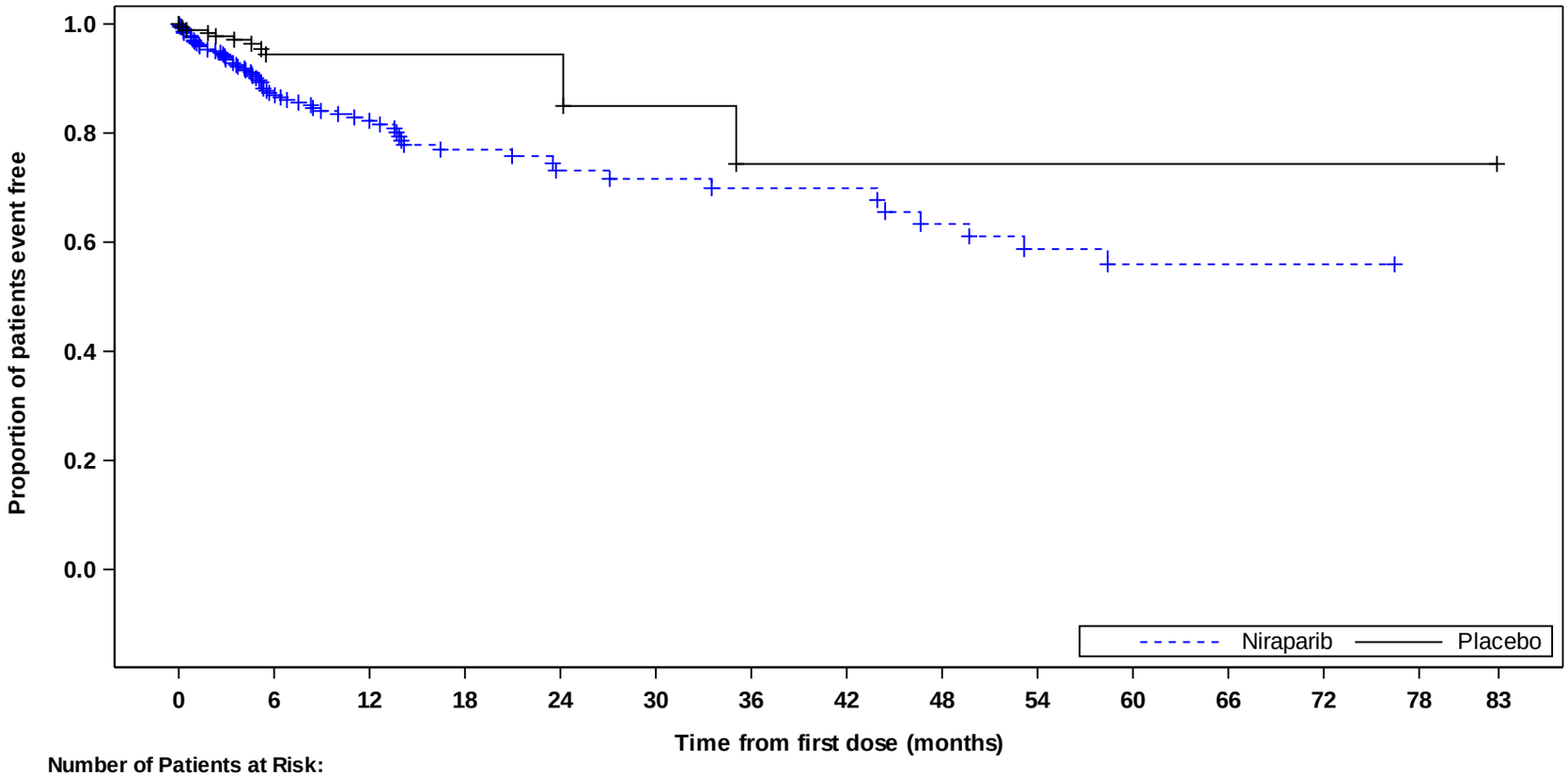
Number of Patients at Risk:

Niraparib	367	153	85	43	27	22	21	14	11	7	7	7	3	0
Placebo	179	74	30	12	7	4	4	3	2	2	2	2	0	

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:55 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough



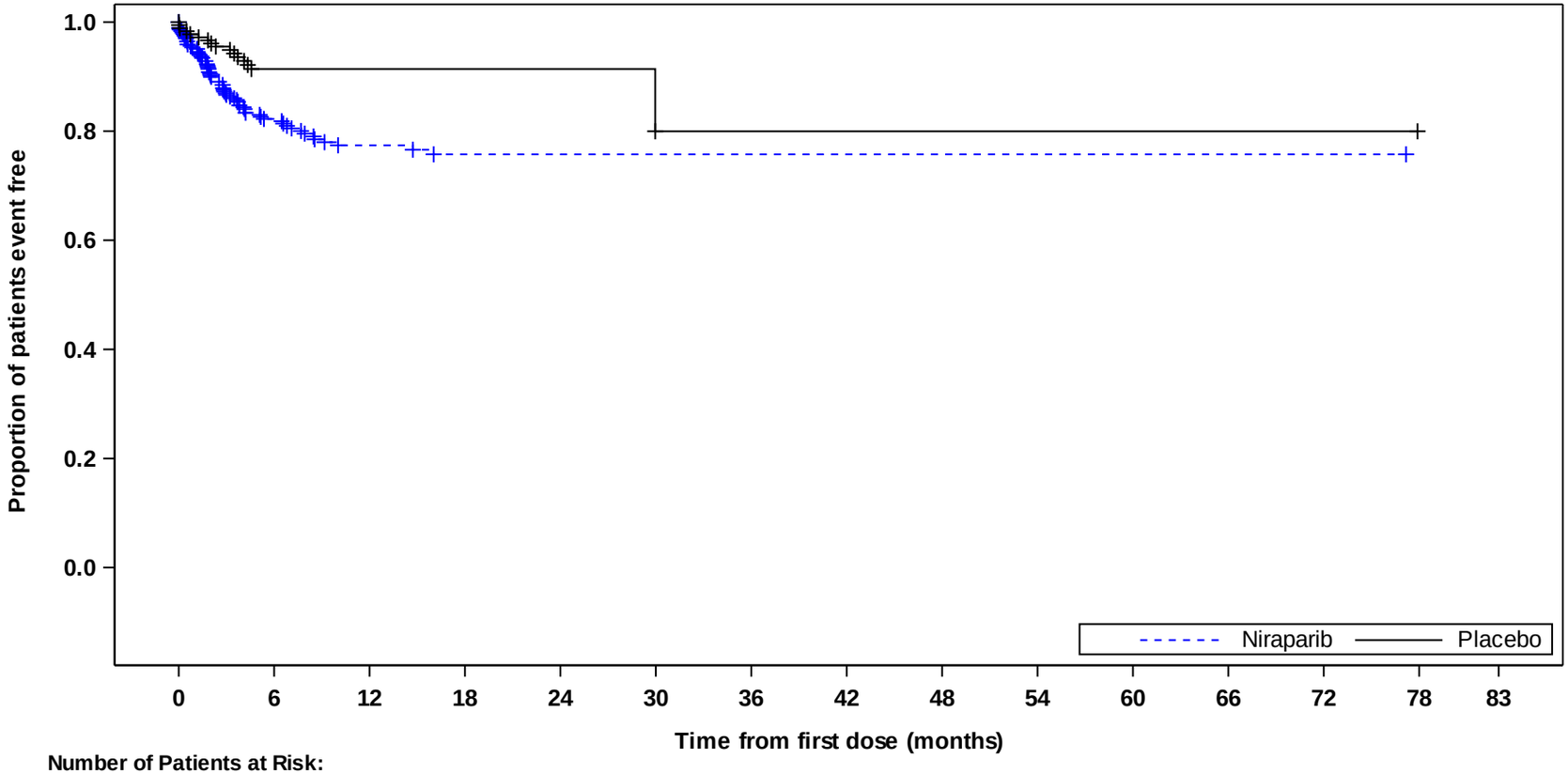
Number of Patients at Risk:

Niraparib	367	211	133	75	53	46	40	33	28	24	20	17	6	0
Placebo	179	87	35	16	10	8	7	6	5	4	4	4	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:56 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea



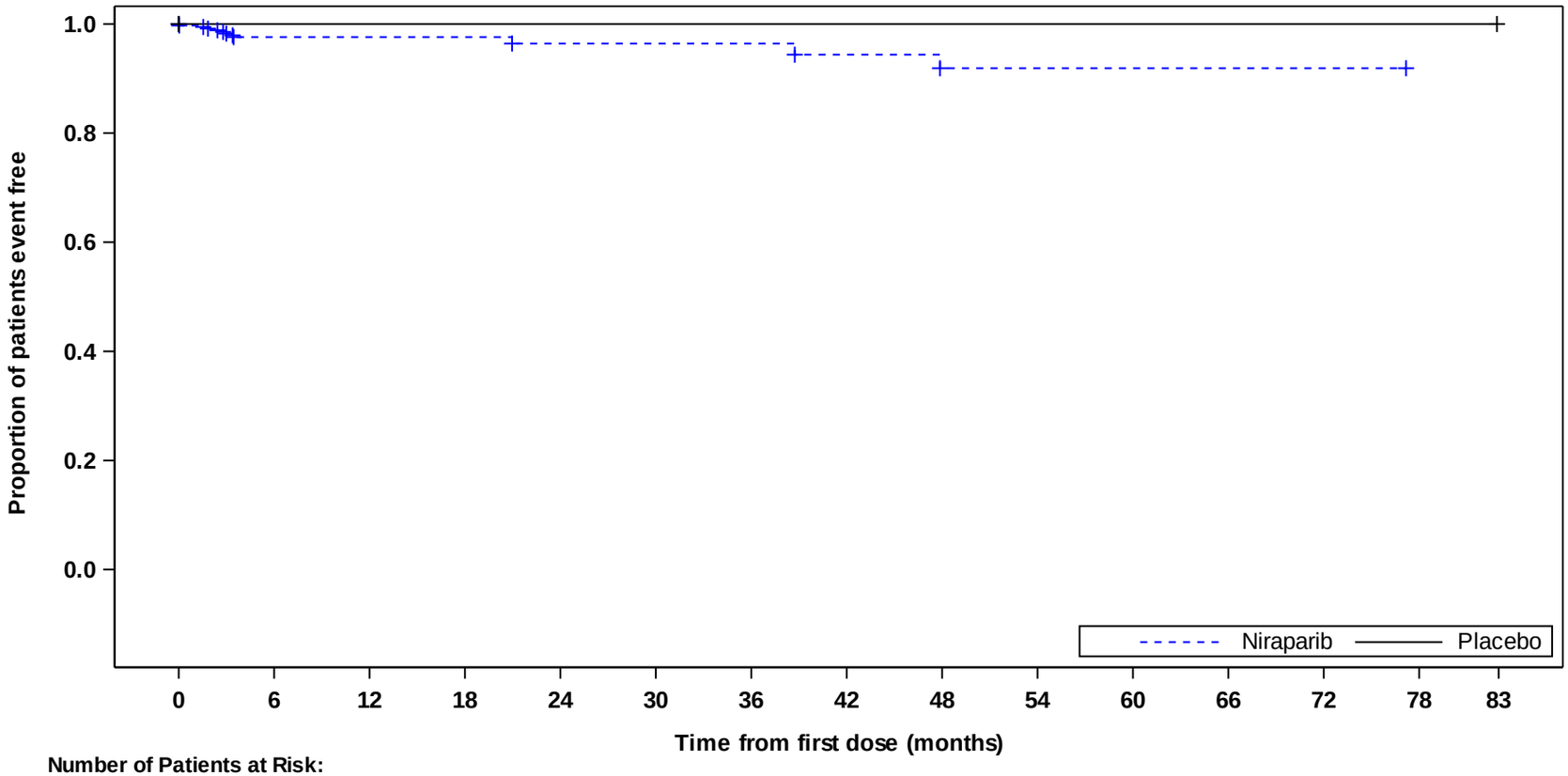
Number of Patients at Risk:

Niraparib	367	203	125	76	55	50	43	34	32	27	24	21	7	0
Placebo	179	86	34	14	9	7	7	6	5	4	4	4	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:57 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea exertional



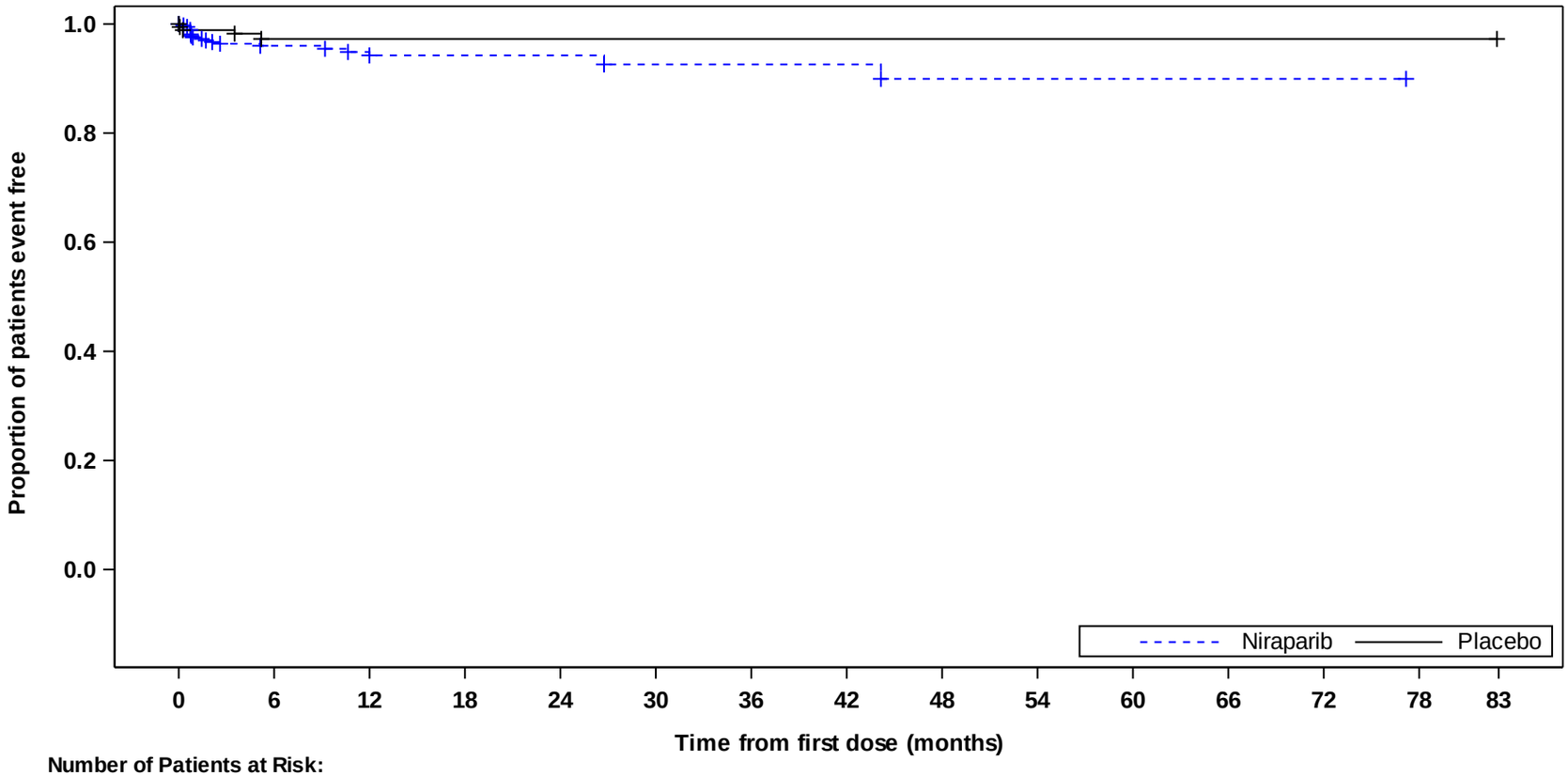
Number of Patients at Risk:

Niraparib	367	242	159	99	70	60	52	41	37	32	27	21	6	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:57 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Epistaxis



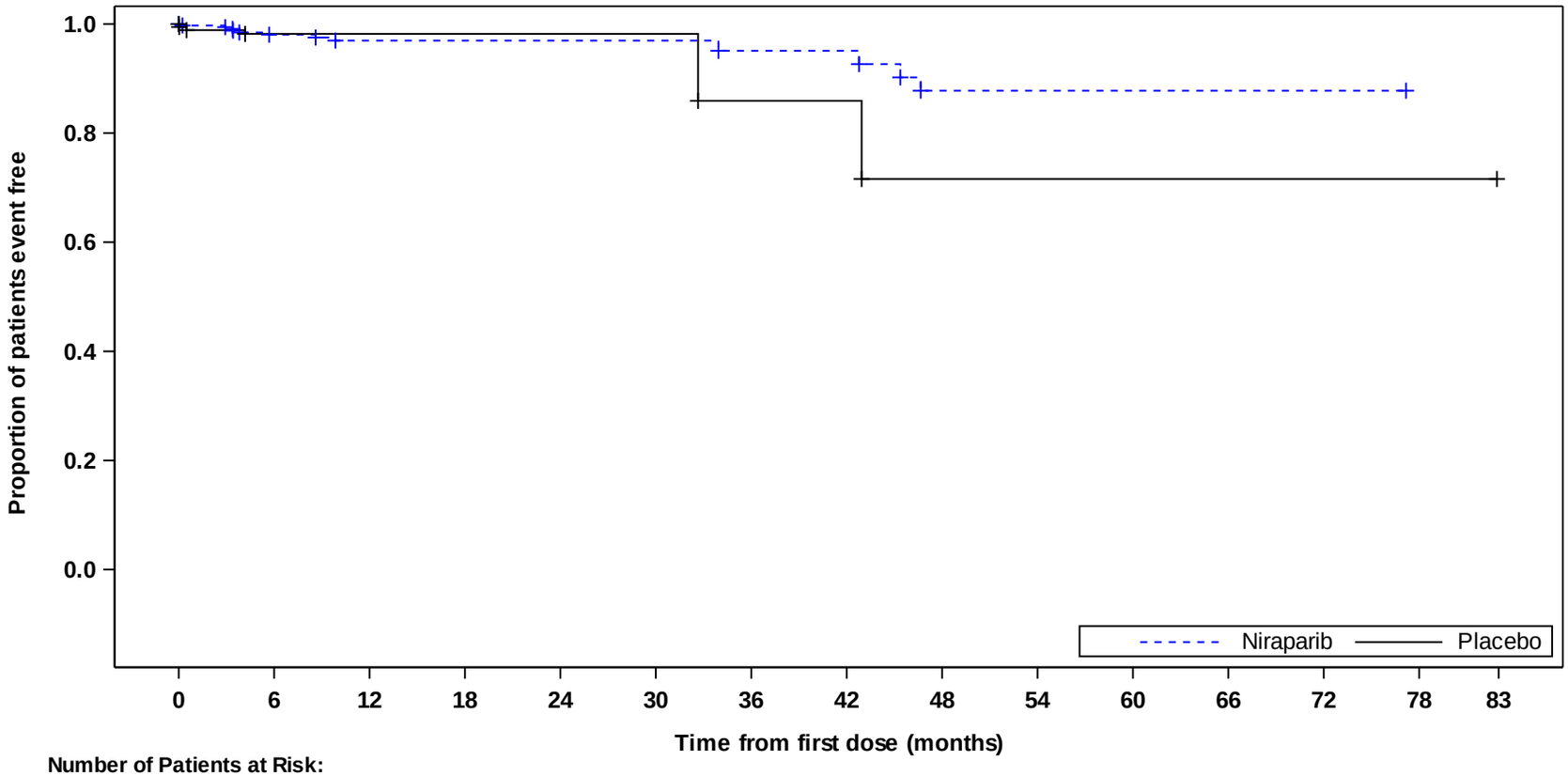
Number of Patients at Risk:

Niraparib	367	237	151	92	63	54	46	36	32	28	24	18	6	0
Placebo	179	90	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:58 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Nasal congestion



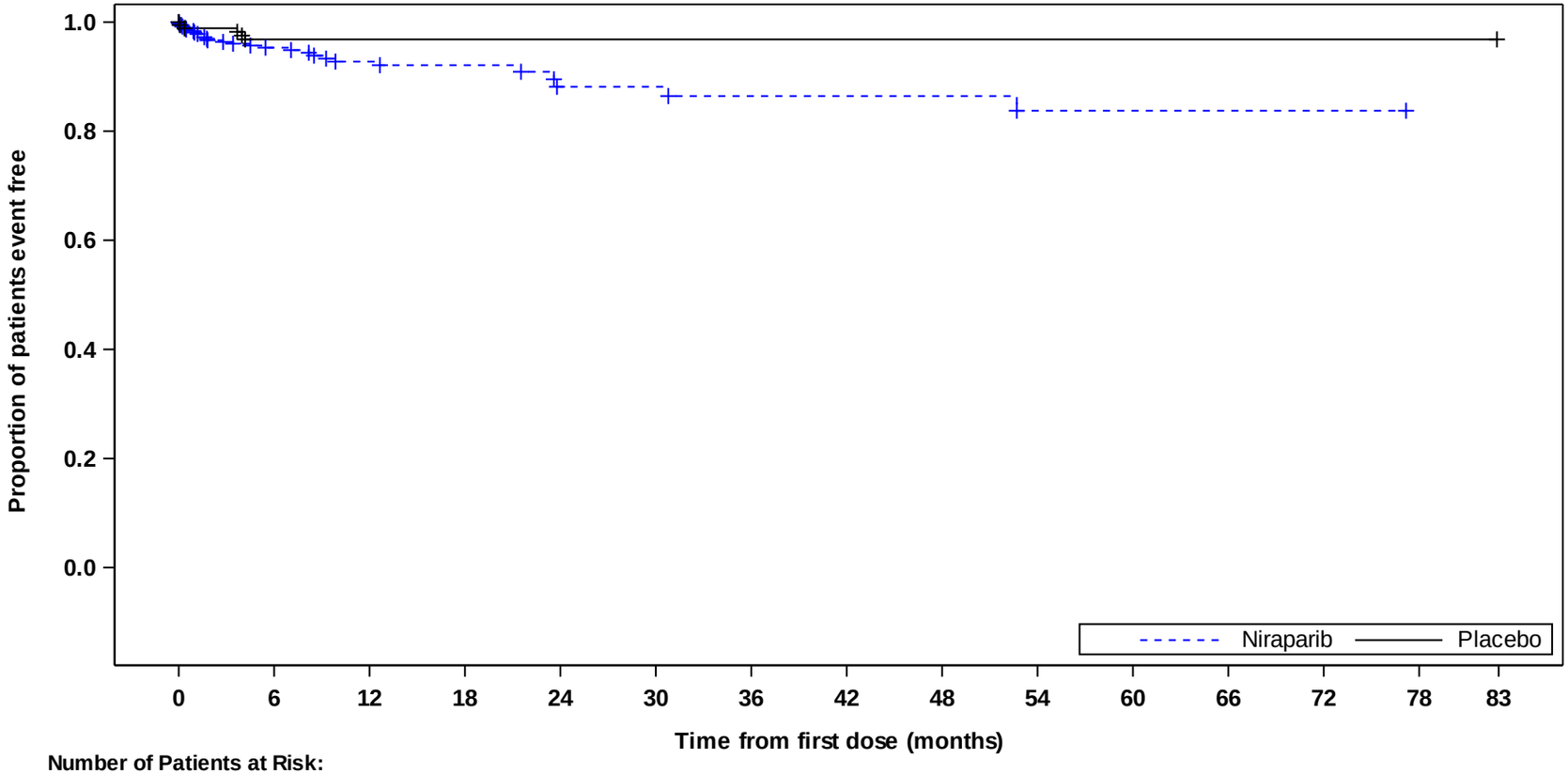
Number of Patients at Risk:

Niraparib	367	241	158	99	69	59	50	40	35	31	27	20	7	0
Placebo	179	90	35	15	9	8	7	6	4	3	3	3	1	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:23:59 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain



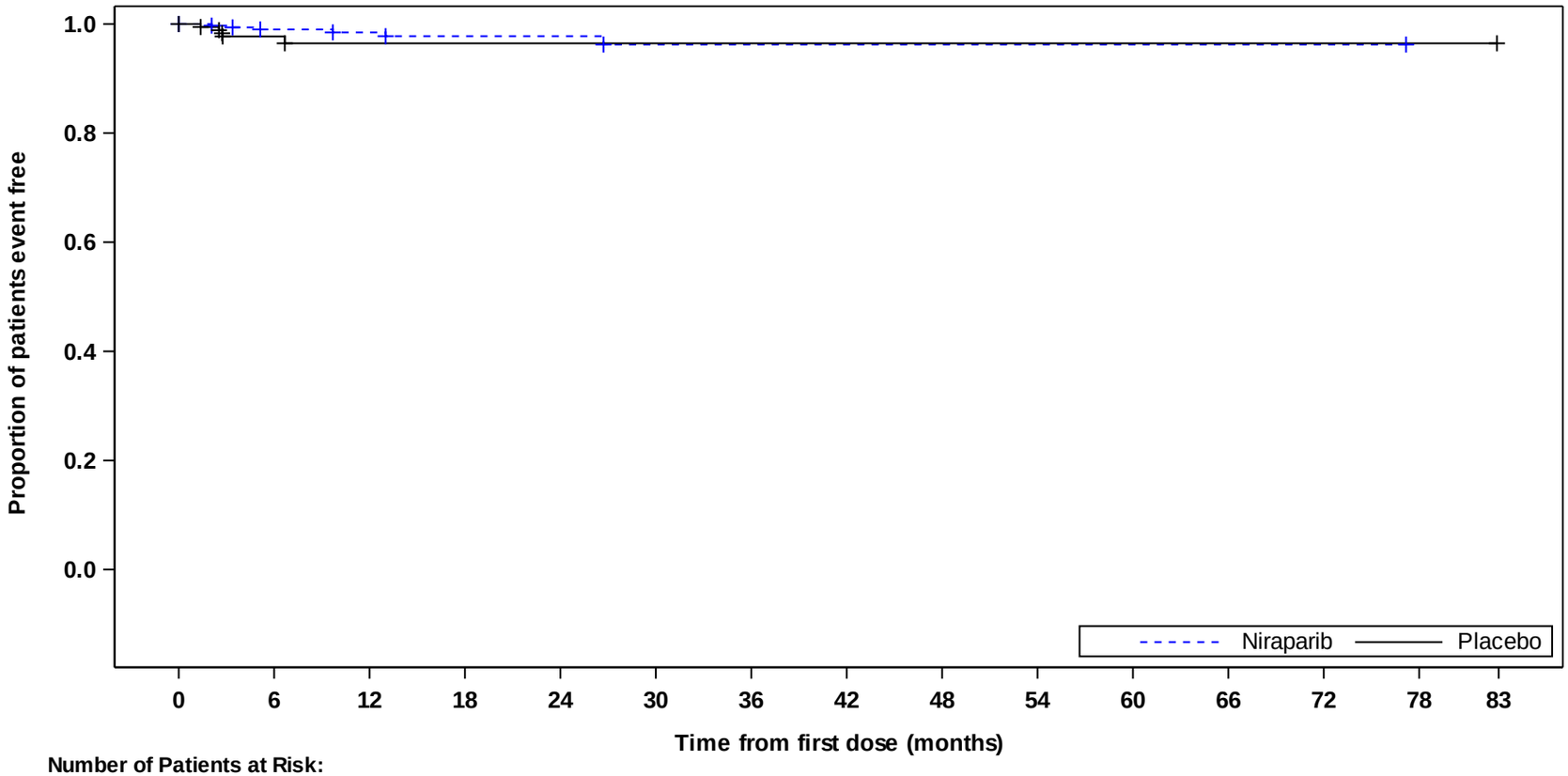
Number of Patients at Risk:

Niraparib	367	235	151	94	62	54	46	37	34	28	23	18	6	0
Placebo	179	87	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:00 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Pleural effusion



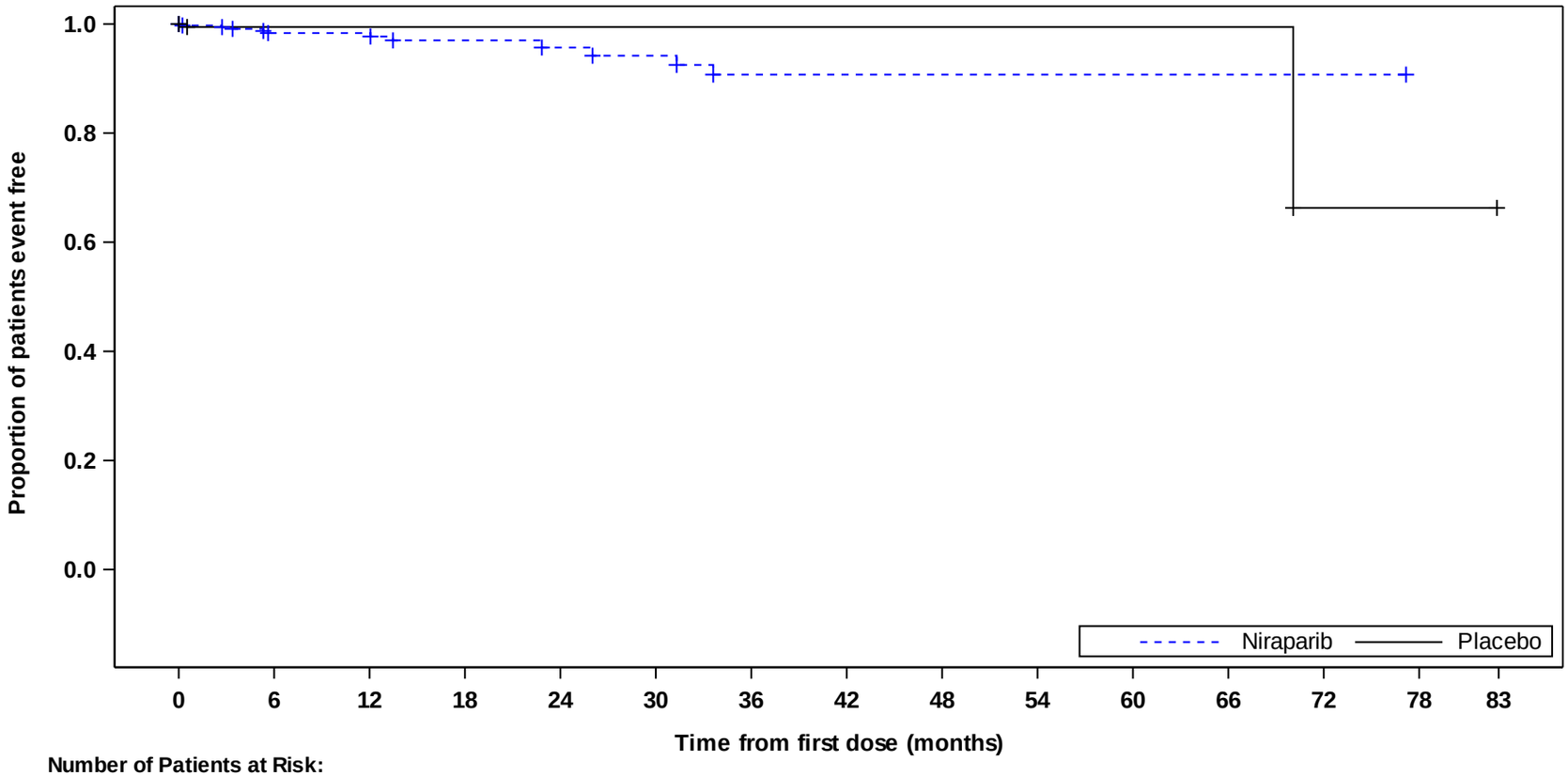
Number of Patients at Risk:

Niraparib	367	246	161	100	71	60	51	41	38	33	28	21	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:01 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Productive cough



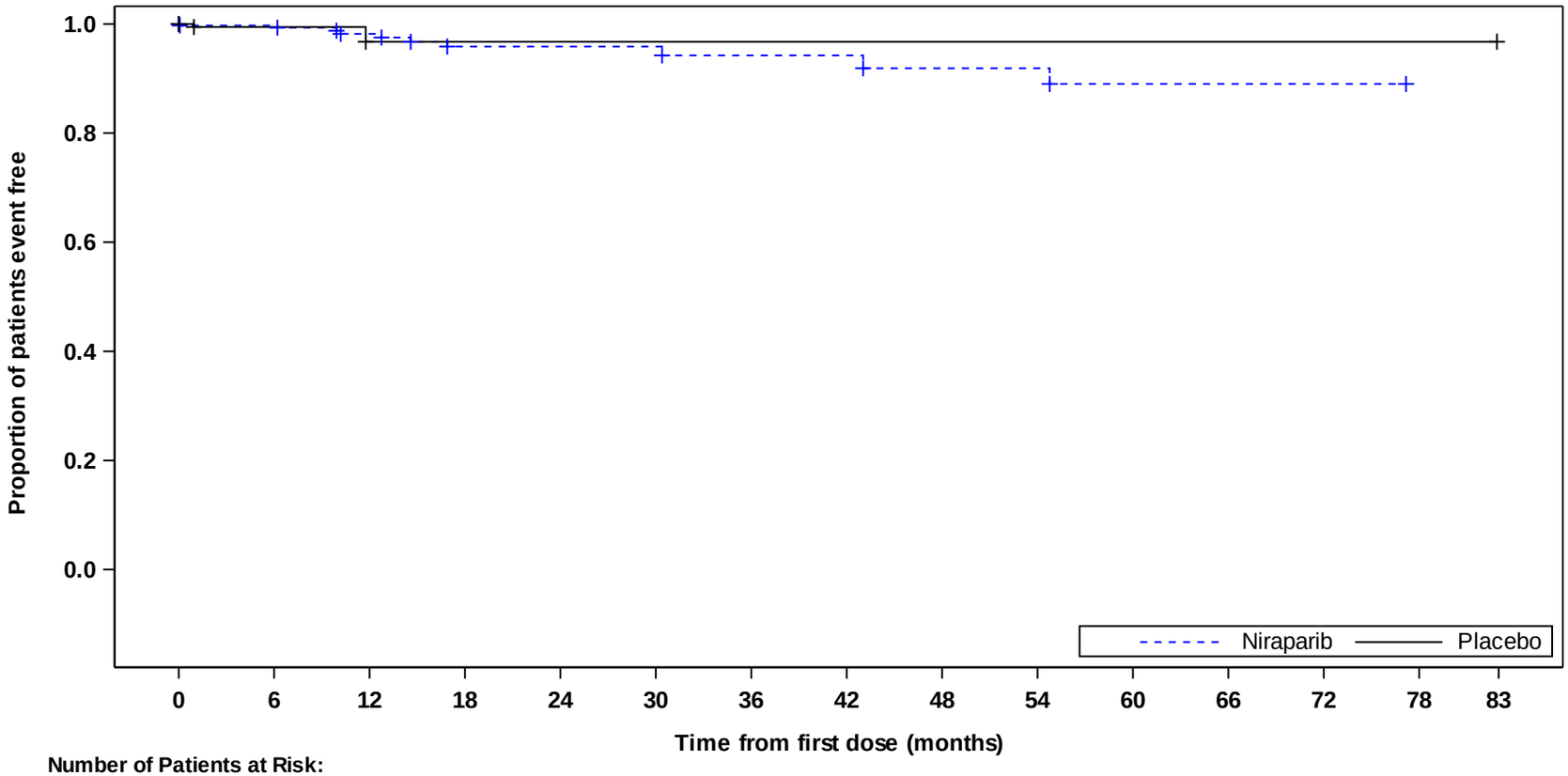
Number of Patients at Risk:

Niraparib	367	242	160	98	69	59	50	41	38	33	28	21	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:03 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Rhinitis allergic



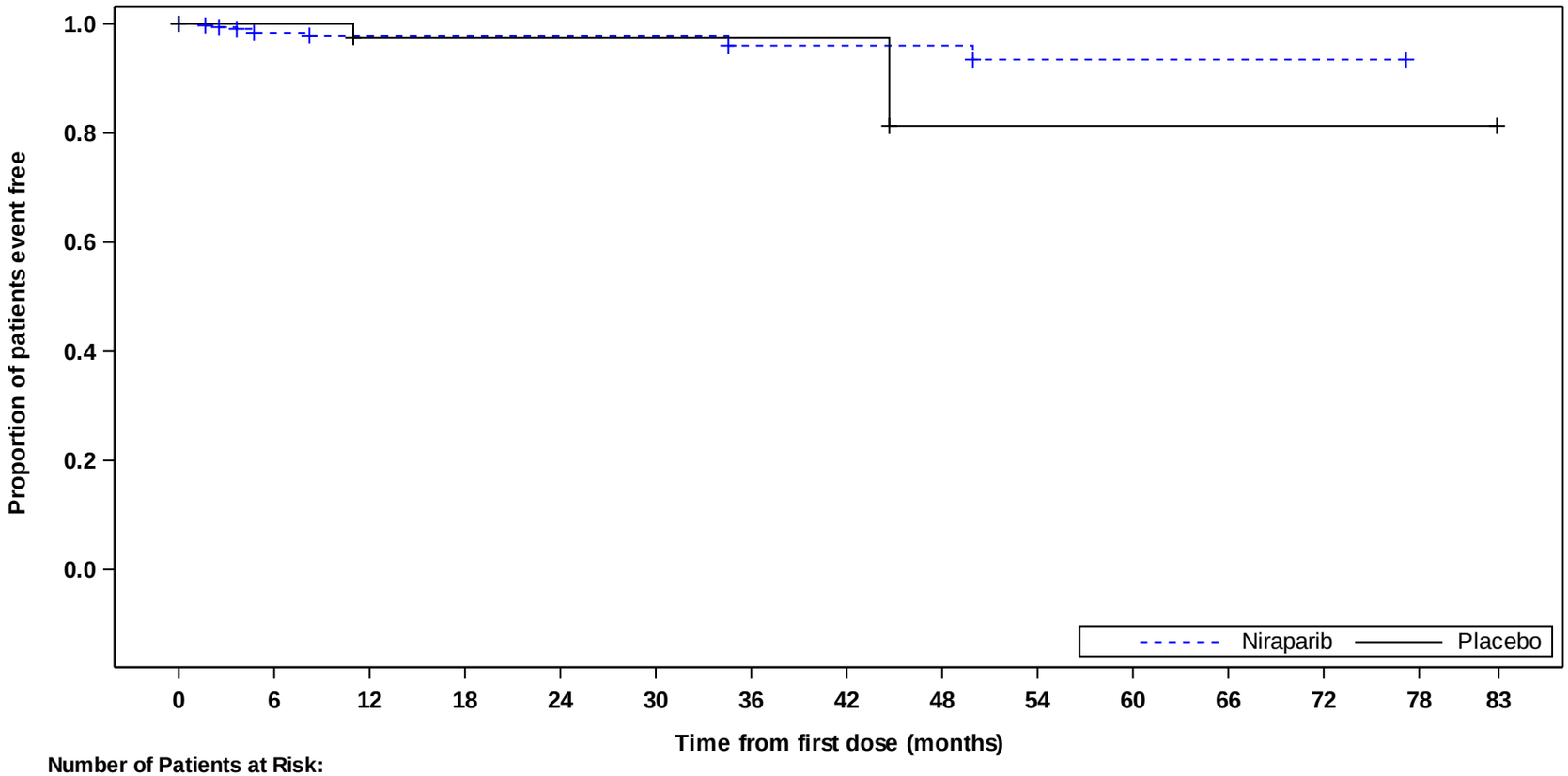
Number of Patients at Risk:

Niraparib	367	247	159	98	70	60	51	41	37	32	27	21	7	0
Placebo	179	92	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:04 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Rhinorrhoea



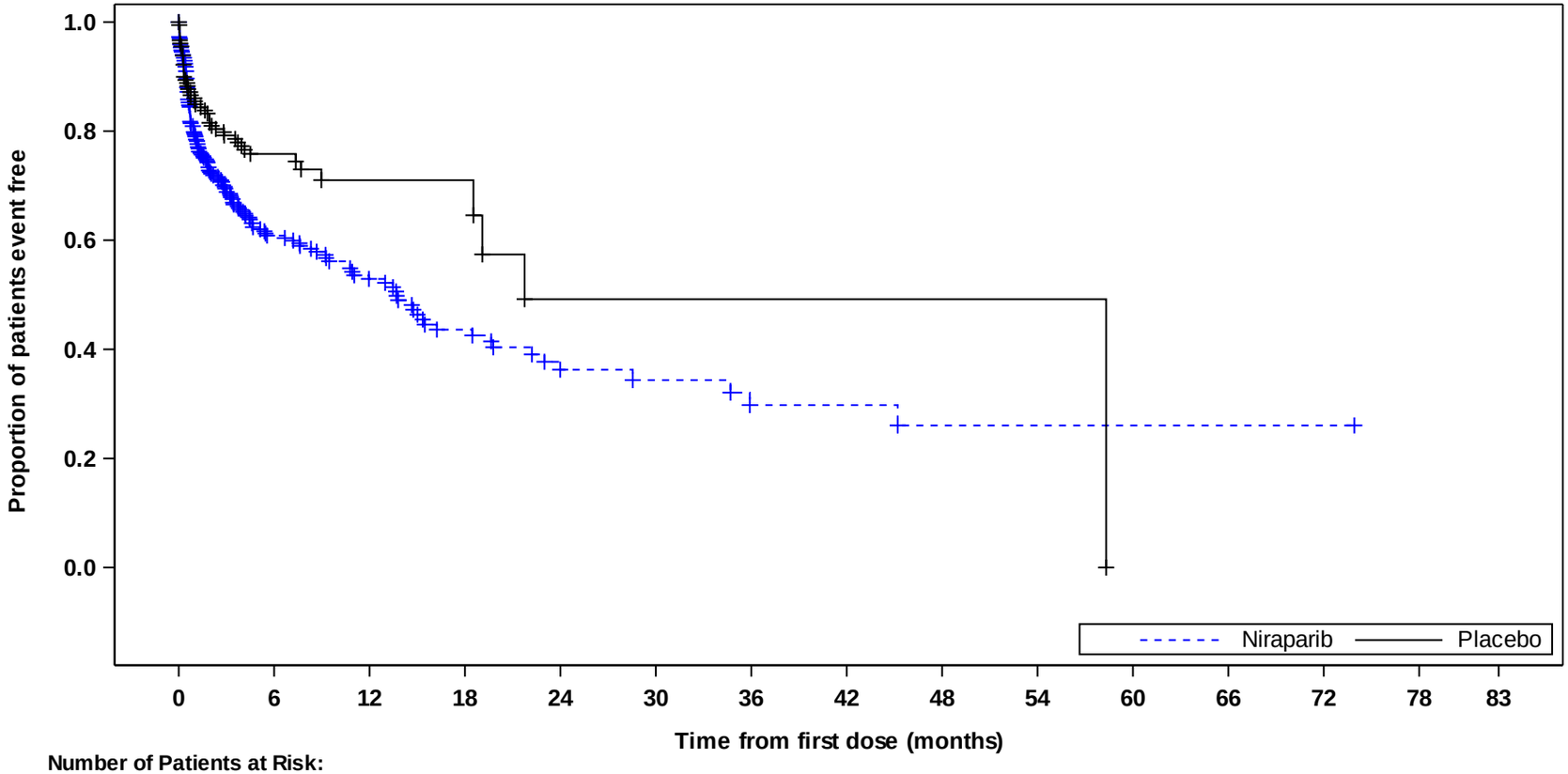
Number of Patients at Risk:

Niraparib	367	242	160	101	71	61	51	42	39	33	28	22	7	0
Placebo	179	92	36	15	9	8	8	7	5	4	4	4	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:05 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Skin and subcutaneous tissue disorders



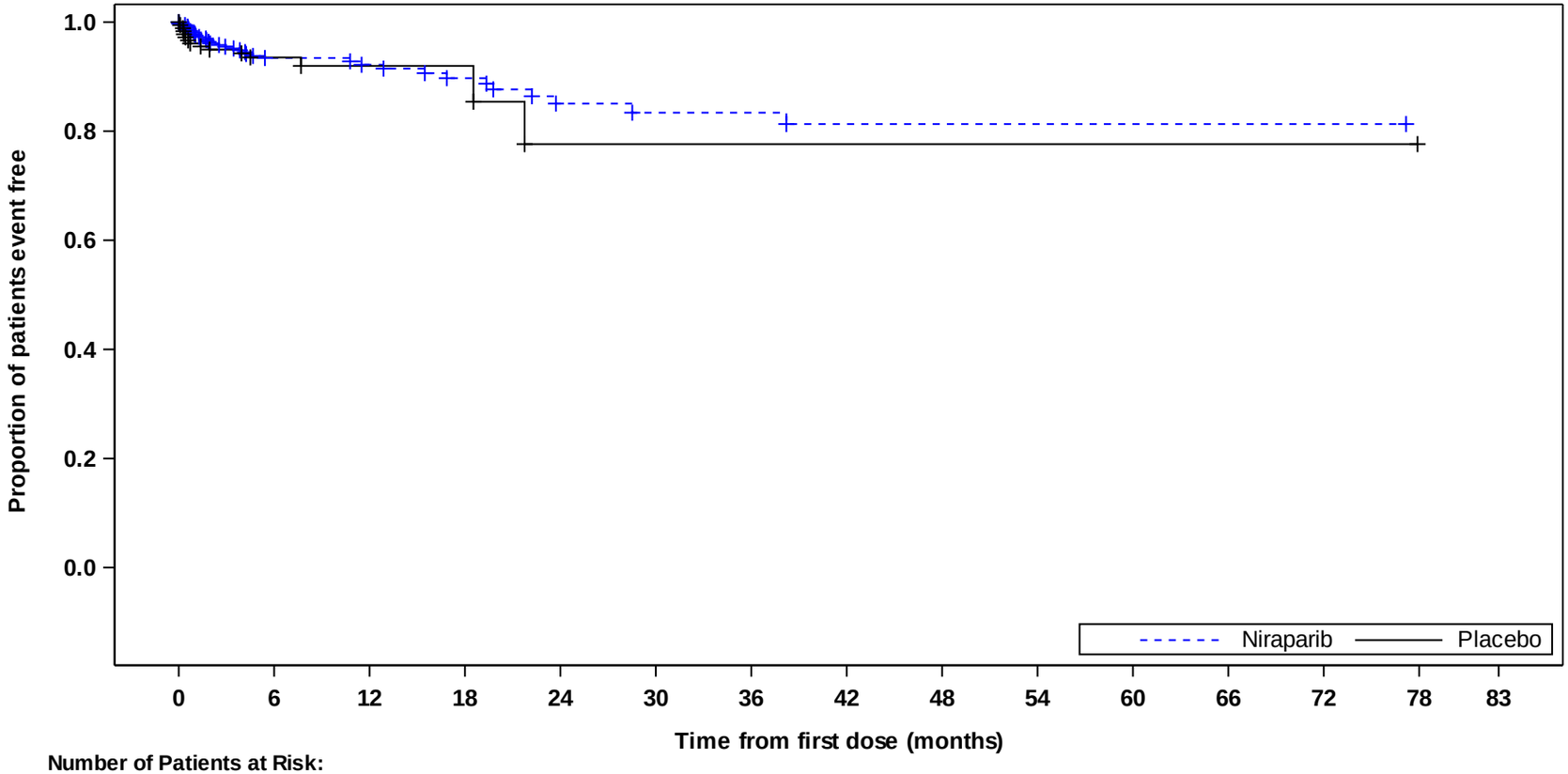
Number of Patients at Risk:

Niraparib	367	149	81	41	25	18	13	8	7	7	6	5	1	0
Placebo	179	71	27	11	3	3	3	2	1	1	0			

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:06 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Skin and subcutaneous tissue disorders, PT: Alopecia



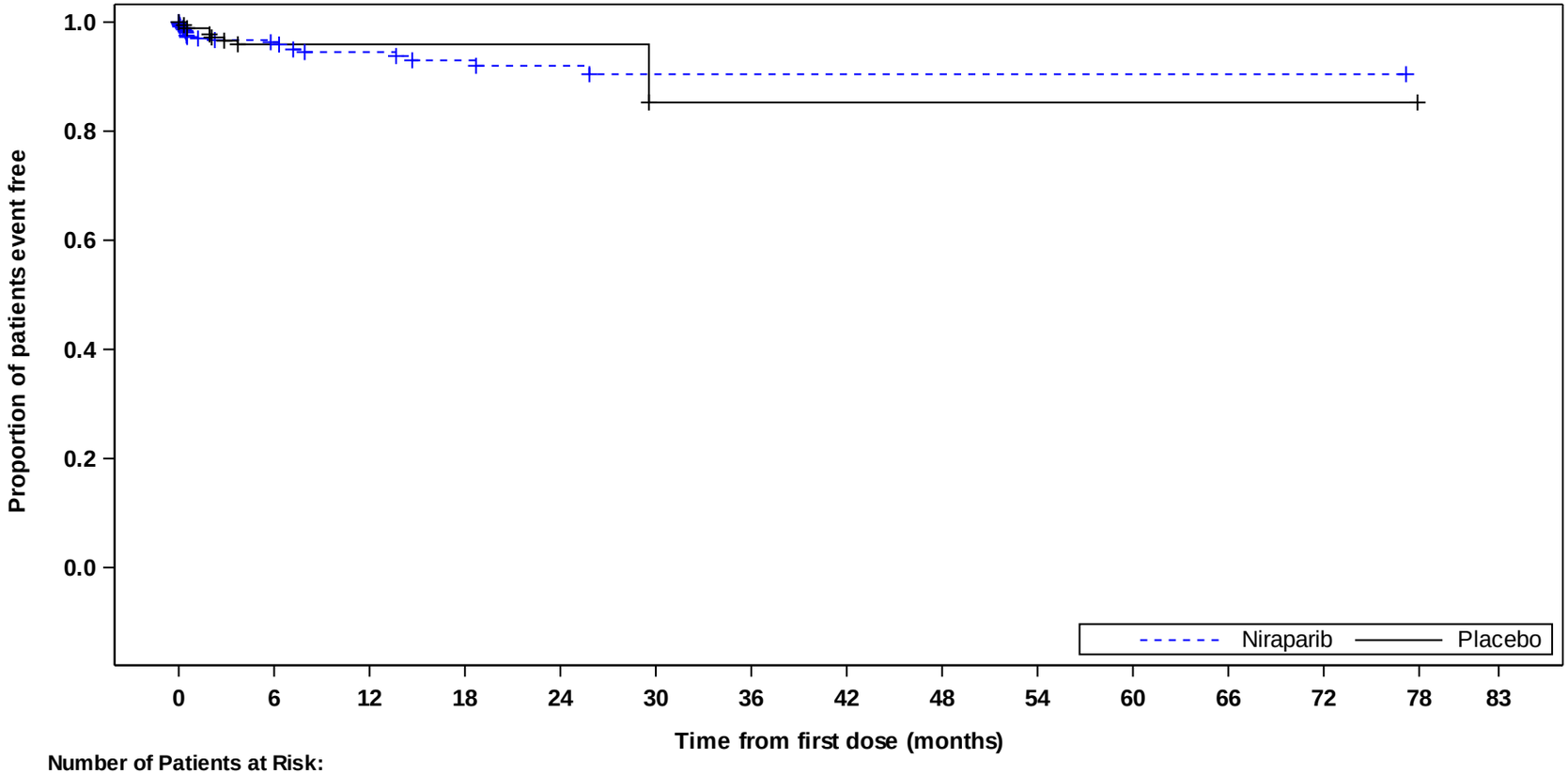
Number of Patients at Risk:

Niraparib	367	229	147	89	61	50	43	32	31	27	23	19	6	0
Placebo	179	84	33	14	7	7	7	6	5	4	4	4	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:07 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Skin and subcutaneous tissue disorders, PT: Dry skin



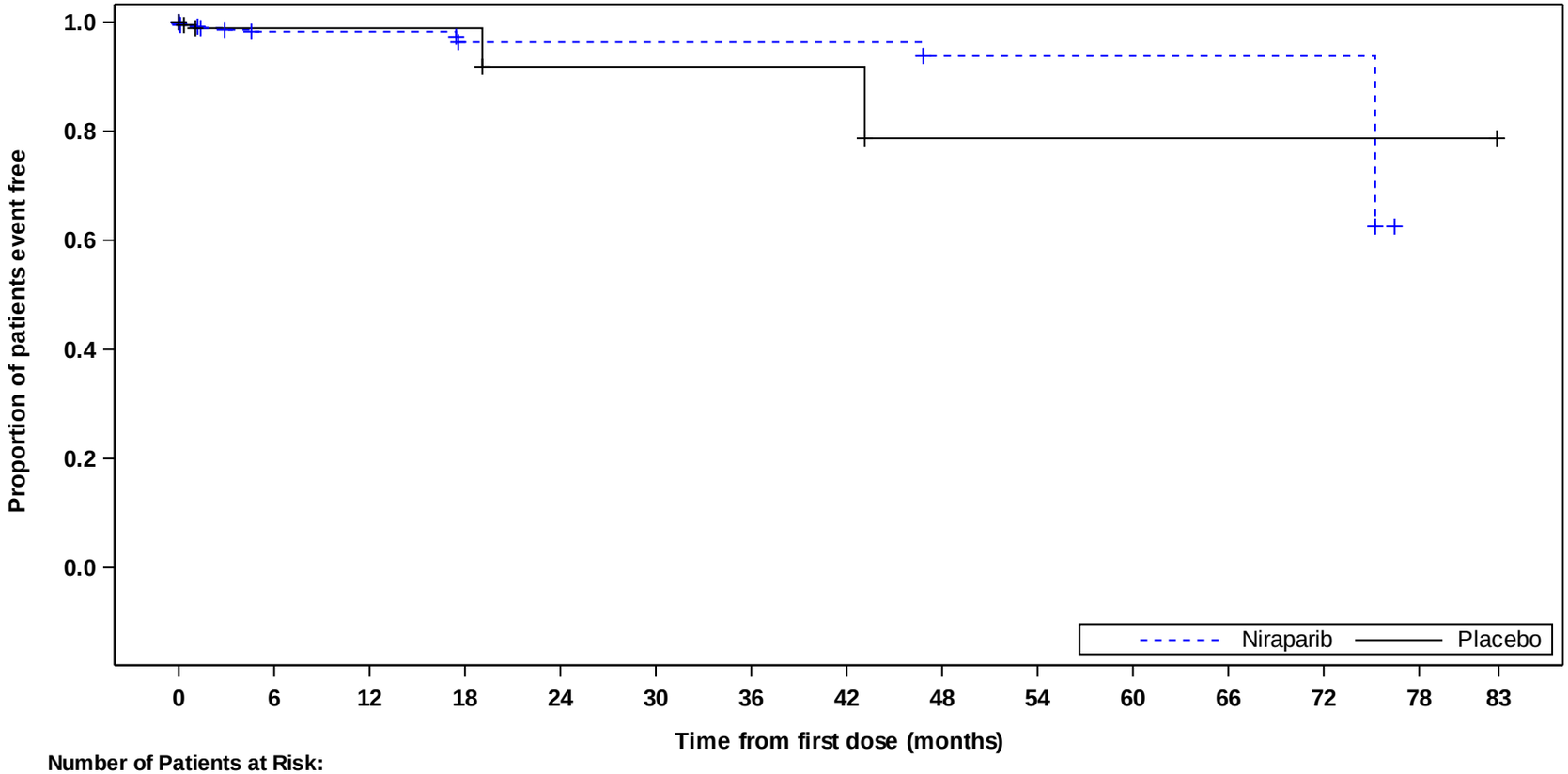
Number of Patients at Risk:

Niraparib	367	238	154	94	64	54	45	35	32	27	23	18	6	0
Placebo	179	87	36	16	10	8	8	7	6	5	5	5	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:08 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Skin and subcutaneous tissue disorders, PT: Erythema



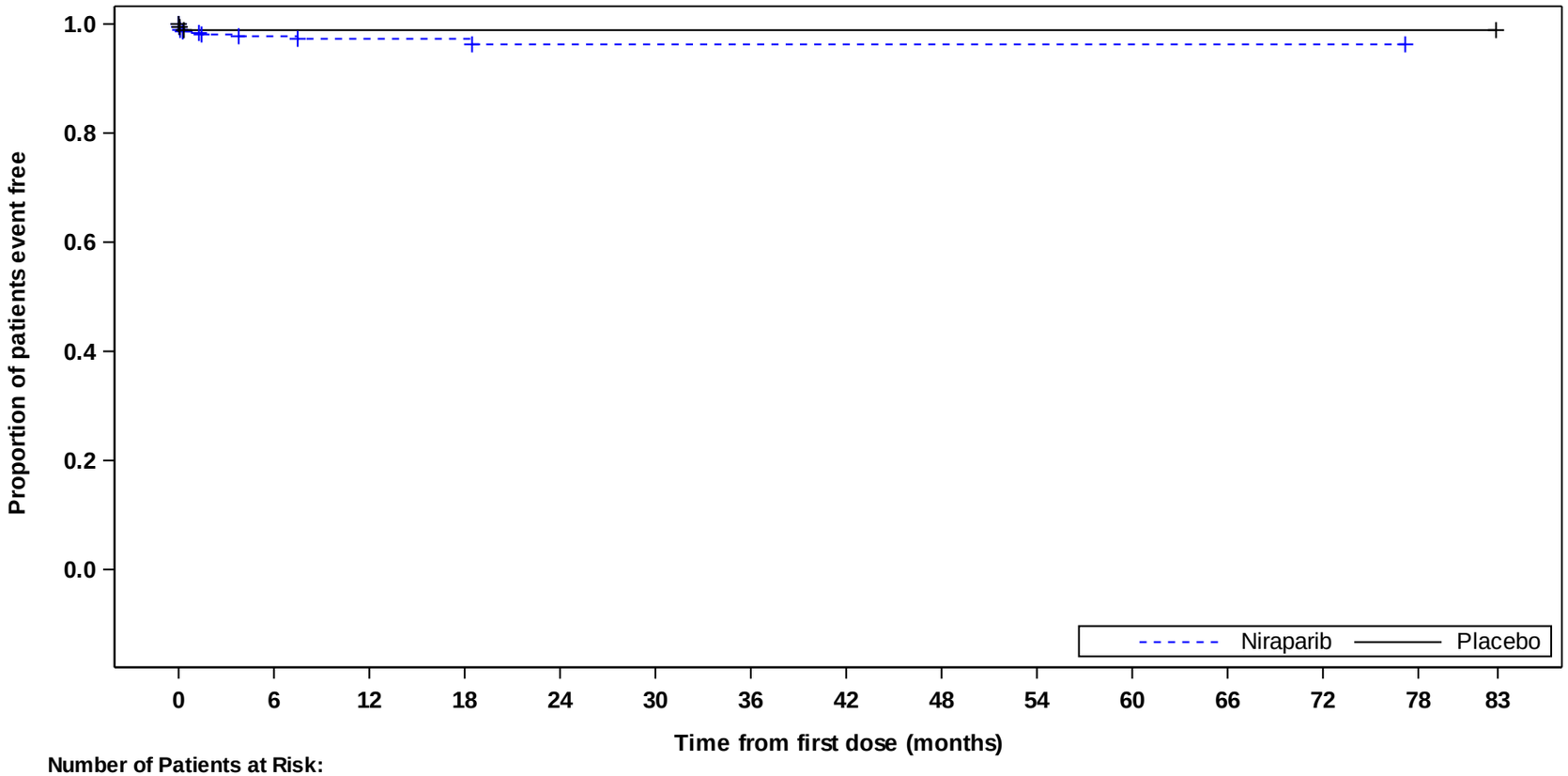
Number of Patients at Risk:

Niraparib	367	243	160	97	69	59	50	40	36	31	26	20	7	0
Placebo	179	92	37	16	9	8	8	7	5	4	4	4	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:08 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Skin and subcutaneous tissue disorders, PT: Hyperhidrosis



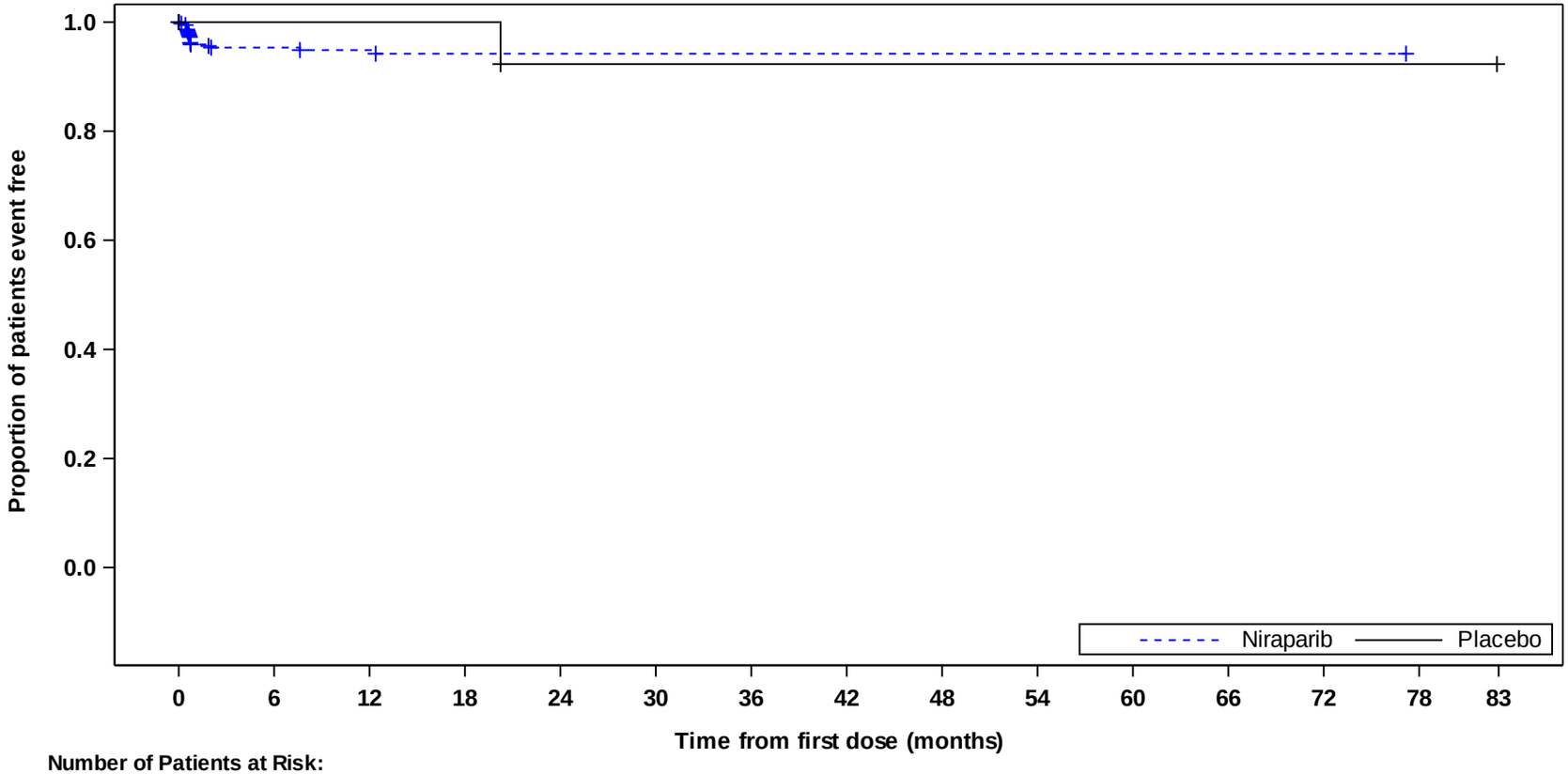
Number of Patients at Risk:

Niraparib	367	241	155	97	67	57	48	38	35	30	25	18	6	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:09 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Skin and subcutaneous tissue disorders, PT: Petechiae



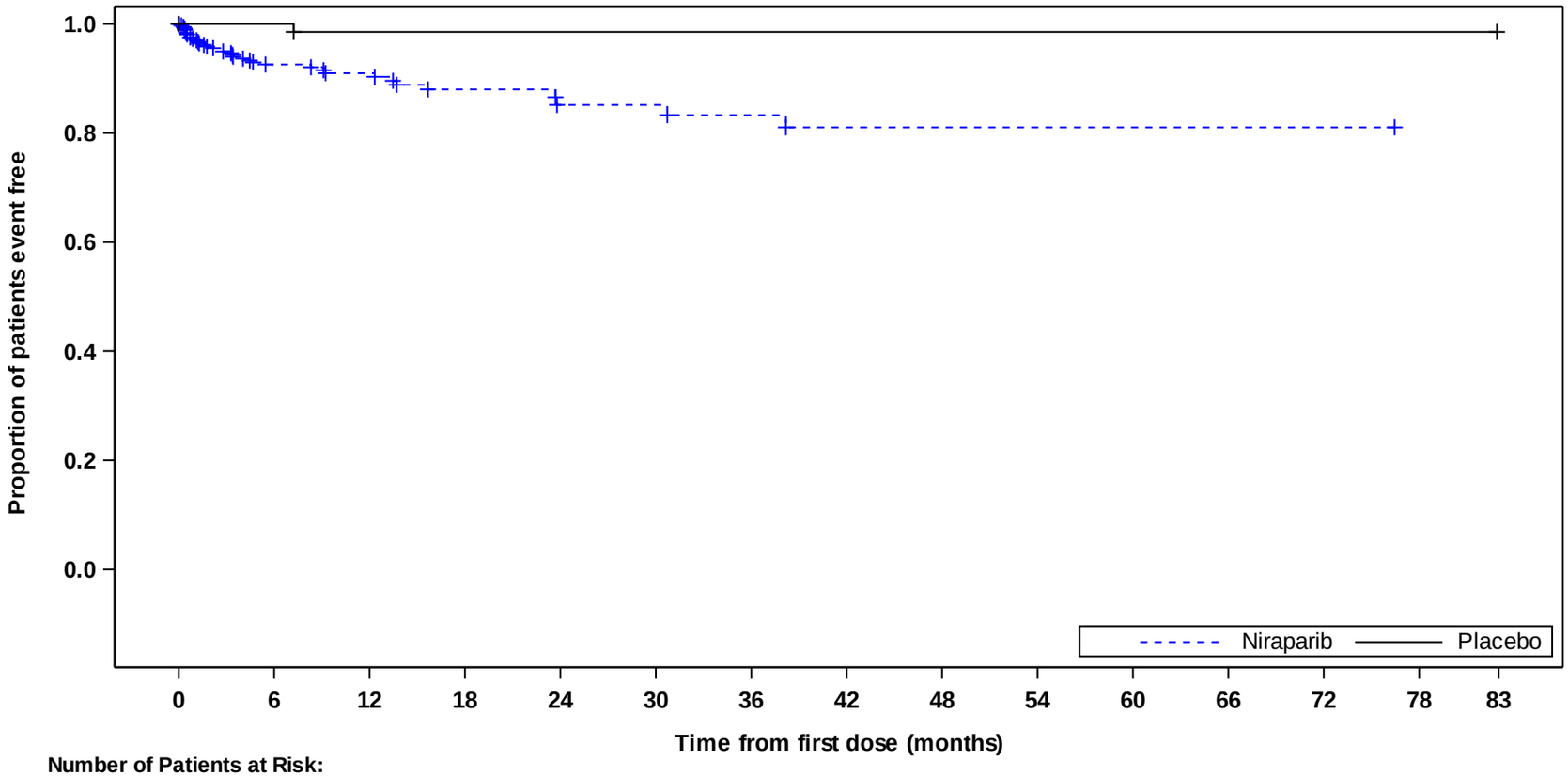
Number of Patients at Risk:

Niraparib	367	237	152	93	65	55	46	36	33	28	23	17	6	0
Placebo	179	92	37	16	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:10 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Skin and subcutaneous tissue disorders, PT: Photosensitivity reaction



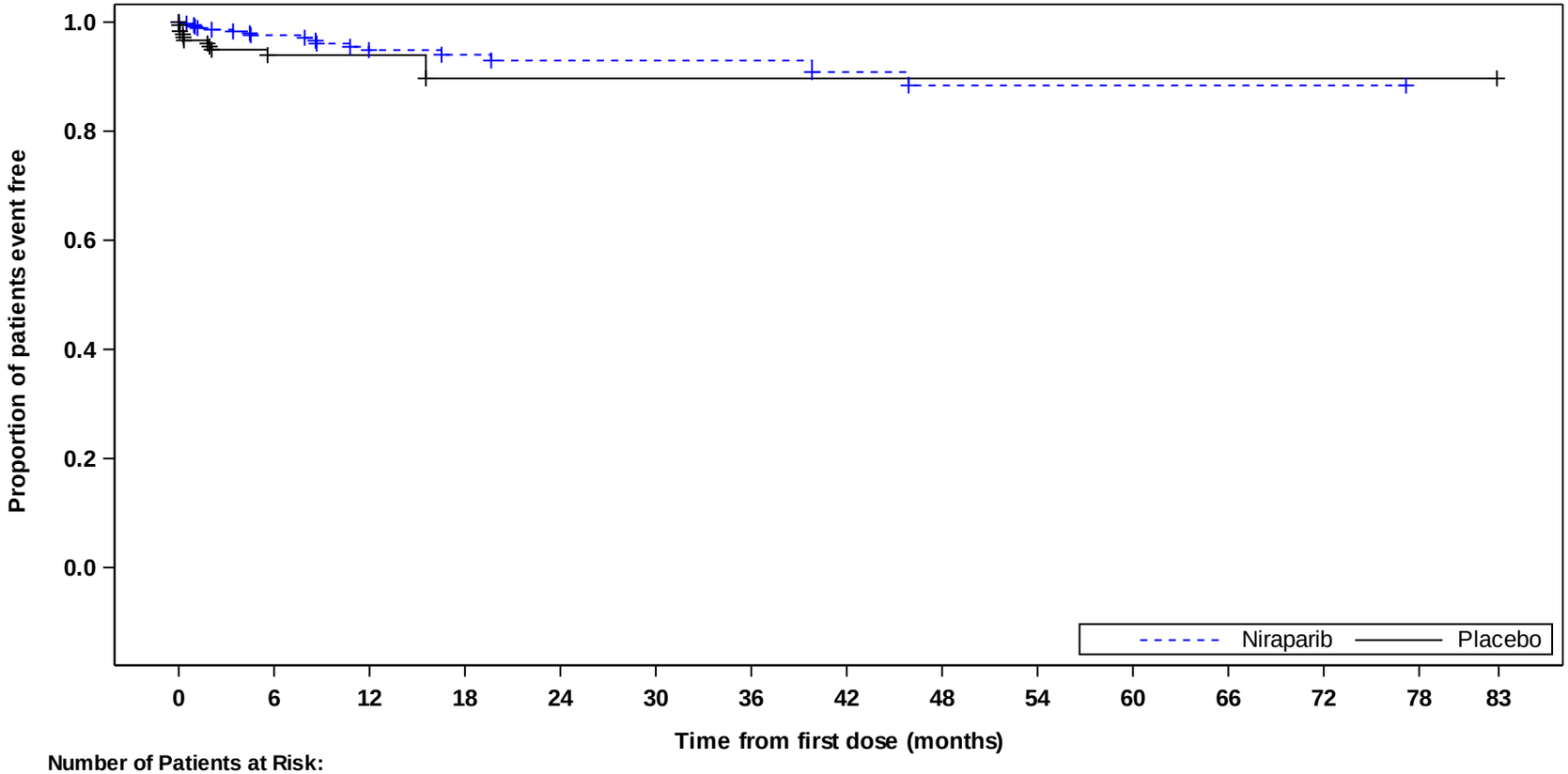
Number of Patients at Risk:

Niraparib	367	228	146	88	58	49	40	30	28	23	21	16	5	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:11 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Skin and subcutaneous tissue disorders, PT: Pruritus



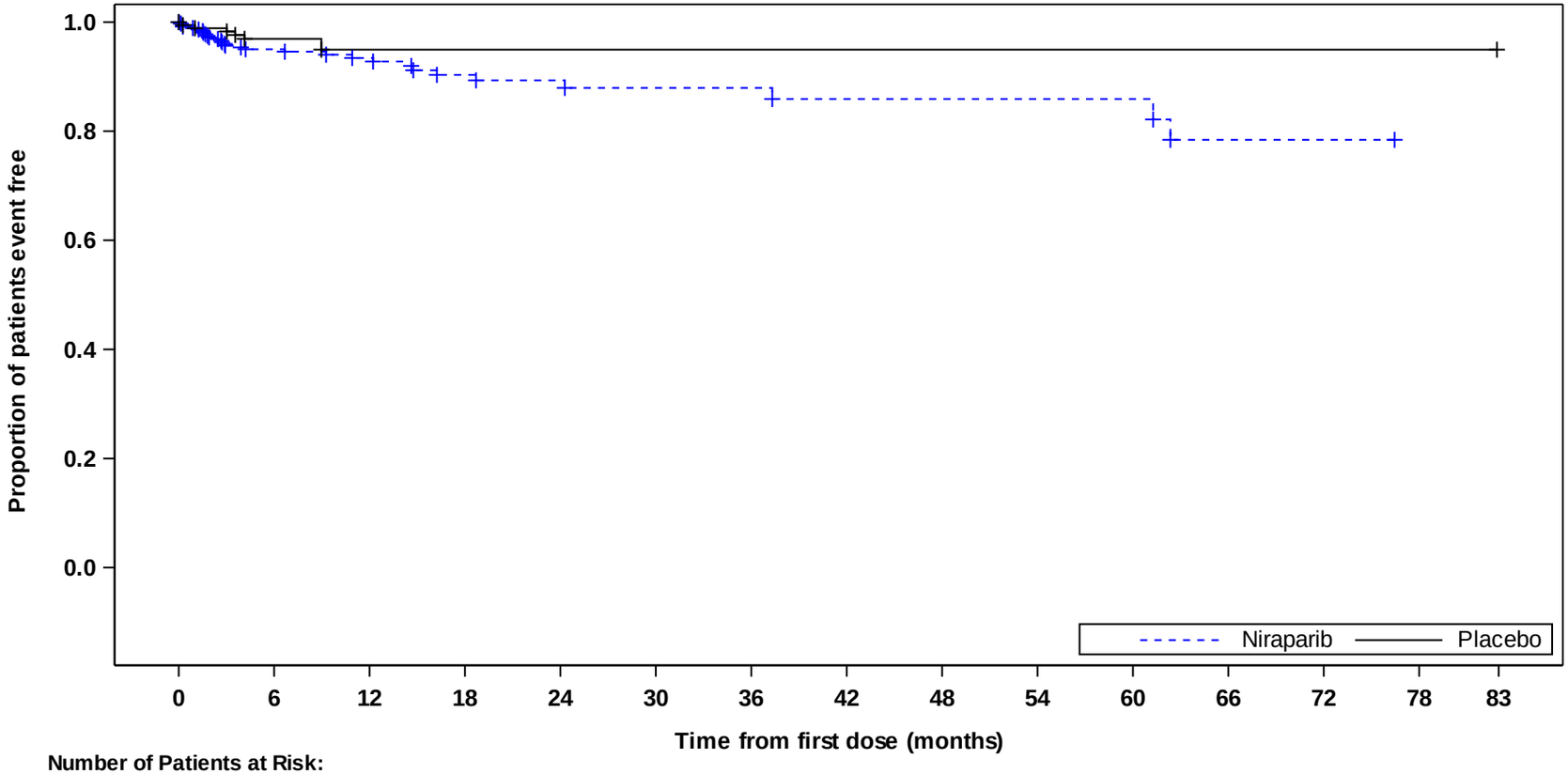
Number of Patients at Risk:

Niraparib	367	242	155	95	66	58	49	39	35	31	26	20	6	0
Placebo	179	88	35	14	9	8	8	7	6	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:12 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Skin and subcutaneous tissue disorders, PT: Rash



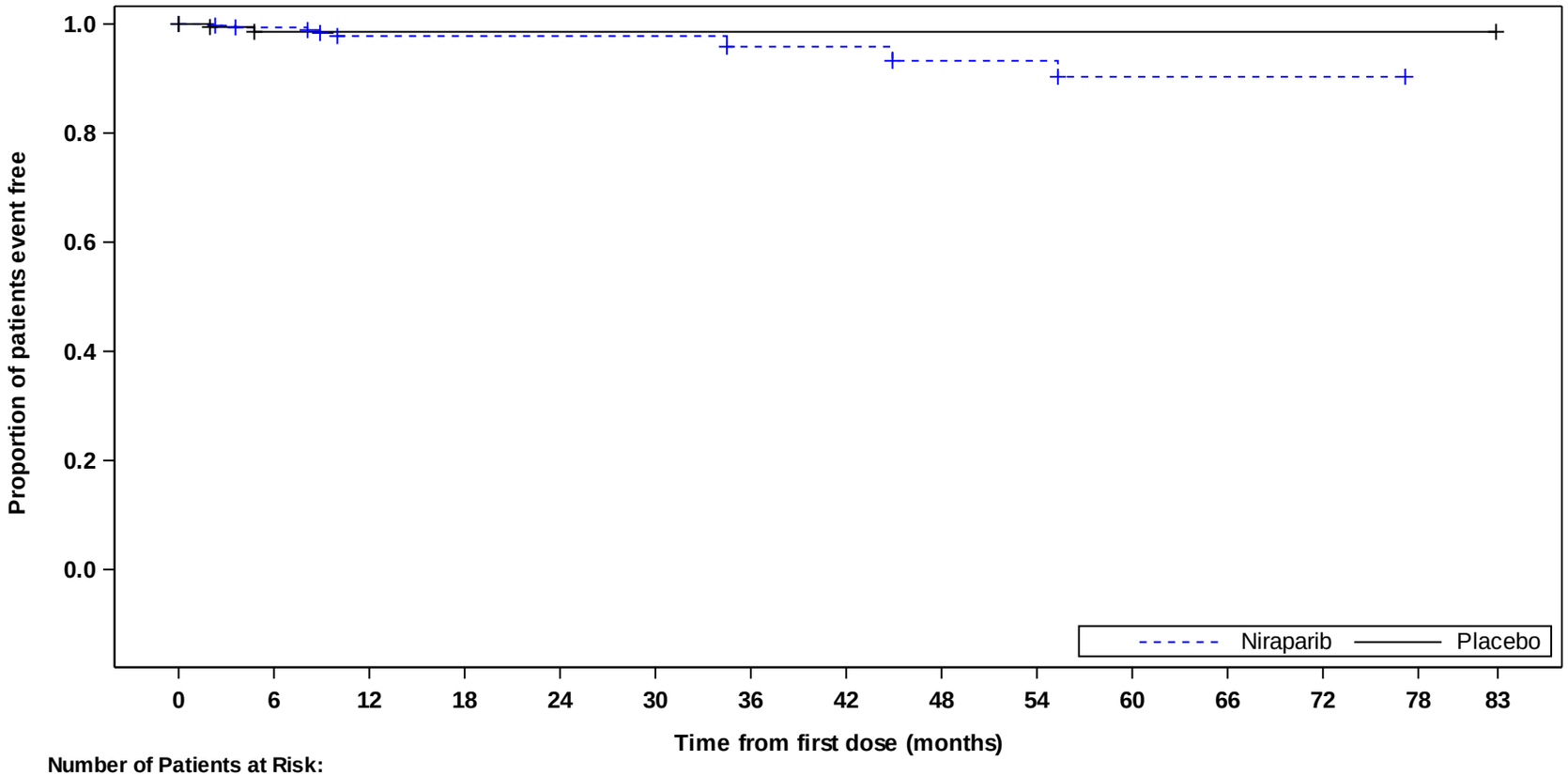
Number of Patients at Risk:

Niraparib	367	234	151	90	65	54	45	35	33	28	23	16	5	0
Placebo	179	88	35	15	9	8	8	7	6	5	5	5	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:13 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Surgical and medical procedures



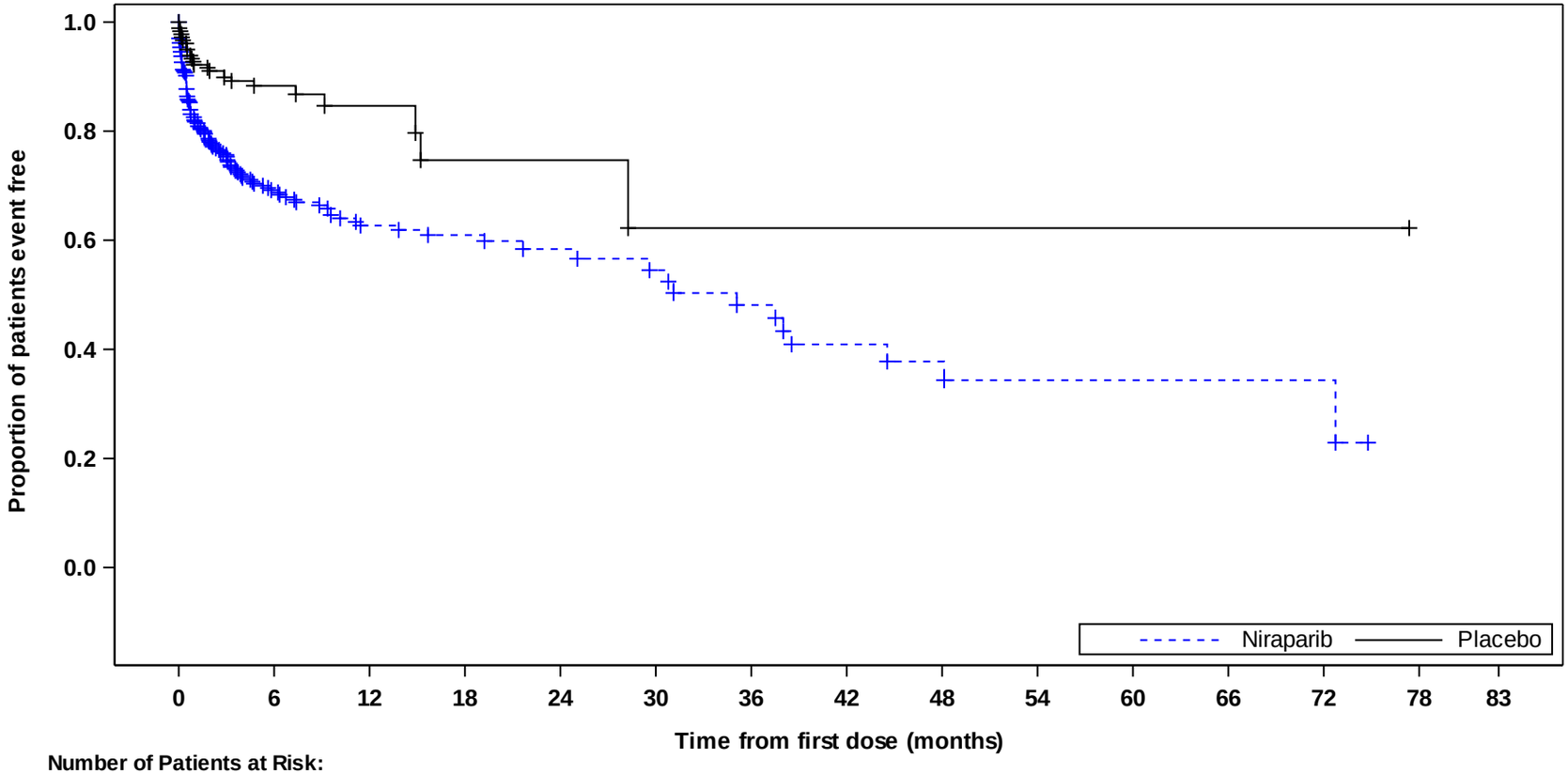
Number of Patients at Risk:

Niraparib	367	245	157	97	69	59	49	39	35	32	26	19	7	0
Placebo	179	91	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:14 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Vascular disorders



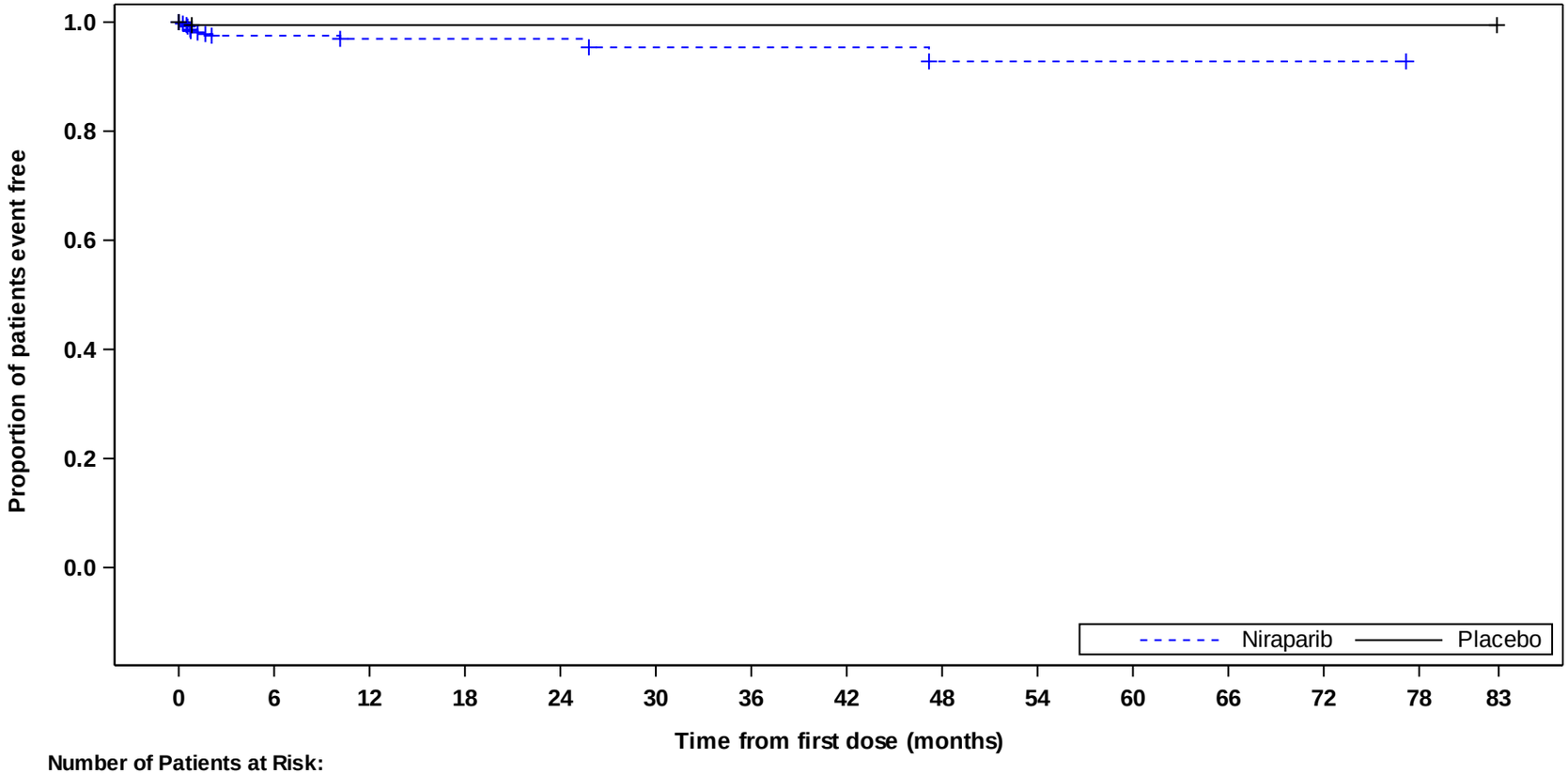
Number of Patients at Risk:

Niraparib	367	167	94	55	35	26	22	14	11	10	6	5	3	0
Placebo	179	77	28	10	6	5	5	4	3	3	3	3	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:15 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Vascular disorders, PT: Haematoma



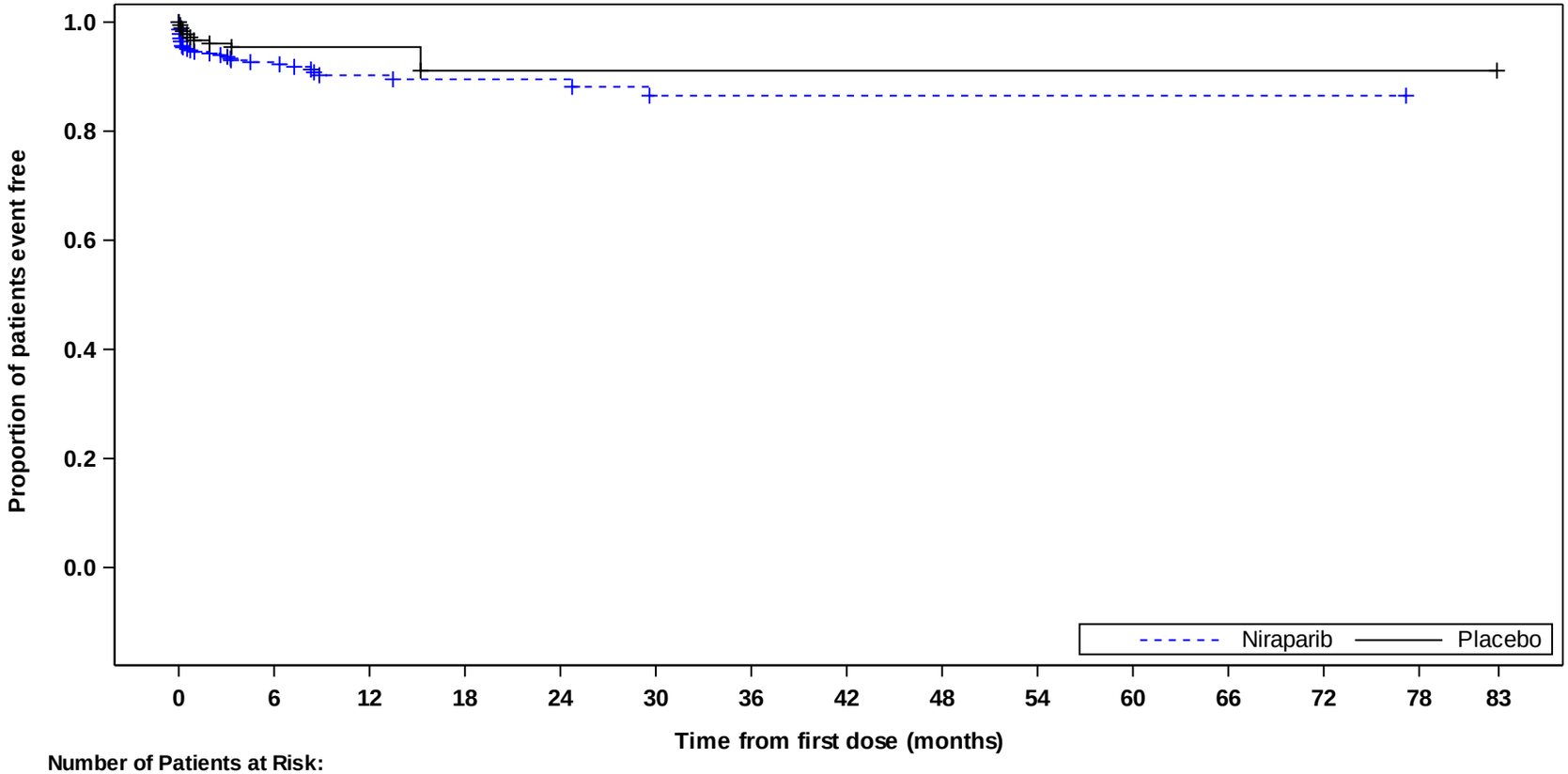
Number of Patients at Risk:

Niraparib	367	241	155	96	67	56	49	39	35	31	26	21	7	0
Placebo	179	91	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:16 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Vascular disorders, PT: Hot flush



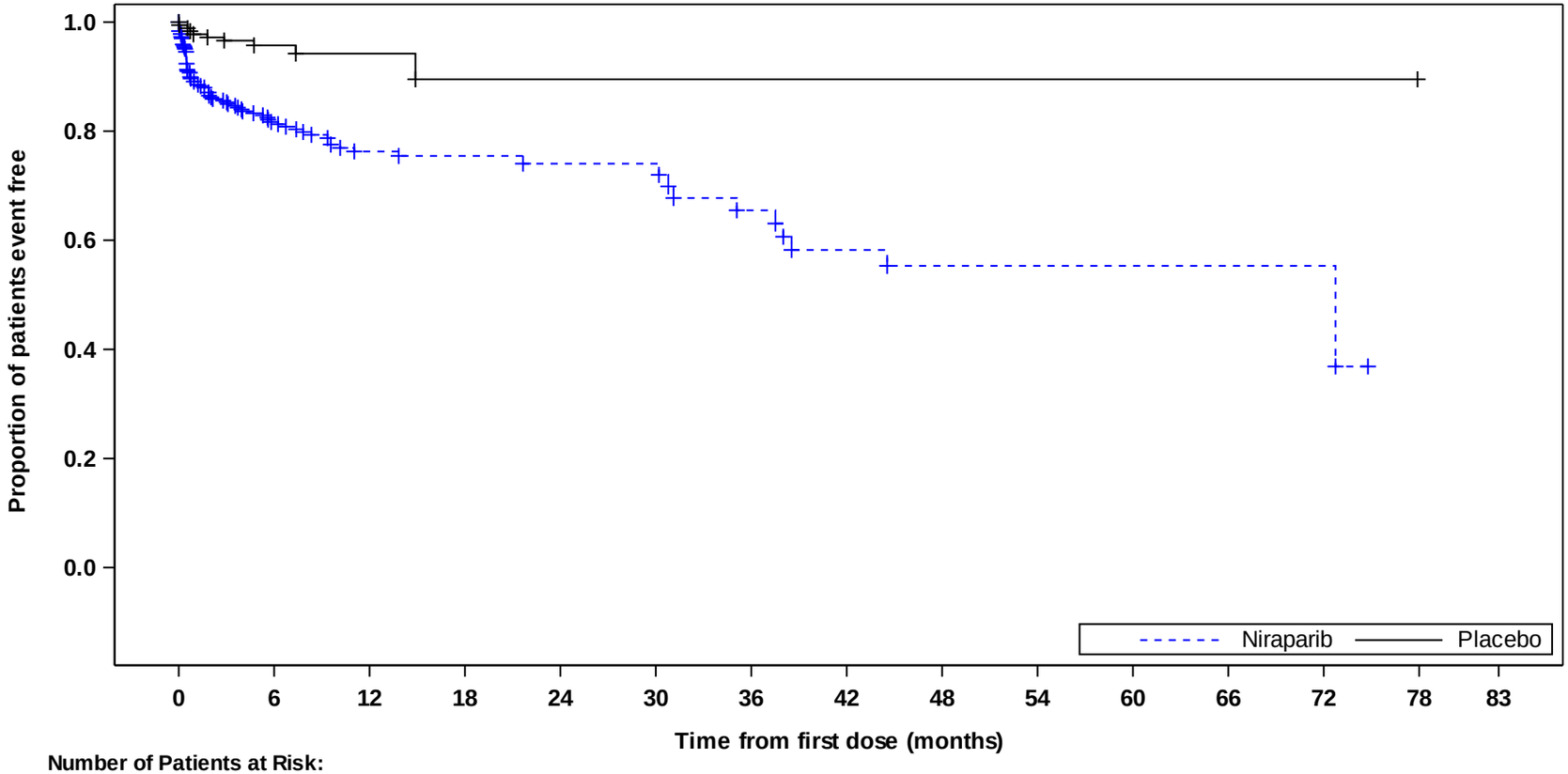
Number of Patients at Risk:

Niraparib	367	229	145	90	65	53	45	35	32	28	23	18	7	0
Placebo	179	87	34	14	8	7	7	6	5	5	5	5	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:17 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Vascular disorders, PT: Hypertension



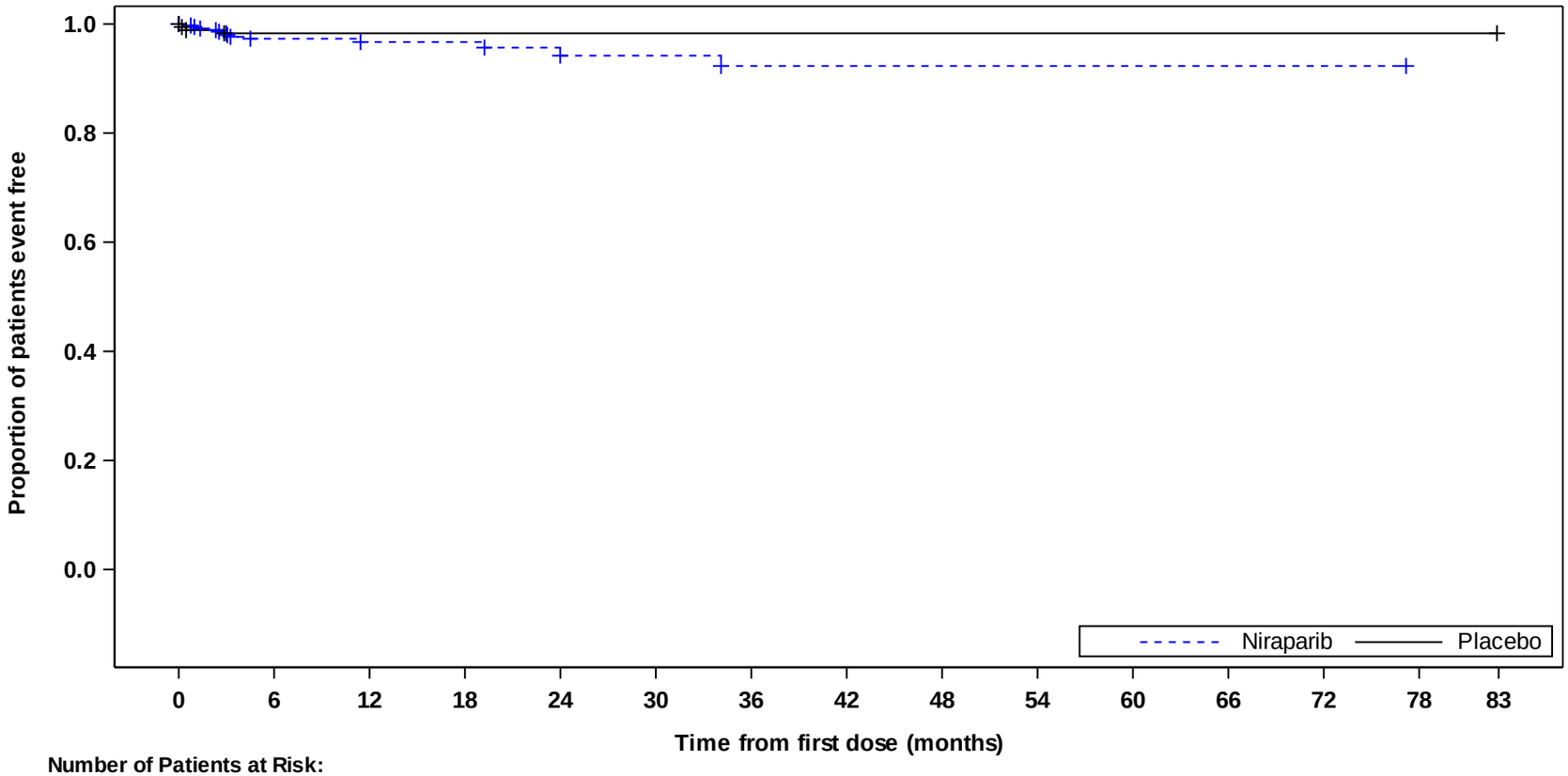
Number of Patients at Risk:

Niraparib	367	197	115	66	45	36	29	21	18	16	11	7	3	0
Placebo	179	86	32	12	8	8	8	7	6	5	5	5	2	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:18 Data Extraction Date: 01OCT2020

Figure 3.9.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Vascular disorders, PT: Hypotension



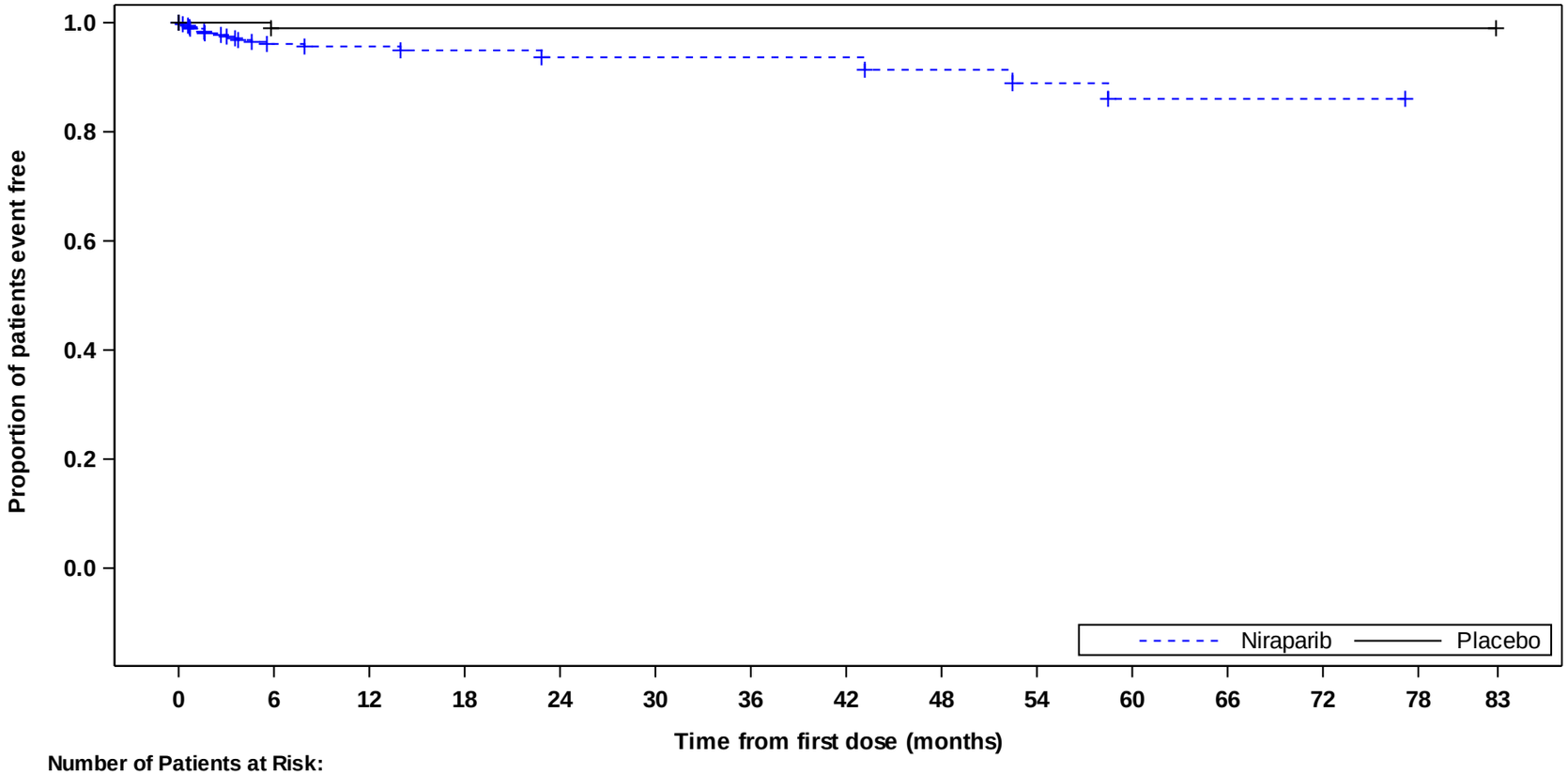
Number of Patients at Risk:

Niraparib	367	239	156	96	64	56	48	38	35	31	26	21	7	0
Placebo	179	90	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:19 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Blood and lymphatic system disorders



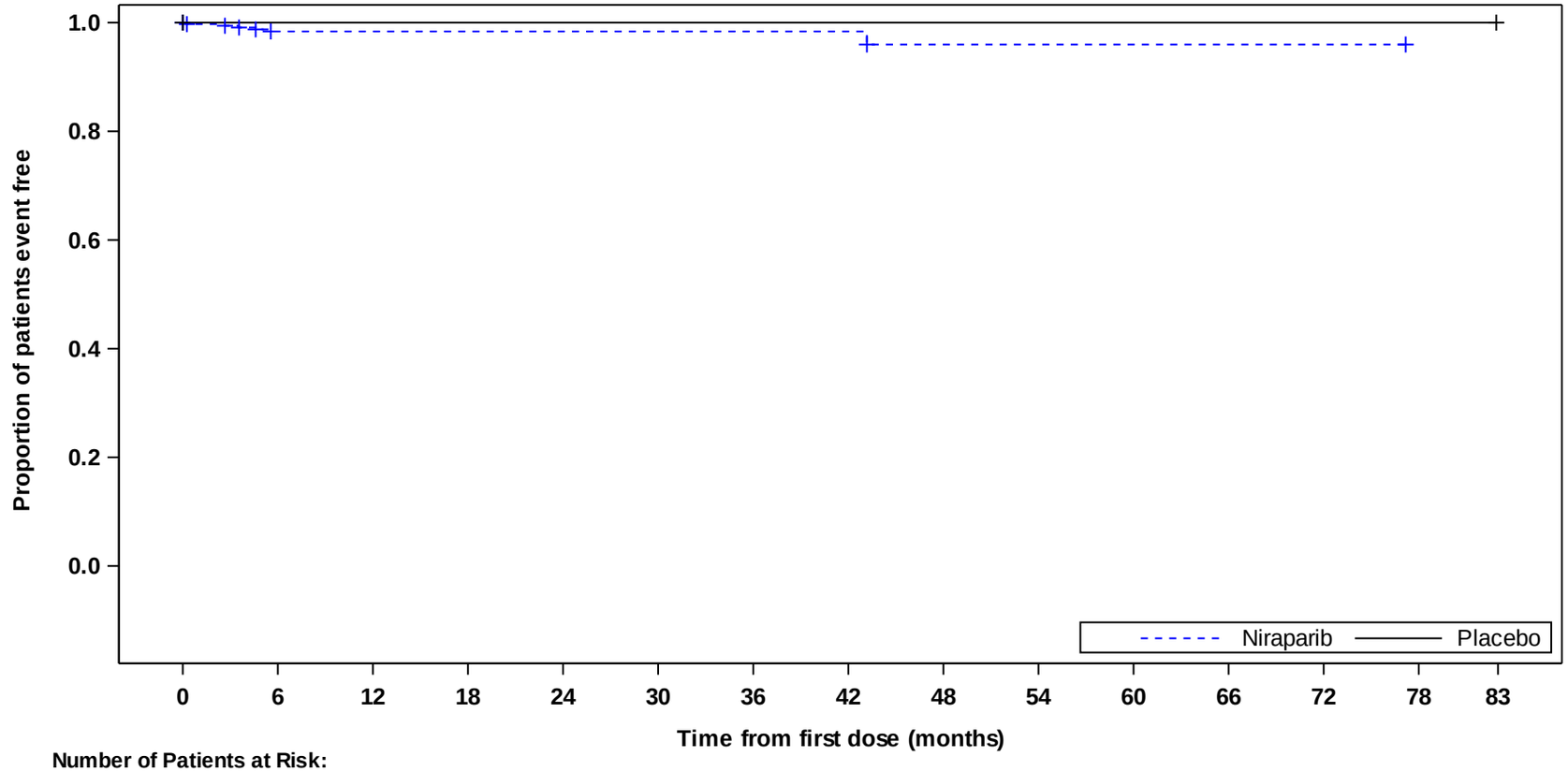
Number of Patients at Risk:

Niraparib	367	246	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:24 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Anaemia



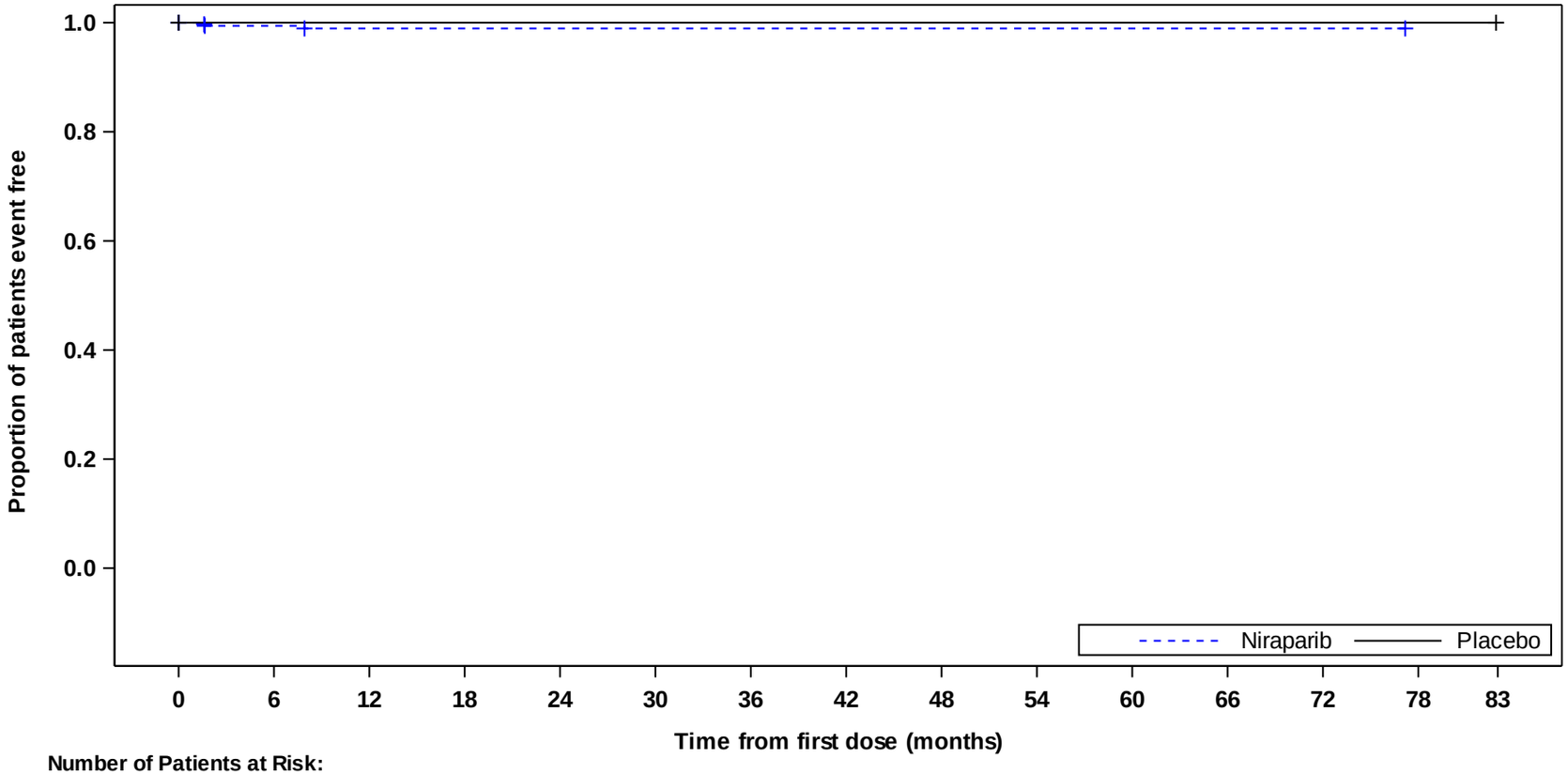
Number of Patients at Risk:

Niraparib	367	246	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:25 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Neutropenia



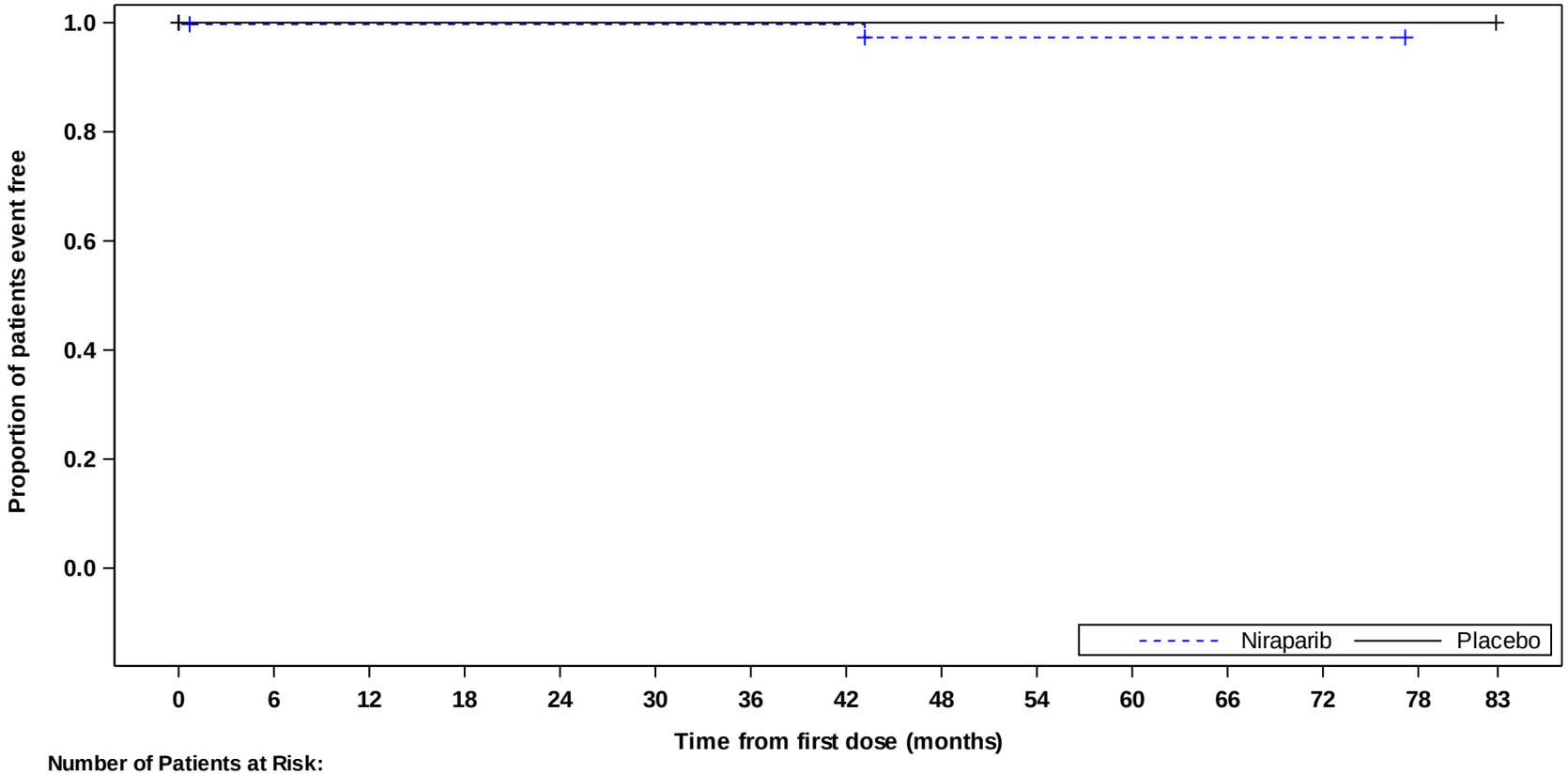
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:26 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Pancytopenia



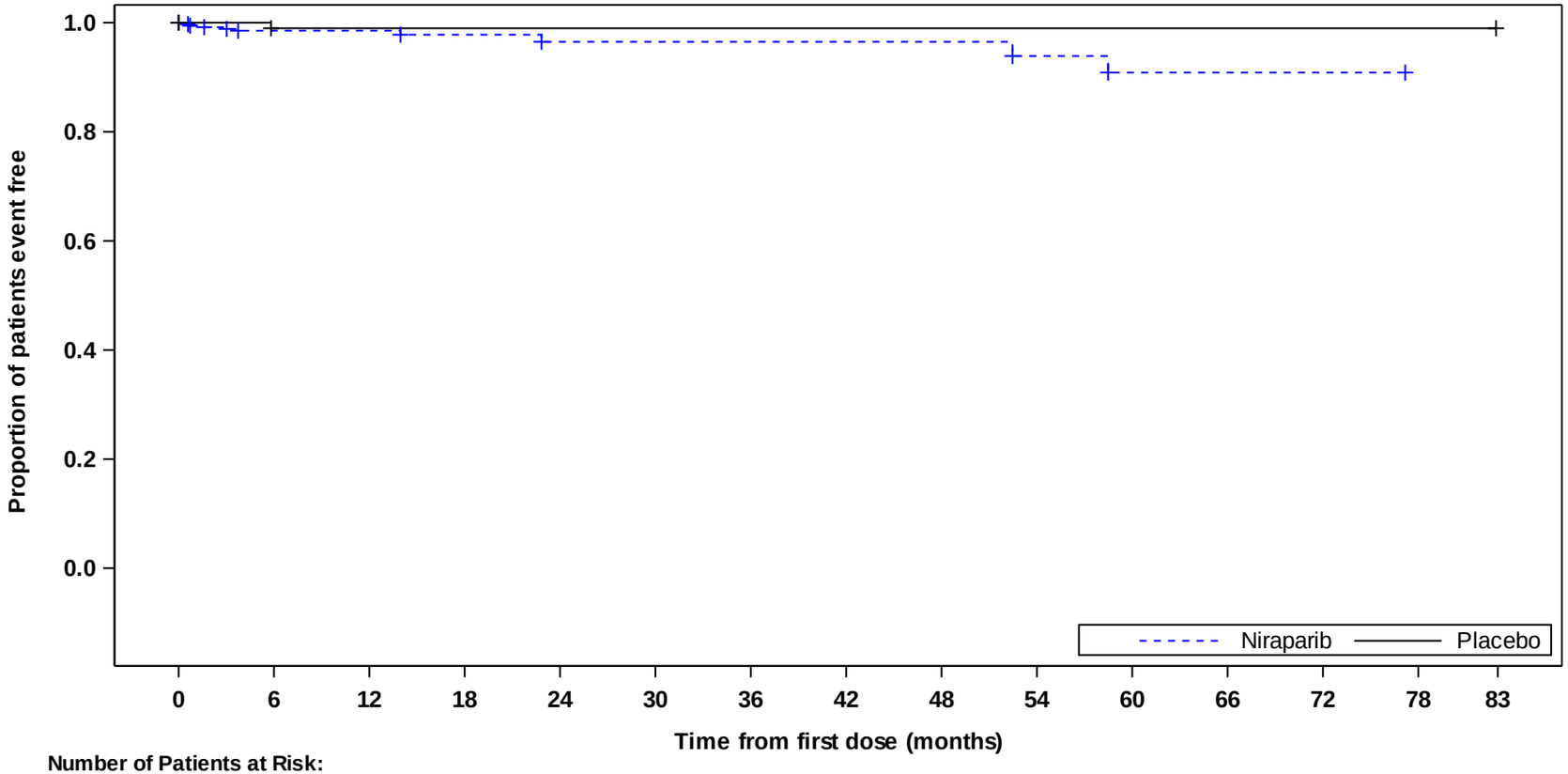
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:26 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia



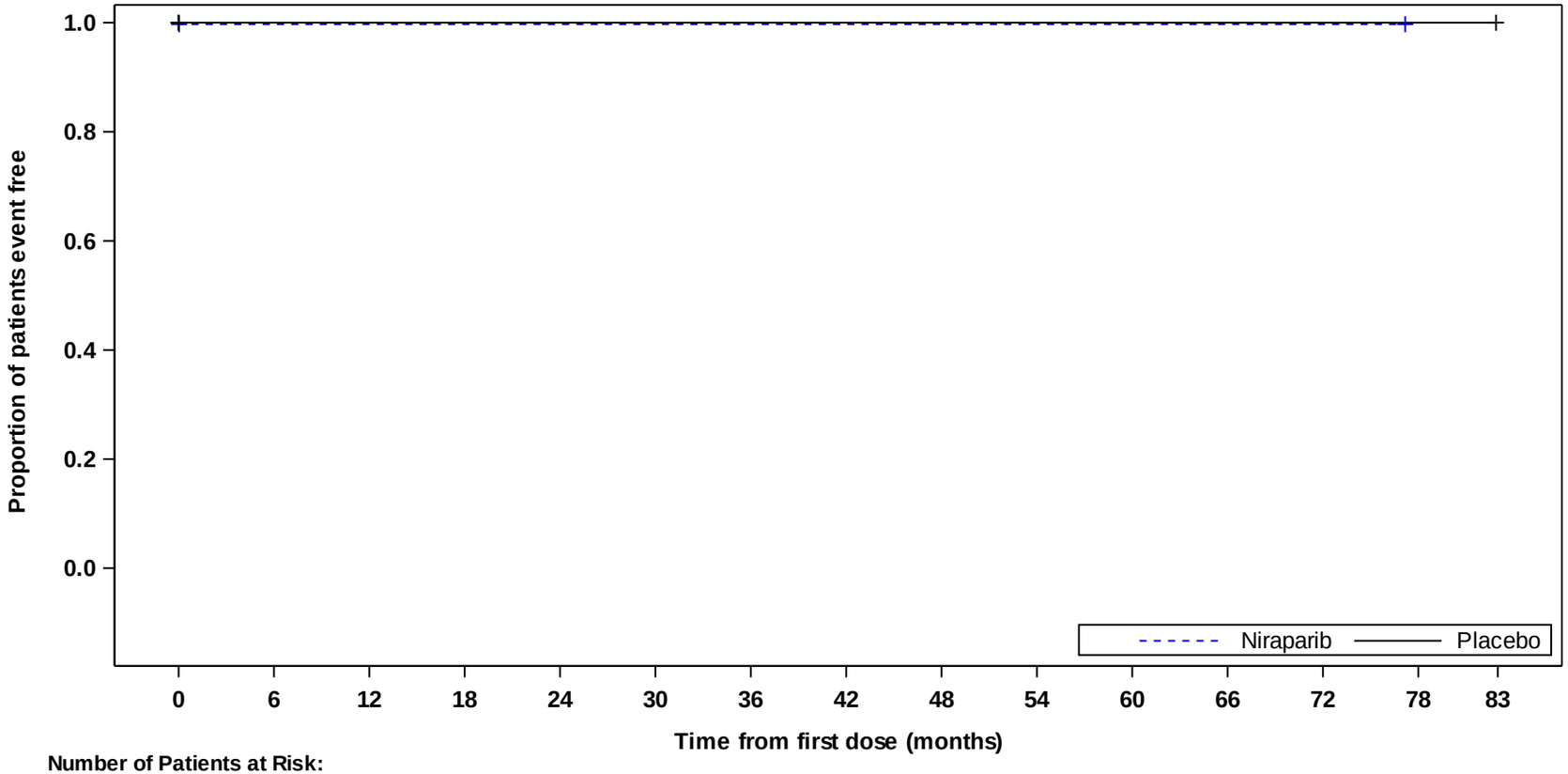
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:27 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Cardiac disorders



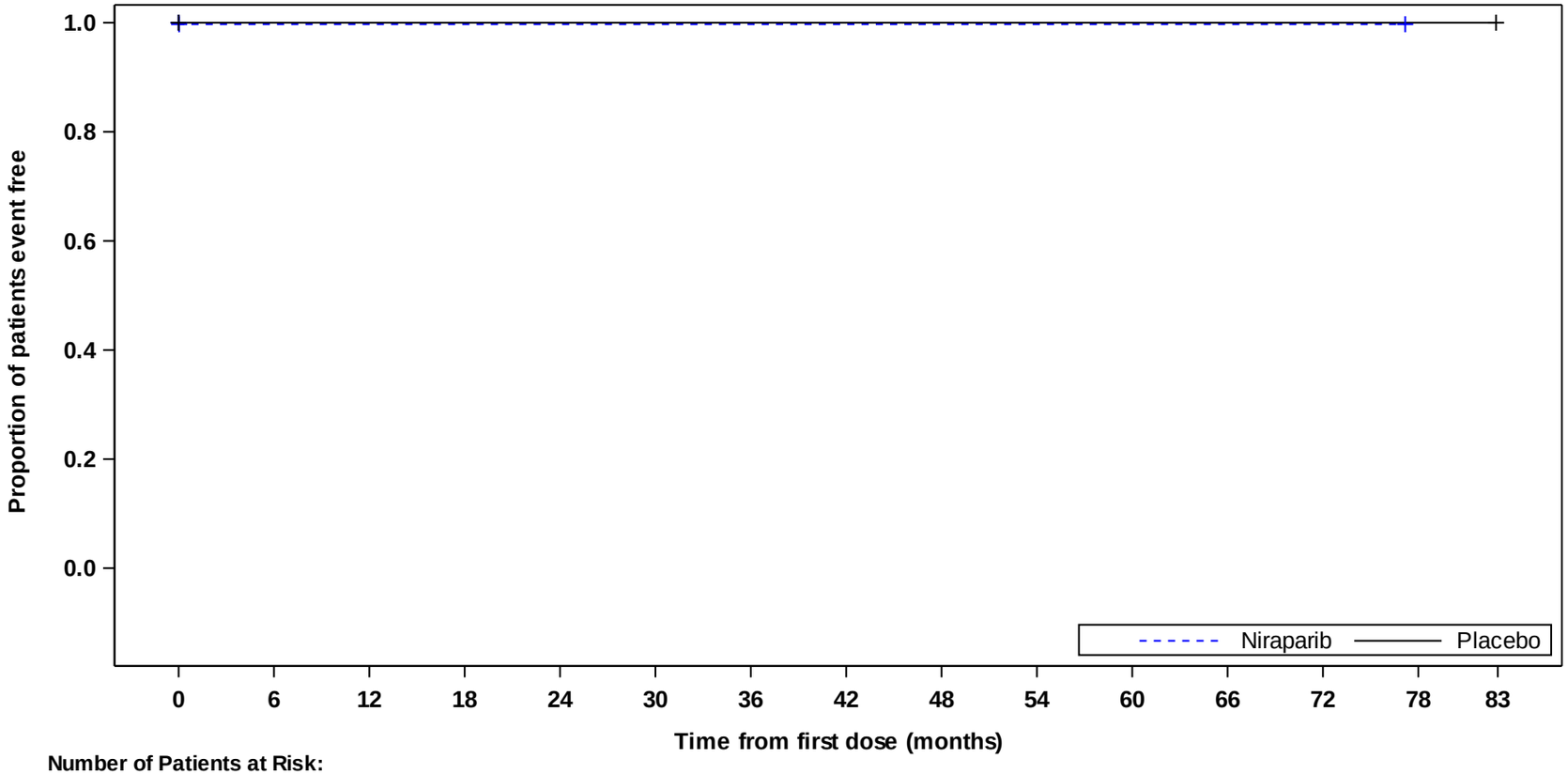
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:28 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Cardiac disorders, PT: Palpitations



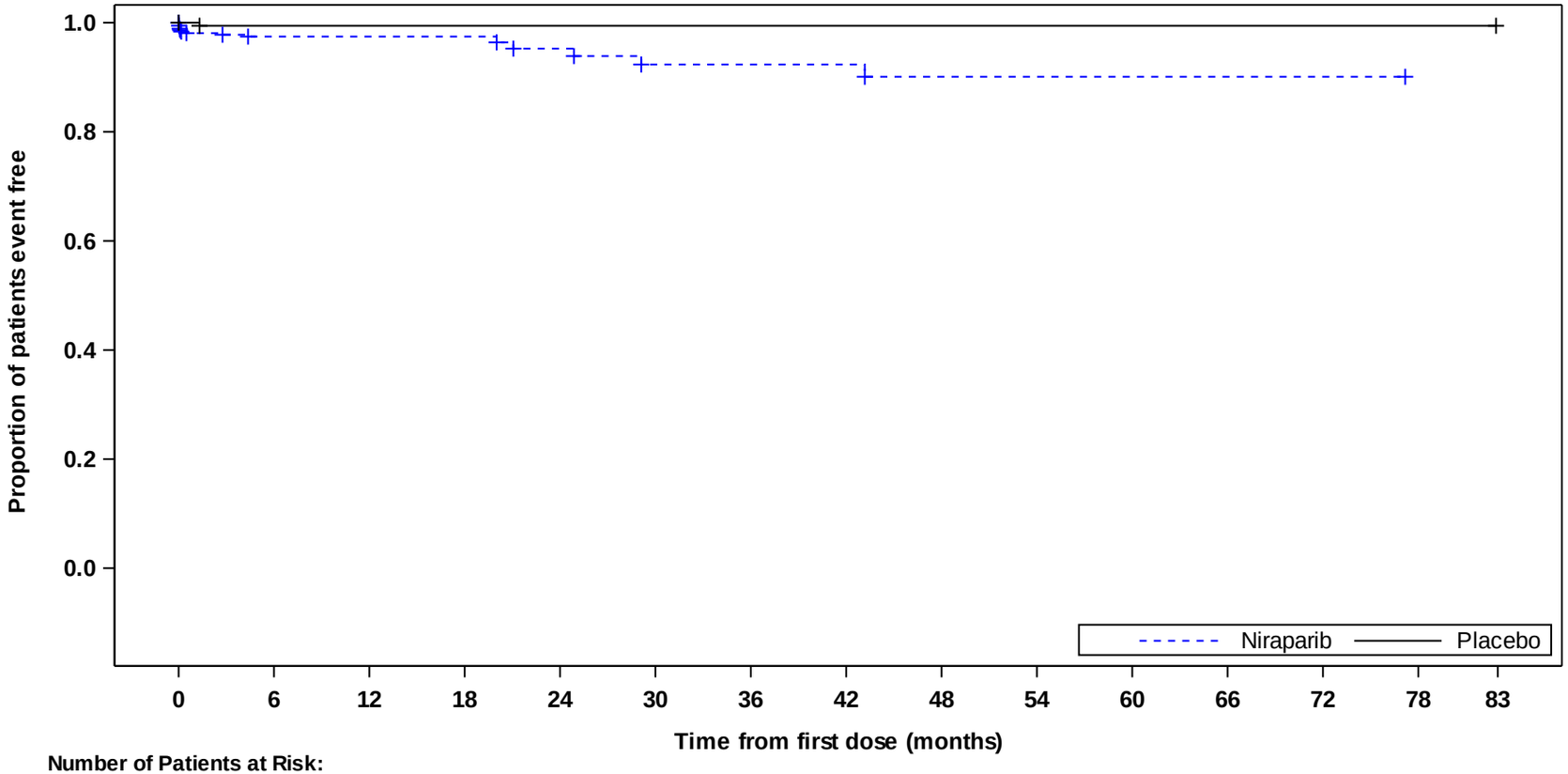
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:29 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Gastrointestinal disorders



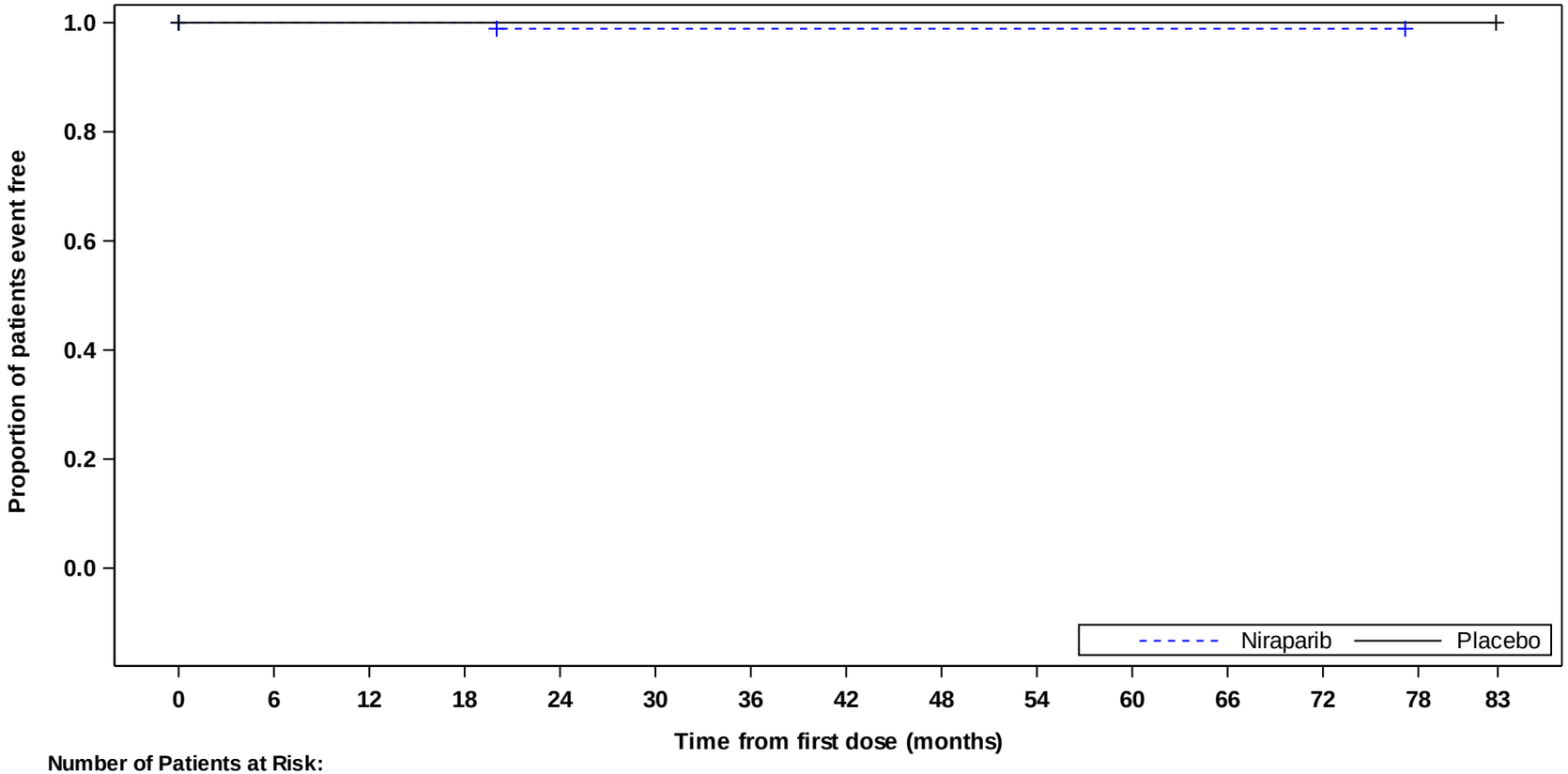
Number of Patients at Risk:

Niraparib	367	247	162	101	71	60	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:30 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Gastrointestinal disorders, PT: Ascites



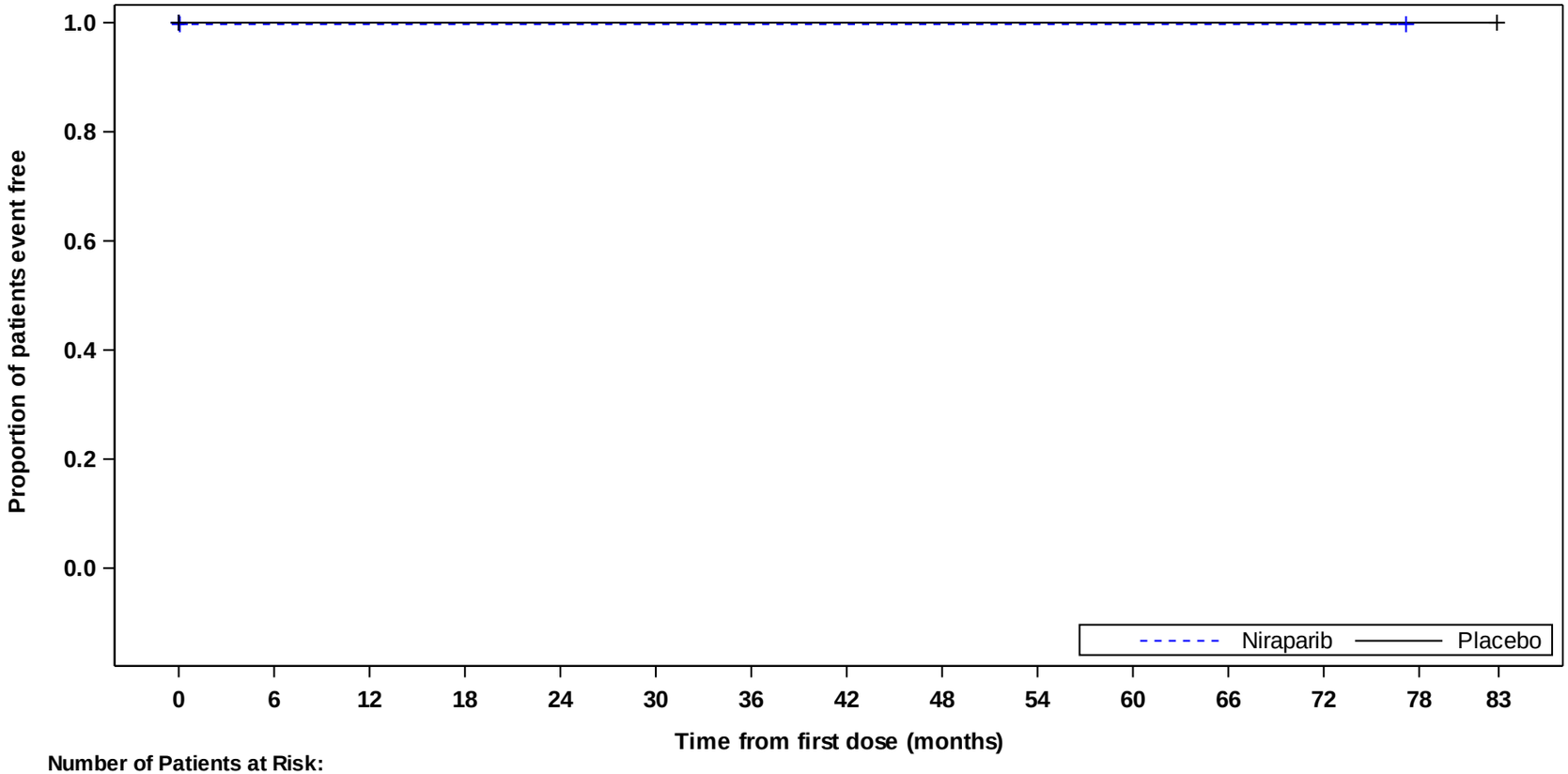
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:31 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Gastrointestinal disorders, PT: Constipation



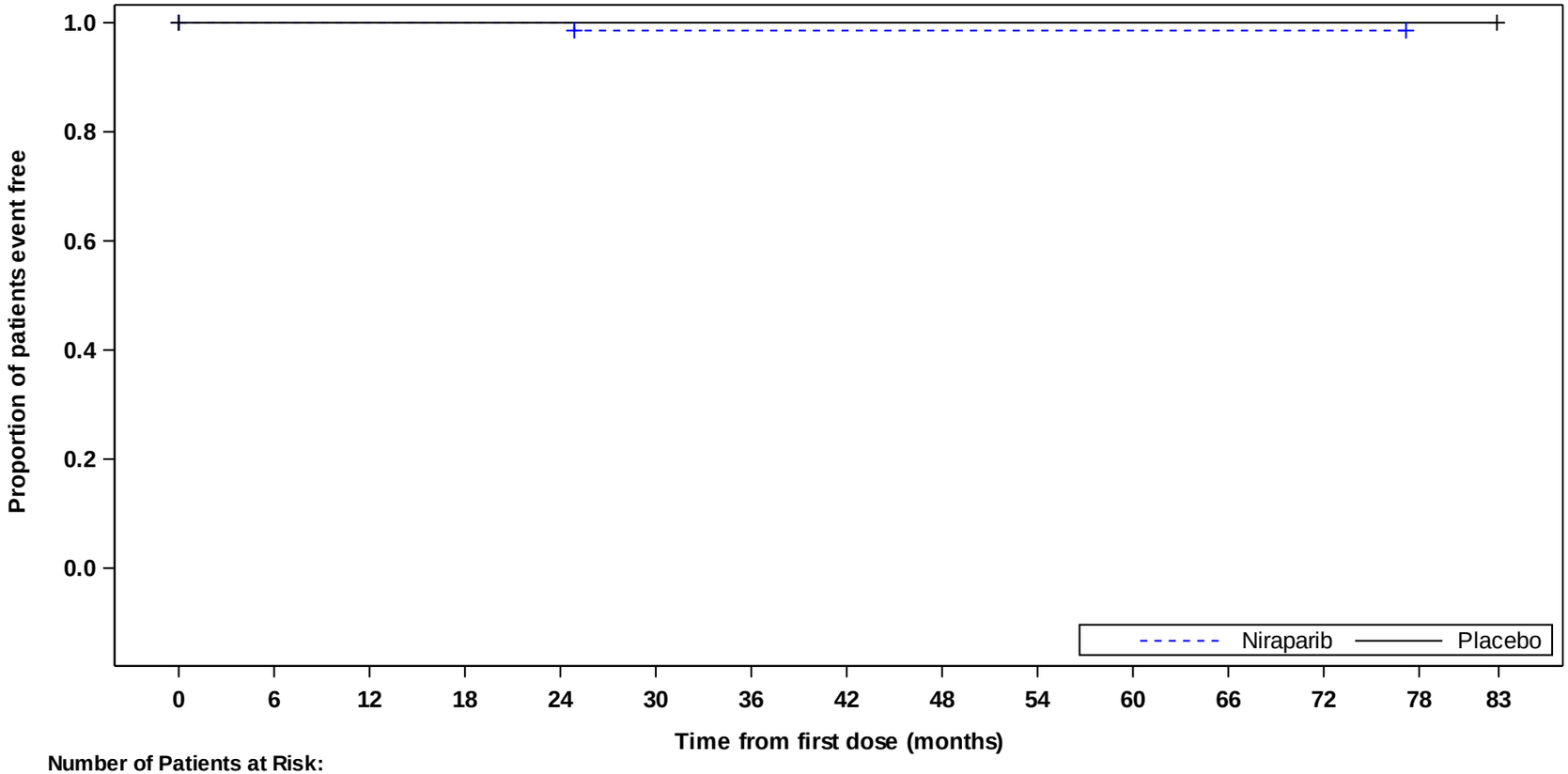
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:31 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Gastrointestinal disorders, PT: Diarrhoea



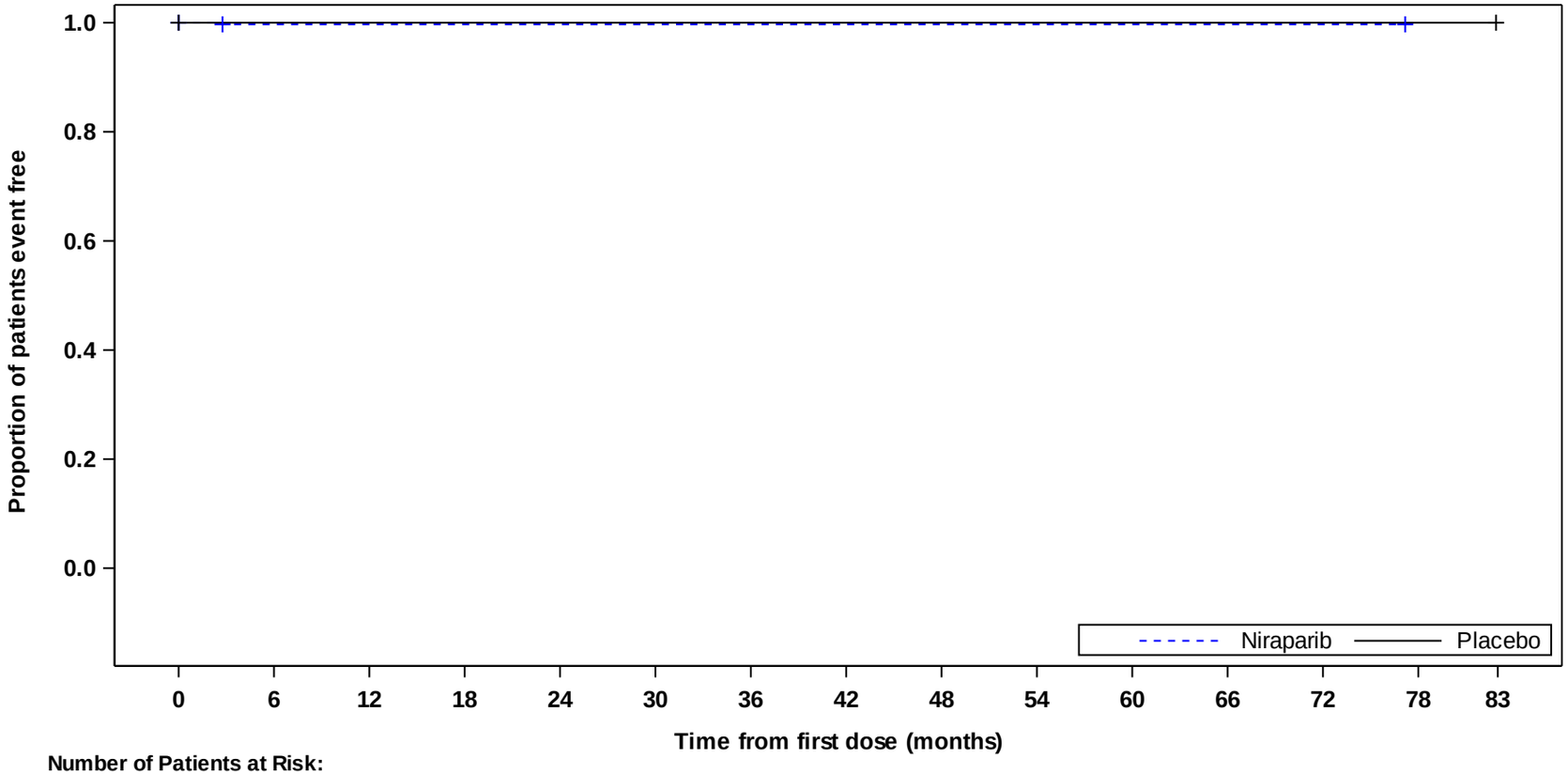
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:32 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Gastrointestinal disorders, PT: Intestinal obstruction



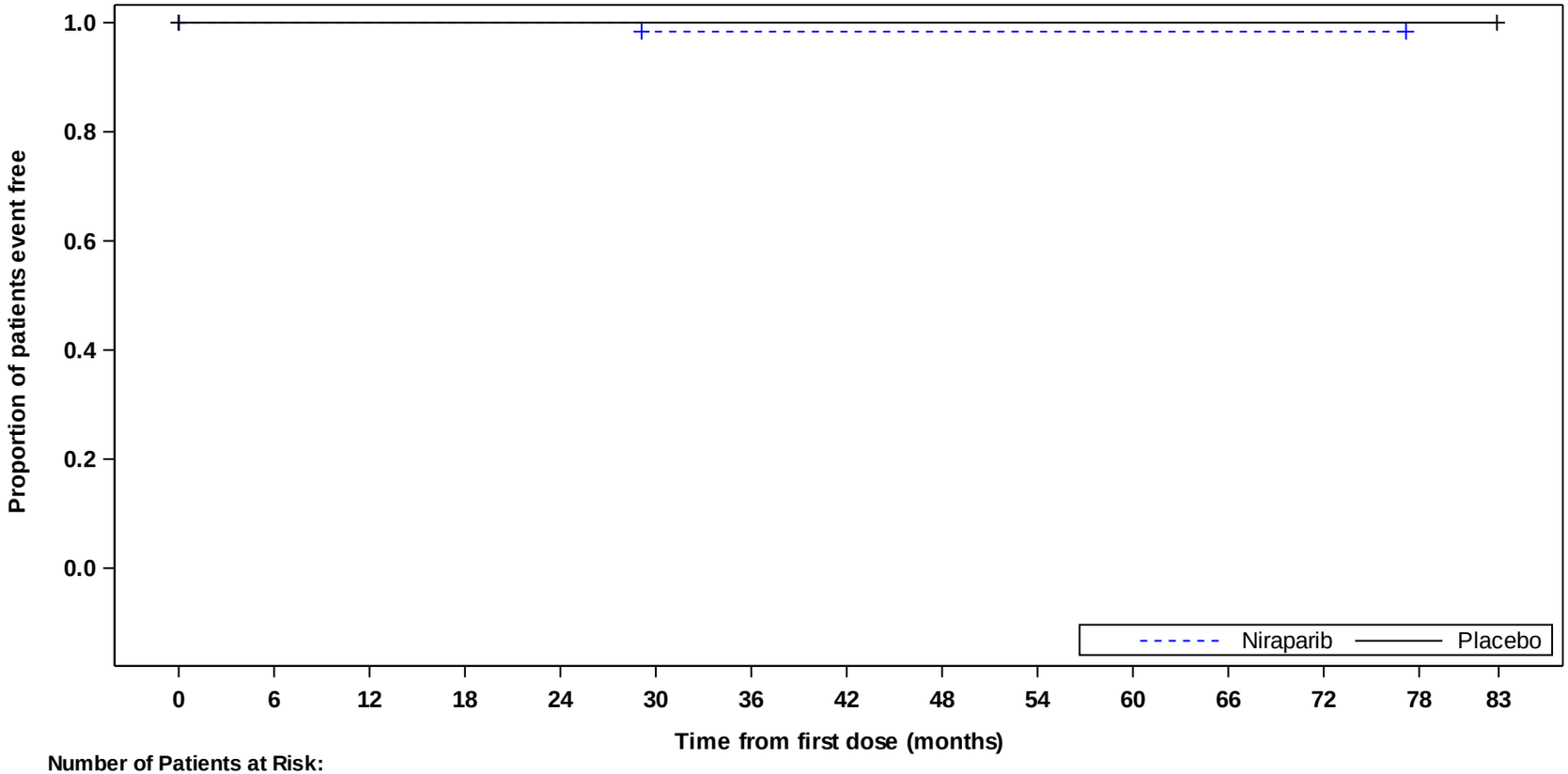
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:33 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Gastrointestinal disorders, PT: Malignant gastrointestinal obstruction



Number of Patients at Risk:

Niraparib	367	247	162	101	71	60	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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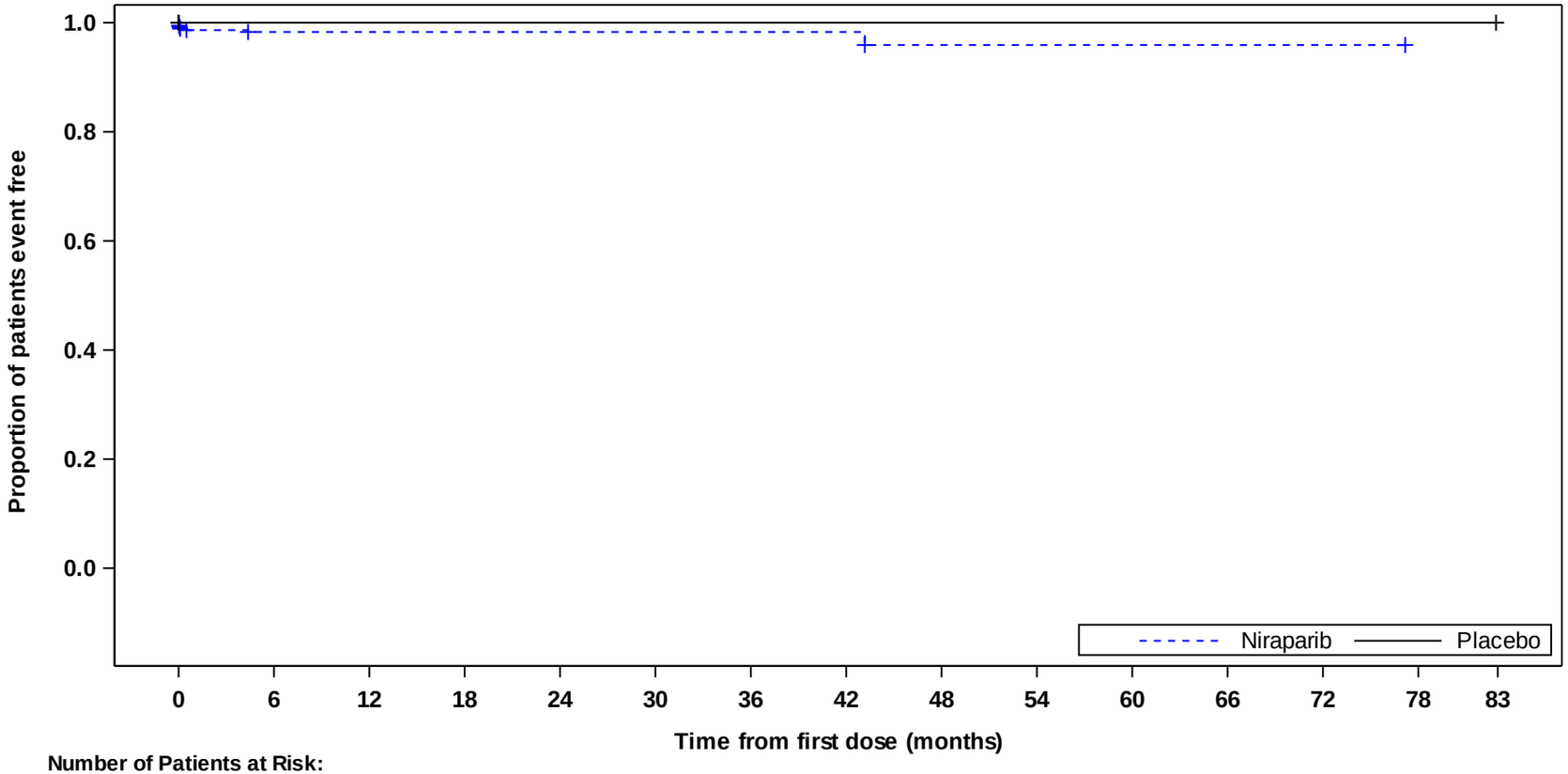
Rundate: 20JAN2021:17:24:34 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Gastrointestinal disorders, PT: Nausea



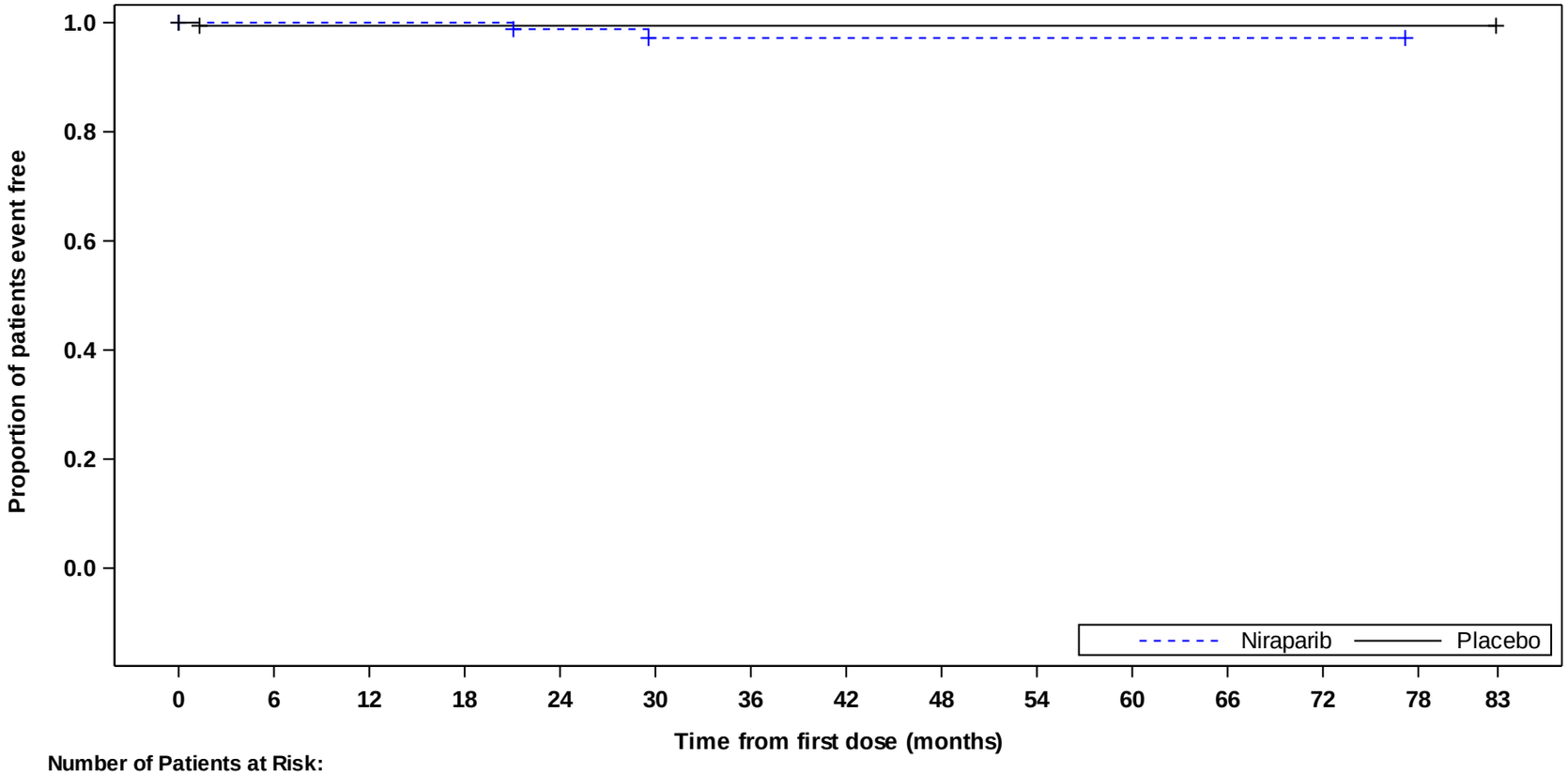
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:35 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Gastrointestinal disorders, PT: Small intestinal obstruction



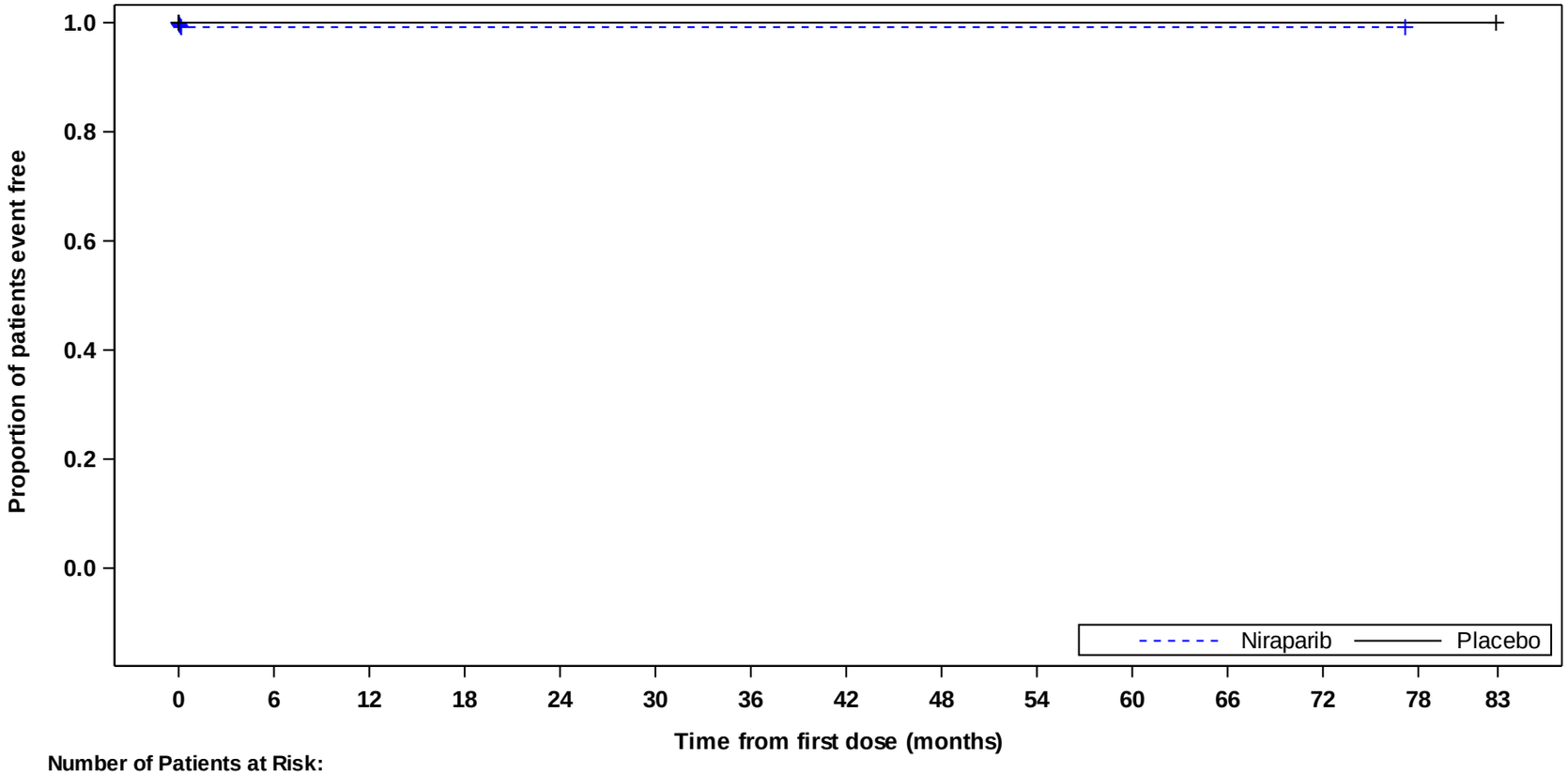
Number of Patients at Risk:

Niraparib	367	247	162	101	71	60	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:36 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Gastrointestinal disorders, PT: Vomiting



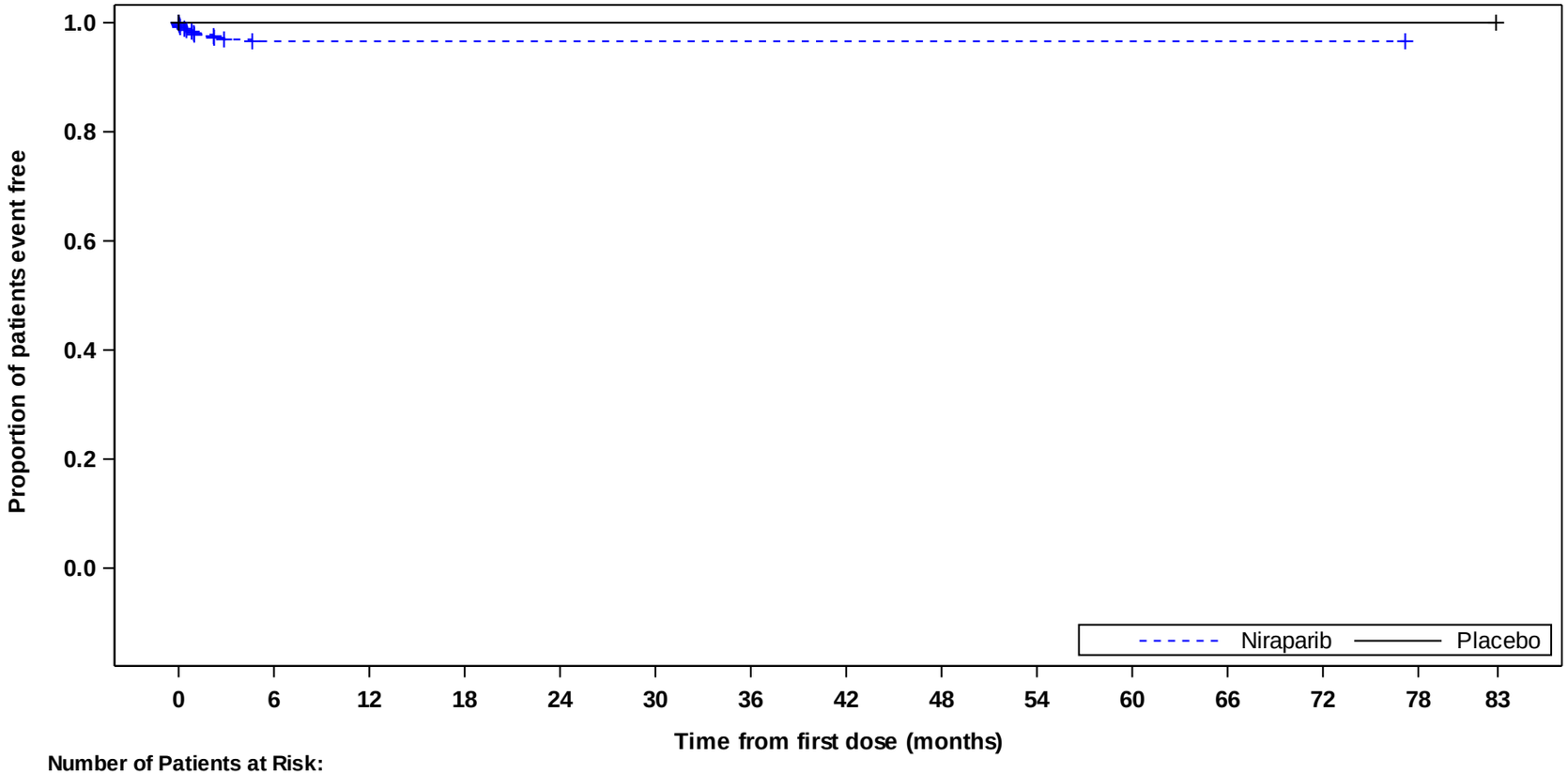
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:36 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: General disorders and administration site conditions



Number of Patients at Risk:

Niraparib	367	246	161	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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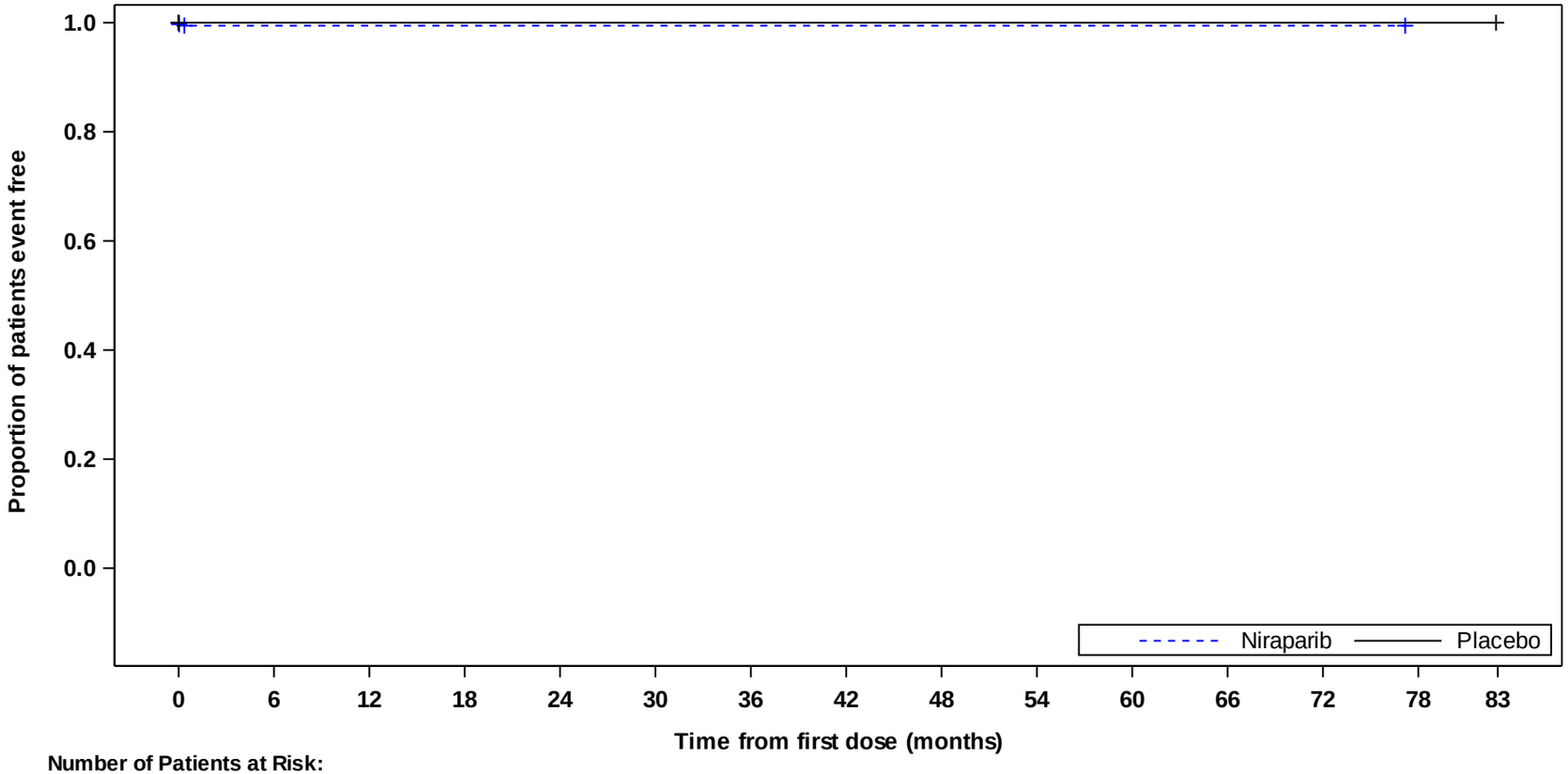
Rundate: 20JAN2021:17:24:37 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: General disorders and administration site conditions, PT: Asthenia



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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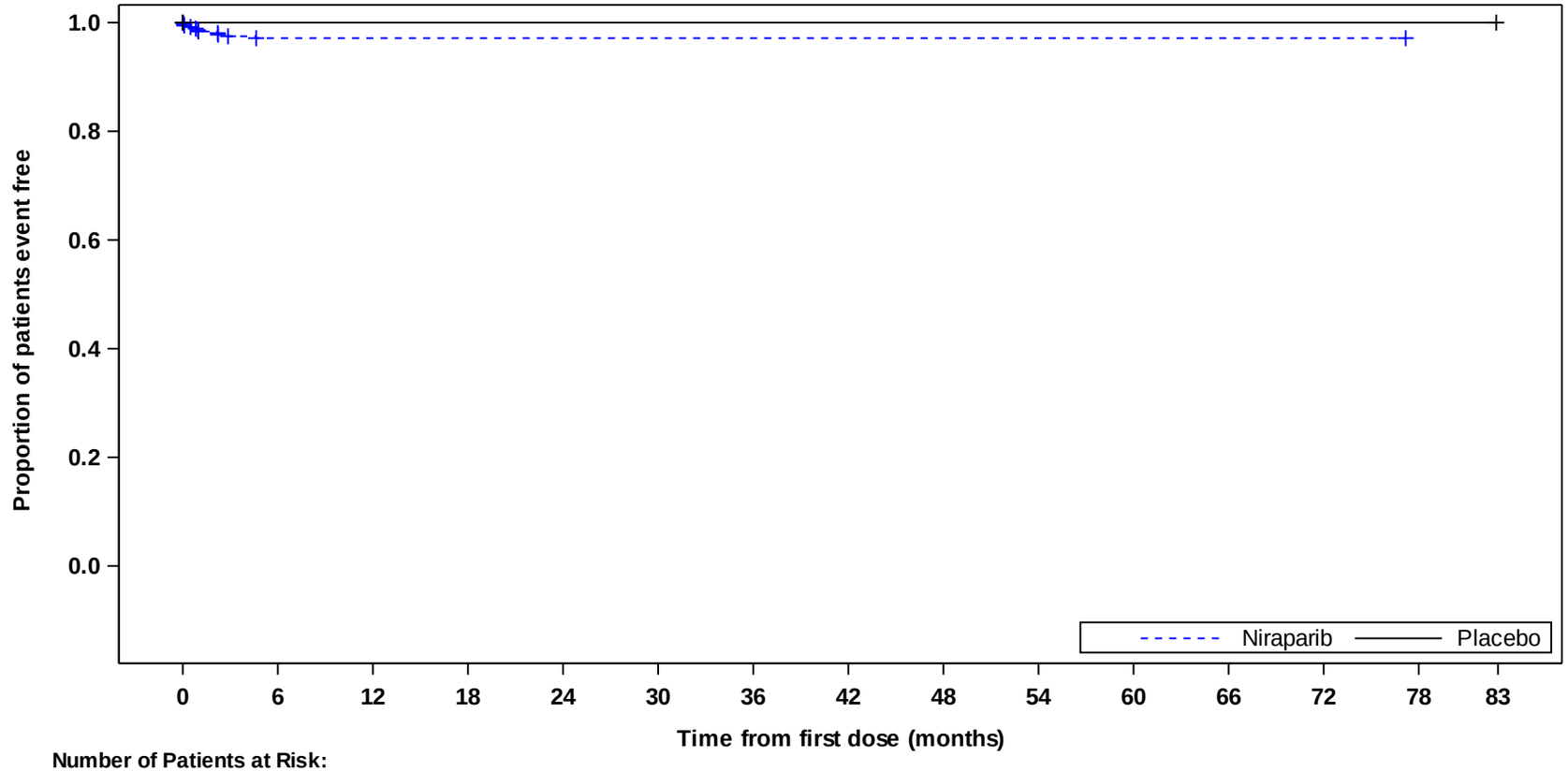
Rundate: 20JAN2021:17:24:38 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: General disorders and administration site conditions, PT: Fatigue



Number of Patients at Risk:

Niraparib	367	246	161	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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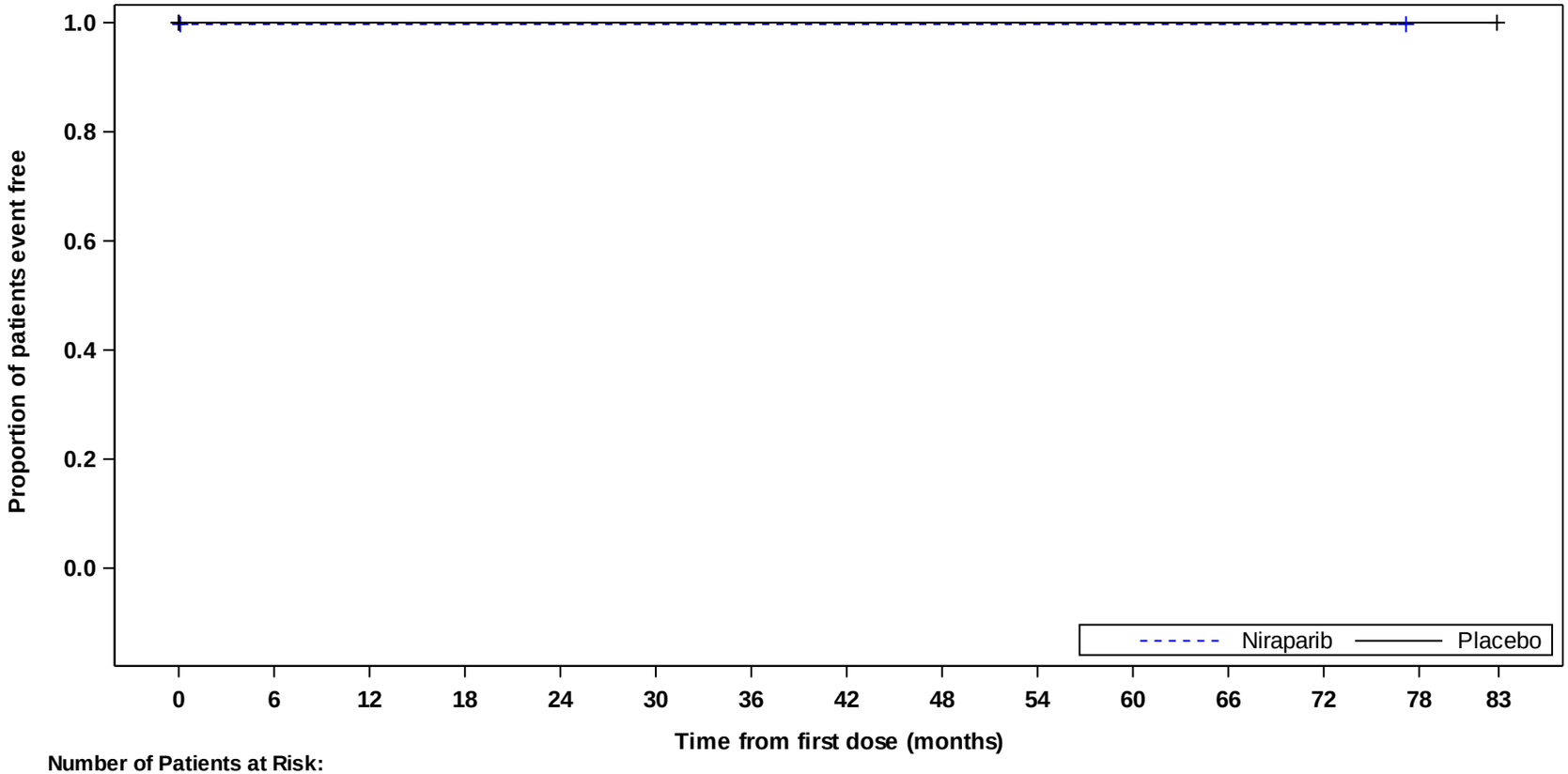
Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: General disorders and administration site conditions, PT: Pain



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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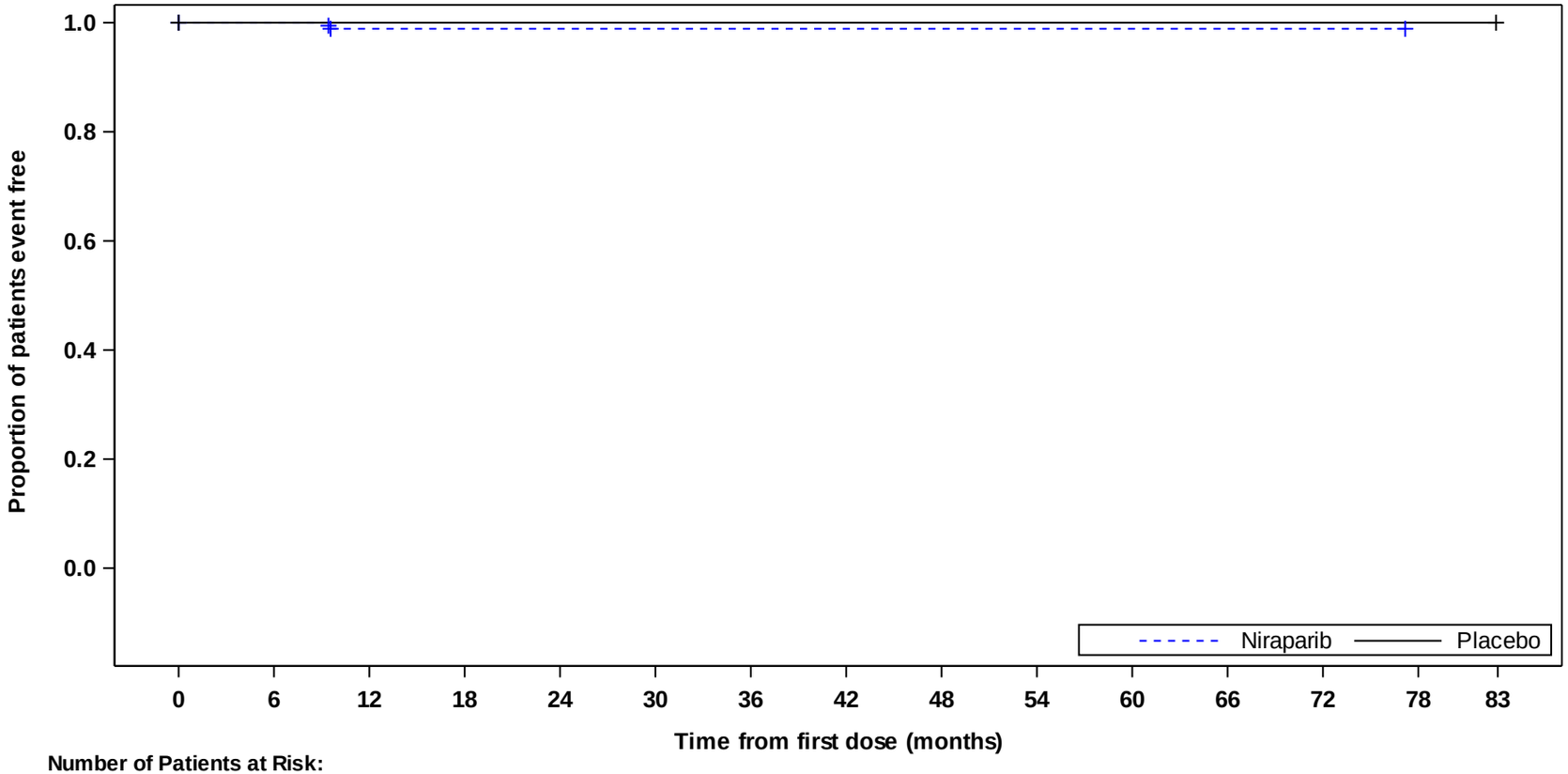
Rundate: 20JAN2021:17:24:40 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Hepatobiliary disorders



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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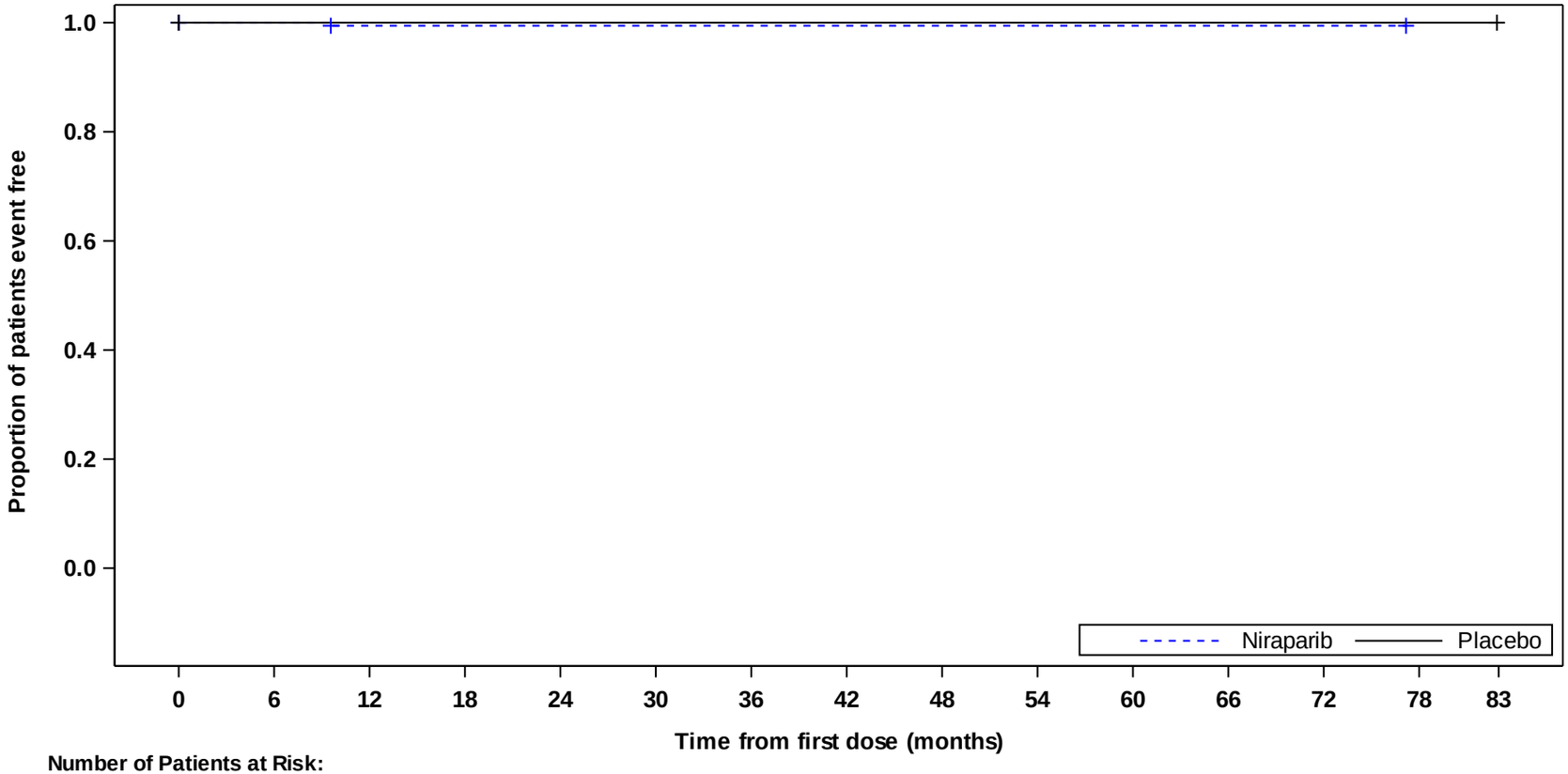
Rundate: 20JAN2021:17:24:41 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Hepatobiliary disorders, PT: Cholestasis



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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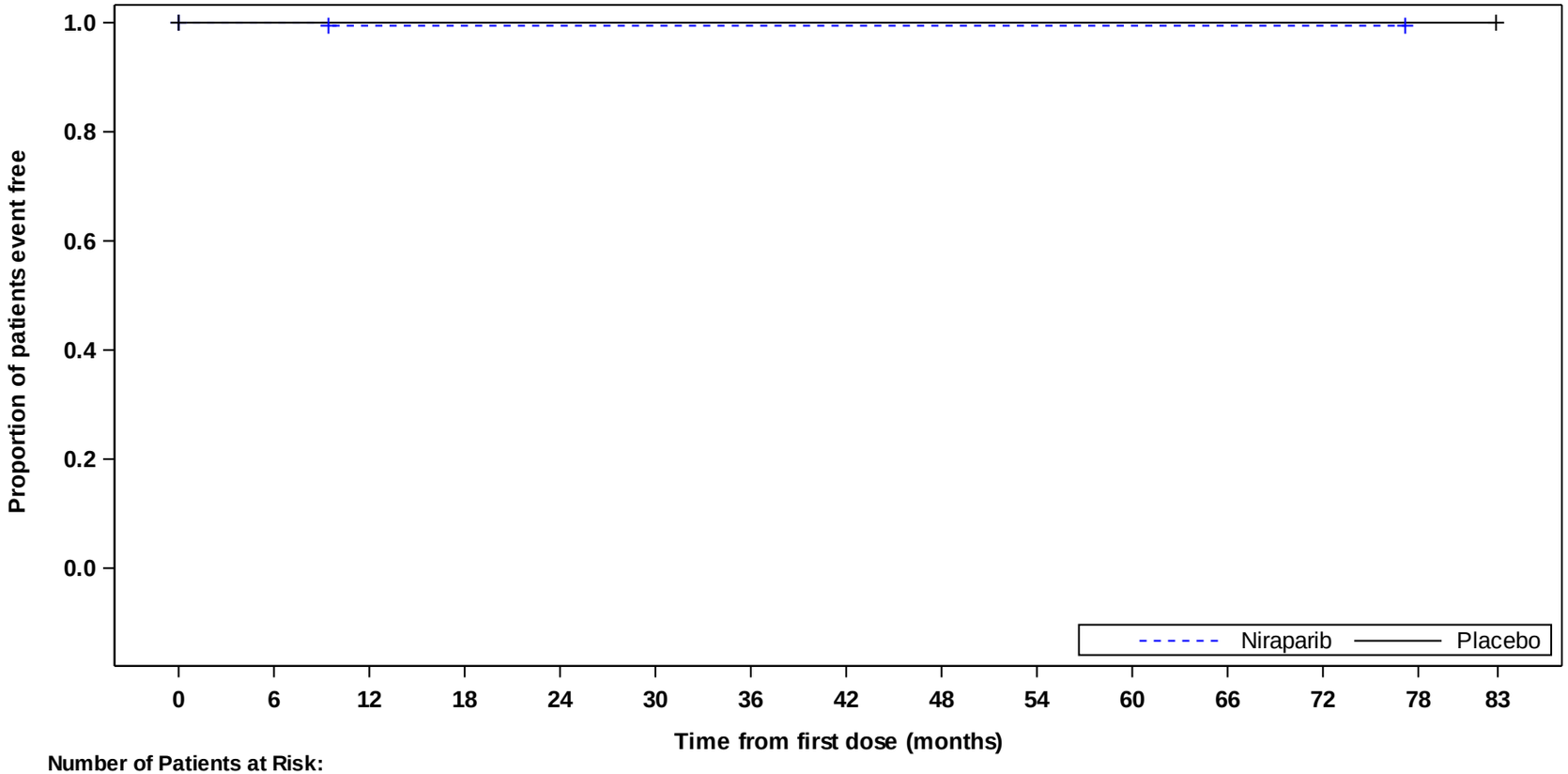
Rundate: 20JAN2021:17:24:41 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Hepatobiliary disorders, PT: Hepatic failure



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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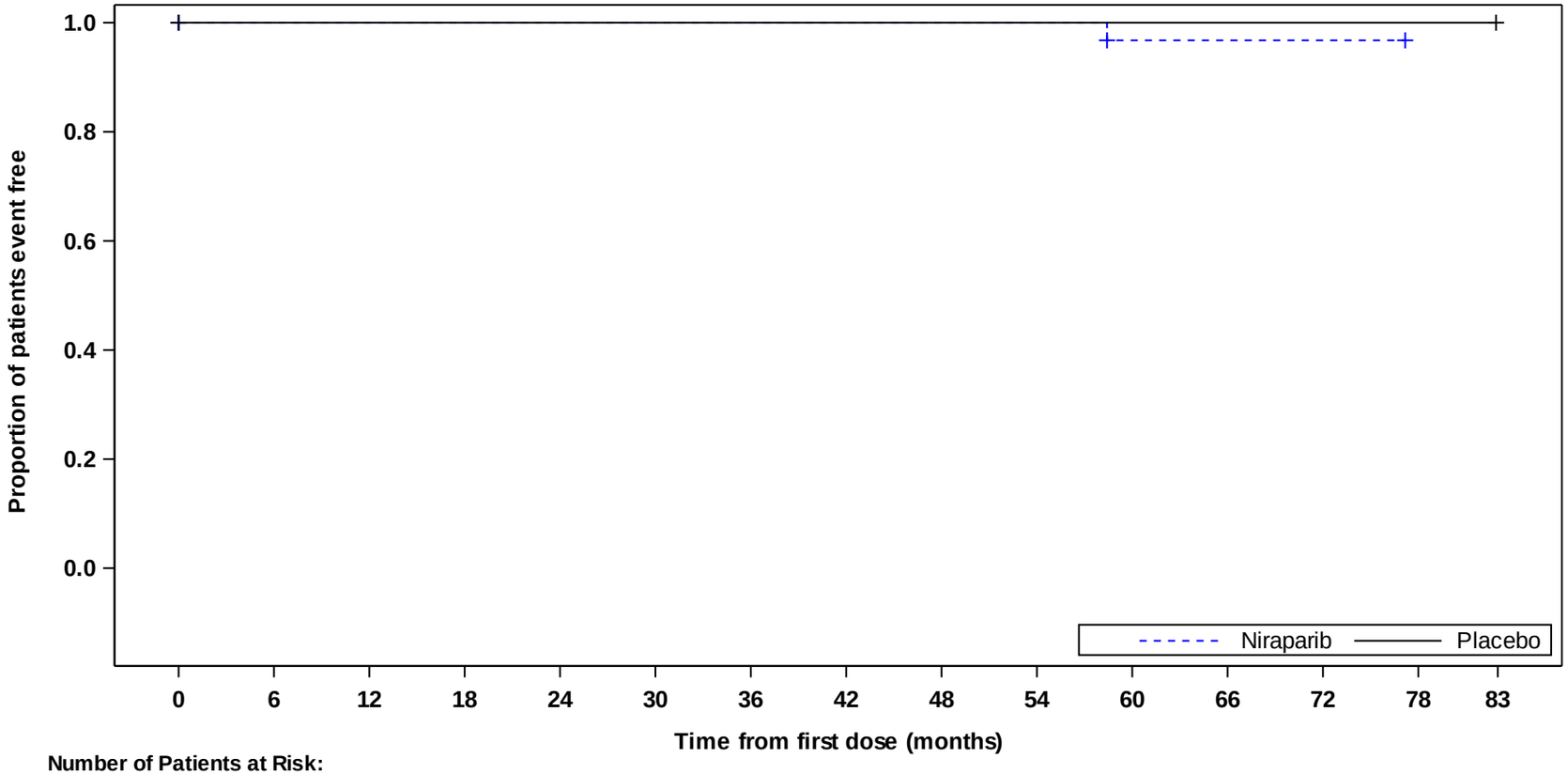
Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Infections and infestations



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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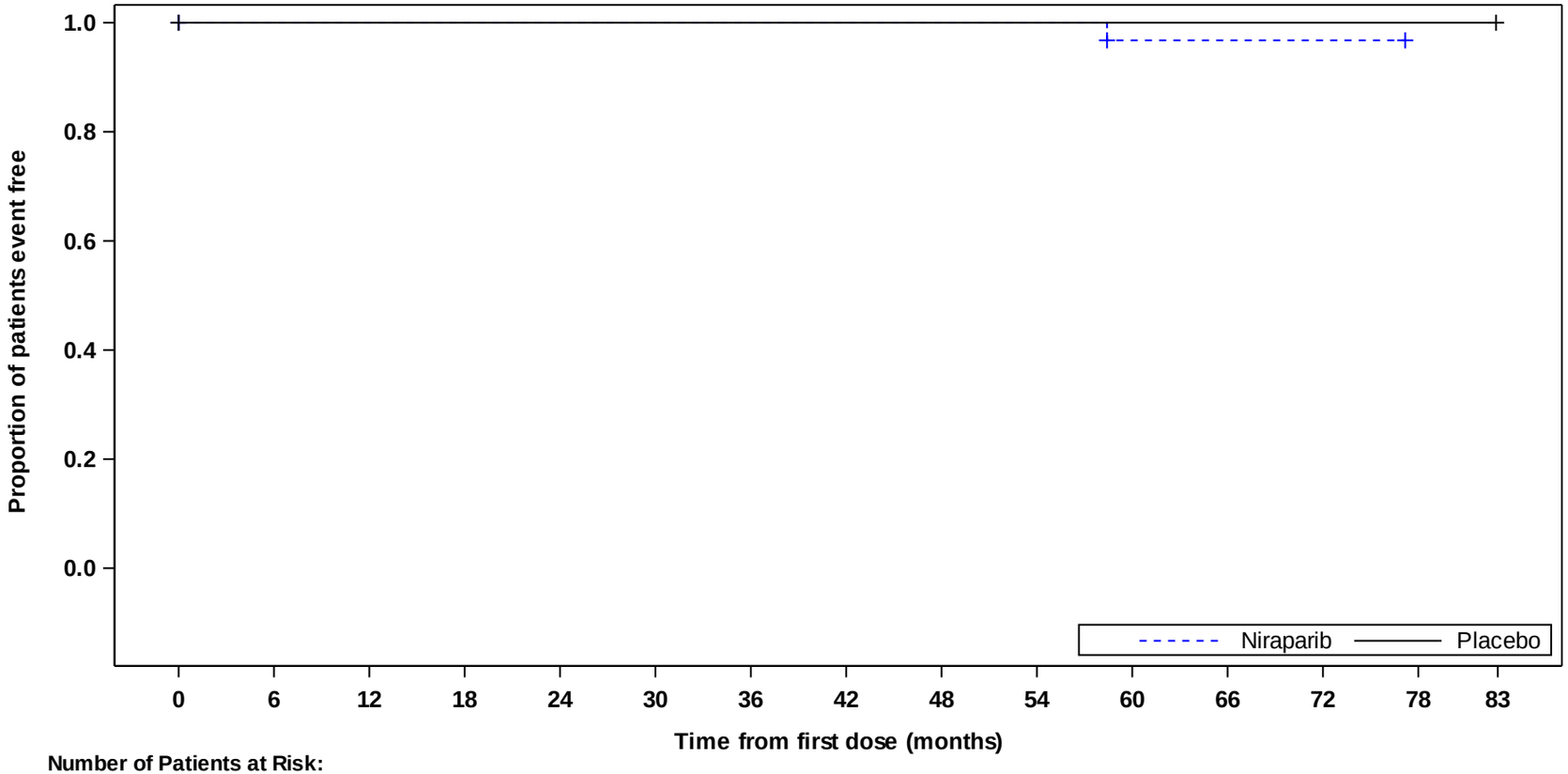
Rundate: 20JAN2021:17:24:43 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Infections and infestations, PT: Pneumonia



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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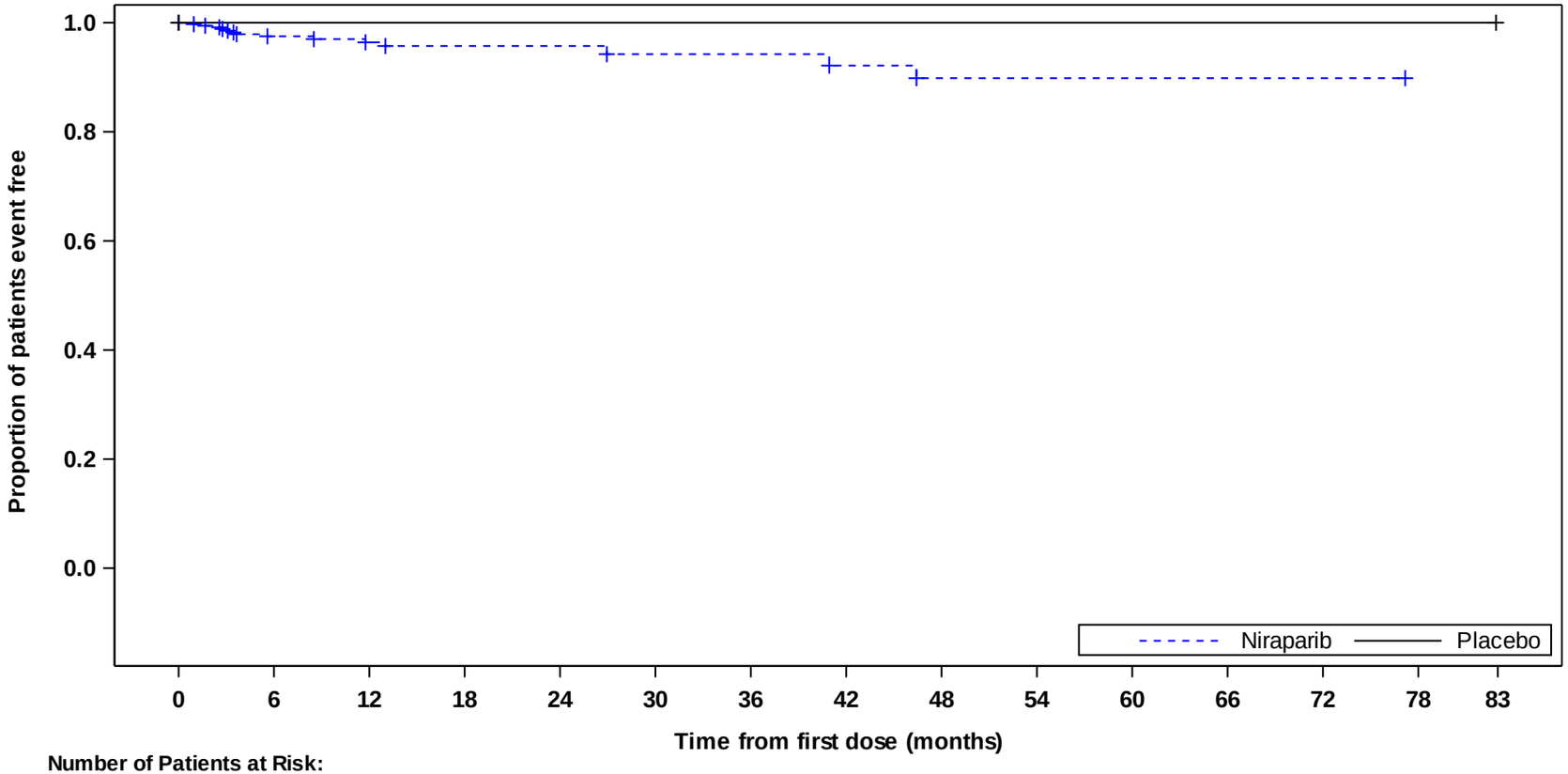
Rundate: 20JAN2021:17:24:44 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Investigations



Number of Patients at Risk:

Niraparib	367	246	161	101	71	61	52	42	38	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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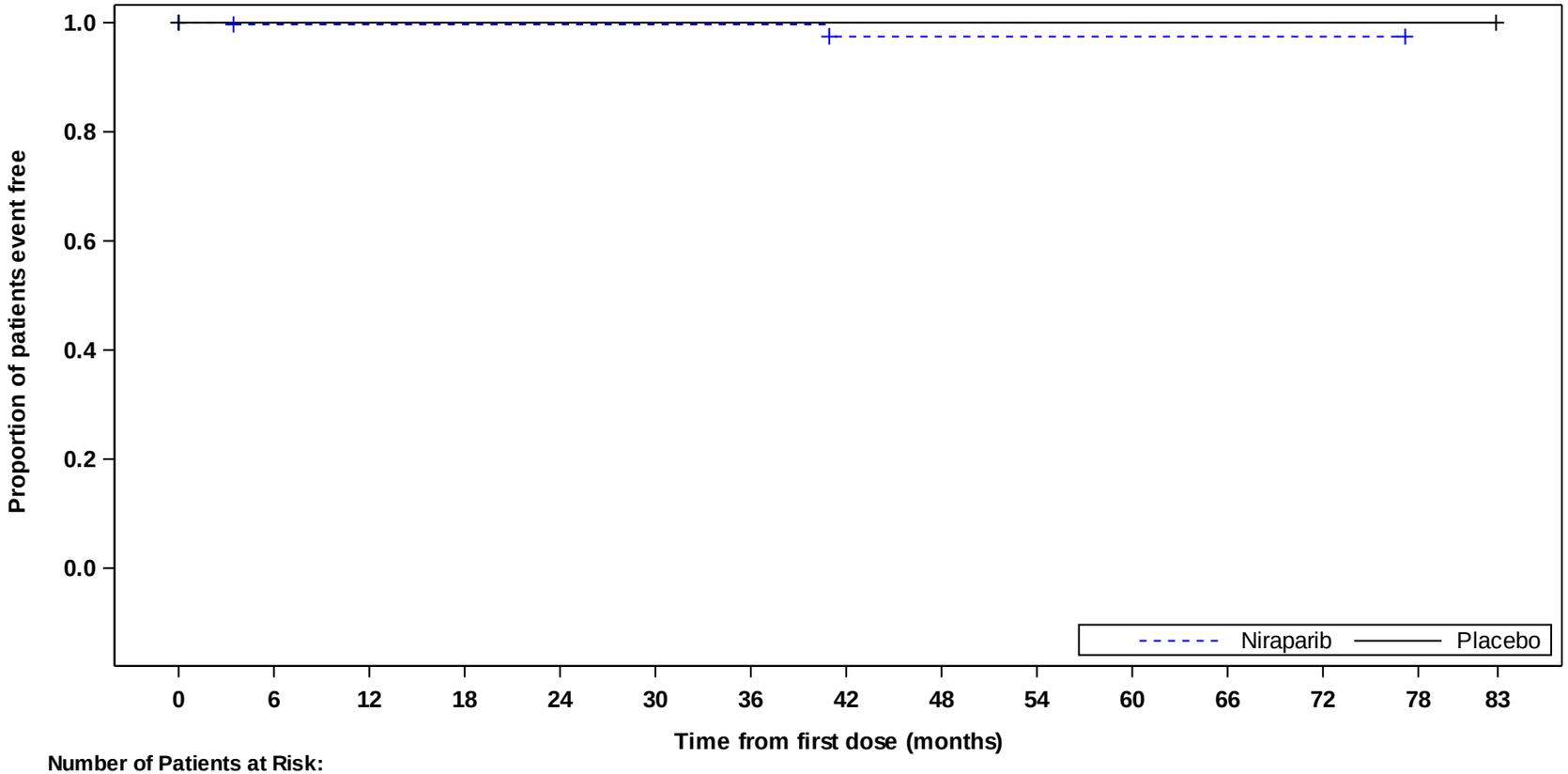
Rundate: 20JAN2021:17:24:45 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Investigations, PT: Gamma-glutamyltransferase increased



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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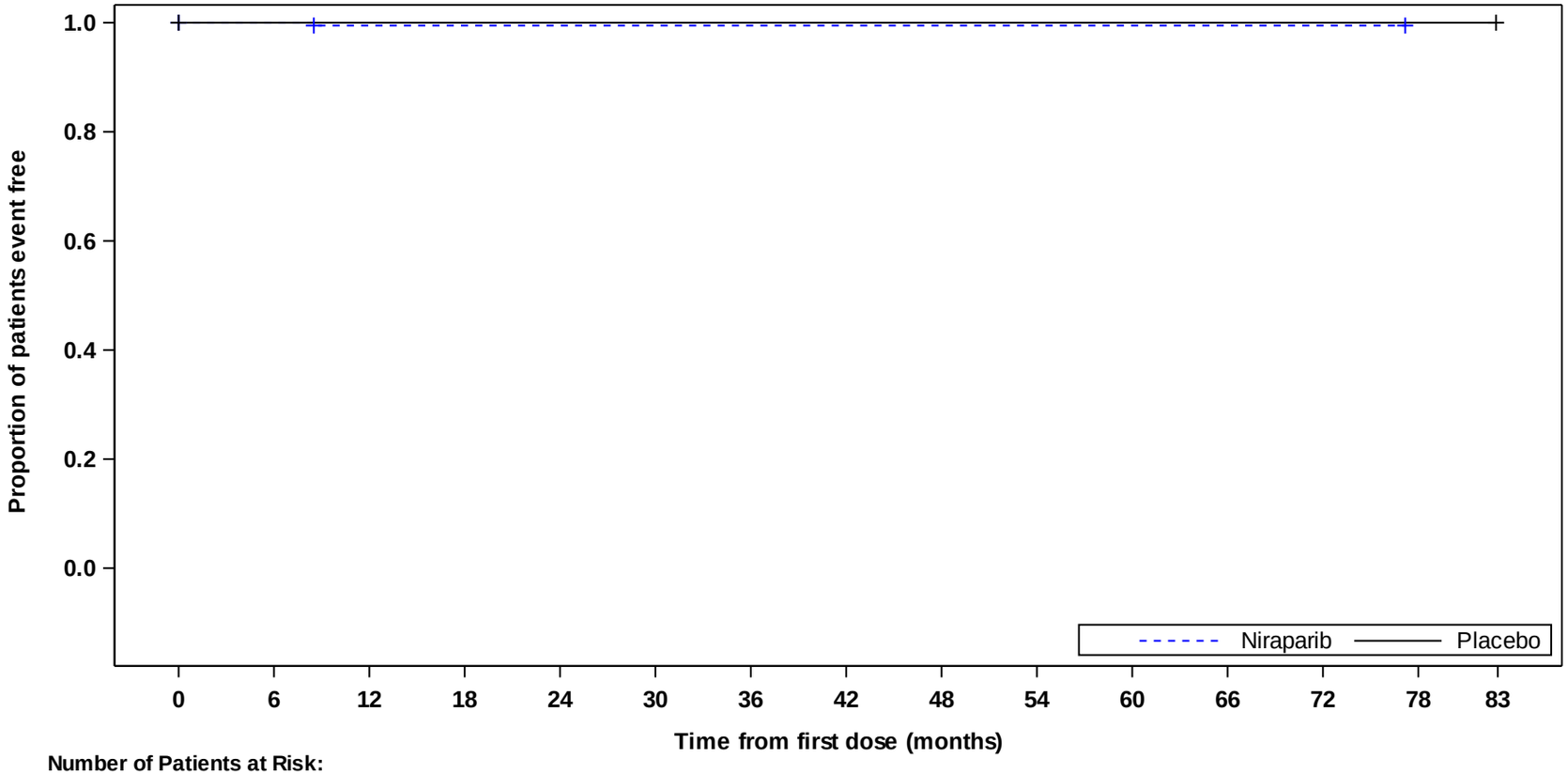
Rundate: 20JAN2021:17:24:46 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Investigations, PT: Lymph node palpable



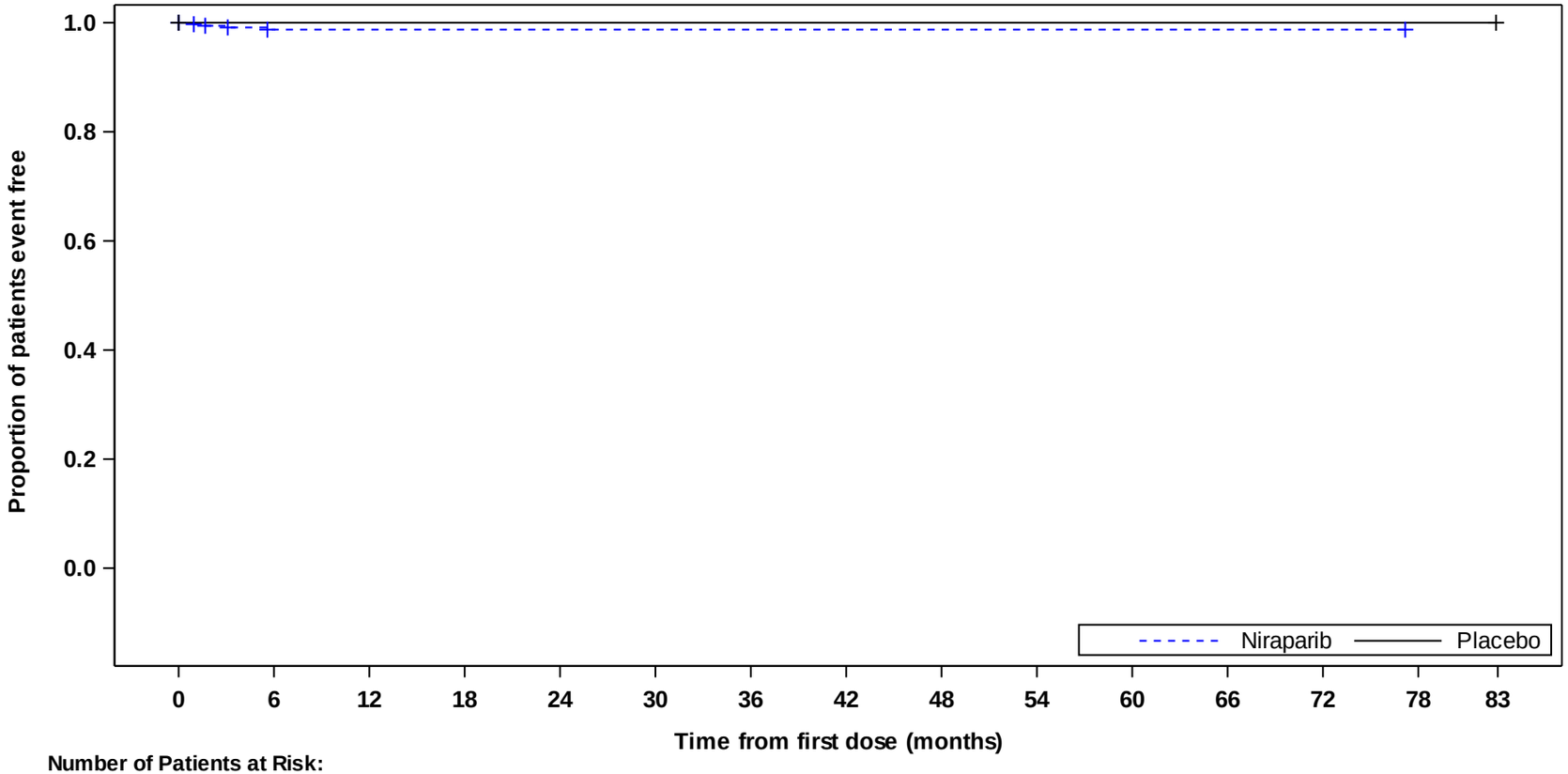
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:46 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Investigations, PT: Neutrophil count decreased



Number of Patients at Risk:

Niraparib	367	246	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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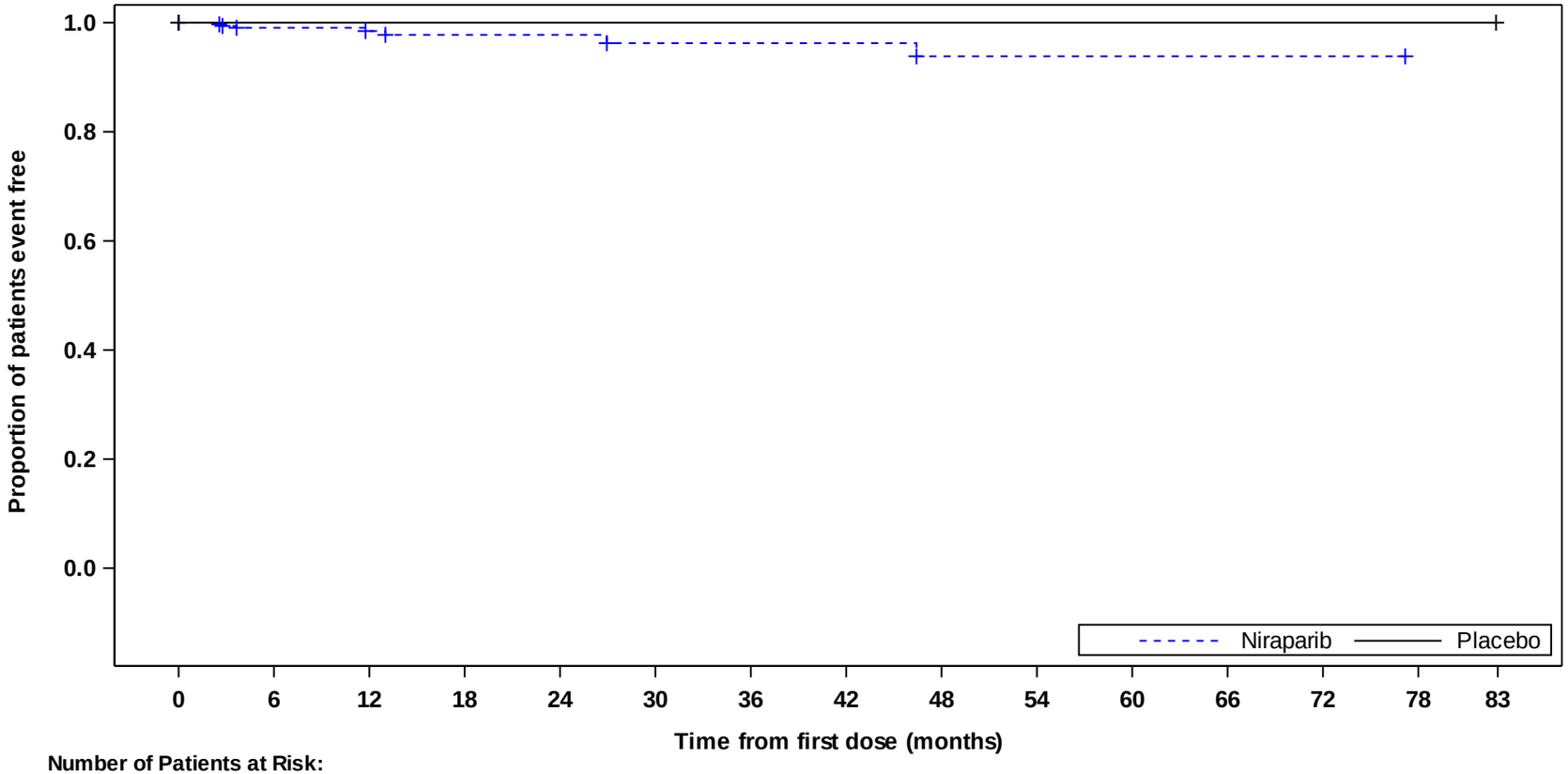
Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Investigations, PT: Platelet count decreased



Number of Patients at Risk:

Niraparib	367	247	161	101	71	61	52	42	38	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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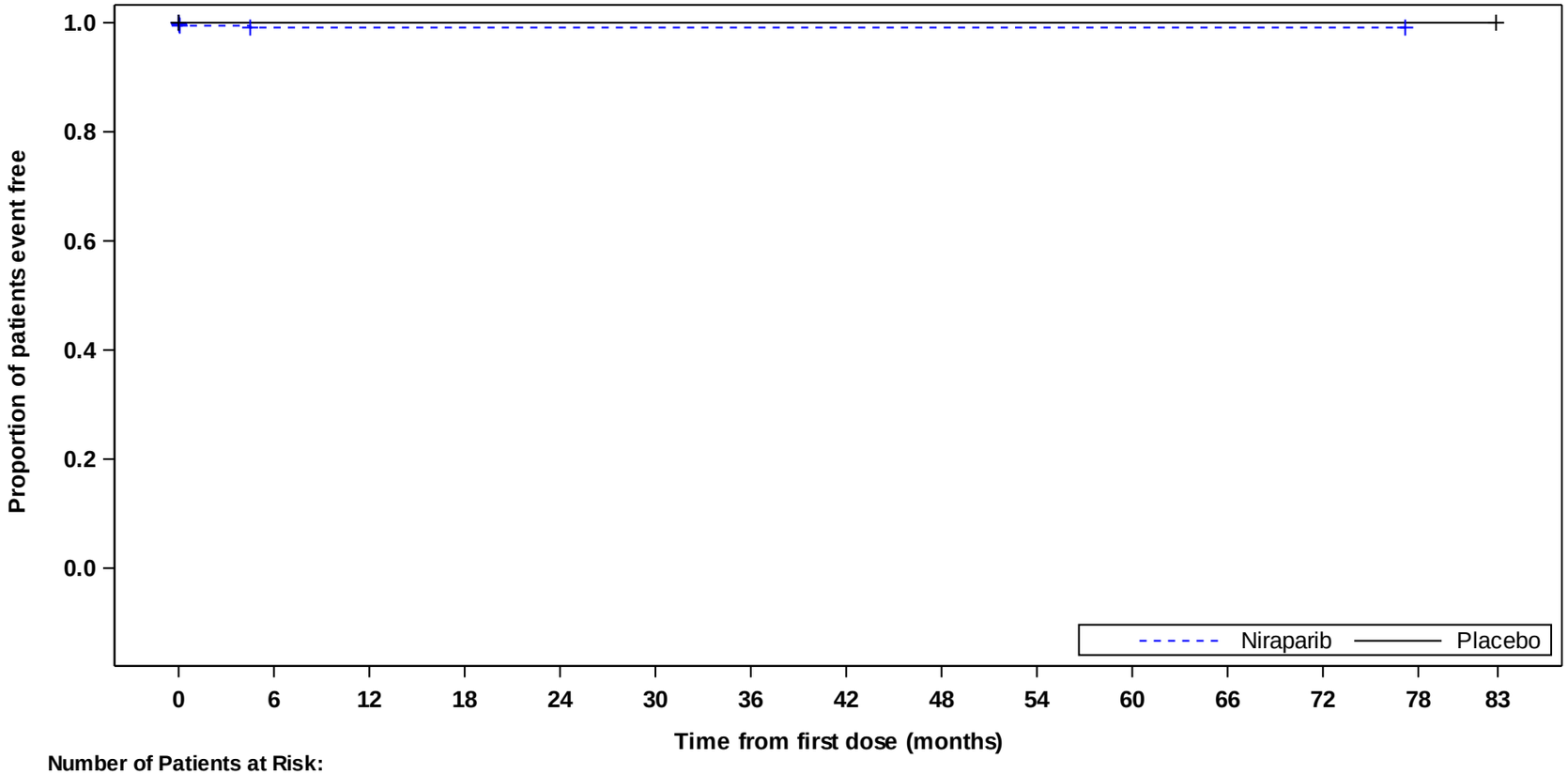
Rundate: 20JAN2021:17:24:48 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Metabolism and nutrition disorders



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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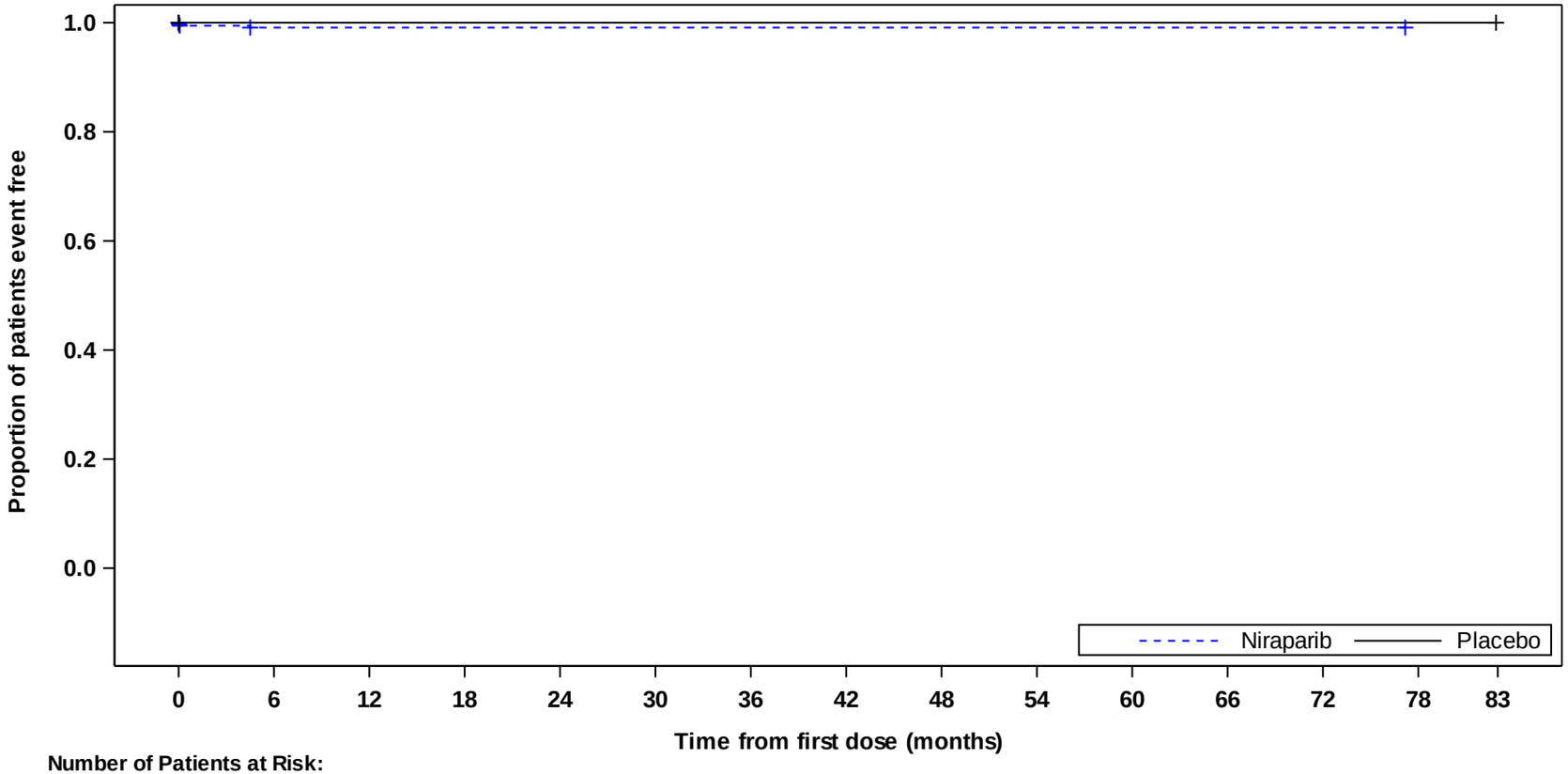
Rundate: 20JAN2021:17:24:49 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Metabolism and nutrition disorders, PT: Decreased appetite



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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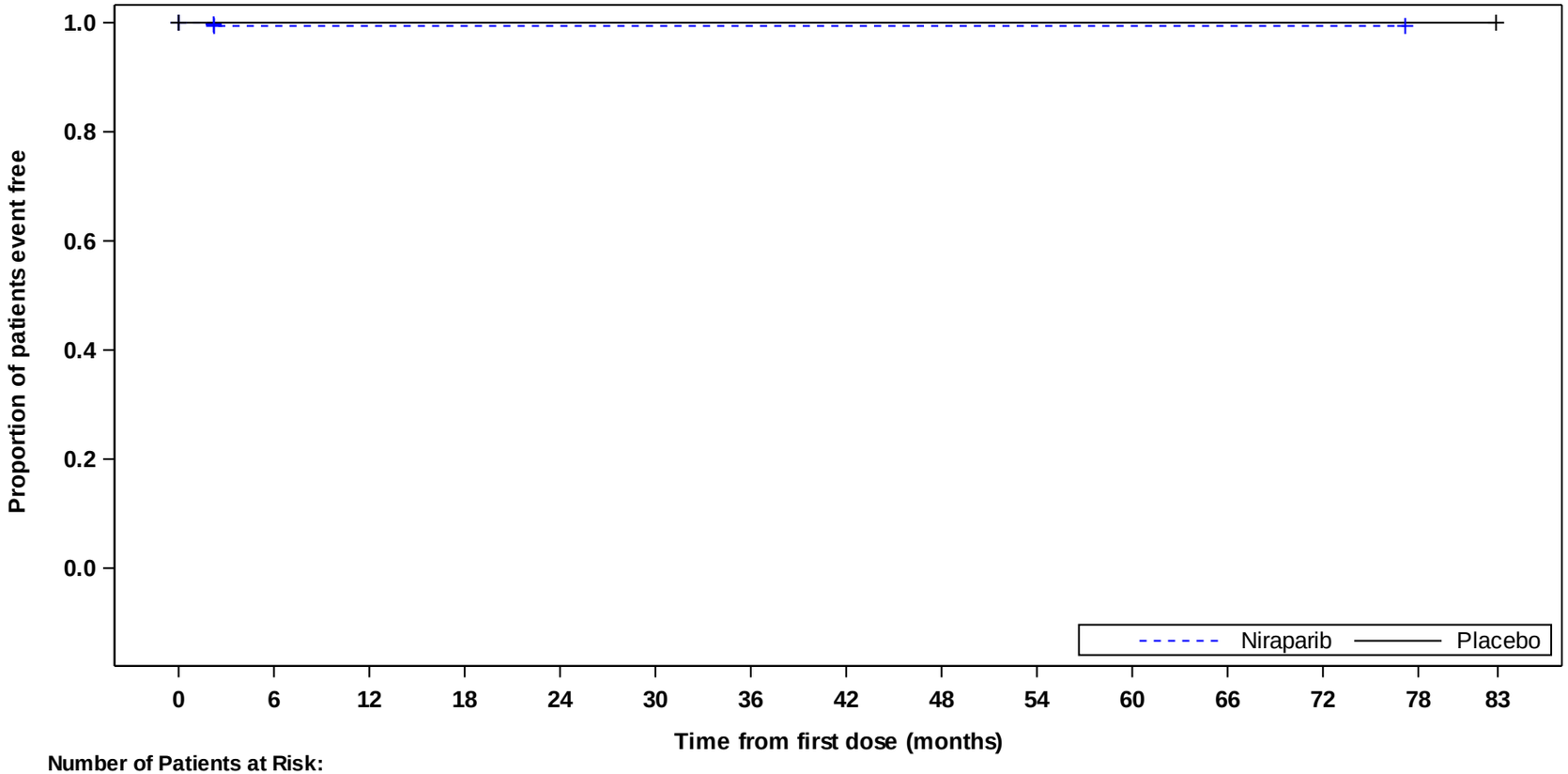
Rundate: 20JAN2021:17:24:50 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Musculoskeletal and connective tissue disorders



Number of Patients at Risk:

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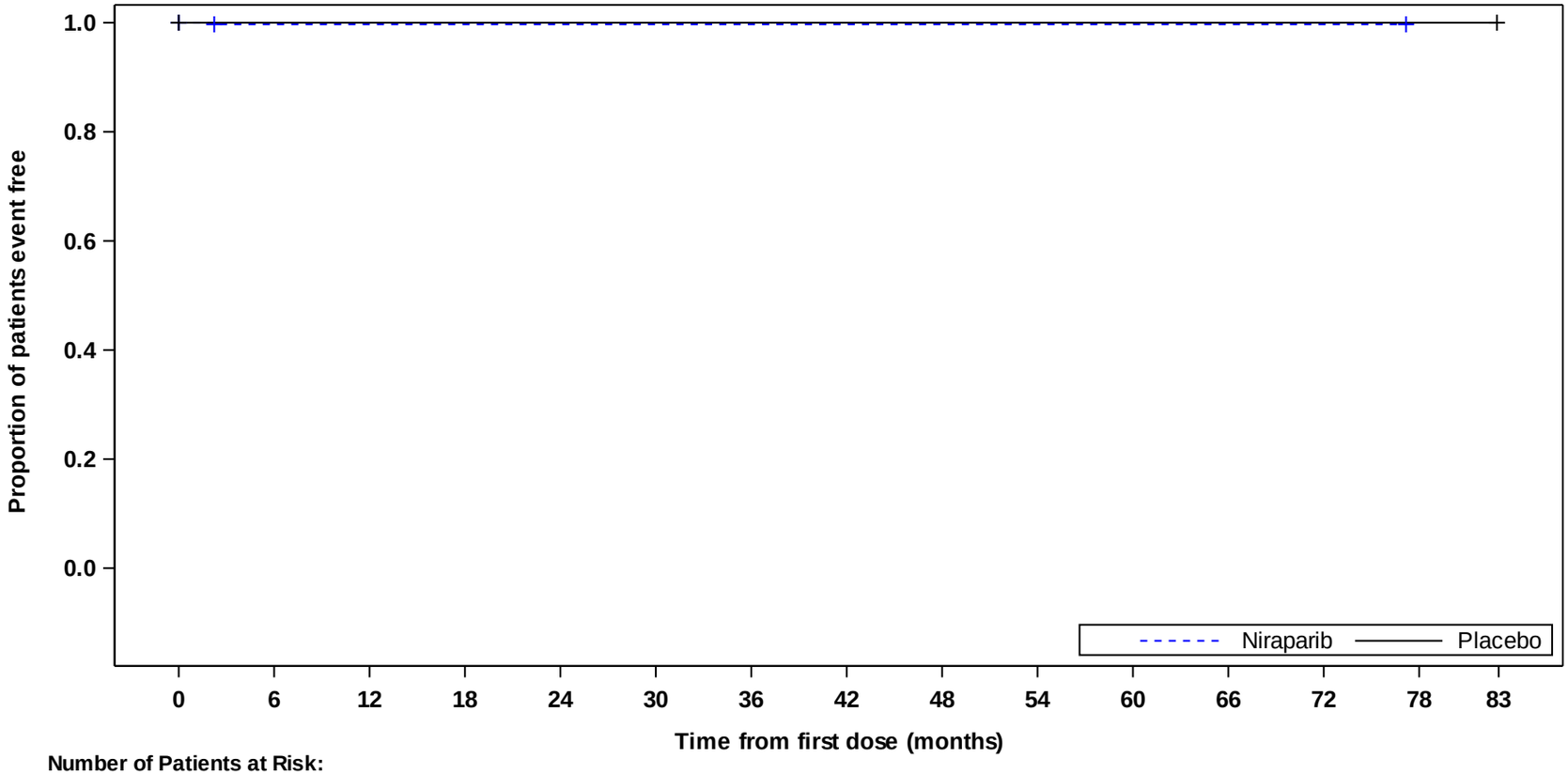
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:51 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia



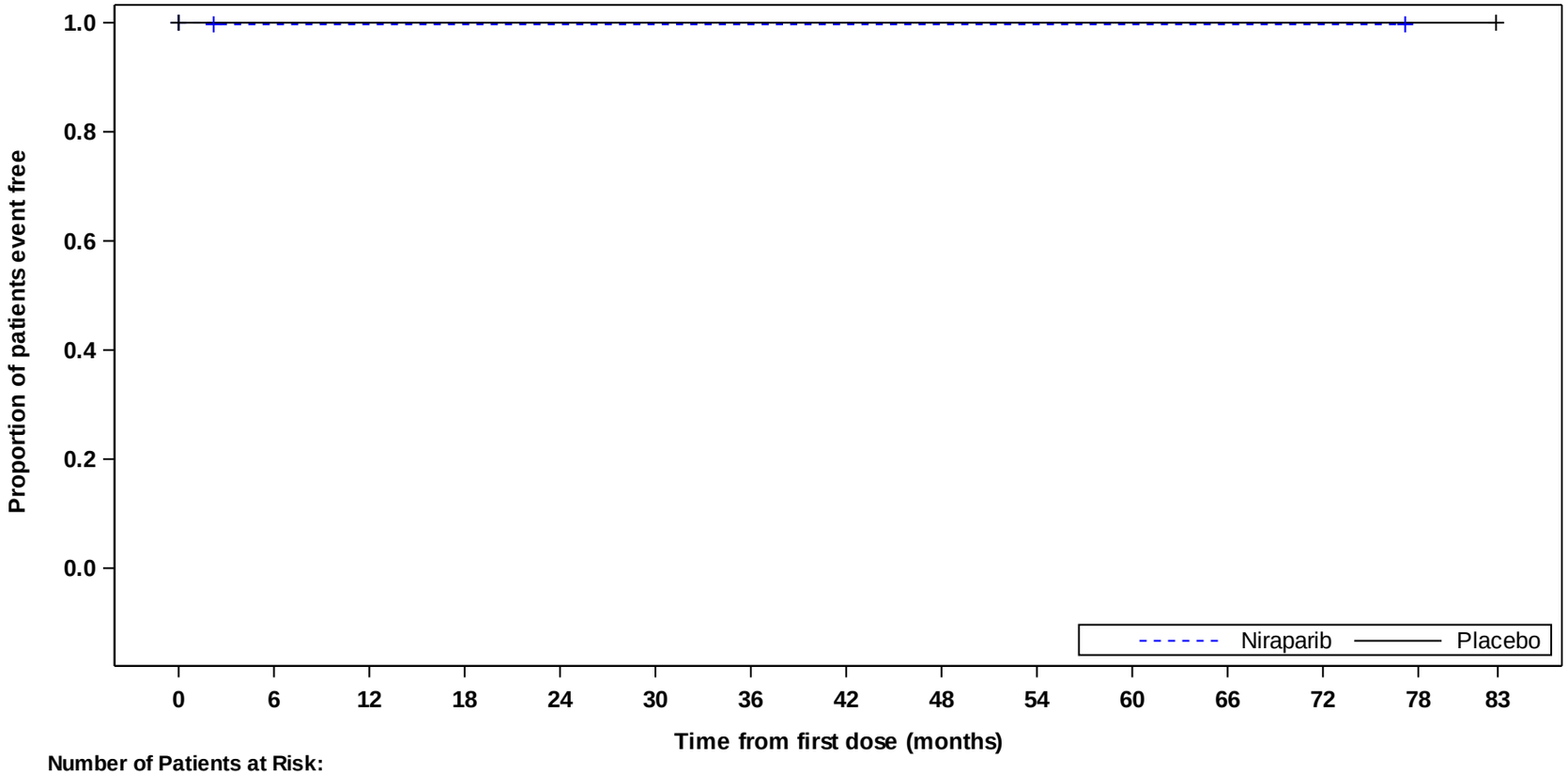
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:24:52 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Musculoskeletal and connective tissue disorders, PT: Neck pain



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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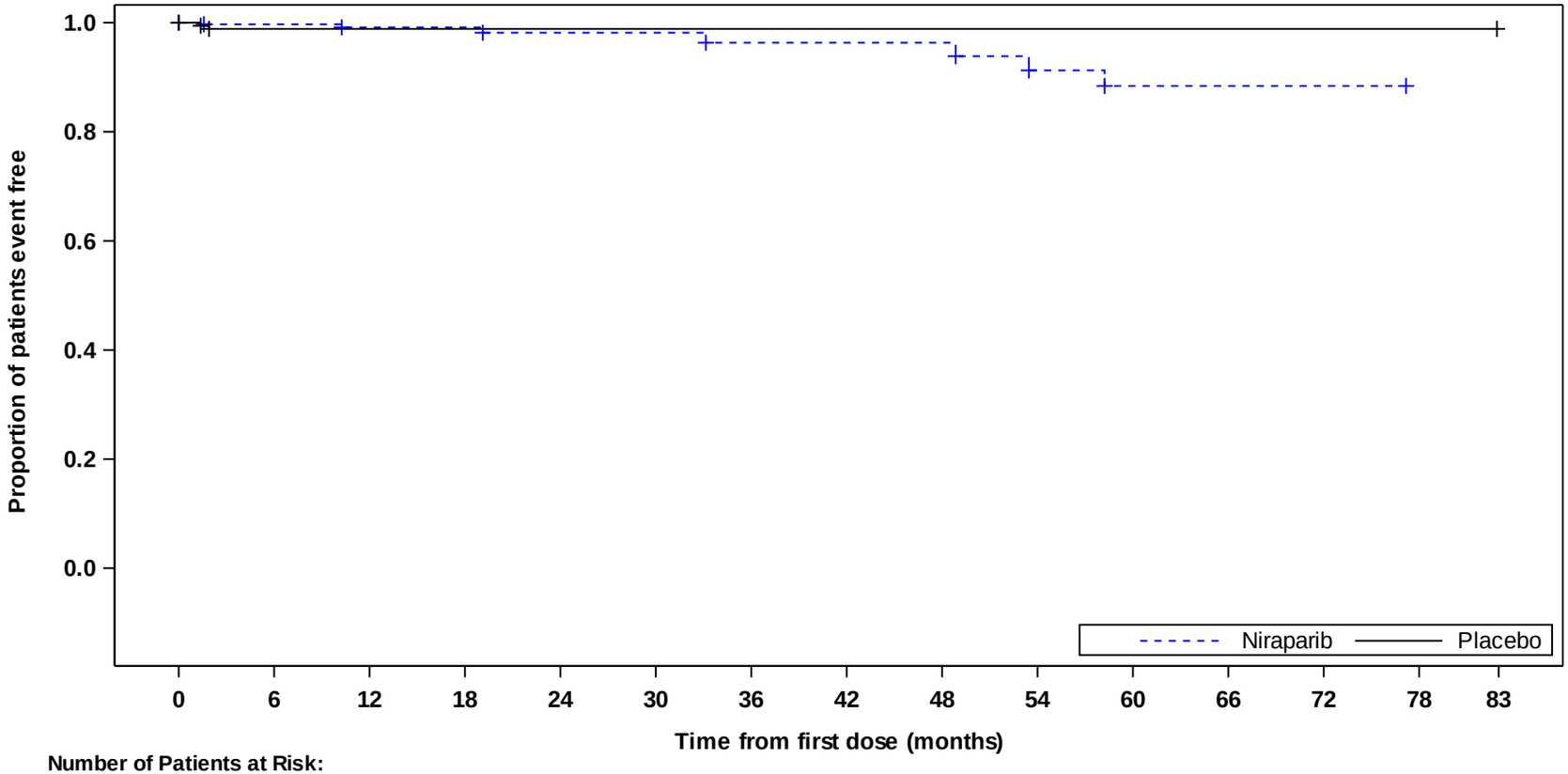
Rundate: 20JAN2021:17:24:52 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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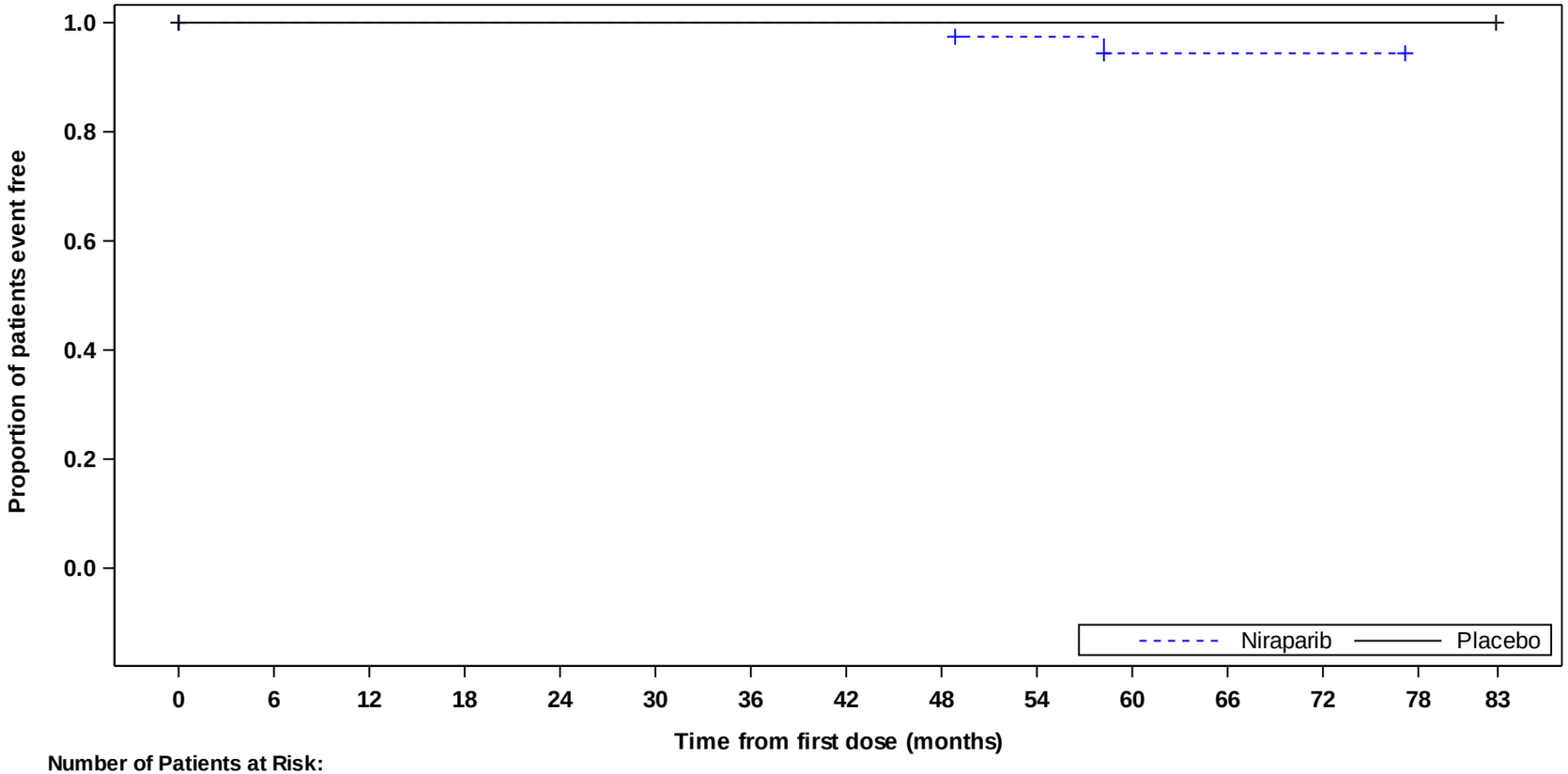
Rundate: 20JAN2021:17:24:53 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), PT: Acute myeloid leukaemia



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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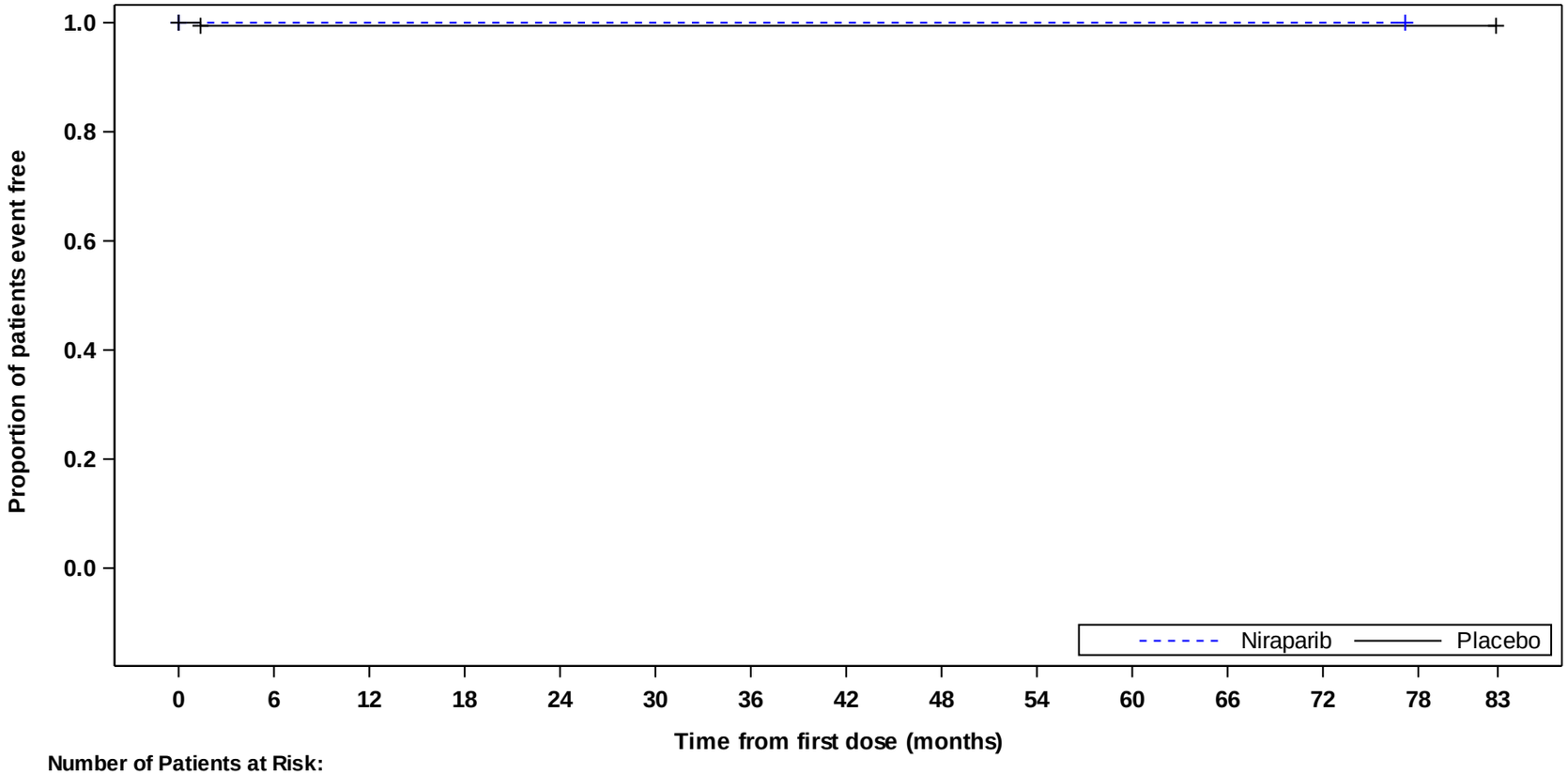
Rundate: 20JAN2021:17:24:54 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), PT: Breast cancer



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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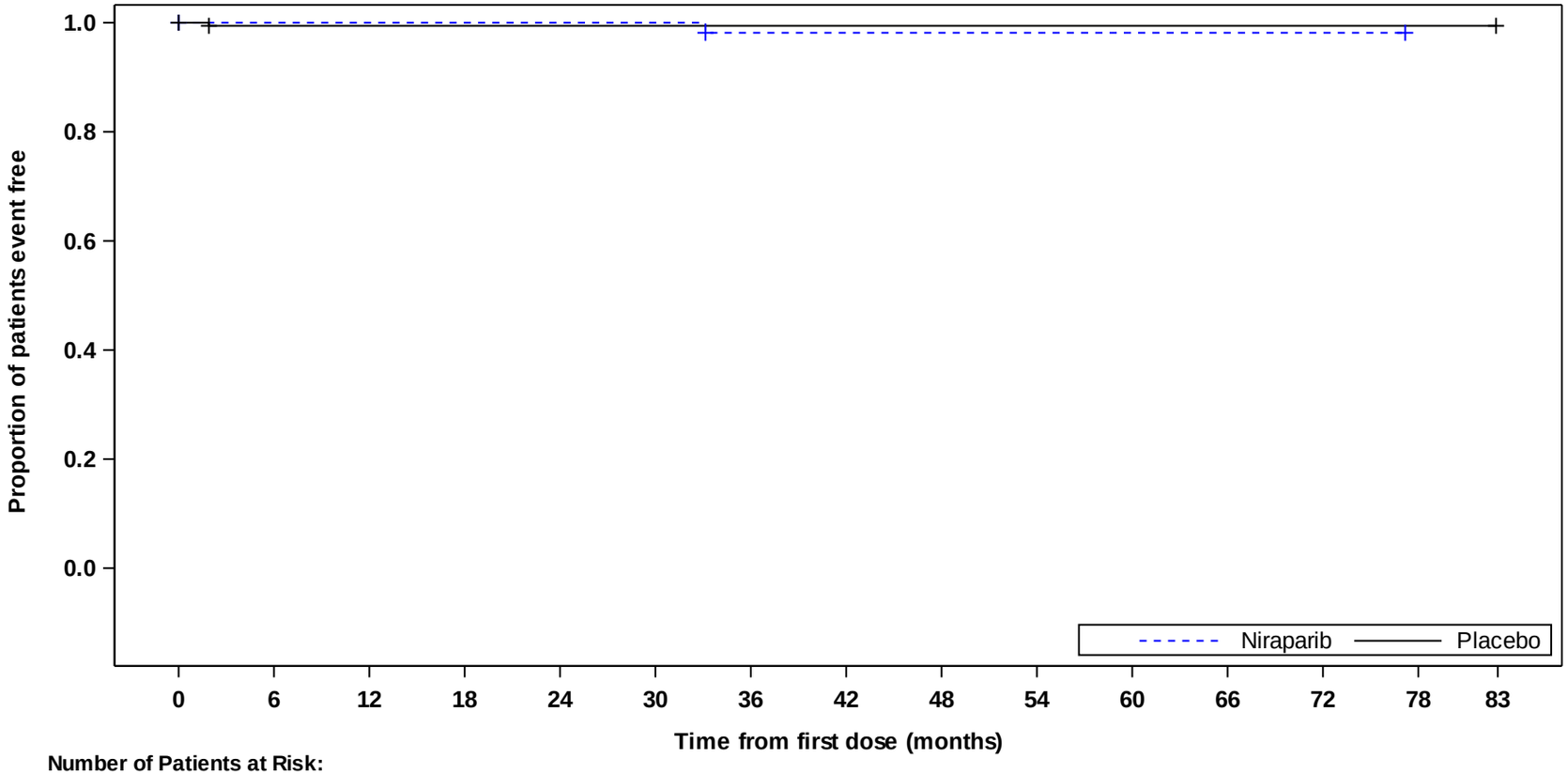
Rundate: 20JAN2021:17:24:55 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), PT: Metastases to central nervous system



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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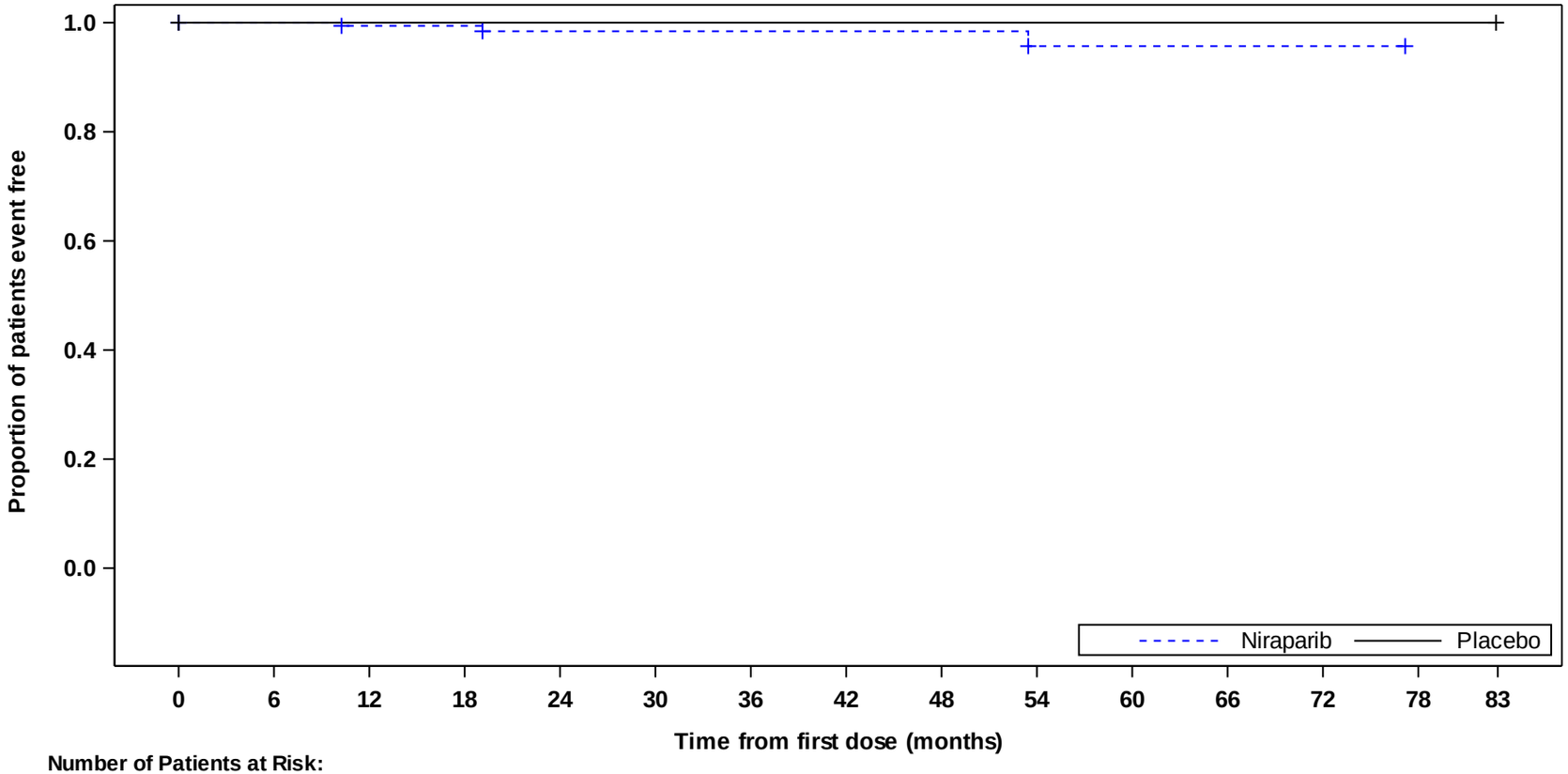
Rundate: 20JAN2021:17:24:56 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), PT: Myelodysplastic syndrome



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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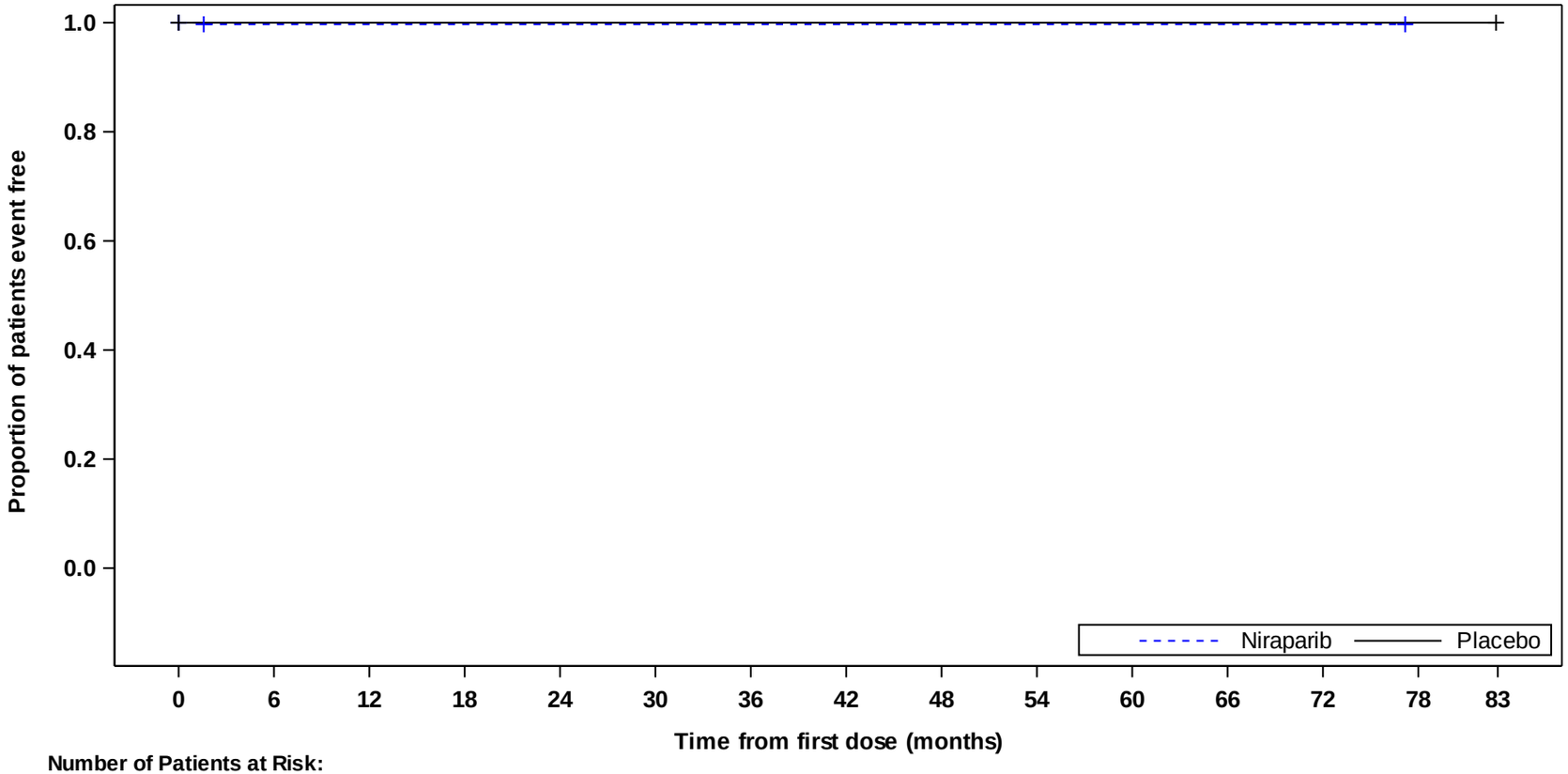
Rundate: 20JAN2021:17:24:57 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), PT: Undifferentiated sarcoma



Number of Patients at Risk:

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Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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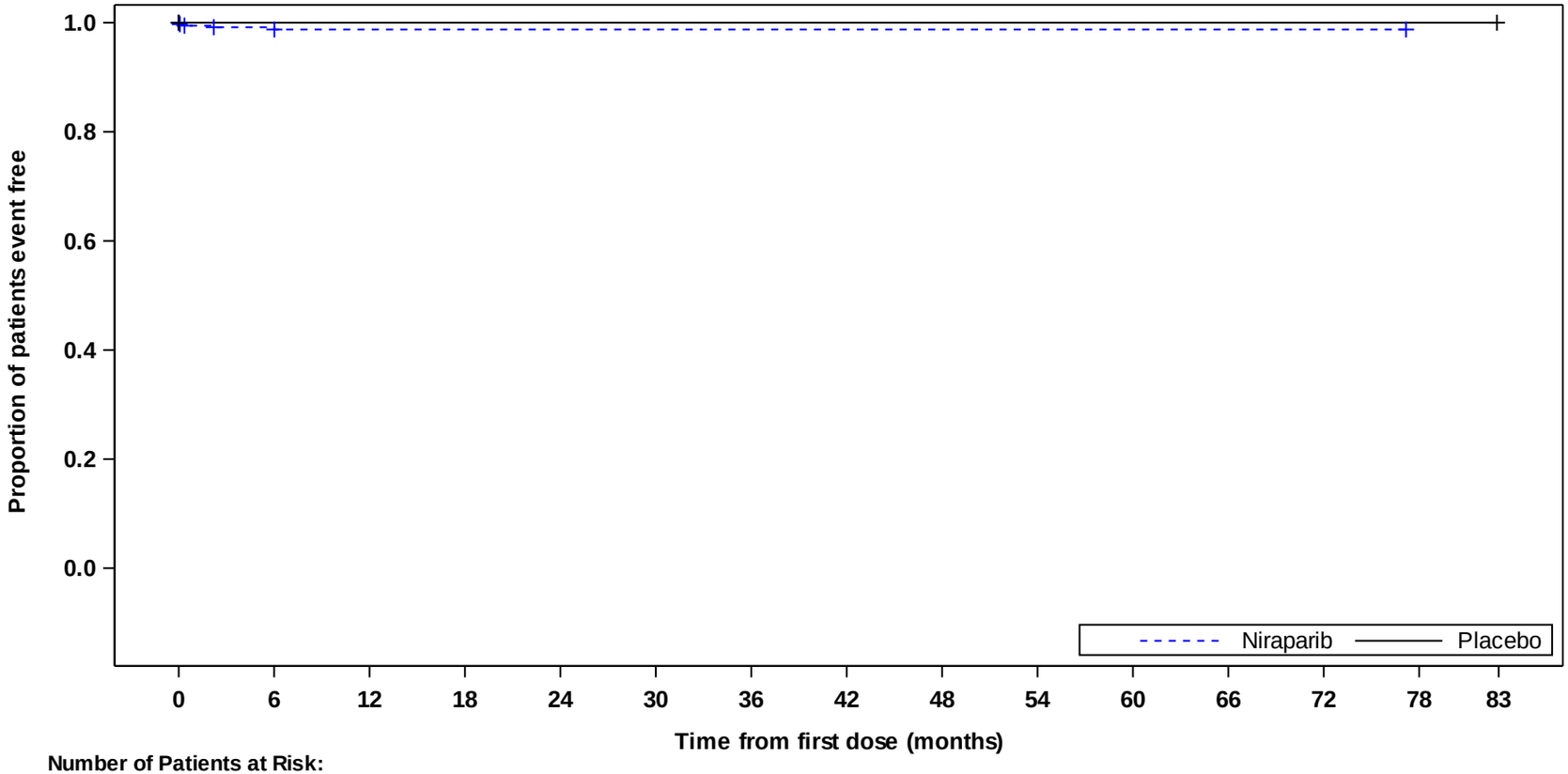
Rundate: 20JAN2021:17:24:58 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Nervous system disorders



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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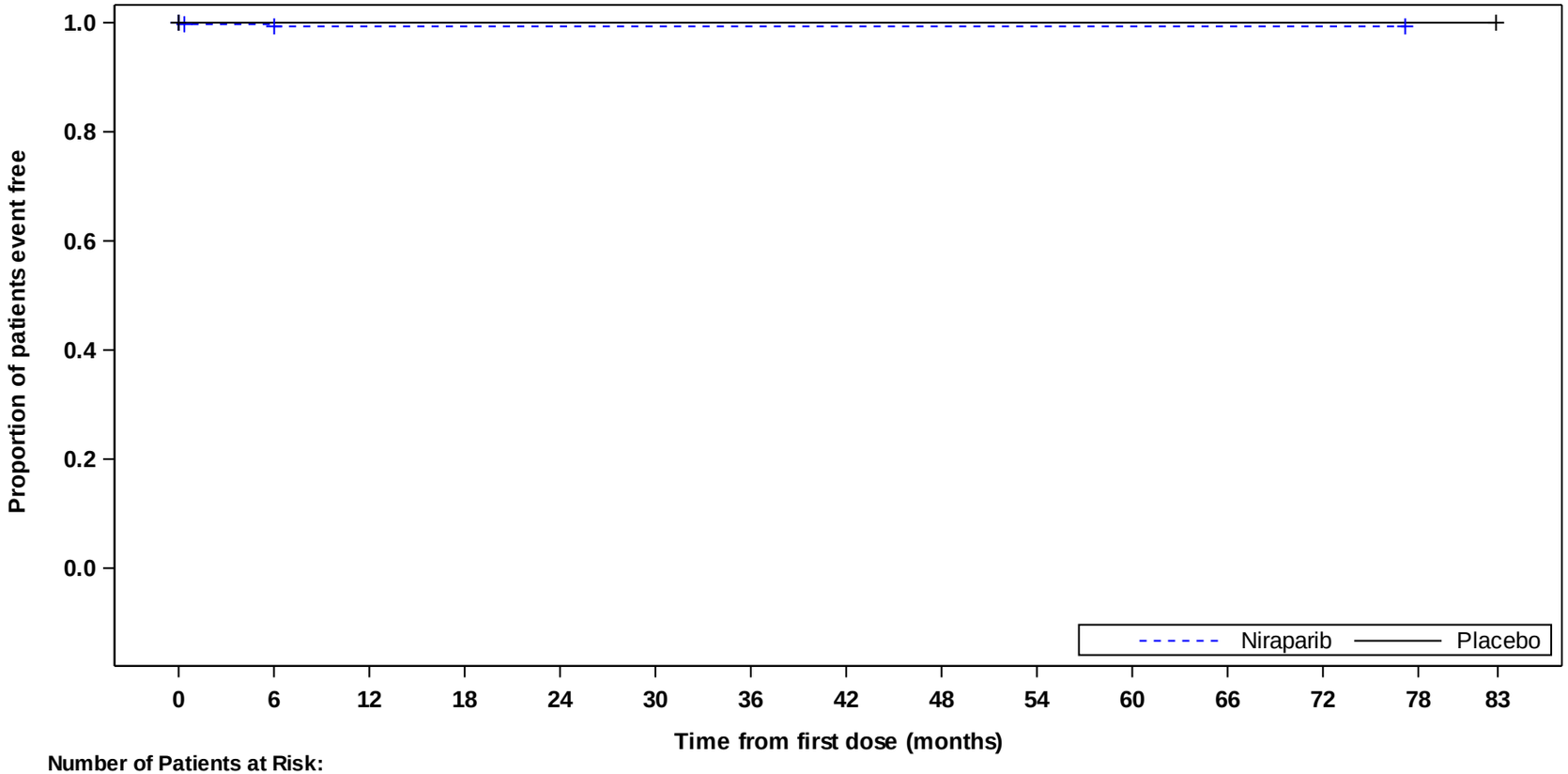
Rundate: 20JAN2021:17:24:58 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Nervous system disorders, PT: Dizziness



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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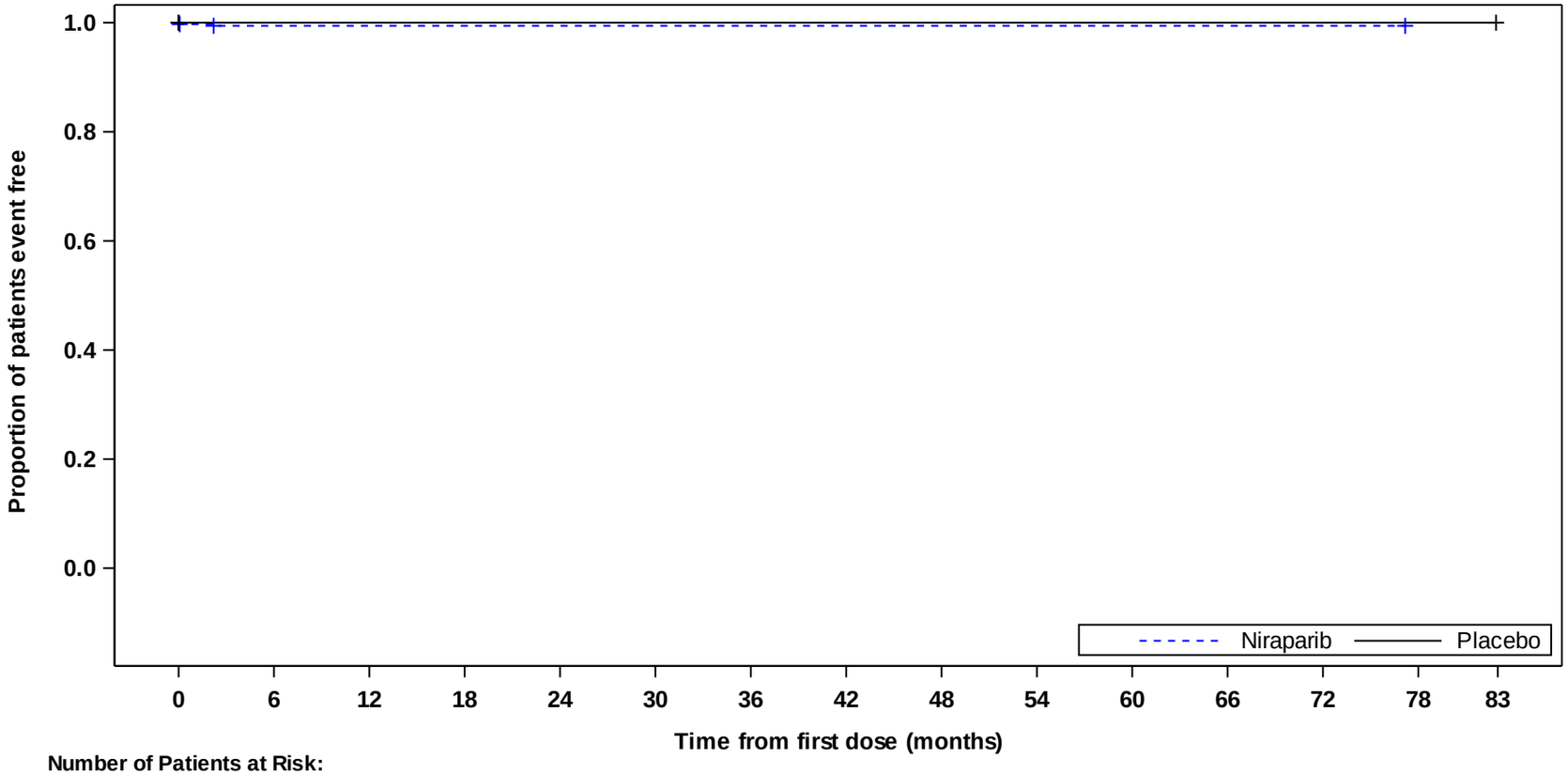
Rundate: 20JAN2021:17:24:59 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Nervous system disorders, PT: Headache



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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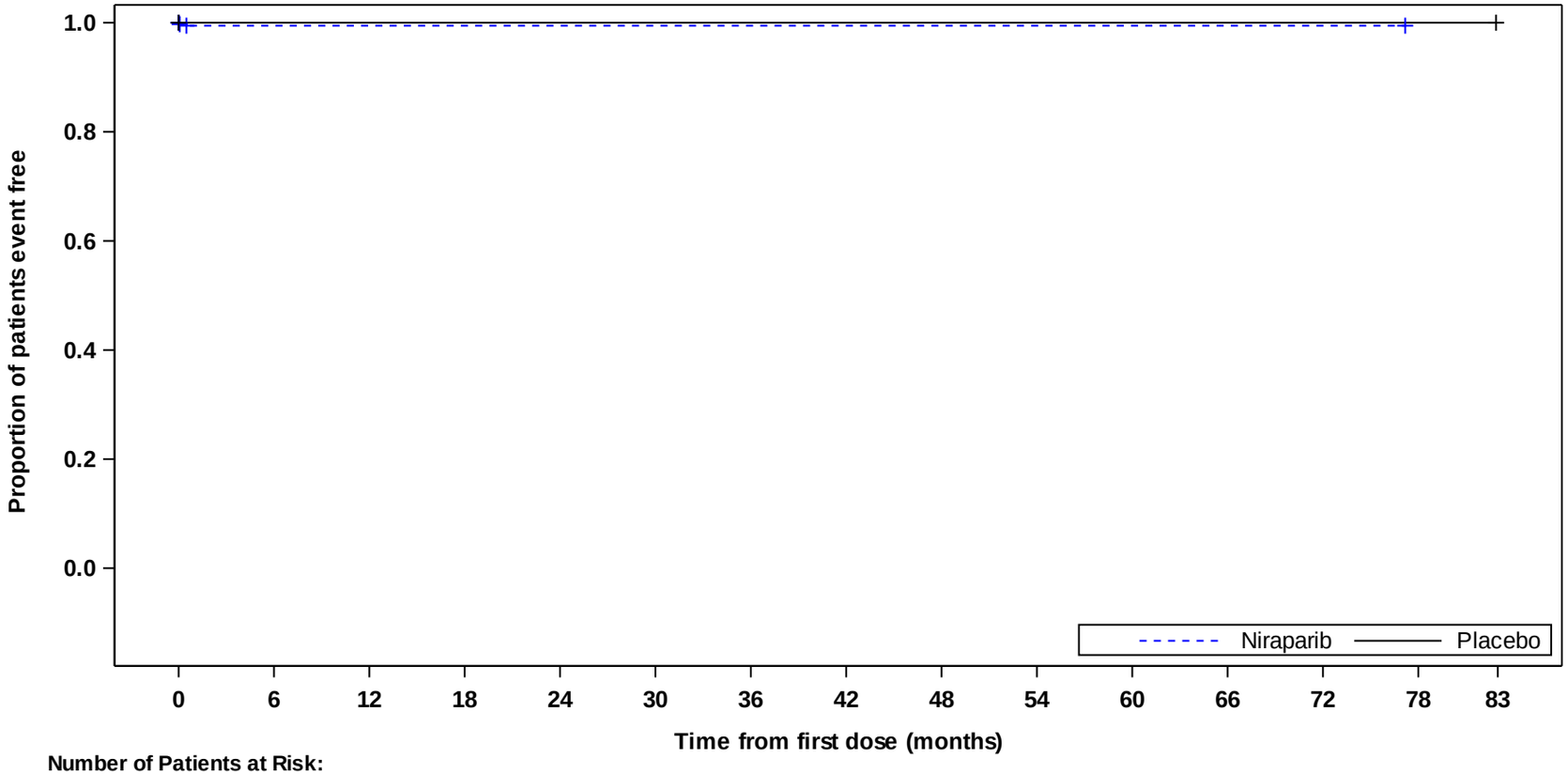
Rundate: 20JAN2021:17:25:00 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Psychiatric disorders



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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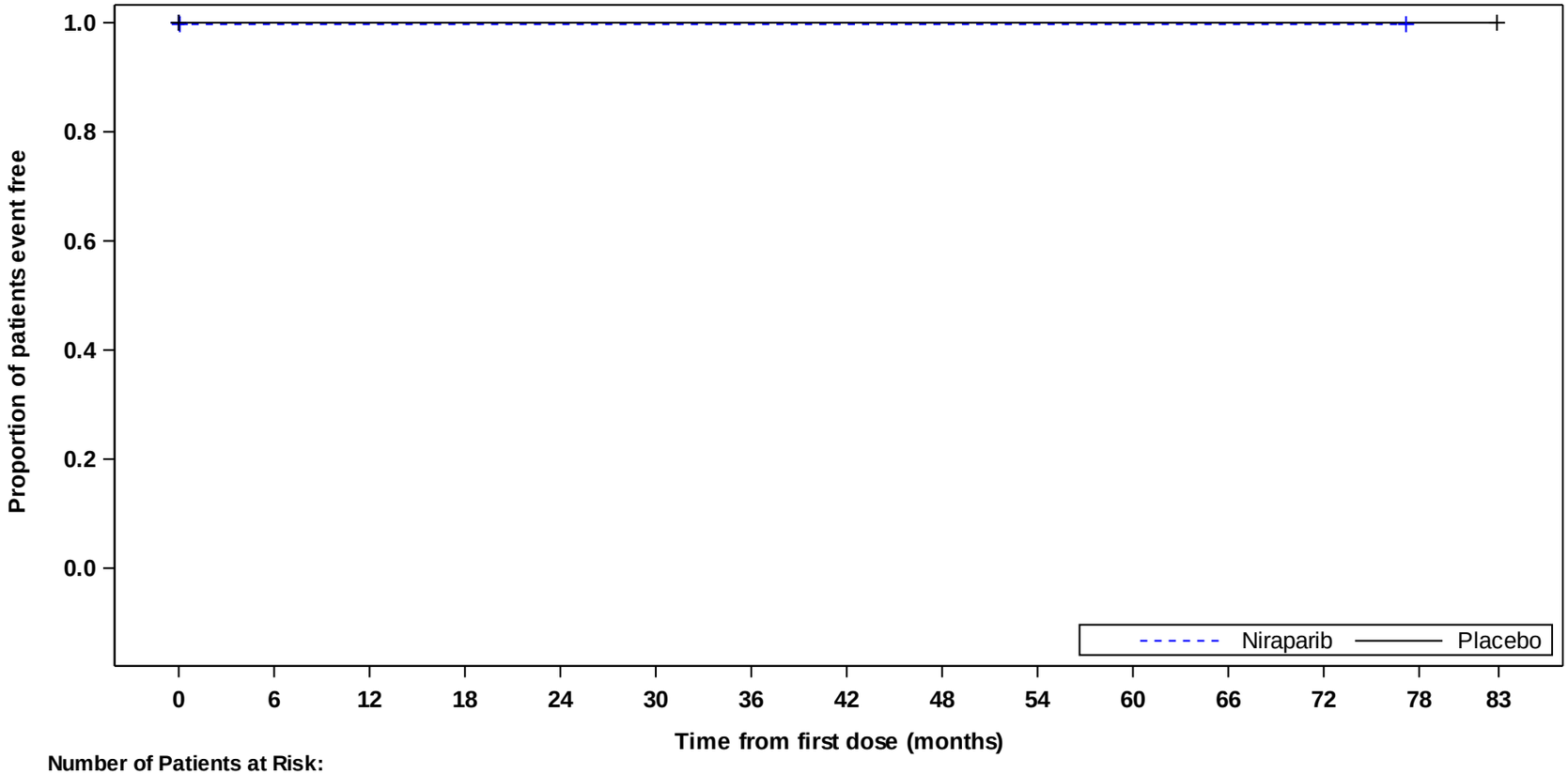
Rundate: 20JAN2021:17:25:01 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Psychiatric disorders, PT: Hallucination



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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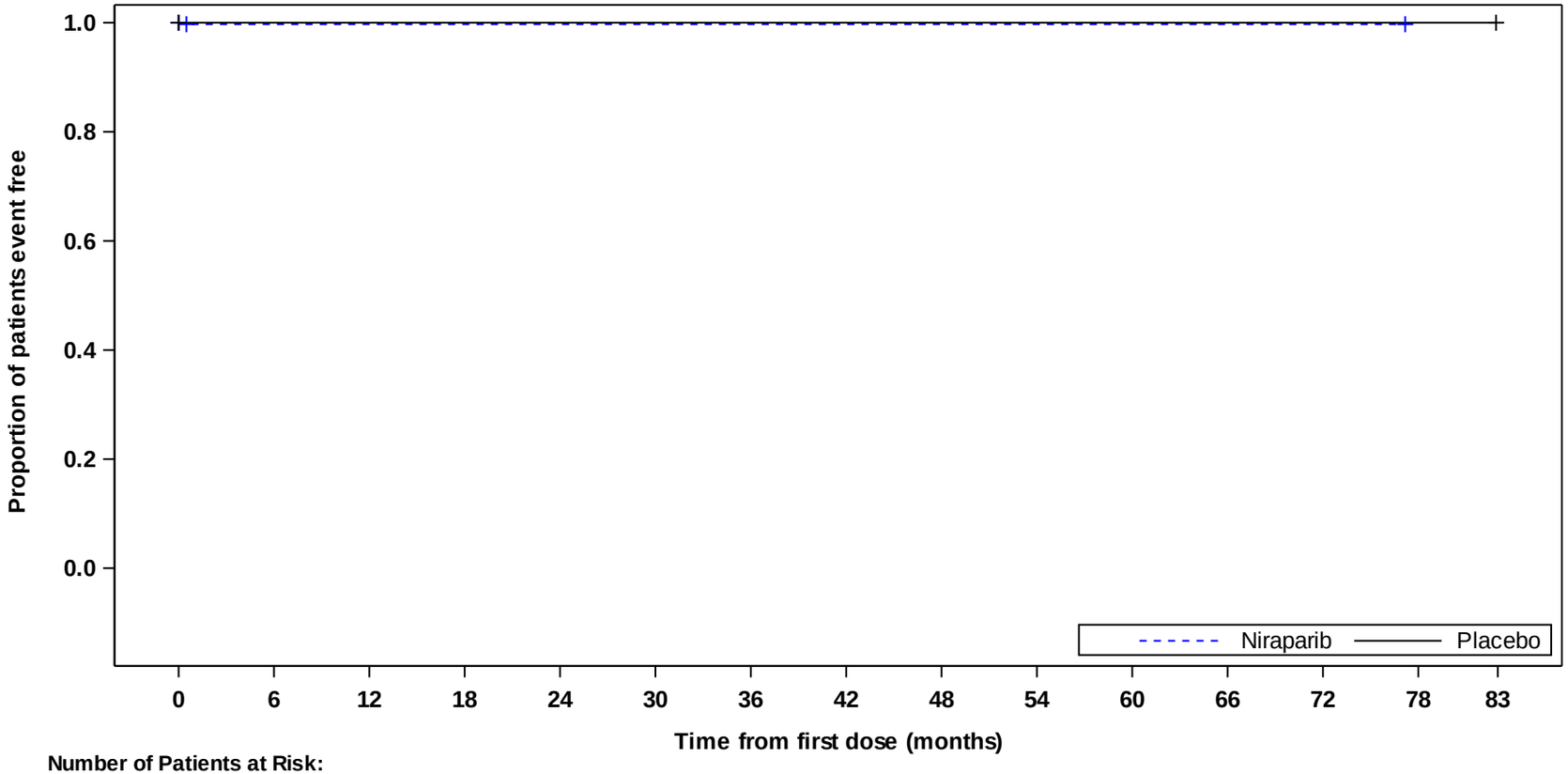
Rundate: 20JAN2021:17:25:02 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Psychiatric disorders, PT: Insomnia



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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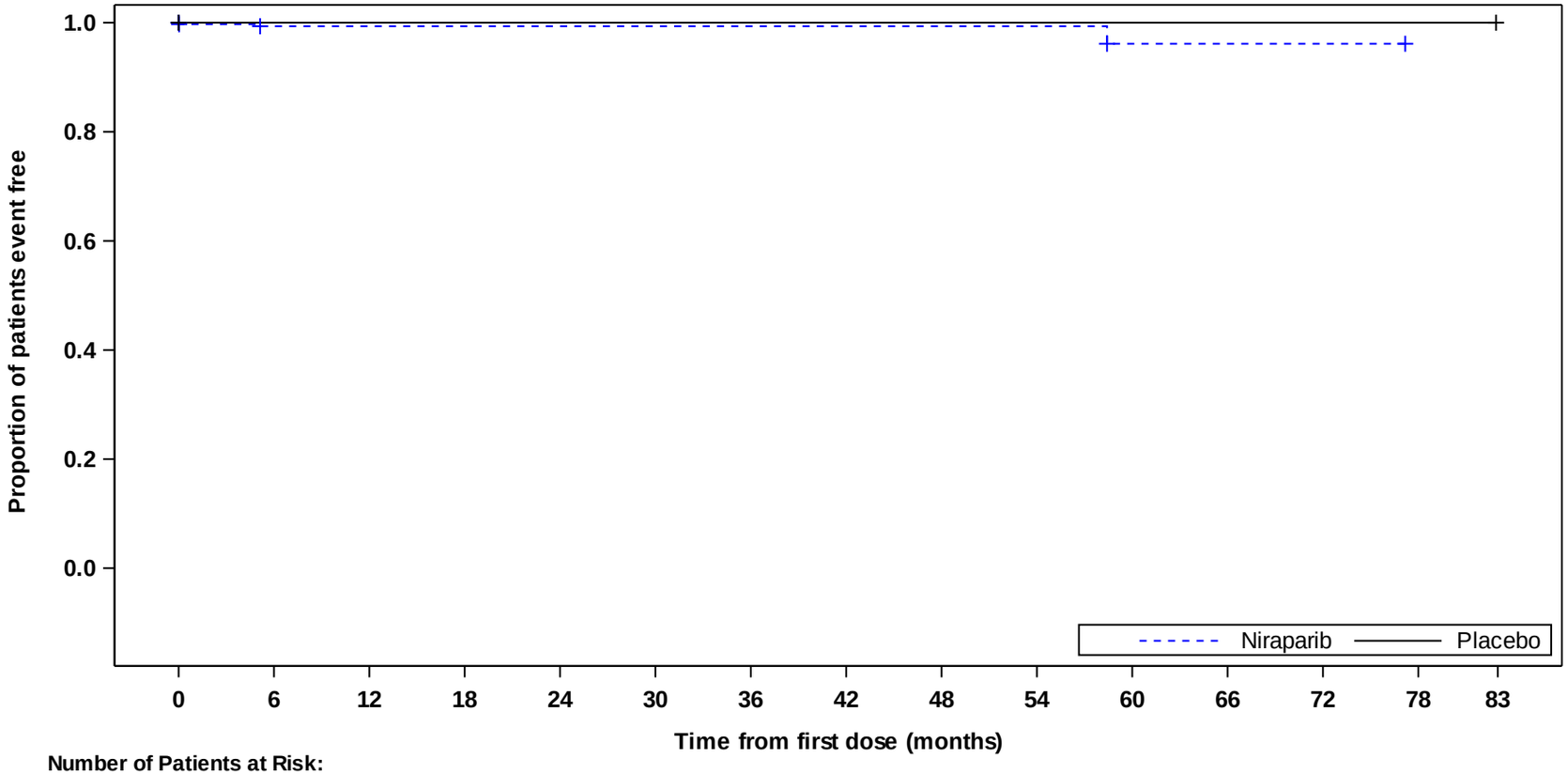
Rundate: 20JAN2021:17:25:03 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders



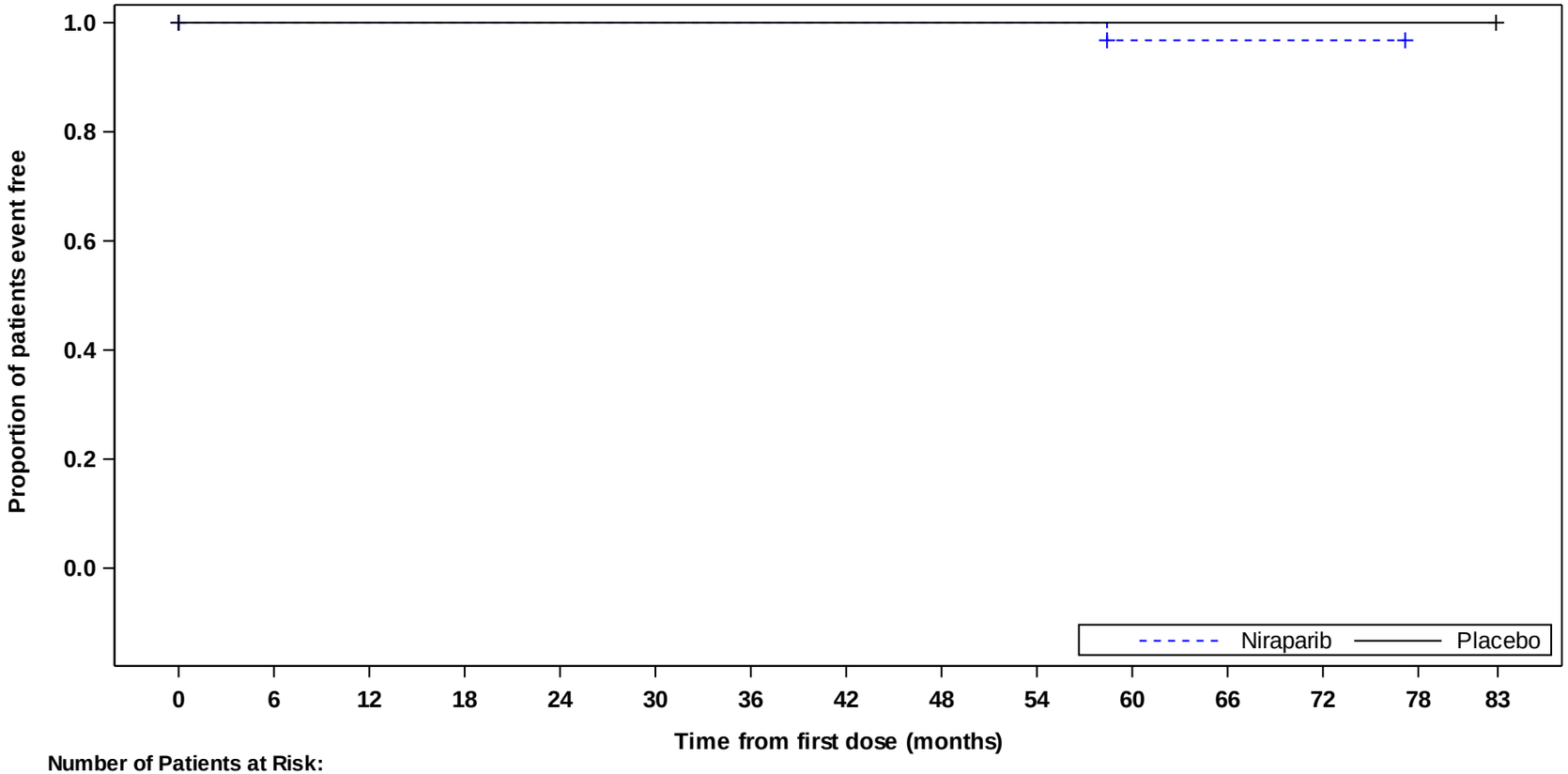
Number of Patients at Risk:

Niraparib	367	246	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:04 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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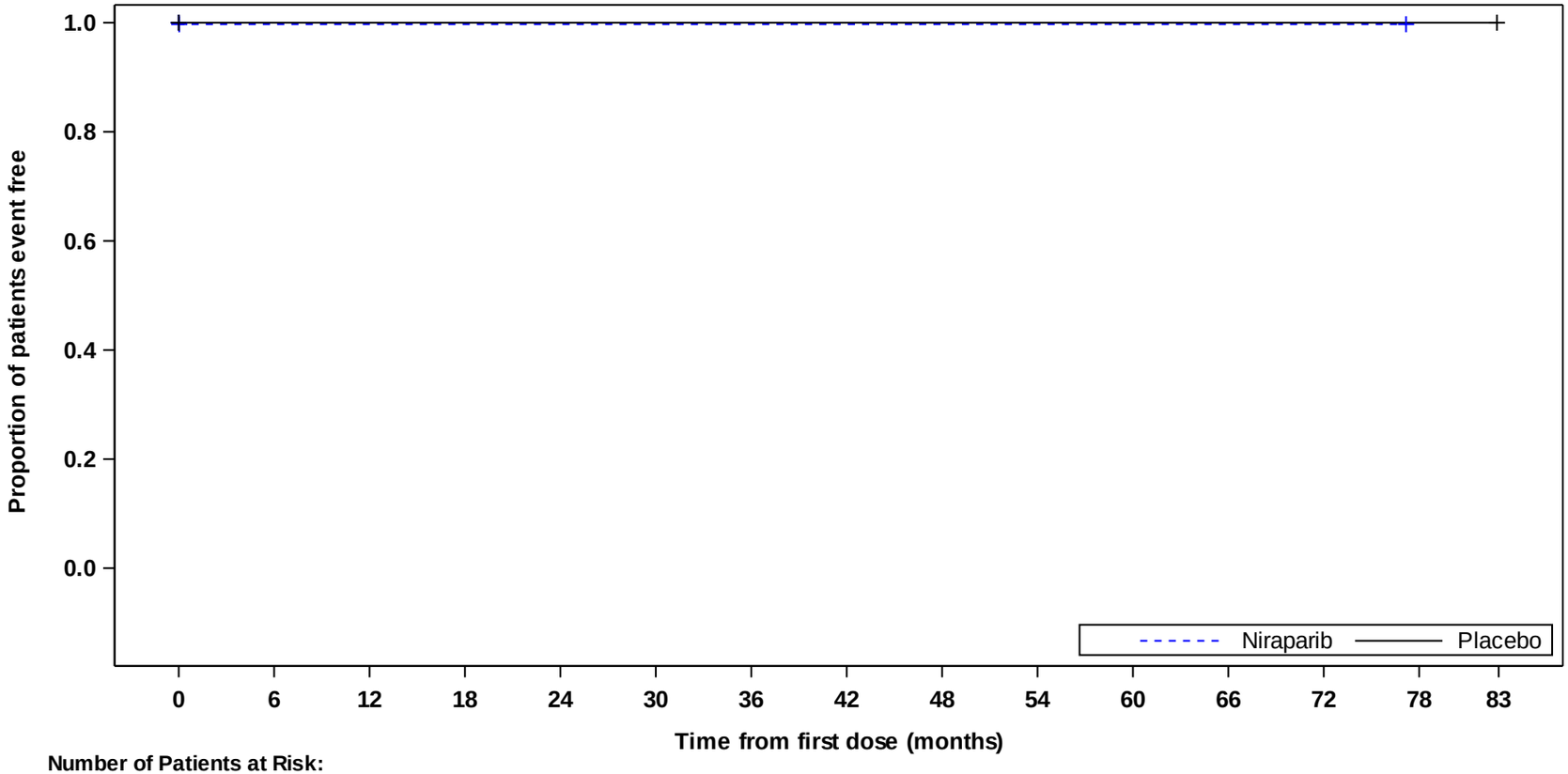
Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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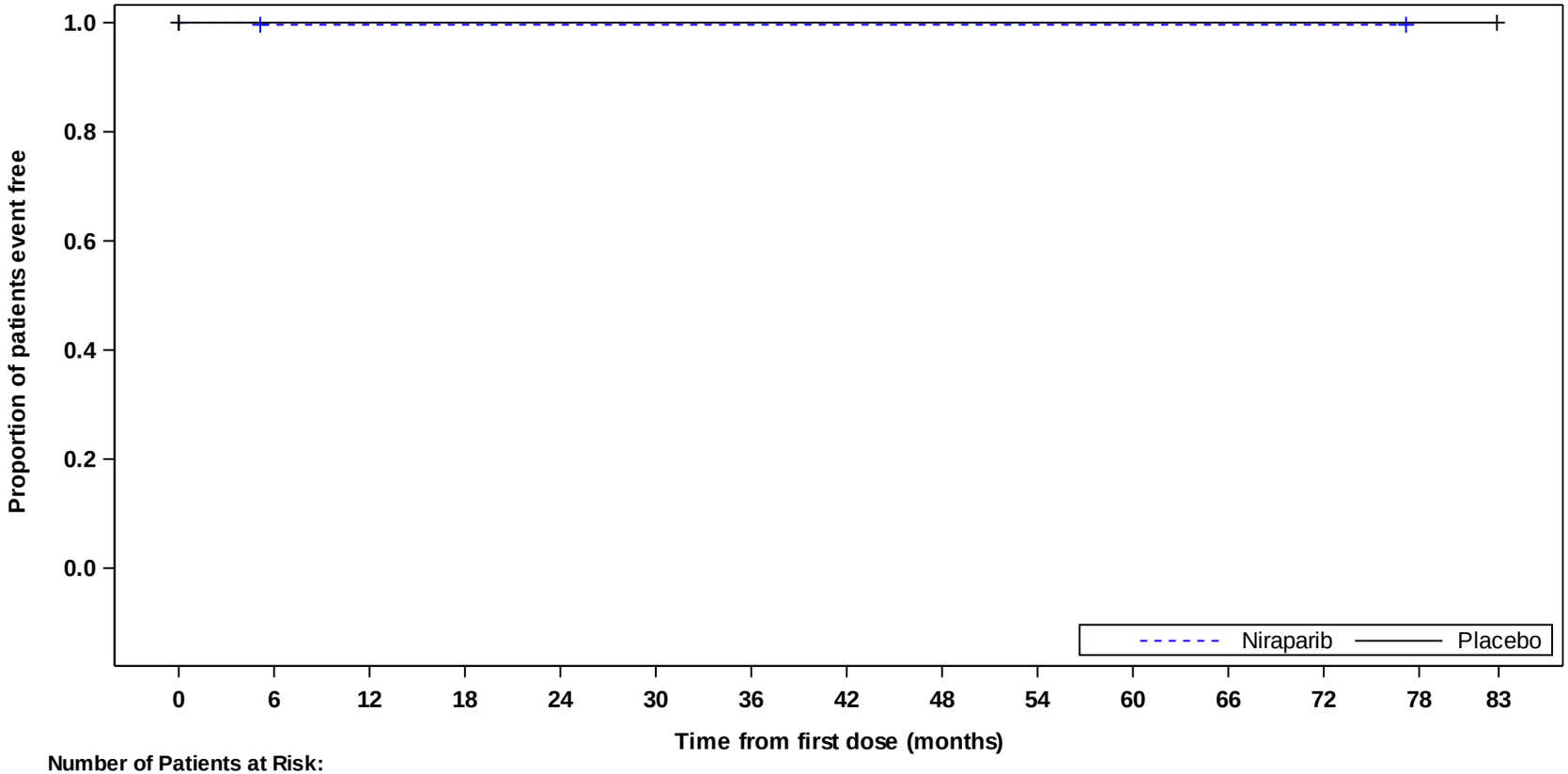
Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders, PT: Pleural effusion



Number of Patients at Risk:

Niraparib	367	246	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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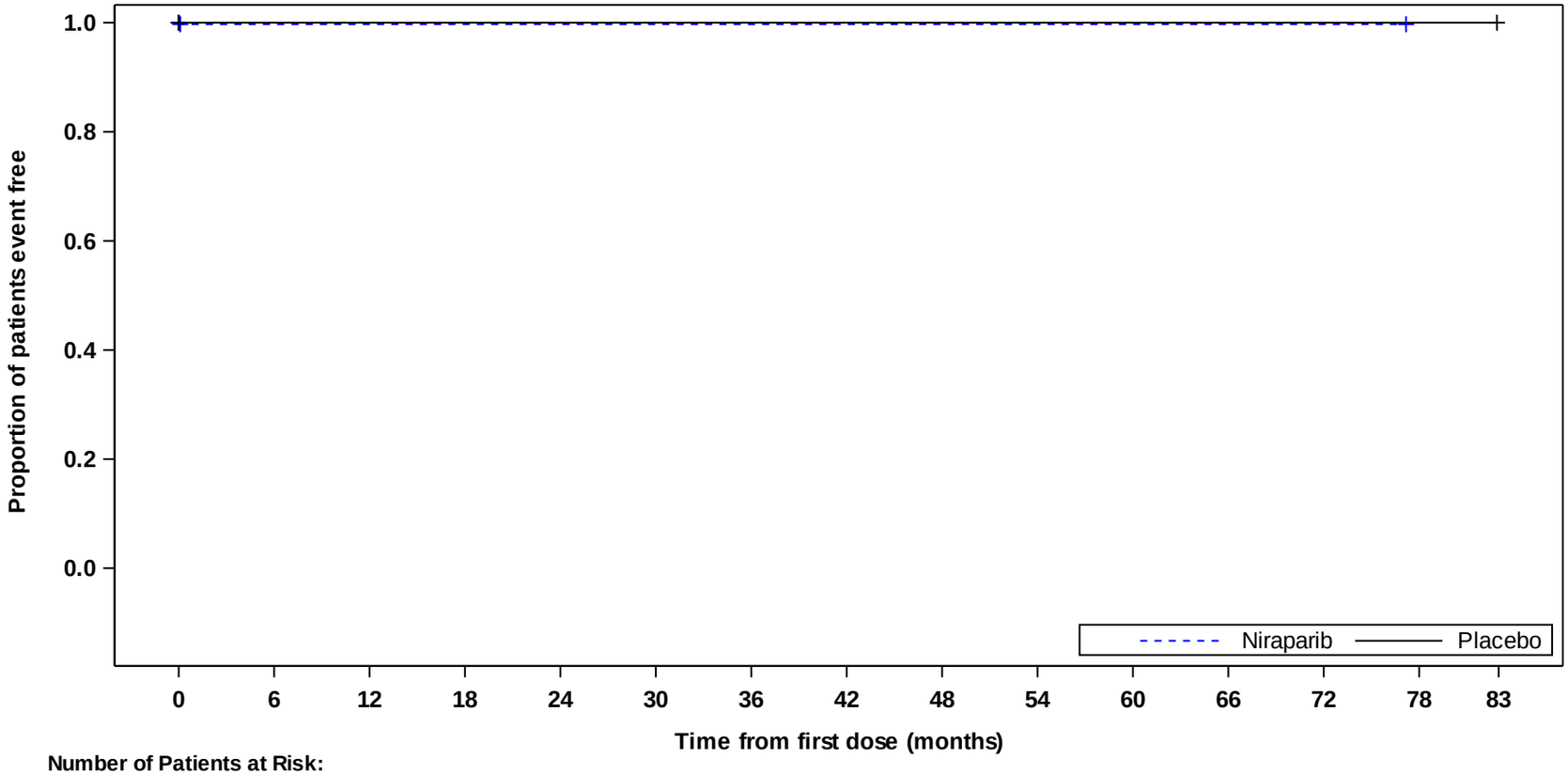
Rundate: 20JAN2021:17:25:06 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Skin and subcutaneous tissue disorders



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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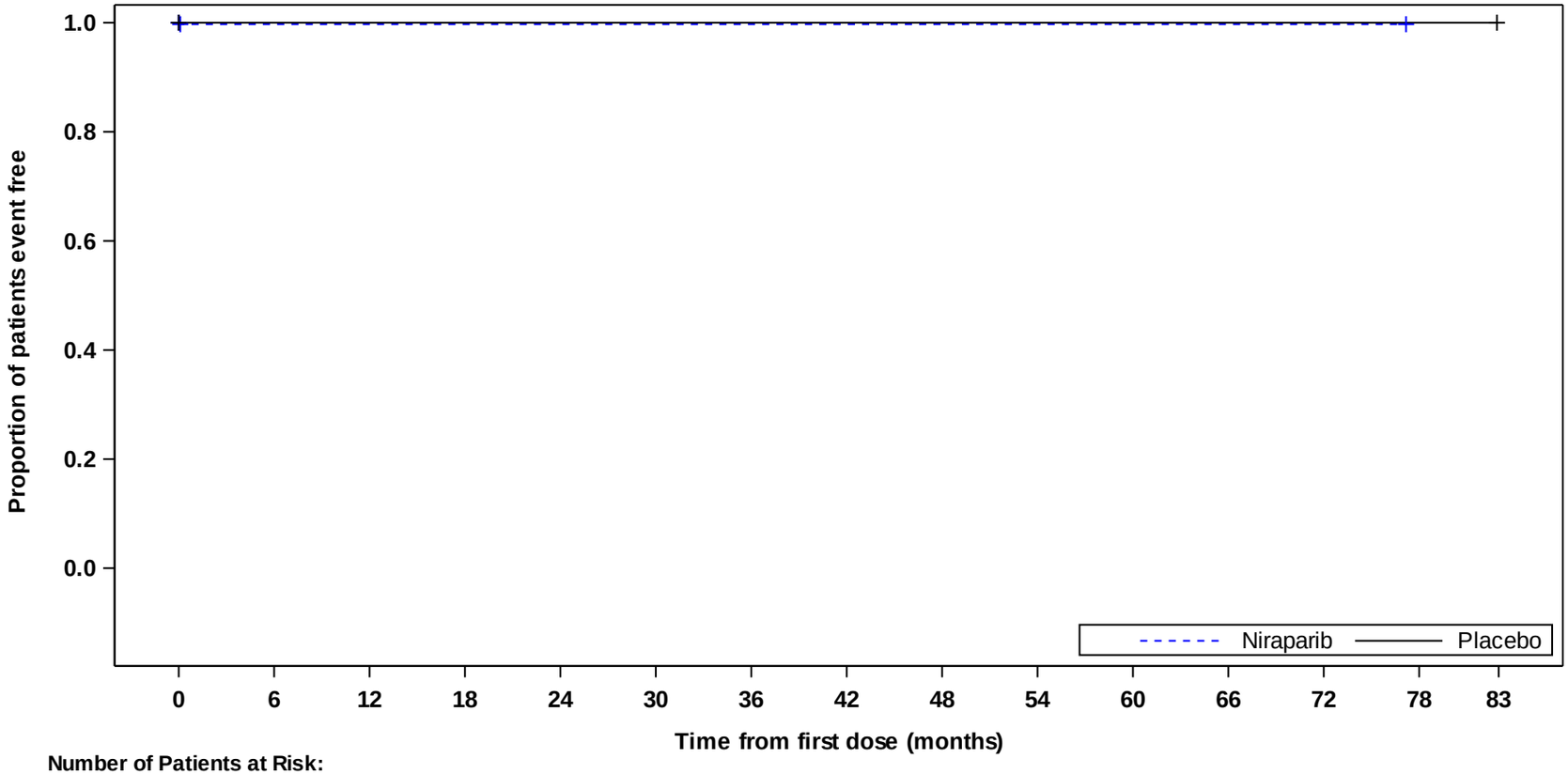
Rundate: 20JAN2021:17:25:07 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Skin and subcutaneous tissue disorders, PT: Hyperhidrosis



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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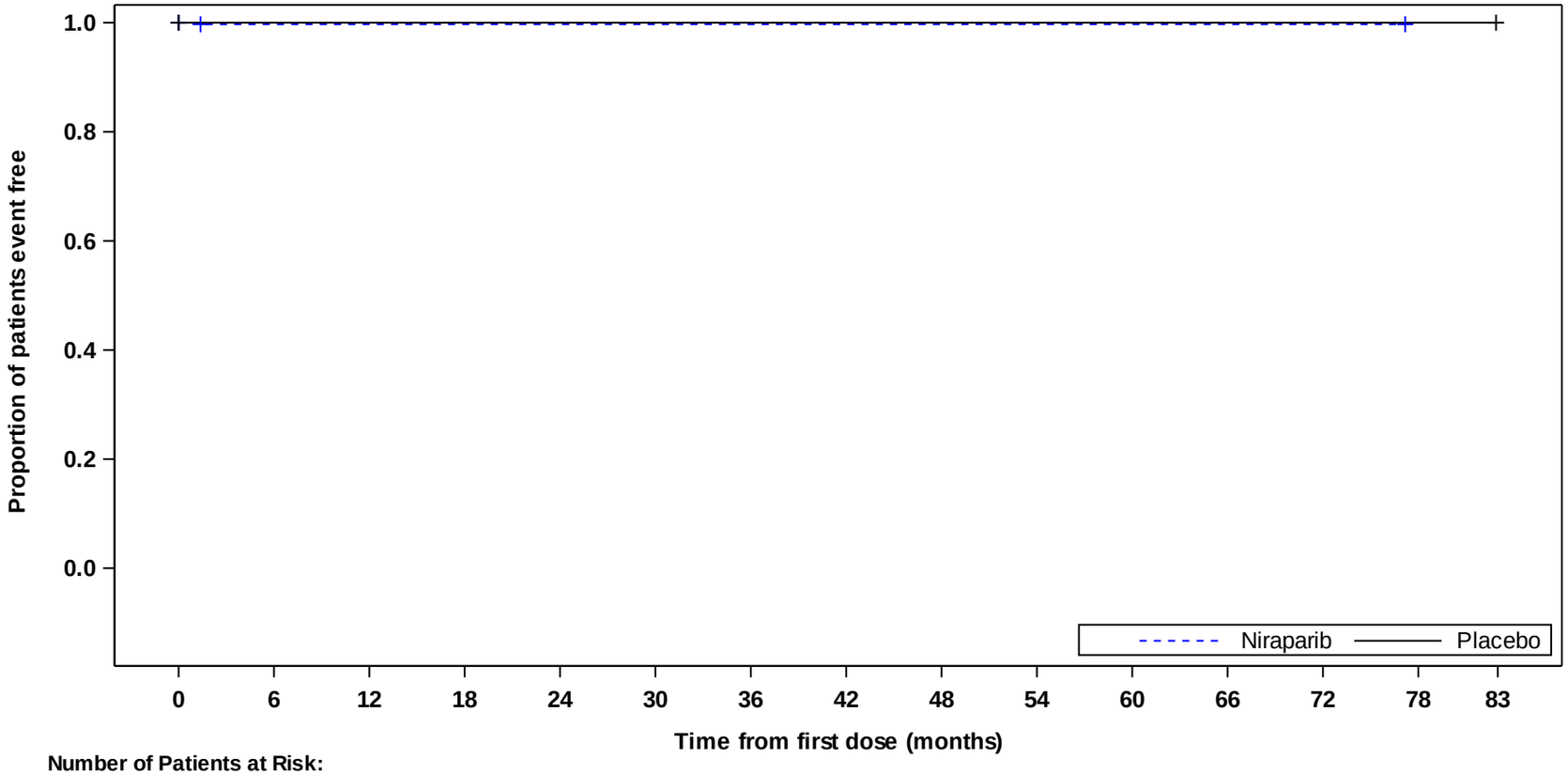
Rundate: 20JAN2021:17:25:08 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Vascular disorders



Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

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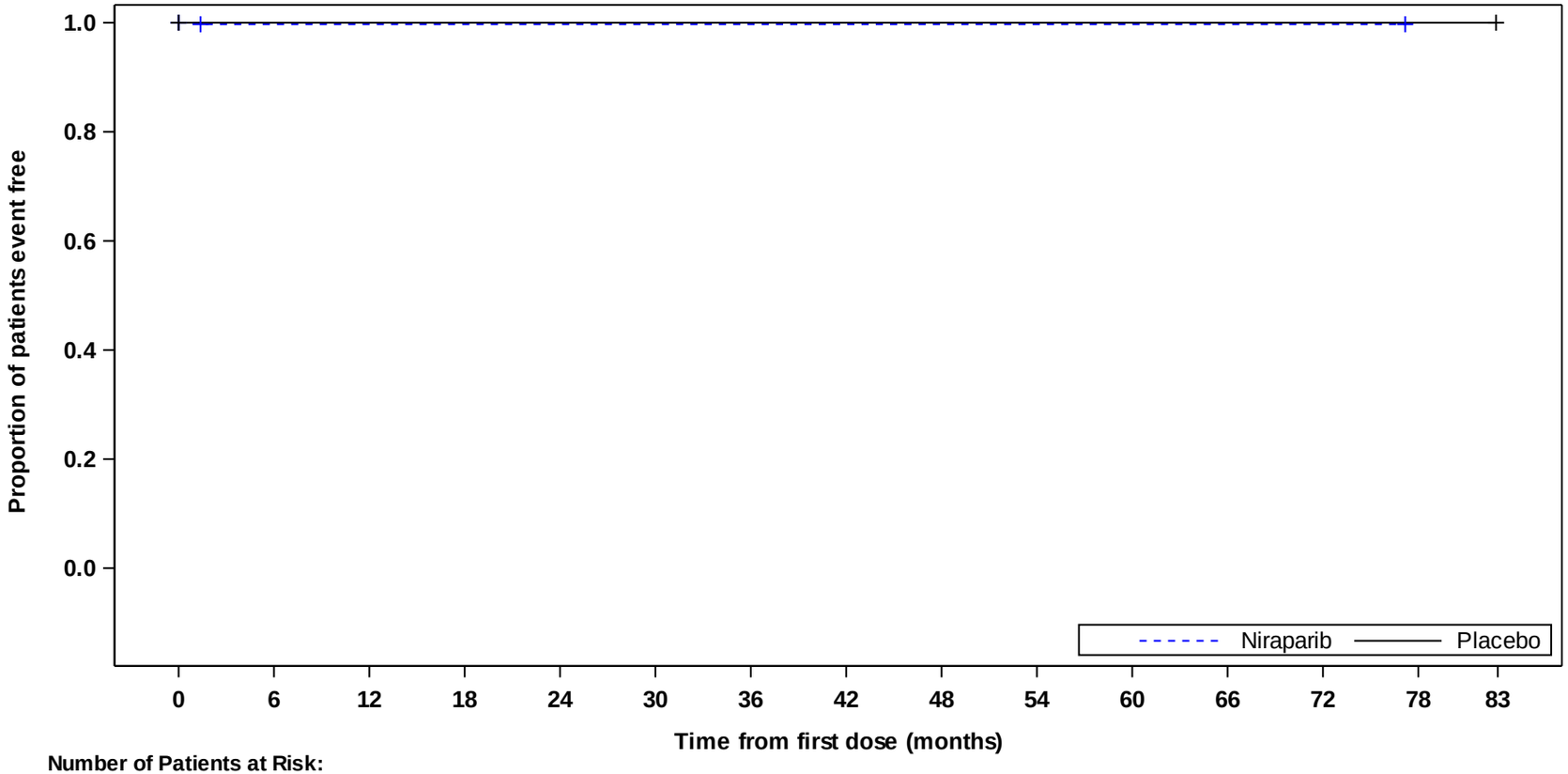
Rundate: 20JAN2021:17:25:09 Data Extraction Date: 01OCT2020

Figure 3.11.9
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Leading to Study Drug Withdrawal by SOC/PT

SOC: Vascular disorders, PT: Hypertensive crisis



Number of Patients at Risk:

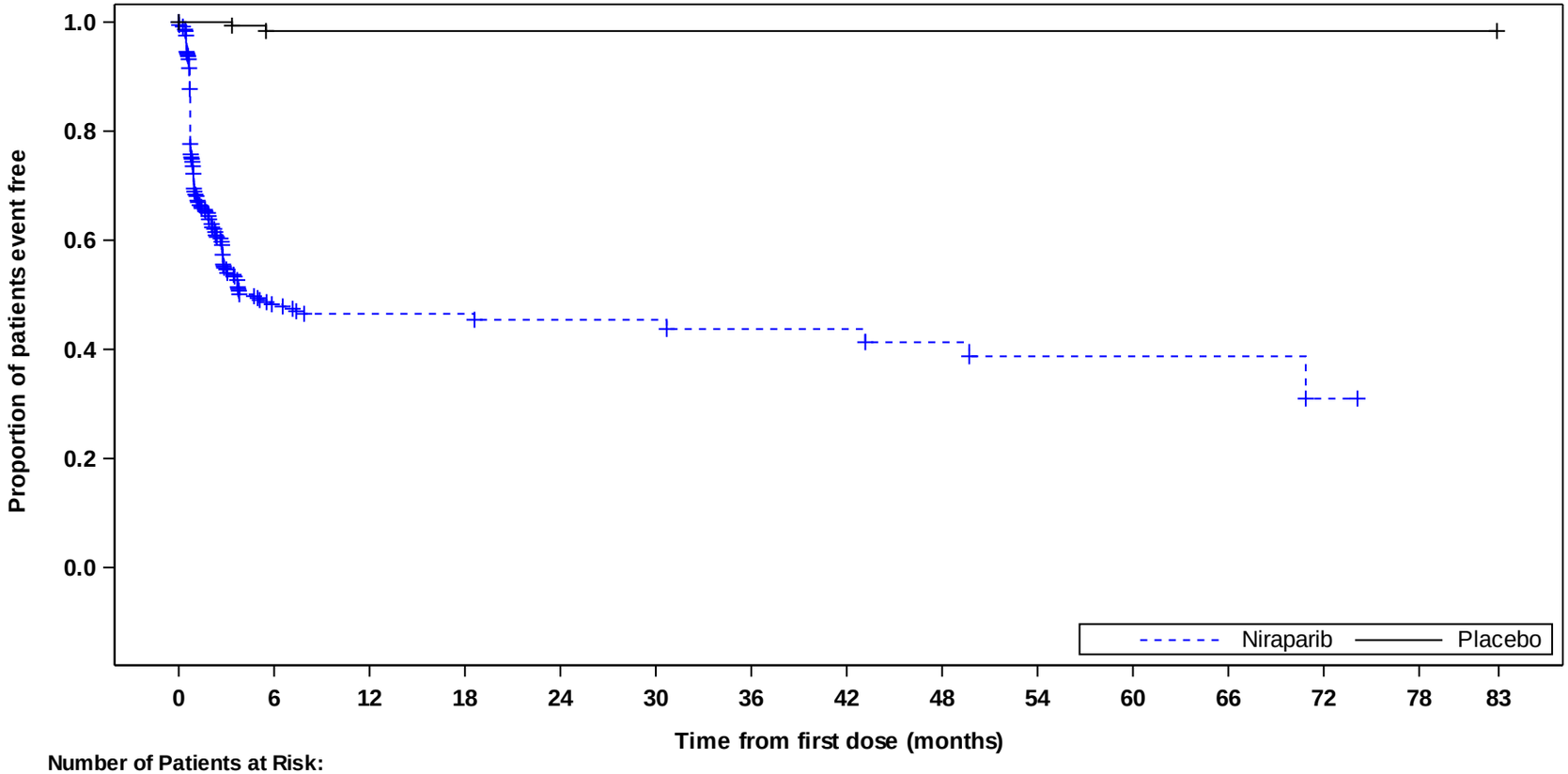
Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:10 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders



Number of Patients at Risk:

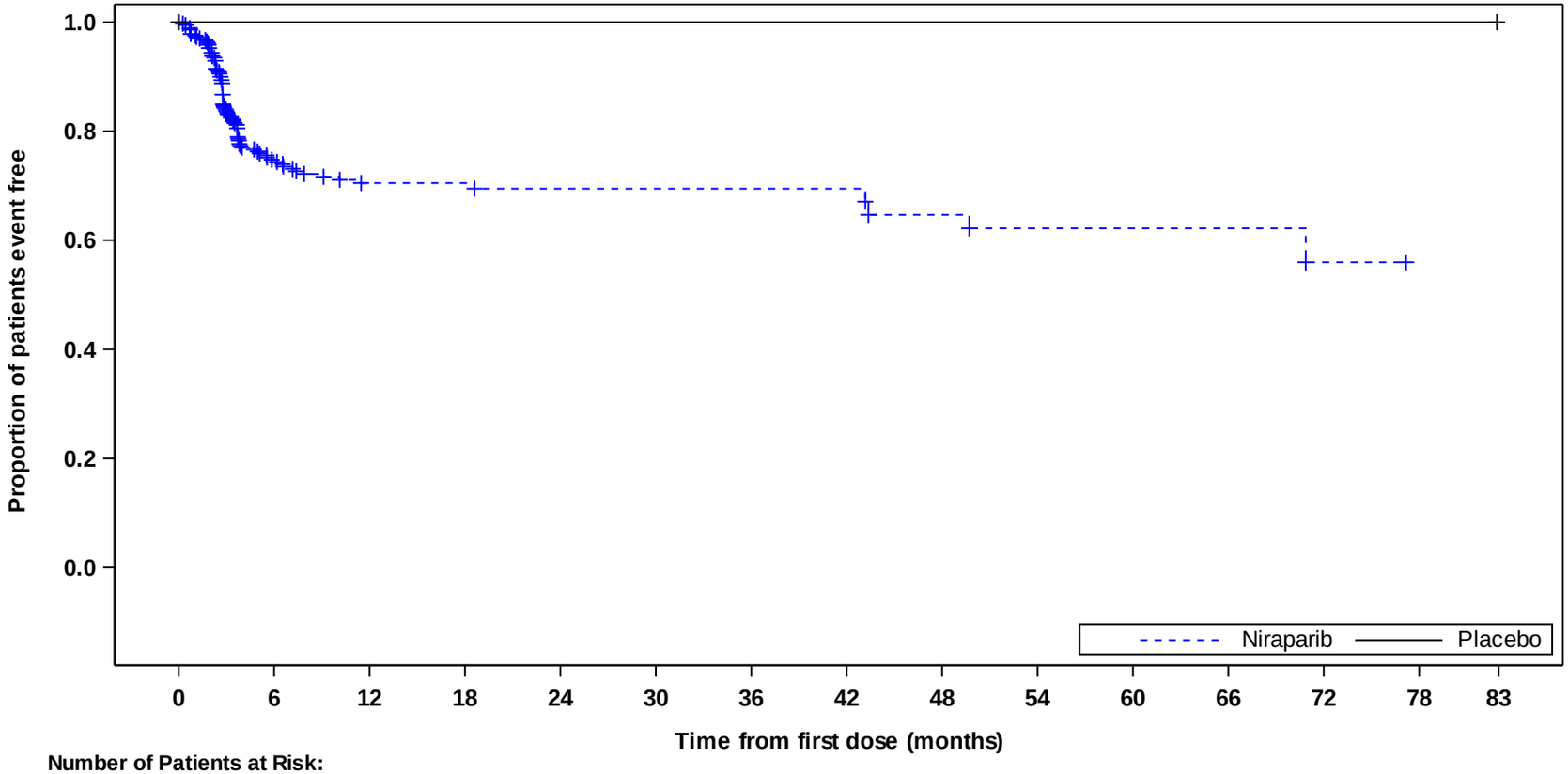
Niraparib	367	123	78	42	31	27	25	19	16	13	11	10	2	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:12 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Anaemia



Number of Patients at Risk:

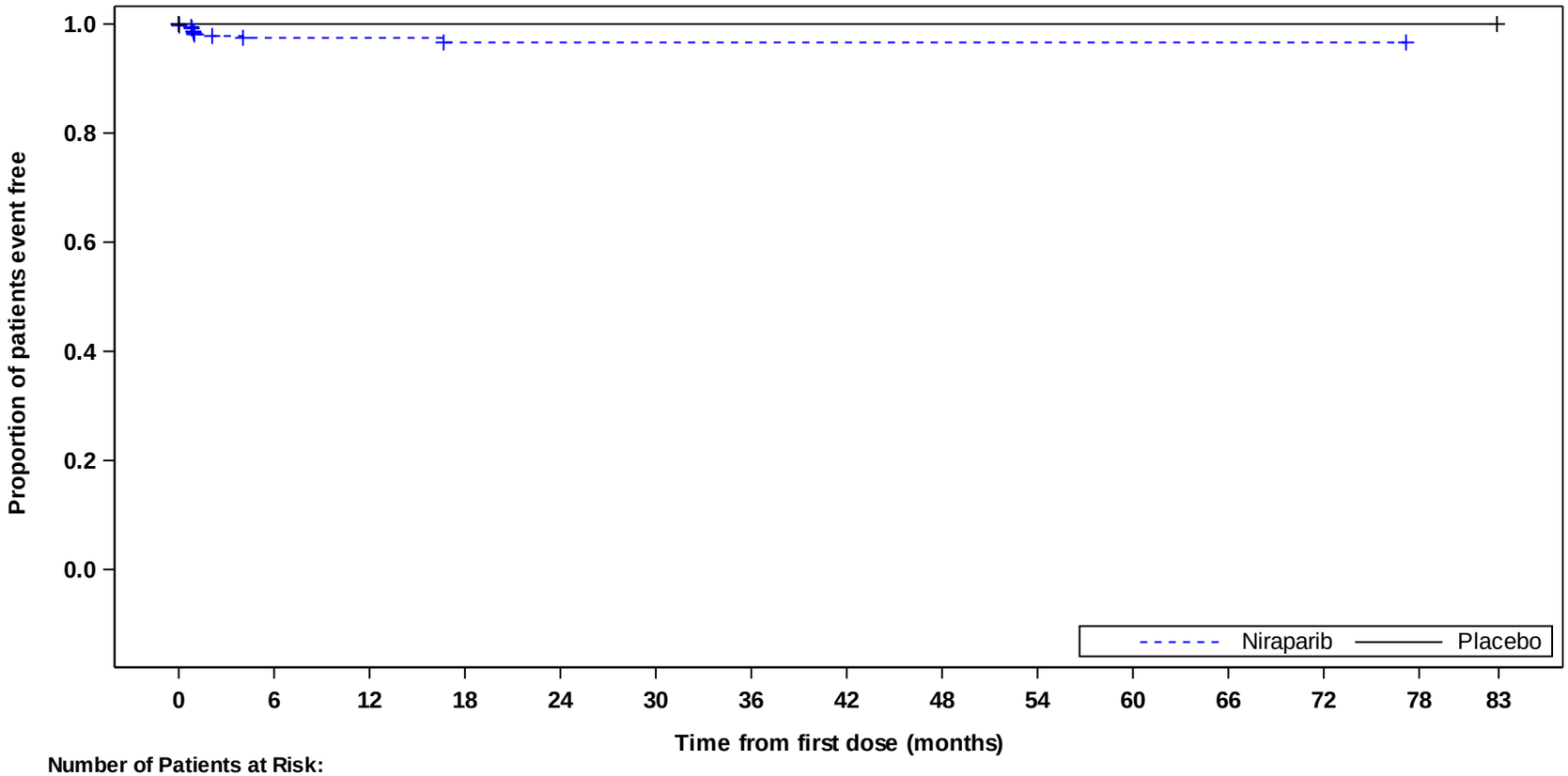
Niraparib	367	188	117	70	50	44	38	30	26	22	20	18	5	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:13 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Leukopenia



Number of Patients at Risk:

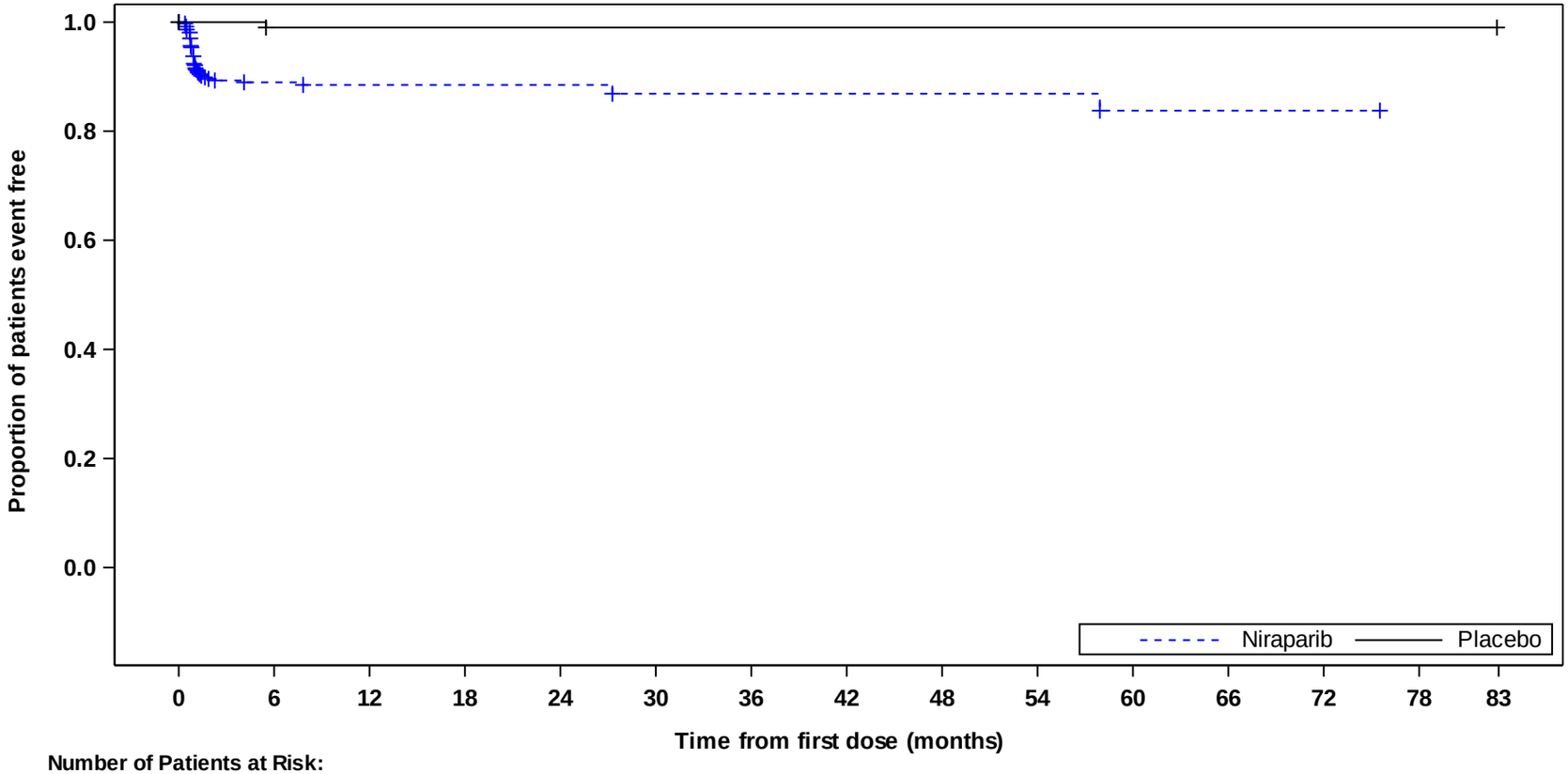
Niraparib	367	242	159	99	69	60	51	41	38	33	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:14 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Neutropenia



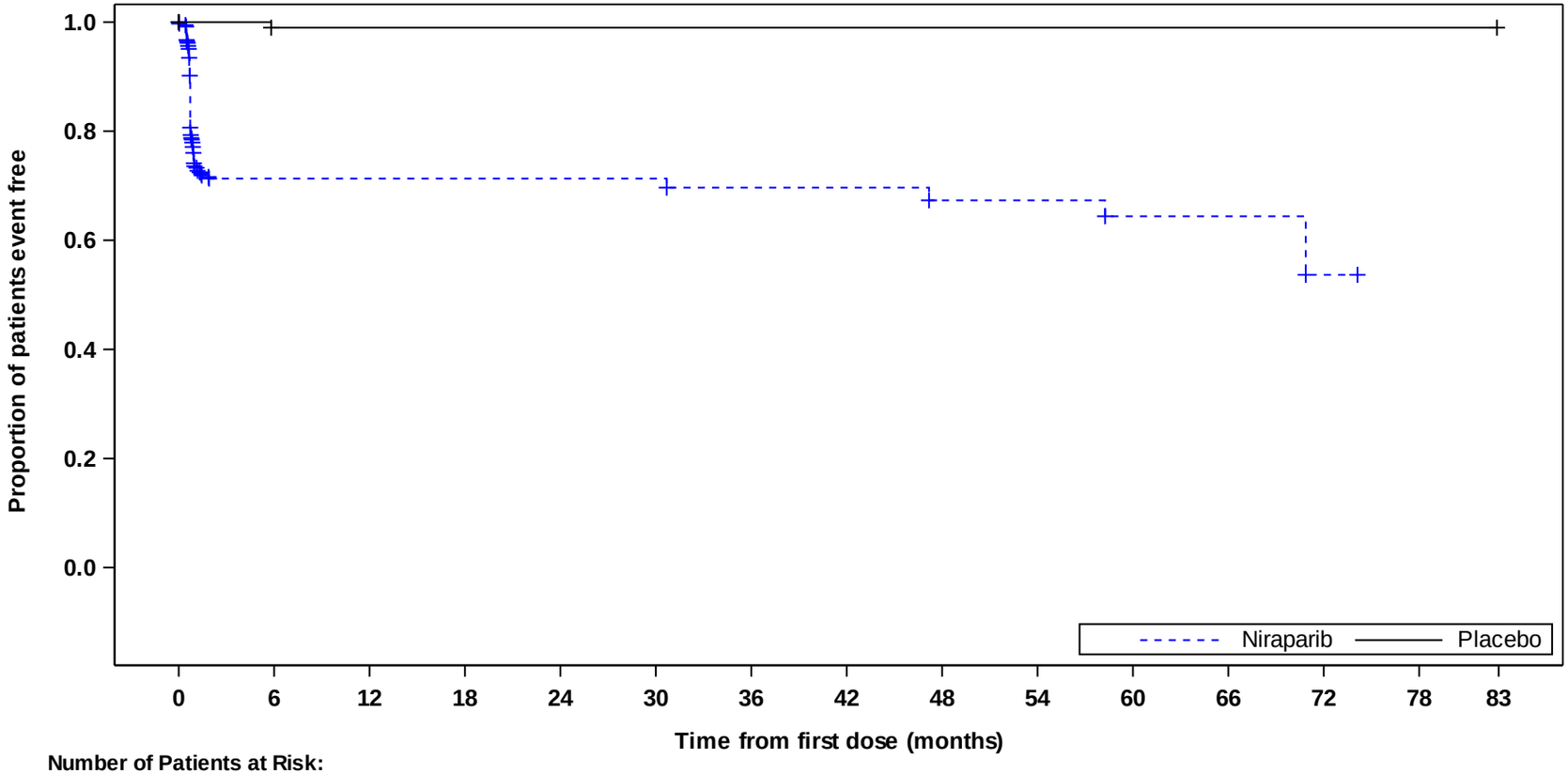
Number of Patients at Risk:

Niraparib	367	221	143	86	60	51	45	36	33	29	25	19	5	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:15 Data Extraction Date: 01OCT2020

Figure 3.13.1
Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia



Number of Patients at Risk:

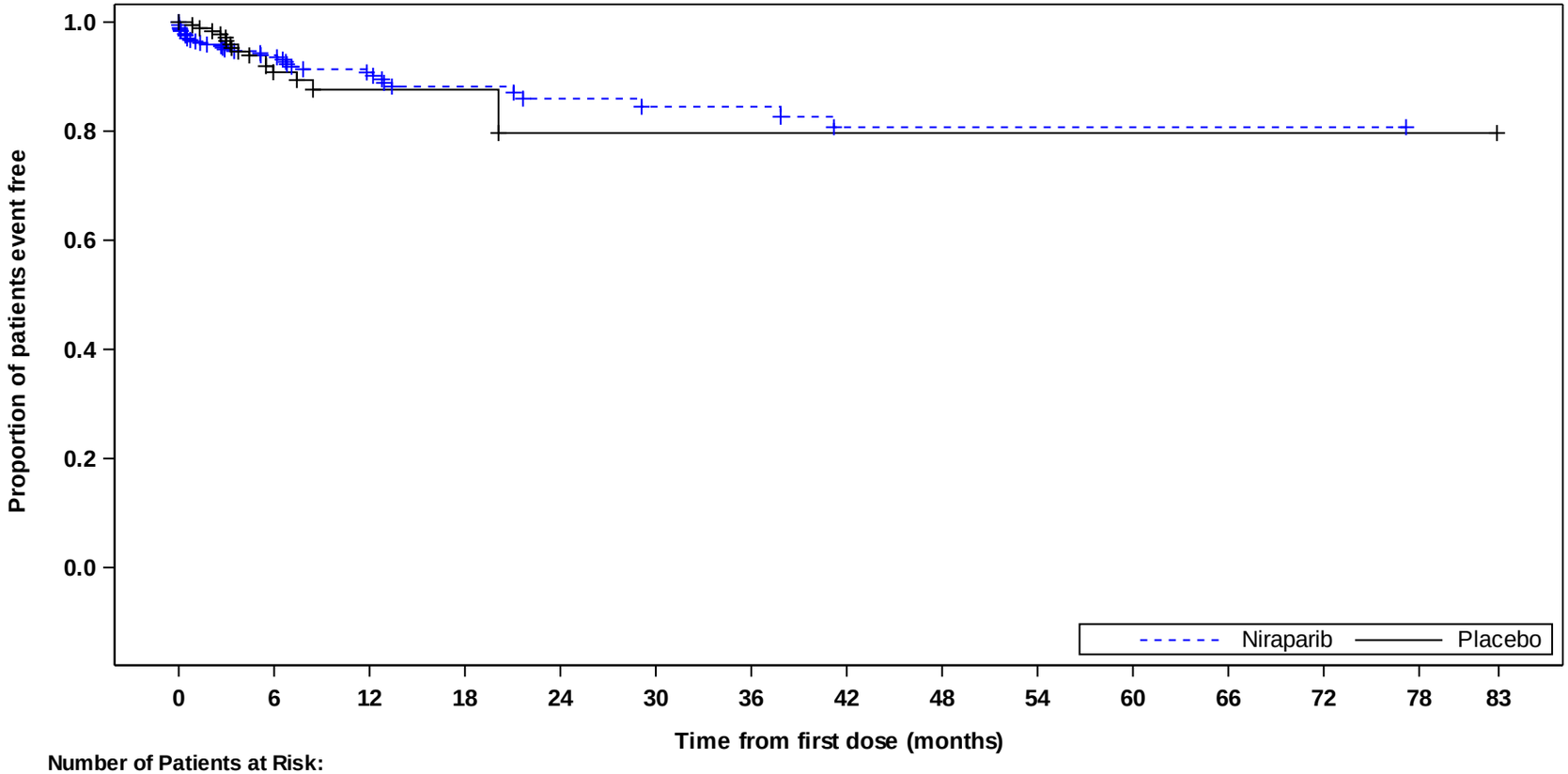
Niraparib	367	177	117	70	51	45	40	32	28	24	20	14	2	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:16 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders



Number of Patients at Risk:

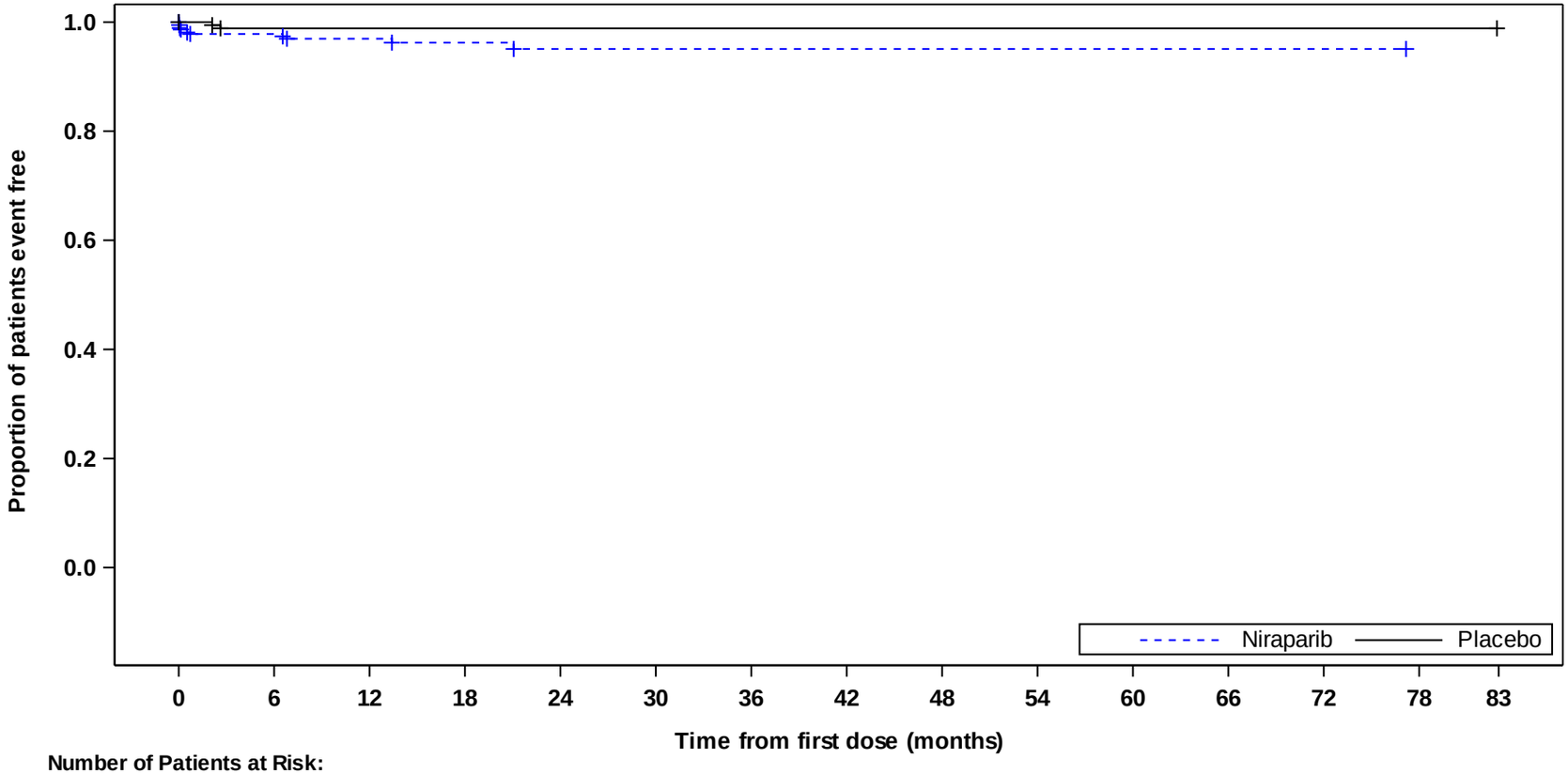
Niraparib	367	239	152	96	67	57	49	40	38	34	29	22	7	0
Placebo	179	83	32	14	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:17 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Nausea



Number of Patients at Risk:

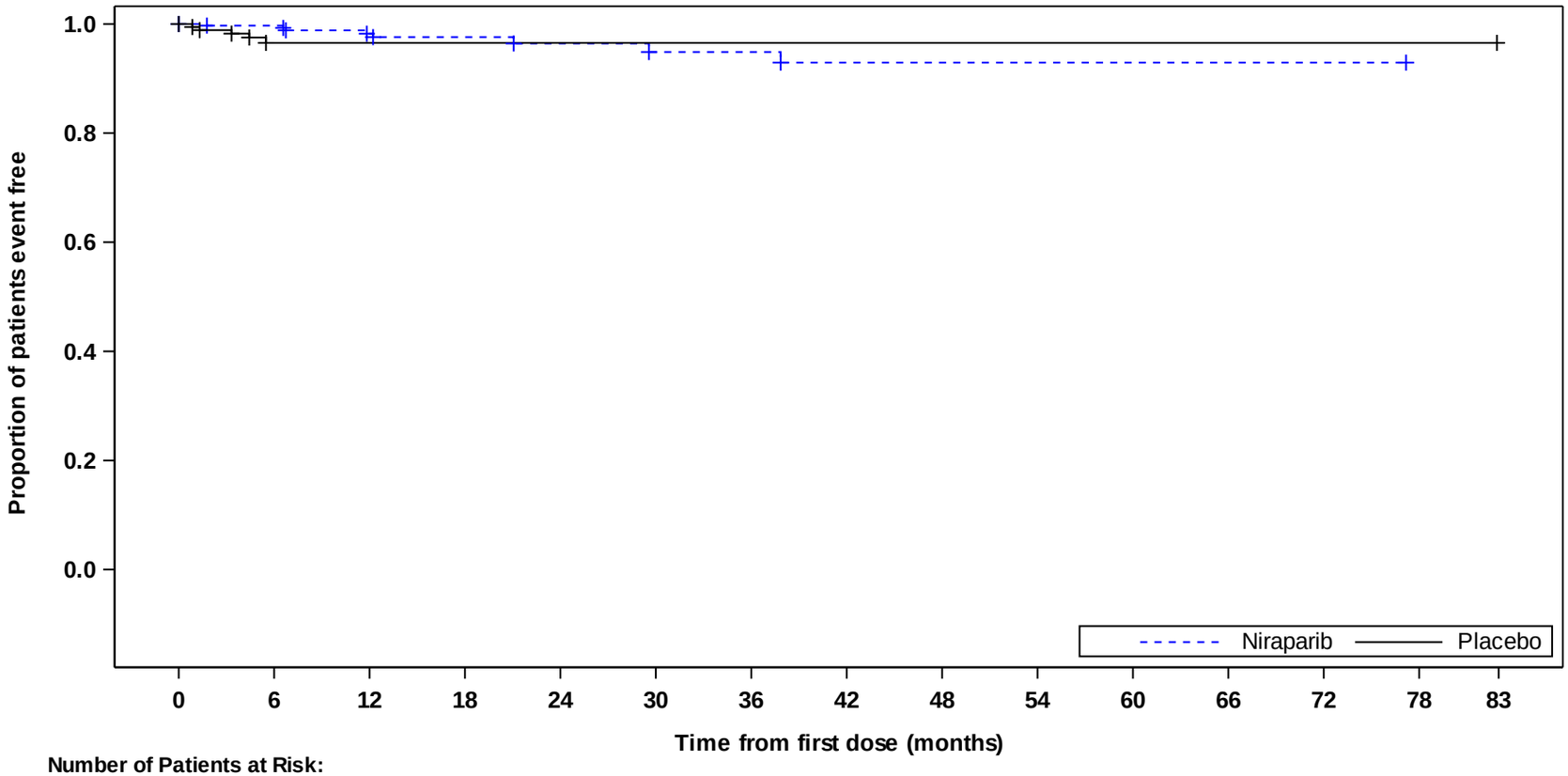
Niraparib	367	242	158	98	70	60	51	42	39	34	29	22	7	0
Placebo	179	90	36	15	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:18 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Small intestinal obstruction



Number of Patients at Risk:

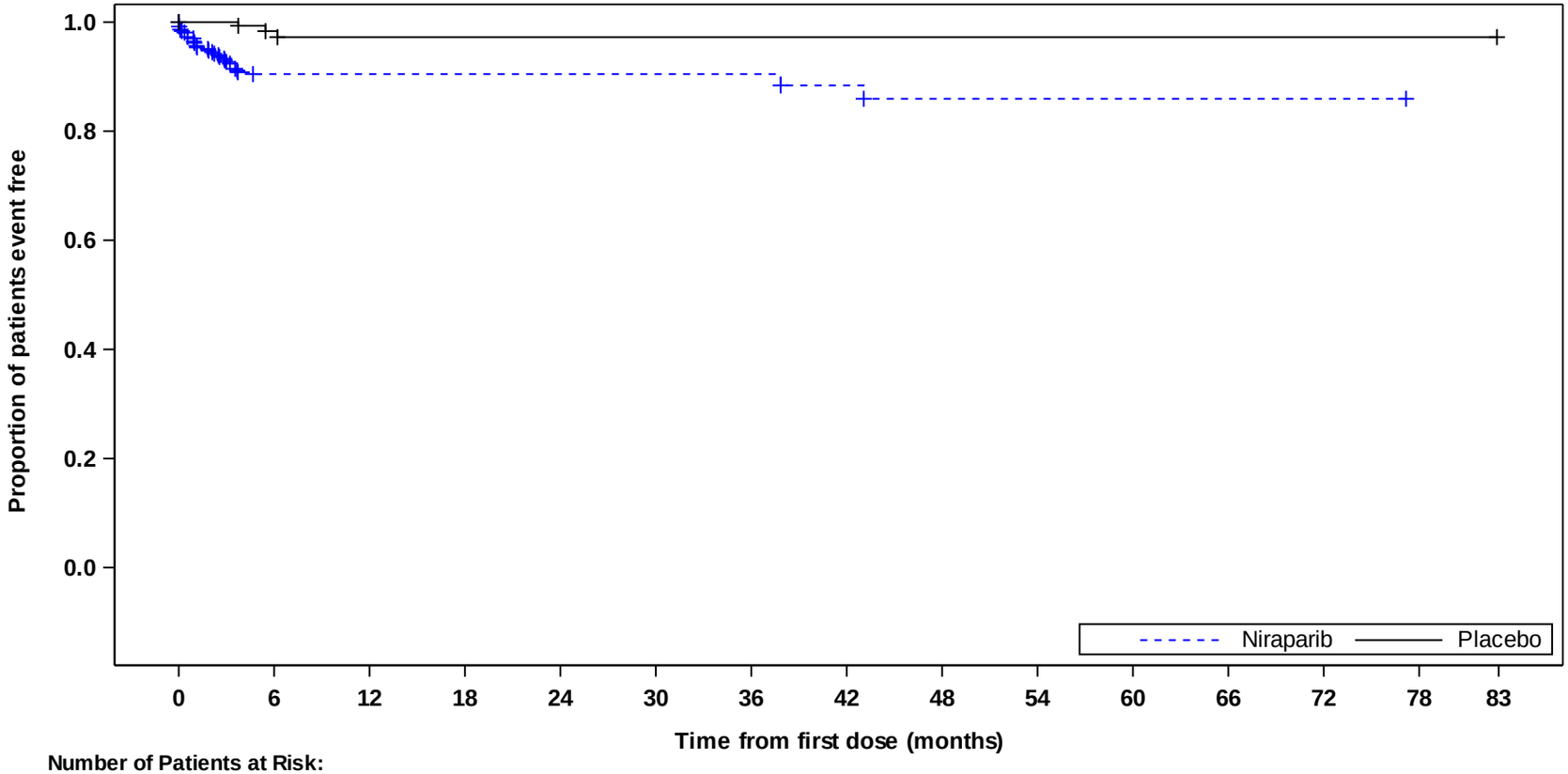
Niraparib	367	247	160	100	71	60	52	41	38	34	29	22	7	0
Placebo	179	89	36	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:18 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions



Number of Patients at Risk:

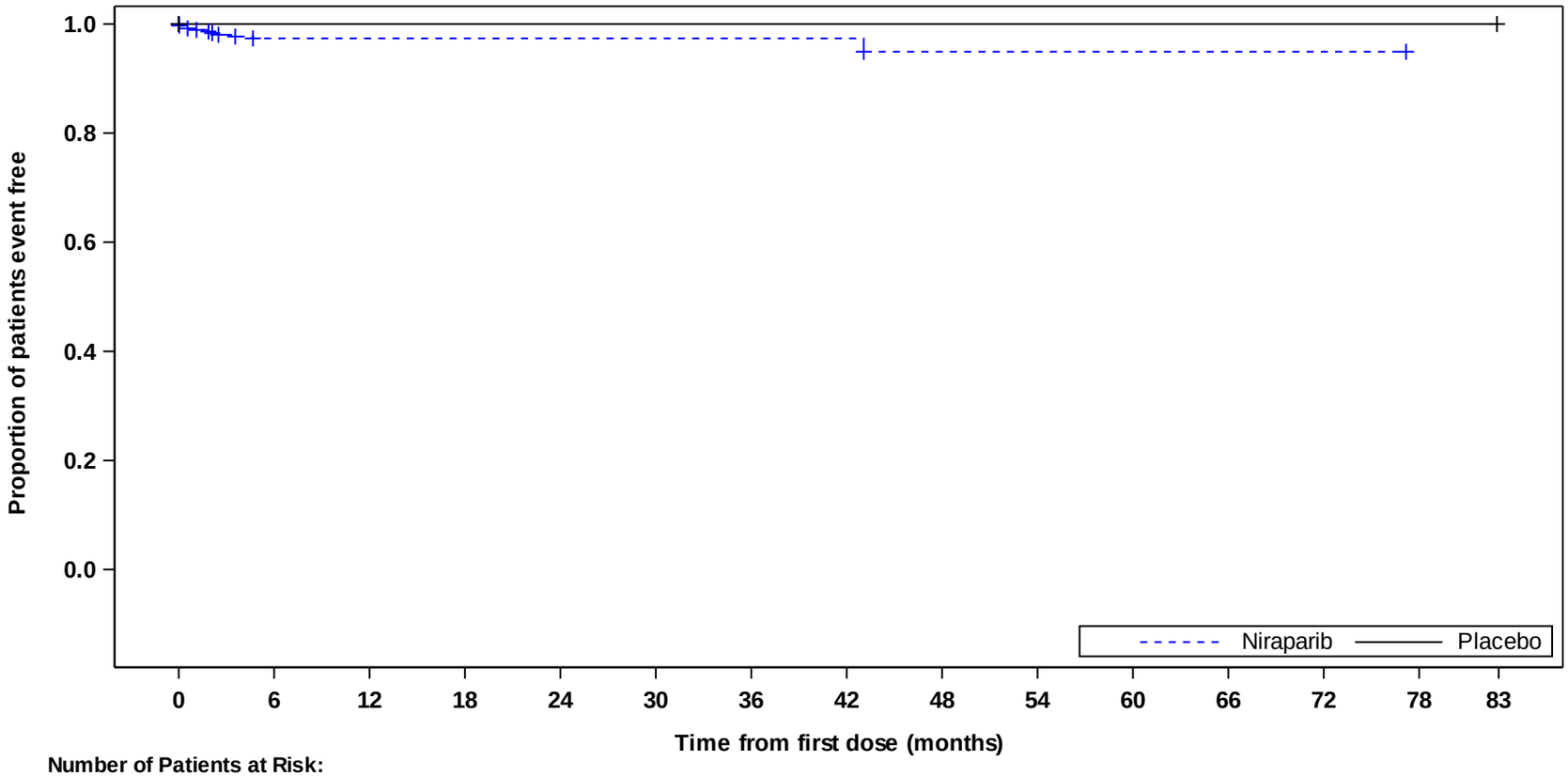
Niraparib	367	230	150	92	65	55	47	37	35	31	26	19	6	0
Placebo	179	90	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:19 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions, PT: Asthenia



Number of Patients at Risk:

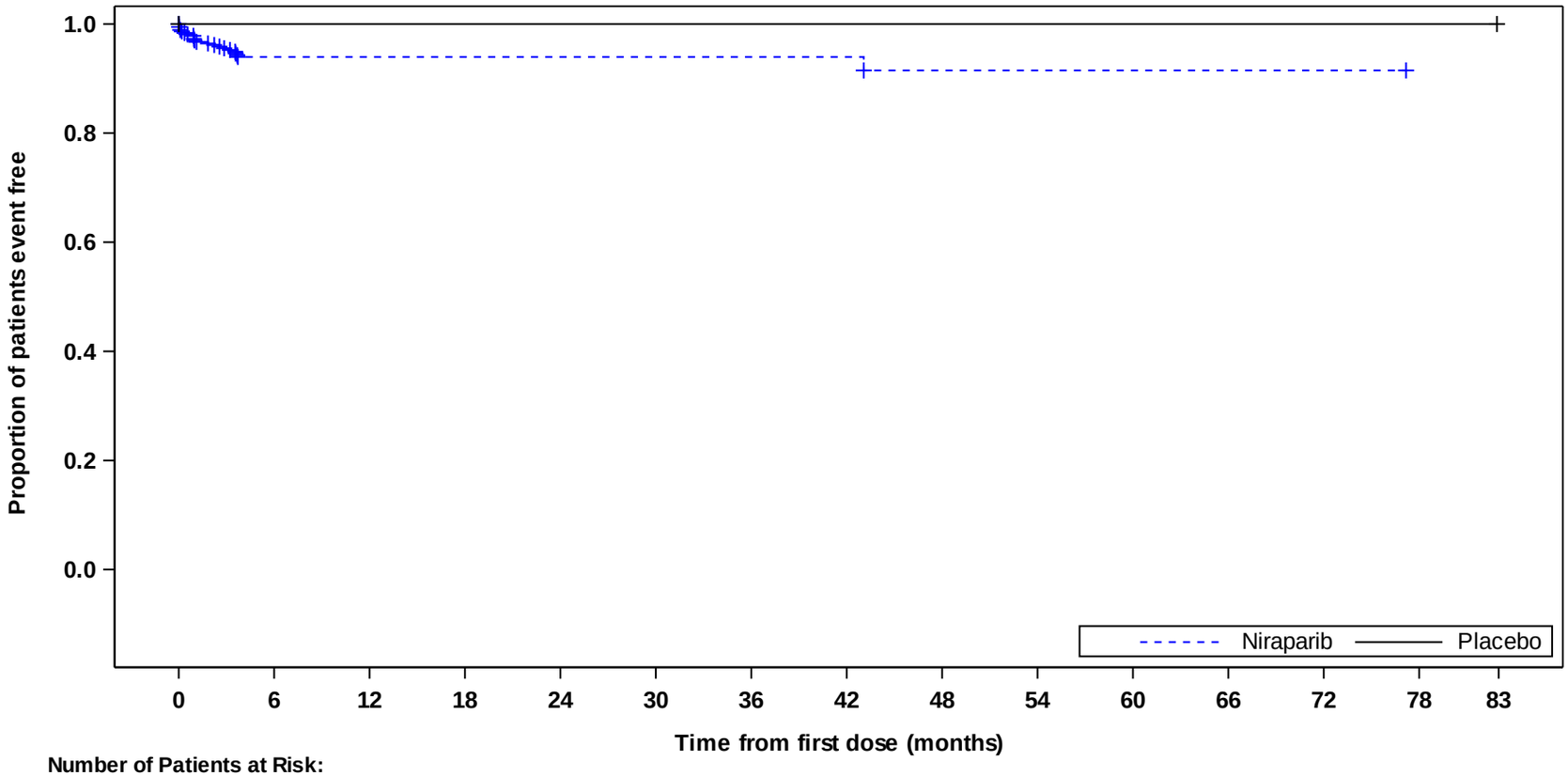
Niraparib	367	243	160	99	69	59	51	41	38	33	28	21	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:20 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: General disorders and administration site conditions, PT: Fatigue



Number of Patients at Risk:

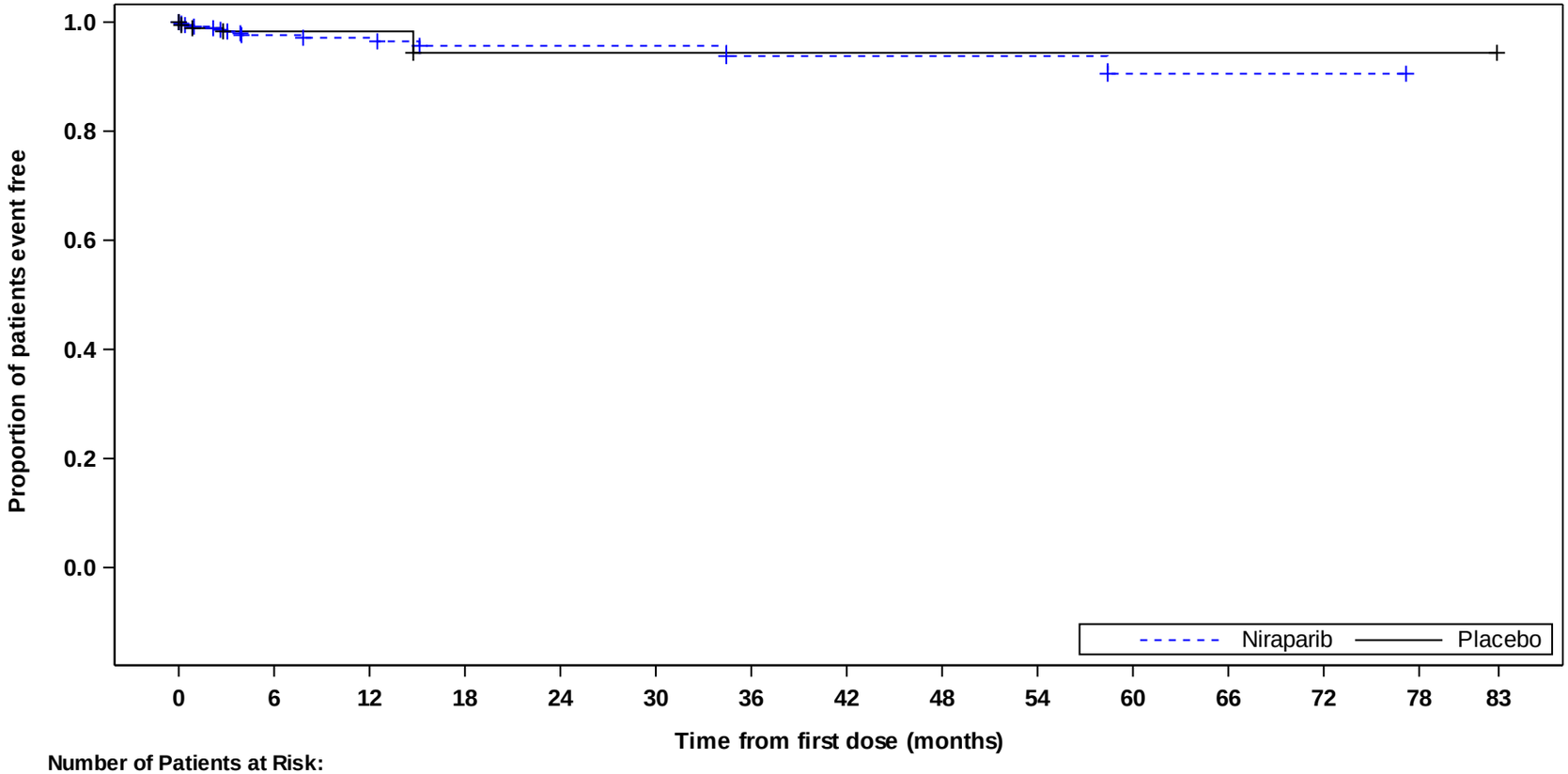
Niraparib	367	236	153	94	67	57	48	39	37	32	27	20	6	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:21 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations



Number of Patients at Risk:

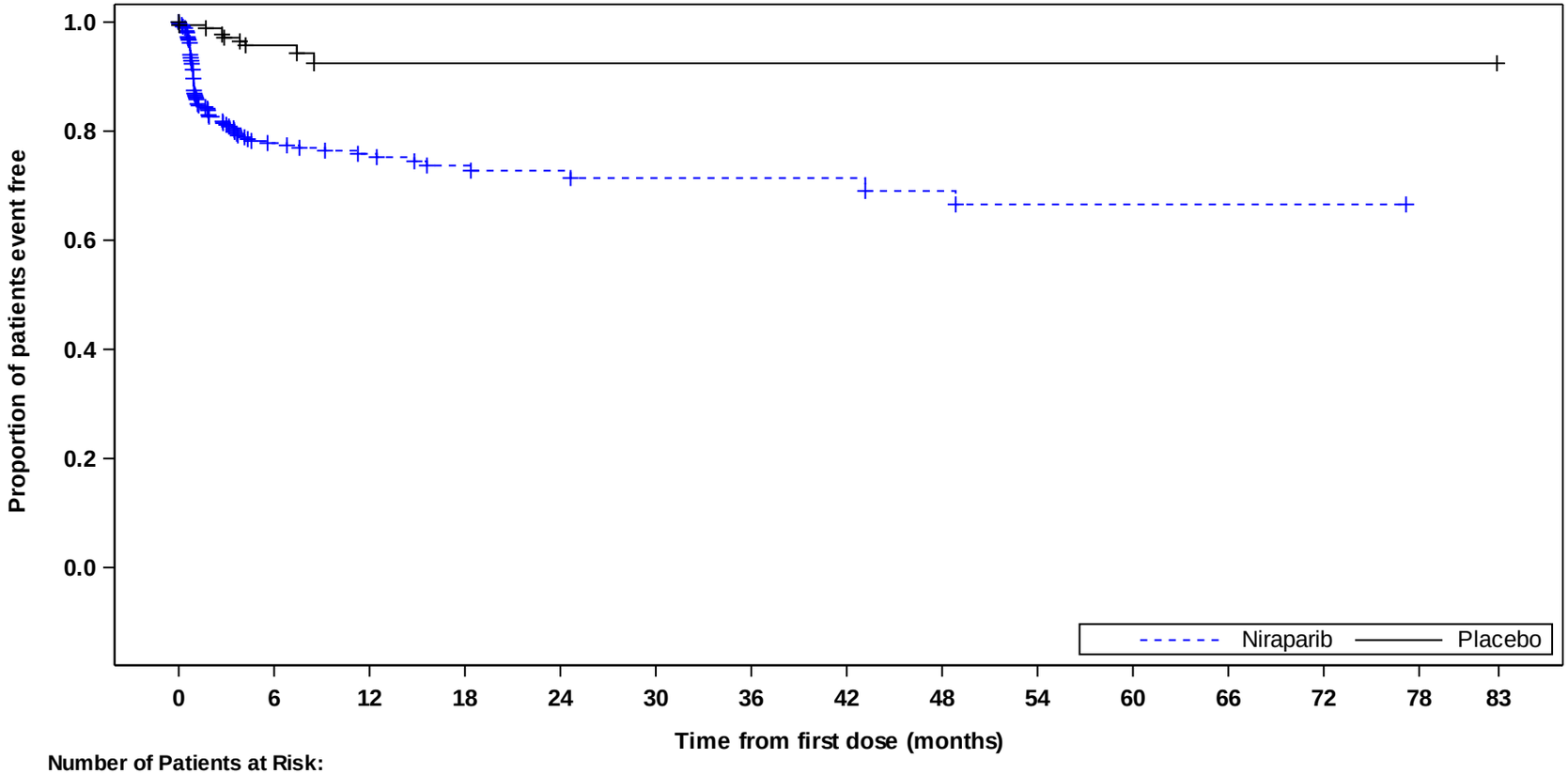
Niraparib	367	241	158	97	68	59	50	40	37	32	27	20	7	0
Placebo	179	91	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:21 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations



Number of Patients at Risk:

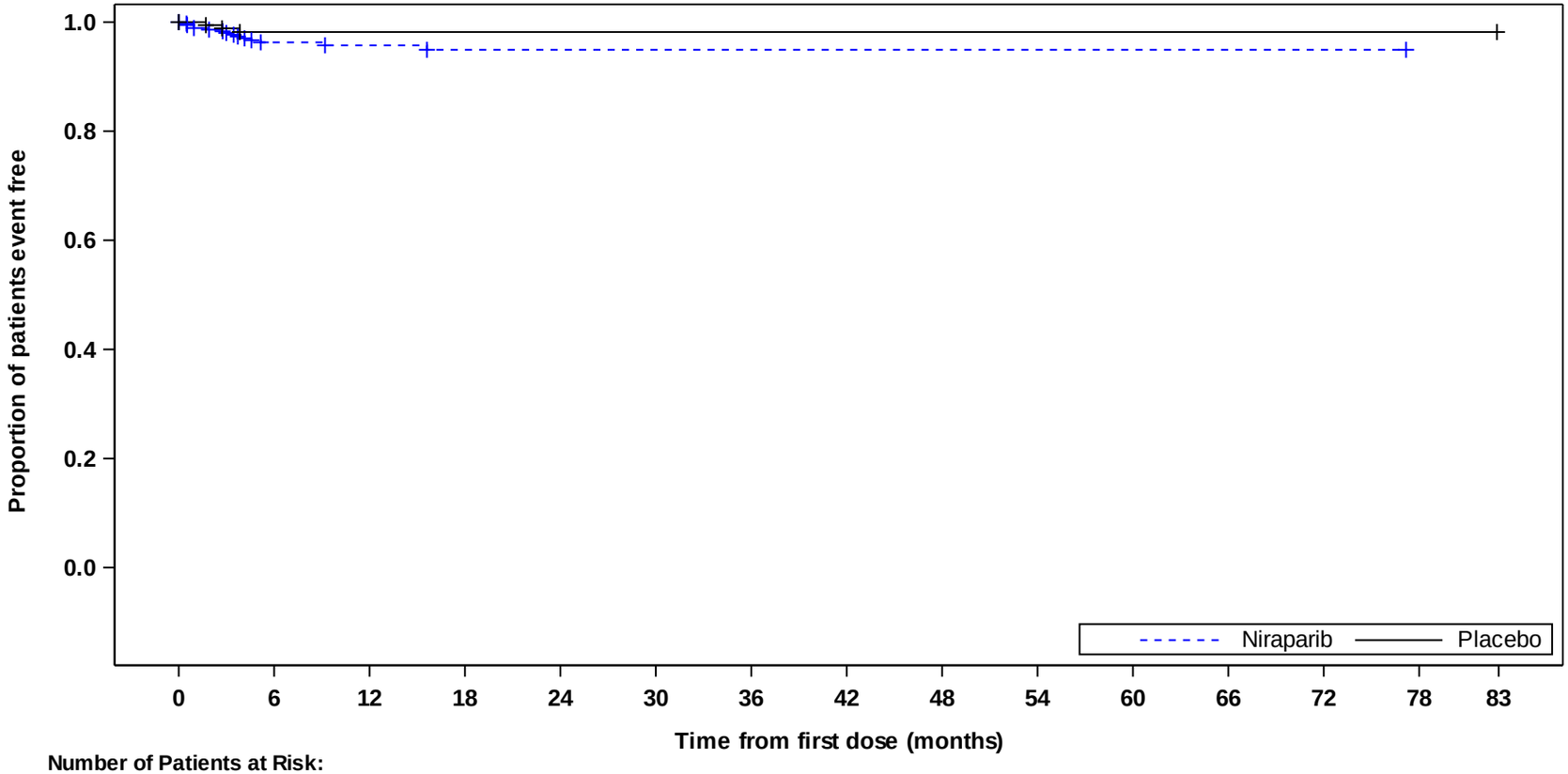
Niraparib	367	200	130	78	54	46	39	31	28	25	21	16	5	0
Placebo	179	88	34	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:22 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Gamma-glutamyltransferase increased



Number of Patients at Risk:

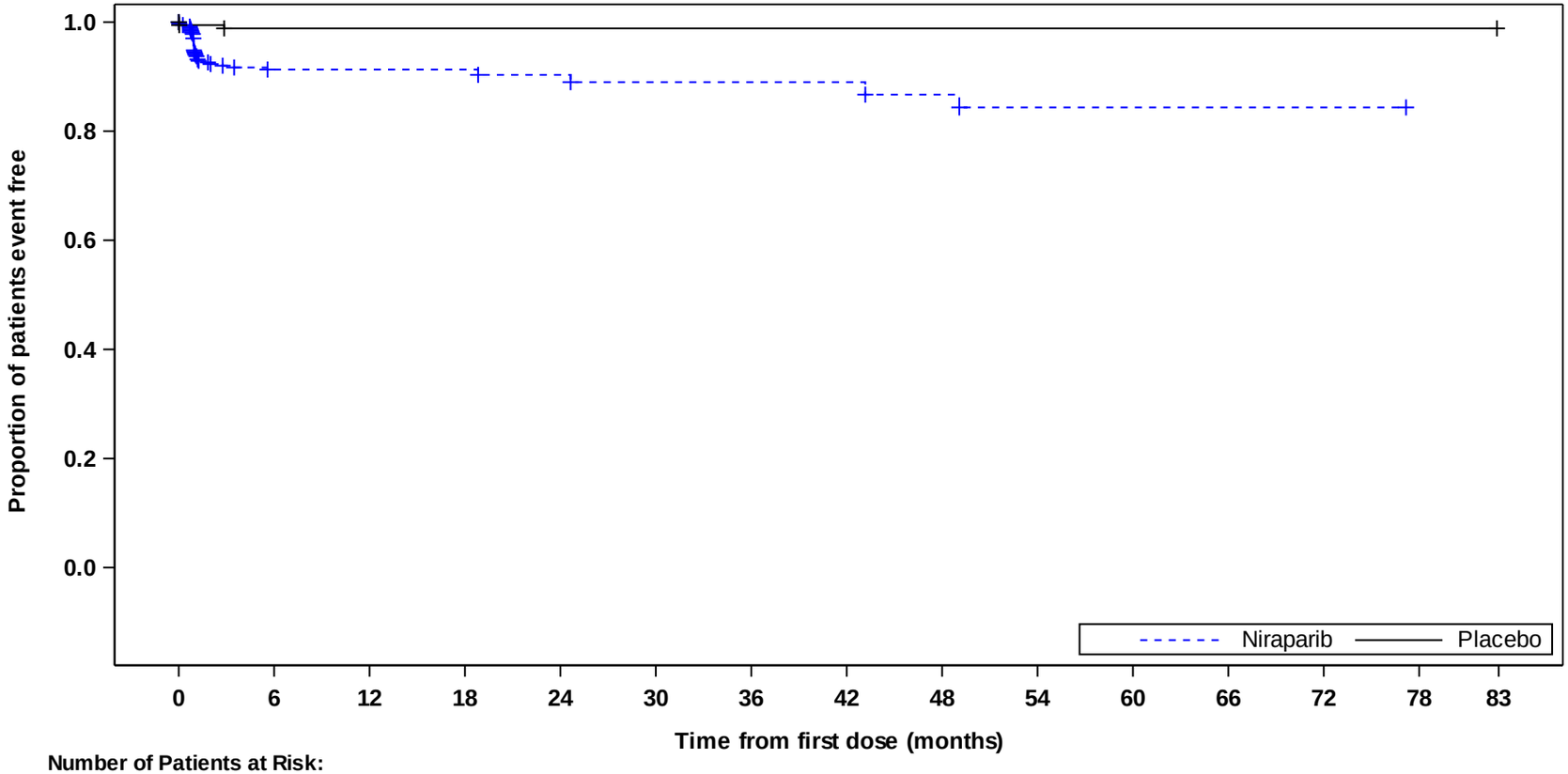
Niraparib	367	239	158	97	67	57	48	39	36	32	27	20	6	0
Placebo	179	90	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:23 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Neutrophil count decreased



Number of Patients at Risk:

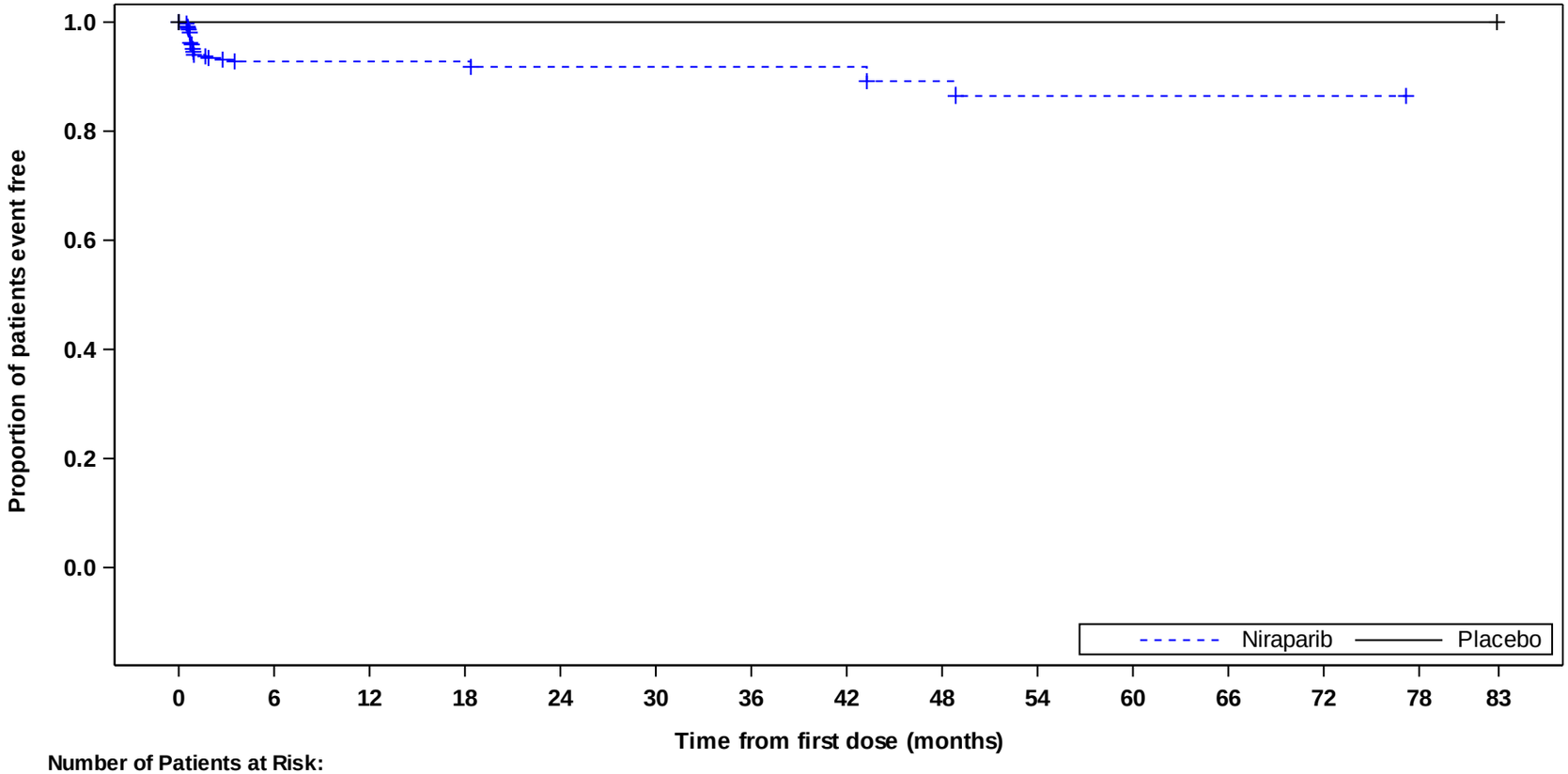
Niraparib	367	229	151	94	67	58	49	40	37	32	27	20	6	0
Placebo	179	90	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:24 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: Platelet count decreased



Number of Patients at Risk:

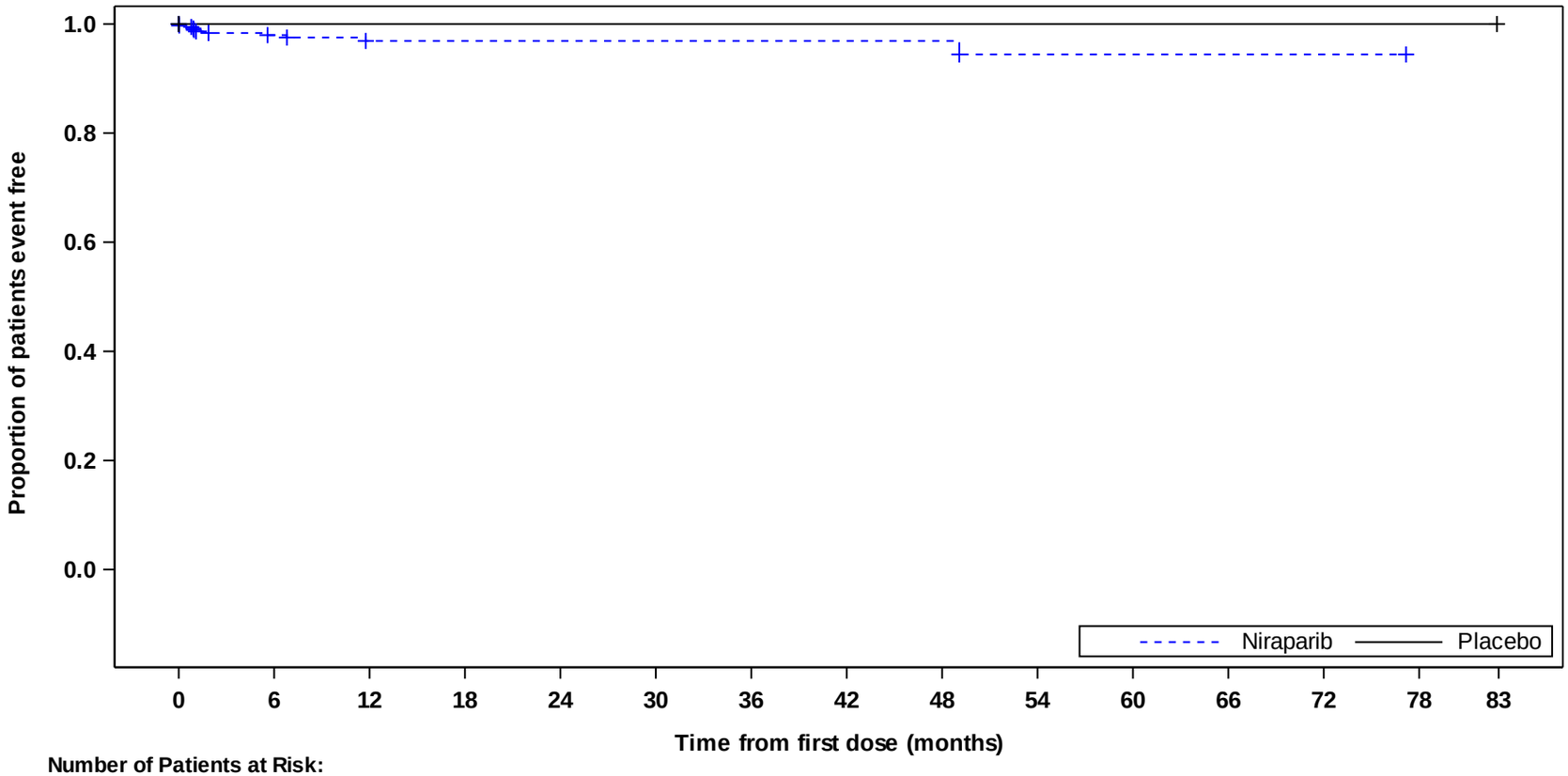
Niraparib	367	234	152	92	64	54	45	36	33	29	25	20	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:25 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Investigations, PT: White blood cell count decreased



Number of Patients at Risk:

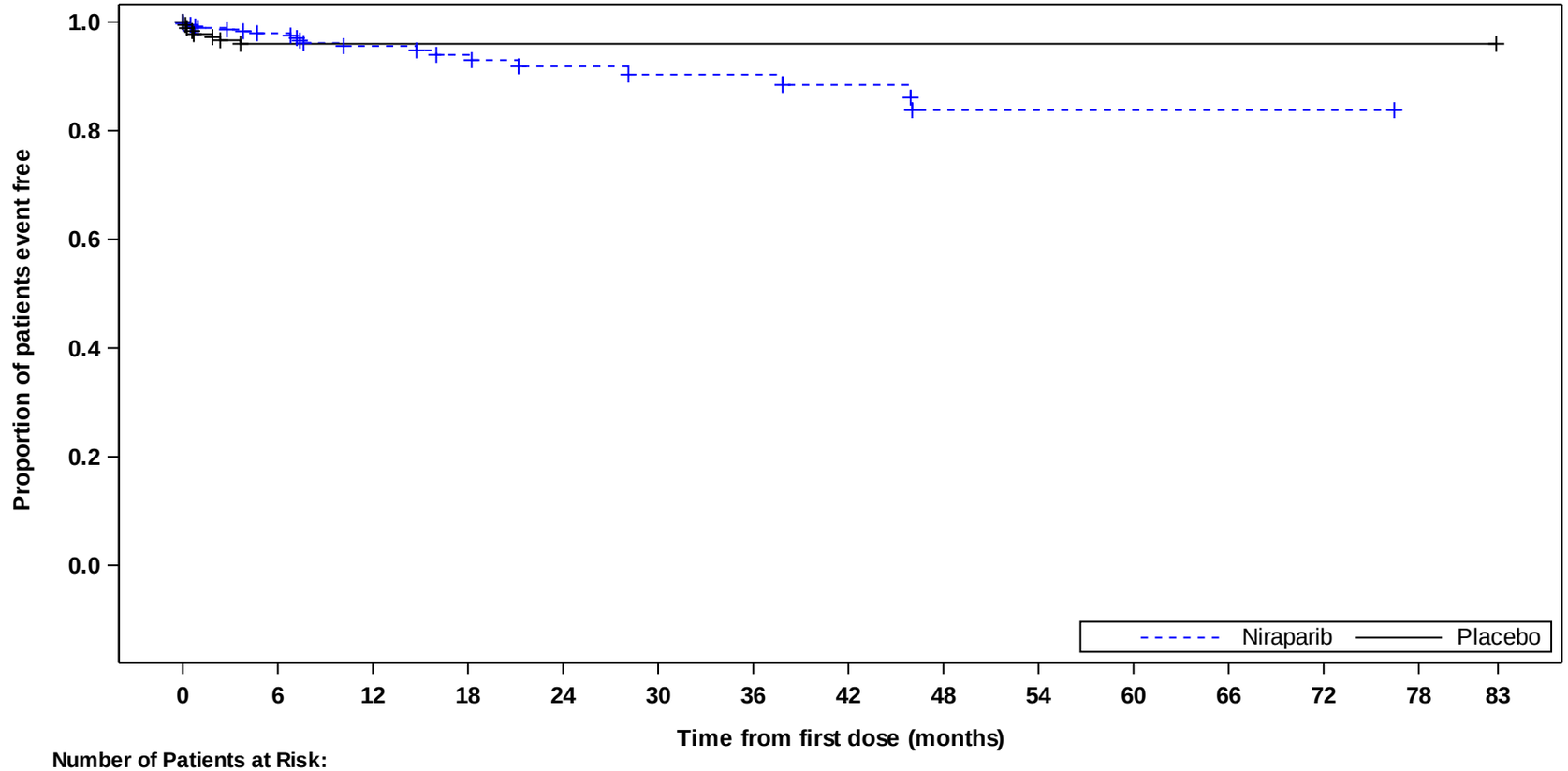
Niraparib	367	242	157	99	70	60	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:26 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Metabolism and nutrition disorders



Number of Patients at Risk:

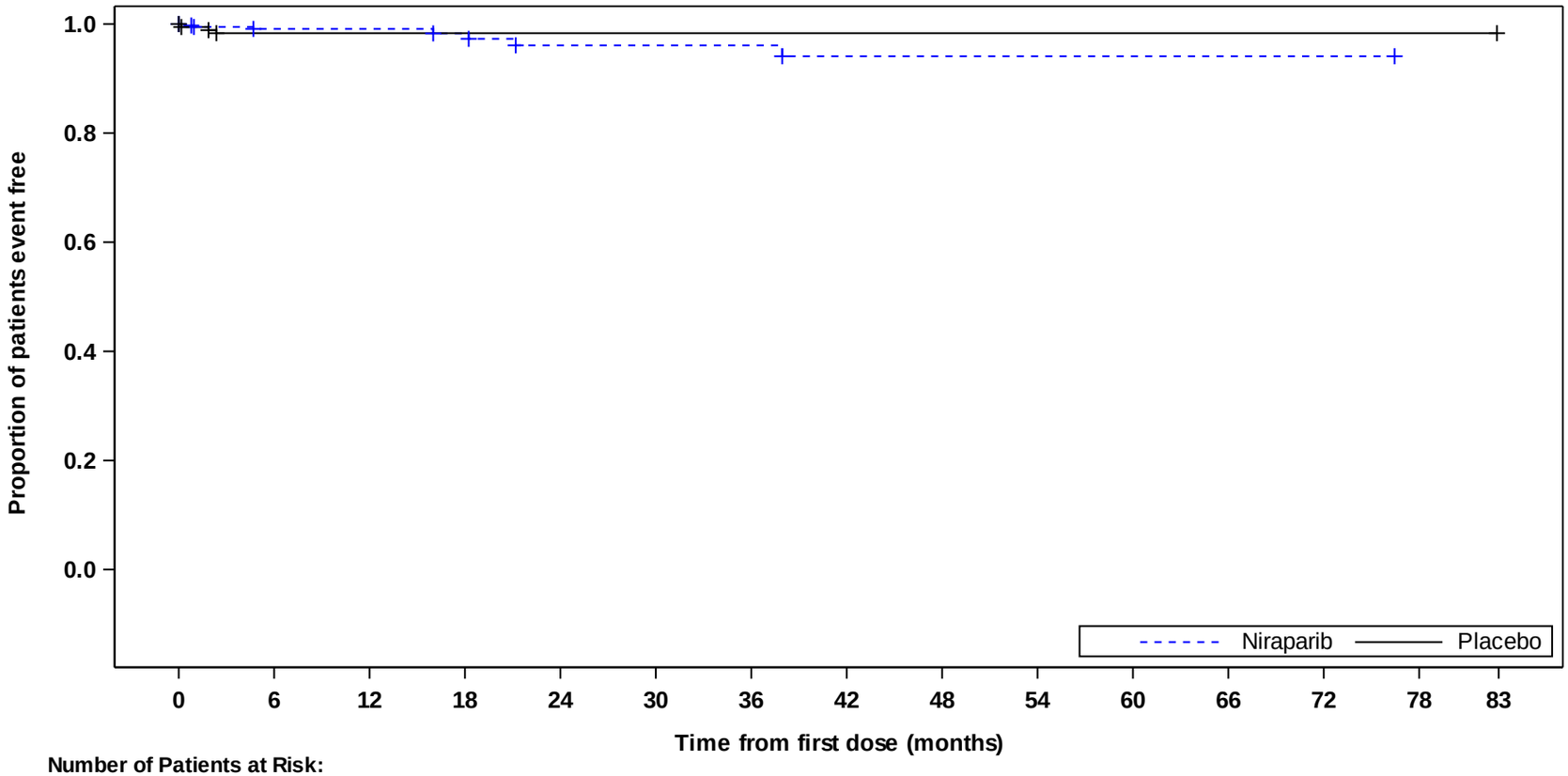
Niraparib	367	244	157	98	70	59	50	40	35	31	26	20	5	0
Placebo	179	90	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:26 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Metabolism and nutrition disorders, PT: Hypokalaemia



Number of Patients at Risk:

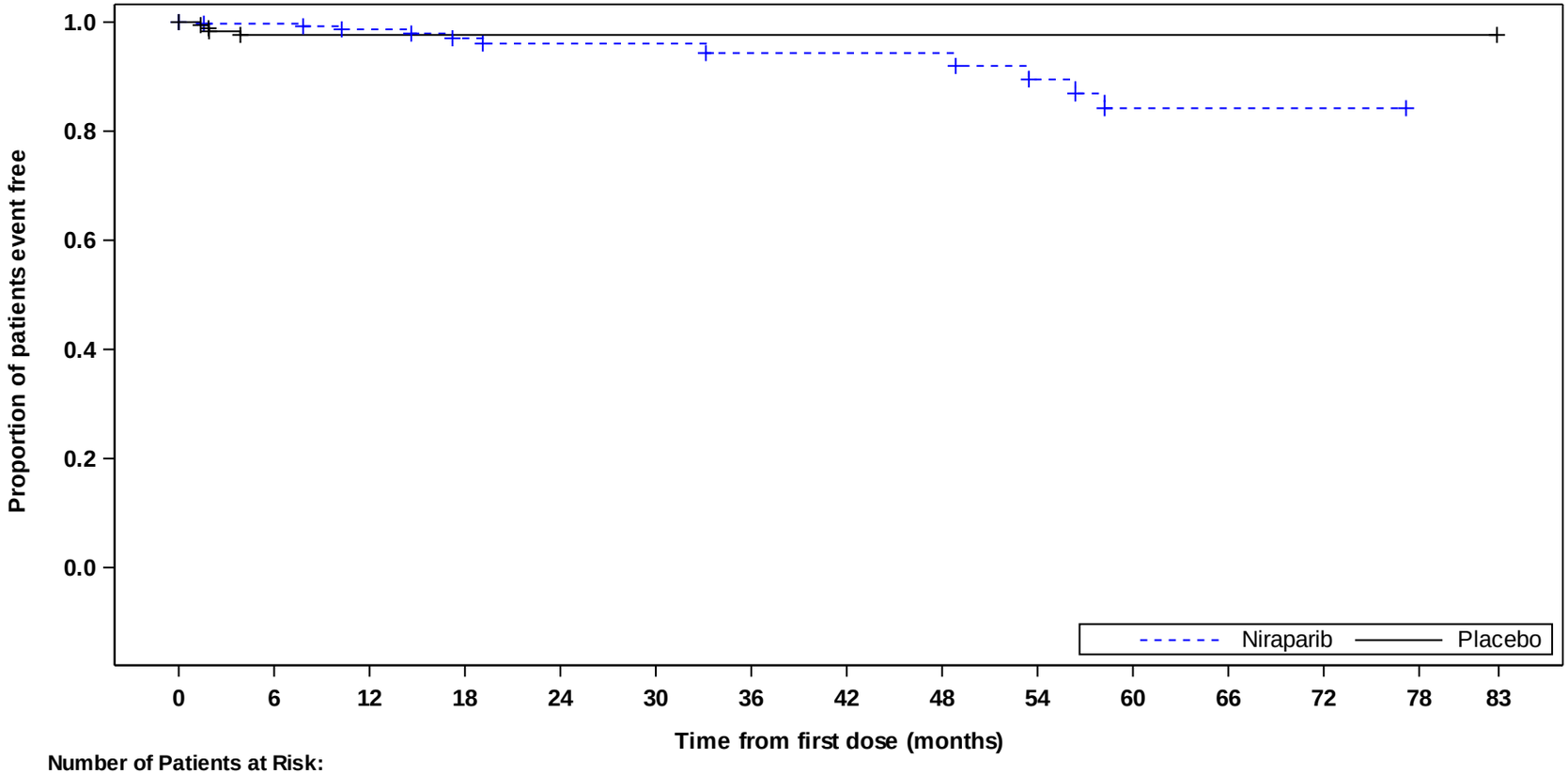
Niraparib	367	246	162	100	70	60	51	40	37	33	28	21	6	0
Placebo	179	90	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:27 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)



Number of Patients at Risk:

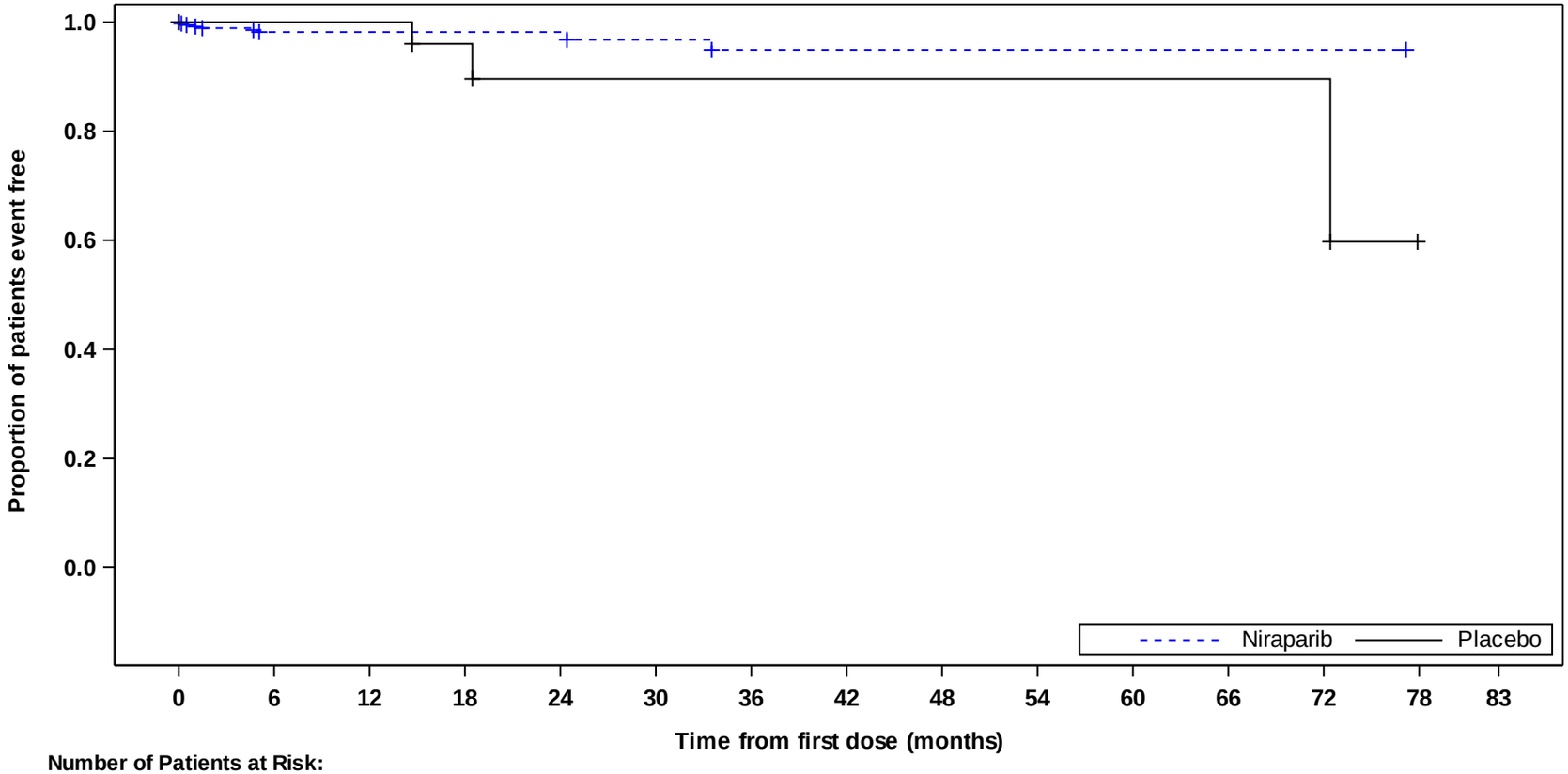
Niraparib	367	248	164	102	72	62	53	43	40	35	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:28 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Nervous system disorders



Number of Patients at Risk:

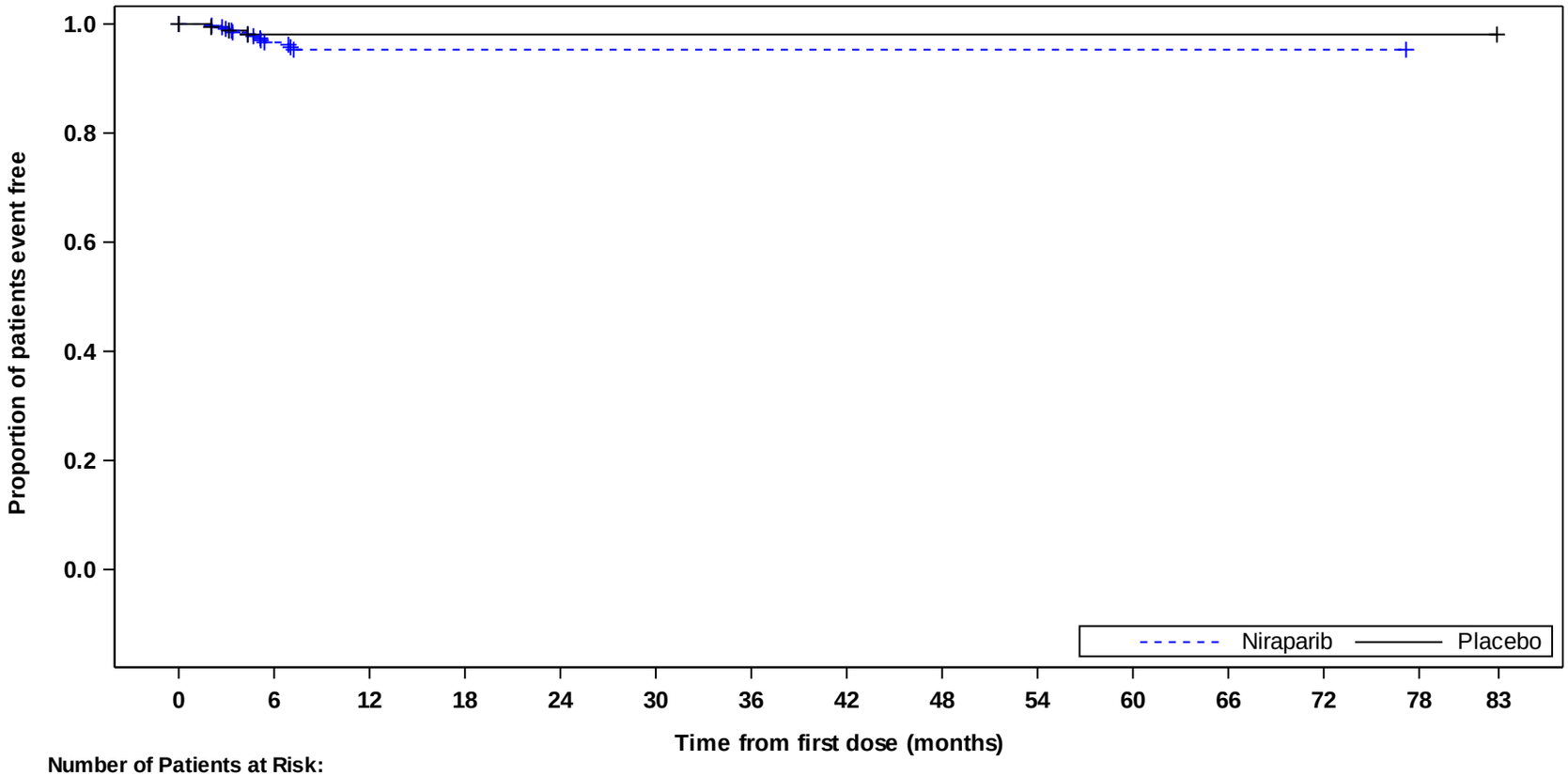
Niraparib	367	244	160	99	70	60	50	40	37	32	27	20	7	0
Placebo	179	92	37	15	9	8	8	7	6	5	5	5	3	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:29 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders



Number of Patients at Risk:

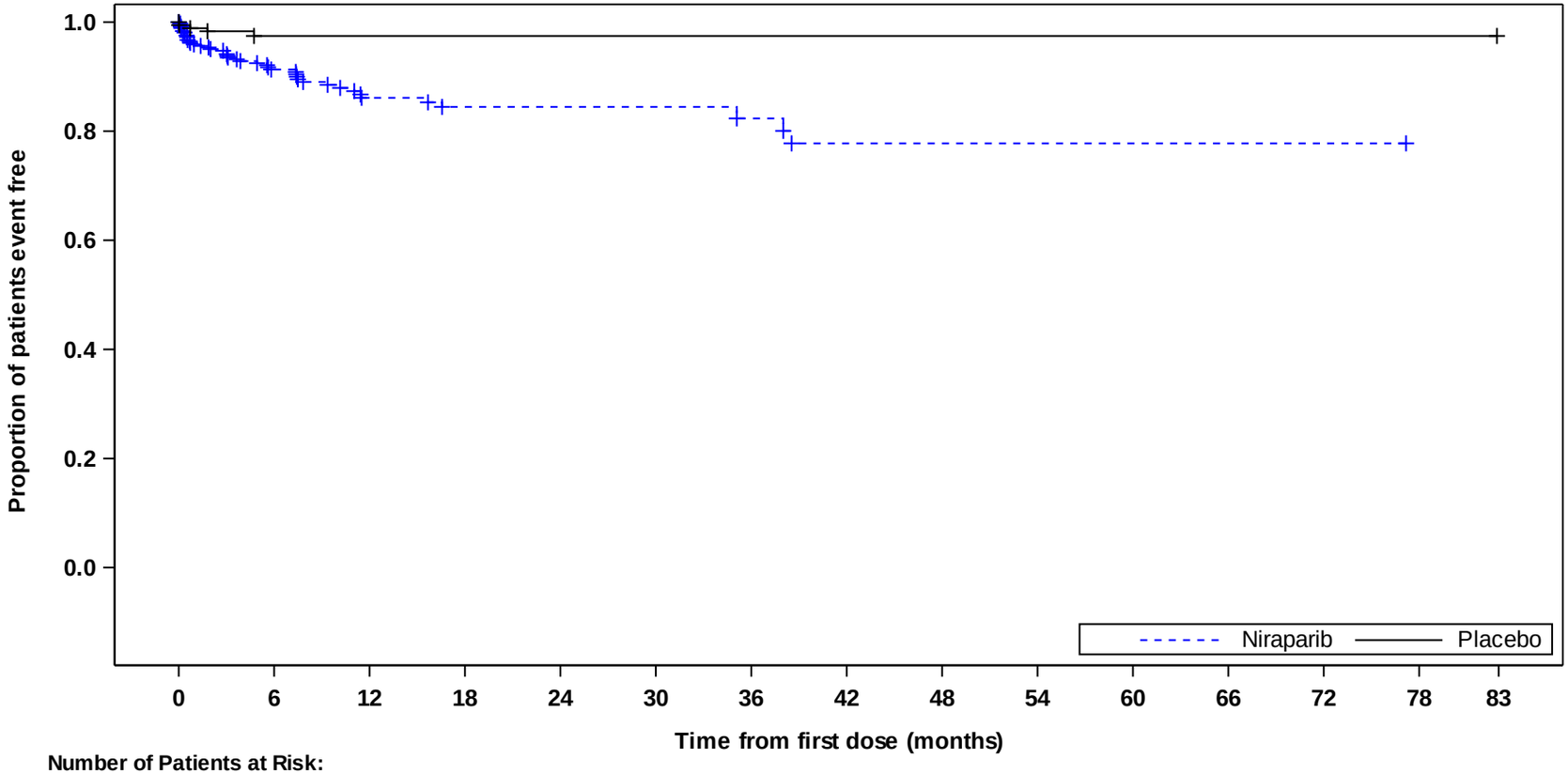
Niraparib	367	242	160	100	70	60	51	41	38	33	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:30 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Vascular disorders



Number of Patients at Risk:

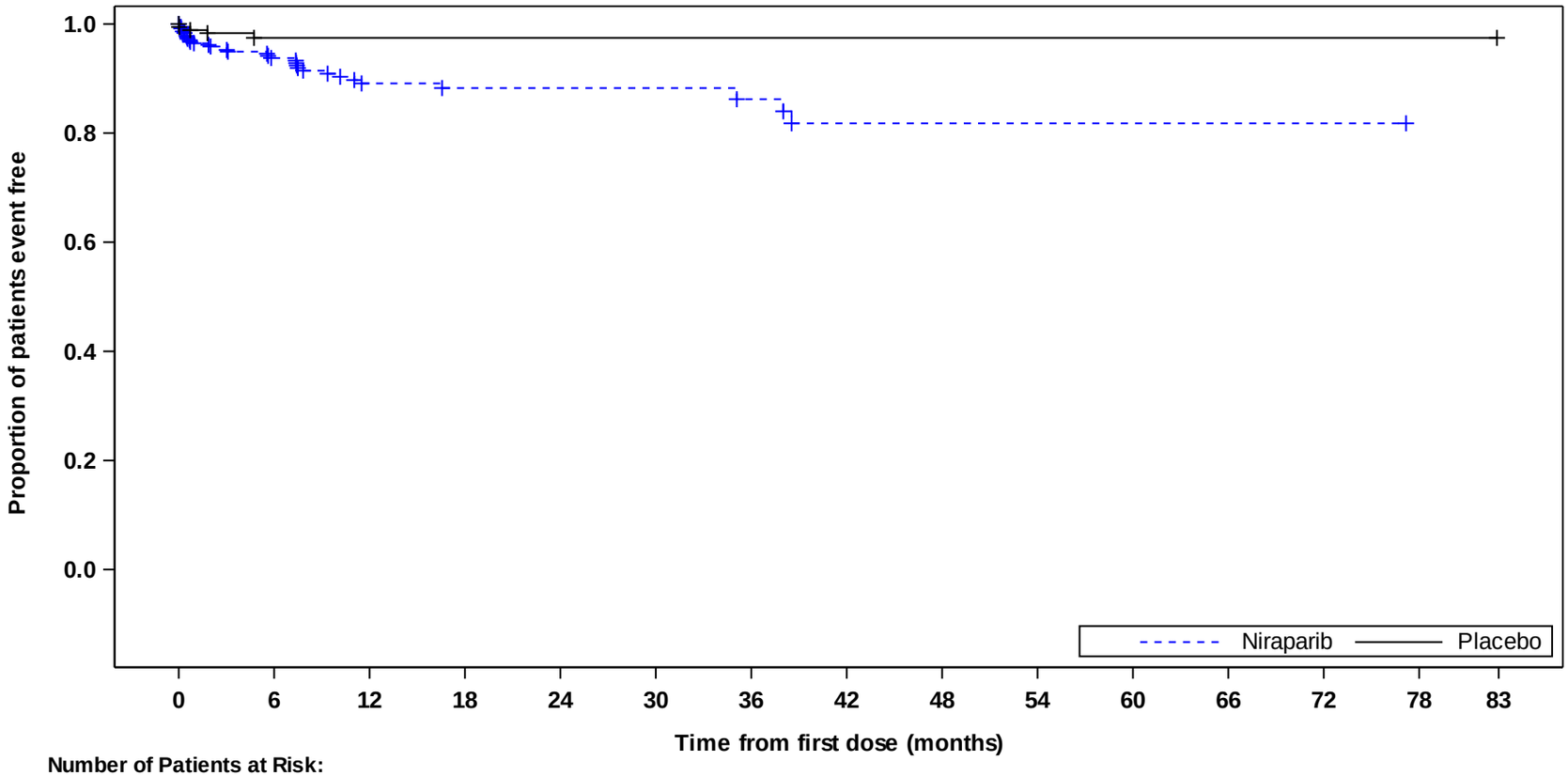
Niraparib	367	228	141	84	58	48	39	28	26	22	17	13	6	0
Placebo	179	89	35	14	9	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:30 Data Extraction Date: 01OCT2020

Figure 3.13.1

Time to Onset of First Occurence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Vascular disorders, PT: Hypertension



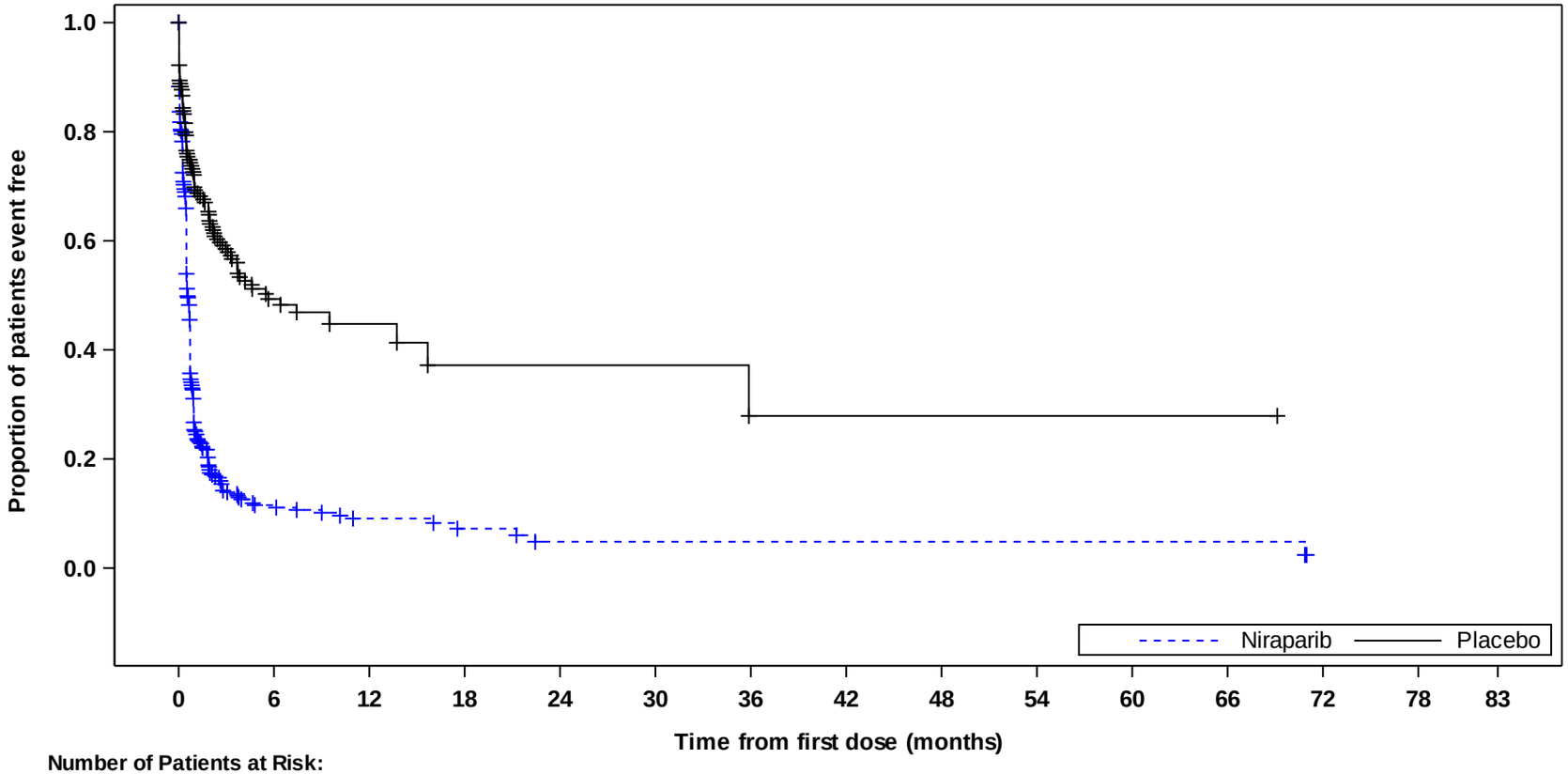
Number of Patients at Risk:

Niraparib	367	233	144	87	61	51	42	31	29	25	20	15	6	0
Placebo	179	89	35	14	9	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:31 Data Extraction Date: 01OCT2020

Figure 3.15.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events

Overall



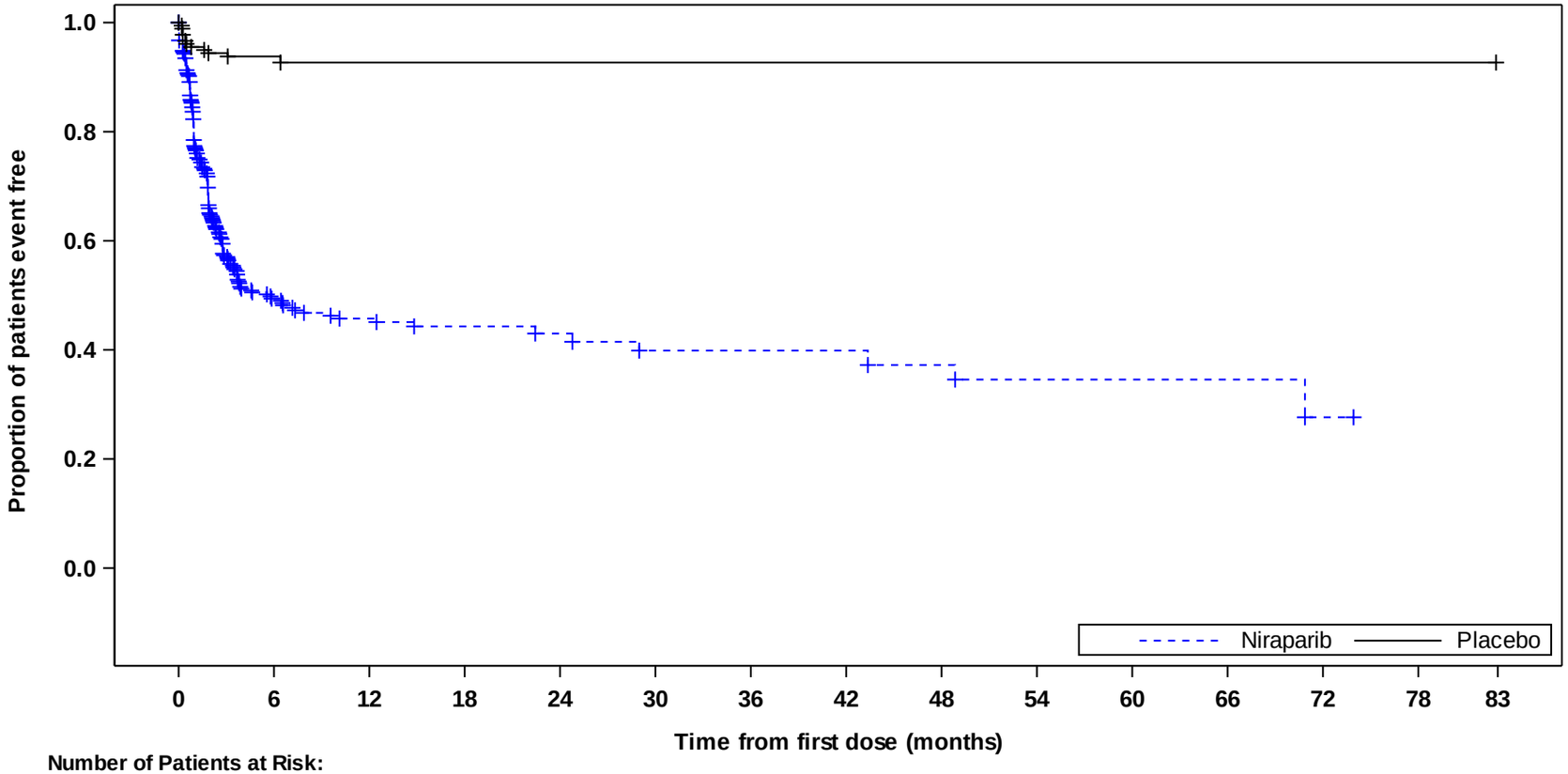
Number of Patients at Risk:

Niraparib	367	27	17	6	4	4	4	3	3	3	3	3	0
Placebo	179	49	17	6	4	4	3	2	1	1	1	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:14 Data Extraction Date: 01OCT2020

Figure 3.15.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events

Anemia



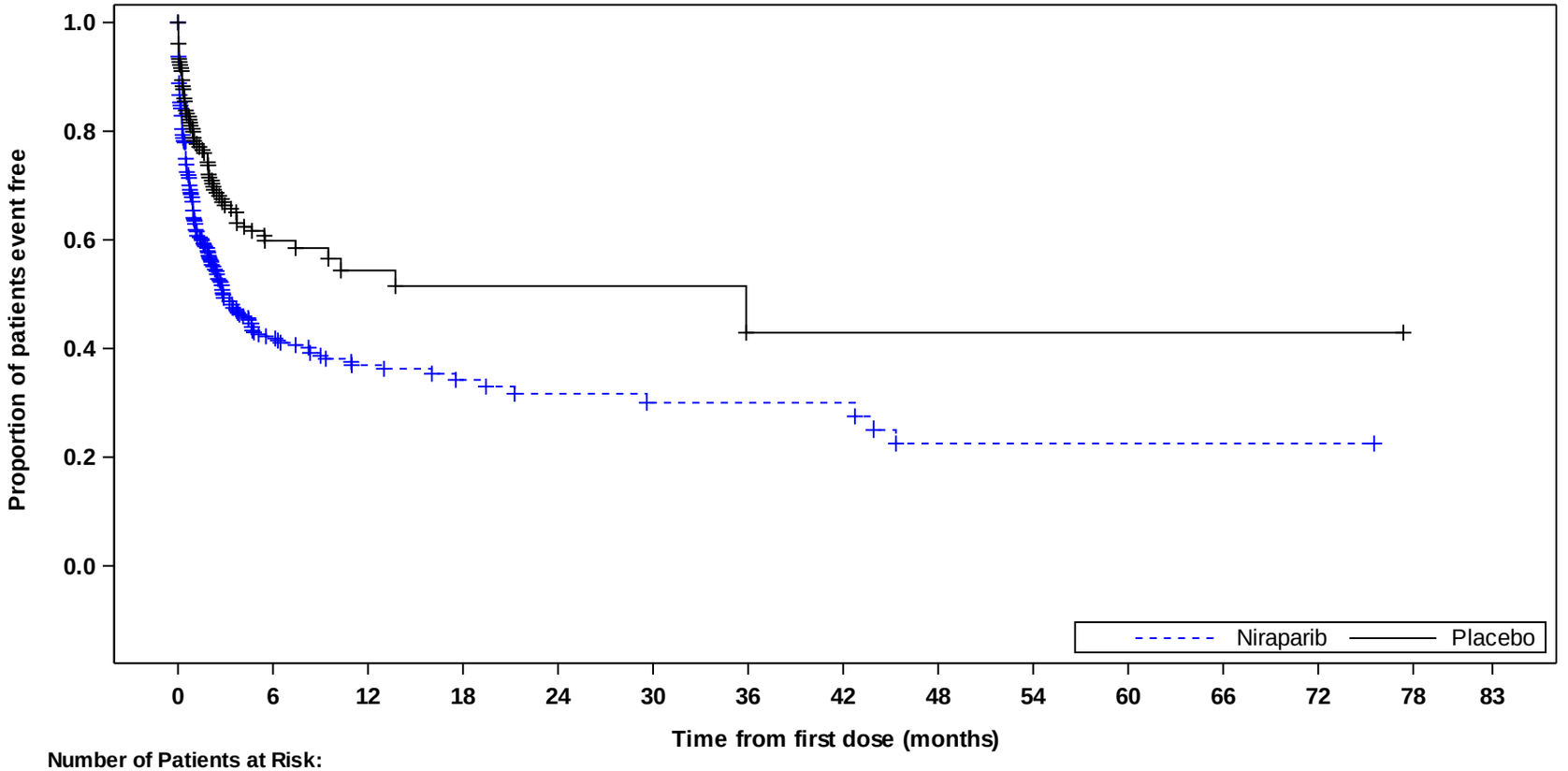
Number of Patients at Risk:

Niraparib	367	123	78	42	28	25	22	16	14	11	10	10	1	0
Placebo	179	87	33	13	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:18 Data Extraction Date: 01OCT2020

Figure 3.15.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events

Fatigue



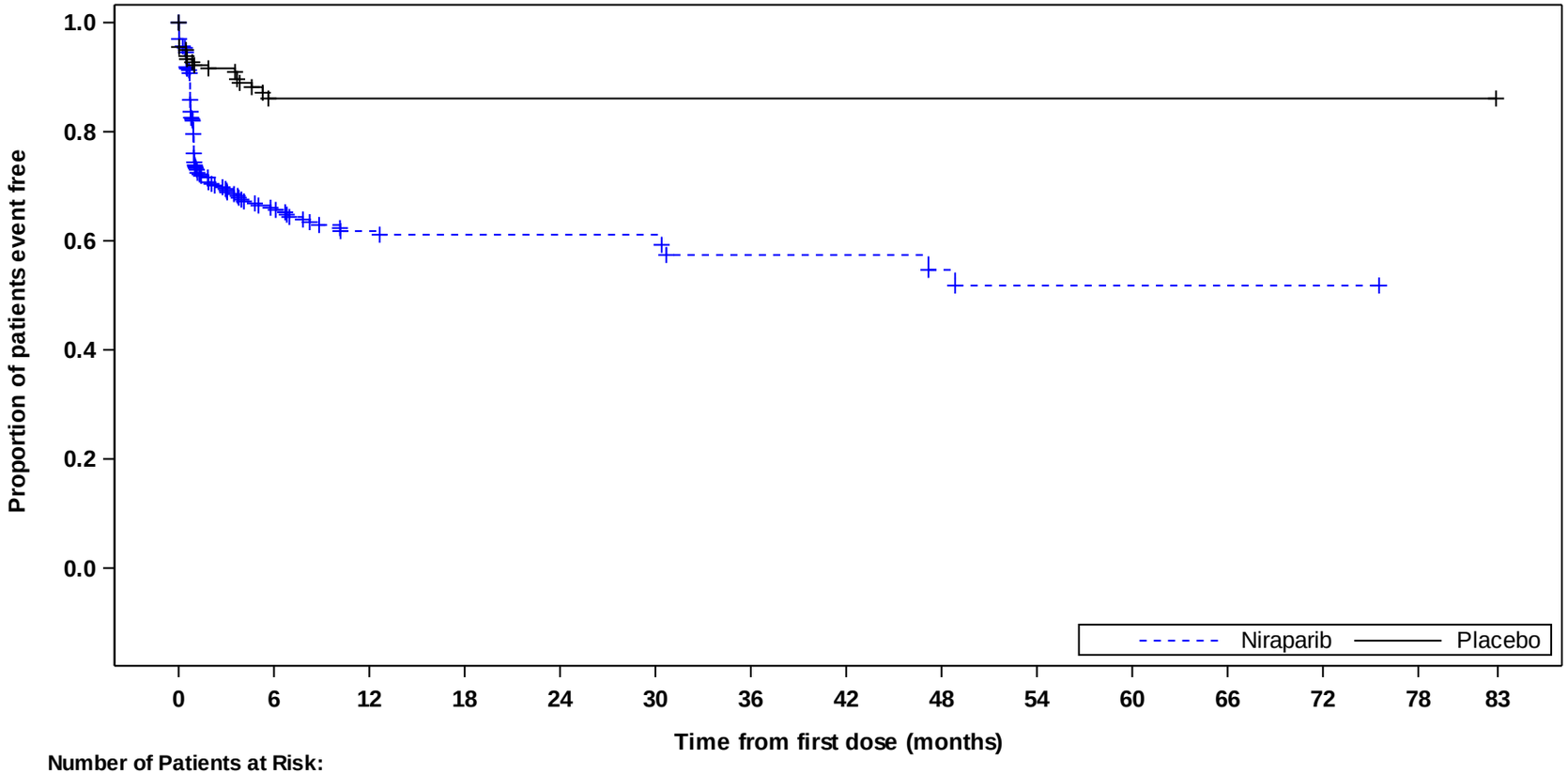
Number of Patients at Risk:

Niraparib	367	110	62	29	21	18	16	12	9	9	8	7	1	0
Placebo	179	59	23	9	6	6	5	4	3	3	3	3	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:19 Data Extraction Date: 01OCT2020

Figure 3.15.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events

Leukopenia



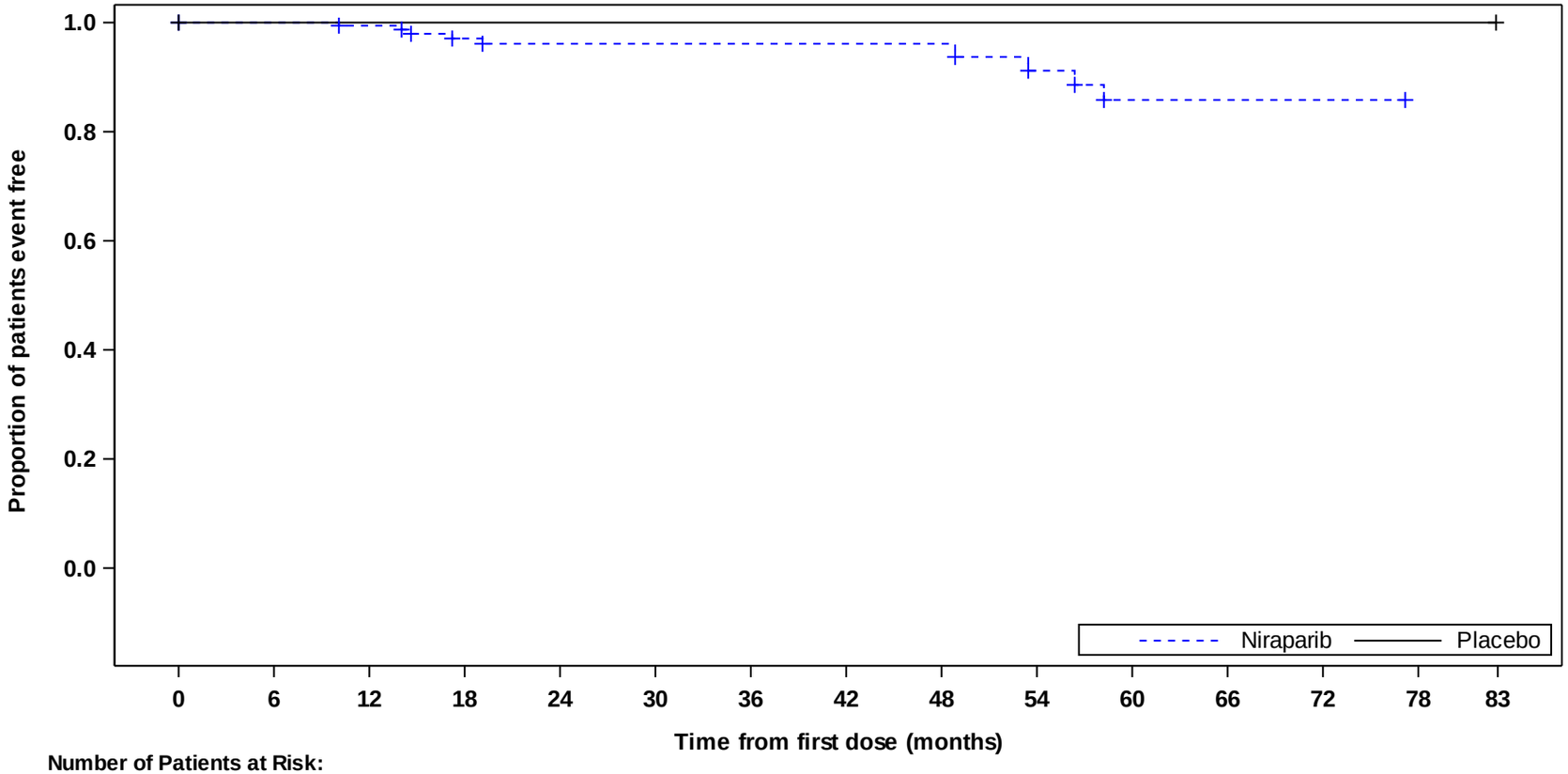
Number of Patients at Risk:

Niraparib	367	163	100	59	38	33	28	22	19	16	14	11	3	0
Placebo	179	76	29	14	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:20 Data Extraction Date: 01OCT2020

Figure 3.15.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events

MDS/AML



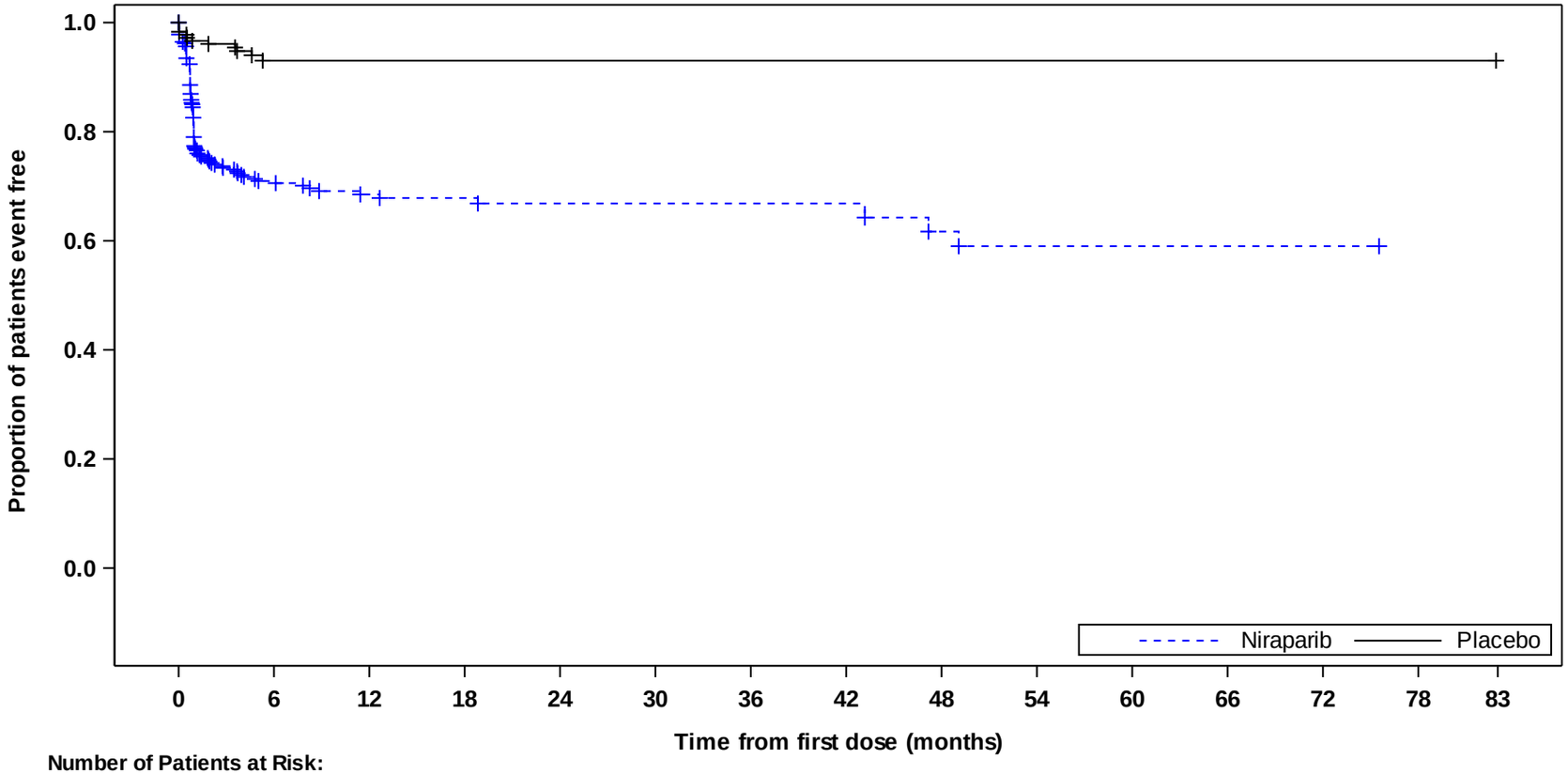
Number of Patients at Risk:

Niraparib	367	248	164	102	72	62	53	43	40	35	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:21 Data Extraction Date: 01OCT2020

Figure 3.15.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events

Neutropenia



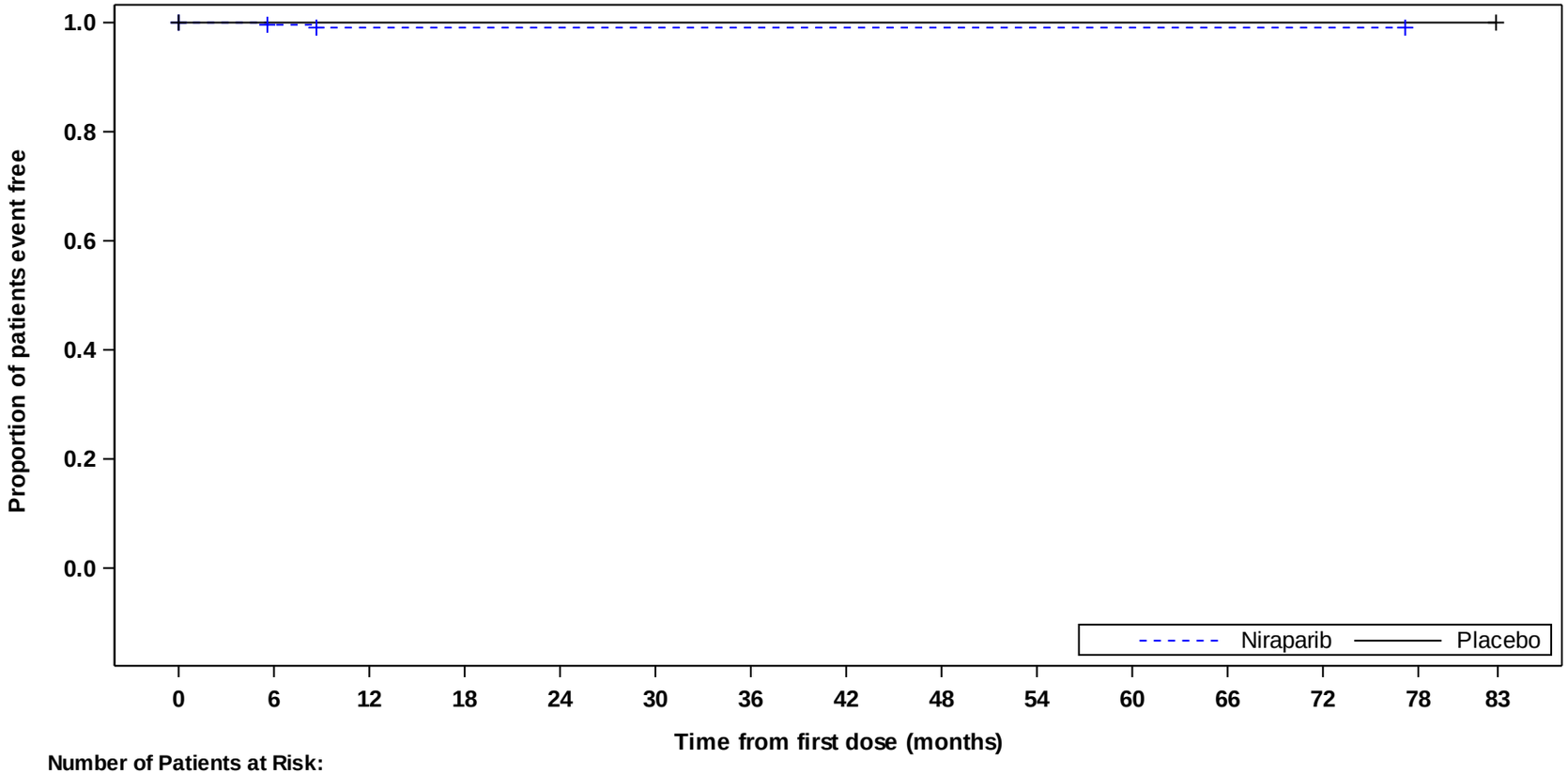
Number of Patients at Risk:

Niraparib	367	177	112	67	45	39	34	27	23	20	18	15	4	0
Placebo	179	84	33	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:22 Data Extraction Date: 01OCT2020

Figure 3.15.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events

Overdose



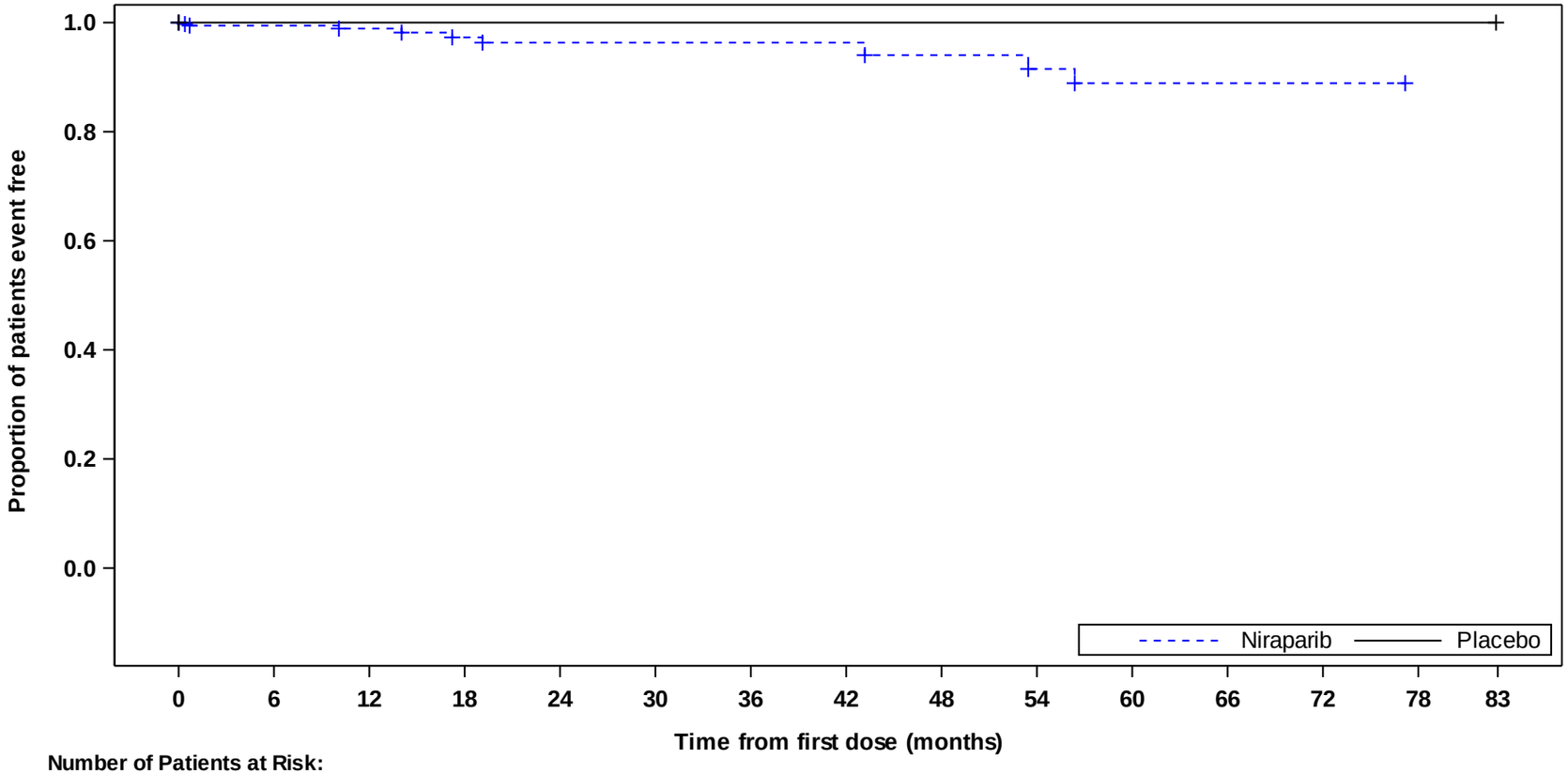
Number of Patients at Risk:

Niraparib	367	246	161	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:22 Data Extraction Date: 01OCT2020

Figure 3.15.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events

Pancytopenia



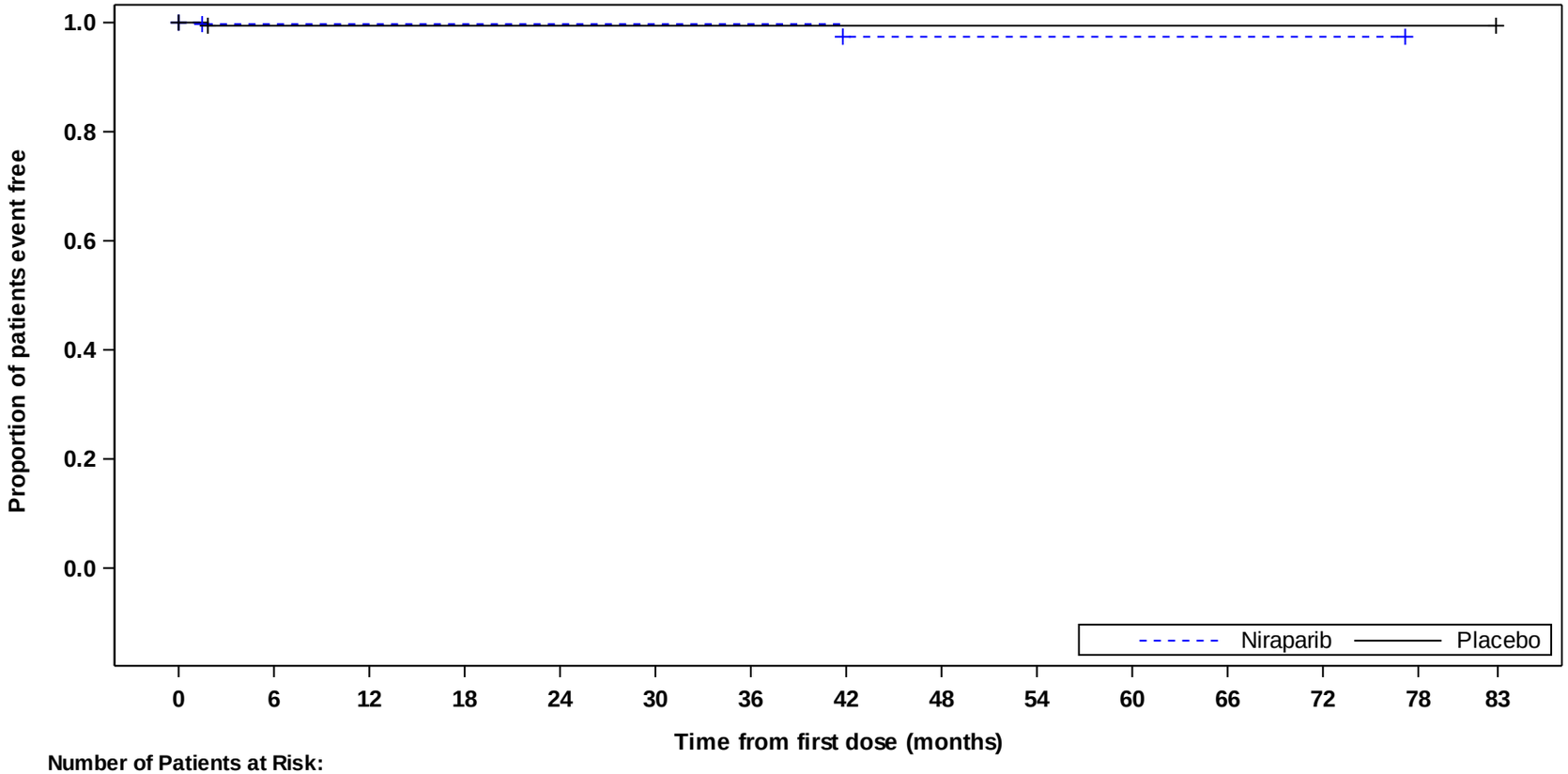
Number of Patients at Risk:

Niraparib	367	248	164	102	72	62	53	43	40	35	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:23 Data Extraction Date: 01OCT2020

Figure 3.15.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events

Pneumonitis



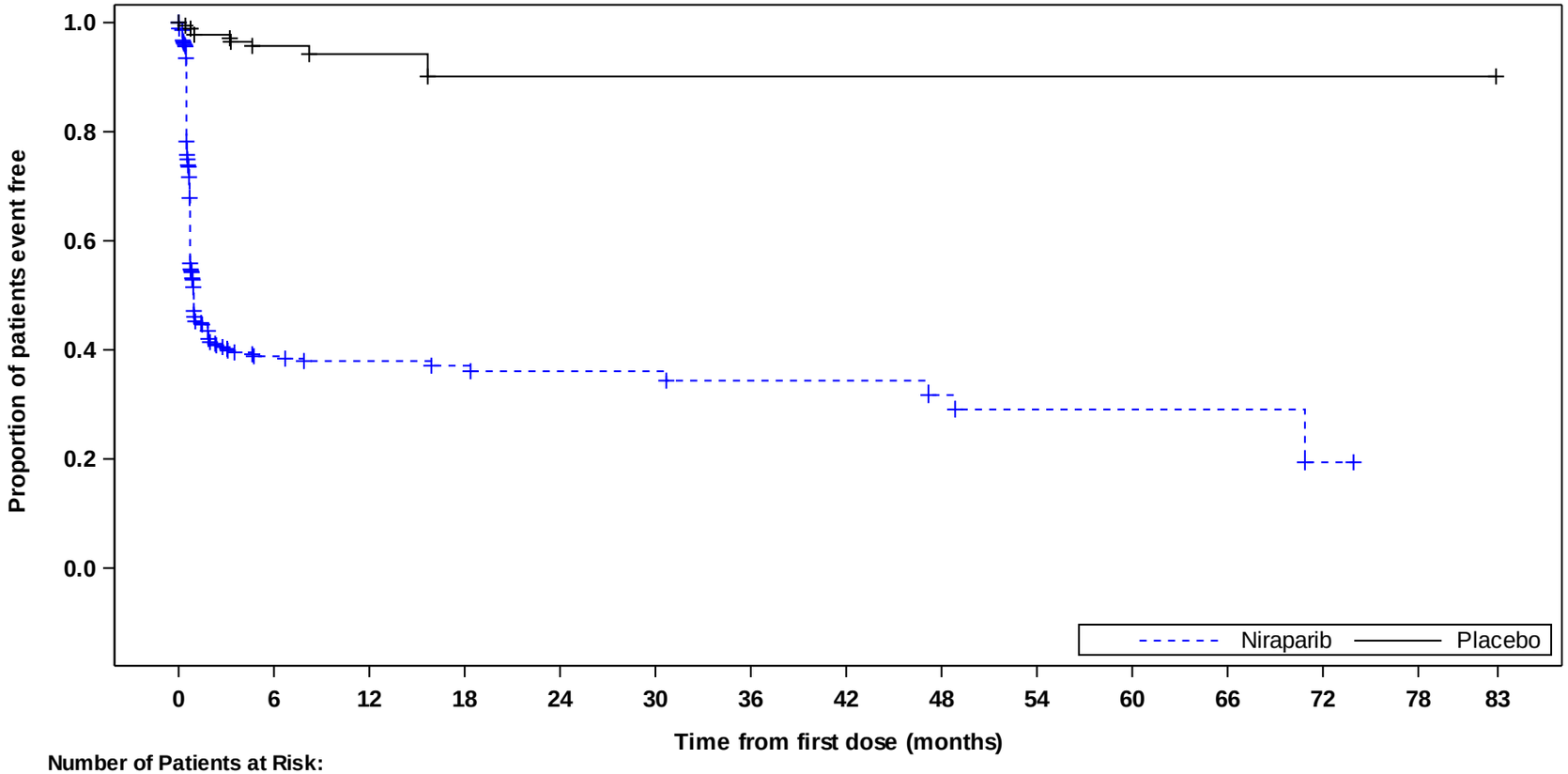
Number of Patients at Risk:

Niraparib	367	246	161	100	70	61	52	41	38	33	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:24 Data Extraction Date: 01OCT2020

Figure 3.15.1
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events

Thrombocytopenia



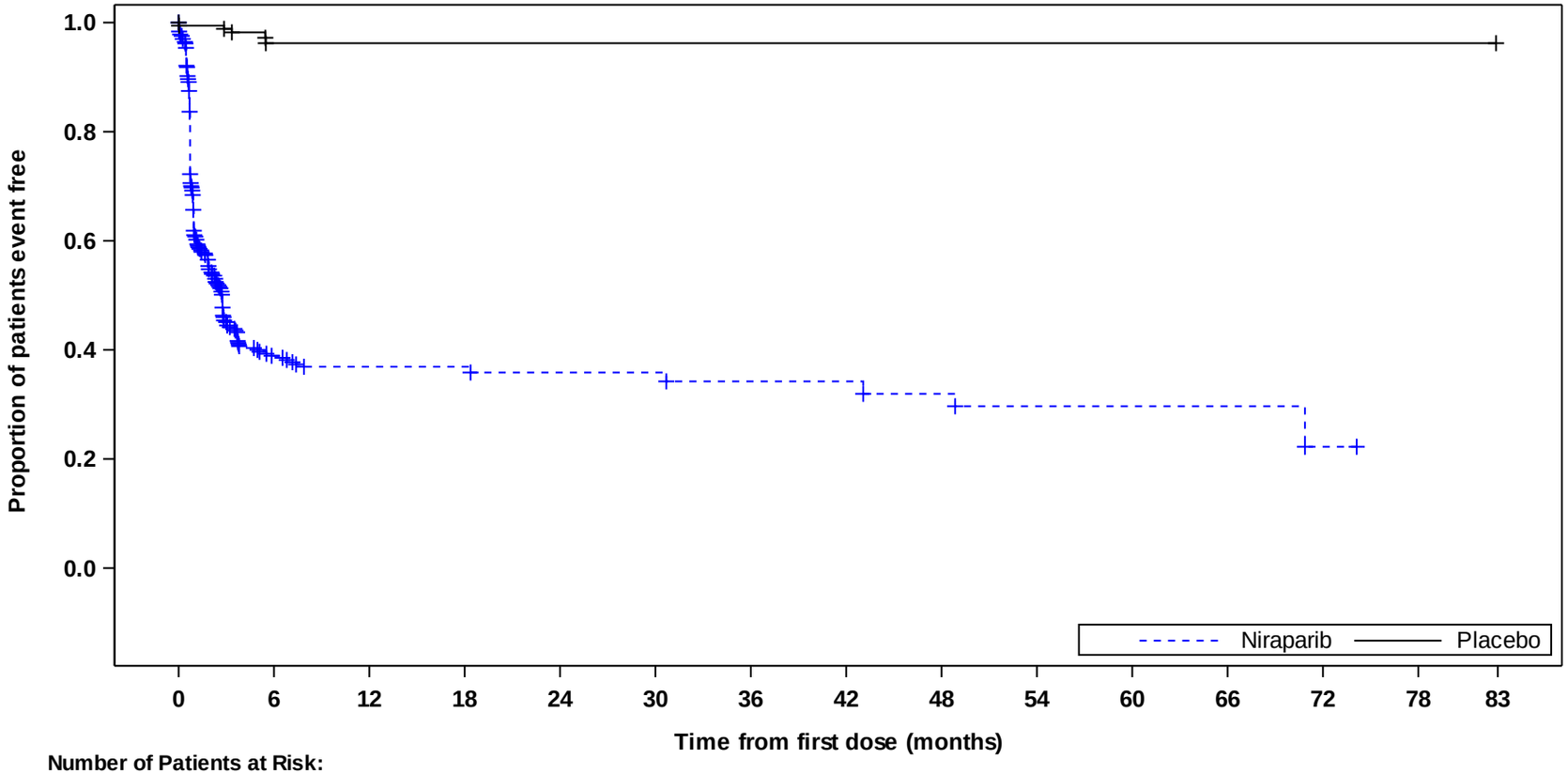
Number of Patients at Risk:

Niraparib	367	97	65	36	25	22	19	13	12	11	9	9	1	0
Placebo	179	90	36	15	9	8	8	7	6	5	5	5	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:25 Data Extraction Date: 01OCT2020

Figure 3.16.1
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest

Overall



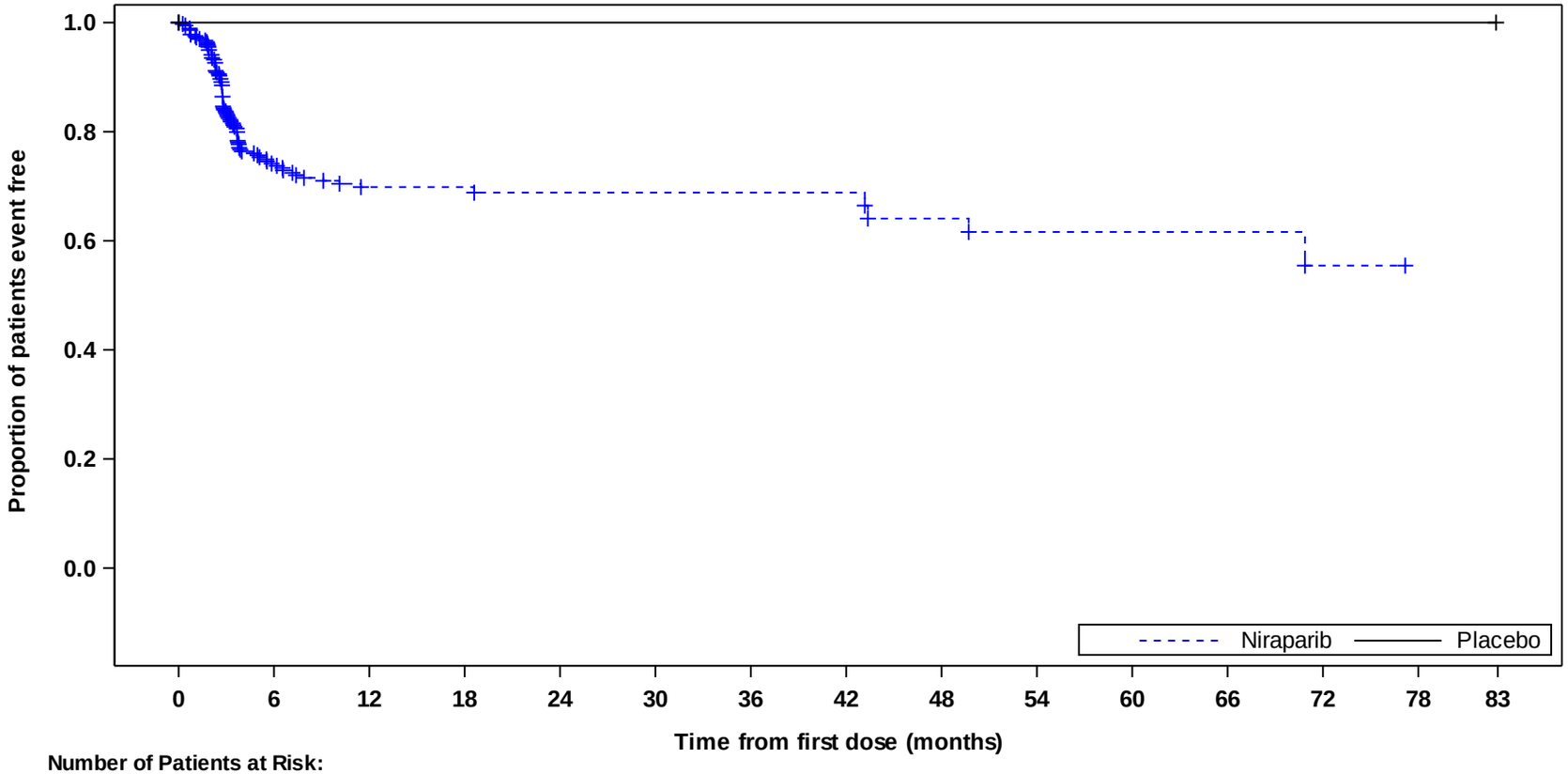
Number of Patients at Risk:

Niraparib	367	105	67	35	26	22	20	16	14	12	10	9	1	0
Placebo	179	89	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:26 Data Extraction Date: 01OCT2020

Figure 3.16.1
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest

Anemia



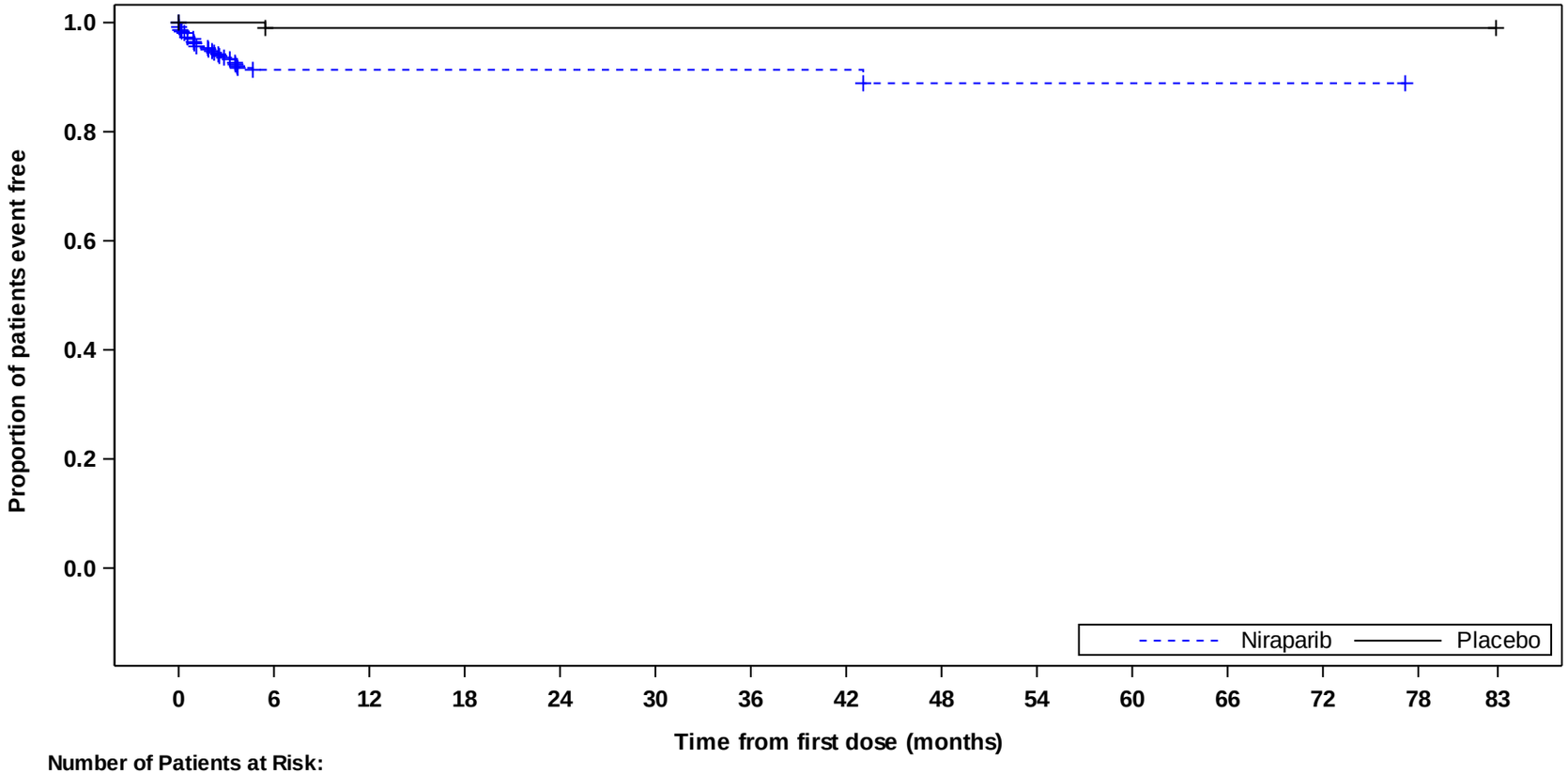
Number of Patients at Risk:

Niraparib	367	186	115	69	49	43	38	30	26	22	20	18	5	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:27 Data Extraction Date: 01OCT2020

Figure 3.16.1
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest

Fatigue



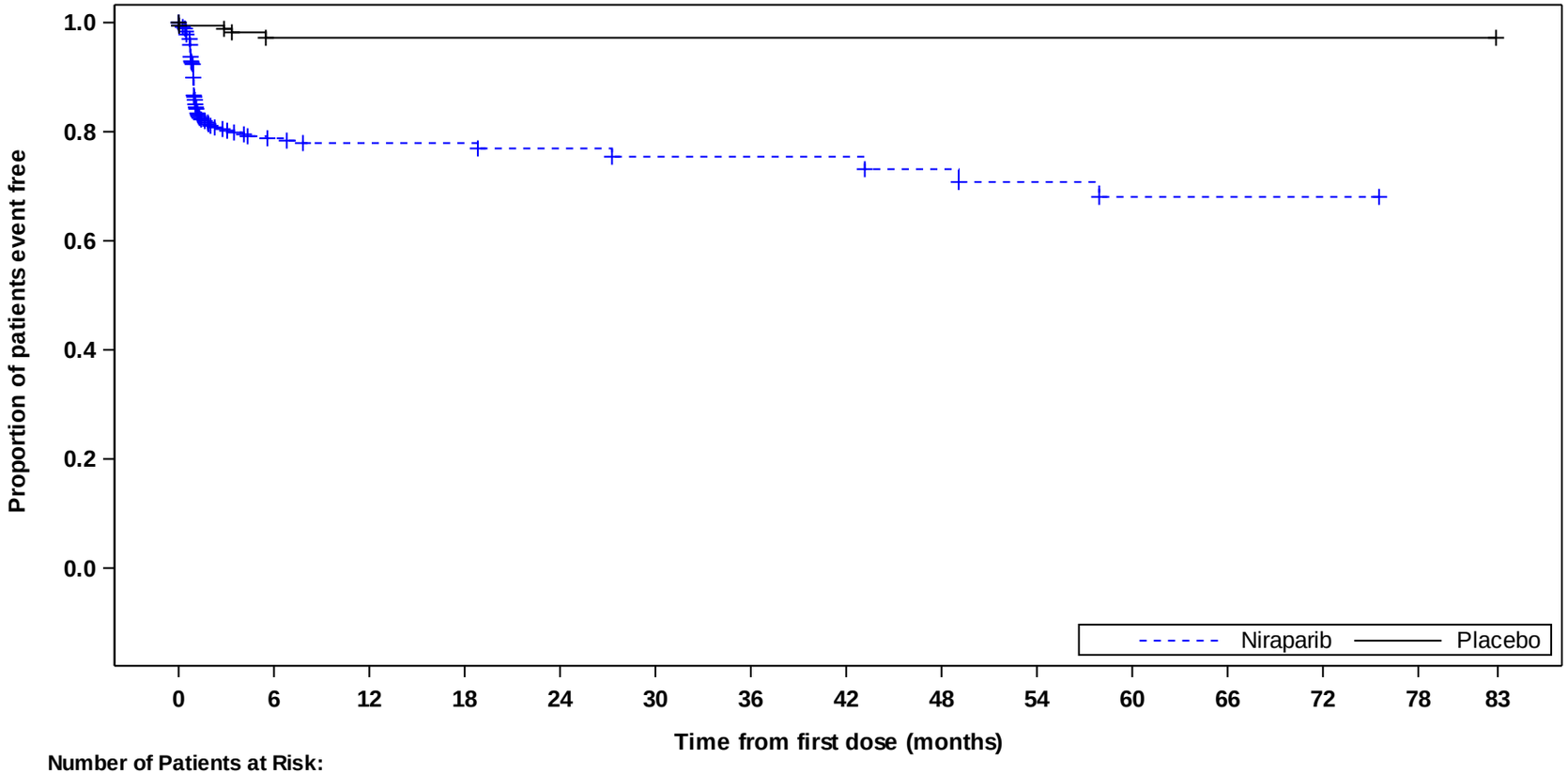
Number of Patients at Risk:

Niraparib	367	232	151	92	65	55	47	38	36	31	26	19	6	0
Placebo	179	91	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:28 Data Extraction Date: 01OCT2020

Figure 3.16.1
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest

Leukopenia



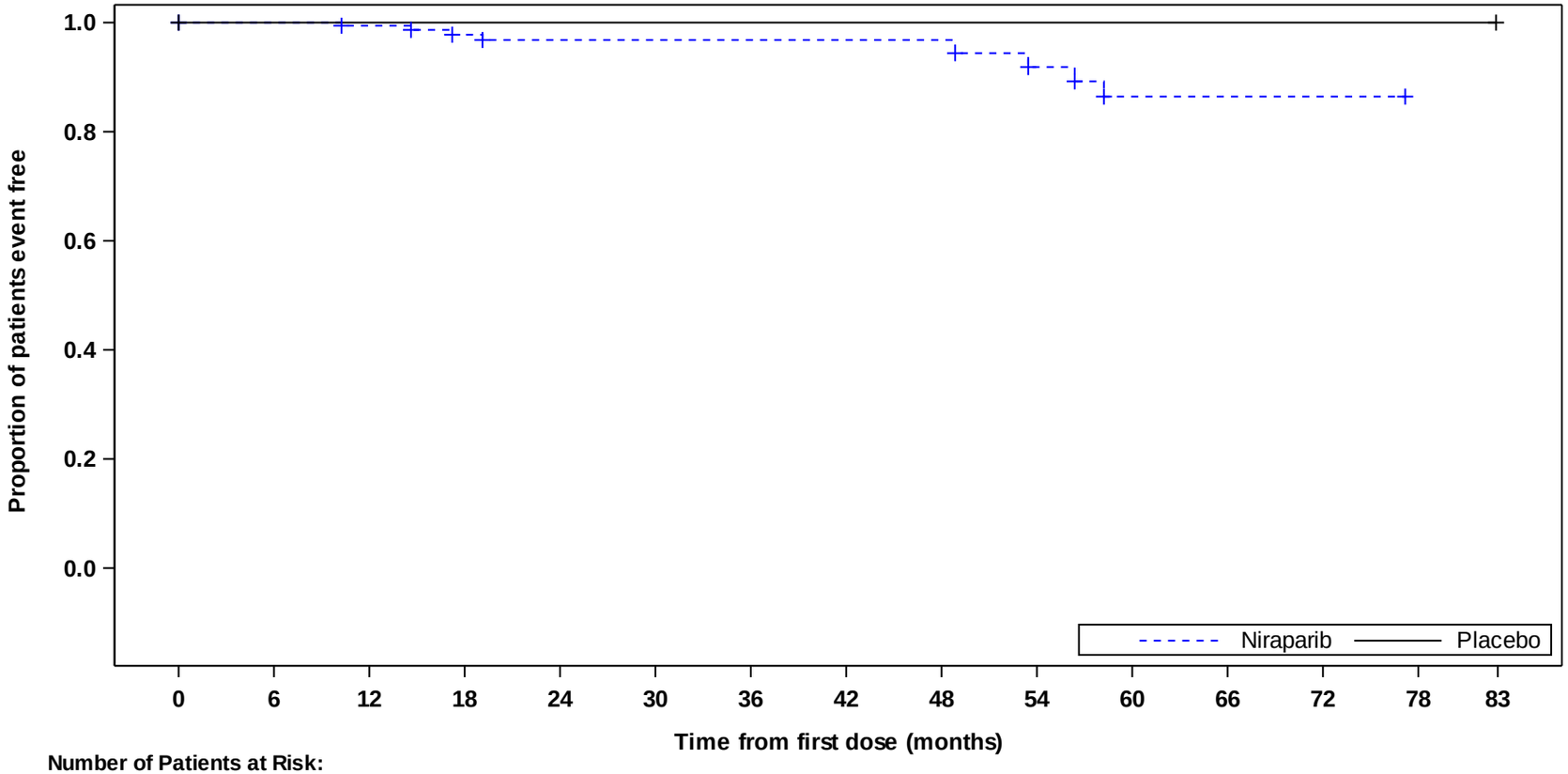
Number of Patients at Risk:

Niraparib	367	200	131	79	56	48	42	34	31	27	23	17	4	0
Placebo	179	90	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:28 Data Extraction Date: 01OCT2020

Figure 3.16.1
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest

MDS/AML



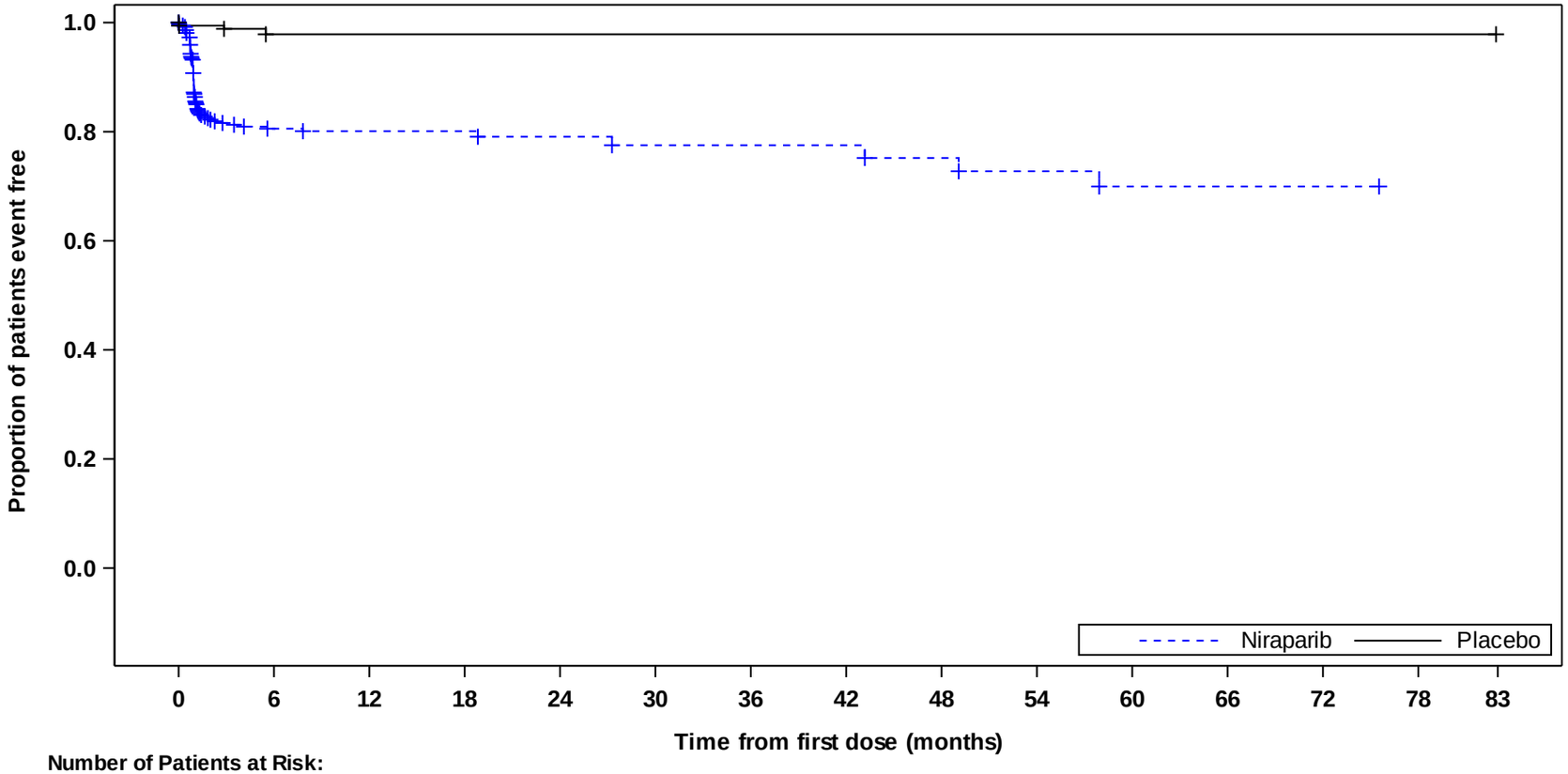
Number of Patients at Risk:

Niraparib	367	248	164	102	72	62	53	43	40	35	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:29 Data Extraction Date: 01OCT2020

Figure 3.16.1
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest

Neutropenia



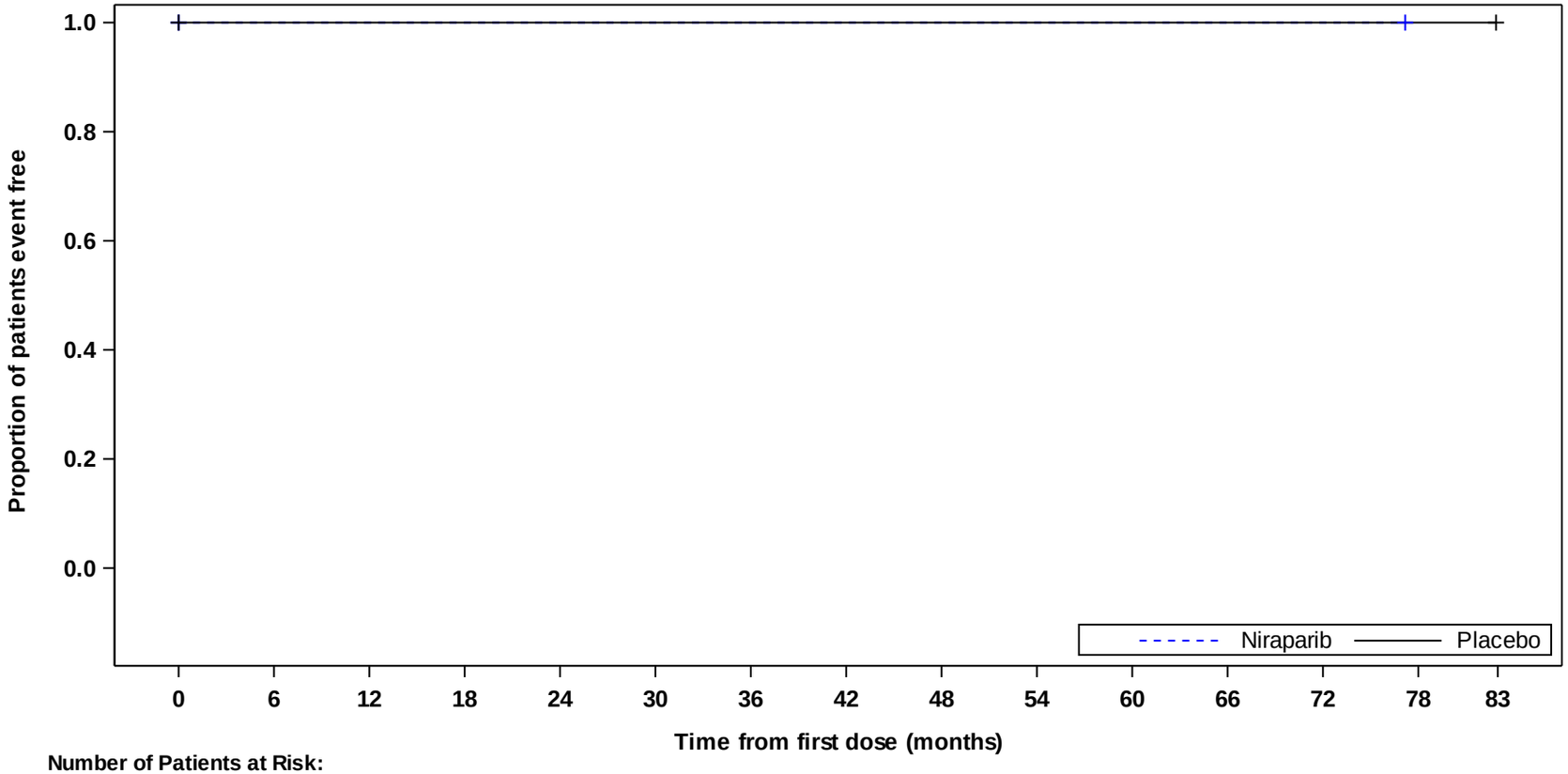
Number of Patients at Risk:

Niraparib	367	203	132	79	56	48	42	34	31	27	23	17	4	0
Placebo	179	90	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:30 Data Extraction Date: 01OCT2020

Figure 3.16.1
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest

Overdose



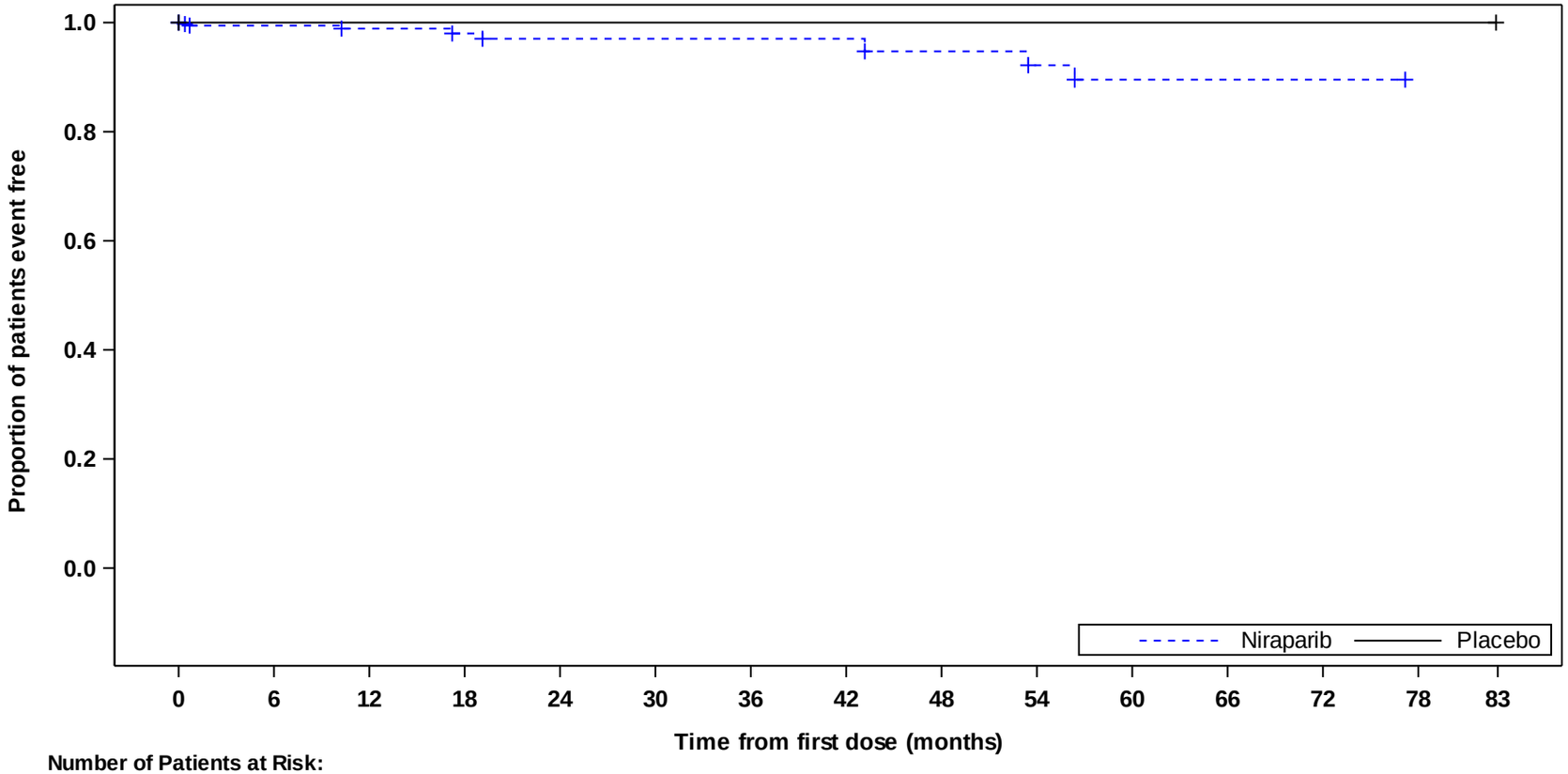
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:30 Data Extraction Date: 01OCT2020

Figure 3.16.1
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest

Pancytopenia



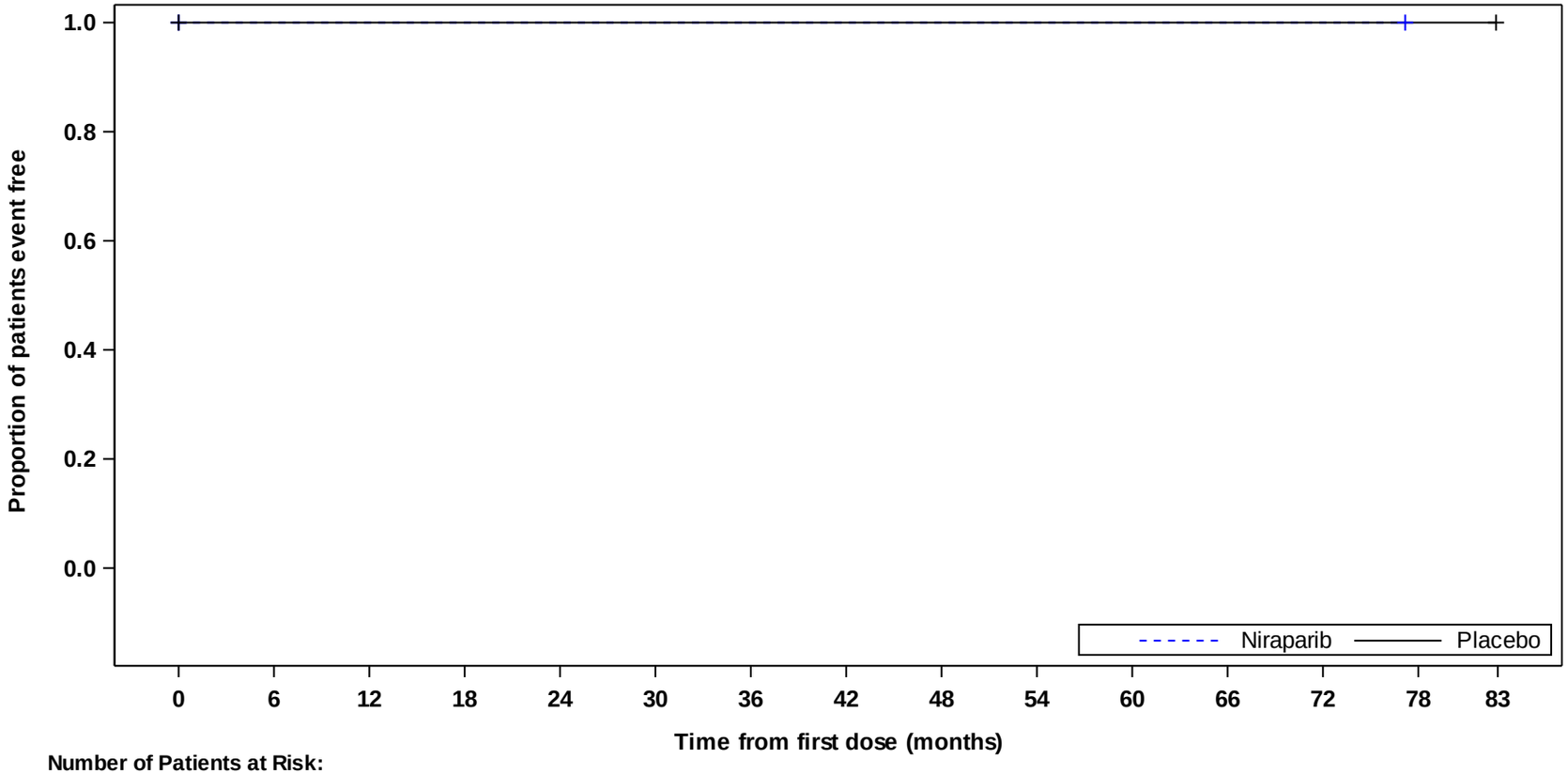
Number of Patients at Risk:

Niraparib	367	248	164	102	72	62	53	43	40	35	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:31 Data Extraction Date: 01OCT2020

Figure 3.16.1
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest

Pneumonitis



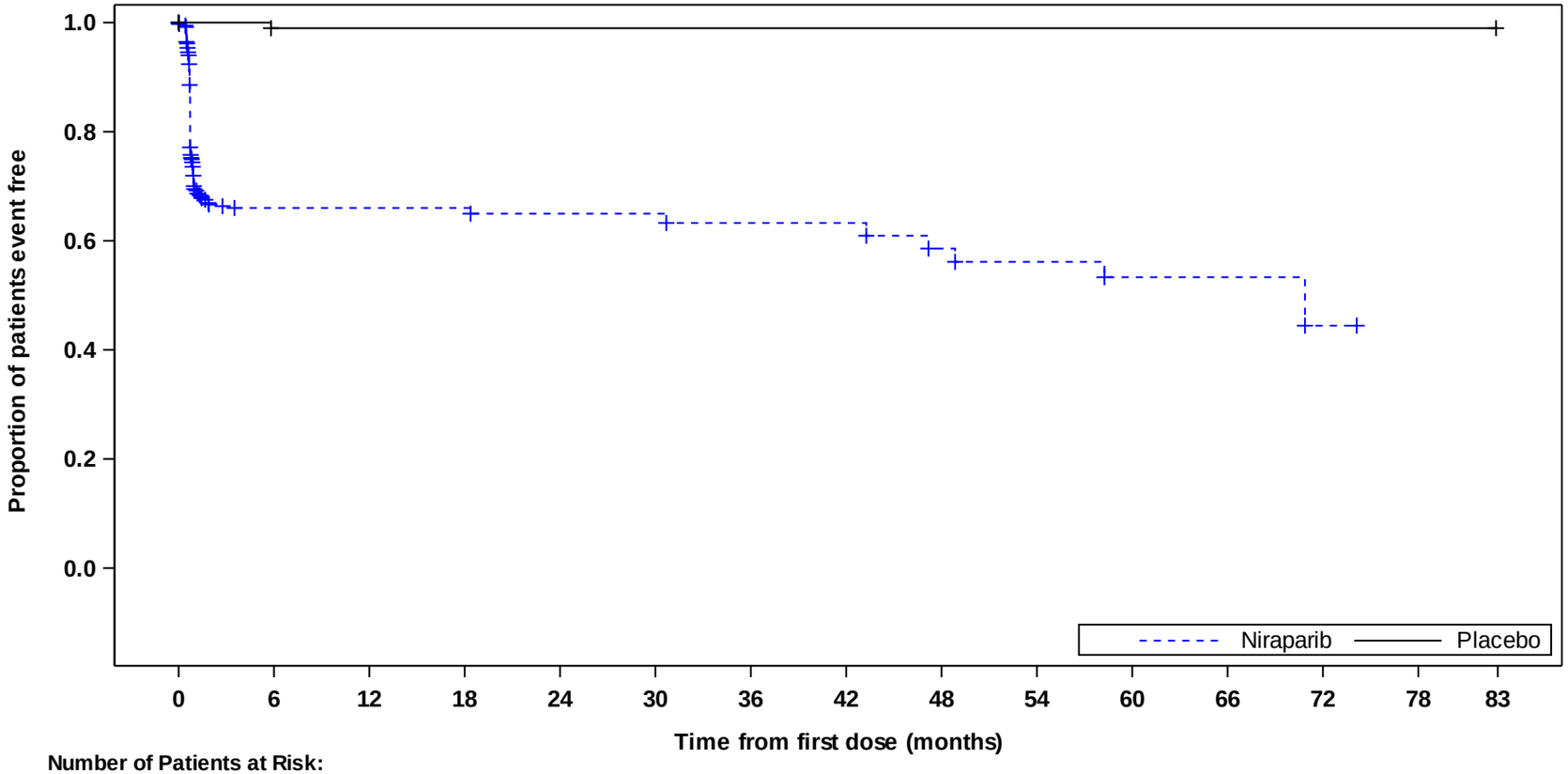
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:32 Data Extraction Date: 01OCT2020

Figure 3.16.1
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest

Thrombocytopenia



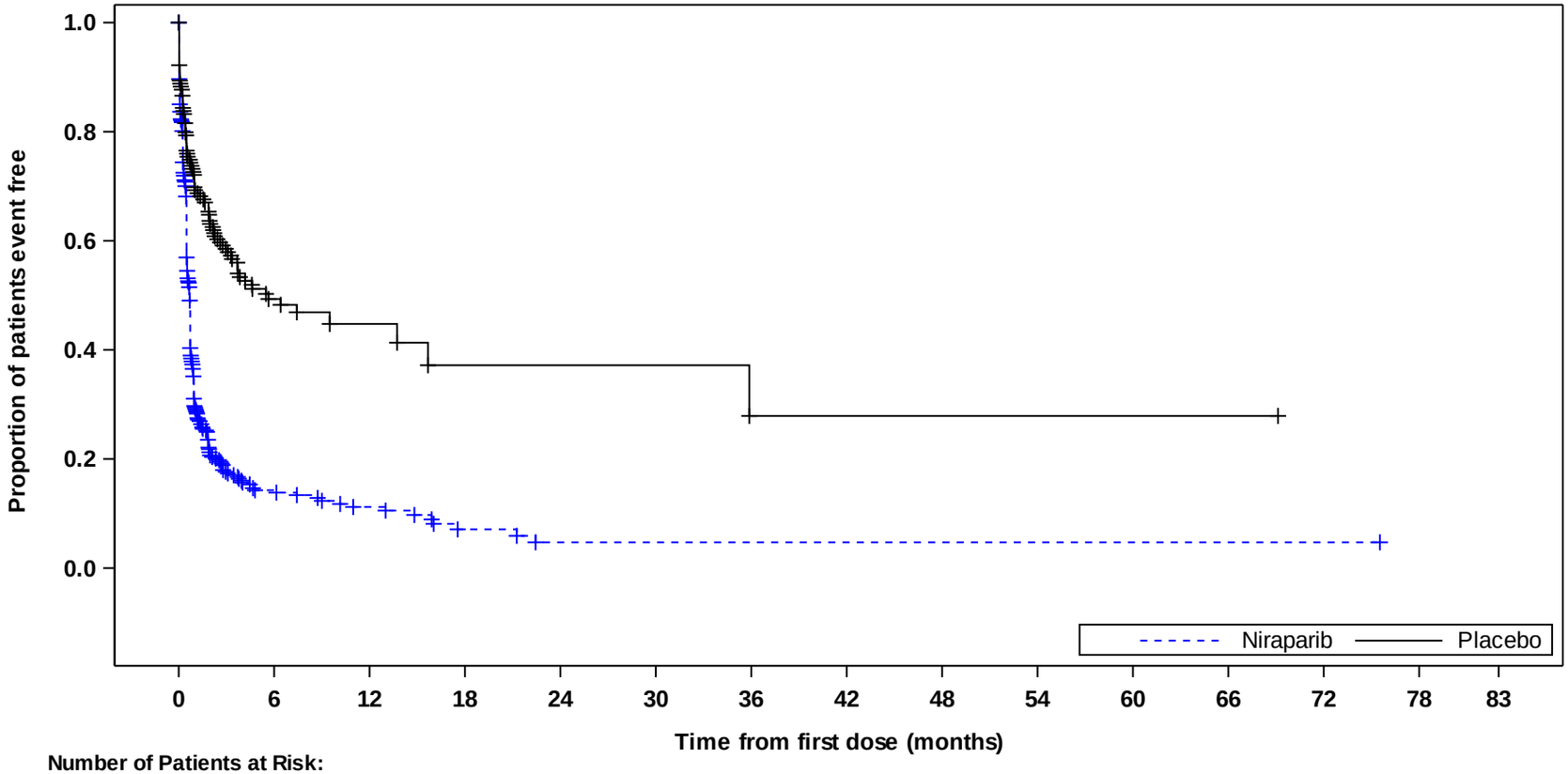
Number of Patients at Risk:

Niraparib	367	167	110	64	46	40	35	28	24	21	18	14	2	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:32 Data Extraction Date: 01OCT2020

Figure 3.18.1
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest

Overall



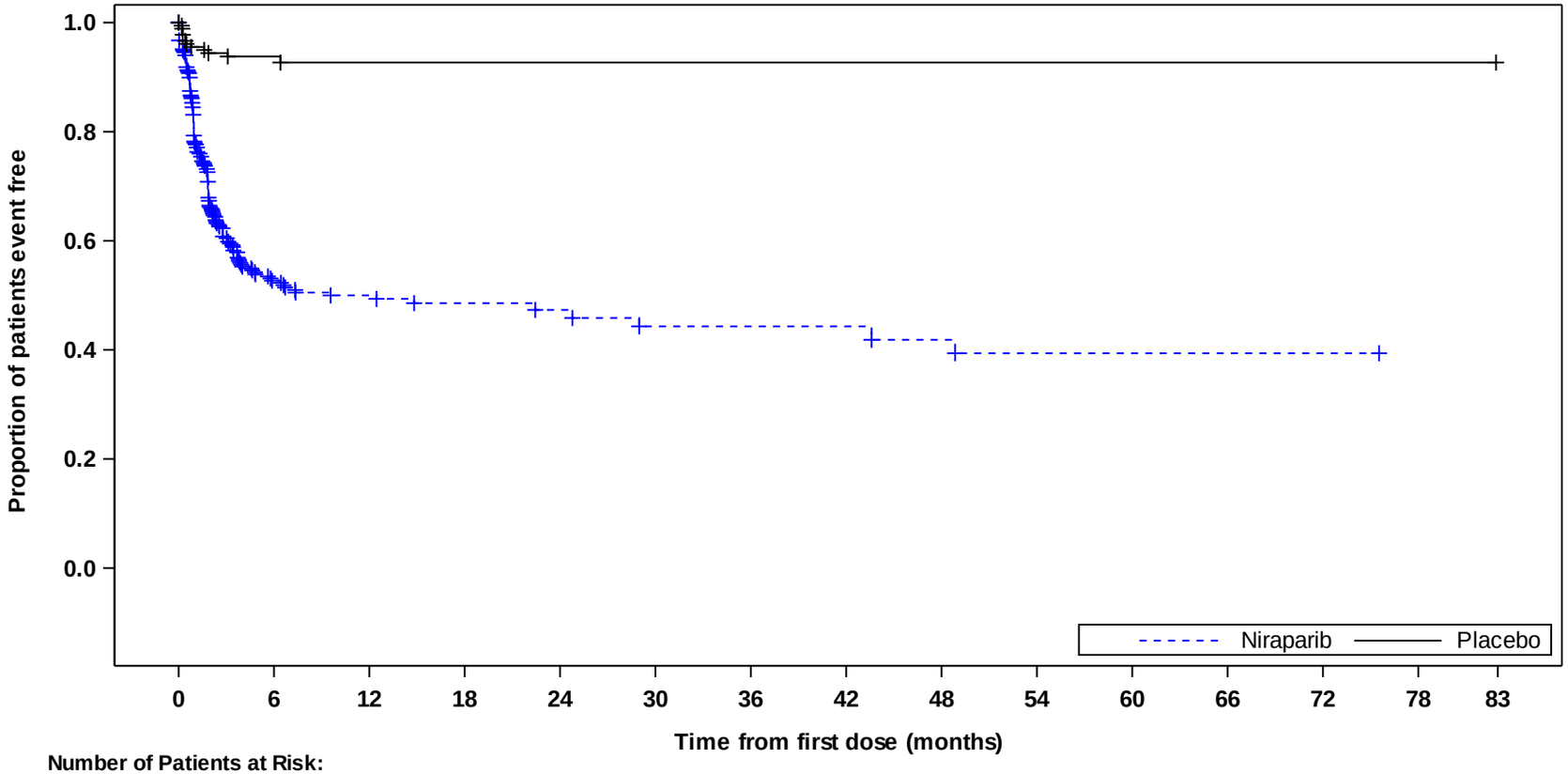
Number of Patients at Risk:

Niraparib	367	33	20	6	4	4	4	3	3	3	3	3	1	0
Placebo	179	49	17	6	4	4	3	2	1	1	1	1	0	

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:34 Data Extraction Date: 01OCT2020

Figure 3.18.1
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest

Anemia



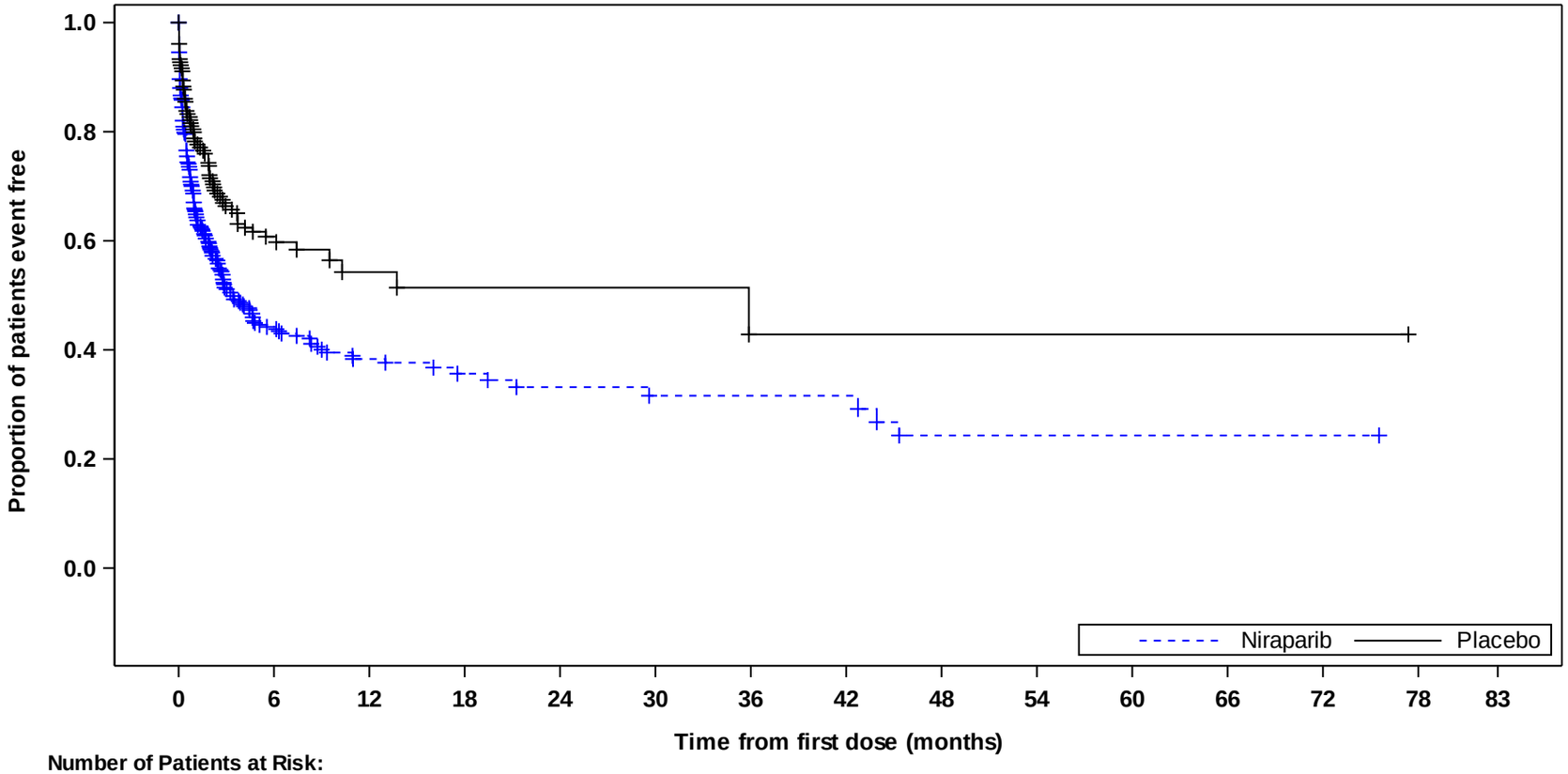
Number of Patients at Risk:

Niraparib	367	130	85	48	32	29	26	19	17	14	11	10	2	0
Placebo	179	87	33	13	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:35 Data Extraction Date: 01OCT2020

Figure 3.18.1
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest

Fatigue



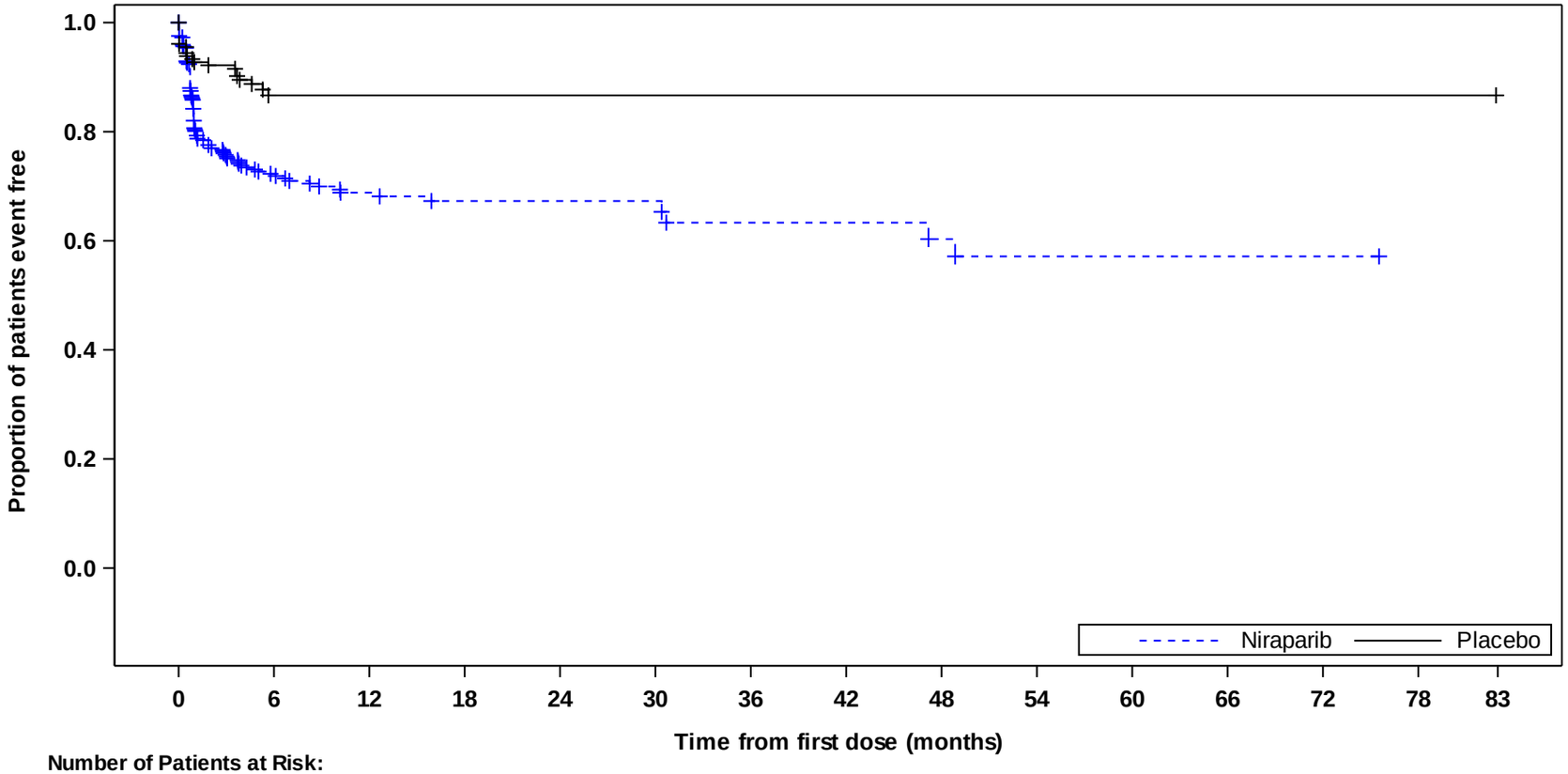
Number of Patients at Risk:

Niraparib	367	113	64	31	23	20	18	13	10	10	9	8	1	0
Placebo	179	60	23	9	6	6	5	4	3	3	3	3	1	0

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:35 Data Extraction Date: 01OCT2020

Figure 3.18.1
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest

Leukopenia



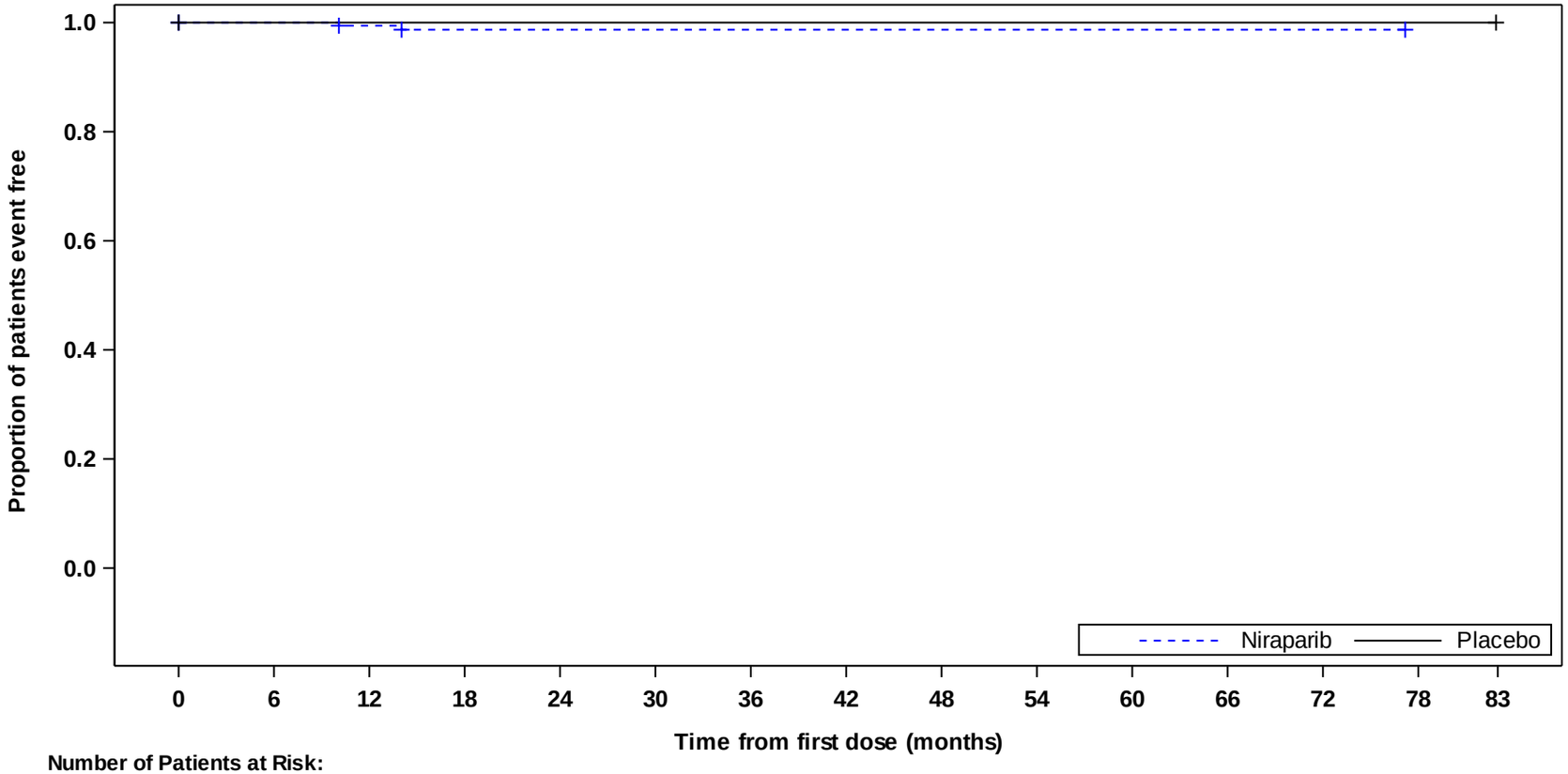
Number of Patients at Risk:

Niraparib	367	175	109	64	40	34	28	22	19	16	14	11	3	0
Placebo	179	77	29	14	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:36 Data Extraction Date: 01OCT2020

Figure 3.18.1
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest

MDS/AML



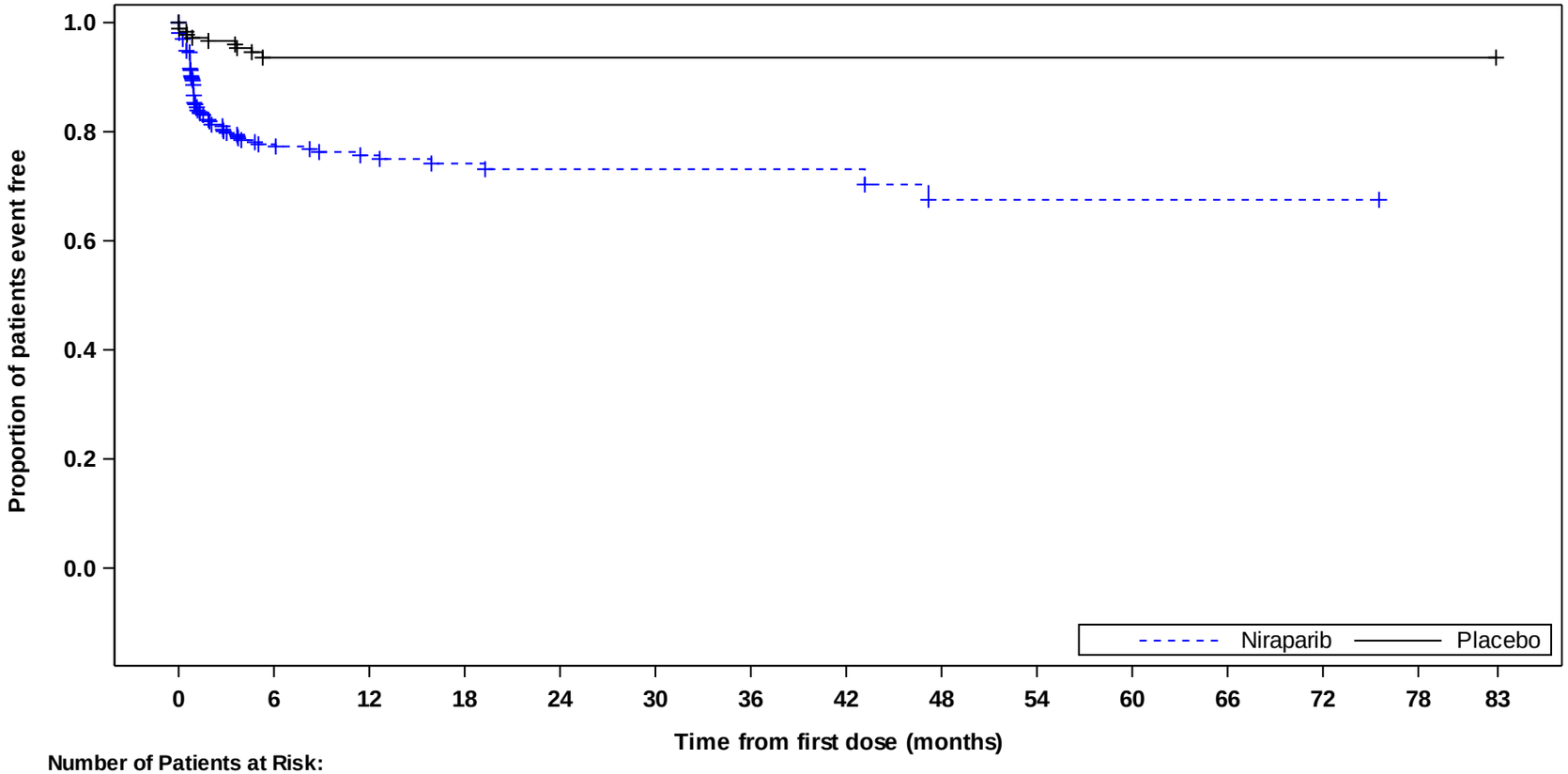
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:37 Data Extraction Date: 01OCT2020

Figure 3.18.1
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest

Neutropenia



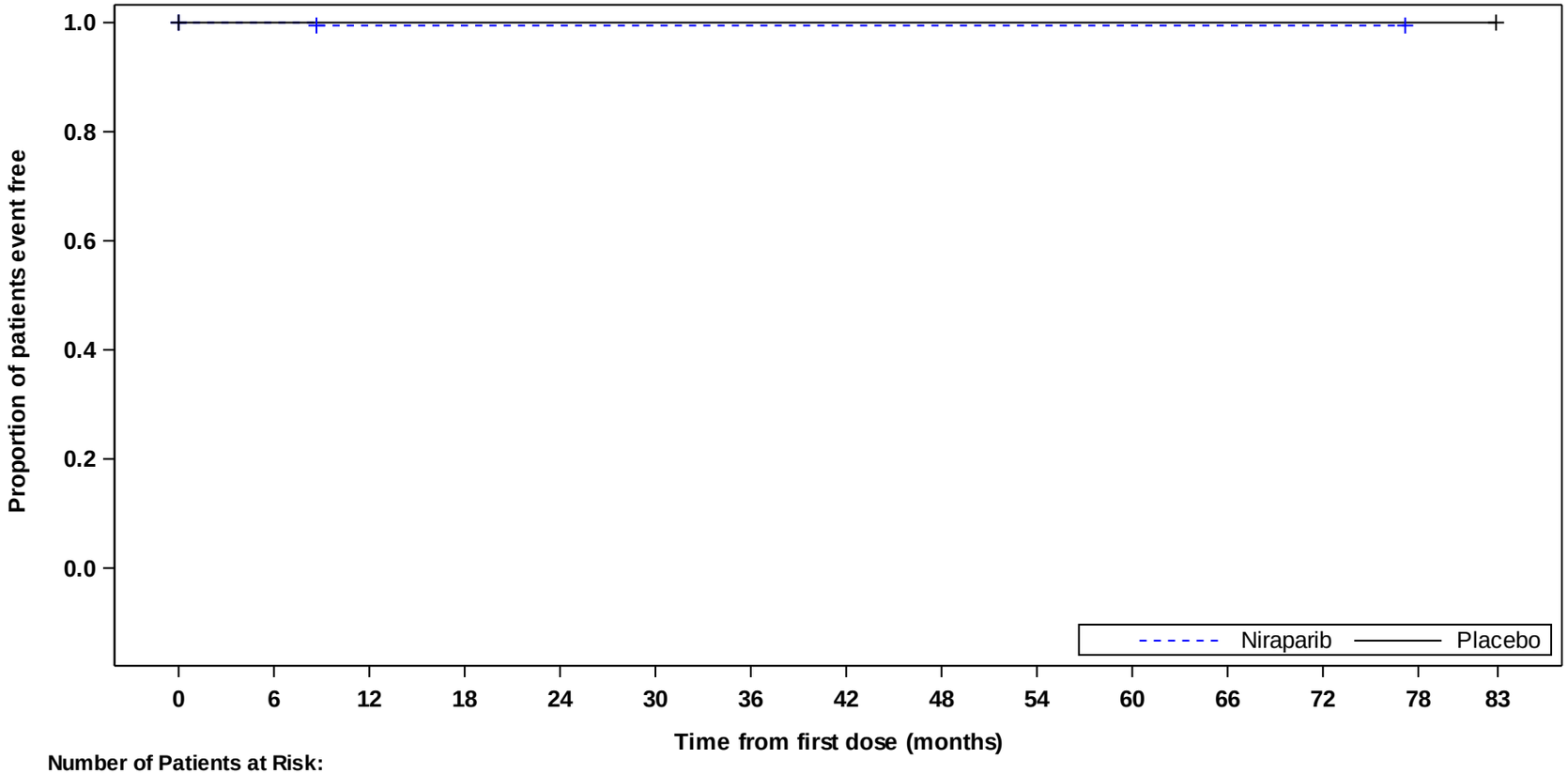
Number of Patients at Risk:

Niraparib	367	190	123	72	47	40	34	27	23	20	18	15	4	0
Placebo	179	85	33	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:38 Data Extraction Date: 01OCT2020

Figure 3.18.1
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest

Overdose



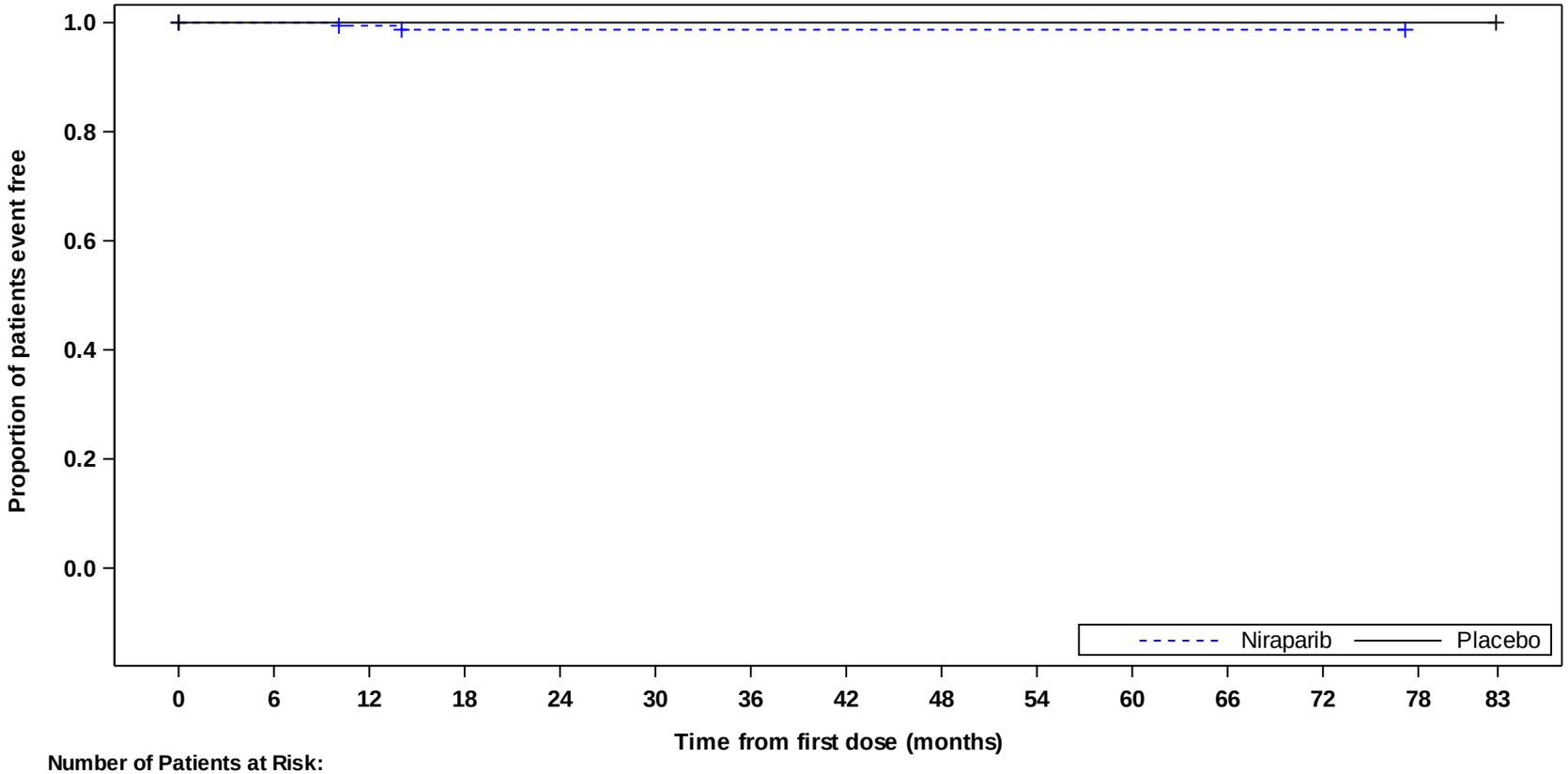
Number of Patients at Risk:

Niraparib	367	247	161	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:38 Data Extraction Date: 01OCT2020

Figure 3.18.1
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest

Pancytopenia



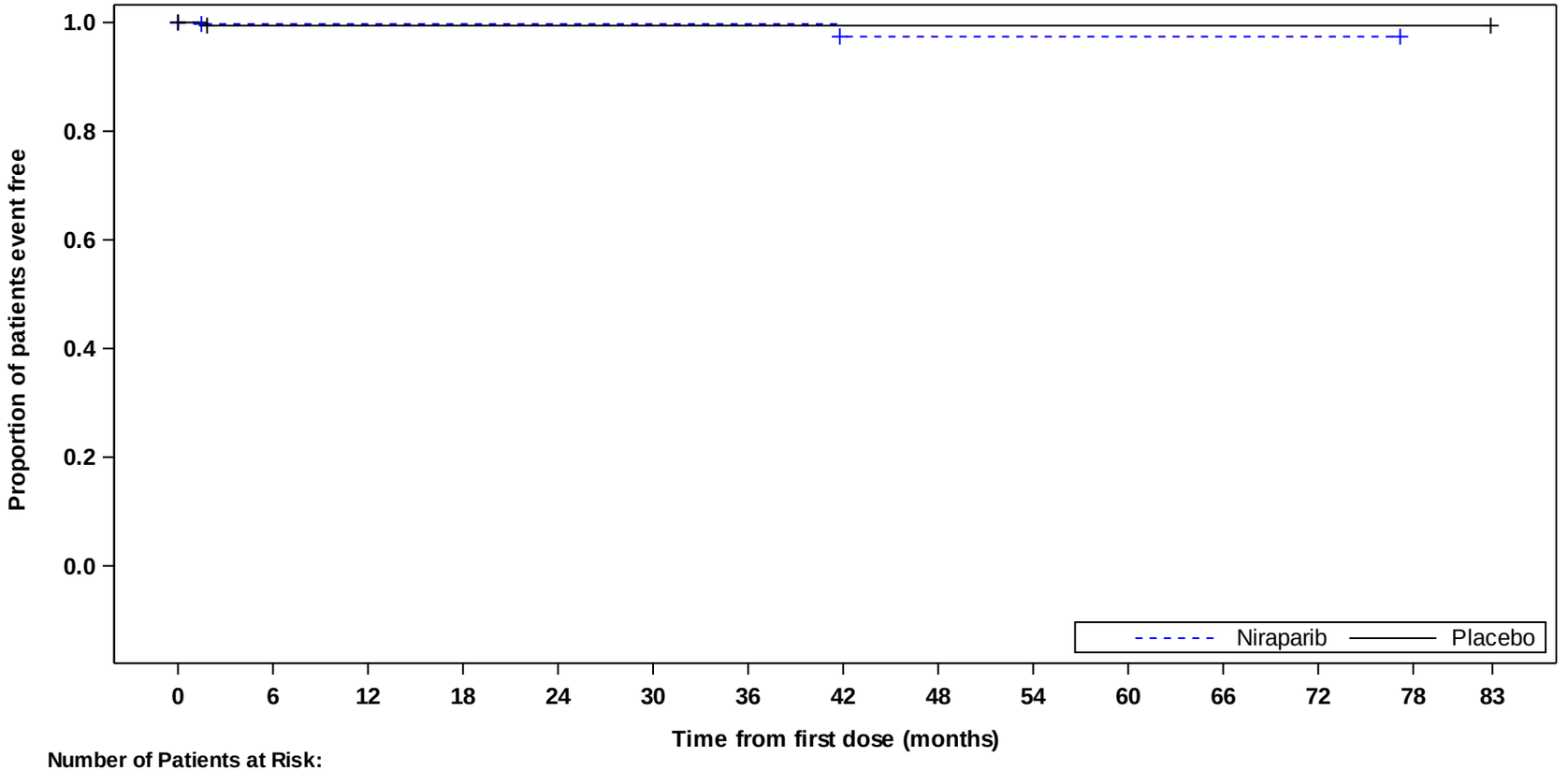
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:39 Data Extraction Date: 01OCT2020

Figure 3.18.1
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest

Pneumonitis



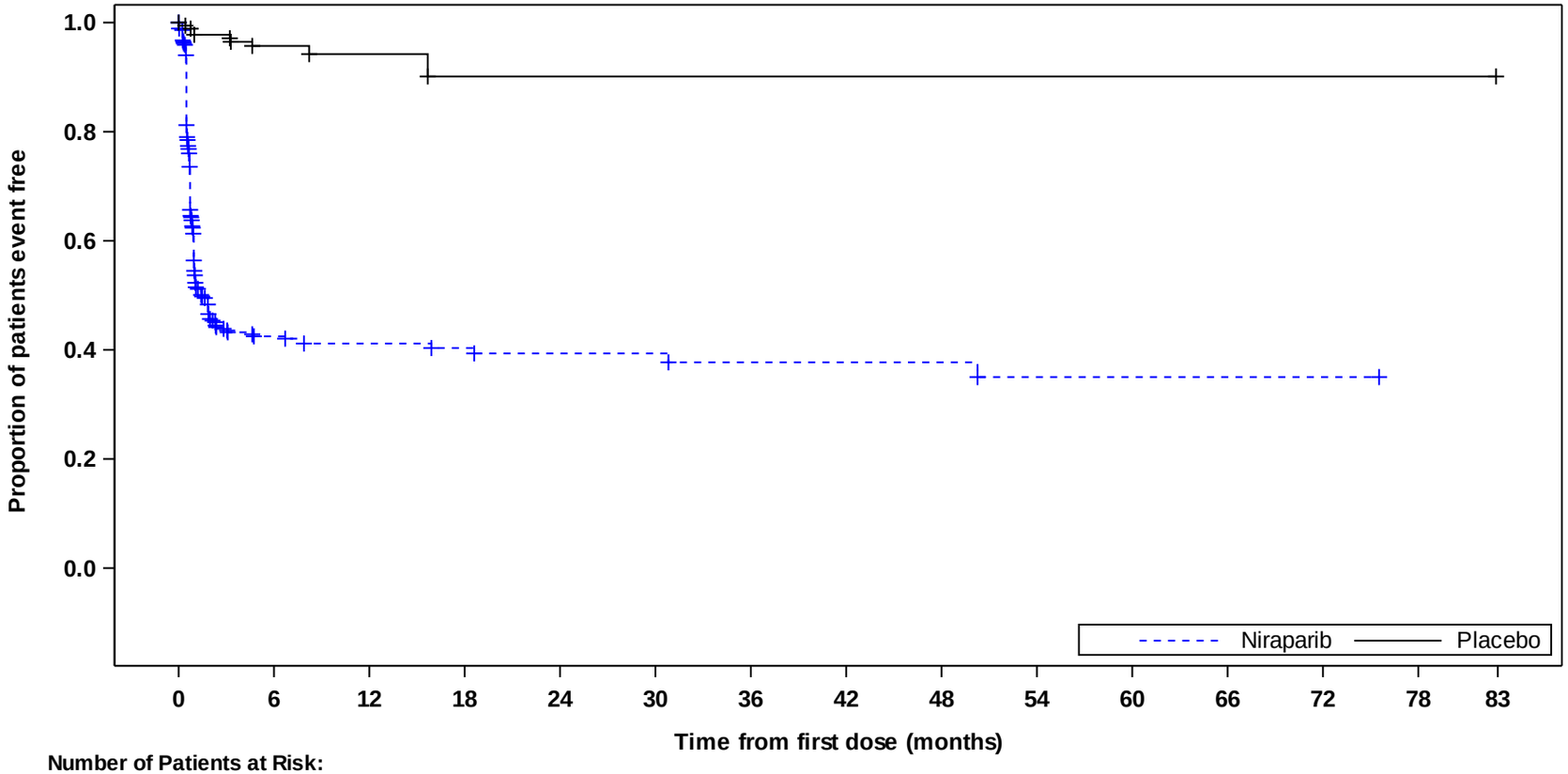
Number of Patients at Risk:

Niraparib	367	246	161	100	70	61	52	41	38	33	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:40 Data Extraction Date: 01OCT2020

Figure 3.18.1
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest

Thrombocytopenia



Number of Patients at Risk:

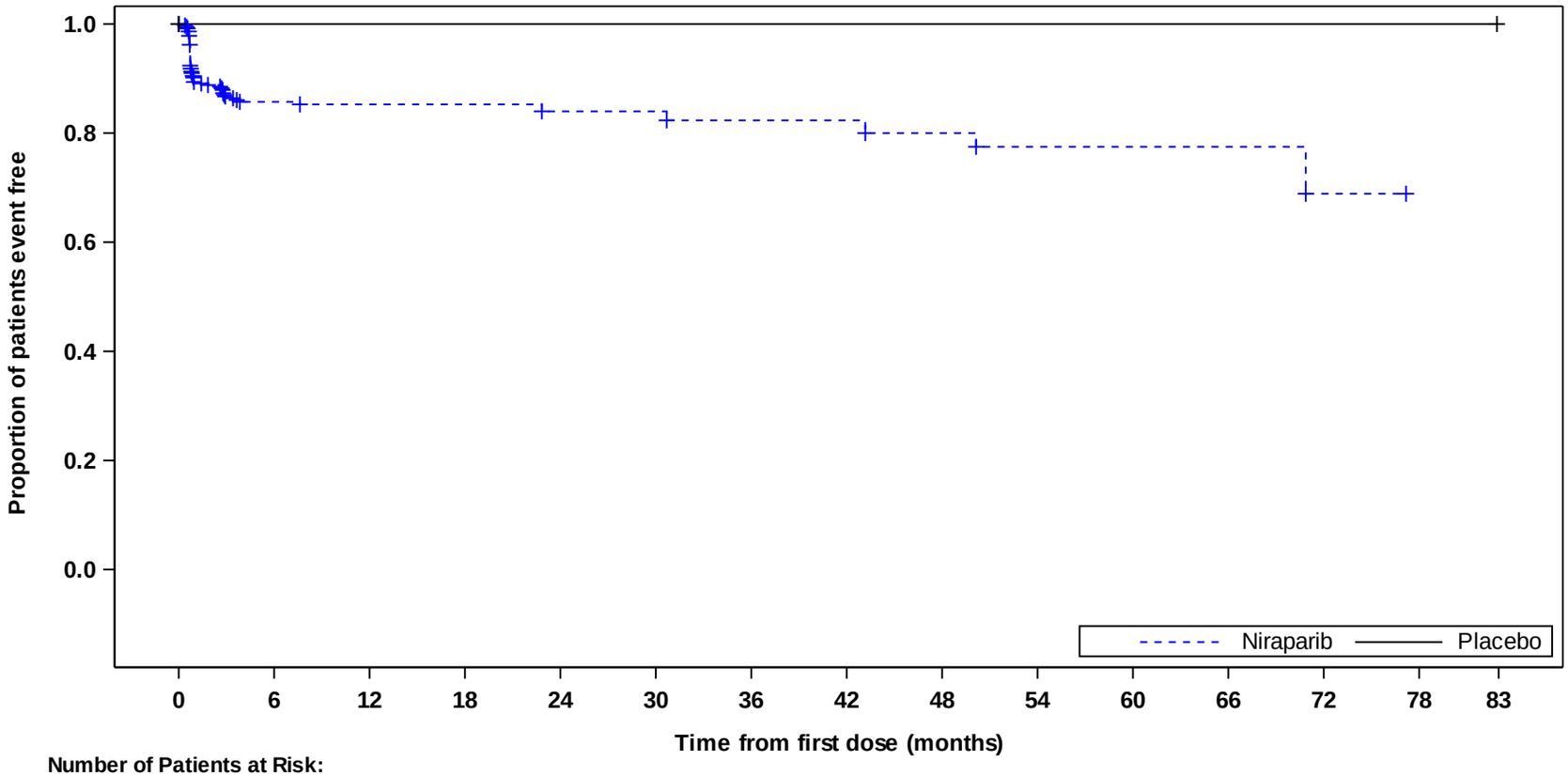
Niraparib	367	105	71	41	28	25	21	14	14	13	10	9	2	0
Placebo	179	90	36	15	9	8	8	7	6	5	5	5	2	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:40 Data Extraction Date: 01OCT2020

Figure 3.22.1

Time to Onset of First Occurence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders



Number of Patients at Risk:

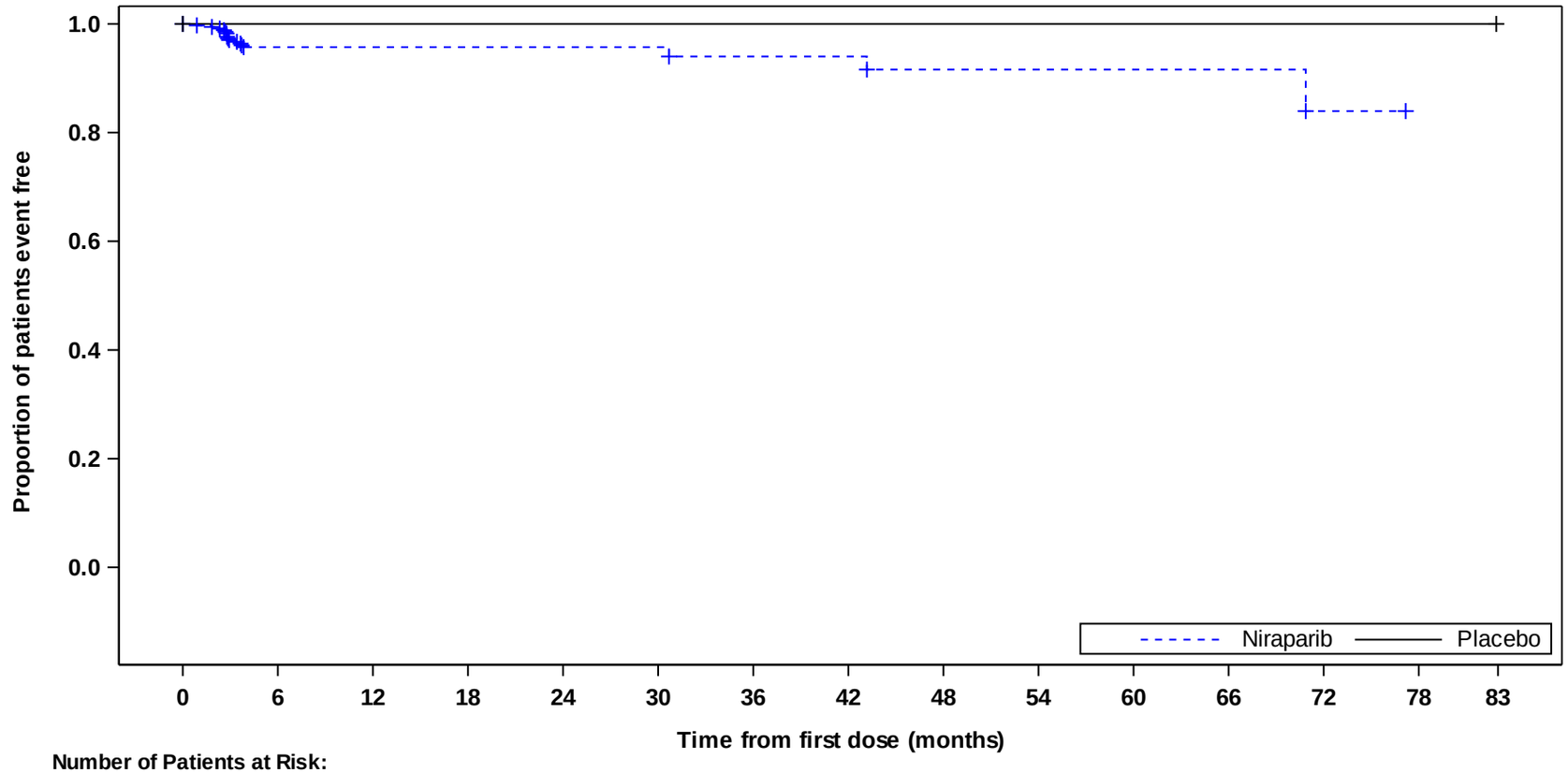
Niraparib	367	218	144	89	63	54	46	36	33	28	23	16	5	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:34 Data Extraction Date: 01OCT2020

Figure 3.22.1

Time to Onset of First Occurence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Anaemia



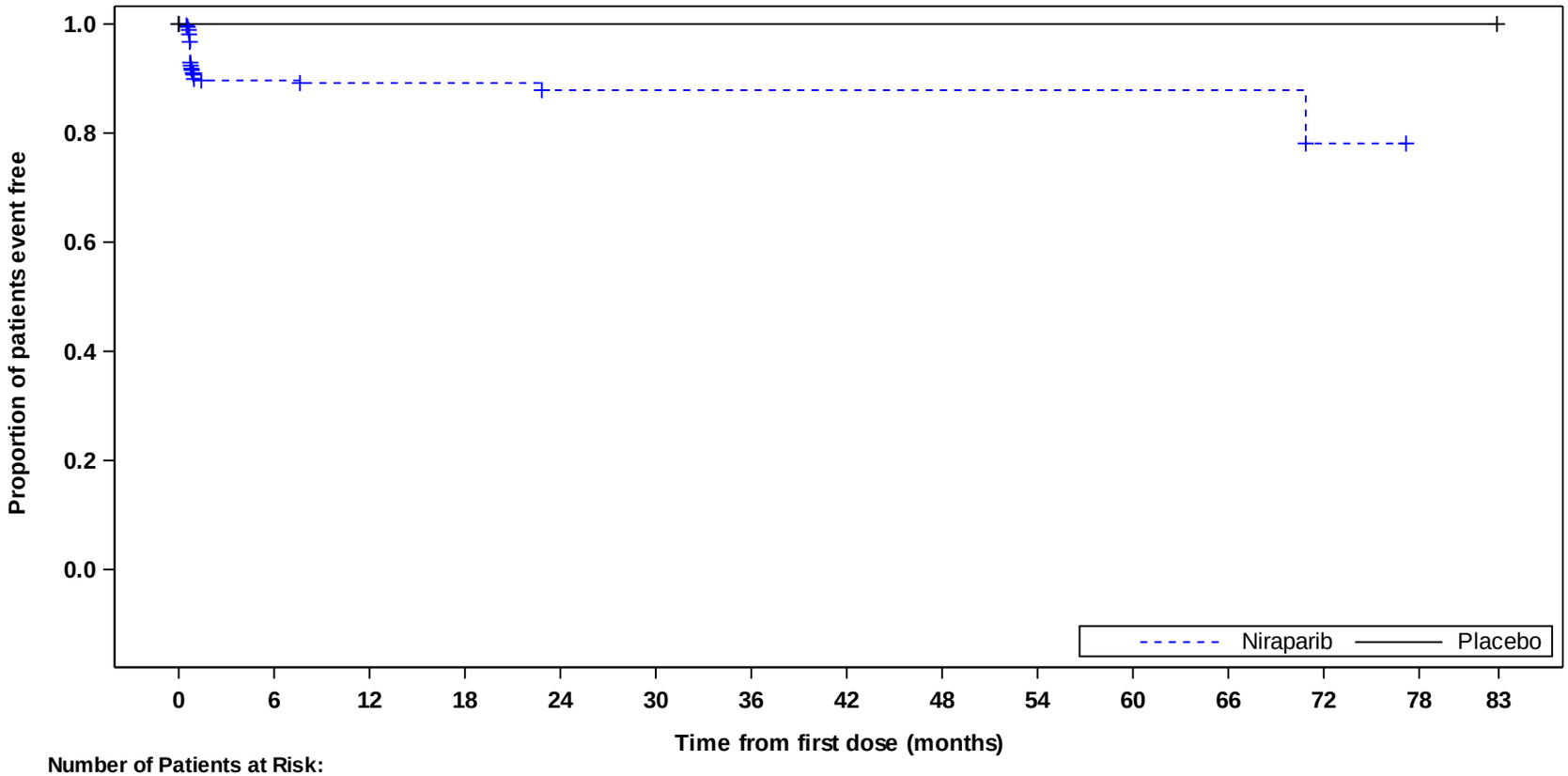
Number of Patients at Risk:

Niraparib	367	237	158	99	69	59	50	40	37	32	27	20	6	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:35 Data Extraction Date: 01OCT2020

Figure 3.22.1
Time to Onset of First Occurence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia



Number of Patients at Risk:

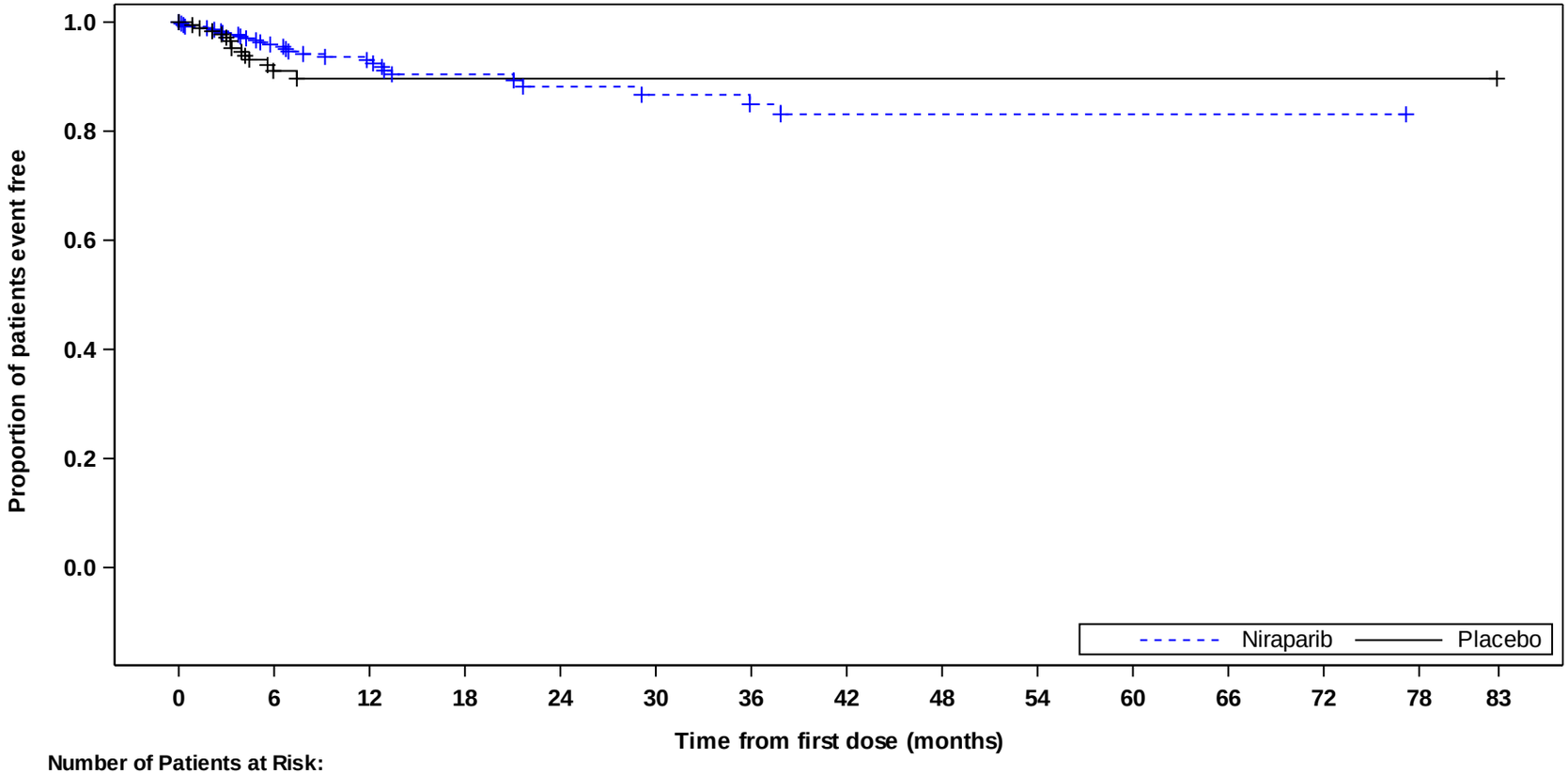
Niraparib	367	226	147	90	64	55	48	38	35	30	25	18	5	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:35 Data Extraction Date: 01OCT2020

Figure 3.22.1

Time to Onset of First Occurence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders



Number of Patients at Risk:

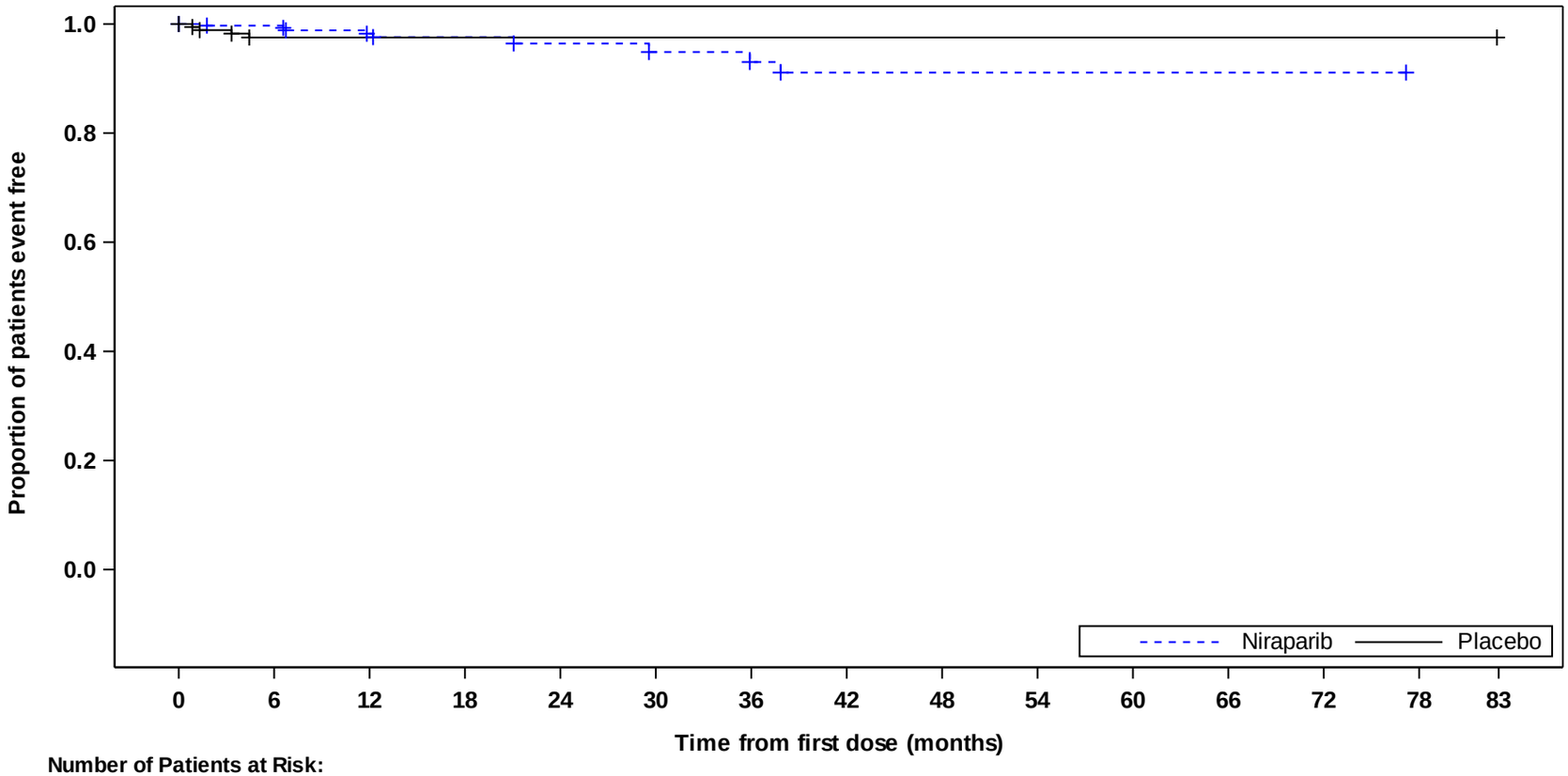
Niraparib	367	244	156	97	68	58	49	39	36	32	28	22	7	0
Placebo	179	85	34	14	9	8	8	7	6	5	5	5	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:36 Data Extraction Date: 01OCT2020

Figure 3.22.1

Time to Onset of First Occurence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Gastrointestinal disorders, PT: Small intestinal obstruction



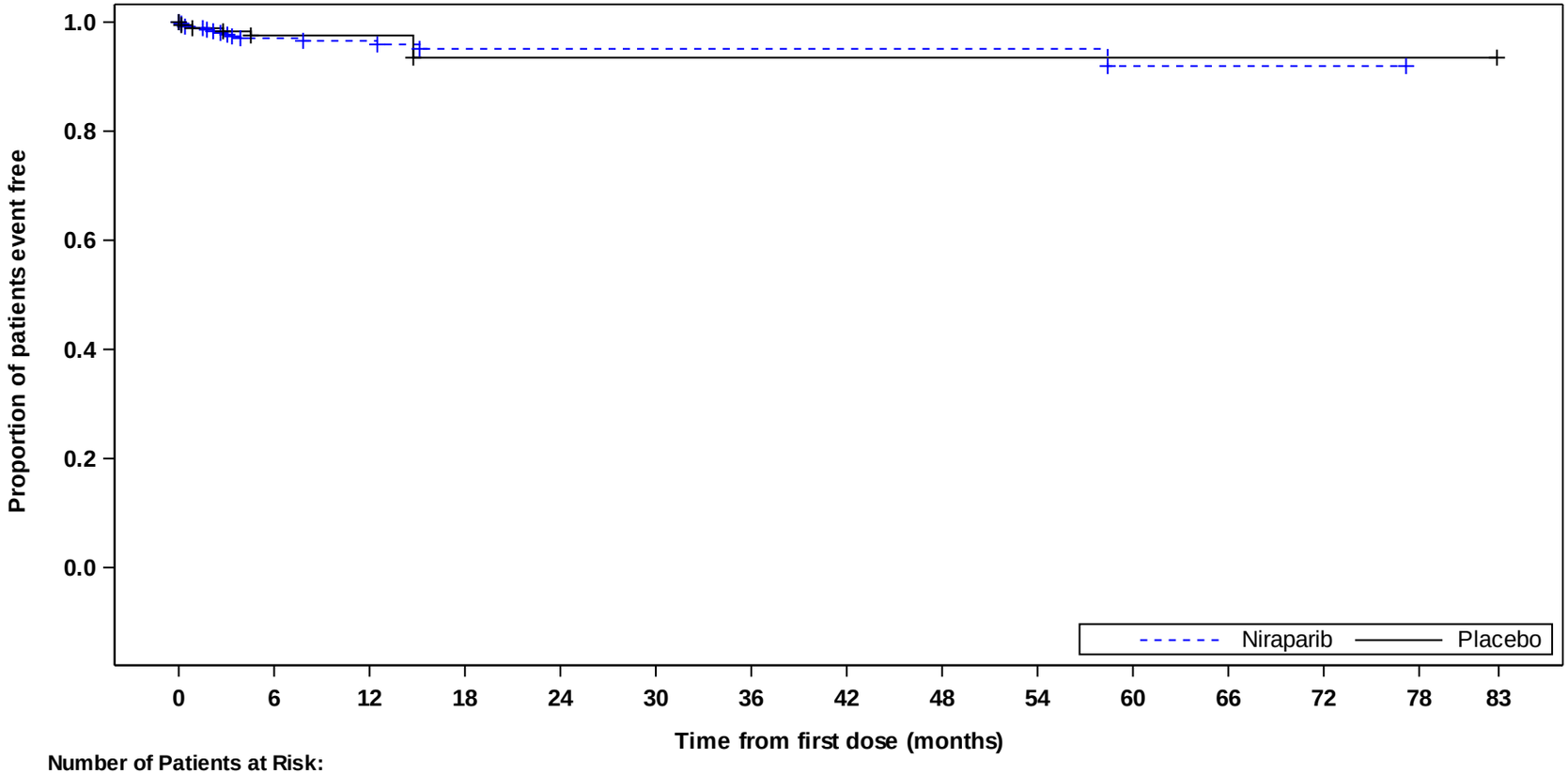
Number of Patients at Risk:

Niraparib	367	247	160	100	71	60	51	40	37	33	29	22	7	0
Placebo	179	90	36	15	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:37 Data Extraction Date: 01OCT2020

Figure 3.22.1
Time to Onset of First Occurence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Infections and infestations



Number of Patients at Risk:

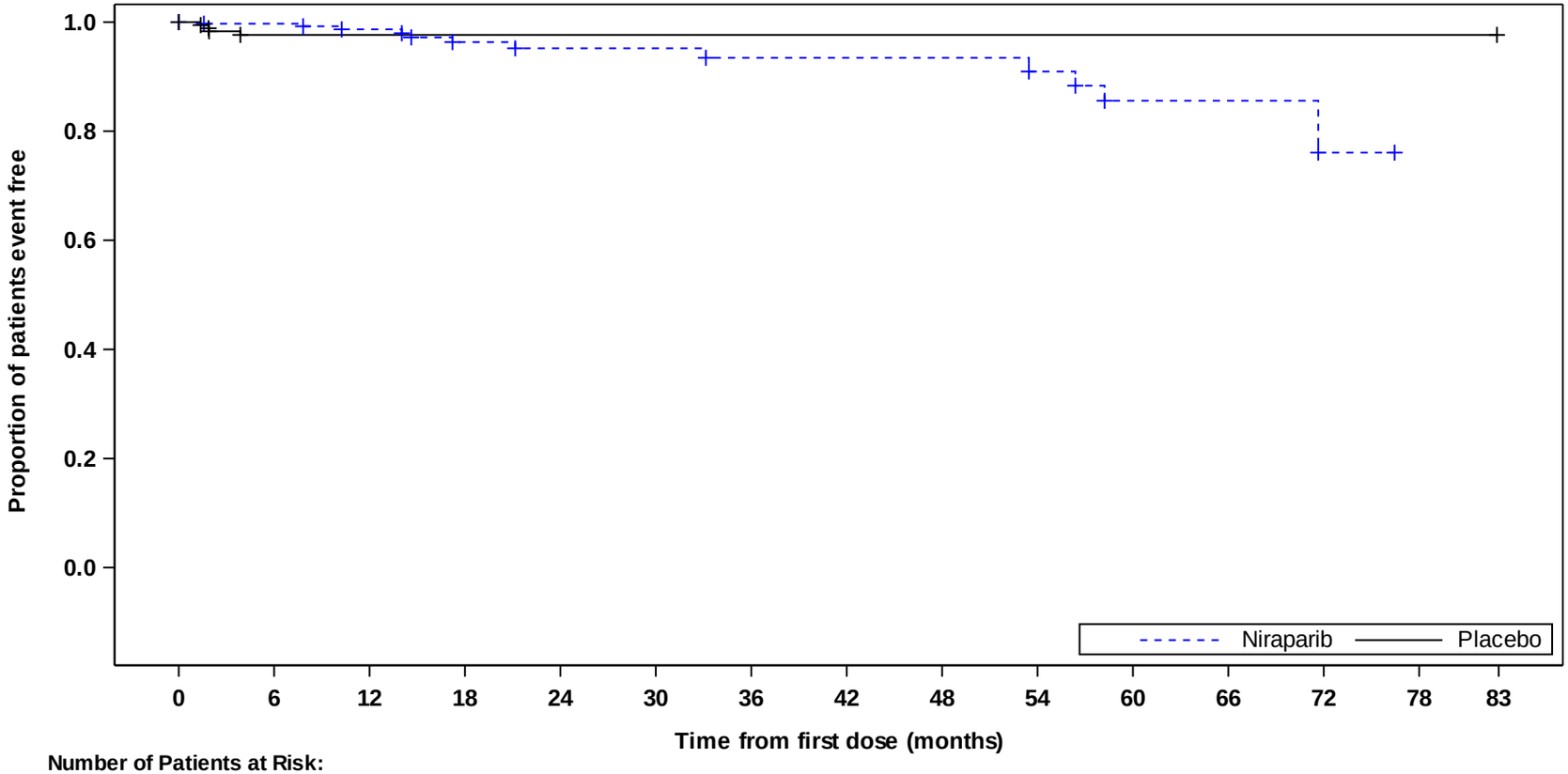
Niraparib	367	240	158	97	69	60	51	41	38	33	28	21	7	0
Placebo	179	90	36	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:38 Data Extraction Date: 01OCT2020

Figure 3.22.1

Time to Onset of First Occurence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)



Number of Patients at Risk:

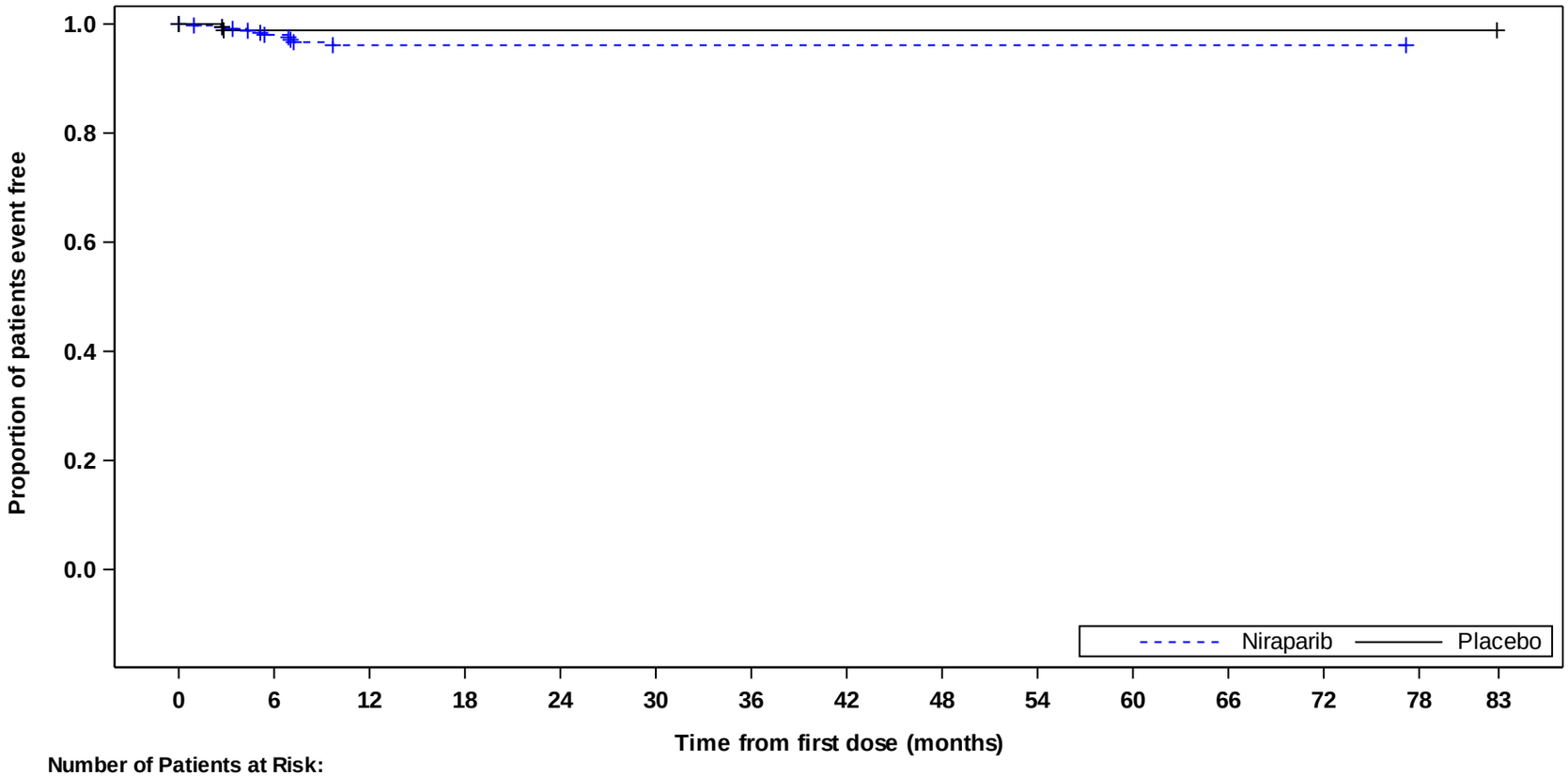
Niraparib	367	248	164	102	71	62	53	43	40	35	29	22	6	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:38 Data Extraction Date: 01OCT2020

Figure 3.22.1

Time to Onset of First Occurence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT

SOC: Respiratory, thoracic and mediastinal disorders



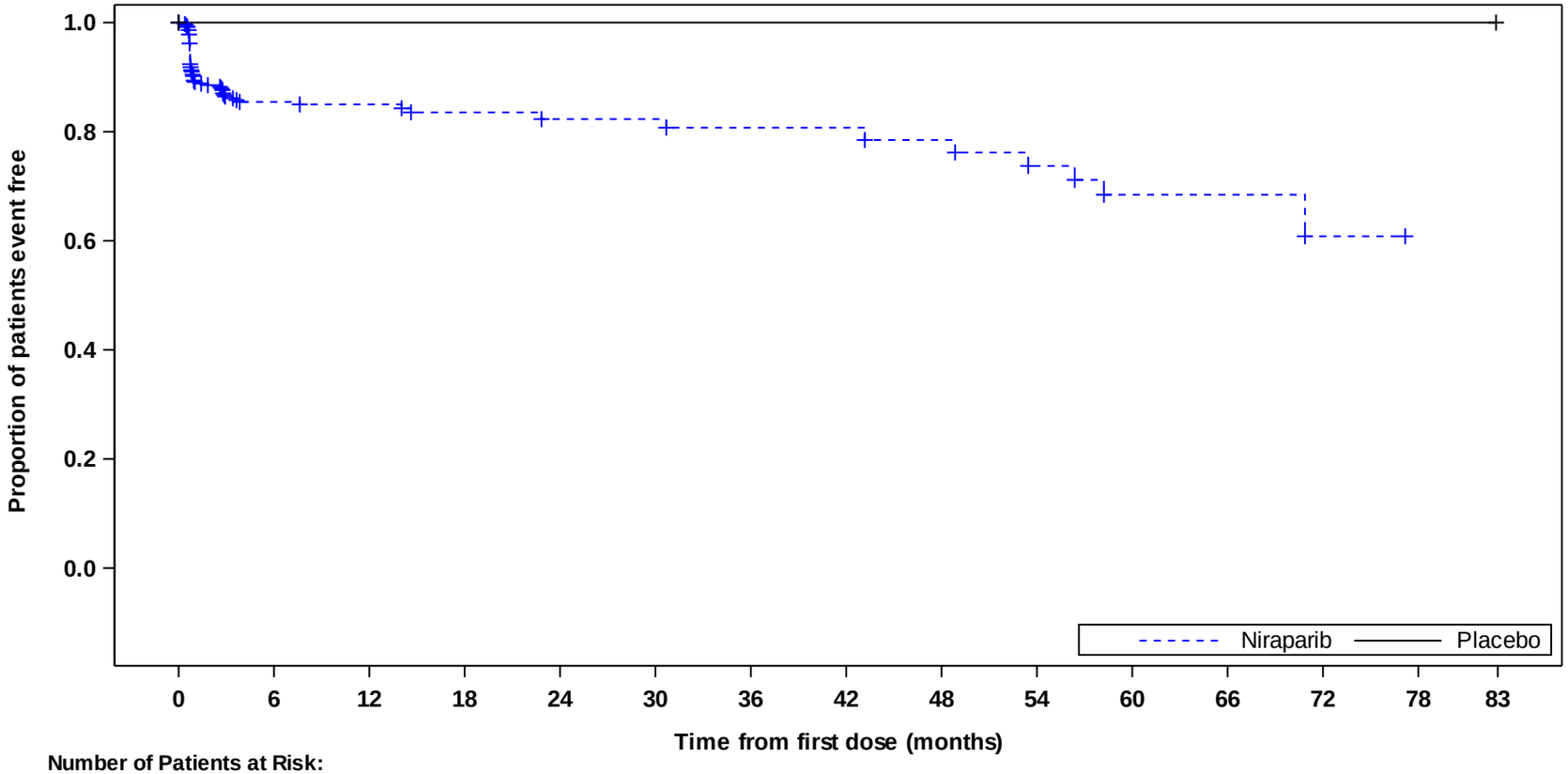
Number of Patients at Risk:

Niraparib	367	243	159	100	70	60	51	41	38	33	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-socpt.sas
Rundate: 20JAN2021:17:25:39 Data Extraction Date: 01OCT2020

Figure 3.24.1
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest

Overall



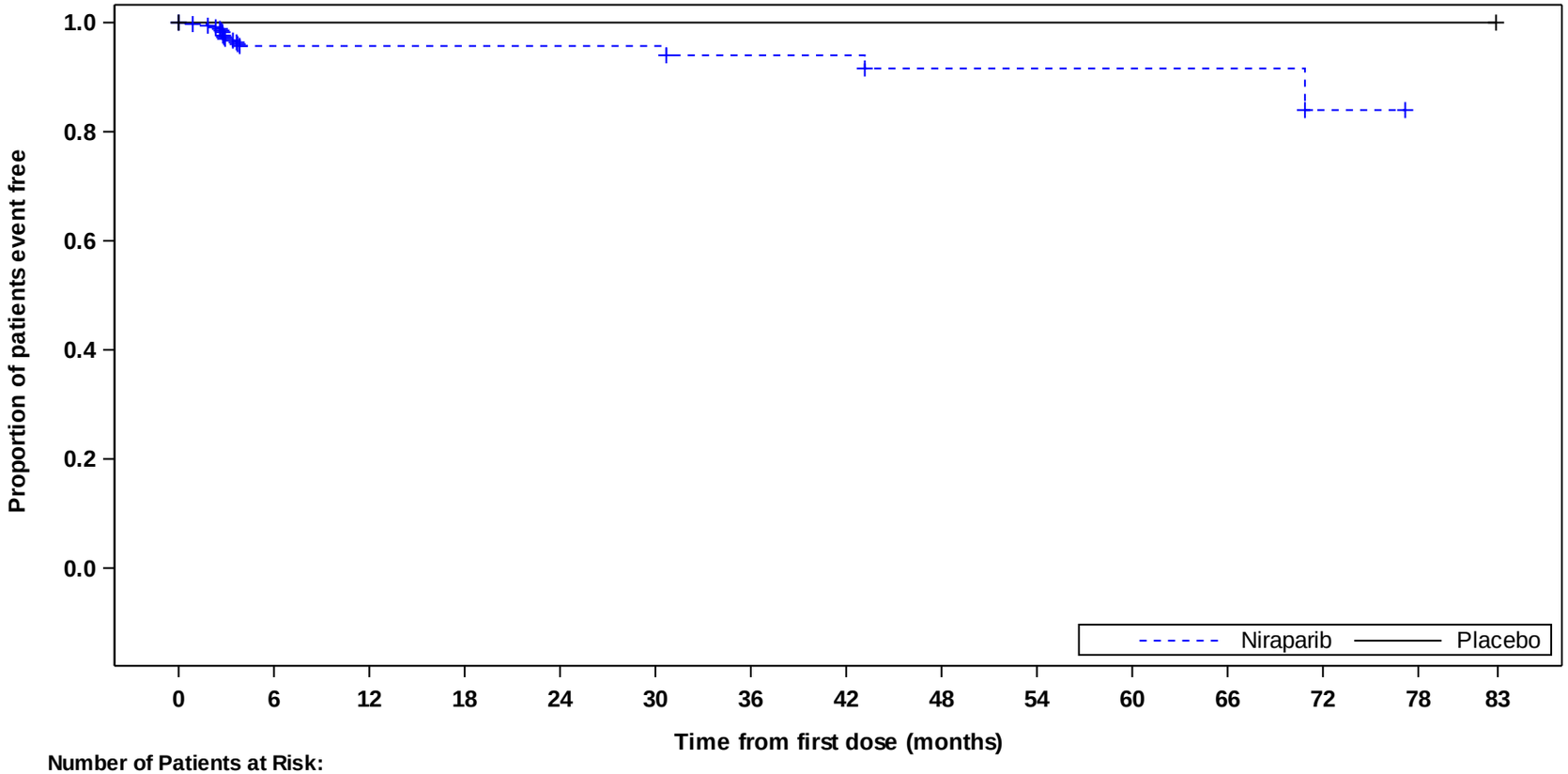
Number of Patients at Risk:

Niraparib	367	218	145	90	64	55	47	37	34	29	23	16	5	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:42 Data Extraction Date: 01OCT2020

Figure 3.24.1
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest

Anemia



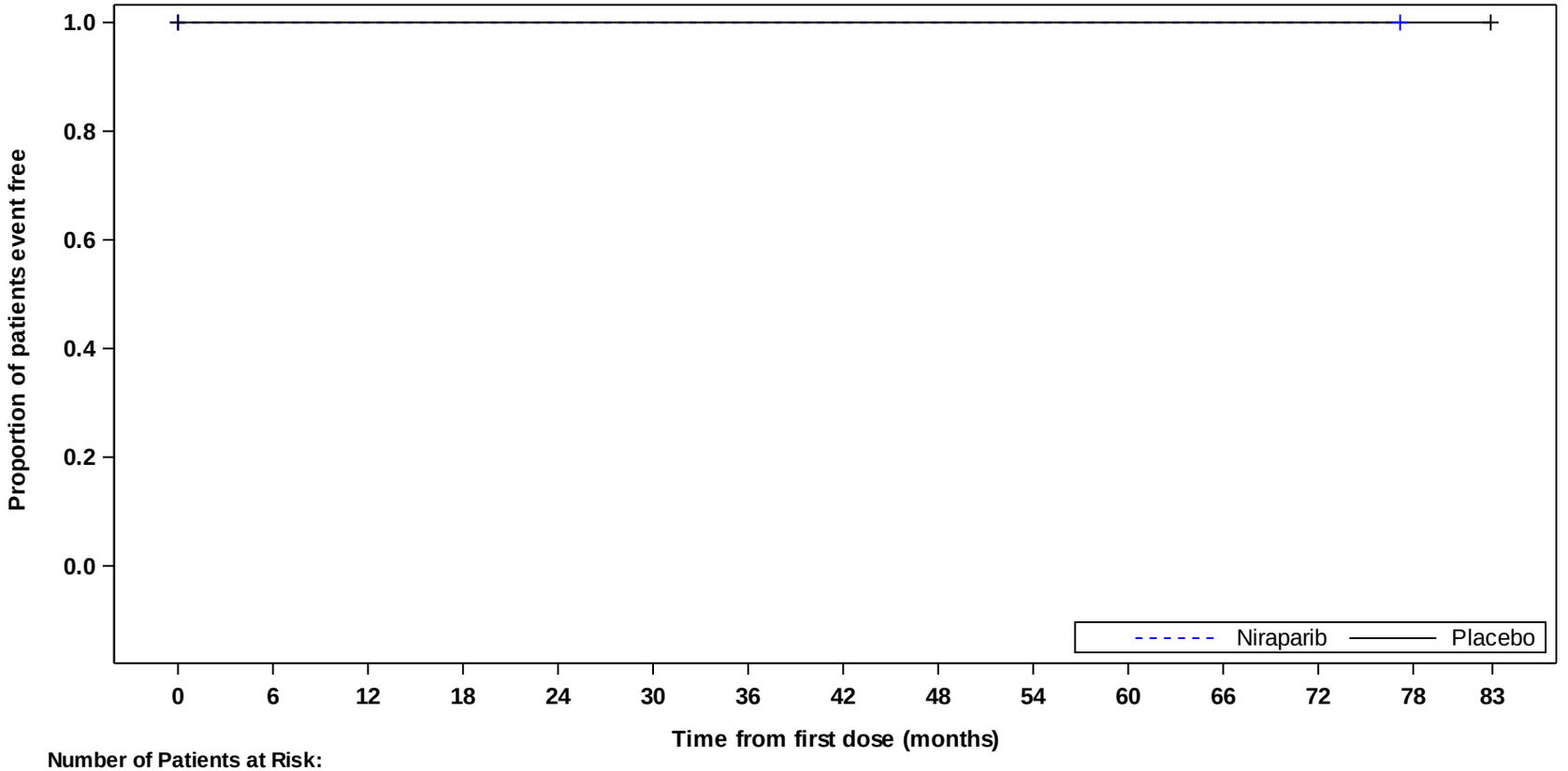
Number of Patients at Risk:

Niraparib	367	237	158	99	69	59	50	40	37	32	27	20	6	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:43 Data Extraction Date: 01OCT2020

Figure 3.24.1
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest

Fatigue



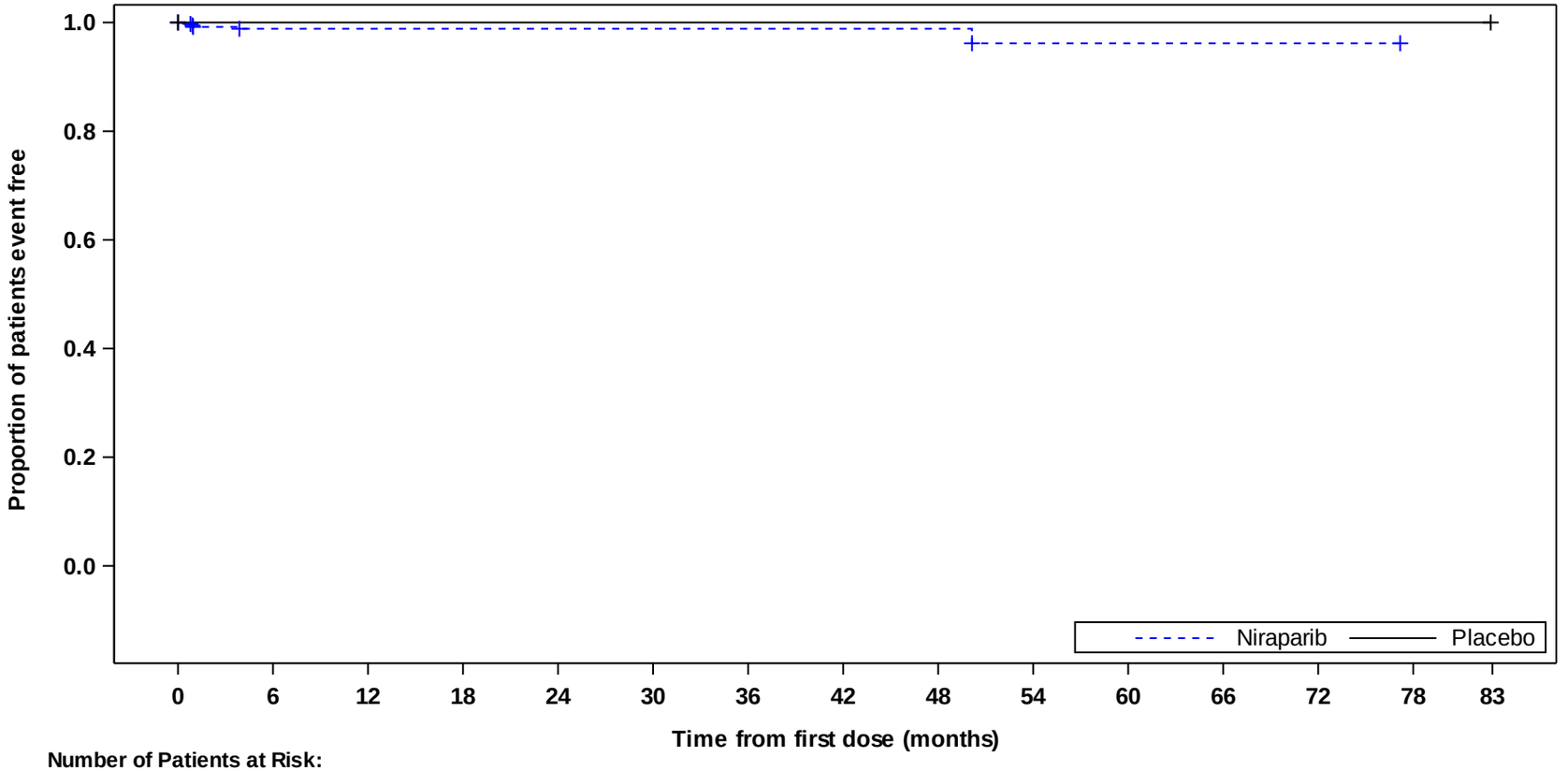
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:43 Data Extraction Date: 01OCT2020

Figure 3.24.1
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest

Leukopenia



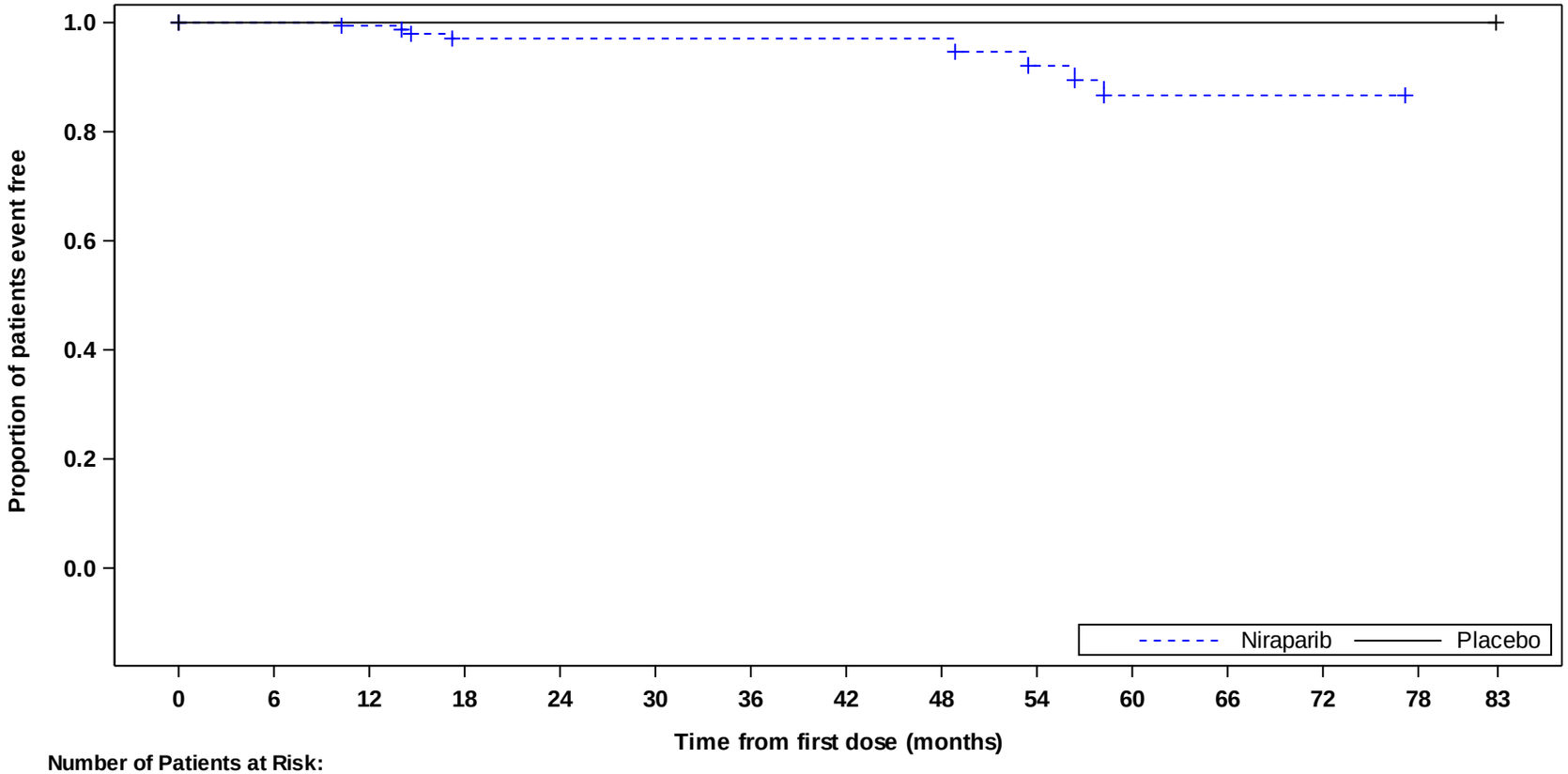
Number of Patients at Risk:

Niraparib	367	244	159	99	69	59	51	41	38	33	28	21	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:44 Data Extraction Date: 01OCT2020

Figure 3.24.1
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest

MDS/AML



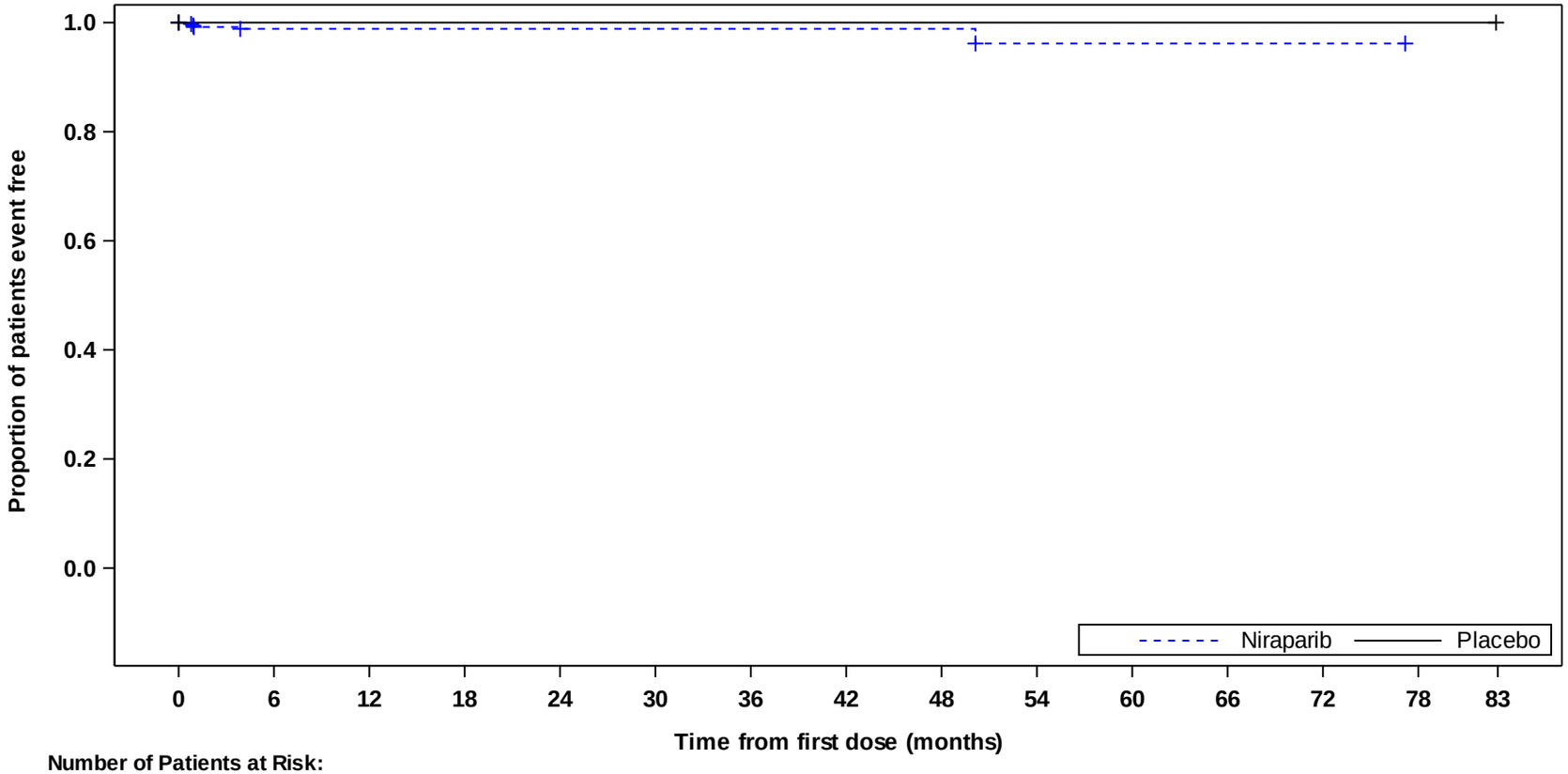
Number of Patients at Risk:

Niraparib	367	248	164	102	72	62	53	43	40	35	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:45 Data Extraction Date: 01OCT2020

Figure 3.24.1
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest

Neutropenia



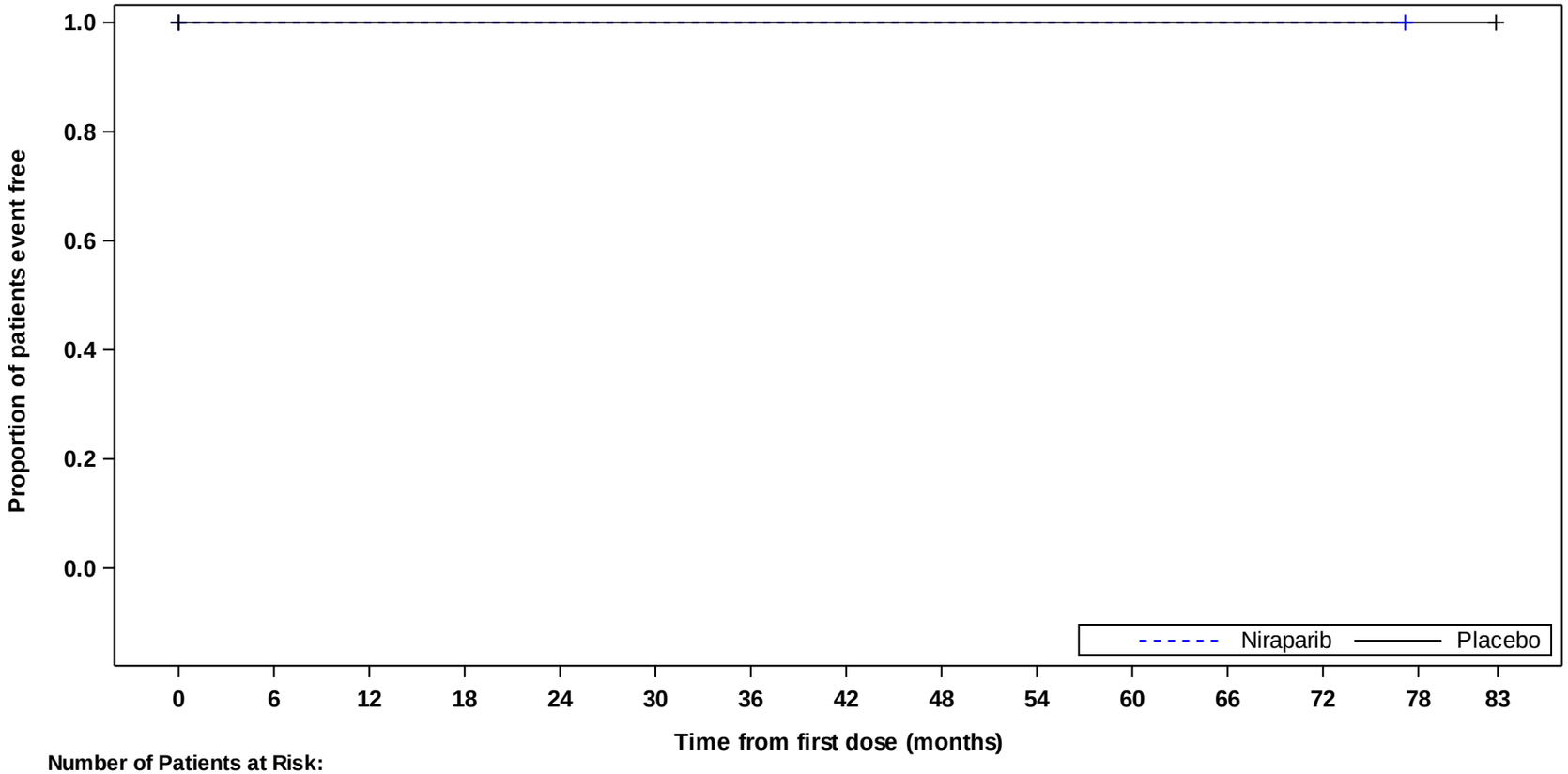
Number of Patients at Risk:

Niraparib	367	244	159	99	69	59	51	41	38	33	28	21	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:46 Data Extraction Date: 01OCT2020

Figure 3.24.1
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest

Overdose



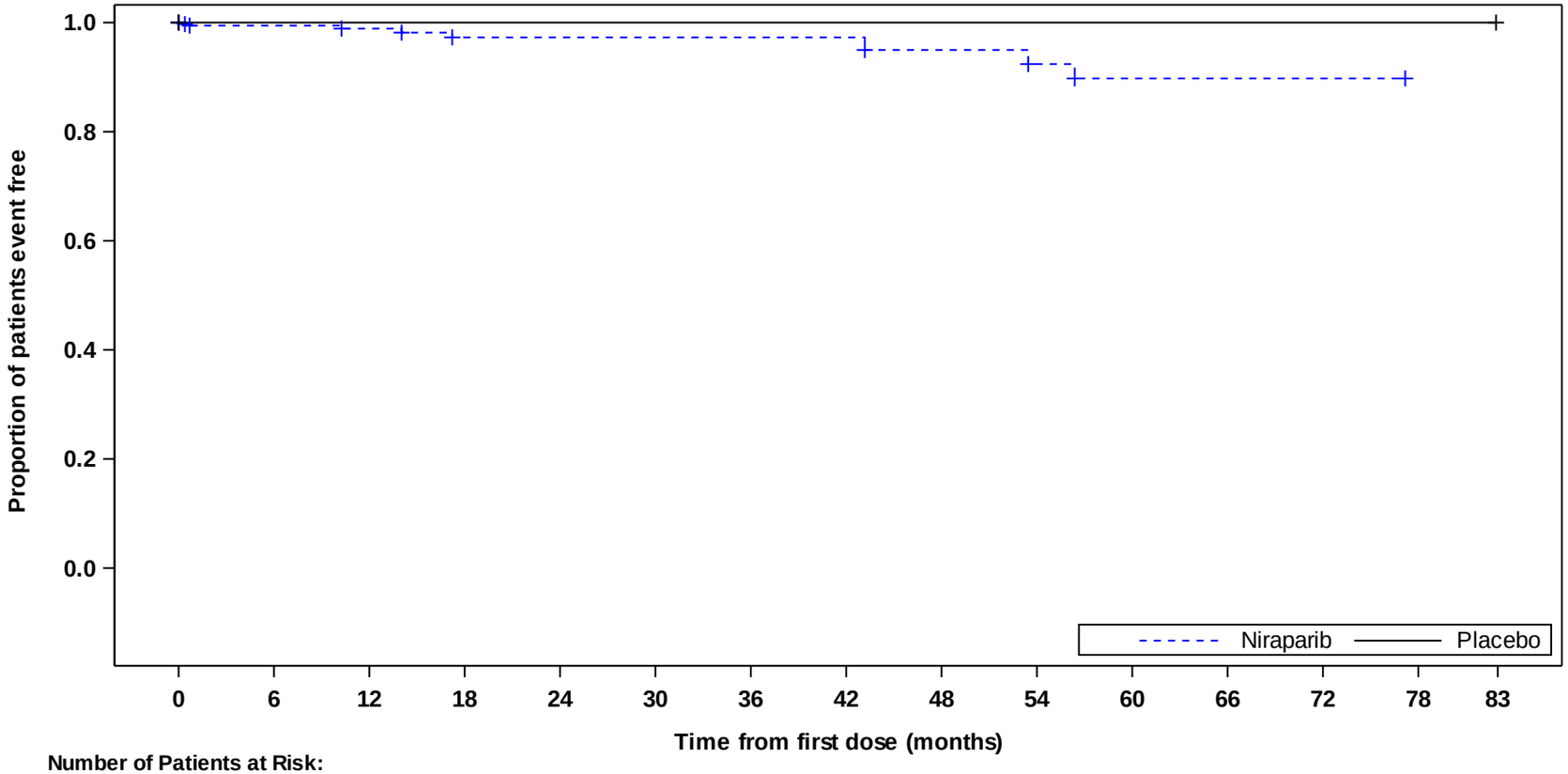
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:46 Data Extraction Date: 01OCT2020

Figure 3.24.1
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest

Pancytopenia



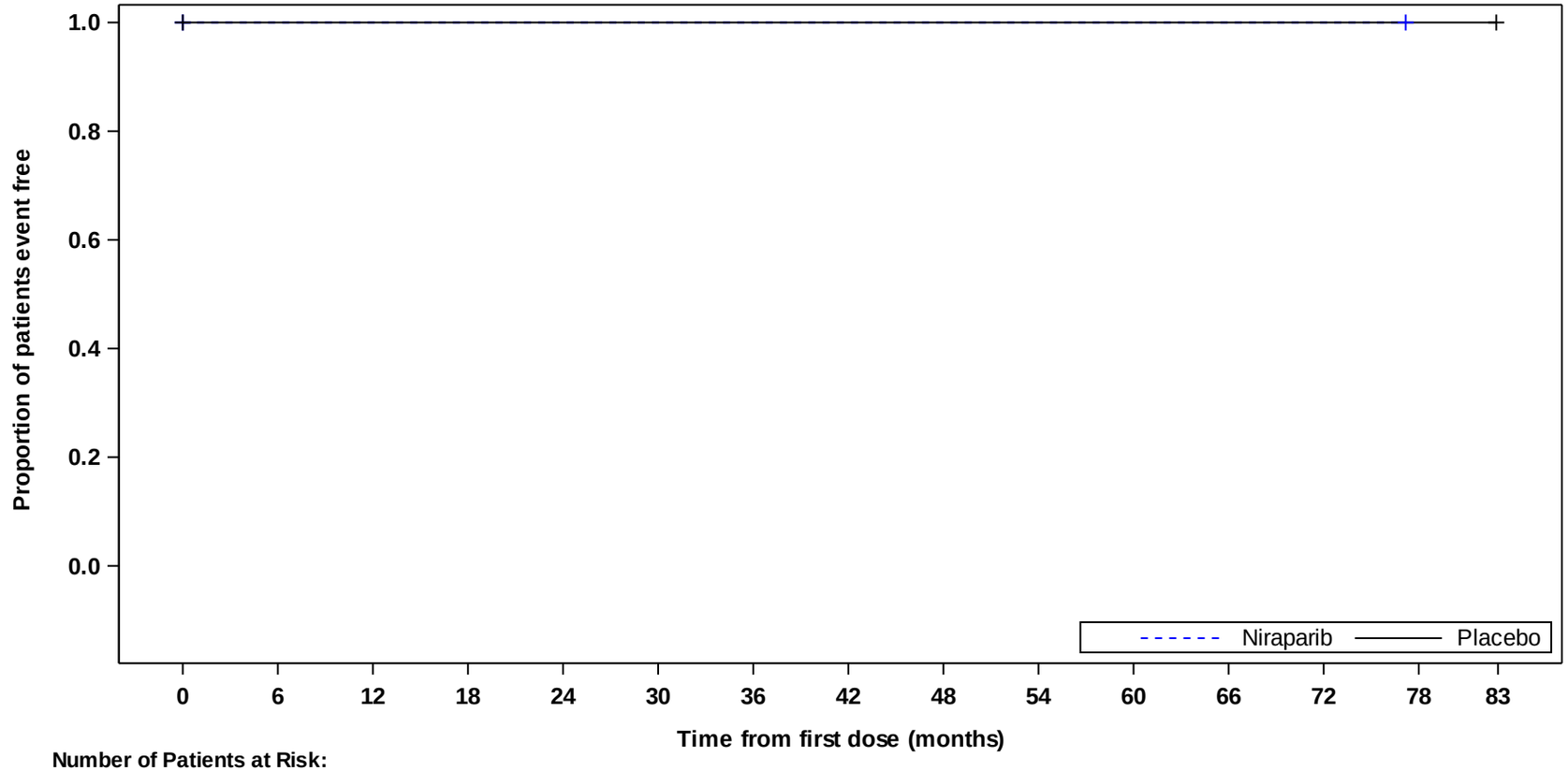
Number of Patients at Risk:

Niraparib	367	248	164	102	72	62	53	43	40	35	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:47 Data Extraction Date: 01OCT2020

Figure 3.24.1
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest

Pneumonitis



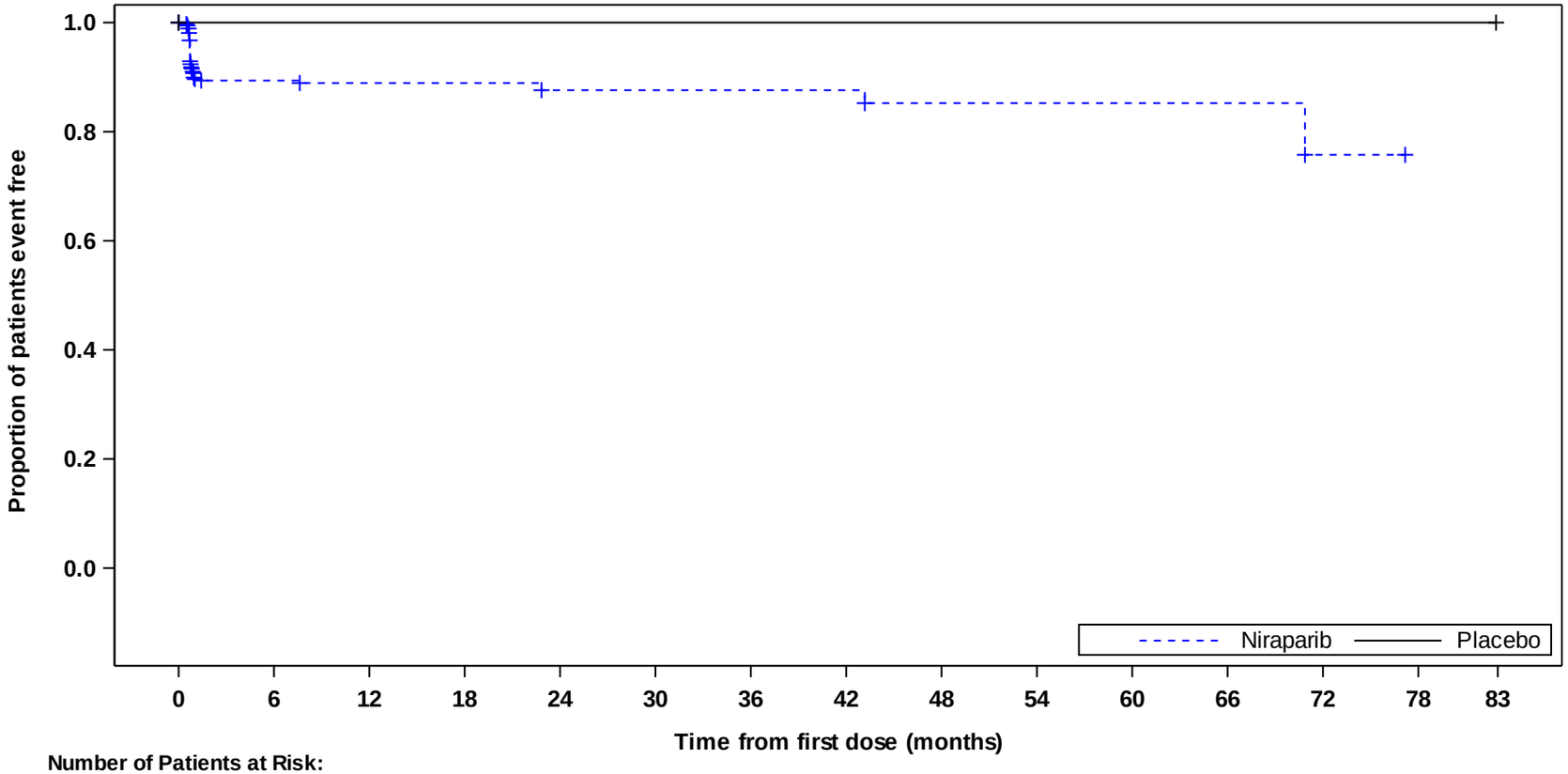
Number of Patients at Risk:

Niraparib	367	247	162	101	71	61	52	42	39	34	29	22	7	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:48 Data Extraction Date: 01OCT2020

Figure 3.24.1
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest

Thrombocytopenia



Number of Patients at Risk:

Niraparib	367	226	147	90	64	55	48	38	35	30	25	18	5	0
Placebo	179	92	37	16	10	9	9	8	7	6	6	6	3	1

PROGRAM NAME: T:\Common\Clinical Operations\Programming\Niraparib\5011 (NOVA)\GVD\Program\Figures\f-aette-aesi.sas
Rundate: 20JAN2021:17:21:48 Data Extraction Date: 01OCT2020