

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Inavolisib (Itovebi®)

Roche Pharma AG

Modul 4 A, Anhang 4-G

Vollständige Darstellung der für das
vorliegende Dossier relevanten
Ergebnisse in unveränderter Form

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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.1 Gesamtüberleben (OS)

Time to Event Summary for Overall Survival, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Patients with event (%)	72 (44.7%)	82 (50%)
Earliest contributing event		
Death	72 (100%)	82 (100%)
Patients without event (%)	89 (55.3%)	82 (50%)
Time to Event (months)		
Median	34.0	27.0
95% CI	(28.4, 44.8)	(22.8, 38.7)
25% and 75%-ile	17.8, 50.9	13.0, 50.0
Range (censored)	0.0 to 52.3	2.1 to 53.9
Range (event)	0.1 to 50.9	0.1 to 50.0
Stratified Analysis		
p-value (log-rank)	0.0190	
Hazard Ratio	0.67	
95% CI	(0.48, 0.94)	
Unstratified Analysis		
p-value (log-rank)	0.0846	
Hazard Ratio	0.76	
95% CI	(0.55, 1.04)	
6 months		
Patients remaining at risk	149	142
Event Free Rate (%)	96.84	90.11
95% CI	(92.58, 98.67)	(84.37, 93.82)
Difference in Event Free Rate	6.73	
95% CI	(1.38, 12.08)	
p-value (Z-test)	0.0136	
12 months		
Patients remaining at risk	131	119
Event Free Rate (%)	86.98	76.71
95% CI	(80.54, 91.40)	(69.32, 82.55)
Difference in Event Free Rate	10.27	
95% CI	(1.80, 18.73)	
p-value (Z-test)	0.0175	
18 months		
Patients remaining at risk	99	90
Event Free Rate (%)	74.33	67.18
95% CI	(66.44, 80.64)	(59.15, 73.99)
Difference in Event Free Rate	7.15	
95% CI	(-3.11, 17.40)	
p-value (Z-test)	0.1718	
24 months		
Patients remaining at risk	78	63
Event Free Rate (%)	65.78	56.25
95% CI	(57.28, 72.99)	(47.58, 64.05)
Difference in Event Free Rate	9.52	
95% CI	(-1.89, 20.93)	
p-value (Z-test)	0.1020	

Summaries of OS (median, percentiles) are Kaplan-Meier estimates. 95% CI for median was computed using the method of Brookmeyer and Crowley. Hazard ratios were estimated by Cox regression. Hazard ratios and log-rank p-values are using stratified methods by stratifying Visceral Disease, Endocrine Resistance, and Region. One patient was not included in the Overall Survival (OS) events due to an incomplete death date.

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: <https://code.roche.com/studies/clinicalreporting/>

W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:30 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/
t_ef_tte_OS_FAS_15NOV2024_41554.out

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Time to Event Summary for Overall Survival, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
30 months		
Patients remaining at risk	54	42
Event Free Rate (%)	56.54	46.29
95% CI	(47.49, 64.63)	(37.27, 54.82)
Difference in Event Free Rate	10.25	
95% CI	(-2.09, 22.59)	
p-value (Z-test)	0.1034	

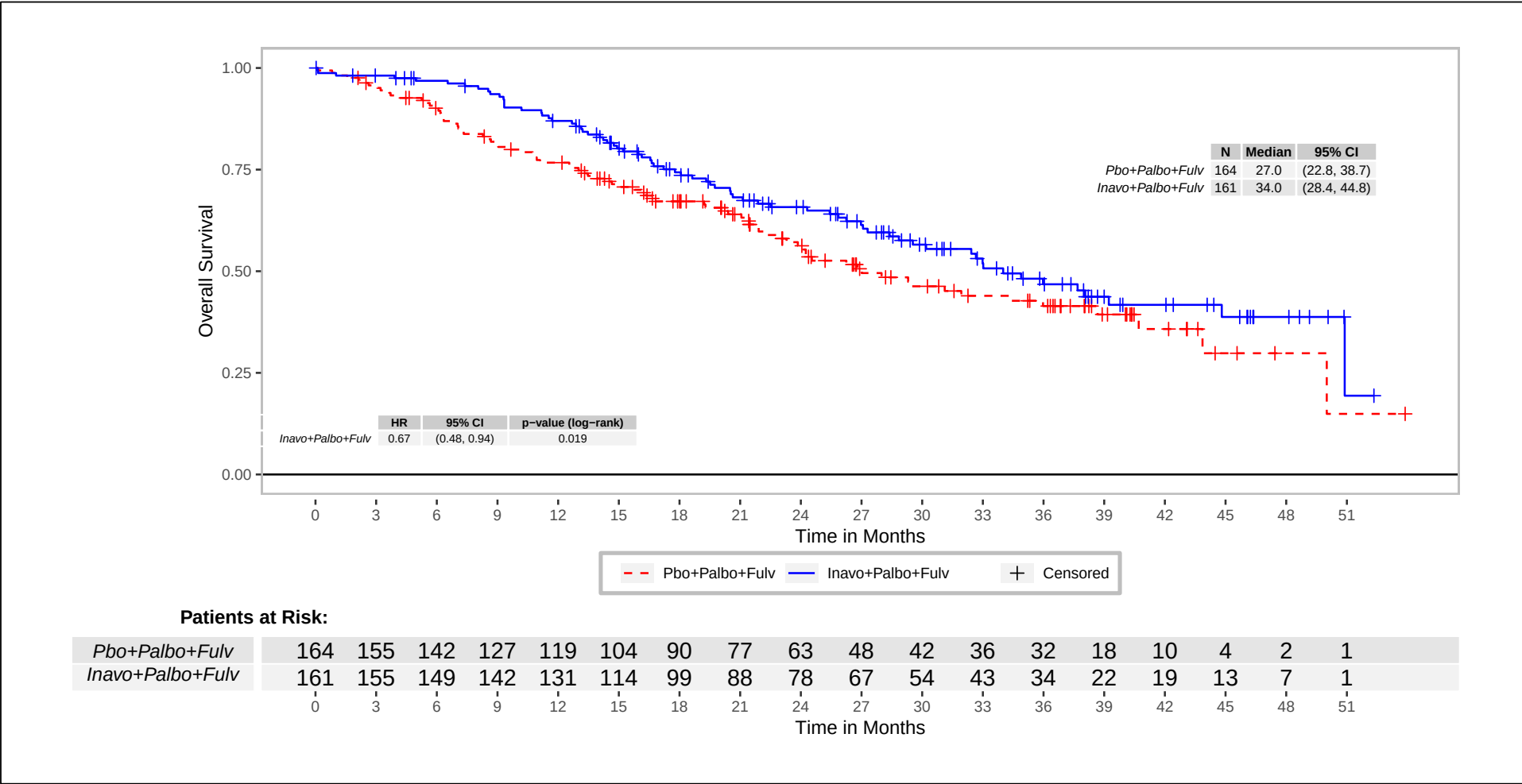
Summaries of OS (median, percentiles) are Kaplan-Meier estimates. 95% CI for median was computed using the method of Brookmeyer and Crowley. Hazard ratios were estimated by Cox regression. Hazard ratios and log-rank p-values are using stratified methods by stratifying Visceral Disease, Endocrine Resistance, and Region. One patient was not included in the Overall Survival (OS) events due to an incomplete death date.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan–Meier Plot for Overall Survival, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



One patient was not included in the Overall Survival (OS) events due to an incomplete death date.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_Overall_Survival_Reporting_Event_8219953
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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.1 Gesamtüberleben (OS)

1.1.1 Subgruppenanalysen Gesamtüberleben (OS)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Efficacy), Overall Survival, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)	
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI					
Overall Survival																
All Patients	325	164	82	50.0	27.01	(22.83, 38.67)	161	72	44.7	34.00	(28.39, 44.81)	0.76	(0.55, 1.04)	0.0846	NE	
Age group (years)																
<65	266	130	68	52.3	26.81	(22.28, 35.98)	136	59	43.4	35.98	(29.54, NA)	0.65	(0.46, 0.92)	0.0150	0.0333	
>=65	59	34	14	41.2	NE	(16.62, NA)	25	13	52.0	14.42	(9.10, NA)	1.65	(0.77, 3.51)	0.1912	0.0333	
Sex																
F	319	163	82	50.3	27.01	(22.83, 35.98)	156	70	44.9	33.02	(27.07, 44.81)	0.76	(0.55, 1.05)	0.0930	0.2839	
M	6	1	0	0.0	NE	NE	5	2	40.0	38.01	(28.85, NA)	>999.99	(0.00, >999.99)	0.4452	0.2839	
Region																
ASIA	120	62	29	46.8	27.01	(20.11, NA)	58	26	44.8	32.66	(20.53, NA)	0.78	(0.45, 1.34)	0.3614	0.2488	
NORTH AMERICA/WESTERN EUROPE	127	64	29	45.3	29.31	(24.11, NA)	63	28	44.4	30.19	(26.25, NA)	0.95	(0.56, 1.59)	0.8345	0.2488	
OTHER	78	38	24	63.2	16.62	(9.03, 38.67)	40	18	45.0	35.98	(27.07, NA)	0.53	(0.28, 0.98)	0.0401	0.2488	
Visceral disease (per eCRF)																
N	65	36	12	33.3	40.71	(26.25, NA)	29	11	37.9	38.01	(27.30, NA)	1.06	(0.46, 2.46)	0.8891	0.3985	
Y	260	128	70	54.7	24.11	(20.40, 31.11)	132	61	46.2	32.99	(26.97, 44.81)	0.70	(0.50, 0.99)	0.0439	0.3985	
Ethnicity																
HISPANIC OR LATINO	20	10	3	30.0	NE	(6.34, NA)	10	2	20.0	38.01	(12.88, NA)	0.82	(0.13, 5.00)	0.8299	0.2291	
NOT HISPANIC OR LATINO	294	149	78	52.3	26.81	(21.82, 34.30)	145	67	46.2	33.02	(28.39, 44.81)	0.71	(0.51, 0.98)	0.0373	0.2291	
NOT REPORTED	5	3	1	33.3	24.25	(24.25, NA)	2	1	50.0	22.51	NE	>999.99	(0.00, >999.99)	0.1573	0.2291	
UNKNOWN	6	2	0	0.0	NE	NE	4	2	50.0	13.21	(7.39, NA)	>999.99	(0.00, >999.99)	0.2253	0.2291	
Race																
Asian	124	63	29	46.0	27.01	(21.45, NA)	61	26	42.6	44.81	(21.13, NA)	0.76	(0.44, 1.30)	0.3100	0.5275	
Black or African American	2	1	0	0.0	NE	NE	1	1	100.0	15.21	NE	>999.99	(0.00, >999.99)	0.3173	0.5275	
White	191	97	52	53.6	26.81	(21.06, 38.67)	94	43	45.7	34.00	(28.39, NA)	0.73	(0.49, 1.09)	0.1231	0.5275	
Unknown	8	3	1	33.3	24.25	(24.25, NA)	5	2	40.0	25.43	(7.39, NA)	1.36	(0.12, 15.33)	0.8043	0.5275	
Liver Metastasis at Enrollment																
N	157	73	29	39.7	35.98	(26.25, NA)	84	33	39.3	38.01	(32.43, NA)	0.87	(0.53, 1.44)	0.5924	0.4971	
Y	168	91	53	58.2	21.91	(14.65, 31.11)	77	39	50.6	28.85	(19.52, 39.23)	0.72	(0.48, 1.10)	0.1253	0.4971	
Number Metastatic Organs at Enrollment																
1	53	32	11	34.4	31.93	(24.54, NA)	21	6	28.6	NE	(32.66, NA)	0.77	(0.28, 2.10)	0.6107	0.4329	
2	104	46	26	56.5	24.11	(19.29, NA)	58	22	37.9	44.81	(27.30, NA)	0.51	(0.28, 0.90)	0.0190	0.4329	
>=3	168	86	45	52.3	24.25	(16.33, 38.67)	82	44	53.7	28.85	(20.50, 35.98)	0.86	(0.57, 1.30)	0.4699	0.4329	
ECOG Performance Status at Baseline																
0	206	106	48	45.3	35.98	(22.83, NA)	100	40	40.0	39.23	(30.19, NA)	0.69	(0.45, 1.05)	0.0845	0.5395	
1	118	58	34	58.6	26.81	(19.22, 31.11)	60	32	53.3	27.07	(16.56, 38.01)	0.85	(0.52, 1.38)	0.5016	0.5395	
Endocrine Resistance (per eCRF)																

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Primary	112	58	34	58.6	22.83	(13.01, 26.81)	54	29	53.7	25.86	(19.52, 38.01)	0.69	(0.42, 1.14)	0.1441	0.7390
Secondary	212	105	48	45.7	34.30	(24.11, 43.86)	107	43	40.2	37.68	(30.19, NA)	0.77	(0.51, 1.16)	0.2096	0.7390
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	27	51.9	23.85	(19.29, 35.98)	52	23	44.2	32.66	(25.43, 44.81)	0.67	(0.38, 1.19)	0.1691	0.7013
POST-MENOPAUSAL	215	111	55	49.5	27.99	(21.91, 43.86)	104	47	45.2	34.00	(25.86, NA)	0.81	(0.55, 1.19)	0.2799	0.7013
Hormone receptor status															
ER+/PR-	90	45	21	46.7	38.67	(21.06, NA)	45	25	55.6	25.86	(19.75, 35.98)	1.16	(0.65, 2.08)	0.6177	0.0238
ER+/PR+	226	113	61	54.0	24.54	(21.39, 31.93)	113	45	39.8	39.23	(29.54, NA)	0.60	(0.41, 0.88)	0.0084	0.0238
Other	9	6	0	0.0	NE	NE	3	2	66.7	32.99	(1.02, NA)	>999.99	(0.00, >999.99)	0.1336	0.0238
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	6	31.6	NE	(24.11, NA)	18	7	38.9	NE	(9.30, NA)	1.15	(0.38, 3.44)	0.8035	0.6134
Aromatase inhibitor only	131	71	42	59.2	24.25	(16.13, 31.93)	60	32	53.3	26.25	(19.75, 33.02)	0.89	(0.56, 1.41)	0.6155	0.6134
Tamoxifen only	155	73	33	45.2	35.98	(22.28, NA)	82	32	39.0	44.81	(32.99, NA)	0.68	(0.42, 1.11)	0.1213	0.6134
Prior (neo)-adjuvant CDK4/6															
N	322	163	82	50.3	27.01	(22.83, 38.67)	159	70	44.0	34.89	(28.85, NA)	0.74	(0.53, 1.01)	0.0592	0.0841
Y	3	1	0	0.0	NE	NE	2	2	100.0	14.05	(12.88, NA)	>999.99	(0.00, >999.99)	0.2253	0.0841
Prior (neo)-adjuvant chemotherapy															
N	56	27	15	55.6	24.25	(12.58, NA)	29	16	55.2	30.19	(19.75, NA)	0.85	(0.42, 1.72)	0.6521	0.6362
Y	269	137	67	48.9	29.31	(22.28, 40.71)	132	56	42.4	34.89	(28.39, NA)	0.72	(0.50, 1.03)	0.0692	0.6362

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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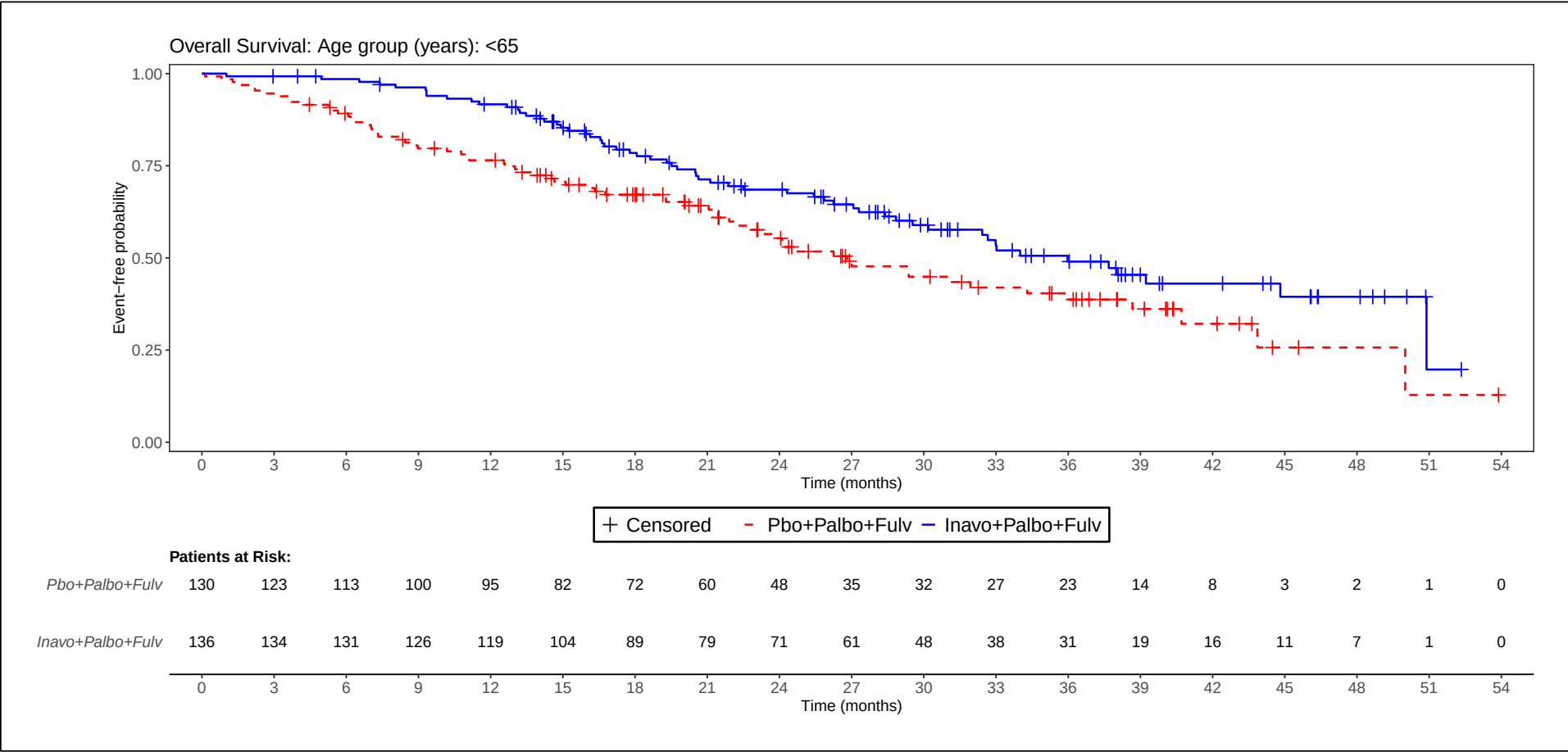
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

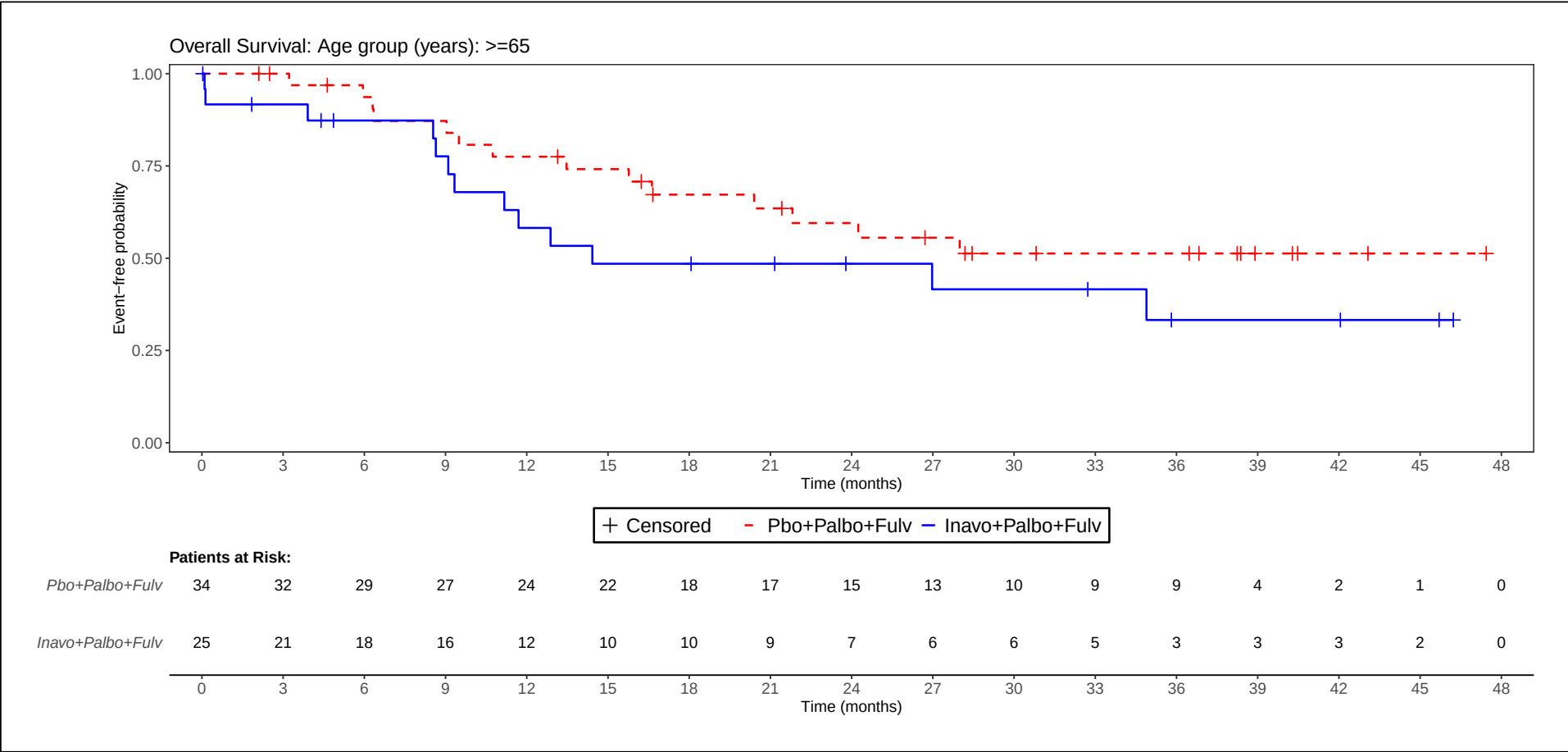
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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18 JUN 2025 17:00 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_km_signsg.R
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Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 0efa981b2a84f5e06c881464de43872934271dc3
18 JUN 2025 17:00 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

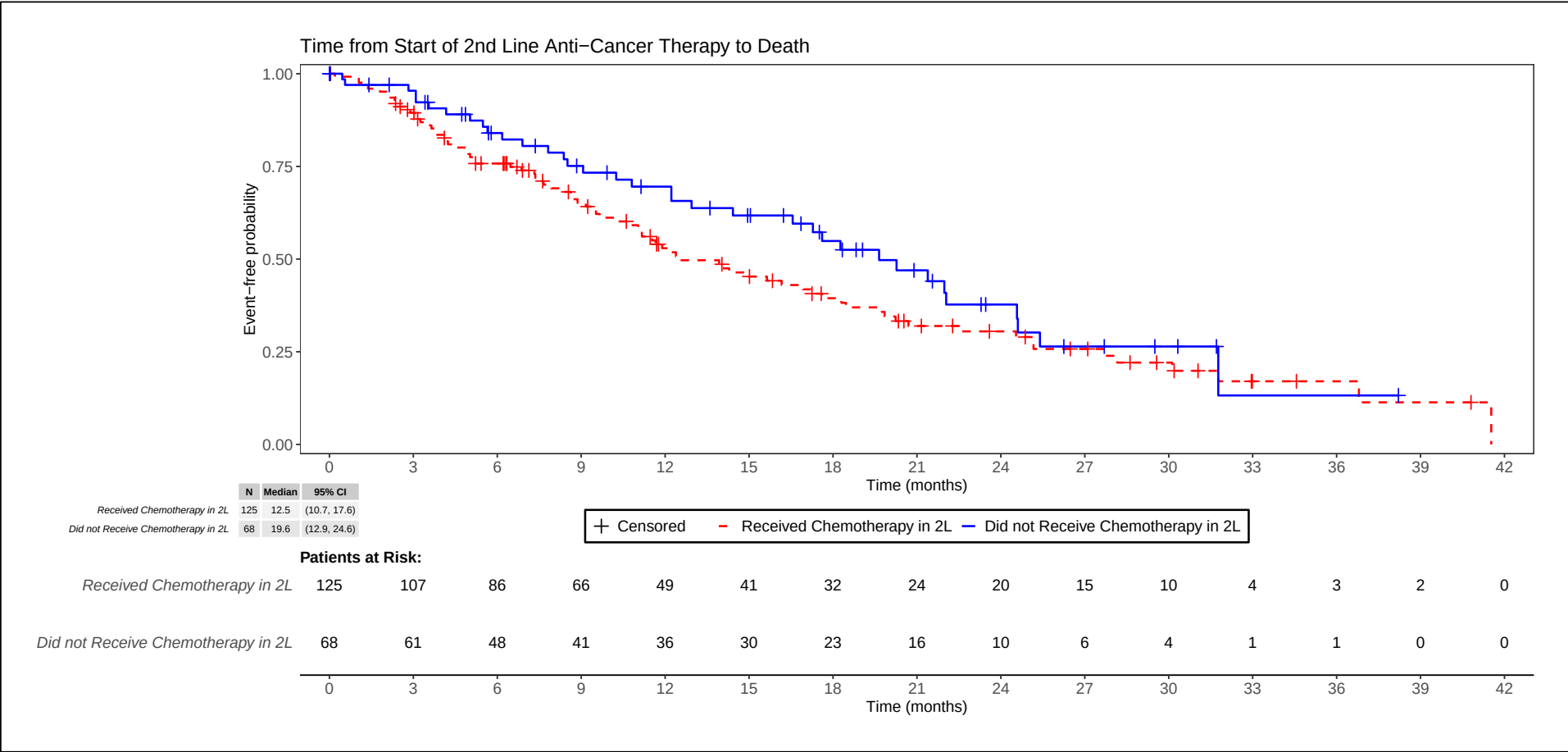
1 Wirksamkeit

1.1 Gesamtüberleben (OS)

1.1.2 Zeit vom Beginn der Zweitlinientherapie bis zum Tod

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Efficacy, Time from Start of 2nd Line Anti-Cancer Therapy to Death, Patients who Received 2L
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.2 Progressionsfreies Überleben (PFS)

Time to Event Summary for Progression-Free Survival by Investigator, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Patients with event (%)	103 (64%)	141 (86%)
Earliest contributing event		
Death	13 (12.6%)	8 (5.7%)
Disease Progression	90 (87.4%)	133 (94.3%)
Patients without event (%)	58 (36%)	23 (14%)
Time to Event (months)		
Median	17.2	7.3
95% CI	(11.6, 22.2)	(5.9, 9.2)
25% and 75%-ile	8.0, 42.1	3.2, 14.9
Range (censored)	0.0 to 51.7	7.2 to 52.5
Range (event)	0.1 to 42.1	0.1 to 37.5
Stratified Analysis		
p-value (log-rank)	<0.0001	
Hazard Ratio	0.42	
95% CI	(0.32, 0.55)	
Unstratified Analysis		
p-value (log-rank)	<0.0001	
Hazard Ratio	0.48	
95% CI	(0.37, 0.62)	
6 months		
Patients remaining at risk	129	95
Event Free Rate (%)	83.38	57.93
95% CI	(76.55, 88.37)	(49.99, 65.05)
Difference in Event Free Rate	25.45	
95% CI	(15.90, 35.00)	
p-value (Z-test)	<0.0001	
12 months		
Patients remaining at risk	89	50
Event Free Rate (%)	57.98	31.31
95% CI	(49.79, 65.31)	(24.33, 38.51)
Difference in Event Free Rate	26.67	
95% CI	(16.11, 37.24)	
p-value (Z-test)	<0.0001	
18 months		
Patients remaining at risk	65	30
Event Free Rate (%)	49.65	20.46
95% CI	(41.45, 57.31)	(14.60, 27.03)
Difference in Event Free Rate	29.19	
95% CI	(19.04, 39.33)	
p-value (Z-test)	<0.0001	
24 months		
Patients remaining at risk	46	21
Event Free Rate (%)	41.80	16.69
95% CI	(33.69, 49.70)	(11.27, 23.03)
Difference in Event Free Rate	25.12	
95% CI	(15.11, 35.13)	
p-value (Z-test)	<0.0001	

Summaries of PFS (median, percentiles) are Kaplan-Meier estimates. 95% CI for median was computed using the method of Brookmeyer and Crowley. Hazard ratios were estimated by Cox regression. Hazard ratios and log-rank p-values are using stratified methods by stratifying Visceral Disease, Endocrine Resistance, and Region.

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: <https://code.roche.com/studies/clinicalreporting/>

W041554_Overall_Survival_Reporting_Event_8219953

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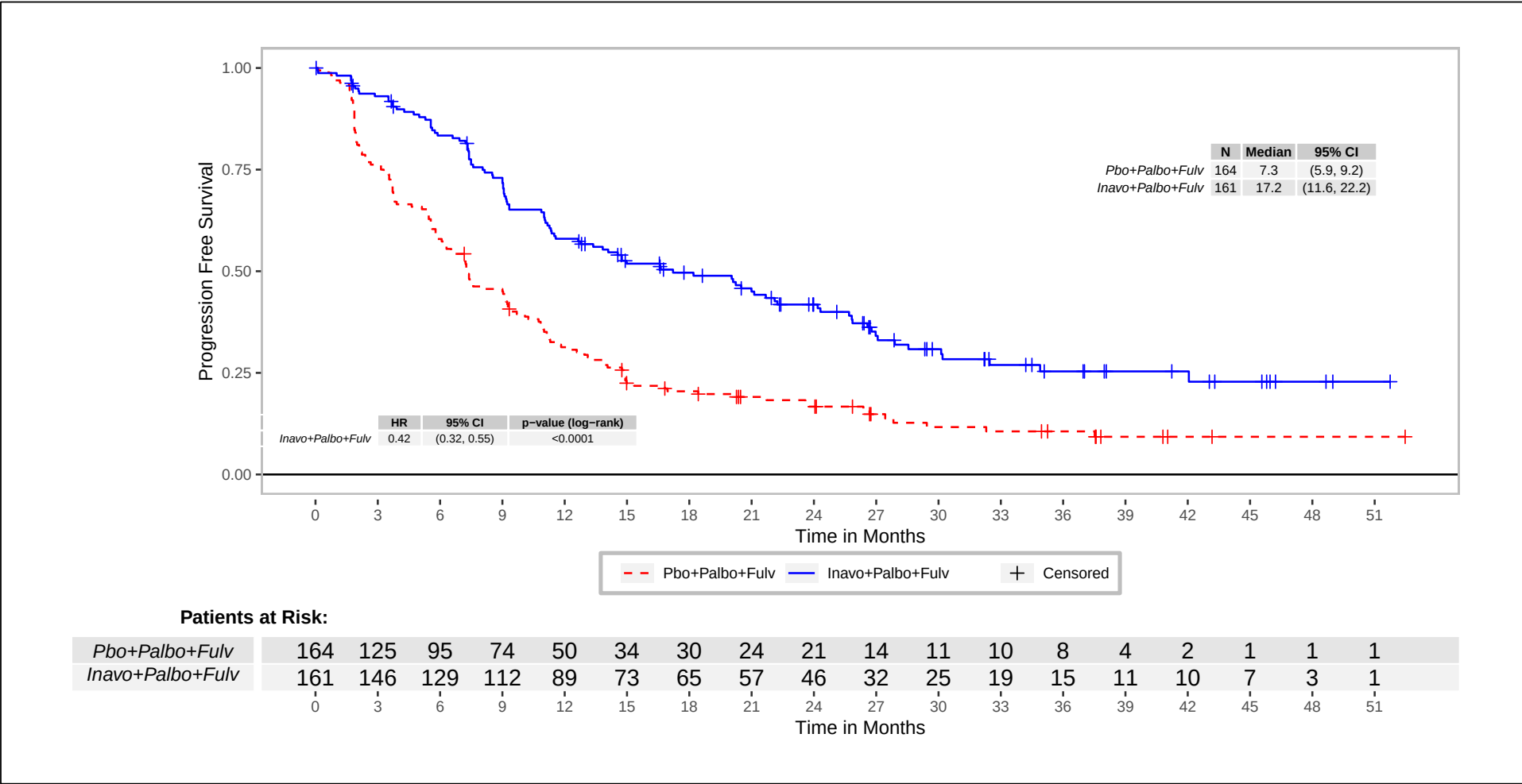
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t_ef_tte_PFS_FAS_15NOV2024_41554.out

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan–Meier Plot for Progression–Free Survival Assessed by Investigator, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_Overall_Survival_Reporting_Event_8219953
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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.2 Progressionsfreies Überleben (PFS)

1.2.1 Subgruppenanalyse Progressionsfreies Überleben (PFS)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Efficacy), Time to Event Summary for Progression-Free Survival by Investigator, Full Analysis Set
Protocol: WO41554, CCOd: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)	
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI					
Earliest Contributing Event to Progression Free Survival by Investigator																
All Patients	325	164	141	86.0	7.29	(5.88, 9.17)	161	103	64.0	17.22	(11.56, 22.24)	0.48	(0.37, 0.62)	<0.0001	NE	
Age group (years)																
<65	266	130	113	86.9	7.29	(5.78, 9.17)	136	85	62.5	18.20	(12.65, 24.31)	0.43	(0.32, 0.57)	<0.0001	0.0632	
>=65	59	34	28	82.4	8.25	(5.42, 14.98)	25	18	72.0	14.09	(4.27, 26.97)	0.81	(0.44, 1.46)	0.4771	0.0632	
Sex																
F	319	163	141	86.5	7.29	(5.88, 9.17)	156	100	64.1	16.62	(11.37, 22.11)	0.48	(0.37, 0.63)	<0.0001	0.1090	
M	6	1	0	0.0	NE	NE	5	3	60.0	32.46	(16.59, NA)	>999.99	(0.00, >999.99)	0.3113	0.1090	
Region																
ASIA	120	62	55	88.7	6.78	(5.42, 9.17)	58	37	63.8	14.75	(9.33, 21.13)	0.44	(0.29, 0.67)	<0.0001	0.4698	
NORTH AMERICA/WESTERN EUROPE	127	64	55	85.9	9.26	(7.20, 13.11)	63	40	63.5	16.59	(9.03, 25.86)	0.58	(0.39, 0.87)	0.0085	0.4698	
OTHER	78	38	31	81.6	5.93	(3.15, 9.13)	40	26	65.0	25.69	(11.50, 34.89)	0.43	(0.25, 0.73)	0.0012	0.4698	
Visceral disease (per eCRF)																
N	65	36	27	75.0	7.43	(6.08, 14.06)	29	15	51.7	24.31	(11.27, NA)	0.48	(0.25, 0.90)	0.0199	0.9317	
Y	260	128	114	89.1	7.23	(5.55, 9.17)	132	88	66.7	14.75	(11.33, 20.99)	0.48	(0.36, 0.63)	<0.0001	0.9317	
Ethnicity																
HISPANIC OR LATINO	20	10	9	90.0	10.22	(1.84, 29.44)	10	3	30.0	24.18	(1.91, NA)	0.35	(0.09, 1.32)	0.1072	0.2420	
NOT HISPANIC OR LATINO	294	149	128	85.9	7.29	(5.78, 9.17)	145	95	65.5	16.62	(11.56, 22.11)	0.47	(0.36, 0.61)	<0.0001	0.2420	
NOT REPORTED	5	3	3	100.0	7.23	(1.61, NA)	2	1	50.0	9.00	NE	0.57	(0.05, 6.33)	0.6419	0.2420	
UNKNOWN	6	2	1	50.0	1.64	(1.64, NA)	4	4	100.0	6.77	(4.99, NA)	1.97	(0.21, 18.35)	0.5458	0.2420	
Race																
Asian	124	63	55	87.3	7.26	(5.45, 9.17)	61	39	63.9	18.20	(9.33, 24.31)	0.46	(0.30, 0.70)	0.0002	0.7279	
Black or African American	2	1	1	100.0	16.82	NE	1	1	100.0	9.03	NE	>999.99	(0.00, >999.99)	0.3173	0.7279	
White	191	97	82	84.5	7.43	(5.78, 10.25)	94	60	63.8	17.22	(11.50, 25.82)	0.50	(0.36, 0.70)	<0.0001	0.7279	
Unknown	8	3	3	100.0	7.23	(1.64, NA)	5	3	60.0	26.58	(4.99, NA)	0.29	(0.05, 1.75)	0.1493	0.7279	
Liver Metastasis at Enrollment																
N	157	73	55	75.3	11.17	(7.26, 14.85)	84	49	58.3	25.69	(20.11, 27.89)	0.56	(0.38, 0.83)	0.0032	0.2350	
Y	168	91	86	94.5	5.62	(3.71, 7.39)	77	54	70.1	11.33	(8.54, 14.75)	0.44	(0.31, 0.62)	<0.0001	0.2350	
Number Metastatic Organs at Enrollment																
1	53	32	25	78.1	10.12	(5.42, 13.11)	21	12	57.1	20.24	(7.59, NA)	0.50	(0.24, 1.01)	0.0497	0.7118	
2	104	46	41	89.1	7.20	(5.45, 9.17)	58	33	56.9	20.50	(11.50, 26.78)	0.41	(0.26, 0.66)	0.0001	0.7118	
>=3	168	86	75	87.2	7.28	(5.45, 9.26)	82	58	70.7	14.75	(9.23, 21.68)	0.53	(0.38, 0.75)	0.0002	0.7118	
ECOG Performance Status at Baseline																
0	206	106	91	85.8	7.39	(6.08, 10.09)	100	60	60.0	20.24	(13.83, 26.58)	0.43	(0.31, 0.60)	<0.0001	0.2770	
1	118	58	50	86.2	7.20	(5.13, 9.69)	60	43	71.7	12.78	(9.07, 24.18)	0.58	(0.39, 0.88)	0.0088	0.2770	

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Endocrine Resistance (per eCRF)															
Primary	112	58	55	94.8	3.79	(2.66, 5.78)	54	41	75.9	12.78	(9.33, 24.18)	0.37	(0.24, 0.56)	<0.0001	0.1694
Secondary	212	105	86	81.9	9.69	(7.39, 11.30)	107	62	57.9	20.24	(13.83, 28.55)	0.52	(0.37, 0.72)	<0.0001	0.1694
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	47	90.4	6.42	(3.75, 9.17)	52	33	63.5	20.04	(11.04, 22.11)	0.38	(0.24, 0.60)	<0.0001	0.3253
POST-MENOPAUSAL	215	111	94	84.7	7.46	(6.08, 10.25)	104	67	64.4	14.98	(11.01, 25.82)	0.53	(0.39, 0.73)	<0.0001	0.3253
Hormone receptor status															
ER+/PR-	90	45	42	93.3	6.54	(5.13, 9.43)	45	32	71.1	12.65	(9.00, 25.86)	0.41	(0.25, 0.67)	0.0002	0.2866
ER+/PR+	226	113	97	85.8	7.43	(5.78, 9.26)	113	69	61.1	20.50	(14.09, 25.69)	0.47	(0.34, 0.64)	<0.0001	0.2866
Other	9	6	2	33.3	NE	(1.94, NA)	3	2	66.7	5.75	(1.02, NA)	2.94	(0.40, 21.44)	0.2664	0.2866
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	13	68.4	14.75	(5.45, 32.30)	18	9	50.0	30.13	(5.29, NA)	0.71	(0.30, 1.67)	0.4338	0.4708
Aromatase inhibitor only	131	71	66	93.0	6.54	(3.81, 9.13)	60	45	75.0	11.27	(9.07, 17.22)	0.55	(0.37, 0.80)	0.0018	0.4708
Tamoxifen only	155	73	61	83.6	7.43	(5.78, 10.97)	82	48	58.5	21.68	(14.75, 27.89)	0.41	(0.28, 0.60)	<0.0001	0.4708
Prior (neo)-adjuvant CDK4/6															
N	322	163	140	85.9	7.29	(5.88, 9.17)	159	101	63.5	18.20	(12.65, 24.18)	0.48	(0.37, 0.62)	<0.0001	0.1352
Y	3	1	1	100.0	14.06	NE	2	2	100.0	5.47	(1.91, NA)	>999.99	(0.00, >999.99)	0.2253	0.1352
Prior (neo)-adjuvant chemotherapy															
N	56	27	21	77.8	9.00	(1.91, 13.17)	29	22	75.9	12.65	(9.03, 25.82)	0.81	(0.44, 1.47)	0.4927	0.0749
Y	269	137	120	87.6	7.26	(5.78, 9.23)	132	81	61.4	18.20	(12.78, 25.69)	0.43	(0.32, 0.57)	<0.0001	0.0749

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.3 Tumoransprechen

1.3.1 Objektive Ansprechrate (ORR)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Objective Response Rate Assessed by Investigator, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Responders	101 (62.7%)	46 (28.0%)
95% CI (Clopper-Pearson)	(54.8, 70.2)	(21.3, 35.6)
Stratified Analysis		
Difference in Response rate (%)	34.7	
95% CI (Wald, without correction)	(24.5, 44.8)	
p-value (Cochran-Mantel-Haenszel Test)	<0.0001	
Complete Response (CR)	6 (3.7%)	1 (0.6%)
95% CI (Clopper-Pearson)	(1.38, 7.93)	(0.02, 3.35)
Partial Response (PR)	95 (59.0%)	45 (27.4%)
95% CI (Clopper-Pearson)	(50.99, 66.68)	(20.77, 34.94)
Stable Disease (SD)	44 (27.3%)	81 (49.4%)
95% CI (Clopper-Pearson)	(20.61, 34.90)	(41.51, 57.30)
Progressive Disease (PD)	9 (5.6%)	35 (21.3%)
95% CI (Clopper-Pearson)	(2.59, 10.35)	(15.34, 28.41)
Missing	7 (4.3%)	2 (1.2%)
95% CI (Clopper-Pearson)	(1.77, 8.75)	(0.15, 4.34)

95% CI for rate was constructed using Clopper-Pearson.

95% CI for difference in rate was constructed using the normal approximation to the binomial distribution (Wald) without continuity correction method.

Strata for CMH test are: Strata Visceral Disease, Endocrine Resistance, and Region.

Objective response rate included patients with a CR or PR on two consecutive occasions ≥ 4 weeks apart per RECIST v1.1.

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: <https://code.roche.com/studies/clinicalreporting/>

W041554_Overall_Survival_Reporting_Event_8219953

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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.3 Tumoransprechen

1.3.2 Dauer des objektiven Ansprechens (DOR)

Time to Event Summary for Duration of Response Assessed by Investigator, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=101)	Pbo+Palbo+Fulv (N=46)
Patients with subsequent event (%)	58 (57.4%)	33 (71.7%)
Earliest contributing event		
Death	6 (10.3%)	0
Disease Progression	52 (89.7%)	33 (100%)
Patients without subsequent event (%)	43 (42.6%)	13 (28.3%)
Time to Event (months)		
Median	19.2	11.1
95% CI	(14.7, 28.3)	(8.5, 20.2)
25% and 75%-ile	7.8, NE	7.4, 28.5
Range (censored)	3.4 to 48.1	5.6 to 41.3
Range (event)	3.2 to 40.2	3.1 to 35.8
Stratified Analysis		
Hazard Ratio	0.60	
95% CI	(0.37, 0.97)	
Unstratified Analysis		
Hazard Ratio	0.63	
95% CI	(0.41, 0.98)	
6 months		
Patients remaining at risk	87	36
Event Free Rate (%)	87.01	80.22
95% CI	(78.68, 92.24)	(65.42, 89.18)
12 months		
Patients remaining at risk	59	17
Event Free Rate (%)	62.67	41.30
95% CI	(52.35, 71.36)	(26.72, 55.30)
18 months		
Patients remaining at risk	47	15
Event Free Rate (%)	55.94	38.72
95% CI	(45.46, 65.18)	(24.40, 52.82)
24 months		
Patients remaining at risk	32	7
Event Free Rate (%)	45.79	26.35
95% CI	(35.25, 55.70)	(13.53, 41.11)

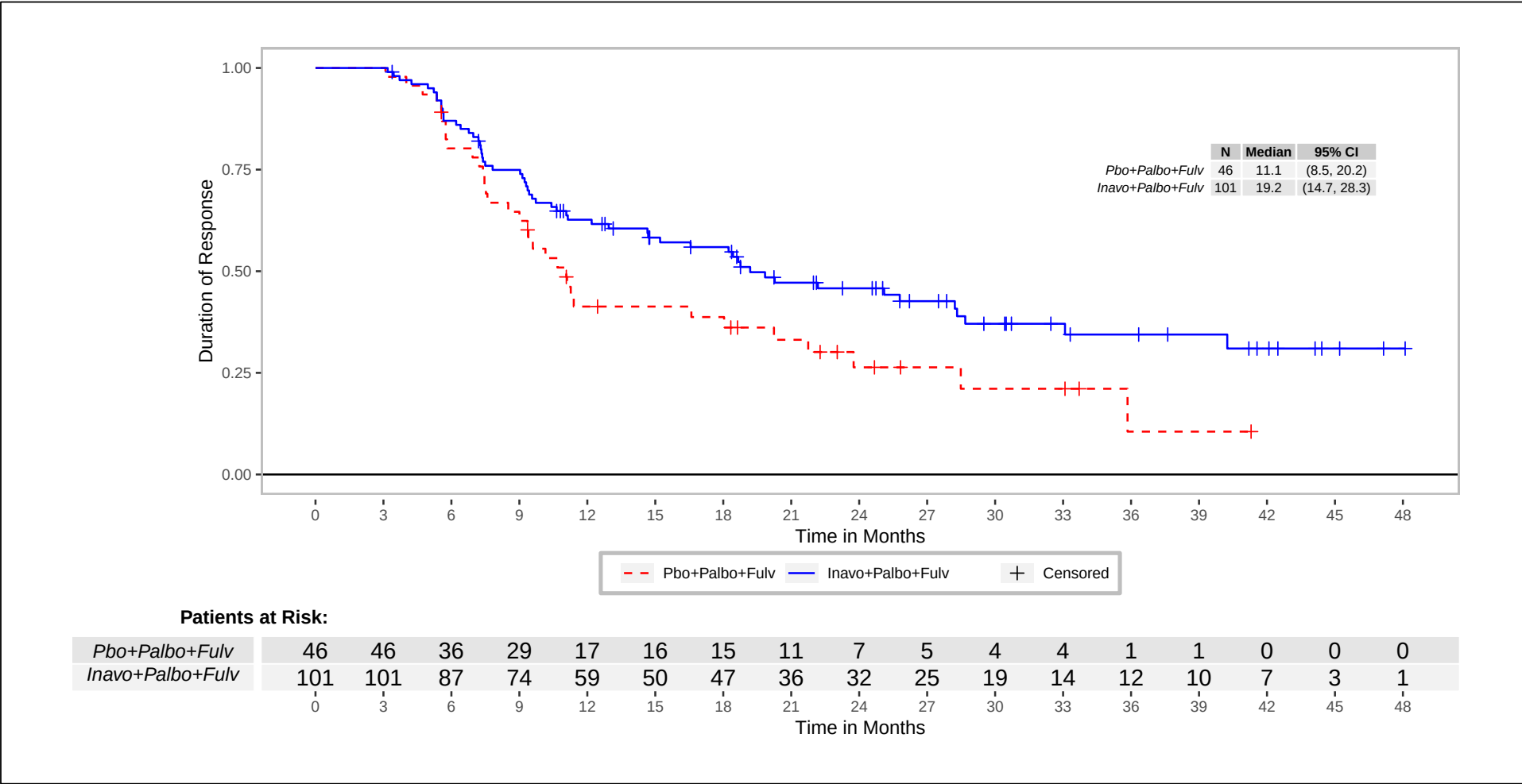
All randomized patients who had an objective response
Duration of response (DOR), defined as the time from the first occurrence of a CR or PR to the first occurrence of disease progression as determined by the investigator according to RECIST v1.1 or death from any cause (whichever occurs first).
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan–Meier Plot for Duration of Response Assessed by Investigator, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_Overall_Survival_Reporting_Event_8219953
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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.4 Zeit bis zur Chemotherapie oder Tod

Time to Event Analysis (Efficacy), Time Between Randomization Until Start of First Subsequent Chemotherapy After Treatment Discontinuation or Death, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

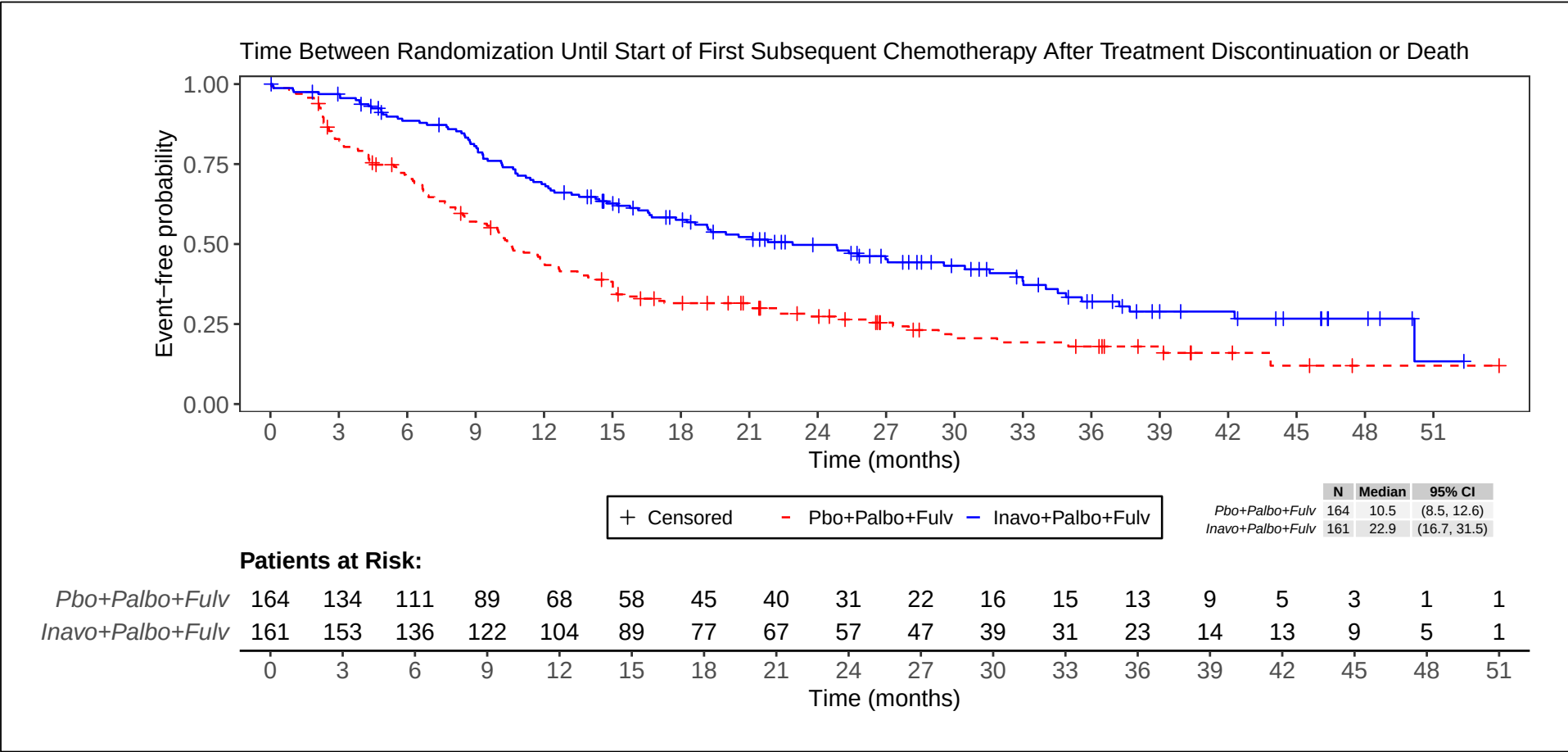
	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Patients with event (%)	94 (58.4%)	123 (75%)
Earliest contributing event		
Death	30	29
Subsequent Chemotherapy After Treatment Discontinuation	64	94
Patients without event (%)	67 (41.6%)	41 (25%)
Time to Event (Months)		
Median	22.90	10.51
95% CI	(16.72, 31.54)	(8.51, 12.65)
Range	0.03 - 52.34 {1}	0.03 - 53.88 {2}
Unstratified Analysis		
p-value (log-rank)	<0.0001	
Hazard Ratio	0.54	
95% CI	(0.41, 0.70)	
Stratified Analysis		
p-value (log-rank)	<0.0001	
Hazard Ratio	0.46	
95% CI	(0.34, 0.61)	

{1} - Censored observations: range minimum & maximum
{2} - Censored observation: range maximum

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ef_tte2.R
Output path:
/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v5/output/t_ef_tte2_CHEMTTE1_FAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 884c7b654f8eaf01b56b221a2c1fd8df1f26a541
07 APR 2025 15:47 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Efficacy, Time Between Randomization Until Start of First Subsequent Chemotherapy After Treatment Discontinuation or Death, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ef_km2.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v1/output/g_ef_km2_CHEMTTE1_FAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 65ba890bf61ac3a2517ff79c20b7283a2af5911f
17 MAR 2025 23:32 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.4 Zeit bis zur Chemotherapie oder Tod

1.4.1 Subgruppenanalyse Zeit bis zur Chemotherapie oder Tod

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Efficacy), Time Between Randomization Until Start of First Subsequent Chemotherapy After Treatment Discontinuation or Death, Full Analysis Set
Protocol: WO41554, CCOd: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Time Between Randomization Until Start of First Subsequent Chemotherapy After Treatment Discontinuation or Death															
All Patients	325	164	123	75.0	10.51	(8.51, 12.65)	161	94	58.4	22.90	(16.72, 31.54)	0.54	(0.41, 0.70)	<0.0001	NE
Age group (years)															
<65	266	130	99	76.2	10.51	(7.85, 12.58)	136	78	57.4	22.90	(17.77, 33.02)	0.48	(0.36, 0.65)	<0.0001	0.0462
>=65	59	34	24	70.6	11.83	(8.15, 22.31)	25	16	64.0	14.42	(8.54, 30.46)	1.05	(0.55, 1.98)	0.8902	0.0462
Sex															
F	319	163	123	75.5	10.51	(8.51, 12.58)	156	91	58.3	21.82	(16.56, 30.46)	0.54	(0.41, 0.71)	<0.0001	0.1310
M	6	1	0	0.0	NE	NE	5	3	60.0	37.22	(19.19, NA)	>999.99	(0.00, >999.99)	0.3113	0.1310
Region															
ASIA	120	62	47	75.8	10.61	(6.67, 14.06)	58	34	58.6	19.15	(12.45, 32.72)	0.54	(0.35, 0.84)	0.0054	0.3824
NORTH AMERICA/WESTERN EUROPE	127	64	47	73.4	15.11	(9.95, 21.06)	63	36	57.1	22.90	(11.53, 34.53)	0.63	(0.41, 0.98)	0.0397	0.3824
OTHER	78	38	29	76.3	7.85	(5.62, 11.10)	40	24	60.0	30.46	(18.27, 37.68)	0.40	(0.23, 0.70)	0.0009	0.3824
Visceral disease (per eCRF)															
N	65	36	20	55.6	12.02	(9.03, NA)	29	14	48.3	33.02	(14.75, NA)	0.60	(0.30, 1.21)	0.1478	0.6181
Y	260	128	103	80.5	10.02	(7.20, 12.58)	132	80	60.6	20.53	(16.13, 29.54)	0.51	(0.38, 0.68)	<0.0001	0.6181
Ethnicity															
HISPANIC OR LATINO	20	10	8	80.0	11.17	(2.10, 34.99)	10	2	20.0	37.22	(3.75, NA)	0.22	(0.05, 1.02)	0.0346	0.3123
NOT HISPANIC OR LATINO	294	149	111	74.5	10.58	(8.51, 12.68)	145	88	60.7	21.82	(16.62, 30.46)	0.54	(0.41, 0.71)	<0.0001	0.3123
NOT REPORTED	5	3	3	100.0	7.33	(2.69, NA)	2	1	50.0	10.15	NE	0.57	(0.05, 6.33)	0.6419	0.3123
UNKNOWN	6	2	1	50.0	2.50	(2.50, NA)	4	3	75.0	7.98	(5.09, NA)	1.16	(0.12, 11.39)	0.8957	0.3123
Race															
Asian	124	63	47	74.6	10.61	(6.67, 14.06)	61	36	59.0	20.53	(13.21, 31.54)	0.56	(0.36, 0.86)	0.0078	0.3470
Black or African American	2	1	0	0.0	NE	NE	1	1	100.0	15.21	NE	>999.99	(0.00, >999.99)	0.3173	0.3470
White	191	97	73	75.3	10.51	(8.51, 13.47)	94	55	58.5	25.79	(18.27, 34.00)	0.54	(0.38, 0.77)	0.0005	0.3470
Unknown	8	3	3	100.0	7.33	(2.50, NA)	5	2	40.0	NE	(5.09, NA)	0.29	(0.05, 1.75)	0.1493	0.3470
Liver Metastasis at Enrollment															
N	157	73	45	61.6	15.01	(10.61, 26.25)	84	45	53.6	31.54	(22.90, 35.58)	0.64	(0.42, 0.97)	0.0332	0.2140
Y	168	91	78	85.7	7.66	(5.88, 10.18)	77	49	63.6	15.77	(10.18, 19.32)	0.49	(0.34, 0.70)	<0.0001	0.2140
Number Metastatic Organs at Enrollment															
1	53	32	21	65.6	15.18	(9.95, 26.25)	21	9	42.9	50.17	(13.21, NA)	0.44	(0.19, 1.02)	0.0491	0.7673
2	104	46	34	73.9	10.38	(7.20, 12.65)	58	30	51.7	25.79	(19.32, 35.58)	0.46	(0.28, 0.76)	0.0019	0.7673
>=3	168	86	68	79.1	9.99	(6.70, 12.58)	82	55	67.1	16.72	(12.19, 26.97)	0.58	(0.41, 0.83)	0.0024	0.7673
ECOG Performance Status at Baseline															
0	206	106	78	73.6	10.28	(8.15, 13.93)	100	54	54.0	26.97	(19.32, 34.53)	0.46	(0.32, 0.65)	<0.0001	0.1534
1	118	58	45	77.6	10.64	(6.87, 14.65)	60	40	66.7	16.13	(11.40, 27.07)	0.68	(0.45, 1.05)	0.0812	0.1534

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Endocrine Resistance (per eCRF)															
Primary	112	58	48	82.8	7.33	(5.52, 10.15)	54	37	68.5	14.75	(11.89, 25.79)	0.50	(0.32, 0.76)	0.0012	0.5955
Secondary	212	105	75	71.4	12.02	(10.38, 15.70)	107	57	53.3	29.54	(19.98, 34.00)	0.55	(0.39, 0.78)	0.0006	0.5955
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	40	76.9	9.99	(6.24, 13.93)	52	30	57.7	24.84	(15.21, 34.53)	0.41	(0.26, 0.67)	0.0002	0.2932
POST-MENOPAUSAL	215	111	83	74.8	10.64	(8.51, 13.47)	104	61	58.7	20.53	(13.54, 32.99)	0.60	(0.43, 0.83)	0.0021	0.2932
Hormone receptor status															
ER+/PR-	90	45	36	80.0	11.10	(6.70, 14.06)	45	30	66.7	14.26	(9.33, 34.89)	0.64	(0.39, 1.05)	0.0782	0.2646
ER+/PR+	226	113	86	76.1	10.15	(8.28, 13.47)	113	62	54.9	25.79	(19.19, 33.02)	0.48	(0.34, 0.66)	<0.0001	0.2646
Other	9	6	1	16.7	NE	(6.93, NA)	3	2	66.7	32.99	(1.02, NA)	2.99	(0.24, 36.66)	0.3751	0.2646
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	12	63.2	15.18	(6.93, NA)	18	9	50.0	24.84	(6.54, NA)	0.71	(0.30, 1.70)	0.4439	0.3103
Aromatase inhibitor only	131	71	58	81.7	10.28	(6.67, 11.73)	60	39	65.0	13.21	(9.53, 20.53)	0.69	(0.46, 1.04)	0.0749	0.3103
Tamoxifen only	155	73	52	71.2	11.99	(8.28, 15.11)	82	45	54.9	31.54	(21.13, 37.68)	0.44	(0.29, 0.66)	<0.0001	0.3103
Prior (neo)-adjuvant CDK4/6															
N	322	163	123	75.5	10.51	(8.51, 12.58)	159	92	57.9	24.84	(17.77, 31.54)	0.52	(0.40, 0.69)	<0.0001	0.0387
Y	3	1	0	0.0	NE	NE	2	2	100.0	9.48	(3.75, NA)	>999.99	(0.00, >999.99)	0.2253	0.0387
Prior (neo)-adjuvant chemotherapy															
N	56	27	19	70.4	12.58	(2.83, 16.92)	29	20	69.0	22.90	(9.53, 31.54)	0.76	(0.40, 1.42)	0.3857	0.2131
Y	269	137	104	75.9	10.51	(8.28, 12.68)	132	74	56.1	24.84	(16.72, 34.00)	0.49	(0.36, 0.66)	<0.0001	0.2131

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_ef_tte_sg.R

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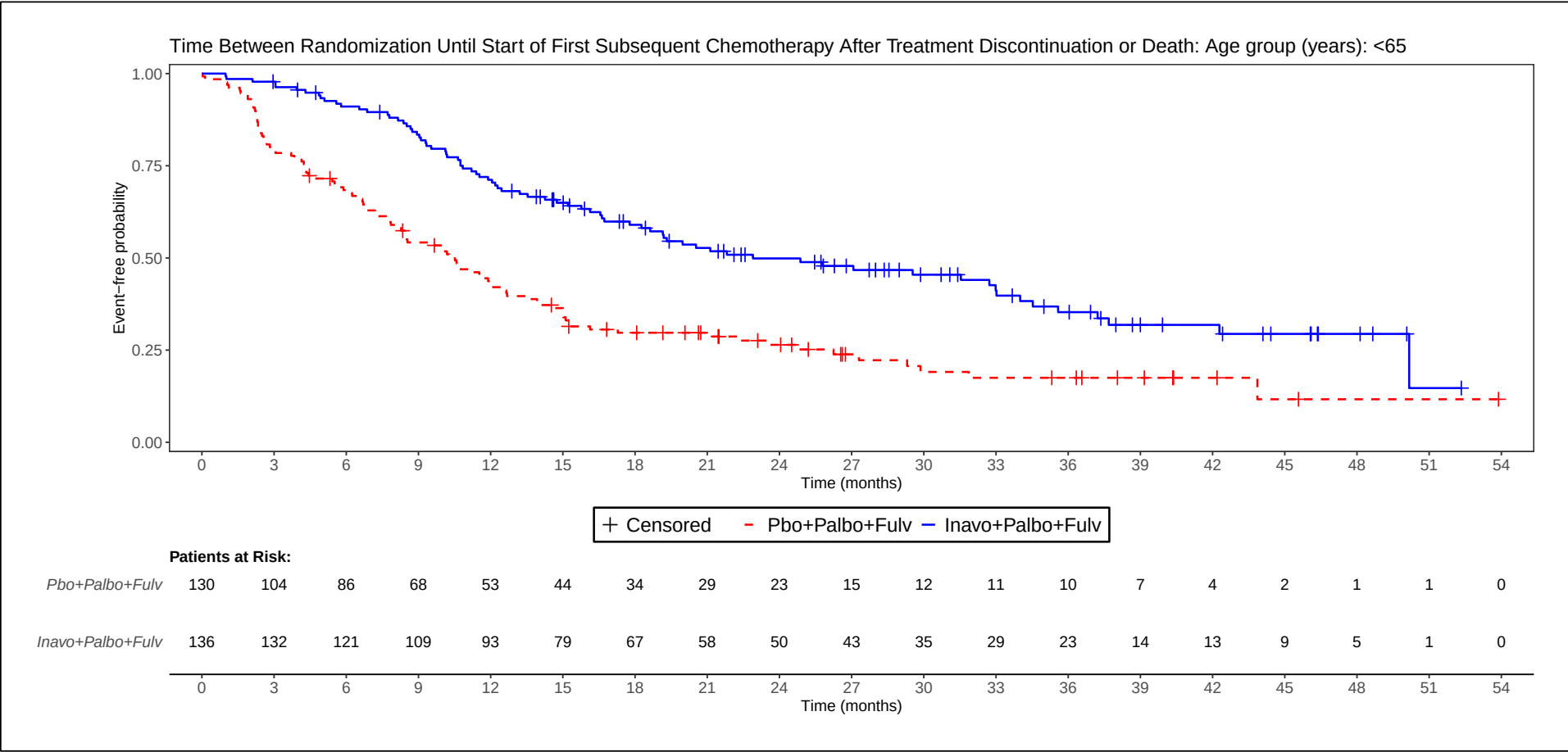
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07 APR 2025 15:47 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

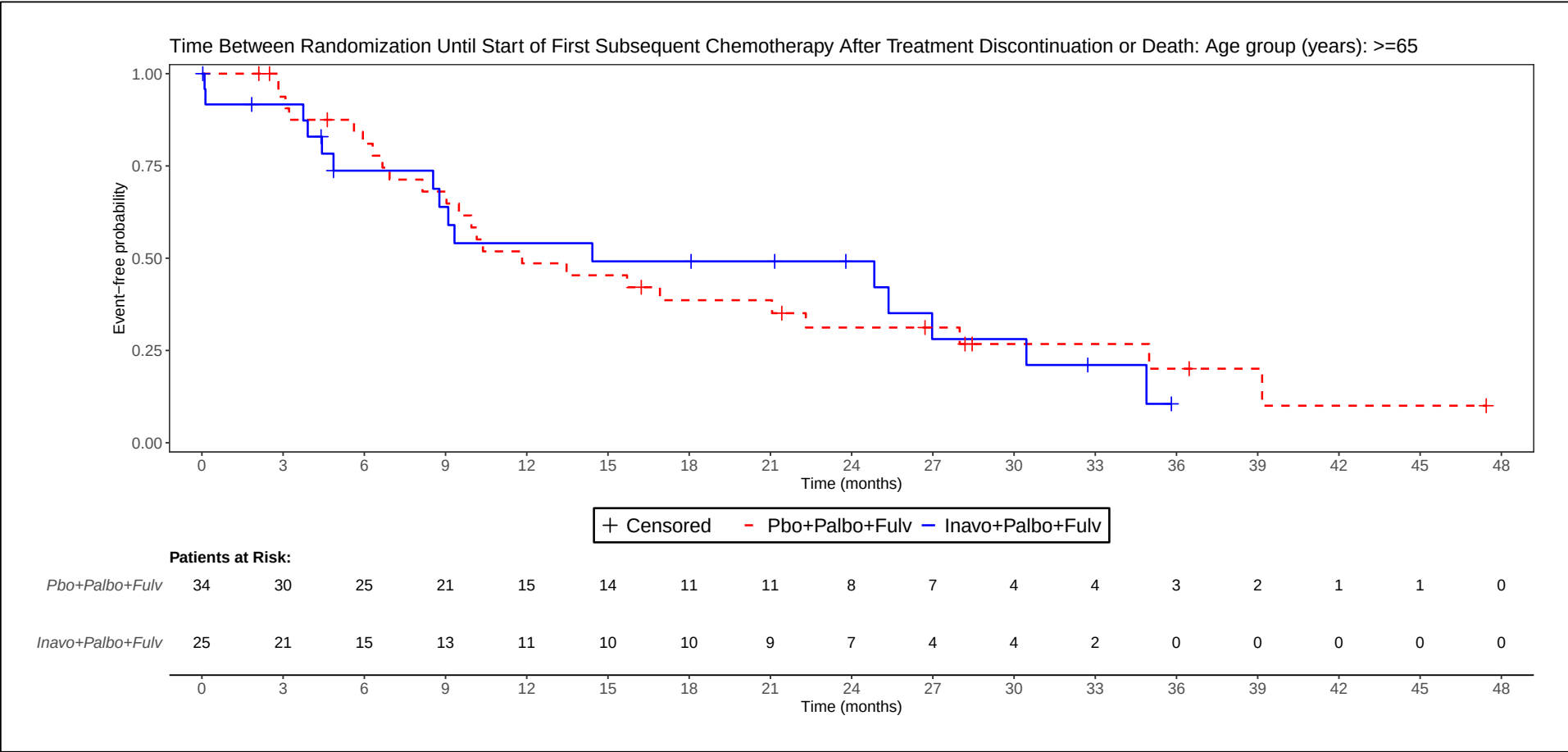
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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18 JUN 2025 17:01 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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18 JUN 2025 17:01 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.4 Zeit bis zur Chemotherapie oder Tod

1.4.2 Einzelkomponenten Zeit bis zur Chemotherapie

Time to Event Analysis (Efficacy), Time Between Randomization Until Start of First Subsequent Chemotherapy
After Treatment Discontinuation, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

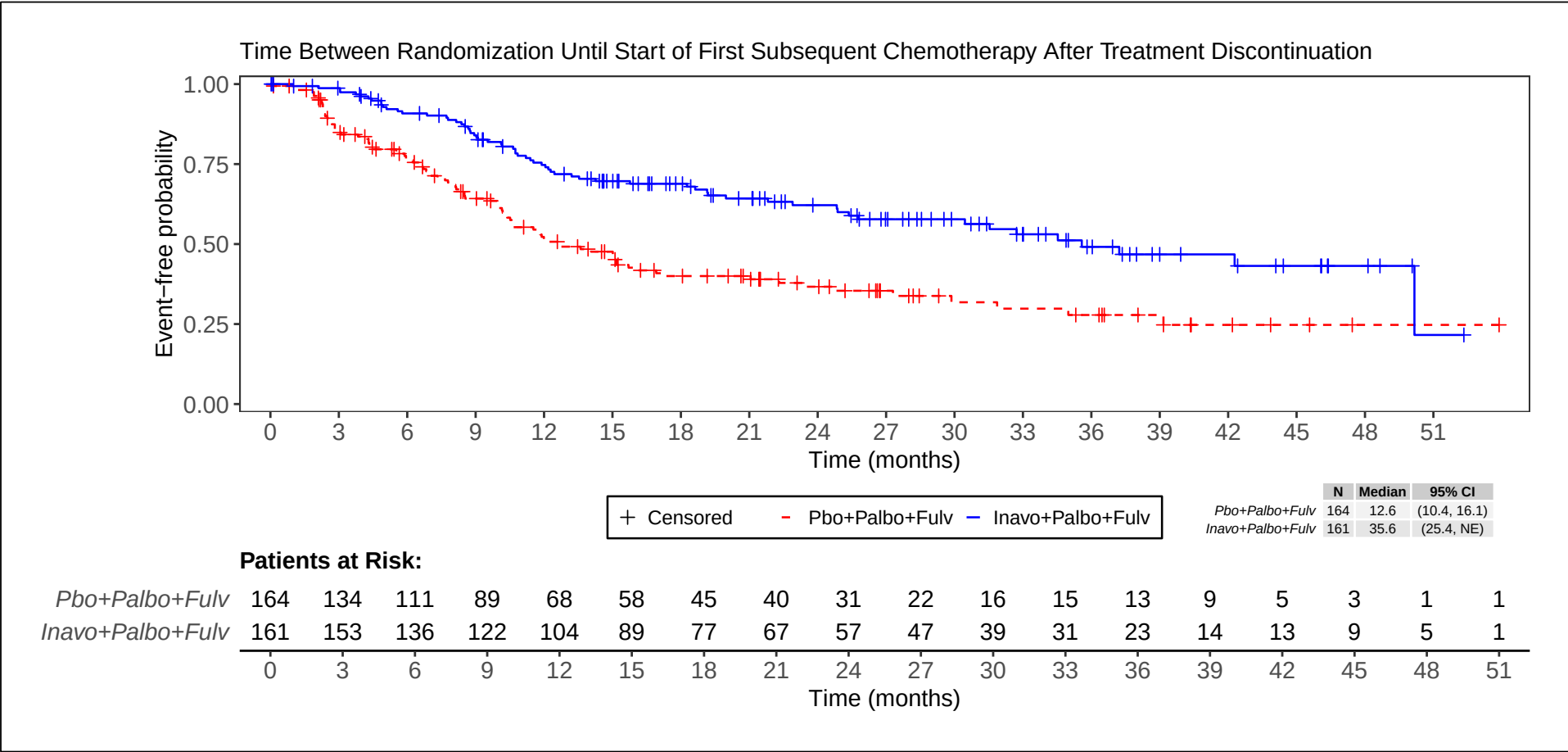
	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Patients with event (%)	64 (39.8%)	94 (57.3%)
Earliest contributing event		
Subsequent Chemotherapy After Treatment Discontinuation	64	94
Patients without event (%)	97 (60.2%)	70 (42.7%)
Time to Event (Months)		
Median	35.58	12.65
95% CI	(25.36, NE)	(10.38, 16.13)
Range	0.03 - 52.34 {1}	0.03 - 53.88 {2}
Unstratified Analysis		
p-value (log-rank)	<0.0001	
Hazard Ratio	0.49	
95% CI	(0.35, 0.67)	
Stratified Analysis		
p-value (log-rank)	<0.0001	
Hazard Ratio	0.43	
95% CI	(0.30, 0.60)	

{1} - Censored observations: range minimum & maximum
{2} - Censored observation: range maximum

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ef_tte2.R
Output path:
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Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 884c7b654f8eaf01b56b221a2c1fd8df1f26a541
07 APR 2025 15:47 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Efficacy, Time Between Randomization Until Start of First Subsequent Chemotherapy After Treatment Discontinuation, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ef_km2.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v1/output/g_ef_km2_CHEMOTTE_FAS_15NOV2024_41554.pdf
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17 MAR 2025 23:33 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.4 Zeit bis zur Chemotherapie oder Tod

1.4.3 Einzelkomponente Zeit bis zum Tod

Time to Event Analysis (Efficacy), Time Between Randomization to Death assuming Start of First Subsequent Chemotherapy as competing risk, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

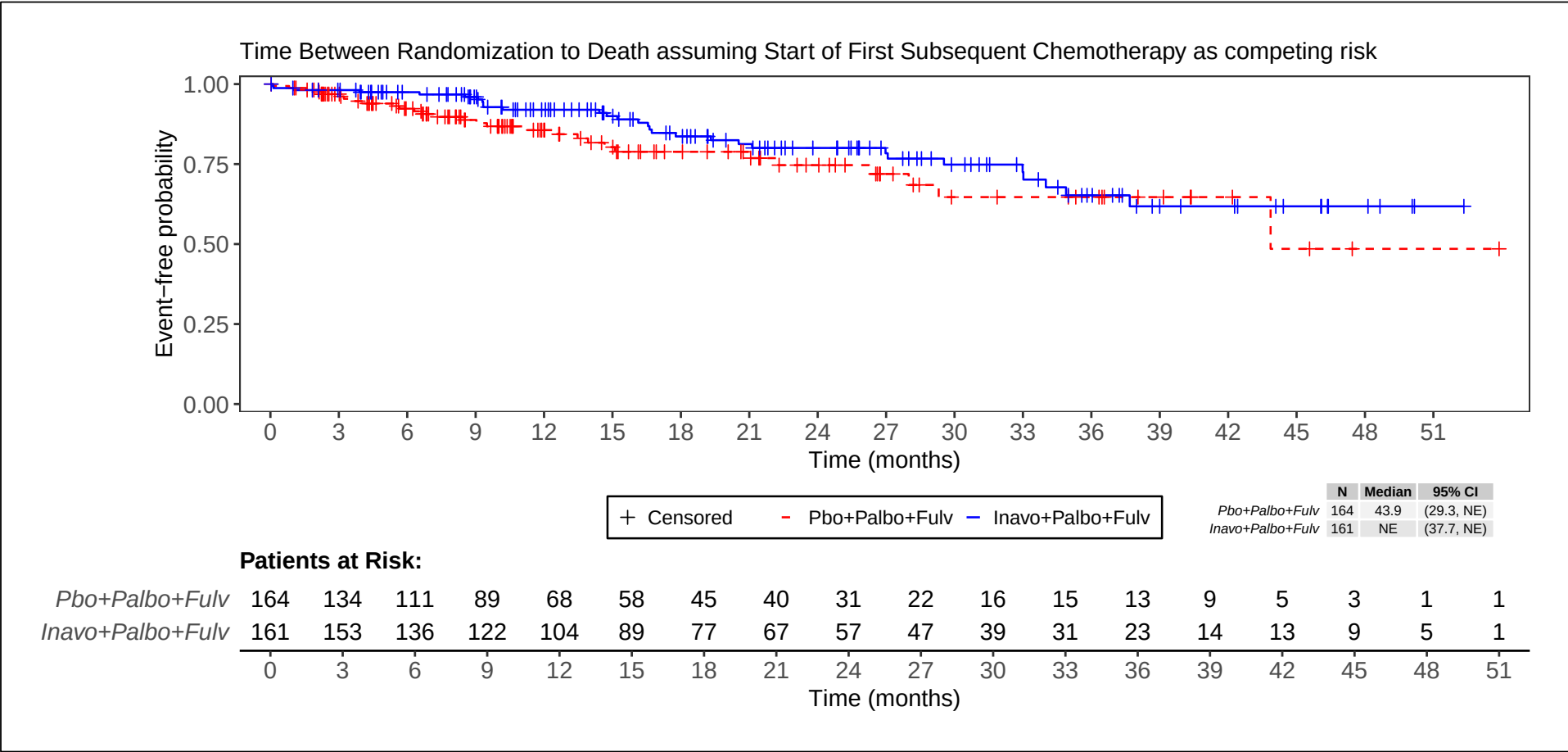
	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Patients with event (%)	30 (18.6%)	29 (17.7%)
Earliest contributing event		
Death	30	29
Patients without event (%)	131 (81.4%)	135 (82.3%)
Time to Event (Months)		
Median	NE	43.86
95% CI	(37.68, NE)	(29.31, NE)
Range	0.03 - 52.34 {1}	0.03 - 53.88 {1}
Unstratified Analysis		
p-value (log-rank)	0.1754	
Hazard Ratio	0.70	
95% CI	(0.42, 1.17)	
Stratified Analysis		
p-value (log-rank)	0.0368	
Hazard Ratio	0.56	
95% CI	(0.32, 0.97)	

{1} - Censored observations: range minimum & maximum

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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07 APR 2025 15:47 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Efficacy, Time Between Randomization to Death assuming Start of First Subsequent Chemotherapy as competing risk, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ef_km2.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v1/output/g_ef_km2_CHEMTTE2_FAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
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17 MAR 2025 23:33 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.4 Zeit bis zur Chemotherapie oder Tod

1.4.4 Listung der im Endpunkt erfassten Chemotherapien

WHODRUG_PREF_NAME	TREATMENT
CAPECITABINE	CHEMOTHERAPY
CARBOPLATIN	CHEMOTHERAPY
CISPLATIN	CHEMOTHERAPY
CYCLOPHOSPHAMIDE	CHEMOTHERAPY
CYCLOPHOSPHAMIDE;PANAX GINSENG TOTAL GINSENOSIDE EXTRACT	CHEMOTHERAPY
CYTARABINE	CHEMOTHERAPY
DEPOXYTHILONE	CHEMOTHERAPY
DOCETAXEL	CHEMOTHERAPY
DOXORUBICIN	CHEMOTHERAPY
EPIRUBICIN	CHEMOTHERAPY
ERIBULIN	CHEMOTHERAPY
ERIBULIN MESILATE	CHEMOTHERAPY
ETOPOSIDE	CHEMOTHERAPY
FLUOROURACIL	CHEMOTHERAPY
GEMCITABINE	CHEMOTHERAPY
GEMCITABINE HYDROCHLORIDE	CHEMOTHERAPY
IXABEPILONE	CHEMOTHERAPY
LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	CHEMOTHERAPY
OXALIPLATIN	CHEMOTHERAPY
PACLITAXEL	CHEMOTHERAPY
PACLITAXEL LIPOSOME	CHEMOTHERAPY
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	CHEMOTHERAPY
PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	CHEMOTHERAPY
PIRARUBICIN	CHEMOTHERAPY
TOPOTECAN	CHEMOTHERAPY
VINORELBINE	CHEMOTHERAPY
VINORELBINE TARTRATE	CHEMOTHERAPY

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.5 Zeit bis zum ersten Auftreten eines skelettalen Ereignisses (SRE)

Time to Event Analysis (Efficacy), Time to Onset of First Skeletal-Related Event, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

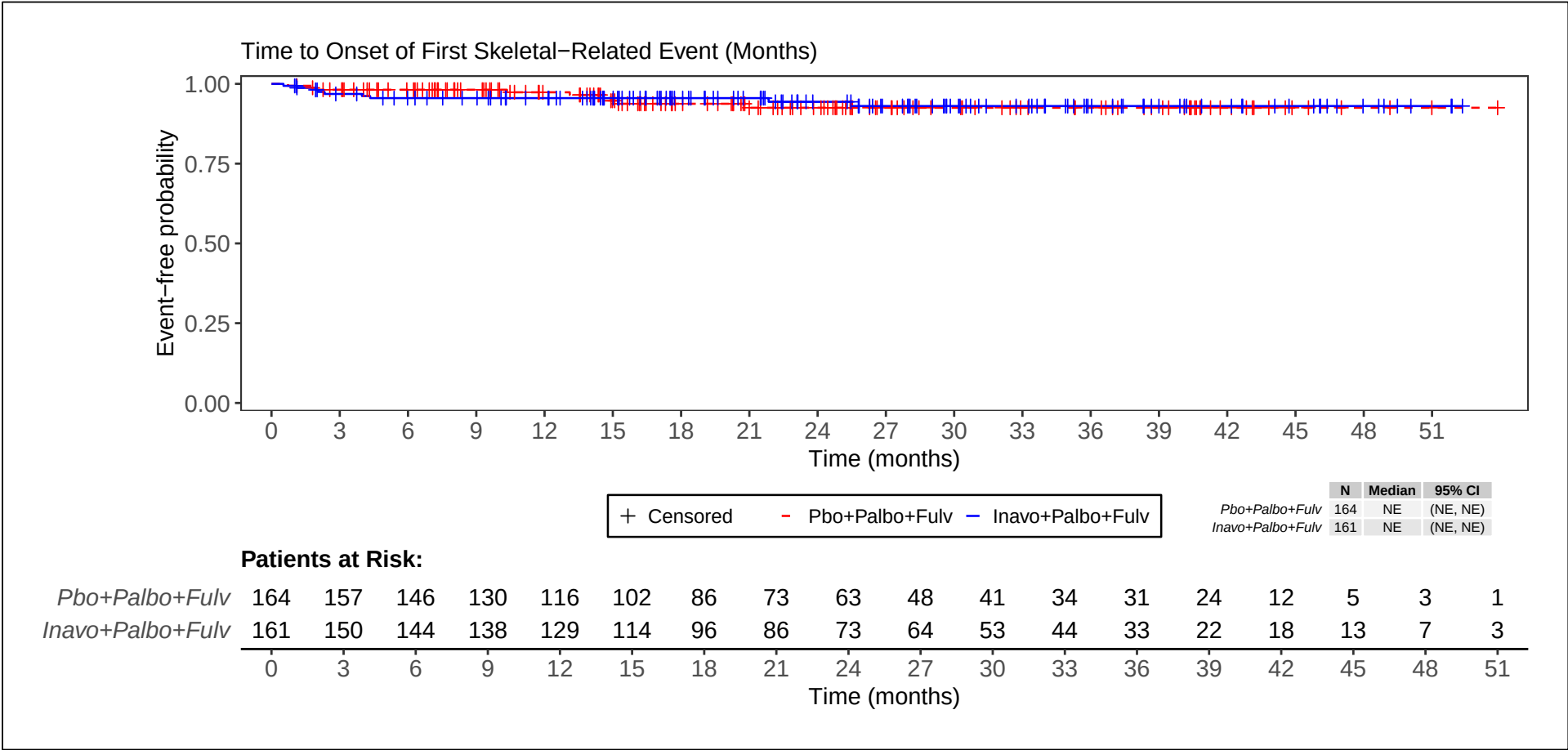
	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Patients with event (%)	9 (5.6%)	9 (5.5%)
Earliest contributing event		
Skeletal-Related Event	9	9
Patients without event (%)	152 (94.4%)	155 (94.5%)
Time to Event (Months)		
Median	NE	NE
95% CI	NE	NE
Range	0.53 - 52.34 {1}	0.72 - 53.88 {1}
Unstratified Analysis		
p-value (log-rank)	0.9331	
Hazard Ratio	0.96	
95% CI	(0.38, 2.42)	
Stratified Analysis		
p-value (log-rank)	0.9555	
Hazard Ratio	1.03	
95% CI	(0.41, 2.60)	

{1} - Censored observation: range maximum

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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ocx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
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07 APR 2025 15:47 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Efficacy, Time to Onset of First Skeletal-Related Event, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ef_km2.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v1/output/g_ef_km2_SRETTE_FAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 65ba890bf61ac3a2517ff79c20b7283a2af5911f
17 MAR 2025 23:33 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

1 Wirksamkeit

1.5 Zeit bis zum ersten Auftreten eines skelettalen Ereignisses (SRE)

1.5.1 Subgruppenanalyse Zeit bis zum ersten Auftreten eines skelettalen Ereignisses (SRE)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Efficacy), Time to Onset of First Skeletal-Related Event, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Time to Onset of First Skeletal-Related Event (Months)															
All Patients	325	164	9	5.5	NE	NE	161	9	5.6	NE	NE	0.96	(0.38, 2.42)	0.9331	NE
Age group (years)															
<65	266	130	6	4.6	NE	NE	136	9	6.6	NE	NE	1.32	(0.47, 3.72)	0.5969	0.0726
>=65	59	34	3	8.8	NE	NE	25	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.1796	0.0726
Sex															
F	319	163	9	5.5	NE	NE	156	9	5.8	NE	NE	0.99	(0.39, 2.50)	0.9863	1.0000
M	6	1	0	0.0	NE	NE	5	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	2	3.2	NE	NE	58	1	1.7	NE	NE	0.52	(0.05, 5.70)	0.5827	0.4716
NORTH AMERICA/WESTERN EUROPE	127	64	5	7.8	NE	NE	63	7	11.1	NE	NE	1.49	(0.47, 4.68)	0.4962	0.4716
OTHER	78	38	2	5.3	NE	NE	40	1	2.5	NE	NE	0.32	(0.03, 3.56)	0.3258	0.4716
Visceral disease (per eCRF)															
N	65	36	3	8.3	NE	NE	29	2	6.9	NE	NE	0.68	(0.11, 4.09)	0.6687	0.7982
Y	260	128	6	4.7	NE	NE	132	7	5.3	NE	NE	1.10	(0.37, 3.26)	0.8697	0.7982
Ethnicity															
HISPANIC OR LATINO	20	10	1	10.0	NE	(14.59, NA)	10	2	20.0	25.49	(3.98, NA)	2.69	(0.24, 30.40)	0.4062	0.8980
NOT HISPANIC OR LATINO	294	149	8	5.4	NE	NE	145	7	4.8	NE	NE	0.85	(0.31, 2.33)	0.7451	0.8980
NOT REPORTED	5	3	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	0.8980
UNKNOWN	6	2	0	0.0	NE	NE	4	0	0.0	NE	NE	NE	NE	1.0000	0.8980
Race															
Asian	124	63	2	3.2	NE	NE	61	1	1.6	NE	NE	0.50	(0.05, 5.54)	0.5666	0.9476
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.9476
White	191	97	7	7.2	NE	NE	94	8	8.5	NE	NE	1.10	(0.40, 3.04)	0.8515	0.9476
Unknown	8	3	0	0.0	NE	NE	5	0	0.0	NE	NE	NE	NE	1.0000	0.9476
Liver Metastasis at Enrollment															
N	157	73	5	6.8	NE	NE	84	3	3.6	NE	NE	0.49	(0.12, 2.07)	0.3231	0.2280
Y	168	91	4	4.4	NE	NE	77	6	7.8	NE	NE	1.72	(0.48, 6.09)	0.3974	0.2280
Number Metastatic Organs at Enrollment															
1	53	32	2	6.2	NE	NE	21	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.2442	0.2774
2	104	46	4	8.7	NE	NE	58	4	6.9	NE	NE	0.72	(0.18, 2.89)	0.6416	0.2774
>=3	168	86	3	3.5	NE	NE	82	5	6.1	NE	NE	1.62	(0.39, 6.79)	0.5060	0.2774
ECOG Performance Status at Baseline															
0	206	106	4	3.8	NE	NE	100	6	6.0	NE	NE	1.53	(0.43, 5.42)	0.5095	0.3037
1	118	58	5	8.6	NE	NE	60	3	5.0	NE	NE	0.55	(0.13, 2.32)	0.4126	0.3037

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Endocrine Resistance (per eCRF)															
Primary	112	58	0	0.0	NE	NE	54	3	5.6	NE	NE	>999.99	(0.00, >999.99)	0.0715	0.0368
Secondary	212	105	8	7.6	NE	NE	107	6	5.6	NE	NE	0.72	(0.25, 2.07)	0.5386	0.0368
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	1	1.9	NE	NE	52	3	5.8	NE	NE	3.10	(0.32, 29.77)	0.3023	0.2594
POST-MENOPAUSAL	215	111	8	7.2	NE	NE	104	6	5.8	NE	NE	0.75	(0.26, 2.15)	0.5869	0.2594
Hormone receptor status															
ER+/PR-	90	45	5	11.1	NE	NE	45	2	4.4	NE	NE	0.40	(0.08, 2.08)	0.2608	0.1668
ER+/PR+	226	113	3	2.7	NE	NE	113	7	6.2	NE	NE	2.17	(0.56, 8.40)	0.2510	0.1668
Other	9	6	1	16.7	NE	(20.93, NA)	3	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.4142	0.1668
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	2	10.5	NE	(14.59, NA)	18	2	11.1	NE	(25.49, NA)	0.91	(0.13, 6.50)	0.9237	0.9726
Aromatase inhibitor only	131	71	4	5.6	NE	NE	60	3	5.0	NE	NE	0.86	(0.19, 3.86)	0.8477	0.9726
Tamoxifen only	155	73	3	4.1	NE	NE	82	4	4.9	NE	NE	1.10	(0.25, 4.93)	0.8989	0.9726
Prior (neo)-adjuvant CDK4/6															
N	322	163	9	5.5	NE	NE	159	9	5.7	NE	NE	0.96	(0.38, 2.43)	0.9392	1.0000
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	0	0.0	NE	NE	29	1	3.4	NE	NE	>999.99	(0.00, >999.99)	0.3560	0.2567
Y	269	137	9	6.6	NE	NE	132	8	6.1	NE	NE	0.88	(0.34, 2.27)	0.7840	0.2567

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_ef_tte_sg.R

Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v5/output/t_ef_tte_sg_SRETTE_FAS_15NOV2024_41554.docx

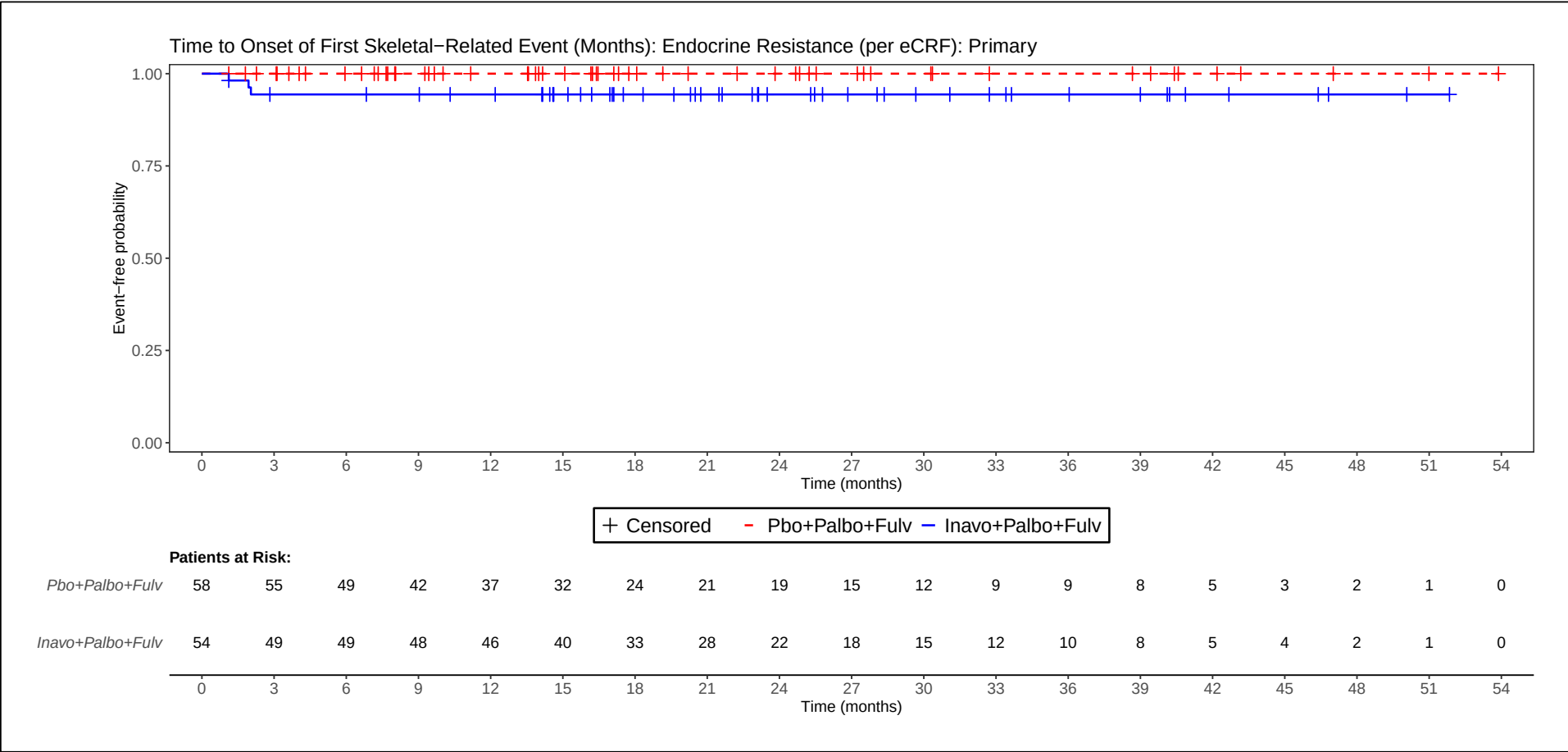
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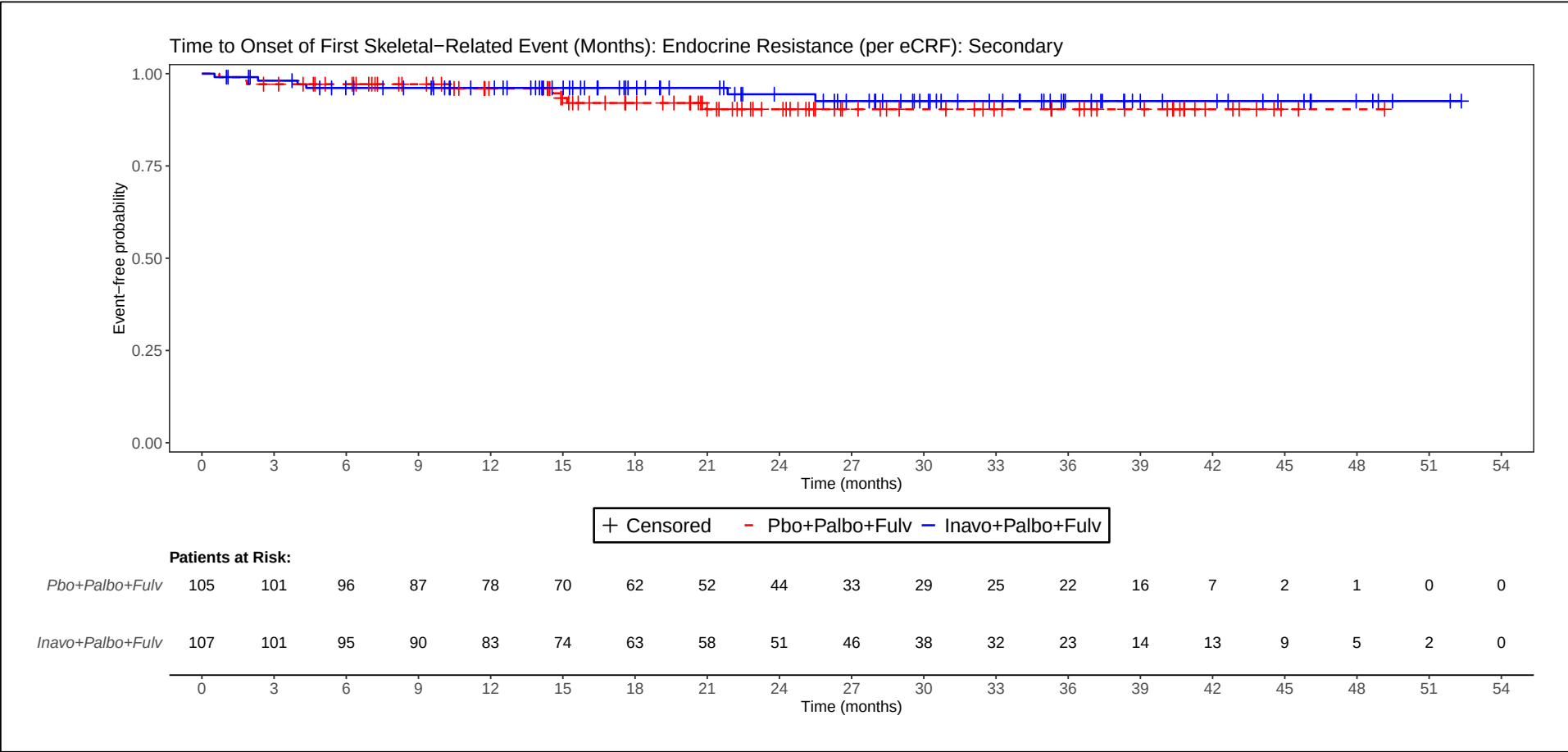
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_km_signsg.R
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18 JUN 2025 17:00 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_km_signsg.R
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18 JUN 2025 17:00 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.1 PRO Items des EORTC QLQ-C30

2.1.1 Rücklaufquoten der PRO Items des EORTC QLQ-C30

Questionnaire Completion by Visit by Scale, EORTC QLQ-C30, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
EORTC QLQ-C30: Appetite loss			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Cognitive functioning			
BASELINE			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Constipation			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Diarrhoea			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	78 (79.6%)	103 (78.0%)	181 (78.7%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Dyspnoea			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	111 (86.0%)	89 (88.1%)	200 (87.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Emotional functioning			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Fatigue			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Financial difficulties			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	88 (87.1%)	200 (87.0%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Nausea and vomiting			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Pain			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Physical functioning (revised)			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Global health status/QoL (revised)			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Role functioning (revised)			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Social functioning			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	16 (72.7%)	55 (83.3%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-C30: Insomnia			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	156 (95.1%)	305 (94.1%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	143 (92.3%)	153 (95.0%)	296 (93.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	133 (91.7%)	270 (91.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	104 (88.9%)	74 (88.1%)	178 (88.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	58 (87.9%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	39 (88.6%)	17 (77.3%)	56 (84.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_qs_compsc.R

Output path:

/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v7/output/t_qs_compsc_EORTC_FAS_15NOV2024_41554.docx

Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685

Git hash: b6027dbd949ffd3bd010747913d30fe0e2c66bc9

14 APR 2025 06:18 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.1 PRO Items des EORTC QLQ-C30

2.1.2 Werte und Veränderung gegenüber dem Ausgangswert der PRO Items des EORTC QLQ-C30

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Global health status/QoL (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	65.5 (21.5)		66.3 (20.9)	
Median	66.7		66.7	
Min - Max	0 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	65.0 (20.5)	-0.3 (18.8)	69.1 (18.1)	2.3 (18.0)
Median	66.7	0.0	66.7	0.0
Min - Max	0 - 100	-58 - 50	17 - 100	-67 - 83
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	67.1 (19.1)	1.5 (20.0)	71.1 (16.0)	5.0 (17.5)
Median	66.7	0.0	66.7	4.2
Min - Max	0 - 100	-50 - 100	25 - 100	-33 - 67
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	67.6 (17.9)	1.9 (20.8)	68.9 (18.6)	1.3 (21.3)
Median	66.7	0.0	66.7	0.0
Min - Max	0 - 100	-58 - 50	17 - 100	-50 - 58
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	69.3 (17.0)	2.9 (20.3)	71.5 (20.6)	3.4 (19.8)
Median	66.7	0.0	75.0	0.0
Min - Max	8 - 100	-50 - 83	0 - 100	-33 - 58
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	69.3 (17.5)	2.6 (20.5)	69.5 (15.2)	2.0 (22.0)
Median	66.7	0.0	66.7	0.0
Min - Max	33 - 100	-50 - 75	33 - 100	-67 - 42

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 1 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Global health status/QoL (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	69.8 (18.2)	2.7 (22.7)	69.1 (14.3)	0.6 (19.7)
Median	66.7	0.0	66.7	0.0
Min - Max	17 - 100	-83 - 100	42 - 100	-50 - 42
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	71.5 (15.4)	3.0 (20.2)	70.0 (17.7)	3.0 (21.9)
Median	75.0	0.0	66.7	0.0
Min - Max	33 - 100	-50 - 75	0 - 100	-50 - 50
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	70.9 (16.1)	3.9 (19.8)	69.5 (16.4)	2.5 (21.5)
Median	66.7	0.0	66.7	0.0
Min - Max	33 - 100	-42 - 83	33 - 100	-58 - 50
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	69.8 (16.0)	1.9 (19.6)	71.4 (16.5)	3.7 (21.8)
Median	66.7	0.0	75.0	0.0
Min - Max	33 - 100	-50 - 83	42 - 100	-33 - 50
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	67.1 (17.9)	-1.0 (21.1)	70.8 (15.9)	1.4 (19.1)
Median	66.7	0.0	66.7	0.0
Min - Max	33 - 100	-50 - 83	42 - 100	-33 - 50
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	70.8 (15.3)	2.6 (19.9)	70.3 (17.6)	-0.8 (20.4)
Median	66.7	0.0	75.0	0.0
Min - Max	33 - 100	-33 - 83	33 - 100	-50 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 2 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Global health status/QoL (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	71.8 (13.3)	3.7 (16.3)	71.2 (13.6)	2.2 (22.0)
Median	66.7	0.0	66.7	0.0
Min - Max	50 - 100	-17 - 67	42 - 92	-42 - 33
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	70.0 (16.3)	2.0 (18.9)	75.9 (18.6)	1.9 (19.5)
Median	66.7	0.0	83.3	0.0
Min - Max	33 - 100	-25 - 67	33 - 100	-42 - 42
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	69.9 (21.9)	1.8 (27.2)	75.5 (14.9)	-1.0 (19.2)
Median	75.0	0.0	83.3	0.0
Min - Max	8 - 100	-83 - 83	50 - 100	-33 - 33
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	71.1 (16.0)	-0.3 (18.5)	75.5 (14.9)	1.0 (23.1)
Median	66.7	0.0	83.3	0.0
Min - Max	33 - 100	-50 - 33	50 - 100	-50 - 50
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	69.3 (13.2)	-2.1 (17.5)	72.7 (17.5)	-0.8 (24.4)
Median	66.7	-8.3	83.3	-16.7
Min - Max	25 - 92	-33 - 42	42 - 100	-25 - 50
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	70.6 (16.6)	-2.4 (16.3)	75.9 (20.6)	0.0 (25.2)
Median	66.7	0.0	83.3	8.3
Min - Max	50 - 100	-25 - 33	33 - 100	-33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 3 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Global health status/QoL (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	69.0 (12.4)	-2.5 (16.6)	76.9 (13.0)	-2.1 (20.3)
Median	66.7	-8.3	66.7	-4.2
Min - Max	50 - 100	-25 - 33	67 - 100	-33 - 33
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	72.1 (15.3)	-3.4 (16.7)	75.0 (24.1)	-6.9 (18.6)
Median	75.0	-8.3	83.3	-8.3
Min - Max	50 - 100	-25 - 33	33 - 100	-33 - 17
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	67.9 (17.9)	-3.6 (21.9)	70.0 (7.5)	-3.3 (21.7)
Median	66.7	-8.3	66.7	0.0
Min - Max	33 - 100	-33 - 50	67 - 83	-33 - 17
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	70.5 (13.0)	-6.4 (13.2)	70.8 (8.3)	-4.2 (25.0)
Median	66.7	-8.3	66.7	0.0
Min - Max	50 - 100	-25 - 17	67 - 83	-33 - 17
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	69.2 (13.8)	-6.4 (16.7)	70.8 (39.4)	-8.3 (16.7)
Median	66.7	-16.7	83.3	0.0
Min - Max	50 - 83	-25 - 33	17 - 100	-33 - 0
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	63.1 (10.6)	-15.5 (14.8)	72.2 (19.2)	0.0 (16.7)
Median	66.7	-16.7	83.3	0.0
Min - Max	50 - 75	-33 - 8	50 - 83	-17 - 17

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 4 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Global health status/QoL (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	72.2 (12.5)	-9.7 (16.2)	83.3 (23.6)	0.0 (0.0)
Median	66.7	-8.3	83.3	0.0
Min - Max	58 - 92	-33 - 17	67 - 100	0 - 0
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	69.4 (4.8)	-5.6 (12.7)	100.0 (NA)	0.0 (NA)
Median	66.7	-8.3	100.0	0.0
Min - Max	67 - 75	-17 - 8	100 - 100	0 - 0
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	62.5 (5.9)	-20.8 (5.9)	100.0 (NA)	0.0 (NA)
Median	62.5	-20.8	100.0	0.0
Min - Max	58 - 67	-25 - -17	100 - 100	0 - 0
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	75.0 (NA)	-16.7 (NA)	83.3 (NA)	-16.7 (NA)
Median	75.0	-16.7	83.3	-16.7
Min - Max	75 - 75	-17 - -17	83 - 83	-17 - -17
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	75.0 (NA)	-16.7 (NA)	100.0 (NA)	0.0 (NA)
Median	75.0	-16.7	100.0	0.0
Min - Max	75 - 75	-17 - -17	100 - 100	0 - 0
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	75.0 (NA)	-16.7 (NA)	83.3 (NA)	-16.7 (NA)
Median	75.0	-16.7	83.3	-16.7
Min - Max	75 - 75	-17 - -17	83 - 83	-17 - -17

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 5 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Global health status/QoL (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	56.3 (21.4)	-7.4 (19.1)	58.8 (21.6)	-7.9 (19.8)
Median	58.3	-8.3	66.7	-8.3
Min - Max	17 - 100	-50 - 50	0 - 100	-58 - 33
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	52.8 (17.7)	-13.0 (26.4)	60.0 (16.0)	-8.3 (11.8)
Median	50.0	-8.3	66.7	-8.3
Min - Max	33 - 83	-50 - 33	33 - 75	-25 - 8
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	41.7 (11.8)	-16.7 (23.6)	NE (NE)	NE (NE)
Median	41.7	-16.7	NE	NE
Min - Max	33 - 50	-33 - 0	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	16.7 (NA)	-16.7 (NA)	NE (NE)	NE (NE)
Median	16.7	-16.7	NE	NE
Min - Max	17 - 17	-17 - -17	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	56.0 (24.2)	-11.0 (23.5)	56.5 (20.2)	-8.6 (22.7)
Median	66.7	-8.3	58.3	-8.3
Min - Max	0 - 100	-67 - 33	8 - 92	-67 - 42
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	59.2 (15.9)	-0.9 (21.5)	66.7 (18.8)	0.5 (18.7)
Median	66.7	0.0	66.7	0.0
Min - Max	17 - 92	-33 - 33	17 - 100	-33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 6 of 105

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Global health status/QoL (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	61.9 (20.9)	8.3 (16.0)	48.3 (22.4)	0.0 (15.6)
Median	66.7	8.3	33.3	8.3
Min - Max	33 - 83	-17 - 33	33 - 83	-17 - 17
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	56.7 (13.7)	-11.7 (9.5)	50.0 (23.6)	12.5 (41.2)
Median	50.0	-8.3	50.0	12.5
Min - Max	42 - 75	-25 - 0	33 - 67	-17 - 42
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	41.7 (22.0)	-13.9 (4.8)	58.3 (NA)	8.3 (NA)
Median	50.0	-16.7	58.3	8.3
Min - Max	17 - 58	-17 - -8	58 - 58	8 - 8
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	61.5 (24.5)	-4.4 (26.8)	65.1 (16.7)	1.4 (21.3)
Median	66.7	0.0	66.7	0.0
Min - Max	8 - 100	-67 - 33	33 - 100	-67 - 50
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	65.2 (18.1)	0.7 (18.6)	64.0 (17.9)	-1.1 (22.3)
Median	66.7	0.0	66.7	0.0
Min - Max	17 - 100	-42 - 50	0 - 100	-67 - 58

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

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03 FEB 2025 14:32 GMT

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Physical functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	80.4 (18.5)		80.2 (19.1)	
Median	86.7		86.7	
Min - Max	13 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	78.7 (19.7)	-1.2 (14.3)	81.3 (15.1)	0.7 (14.3)
Median	80.0	0.0	80.0	0.0
Min - Max	20 - 100	-40 - 40	40 - 100	-40 - 53
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	81.1 (19.6)	0.7 (15.6)	81.7 (15.8)	1.9 (15.1)
Median	86.7	0.0	86.7	0.0
Min - Max	13 - 100	-40 - 47	27 - 100	-53 - 60
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	82.5 (18.2)	1.5 (16.9)	81.7 (16.5)	1.2 (15.1)
Median	86.7	0.0	86.7	0.0
Min - Max	20 - 100	-67 - 47	27 - 100	-33 - 60
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	81.7 (18.5)	0.3 (17.4)	84.3 (14.7)	3.2 (14.5)
Median	86.7	0.0	86.7	0.0
Min - Max	20 - 100	-47 - 53	33 - 100	-27 - 60
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	81.5 (19.2)	0.1 (15.6)	83.6 (17.7)	2.0 (12.5)
Median	86.7	0.0	86.7	0.0
Min - Max	20 - 100	-73 - 33	27 - 100	-27 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 8 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Physical functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	81.9 (19.0)	0.3 (15.5)	83.0 (15.6)	2.7 (14.9)
Median	86.7	0.0	80.0	0.0
Min - Max	27 - 100	-47 - 33	40 - 100	-27 - 40
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	83.5 (19.0)	2.2 (16.9)	82.2 (15.4)	0.3 (17.2)
Median	93.3	0.0	80.0	0.0
Min - Max	7 - 100	-87 - 33	33 - 100	-40 - 40
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	82.4 (19.3)	1.7 (17.0)	82.4 (16.2)	1.3 (18.7)
Median	86.7	0.0	86.7	0.0
Min - Max	13 - 100	-80 - 40	33 - 100	-47 - 40
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	84.2 (17.3)	1.9 (16.1)	82.2 (14.7)	5.3 (15.8)
Median	86.7	0.0	80.0	0.0
Min - Max	13 - 100	-80 - 40	60 - 100	-27 - 33
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	83.8 (15.7)	2.9 (15.4)	83.9 (12.1)	4.6 (17.0)
Median	86.7	0.0	86.7	0.0
Min - Max	33 - 100	-20 - 53	60 - 100	-27 - 33
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	83.9 (18.1)	1.4 (20.6)	82.6 (15.3)	1.0 (14.2)
Median	86.7	0.0	86.7	0.0
Min - Max	13 - 100	-80 - 67	47 - 100	-20 - 27

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 9 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Physical functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	82.9 (19.2)	0.8 (18.5)	85.3 (12.5)	4.9 (11.7)
Median	86.7	0.0	86.7	6.7
Min - Max	13 - 100	-80 - 33	60 - 100	-13 - 27
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	83.6 (16.7)	2.4 (18.8)	83.9 (18.8)	0.4 (12.6)
Median	86.7	0.0	93.3	0.0
Min - Max	27 - 100	-67 - 60	27 - 100	-13 - 27
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	81.7 (16.9)	1.1 (17.2)	83.9 (14.7)	-2.5 (12.6)
Median	80.0	0.0	86.7	-3.3
Min - Max	33 - 100	-40 - 40	47 - 100	-20 - 27
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	81.7 (17.1)	0.6 (20.9)	83.6 (17.0)	-0.3 (15.9)
Median	86.7	0.0	86.7	0.0
Min - Max	33 - 100	-40 - 73	47 - 100	-20 - 33
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	82.5 (15.6)	0.7 (15.9)	84.8 (15.2)	6.0 (19.5)
Median	86.7	0.0	86.7	10.0
Min - Max	40 - 100	-40 - 33	60 - 100	-20 - 27
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	87.0 (12.6)	5.4 (13.6)	81.5 (20.2)	3.3 (21.1)
Median	93.3	0.0	86.7	3.3
Min - Max	53 - 100	-20 - 40	47 - 100	-27 - 27

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 10 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Physical functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	84.4 (14.1)	7.8 (12.1)	88.1 (12.4)	5.8 (18.7)
Median	86.7	0.0	93.3	6.7
Min - Max	53 - 100	-7 - 33	60 - 100	-20 - 33
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	83.9 (18.3)	4.3 (18.4)	87.6 (14.1)	7.8 (26.1)
Median	86.7	0.0	93.3	6.7
Min - Max	33 - 100	-40 - 33	67 - 100	-27 - 47
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	80.5 (17.4)	0.5 (14.4)	82.7 (13.0)	6.7 (26.2)
Median	83.3	-3.3	86.7	0.0
Min - Max	40 - 100	-27 - 20	67 - 100	-27 - 33
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	82.1 (15.7)	0.0 (12.5)	86.7 (18.9)	11.7 (35.8)
Median	86.7	0.0	93.3	16.7
Min - Max	47 - 100	-27 - 20	60 - 100	-33 - 47
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	85.1 (15.4)	3.1 (16.7)	77.5 (19.5)	-4.2 (5.0)
Median	86.7	0.0	78.3	-3.3
Min - Max	40 - 100	-33 - 33	53 - 100	-10 - 0
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	80.0 (14.4)	0.0 (12.2)	77.8 (3.8)	2.2 (21.4)
Median	86.7	6.7	80.0	-6.7
Min - Max	53 - 93	-20 - 13	73 - 80	-13 - 27

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
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03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 11 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Physical functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	80.0 (12.6)	-2.2 (12.4)	66.7 (9.4)	-20.0 (0.0)
Median	80.0	-3.3	66.7	-20.0
Min - Max	60 - 93	-13 - 20	60 - 73	-20 - -20
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	80.0 (13.3)	2.2 (10.2)	86.7 (NA)	-6.7 (NA)
Median	80.0	0.0	86.7	-6.7
Min - Max	67 - 93	-7 - 13	87 - 87	-7 - -7
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	80.0 (18.9)	-3.3 (4.7)	86.7 (NA)	-6.7 (NA)
Median	80.0	-3.3	86.7	-6.7
Min - Max	67 - 93	-7 - 0	87 - 87	-7 - -7
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	93.3 (NA)	0.0 (NA)	100.0 (NA)	6.7 (NA)
Median	93.3	0.0	100.0	6.7
Min - Max	93 - 93	0 - 0	100 - 100	7 - 7
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	93.3 (NA)	0.0 (NA)	73.3 (NA)	-20.0 (NA)
Median	93.3	0.0	73.3	-20.0
Min - Max	93 - 93	0 - 0	73 - 73	-20 - -20
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	93.3 (NA)	0.0 (NA)	100.0 (NA)	6.7 (NA)
Median	93.3	0.0	100.0	6.7
Min - Max	93 - 93	0 - 0	100 - 100	7 - 7

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 12 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Physical functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	72.2 (25.3)	-7.2 (23.3)	76.1 (22.3)	-4.7 (18.9)
Median	80.0	-6.7	80.0	-3.3
Min - Max	0 - 100	-80 - 80	0 - 100	-73 - 47
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	77.0 (19.2)	1.5 (21.5)	72.0 (17.9)	0.0 (19.4)
Median	80.0	0.0	80.0	-6.7
Min - Max	47 - 100	-47 - 27	40 - 80	-13 - 33
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	63.3 (33.0)	-6.7 (0.0)	NE (NE)	NE (NE)
Median	63.3	-6.7	NE	NE
Min - Max	40 - 87	-7 - -7	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	13.3 (NA)	-33.3 (NA)	NE (NE)	NE (NE)
Median	13.3	-33.3	NE	NE
Min - Max	13 - 13	-33 - -33	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	72.5 (26.1)	-4.7 (25.4)	71.2 (23.5)	-7.9 (21.6)
Median	80.0	0.0	76.7	-6.7
Min - Max	0 - 100	-60 - 60	0 - 100	-67 - 27
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	80.4 (16.3)	-3.9 (16.1)	78.9 (17.1)	-2.0 (19.3)
Median	86.7	0.0	86.7	0.0
Min - Max	33 - 100	-47 - 27	40 - 100	-33 - 60

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 13 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Physical functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	78.1 (26.6)	0.0 (26.4)	65.3 (15.9)	0.0 (20.5)
Median	86.7	6.7	66.7	-6.7
Min - Max	20 - 100	-53 - 20	47 - 87	-27 - 27
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	62.7 (26.1)	-16.0 (20.9)	63.3 (14.1)	10.0 (42.4)
Median	66.7	-20.0	63.3	10.0
Min - Max	27 - 87	-47 - 7	53 - 73	-20 - 40
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	62.2 (16.8)	-22.2 (13.9)	80.0 (NA)	0.0 (NA)
Median	60.0	-26.7	80.0	0.0
Min - Max	47 - 80	-33 - -7	80 - 80	0 - 0
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	77.5 (22.0)	0.4 (26.9)	77.3 (18.1)	-1.9 (13.0)
Median	80.0	0.0	80.0	0.0
Min - Max	13 - 100	-40 - 73	33 - 100	-27 - 33
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	79.1 (19.3)	-1.5 (19.4)	77.6 (19.1)	-0.4 (15.7)
Median	80.0	0.0	80.0	0.0
Min - Max	20 - 100	-47 - 73	0 - 100	-27 - 60

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Role functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	80.2 (25.8)		78.8 (25.6)	
Median	83.3		83.3	
Min - Max	0 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	77.3 (24.7)	-2.3 (23.6)	79.2 (22.3)	-0.3 (18.8)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-83 - 67	0 - 100	-67 - 50
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	80.3 (23.6)	-0.0 (24.5)	81.2 (20.2)	3.6 (20.2)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-33 - 50
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	81.6 (23.0)	1.8 (23.0)	78.6 (24.6)	0.2 (23.6)
Median	100.0	0.0	83.3	0.0
Min - Max	17 - 100	-67 - 83	0 - 100	-50 - 50
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	81.5 (23.1)	2.2 (24.2)	79.2 (27.1)	-0.4 (23.6)
Median	91.7	0.0	83.3	0.0
Min - Max	0 - 100	-83 - 83	0 - 100	-83 - 67
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	81.1 (24.3)	0.5 (24.1)	79.5 (24.8)	1.2 (21.1)
Median	100.0	0.0	83.3	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-67 - 50

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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03 FEB 2025 14:32 GMT

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Role functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	78.9 (25.9)	-1.3 (27.5)	83.0 (21.3)	4.4 (19.3)
Median	83.3	0.0	91.7	0.0
Min - Max	0 - 100	-100 - 83	17 - 100	-33 - 50
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	80.8 (21.5)	-1.1 (26.5)	79.3 (23.1)	1.1 (21.4)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-67 - 100	17 - 100	-50 - 50
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	82.9 (20.6)	2.4 (26.4)	77.6 (23.7)	0.4 (26.6)
Median	100.0	0.0	83.3	0.0
Min - Max	17 - 100	-50 - 100	17 - 100	-67 - 50
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	83.1 (21.3)	2.2 (25.6)	80.0 (20.7)	7.5 (25.8)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-67 - 100	17 - 100	-33 - 67
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	81.1 (19.6)	1.0 (28.7)	85.4 (15.8)	8.0 (24.0)
Median	83.3	0.0	91.7	0.0
Min - Max	33 - 100	-33 - 100	67 - 100	-33 - 50
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	82.0 (24.2)	2.1 (30.3)	82.6 (17.8)	7.1 (20.1)
Median	100.0	0.0	83.3	0.0
Min - Max	0 - 100	-67 - 100	50 - 100	-33 - 50

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 16 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Role functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	81.1 (19.8)	1.0 (29.5)	85.8 (18.2)	8.8 (29.1)
Median	83.3	0.0	91.7	0.0
Min - Max	17 - 100	-50 - 100	33 - 100	-50 - 50
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	82.6 (20.2)	4.4 (30.1)	86.0 (19.5)	8.3 (23.0)
Median	100.0	0.0	100.0	0.0
Min - Max	17 - 100	-50 - 100	33 - 100	-33 - 50
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	81.6 (23.8)	2.6 (25.3)	89.2 (15.5)	7.3 (23.5)
Median	100.0	0.0	100.0	0.0
Min - Max	17 - 100	-50 - 67	50 - 100	-33 - 50
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	80.2 (24.1)	0.0 (29.0)	85.3 (16.5)	6.2 (23.5)
Median	100.0	0.0	100.0	0.0
Min - Max	33 - 100	-50 - 83	67 - 100	-33 - 50
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	82.8 (20.2)	2.4 (26.7)	81.8 (21.7)	10.0 (33.5)
Median	100.0	0.0	83.3	16.7
Min - Max	33 - 100	-67 - 67	33 - 100	-67 - 50
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	86.5 (25.1)	2.4 (29.5)	85.2 (17.6)	16.7 (15.4)
Median	100.0	0.0	83.3	16.7
Min - Max	0 - 100	-83 - 50	50 - 100	0 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Role functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	80.6 (20.8)	4.9 (24.8)	87.0 (16.2)	14.6 (20.8)
Median	83.3	0.0	100.0	16.7
Min - Max	50 - 100	-33 - 50	67 - 100	-17 - 50
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	82.4 (26.7)	1.0 (29.7)	88.1 (12.6)	16.7 (18.3)
Median	100.0	0.0	83.3	16.7
Min - Max	0 - 100	-67 - 33	67 - 100	0 - 33
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	76.2 (16.9)	-0.0 (31.4)	93.3 (14.9)	33.3 (23.6)
Median	66.7	0.0	100.0	50.0
Min - Max	50 - 100	-33 - 67	67 - 100	0 - 50
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	74.4 (17.5)	-5.1 (26.7)	95.8 (8.3)	33.3 (23.6)
Median	66.7	-16.7	100.0	41.7
Min - Max	50 - 100	-33 - 33	83 - 100	0 - 50
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	83.3 (21.5)	5.1 (26.7)	87.5 (16.0)	25.0 (21.5)
Median	100.0	0.0	91.7	25.0
Min - Max	33 - 100	-33 - 33	67 - 100	0 - 50
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	71.4 (20.9)	-4.8 (24.9)	88.9 (9.6)	38.9 (9.6)
Median	66.7	0.0	83.3	33.3
Min - Max	50 - 100	-33 - 33	83 - 100	33 - 50

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Role functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	72.2 (13.6)	-11.1 (27.2)	66.7 (0.0)	16.7 (0.0)
Median	66.7	-16.7	66.7	16.7
Min - Max	67 - 100	-33 - 33	67 - 67	17 - 17
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	77.8 (19.2)	11.1 (19.2)	83.3 (NA)	33.3 (NA)
Median	66.7	0.0	83.3	33.3
Min - Max	67 - 100	0 - 33	83 - 83	33 - 33
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	83.3 (23.6)	0.0 (0.0)	83.3 (NA)	33.3 (NA)
Median	83.3	0.0	83.3	33.3
Min - Max	67 - 100	0 - 0	83 - 83	33 - 33
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	100.0 (NA)	0.0 (NA)	100.0 (NA)	50.0 (NA)
Median	100.0	0.0	100.0	50.0
Min - Max	100 - 100	0 - 0	100 - 100	50 - 50
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	100.0 (NA)	0.0 (NA)	83.3 (NA)	33.3 (NA)
Median	100.0	0.0	83.3	33.3
Min - Max	100 - 100	0 - 0	83 - 83	33 - 33
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	100.0 (NA)	0.0 (NA)	100.0 (NA)	50.0 (NA)
Median	100.0	0.0	100.0	50.0
Min - Max	100 - 100	0 - 0	100 - 100	50 - 50

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Role functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	69.2 (29.4)	-8.2 (32.4)	73.8 (27.0)	-7.5 (23.6)
Median	66.7	0.0	66.7	0.0
Min - Max	0 - 100	-100 - 83	0 - 100	-83 - 50
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	75.9 (25.2)	-3.7 (29.8)	56.7 (36.5)	-13.3 (13.9)
Median	66.7	0.0	66.7	-16.7
Min - Max	33 - 100	-67 - 33	0 - 100	-33 - 0
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	75.0 (35.4)	0.0 (0.0)	NE (NE)	NE (NE)
Median	75.0	0.0	NE	NE
Min - Max	50 - 100	0 - 0	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	50.0 (NA)	0.0 (NA)	NE (NE)	NE (NE)
Median	50.0	0.0	NE	NE
Min - Max	50 - 50	0 - 0	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	72.9 (33.5)	-4.3 (35.7)	63.3 (27.5)	-15.4 (26.1)
Median	91.7	0.0	66.7	-16.7
Min - Max	0 - 100	-67 - 67	0 - 100	-83 - 33
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	79.8 (18.1)	-0.9 (32.6)	71.9 (20.1)	-8.8 (27.7)
Median	83.3	0.0	66.7	-16.7
Min - Max	50 - 100	-50 - 67	33 - 100	-33 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 20 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Role functioning (revised)

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	66.7 (25.5)	-0.0 (41.9)	56.7 (14.9)	-3.3 (29.8)
Median	66.7	0.0	66.7	0.0
Min - Max	17 - 100	-67 - 50	33 - 67	-33 - 33
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	60.0 (36.5)	-26.7 (38.4)	50.0 (23.6)	8.3 (58.9)
Median	66.7	-33.3	50.0	8.3
Min - Max	0 - 100	-83 - 17	33 - 67	-33 - 50
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	50.0 (16.7)	-27.8 (25.5)	50.0 (NA)	-16.7 (NA)
Median	50.0	-33.3	50.0	-16.7
Min - Max	33 - 67	-50 - 0	50 - 50	-17 - -17
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	74.6 (28.2)	-2.6 (32.5)	76.0 (26.1)	-2.9 (21.3)
Median	66.7	0.0	83.3	0.0
Min - Max	0 - 100	-67 - 83	0 - 100	-67 - 50
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	80.6 (23.7)	-0.0 (32.1)	76.9 (24.8)	-1.3 (21.8)
Median	91.7	0.0	83.3	0.0
Min - Max	0 - 100	-83 - 100	0 - 100	-67 - 50

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 21 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Emotional functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	73.2 (20.4)		73.5 (21.6)	
Median	75.0		75.0	
Min - Max	17 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	78.0 (21.0)	4.8 (20.2)	80.3 (18.4)	6.6 (18.7)
Median	83.3	0.0	83.3	8.3
Min - Max	0 - 100	-67 - 83	0 - 100	-33 - 67
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	79.7 (19.5)	5.7 (19.6)	77.9 (16.3)	4.2 (15.0)
Median	83.3	0.0	75.0	0.0
Min - Max	8 - 100	-58 - 75	33 - 100	-33 - 58
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	79.3 (21.1)	6.4 (20.0)	77.8 (19.0)	5.6 (18.3)
Median	83.3	8.3	75.0	0.0
Min - Max	0 - 100	-58 - 58	8 - 100	-33 - 58
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	79.0 (22.1)	5.9 (21.8)	79.8 (18.2)	7.6 (18.2)
Median	83.3	8.3	83.3	8.3
Min - Max	0 - 100	-58 - 83	25 - 100	-42 - 58
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	76.3 (20.9)	1.7 (19.2)	77.1 (19.7)	4.3 (17.4)
Median	75.0	0.0	75.0	0.0
Min - Max	8 - 100	-67 - 58	25 - 100	-42 - 42

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

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Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 22 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Emotional functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	76.7 (21.8)	2.5 (23.1)	77.3 (20.6)	3.7 (18.0)
Median	83.3	8.3	75.0	0.0
Min - Max	8 - 100	-67 - 75	25 - 100	-42 - 67
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	78.0 (22.4)	2.9 (22.1)	76.3 (21.5)	3.0 (24.9)
Median	83.3	8.3	75.0	0.0
Min - Max	8 - 100	-58 - 67	0 - 100	-67 - 100
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	78.3 (18.9)	3.9 (22.5)	74.8 (22.3)	-0.6 (17.0)
Median	83.3	0.0	75.0	0.0
Min - Max	8 - 100	-50 - 67	17 - 100	-58 - 25
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	77.9 (21.9)	2.6 (21.4)	79.2 (19.4)	5.2 (11.9)
Median	75.0	0.0	83.3	8.3
Min - Max	8 - 100	-67 - 50	33 - 100	-25 - 33
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	75.6 (17.7)	1.2 (16.1)	83.3 (20.1)	7.2 (13.1)
Median	75.0	0.0	91.7	8.3
Min - Max	17 - 100	-25 - 42	42 - 100	-25 - 33
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	76.8 (20.8)	1.6 (22.5)	80.1 (19.7)	6.0 (11.5)
Median	75.0	0.0	91.7	8.3
Min - Max	17 - 100	-50 - 50	33 - 100	-17 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 23 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Emotional functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	76.4 (20.8)	2.6 (23.1)	81.7 (17.4)	7.9 (11.3)
Median	75.0	0.0	83.3	8.3
Min - Max	25 - 100	-58 - 50	42 - 100	-17 - 33
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	76.9 (20.8)	5.4 (23.0)	79.8 (23.3)	2.8 (12.1)
Median	75.0	4.2	83.3	8.3
Min - Max	0 - 100	-67 - 50	8 - 100	-25 - 17
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	77.1 (19.9)	6.8 (20.9)	83.8 (16.0)	5.2 (15.5)
Median	75.0	8.3	83.3	8.3
Min - Max	0 - 100	-25 - 67	50 - 100	-25 - 42
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	72.7 (22.2)	0.3 (19.7)	81.4 (16.5)	4.7 (14.6)
Median	75.0	4.2	83.3	8.3
Min - Max	0 - 100	-42 - 50	58 - 100	-25 - 33
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	75.3 (20.6)	3.3 (19.7)	85.6 (15.4)	13.3 (18.1)
Median	75.0	8.3	91.7	8.3
Min - Max	25 - 100	-50 - 50	67 - 100	-8 - 42
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	75.4 (23.8)	-0.4 (19.3)	81.5 (19.9)	7.3 (14.4)
Median	75.0	0.0	83.3	12.5
Min - Max	0 - 100	-67 - 25	50 - 100	-25 - 17

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 24 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Emotional functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	75.0 (15.9)	4.4 (17.0)	87.0 (13.9)	13.5 (9.9)
Median	70.8	0.0	83.3	16.7
Min - Max	50 - 100	-17 - 50	67 - 100	0 - 25
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	73.0 (26.6)	-2.9 (22.2)	86.9 (17.9)	15.3 (11.1)
Median	75.0	0.0	100.0	16.7
Min - Max	0 - 100	-67 - 17	58 - 100	0 - 33
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	73.8 (18.7)	-6.0 (16.5)	90.0 (18.1)	18.3 (12.4)
Median	70.8	-8.3	100.0	16.7
Min - Max	33 - 100	-33 - 33	58 - 100	0 - 33
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	72.4 (14.2)	0.6 (20.0)	77.1 (28.4)	8.3 (24.5)
Median	75.0	0.0	83.3	12.5
Min - Max	42 - 100	-25 - 50	42 - 100	-25 - 33
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	81.4 (16.4)	9.0 (20.8)	75.0 (21.5)	2.1 (14.2)
Median	83.3	8.3	75.0	4.2
Min - Max	50 - 100	-33 - 50	50 - 100	-17 - 17
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	72.6 (19.1)	4.8 (23.0)	77.8 (19.2)	8.3 (8.3)
Median	66.7	0.0	66.7	8.3
Min - Max	42 - 100	-25 - 50	67 - 100	0 - 17

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
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03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 25 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Emotional functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	76.4 (22.6)	-0.0 (18.3)	91.7 (11.8)	20.8 (5.9)
Median	75.0	4.2	91.7	20.8
Min - Max	42 - 100	-25 - 25	83 - 100	17 - 25
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	66.7 (33.3)	8.3 (41.7)	58.3 (NA)	0.0 (NA)
Median	66.7	8.3	58.3	0.0
Min - Max	33 - 100	-33 - 50	58 - 58	0 - 0
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	58.3 (58.9)	-20.8 (41.2)	58.3 (NA)	0.0 (NA)
Median	58.3	-20.8	58.3	0.0
Min - Max	17 - 100	-50 - 8	58 - 58	0 - 0
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	100.0 (NA)	8.3 (NA)	100.0 (NA)	41.7 (NA)
Median	100.0	8.3	100.0	41.7
Min - Max	100 - 100	8 - 8	100 - 100	42 - 42
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	100.0 (NA)	8.3 (NA)	58.3 (NA)	0.0 (NA)
Median	100.0	8.3	58.3	0.0
Min - Max	100 - 100	8 - 8	58 - 58	0 - 0
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	91.7 (NA)	0.0 (NA)	91.7 (NA)	33.3 (NA)
Median	91.7	0.0	91.7	33.3
Min - Max	92 - 92	0 - 0	92 - 92	33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
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03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 26 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Emotional functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	68.5 (23.7)	-1.7 (20.5)	68.8 (22.3)	-3.5 (18.9)
Median	66.7	0.0	66.7	0.0
Min - Max	0 - 100	-58 - 50	0 - 100	-58 - 67
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	77.8 (18.2)	-2.8 (17.7)	73.3 (10.9)	10.0 (10.9)
Median	75.0	-8.3	66.7	8.3
Min - Max	50 - 100	-25 - 33	67 - 92	0 - 25
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	75.0 (11.8)	-8.3 (11.8)	NE (NE)	NE (NE)
Median	75.0	-8.3	NE	NE
Min - Max	67 - 83	-17 - 0	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	75.0 (NA)	8.3 (NA)	NE (NE)	NE (NE)
Median	75.0	8.3	NE	NE
Min - Max	75 - 75	8 - 8	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	74.5 (23.3)	-0.8 (19.4)	68.1 (22.2)	-0.7 (27.0)
Median	75.0	0.0	66.7	0.0
Min - Max	25 - 100	-50 - 33	0 - 100	-83 - 67
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	66.7 (22.0)	3.5 (25.0)	75.0 (17.8)	9.8 (20.9)
Median	75.0	8.3	75.0	8.3
Min - Max	25 - 100	-50 - 42	42 - 100	-25 - 58

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 27 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Emotional functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	72.6 (22.4)	15.5 (29.0)	65.0 (16.0)	15.0 (16.0)
Median	66.7	25.0	58.3	8.3
Min - Max	42 - 100	-25 - 58	50 - 92	0 - 42
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	66.7 (19.5)	-3.3 (20.9)	66.7 (0.0)	25.0 (11.8)
Median	58.3	8.3	66.7	25.0
Min - Max	50 - 92	-33 - 17	67 - 67	17 - 33
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	61.1 (29.3)	-5.6 (25.5)	100.0 (NA)	83.3 (NA)
Median	58.3	0.0	100.0	83.3
Min - Max	33 - 92	-33 - 17	100 - 100	83 - 83
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	71.8 (23.9)	-0.0 (24.1)	76.3 (20.5)	3.4 (22.5)
Median	66.7	0.0	75.0	0.0
Min - Max	8 - 100	-58 - 33	0 - 100	-33 - 100
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	73.9 (22.9)	1.9 (21.4)	75.6 (22.3)	1.8 (22.7)
Median	75.0	0.0	79.2	0.0
Min - Max	0 - 100	-67 - 50	0 - 100	-58 - 100

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

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Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 28 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Cognitive functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	86.5 (16.3)		86.1 (17.2)	
Median	83.3		100.0	
Min - Max	17 - 100		33 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	85.1 (17.9)	-1.3 (15.4)	85.3 (17.4)	-0.9 (15.5)
Median	83.3	0.0	83.3	0.0
Min - Max	33 - 100	-50 - 33	33 - 100	-50 - 33
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	83.9 (19.7)	-2.4 (16.7)	85.3 (17.3)	-0.7 (14.8)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-83 - 50	33 - 100	-50 - 50
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	84.0 (18.5)	-2.2 (15.1)	81.2 (18.3)	-3.3 (14.4)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-50 - 50	17 - 100	-50 - 33
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	84.5 (18.5)	-3.0 (15.5)	82.8 (21.1)	-3.0 (18.9)
Median	83.3	0.0	83.3	0.0
Min - Max	17 - 100	-50 - 50	17 - 100	-50 - 50
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	82.1 (19.5)	-4.6 (19.2)	82.2 (20.7)	-3.5 (17.8)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-83 - 50	17 - 100	-50 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 29 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Cognitive functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	81.3 (22.6)	-6.3 (20.2)	83.3 (19.0)	-2.3 (19.0)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-100 - 33	33 - 100	-67 - 67
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	81.2 (22.5)	-5.8 (17.9)	80.0 (23.7)	-3.4 (19.9)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-67 - 33	0 - 100	-67 - 33
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	82.0 (19.4)	-5.3 (17.5)	79.7 (21.2)	-2.1 (20.7)
Median	83.3	0.0	83.3	0.0
Min - Max	17 - 100	-67 - 33	33 - 100	-67 - 67
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	80.5 (23.6)	-6.2 (22.8)	79.4 (20.8)	2.3 (13.9)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-83 - 33	33 - 100	-17 - 33
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	81.1 (21.7)	-5.7 (18.0)	80.6 (22.9)	1.4 (14.1)
Median	83.3	0.0	83.3	0.0
Min - Max	17 - 100	-50 - 33	17 - 100	-17 - 33
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	80.7 (22.2)	-5.6 (18.3)	74.6 (25.6)	-3.2 (14.5)
Median	83.3	0.0	83.3	0.0
Min - Max	17 - 100	-67 - 33	17 - 100	-33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 30 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Cognitive functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	82.1 (18.9)	-5.4 (17.1)	78.3 (20.3)	2.6 (20.2)
Median	83.3	0.0	83.3	0.0
Min - Max	33 - 100	-67 - 33	33 - 100	-33 - 50
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	84.5 (19.0)	-3.6 (17.5)	80.7 (21.0)	0.9 (13.4)
Median	83.3	0.0	83.3	0.0
Min - Max	17 - 100	-67 - 33	33 - 100	-17 - 33
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	80.3 (23.8)	-7.0 (18.4)	83.3 (22.0)	-0.0 (21.9)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-50 - 33	33 - 100	-33 - 50
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	80.2 (24.5)	-8.3 (16.9)	76.5 (24.3)	-3.1 (17.4)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-50 - 17	33 - 100	-33 - 33
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	79.9 (20.6)	-6.5 (17.8)	89.4 (17.1)	11.7 (20.9)
Median	83.3	0.0	100.0	0.0
Min - Max	33 - 100	-50 - 17	50 - 100	-17 - 50
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	82.5 (23.3)	-5.6 (18.5)	85.2 (19.4)	6.2 (8.6)
Median	83.3	0.0	100.0	0.0
Min - Max	0 - 100	-50 - 17	50 - 100	0 - 17

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 31 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Cognitive functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	81.5 (26.1)	-4.9 (20.2)	94.4 (11.8)	12.5 (19.4)
Median	91.7	0.0	100.0	0.0
Min - Max	0 - 100	-50 - 17	67 - 100	0 - 50
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	75.5 (27.1)	-12.7 (20.9)	92.9 (13.1)	13.9 (26.7)
Median	83.3	0.0	100.0	0.0
Min - Max	0 - 100	-50 - 17	67 - 100	0 - 67
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	85.7 (12.8)	-6.0 (10.6)	90.0 (14.9)	20.0 (29.8)
Median	83.3	0.0	100.0	0.0
Min - Max	50 - 100	-17 - 17	67 - 100	0 - 67
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	78.2 (20.8)	-14.1 (19.1)	95.8 (8.3)	33.3 (27.2)
Median	83.3	-16.7	100.0	33.3
Min - Max	50 - 100	-50 - 17	83 - 100	0 - 67
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	88.5 (14.2)	-5.1 (17.2)	75.0 (31.9)	4.2 (8.3)
Median	100.0	0.0	83.3	0.0
Min - Max	67 - 100	-33 - 17	33 - 100	0 - 17
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	76.2 (8.9)	-19.0 (15.0)	88.9 (19.2)	16.7 (16.7)
Median	83.3	-16.7	100.0	16.7
Min - Max	67 - 83	-33 - 0	67 - 100	0 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 32 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Cognitive functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	75.0 (9.1)	-19.4 (12.5)	83.3 (23.6)	8.3 (11.8)
Median	75.0	-16.7	83.3	8.3
Min - Max	67 - 83	-33 - 0	67 - 100	0 - 17
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	72.2 (9.6)	-27.8 (9.6)	66.7 (NA)	16.7 (NA)
Median	66.7	-33.3	66.7	16.7
Min - Max	67 - 83	-33 - -17	67 - 67	17 - 17
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	83.3 (23.6)	-16.7 (23.6)	83.3 (NA)	33.3 (NA)
Median	83.3	-16.7	83.3	33.3
Min - Max	67 - 100	-33 - 0	83 - 83	33 - 33
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	100.0 (NA)	0.0 (NA)	83.3 (NA)	33.3 (NA)
Median	100.0	0.0	83.3	33.3
Min - Max	100 - 100	0 - 0	83 - 83	33 - 33
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	100.0 (NA)	0.0 (NA)	66.7 (NA)	16.7 (NA)
Median	100.0	0.0	66.7	16.7
Min - Max	100 - 100	0 - 0	67 - 67	17 - 17
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	83.3 (NA)	-16.7 (NA)	100.0 (NA)	50.0 (NA)
Median	83.3	-16.7	100.0	50.0
Min - Max	83 - 83	-17 - -17	100 - 100	50 - 50

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 33 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Cognitive functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	74.9 (26.5)	-9.1 (24.3)	79.8 (19.1)	-8.0 (18.9)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-100 - 33	17 - 100	-67 - 33
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	77.8 (22.0)	-11.1 (16.7)	70.0 (21.7)	-10.0 (9.1)
Median	83.3	-16.7	83.3	-16.7
Min - Max	33 - 100	-33 - 17	33 - 83	-17 - 0
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	66.7 (47.1)	-16.7 (23.6)	NE (NE)	NE (NE)
Median	66.7	-16.7	NE	NE
Min - Max	33 - 100	-33 - 0	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	66.7 (NA)	0.0 (NA)	NE (NE)	NE (NE)
Median	66.7	0.0	NE	NE
Min - Max	67 - 67	0 - 0	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	78.6 (21.7)	-10.2 (20.9)	77.5 (17.5)	-5.3 (19.4)
Median	83.3	0.0	83.3	0.0
Min - Max	17 - 100	-83 - 33	33 - 100	-50 - 33
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	77.2 (20.9)	-7.0 (17.8)	78.1 (22.3)	-4.9 (24.1)
Median	83.3	0.0	83.3	0.0
Min - Max	33 - 100	-33 - 17	33 - 100	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 34 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Cognitive functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	88.1 (15.9)	-2.4 (17.8)	66.7 (31.2)	-6.7 (25.3)
Median	100.0	0.0	83.3	-16.7
Min - Max	67 - 100	-33 - 17	33 - 100	-33 - 33
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	83.3 (16.7)	-13.3 (21.7)	66.7 (23.6)	8.3 (11.8)
Median	83.3	-16.7	66.7	8.3
Min - Max	67 - 100	-33 - 17	50 - 83	0 - 17
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	66.7 (28.9)	-33.3 (28.9)	83.3 (NA)	16.7 (NA)
Median	83.3	-16.7	83.3	16.7
Min - Max	33 - 83	-67 - -17	83 - 83	17 - 17
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	82.5 (24.4)	-7.0 (25.6)	85.6 (17.9)	-2.2 (17.2)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-83 - 50	33 - 100	-50 - 33
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	78.9 (23.0)	-10.1 (21.4)	83.9 (19.0)	-3.2 (17.5)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-83 - 50	17 - 100	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 35 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Social functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	82.2 (21.1)		80.1 (23.7)	
Median	83.3		83.3	
Min - Max	17 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	78.8 (23.4)	-2.7 (22.0)	83.8 (21.2)	2.8 (19.8)
Median	83.3	0.0	100.0	0.0
Min - Max	0 - 100	-100 - 67	0 - 100	-50 - 67
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	80.9 (22.2)	-1.4 (21.2)	83.1 (21.4)	3.0 (21.1)
Median	83.3	0.0	100.0	0.0
Min - Max	0 - 100	-67 - 50	0 - 100	-67 - 50
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	83.5 (20.4)	0.8 (22.8)	82.0 (22.0)	2.1 (22.7)
Median	100.0	0.0	91.7	0.0
Min - Max	0 - 100	-100 - 67	0 - 100	-50 - 67
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	82.6 (21.2)	0.0 (19.6)	81.3 (24.5)	0.4 (23.0)
Median	91.7	0.0	100.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-67 - 67
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	80.1 (23.5)	-3.0 (21.4)	81.8 (20.1)	0.5 (22.7)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-100 - 67	33 - 100	-67 - 50

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 36 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Social functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	79.3 (25.6)	-4.2 (21.7)	83.3 (20.5)	1.2 (20.9)
Median	83.3	0.0	100.0	0.0
Min - Max	0 - 100	-100 - 33	17 - 100	-50 - 50
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	82.9 (23.1)	-1.3 (24.9)	81.9 (20.4)	1.9 (23.1)
Median	100.0	0.0	83.3	0.0
Min - Max	0 - 100	-100 - 33	33 - 100	-67 - 50
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	83.3 (21.5)	-0.5 (26.2)	83.7 (19.9)	6.2 (27.1)
Median	100.0	0.0	100.0	0.0
Min - Max	0 - 100	-100 - 67	33 - 100	-67 - 50
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	81.4 (23.1)	-2.2 (25.1)	82.2 (20.0)	8.6 (24.2)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-100 - 50	33 - 100	-50 - 50
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	80.2 (21.4)	-5.3 (26.2)	81.2 (19.2)	5.1 (21.6)
Median	83.3	0.0	75.0	0.0
Min - Max	33 - 100	-67 - 33	33 - 100	-33 - 50
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	82.4 (22.2)	-3.8 (25.6)	79.7 (19.4)	5.6 (23.2)
Median	100.0	0.0	83.3	0.0
Min - Max	0 - 100	-100 - 33	33 - 100	-33 - 50

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 37 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Social functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	81.4 (19.7)	-4.8 (24.3)	82.5 (18.3)	8.8 (27.4)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-100 - 33	50 - 100	-33 - 50
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	82.2 (21.3)	-2.4 (27.9)	78.1 (28.9)	1.9 (20.5)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-100 - 50	17 - 100	-33 - 50
Cycle 27 Day 1				
n	39	38	16	15
Mean (SD)	78.6 (21.6)	-4.8 (24.8)	91.7 (18.3)	14.4 (29.5)
Median	83.3	0.0	100.0	0.0
Min - Max	0 - 100	-67 - 50	50 - 100	-33 - 67
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	79.7 (23.8)	-7.8 (25.7)	90.2 (16.7)	13.5 (23.7)
Median	83.3	0.0	100.0	8.3
Min - Max	0 - 100	-67 - 33	50 - 100	-33 - 50
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	79.3 (19.7)	-5.4 (26.1)	84.8 (18.9)	15.0 (31.9)
Median	83.3	0.0	100.0	16.7
Min - Max	33 - 100	-67 - 50	50 - 100	-33 - 50
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	85.7 (17.7)	-4.8 (20.5)	90.7 (18.8)	25.0 (26.7)
Median	100.0	0.0	100.0	33.3
Min - Max	50 - 100	-50 - 33	50 - 100	-17 - 50

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 38 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Social functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	86.1 (15.4)	4.9 (21.1)	83.3 (22.0)	12.5 (29.2)
Median	91.7	0.0	100.0	16.7
Min - Max	67 - 100	-33 - 33	50 - 100	-33 - 50
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	83.3 (19.5)	-6.9 (22.1)	85.7 (20.2)	16.7 (21.1)
Median	83.3	0.0	100.0	8.3
Min - Max	33 - 100	-67 - 33	50 - 100	0 - 50
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	78.6 (17.8)	-9.5 (20.4)	93.3 (9.1)	30.0 (18.3)
Median	66.7	-8.3	100.0	33.3
Min - Max	50 - 100	-33 - 33	83 - 100	0 - 50
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	85.9 (15.0)	-1.3 (20.9)	95.8 (8.3)	37.5 (8.3)
Median	83.3	0.0	100.0	33.3
Min - Max	67 - 100	-33 - 33	83 - 100	33 - 50
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	83.3 (20.4)	-5.1 (26.7)	83.3 (13.6)	20.8 (25.0)
Median	83.3	0.0	83.3	33.3
Min - Max	33 - 100	-67 - 33	67 - 100	-17 - 33
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	66.7 (19.2)	-19.0 (22.4)	88.9 (19.2)	22.2 (9.6)
Median	66.7	-16.7	100.0	16.7
Min - Max	50 - 100	-50 - 17	67 - 100	17 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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03 FEB 2025 14:32 GMT
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Social functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	75.0 (13.9)	-19.4 (16.4)	91.7 (11.8)	25.0 (11.8)
Median	66.7	-25.0	91.7	25.0
Min - Max	67 - 100	-33 - 0	83 - 100	17 - 33
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	66.7 (28.9)	-11.1 (34.7)	100.0 (NA)	50.0 (NA)
Median	50.0	0.0	100.0	50.0
Min - Max	50 - 100	-50 - 17	100 - 100	50 - 50
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	83.3 (23.6)	-16.7 (23.6)	100.0 (NA)	50.0 (NA)
Median	83.3	-16.7	100.0	50.0
Min - Max	67 - 100	-33 - 0	100 - 100	50 - 50
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	100.0 (NA)	0.0 (NA)	100.0 (NA)	50.0 (NA)
Median	100.0	0.0	100.0	50.0
Min - Max	100 - 100	0 - 0	100 - 100	50 - 50
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	100.0 (NA)	0.0 (NA)	66.7 (NA)	16.7 (NA)
Median	100.0	0.0	66.7	16.7
Min - Max	100 - 100	0 - 0	67 - 67	17 - 17
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	100.0 (NA)	0.0 (NA)	100.0 (NA)	50.0 (NA)
Median	100.0	0.0	100.0	50.0
Min - Max	100 - 100	0 - 0	100 - 100	50 - 50

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Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 40 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Social functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	70.9 (27.7)	-9.5 (27.5)	75.7 (27.4)	-6.1 (26.4)
Median	66.7	0.0	83.3	0.0
Min - Max	0 - 100	-100 - 67	0 - 100	-100 - 67
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	75.9 (23.7)	-11.1 (28.9)	63.3 (24.7)	-10.0 (19.0)
Median	83.3	-16.7	66.7	-16.7
Min - Max	33 - 100	-67 - 33	33 - 100	-33 - 17
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	75.0 (35.4)	-8.3 (11.8)	NE (NE)	NE (NE)
Median	75.0	-8.3	NE	NE
Min - Max	50 - 100	-17 - 0	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	16.7 (NA)	-50.0 (NA)	NE (NE)	NE (NE)
Median	16.7	-50.0	NE	NE
Min - Max	17 - 17	-50 - -50	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	72.4 (27.3)	-9.7 (26.1)	70.4 (29.4)	-7.0 (30.2)
Median	75.0	0.0	66.7	0.0
Min - Max	0 - 100	-83 - 33	0 - 100	-67 - 67
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	69.3 (24.4)	-14.0 (25.6)	81.6 (18.3)	-2.0 (25.6)
Median	66.7	-16.7	83.3	0.0
Min - Max	17 - 100	-67 - 33	50 - 100	-33 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 41 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Social functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	76.2 (27.0)	2.4 (26.2)	53.3 (36.1)	-16.7 (40.8)
Median	83.3	0.0	50.0	-16.7
Min - Max	33 - 100	-33 - 33	0 - 100	-83 - 17
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	73.3 (25.3)	-10.0 (14.9)	41.7 (11.8)	-16.7 (47.1)
Median	83.3	0.0	41.7	-16.7
Min - Max	33 - 100	-33 - 0	33 - 50	-50 - 17
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	44.4 (38.5)	-22.2 (19.2)	66.7 (NA)	0.0 (NA)
Median	66.7	-33.3	66.7	0.0
Min - Max	0 - 67	-33 - 0	67 - 67	0 - 0
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	77.0 (26.1)	-8.8 (17.0)	80.2 (23.1)	-1.6 (22.4)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-50 - 17	0 - 100	-50 - 50
TIME OF LAST TX DOSE				
n	68	61	85	76
Mean (SD)	78.7 (22.1)	-6.3 (24.8)	78.4 (25.3)	-0.0 (22.4)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-67 - 50	0 - 100	-50 - 50

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

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03 FEB 2025 14:32 GMT

Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 42 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Fatigue

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	32.0 (24.0)		32.2 (23.5)	
Median	33.3		33.3	
Min - Max	0 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	35.7 (25.8)	3.2 (22.4)	33.0 (20.9)	1.0 (19.6)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-78 - 44
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	32.7 (23.8)	0.8 (20.2)	31.8 (21.3)	-0.5 (20.6)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-44 - 56	0 - 100	-67 - 56
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	31.1 (22.0)	-0.2 (22.0)	33.7 (21.5)	1.4 (18.5)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-44 - 78	0 - 100	-44 - 44
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	33.4 (23.1)	2.1 (23.9)	32.7 (23.7)	0.8 (19.4)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-56 - 78	0 - 100	-44 - 56
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	31.3 (21.3)	0.0 (20.3)	30.9 (19.7)	0.8 (17.4)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-56 - 78	0 - 89	-44 - 44

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 43 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Fatigue

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	33.6 (23.4)	3.2 (24.3)	33.0 (16.8)	1.2 (21.3)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 100	0 - 78	-56 - 44
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	29.4 (22.0)	-0.3 (22.0)	32.3 (19.5)	1.3 (22.4)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 89	-56 - 78	0 - 67	-56 - 56
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	29.7 (22.1)	-1.6 (24.9)	32.2 (20.3)	1.4 (24.0)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 89	-67 - 78	0 - 78	-44 - 67
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	30.6 (21.1)	1.2 (23.7)	32.2 (19.2)	-1.5 (23.7)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 78	-44 - 67	0 - 67	-56 - 33
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	31.9 (19.6)	2.0 (17.2)	25.9 (15.9)	-3.4 (23.6)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 78	-44 - 44	0 - 56	-56 - 33
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	30.1 (17.0)	1.2 (22.3)	29.5 (20.3)	-0.5 (22.9)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 67	-56 - 56	0 - 67	-44 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 44 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Fatigue

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	31.4 (19.6)	1.6 (23.7)	26.1 (16.2)	-8.2 (32.9)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 78	-44 - 56	0 - 56	-67 - 33
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	33.6 (19.5)	3.2 (22.4)	29.2 (22.6)	-1.2 (25.2)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 89	-44 - 78	0 - 89	-56 - 33
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	33.0 (18.3)	1.5 (20.0)	23.5 (19.2)	-3.5 (18.9)
Median	33.3	0.0	22.2	0.0
Min - Max	0 - 67	-33 - 44	0 - 56	-44 - 22
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	30.2 (18.1)	2.8 (18.7)	24.8 (19.8)	-4.2 (21.4)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 78	-33 - 44	0 - 56	-56 - 33
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	31.0 (16.4)	0.4 (17.8)	22.2 (19.9)	-13.3 (29.5)
Median	33.3	0.0	33.3	-11.1
Min - Max	0 - 78	-33 - 44	0 - 44	-56 - 33
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	30.7 (19.2)	3.7 (20.3)	27.2 (30.0)	-6.9 (30.8)
Median	33.3	0.0	33.3	-11.1
Min - Max	0 - 100	-33 - 67	0 - 78	-44 - 56

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Fatigue

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	29.6 (12.1)	-3.9 (17.1)	23.5 (21.1)	-8.3 (22.0)
Median	33.3	0.0	22.2	-5.6
Min - Max	0 - 56	-33 - 33	0 - 56	-33 - 33
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	30.1 (14.0)	2.0 (17.2)	22.2 (22.2)	-9.3 (19.1)
Median	33.3	0.0	33.3	-5.6
Min - Max	0 - 67	-33 - 33	0 - 56	-44 - 11
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	35.7 (10.8)	4.8 (12.1)	20.0 (16.5)	-22.2 (28.3)
Median	33.3	5.6	22.2	-11.1
Min - Max	11 - 56	-22 - 22	0 - 44	-67 - 0
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	35.0 (8.9)	3.4 (15.3)	22.2 (27.2)	-25.0 (36.7)
Median	33.3	0.0	16.7	-11.1
Min - Max	22 - 56	-33 - 22	0 - 56	-78 - 0
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	29.1 (15.4)	-1.7 (18.6)	25.0 (19.0)	-13.9 (22.9)
Median	33.3	0.0	27.8	-16.7
Min - Max	0 - 56	-33 - 22	0 - 44	-33 - 11
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	46.0 (20.7)	12.7 (29.0)	40.7 (12.8)	-3.7 (32.1)
Median	33.3	22.2	33.3	-22.2
Min - Max	22 - 78	-33 - 44	33 - 56	-22 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 46 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Fatigue

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	35.2 (16.4)	7.4 (19.5)	38.9 (7.9)	0.0 (31.4)
Median	33.3	0.0	38.9	0.0
Min - Max	22 - 67	-11 - 44	33 - 44	-22 - 22
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	29.6 (6.4)	-14.8 (17.0)	33.3 (NA)	-22.2 (NA)
Median	33.3	-11.1	33.3	-22.2
Min - Max	22 - 33	-33 - 0	33 - 33	-22 - -22
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	38.9 (7.9)	5.6 (7.9)	33.3 (NA)	-22.2 (NA)
Median	38.9	5.6	33.3	-22.2
Min - Max	33 - 44	0 - 11	33 - 33	-22 - -22
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	22.2 (NA)	-11.1 (NA)	22.2 (NA)	-33.3 (NA)
Median	22.2	-11.1	22.2	-33.3
Min - Max	22 - 22	-11 - -11	22 - 22	-33 - -33
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	22.2 (NA)	-11.1 (NA)	33.3 (NA)	-22.2 (NA)
Median	22.2	-11.1	33.3	-22.2
Min - Max	22 - 22	-11 - -11	33 - 33	-22 - -22
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	33.3 (NA)	0.0 (NA)	33.3 (NA)	-22.2 (NA)
Median	33.3	0.0	33.3	-22.2
Min - Max	33 - 33	0 - 0	33 - 33	-22 - -22

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 47 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Fatigue

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	41.5 (26.9)	6.9 (26.1)	39.6 (25.6)	7.3 (20.4)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-44 - 100	0 - 100	-44 - 67
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	40.7 (22.2)	8.6 (24.7)	37.8 (12.7)	6.7 (16.9)
Median	33.3	11.1	33.3	0.0
Min - Max	0 - 67	-44 - 33	22 - 56	-11 - 33
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	50.0 (23.6)	0.0 (0.0)	NE (NE)	NE (NE)
Median	50.0	0.0	NE	NE
Min - Max	33 - 67	0 - 0	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	88.9 (NA)	22.2 (NA)	NE (NE)	NE (NE)
Median	88.9	22.2	NE	NE
Min - Max	89 - 89	22 - 22	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	39.6 (25.4)	6.8 (25.6)	43.3 (21.5)	4.7 (17.6)
Median	33.3	11.1	33.3	0.0
Min - Max	0 - 100	-44 - 56	0 - 89	-56 - 33
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	45.3 (16.4)	13.7 (17.0)	35.7 (19.8)	-0.7 (25.9)
Median	44.4	11.1	33.3	0.0
Min - Max	22 - 78	-11 - 56	0 - 78	-89 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 48 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Fatigue

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	38.1 (26.3)	0.0 (24.8)	55.6 (38.5)	11.1 (31.4)
Median	44.4	-11.1	66.7	33.3
Min - Max	0 - 78	-22 - 44	0 - 89	-33 - 33
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	60.0 (32.0)	33.3 (20.8)	66.7 (31.4)	-11.1 (62.9)
Median	44.4	22.2	66.7	-11.1
Min - Max	33 - 100	11 - 56	44 - 89	-56 - 33
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	48.1 (17.0)	14.8 (17.0)	77.8 (NA)	22.2 (NA)
Median	44.4	11.1	77.8	22.2
Min - Max	33 - 67	0 - 33	78 - 78	22 - 22
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	36.0 (24.8)	6.4 (26.3)	37.1 (22.0)	2.6 (19.0)
Median	33.3	11.1	33.3	0.0
Min - Max	0 - 100	-44 - 44	0 - 100	-44 - 44
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	35.5 (22.2)	3.5 (26.1)	37.7 (22.9)	3.3 (19.2)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-44 - 67	0 - 100	-56 - 44

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 49 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Nausea and vomiting

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	5.9 (12.7)		7.4 (16.4)	
Median	0.0		0.0	
Min - Max	0 - 67		0 - 83	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	8.7 (16.4)	2.7 (18.1)	5.8 (12.3)	-1.4 (14.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-50 - 83	0 - 67	-83 - 67
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	6.6 (11.8)	0.5 (14.4)	7.1 (11.5)	0.1 (16.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 50	-50 - 33	0 - 50	-83 - 50
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	6.6 (12.3)	0.4 (16.3)	6.0 (12.1)	-1.4 (16.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 33	0 - 67	-67 - 50
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	6.0 (11.8)	-0.5 (14.7)	6.7 (13.9)	-1.2 (19.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 50	-67 - 50	0 - 67	-83 - 67
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	5.9 (12.9)	0.5 (17.2)	5.2 (11.0)	-3.1 (17.4)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 50	-83 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 50 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Nausea and vomiting

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	5.1 (13.1)	0.4 (18.0)	6.6 (13.2)	-2.0 (18.9)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 67	-83 - 33
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	3.2 (8.5)	-1.6 (13.5)	4.4 (10.3)	-4.9 (13.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 50	-50 - 50	0 - 33	-50 - 17
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	4.3 (8.3)	-0.2 (13.6)	8.9 (16.3)	-0.4 (17.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-50 - 33	0 - 67	-67 - 33
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	4.0 (9.2)	-1.0 (14.8)	6.1 (14.2)	-4.0 (15.2)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-67 - 33	0 - 67	-67 - 17
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	6.0 (10.9)	0.3 (16.0)	2.8 (8.0)	-4.3 (16.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 50	-67 - 33	0 - 33	-67 - 17
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	3.6 (7.7)	-2.1 (14.8)	8.0 (12.2)	0.8 (19.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-67 - 33	0 - 33	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 51 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Nausea and vomiting

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	3.2 (8.1)	-1.7 (16.0)	5.8 (11.2)	-2.6 (24.4)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-67 - 33	0 - 33	-83 - 33
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	4.3 (8.2)	0.0 (13.8)	7.9 (14.0)	0.9 (25.9)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-50 - 33	0 - 33	-83 - 33
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	6.0 (11.1)	2.6 (13.2)	4.9 (9.8)	3.1 (12.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 33	-17 - 33
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	4.7 (8.7)	1.0 (12.7)	5.9 (11.7)	3.1 (13.9)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 33	-17 - 33
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	4.6 (8.8)	0.6 (13.2)	1.5 (5.0)	-1.7 (9.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 17	-17 - 17
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	3.2 (8.5)	0.0 (11.8)	5.6 (8.3)	-4.2 (33.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 17	-83 - 17

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 52 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Nausea and vomiting

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	3.7 (9.1)	0.0 (13.2)	1.9 (5.6)	2.1 (5.9)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 17	0 - 17
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	3.9 (12.5)	-0.0 (16.7)	2.4 (6.3)	-11.1 (36.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 50	-33 - 50	0 - 17	-83 - 17
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	4.8 (10.2)	2.4 (12.8)	0.0 (0.0)	-16.7 (37.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-17 - 33	0 - 0	-83 - 0
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	3.8 (7.3)	2.6 (9.2)	0.0 (0.0)	-20.8 (41.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 17	-17 - 17	0 - 0	-83 - 0
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	2.6 (6.3)	1.3 (8.2)	0.0 (0.0)	-20.8 (41.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 17	-17 - 17	0 - 0	-83 - 0
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	4.8 (8.1)	4.8 (8.1)	0.0 (0.0)	0.0 (0.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 17	0 - 17	0 - 0	0 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 53 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Nausea and vomiting

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	5.6 (8.6)	5.6 (8.6)	0.0 (0.0)	0.0 (0.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 17	0 - 17	0 - 0	0 - 0
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	5.6 (9.6)	5.6 (9.6)	0.0 (NA)	0.0 (NA)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 17	0 - 17	0 - 0	0 - 0
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	16.7 (0.0)	16.7 (0.0)	0.0 (NA)	0.0 (NA)
Median	16.7	16.7	0.0	0.0
Min - Max	17 - 17	17 - 17	0 - 0	0 - 0
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	0.0 (NA)	0.0 (NA)	0.0 (NA)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 0	0 - 0	0 - 0	0 - 0
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	0.0 (NA)	0.0 (NA)	0.0 (NA)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 0	0 - 0	0 - 0	0 - 0
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	0.0 (NA)	0.0 (NA)	0.0 (NA)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 0	0 - 0	0 - 0	0 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 54 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Nausea and vomiting

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	13.3 (20.9)	6.5 (22.8)	11.3 (20.8)	3.6 (23.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-50 - 83	0 - 100	-50 - 100
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	11.1 (18.6)	7.4 (12.1)	6.7 (14.9)	-6.7 (14.9)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 50	0 - 33	0 - 33	-33 - 0
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	16.7 (23.6)	16.7 (23.6)	NE (NE)	NE (NE)
Median	16.7	16.7	NE	NE
Min - Max	0 - 33	0 - 33	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	0.0 (NA)	0.0 (NA)	NE (NE)	NE (NE)
Median	0.0	0.0	NE	NE
Min - Max	0 - 0	0 - 0	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	9.9 (21.1)	4.8 (22.8)	16.7 (19.6)	8.3 (26.5)
Median	0.0	0.0	16.7	0.0
Min - Max	0 - 100	-50 - 83	0 - 67	-33 - 67
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	13.2 (18.1)	2.6 (13.9)	8.8 (14.0)	4.9 (21.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-17 - 33	0 - 50	-33 - 50

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 55 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Nausea and vomiting

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	19.0 (20.2)	14.3 (24.4)	3.3 (7.5)	-3.3 (18.3)
Median	16.7	0.0	0.0	0.0
Min - Max	0 - 50	-17 - 50	0 - 17	-33 - 17
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	10.0 (14.9)	6.7 (9.1)	0.0 (0.0)	-16.7 (23.6)
Median	0.0	0.0	0.0	-16.7
Min - Max	0 - 33	0 - 17	0 - 0	-33 - 0
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	22.2 (38.5)	22.2 (38.5)	0.0 (NA)	0.0 (NA)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	0 - 67	0 - 0	0 - 0
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	11.1 (20.6)	7.0 (21.0)	9.6 (16.1)	1.9 (15.4)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 67	0 - 67	-33 - 33
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	9.6 (19.0)	7.1 (20.3)	10.1 (15.6)	2.6 (15.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-50 - 83	0 - 67	-33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 56 of 105

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Pain

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	28.0 (26.3)		28.5 (28.0)	
Median	16.7		16.7	
Min - Max	0 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	23.4 (25.1)	-4.4 (23.3)	21.8 (21.3)	-6.2 (22.6)
Median	16.7	0.0	16.7	0.0
Min - Max	0 - 100	-67 - 83	0 - 83	-83 - 67
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	20.1 (22.2)	-7.4 (23.5)	19.7 (20.7)	-8.6 (24.1)
Median	16.7	0.0	16.7	0.0
Min - Max	0 - 100	-50 - 67	0 - 67	-100 - 50
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	19.4 (22.3)	-8.0 (24.7)	23.0 (24.9)	-3.0 (23.9)
Median	16.7	0.0	16.7	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-67 - 50
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	19.6 (22.7)	-7.9 (23.2)	23.0 (26.7)	-3.0 (25.8)
Median	16.7	0.0	16.7	0.0
Min - Max	0 - 100	-83 - 67	0 - 100	-67 - 83
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	19.7 (21.1)	-7.9 (24.9)	21.6 (18.7)	-5.9 (23.6)
Median	16.7	0.0	16.7	0.0
Min - Max	0 - 83	-67 - 67	0 - 67	-100 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 57 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Pain

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	21.1 (23.8)	-6.5 (24.4)	19.5 (18.2)	-9.6 (25.2)
Median	16.7	0.0	16.7	0.0
Min - Max	0 - 100	-67 - 67	0 - 67	-100 - 33
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	18.1 (20.7)	-6.9 (28.1)	21.5 (18.3)	-7.2 (22.0)
Median	16.7	0.0	16.7	0.0
Min - Max	0 - 83	-67 - 67	0 - 67	-67 - 33
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	13.9 (19.8)	-13.0 (23.9)	20.3 (22.2)	-9.2 (22.9)
Median	0.0	-16.7	16.7	0.0
Min - Max	0 - 83	-67 - 67	0 - 67	-67 - 33
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	16.4 (20.0)	-8.7 (23.6)	20.6 (20.4)	-12.6 (23.8)
Median	0.0	0.0	16.7	-16.7
Min - Max	0 - 83	-67 - 50	0 - 67	-67 - 33
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	16.4 (16.8)	-8.0 (27.0)	20.8 (20.4)	-7.2 (21.8)
Median	16.7	0.0	16.7	0.0
Min - Max	0 - 67	-83 - 50	0 - 83	-67 - 33
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	18.6 (20.7)	-3.8 (29.8)	20.3 (20.7)	-9.5 (23.9)
Median	16.7	0.0	16.7	0.0
Min - Max	0 - 67	-83 - 50	0 - 67	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 58 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Pain

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	19.2 (21.2)	-5.8 (26.5)	15.8 (18.3)	-14.9 (27.2)
Median	16.7	0.0	16.7	-16.7
Min - Max	0 - 67	-67 - 50	0 - 67	-67 - 33
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	15.5 (18.3)	-9.1 (25.3)	19.3 (26.2)	-8.3 (22.3)
Median	16.7	-8.3	16.7	0.0
Min - Max	0 - 67	-67 - 50	0 - 100	-50 - 17
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	17.9 (25.5)	-7.0 (30.9)	18.6 (23.5)	-6.2 (22.7)
Median	0.0	-8.3	16.7	0.0
Min - Max	0 - 100	-50 - 100	0 - 67	-50 - 33
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	18.2 (22.1)	-4.2 (27.4)	15.7 (22.4)	-12.5 (22.4)
Median	16.7	0.0	0.0	0.0
Min - Max	0 - 67	-83 - 67	0 - 67	-50 - 33
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	17.2 (19.1)	-4.8 (26.4)	16.7 (25.8)	-18.3 (29.9)
Median	16.7	0.0	0.0	-25.0
Min - Max	0 - 67	-50 - 67	0 - 67	-50 - 33
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	16.7 (22.4)	-1.6 (25.2)	25.9 (32.4)	-8.3 (19.9)
Median	0.0	0.0	33.3	-16.7
Min - Max	0 - 83	-50 - 50	0 - 100	-33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 59 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Pain

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	15.7 (18.5)	-9.8 (25.7)	20.4 (28.6)	-12.5 (26.4)
Median	8.3	-16.7	0.0	-8.3
Min - Max	0 - 50	-50 - 50	0 - 67	-50 - 33
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	16.7 (22.8)	-2.9 (29.0)	19.0 (24.4)	-16.7 (21.1)
Median	0.0	0.0	16.7	-8.3
Min - Max	0 - 83	-50 - 83	0 - 67	-50 - 0
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	16.7 (20.7)	-3.6 (21.9)	13.3 (13.9)	-30.0 (21.7)
Median	8.3	0.0	16.7	-33.3
Min - Max	0 - 67	-50 - 33	0 - 33	-50 - 0
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	23.1 (19.9)	3.8 (28.2)	4.2 (8.3)	-33.3 (19.2)
Median	33.3	0.0	0.0	-33.3
Min - Max	0 - 67	-50 - 67	0 - 17	-50 - -17
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	16.7 (27.2)	-2.6 (33.9)	25.0 (31.9)	-20.8 (21.0)
Median	0.0	0.0	16.7	-16.7
Min - Max	0 - 67	-50 - 67	0 - 67	-50 - 0
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	21.4 (24.9)	0.0 (34.7)	16.7 (28.9)	-33.3 (16.7)
Median	16.7	0.0	0.0	-33.3
Min - Max	0 - 67	-50 - 67	0 - 50	-50 - -17

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 60 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Pain

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	11.1 (17.2)	0.0 (18.3)	33.3 (23.6)	-25.0 (11.8)
Median	0.0	0.0	33.3	-25.0
Min - Max	0 - 33	-17 - 33	17 - 50	-33 - -17
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	33.3 (0.0)	-0.0 (44.1)	0.0 (NA)	-50.0 (NA)
Median	33.3	16.7	0.0	-50.0
Min - Max	33 - 33	-50 - 33	0 - 0	-50 - -50
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	8.3 (11.8)	0.0 (0.0)	0.0 (NA)	-50.0 (NA)
Median	8.3	0.0	0.0	-50.0
Min - Max	0 - 17	0 - 0	0 - 0	-50 - -50
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-16.7 (NA)	0.0 (NA)	-50.0 (NA)
Median	0.0	-16.7	0.0	-50.0
Min - Max	0 - 0	-17 - -17	0 - 0	-50 - -50
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-16.7 (NA)	0.0 (NA)	-50.0 (NA)
Median	0.0	-16.7	0.0	-50.0
Min - Max	0 - 0	-17 - -17	0 - 0	-50 - -50
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-16.7 (NA)	0.0 (NA)	-50.0 (NA)
Median	0.0	-16.7	0.0	-50.0
Min - Max	0 - 0	-17 - -17	0 - 0	-50 - -50

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 61 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Pain

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	32.3 (29.6)	-0.2 (31.0)	32.2 (29.9)	4.2 (27.5)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 83	0 - 100	-67 - 67
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	22.2 (20.4)	-13.0 (27.4)	36.7 (38.0)	13.3 (24.7)
Median	16.7	0.0	33.3	16.7
Min - Max	0 - 67	-67 - 17	0 - 100	-17 - 50
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	58.3 (35.4)	25.0 (11.8)	NE (NE)	NE (NE)
Median	58.3	25.0	NE	NE
Min - Max	33 - 83	17 - 33	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	83.3 (NA)	16.7 (NA)	NE (NE)	NE (NE)
Median	83.3	16.7	NE	NE
Min - Max	83 - 83	17 - 17	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	29.7 (31.6)	-5.4 (31.7)	40.8 (25.3)	6.6 (22.8)
Median	25.0	-16.7	33.3	0.0
Min - Max	0 - 100	-50 - 67	0 - 100	-33 - 50
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	28.9 (20.7)	-0.0 (23.6)	23.7 (21.7)	-3.9 (26.7)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 67	-50 - 33	0 - 67	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 62 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Pain

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	23.8 (30.2)	-26.2 (47.0)	36.7 (38.0)	-3.3 (36.1)
Median	16.7	-33.3	33.3	-16.7
Min - Max	0 - 83	-83 - 50	0 - 83	-33 - 50
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	26.7 (25.3)	-10.0 (19.0)	50.0 (0.0)	-16.7 (47.1)
Median	16.7	-16.7	50.0	-16.7
Min - Max	0 - 67	-33 - 17	50 - 50	-50 - 17
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	44.4 (19.2)	5.6 (9.6)	0.0 (NA)	-33.3 (NA)
Median	33.3	0.0	0.0	-33.3
Min - Max	33 - 67	0 - 17	0 - 0	-33 - -33
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	31.0 (31.3)	-1.8 (37.6)	26.8 (25.5)	-5.8 (27.8)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-83 - 50	0 - 83	-100 - 67
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	23.3 (27.2)	-1.1 (30.7)	28.7 (25.0)	-2.2 (28.0)
Median	16.7	0.0	33.3	0.0
Min - Max	0 - 100	-83 - 100	0 - 100	-100 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 63 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Dyspnoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	19.0 (22.0)		17.1 (22.6)	
Median	0.0		0.0	
Min - Max	0 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	18.2 (22.3)	-1.9 (19.7)	17.6 (23.9)	0.7 (23.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 33	0 - 100	-67 - 67
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	17.0 (24.0)	-2.0 (22.1)	17.5 (23.1)	-1.1 (18.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-33 - 33
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	14.4 (21.7)	-3.5 (22.9)	19.9 (22.6)	1.7 (21.3)
Median	0.0	0.0	16.7	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-67 - 33
Cycle 7 Day 1				
n	111	106	89	84
Mean (SD)	14.7 (20.4)	-1.6 (21.8)	17.6 (23.6)	0.4 (24.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 33	0 - 100	-100 - 67
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	15.4 (20.7)	-3.3 (22.9)	19.8 (25.8)	4.7 (22.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-67 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 64 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Dyspnoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	16.5 (21.3)	-0.4 (25.2)	18.4 (20.9)	2.3 (22.6)
Median	0.0	0.0	16.7	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-100 - 33
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	14.3 (20.5)	-0.4 (19.4)	16.3 (22.0)	0.8 (24.4)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 100	-100 - 67
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	15.1 (18.5)	-1.0 (24.2)	19.5 (23.5)	5.8 (22.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 100	-33 - 33
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	13.8 (18.4)	-3.5 (24.7)	18.9 (18.9)	4.6 (23.1)
Median	0.0	0.0	33.3	0.0
Min - Max	0 - 67	-67 - 33	0 - 67	-67 - 67
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	12.6 (18.7)	-2.0 (22.7)	15.3 (19.6)	-1.4 (18.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 67	-33 - 33
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	12.4 (20.0)	-1.4 (21.7)	24.6 (25.1)	7.9 (20.8)
Median	0.0	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 33	0 - 100	-33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 65 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Dyspnoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	11.5 (18.5)	-4.8 (24.5)	15.0 (17.0)	-3.5 (24.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 33	-67 - 33
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	11.6 (16.1)	-6.3 (24.7)	19.3 (25.6)	5.6 (20.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-67 - 33	0 - 100	-33 - 33
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	12.8 (18.1)	-5.3 (26.3)	11.8 (16.4)	4.2 (20.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 33	0 - 33	-33 - 33
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	9.4 (15.2)	-4.2 (22.0)	15.7 (17.1)	6.2 (25.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 33	-33 - 33
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	12.6 (18.7)	-4.8 (25.2)	9.1 (15.6)	0.0 (15.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 33	0 - 33	-33 - 33
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	9.5 (15.4)	-4.8 (24.2)	22.2 (28.9)	8.3 (34.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 67	-33 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 66 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Dyspnoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	11.1 (16.2)	-7.8 (27.7)	7.4 (14.7)	4.2 (21.4)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-67 - 33	0 - 33	-33 - 33
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	7.8 (14.6)	-9.8 (19.6)	23.8 (25.2)	11.1 (45.5)
Median	0.0	0.0	33.3	16.7
Min - Max	0 - 33	-33 - 33	0 - 67	-67 - 67
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	7.1 (14.2)	-14.3 (25.2)	20.0 (18.3)	-0.0 (40.8)
Median	0.0	0.0	33.3	0.0
Min - Max	0 - 33	-67 - 33	0 - 33	-67 - 33
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	15.4 (17.3)	-10.3 (28.5)	16.7 (33.3)	-8.3 (68.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-67 - 33	0 - 67	-100 - 67
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	5.1 (12.5)	-20.5 (29.0)	41.7 (41.9)	16.7 (19.2)
Median	0.0	-33.3	33.3	16.7
Min - Max	0 - 33	-67 - 33	0 - 100	0 - 33
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	14.3 (17.8)	-14.3 (32.5)	33.3 (33.3)	33.3 (33.3)
Median	0.0	0.0	33.3	33.3
Min - Max	0 - 33	-67 - 33	0 - 67	0 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 67 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Dyspnoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	16.7 (18.3)	0.0 (29.8)	33.3 (0.0)	33.3 (0.0)
Median	16.7	0.0	33.3	33.3
Min - Max	0 - 33	-33 - 33	33 - 33	33 - 33
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	22.2 (19.2)	-33.3 (33.3)	33.3 (NA)	33.3 (NA)
Median	33.3	-33.3	33.3	33.3
Min - Max	0 - 33	-67 - 0	33 - 33	33 - 33
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	16.7 (23.6)	-16.7 (23.6)	66.7 (NA)	66.7 (NA)
Median	16.7	-16.7	66.7	66.7
Min - Max	0 - 33	-33 - 0	67 - 67	67 - 67
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-33.3 (NA)	0.0 (NA)	0.0 (NA)
Median	0.0	-33.3	0.0	0.0
Min - Max	0 - 0	-33 - -33	0 - 0	0 - 0
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-33.3 (NA)	66.7 (NA)	66.7 (NA)
Median	0.0	-33.3	66.7	66.7
Min - Max	0 - 0	-33 - -33	67 - 67	67 - 67
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-33.3 (NA)	0.0 (NA)	0.0 (NA)
Median	0.0	-33.3	0.0	0.0
Min - Max	0 - 0	-33 - -33	0 - 0	0 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 68 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Dyspnoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	22.8 (28.5)	0.9 (27.6)	22.3 (24.0)	6.2 (25.3)
Median	0.0	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-67 - 67
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	25.9 (32.4)	11.1 (28.9)	20.0 (18.3)	6.7 (27.9)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-33 - 67	0 - 33	-33 - 33
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	50.0 (70.7)	33.3 (47.1)	NE (NE)	NE (NE)
Median	50.0	33.3	NE	NE
Min - Max	0 - 100	0 - 67	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	0.0 (NA)	-33.3 (NA)	NE (NE)	NE (NE)
Median	0.0	-33.3	NE	NE
Min - Max	0 - 0	-33 - -33	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	21.9 (24.8)	5.4 (24.5)	27.5 (28.1)	7.9 (30.4)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-33 - 67	0 - 100	-67 - 67
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	21.1 (29.8)	1.8 (32.3)	24.6 (29.1)	7.8 (30.1)
Median	0.0	0.0	33.3	0.0
Min - Max	0 - 100	-33 - 100	0 - 100	-33 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 69 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Dyspnoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	9.5 (25.2)	-14.3 (26.2)	26.7 (14.9)	13.3 (29.8)
Median	0.0	-33.3	33.3	33.3
Min - Max	0 - 67	-33 - 33	0 - 33	-33 - 33
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	20.0 (18.3)	-6.7 (14.9)	33.3 (0.0)	16.7 (23.6)
Median	33.3	0.0	33.3	16.7
Min - Max	0 - 33	-33 - 0	33 - 33	0 - 33
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	33.3 (33.3)	22.2 (38.5)	33.3 (NA)	0.0 (NA)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 67	0 - 67	33 - 33	0 - 0
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	17.5 (20.1)	0.0 (19.2)	18.6 (24.2)	1.3 (26.4)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 100	-100 - 67
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	16.7 (21.2)	-0.5 (21.5)	23.3 (25.1)	6.1 (27.4)
Median	0.0	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-100 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 70 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Insomnia

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	28.0 (28.5)		28.2 (29.6)	
Median	33.3		33.3	
Min - Max	0 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	25.4 (28.8)	-3.6 (24.8)	21.4 (26.1)	-6.6 (23.9)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-67 - 67
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	25.5 (28.4)	-3.3 (28.8)	23.1 (25.4)	-5.0 (25.7)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-100 - 100	0 - 100	-100 - 67
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	26.5 (28.3)	-3.8 (28.1)	27.1 (26.8)	-1.4 (25.6)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-67 - 67
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	25.6 (27.9)	-5.6 (28.4)	24.0 (26.6)	-4.0 (28.5)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-100 - 67	0 - 100	-100 - 67
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	24.7 (25.4)	-6.3 (27.8)	25.7 (26.2)	-2.3 (24.1)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-100 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 71 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Insomnia

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	24.2 (25.9)	-3.4 (31.3)	24.7 (25.4)	-2.9 (26.2)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-100 - 100	0 - 100	-67 - 33
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	27.8 (26.4)	1.3 (26.0)	29.6 (26.8)	-4.5 (27.5)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-67 - 33
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	25.6 (27.5)	-2.9 (29.6)	29.3 (28.1)	-3.3 (30.9)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-100 - 67	0 - 100	-100 - 67
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	28.6 (27.4)	0.0 (30.7)	32.2 (25.5)	-5.7 (29.6)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-100 - 100	0 - 100	-67 - 33
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	30.8 (26.0)	2.7 (28.4)	29.2 (26.6)	-7.2 (26.5)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-67 - 33
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	28.8 (25.0)	4.2 (29.7)	33.3 (34.8)	-4.8 (33.8)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-100 - 67	0 - 100	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 72 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Insomnia

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	26.9 (23.8)	2.0 (30.0)	30.0 (26.3)	-12.3 (35.5)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 67	-100 - 67	0 - 67	-100 - 33
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	27.9 (27.1)	3.2 (30.2)	22.8 (27.3)	-14.8 (34.7)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-67 - 33
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	26.5 (25.6)	4.4 (31.2)	27.5 (24.3)	-6.2 (37.0)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 67	-100 - 33
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	25.0 (28.1)	7.3 (31.4)	25.5 (25.1)	-12.5 (24.0)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 67	-67 - 33
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	24.1 (25.0)	4.8 (25.2)	9.1 (15.6)	-33.3 (35.1)
Median	33.3	0.0	0.0	-33.3
Min - Max	0 - 100	-33 - 67	0 - 33	-100 - 0
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	17.5 (20.1)	0.0 (18.3)	25.9 (27.8)	-20.8 (35.4)
Median	0.0	0.0	33.3	-16.7
Min - Max	0 - 67	-33 - 33	0 - 67	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 73 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Insomnia

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	22.2 (22.9)	-2.0 (18.5)	14.8 (17.6)	-25.0 (38.8)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 33	-100 - 0
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	19.6 (23.7)	2.0 (18.5)	19.0 (26.2)	-27.8 (49.1)
Median	0.0	0.0	0.0	-16.7
Min - Max	0 - 67	-33 - 33	0 - 67	-100 - 33
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	23.8 (20.4)	4.8 (17.8)	20.0 (29.8)	-33.3 (52.7)
Median	33.3	0.0	0.0	-33.3
Min - Max	0 - 67	-33 - 33	0 - 67	-100 - 33
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	23.1 (16.0)	2.6 (16.5)	0.0 (0.0)	-58.3 (50.0)
Median	33.3	0.0	0.0	-66.7
Min - Max	0 - 33	-33 - 33	0 - 0	-100 - 0
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	23.1 (16.0)	2.6 (21.4)	41.7 (50.0)	-16.7 (57.7)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 33	-33 - 33	0 - 100	-100 - 33
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	33.3 (19.2)	4.8 (23.0)	22.2 (38.5)	-33.3 (66.7)
Median	33.3	0.0	0.0	-33.3
Min - Max	0 - 67	-33 - 33	0 - 67	-100 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 74 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Insomnia

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	33.3 (21.1)	11.1 (17.2)	33.3 (47.1)	-33.3 (94.3)
Median	33.3	0.0	33.3	-33.3
Min - Max	0 - 67	0 - 33	0 - 67	-100 - 33
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	44.4 (19.2)	11.1 (38.5)	0.0 (NA)	-100.0 (NA)
Median	33.3	33.3	0.0	-100.0
Min - Max	33 - 67	-33 - 33	0 - 0	-100 - -100
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	33.3 (0.0)	16.7 (23.6)	0.0 (NA)	-100.0 (NA)
Median	33.3	16.7	0.0	-100.0
Min - Max	33 - 33	0 - 33	0 - 0	-100 - -100
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	33.3 (NA)	0.0 (NA)	0.0 (NA)	-100.0 (NA)
Median	33.3	0.0	0.0	-100.0
Min - Max	33 - 33	0 - 0	0 - 0	-100 - -100
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	66.7 (NA)	33.3 (NA)	0.0 (NA)	-100.0 (NA)
Median	66.7	33.3	0.0	-100.0
Min - Max	67 - 67	33 - 33	0 - 0	-100 - -100
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	66.7 (NA)	33.3 (NA)	33.3 (NA)	-66.7 (NA)
Median	66.7	33.3	33.3	-66.7
Min - Max	67 - 67	33 - 33	33 - 33	-67 - -67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 75 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Insomnia

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	30.8 (28.1)	2.2 (29.8)	29.1 (28.7)	1.4 (26.5)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-67 - 67
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	18.5 (17.6)	0.0 (0.0)	33.3 (23.6)	0.0 (23.6)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 33	0 - 0	0 - 67	-33 - 33
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	16.7 (23.6)	-16.7 (23.6)	NE (NE)	NE (NE)
Median	16.7	-16.7	NE	NE
Min - Max	0 - 33	-33 - 0	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	100.0 (NA)	66.7 (NA)	NE (NE)	NE (NE)
Median	100.0	66.7	NE	NE
Min - Max	100 - 100	67 - 67	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	27.1 (28.6)	-1.1 (32.8)	30.8 (27.6)	-0.0 (31.0)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-67 - 67
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	28.1 (27.8)	1.8 (28.3)	24.6 (21.8)	-5.9 (27.0)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 67	-33 - 67	0 - 67	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 76 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Insomnia

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	28.6 (30.0)	4.8 (35.6)	26.7 (14.9)	-6.7 (14.9)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 67	-33 - 67	0 - 33	-33 - 0
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	20.0 (18.3)	6.7 (14.9)	50.0 (23.6)	0.0 (47.1)
Median	33.3	0.0	50.0	0.0
Min - Max	0 - 33	0 - 33	33 - 67	-33 - 33
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	33.3 (33.3)	11.1 (19.2)	66.7 (NA)	33.3 (NA)
Median	33.3	0.0	66.7	33.3
Min - Max	0 - 67	0 - 33	67 - 67	33 - 33
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	33.3 (35.0)	12.3 (38.8)	25.4 (29.3)	0.6 (28.4)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-100 - 67
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	27.9 (28.0)	3.8 (30.5)	27.1 (29.2)	0.4 (28.4)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-100 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 77 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Appetite loss

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	17.2 (25.0)		15.8 (23.5)	
Median	0.0		0.0	
Min - Max	0 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	29.6 (30.4)	12.7 (30.6)	15.7 (22.0)	0.2 (22.2)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 100	-100 - 100	0 - 100	-67 - 67
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	25.1 (26.7)	7.8 (29.7)	15.8 (21.2)	0.5 (24.2)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 100	-100 - 100	0 - 100	-67 - 67
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	22.3 (25.2)	6.0 (30.8)	13.1 (21.6)	-2.8 (27.6)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 100	-100 - 100	0 - 100	-67 - 100
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	22.6 (24.6)	6.9 (28.1)	12.4 (20.3)	-2.4 (22.4)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-67 - 67
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	19.9 (23.9)	5.9 (27.6)	13.5 (20.6)	-2.3 (24.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-67 - 100

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 78 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Appetite loss

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	19.4 (25.4)	6.5 (30.4)	15.5 (19.0)	-2.3 (22.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 100	0 - 67	-67 - 67
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	17.7 (23.2)	4.4 (28.1)	15.6 (19.6)	-1.5 (23.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 67	-67 - 33
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	16.9 (21.6)	3.4 (28.1)	16.3 (18.4)	-2.5 (24.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 67	-67 - 33
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	18.1 (23.2)	3.0 (27.0)	13.3 (24.1)	-8.0 (27.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 100	-67 - 67
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	21.4 (23.7)	6.0 (27.5)	13.9 (16.8)	-2.9 (26.4)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 100	-33 - 67	0 - 33	-67 - 33
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	20.3 (25.9)	4.2 (30.5)	15.9 (19.8)	-1.6 (26.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 67	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 79 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Appetite loss

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	16.0 (21.4)	1.4 (28.0)	11.7 (16.3)	-8.8 (24.4)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 33	-67 - 33
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	17.1 (18.4)	1.6 (23.2)	10.5 (15.9)	-7.4 (29.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 67	0 - 33	-67 - 33
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	13.7 (18.3)	-0.9 (22.6)	11.8 (16.4)	-8.3 (31.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 33	-67 - 33
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	17.7 (23.9)	5.2 (28.2)	19.6 (20.6)	-2.1 (25.7)
Median	0.0	0.0	33.3	0.0
Min - Max	0 - 67	-33 - 67	0 - 67	-67 - 33
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	21.8 (27.1)	7.1 (30.6)	12.1 (16.8)	-13.3 (28.1)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 100	-33 - 100	0 - 33	-67 - 33
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	14.3 (16.9)	3.2 (23.3)	7.4 (14.7)	-12.5 (24.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 33	-67 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

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03 FEB 2025 14:32 GMT

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Appetite loss

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	11.1 (16.2)	0.0 (26.4)	3.7 (11.1)	-20.8 (24.8)
Median	0.0	0.0	0.0	-16.7
Min - Max	0 - 33	-33 - 33	0 - 33	-67 - 0
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	17.6 (17.1)	5.9 (27.0)	4.8 (12.6)	-5.6 (13.6)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 33	-33 - 0
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	16.7 (21.7)	4.8 (31.6)	6.7 (14.9)	-13.3 (18.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 67	0 - 33	-33 - 0
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	20.5 (16.9)	7.7 (27.7)	16.7 (33.3)	0.0 (27.2)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 67	-33 - 33
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	17.9 (25.9)	5.1 (35.6)	0.0 (0.0)	-16.7 (19.2)
Median	0.0	0.0	0.0	-16.7
Min - Max	0 - 67	-33 - 67	0 - 0	-33 - 0
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	23.8 (25.2)	4.8 (40.5)	0.0 (0.0)	-33.3 (0.0)
Median	33.3	0.0	0.0	-33.3
Min - Max	0 - 67	-33 - 67	0 - 0	-33 - -33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 81 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Appetite loss

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	27.8 (25.1)	11.1 (40.4)	16.7 (23.6)	-16.7 (23.6)
Median	33.3	16.7	16.7	-16.7
Min - Max	0 - 67	-33 - 67	0 - 33	-33 - 0
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	11.1 (19.2)	-11.1 (38.5)	0.0 (NA)	-33.3 (NA)
Median	0.0	-33.3	0.0	-33.3
Min - Max	0 - 33	-33 - 33	0 - 0	-33 - -33
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	33.3 (0.0)	16.7 (23.6)	0.0 (NA)	-33.3 (NA)
Median	33.3	16.7	0.0	-33.3
Min - Max	33 - 33	0 - 33	0 - 0	-33 - -33
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	33.3 (NA)	33.3 (NA)	0.0 (NA)	-33.3 (NA)
Median	33.3	33.3	0.0	-33.3
Min - Max	33 - 33	33 - 33	0 - 0	-33 - -33
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	33.3 (NA)	33.3 (NA)	0.0 (NA)	-33.3 (NA)
Median	33.3	33.3	0.0	-33.3
Min - Max	33 - 33	33 - 33	0 - 0	-33 - -33
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	33.3 (NA)	33.3 (NA)	0.0 (NA)	-33.3 (NA)
Median	33.3	33.3	0.0	-33.3
Min - Max	33 - 33	33 - 33	0 - 0	-33 - -33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
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03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 82 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Appetite loss

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	33.3 (31.6)	13.4 (35.6)	24.6 (28.4)	8.3 (26.0)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-67 - 100
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	18.5 (24.2)	3.7 (26.1)	33.3 (23.6)	13.3 (18.3)
Median	0.0	0.0	33.3	0.0
Min - Max	0 - 67	-33 - 33	0 - 67	0 - 33
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	16.7 (23.6)	0.0 (0.0)	NE (NE)	NE (NE)
Median	16.7	0.0	NE	NE
Min - Max	0 - 33	0 - 0	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	33.3 (NA)	0.0 (NA)	NE (NE)	NE (NE)
Median	33.3	0.0	NE	NE
Min - Max	33 - 33	0 - 0	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	24.0 (29.6)	6.5 (30.3)	27.5 (31.9)	7.9 (29.4)
Median	16.7	0.0	33.3	0.0
Min - Max	0 - 100	-33 - 100	0 - 100	-33 - 67
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	40.4 (30.6)	15.8 (32.1)	21.1 (22.8)	2.0 (24.9)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-33 - 100	0 - 67	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 83 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Appetite loss

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	28.6 (30.0)	4.8 (40.5)	26.7 (43.5)	0.0 (23.6)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 67	0 - 100	-33 - 33
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	33.3 (33.3)	20.0 (29.8)	33.3 (47.1)	-16.7 (23.6)
Median	33.3	0.0	33.3	-16.7
Min - Max	0 - 67	0 - 67	0 - 67	-33 - 0
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	33.3 (33.3)	22.2 (19.2)	0.0 (NA)	0.0 (NA)
Median	33.3	33.3	0.0	0.0
Min - Max	0 - 67	0 - 33	0 - 0	0 - 0
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	34.9 (34.1)	14.0 (35.7)	20.3 (24.8)	3.8 (26.1)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 100	-33 - 100	0 - 67	-67 - 67
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	29.4 (31.8)	16.9 (33.7)	18.2 (23.2)	2.2 (23.2)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 100	-33 - 100	0 - 100	-67 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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03 FEB 2025 14:32 GMT

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Constipation

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	15.4 (24.4)		15.8 (24.1)	
Median	0.0		0.0	
Min - Max	0 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	11.2 (20.5)	-4.1 (23.7)	17.6 (23.9)	2.5 (25.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-67 - 100
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	9.5 (18.9)	-5.1 (26.8)	15.8 (21.5)	1.3 (25.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-100 - 100	0 - 100	-100 - 100
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	8.7 (17.4)	-5.1 (22.6)	16.0 (23.8)	1.4 (27.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 100	-100 - 100
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	11.0 (20.2)	-2.8 (24.3)	14.6 (21.9)	0.4 (25.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-100 - 100
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	10.9 (19.9)	-1.7 (20.8)	15.8 (23.6)	-0.9 (25.2)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-67 - 100

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
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03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 85 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Constipation

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	6.6 (13.4)	-5.0 (21.9)	15.5 (23.5)	-2.3 (24.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-67 - 33	0 - 67	-67 - 67
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	7.2 (14.8)	-5.3 (23.9)	23.0 (26.4)	4.5 (30.2)
Median	0.0	0.0	33.3	0.0
Min - Max	0 - 67	-67 - 33	0 - 100	-100 - 100
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	5.5 (12.4)	-7.2 (20.5)	15.4 (27.0)	-5.0 (29.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-67 - 33	0 - 100	-100 - 100
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	6.2 (15.3)	-6.5 (23.4)	20.0 (29.8)	-3.4 (28.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 100	-100 - 33
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	10.7 (18.2)	-4.0 (23.9)	12.5 (21.6)	-8.7 (27.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 33	0 - 67	-100 - 33
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	9.2 (17.7)	-3.5 (25.9)	23.2 (32.5)	0.0 (25.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 33	0 - 100	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

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03 FEB 2025 14:32 GMT

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Constipation

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	5.1 (15.3)	-7.5 (24.8)	28.3 (31.1)	7.0 (21.0)
Median	0.0	0.0	33.3	0.0
Min - Max	0 - 67	-67 - 67	0 - 100	-33 - 33
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	5.4 (12.5)	-5.6 (20.7)	24.6 (31.1)	5.6 (26.2)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-67 - 33	0 - 100	-33 - 33
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	6.0 (15.0)	-5.3 (21.3)	15.7 (26.7)	2.1 (22.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 33	0 - 67	-33 - 33
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	3.1 (9.9)	-7.3 (23.5)	19.6 (20.6)	4.2 (20.6)
Median	0.0	0.0	33.3	0.0
Min - Max	0 - 33	-67 - 33	0 - 67	-33 - 33
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	2.3 (8.6)	-9.5 (15.3)	9.1 (15.6)	-6.7 (14.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 0	0 - 33	-33 - 0
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	0.0 (0.0)	-11.1 (19.2)	14.8 (24.2)	-8.3 (42.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 0	-67 - 0	0 - 67	-100 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Constipation

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	1.9 (7.9)	-11.8 (20.2)	14.8 (24.2)	0.0 (17.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-67 - 0	0 - 67	-33 - 33
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	3.9 (11.1)	-7.8 (25.1)	14.3 (26.2)	-16.7 (50.6)
Median	0.0	0.0	0.0	-16.7
Min - Max	0 - 33	-67 - 33	0 - 67	-100 - 33
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	4.8 (12.1)	-4.8 (25.7)	6.7 (14.9)	-26.7 (43.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-67 - 33	0 - 33	-100 - 0
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	5.1 (12.5)	-7.7 (24.2)	0.0 (0.0)	-33.3 (47.1)
Median	0.0	0.0	0.0	-16.7
Min - Max	0 - 33	-67 - 33	0 - 0	-100 - 0
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	0.0 (0.0)	-12.8 (21.7)	8.3 (16.7)	-33.3 (27.2)
Median	0.0	0.0	0.0	-33.3
Min - Max	0 - 0	-67 - 0	0 - 33	-67 - 0
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	0.0 (0.0)	-19.0 (26.2)	11.1 (19.2)	-11.1 (38.5)
Median	0.0	0.0	0.0	-33.3
Min - Max	0 - 0	-67 - 0	0 - 33	-33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Constipation

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	0.0 (0.0)	-16.7 (27.9)	0.0 (0.0)	-33.3 (0.0)
Median	0.0	0.0	0.0	-33.3
Min - Max	0 - 0	-67 - 0	0 - 0	-33 - -33
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	0.0 (0.0)	-33.3 (33.3)	0.0 (NA)	-33.3 (NA)
Median	0.0	-33.3	0.0	-33.3
Min - Max	0 - 0	-67 - 0	0 - 0	-33 - -33
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	0.0 (0.0)	-33.3 (47.1)	0.0 (NA)	-33.3 (NA)
Median	0.0	-33.3	0.0	-33.3
Min - Max	0 - 0	-67 - 0	0 - 0	-33 - -33
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-66.7 (NA)	0.0 (NA)	-33.3 (NA)
Median	0.0	-66.7	0.0	-33.3
Min - Max	0 - 0	-67 - -67	0 - 0	-33 - -33
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-66.7 (NA)	0.0 (NA)	-33.3 (NA)
Median	0.0	-66.7	0.0	-33.3
Min - Max	0 - 0	-67 - -67	0 - 0	-33 - -33
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-66.7 (NA)	0.0 (NA)	-33.3 (NA)
Median	0.0	-66.7	0.0	-33.3
Min - Max	0 - 0	-67 - -67	0 - 0	-33 - -33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 89 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Constipation

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	16.9 (25.0)	-2.6 (33.2)	15.9 (21.8)	1.4 (22.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-100 - 100	0 - 100	-33 - 67
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	29.6 (35.1)	3.7 (20.0)	40.0 (43.5)	20.0 (29.8)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-33 - 33	0 - 100	0 - 67
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	50.0 (23.6)	16.7 (23.6)	NE (NE)	NE (NE)
Median	50.0	16.7	NE	NE
Min - Max	33 - 67	0 - 33	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	66.7 (NA)	33.3 (NA)	NE (NE)	NE (NE)
Median	66.7	33.3	NE	NE
Min - Max	67 - 67	33 - 33	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	15.6 (20.7)	-9.7 (28.8)	20.8 (29.9)	2.6 (31.4)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-100 - 33	0 - 100	-67 - 100
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	15.8 (25.7)	3.5 (24.6)	17.5 (25.7)	2.0 (22.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 100	-33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 90 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Constipation

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	19.0 (37.8)	9.5 (41.8)	13.3 (18.3)	-6.7 (14.9)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-33 - 100	0 - 33	-33 - 0
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	20.0 (29.8)	13.3 (29.8)	0.0 (0.0)	0.0 (0.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	0 - 67	0 - 0	0 - 0
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	0.0 (0.0)	0.0 (0.0)	0.0 (NA)	-33.3 (NA)
Median	0.0	0.0	0.0	-33.3
Min - Max	0 - 0	0 - 0	0 - 0	-33 - -33
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	6.3 (13.4)	-10.5 (22.4)	20.3 (28.4)	3.2 (24.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-67 - 0	0 - 100	-33 - 67
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	7.8 (17.4)	-8.7 (27.8)	21.3 (30.6)	6.1 (25.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-100 - 67	0 - 100	-33 - 100

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
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Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 91 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Diarrhoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	6.5 (17.6)		7.1 (17.4)	
Median	0.0		0.0	
Min - Max	0 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	17.5 (25.9)	10.9 (23.3)	5.4 (15.5)	-2.3 (18.2)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-33 - 100	0 - 100	-100 - 67
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	16.1 (22.5)	8.8 (23.6)	7.3 (16.1)	-0.3 (18.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-100 - 100	0 - 67	-100 - 67
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	18.1 (23.7)	10.8 (26.8)	6.2 (14.6)	-0.3 (17.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 100	0 - 67	-67 - 67
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	17.9 (24.9)	10.0 (25.2)	5.6 (14.4)	-1.6 (16.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-100 - 100	0 - 67	-67 - 33
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	18.3 (25.8)	10.2 (25.7)	8.6 (17.5)	1.4 (19.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-100 - 67	0 - 67	-67 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 92 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Diarrhoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	18.3 (26.9)	10.3 (28.4)	8.0 (18.0)	-0.6 (14.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 100	0 - 67	-33 - 33
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	18.1 (24.3)	11.1 (25.9)	6.7 (15.2)	-2.3 (20.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 67	-100 - 33
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	16.4 (23.7)	9.2 (26.7)	9.8 (17.1)	2.5 (17.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-100 - 67	0 - 67	-33 - 33
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	20.5 (28.5)	12.9 (31.2)	7.8 (18.9)	0.0 (29.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 100	0 - 67	-67 - 67
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	20.1 (26.4)	9.3 (24.3)	4.2 (11.3)	0.0 (14.2)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 33	-33 - 33
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	16.3 (22.5)	5.6 (26.0)	1.4 (7.0)	-4.8 (19.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 33	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 93 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Diarrhoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	15.4 (21.4)	7.5 (23.8)	10.0 (15.7)	7.0 (17.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 33	-33 - 33
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	14.7 (18.3)	9.5 (19.9)	7.0 (14.0)	3.7 (15.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 33	-33 - 33
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	12.0 (17.9)	7.0 (19.2)	3.9 (11.1)	0.0 (12.2)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 33	-33 - 33
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	17.7 (25.4)	12.5 (25.0)	7.8 (14.6)	4.2 (16.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-33 - 67	0 - 33	-33 - 33
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	11.5 (20.5)	4.8 (19.7)	3.0 (10.1)	3.3 (10.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 33	0 - 33	0 - 33
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	12.7 (24.7)	7.9 (20.8)	3.7 (11.1)	4.2 (11.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-33 - 67	0 - 33	0 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 94 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Diarrhoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	13.0 (20.3)	3.9 (16.2)	7.4 (14.7)	8.3 (15.4)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 33	0 - 33
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	21.6 (26.2)	15.7 (23.9)	9.5 (16.3)	11.1 (17.2)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 100	-33 - 67	0 - 33	0 - 33
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	23.8 (27.5)	11.9 (24.8)	6.7 (14.9)	6.7 (14.9)
Median	16.7	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 67	0 - 33	0 - 33
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	23.1 (31.6)	15.4 (22.0)	16.7 (33.3)	16.7 (33.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	0 - 67	0 - 67	0 - 67
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	17.9 (22.0)	10.3 (21.0)	0.0 (0.0)	0.0 (0.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 0	0 - 0
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	33.3 (27.2)	19.0 (32.5)	0.0 (0.0)	0.0 (0.0)
Median	33.3	33.3	0.0	0.0
Min - Max	0 - 67	-33 - 67	0 - 0	0 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 95 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Diarrhoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	27.8 (25.1)	11.1 (27.2)	0.0 (0.0)	0.0 (0.0)
Median	33.3	16.7	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 0	0 - 0
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	33.3 (33.3)	0.0 (33.3)	0.0 (NA)	0.0 (NA)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 0	0 - 0
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	100.0 (0.0)	50.0 (23.6)	0.0 (NA)	0.0 (NA)
Median	100.0	50.0	0.0	0.0
Min - Max	100 - 100	33 - 67	0 - 0	0 - 0
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-66.7 (NA)	0.0 (NA)	0.0 (NA)
Median	0.0	-66.7	0.0	0.0
Min - Max	0 - 0	-67 - -67	0 - 0	0 - 0
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	33.3 (NA)	-33.3 (NA)	0.0 (NA)	0.0 (NA)
Median	33.3	-33.3	0.0	0.0
Min - Max	33 - 33	-33 - -33	0 - 0	0 - 0
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-66.7 (NA)	0.0 (NA)	0.0 (NA)
Median	0.0	-66.7	0.0	0.0
Min - Max	0 - 0	-67 - -67	0 - 0	0 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Diarrhoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	78	76	103	96
Mean (SD)	13.7 (20.4)	6.6 (22.5)	5.8 (15.8)	-2.8 (20.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 100	-100 - 33
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	11.1 (16.7)	7.4 (14.7)	13.3 (18.3)	13.3 (18.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	0 - 33	0 - 33	0 - 33
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	16.7 (23.6)	16.7 (23.6)	NE (NE)	NE (NE)
Median	16.7	16.7	NE	NE
Min - Max	0 - 33	0 - 33	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	0.0 (NA)	0.0 (NA)	NE (NE)	NE (NE)
Median	0.0	0.0	NE	NE
Min - Max	0 - 0	0 - 0	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	6.2 (15.7)	2.2 (17.1)	8.3 (18.1)	-3.5 (25.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 67	0 - 67	-100 - 33
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	3.5 (10.5)	-1.8 (13.5)	5.3 (12.5)	-2.0 (30.0)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 33	-100 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
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Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 97 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Diarrhoea

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	14.3 (26.2)	9.5 (25.2)	6.7 (14.9)	-13.3 (50.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	0 - 67	0 - 33	-100 - 33
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	6.7 (14.9)	6.7 (14.9)	33.3 (47.1)	-16.7 (117.9)
Median	0.0	0.0	33.3	-16.7
Min - Max	0 - 33	0 - 33	0 - 67	-100 - 67
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	0.0 (0.0)	0.0 (0.0)	0.0 (NA)	0.0 (NA)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 0	0 - 0	0 - 0	0 - 0
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	14.3 (22.5)	10.5 (19.4)	5.1 (13.6)	-2.6 (19.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	0 - 67	0 - 67	-100 - 33
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	13.2 (21.7)	7.1 (22.0)	5.0 (14.0)	-1.7 (17.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 67	-100 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 98 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Financial difficulties

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		156	
Mean (SD)	21.5 (26.3)		20.9 (29.6)	
Median	0.0		0.0	
Min - Max	0 - 100		0 - 100	
Cycle 2 Day 1				
n	143	137	153	147
Mean (SD)	16.8 (24.3)	-5.4 (20.7)	15.5 (25.7)	-4.3 (24.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 33	0 - 100	-67 - 100
Cycle 3 Day 1				
n	137	132	133	126
Mean (SD)	18.0 (25.2)	-3.8 (24.9)	17.8 (25.5)	-0.5 (25.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-100 - 67	0 - 100	-67 - 67
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	14.2 (21.2)	-7.0 (26.0)	14.7 (22.8)	-4.9 (25.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-67 - 67
Cycle 7 Day 1				
n	112	107	88	83
Mean (SD)	16.7 (22.4)	-2.8 (22.5)	17.0 (26.3)	-2.8 (29.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 33	0 - 100	-67 - 100
Cycle 9 Day 1				
n	104	101	74	71
Mean (SD)	18.6 (24.1)	-2.0 (22.5)	15.8 (26.6)	-4.7 (31.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-100 - 100

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 99 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Financial difficulties

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	91	87	58	57
Mean (SD)	16.8 (23.0)	-2.7 (25.5)	17.2 (27.4)	-2.3 (28.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-100 - 67	0 - 100	-67 - 100
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	18.1 (25.5)	0.9 (26.3)	14.8 (19.5)	-1.5 (23.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 100	0 - 67	-67 - 67
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	15.1 (20.8)	-2.9 (24.1)	12.2 (19.4)	-5.0 (29.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 67	-100 - 33
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	16.2 (21.0)	-1.5 (25.6)	11.1 (16.0)	-11.5 (27.1)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 33	-67 - 33
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	20.1 (25.6)	4.7 (27.8)	15.3 (24.0)	-1.4 (21.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 100	0 - 67	-33 - 33
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	16.3 (21.5)	0.7 (25.3)	10.1 (15.7)	-7.9 (23.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 33	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 100 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Financial difficulties

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	15.4 (19.2)	0.7 (25.0)	11.7 (16.3)	-12.3 (29.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 33	-67 - 33
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	16.3 (21.0)	1.6 (25.5)	19.3 (23.1)	-3.7 (27.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 67	0 - 67	-67 - 33
Cycle 27 Day 1				
n	39	38	17	16
Mean (SD)	17.1 (20.0)	2.6 (25.0)	11.8 (16.4)	-10.4 (33.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 67	0 - 33	-100 - 33
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	20.8 (23.6)	7.3 (27.7)	13.7 (20.6)	-6.2 (32.7)
Median	16.7	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 67	0 - 67	-100 - 33
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	23.0 (25.4)	7.1 (24.6)	3.0 (10.1)	-23.3 (35.3)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 67	0 - 33	-100 - 0
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	20.6 (19.7)	4.8 (21.8)	7.4 (14.7)	-25.0 (34.5)
Median	33.3	0.0	0.0	-16.7
Min - Max	0 - 67	-33 - 33	0 - 33	-100 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 101 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Financial difficulties

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	16.7 (17.1)	2.0 (22.0)	11.1 (16.7)	-16.7 (35.6)
Median	16.7	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 33	-67 - 33
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	21.6 (23.4)	5.9 (27.0)	4.8 (12.6)	-22.2 (27.2)
Median	33.3	0.0	0.0	-16.7
Min - Max	0 - 67	-33 - 67	0 - 33	-67 - 0
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	19.0 (21.5)	9.5 (20.4)	0.0 (0.0)	-26.7 (27.9)
Median	16.7	0.0	0.0	-33.3
Min - Max	0 - 67	-33 - 33	0 - 0	-67 - 0
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	20.5 (21.7)	7.7 (20.0)	16.7 (19.2)	-16.7 (19.2)
Median	33.3	0.0	16.7	-16.7
Min - Max	0 - 67	-33 - 33	0 - 33	-33 - 0
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	17.9 (25.9)	5.1 (26.7)	8.3 (16.7)	-25.0 (31.9)
Median	0.0	0.0	0.0	-16.7
Min - Max	0 - 67	-67 - 33	0 - 33	-67 - 0
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	23.8 (25.2)	9.5 (16.3)	0.0 (0.0)	-22.2 (38.5)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 67	0 - 33	0 - 0	-67 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 102 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-C30: Financial difficulties

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	16.7 (18.3)	5.6 (13.6)	16.7 (23.6)	-16.7 (70.7)
Median	16.7	0.0	16.7	-16.7
Min - Max	0 - 33	0 - 33	0 - 33	-67 - 33
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	33.3 (33.3)	11.1 (19.2)	0.0 (NA)	-66.7 (NA)
Median	33.3	0.0	0.0	-66.7
Min - Max	0 - 67	0 - 33	0 - 0	-67 - -67
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	16.7 (23.6)	0.0 (0.0)	0.0 (NA)	-66.7 (NA)
Median	16.7	0.0	0.0	-66.7
Min - Max	0 - 33	0 - 0	0 - 0	-67 - -67
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	0.0 (NA)	0.0 (NA)	-66.7 (NA)
Median	0.0	0.0	0.0	-66.7
Min - Max	0 - 0	0 - 0	0 - 0	-67 - -67
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	0.0 (NA)	33.3 (NA)	-33.3 (NA)
Median	0.0	0.0	33.3	-33.3
Min - Max	0 - 0	0 - 0	33 - 33	-33 - -33
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	0.0 (NA)	0.0 (NA)	-66.7 (NA)
Median	0.0	0.0	0.0	-66.7
Min - Max	0 - 0	0 - 0	0 - 0	-67 - -67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:32 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 103 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Financial difficulties

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	27.4 (29.1)	2.2 (30.3)	21.4 (29.5)	0.7 (31.7)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-100 - 100
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	25.9 (32.4)	3.7 (35.1)	6.7 (14.9)	0.0 (23.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 67	0 - 33	-33 - 33
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	33.3 (47.1)	16.7 (23.6)	NE (NE)	NE (NE)
Median	33.3	16.7	NE	NE
Min - Max	0 - 67	0 - 33	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	66.7 (NA)	33.3 (NA)	NE (NE)	NE (NE)
Median	66.7	33.3	NE	NE
Min - Max	67 - 67	33 - 33	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	38
Mean (SD)	21.9 (26.2)	-1.1 (20.2)	27.5 (31.9)	0.9 (25.1)
Median	16.7	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 33	0 - 100	-67 - 67
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	24.6 (26.9)	7.0 (23.8)	17.5 (23.2)	-3.9 (20.0)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 100	-33 - 67	0 - 67	-33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 104 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-C30, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-C30: Financial difficulties

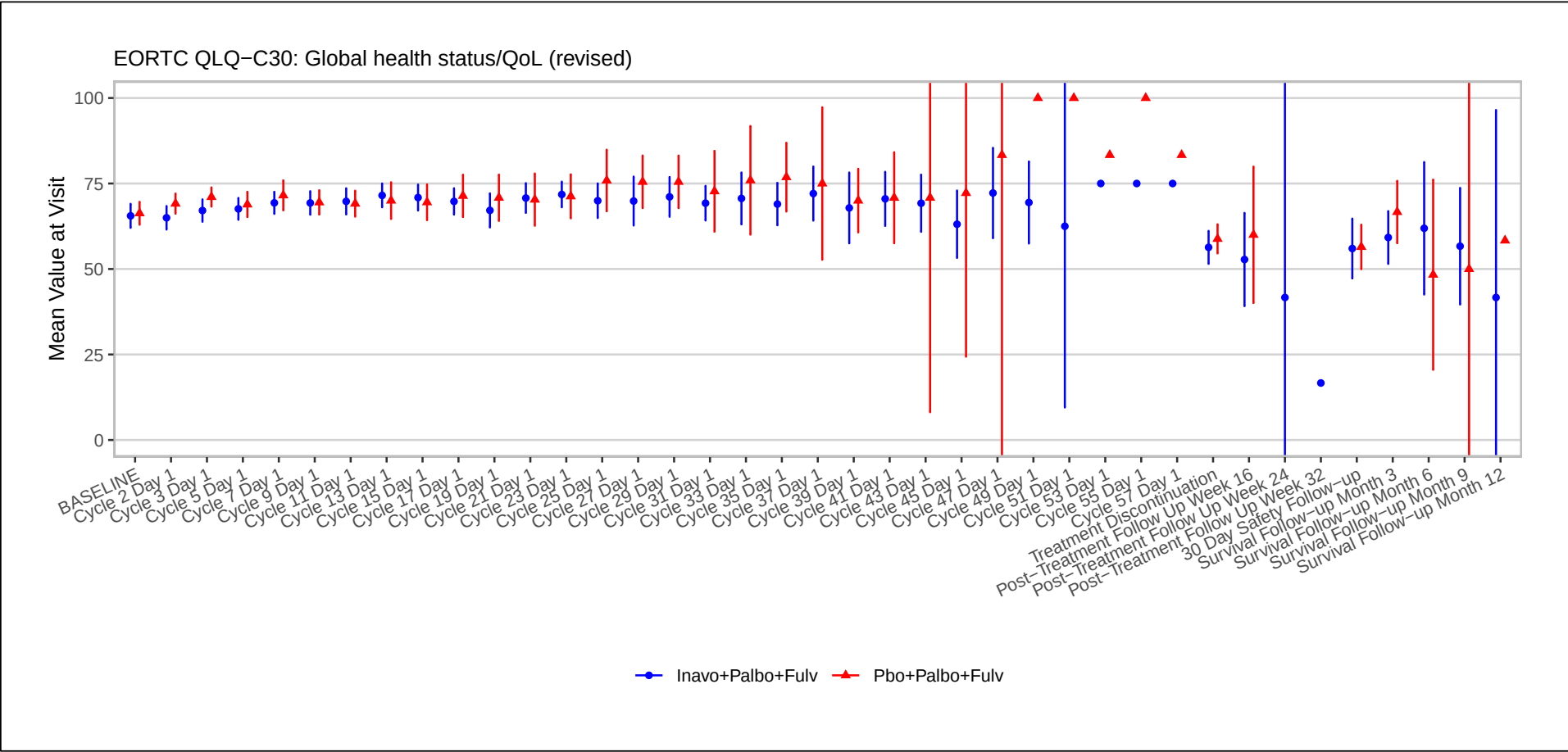
Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	38.1 (30.0)	19.0 (26.2)	33.3 (40.8)	6.7 (36.5)
Median	33.3	0.0	33.3	33.3
Min - Max	0 - 67	0 - 67	0 - 100	-33 - 33
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	40.0 (27.9)	26.7 (27.9)	66.7 (47.1)	16.7 (23.6)
Median	33.3	33.3	66.7	16.7
Min - Max	0 - 67	0 - 67	33 - 100	0 - 33
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	55.6 (19.2)	44.4 (19.2)	33.3 (NA)	33.3 (NA)
Median	66.7	33.3	33.3	33.3
Min - Max	33 - 67	33 - 67	33 - 33	33 - 33
TIME OF FIRST PD				
n	21	19	59	52
Mean (SD)	20.6 (22.3)	-10.5 (25.0)	16.4 (25.8)	-3.8 (26.1)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 33	0 - 100	-67 - 33
TIME OF LAST TX DOSE				
n	68	61	86	77
Mean (SD)	19.1 (24.0)	-1.1 (26.5)	20.5 (29.0)	-0.0 (27.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-67 - 100

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:32 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_C30_FAS_15NOV2024_41554.out Page 105 of 105

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

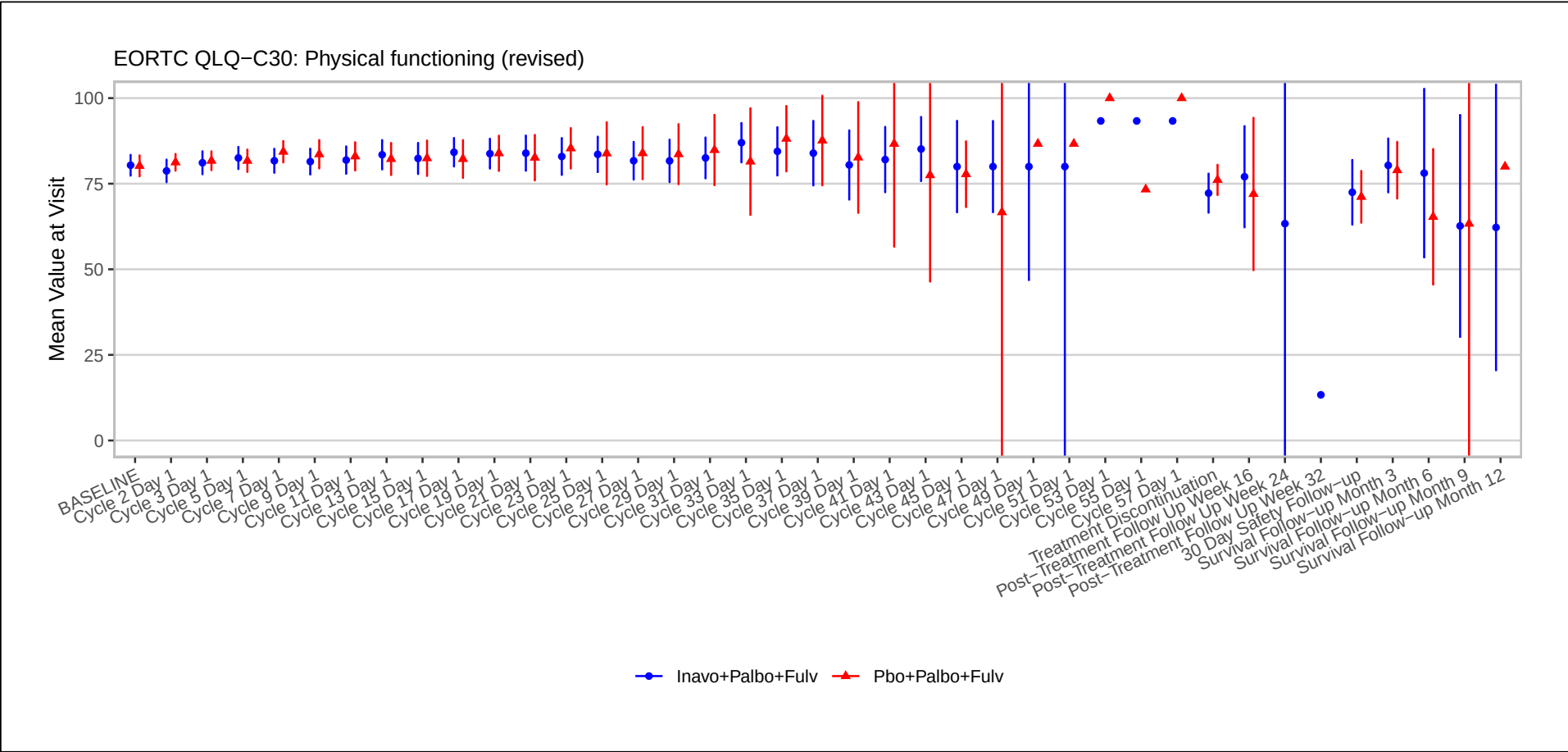
Plot of Mean and 95% Confidence Interval, EORTC QLQ-C30, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_qs_cfb2.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v14/output/g_qs_cfb2_EORTC_FAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 0efa981b2a84f5e06c881464de43872934271dc3
18 JUN 2025 17:00 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

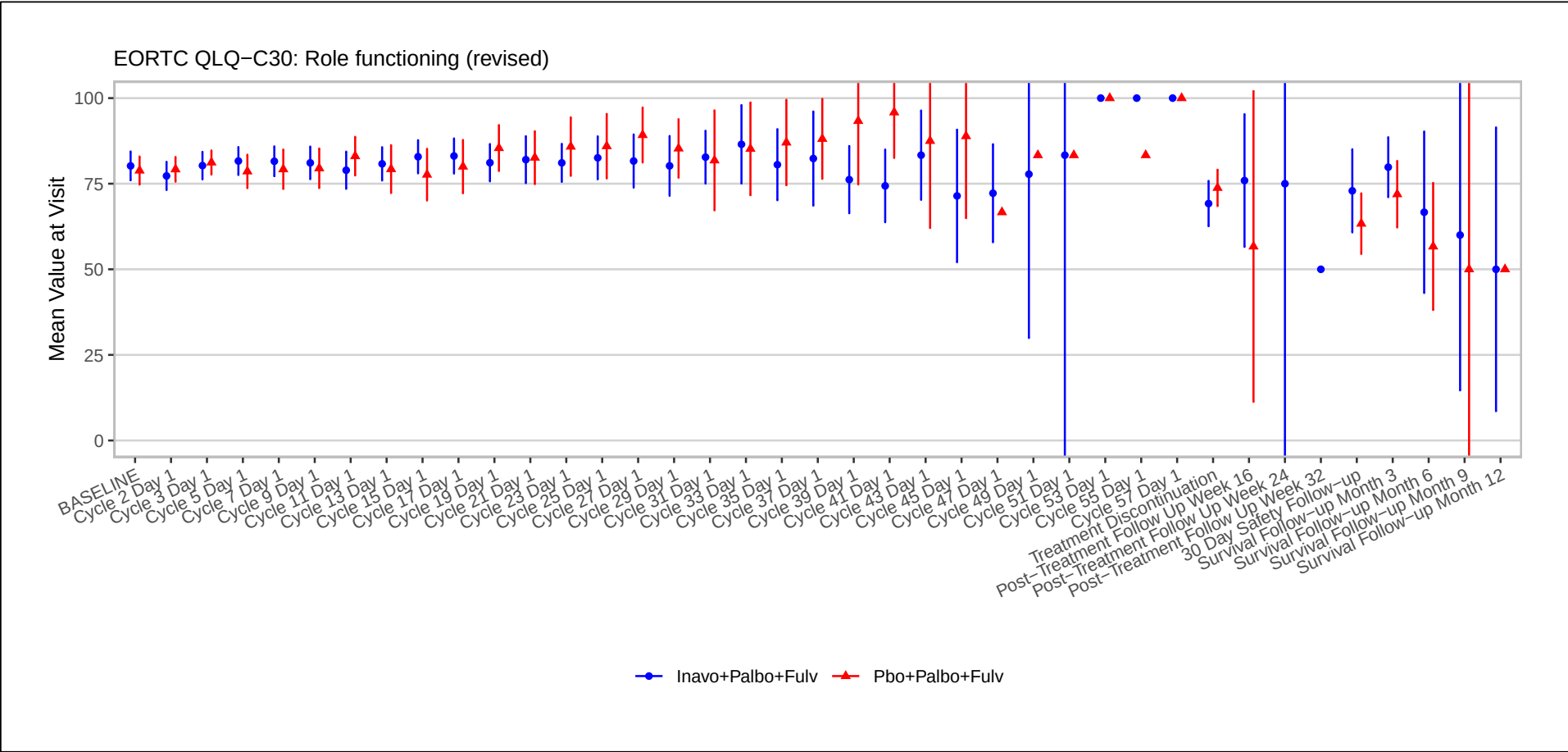
Plot of Mean and 95% Confidence Interval, EORTC QLQ-C30, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_qs_cfb2.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v14/output/g_qs_cfb2_EORTC_FAS_15NOV2024_41554.pdf
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Git hash: 0efa981b2a84f5e06c881464de43872934271dc3
18 JUN 2025 17:00 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

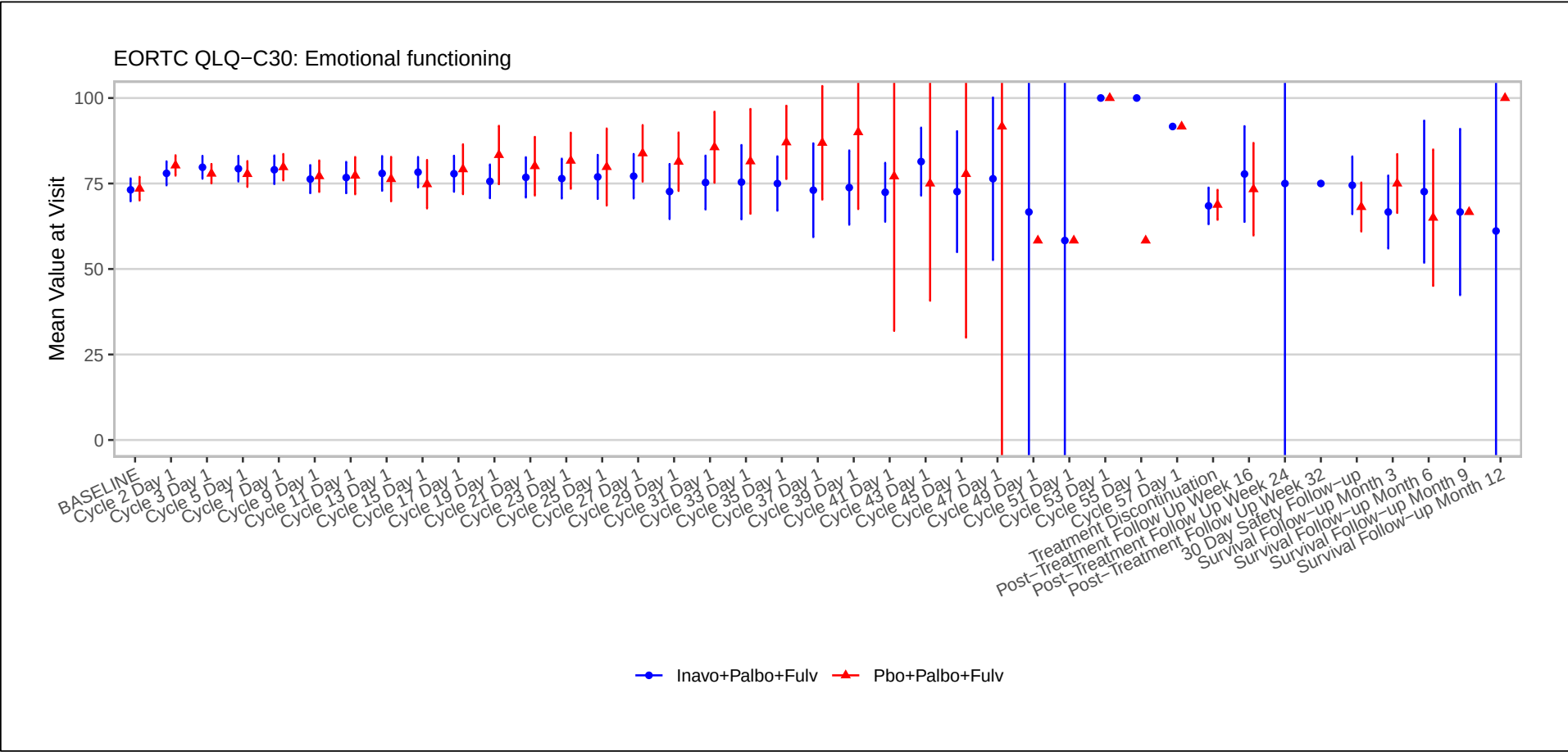
Plot of Mean and 95% Confidence Interval, EORTC QLQ-C30, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_qs_cfb2.R
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

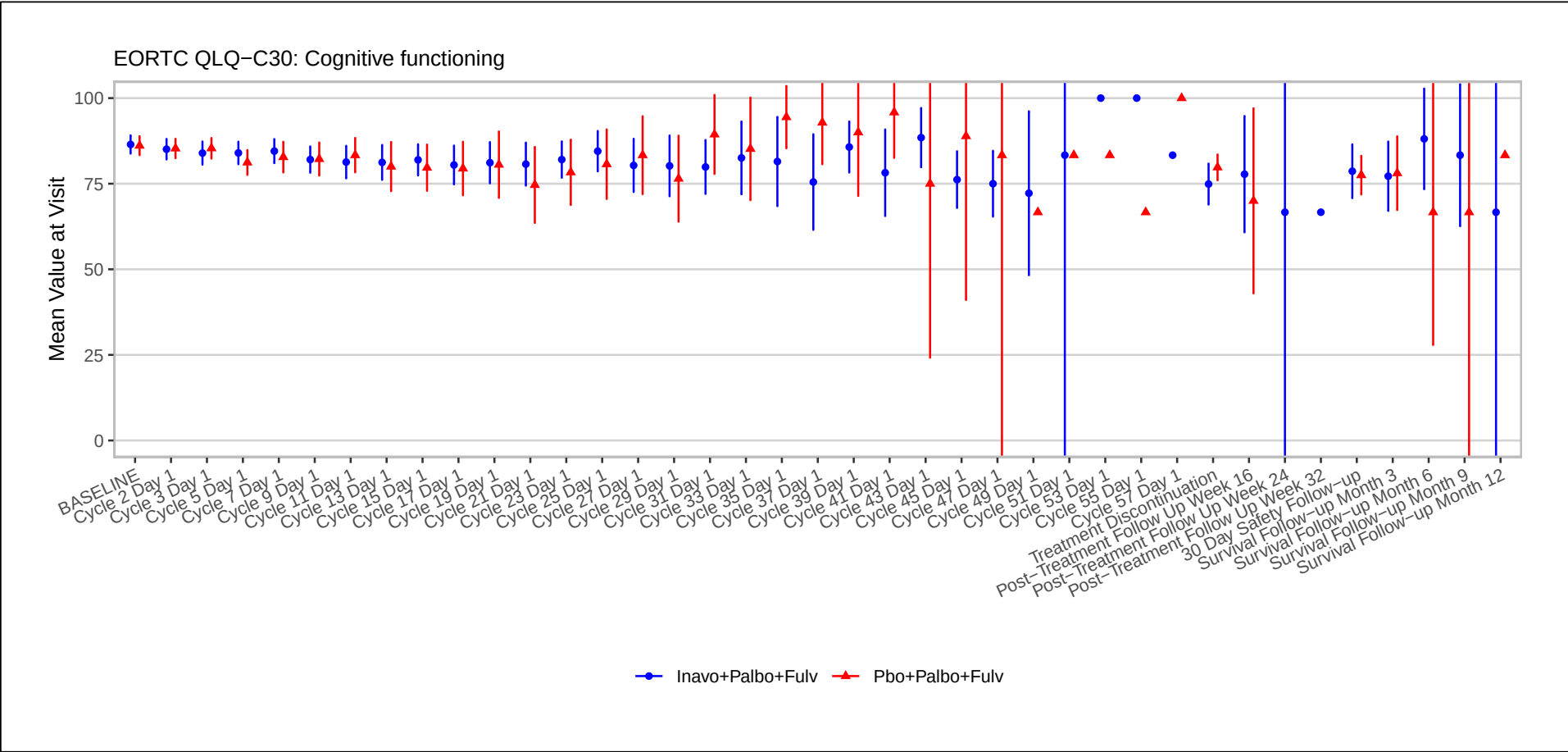
Plot of Mean and 95% Confidence Interval, EORTC QLQ–C30, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

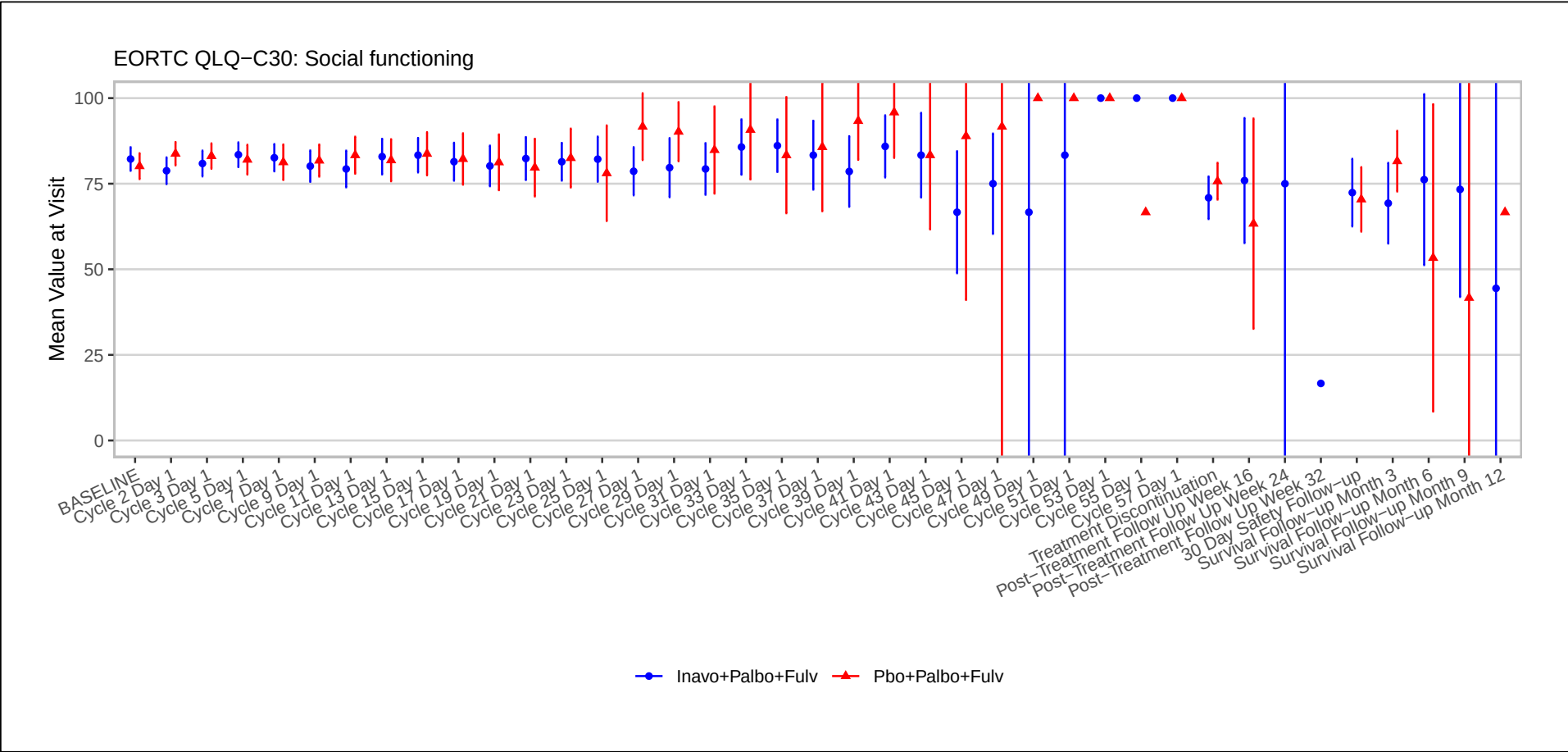
Plot of Mean and 95% Confidence Interval, EORTC QLQ-C30, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

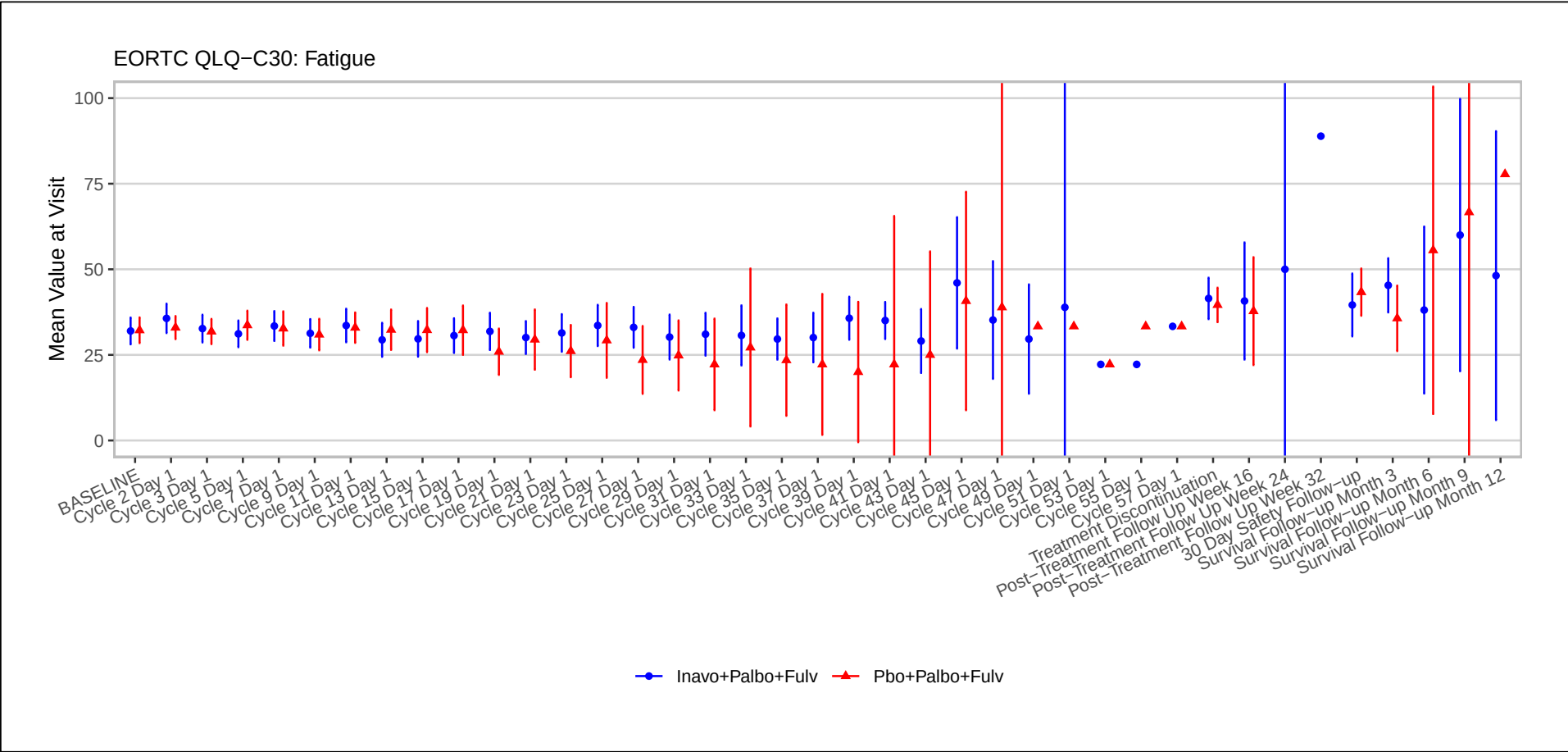
Plot of Mean and 95% Confidence Interval, EORTC QLQ-C30, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

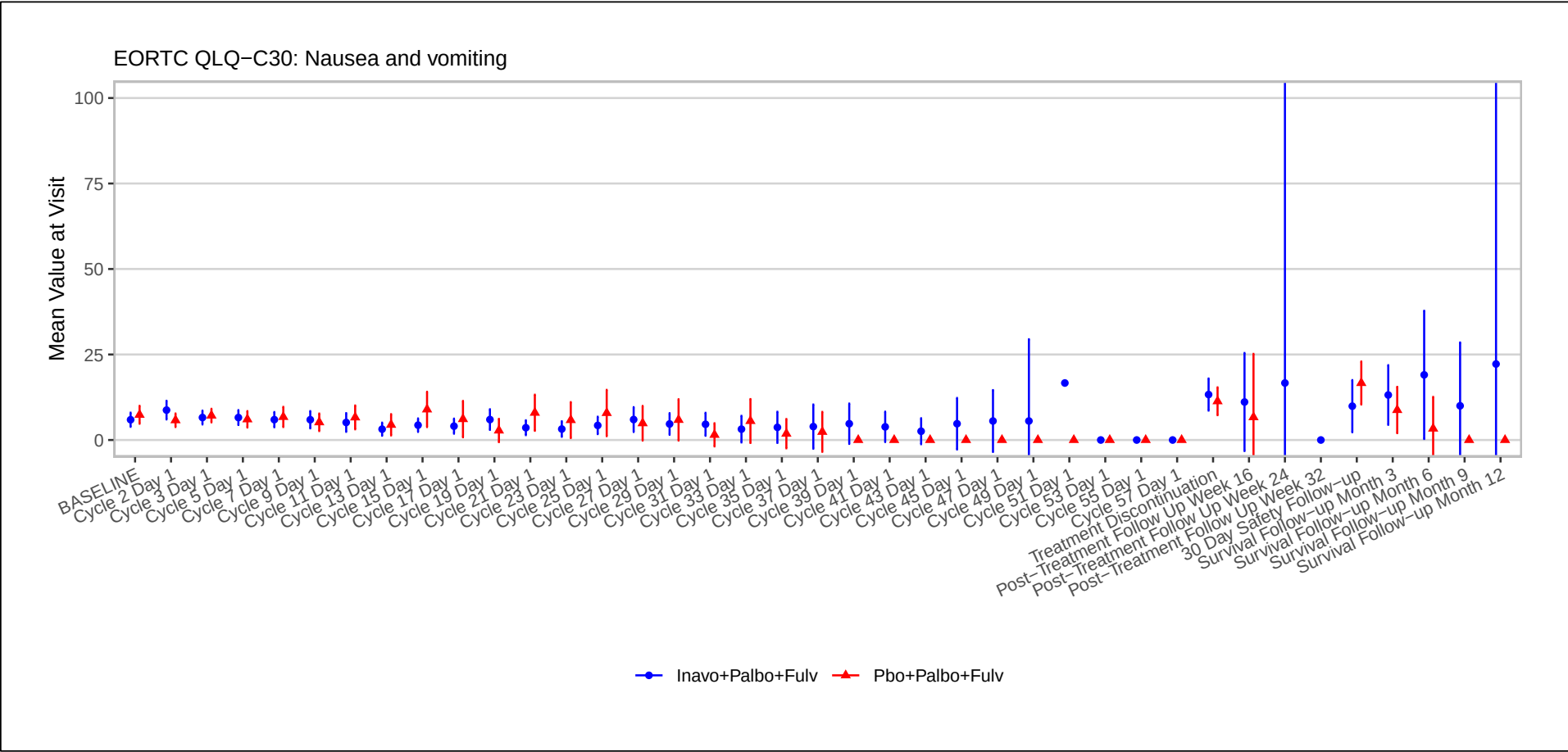
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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18 JUN 2025 17:00 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

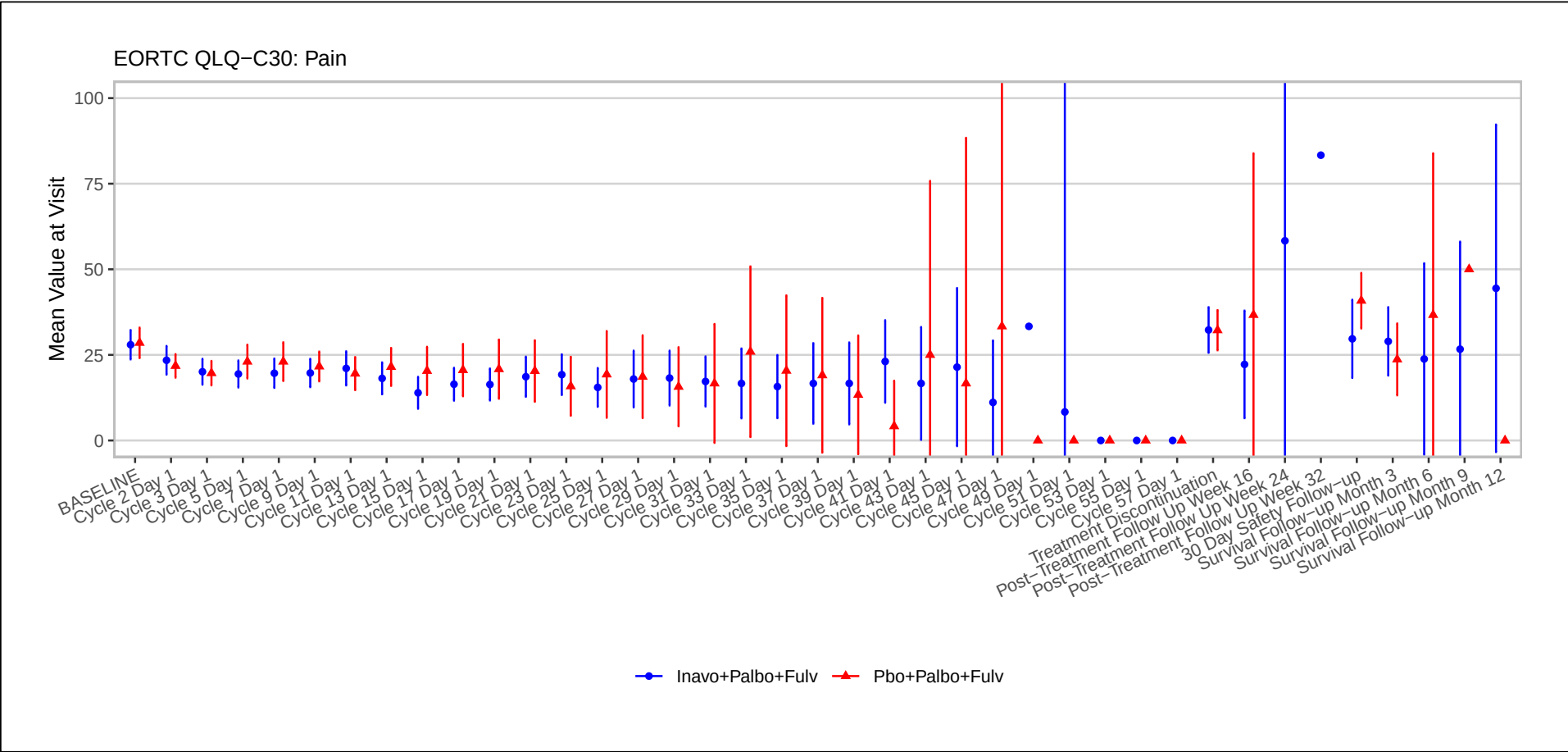
Plot of Mean and 95% Confidence Interval, EORTC QLQ-C30, Full Analysis Set
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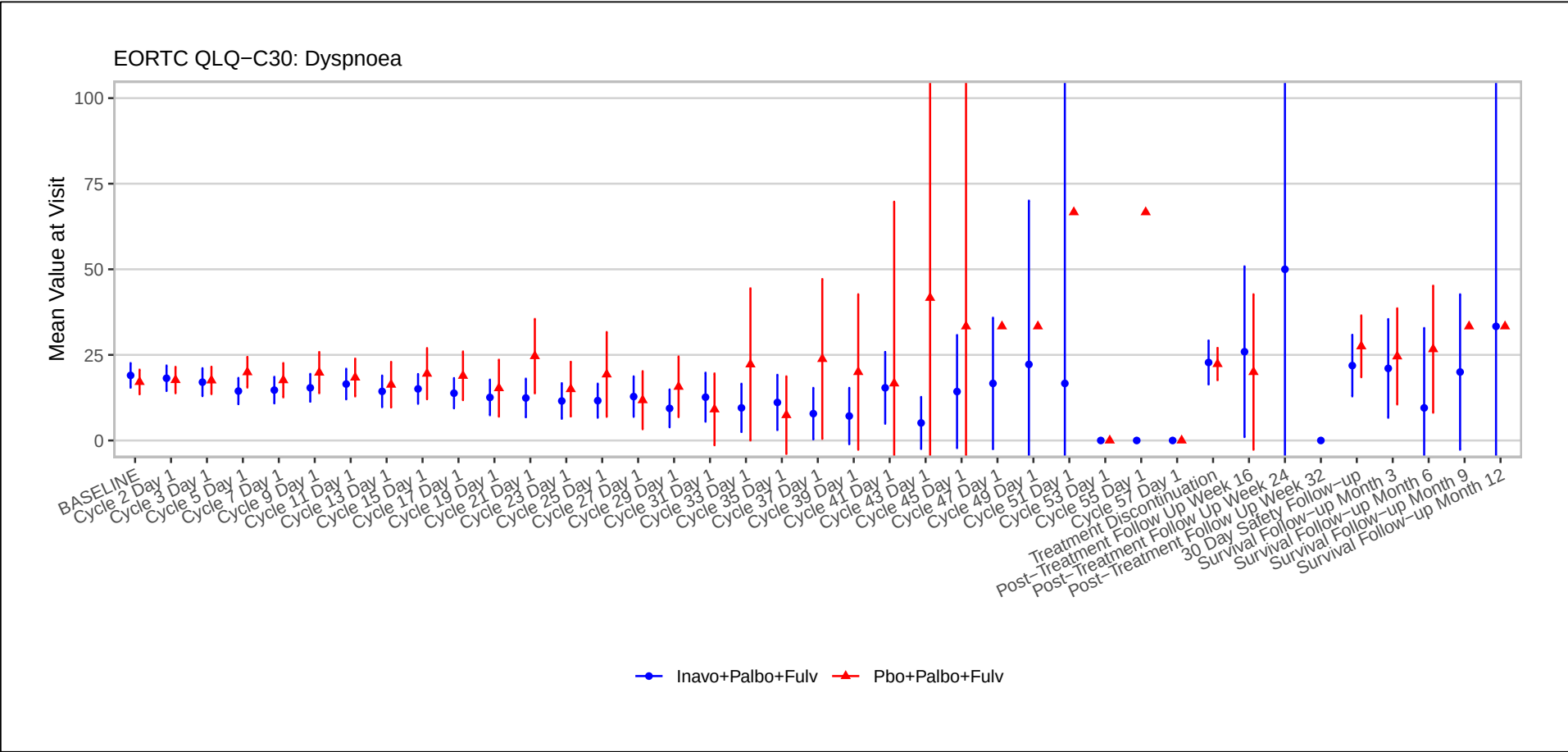
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Plot of Mean and 95% Confidence Interval, EORTC QLQ-C30, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

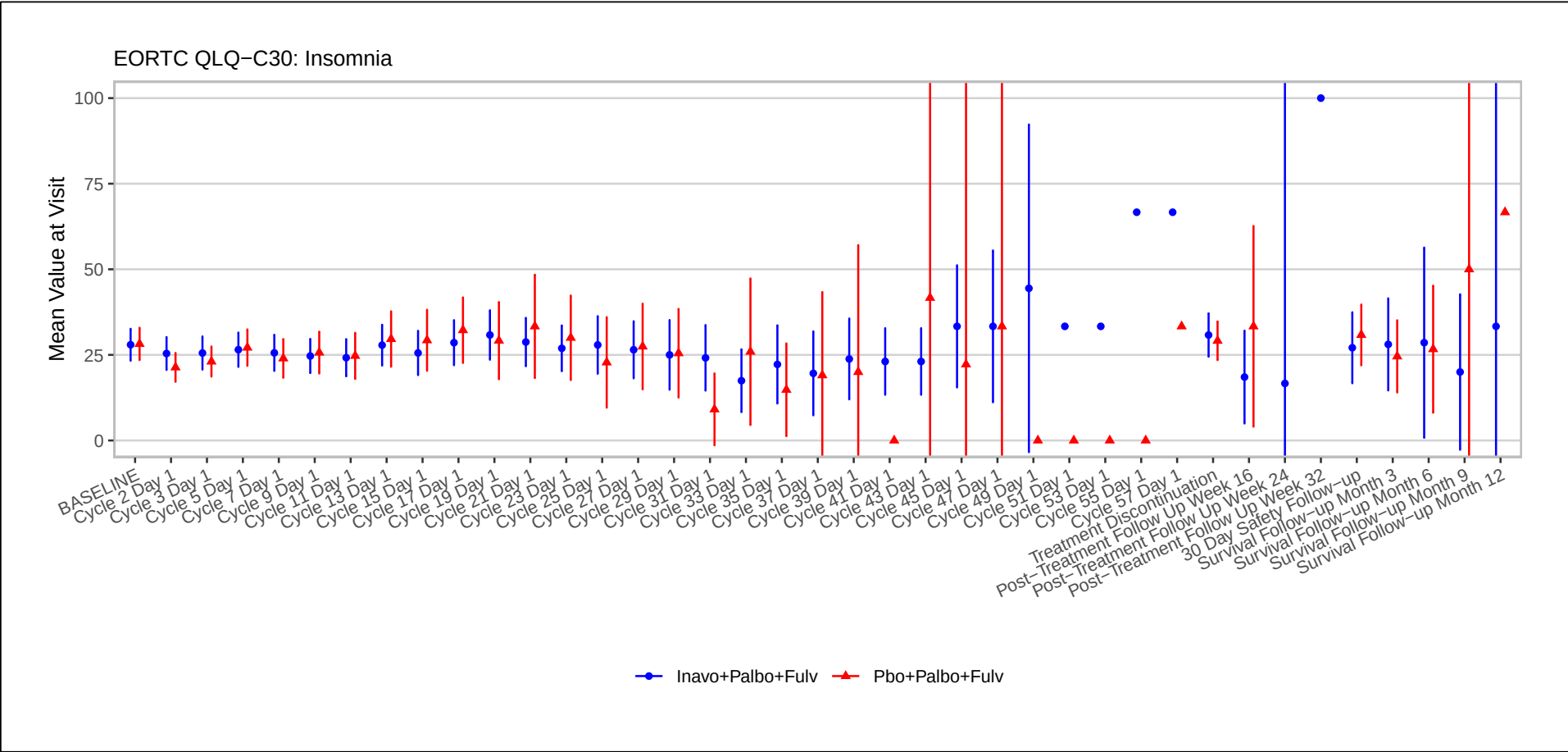
Plot of Mean and 95% Confidence Interval, EORTC QLQ-C30, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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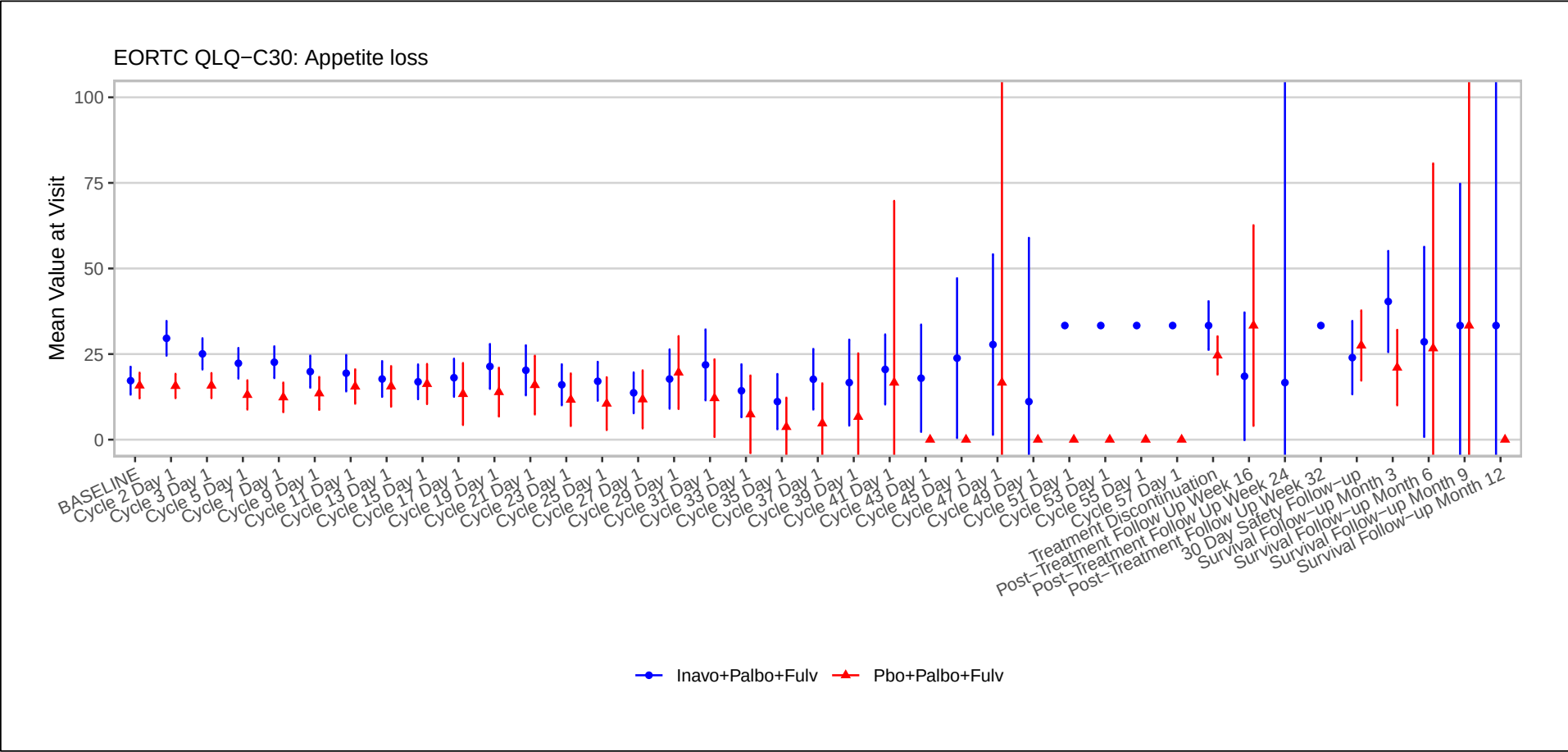
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

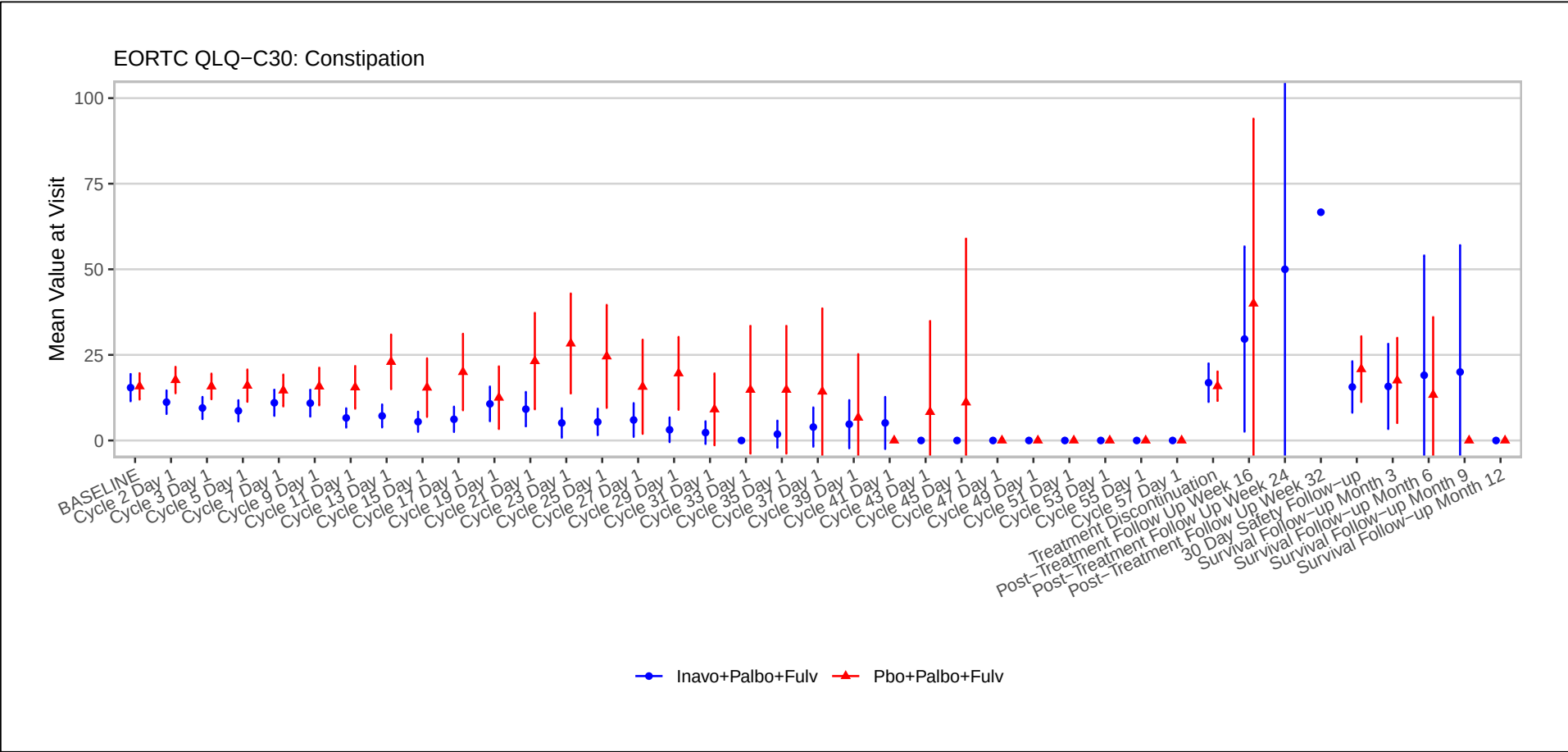
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

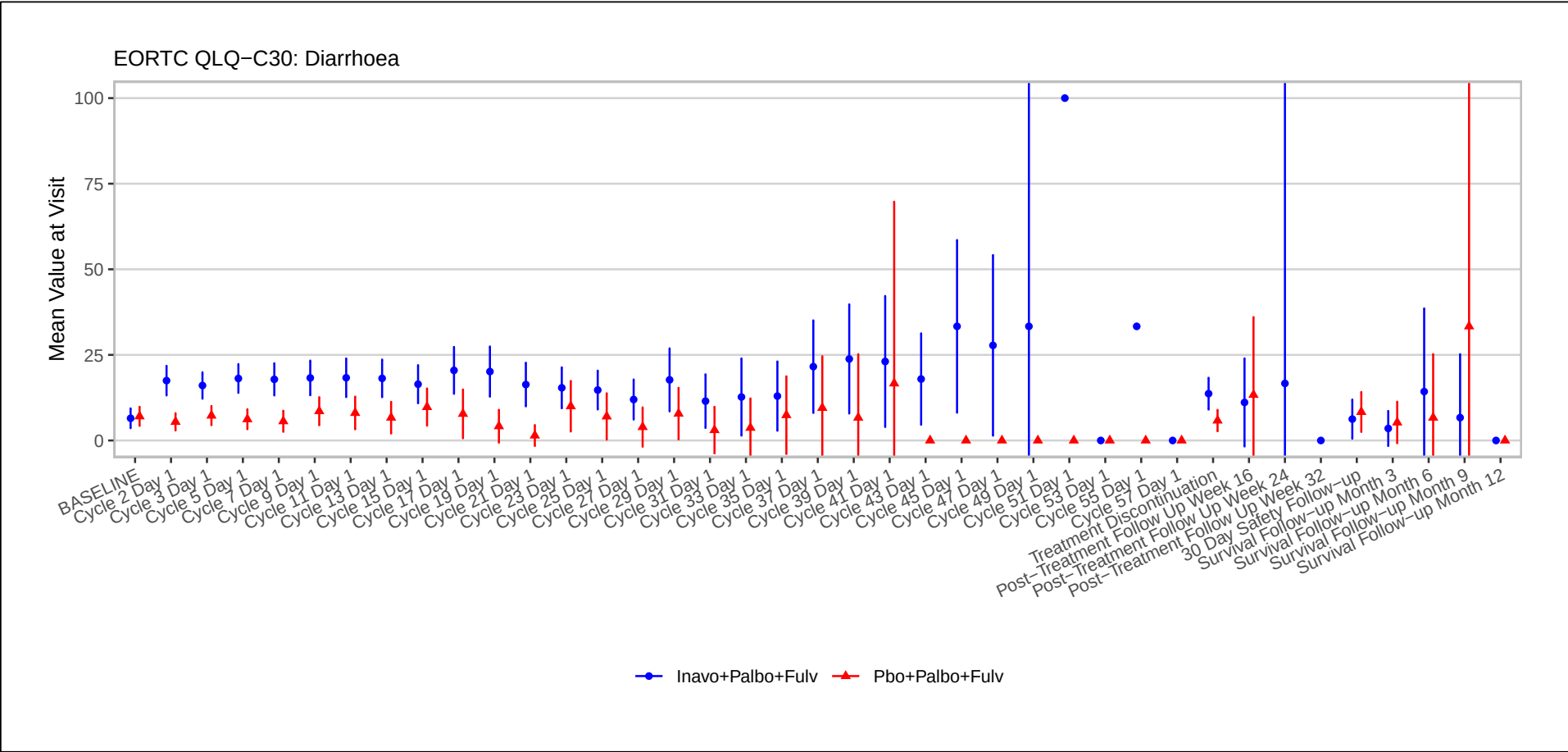
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

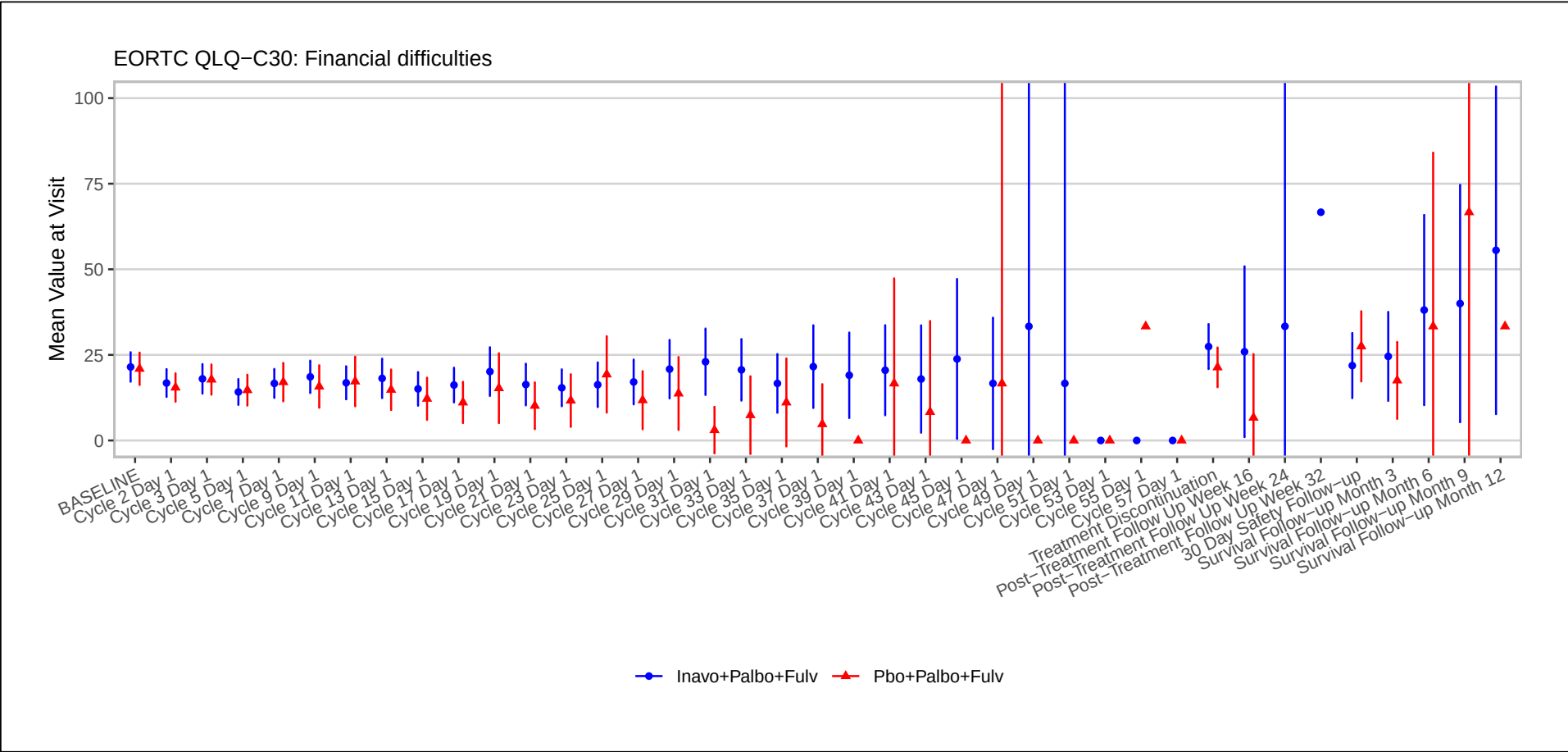
Plot of Mean and 95% Confidence Interval, EORTC QLQ-C30, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Plot of Mean and 95% Confidence Interval, EORTC QLQ-C30, Full Analysis Set
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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.1 PRO Items des EORTC QLQ-C30

2.1.3 Zeit bis zur ersten Verschlechterung der PRO Items des EORTC QLQ-C30, MID = 10 Punkte

Time to Event Analysis (Efficacy), EORTC QLQ-C30 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Appetite loss (MID >=10)		
Patients with event		
n (%)	105 (65.2%)	70 (42.7%)
Patients without event		
n (%)	56 (34.8%)	94 (57.3%)
Time to Event (Months)		
Median	3.68	11.76
95% CI	(1.87, 5.55)	(7.52, 16.59)
Range	0.03 - 47.21 {1}	0.03 - 51.55 {1}
Unstratified Analysis		
p-value (log-rank)	<0.0001	
Hazard Ratio	1.94	
95% CI	(1.43, 2.62)	
Stratified Analysis		
p-value (log-rank)	<0.0001	
Hazard Ratio	1.89	
95% CI	(1.39, 2.59)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Cognitive functioning (MID >=10)		
Patients with event		
n (%)	98 (60.9%)	85 (51.8%)
Patients without event		
n (%)	63 (39.1%)	79 (48.2%)
Time to Event (Months)		
Median	7.89	7.52
95% CI	(5.49, 9.43)	(5.59, 9.53)
Range	0.03 - 49.48 {1}	0.03 - 51.55 {1}
Unstratified Analysis		
p-value (log-rank)	0.8685	
Hazard Ratio	1.02	
95% CI	(0.77, 1.37)	
Stratified Analysis		
p-value (log-rank)	0.5083	
Hazard Ratio	1.10	
95% CI	(0.81, 1.50)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Constipation (MID >=10)		
Patients with event		
n (%)	63 (39.1%)	70 (42.7%)
Patients without event		
n (%)	98 (60.9%)	94 (57.3%)
Time to Event (Months)		
Median	18.40	12.42
95% CI	(9.53, NE)	(7.62, 21.16)
Range	0.03 - 52.30 {1}	0.03 - 51.55 {1}
Unstratified Analysis		
p-value (log-rank)	0.0842	
Hazard Ratio	0.74	
95% CI	(0.52, 1.04)	
Stratified Analysis		
p-value (log-rank)	0.1481	

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Hazard Ratio	0.77	
95% CI	(0.54, 1.09)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Diarrhoea (MID >=10)		
Patients with event		
n (%)	100 (62.1%)	52 (31.7%)
Patients without event		
n (%)	61 (37.9%)	112 (68.3%)
Time to Event (Months)		
Median	3.81	16.95
95% CI	(3.71, 6.70)	(11.83, NE)
Range	0.03 - 46.78 {2}	0.03 - 51.55 {1}
Unstratified Analysis		
p-value (log-rank)	<0.0001	
Hazard Ratio	2.44	
95% CI	(1.75, 3.41)	
Stratified Analysis		
p-value (log-rank)	<0.0001	
Hazard Ratio	2.47	
95% CI	(1.75, 3.49)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Dyspnoea (MID >=10)		
Patients with event		
n (%)	74 (46%)	70 (42.7%)
Patients without event		
n (%)	87 (54%)	94 (57.3%)
Time to Event (Months)		
Median	13.27	10.91
95% CI	(8.31, 24.57)	(7.33, 15.67)
Range	0.03 - 52.30 {1}	0.03 - 42.61 {1}
Unstratified Analysis		
p-value (log-rank)	0.4027	
Hazard Ratio	0.87	
95% CI	(0.62, 1.21)	
Stratified Analysis		
p-value (log-rank)	0.4775	
Hazard Ratio	0.89	
95% CI	(0.63, 1.25)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Emotional functioning (MID >=10)		
Patients with event		
n (%)	69 (42.9%)	66 (40.2%)
Patients without event		
n (%)	92 (57.1%)	98 (59.8%)
Time to Event (Months)		
Median	15.05	12.88
95% CI	(11.70, 35.52)	(7.52, 27.37)
Range	0.03 - 52.30 {1}	0.03 - 51.55 {1}
Unstratified Analysis		
p-value (log-rank)	0.3547	
Hazard Ratio	0.85	
95% CI	(0.61, 1.20)	
Stratified Analysis		
p-value (log-rank)	0.5959	

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Hazard Ratio	0.91	
95% CI	(0.63, 1.31)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Fatigue (MID >=10)		
Patients with event		
n (%)	108 (67.1%)	103 (62.8%)
Patients without event		
n (%)	53 (32.9%)	61 (37.2%)
Time to Event (Months)		
Median	2.07	3.71
95% CI	(1.87, 3.78)	(1.97, 5.19)
Range	0.03 - 42.12 {1}	0.03 - 42.61 {1}
Unstratified Analysis		
p-value (log-rank)	0.7199	
Hazard Ratio	1.06	
95% CI	(0.81, 1.39)	
Stratified Analysis		
p-value (log-rank)	0.5739	
Hazard Ratio	1.10	
95% CI	(0.83, 1.45)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Financial difficulties (MID >=10)		
Patients with event		
n (%)	54 (33.5%)	46 (28%)
Patients without event		
n (%)	107 (66.5%)	118 (72%)
Time to Event (Months)		
Median	28.09	27.37
95% CI	(18.69, NE)	(16.36, NE)
Range	0.03 - 52.30 {1}	0.03 - 51.55 {1}
Unstratified Analysis		
p-value (log-rank)	0.8135	
Hazard Ratio	0.95	
95% CI	(0.64, 1.42)	
Stratified Analysis		
p-value (log-rank)	0.7198	
Hazard Ratio	1.08	
95% CI	(0.71, 1.62)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Nausea and vomiting (MID >=10)		
Patients with event		
n (%)	83 (51.6%)	70 (42.7%)
Patients without event		
n (%)	78 (48.4%)	94 (57.3%)
Time to Event (Months)		
Median	11.83	11.76
95% CI	(5.72, 19.61)	(8.87, 15.74)
Range	0.03 - 44.98 {1}	0.03 - 51.55 {1}
Unstratified Analysis		
p-value (log-rank)	0.5442	
Hazard Ratio	1.11	
95% CI	(0.80, 1.53)	
Stratified Analysis		
p-value (log-rank)	0.9136	

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Hazard Ratio	1.02	
95% CI	(0.73, 1.42)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Pain (MID >=10)		
Patients with event		
n (%)	84 (52.2%)	82 (50%)
Patients without event		
n (%)	77 (47.8%)	82 (50%)
Time to Event (Months)		
Median	9.43	7.46
95% CI	(5.75, 18.69)	(4.40, 11.99)
Range	0.03 - 46.49 {1}	0.03 - 51.55 {1}
Unstratified Analysis		
p-value (log-rank)	0.6161	
Hazard Ratio	0.93	
95% CI	(0.68, 1.26)	
Stratified Analysis		
p-value (log-rank)	0.7135	
Hazard Ratio	0.95	
95% CI	(0.70, 1.30)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Physical functioning (revised) (MID >=10)		
Patients with event		
n (%)	84 (52.2%)	73 (44.5%)
Patients without event		
n (%)	77 (47.8%)	91 (55.5%)
Time to Event (Months)		
Median	8.05	9.53
95% CI	(3.78, 18.40)	(7.39, 17.77)
Range	0.03 - 49.48 {1}	0.03 - 42.61 {1}
Unstratified Analysis		
p-value (log-rank)	0.4847	
Hazard Ratio	1.13	
95% CI	(0.82, 1.54)	
Stratified Analysis		
p-value (log-rank)	0.4907	
Hazard Ratio	1.13	
95% CI	(0.81, 1.56)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Global health status/QoL (revised) (MID >=10)		
Patients with event		
n (%)	82 (50.9%)	85 (51.8%)
Patients without event		
n (%)	79 (49.1%)	79 (48.2%)
Time to Event (Months)		
Median	13.11	7.39
95% CI	(5.91, 22.34)	(5.55, 10.58)
Range	0.03 - 42.78 {1}	0.03 - 26.71 {1}
Unstratified Analysis		
p-value (log-rank)	0.1053	
Hazard Ratio	0.78	
95% CI	(0.57, 1.06)	
Stratified Analysis		
p-value (log-rank)	0.1270	

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Hazard Ratio	0.79	
95% CI	(0.57, 1.09)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Role functioning (revised) (MID >=10)		
Patients with event		
n (%)	92 (57.1%)	84 (51.2%)
Patients without event		
n (%)	69 (42.9%)	80 (48.8%)
Time to Event (Months)		
Median	6.01	5.78
95% CI	(3.65, 11.93)	(3.94, 11.27)
Range	0.03 - 44.98 {1}	0.03 - 51.55 {1}
Unstratified Analysis		
p-value (log-rank)	0.6793	
Hazard Ratio	1.07	
95% CI	(0.79, 1.44)	
Stratified Analysis		
p-value (log-rank)	0.9291	
Hazard Ratio	1.00	
95% CI	(0.73, 1.37)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Social functioning (MID >=10)		
Patients with event		
n (%)	97 (60.2%)	78 (47.6%)
Patients without event		
n (%)	64 (39.8%)	86 (52.4%)
Time to Event (Months)		
Median	6.01	9.23
95% CI	(3.71, 9.46)	(4.44, 19.35)
Range	0.03 - 42.32 {2}	0.03 - 51.55 {1}
Unstratified Analysis		
p-value (log-rank)	0.1403	
Hazard Ratio	1.26	
95% CI	(0.93, 1.69)	
Stratified Analysis		
p-value (log-rank)	0.2205	
Hazard Ratio	1.22	
95% CI	(0.89, 1.66)	
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Insomnia (MID >=10)		
Patients with event		
n (%)	77 (47.8%)	62 (37.8%)
Patients without event		
n (%)	84 (52.2%)	102 (62.2%)
Time to Event (Months)		
Median	13.96	16.62
95% CI	(11.01, 19.15)	(9.46, 26.48)
Range	0.03 - 46.49 {1}	0.03 - 51.55 {1}
Unstratified Analysis		
p-value (log-rank)	0.4661	
Hazard Ratio	1.13	
95% CI	(0.81, 1.59)	
Stratified Analysis		
p-value (log-rank)	0.4136	

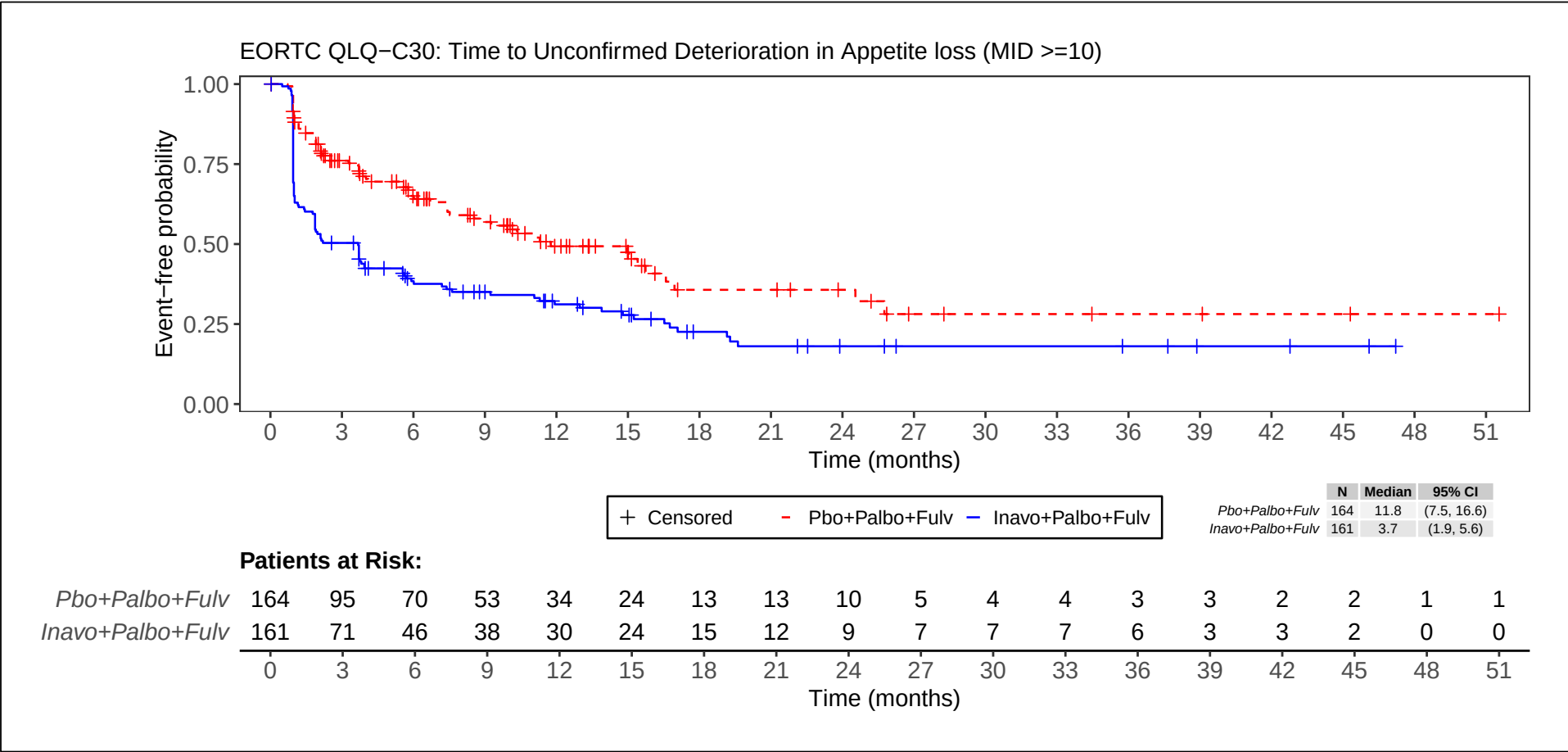
	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Hazard Ratio	1.16	
95% CI	(0.82, 1.63)	

{1} - Censored observations: range minimum & maximum
{2} - Censored observation: range minimum

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

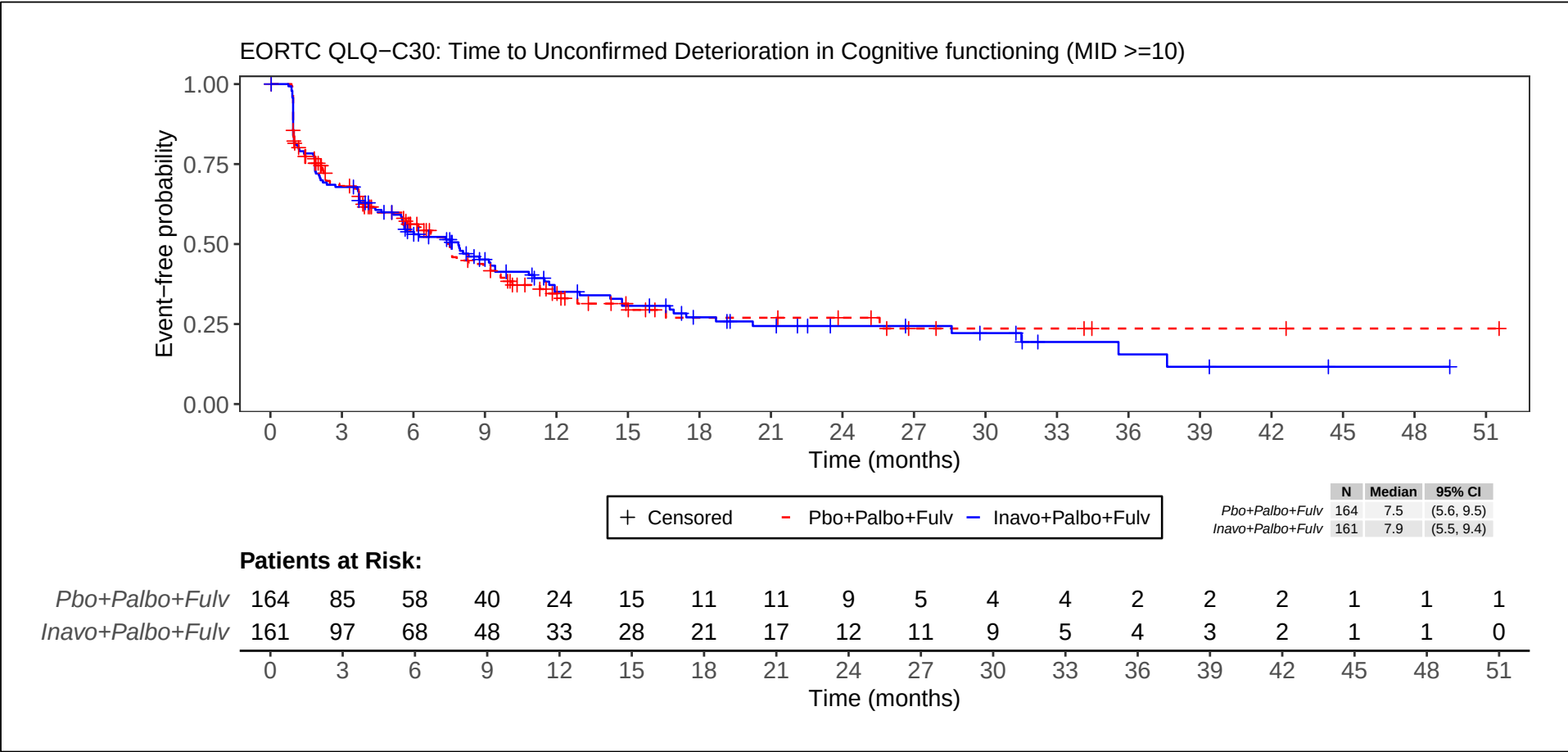
Kaplan Meier Plot for Efficacy, EORTC QLQ-C30 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

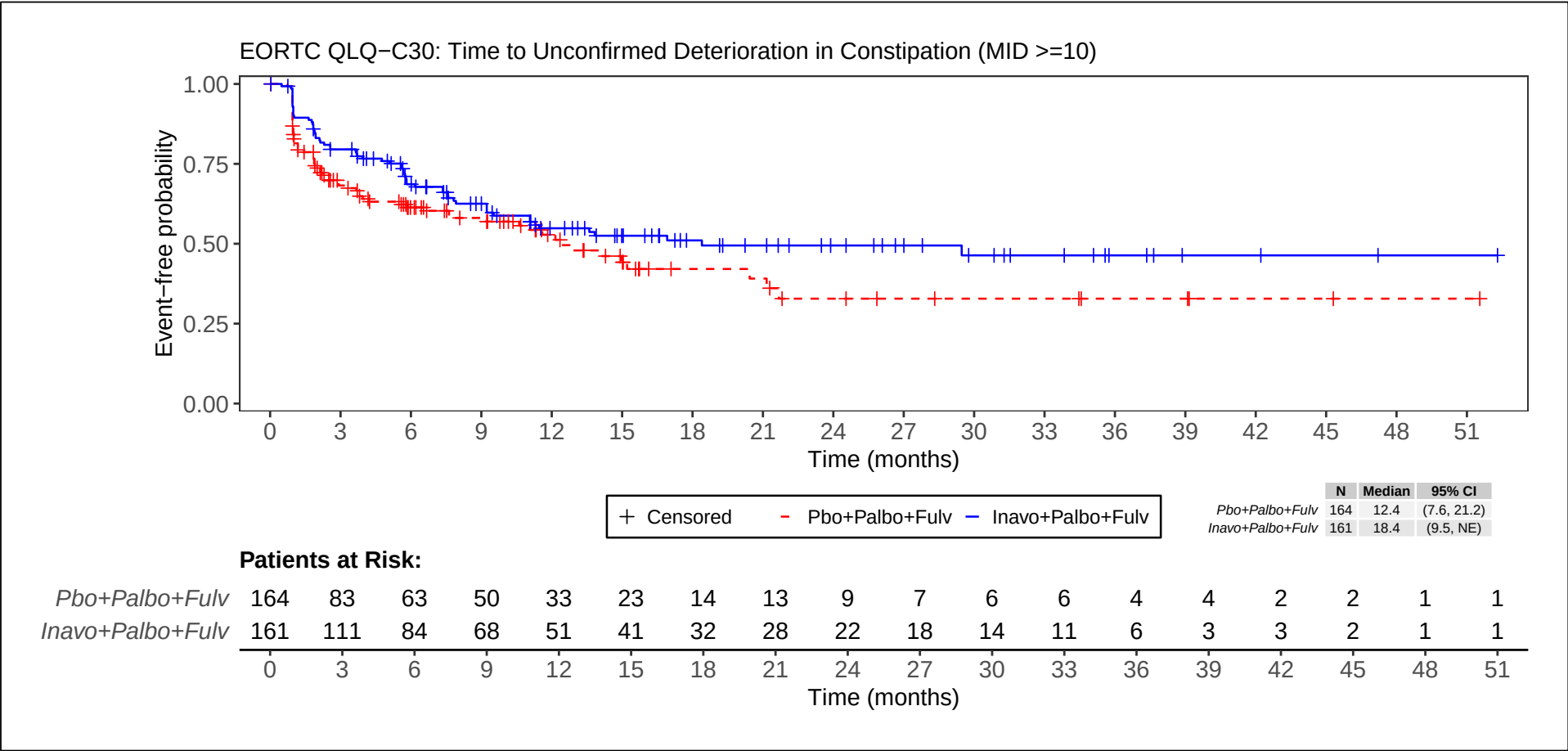
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

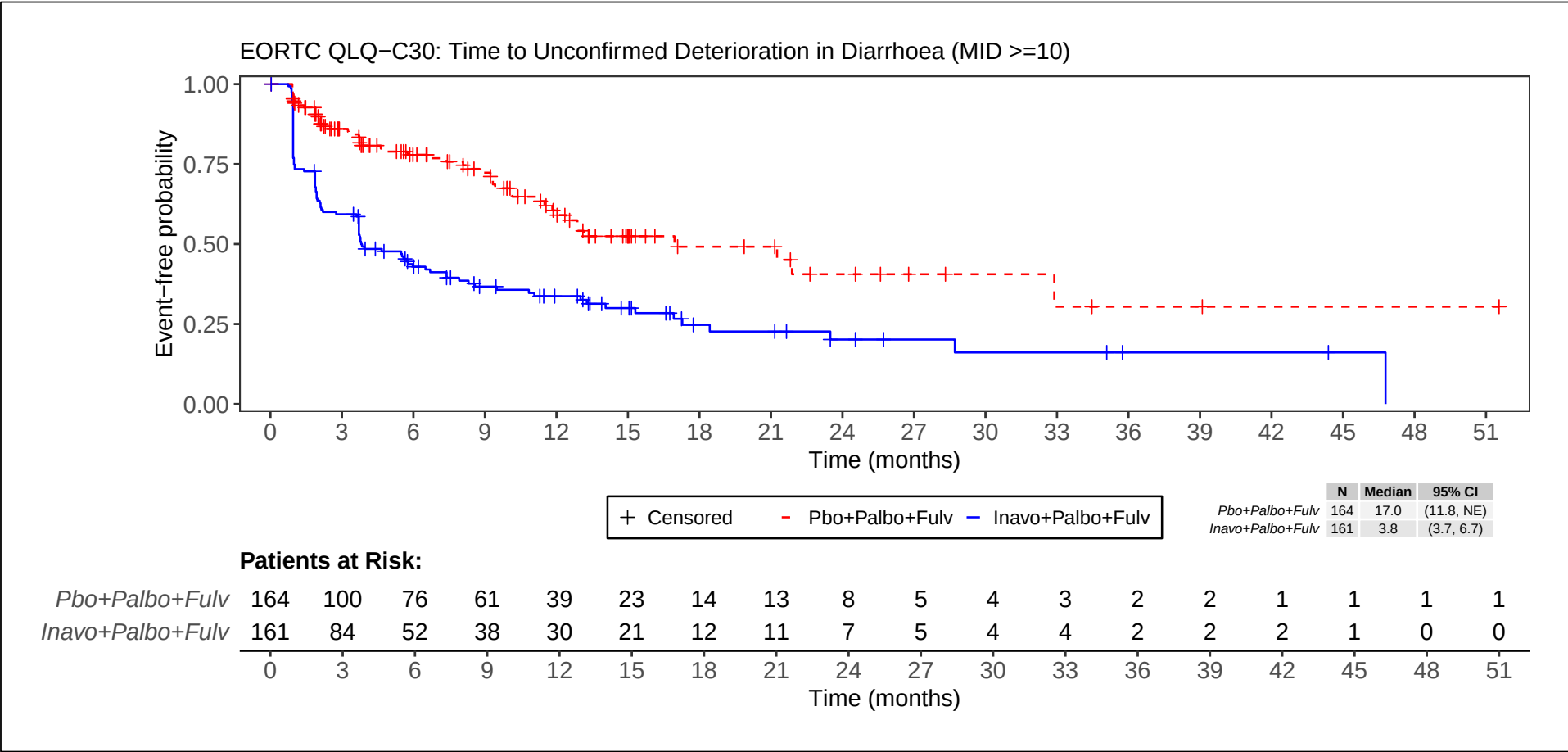
Kaplan Meier Plot for Efficacy, EORTC QLQ-C30 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

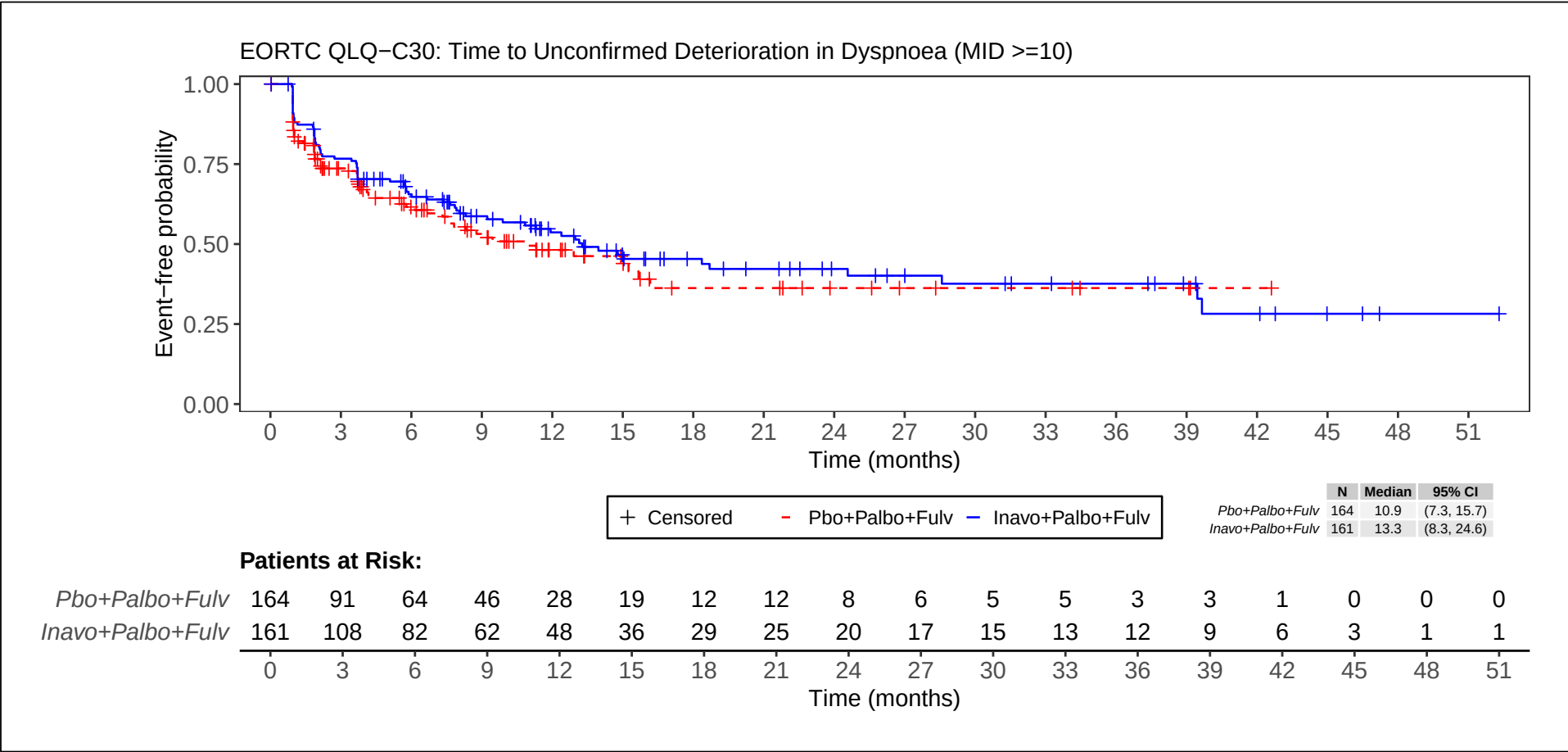
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

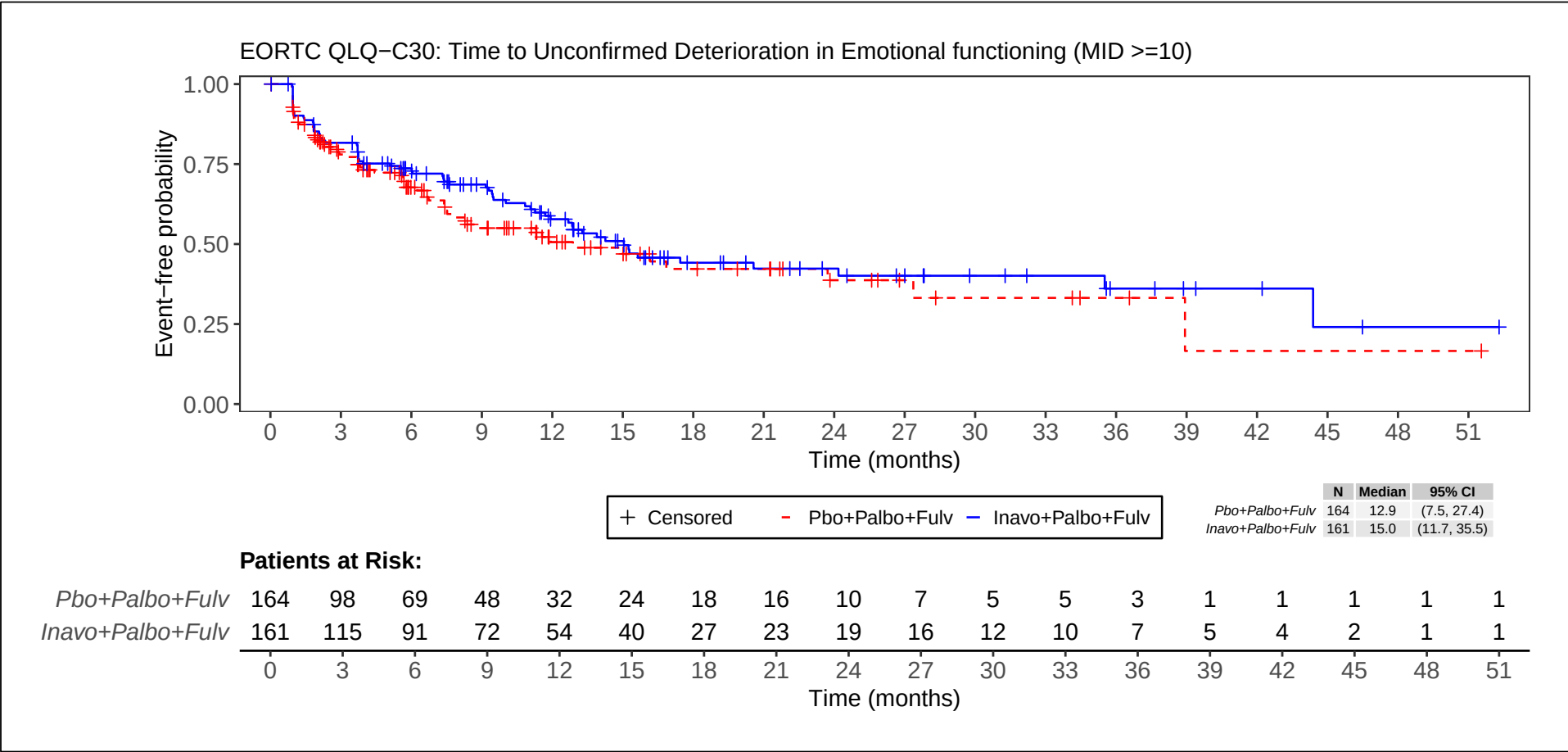
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

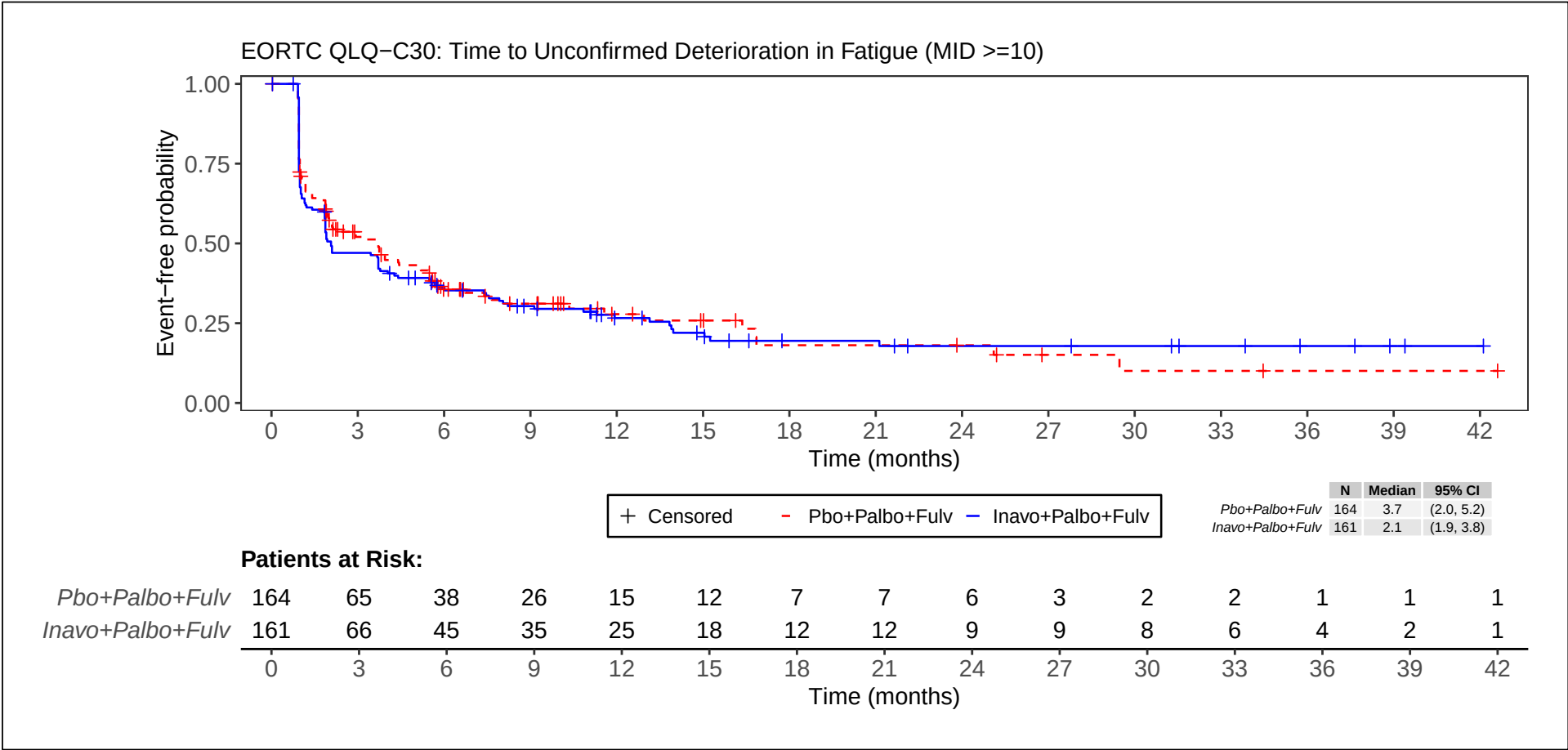
Kaplan Meier Plot for Efficacy, EORTC QLQ-C30 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

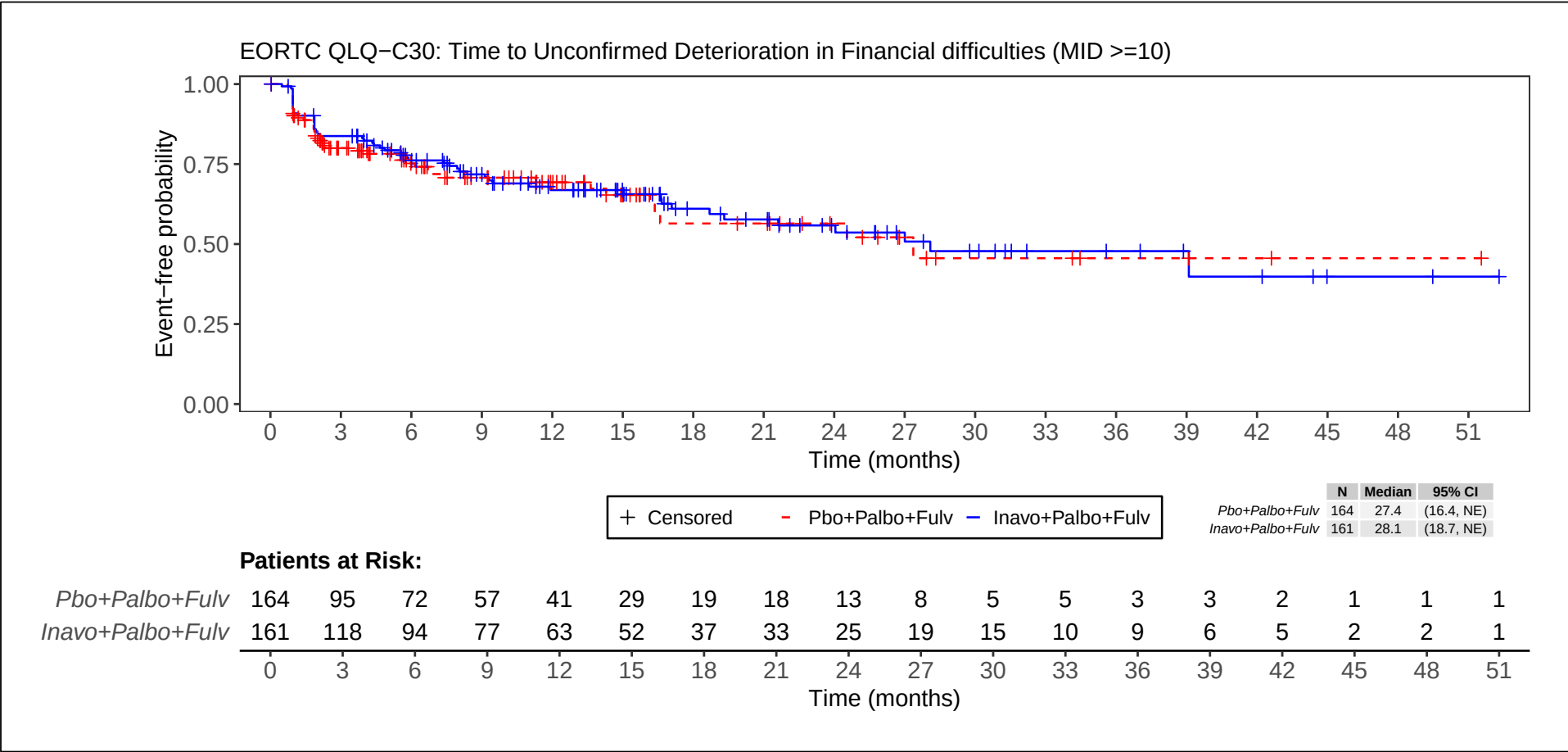
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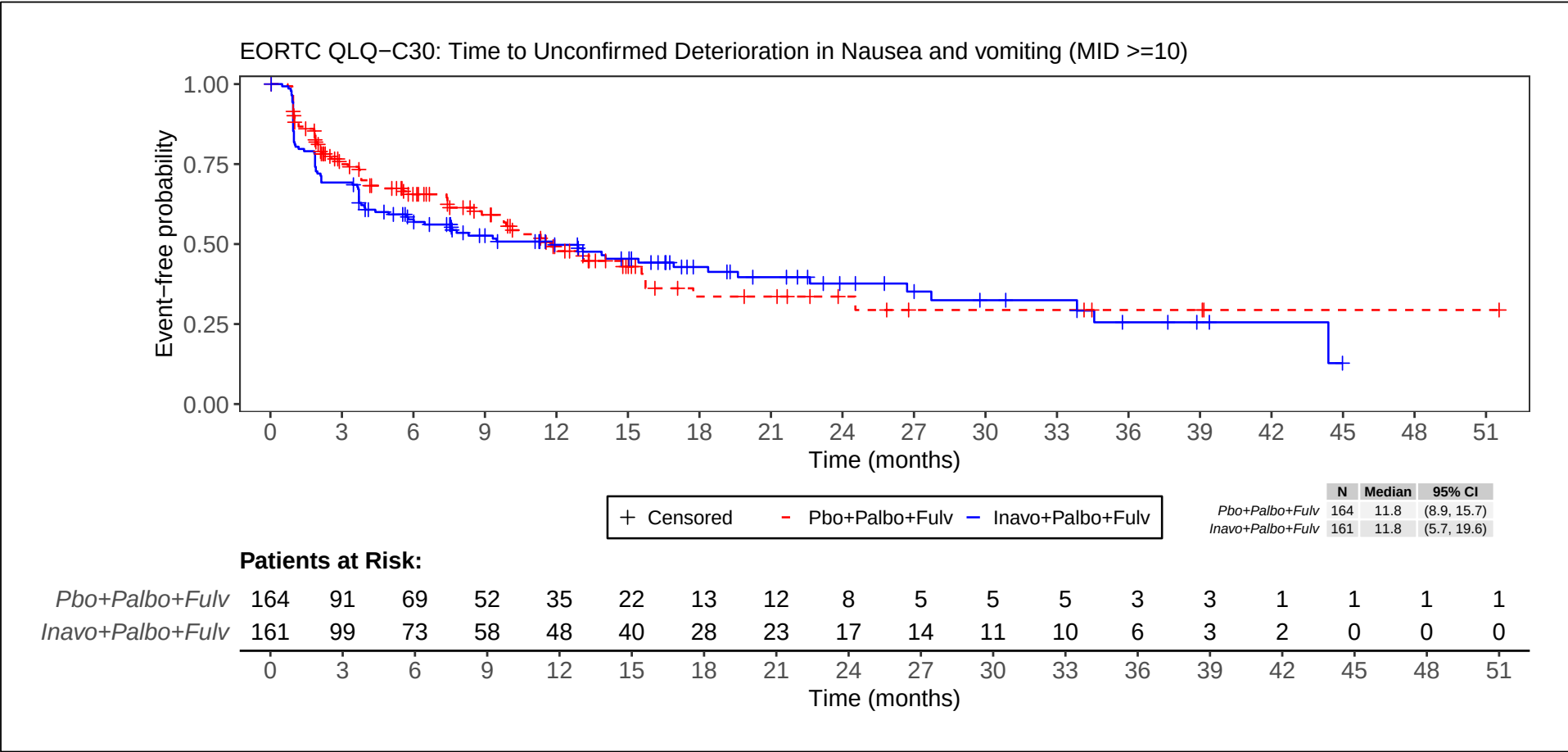
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

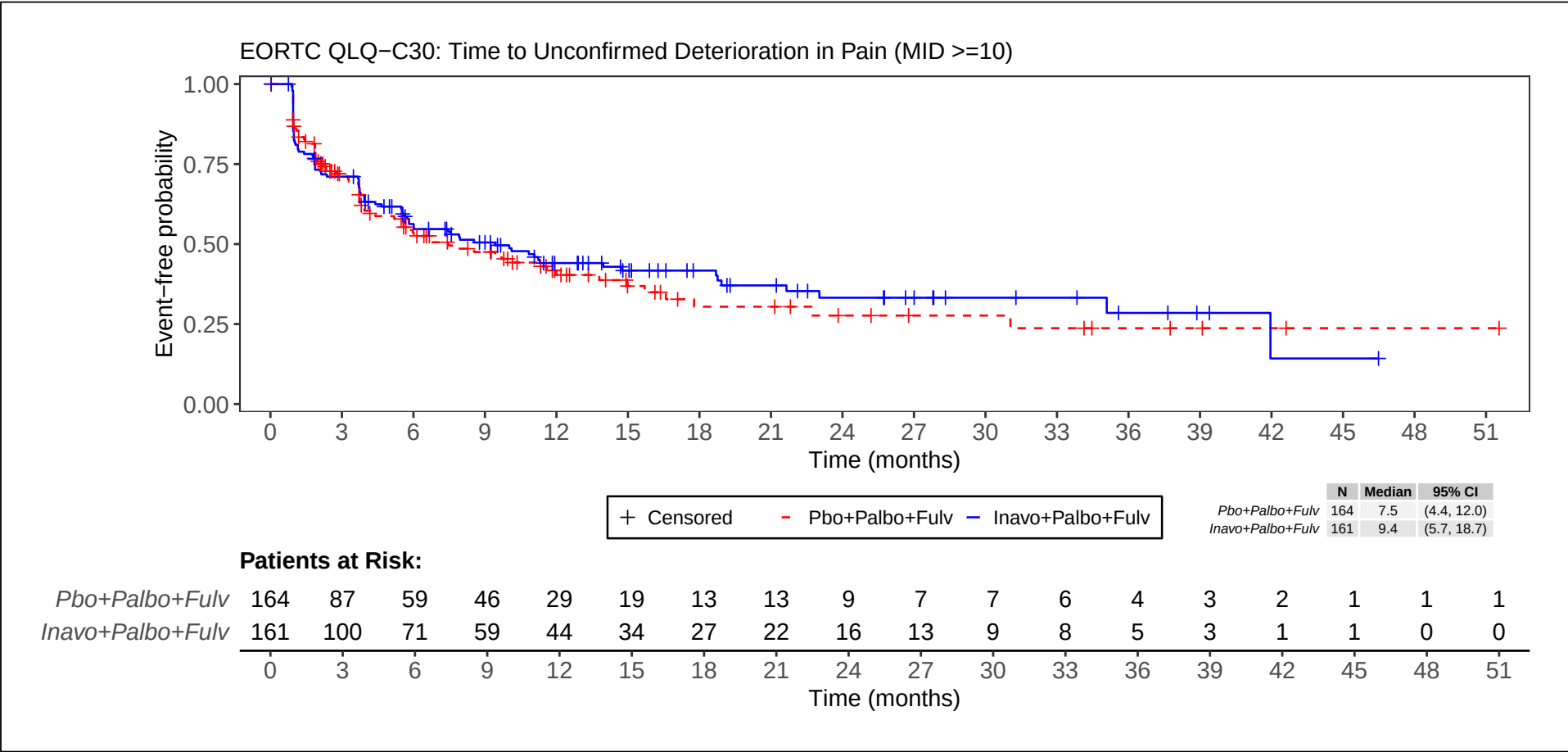
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

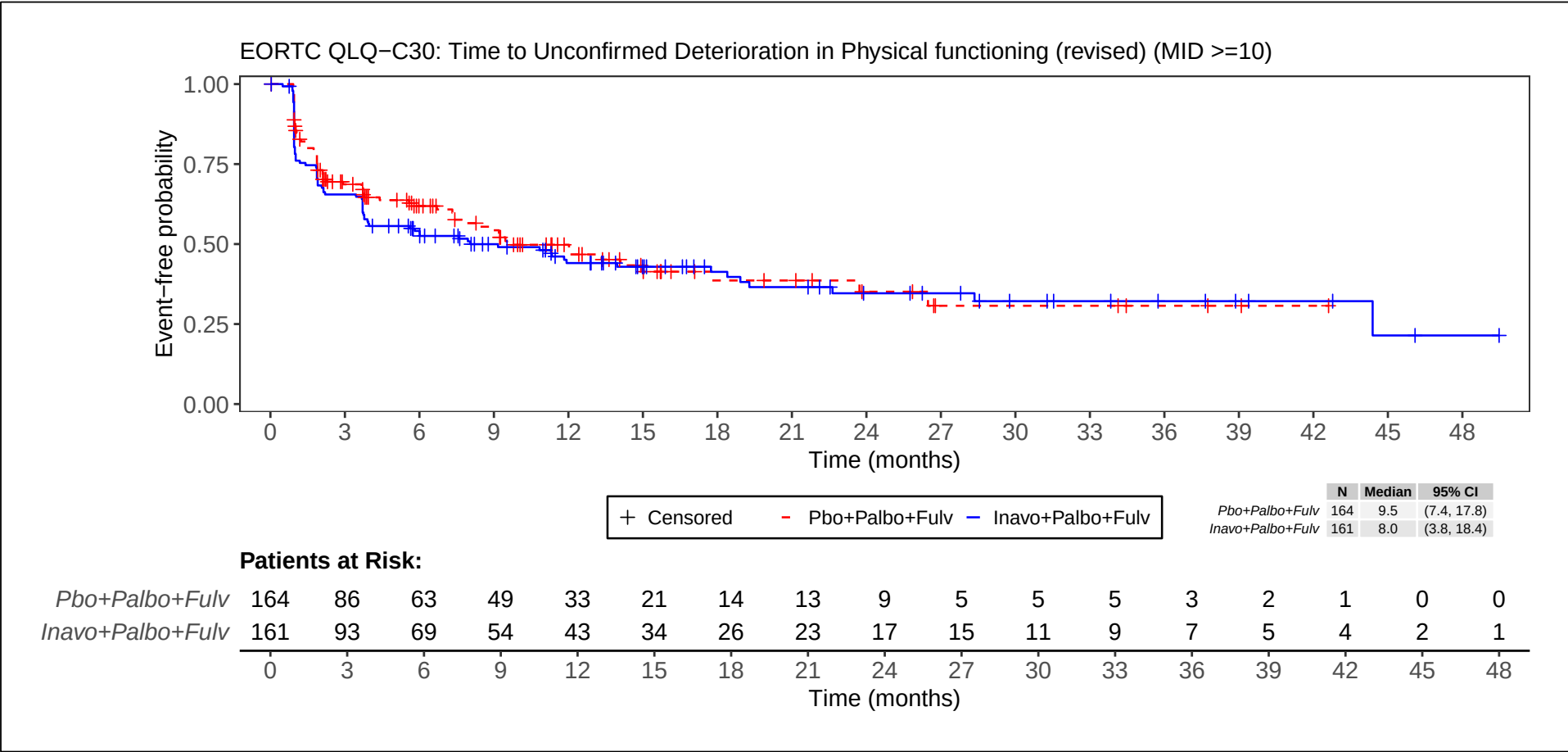
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

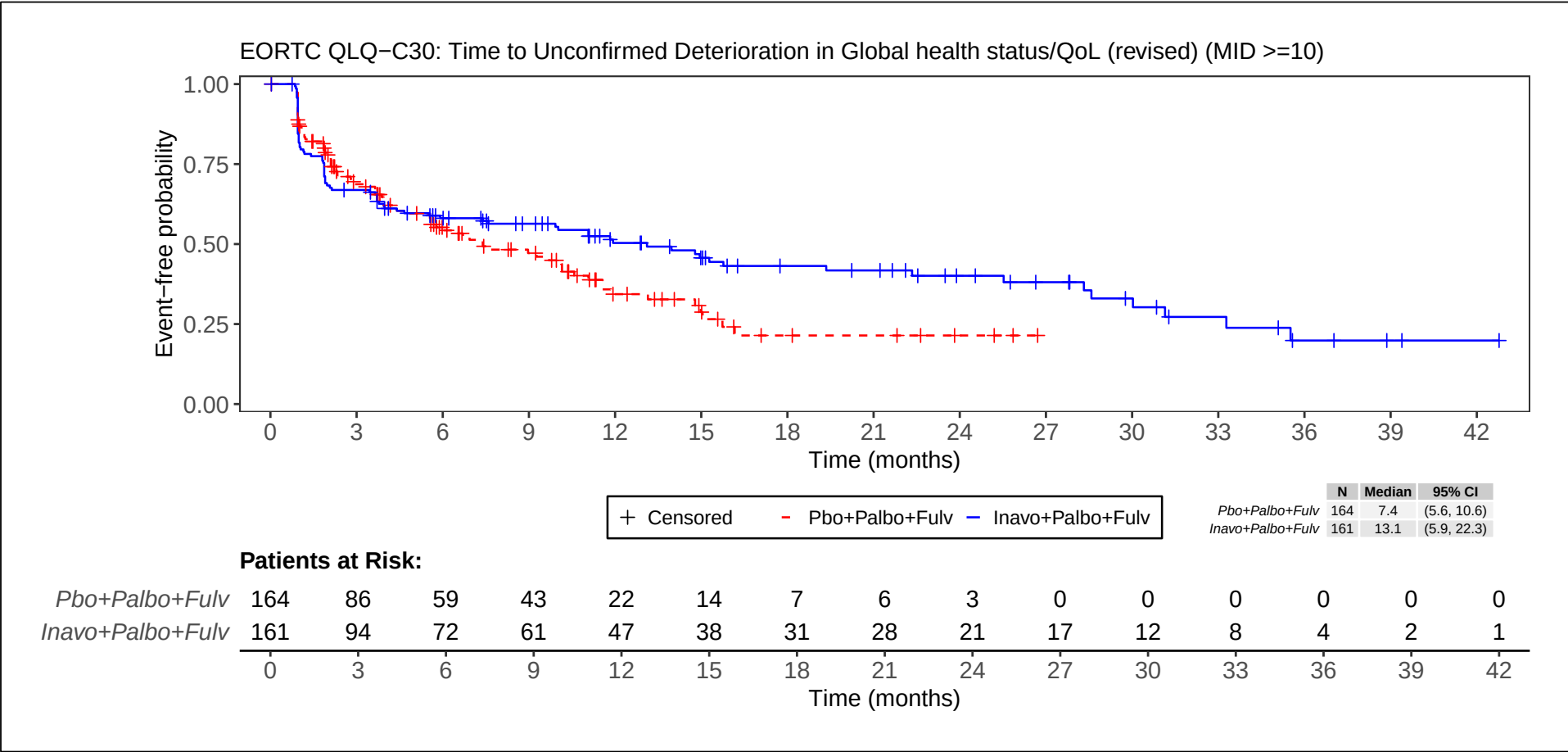
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

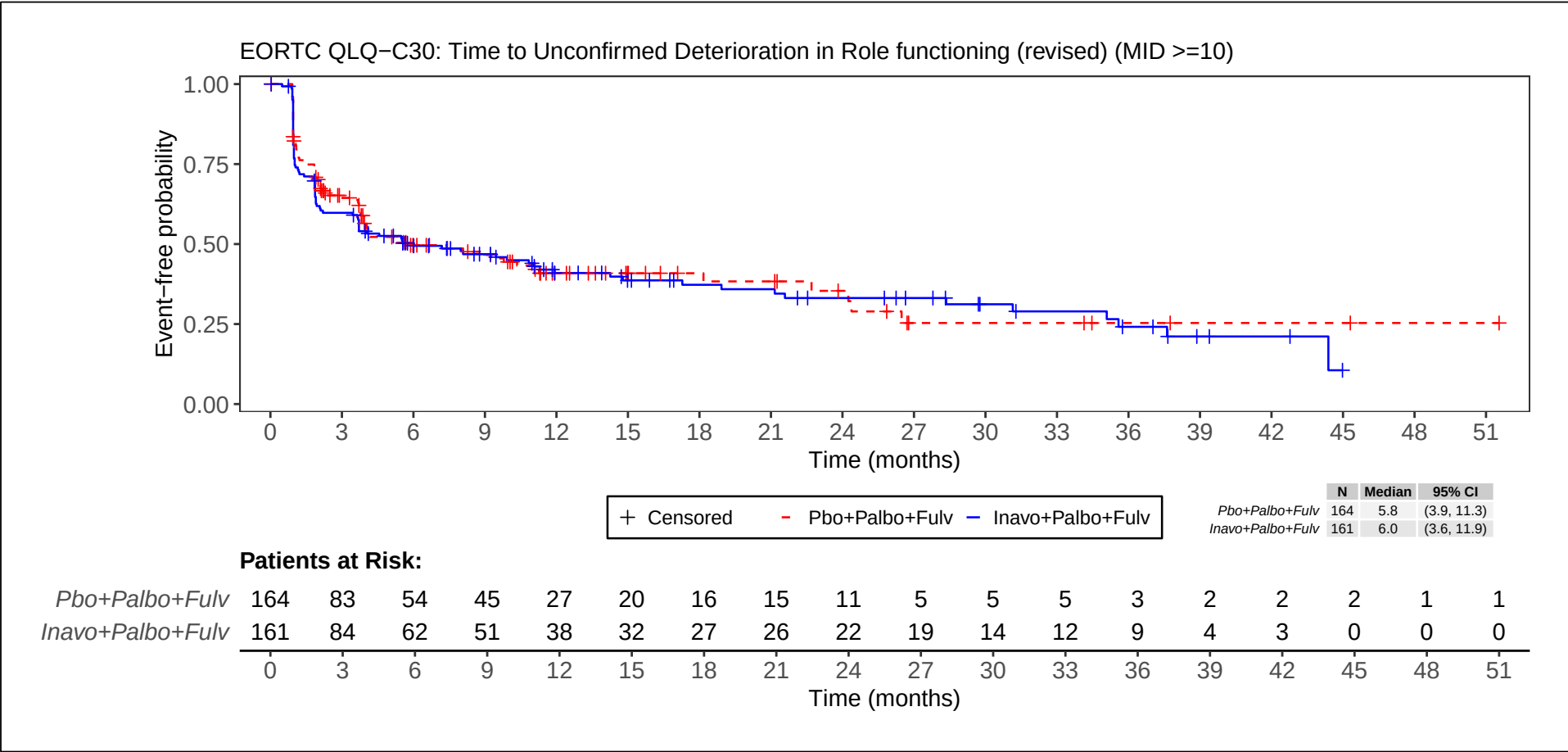
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

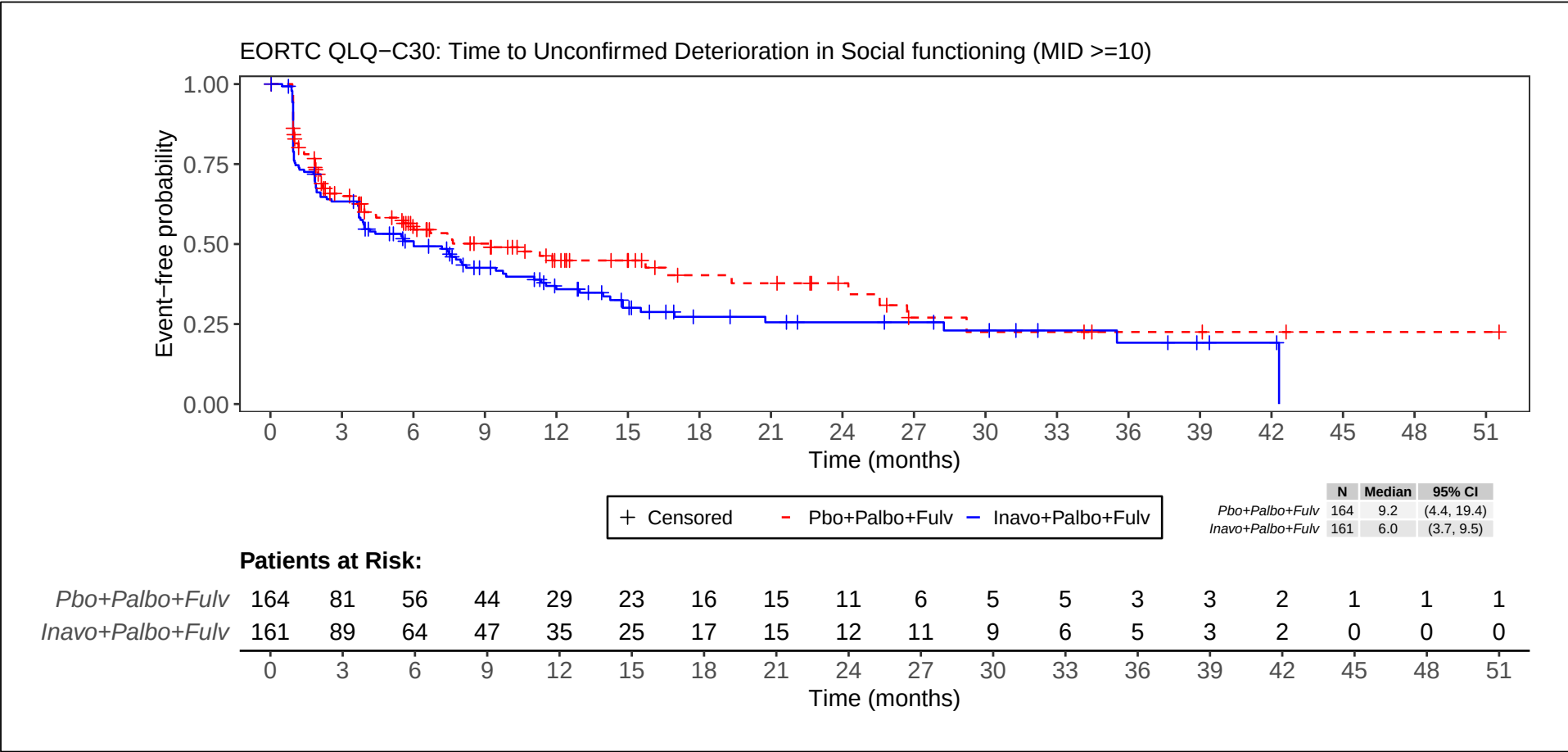
Kaplan Meier Plot for Efficacy, EORTC QLQ-C30 (Unconfirmed Deterioration), Full Analysis Set
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

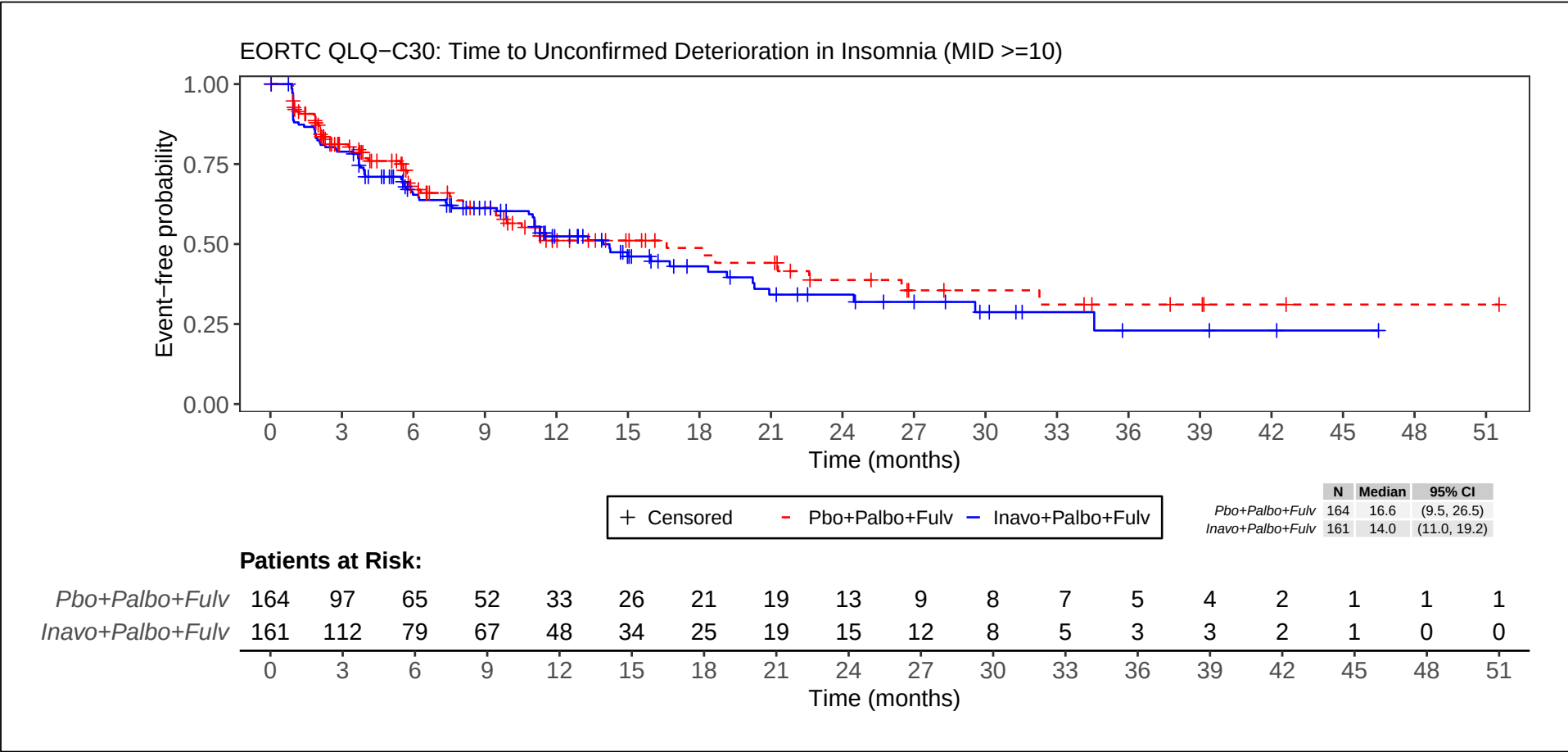
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Efficacy, EORTC QLQ-C30 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.1 PRO Items des EORTC QLQ-C30

2.1.3 Zeit bis zur ersten Verschlechterung der PRO Items des EORTC QLQ-C30, MID = 10 Punkte

2.1.3.1 Subgruppenanalyse Zeit bis zur ersten Verschlechterung der PRO Items des EORTC QLQ-C30, MID = 10 Punkte

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Efficacy), EORTC QLQ-C30 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOd: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)	
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI					
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Appetite loss (MID >=10)																
All Patients	325	164	70	42.7	11.76	(7.52, 16.59)	161	105	65.2	3.68	(1.87, 5.55)	1.94	(1.43, 2.62)	<0.0001	NE	
Age group (years)																
<65	266	130	55	42.3	11.76	(7.52, 16.95)	136	90	66.2	2.20	(1.77, 5.55)	1.90	(1.36, 2.67)	0.0002	0.7374	
>=65	59	34	15	44.1	16.59	(4.11, NA)	25	15	60.0	3.68	(0.95, 7.20)	2.15	(1.04, 4.43)	0.0353	0.7374	
Sex																
F	319	163	70	42.9	11.76	(7.52, 16.59)	156	100	64.1	3.68	(1.87, 5.55)	1.91	(1.40, 2.59)	<0.0001	1.0000	
M	6	1	0	0.0	NE	NE	5	5	100.0	1.97	(0.95, NA)	NE	NE	1.0000	1.0000	
Region																
ASIA	120	62	23	37.1	15.41	(7.43, NA)	58	39	67.2	2.20	(0.95, 11.30)	2.23	(1.33, 3.74)	0.0025	0.2867	
NORTH AMERICA/WESTERN EUROPE	127	64	26	40.6	15.05	(8.54, NA)	63	36	57.1	3.71	(1.45, 5.55)	2.14	(1.29, 3.55)	0.0031	0.2867	
OTHER	78	38	21	55.3	4.11	(2.10, 10.35)	40	30	75.0	1.89	(0.99, 7.39)	1.24	(0.70, 2.18)	0.4730	0.2867	
Visceral disease (per eCRF)																
N	65	36	19	52.8	9.26	(2.37, 25.76)	29	21	72.4	4.75	(1.87, 13.90)	1.49	(0.80, 2.79)	0.2026	0.2725	
Y	260	128	51	39.8	14.98	(8.54, 16.59)	132	84	63.6	2.10	(1.15, 3.94)	2.14	(1.51, 3.04)	<0.0001	0.2725	
Ethnicity																
HISPANIC OR LATINO	20	10	4	40.0	14.98	(1.41, NA)	10	7	70.0	5.55	(0.95, 13.90)	3.01	(0.87, 10.40)	0.0671	0.8387	
NOT HISPANIC OR LATINO	294	149	64	43.0	11.76	(7.39, 24.54)	145	94	64.8	2.20	(1.45, 3.94)	1.88	(1.37, 2.59)	0.0001	0.8387	
NOT REPORTED	5	3	1	33.3	15.74	NE	2	2	100.0	3.24	(0.92, NA)	>999.99	(0.00, >999.99)	0.1573	0.8387	
UNKNOWN	6	2	1	50.0	11.07	NE	4	2	50.0	6.90	(1.87, NA)	1.00	(0.06, 15.99)	1.0000	0.8387	
Race																
Asian	124	63	23	36.5	15.41	(7.43, NA)	61	40	65.6	3.71	(0.99, 11.30)	2.16	(1.29, 3.62)	0.0035	0.5576	
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.5576	
White	191	97	46	47.4	10.35	(5.52, 15.05)	94	64	68.1	2.10	(1.41, 3.81)	1.88	(1.29, 2.76)	0.0011	0.5576	
Unknown	8	3	1	33.3	15.74	NE	5	1	20.0	11.93	(11.93, NA)	0.71	(0.04, 11.79)	0.8084	0.5576	
Liver Metastasis at Enrollment																
N	157	73	32	43.8	16.59	(7.52, 25.76)	84	58	69.0	3.71	(1.87, 6.01)	2.18	(1.41, 3.37)	0.0004	0.5174	
Y	168	91	38	41.8	9.26	(6.70, 15.41)	77	47	61.0	1.99	(1.02, 3.94)	1.83	(1.19, 2.82)	0.0065	0.5174	
Number Metastatic Organs at Enrollment																
1	53	32	15	46.9	15.05	(3.68, NA)	21	15	71.4	1.02	(0.95, 13.90)	1.99	(0.97, 4.11)	0.0686	0.2304	
2	104	46	25	54.3	7.52	(4.11, 14.98)	58	38	65.5	4.63	(2.10, 11.30)	1.40	(0.84, 2.33)	0.1949	0.2304	
>=3	168	86	30	34.9	16.59	(8.54, NA)	82	52	63.4	1.87	(0.99, 3.94)	2.48	(1.58, 3.90)	<0.0001	0.2304	
ECOG Performance Status at Baseline																
0	206	106	42	39.6	14.98	(8.54, NA)	100	72	72.0	2.10	(0.99, 3.75)	2.65	(1.81, 3.87)	<0.0001	0.0109	
1	118	58	28	48.3	10.35	(3.81, 24.54)	60	33	55.0	7.62	(1.45, 17.08)	1.13	(0.68, 1.87)	0.6564	0.0109	
Endocrine Resistance (per eCRF)																

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Primary	112	58	26	44.8	7.43	(5.52, 15.74)	54	37	68.5	2.10	(0.95, 5.72)	1.78	(1.07, 2.95)	0.0279	0.7305
Secondary	212	105	43	41.0	15.41	(9.26, 25.76)	107	68	63.6	3.71	(1.77, 5.91)	2.05	(1.40, 3.00)	0.0002	0.7305
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	22	42.3	9.26	(6.01, NA)	52	37	71.2	1.87	(0.95, 5.72)	2.12	(1.25, 3.61)	0.0064	0.5897
POST-MENOPAUSAL	215	111	48	43.2	11.76	(7.43, 24.54)	104	63	60.6	3.71	(1.87, 6.01)	1.80	(1.23, 2.62)	0.0023	0.5897
Hormone receptor status															
ER+/PR-	90	45	16	35.6	15.74	(7.52, NA)	45	28	62.2	3.71	(1.18, 15.24)	2.09	(1.13, 3.88)	0.0172	0.3015
ER+/PR+	226	113	50	44.2	11.30	(7.39, 16.59)	113	76	67.3	2.17	(1.15, 5.55)	1.99	(1.39, 2.85)	0.0002	0.3015
Other	9	6	4	66.7	8.46	(3.71, NA)	3	1	33.3	NE	(0.76, NA)	0.39	(0.04, 3.52)	0.3837	0.3015
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	9	47.4	14.98	(5.52, 16.95)	18	10	55.6	1.41	(0.95, NA)	1.82	(0.73, 4.56)	0.2074	0.9690
Aromatase inhibitor only	131	71	29	40.8	10.35	(5.85, 25.76)	60	38	63.3	3.71	(1.87, 7.20)	1.89	(1.17, 3.08)	0.0093	0.9690
Tamoxifen only	155	73	31	42.5	15.05	(6.01, NA)	82	56	68.3	2.91	(0.95, 5.72)	2.03	(1.30, 3.15)	0.0019	0.9690
Prior (neo)-adjuvant CDK4/6															
N	322	163	70	42.9	11.76	(7.52, 16.59)	159	105	66.0	3.68	(1.87, 5.55)	1.91	(1.41, 2.59)	<0.0001	1.0000
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	8	29.6	NE	(2.10, NA)	29	15	51.7	5.55	(1.87, 17.08)	2.14	(0.90, 5.06)	0.0781	0.7822
Y	269	137	62	45.3	10.35	(7.43, 16.59)	132	90	68.2	2.10	(1.18, 3.94)	1.91	(1.38, 2.65)	0.0001	0.7822
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Cognitive functioning (MID >=10)															
All Patients	325	164	85	51.8	7.52	(5.59, 9.53)	161	98	60.9	7.89	(5.49, 9.43)	1.02	(0.77, 1.37)	0.8685	NE
Age group (years)															
<65	266	130	64	49.2	7.52	(5.59, 9.53)	136	83	61.0	7.92	(5.55, 11.07)	1.01	(0.73, 1.41)	0.9340	0.5981
>=65	59	34	21	61.8	6.97	(2.33, 12.88)	25	15	60.0	5.49	(0.95, 18.69)	1.13	(0.58, 2.21)	0.7224	0.5981
Sex															
F	319	163	85	52.1	7.52	(5.59, 9.53)	156	94	60.3	7.89	(5.49, 9.43)	1.04	(0.77, 1.39)	0.8085	1.0000
M	6	1	0	0.0	NE	NE	5	4	80.0	14.75	(0.99, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	34	54.8	6.74	(3.75, 12.88)	58	37	63.8	8.77	(2.20, 16.76)	0.96	(0.60, 1.55)	0.8517	0.2989
NORTH AMERICA/WESTERN EUROPE	127	64	39	60.9	5.59	(2.33, 9.23)	63	32	50.8	5.68	(3.71, 8.31)	0.89	(0.56, 1.42)	0.6493	0.2989
OTHER	78	38	12	31.6	9.53	(6.97, NA)	40	29	72.5	9.23	(4.14, 11.70)	1.63	(0.82, 3.21)	0.1516	0.2989
Visceral disease (per eCRF)															
N	65	36	25	69.4	6.21	(1.18, 7.52)	29	15	51.7	11.93	(4.14, 37.62)	0.34	(0.17, 0.69)	0.0020	0.0007
Y	260	128	60	46.9	8.94	(5.59, 12.16)	132	83	62.9	6.01	(4.40, 8.77)	1.33	(0.95, 1.85)	0.0934	0.0007
Ethnicity															
HISPANIC OR LATINO	20	10	6	60.0	7.82	(1.41, NA)	10	6	60.0	5.62	(1.41, 14.75)	0.97	(0.31, 3.02)	0.9570	0.0338
NOT HISPANIC OR LATINO	294	149	76	51.0	7.52	(5.68, 9.66)	145	89	61.4	7.92	(5.16, 10.84)	1.03	(0.76, 1.40)	0.8397	0.0338

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
NOT REPORTED	5	3	1	33.3	0.95	(0.95, NA)	2	2	100.0	0.94	(0.92, NA)	3.77	(0.32, 43.72)	0.2253	0.0338
UNKNOWN	6	2	2	100.0	2.40	(1.08, NA)	4	1	25.0	5.68	(5.68, NA)	<0.01	(0.00, >999.99)	0.0896	0.0338
Race															
Asian	124	63	34	54.0	6.74	(3.75, 12.88)	61	39	63.9	8.08	(2.20, 16.76)	1.00	(0.62, 1.59)	0.9686	0.2408
Black or African American	2	1	1	100.0	0.95	NE	1	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	0.2408
White	191	97	49	50.5	7.62	(4.40, 9.92)	94	59	62.8	6.01	(4.14, 9.43)	1.10	(0.75, 1.61)	0.6084	0.2408
Unknown	8	3	1	33.3	1.08	(1.08, NA)	5	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.2207	0.2408
Liver Metastasis at Enrollment															
N	157	73	43	58.9	7.39	(3.78, 8.94)	84	52	61.9	8.77	(5.55, 11.70)	0.86	(0.57, 1.29)	0.4620	0.2499
Y	168	91	42	46.2	7.62	(3.91, 12.16)	77	46	59.7	5.62	(3.75, 9.17)	1.22	(0.80, 1.86)	0.3399	0.2499
Number Metastatic Organs at Enrollment															
1	53	32	22	68.8	3.71	(1.18, 8.31)	21	14	66.7	7.89	(0.99, 9.23)	0.83	(0.42, 1.64)	0.6042	0.3503
2	104	46	24	52.2	7.62	(5.68, 12.88)	58	33	56.9	9.43	(4.14, 16.76)	0.90	(0.52, 1.54)	0.7031	0.3503
>=3	168	86	39	45.3	7.82	(4.40, 16.59)	82	51	62.2	6.24	(4.40, 11.07)	1.29	(0.85, 1.96)	0.2300	0.3503
ECOG Performance Status at Baseline															
0	206	106	54	50.9	7.52	(3.91, 11.30)	100	56	56.0	9.17	(5.62, 14.75)	0.88	(0.60, 1.29)	0.5107	0.1573
1	118	58	31	53.4	7.43	(3.52, 9.66)	60	42	70.0	4.67	(2.04, 8.31)	1.31	(0.82, 2.09)	0.2535	0.1573
Endocrine Resistance (per eCRF)															
Primary	112	58	30	51.7	7.39	(2.33, 11.30)	54	32	59.3	9.23	(5.55, 11.93)	0.86	(0.52, 1.43)	0.5783	0.3378
Secondary	212	105	54	51.4	7.62	(5.59, 10.15)	107	66	61.7	5.68	(4.14, 9.43)	1.15	(0.80, 1.65)	0.4564	0.3378
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	26	50.0	7.52	(2.50, 14.98)	52	33	63.5	7.92	(2.20, 11.93)	1.05	(0.63, 1.77)	0.8497	0.9677
POST-MENOPAUSAL	215	111	59	53.2	7.43	(4.40, 9.92)	104	61	58.7	6.01	(4.40, 10.84)	1.02	(0.71, 1.47)	0.9010	0.9677
Hormone receptor status															
ER+/PR-	90	45	20	44.4	11.30	(2.89, NA)	45	27	60.0	7.92	(4.14, 16.92)	1.07	(0.59, 1.93)	0.8294	0.6591
ER+/PR+	226	113	62	54.9	6.31	(4.40, 8.94)	113	69	61.1	7.56	(5.16, 11.07)	0.97	(0.68, 1.36)	0.8352	0.6591
Other	9	6	3	50.0	7.43	(0.99, NA)	3	2	66.7	2.07	(0.76, NA)	1.37	(0.23, 8.29)	0.7329	0.6591
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	11	57.9	3.78	(0.95, NA)	18	9	50.0	4.40	(0.95, NA)	0.85	(0.35, 2.06)	0.7384	0.8104
Aromatase inhibitor only	131	71	40	56.3	6.97	(3.91, 9.92)	60	37	61.7	5.55	(3.71, 9.23)	0.91	(0.58, 1.44)	0.6770	0.8104
Tamoxifen only	155	73	34	46.6	7.62	(5.68, NA)	82	51	62.2	9.17	(5.62, 11.93)	1.15	(0.75, 1.79)	0.5016	0.8104
Prior (neo)-adjuvant CDK4/6															
N	322	163	84	51.5	7.52	(5.59, 9.53)	159	98	61.6	7.89	(5.49, 9.43)	1.03	(0.77, 1.38)	0.8329	1.0000
Y	3	1	1	100.0	4.40	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	12	44.4	9.92	(2.33, NA)	29	18	62.1	7.95	(2.73, 17.45)	1.48	(0.71, 3.09)	0.2970	0.1995
Y	269	137	73	53.3	6.97	(4.40, 8.94)	132	80	60.6	7.89	(5.49, 10.84)	0.95	(0.69, 1.30)	0.7399	0.1995
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Constipation (MID >=10)															

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Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
All Patients	325	164	70	42.7	12.42	(7.62, 21.16)	161	63	39.1	18.40	(9.53, NA)	0.74	(0.52, 1.04)	0.0842	NE
Age group (years)															
<65	266	130	52	40.0	12.42	(7.62, NA)	136	58	42.6	13.83	(9.23, NA)	0.84	(0.57, 1.22)	0.3632	0.0877
>=65	59	34	18	52.9	12.88	(2.14, 21.16)	25	5	20.0	NE	(7.36, NA)	0.32	(0.12, 0.88)	0.0207	0.0877
Sex															
F	319	163	70	42.9	12.42	(7.62, 21.16)	156	61	39.1	18.40	(9.23, NA)	0.75	(0.53, 1.05)	0.1005	1.0000
M	6	1	0	0.0	NE	NE	5	2	40.0	NE	(0.99, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	25	40.3	12.42	(6.67, NA)	58	24	41.4	NE	(7.56, NA)	0.80	(0.46, 1.41)	0.4513	0.4069
NORTH AMERICA/WESTERN EUROPE	127	64	34	53.1	11.60	(2.37, 20.44)	63	21	33.3	18.40	(7.92, NA)	0.56	(0.32, 0.97)	0.0386	0.4069
OTHER	78	38	11	28.9	NE	(2.89, NA)	40	18	45.0	11.07	(5.82, NA)	1.15	(0.54, 2.44)	0.7295	0.4069
Visceral disease (per eCRF)															
N	65	36	16	44.4	12.88	(1.18, NA)	29	11	37.9	NE	(7.82, NA)	0.59	(0.27, 1.28)	0.1791	0.4743
Y	260	128	54	42.2	12.42	(7.62, 20.44)	132	52	39.4	18.40	(9.23, NA)	0.78	(0.53, 1.15)	0.2135	0.4743
Ethnicity															
HISPANIC OR LATINO	20	10	5	50.0	14.52	(0.95, NA)	10	4	40.0	9.23	(0.95, NA)	0.95	(0.25, 3.57)	0.9547	0.1915
NOT HISPANIC OR LATINO	294	149	64	43.0	12.16	(6.67, 21.16)	145	56	38.6	29.47	(11.07, NA)	0.69	(0.48, 0.99)	0.0449	0.1915
NOT REPORTED	5	3	0	0.0	NE	NE	2	2	100.0	3.83	(3.71, NA)	>999.99	(0.00, >999.99)	0.2253	0.1915
UNKNOWN	6	2	1	50.0	1.08	(1.08, NA)	4	1	25.0	1.87	(1.87, NA)	0.71	(0.04, 11.79)	0.8084	0.1915
Race															
Asian	124	63	25	39.7	12.42	(6.67, NA)	61	26	42.6	29.47	(7.59, NA)	0.82	(0.47, 1.42)	0.4832	0.8270
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.8270
White	191	97	44	45.4	12.16	(3.94, 21.16)	94	36	38.3	16.92	(9.23, NA)	0.71	(0.46, 1.10)	0.1298	0.8270
Unknown	8	3	1	33.3	1.08	(1.08, NA)	5	1	20.0	NE	(11.47, NA)	0.47	(0.03, 7.86)	0.5924	0.8270
Liver Metastasis at Enrollment															
N	157	73	34	46.6	12.88	(5.85, 21.68)	84	34	40.5	29.47	(9.23, NA)	0.73	(0.45, 1.17)	0.1928	0.9047
Y	168	91	36	39.6	12.16	(4.21, NA)	77	29	37.7	18.40	(7.56, NA)	0.76	(0.46, 1.24)	0.2758	0.9047
Number Metastatic Organs at Enrollment															
1	53	32	15	46.9	21.16	(2.14, 21.68)	21	10	47.6	9.38	(2.56, NA)	0.84	(0.38, 1.89)	0.6828	0.8073
2	104	46	21	45.7	12.88	(3.94, NA)	58	21	36.2	NE	(7.82, NA)	0.65	(0.35, 1.20)	0.1655	0.8073
>=3	168	86	34	39.5	12.42	(5.52, NA)	82	32	39.0	18.40	(9.23, NA)	0.78	(0.48, 1.26)	0.3193	0.8073
ECOG Performance Status at Baseline															
0	206	106	43	40.6	14.06	(7.62, NA)	100	41	41.0	18.40	(9.53, NA)	0.76	(0.49, 1.17)	0.2211	0.7611
1	118	58	27	46.6	12.42	(2.89, 21.16)	60	22	36.7	NE	(5.75, NA)	0.69	(0.39, 1.22)	0.2033	0.7611
Endocrine Resistance (per eCRF)															
Primary	112	58	21	36.2	10.61	(3.94, NA)	54	20	37.0	NE	(7.82, NA)	0.75	(0.41, 1.40)	0.3696	0.9924
Secondary	212	105	48	45.7	12.88	(5.85, 21.68)	107	43	40.2	18.40	(9.23, NA)	0.73	(0.48, 1.11)	0.1468	0.9924
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	20	38.5	12.42	(4.21, NA)	52	22	42.3	18.40	(7.82, NA)	0.78	(0.42, 1.45)	0.4488	0.8739

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
POST-MENOPAUSAL	215	111	50	45.0	12.88	(5.85, 21.16)	104	39	37.5	29.47	(7.59, NA)	0.73	(0.48, 1.11)	0.1427	0.8739
Hormone receptor status															
ER+/PR-	90	45	23	51.1	7.62	(2.14, 15.21)	45	16	35.6	NE	(5.82, NA)	0.48	(0.25, 0.93)	0.0277	0.3145
ER+/PR+	226	113	45	39.8	14.98	(10.61, NA)	113	46	40.7	18.40	(9.23, NA)	0.85	(0.56, 1.29)	0.4539	0.3145
Other	9	6	2	33.3	NE	(0.99, NA)	3	1	33.3	7.59	NE	0.97	(0.09, 10.84)	0.9814	0.3145
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	8	42.1	15.21	(3.94, NA)	18	6	33.3	18.40	(4.76, NA)	0.71	(0.24, 2.08)	0.5231	0.7508
Aromatase inhibitor only	131	71	32	45.1	11.07	(3.75, 20.44)	60	21	35.0	NE	(7.56, NA)	0.62	(0.36, 1.07)	0.0888	0.7508
Tamoxifen only	155	73	30	41.1	14.06	(4.21, NA)	82	36	43.9	13.83	(7.92, NA)	0.86	(0.53, 1.40)	0.5626	0.7508
Prior (neo)-adjuvant CDK4/6															
N	322	163	70	42.9	12.42	(7.62, 20.44)	159	63	39.6	18.40	(9.53, NA)	0.73	(0.52, 1.03)	0.0717	1.0000
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	12	44.4	4.21	(1.08, NA)	29	9	31.0	29.47	(5.78, NA)	0.55	(0.23, 1.31)	0.1782	0.3977
Y	269	137	58	42.3	12.42	(7.62, 21.16)	132	54	40.9	16.92	(9.23, NA)	0.78	(0.54, 1.13)	0.1955	0.3977
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Diarrhoea (MID >=10)															
All Patients	325	164	52	31.7	16.95	(11.83, NA)	161	100	62.1	3.81	(3.71, 6.70)	2.44	(1.75, 3.41)	<0.0001	NE
Age group (years)															
<65	266	130	41	31.5	16.95	(11.30, 32.89)	136	89	65.4	3.84	(3.61, 6.70)	2.51	(1.73, 3.64)	<0.0001	0.5963
>=65	59	34	11	32.4	NE	(9.43, NA)	25	11	44.0	3.71	(0.95, NA)	1.95	(0.84, 4.52)	0.1238	0.5963
Sex															
F	319	163	52	31.9	16.95	(11.83, NA)	156	96	61.5	3.78	(2.76, 6.70)	2.47	(1.76, 3.46)	<0.0001	1.0000
M	6	1	0	0.0	NE	NE	5	4	80.0	5.59	(0.95, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	21	33.9	13.14	(11.30, NA)	58	39	67.2	5.49	(2.20, 9.49)	2.23	(1.31, 3.81)	0.0027	0.6971
NORTH AMERICA/WESTERN EUROPE	127	64	20	31.2	21.88	(11.50, NA)	63	31	49.2	5.72	(2.14, 15.31)	2.39	(1.35, 4.24)	0.0024	0.6971
OTHER	78	38	11	28.9	11.99	(9.33, NA)	40	30	75.0	2.81	(0.95, 5.52)	2.97	(1.48, 5.95)	0.0015	0.6971
Visceral disease (per eCRF)															
N	65	36	14	38.9	12.88	(9.26, NA)	29	17	58.6	4.62	(1.41, 28.71)	1.79	(0.87, 3.66)	0.1127	0.3549
Y	260	128	38	29.7	21.26	(11.99, NA)	132	83	62.9	3.81	(3.61, 7.39)	2.64	(1.80, 3.87)	<0.0001	0.3549
Ethnicity															
HISPANIC OR LATINO	20	10	5	50.0	21.88	(1.41, NA)	10	4	40.0	28.71	(0.95, NA)	1.17	(0.28, 4.82)	0.8291	0.2208
NOT HISPANIC OR LATINO	294	149	46	30.9	16.95	(11.83, NA)	145	92	63.4	3.75	(2.14, 6.51)	2.59	(1.82, 3.70)	<0.0001	0.2208
NOT REPORTED	5	3	0	0.0	NE	NE	2	2	100.0	4.75	(3.71, NA)	>999.99	(0.00, >999.99)	0.2253	0.2208
UNKNOWN	6	2	1	50.0	12.88	NE	4	2	50.0	4.75	(3.78, NA)	>999.99	(0.00, >999.99)	0.2253	0.2208
Race															
Asian	124	63	21	33.3	13.14	(11.30, NA)	61	41	67.2	4.67	(2.20, 8.57)	2.31	(1.36, 3.93)	0.0015	0.5103
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.5103
White	191	97	31	32.0	16.95	(10.15, NA)	94	57	60.6	3.71	(1.97, 7.39)	2.46	(1.59, 3.81)	<0.0001	0.5103

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Unknown	8	3	0	0.0	NE	NE	5	2	40.0	5.72	(0.95, NA)	>999.99	(0.00, >999.99)	0.2807	0.5103
Liver Metastasis at Enrollment															
N	157	73	27	37.0	21.26	(11.50, NA)	84	50	59.5	5.52	(3.61, 11.07)	2.09	(1.31, 3.33)	0.0020	0.4201
Y	168	91	25	27.5	12.42	(9.33, NA)	77	50	64.9	3.75	(1.94, 5.98)	2.86	(1.76, 4.63)	<0.0001	0.4201
Number Metastatic Organs at Enrollment															
1	53	32	7	21.9	16.95	(16.95, NA)	21	16	76.2	1.41	(0.95, 3.78)	6.36	(2.59, 15.60)	<0.0001	0.0365
2	104	46	16	34.8	11.50	(9.26, NA)	58	33	56.9	6.70	(3.71, 14.06)	1.78	(0.98, 3.24)	0.0568	0.0365
>=3	168	86	29	33.7	13.14	(9.33, 32.89)	82	51	62.2	3.84	(1.91, 8.57)	2.24	(1.42, 3.53)	0.0005	0.0365
ECOG Performance Status at Baseline															
0	206	106	34	32.1	21.26	(10.15, NA)	100	63	63.0	3.94	(2.20, 8.31)	2.30	(1.51, 3.50)	<0.0001	0.6445
1	118	58	18	31.0	16.95	(11.83, NA)	60	37	61.7	3.78	(1.94, 7.39)	2.64	(1.50, 4.66)	0.0005	0.6445
Endocrine Resistance (per eCRF)															
Primary	112	58	13	22.4	NE	(8.77, NA)	54	33	61.1	3.81	(2.20, 8.57)	2.77	(1.46, 5.27)	0.0011	0.5909
Secondary	212	105	39	37.1	13.14	(11.50, 32.89)	107	67	62.6	3.78	(1.94, 7.92)	2.27	(1.52, 3.37)	<0.0001	0.5909
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	16	30.8	11.83	(8.28, NA)	52	32	61.5	5.52	(2.20, 17.28)	2.08	(1.14, 3.80)	0.0161	0.5054
POST-MENOPAUSAL	215	111	36	32.4	21.26	(11.99, NA)	104	64	61.5	3.71	(1.97, 6.51)	2.66	(1.76, 4.00)	<0.0001	0.5054
Hormone receptor status															
ER+/PR-	90	45	11	24.4	NE	(9.33, NA)	45	26	57.8	5.78	(2.07, 15.31)	2.41	(1.18, 4.91)	0.0125	0.7754
ER+/PR+	226	113	39	34.5	16.95	(11.30, 32.89)	113	72	63.7	3.71	(2.10, 6.51)	2.47	(1.67, 3.65)	<0.0001	0.7754
Other	9	6	2	33.3	12.88	(1.18, NA)	3	2	66.7	0.92	(0.76, NA)	5.69	(0.49, 66.34)	0.1228	0.7754
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	7	36.8	16.95	(2.10, NA)	18	9	50.0	3.71	(0.95, NA)	1.73	(0.64, 4.70)	0.2772	0.8096
Aromatase inhibitor only	131	71	23	32.4	12.88	(9.33, NA)	60	40	66.7	3.71	(1.94, 5.72)	2.85	(1.69, 4.79)	<0.0001	0.8096
Tamoxifen only	155	73	22	30.1	21.26	(11.83, NA)	82	50	61.0	5.78	(3.71, 9.49)	2.37	(1.43, 3.91)	0.0006	0.8096
Prior (neo)-adjuvant CDK4/6															
N	322	163	51	31.3	16.95	(11.99, NA)	159	100	62.9	3.81	(3.71, 6.70)	2.47	(1.76, 3.46)	<0.0001	1.0000
Y	3	1	1	100.0	8.28	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	8	29.6	32.89	(8.77, NA)	29	14	48.3	6.51	(1.97, NA)	2.13	(0.86, 5.30)	0.1042	0.7580
Y	269	137	44	32.1	16.95	(11.99, NA)	132	86	65.2	3.81	(2.14, 6.70)	2.49	(1.73, 3.59)	<0.0001	0.7580
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Dyspnoea (MID >=10)															
All Patients	325	164	70	42.7	10.91	(7.33, 15.67)	161	74	46.0	13.27	(8.31, 24.57)	0.87	(0.62, 1.21)	0.4027	NE
Age group (years)															
<65	266	130	54	41.5	10.91	(6.70, NA)	136	63	46.3	13.96	(9.89, 39.46)	0.81	(0.56, 1.17)	0.2616	0.2829
>=65	59	34	16	47.1	15.24	(4.11, NA)	25	11	44.0	7.85	(1.87, NA)	1.25	(0.58, 2.70)	0.5742	0.2829
Sex															

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
F	319	163	70	42.9	10.91	(7.33, 15.67)	156	71	45.5	13.27	(9.23, 24.57)	0.86	(0.61, 1.20)	0.3673	1.0000
M	6	1	0	0.0	NE	NE	5	3	60.0	5.78	(0.95, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	29	46.8	9.46	(6.14, NA)	58	33	56.9	10.84	(7.36, 18.37)	1.01	(0.61, 1.68)	0.9772	0.5490
NORTH AMERICA/WESTERN EUROPE	127	64	30	46.9	7.82	(3.71, NA)	63	24	38.1	11.93	(5.78, NA)	0.75	(0.44, 1.28)	0.3096	0.5490
OTHER	78	38	11	28.9	16.16	(5.52, NA)	40	17	42.5	28.58	(7.92, NA)	0.94	(0.43, 2.02)	0.8708	0.5490
Visceral disease (per eCRF)															
N	65	36	18	50.0	7.33	(3.71, NA)	29	11	37.9	28.58	(7.92, NA)	0.34	(0.14, 0.80)	0.0103	0.0986
Y	260	128	52	40.6	12.91	(7.62, NA)	132	63	47.7	12.39	(7.66, 18.37)	1.02	(0.71, 1.48)	0.9099	0.0986
Ethnicity															
HISPANIC OR LATINO	20	10	5	50.0	7.62	(0.95, NA)	10	1	10.0	NE	(7.92, NA)	0.12	(0.01, 1.03)	0.0227	0.1017
NOT HISPANIC OR LATINO	294	149	64	43.0	10.91	(6.70, 15.67)	145	71	49.0	12.98	(8.05, 18.69)	0.92	(0.65, 1.29)	0.6168	0.1017
NOT REPORTED	5	3	1	33.3	0.95	(0.95, NA)	2	1	50.0	5.78	(5.78, NA)	0.71	(0.04, 11.79)	0.8084	0.1017
UNKNOWN	6	2	0	0.0	NE	NE	4	1	25.0	5.72	(5.72, NA)	>999.99	(0.00, >999.99)	0.4795	0.1017
Race															
Asian	124	63	29	46.0	9.46	(6.14, NA)	61	34	55.7	10.84	(7.36, 18.37)	1.00	(0.60, 1.65)	0.9787	0.3669
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.3669
White	191	97	41	42.3	11.30	(5.52, NA)	94	39	41.5	24.57	(7.85, NA)	0.75	(0.48, 1.16)	0.2075	0.3669
Unknown	8	3	0	0.0	NE	NE	5	1	20.0	NE	(5.72, NA)	>999.99	(0.00, >999.99)	0.5637	0.3669
Liver Metastasis at Enrollment															
N	157	73	38	52.1	7.82	(4.24, 14.98)	84	37	44.0	18.37	(8.05, 39.66)	0.64	(0.41, 1.02)	0.0601	0.0848
Y	168	91	32	35.2	15.24	(6.70, NA)	77	37	48.1	11.93	(5.88, 24.57)	1.16	(0.72, 1.87)	0.5319	0.0848
Number Metastatic Organs at Enrollment															
1	53	32	15	46.9	8.31	(2.14, NA)	21	13	61.9	7.79	(2.10, 28.58)	1.17	(0.56, 2.48)	0.6653	0.6484
2	104	46	21	45.7	10.91	(5.55, 15.67)	58	27	46.6	15.05	(5.78, 39.66)	0.83	(0.46, 1.50)	0.5332	0.6484
>=3	168	86	34	39.5	12.91	(5.52, NA)	82	34	41.5	14.78	(9.23, NA)	0.81	(0.50, 1.30)	0.3844	0.6484
ECOG Performance Status at Baseline															
0	206	106	44	41.5	9.46	(5.78, NA)	100	48	48.0	13.96	(7.85, 39.46)	0.88	(0.58, 1.33)	0.5434	0.8801
1	118	58	26	44.8	11.30	(4.24, 16.16)	60	26	43.3	13.27	(6.67, NA)	0.83	(0.48, 1.43)	0.4934	0.8801
Endocrine Resistance (per eCRF)															
Primary	112	58	25	43.1	6.70	(3.71, 14.98)	54	33	61.1	7.66	(3.71, 11.93)	0.98	(0.58, 1.66)	0.9332	0.3223
Secondary	212	105	44	41.9	15.24	(7.62, NA)	107	41	38.3	24.57	(13.14, NA)	0.78	(0.50, 1.19)	0.2500	0.3223
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	19	36.5	14.98	(5.78, NA)	52	30	57.7	11.93	(5.72, 14.78)	1.26	(0.71, 2.25)	0.4370	0.0627
POST-MENOPAUSAL	215	111	51	45.9	9.46	(5.52, 15.67)	104	41	39.4	18.69	(9.89, NA)	0.69	(0.45, 1.04)	0.0746	0.0627
Hormone receptor status															
ER+/PR-	90	45	18	40.0	10.91	(3.71, NA)	45	22	48.9	13.96	(5.72, 39.46)	0.94	(0.50, 1.79)	0.8436	0.1429
ER+/PR+	226	113	49	43.4	11.30	(7.62, 16.16)	113	52	46.0	13.14	(8.05, 39.66)	0.87	(0.59, 1.29)	0.4945	0.1429
Other	9	6	3	50.0	3.71	(0.95, NA)	3	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.1736	0.1429

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	6	31.6	NE	(5.52, NA)	18	3	16.7	NE	(7.85, NA)	0.55	(0.14, 2.21)	0.3910	0.6638
Aromatase inhibitor only	131	71	34	47.9	7.82	(3.71, 15.24)	60	28	46.7	11.30	(3.71, NA)	0.84	(0.50, 1.39)	0.4769	0.6638
Tamoxifen only	155	73	30	41.1	14.98	(5.55, NA)	82	43	52.4	13.27	(7.92, 28.58)	0.94	(0.59, 1.51)	0.8157	0.6638
Prior (neo)-adjuvant CDK4/6															
N	322	163	69	42.3	10.91	(7.33, 16.16)	159	74	46.5	13.27	(8.31, 24.57)	0.88	(0.63, 1.22)	0.4445	1.0000
Y	3	1	1	100.0	0.95	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	13	48.1	7.82	(1.02, NA)	29	10	34.5	39.46	(6.67, NA)	0.42	(0.18, 1.00)	0.0442	0.0816
Y	269	137	57	41.6	11.30	(7.62, NA)	132	64	48.5	12.98	(7.85, 24.57)	0.99	(0.69, 1.42)	0.9410	0.0816
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Emotional functioning (MID >=10)															
All Patients	325	164	66	40.2	12.88	(7.52, 27.37)	161	69	42.9	15.05	(11.70, 35.52)	0.85	(0.61, 1.20)	0.3547	NE
Age group (years)															
<65	266	130	48	36.9	14.98	(7.52, NA)	136	60	44.1	15.05	(11.27, 35.52)	0.89	(0.61, 1.31)	0.5586	0.8751
>=65	59	34	18	52.9	8.31	(5.65, NA)	25	9	36.0	15.24	(1.81, NA)	0.87	(0.39, 1.97)	0.7318	0.8751
Sex															
F	319	163	66	40.5	12.88	(7.52, 27.37)	156	65	41.7	15.24	(11.70, 35.52)	0.83	(0.59, 1.17)	0.2755	1.0000
M	6	1	0	0.0	NE	NE	5	4	80.0	3.75	(0.95, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	22	35.5	14.98	(6.74, NA)	58	28	48.3	15.64	(9.46, NA)	0.98	(0.55, 1.74)	0.9368	0.5276
NORTH AMERICA/WESTERN EUROPE	127	64	28	43.8	11.93	(7.39, 27.37)	63	23	36.5	15.28	(3.75, NA)	0.97	(0.56, 1.68)	0.8931	0.5276
OTHER	78	38	16	42.1	7.52	(3.29, NA)	40	18	45.0	14.26	(11.27, NA)	0.58	(0.29, 1.15)	0.1182	0.5276
Visceral disease (per eCRF)															
N	65	36	23	63.9	7.52	(3.71, 11.93)	29	12	41.4	15.64	(11.93, NA)	0.33	(0.16, 0.70)	0.0025	0.0116
Y	260	128	43	33.6	23.72	(8.71, NA)	132	57	43.2	14.26	(10.02, 35.52)	1.11	(0.75, 1.66)	0.6086	0.0116
Ethnicity															
HISPANIC OR LATINO	20	10	4	40.0	25.54	(7.39, NA)	10	5	50.0	12.85	(0.95, NA)	3.71	(0.69, 19.90)	0.1034	0.2589
NOT HISPANIC OR LATINO	294	149	59	39.6	12.88	(7.52, NA)	145	62	42.8	15.28	(11.70, 35.52)	0.82	(0.57, 1.18)	0.2751	0.2589
NOT REPORTED	5	3	1	33.3	2.69	(2.69, NA)	2	1	50.0	1.87	(1.87, NA)	1.41	(0.08, 23.57)	0.8084	0.2589
UNKNOWN	6	2	2	100.0	2.40	(1.08, NA)	4	1	25.0	1.87	(1.87, NA)	0.39	(0.03, 4.44)	0.4328	0.2589
Race															
Asian	124	63	22	34.9	14.98	(6.74, NA)	61	30	49.2	13.27	(9.46, 44.39)	1.05	(0.60, 1.84)	0.8797	0.2298
Black or African American	2	1	1	100.0	16.85	NE	1	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	0.2298
White	191	97	42	43.3	11.30	(7.39, 27.37)	94	39	41.5	14.26	(11.07, 24.18)	0.80	(0.52, 1.24)	0.3246	0.2298
Unknown	8	3	1	33.3	1.08	(1.08, NA)	5	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.2207	0.2298
Liver Metastasis at Enrollment															
N	157	73	40	54.8	8.31	(5.78, 14.98)	84	39	46.4	14.26	(10.84, 35.52)	0.70	(0.45, 1.09)	0.1121	0.2255

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Y	168	91	26	28.6	38.93	(16.85, NA)	77	30	39.0	20.57	(9.46, NA)	1.11	(0.65, 1.88)	0.7172	0.2255
Number Metastatic Organs at Enrollment															
1	53	32	16	50.0	6.74	(3.71, NA)	21	10	47.6	13.90	(3.75, NA)	0.76	(0.34, 1.70)	0.5088	0.1111
2	104	46	23	50.0	11.30	(5.59, 16.16)	58	20	34.5	35.52	(12.85, NA)	0.55	(0.30, 1.00)	0.0460	0.1111
>=3	168	86	27	31.4	27.37	(8.71, NA)	82	39	47.6	12.88	(9.46, 24.18)	1.26	(0.77, 2.06)	0.3640	0.1111
ECOG Performance Status at Baseline															
0	206	106	37	34.9	23.72	(7.52, NA)	100	43	43.0	15.64	(11.27, 44.39)	0.97	(0.62, 1.51)	0.8688	0.4313
1	118	58	29	50.0	8.71	(5.65, 16.16)	60	26	43.3	13.27	(9.49, NA)	0.72	(0.42, 1.22)	0.2194	0.4313
Endocrine Resistance (per eCRF)															
Primary	112	58	29	50.0	6.67	(2.86, 14.98)	54	24	44.4	12.85	(9.30, 35.52)	0.53	(0.31, 0.93)	0.0231	0.0758
Secondary	212	105	36	34.3	23.72	(11.56, NA)	107	45	42.1	15.64	(11.27, NA)	1.08	(0.69, 1.69)	0.7382	0.0758
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	18	34.6	14.98	(7.52, NA)	52	25	48.1	13.27	(10.02, NA)	1.06	(0.57, 1.97)	0.8825	0.3121
POST-MENOPAUSAL	215	111	48	43.2	11.93	(7.39, 27.37)	104	40	38.5	15.24	(10.84, NA)	0.73	(0.48, 1.11)	0.1409	0.3121
Hormone receptor status															
ER+/PR-	90	45	18	40.0	11.93	(5.78, NA)	45	16	35.6	NE	(7.62, NA)	0.71	(0.36, 1.40)	0.3156	0.3079
ER+/PR+	226	113	43	38.1	16.16	(8.31, 38.93)	113	52	46.0	13.90	(10.84, 20.57)	1.03	(0.68, 1.54)	0.9045	0.3079
Other	9	6	5	83.3	3.71	(0.95, NA)	3	1	33.3	2.07	(2.07, NA)	0.36	(0.04, 3.16)	0.3384	0.3079
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	6	31.6	NE	(3.81, NA)	18	9	50.0	7.33	(2.07, NA)	1.98	(0.70, 5.62)	0.1824	0.1202
Aromatase inhibitor only	131	71	30	42.3	11.30	(5.78, 16.16)	60	21	35.0	NE	(9.49, NA)	0.63	(0.36, 1.11)	0.1041	0.1202
Tamoxifen only	155	73	30	41.1	16.85	(6.67, NA)	82	39	47.6	13.90	(11.07, 35.52)	0.87	(0.54, 1.41)	0.5682	0.1202
Prior (neo)-adjuvant CDK4/6															
N	322	163	65	39.9	12.88	(7.52, 27.37)	159	69	43.4	15.05	(11.70, 35.52)	0.86	(0.61, 1.21)	0.3849	1.0000
Y	3	1	1	100.0	8.28	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	10	37.0	27.37	(2.33, NA)	29	10	34.5	15.24	(3.75, NA)	1.02	(0.42, 2.47)	0.9752	0.6763
Y	269	137	56	40.9	11.93	(7.46, 23.72)	132	59	44.7	14.26	(10.84, 35.52)	0.82	(0.57, 1.19)	0.2890	0.6763
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Fatigue (MID >=10)															
All Patients	325	164	103	62.8	3.71	(1.97, 5.19)	161	108	67.1	2.07	(1.87, 3.78)	1.06	(0.81, 1.39)	0.7199	NE
Age group (years)															
<65	266	130	80	61.5	3.75	(2.10, 5.45)	136	94	69.1	2.07	(1.41, 4.04)	1.08	(0.80, 1.46)	0.6587	0.7218
>=65	59	34	23	67.6	1.94	(0.99, 7.39)	25	14	56.0	1.91	(1.15, 15.24)	0.98	(0.50, 1.90)	0.9378	0.7218
Sex															
F	319	163	103	63.2	3.71	(1.97, 5.19)	156	105	67.3	2.07	(1.87, 3.78)	1.07	(0.82, 1.41)	0.6451	1.0000
M	6	1	0	0.0	NE	NE	5	3	60.0	2.10	(0.95, NA)	NE	NE	1.0000	1.0000
Region															

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
ASIA	120	62	35	56.5	5.19	(2.10, 11.56)	58	43	74.1	1.81	(0.95, 5.49)	1.44	(0.92, 2.26)	0.1380	0.1960
NORTH AMERICA/WESTERN EUROPE	127	64	46	71.9	1.87	(0.99, 2.92)	63	39	61.9	1.99	(1.15, 3.71)	0.91	(0.60, 1.40)	0.6949	0.1960
OTHER	78	38	22	57.9	3.75	(2.10, 10.35)	40	26	65.0	7.39	(1.94, 13.96)	0.78	(0.44, 1.39)	0.4070	0.1960
Visceral disease (per eCRF)															
N	65	36	27	75.0	1.87	(0.95, 5.55)	29	17	58.6	5.82	(1.91, 21.13)	0.47	(0.25, 0.88)	0.0181	0.0049
Y	260	128	76	59.4	3.75	(2.10, 5.98)	132	91	68.9	1.87	(1.05, 3.71)	1.29	(0.95, 1.75)	0.1239	0.0049
Ethnicity															
HISPANIC OR LATINO	20	10	6	60.0	5.78	(0.95, NA)	10	6	60.0	3.75	(1.41, NA)	0.91	(0.29, 2.82)	0.8603	0.8685
NOT HISPANIC OR LATINO	294	149	93	62.4	3.71	(2.00, 5.45)	145	98	67.6	1.94	(1.22, 4.04)	1.09	(0.82, 1.44)	0.6267	0.8685
NOT REPORTED	5	3	2	66.7	1.07	(0.95, NA)	2	2	100.0	2.32	(0.92, NA)	0.62	(0.05, 7.00)	0.6949	0.8685
UNKNOWN	6	2	2	100.0	2.40	(1.08, NA)	4	2	50.0	11.50	(1.87, NA)	0.39	(0.03, 4.44)	0.4328	0.8685
Race															
Asian	124	63	35	55.6	5.19	(2.10, 11.56)	61	45	73.8	1.87	(0.95, 4.40)	1.46	(0.94, 2.28)	0.1148	0.0226
Black or African American	2	1	1	100.0	16.85	NE	1	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	0.0226
White	191	97	65	67.0	2.14	(1.41, 3.94)	94	62	66.0	2.78	(1.87, 4.27)	0.90	(0.63, 1.28)	0.5745	0.0226
Unknown	8	3	2	66.7	1.13	(1.08, NA)	5	1	20.0	21.13	(21.13, NA)	<0.01	(0.00, >999.99)	0.0389	0.0226
Liver Metastasis at Enrollment															
N	157	73	54	74.0	1.89	(1.02, 3.71)	84	56	66.7	3.71	(1.91, 5.82)	0.70	(0.48, 1.01)	0.0518	0.0048
Y	168	91	49	53.8	5.19	(3.29, 10.35)	77	52	67.5	1.51	(0.99, 3.71)	1.52	(1.03, 2.25)	0.0394	0.0048
Number Metastatic Organs at Enrollment															
1	53	32	22	68.8	2.37	(1.18, 3.75)	21	17	81.0	1.02	(0.95, 5.82)	1.25	(0.65, 2.41)	0.5138	0.7760
2	104	46	30	65.2	4.44	(2.10, 5.78)	58	39	67.2	2.10	(1.87, 4.40)	1.10	(0.68, 1.78)	0.6909	0.7760
>=3	168	86	51	59.3	2.14	(1.22, 7.95)	82	52	63.4	1.92	(1.81, 5.68)	1.03	(0.70, 1.52)	0.9334	0.7760
ECOG Performance Status at Baseline															
0	206	106	68	64.2	3.29	(1.91, 4.40)	100	71	71.0	1.91	(1.05, 3.71)	1.15	(0.83, 1.61)	0.4442	0.5204
1	118	58	35	60.3	5.09	(1.41, 10.35)	60	37	61.7	3.71	(1.81, 9.13)	0.93	(0.58, 1.47)	0.7435	0.5204
Endocrine Resistance (per eCRF)															
Primary	112	58	36	62.1	3.68	(1.74, 5.55)	54	39	72.2	2.10	(1.87, 7.39)	0.97	(0.61, 1.53)	0.8648	0.7815
Secondary	212	105	66	62.9	3.71	(1.94, 5.78)	107	69	64.5	2.07	(1.15, 4.04)	1.11	(0.79, 1.55)	0.5922	0.7815
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	29	55.8	5.55	(2.14, 16.85)	52	34	65.4	2.78	(0.99, 9.13)	1.12	(0.68, 1.85)	0.7148	0.7720
POST-MENOPAUSAL	215	111	74	66.7	2.10	(1.87, 3.94)	104	71	68.3	1.94	(1.81, 3.78)	1.05	(0.76, 1.46)	0.7653	0.7720
Hormone receptor status															
ER+/PR-	90	45	24	53.3	5.45	(1.91, 11.56)	45	33	73.3	1.53	(0.99, 4.27)	1.64	(0.97, 2.77)	0.0750	0.0896
ER+/PR+	226	113	75	66.4	2.10	(1.74, 3.94)	113	73	64.6	3.56	(1.87, 5.55)	0.89	(0.64, 1.23)	0.4780	0.0896
Other	9	6	4	66.7	5.59	(1.18, NA)	3	2	66.7	1.51	(0.95, NA)	6.79	(0.60, 76.65)	0.0748	0.0896
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	11	57.9	2.00	(1.18, 7.66)	18	9	50.0	5.49	(0.95, NA)	0.85	(0.35, 2.07)	0.7157	0.8320
Aromatase inhibitor only	131	71	46	64.8	2.10	(1.18, 3.75)	60	46	76.7	1.87	(1.02, 3.71)	1.14	(0.75, 1.72)	0.5245	0.8320

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Tamoxifen only	155	73	45	61.6	5.19	(2.14, 7.95)	82	53	64.6	2.91	(1.87, 7.46)	1.06	(0.71, 1.58)	0.8300	0.8320
Prior (neo)-adjuvant CDK4/6															
N	322	163	102	62.6	3.71	(1.97, 5.19)	159	108	67.9	2.07	(1.87, 3.78)	1.07	(0.81, 1.40)	0.6813	1.0000
Y	3	1	1	100.0	0.95	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	18	66.7	1.91	(1.02, 16.36)	29	17	58.6	7.39	(1.87, 13.83)	0.90	(0.46, 1.77)	0.7666	0.4793
Y	269	137	85	62.0	3.71	(2.10, 5.19)	132	91	68.9	1.91	(1.18, 3.68)	1.13	(0.84, 1.52)	0.4541	0.4793
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Financial difficulties (MID >=10)															
All Patients	325	164	46	28.0	27.37	(16.36, NA)	161	54	33.5	28.09	(18.69, NA)	0.95	(0.64, 1.42)	0.8135	NE
Age group (years)															
<65	266	130	38	29.2	27.37	(14.29, NA)	136	48	35.3	28.09	(19.32, NA)	0.88	(0.57, 1.35)	0.5569	0.4608
>=65	59	34	8	23.5	NE	(16.16, NA)	25	6	24.0	18.69	(17.08, NA)	1.12	(0.39, 3.25)	0.8345	0.4608
Sex															
F	319	163	46	28.2	27.37	(16.36, NA)	156	52	33.3	27.01	(18.69, NA)	0.95	(0.64, 1.42)	0.7976	1.0000
M	6	1	0	0.0	NE	NE	5	2	40.0	NE	(0.95, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	17	27.4	NE	NE	58	16	27.6	NE	(19.32, NA)	0.76	(0.38, 1.51)	0.4279	0.3353
NORTH AMERICA/WESTERN EUROPE	127	64	21	32.8	27.37	(13.63, NA)	63	20	31.7	28.09	(9.30, NA)	0.91	(0.49, 1.70)	0.7718	0.3353
OTHER	78	38	8	21.1	24.54	(16.16, NA)	40	18	45.0	24.05	(7.95, NA)	1.52	(0.65, 3.55)	0.3327	0.3353
Visceral disease (per eCRF)															
N	65	36	14	38.9	24.54	(5.59, NA)	29	12	41.4	18.69	(5.55, NA)	0.77	(0.35, 1.70)	0.5214	0.5008
Y	260	128	32	25.0	NE	(16.36, NA)	132	42	31.8	28.09	(19.32, NA)	1.05	(0.66, 1.67)	0.8309	0.5008
Ethnicity															
HISPANIC OR LATINO	20	10	2	20.0	27.37	(11.30, NA)	10	1	10.0	NE	(4.86, NA)	0.47	(0.04, 5.19)	0.5282	0.3475
NOT HISPANIC OR LATINO	294	149	42	28.2	24.54	(16.16, NA)	145	51	35.2	27.01	(17.08, NA)	0.97	(0.64, 1.47)	0.9012	0.3475
NOT REPORTED	5	3	1	33.3	0.95	(0.95, NA)	2	2	100.0	3.71	(1.87, NA)	1.62	(0.14, 18.31)	0.6949	0.3475
UNKNOWN	6	2	1	50.0	5.55	NE	4	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.1573	0.3475
Race															
Asian	124	63	17	27.0	NE	NE	61	18	29.5	39.10	(19.32, NA)	0.79	(0.40, 1.54)	0.4826	0.3934
Black or African American	2	1	1	100.0	0.95	NE	1	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	0.3934
White	191	97	28	28.9	24.54	(16.16, NA)	94	35	37.2	24.05	(9.46, NA)	1.14	(0.69, 1.87)	0.6202	0.3934
Unknown	8	3	0	0.0	NE	NE	5	1	20.0	16.62	(16.62, NA)	NE	NE	1.0000	0.3934
Liver Metastasis at Enrollment															
N	157	73	24	32.9	24.54	(16.16, NA)	84	29	34.5	28.09	(18.69, NA)	0.87	(0.50, 1.49)	0.6063	0.6602
Y	168	91	22	24.2	NE	(14.29, NA)	77	25	32.5	24.05	(16.62, NA)	1.05	(0.59, 1.88)	0.8747	0.6602
Number Metastatic Organs at Enrollment															
1	53	32	11	34.4	NE	(5.55, NA)	21	6	28.6	39.10	(7.95, NA)	0.58	(0.20, 1.68)	0.3068	0.0348
2	104	46	16	34.8	14.29	(11.30, NA)	58	16	27.6	NE	(21.62, NA)	0.56	(0.28, 1.15)	0.1073	0.0348

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
>=3	168	86	19	22.1	NE	(16.59, NA)	82	32	39.0	18.69	(11.01, 28.09)	1.63	(0.93, 2.89)	0.0851	0.0348
ECOG Performance Status at Baseline															
0	206	106	28	26.4	NE	(27.37, NA)	100	32	32.0	39.10	(24.05, NA)	0.91	(0.55, 1.53)	0.7328	0.5538
1	118	58	18	31.0	16.59	(13.63, NA)	60	22	36.7	17.08	(9.13, NA)	1.09	(0.58, 2.04)	0.7848	0.5538
Endocrine Resistance (per eCRF)															
Primary	112	58	15	25.9	NE	(13.63, NA)	54	20	37.0	24.05	(8.38, NA)	1.00	(0.51, 1.99)	0.9859	0.9501
Secondary	212	105	31	29.5	27.37	(16.16, NA)	107	34	31.8	28.09	(19.32, NA)	0.90	(0.55, 1.48)	0.6851	0.9501
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	18	34.6	NE	(6.14, NA)	52	19	36.5	27.01	(9.46, NA)	0.77	(0.40, 1.48)	0.4348	0.2665
POST-MENOPAUSAL	215	111	28	25.2	27.37	(16.36, NA)	104	33	31.7	24.05	(17.08, NA)	1.07	(0.64, 1.78)	0.7941	0.2665
Hormone receptor status															
ER+/PR-	90	45	9	20.0	NE	NE	45	13	28.9	NE	(18.69, NA)	1.15	(0.49, 2.72)	0.7390	0.8798
ER+/PR+	226	113	34	30.1	27.37	(14.29, NA)	113	40	35.4	27.01	(16.62, NA)	0.96	(0.60, 1.52)	0.8427	0.8798
Other	9	6	3	50.0	15.06	(5.55, NA)	3	1	33.3	39.10	NE	<0.01	(0.00, >999.99)	0.1973	0.8798
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	5	26.3	NE	(6.70, NA)	18	5	27.8	39.10	(4.40, NA)	0.83	(0.22, 3.10)	0.7804	0.7956
Aromatase inhibitor only	131	71	16	22.5	27.37	(16.16, NA)	60	17	28.3	NE	(15.05, NA)	1.06	(0.54, 2.12)	0.8646	0.7956
Tamoxifen only	155	73	25	34.2	NE	(6.14, NA)	82	32	39.0	27.01	(16.62, NA)	0.86	(0.51, 1.46)	0.5816	0.7956
Prior (neo)-adjuvant CDK4/6															
N	322	163	46	28.2	27.37	(16.36, NA)	159	54	34.0	28.09	(18.69, NA)	0.94	(0.64, 1.40)	0.7770	1.0000
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	8	29.6	27.37	(14.29, NA)	29	9	31.0	19.32	(9.13, NA)	0.92	(0.35, 2.41)	0.8730	0.9603
Y	269	137	38	27.7	NE	(16.16, NA)	132	45	34.1	28.09	(18.69, NA)	0.97	(0.63, 1.51)	0.9042	0.9603
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Nausea and vomiting (MID >=10)															
All Patients	325	164	70	42.7	11.76	(8.87, 15.74)	161	83	51.6	11.83	(5.72, 19.61)	1.11	(0.80, 1.53)	0.5442	NE
Age group (years)															
<65	266	130	53	40.8	11.76	(9.69, 17.74)	136	71	52.2	12.91	(6.01, 19.61)	1.15	(0.80, 1.64)	0.4466	0.8079
>=65	59	34	17	50.0	10.58	(3.78, 14.75)	25	12	48.0	3.71	(0.95, NA)	1.04	(0.48, 2.23)	0.9509	0.8079
Sex															
F	319	163	70	42.9	11.76	(8.87, 15.74)	156	79	50.6	12.91	(5.78, 22.64)	1.09	(0.79, 1.51)	0.6181	1.0000
M	6	1	0	0.0	NE	NE	5	4	80.0	2.10	(0.99, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	27	43.5	9.89	(7.39, NA)	58	30	51.7	9.33	(5.78, NA)	1.04	(0.62, 1.77)	0.8908	0.7876
NORTH AMERICA/WESTERN EUROPE	127	64	29	45.3	13.14	(9.69, 15.74)	63	29	46.0	13.11	(3.71, 26.71)	0.97	(0.57, 1.64)	0.9154	0.7876
OTHER	78	38	14	36.8	11.33	(3.81, NA)	40	24	60.0	12.91	(1.87, 27.73)	1.38	(0.71, 2.69)	0.3413	0.7876

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)	
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI					
Visceral disease (per eCRF)																
N	65	36	15	41.7	15.57	(4.67, NA)	29	19	65.5	5.72	(1.91, 19.61)	1.13	(0.55, 2.33)	0.7277	0.7298	
Y	260	128	55	43.0	11.76	(7.49, 15.74)	132	64	48.5	12.91	(5.78, 26.71)	1.08	(0.75, 1.55)	0.7071	0.7298	
Ethnicity																
HISPANIC OR LATINO	20	10	6	60.0	10.12	(0.95, NA)	10	5	50.0	13.90	(1.41, NA)	0.45	(0.12, 1.66)	0.2183	0.1222	
NOT HISPANIC OR LATINO	294	149	63	42.3	12.02	(7.49, 15.74)	145	75	51.7	11.83	(5.78, 22.64)	1.12	(0.80, 1.57)	0.5313	0.1222	
NOT REPORTED	5	3	1	33.3	15.74	NE	2	1	50.0	0.92	(0.92, NA)	>999.99	(0.00, >999.99)	0.3173	0.1222	
UNKNOWN	6	2	0	0.0	NE	NE	4	2	50.0	3.79	(1.87, NA)	>999.99	(0.00, >999.99)	0.1573	0.1222	
Race																
Asian	124	63	27	42.9	9.89	(7.39, NA)	61	32	52.5	9.33	(5.78, NA)	1.06	(0.63, 1.79)	0.8263	0.9843	
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.9843	
White	191	97	42	43.3	12.91	(8.54, 15.74)	94	49	52.1	13.90	(3.71, 22.64)	1.09	(0.72, 1.65)	0.7035	0.9843	
Unknown	8	3	1	33.3	15.74	NE	5	2	40.0	5.72	(4.96, NA)	1.14	(0.10, 13.27)	0.9183	0.9843	
Liver Metastasis at Enrollment																
N	157	73	30	41.1	14.75	(10.58, 24.54)	84	44	52.4	12.91	(3.98, 26.71)	1.20	(0.75, 1.91)	0.4329	0.6164	
Y	168	91	40	44.0	8.87	(5.59, 11.76)	77	39	50.6	9.33	(3.71, 27.73)	1.02	(0.65, 1.60)	0.9387	0.6164	
Number Metastatic Organs at Enrollment																
1	53	32	10	31.2	NE	(9.79, NA)	21	12	57.1	13.11	(0.99, NA)	1.94	(0.83, 4.54)	0.1201	0.2828	
2	104	46	24	52.2	9.69	(4.11, 12.02)	58	30	51.7	14.06	(3.98, 22.64)	0.83	(0.48, 1.43)	0.4908	0.2828	
>=3	168	86	36	41.9	12.91	(7.43, 17.74)	82	41	50.0	9.33	(3.81, 34.56)	1.08	(0.69, 1.70)	0.7493	0.2828	
ECOG Performance Status at Baseline																
0	206	106	43	40.6	11.76	(9.79, NA)	100	51	51.0	15.44	(4.96, 27.73)	1.14	(0.75, 1.71)	0.5483	0.8312	
1	118	58	27	46.6	7.49	(4.11, 15.74)	60	32	53.3	7.82	(3.65, 19.61)	1.02	(0.61, 1.70)	0.9661	0.8312	
Endocrine Resistance (per eCRF)																
Primary	112	58	25	43.1	7.43	(3.75, 15.74)	54	32	59.3	7.62	(1.97, 19.61)	1.08	(0.63, 1.84)	0.7674	0.9861	
Secondary	212	105	44	41.9	12.91	(9.89, 24.54)	107	51	47.7	12.91	(4.96, NA)	1.12	(0.75, 1.68)	0.6003	0.9861	
Menopausal Status at Randomization																
NOT POST-MENOPAUSAL	104	52	17	32.7	15.57	(8.87, NA)	52	28	53.8	12.91	(3.71, NA)	1.49	(0.80, 2.74)	0.2067	0.2813	
POST-MENOPAUSAL	215	111	53	47.7	10.58	(7.43, 14.75)	104	51	49.0	11.83	(4.40, 26.71)	0.96	(0.65, 1.42)	0.8435	0.2813	
Hormone receptor status																
ER+/PR-	90	45	18	40.0	11.56	(5.78, NA)	45	24	53.3	11.83	(3.71, 26.71)	1.16	(0.63, 2.16)	0.6354	0.5554	
ER+/PR+	226	113	50	44.2	11.33	(7.43, 15.74)	113	57	50.4	9.49	(3.94, 27.73)	1.05	(0.72, 1.54)	0.8126	0.5554	
Other	9	6	2	33.3	24.54	(13.14, NA)	3	2	66.7	13.11	(0.76, NA)	>999.99	(0.00, >999.99)	0.0343	0.5554	
Prior (neo)-adjuvant endocrine																
Aromatase inhibitor and tamoxifen	37	19	6	31.6	15.74	(3.81, NA)	18	10	55.6	4.96	(0.95, NA)	2.25	(0.82, 6.22)	0.1077	0.3204	
Aromatase inhibitor only	131	71	32	45.1	10.12	(7.39, 14.75)	60	31	51.7	9.49	(3.71, 16.92)	0.97	(0.59, 1.61)	0.8993	0.3204	
Tamoxifen only	155	73	31	42.5	11.56	(7.43, NA)	82	41	50.0	18.37	(6.47, 27.73)	1.06	(0.66, 1.70)	0.8165	0.3204	
Prior (neo)-adjuvant CDK4/6																
N	322	163	69	42.3	11.76	(8.87, 15.74)	159	83	52.2	11.83	(5.72, 19.61)	1.11	(0.81, 1.54)	0.5174	1.0000	
Y	3	1	1	100.0	15.57	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000	

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Prior (neo)-adjuvant chemotherapy															
N	56	27	13	48.1	10.12	(2.10, 14.75)	29	14	48.3	8.31	(1.87, 34.56)	0.96	(0.45, 2.06)	0.9120	0.7695
Y	269	137	57	41.6	12.91	(8.54, 17.74)	132	69	52.3	11.83	(5.72, 22.64)	1.12	(0.79, 1.60)	0.5305	0.7695
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Pain (MID >=10)															
All Patients	325	164	82	50.0	7.46	(4.40, 11.99)	161	84	52.2	9.43	(5.75, 18.69)	0.93	(0.68, 1.26)	0.6161	NE
Age group (years)															
<65	266	130	63	48.5	6.74	(4.17, 13.80)	136	72	52.9	7.95	(5.55, 14.75)	0.94	(0.67, 1.32)	0.6983	0.9720
>=65	59	34	19	55.9	8.54	(1.87, 16.59)	25	12	48.0	18.69	(1.15, 21.65)	0.93	(0.45, 1.92)	0.8331	0.9720
Sex															
F	319	163	82	50.3	7.46	(4.40, 11.99)	156	81	51.9	9.43	(5.75, 18.69)	0.93	(0.68, 1.26)	0.6105	1.0000
M	6	1	0	0.0	NE	NE	5	3	60.0	2.37	(0.95, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	33	53.2	6.74	(3.25, 14.98)	58	33	56.9	8.54	(5.49, 18.76)	0.89	(0.55, 1.46)	0.6199	0.9436
NORTH AMERICA/WESTERN EUROPE	127	64	35	54.7	6.01	(3.75, 15.70)	63	32	50.8	3.94	(2.37, 11.30)	1.03	(0.64, 1.67)	0.9010	0.9436
OTHER	78	38	14	36.8	9.43	(3.75, NA)	40	19	47.5	14.75	(7.95, NA)	0.87	(0.43, 1.75)	0.6950	0.9436
Visceral disease (per eCRF)															
N	65	36	21	58.3	9.43	(3.71, 22.70)	29	14	48.3	18.69	(3.94, NA)	0.70	(0.35, 1.38)	0.3036	0.3585
Y	260	128	61	47.7	7.46	(4.17, 14.98)	132	70	53.0	7.92	(5.49, 13.96)	1.01	(0.72, 1.43)	0.9766	0.3585
Ethnicity															
HISPANIC OR LATINO	20	10	5	50.0	8.54	(0.95, NA)	10	5	50.0	3.07	(0.95, NA)	1.45	(0.39, 5.40)	0.5778	0.4877
NOT HISPANIC OR LATINO	294	149	74	49.7	7.46	(5.19, 13.80)	145	76	52.4	10.12	(5.82, 18.69)	0.91	(0.66, 1.26)	0.5723	0.4877
NOT REPORTED	5	3	1	33.3	1.18	(1.18, NA)	2	2	100.0	2.45	(0.95, NA)	1.41	(0.08, 23.57)	0.8084	0.4877
UNKNOWN	6	2	2	100.0	2.40	(1.08, NA)	4	1	25.0	1.87	(1.87, NA)	0.39	(0.03, 4.44)	0.4328	0.4877
Race															
Asian	124	63	33	52.4	6.74	(3.25, 14.98)	61	35	57.4	7.56	(4.67, 18.76)	0.94	(0.58, 1.52)	0.7608	0.0128
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.0128
White	191	97	47	48.5	8.54	(3.94, 15.70)	94	49	52.1	9.43	(3.94, 18.92)	0.96	(0.64, 1.43)	0.8360	0.0128
Unknown	8	3	2	66.7	1.13	(1.08, NA)	5	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.0389	0.0128
Liver Metastasis at Enrollment															
N	157	73	42	57.5	7.62	(3.71, 13.80)	84	44	52.4	10.02	(4.40, 18.92)	0.85	(0.55, 1.29)	0.4363	0.5131
Y	168	91	40	44.0	6.74	(4.17, 15.70)	77	40	51.9	7.46	(4.67, 23.03)	1.03	(0.66, 1.60)	0.9267	0.5131
Number Metastatic Organs at Enrollment															
1	53	32	17	53.1	6.01	(3.29, NA)	21	12	57.1	5.82	(1.02, NA)	1.13	(0.54, 2.37)	0.7692	0.1483
2	104	46	28	60.9	5.59	(3.75, 10.05)	58	27	46.6	18.76	(5.52, NA)	0.60	(0.35, 1.03)	0.0586	0.1483
>=3	168	86	37	43.0	13.80	(4.40, 31.05)	82	45	54.9	9.43	(4.40, 14.75)	1.18	(0.76, 1.82)	0.4742	0.1483
ECOG Performance Status at Baseline															
0	206	106	56	52.8	5.59	(3.75, 11.60)	100	54	54.0	7.95	(3.94, 21.65)	0.86	(0.59, 1.26)	0.4295	0.4051
1	118	58	26	44.8	11.30	(5.78, 22.70)	60	30	50.0	10.02	(5.52, 18.69)	1.09	(0.64, 1.84)	0.7582	0.4051

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Endocrine Resistance (per eCRF)															
Primary	112	58	27	46.6	4.40	(3.25, 11.30)	54	27	50.0	11.30	(5.82, 35.09)	0.70	(0.41, 1.21)	0.2024	0.3174
Secondary	212	105	55	52.4	9.69	(5.19, 14.98)	107	57	53.3	7.46	(3.78, 14.75)	1.03	(0.71, 1.49)	0.9058	0.3174
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	23	44.2	13.80	(5.55, NA)	52	27	51.9	11.24	(5.82, NA)	0.95	(0.54, 1.66)	0.8251	0.9449
POST-MENOPAUSAL	215	111	59	53.2	7.46	(3.75, 11.60)	104	54	51.9	8.54	(3.94, 18.69)	0.92	(0.64, 1.34)	0.6683	0.9449
Hormone receptor status															
ER+/PR-	90	45	20	44.4	10.05	(3.68, NA)	45	23	51.1	8.54	(4.67, NA)	0.98	(0.54, 1.79)	0.9390	0.0651
ER+/PR+	226	113	57	50.4	7.46	(3.88, 13.80)	113	59	52.2	10.02	(5.49, 18.92)	0.93	(0.64, 1.34)	0.6945	0.0651
Other	9	6	5	83.3	3.71	(0.99, NA)	3	2	66.7	0.94	(0.92, NA)	>999.99	(0.00, >999.99)	0.0082	0.0651
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	10	52.6	5.59	(2.10, NA)	18	8	44.4	21.65	(0.95, NA)	0.88	(0.34, 2.23)	0.7749	0.4902
Aromatase inhibitor only	131	71	41	57.7	5.78	(3.29, 11.30)	60	31	51.7	8.54	(3.75, 18.92)	0.77	(0.48, 1.23)	0.2636	0.4902
Tamoxifen only	155	73	31	42.5	11.99	(5.55, NA)	82	45	54.9	9.43	(5.52, 18.69)	1.17	(0.74, 1.85)	0.5123	0.4902
Prior (neo)-adjuvant CDK4/6															
N	322	163	81	49.7	7.46	(4.40, 11.99)	159	84	52.8	9.43	(5.75, 18.69)	0.93	(0.69, 1.27)	0.6330	1.0000
Y	3	1	1	100.0	13.80	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	9	33.3	31.05	(2.33, NA)	29	16	55.2	8.54	(3.71, 14.75)	1.73	(0.76, 3.95)	0.1860	0.0983
Y	269	137	73	53.3	6.74	(4.17, 11.30)	132	68	51.5	9.43	(5.52, 21.65)	0.83	(0.60, 1.16)	0.2689	0.0983
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Physical functioning (revised) (MID >=10)															
All Patients	325	164	73	44.5	9.53	(7.39, 17.77)	161	84	52.2	8.05	(3.78, 18.40)	1.13	(0.82, 1.54)	0.4847	NE
Age group (years)															
<65	266	130	54	41.5	12.02	(7.82, 23.72)	136	71	52.2	10.84	(3.91, 19.29)	1.15	(0.80, 1.64)	0.4578	0.8776
>=65	59	34	19	55.9	3.71	(1.41, 26.48)	25	13	52.0	3.70	(0.95, 18.92)	1.20	(0.59, 2.43)	0.6323	0.8776
Sex															
F	319	163	73	44.8	9.53	(7.39, 17.77)	156	81	51.9	8.05	(3.71, 17.74)	1.15	(0.83, 1.58)	0.4226	1.0000
M	6	1	0	0.0	NE	NE	5	3	60.0	22.64	(3.75, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	25	40.3	12.02	(7.43, NA)	58	33	56.9	10.84	(1.91, 44.39)	1.37	(0.81, 2.31)	0.2582	0.3992
NORTH	127	64	28	43.8	17.77	(2.10, 26.48)	63	29	46.0	3.84	(3.68, NA)	1.16	(0.69, 1.95)	0.5876	0.3992
AMERICA/WESTERN															
EUROPE															
OTHER	78	38	20	52.6	7.33	(1.87, 13.34)	40	22	55.0	11.33	(5.62, 18.92)	0.75	(0.41, 1.39)	0.3583	0.3992
Visceral disease (per eCRF)															
N	65	36	19	52.8	3.78	(1.87, NA)	29	17	58.6	11.93	(3.91, 19.29)	0.78	(0.40, 1.54)	0.4880	0.3130
Y	260	128	54	42.2	12.02	(8.38, 23.72)	132	67	50.8	8.05	(3.71, 18.40)	1.24	(0.87, 1.78)	0.2563	0.3130
Ethnicity															

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
HISPANIC OR LATINO	20	10	6	60.0	7.82	(0.95, NA)	10	3	30.0	NE	(1.41, NA)	0.45	(0.11, 1.85)	0.2554	0.2458
NOT HISPANIC OR LATINO	294	149	64	43.0	12.02	(7.39, NA)	145	77	53.1	9.17	(3.75, 18.40)	1.18	(0.85, 1.65)	0.3429	0.2458
NOT REPORTED	5	3	2	66.7	1.07	(0.95, NA)	2	2	100.0	0.94	(0.92, NA)	3.77	(0.32, 43.72)	0.2253	0.2458
UNKNOWN	6	2	1	50.0	9.20	NE	4	2	50.0	2.33	(0.89, NA)	>999.99	(0.00, >999.99)	0.1573	0.2458
Race															
Asian	124	63	25	39.7	12.02	(7.43, NA)	61	34	55.7	10.84	(2.20, 44.39)	1.35	(0.80, 2.27)	0.2761	0.5222
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.5222
White	191	97	47	48.5	8.38	(3.71, 17.77)	94	49	52.1	6.01	(3.71, 18.40)	1.01	(0.67, 1.51)	0.9767	0.5222
Unknown	8	3	1	33.3	1.18	(1.18, NA)	5	1	20.0	NE	(0.89, NA)	0.82	(0.05, 13.24)	0.8864	0.5222
Liver Metastasis at Enrollment															
N	157	73	42	57.5	7.39	(2.10, 12.02)	84	46	54.8	8.05	(3.91, 18.92)	0.85	(0.55, 1.29)	0.4308	0.0797
Y	168	91	31	34.1	14.98	(9.23, NA)	77	38	49.4	9.17	(3.68, NA)	1.51	(0.94, 2.43)	0.0945	0.0797
Number Metastatic Organs at Enrollment															
1	53	32	17	53.1	9.20	(1.87, NA)	21	13	61.9	1.22	(0.95, 10.84)	1.59	(0.77, 3.29)	0.2193	0.6604
2	104	46	20	43.5	14.09	(5.59, NA)	58	26	44.8	17.74	(3.91, NA)	0.95	(0.53, 1.71)	0.8774	0.6604
>=3	168	86	36	41.9	9.23	(7.33, 26.48)	82	45	54.9	8.05	(3.71, 18.40)	1.20	(0.77, 1.87)	0.4413	0.6604
ECOG Performance Status at Baseline															
0	206	106	46	43.4	9.53	(7.43, 26.48)	100	54	54.0	5.82	(3.71, 17.74)	1.25	(0.84, 1.85)	0.2956	0.4109
1	118	58	27	46.6	9.23	(3.71, NA)	60	30	50.0	11.83	(3.71, 28.35)	0.93	(0.55, 1.57)	0.7846	0.4109
Endocrine Resistance (per eCRF)															
Primary	112	58	25	43.1	7.33	(3.68, NA)	54	30	55.6	8.05	(2.14, 18.92)	1.11	(0.65, 1.91)	0.7312	0.9806
Secondary	212	105	48	45.7	12.02	(7.82, 26.48)	107	54	50.5	9.17	(3.75, 19.29)	1.10	(0.74, 1.62)	0.6568	0.9806
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	18	34.6	14.98	(9.53, NA)	52	25	48.1	17.74	(2.20, NA)	1.38	(0.74, 2.55)	0.3406	0.4930
POST-MENOPAUSAL	215	111	55	49.5	8.38	(3.78, 14.09)	104	56	53.8	6.01	(3.71, 11.83)	1.07	(0.74, 1.56)	0.7262	0.4930
Hormone receptor status															
ER+/PR-	90	45	21	46.7	8.97	(1.91, NA)	45	30	66.7	2.92	(1.02, 11.83)	1.51	(0.86, 2.65)	0.1541	0.1664
ER+/PR+	226	113	47	41.6	13.34	(7.82, 26.48)	113	53	46.9	11.93	(5.62, 44.39)	1.05	(0.71, 1.56)	0.8162	0.1664
Other	9	6	5	83.3	1.91	(0.95, NA)	3	1	33.3	0.95	(0.95, NA)	0.45	(0.05, 3.95)	0.4274	0.1664
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	7	36.8	17.77	(2.10, NA)	18	7	38.9	NE	(0.95, NA)	1.27	(0.45, 3.63)	0.6510	0.9883
Aromatase inhibitor only	131	71	36	50.7	7.39	(2.27, 14.09)	60	36	60.0	3.78	(2.07, 11.33)	1.12	(0.70, 1.78)	0.6549	0.9883
Tamoxifen only	155	73	30	41.1	13.34	(9.46, NA)	82	41	50.0	13.96	(5.62, 44.39)	1.14	(0.71, 1.84)	0.5910	0.9883
Prior (neo)-adjuvant CDK4/6															
N	322	163	73	44.8	9.53	(7.39, 17.77)	159	84	52.8	8.05	(3.78, 18.40)	1.11	(0.81, 1.53)	0.5298	1.0000
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	13	48.1	7.82	(1.41, NA)	29	14	48.3	11.30	(2.14, 18.92)	0.85	(0.40, 1.81)	0.6627	0.4980
Y	269	137	60	43.8	12.02	(7.43, 23.72)	132	70	53.0	7.59	(3.75, 19.29)	1.19	(0.84, 1.68)	0.3530	0.4980

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Global health status/QoL (revised) (MID >=10)															
All Patients	325	164	85	51.8	7.39	(5.55, 10.58)	161	82	50.9	13.11	(5.91, 22.34)	0.78	(0.57, 1.06)	0.1053	NE
Age group (years)															
<65	266	130	66	50.8	7.66	(5.55, 11.07)	136	72	52.9	11.93	(5.55, 19.35)	0.81	(0.57, 1.14)	0.2167	0.7456
>=65	59	34	19	55.9	6.93	(2.33, 13.14)	25	10	40.0	28.58	(1.15, NA)	0.62	(0.27, 1.43)	0.2487	0.7456
Sex															
F	319	163	85	52.1	7.39	(5.55, 10.58)	156	79	50.6	11.93	(5.91, 19.35)	0.78	(0.57, 1.08)	0.1223	1.0000
M	6	1	0	0.0	NE	NE	5	3	60.0	28.32	(0.95, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	32	51.6	8.97	(3.65, 14.78)	58	33	56.9	11.07	(1.91, 33.28)	0.93	(0.56, 1.54)	0.7694	0.1541
NORTH AMERICA/WESTERN EUROPE	127	64	34	53.1	7.39	(3.94, 13.14)	63	31	49.2	5.91	(1.97, 19.35)	0.97	(0.59, 1.59)	0.8765	0.1541
OTHER	78	38	19	50.0	7.39	(3.29, 11.07)	40	18	45.0	25.53	(11.07, NA)	0.36	(0.17, 0.74)	0.0039	0.1541
Visceral disease (per eCRF)															
N	65	36	24	66.7	7.39	(3.71, 10.15)	29	14	48.3	11.93	(2.07, NA)	0.50	(0.25, 1.01)	0.0496	0.2047
Y	260	128	61	47.7	7.66	(4.40, 14.78)	132	68	51.5	13.11	(4.67, 22.34)	0.89	(0.62, 1.27)	0.4822	0.2047
Ethnicity															
HISPANIC OR LATINO	20	10	7	70.0	10.12	(0.95, 10.58)	10	5	50.0	3.88	(0.99, NA)	0.76	(0.24, 2.40)	0.6489	0.6038
NOT HISPANIC OR LATINO	294	149	75	50.3	7.39	(5.55, 11.56)	145	76	52.4	13.11	(5.91, 22.34)	0.81	(0.58, 1.12)	0.1861	0.6038
NOT REPORTED	5	3	1	33.3	15.74	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	0.6038
UNKNOWN	6	2	2	100.0	6.08	(1.08, NA)	4	1	25.0	1.87	(1.87, NA)	0.39	(0.03, 4.44)	0.4328	0.6038
Race															
Asian	124	63	32	50.8	8.97	(3.65, 14.78)	61	34	55.7	11.07	(3.65, 33.28)	0.92	(0.56, 1.51)	0.7284	0.1010
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.1010
White	191	97	51	52.6	7.39	(4.40, 10.15)	94	48	51.1	13.11	(3.98, 22.34)	0.72	(0.47, 1.08)	0.1055	0.1010
Unknown	8	3	2	66.7	8.41	(1.08, NA)	5	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.0624	0.1010
Liver Metastasis at Enrollment															
N	157	73	41	56.2	7.39	(4.40, 10.58)	84	39	46.4	19.35	(5.91, 31.15)	0.64	(0.41, 1.01)	0.0511	0.1943
Y	168	91	44	48.4	7.66	(3.94, 14.78)	77	43	55.8	11.07	(2.14, 15.28)	0.95	(0.62, 1.47)	0.8179	0.1943
Number Metastatic Organs at Enrollment															
1	53	32	17	53.1	11.86	(3.71, 15.05)	21	10	47.6	10.38	(0.99, NA)	0.80	(0.35, 1.86)	0.5743	0.4595
2	104	46	30	65.2	5.78	(3.65, 9.69)	58	28	48.3	11.83	(3.78, NA)	0.63	(0.37, 1.07)	0.0812	0.4595
>=3	168	86	38	44.2	7.39	(3.94, NA)	82	44	53.7	13.96	(4.67, 25.53)	0.86	(0.55, 1.36)	0.5149	0.4595
ECOG Performance Status at Baseline															
0	206	106	53	50.0	9.69	(5.59, 11.56)	100	52	52.0	13.96	(3.94, 22.34)	0.89	(0.60, 1.32)	0.5336	0.3875
1	118	58	32	55.2	5.55	(2.79, 11.56)	60	30	50.0	11.93	(3.98, 30.03)	0.60	(0.36, 1.02)	0.0558	0.3875
Endocrine Resistance (per eCRF)															
Primary	112	58	33	56.9	5.55	(2.79, 7.39)	54	32	59.3	7.39	(1.91, 19.35)	0.75	(0.45, 1.25)	0.2611	0.8773

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Secondary	212	105	51	48.6	10.15	(5.59, 14.78)	107	50	46.7	14.95	(7.59, 30.03)	0.79	(0.53, 1.19)	0.2405	0.8773
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	28	53.8	6.70	(3.94, 14.78)	52	25	48.1	14.78	(5.55, NA)	0.71	(0.41, 1.23)	0.2199	0.6826
POST-MENOPAUSAL	215	111	57	51.4	7.66	(4.11, 11.07)	104	54	51.9	11.83	(3.78, 25.53)	0.83	(0.56, 1.22)	0.3154	0.6826
Hormone receptor status															
ER+/PR-	90	45	20	44.4	11.56	(5.55, 15.74)	45	22	48.9	15.28	(4.67, 30.03)	0.85	(0.46, 1.58)	0.5909	0.0795
ER+/PR+	226	113	61	54.0	6.70	(3.94, 10.15)	113	60	53.1	11.07	(3.78, 25.53)	0.80	(0.55, 1.16)	0.2270	0.0795
Other	9	6	4	66.7	5.59	(1.18, NA)	3	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.0788	0.0795
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	11	57.9	7.66	(2.10, NA)	18	7	38.9	NE	(0.95, NA)	0.67	(0.26, 1.78)	0.4202	0.5890
Aromatase inhibitor only	131	71	33	46.5	9.69	(5.55, 13.14)	60	29	48.3	11.83	(3.45, 31.15)	0.91	(0.55, 1.52)	0.6985	0.5890
Tamoxifen only	155	73	40	54.8	6.47	(3.71, 11.56)	82	46	56.1	13.96	(5.55, 25.53)	0.74	(0.48, 1.15)	0.1721	0.5890
Prior (neo)-adjuvant CDK4/6															
N	322	163	85	52.1	7.39	(5.55, 10.15)	159	82	51.6	13.11	(5.91, 22.34)	0.76	(0.56, 1.05)	0.0867	1.0000
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	15	55.6	6.93	(1.41, 13.14)	29	14	48.3	11.83	(1.97, NA)	0.70	(0.33, 1.49)	0.3485	0.9757
Y	269	137	70	51.1	8.97	(4.86, 11.56)	132	68	51.5	13.11	(5.55, 25.53)	0.79	(0.56, 1.11)	0.1625	0.9757
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Role functioning (revised) (MID >=10)															
All Patients	325	164	84	51.2	5.78	(3.94, 11.27)	161	92	57.1	6.01	(3.65, 11.93)	1.07	(0.79, 1.44)	0.6793	NE
Age group (years)															
<65	266	130	67	51.5	8.08	(3.78, 18.17)	136	79	58.1	6.01	(2.20, 14.78)	1.04	(0.75, 1.45)	0.8050	0.5629
>=65	59	34	17	50.0	4.11	(2.37, NA)	25	13	52.0	5.49	(1.87, 18.92)	1.30	(0.63, 2.69)	0.5003	0.5629
Sex															
F	319	163	84	51.5	5.78	(3.94, 11.27)	156	88	56.4	5.55	(3.65, 11.30)	1.08	(0.80, 1.46)	0.6305	1.0000
M	6	1	0	0.0	NE	NE	5	4	80.0	21.59	(1.87, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	35	56.5	5.78	(2.92, 18.17)	58	41	70.7	3.65	(1.02, 11.93)	1.24	(0.78, 1.95)	0.3858	0.6553
NORTH AMERICA/WESTERN EUROPE	127	64	31	48.4	5.59	(3.68, 26.48)	63	28	44.4	6.01	(3.45, NA)	0.96	(0.58, 1.61)	0.8961	0.6553
OTHER	78	38	18	47.4	10.35	(2.37, NA)	40	23	57.5	11.07	(1.91, 35.09)	0.89	(0.47, 1.68)	0.7113	0.6553
Visceral disease (per eCRF)															
N	65	36	20	55.6	3.75	(0.95, 22.70)	29	13	44.8	21.59	(4.57, NA)	0.57	(0.28, 1.16)	0.1326	0.0338
Y	260	128	64	50.0	8.08	(3.94, 18.17)	132	79	59.8	3.71	(1.87, 9.92)	1.25	(0.89, 1.74)	0.2097	0.0338
Ethnicity															
HISPANIC OR LATINO	20	10	4	40.0	26.48	(0.95, NA)	10	4	40.0	21.59	(1.41, NA)	1.49	(0.37, 6.07)	0.5762	0.0523
NOT HISPANIC OR LATINO	294	149	76	51.0	5.59	(3.78, 11.27)	145	87	60.0	5.52	(3.45, 11.07)	1.13	(0.83, 1.54)	0.4554	0.0523
NOT REPORTED	5	3	2	66.7	1.07	(0.95, NA)	2	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.0896	0.0523

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
UNKNOWN	6	2	2	100.0	6.08	(1.08, NA)	4	1	25.0	1.87	(1.87, NA)	0.39	(0.03, 4.44)	0.4328	0.0523
Race															
Asian	124	63	35	55.6	5.78	(2.92, 18.17)	61	42	68.9	3.71	(1.02, 11.93)	1.20	(0.76, 1.89)	0.4557	0.0164
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.0164
White	191	97	47	48.5	7.39	(3.78, 24.25)	94	50	53.2	7.98	(3.68, 18.92)	1.02	(0.68, 1.52)	0.9116	0.0164
Unknown	8	3	2	66.7	1.13	(1.08, NA)	5	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.0389	0.0164
Liver Metastasis at Enrollment															
N	157	73	41	56.2	5.59	(2.10, 22.70)	84	47	56.0	7.98	(3.65, 21.16)	0.93	(0.61, 1.41)	0.7559	0.3384
Y	168	91	43	47.3	9.26	(3.75, 26.48)	77	45	58.4	3.71	(1.87, 11.30)	1.24	(0.81, 1.89)	0.3450	0.3384
Number Metastatic Organs at Enrollment															
1	53	32	21	65.6	3.68	(1.08, 11.07)	21	11	52.4	6.32	(1.02, NA)	0.74	(0.35, 1.53)	0.4204	0.2247
2	104	46	21	45.7	8.08	(3.94, NA)	58	31	53.4	14.26	(3.71, 35.09)	1.09	(0.62, 1.90)	0.7691	0.2247
>=3	168	86	42	48.8	8.97	(3.78, 24.25)	82	50	61.0	3.71	(1.87, 11.07)	1.32	(0.87, 1.99)	0.2053	0.2247
ECOG Performance Status at Baseline															
0	206	106	54	50.9	8.97	(3.78, 24.25)	100	59	59.0	5.55	(2.10, 14.78)	1.08	(0.74, 1.56)	0.7102	0.9668
1	118	58	30	51.7	4.04	(2.27, 22.70)	60	33	55.0	8.08	(1.87, 21.59)	1.04	(0.63, 1.71)	0.8873	0.9668
Endocrine Resistance (per eCRF)															
Primary	112	58	29	50.0	3.71	(1.87, NA)	54	33	61.1	10.84	(3.71, 17.28)	0.91	(0.54, 1.51)	0.7126	0.6166
Secondary	212	105	55	52.4	9.26	(4.04, 22.70)	107	59	55.1	4.04	(1.87, 14.26)	1.13	(0.78, 1.64)	0.5297	0.6166
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	26	50.0	5.59	(2.14, NA)	52	32	61.5	6.77	(1.91, 11.93)	1.15	(0.68, 1.94)	0.6045	0.7147
POST-MENOPAUSAL	215	111	58	52.3	7.39	(3.75, 11.27)	104	56	53.8	5.49	(2.07, 18.92)	1.01	(0.70, 1.47)	0.9671	0.7147
Hormone receptor status															
ER+/PR-	90	45	24	53.3	8.08	(1.87, 11.27)	45	24	53.3	7.20	(1.87, 37.62)	0.87	(0.49, 1.56)	0.6230	0.4861
ER+/PR+	226	113	56	49.6	5.59	(3.75, 24.38)	113	67	59.3	5.55	(3.45, 11.93)	1.18	(0.83, 1.69)	0.3426	0.4861
Other	9	6	4	66.7	8.33	(3.94, NA)	3	1	33.3	0.95	(0.95, NA)	0.53	(0.06, 4.97)	0.5738	0.4861
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	10	52.6	4.68	(1.18, NA)	18	9	50.0	3.65	(0.95, NA)	1.18	(0.48, 2.92)	0.7440	0.9233
Aromatase inhibitor only	131	71	35	49.3	4.17	(3.75, 24.38)	60	35	58.3	4.04	(1.87, 11.30)	1.13	(0.70, 1.81)	0.6137	0.9233
Tamoxifen only	155	73	38	52.1	9.79	(3.65, 24.25)	82	48	58.5	9.46	(3.71, 21.59)	1.04	(0.68, 1.60)	0.8602	0.9233
Prior (neo)-adjuvant CDK4/6															
N	322	163	83	50.9	5.78	(3.94, 11.27)	159	92	57.9	6.01	(3.65, 11.93)	1.08	(0.80, 1.45)	0.6343	1.0000
Y	3	1	1	100.0	0.95	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	11	40.7	18.17	(1.18, NA)	29	16	55.2	11.07	(1.05, 21.16)	1.70	(0.79, 3.68)	0.1707	0.1405
Y	269	137	73	53.3	4.17	(3.75, 10.35)	132	76	57.6	5.55	(2.20, 14.26)	0.95	(0.68, 1.32)	0.7325	0.1405
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Social functioning (MID >=10)															

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
All Patients	325	164	78	47.6	9.23	(4.44, 19.35)	161	97	60.2	6.01	(3.71, 9.46)	1.26	(0.93, 1.69)	0.1403	NE
Age group (years)															
<65	266	130	62	47.7	7.43	(3.94, 19.35)	136	83	61.0	6.01	(3.71, 9.89)	1.16	(0.84, 1.62)	0.3769	0.2177
>=65	59	34	16	47.1	16.59	(2.20, 26.71)	25	14	56.0	4.40	(0.95, 14.26)	2.04	(0.97, 4.31)	0.0572	0.2177
Sex															
F	319	163	78	47.9	9.23	(4.44, 19.35)	156	93	59.6	6.01	(3.78, 9.76)	1.25	(0.92, 1.69)	0.1547	1.0000
M	6	1	0	0.0	NE	NE	5	4	80.0	2.37	(0.95, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	30	48.4	7.62	(3.71, NA)	58	44	75.9	3.78	(1.87, 7.49)	1.57	(0.99, 2.51)	0.0561	0.4381
NORTH AMERICA/WESTERN EUROPE	127	64	33	51.6	10.61	(3.88, 16.59)	63	31	49.2	5.62	(2.37, 14.78)	1.14	(0.69, 1.87)	0.6086	0.4381
OTHER	78	38	15	39.5	9.23	(1.87, NA)	40	22	55.0	12.98	(5.55, 20.76)	1.01	(0.52, 1.97)	0.9874	0.4381
Visceral disease (per eCRF)															
N	65	36	19	52.8	5.59	(1.97, 26.71)	29	14	48.3	20.76	(2.56, NA)	0.70	(0.34, 1.44)	0.3268	0.0991
Y	260	128	59	46.1	9.23	(5.49, 16.59)	132	83	62.9	5.55	(3.71, 8.05)	1.40	(1.00, 1.95)	0.0507	0.0991
Ethnicity															
HISPANIC OR LATINO	20	10	7	70.0	18.04	(1.22, NA)	10	3	30.0	NE	(1.41, NA)	0.82	(0.18, 3.65)	0.7891	0.0393
NOT HISPANIC OR LATINO	294	149	69	46.3	7.62	(4.17, 19.35)	145	90	62.1	7.20	(3.78, 9.76)	1.27	(0.93, 1.74)	0.1391	0.0393
NOT REPORTED	5	3	1	33.3	15.74	NE	2	2	100.0	0.94	(0.92, NA)	>999.99	(0.00, >999.99)	0.0896	0.0393
UNKNOWN	6	2	1	50.0	3.71	NE	4	2	50.0	1.38	(0.89, NA)	>999.99	(0.00, >999.99)	0.0896	0.0393
Race															
Asian	124	63	30	47.6	7.62	(3.71, NA)	61	46	75.4	3.78	(1.87, 7.49)	1.59	(1.00, 2.53)	0.0471	0.2996
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.2996
White	191	97	47	48.5	7.66	(3.71, 16.59)	94	50	53.2	9.46	(4.40, 14.26)	1.00	(0.67, 1.49)	0.9906	0.2996
Unknown	8	3	1	33.3	15.74	NE	5	1	20.0	NE	(0.89, NA)	0.82	(0.05, 13.24)	0.8864	0.2996
Liver Metastasis at Enrollment															
N	157	73	38	52.1	11.30	(2.37, 24.25)	84	50	59.5	7.20	(3.71, 11.99)	1.17	(0.77, 1.79)	0.4673	0.6611
Y	168	91	40	44.0	7.62	(4.44, 25.56)	77	47	61.0	5.55	(1.87, 11.37)	1.35	(0.88, 2.06)	0.1729	0.6611
Number Metastatic Organs at Enrollment															
1	53	32	18	56.2	3.71	(1.97, NA)	21	14	66.7	2.33	(0.95, 4.17)	1.49	(0.74, 3.00)	0.2589	0.0040
2	104	46	31	67.4	4.17	(2.92, 7.66)	58	30	51.7	11.37	(3.71, 35.52)	0.63	(0.38, 1.05)	0.0710	0.0040
>=3	168	86	29	33.7	25.56	(16.59, NA)	82	53	64.6	7.43	(3.65, 9.89)	2.07	(1.31, 3.25)	0.0014	0.0040
ECOG Performance Status at Baseline															
0	206	106	48	45.3	7.66	(5.59, 25.56)	100	61	61.0	8.21	(4.17, 12.98)	1.16	(0.79, 1.70)	0.4388	0.6529
1	118	58	30	51.7	4.44	(2.00, 19.35)	60	36	60.0	3.71	(1.18, 7.49)	1.35	(0.83, 2.19)	0.2441	0.6529
Endocrine Resistance (per eCRF)															
Primary	112	58	26	44.8	10.61	(2.92, 19.35)	54	35	64.8	7.59	(2.37, 11.37)	1.25	(0.75, 2.08)	0.3961	0.8280
Secondary	212	105	51	48.6	9.23	(3.94, 25.56)	107	62	57.9	5.62	(3.68, 11.56)	1.24	(0.86, 1.80)	0.2546	0.8280
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	23	44.2	6.70	(5.49, NA)	52	35	67.3	7.43	(2.56, 11.07)	1.28	(0.75, 2.18)	0.3622	0.7785

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
POST-MENOPAUSAL	215	111	55	49.5	10.61	(3.71, 24.25)	104	58	55.8	5.62	(3.71, 11.37)	1.19	(0.82, 1.73)	0.3598	0.7785
Hormone receptor status															
ER+/PR-	90	45	17	37.8	15.74	(5.98, NA)	45	29	64.4	3.71	(1.18, 9.76)	1.95	(1.07, 3.56)	0.0260	0.2781
ER+/PR+	226	113	58	51.3	7.43	(3.88, 19.35)	113	67	59.3	7.59	(3.78, 11.99)	1.10	(0.77, 1.56)	0.6134	0.2781
Other	9	6	3	50.0	5.59	(1.18, NA)	3	1	33.3	3.91	(3.91, NA)	0.54	(0.05, 5.29)	0.5877	0.2781
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	8	42.1	15.74	(1.97, NA)	18	10	55.6	3.88	(1.18, NA)	1.79	(0.70, 4.56)	0.2118	0.7196
Aromatase inhibitor only	131	71	34	47.9	11.30	(2.33, 25.56)	60	35	58.3	3.94	(1.87, 11.37)	1.30	(0.81, 2.08)	0.2887	0.7196
Tamoxifen only	155	73	36	49.3	6.01	(3.71, 24.25)	82	52	63.4	8.05	(5.49, 11.99)	1.11	(0.73, 1.71)	0.6165	0.7196
Prior (neo)-adjuvant CDK4/6															
N	322	163	78	47.9	7.66	(4.44, 16.59)	159	97	61.0	6.01	(3.71, 9.46)	1.24	(0.92, 1.67)	0.1632	1.0000
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	14	51.9	5.98	(1.41, 29.21)	29	16	55.2	3.94	(0.95, 13.96)	1.32	(0.64, 2.71)	0.4836	0.9010
Y	269	137	64	46.7	10.61	(4.44, 24.25)	132	81	61.4	6.01	(3.78, 9.46)	1.24	(0.89, 1.73)	0.1978	0.9010
EORTC QLQ-C30: Time to Unconfirmed Deterioration in Insomnia (MID >=10)															
All Patients	325	164	62	37.8	16.62	(9.46, 26.48)	161	77	47.8	13.96	(11.01, 19.15)	1.13	(0.81, 1.59)	0.4661	NE
Age group (years)															
<65	266	130	47	36.2	11.53	(8.08, NA)	136	65	47.8	14.23	(11.01, 20.24)	1.05	(0.72, 1.53)	0.8188	0.3638
>=65	59	34	15	44.1	22.60	(5.98, 32.26)	25	12	48.0	14.26	(0.95, 34.56)	1.50	(0.69, 3.23)	0.3168	0.3638
Sex															
F	319	163	62	38.0	16.62	(9.46, 26.48)	156	74	47.4	13.96	(11.01, 18.37)	1.15	(0.82, 1.61)	0.4370	1.0000
M	6	1	0	0.0	NE	NE	5	3	60.0	24.48	(0.95, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	24	38.7	11.53	(5.85, NA)	58	29	50.0	16.76	(7.62, 24.48)	1.05	(0.61, 1.81)	0.8692	0.8882
NORTH AMERICA/WESTERN EUROPE	127	64	27	42.2	11.30	(8.08, 26.48)	63	29	46.0	9.49	(3.91, 20.30)	1.30	(0.77, 2.20)	0.3291	0.8882
OTHER	78	38	11	28.9	32.26	(4.11, NA)	40	19	47.5	14.23	(11.07, 34.56)	1.21	(0.57, 2.55)	0.6267	0.8882
Visceral disease (per eCRF)															
N	65	36	15	41.7	11.53	(7.52, NA)	29	13	44.8	13.34	(5.72, NA)	0.88	(0.41, 1.86)	0.7363	0.4570
Y	260	128	47	36.7	18.17	(9.46, 26.48)	132	64	48.5	14.23	(10.84, 19.15)	1.20	(0.83, 1.76)	0.3398	0.4570
Ethnicity															
HISPANIC OR LATINO	20	10	4	40.0	26.48	(2.10, NA)	10	4	40.0	13.34	(0.95, NA)	1.13	(0.28, 4.56)	0.8655	0.4063
NOT HISPANIC OR LATINO	294	149	57	38.3	16.62	(9.46, 22.60)	145	70	48.3	14.23	(11.01, 20.24)	1.08	(0.76, 1.54)	0.6656	0.4063
NOT REPORTED	5	3	0	0.0	NE	NE	2	1	50.0	0.95	(0.95, NA)	>999.99	(0.00, >999.99)	0.3173	0.4063
UNKNOWN	6	2	1	50.0	1.08	(1.08, NA)	4	2	50.0	4.75	(3.78, NA)	1.62	(0.14, 18.31)	0.6949	0.4063
Race															
Asian	124	63	24	38.1	11.53	(5.85, NA)	61	31	50.8	16.76	(7.39, 20.93)	1.11	(0.65, 1.90)	0.7069	0.7713
Black or African American	2	1	1	100.0	8.08	NE	1	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	0.7713
White	191	97	36	37.1	18.66	(8.28, 32.26)	94	45	47.9	11.56	(7.36, 20.30)	1.18	(0.76, 1.83)	0.4601	0.7713

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Unknown	8	3	1	33.3	1.08	(1.08, NA)	5	1	20.0	NE	(5.72, NA)	0.47	(0.03, 7.86)	0.5924	0.7713
Liver Metastasis at Enrollment															
N	157	73	29	39.7	18.66	(9.92, NA)	84	43	51.2	14.23	(7.62, 20.24)	1.30	(0.81, 2.07)	0.2824	0.4166
Y	168	91	33	36.3	18.17	(5.85, 26.48)	77	34	44.2	13.96	(6.24, 29.57)	1.00	(0.61, 1.61)	0.9776	0.4166
Number Metastatic Organs at Enrollment															
1	53	32	12	37.5	11.53	(3.71, NA)	21	9	42.9	10.84	(1.91, NA)	1.23	(0.52, 2.92)	0.6443	0.4542
2	104	46	21	45.7	9.46	(5.75, 32.26)	58	27	46.6	15.97	(11.01, 29.57)	0.85	(0.48, 1.52)	0.5897	0.4542
>=3	168	86	29	33.7	18.17	(9.66, NA)	82	41	50.0	11.30	(6.24, 20.30)	1.39	(0.86, 2.24)	0.1841	0.4542
ECOG Performance Status at Baseline															
0	206	106	38	35.8	18.17	(7.82, NA)	100	48	48.0	14.26	(9.49, 20.30)	1.13	(0.73, 1.73)	0.5938	0.9990
1	118	58	24	41.4	16.62	(5.78, 32.26)	60	29	48.3	13.34	(7.36, 20.93)	1.17	(0.68, 2.01)	0.5825	0.9990
Endocrine Resistance (per eCRF)															
Primary	112	58	18	31.0	11.30	(7.52, NA)	54	24	44.4	15.97	(10.84, NA)	0.95	(0.51, 1.79)	0.8893	0.5550
Secondary	212	105	44	41.9	18.17	(9.46, 26.48)	107	53	49.5	11.56	(6.24, 19.15)	1.21	(0.81, 1.81)	0.3478	0.5550
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	21	40.4	8.28	(5.78, NA)	52	27	51.9	11.07	(6.21, 20.24)	0.99	(0.56, 1.77)	0.9693	0.6576
POST-MENOPAUSAL	215	111	41	36.9	18.66	(9.92, 32.26)	104	47	45.2	14.23	(10.84, 20.30)	1.20	(0.79, 1.83)	0.3851	0.6576
Hormone receptor status															
ER+/PR-	90	45	21	46.7	8.28	(5.45, NA)	45	19	42.2	13.96	(9.49, NA)	0.66	(0.35, 1.24)	0.1924	0.1064
ER+/PR+	226	113	37	32.7	22.60	(9.92, NA)	113	57	50.4	14.23	(7.36, 19.15)	1.46	(0.97, 2.22)	0.0721	0.1064
Other	9	6	4	66.7	16.62	(1.91, NA)	3	1	33.3	2.07	(2.07, NA)	1.34	(0.12, 15.07)	0.8132	0.1064
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	8	42.1	11.53	(2.10, NA)	18	11	61.1	2.07	(0.95, 18.37)	2.24	(0.87, 5.81)	0.0888	0.1003
Aromatase inhibitor only	131	71	28	39.4	11.30	(7.82, 26.48)	60	21	35.0	20.30	(11.07, NA)	0.72	(0.41, 1.27)	0.2560	0.1003
Tamoxifen only	155	73	26	35.6	16.62	(8.08, NA)	82	45	54.9	13.34	(6.24, 19.15)	1.36	(0.84, 2.21)	0.2113	0.1003
Prior (neo)-adjuvant CDK4/6															
N	322	163	62	38.0	16.62	(9.46, 26.48)	159	77	48.4	13.96	(11.01, 19.15)	1.12	(0.80, 1.57)	0.5080	1.0000
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	12	44.4	10.55	(5.98, NA)	29	16	55.2	11.07	(3.71, 20.30)	1.32	(0.62, 2.80)	0.4795	0.6193
Y	269	137	50	36.5	18.66	(9.46, 32.26)	132	61	46.2	14.98	(11.01, 20.93)	1.11	(0.76, 1.62)	0.5938	0.6193

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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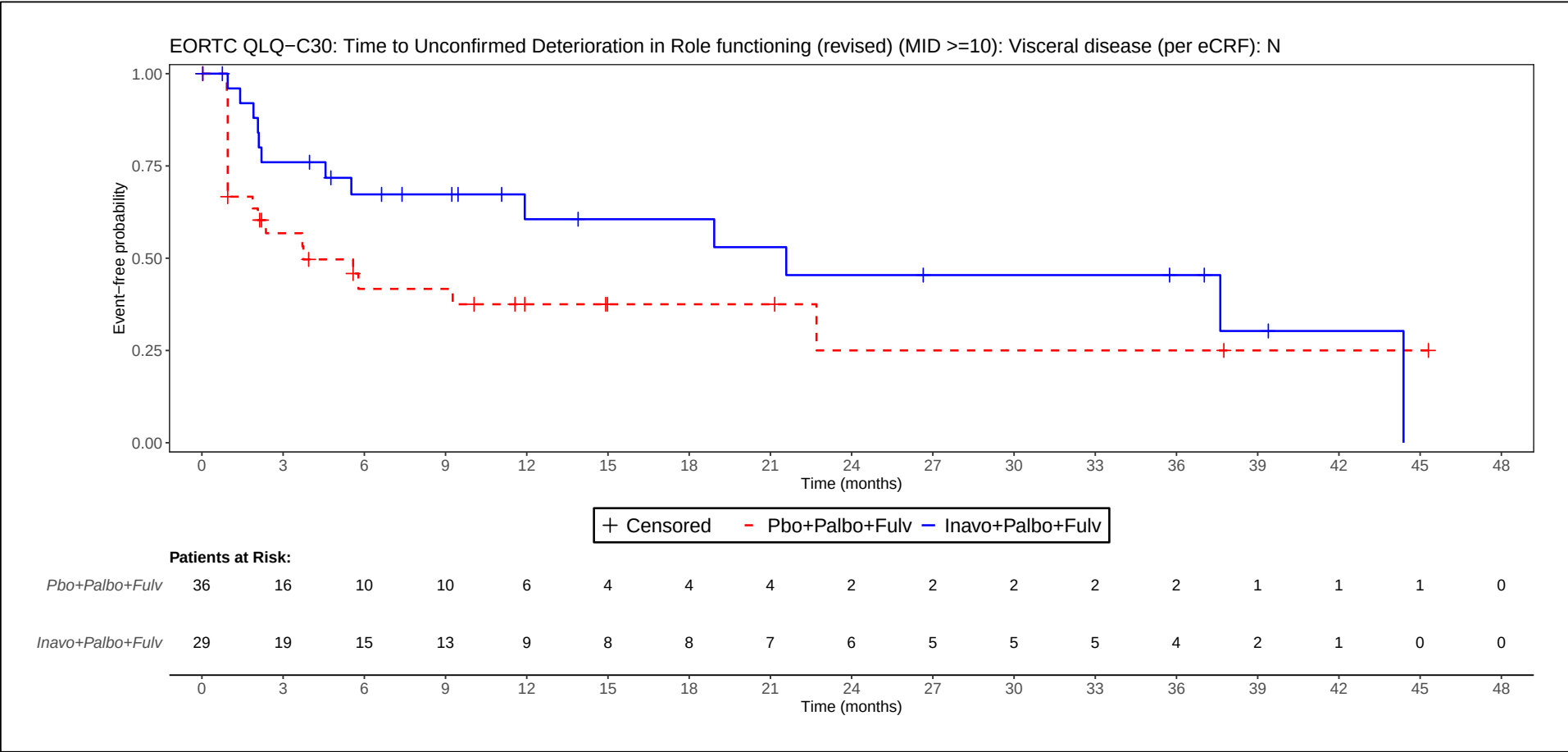
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

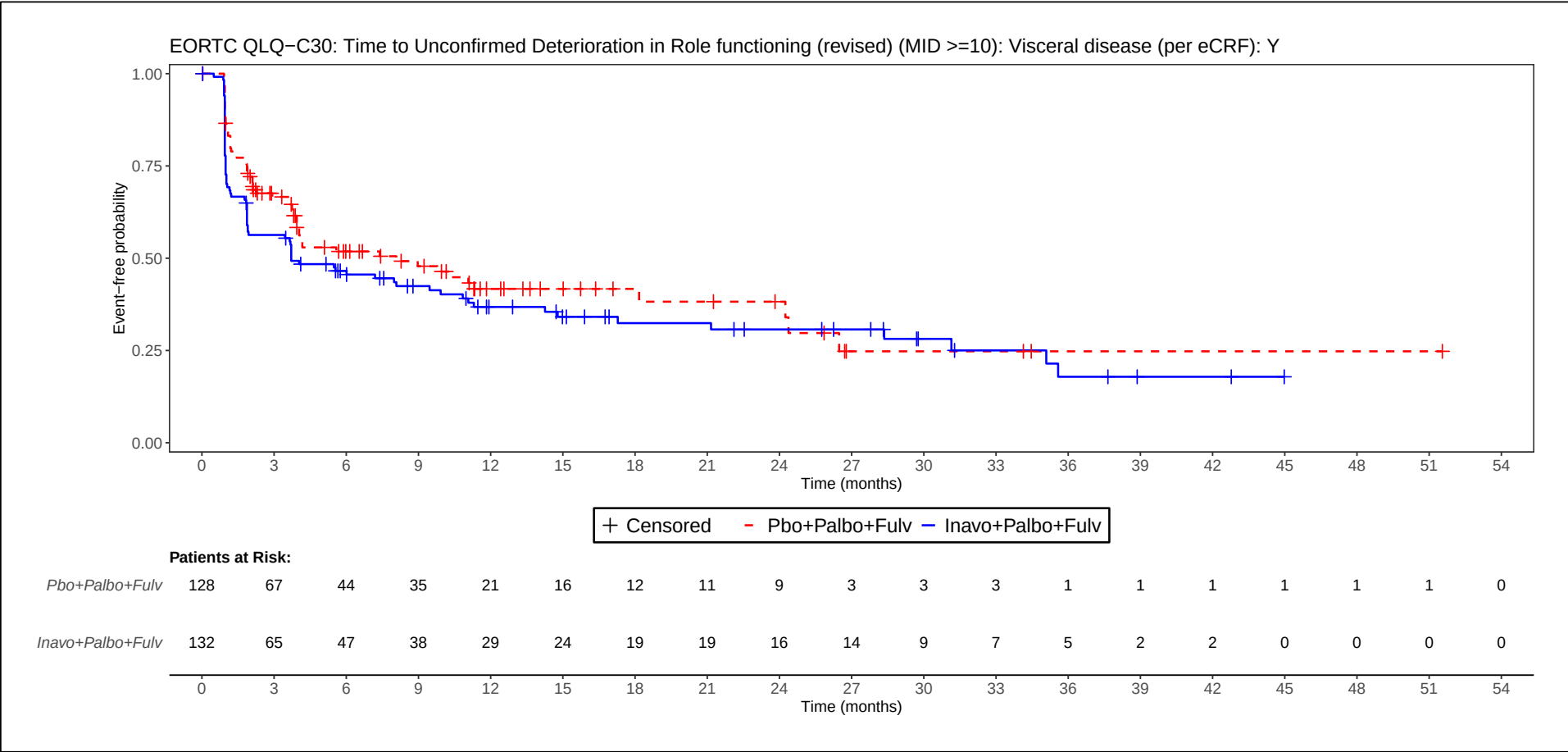
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

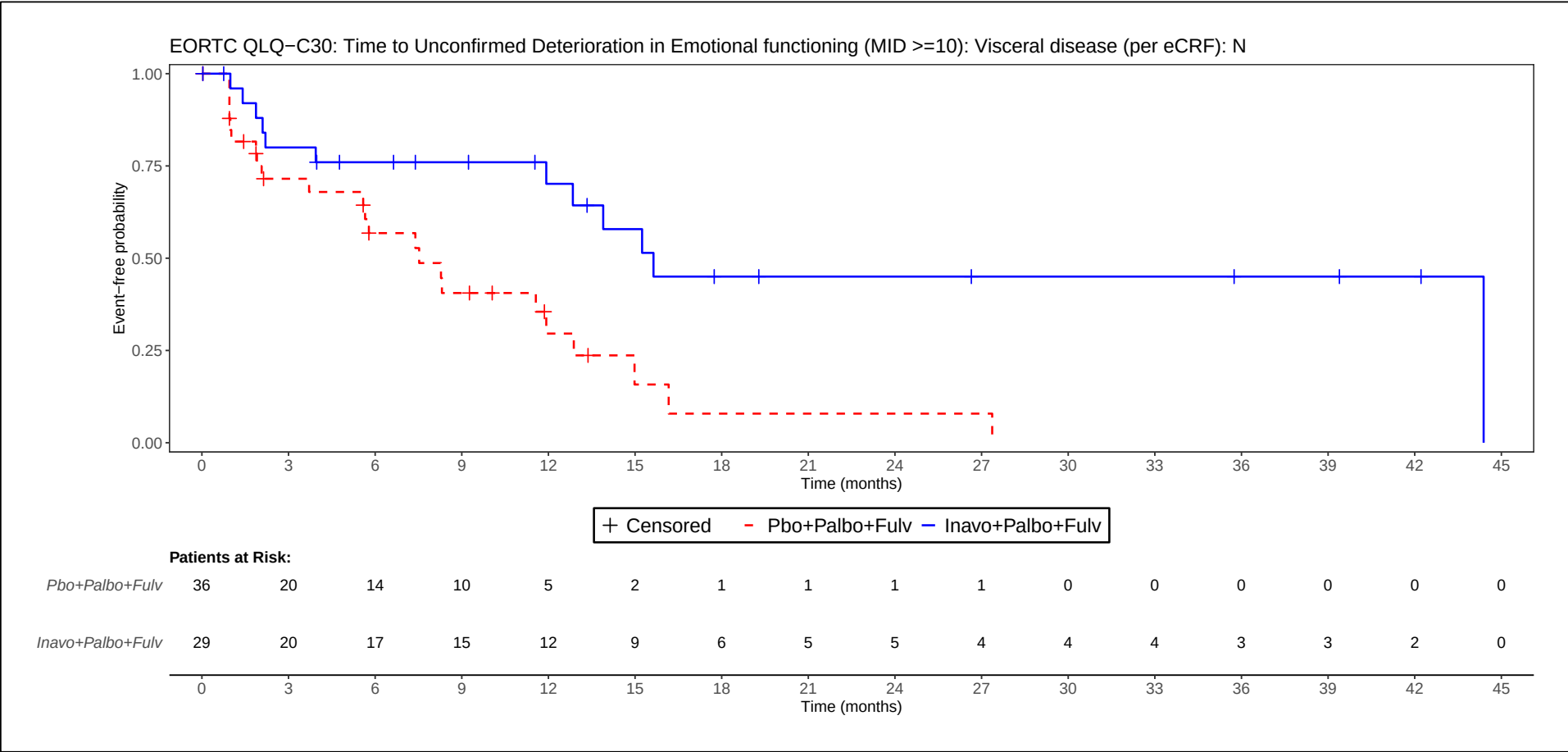
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

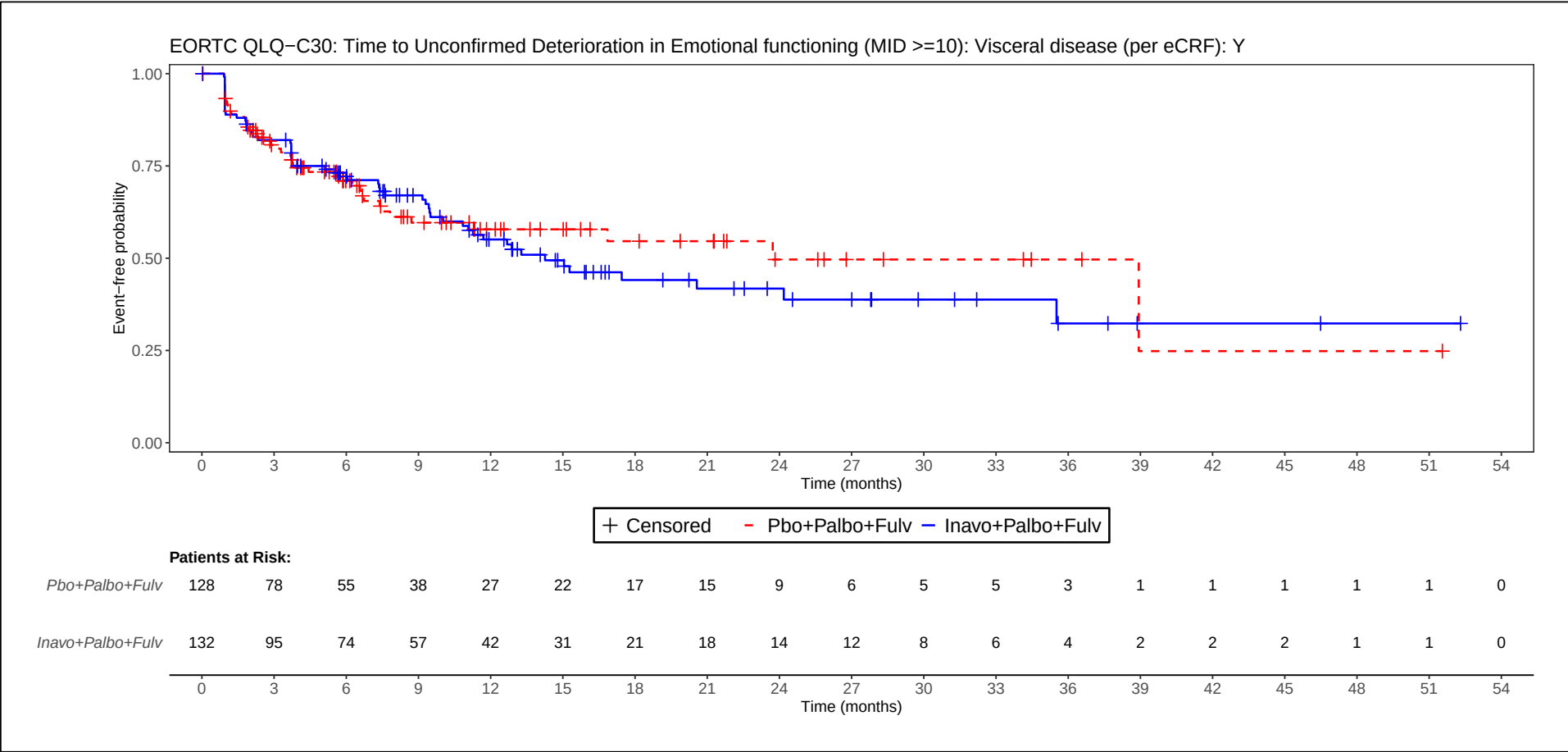
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

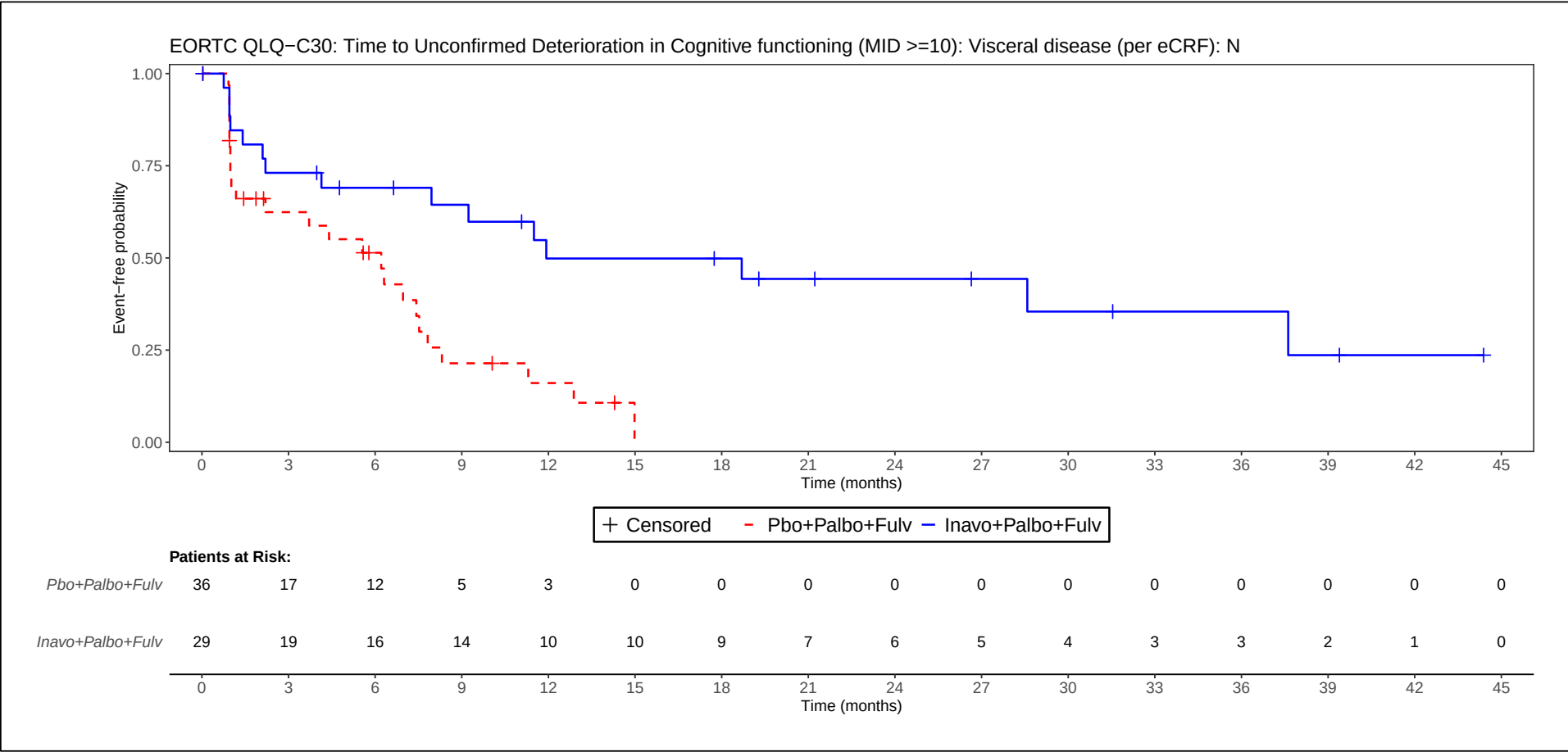
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

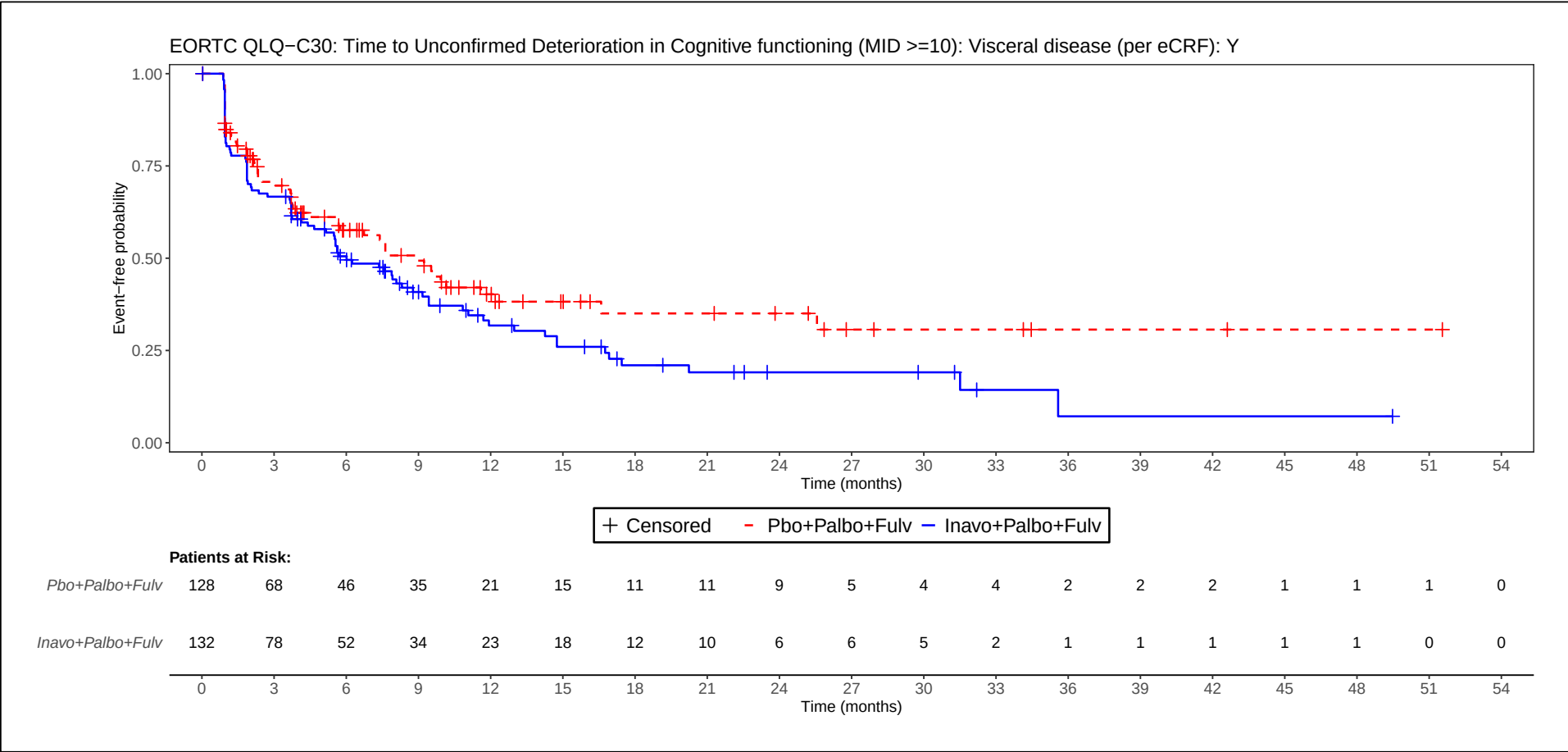
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

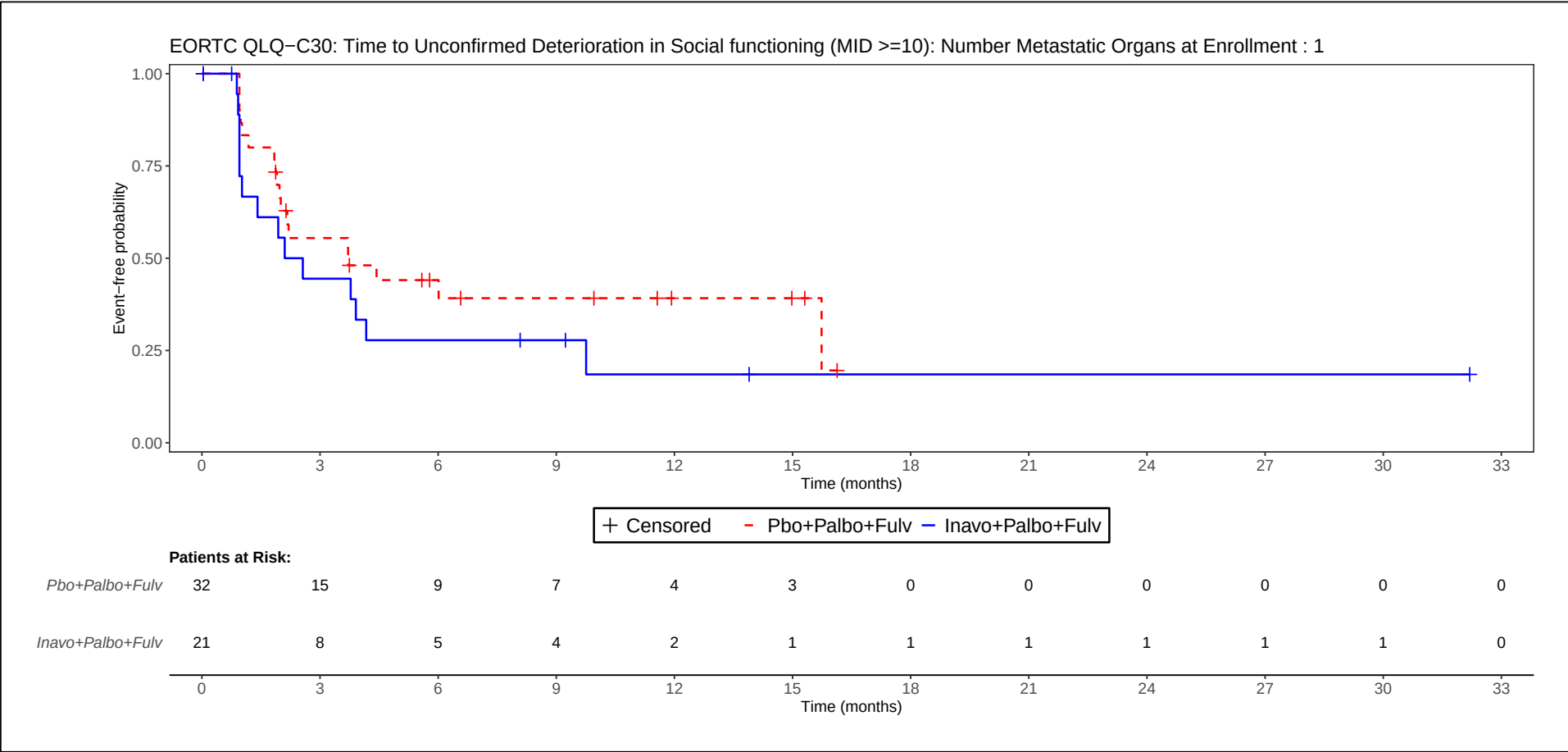
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

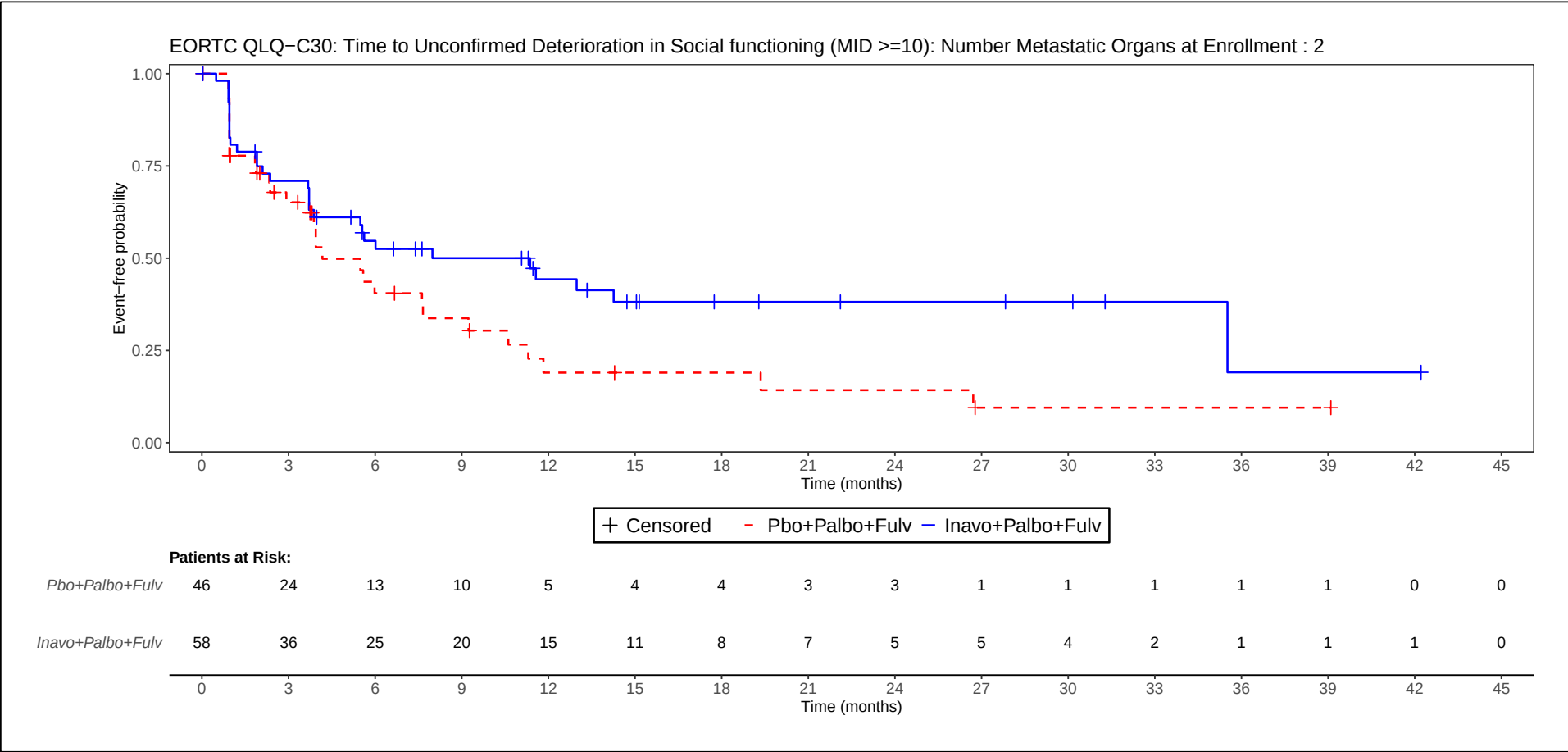
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

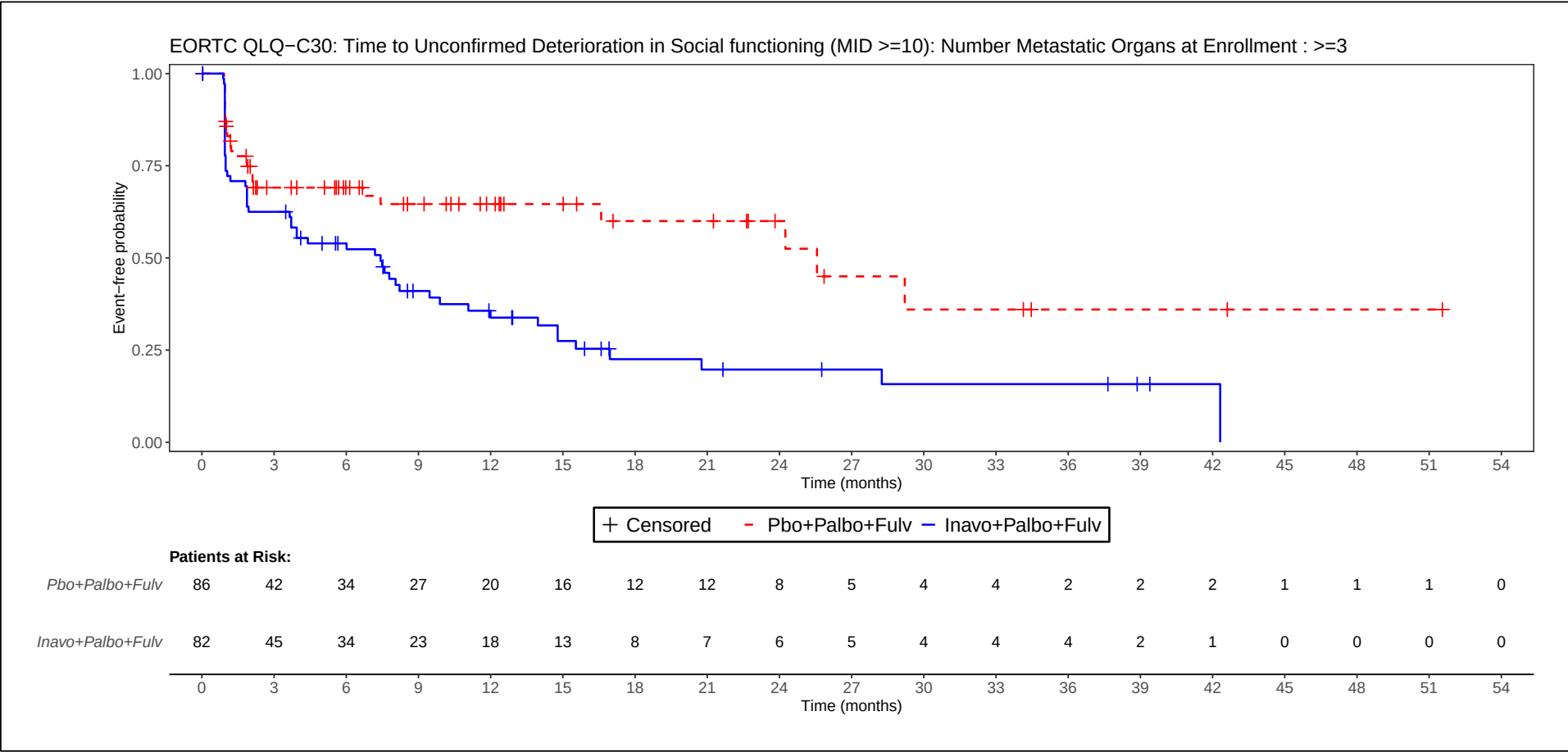
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

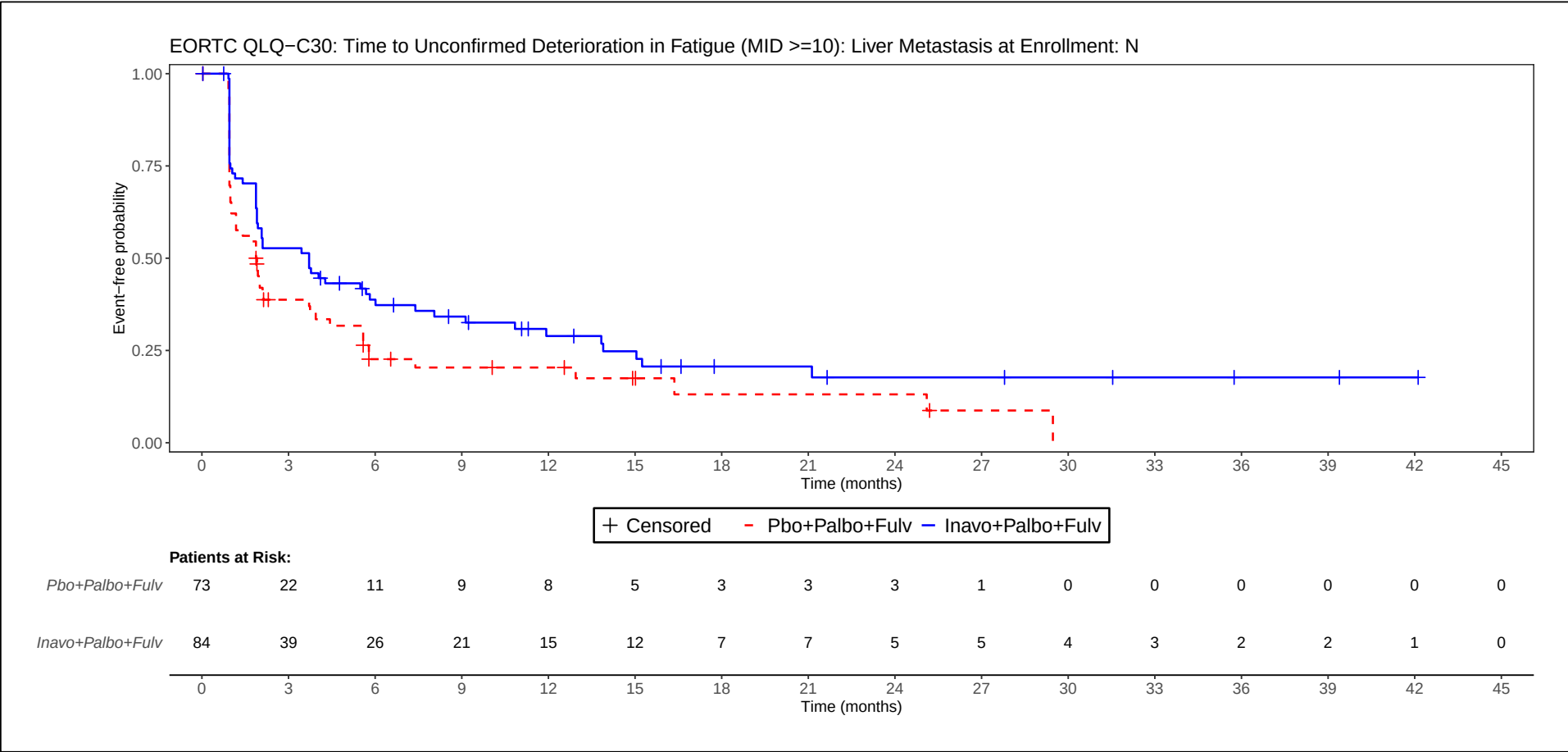
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

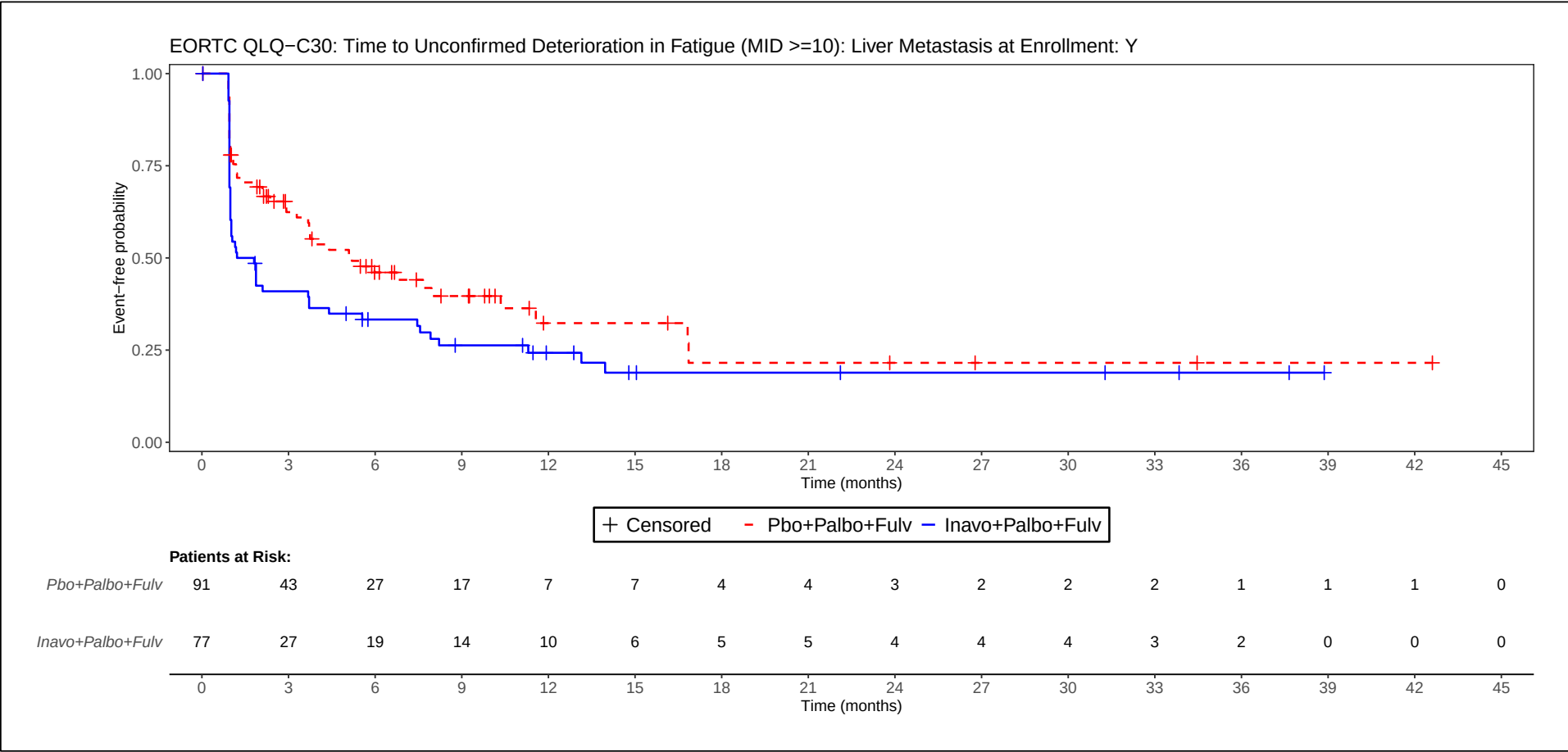
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

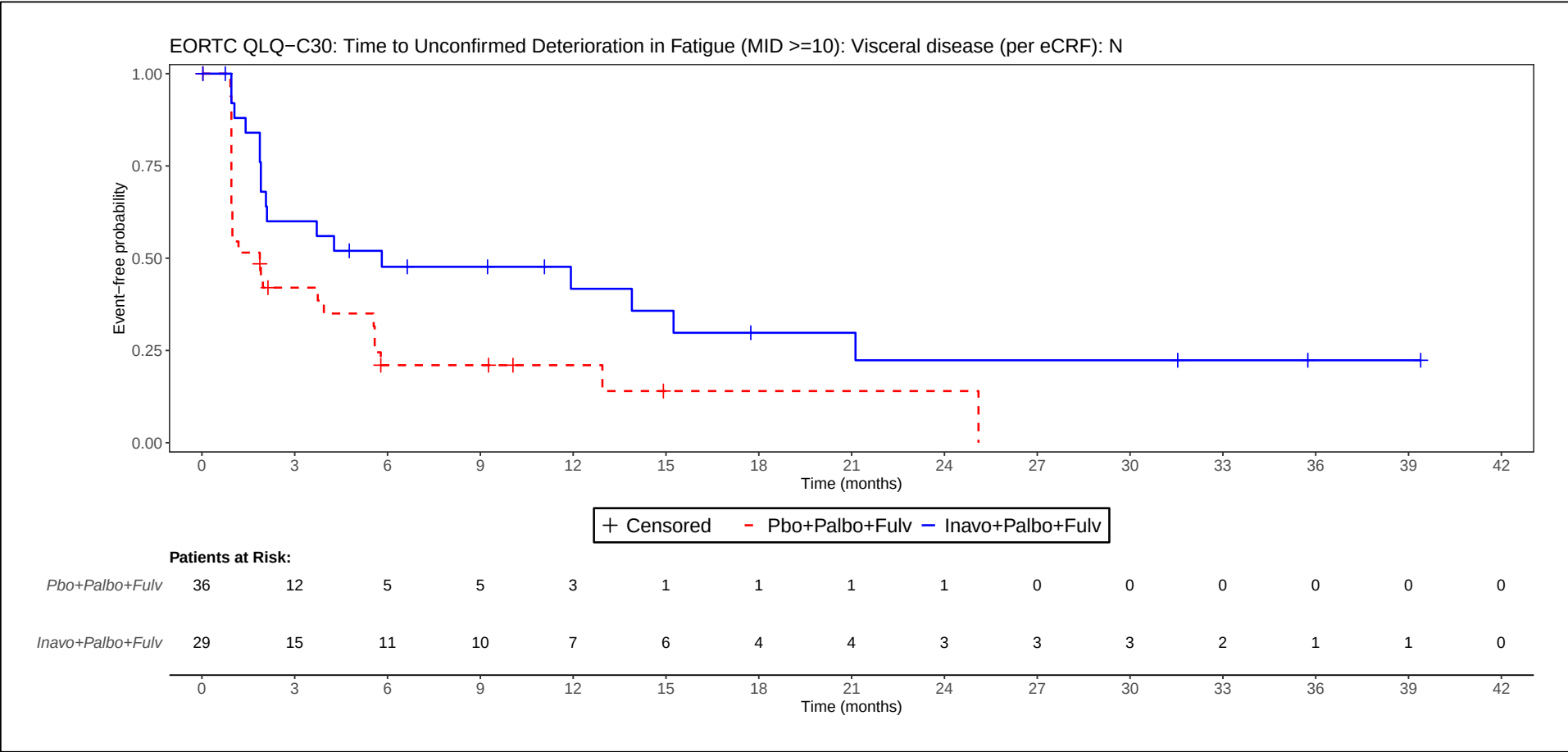
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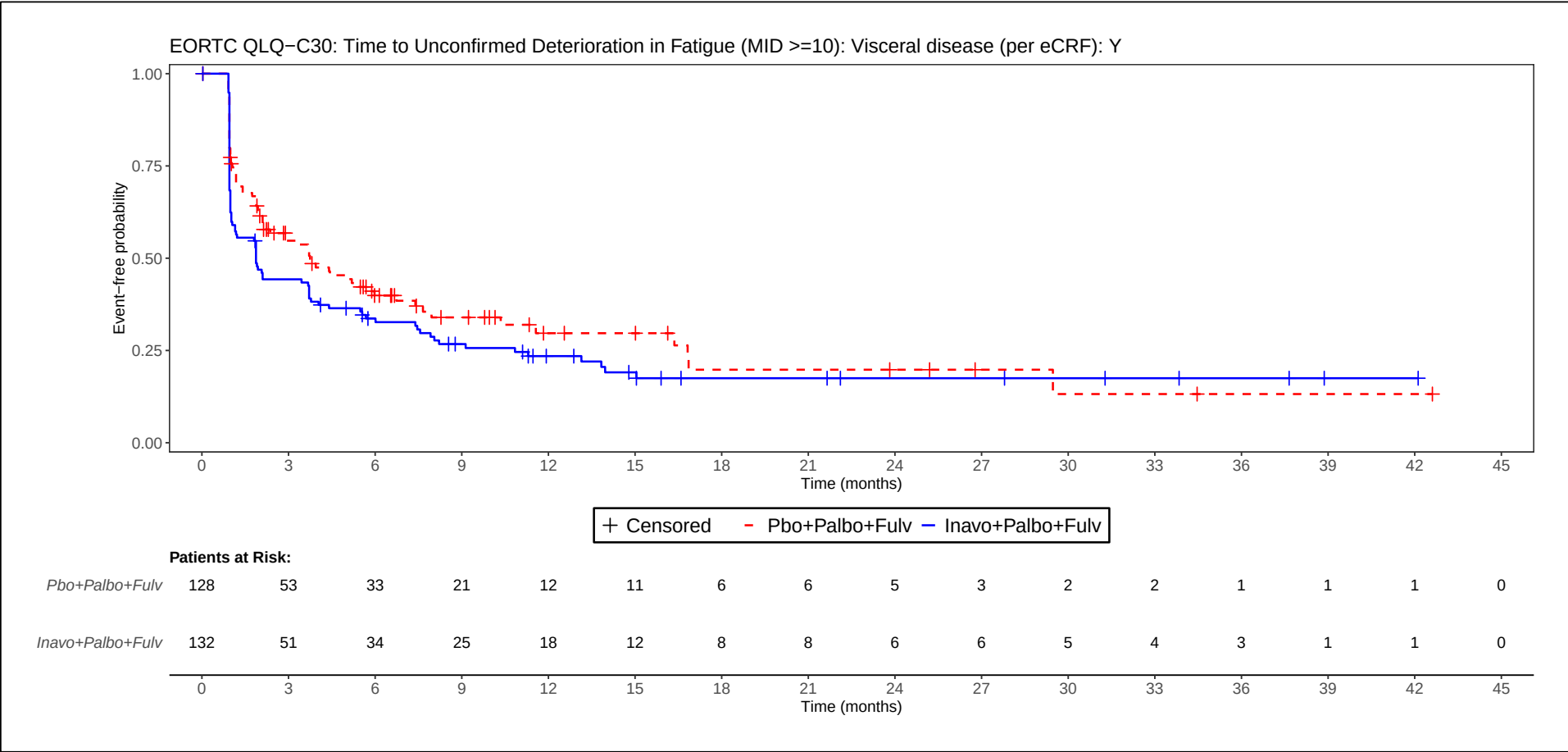
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

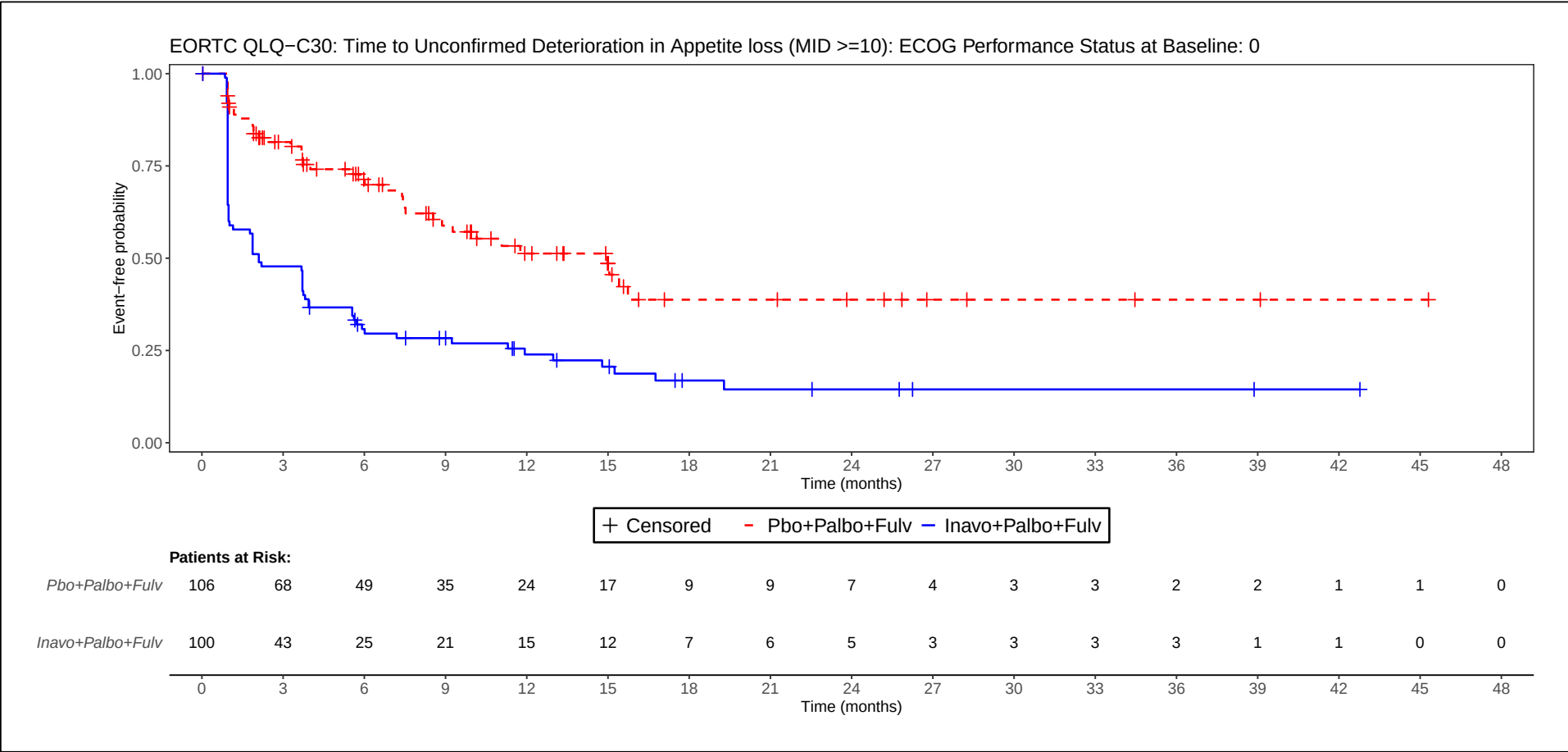
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

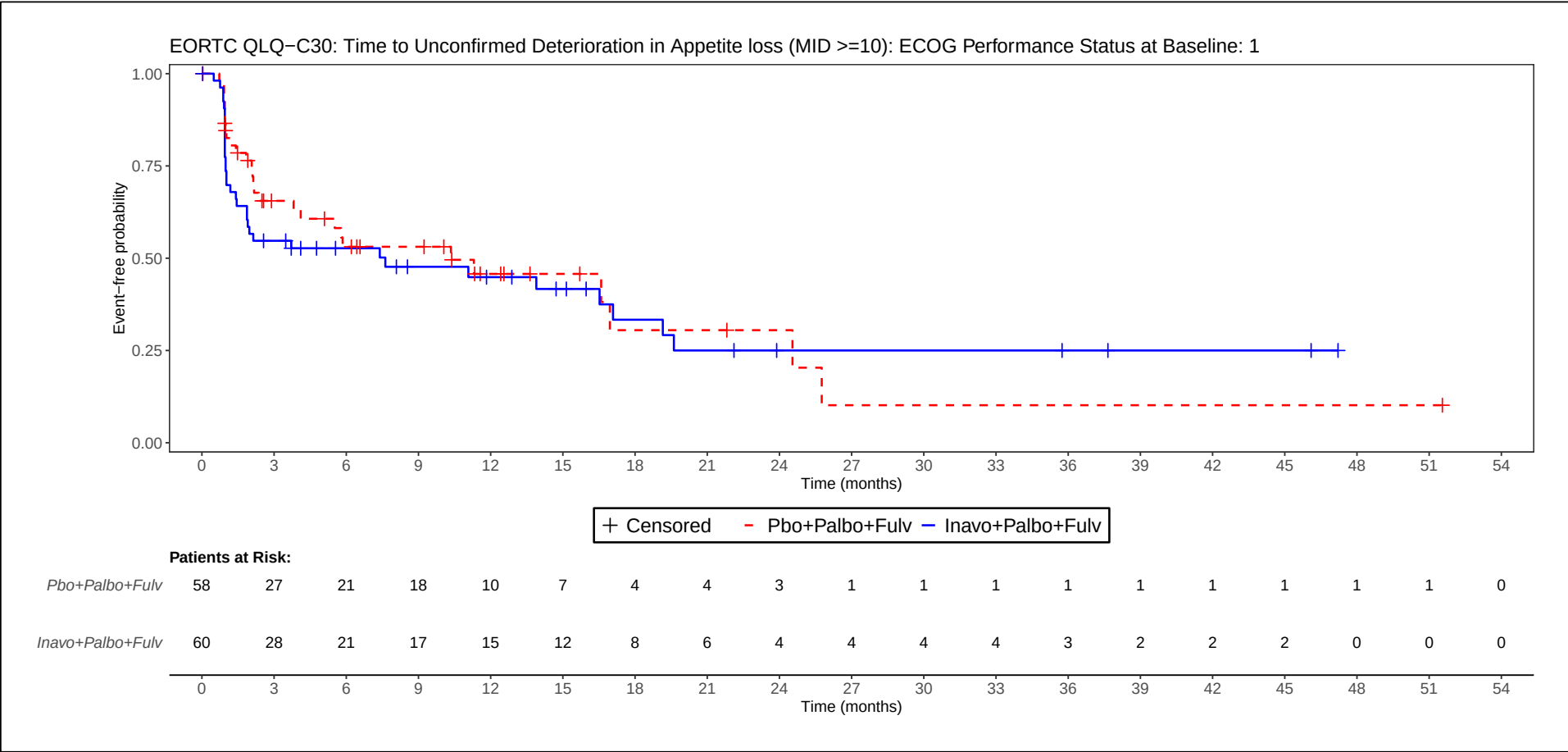
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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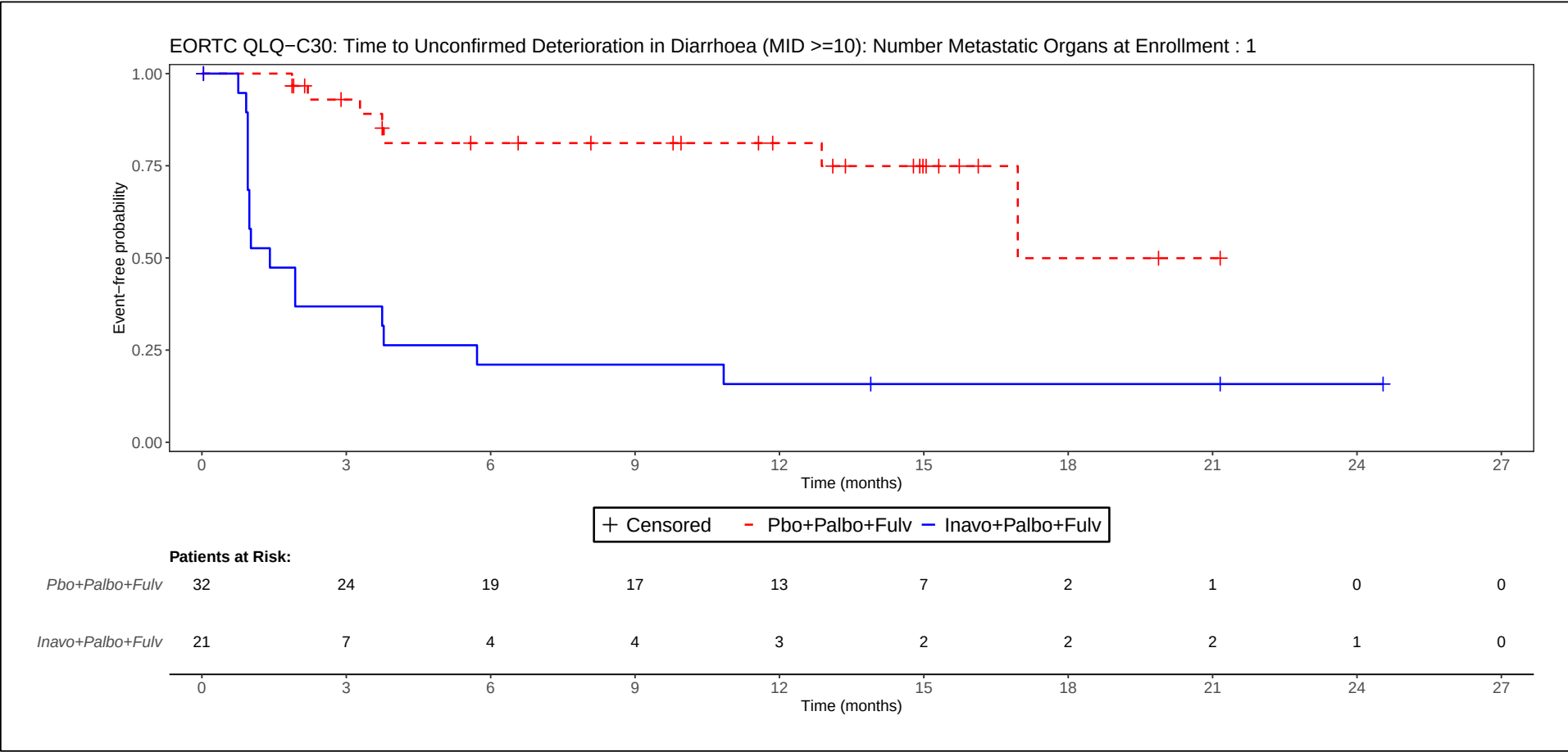
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

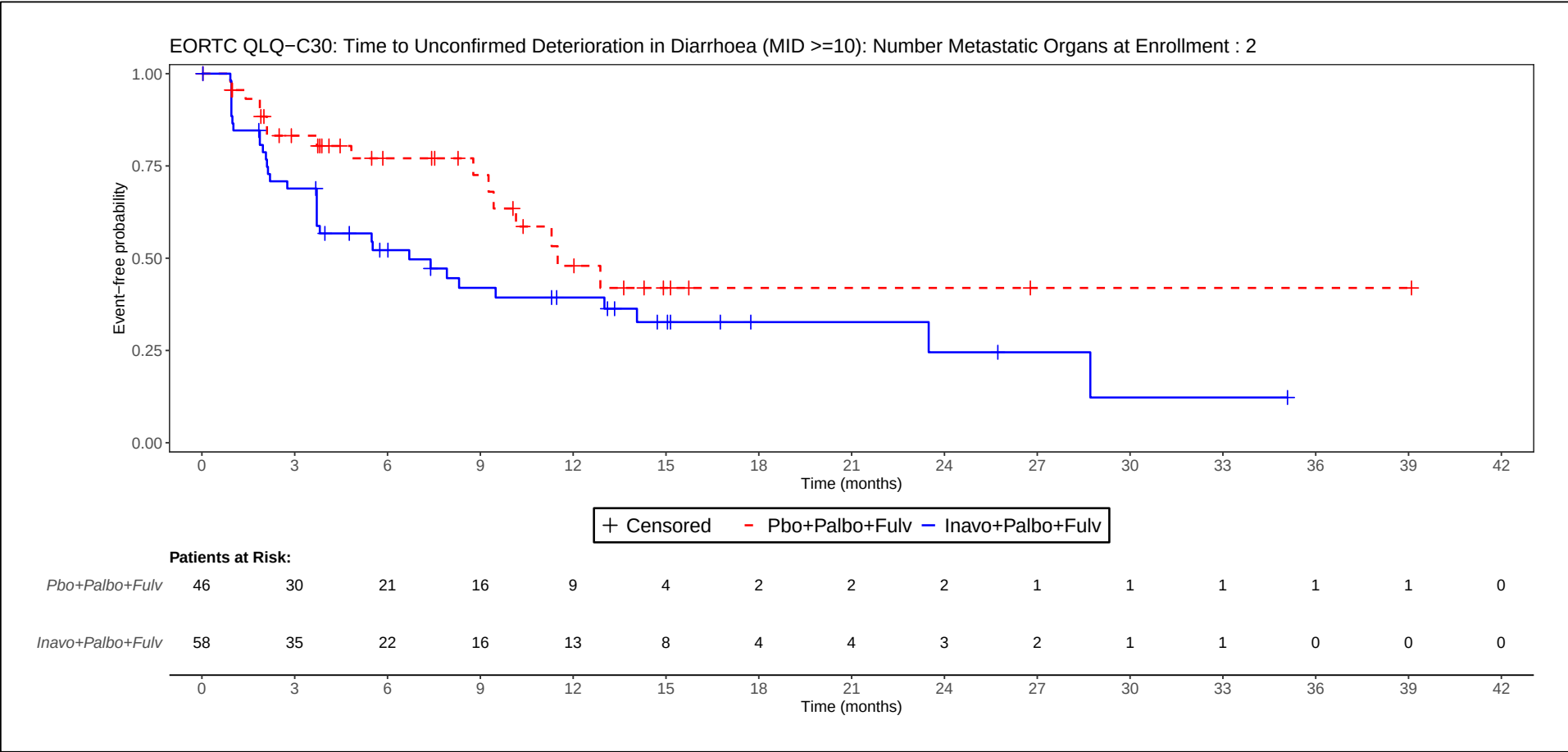
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

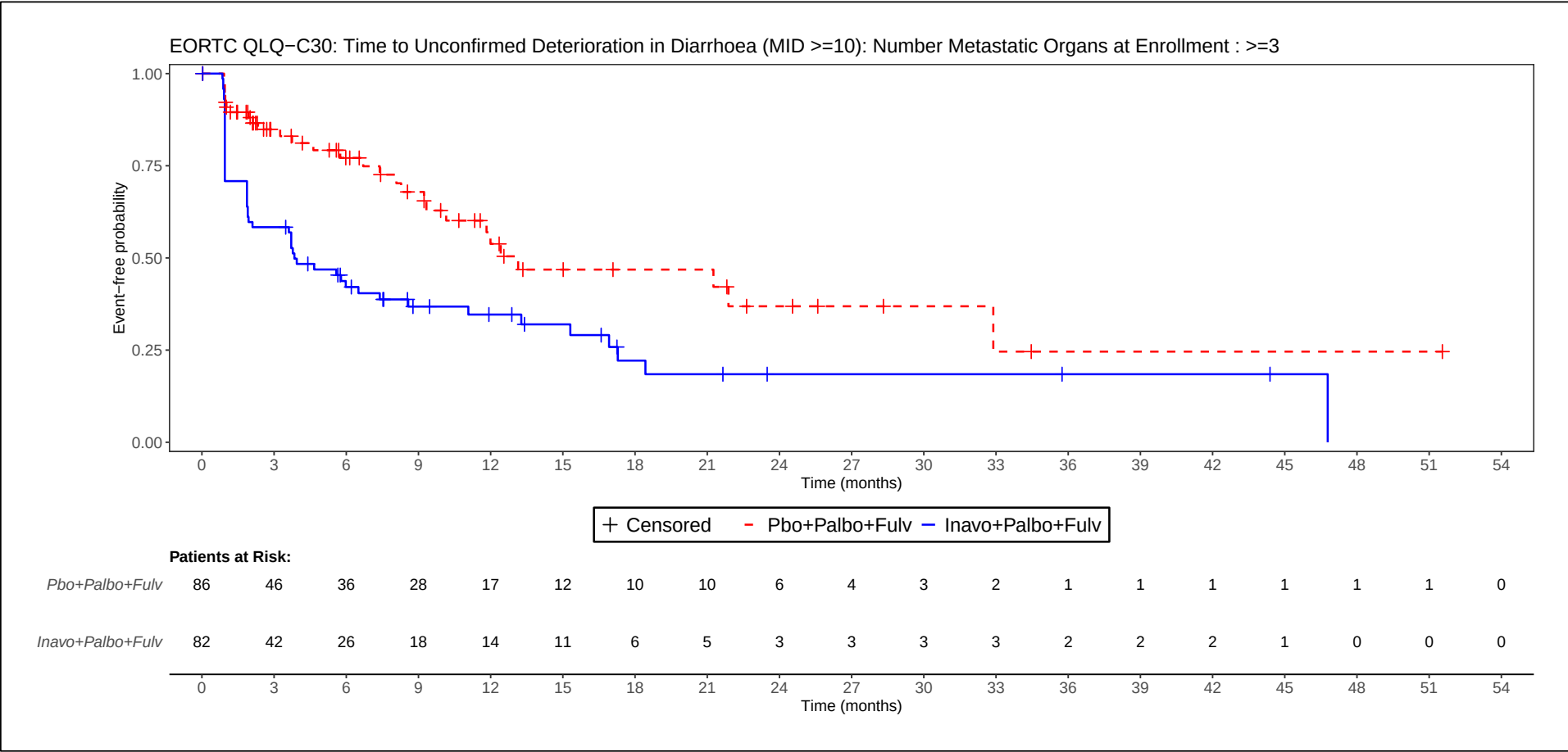
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

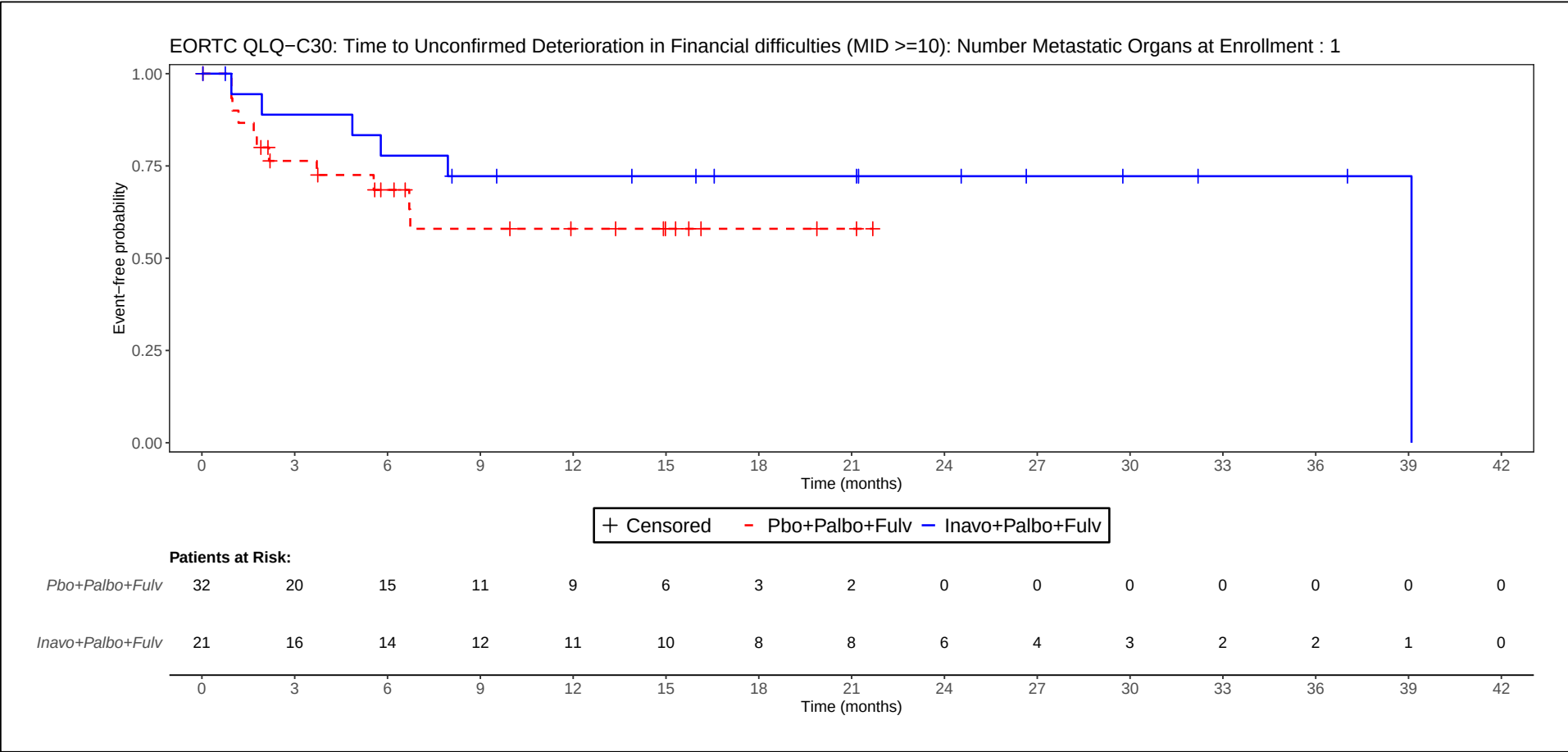
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

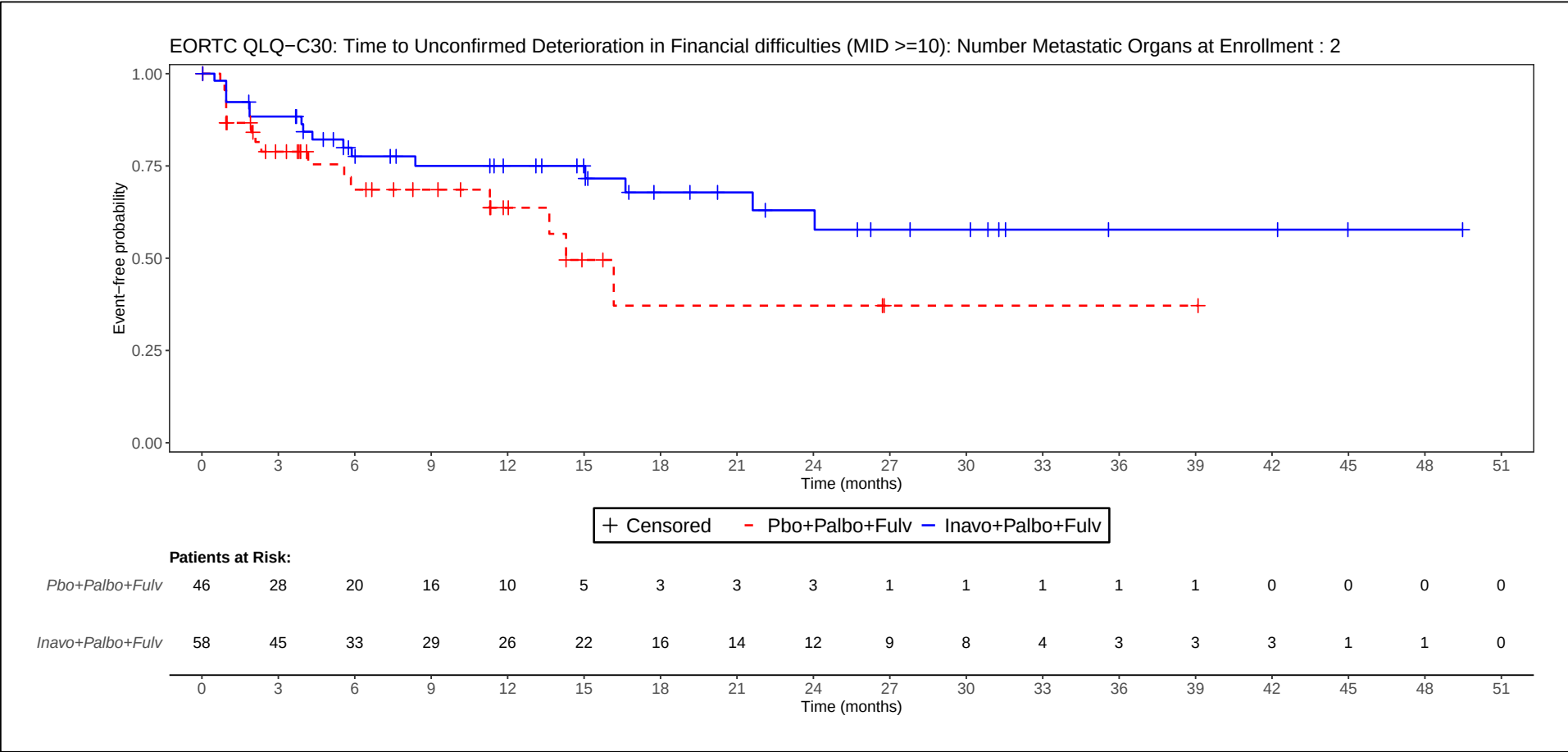
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

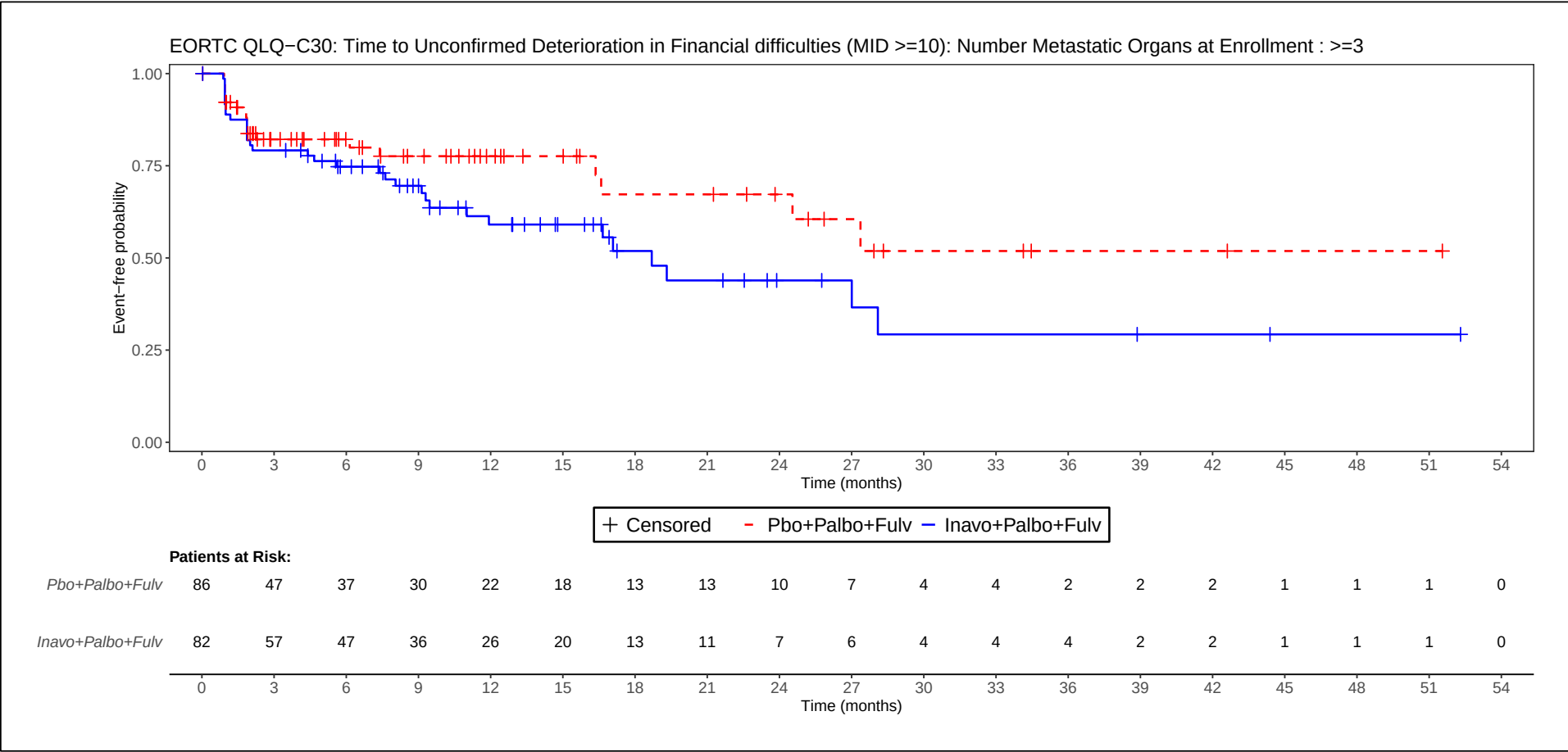
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.1 PRO Items des EORTC QLQ-C30

2.1.4 MMRM Analyse der PRO Items des EORTC QLQ-C30

Analysis of MMRM, EORTC QLQ-C30, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Questionnaire Visit Statistics	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
EORTC QLQ-C30: Global health status/QoL (revised)		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	-8.472 (1.663)	-8.438 (1.529)
95% CI	(-11.735, -5.209)	(-11.439, -5.438)
Difference in Adjusted Means (SE) of Change from Baseline	-0.033 (2.248)	
95% CI	(-4.444, 4.377)	
p-value (MMRM)	0.9881	
EORTC QLQ-C30: Physical functioning (revised)		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	-5.831 (1.482)	-5.345 (1.378)
95% CI	(-8.739, -2.922)	(-8.050, -2.641)
Difference in Adjusted Means (SE) of Change from Baseline	-0.486 (2.013)	
95% CI	(-4.436, 3.465)	
p-value (MMRM)	0.8095	
EORTC QLQ-C30: Role functioning (revised)		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	-8.094 (2.074)	-6.131 (1.924)
95% CI	(-12.163, -4.025)	(-9.907, -2.355)
Difference in Adjusted Means (SE) of Change from Baseline	-1.963 (2.815)	
95% CI	(-7.486, 3.561)	
p-value (MMRM)	0.4858	
EORTC QLQ-C30: Emotional functioning		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	-2.086 (1.782)	-3.921 (1.647)
95% CI	(-5.582, 1.410)	(-7.152, -0.690)
Difference in Adjusted Means (SE) of Change from Baseline	1.835 (2.414)	
95% CI	(-2.902, 6.571)	
p-value (MMRM)	0.4475	
EORTC QLQ-C30: Cognitive functioning		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	-9.414 (1.690)	-7.076 (1.571)
95% CI	(-12.730, -6.097)	(-10.159, -3.993)
Difference in Adjusted Means (SE) of Change from Baseline	-2.338 (2.296)	
95% CI	(-6.843, 2.167)	
p-value (MMRM)	0.3088	
EORTC QLQ-C30: Social functioning		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	-8.648 (2.052)	-5.488 (1.906)
95% CI	(-12.675, -4.622)	(-9.228, -1.747)
Difference in Adjusted Means (SE) of Change from Baseline	-3.161 (2.787)	

Questionnaire		
Visit		
Statistics	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
95% CI	(-8.629, 2.308)	
p-value (MMRM)	0.2570	
EORTC QLQ-C30: Fatigue		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	7.961 (1.942)	8.950 (1.794)
95% CI	(4.152, 11.771)	(5.430, 12.471)
Difference in Adjusted Means (SE) of Change from Baseline	-0.989 (2.631)	
95% CI	(-6.150, 4.173)	
p-value (MMRM)	0.7071	
EORTC QLQ-C30: Nausea and vomiting		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	5.649 (1.363)	4.345 (1.259)
95% CI	(2.975, 8.323)	(1.875, 6.815)
Difference in Adjusted Means (SE) of Change from Baseline	1.304 (1.847)	
95% CI	(-2.319, 4.927)	
p-value (MMRM)	0.4803	
EORTC QLQ-C30: Pain		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	2.542 (2.094)	4.069 (1.928)
95% CI	(-1.565, 6.649)	(0.287, 7.851)
Difference in Adjusted Means (SE) of Change from Baseline	-1.527 (2.832)	
95% CI	(-7.083, 4.028)	
p-value (MMRM)	0.5898	
EORTC QLQ-C30: Dyspnoea		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	1.752 (2.073)	6.530 (1.909)
95% CI	(-2.314, 5.819)	(2.784, 10.275)
Difference in Adjusted Means (SE) of Change from Baseline	-4.777 (2.805)	
95% CI	(-10.280, 0.726)	
p-value (MMRM)	0.0888	
EORTC QLQ-C30: Insomnia		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	3.354 (2.420)	0.616 (2.226)
95% CI	(-1.392, 8.101)	(-3.751, 4.983)
Difference in Adjusted Means (SE) of Change from Baseline	2.738 (3.272)	
95% CI	(-3.681, 9.157)	
p-value (MMRM)	0.4029	
EORTC QLQ-C30: Appetite loss		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	13.587 (2.408)	9.436 (2.222)
95% CI	(8.863, 18.311)	(5.076, 13.795)
Difference in Adjusted Means (SE) of Change from Baseline	4.151 (3.261)	
95% CI	(-2.247, 10.550)	

Questionnaire Visit Statistics	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
p-value (MMRM)	0.2033	
EORTC QLQ-C30: Constipation		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	0.355 (2.025)	2.322 (1.869)
95% CI	(-3.618, 4.328)	(-1.346, 5.989)
Difference in Adjusted Means (SE) of Change from Baseline	-1.967 (2.743)	
95% CI	(-7.349, 3.415)	
p-value (MMRM)	0.4735	
EORTC QLQ-C30: Diarrhoea		
Treatment Discontinuation		
n	76	96
Adjusted Mean (SE) of Change from Baseline	6.905 (2.077)	-2.066 (1.885)
95% CI	(2.831, 10.978)	(-5.763, 1.632)
Difference in Adjusted Means (SE) of Change from Baseline	8.970 (2.793)	
95% CI	(3.493, 14.447)	
p-value (MMRM)	0.0013	
EORTC QLQ-C30: Financial difficulties		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	4.030 (2.170)	1.040 (2.017)
95% CI	(-0.227, 8.287)	(-2.918, 4.997)
Difference in Adjusted Means (SE) of Change from Baseline	2.991 (2.946)	
95% CI	(-2.791, 8.772)	
p-value (MMRM)	0.3103	

The model includes treatment groups, study visits, baseline value, and stratification factors as fixed effects. Visits that were unscheduled or happened after the assessment of progressive disease during the follow-up period were excluded. Compound symmetry covariance structure was used.

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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Output path:

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Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685

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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.2 PRO Items des EORTC QLQ-BR23

2.2.1 Rücklaufquoten der PRO Items des EORTC QLQ-BR23

Questionnaire Completion by Visit by Scale, EORTC QLQ-BR23, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
EORTC QLQ-BR23: Arm symptoms			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	155 (94.5%)	304 (93.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	126 (90.6%)	101 (85.6%)	227 (88.3%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	57 (86.4%)	148 (89.2%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	102 (77.3%)	181 (78.7%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-BR23: Body image			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	155 (94.5%)	304 (93.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	126 (90.6%)	101 (85.6%)	227 (88.3%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	57 (86.4%)	148 (89.2%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 29 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	101 (76.5%)	180 (78.3%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	39 (86.7%)	71 (85.5%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-BR23: Breast symptoms			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	155 (94.5%)	304 (93.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	126 (90.6%)	101 (85.6%)	227 (88.3%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	57 (86.4%)	148 (89.2%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	79 (80.6%)	102 (77.3%)	181 (78.7%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-BR23: Future perspective			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	155 (94.5%)	304 (93.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	126 (90.6%)	101 (85.6%)	227 (88.3%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	57 (86.4%)	148 (89.2%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	102 (77.3%)	181 (78.7%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-BR23: Upset by hair loss			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	38 (23.8%)	33 (20.1%)	71 (21.9%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	80 (57.6%)	58 (49.2%)	138 (53.7%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	63 (63.0%)	36 (54.5%)	99 (59.6%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	44 (59.5%)	16 (41.0%)	60 (53.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	29 (50.0%)	9 (34.6%)	38 (45.2%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	17 (42.5%)	9 (50.0%)	26 (44.8%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	9 (37.5%)	4 (40.0%)	13 (38.2%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	10 (62.5%)	1 (14.3%)	11 (47.8%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 53 Day 1			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	46 (46.9%)	51 (38.6%)	97 (42.2%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	21 (55.3%)	25 (55.6%)	46 (55.4%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	7 (70.0%)	5 (83.3%)	12 (75.0%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	1 (25.0%)	0 (0.0%)	1 (20.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	8 (9.6%)	12 (10.4%)	20 (10.1%)
Survival Follow-up Month 6			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	5 (7.0%)	3 (3.3%)	8 (4.9%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	2 (3.9%)	1 (1.4%)	3 (2.4%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	0 (0.0%)	1 (1.6%)	1 (1.0%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-BR23: Sexual enjoyment			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	39 (24.4%)	47 (28.7%)	86 (26.5%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	38 (27.3%)	25 (21.2%)	63 (24.5%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	18 (18.0%)	11 (16.7%)	29 (17.5%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	16 (21.6%)	7 (17.9%)	23 (20.4%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	16 (27.6%)	4 (15.4%)	20 (23.8%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	7 (17.5%)	5 (27.8%)	12 (20.7%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	8 (33.3%)	1 (10.0%)	9 (26.5%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	4 (25.0%)	1 (14.3%)	5 (21.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	2 (25.0%)	0 (0.0%)	2 (20.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	21 (21.4%)	18 (13.6%)	39 (17.0%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	9 (23.7%)	9 (20.0%)	18 (21.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	4 (40.0%)	2 (33.3%)	6 (37.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	1 (25.0%)	0 (0.0%)	1 (20.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	1 (1.2%)	1 (0.9%)	2 (1.0%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	3 (4.2%)	1 (1.1%)	4 (2.5%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	0 (0.0%)	1 (1.4%)	1 (0.8%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-BR23: Sexual functioning			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	148 (92.5%)	152 (92.7%)	300 (92.6%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	126 (90.6%)	98 (83.1%)	224 (87.2%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	56 (84.8%)	147 (88.6%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	78 (79.6%)	100 (75.8%)	178 (77.4%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	31 (81.6%)	40 (88.9%)	71 (85.5%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	8 (80.0%)	5 (83.3%)	13 (81.2%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
EORTC QLQ-BR23: Systemic therapy side effects			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	155 (94.5%)	304 (93.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	126 (90.6%)	101 (85.6%)	227 (88.3%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	91 (91.0%)	57 (86.4%)	148 (89.2%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	102 (77.3%)	181 (78.7%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_qs_compsc.R

Output path:

/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v8/output/t_qs_compsc_BR23_FAS_15NOV2024_41554.docx

Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685

Git hash: 760ce3da414a8350fb1d4749c450638da2cc9bcc

15 APR 2025 06:06 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.2 PRO Items des EORTC QLQ-BR23

2.2.2 Werte und Veränderung gegenüber dem Ausgangswert der PRO Items des EORTC QLQ-BR23

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Body image

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		155	
Mean (SD)	79.5 (23.5)		79.2 (22.5)	
Median	83.3		83.3	
Min - Max	0 - 100		0 - 100	
Cycle 5 Day 1				
n	126	122	101	95
Mean (SD)	80.8 (21.2)	1.2 (22.2)	80.3 (23.2)	0.7 (16.9)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-83 - 83	0 - 100	-50 - 42
Cycle 11 Day 1				
n	91	87	57	56
Mean (SD)	77.2 (24.1)	-3.1 (22.1)	81.7 (20.9)	0.1 (18.2)
Median	83.3	0.0	83.3	0.0
Min - Max	0 - 100	-58 - 67	25 - 100	-50 - 50
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	79.6 (24.7)	-3.9 (20.3)	80.8 (20.5)	2.0 (25.2)
Median	90.3	0.0	83.3	0.0
Min - Max	0 - 100	-75 - 33	33 - 100	-42 - 67
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	81.9 (19.0)	-3.5 (19.3)	81.2 (17.9)	7.9 (24.1)
Median	83.3	0.0	83.3	0.0
Min - Max	25 - 100	-50 - 33	42 - 100	-17 - 58
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	78.0 (23.9)	-6.3 (17.9)	81.9 (17.5)	-0.0 (26.5)
Median	83.3	-8.3	83.3	-4.2
Min - Max	0 - 100	-50 - 25	42 - 100	-33 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 1 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Body image

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	78.9 (24.8)	-3.9 (18.3)	95.4 (11.1)	14.6 (21.2)
Median	83.3	0.0	100.0	4.2
Min - Max	0 - 100	-50 - 25	67 - 100	0 - 58
Cycle 39 Day 1				
n	1	1	0	0
Mean (SD)	58.3 (NA)	-41.7 (NA)	NE (NE)	NE (NE)
Median	58.3	-41.7	NE	NE
Min - Max	58 - 58	-42 - -42	NE - NE	NE - NE
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	73.5 (21.6)	-9.4 (16.4)	75.0 (39.7)	6.2 (23.9)
Median	66.7	-8.3	91.7	8.3
Min - Max	17 - 100	-33 - 22	17 - 100	-25 - 33
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	73.6 (17.8)	-12.5 (19.5)	58.3 (58.9)	-12.5 (17.7)
Median	75.0	-12.5	58.3	-12.5
Min - Max	50 - 100	-33 - 17	17 - 100	-25 - 0
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	83.3 (NA)	-8.3 (NA)	100.0 (NA)	58.3 (NA)
Median	83.3	-8.3	100.0	58.3
Min - Max	83 - 83	-8 - -8	100 - 100	58 - 58
Treatment Discontinuation				
n	79	77	101	95
Mean (SD)	72.2 (26.9)	-4.6 (24.5)	79.4 (22.3)	-1.1 (16.6)
Median	75.0	0.0	83.3	0.0
Min - Max	0 - 100	-75 - 67	0 - 100	-58 - 42

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 2 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Body image

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	87.7 (21.7)	0.6 (24.6)	90.0 (14.9)	1.7 (16.0)
Median	100.0	0.0	100.0	0.0
Min - Max	33 - 100	-50 - 33	67 - 100	-17 - 25
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	75.0 (35.4)	0.0 (0.0)	NE (NE)	NE (NE)
Median	75.0	0.0	NE	NE
Min - Max	50 - 100	0 - 0	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	50.0 (NA)	0.0 (NA)	NE (NE)	NE (NE)
Median	50.0	0.0	NE	NE
Min - Max	50 - 50	0 - 0	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	39	37
Mean (SD)	79.9 (22.0)	-6.7 (20.7)	73.5 (29.2)	-3.4 (22.3)
Median	83.3	0.0	83.3	0.0
Min - Max	25 - 100	-58 - 42	0 - 100	-67 - 25
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	69.7 (31.9)	-5.3 (26.1)	76.3 (28.4)	2.0 (20.9)
Median	75.0	0.0	83.3	0.0
Min - Max	0 - 100	-67 - 58	0 - 100	-42 - 25
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	73.0 (28.4)	-5.6 (33.4)	76.7 (27.9)	-1.7 (20.7)
Median	83.3	8.3	83.3	-16.7
Min - Max	33 - 100	-67 - 33	33 - 100	-17 - 25

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 3 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-BR23: Body image

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	63.3 (28.0)	-20.0 (26.7)	54.2 (17.7)	-12.5 (5.9)
Median	58.3	-16.7	54.2	-12.5
Min - Max	33 - 100	-58 - 8	42 - 67	-17 - -8
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	50.0 (22.0)	-30.6 (29.3)	58.3 (NA)	-16.7 (NA)
Median	41.7	-33.3	58.3	-16.7
Min - Max	33 - 75	-58 - 0	58 - 58	-17 - -17

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:36 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 4 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Sexual functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	148		152	
Mean (SD)	12.3 (17.7)		12.9 (17.1)	
Median	0.0		0.0	
Min - Max	0 - 67		0 - 67	
Cycle 5 Day 1				
n	126	122	98	92
Mean (SD)	13.2 (18.1)	-0.3 (13.9)	13.3 (17.9)	-2.0 (20.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-33 - 33	0 - 83	-67 - 67
Cycle 11 Day 1				
n	91	86	56	55
Mean (SD)	11.0 (18.1)	-1.7 (17.9)	9.2 (15.9)	-4.2 (20.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-50 - 50	0 - 67	-67 - 67
Cycle 17 Day 1				
n	70	66	30	29
Mean (SD)	9.5 (16.4)	-2.0 (14.8)	11.1 (14.7)	-1.1 (17.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 50	0 - 33	-33 - 33
Cycle 23 Day 1				
n	52	48	20	19
Mean (SD)	12.5 (16.8)	0.7 (20.6)	10.8 (14.6)	0.9 (21.9)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-67 - 50	0 - 33	-33 - 33
Cycle 29 Day 1				
n	32	31	17	16
Mean (SD)	9.9 (17.4)	-1.6 (14.5)	9.8 (14.5)	-1.0 (20.6)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 33	-33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 5 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Sexual functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	13.9 (17.4)	3.9 (18.2)	7.4 (12.1)	-14.6 (16.5)
Median	0.0	0.0	0.0	-8.3
Min - Max	0 - 50	-33 - 50	0 - 33	-33 - 0
Cycle 39 Day 1				
n	1	0	0	0
Mean (SD)	0.0 (NA)	NE (NE)	NE (NE)	NE (NE)
Median	0.0	NE	NE	NE
Min - Max	0 - 0	NE - NE	NE - NE	NE - NE
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	12.8 (20.6)	-3.8 (13.9)	8.3 (16.7)	-20.8 (16.0)
Median	0.0	0.0	0.0	-25.0
Min - Max	0 - 67	-33 - 17	0 - 33	-33 - 0
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	16.7 (27.9)	-2.8 (16.4)	0.0 (0.0)	-16.7 (23.6)
Median	0.0	0.0	0.0	-16.7
Min - Max	0 - 67	-33 - 17	0 - 0	-33 - 0
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-33.3 (NA)	0.0 (NA)	-33.3 (NA)
Median	0.0	-33.3	0.0	-33.3
Min - Max	0 - 0	-33 - -33	0 - 0	-33 - -33
Treatment Discontinuation				
n	78	76	100	93
Mean (SD)	11.5 (18.9)	-1.1 (18.1)	7.5 (13.3)	-4.3 (17.4)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 100	-50 - 67	0 - 50	-67 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 6 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Sexual functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Post-Treatment Follow Up Week 16				
n	8	8	5	5
Mean (SD)	14.6 (16.5)	-4.2 (23.1)	13.3 (18.3)	-3.3 (18.3)
Median	8.3	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 33	-33 - 17
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	33.3 (47.1)	0.0 (0.0)	NE (NE)	NE (NE)
Median	33.3	0.0	NE	NE
Min - Max	0 - 67	0 - 0	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	0.0 (NA)	0.0 (NA)	NE (NE)	NE (NE)
Median	0.0	0.0	NE	NE
Min - Max	0 - 0	0 - 0	NE - NE	NE - NE
30 Day Safety Follow-up				
n	31	30	40	37
Mean (SD)	8.1 (13.5)	-6.1 (16.7)	10.0 (15.5)	-2.3 (19.7)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-50 - 33	0 - 50	-67 - 33
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	4.4 (10.9)	-5.3 (15.8)	2.6 (8.4)	-6.9 (11.9)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 33	-33 - 33	0 - 33	-33 - 0
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	19.0 (26.2)	4.8 (23.0)	3.3 (7.5)	-3.3 (7.5)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 67	-33 - 33	0 - 17	-17 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 7 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-BR23: Sexual functioning

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	0.0 (0.0)	-13.3 (18.3)	16.7 (23.6)	8.3 (11.8)
Median	0.0	0.0	16.7	8.3
Min - Max	0 - 0	-33 - 0	0 - 33	0 - 17
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	0.0 (0.0)	-22.2 (19.2)	0.0 (NA)	-16.7 (NA)
Median	0.0	-33.3	0.0	-16.7
Min - Max	0 - 0	-33 - 0	0 - 0	-17 - -17

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:36 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 8 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Sexual enjoyment

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	39		47	
Mean (SD)	45.3 (25.9)		32.6 (21.4)	
Median	33.3		33.3	
Min - Max	0 - 100		0 - 67	
Cycle 5 Day 1				
n	38	25	25	13
Mean (SD)	43.9 (27.0)	-5.3 (24.9)	38.7 (24.9)	0.0 (19.2)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-33 - 67	0 - 100	-33 - 33
Cycle 11 Day 1				
n	18	12	11	6
Mean (SD)	48.1 (32.8)	-11.1 (29.6)	45.5 (22.5)	5.6 (13.6)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 33	33 - 100	0 - 33
Cycle 17 Day 1				
n	16	11	7	4
Mean (SD)	43.7 (31.5)	-6.1 (13.5)	33.3 (19.2)	-8.3 (16.7)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-33 - 0	0 - 67	-33 - 0
Cycle 23 Day 1				
n	16	7	4	2
Mean (SD)	39.6 (30.4)	0.0 (19.2)	33.3 (0.0)	0.0 (0.0)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-33 - 33	33 - 33	0 - 0
Cycle 29 Day 1				
n	7	5	5	2
Mean (SD)	52.4 (26.2)	0.0 (0.0)	46.7 (18.3)	0.0 (0.0)
Median	33.3	0.0	33.3	0.0
Min - Max	33 - 100	0 - 0	33 - 67	0 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 9 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Sexual enjoyment

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	8	3	1	1
Mean (SD)	33.3 (25.2)	-11.1 (19.2)	33.3 (NA)	0.0 (NA)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 67	-33 - 0	33 - 33	0 - 0
Cycle 41 Day 1				
n	4	3	1	0
Mean (SD)	58.3 (41.9)	0.0 (0.0)	0.0 (NA)	NE (NE)
Median	66.7	0.0	0.0	NE
Min - Max	0 - 100	0 - 0	0 - 0	NE - NE
Cycle 47 Day 1				
n	2	1	0	0
Mean (SD)	66.7 (47.1)	0.0 (NA)	NE (NE)	NE (NE)
Median	66.7	0.0	NE	NE
Min - Max	33 - 100	0 - 0	NE - NE	NE - NE
Treatment Discontinuation				
n	21	14	18	12
Mean (SD)	38.1 (24.2)	-11.9 (24.8)	38.9 (20.6)	2.8 (17.2)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 33	0 - 67	-33 - 33
Post-Treatment Follow Up Week 16				
n	4	3	2	1
Mean (SD)	25.0 (16.7)	-22.2 (19.2)	16.7 (23.6)	0.0 (NA)
Median	33.3	-33.3	16.7	0.0
Min - Max	0 - 33	-33 - 0	0 - 33	0 - 0
Post-Treatment Follow Up Week 24				
n	1	1	0	0
Mean (SD)	66.7 (NA)	0.0 (NA)	NE (NE)	NE (NE)
Median	66.7	0.0	NE	NE
Min - Max	67 - 67	0 - 0	NE - NE	NE - NE

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 10 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-BR23: Sexual enjoyment

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
30 Day Safety Follow-up				
n	9	8	9	4
Mean (SD)	33.3 (16.7)	-16.7 (30.9)	44.4 (16.7)	16.7 (19.2)
Median	33.3	-16.7	33.3	16.7
Min - Max	0 - 67	-67 - 33	33 - 67	0 - 33
Survival Follow-up Month 3				
n	1	1	1	1
Mean (SD)	33.3 (NA)	33.3 (NA)	33.3 (NA)	33.3 (NA)
Median	33.3	33.3	33.3	33.3
Min - Max	33 - 33	33 - 33	33 - 33	33 - 33
Survival Follow-up Month 6				
n	3	2	1	1
Mean (SD)	44.4 (19.2)	33.3 (47.1)	0.0 (NA)	-33.3 (NA)
Median	33.3	33.3	0.0	-33.3
Min - Max	33 - 67	0 - 67	0 - 0	-33 - -33
Survival Follow-up Month 9				
n	0	0	1	1
Mean (SD)	NE (NE)	NE (NE)	33.3 (NA)	33.3 (NA)
Median	NE	NE	33.3	33.3
Min - Max	NE - NE	NE - NE	33 - 33	33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:36 GMT
Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 11 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Future perspective

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		155	
Mean (SD)	45.0 (33.8)		45.2 (31.3)	
Median	66.7		33.3	
Min - Max	0 - 100		0 - 100	
Cycle 5 Day 1				
n	126	122	101	95
Mean (SD)	57.4 (28.5)	12.6 (29.5)	57.4 (29.9)	11.9 (27.0)
Median	66.7	0.0	66.7	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-67 - 67
Cycle 11 Day 1				
n	91	87	57	56
Mean (SD)	53.1 (31.0)	7.7 (34.7)	58.5 (31.7)	10.7 (34.9)
Median	66.7	0.0	66.7	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-67 - 100
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	62.4 (31.6)	12.4 (37.5)	60.0 (32.0)	10.3 (33.5)
Median	66.7	0.0	66.7	0.0
Min - Max	0 - 100	-100 - 100	0 - 100	-33 - 100
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	57.1 (27.5)	8.2 (35.7)	71.7 (22.4)	21.1 (35.5)
Median	66.7	0.0	66.7	33.3
Min - Max	0 - 100	-67 - 100	33 - 100	-67 - 100
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	61.5 (31.8)	13.5 (42.2)	64.7 (27.6)	4.2 (36.3)
Median	66.7	0.0	66.7	0.0
Min - Max	0 - 100	-67 - 100	0 - 100	-67 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 12 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Future perspective

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	64.8 (31.3)	21.6 (31.0)	77.8 (23.6)	29.2 (27.8)
Median	66.7	33.3	66.7	33.3
Min - Max	0 - 100	-33 - 67	33 - 100	0 - 67
Cycle 39 Day 1				
n	1	1	0	0
Mean (SD)	33.3 (NA)	-33.3 (NA)	NE (NE)	NE (NE)
Median	33.3	-33.3	NE	NE
Min - Max	33 - 33	-33 - -33	NE - NE	NE - NE
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	51.3 (25.9)	2.6 (34.6)	58.3 (41.9)	16.7 (57.7)
Median	66.7	0.0	66.7	33.3
Min - Max	0 - 67	-33 - 67	0 - 100	-67 - 67
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	61.1 (25.1)	11.1 (34.4)	83.3 (23.6)	50.0 (23.6)
Median	66.7	0.0	83.3	50.0
Min - Max	33 - 100	-33 - 67	67 - 100	33 - 67
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	100.0 (NA)	33.3 (NA)	66.7 (NA)	33.3 (NA)
Median	100.0	33.3	66.7	33.3
Min - Max	100 - 100	33 - 33	67 - 67	33 - 33
Treatment Discontinuation				
n	79	77	102	95
Mean (SD)	47.7 (33.2)	3.9 (26.5)	50.0 (28.8)	5.6 (26.9)
Median	33.3	0.0	66.7	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-100 - 100

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 13 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Future perspective

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	51.9 (29.4)	-7.4 (40.1)	40.0 (27.9)	13.3 (29.8)
Median	66.7	0.0	33.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 67	0 - 67
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	33.3 (47.1)	-16.7 (23.6)	NE (NE)	NE (NE)
Median	33.3	-16.7	NE	NE
Min - Max	0 - 67	-33 - 0	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	0.0 (NA)	0.0 (NA)	NE (NE)	NE (NE)
Median	0.0	0.0	NE	NE
Min - Max	0 - 0	0 - 0	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	37
Mean (SD)	51.0 (33.9)	2.2 (36.4)	48.3 (34.6)	13.5 (33.8)
Median	66.7	0.0	50.0	0.0
Min - Max	0 - 100	-100 - 67	0 - 100	-33 - 100
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	42.1 (26.9)	14.0 (37.4)	52.6 (27.9)	9.8 (19.6)
Median	33.3	0.0	66.7	0.0
Min - Max	0 - 67	-33 - 67	0 - 100	0 - 67
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	47.6 (32.5)	23.8 (37.1)	33.3 (33.3)	-6.7 (14.9)
Median	33.3	33.3	33.3	0.0
Min - Max	0 - 100	-33 - 67	0 - 67	-33 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

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Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 14 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-BR23: Future perspective

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	53.3 (38.0)	13.3 (18.3)	33.3 (0.0)	-16.7 (23.6)
Median	66.7	0.0	33.3	-16.7
Min - Max	0 - 100	0 - 33	33 - 33	-33 - 0
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	44.4 (38.5)	-11.1 (19.2)	66.7 (NA)	66.7 (NA)
Median	66.7	0.0	66.7	66.7
Min - Max	0 - 67	-33 - 0	67 - 67	67 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
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Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 15 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Systemic therapy side effects

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		155	
Mean (SD)	14.3 (12.4)		14.7 (12.5)	
Median	9.5		9.5	
Min - Max	0 - 62		0 - 57	
Cycle 5 Day 1				
n	126	122	101	95
Mean (SD)	23.4 (15.6)	9.8 (15.4)	20.0 (16.0)	5.1 (11.7)
Median	23.8	9.5	19.0	4.8
Min - Max	0 - 67	-29 - 52	0 - 71	-24 - 33
Cycle 11 Day 1				
n	91	87	57	56
Mean (SD)	24.2 (16.4)	11.8 (15.7)	21.6 (17.1)	7.0 (14.2)
Median	23.8	9.5	19.0	4.8
Min - Max	0 - 67	-19 - 62	0 - 67	-29 - 52
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	22.7 (17.5)	10.5 (17.5)	19.7 (15.1)	0.8 (14.8)
Median	19.0	4.8	16.7	0.0
Min - Max	0 - 71	-33 - 62	0 - 57	-48 - 29
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	19.4 (13.7)	7.5 (16.2)	17.6 (14.9)	1.3 (17.4)
Median	19.0	4.8	14.3	4.8
Min - Max	0 - 62	-33 - 57	0 - 57	-38 - 29
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	19.2 (13.2)	9.4 (12.4)	15.1 (9.1)	0.6 (14.4)
Median	19.0	4.8	14.3	4.8
Min - Max	0 - 52	-5 - 48	0 - 33	-38 - 19

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 16 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Systemic therapy side effects

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	19.6 (14.9)	7.0 (13.2)	12.2 (11.7)	-4.2 (16.2)
Median	19.0	4.8	9.5	-2.4
Min - Max	0 - 62	-10 - 43	0 - 38	-38 - 14
Cycle 39 Day 1				
n	1	1	0	0
Mean (SD)	19.0 (NA)	19.0 (NA)	NE (NE)	NE (NE)
Median	19.0	19.0	NE	NE
Min - Max	19 - 19	19 - 19	NE - NE	NE - NE
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	27.1 (15.8)	16.8 (15.1)	16.7 (21.5)	-7.1 (31.2)
Median	28.6	14.3	9.5	-11.9
Min - Max	0 - 62	-5 - 43	0 - 48	-38 - 33
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	23.0 (3.6)	12.7 (11.1)	14.3 (6.7)	-7.1 (16.8)
Median	23.8	14.3	14.3	-7.1
Min - Max	19 - 29	-5 - 24	10 - 19	-19 - 5
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	28.6 (NA)	0.0 (NA)	9.5 (NA)	-28.6 (NA)
Median	28.6	0.0	9.5	-28.6
Min - Max	29 - 29	0 - 0	10 - 10	-29 - -29
Treatment Discontinuation				
n	79	77	102	95
Mean (SD)	25.9 (18.3)	9.3 (17.1)	20.8 (15.4)	6.8 (12.9)
Median	23.8	4.8	19.0	4.8
Min - Max	0 - 81	-24 - 62	0 - 76	-29 - 48

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 17 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-BR23: Systemic therapy side effects

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	21.7 (14.5)	6.9 (16.5)	25.7 (14.1)	9.5 (8.9)
Median	23.8	9.5	19.0	14.3
Min - Max	0 - 43	-24 - 33	10 - 43	0 - 19
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	35.7 (10.1)	14.3 (6.7)	NE (NE)	NE (NE)
Median	35.7	14.3	NE	NE
Min - Max	29 - 43	10 - 19	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	52.4 (NA)	19.0 (NA)	NE (NE)	NE (NE)
Median	52.4	19.0	NE	NE
Min - Max	52 - 52	19 - 19	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	37
Mean (SD)	21.3 (15.9)	5.9 (13.4)	25.4 (18.5)	10.0 (16.7)
Median	23.8	4.8	21.4	9.5
Min - Max	0 - 62	-29 - 38	0 - 90	-14 - 52
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	26.1 (13.7)	10.3 (12.0)	21.6 (14.1)	7.0 (12.7)
Median	23.8	9.5	14.3	4.8
Min - Max	5 - 62	-10 - 38	5 - 52	-14 - 29
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	23.8 (18.8)	6.1 (18.6)	33.3 (22.3)	10.5 (12.3)
Median	23.8	0.0	23.8	14.3
Min - Max	0 - 62	-10 - 43	14 - 62	-5 - 24

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:36 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 18 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-BR23: Systemic therapy side effects

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	26.7 (24.0)	17.1 (19.5)	38.1 (0.0)	2.4 (10.1)
Median	19.0	9.5	38.1	2.4
Min - Max	0 - 62	0 - 38	38 - 38	-5 - 10
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	22.2 (19.2)	12.7 (11.0)	61.9 (NA)	33.3 (NA)
Median	19.0	19.0	61.9	33.3
Min - Max	5 - 43	0 - 19	62 - 62	33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:36 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 19 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Breast symptoms

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		155	
Mean (SD)	12.4 (15.5)		11.3 (14.3)	
Median	8.3		8.3	
Min - Max	0 - 83		0 - 67	
Cycle 5 Day 1				
n	126	122	101	95
Mean (SD)	10.4 (15.6)	-1.5 (15.2)	10.7 (14.4)	-2.4 (14.3)
Median	8.3	0.0	8.3	0.0
Min - Max	0 - 83	-50 - 58	0 - 83	-58 - 25
Cycle 11 Day 1				
n	91	87	57	56
Mean (SD)	8.6 (13.6)	-2.6 (14.2)	8.9 (13.5)	-0.9 (11.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 58	-58 - 25	0 - 50	-25 - 33
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	10.0 (16.1)	-1.1 (15.7)	10.6 (15.0)	2.6 (14.6)
Median	0.0	0.0	8.3	0.0
Min - Max	0 - 83	-58 - 50	0 - 67	-33 - 33
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	9.9 (15.1)	0.2 (15.0)	8.8 (17.2)	3.5 (12.8)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 75	-33 - 50	0 - 75	-25 - 42
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	8.3 (12.3)	0.3 (14.0)	8.3 (11.4)	5.7 (11.3)
Median	0.0	0.0	0.0	0.0
Min - Max	0 - 42	-33 - 42	0 - 33	-17 - 25

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 20 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Breast symptoms

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	7.4 (9.0)	-3.9 (13.9)	2.8 (5.9)	0.0 (11.8)
Median	4.2	0.0	0.0	0.0
Min - Max	0 - 25	-42 - 17	0 - 17	-25 - 17
Cycle 39 Day 1				
n	1	1	0	0
Mean (SD)	16.7 (NA)	16.7 (NA)	NE (NE)	NE (NE)
Median	16.7	16.7	NE	NE
Min - Max	17 - 17	17 - 17	NE - NE	NE - NE
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	6.4 (8.4)	-1.9 (11.4)	4.2 (8.3)	-10.4 (22.9)
Median	0.0	0.0	0.0	-12.5
Min - Max	0 - 25	-25 - 17	0 - 17	-33 - 17
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	8.3 (10.5)	2.8 (4.3)	12.5 (5.9)	0.0 (23.6)
Median	4.2	0.0	12.5	0.0
Min - Max	0 - 25	0 - 8	8 - 17	-17 - 17
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	0.0 (NA)	-16.7 (NA)	0.0 (NA)	-25.0 (NA)
Median	0.0	-16.7	0.0	-25.0
Min - Max	0 - 0	-17 - -17	0 - 0	-25 - -25
Treatment Discontinuation				
n	79	77	102	95
Mean (SD)	11.4 (15.0)	-1.5 (14.7)	9.6 (12.8)	-1.5 (12.5)
Median	8.3	0.0	0.0	0.0
Min - Max	0 - 75	-42 - 42	0 - 58	-33 - 42

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 21 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Breast symptoms

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	7.4 (14.1)	1.9 (17.6)	6.7 (3.7)	0.0 (8.3)
Median	0.0	0.0	8.3	0.0
Min - Max	0 - 42	-25 - 42	0 - 8	-8 - 8
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	25.0 (0.0)	16.7 (11.8)	NE (NE)	NE (NE)
Median	25.0	16.7	NE	NE
Min - Max	25 - 25	8 - 25	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	8.3 (NA)	8.3 (NA)	NE (NE)	NE (NE)
Median	8.3	8.3	NE	NE
Min - Max	8 - 8	8 - 8	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	37
Mean (SD)	7.8 (11.4)	-4.0 (14.7)	19.0 (18.8)	2.0 (17.2)
Median	0.0	-8.3	16.7	0.0
Min - Max	0 - 33	-58 - 25	0 - 67	-25 - 50
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	8.3 (8.8)	-3.5 (13.1)	8.8 (13.2)	-3.9 (19.6)
Median	8.3	0.0	0.0	0.0
Min - Max	0 - 25	-33 - 17	0 - 42	-58 - 25
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	9.5 (12.2)	-7.1 (18.3)	13.3 (20.9)	-0.0 (23.6)
Median	8.3	-8.3	8.3	0.0
Min - Max	0 - 33	-25 - 25	0 - 50	-33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 22 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-BR23: Breast symptoms

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	8.3 (14.4)	-6.7 (9.1)	45.8 (17.7)	16.7 (0.0)
Median	0.0	-8.3	45.8	16.7
Min - Max	0 - 33	-17 - 8	33 - 58	17 - 17
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	0.0 (0.0)	-16.7 (8.3)	0.0 (NA)	0.0 (NA)
Median	0.0	-16.7	0.0	0.0
Min - Max	0 - 0	-25 - -8	0 - 0	0 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
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Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 23 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Arm symptoms

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		155	
Mean (SD)	17.6 (19.1)		17.3 (19.6)	
Median	11.1		11.1	
Min - Max	0 - 78		0 - 78	
Cycle 5 Day 1				
n	126	122	101	95
Mean (SD)	16.6 (21.6)	-0.9 (19.3)	17.4 (20.4)	-0.6 (15.7)
Median	11.1	0.0	11.1	0.0
Min - Max	0 - 100	-56 - 67	0 - 89	-44 - 56
Cycle 11 Day 1				
n	91	87	57	56
Mean (SD)	18.2 (19.6)	1.7 (20.0)	17.2 (20.0)	3.6 (17.1)
Median	11.1	0.0	11.1	0.0
Min - Max	0 - 67	-44 - 56	0 - 100	-44 - 89
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	14.4 (17.2)	-2.3 (19.3)	14.8 (18.5)	1.1 (18.6)
Median	11.1	0.0	5.6	0.0
Min - Max	0 - 89	-44 - 44	0 - 78	-44 - 33
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	16.5 (19.1)	-0.0 (19.9)	16.7 (23.2)	4.7 (14.0)
Median	11.1	0.0	11.1	11.1
Min - Max	0 - 89	-44 - 33	0 - 100	-22 - 22
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	14.6 (18.4)	-3.1 (17.5)	16.3 (17.6)	9.7 (17.2)
Median	11.1	0.0	11.1	11.1
Min - Max	0 - 78	-44 - 22	0 - 56	-22 - 44

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

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Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 24 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Arm symptoms

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	13.6 (14.0)	-5.2 (18.5)	8.6 (15.5)	0.0 (10.3)
Median	11.1	0.0	0.0	0.0
Min - Max	0 - 44	-44 - 22	0 - 44	-11 - 22
Cycle 39 Day 1				
n	1	1	0	0
Mean (SD)	0.0 (NA)	0.0 (NA)	NE (NE)	NE (NE)
Median	0.0	0.0	NE	NE
Min - Max	0 - 0	0 - 0	NE - NE	NE - NE
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	22.2 (17.6)	3.4 (23.3)	13.9 (16.7)	-8.3 (24.6)
Median	22.2	11.1	11.1	0.0
Min - Max	0 - 56	-44 - 33	0 - 33	-44 - 11
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	27.8 (9.3)	7.4 (23.0)	33.3 (15.7)	22.2 (15.7)
Median	33.3	11.1	33.3	22.2
Min - Max	11 - 33	-33 - 33	22 - 44	11 - 33
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	33.3 (NA)	0.0 (NA)	22.2 (NA)	11.1 (NA)
Median	33.3	0.0	22.2	11.1
Min - Max	33 - 33	0 - 0	22 - 22	11 - 11
Treatment Discontinuation				
n	79	77	102	95
Mean (SD)	20.8 (19.9)	1.2 (20.0)	15.6 (17.8)	-0.9 (19.2)
Median	22.2	0.0	11.1	0.0
Min - Max	0 - 100	-33 - 89	0 - 78	-67 - 67

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

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Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 25 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Arm symptoms

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	9.9 (11.7)	-6.2 (15.8)	17.8 (16.9)	-4.4 (18.6)
Median	0.0	0.0	11.1	0.0
Min - Max	0 - 22	-33 - 22	0 - 44	-22 - 22
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	38.9 (7.9)	0.0 (0.0)	NE (NE)	NE (NE)
Median	38.9	0.0	NE	NE
Min - Max	33 - 44	0 - 0	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	33.3 (NA)	-11.1 (NA)	NE (NE)	NE (NE)
Median	33.3	-11.1	NE	NE
Min - Max	33 - 33	-11 - -11	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	37
Mean (SD)	17.7 (19.3)	-2.2 (18.9)	22.8 (24.0)	1.8 (23.2)
Median	11.1	0.0	11.1	0.0
Min - Max	0 - 67	-44 - 33	0 - 89	-44 - 56
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	19.3 (12.7)	0.6 (17.2)	19.3 (27.2)	3.3 (29.6)
Median	22.2	0.0	11.1	0.0
Min - Max	0 - 44	-33 - 33	0 - 89	-56 - 78
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	12.7 (13.5)	-7.9 (16.6)	24.4 (28.8)	11.1 (29.4)
Median	11.1	-11.1	11.1	0.0
Min - Max	0 - 33	-33 - 11	0 - 56	-22 - 56

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:36 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 26 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-BR23: Arm symptoms

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	11.1 (11.1)	-8.9 (16.5)	55.6 (15.7)	38.9 (39.3)
Median	11.1	-11.1	55.6	38.9
Min - Max	0 - 22	-33 - 11	44 - 67	11 - 67
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	22.2 (19.2)	3.7 (28.0)	0.0 (NA)	0.0 (NA)
Median	33.3	0.0	0.0	0.0
Min - Max	0 - 33	-22 - 33	0 - 0	0 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
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Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 27 of 31

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-BR23: Upset by hair loss

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	38		33	
Mean (SD)	28.9 (30.2)		29.3 (29.8)	
Median	33.3		33.3	
Min - Max	0 - 100		0 - 100	
Cycle 5 Day 1				
n	80	24	58	22
Mean (SD)	33.7 (28.3)	4.2 (28.3)	28.7 (28.9)	3.0 (32.4)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-100 - 33	0 - 100	-100 - 67
Cycle 11 Day 1				
n	63	15	36	13
Mean (SD)	37.6 (33.1)	13.3 (37.4)	32.4 (31.4)	0.0 (27.2)
Median	33.3	33.3	33.3	0.0
Min - Max	0 - 100	-67 - 67	0 - 100	-33 - 33
Cycle 17 Day 1				
n	44	9	16	8
Mean (SD)	37.1 (33.9)	14.8 (24.2)	25.0 (25.8)	0.0 (17.8)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	0 - 67	0 - 100	-33 - 33
Cycle 23 Day 1				
n	29	6	9	5
Mean (SD)	40.2 (27.3)	27.8 (32.8)	18.5 (24.2)	-20.0 (18.3)
Median	33.3	16.7	0.0	-33.3
Min - Max	0 - 100	0 - 67	0 - 67	-33 - 0
Cycle 29 Day 1				
n	17	3	9	5
Mean (SD)	25.5 (14.6)	11.1 (19.2)	18.5 (17.6)	-6.7 (27.9)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 33	0 - 33	0 - 33	-33 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
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Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 28 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Upset by hair loss

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	9	1	4	2
Mean (SD)	40.7 (32.4)	66.7 (NA)	25.0 (16.7)	-16.7 (23.6)
Median	33.3	66.7	33.3	-16.7
Min - Max	0 - 100	67 - 67	0 - 33	-33 - 0
Cycle 39 Day 1				
n	1	0	0	0
Mean (SD)	33.3 (NA)	NE (NE)	NE (NE)	NE (NE)
Median	33.3	NE	NE	NE
Min - Max	33 - 33	NE - NE	NE - NE	NE - NE
Cycle 41 Day 1				
n	10	2	1	1
Mean (SD)	33.3 (31.4)	33.3 (47.1)	33.3 (NA)	33.3 (NA)
Median	33.3	33.3	33.3	33.3
Min - Max	0 - 100	0 - 67	33 - 33	33 - 33
Cycle 47 Day 1				
n	6	1	2	1
Mean (SD)	38.9 (32.8)	0.0 (NA)	16.7 (23.6)	0.0 (NA)
Median	33.3	0.0	16.7	0.0
Min - Max	0 - 100	0 - 0	0 - 33	0 - 0
Cycle 53 Day 1				
n	1	0	1	1
Mean (SD)	33.3 (NA)	NE (NE)	0.0 (NA)	0.0 (NA)
Median	33.3	NE	0.0	0.0
Min - Max	33 - 33	NE - NE	0 - 0	0 - 0
Treatment Discontinuation				
n	46	18	51	15
Mean (SD)	40.6 (29.7)	-0.0 (39.6)	30.1 (26.0)	11.1 (27.2)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-100 - 67	0 - 100	0 - 100

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

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Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 29 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: EORTC QLQ-BR23: Upset by hair loss

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Post-Treatment Follow Up Week 16				
n	7	1	5	3
Mean (SD)	19.0 (17.8)	33.3 (NA)	26.7 (27.9)	0.0 (33.3)
Median	33.3	33.3	33.3	0.0
Min - Max	0 - 33	33 - 33	0 - 67	-33 - 33
Post-Treatment Follow Up Week 24				
n	1	0	0	0
Mean (SD)	100.0 (NA)	NE (NE)	NE (NE)	NE (NE)
Median	100.0	NE	NE	NE
Min - Max	100 - 100	NE - NE	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	0	0	0
Mean (SD)	100.0 (NA)	NE (NE)	NE (NE)	NE (NE)
Median	100.0	NE	NE	NE
Min - Max	100 - 100	NE - NE	NE - NE	NE - NE
30 Day Safety Follow-up				
n	21	10	25	9
Mean (SD)	31.7 (26.8)	3.3 (24.6)	32.0 (34.0)	3.7 (20.0)
Median	33.3	0.0	33.3	0.0
Min - Max	0 - 100	-33 - 33	0 - 100	-33 - 33
Survival Follow-up Month 3				
n	8	3	12	3
Mean (SD)	50.0 (47.1)	11.1 (50.9)	38.9 (42.2)	33.3 (33.3)
Median	50.0	0.0	33.3	33.3
Min - Max	0 - 100	-33 - 67	0 - 100	0 - 67
Survival Follow-up Month 6				
n	5	1	3	2
Mean (SD)	46.7 (18.3)	0.0 (NA)	44.4 (38.5)	16.7 (23.6)
Median	33.3	0.0	66.7	16.7
Min - Max	33 - 67	0 - 0	0 - 67	0 - 33

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

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Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BR23_FAS_15NOV2024_41554.out Page 30 of 31

PRO Scores and Change from Baseline by Visit for EORTC QLQ-BR23, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
Parameter: EORTC QLQ-BR23: Upset by hair loss

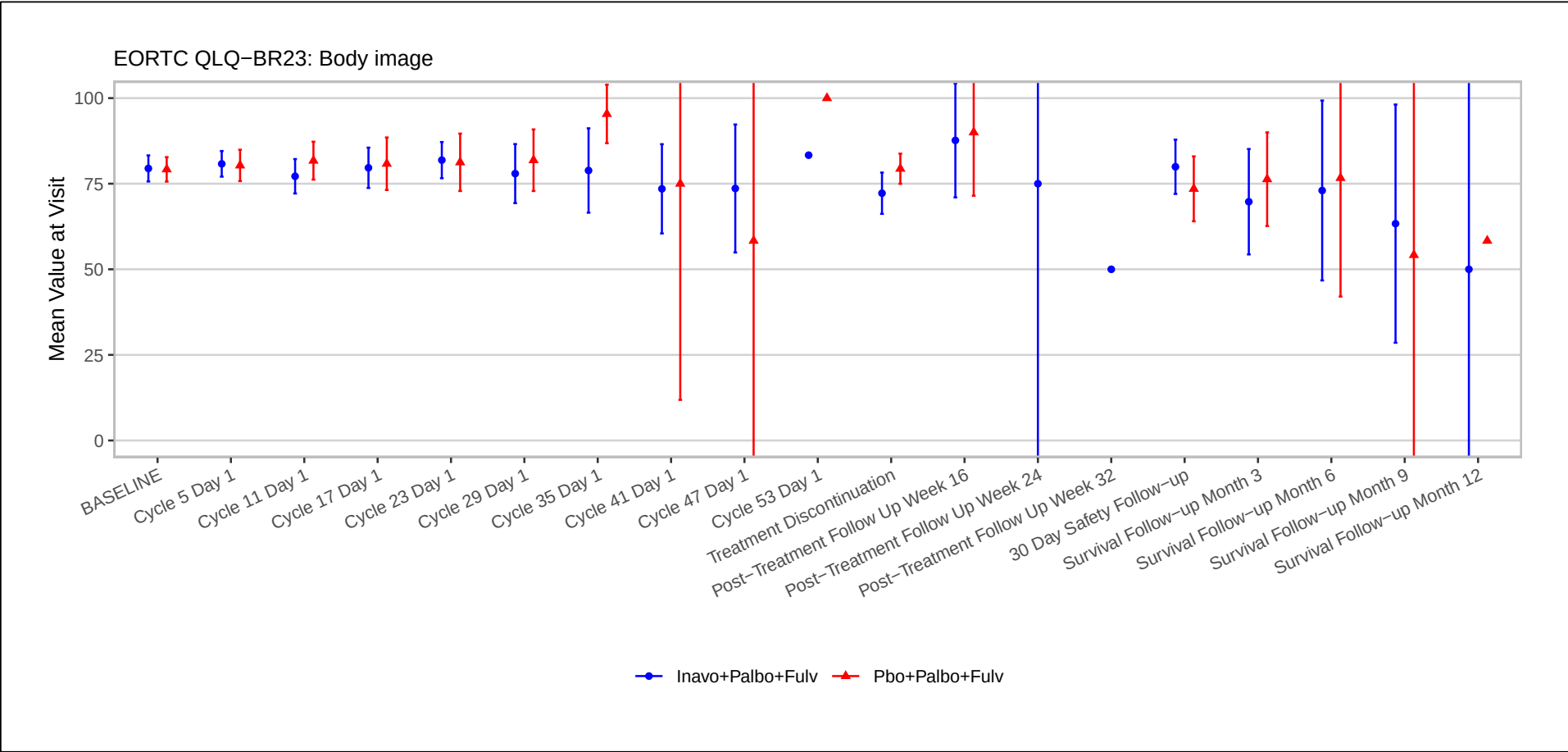
Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 9				
n	2	1	1	1
Mean (SD)	83.3 (23.6)	33.3 (NA)	66.7 (NA)	33.3 (NA)
Median	83.3	33.3	66.7	33.3
Min - Max	67 - 100	33 - 33	67 - 67	33 - 33
Survival Follow-up Month 12				
n	0	0	1	0
Mean (SD)	NE (NE)	NE (NE)	33.3 (NA)	NE (NE)
Median	NE	NE	33.3	NE
Min - Max	NE - NE	NE - NE	33 - 33	NE - NE

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

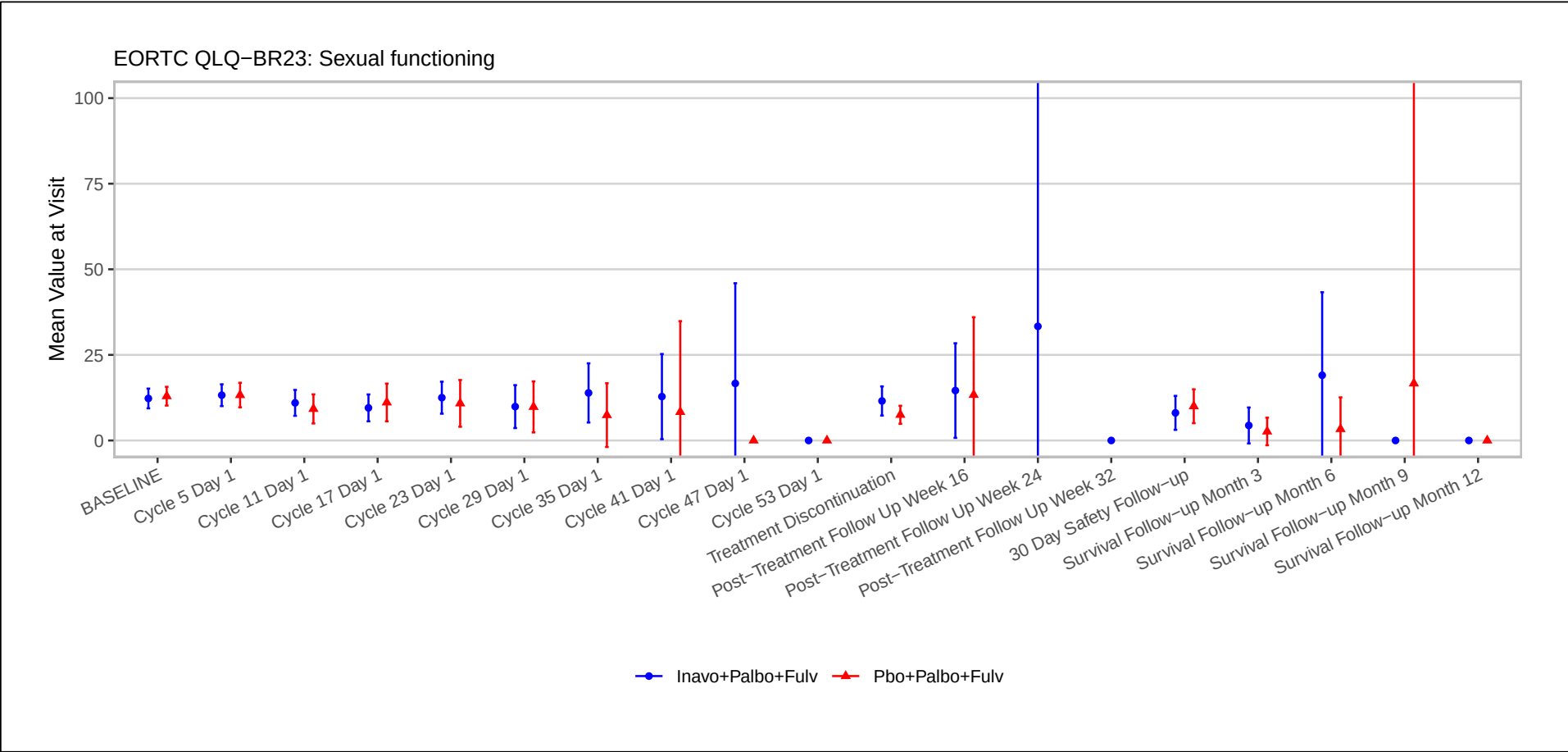
Plot of Mean and 95% Confidence Interval, EORTC QLQ-BR23, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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18 JUN 2025 17:00 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

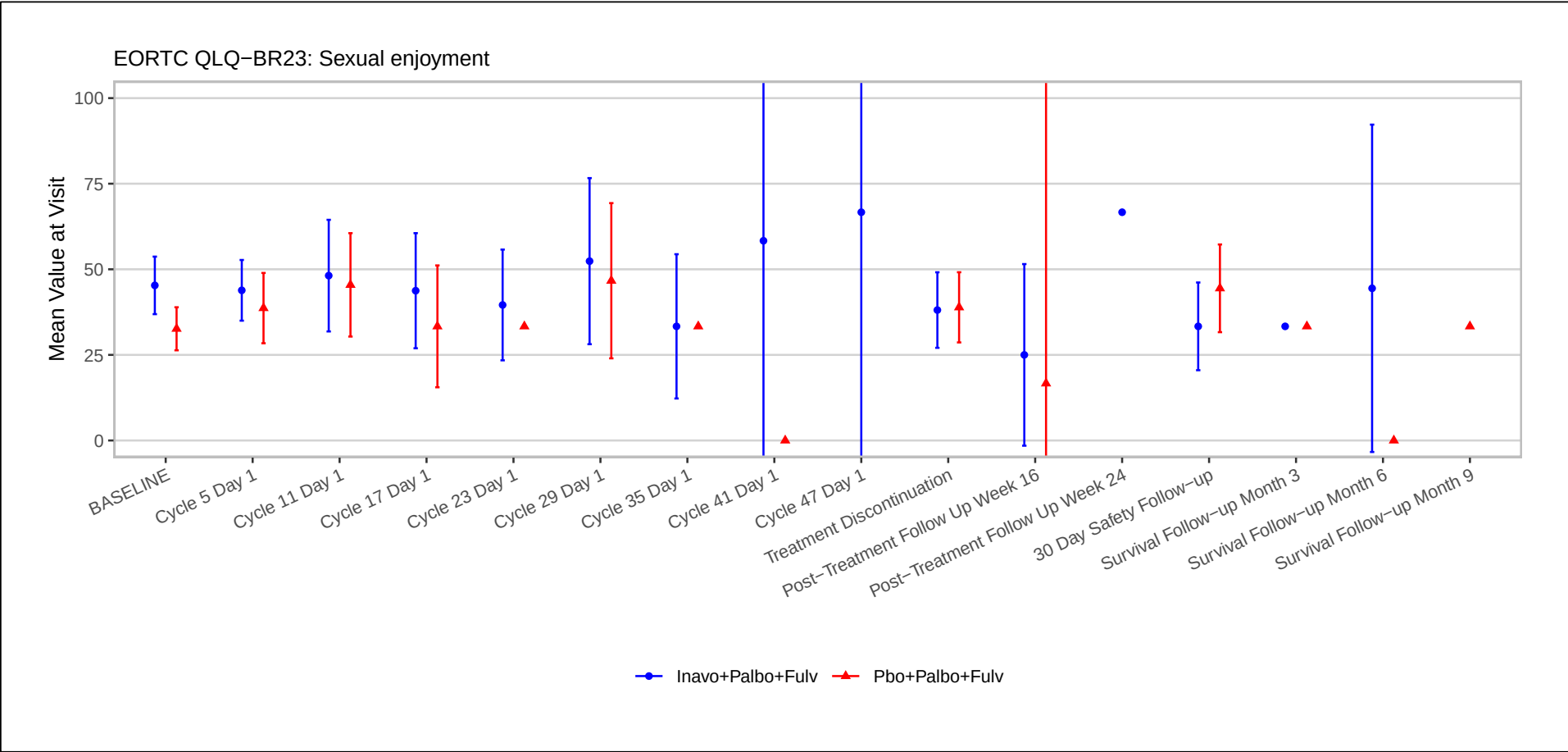
Plot of Mean and 95% Confidence Interval, EORTC QLQ–BR23, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

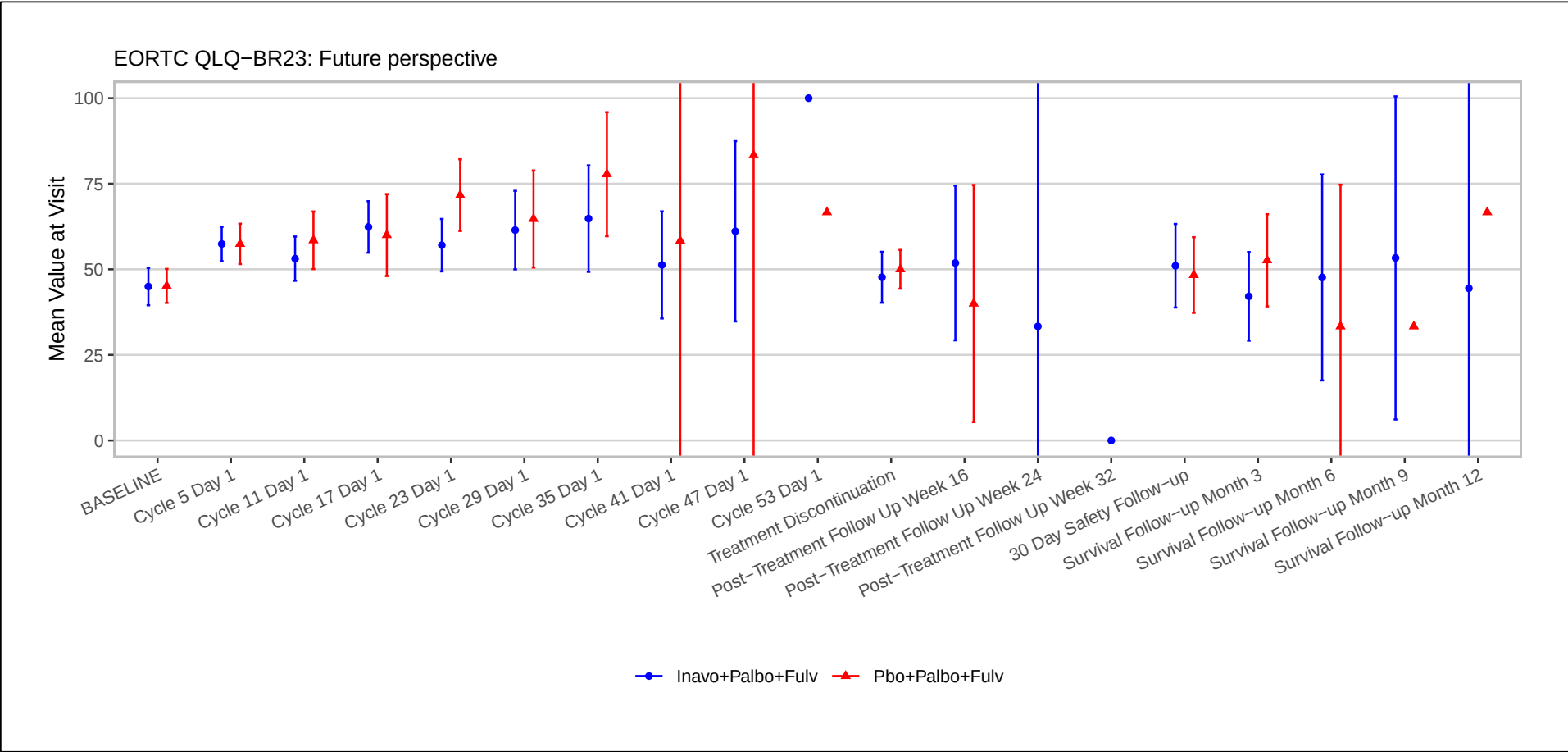
Plot of Mean and 95% Confidence Interval, EORTC QLQ-BR23, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_qs_cfb2.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v14/output/g_qs_cfb2_BR23_FAS_15NOV2024_41554.pdf
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

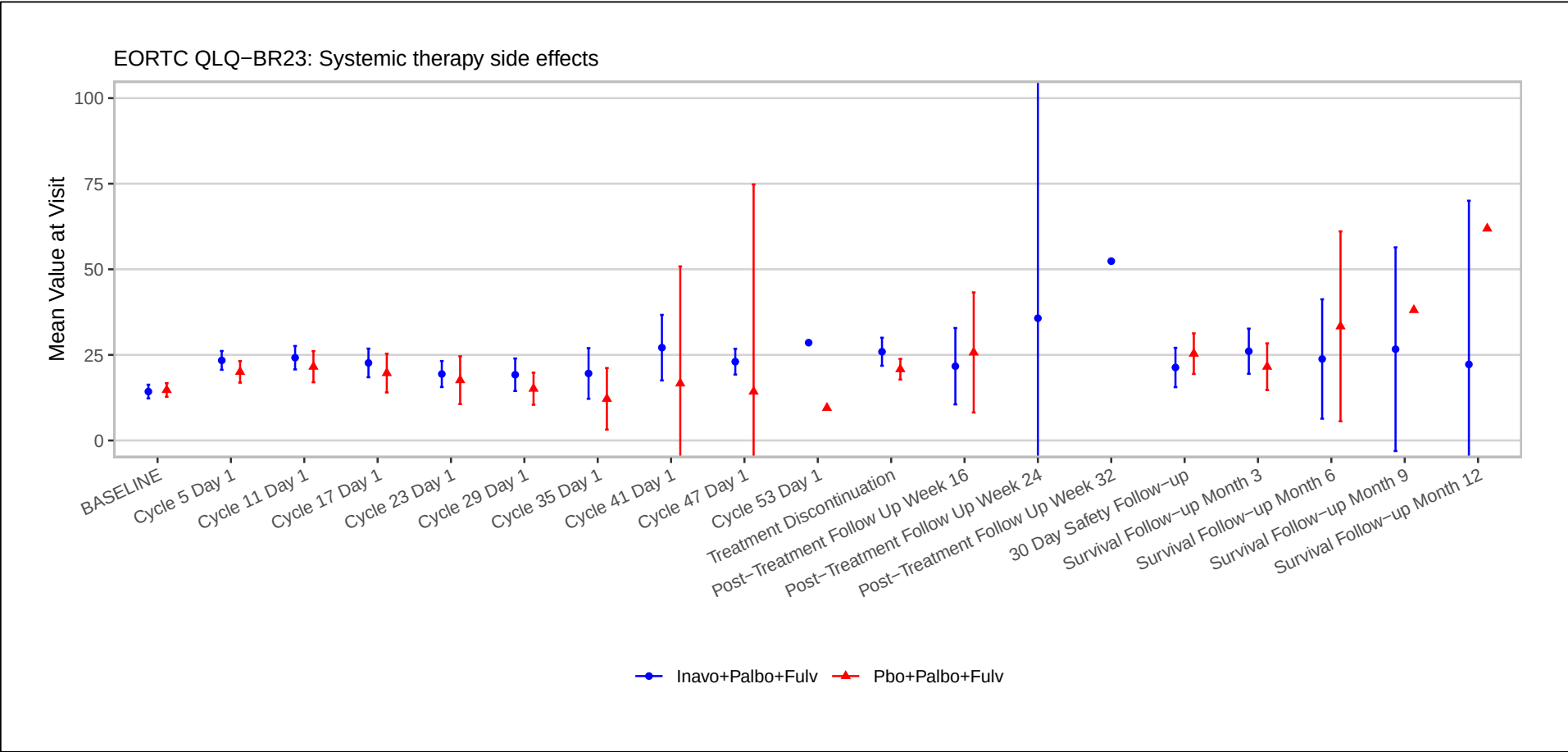
Plot of Mean and 95% Confidence Interval, EORTC QLQ-BR23, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Program name: programs/tlg/g_qs_cfb2.R
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

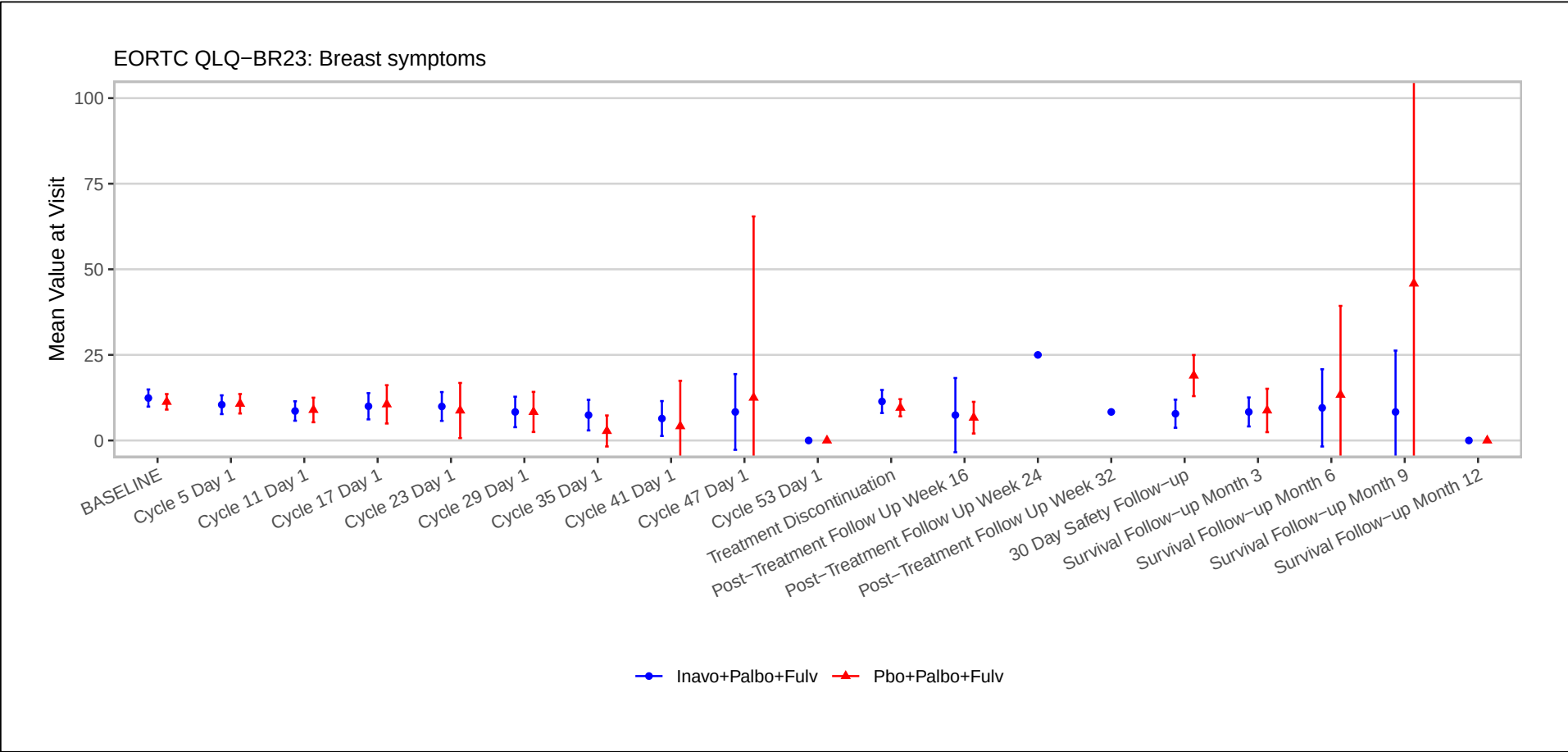
Plot of Mean and 95% Confidence Interval, EORTC QLQ-BR23, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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18 JUN 2025 17:00 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

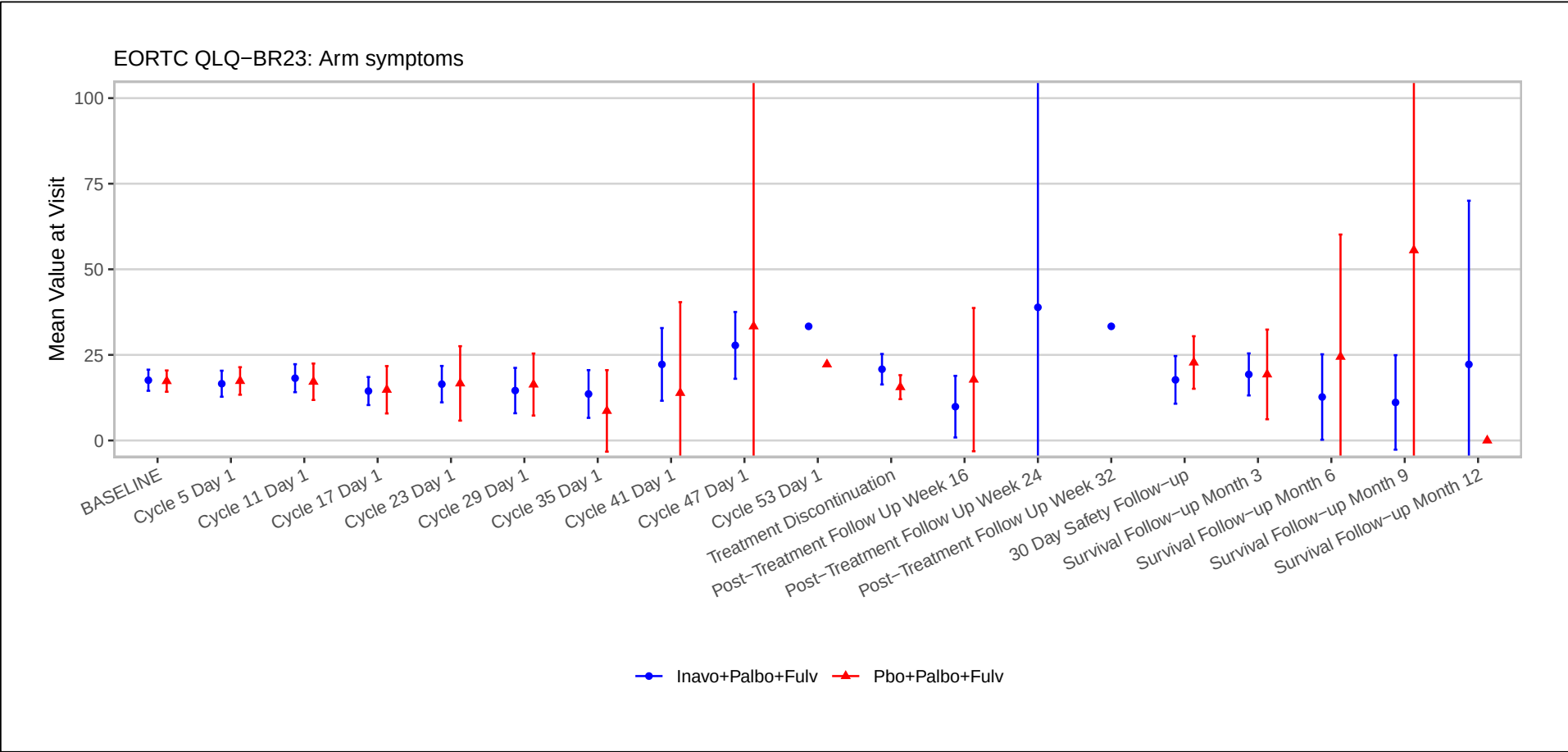
Plot of Mean and 95% Confidence Interval, EORTC QLQ–BR23, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_qs_cfb2.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v14/output/g_qs_cfb2_BR23_FAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 0efa981b2a84f5e06c881464de43872934271dc3
18 JUN 2025 17:00 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

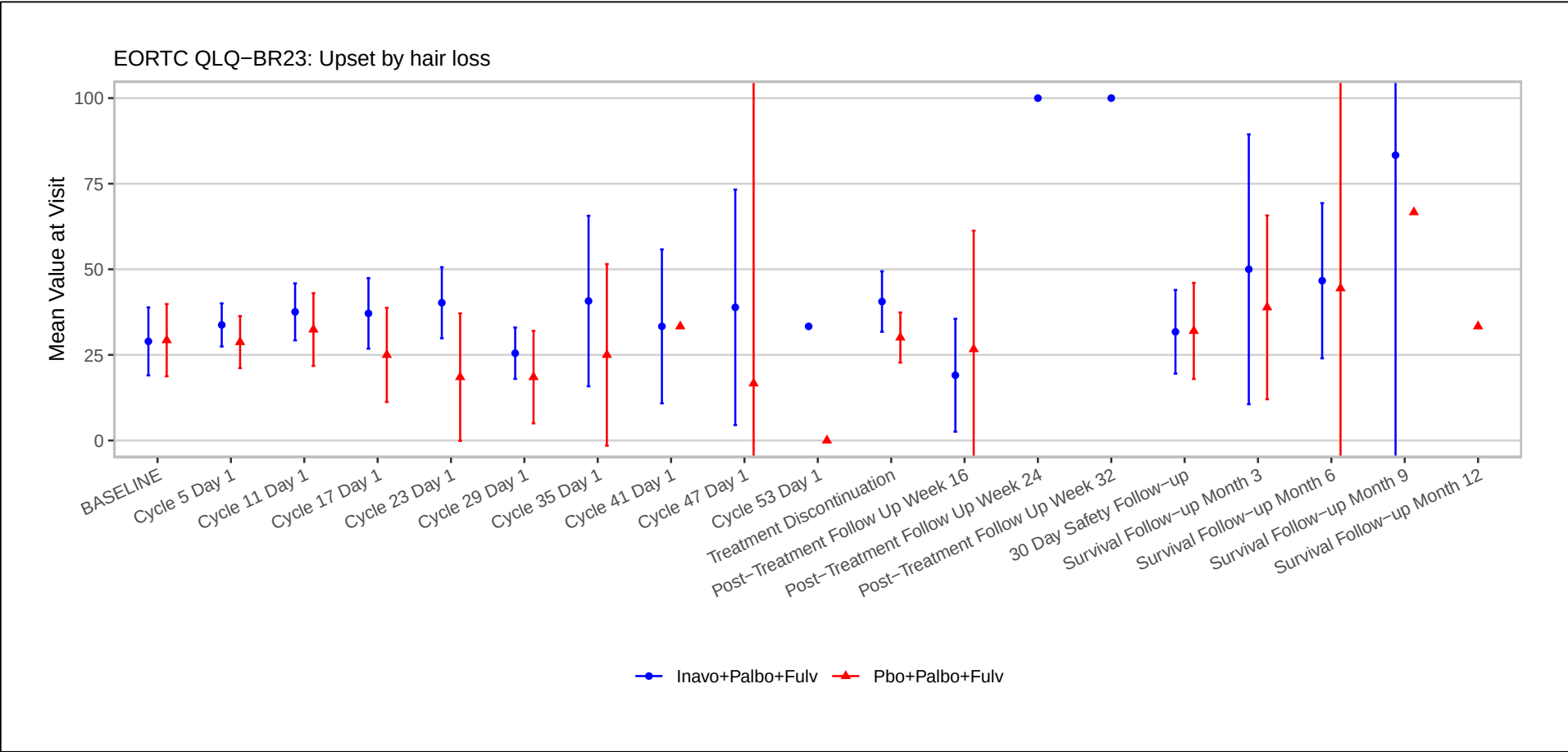
Plot of Mean and 95% Confidence Interval, EORTC QLQ-BR23, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_qs_cfb2.R
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Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
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18 JUN 2025 17:00 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Plot of Mean and 95% Confidence Interval, EORTC QLQ-BR23, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_qs_cfb2.R
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18 JUN 2025 17:00 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.2 PRO Items des EORTC QLQ-BR23

2.2.3 Zeit bis zur ersten Verschlechterung der PRO Items des EORTC QLQ-BR23, MID = 10 Punkte

Time to Event Analysis (Efficacy), EORTC QLQ-BR23 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Arm Symptoms (MID >=10)		
Patients with event		
n (%)	75 (46.6%)	63 (38.4%)
Patients without event		
n (%)	86 (53.4%)	101 (61.6%)
Time to Event (Months)		
Median	11.93	11.93
95% CI	(9.72, 21.65)	(9.46, 16.13)
Range	0.03 - 46.78 {1}	0.03 - 37.29 {1}
Unstratified Analysis		
p-value (log-rank)	0.3866	
Hazard Ratio	0.86	
95% CI	(0.61, 1.21)	
Stratified Analysis		
p-value (log-rank)	0.6115	
Hazard Ratio	0.92	
95% CI	(0.64, 1.31)	
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Body Image (MID >=10)		
Patients with event		
n (%)	63 (39.1%)	49 (29.9%)
Patients without event		
n (%)	98 (60.9%)	115 (70.1%)
Time to Event (Months)		
Median	20.27	17.35
95% CI	(14.75, 25.89)	(14.75, 24.25)
Range	0.03 - 46.78 {1}	0.03 - 38.93 {1}
Unstratified Analysis		
p-value (log-rank)	0.7794	
Hazard Ratio	0.95	
95% CI	(0.65, 1.38)	
Stratified Analysis		
p-value (log-rank)	0.9065	
Hazard Ratio	0.98	
95% CI	(0.66, 1.45)	
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Breast Symptoms (MID >=10)		
Patients with event		
n (%)	39 (24.2%)	28 (17.1%)
Patients without event		
n (%)	122 (75.8%)	136 (82.9%)
Time to Event (Months)		
Median	NE	NE
95% CI	(25.95, NE)	(20.44, NE)
Range	0.03 - 46.78 {1}	0.03 - 47.87 {1}
Unstratified Analysis		
p-value (log-rank)	0.7297	
Hazard Ratio	0.92	
95% CI	(0.56, 1.50)	
Stratified Analysis		
p-value (log-rank)	0.4393	

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Hazard Ratio	0.81	
95% CI	(0.48, 1.37)	
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Future Perspective (MID >=10)		
Patients with event		
n (%)	40 (24.8%)	29 (17.7%)
Patients without event		
n (%)	121 (75.2%)	135 (82.3%)
Time to Event (Months)		
Median	37.52	NE
95% CI	(25.95, NE)	(18.46, NE)
Range	0.03 - 48.62 {1}	0.03 - 47.87 {1}
Unstratified Analysis		
p-value (log-rank)	0.9759	
Hazard Ratio	0.99	
95% CI	(0.61, 1.61)	
Stratified Analysis		
p-value (log-rank)	0.5371	
Hazard Ratio	0.86	
95% CI	(0.52, 1.42)	
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Upset by Hair Loss (MID >=10)		
Patients with event		
n (%)	21 (13%)	11 (6.7%)
Patients without event		
n (%)	140 (87%)	153 (93.3%)
Time to Event (Months)		
Median	9.63	NE
95% CI	(7.92, 11.83)	(6.57, NE)
Range	0.03 - 22.11 {1}	0.03 - 34.46 {1}
Unstratified Analysis		
p-value (log-rank)	0.1558	
Hazard Ratio	1.69	
95% CI	(0.81, 3.52)	
Stratified Analysis		
p-value (log-rank)	0.1242	
Hazard Ratio	1.91	
95% CI	(0.83, 4.42)	
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Sexual Enjoyment (MID >=10)		
Patients with event		
n (%)	13 (8.1%)	5 (3%)
Patients without event		
n (%)	148 (91.9%)	159 (97%)
Time to Event (Months)		
Median	20.50	NE
95% CI	(4.27, NE)	(12.16, NE)
Range	0.03 - 46.49 {1}	0.03 - 36.57 {1}
Unstratified Analysis		
p-value (log-rank)	0.3225	
Hazard Ratio	1.67	
95% CI	(0.60, 4.70)	
Stratified Analysis		
p-value (log-rank)	0.2264	

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
Hazard Ratio	2.76	
95% CI	(0.54, 14.18)	
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Sexual Functioning (MID >=10)		
Patients with event		
n (%)	41 (25.5%)	43 (26.2%)
Patients without event		
n (%)	120 (74.5%)	121 (73.8%)
Time to Event (Months)		
Median	NE	34.46
95% CI	NE	(15.05, NE)
Range	0.03 - 46.78 {1}	0.03 - 45.31 {1}
Unstratified Analysis		
p-value (log-rank)	0.0773	
Hazard Ratio	0.68	
95% CI	(0.44, 1.05)	
Stratified Analysis		
p-value (log-rank)	0.0561	
Hazard Ratio	0.64	
95% CI	(0.41, 1.00)	
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Systemic Therapy Side Effects (MID >=10)		
Patients with event		
n (%)	91 (56.5%)	60 (36.6%)
Patients without event		
n (%)	70 (43.5%)	104 (63.4%)
Time to Event (Months)		
Median	10.02	11.76
95% CI	(7.39, 11.93)	(9.23, 20.44)
Range	0.03 - 39.66 {2}	0.03 - 47.87 {1}
Unstratified Analysis		
p-value (log-rank)	0.0805	
Hazard Ratio	1.34	
95% CI	(0.97, 1.86)	
Stratified Analysis		
p-value (log-rank)	0.0184	
Hazard Ratio	1.53	
95% CI	(1.08, 2.16)	

{1} - Censored observations: range minimum & maximum

{2} - Censored observation: range minimum

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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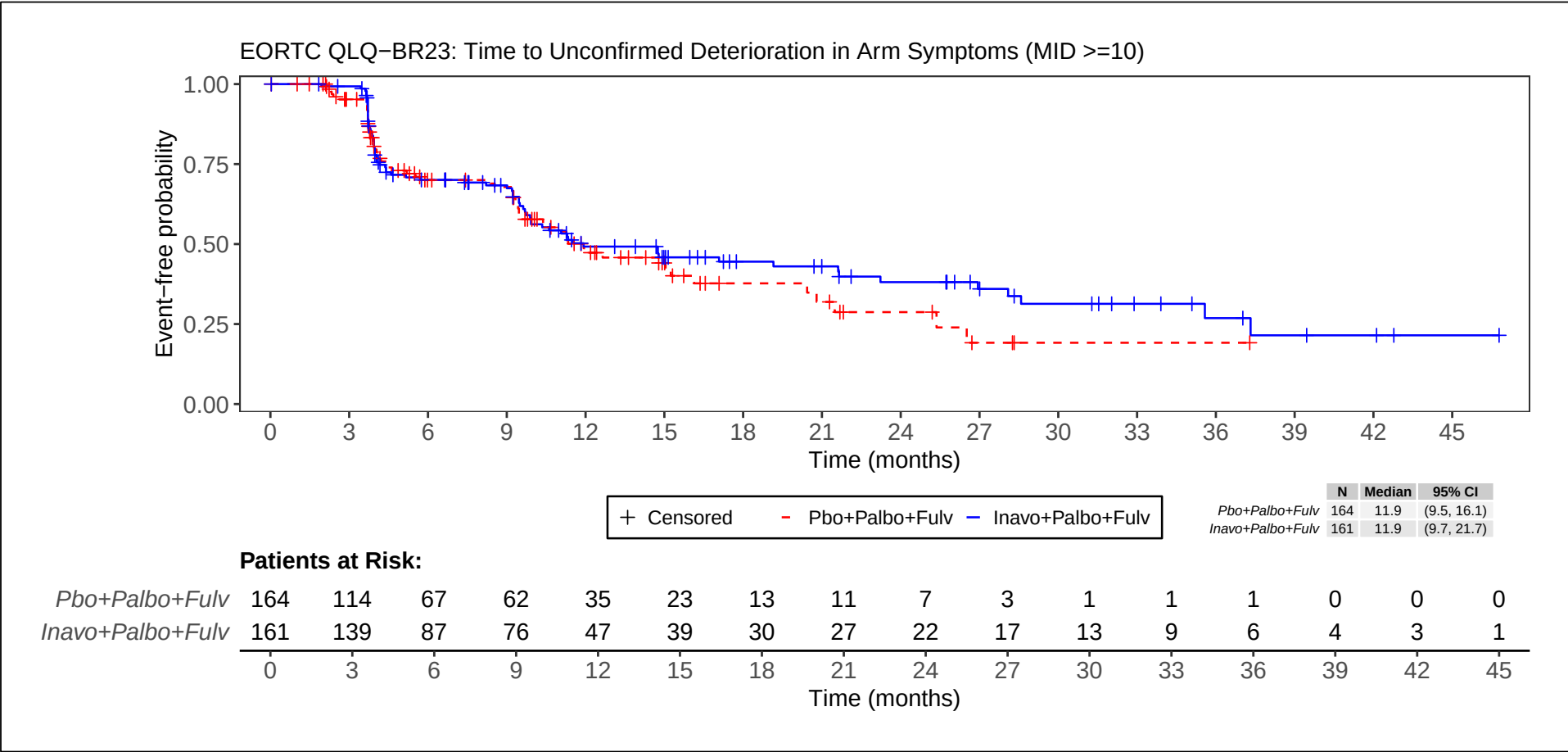
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

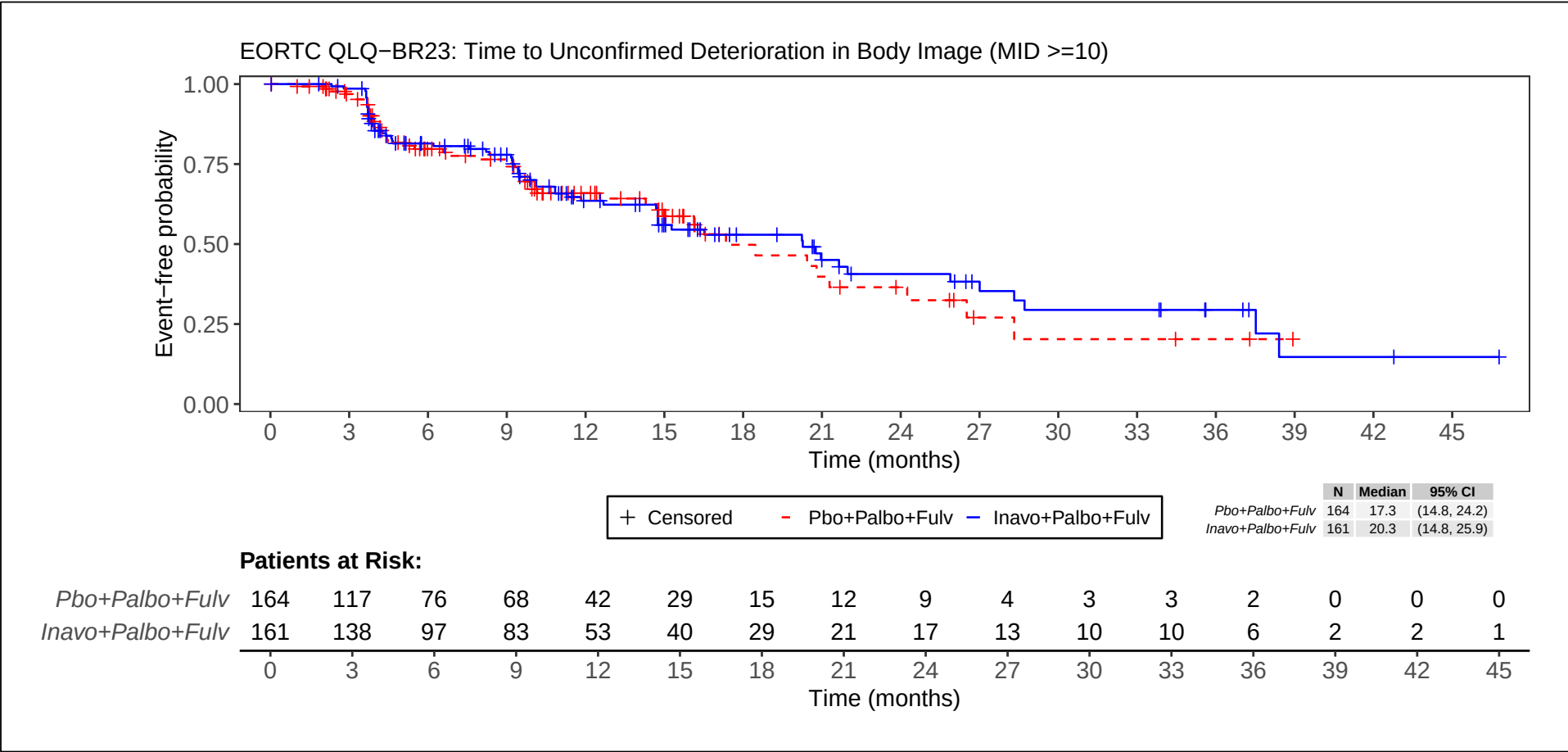
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

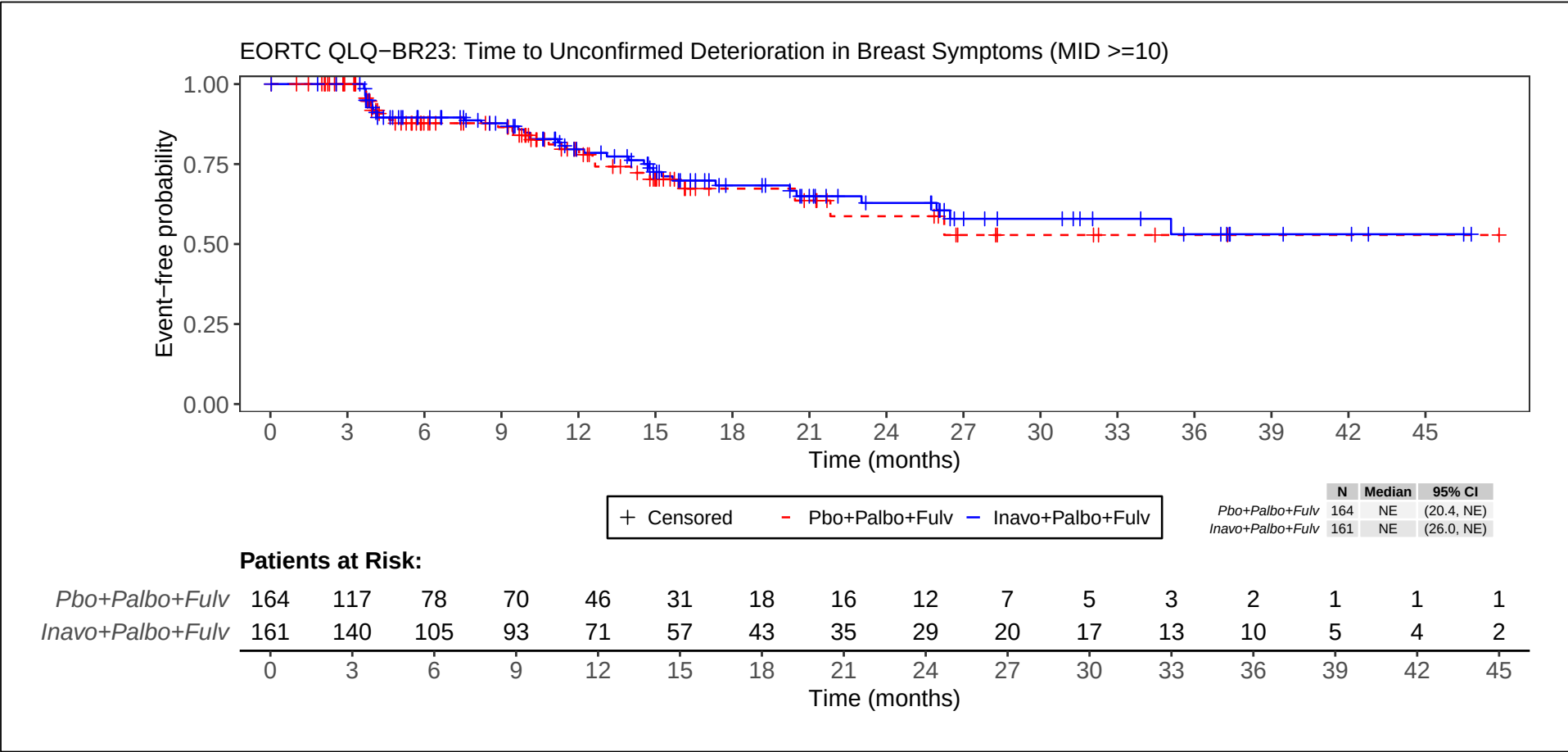
Kaplan Meier Plot for Efficacy, EORTC QLQ-BR23 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

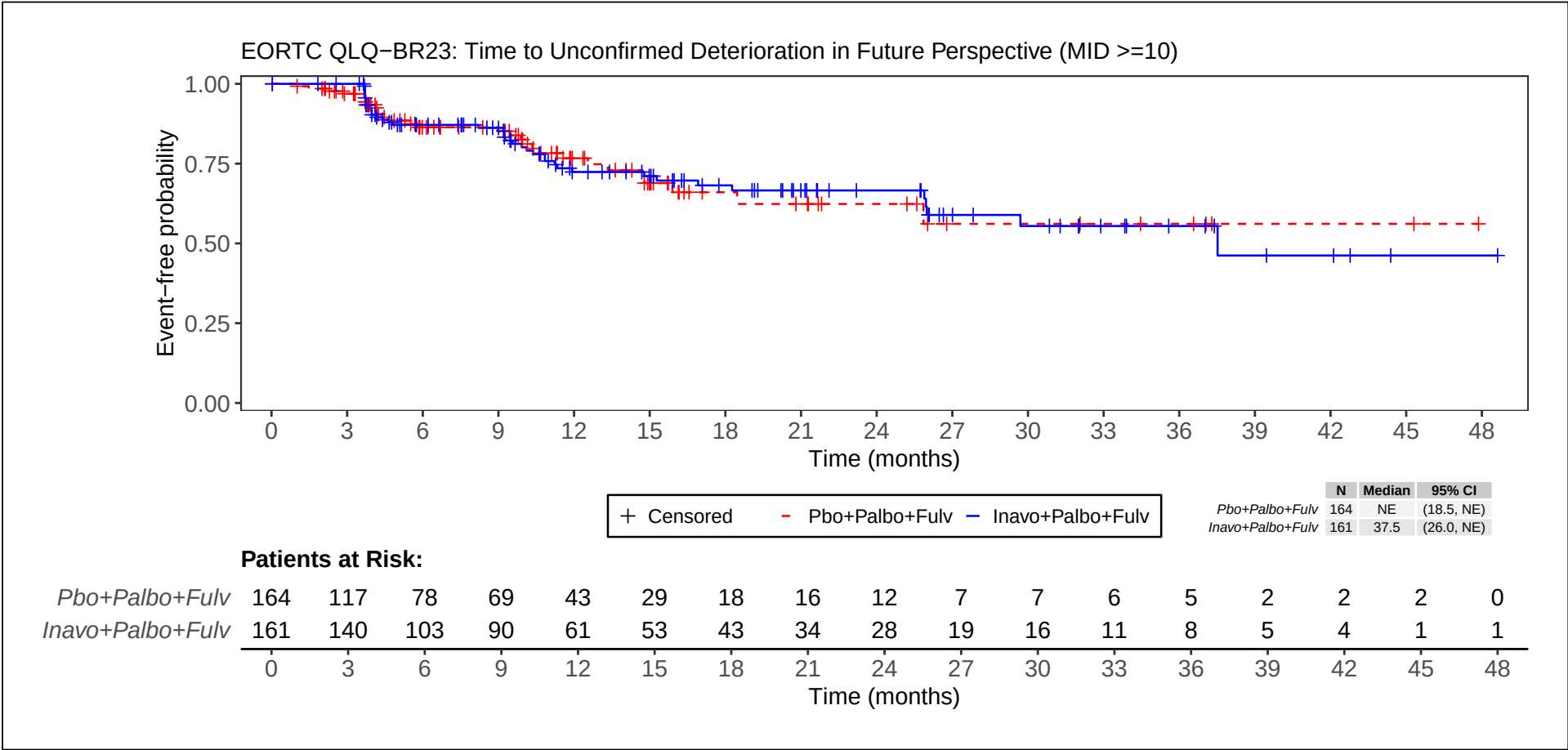
Kaplan Meier Plot for Efficacy, EORTC QLQ-BR23 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

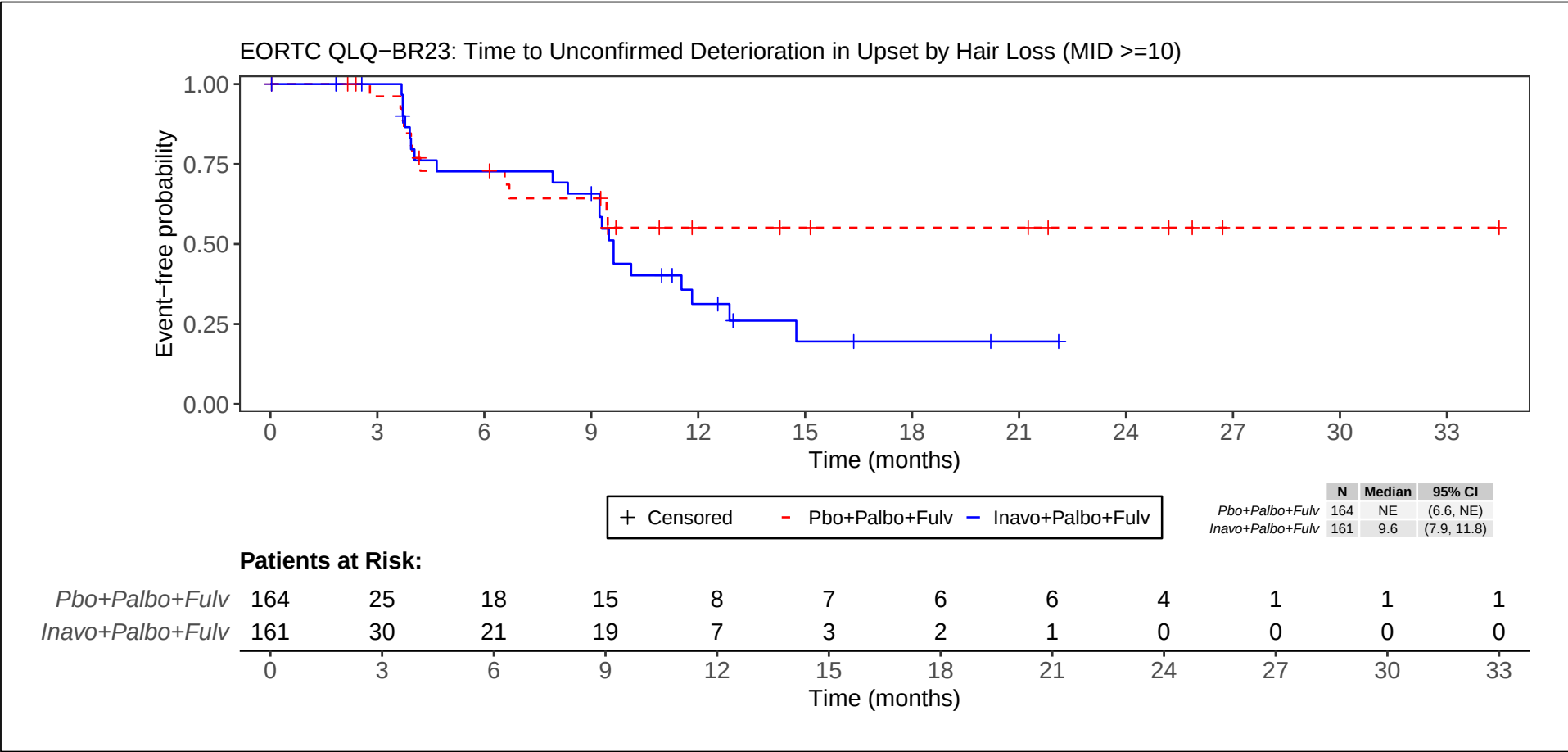
Kaplan Meier Plot for Efficacy, EORTC QLQ-BR23 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

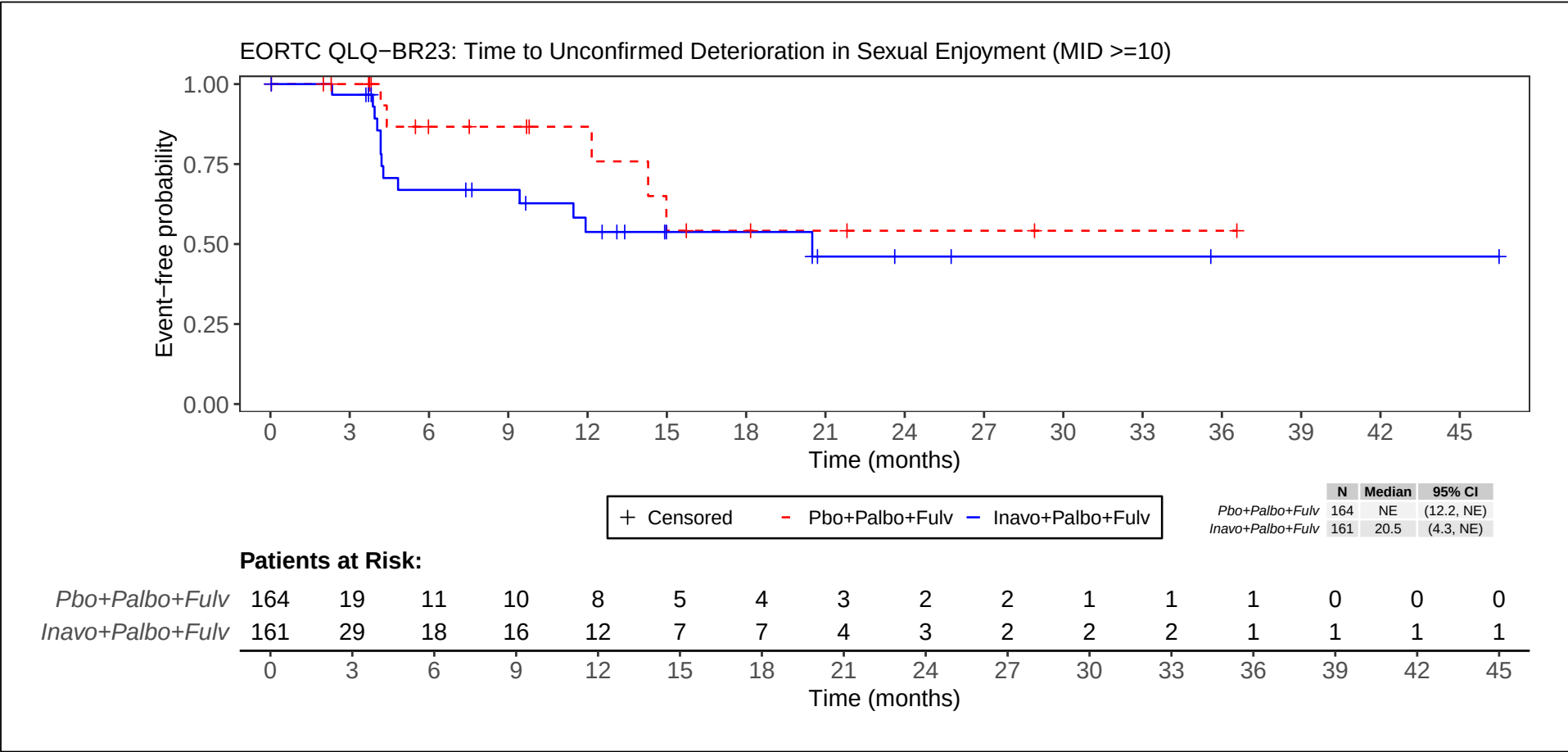
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

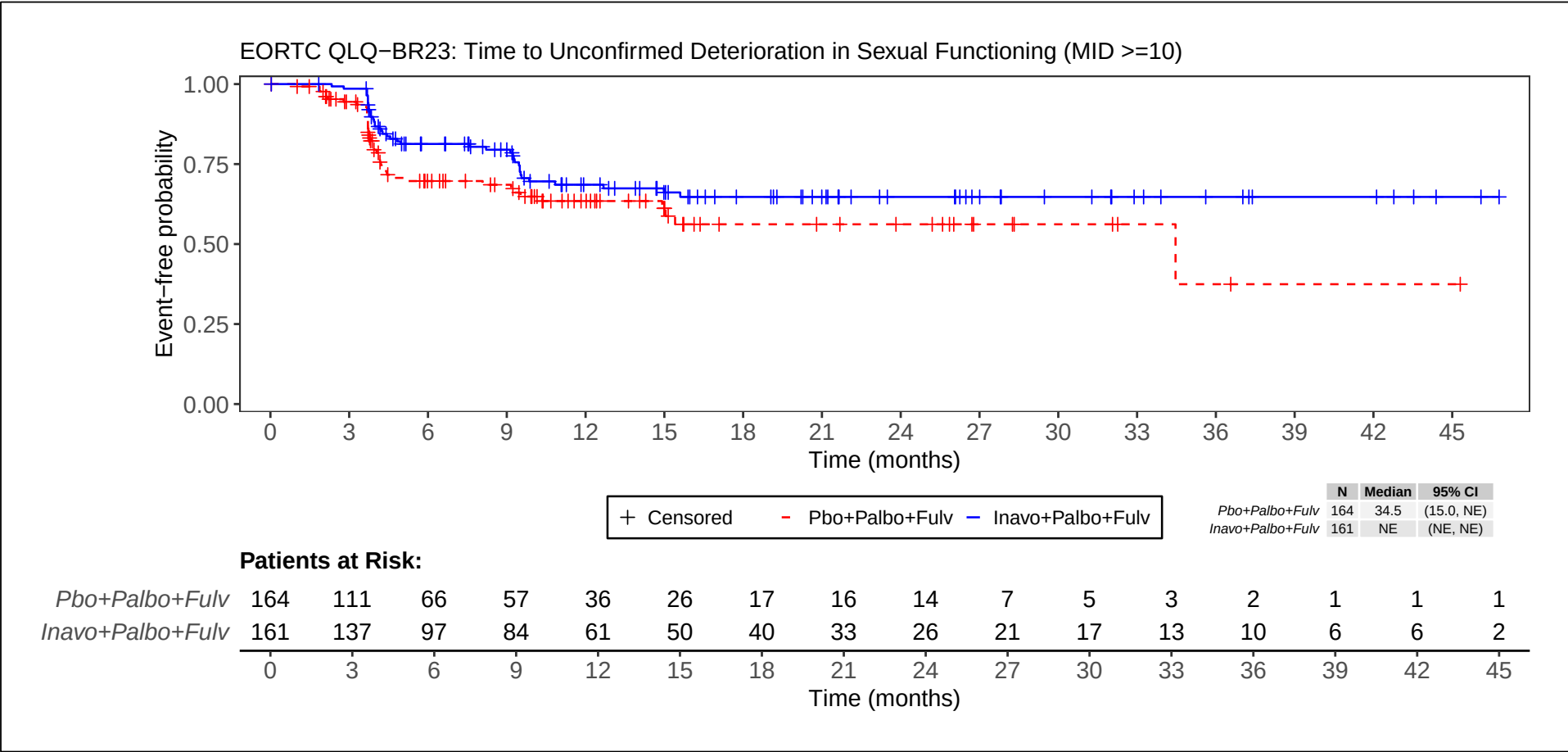
Kaplan Meier Plot for Efficacy, EORTC QLQ-BR23 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

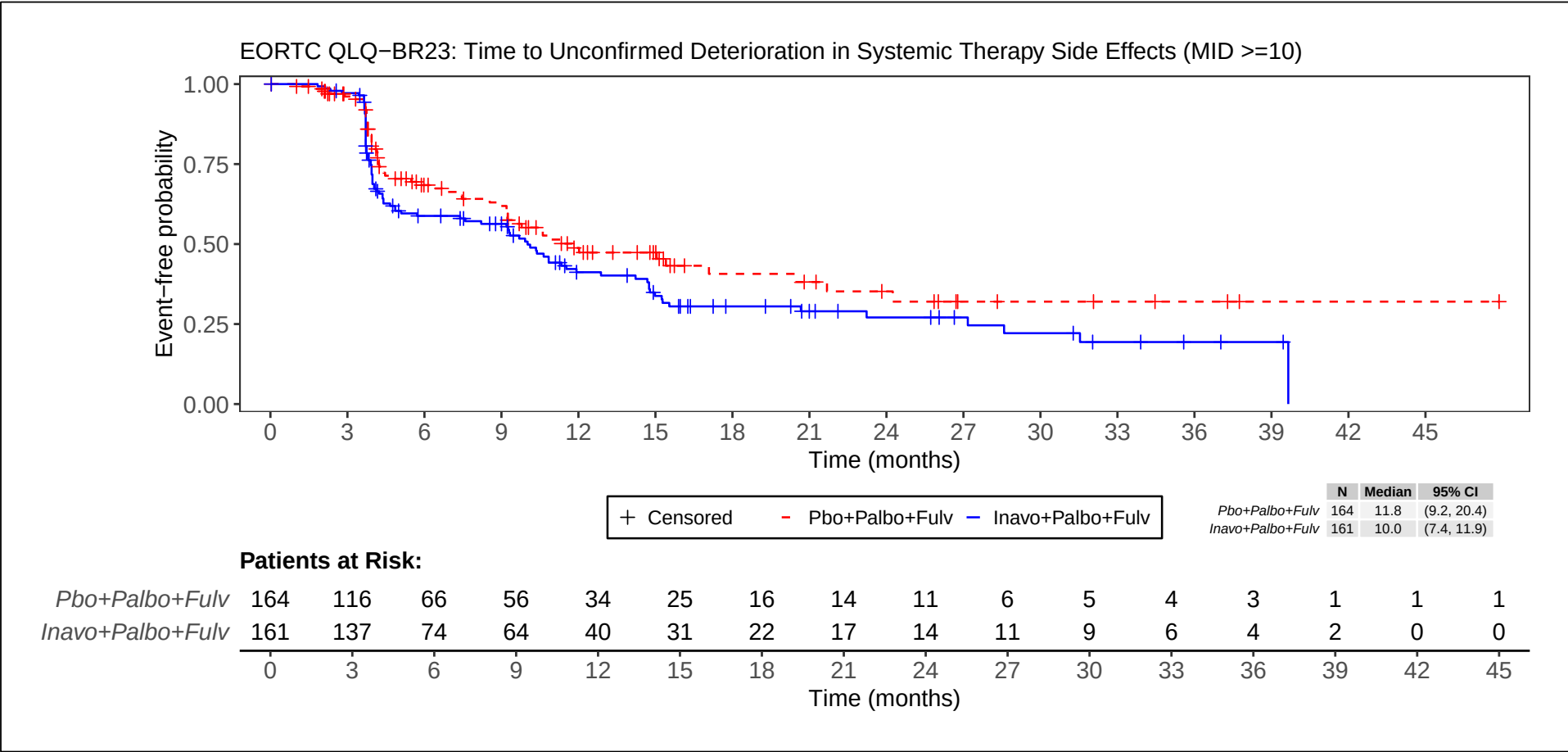
Kaplan Meier Plot for Efficacy, EORTC QLQ-BR23 (Unconfirmed Deterioration), Full Analysis Set
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Efficacy, EORTC QLQ-BR23 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.2 PRO Items des EORTC QLQ-BR23

2.2.3 Zeit bis zur ersten Verschlechterung der PRO Items des EORTC QLQ-BR23, MID = 10 Punkte

2.2.3.1 Subgruppenanalyse Zeit bis zur ersten Verschlechterung der PRO Items des EORTC QLQ-BR23, MID = 10 Punkte

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Efficacy), EORTC QLQ-BR23 (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOd: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Arm Symptoms (MID >=10)															
All Patients	325	164	63	38.4	11.93	(9.46, 16.13)	161	75	46.6	11.93	(9.72, 21.65)	0.86	(0.61, 1.21)	0.3866	NE
Age group (years)															
<65	266	130	48	36.9	11.33	(9.33, 15.05)	136	66	48.5	11.93	(9.72, 23.23)	0.85	(0.58, 1.23)	0.3823	0.4650
>=65	59	34	15	44.1	15.24	(4.21, 25.36)	25	9	36.0	10.35	(3.71, 28.58)	0.98	(0.41, 2.33)	0.9564	0.4650
Sex															
F	319	163	63	38.7	11.93	(9.46, 16.13)	156	73	46.8	11.33	(9.69, 21.62)	0.90	(0.64, 1.27)	0.5342	1.0000
M	6	1	0	0.0	NE	NE	5	2	40.0	35.58	(3.91, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	29	46.8	9.46	(4.44, 12.65)	58	30	51.7	14.78	(9.46, 26.94)	0.71	(0.42, 1.21)	0.2062	0.0250
NORTH AMERICA/WESTERN EUROPE	127	64	21	32.8	16.13	(10.41, 21.49)	63	28	44.4	9.49	(4.04, 21.62)	1.68	(0.95, 2.97)	0.0748	0.0250
OTHER	78	38	13	34.2	9.33	(4.11, NA)	40	17	42.5	21.65	(11.33, NA)	0.49	(0.23, 1.04)	0.0562	0.0250
Visceral disease (per eCRF)															
N	65	36	16	44.4	11.93	(3.94, 25.36)	29	15	51.7	11.53	(4.60, NA)	0.75	(0.36, 1.54)	0.4237	0.5278
Y	260	128	47	36.7	11.33	(9.46, 20.44)	132	60	45.5	14.75	(9.69, 23.23)	0.90	(0.61, 1.33)	0.5995	0.5278
Ethnicity															
HISPANIC OR LATINO	20	10	4	40.0	12.80	(3.71, NA)	10	4	40.0	10.61	(3.78, NA)	0.82	(0.20, 3.32)	0.7617	0.0201
NOT HISPANIC OR LATINO	294	149	58	38.9	11.33	(9.46, 15.24)	145	69	47.6	11.93	(9.72, 21.65)	0.86	(0.60, 1.22)	0.3832	0.0201
NOT REPORTED	5	3	0	0.0	NE	NE	2	2	100.0	6.47	(3.71, NA)	>999.99	(0.00, >999.99)	0.2253	0.0201
UNKNOWN	6	2	1	50.0	3.71	NE	4	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.1573	0.0201
Race															
Asian	124	63	29	46.0	9.46	(4.44, 12.65)	61	31	50.8	14.78	(9.23, 26.94)	0.71	(0.42, 1.20)	0.2000	0.3717
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.3717
White	191	97	34	35.1	15.05	(9.46, 20.80)	94	43	45.7	11.33	(9.49, 21.65)	0.98	(0.62, 1.55)	0.9371	0.3717
Unknown	8	3	0	0.0	NE	NE	5	1	20.0	NE	(3.71, NA)	>999.99	(0.00, >999.99)	0.5637	0.3717
Liver Metastasis at Enrollment															
N	157	73	34	46.6	12.02	(9.23, 21.49)	84	38	45.2	19.15	(10.35, 28.58)	0.75	(0.47, 1.20)	0.2318	0.4157
Y	168	91	29	31.9	11.27	(9.33, 15.24)	77	37	48.1	9.92	(9.23, 21.62)	0.99	(0.61, 1.63)	0.9766	0.4157
Number Metastatic Organs at Enrollment															
1	53	32	13	40.6	10.41	(3.94, NA)	21	8	38.1	17.08	(10.35, NA)	0.57	(0.23, 1.40)	0.2145	0.4238
2	104	46	19	41.3	10.38	(4.47, NA)	58	26	44.8	19.15	(5.72, 35.58)	0.82	(0.45, 1.49)	0.5021	0.4238
>=3	168	86	31	36.0	14.78	(9.33, 20.44)	82	41	50.0	9.92	(9.23, 14.78)	1.00	(0.62, 1.62)	0.9981	0.4238
ECOG Performance Status at Baseline															
0	206	106	40	37.7	11.33	(9.46, 15.05)	100	50	50.0	9.92	(9.23, 28.09)	0.94	(0.62, 1.43)	0.7740	0.7663
1	118	58	23	39.7	15.24	(5.52, NA)	60	25	41.7	14.75	(11.30, 26.94)	0.70	(0.39, 1.26)	0.2297	0.7663
Endocrine Resistance (per eCRF)															

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Primary	112	58	22	37.9	5.85	(3.81, NA)	54	25	46.3	11.30	(9.23, 35.58)	0.62	(0.35, 1.12)	0.1117	0.1057
Secondary	212	105	41	39.0	12.65	(10.41, 20.44)	107	50	46.7	14.75	(9.72, 23.23)	0.99	(0.65, 1.51)	0.9577	0.1057
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	23	44.2	10.41	(4.44, 14.78)	52	30	57.7	9.72	(5.72, 14.75)	0.83	(0.48, 1.44)	0.4948	0.7302
POST-MENOPAUSAL	215	111	40	36.0	15.24	(9.46, 21.49)	104	43	41.3	17.08	(10.35, 28.09)	0.91	(0.59, 1.40)	0.6557	0.7302
Hormone receptor status															
ER+/PR-	90	45	20	44.4	9.43	(3.94, 12.02)	45	15	33.3	35.58	(10.35, NA)	0.35	(0.17, 0.73)	0.0031	0.0015
ER+/PR+	226	113	41	36.3	14.78	(10.38, 20.80)	113	60	53.1	9.92	(8.21, 14.78)	1.23	(0.83, 1.84)	0.3088	0.0015
Other	9	6	2	33.3	21.49	(3.71, NA)	3	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.1985	0.0015
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	6	31.6	NE	(5.52, NA)	18	8	44.4	10.61	(3.71, NA)	1.74	(0.60, 5.08)	0.2928	0.3675
Aromatase inhibitor only	131	71	29	40.8	11.93	(9.33, 20.44)	60	22	36.7	21.62	(9.63, NA)	0.69	(0.39, 1.20)	0.1805	0.3675
Tamoxifen only	155	73	28	38.4	11.27	(5.85, 26.51)	82	45	54.9	11.93	(9.23, 23.23)	0.87	(0.53, 1.41)	0.5529	0.3675
Prior (neo)-adjuvant CDK4/6															
N	322	163	62	38.0	11.33	(9.46, 16.13)	159	75	47.2	11.93	(9.72, 21.65)	0.87	(0.62, 1.22)	0.4018	1.0000
Y	3	1	1	100.0	14.78	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	10	37.0	11.33	(9.23, NA)	29	13	44.8	11.30	(3.98, 28.58)	1.02	(0.44, 2.37)	0.9625	0.7915
Y	269	137	53	38.7	11.93	(9.43, 20.80)	132	62	47.0	14.75	(9.69, 23.23)	0.85	(0.59, 1.23)	0.3877	0.7915
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Body Image (MID >=10)															
All Patients	325	164	49	29.9	17.35	(14.75, 24.25)	161	63	39.1	20.27	(14.75, 25.89)	0.95	(0.65, 1.38)	0.7794	NE
Age group (years)															
<65	266	130	39	30.0	17.35	(10.15, 24.25)	136	54	39.7	20.27	(14.75, 28.32)	0.80	(0.53, 1.22)	0.3005	0.0617
>=65	59	34	10	29.4	20.44	(12.55, NA)	25	9	36.0	20.76	(3.71, NA)	1.74	(0.70, 4.30)	0.2333	0.0617
Sex															
F	319	163	49	30.1	17.35	(14.75, 24.25)	156	61	39.1	20.24	(14.69, 21.98)	1.02	(0.70, 1.49)	0.9300	1.0000
M	6	1	0	0.0	NE	NE	5	2	40.0	28.71	(28.32, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	26	41.9	14.29	(5.49, NA)	58	22	37.9	38.41	(10.84, NA)	0.58	(0.33, 1.05)	0.0664	0.0269
NORTH AMERICA/WESTERN EUROPE	127	64	14	21.9	21.29	(16.36, NA)	63	23	36.5	14.75	(9.30, 28.71)	1.67	(0.85, 3.31)	0.1300	0.0269
OTHER	78	38	9	23.7	18.46	(9.33, NA)	40	18	45.0	20.76	(12.68, 25.89)	1.04	(0.46, 2.33)	0.9277	0.0269
Visceral disease (per eCRF)															
N	65	36	12	33.3	16.13	(9.17, NA)	29	8	27.6	28.71	(20.76, NA)	0.21	(0.07, 0.69)	0.0054	0.0359
Y	260	128	37	28.9	20.80	(14.75, 28.32)	132	55	41.7	15.28	(11.33, 21.65)	1.16	(0.76, 1.76)	0.4892	0.0359
Ethnicity															
HISPANIC OR LATINO	20	10	4	40.0	24.25	(9.46, NA)	10	2	20.0	28.71	(14.75, NA)	0.30	(0.03, 2.75)	0.2626	0.4649
NOT HISPANIC OR LATINO	294	149	44	29.5	18.46	(14.29, 26.51)	145	59	40.7	20.27	(14.69, 25.89)	0.98	(0.66, 1.46)	0.9228	0.4649
NOT REPORTED	5	3	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	0.4649

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
UNKNOWN	6	2	1	50.0	14.75	NE	4	2	50.0	3.83	(3.78, NA)	>999.99	(0.00, >999.99)	0.2253	0.4649
Race															
Asian	124	63	26	41.3	14.29	(5.49, NA)	61	23	37.7	38.41	(10.84, NA)	0.59	(0.33, 1.04)	0.0650	0.0115
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.0115
White	191	97	23	23.7	20.80	(16.13, 26.51)	94	38	40.4	16.53	(14.75, 21.98)	1.32	(0.78, 2.22)	0.2993	0.0115
Unknown	8	3	0	0.0	NE	NE	5	2	40.0	9.23	(3.88, NA)	>999.99	(0.00, >999.99)	0.3621	0.0115
Liver Metastasis at Enrollment															
N	157	73	28	38.4	16.36	(12.55, 20.80)	84	31	36.9	20.76	(14.75, 28.71)	0.70	(0.42, 1.18)	0.1752	0.1110
Y	168	91	21	23.1	28.32	(14.98, NA)	77	32	41.6	20.27	(10.12, 28.32)	1.36	(0.78, 2.35)	0.2789	0.1110
Number Metastatic Organs at Enrollment															
1	53	32	9	28.1	NE	(6.57, NA)	21	7	33.3	NE	(3.98, NA)	1.07	(0.40, 2.89)	0.8877	0.1262
2	104	46	18	39.1	14.29	(7.85, 18.46)	58	20	34.5	21.65	(14.75, 28.71)	0.53	(0.28, 1.01)	0.0499	0.1262
>=3	168	86	22	25.6	20.80	(16.13, 28.32)	82	36	43.9	14.75	(11.33, 27.01)	1.31	(0.77, 2.24)	0.3179	0.1262
ECOG Performance Status at Baseline															
0	206	106	31	29.2	20.80	(14.75, 26.51)	100	40	40.0	20.96	(14.75, 27.01)	0.91	(0.57, 1.47)	0.7024	0.7122
1	118	58	18	31.0	17.35	(12.55, 20.44)	60	23	38.3	14.69	(9.49, NA)	1.08	(0.58, 2.02)	0.8003	0.7122
Endocrine Resistance (per eCRF)															
Primary	112	58	17	29.3	14.29	(6.70, NA)	54	15	27.8	25.89	(16.53, NA)	0.41	(0.19, 0.87)	0.0161	0.0082
Secondary	212	105	32	30.5	20.44	(14.98, 26.51)	107	48	44.9	14.75	(11.33, 21.65)	1.29	(0.82, 2.02)	0.2691	0.0082
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	13	25.0	17.35	(9.53, NA)	52	26	50.0	15.28	(8.34, 20.96)	1.28	(0.66, 2.52)	0.4655	0.3090
POST-MENOPAUSAL	215	111	36	32.4	18.46	(14.29, 24.25)	104	35	33.7	20.76	(14.69, 27.52)	0.88	(0.55, 1.41)	0.5882	0.3090
Hormone receptor status															
ER+/PR-	90	45	11	24.4	NE	(9.17, NA)	45	14	31.1	20.27	(12.68, NA)	0.87	(0.40, 1.93)	0.7389	0.4861
ER+/PR+	226	113	37	32.7	18.46	(12.55, 21.29)	113	49	43.4	20.24	(10.84, 27.01)	0.98	(0.64, 1.51)	0.9296	0.4861
Other	9	6	1	16.7	NE	(14.75, NA)	3	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.5637	0.4861
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	3	15.8	NE	(9.46, NA)	18	5	27.8	21.65	(4.40, NA)	2.10	(0.50, 8.84)	0.3005	0.3303
Aromatase inhibitor only	131	71	25	35.2	16.13	(9.92, 20.44)	60	18	30.0	20.76	(11.83, NA)	0.70	(0.38, 1.29)	0.2499	0.3303
Tamoxifen only	155	73	21	28.8	17.35	(9.89, NA)	82	40	48.8	16.53	(10.84, 27.01)	1.05	(0.61, 1.78)	0.8740	0.3303
Prior (neo)-adjuvant CDK4/6															
N	322	163	49	30.1	17.35	(14.75, 24.25)	159	63	39.6	20.27	(14.75, 25.89)	0.94	(0.64, 1.37)	0.7326	1.0000
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	8	29.6	16.36	(9.89, NA)	29	12	41.4	14.75	(9.30, 21.98)	1.49	(0.60, 3.65)	0.3944	0.3630
Y	269	137	41	29.9	20.44	(14.29, 26.51)	132	51	38.6	20.96	(14.75, 28.32)	0.89	(0.59, 1.35)	0.5833	0.3630
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Breast Symptoms (MID >=10)															

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
All Patients	325	164	28	17.1	NE	(20.44, NA)	161	39	24.2	NE	(25.95, NA)	0.92	(0.56, 1.50)	0.7297	NE
Age group (years)															
<65	266	130	20	15.4	NE	(26.25, NA)	136	34	25.0	NE	(25.95, NA)	0.94	(0.54, 1.65)	0.8358	0.9316
>=65	59	34	8	23.5	21.82	(12.55, NA)	25	5	20.0	NE	(10.12, NA)	0.92	(0.30, 2.84)	0.8803	0.9316
Sex															
F	319	163	28	17.2	NE	(20.44, NA)	156	39	25.0	35.09	(23.03, NA)	0.98	(0.60, 1.60)	0.9429	1.0000
M	6	1	0	0.0	NE	NE	5	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	14	22.6	NE	(12.02, NA)	58	15	25.9	NE	(17.35, NA)	0.68	(0.32, 1.42)	0.2992	0.3544
NORTH AMERICA/WESTERN EUROPE	127	64	11	17.2	26.25	(20.44, NA)	63	11	17.5	NE	(23.03, NA)	0.81	(0.35, 1.89)	0.6225	0.3544
OTHER	78	38	3	7.9	NE	(15.90, NA)	40	13	32.5	35.09	(14.55, NA)	1.89	(0.53, 6.70)	0.3112	0.3544
Visceral disease (per eCRF)															
N	65	36	6	16.7	NE	(10.84, NA)	29	6	20.7	NE	(15.24, NA)	0.79	(0.25, 2.48)	0.6737	0.5258
Y	260	128	22	17.2	NE	(20.44, NA)	132	33	25.0	35.09	(23.03, NA)	0.97	(0.56, 1.67)	0.9108	0.5258
Ethnicity															
HISPANIC OR LATINO	20	10	4	40.0	18.18	(3.71, NA)	10	1	10.0	NE	(3.98, NA)	0.18	(0.02, 1.59)	0.0848	0.0045
NOT HISPANIC OR LATINO	294	149	23	15.4	NE	(20.44, NA)	145	36	24.8	NE	(25.95, NA)	1.03	(0.61, 1.75)	0.9130	0.0045
NOT REPORTED	5	3	0	0.0	NE	NE	2	2	100.0	7.97	(3.71, NA)	>999.99	(0.00, >999.99)	0.2253	0.0045
UNKNOWN	6	2	1	50.0	3.71	NE	4	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.1573	0.0045
Race															
Asian	124	63	14	22.2	NE	(12.02, NA)	61	16	26.2	NE	(17.35, NA)	0.71	(0.34, 1.46)	0.3459	0.4618
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.4618
White	191	97	14	14.4	NE	(20.44, NA)	94	22	23.4	NE	(23.03, NA)	1.05	(0.53, 2.07)	0.8873	0.4618
Unknown	8	3	0	0.0	NE	NE	5	1	20.0	NE	(9.23, NA)	>999.99	(0.00, >999.99)	0.5637	0.4618
Liver Metastasis at Enrollment															
N	157	73	14	19.2	NE	(20.44, NA)	84	18	21.4	NE	(25.95, NA)	0.84	(0.42, 1.70)	0.6325	0.6324
Y	168	91	14	15.4	NE	(14.06, NA)	77	21	27.3	26.48	(17.35, NA)	0.97	(0.49, 1.93)	0.9286	0.6324
Number Metastatic Organs at Enrollment															
1	53	32	4	12.5	NE	(14.78, NA)	21	4	19.0	NE	(15.24, NA)	1.08	(0.27, 4.38)	0.9107	0.8567
2	104	46	8	17.4	NE	(12.02, NA)	58	11	19.0	NE	(25.95, NA)	0.77	(0.31, 1.92)	0.5691	0.8567
>=3	168	86	16	18.6	21.82	(14.06, NA)	82	24	29.3	26.48	(14.92, NA)	1.00	(0.53, 1.89)	0.9965	0.8567
ECOG Performance Status at Baseline															
0	206	106	18	17.0	NE	(26.25, NA)	100	23	23.0	NE	(26.48, NA)	0.75	(0.40, 1.41)	0.3745	0.2672
1	118	58	10	17.2	21.82	(14.78, NA)	60	16	26.7	NE	(14.75, NA)	1.34	(0.60, 2.96)	0.4737	0.2672
Endocrine Resistance (per eCRF)															
Primary	112	58	6	10.3	NE	NE	54	15	27.8	35.09	(12.22, NA)	1.30	(0.50, 3.42)	0.5870	0.4306
Secondary	212	105	22	21.0	26.25	(15.90, NA)	107	24	22.4	NE	(25.95, NA)	0.78	(0.44, 1.40)	0.4049	0.4306
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	10	19.2	NE	(12.65, NA)	52	13	25.0	26.48	(20.50, NA)	0.54	(0.23, 1.27)	0.1529	0.1889

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
POST-MENOPAUSAL	215	111	18	16.2	NE	(20.44, NA)	104	26	25.0	NE	(15.24, NA)	1.25	(0.68, 2.28)	0.4735	0.1889
Hormone receptor status															
ER+/PR-	90	45	7	15.6	NE	(12.02, NA)	45	8	17.8	NE	(15.24, NA)	0.70	(0.25, 1.95)	0.4896	0.3500
ER+/PR+	226	113	20	17.7	NE	(20.44, NA)	113	31	27.4	35.09	(20.50, NA)	1.06	(0.60, 1.87)	0.8428	0.3500
Other	9	6	1	16.7	NE	(3.71, NA)	3	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.4142	0.3500
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	2	10.5	26.25	(9.43, NA)	18	4	22.2	23.03	(10.12, NA)	2.13	(0.39, 11.71)	0.3758	0.4113
Aromatase inhibitor only	131	71	10	14.1	NE	(14.06, NA)	60	9	15.0	NE	NE	0.74	(0.30, 1.82)	0.5029	0.4113
Tamoxifen only	155	73	16	21.9	21.82	(14.78, NA)	82	26	31.7	35.09	(20.24, NA)	0.79	(0.42, 1.49)	0.4620	0.4113
Prior (neo)-adjuvant CDK4/6															
N	322	163	28	17.2	NE	(20.44, NA)	159	39	24.5	NE	(25.95, NA)	0.91	(0.56, 1.48)	0.6910	1.0000
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	4	14.8	NE	(10.84, NA)	29	6	20.7	NE	(13.96, NA)	1.10	(0.31, 3.89)	0.8932	0.7527
Y	269	137	24	17.5	26.25	(20.44, NA)	132	33	25.0	NE	(23.03, NA)	0.87	(0.51, 1.49)	0.6137	0.7527
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Future Perspective (MID >=10)															
All Patients	325	164	29	17.7	NE	(18.46, NA)	161	40	24.8	37.52	(25.95, NA)	0.99	(0.61, 1.61)	0.9759	NE
Age group (years)															
<65	266	130	22	16.9	NE	(25.86, NA)	136	38	27.9	37.52	(25.95, NA)	1.06	(0.63, 1.81)	0.8211	0.3506
>=65	59	34	7	20.6	NE	(14.72, NA)	25	2	8.0	NE	(10.38, NA)	0.48	(0.10, 2.35)	0.3580	0.3506
Sex															
F	319	163	29	17.8	NE	(18.46, NA)	156	37	23.7	37.52	(25.95, NA)	0.95	(0.58, 1.54)	0.8161	1.0000
M	6	1	0	0.0	NE	NE	5	3	60.0	9.26	(3.91, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	16	25.8	25.86	(10.15, NA)	58	15	25.9	NE	(18.27, NA)	0.61	(0.30, 1.25)	0.1726	0.0905
NORTH AMERICA/WESTERN EUROPE	127	64	7	10.9	NE	NE	63	15	23.8	29.70	(15.28, NA)	2.11	(0.86, 5.20)	0.0964	0.0905
OTHER	78	38	6	15.8	18.46	(13.34, NA)	40	10	25.0	37.52	(25.89, NA)	0.82	(0.30, 2.29)	0.7113	0.0905
Visceral disease (per eCRF)															
N	65	36	8	22.2	18.46	(11.56, NA)	29	6	20.7	NE	(11.93, NA)	0.65	(0.22, 1.92)	0.4340	0.2844
Y	260	128	21	16.4	NE	(25.86, NA)	132	34	25.8	37.52	(25.89, NA)	1.13	(0.65, 1.95)	0.6675	0.2844
Ethnicity															
HISPANIC OR LATINO	20	10	1	10.0	NE	(10.61, NA)	10	2	20.0	NE	(4.14, NA)	2.28	(0.20, 25.73)	0.4933	0.8672
NOT HISPANIC OR LATINO	294	149	28	18.8	NE	(15.90, NA)	145	38	26.2	37.52	(25.95, NA)	0.92	(0.56, 1.52)	0.7460	0.8672
NOT REPORTED	5	3	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	0.8672
UNKNOWN	6	2	0	0.0	NE	NE	4	0	0.0	NE	NE	NE	NE	1.0000	0.8672
Race															
Asian	124	63	16	25.4	25.86	(10.15, NA)	61	16	26.2	NE	(18.27, NA)	0.64	(0.32, 1.29)	0.2044	0.1872
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.1872

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
White	191	97	13	13.4	NE	(18.46, NA)	94	23	24.5	37.52	(25.89, NA)	1.39	(0.70, 2.76)	0.3389	0.1872
Unknown	8	3	0	0.0	NE	NE	5	1	20.0	NE	(11.24, NA)	>999.99	(0.00, >999.99)	0.5637	0.1872
Liver Metastasis at Enrollment															
N	157	73	14	19.2	NE	(18.46, NA)	84	18	21.4	NE	(29.70, NA)	0.94	(0.47, 1.90)	0.8648	0.8042
Y	168	91	15	16.5	NE	(13.34, NA)	77	22	28.6	25.99	(15.28, NA)	1.01	(0.52, 1.99)	0.9745	0.8042
Number Metastatic Organs at Enrollment															
1	53	32	3	9.4	NE	NE	21	4	19.0	NE	(29.70, NA)	1.35	(0.29, 6.22)	0.6971	0.7840
2	104	46	10	21.7	18.46	(10.15, NA)	58	14	24.1	NE	(18.27, NA)	0.76	(0.33, 1.71)	0.4983	0.7840
>=3	168	86	16	18.6	NE	(14.78, NA)	82	22	26.8	37.52	(14.78, NA)	1.06	(0.56, 2.03)	0.8545	0.7840
ECOG Performance Status at Baseline															
0	206	106	18	17.0	NE	(25.86, NA)	100	26	26.0	NE	(25.89, NA)	0.98	(0.54, 1.80)	0.9534	0.8159
1	118	58	11	19.0	NE	(14.72, NA)	60	14	23.3	37.52	(11.93, NA)	1.08	(0.49, 2.39)	0.8564	0.8159
Endocrine Resistance (per eCRF)															
Primary	112	58	12	20.7	NE	(8.97, NA)	54	15	27.8	29.70	(14.78, NA)	0.65	(0.30, 1.41)	0.2607	0.2448
Secondary	212	105	17	16.2	NE	(18.46, NA)	107	25	23.4	NE	(25.99, NA)	1.16	(0.62, 2.16)	0.6441	0.2448
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	10	19.2	NE	(11.56, NA)	52	16	30.8	NE	(11.93, NA)	0.94	(0.42, 2.08)	0.8752	0.9420
POST-MENOPAUSAL	215	111	19	17.1	NE	(18.46, NA)	104	21	20.2	37.52	(25.99, NA)	0.90	(0.48, 1.69)	0.7472	0.9420
Hormone receptor status															
ER+/PR-	90	45	11	24.4	NE	(9.46, NA)	45	10	22.2	NE	(16.92, NA)	0.42	(0.17, 1.07)	0.0607	0.1433
ER+/PR+	226	113	18	15.9	NE	(18.46, NA)	113	30	26.5	37.52	(25.89, NA)	1.31	(0.73, 2.36)	0.3645	0.1433
Other	9	6	0	0.0	NE	NE	3	0	0.0	NE	NE	NE	NE	1.0000	0.1433
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	1	5.3	NE	(11.56, NA)	18	3	16.7	NE	(10.38, NA)	3.25	(0.34, 31.44)	0.2805	0.1236
Aromatase inhibitor only	131	71	15	21.1	18.46	(12.55, NA)	60	9	15.0	NE	(25.99, NA)	0.49	(0.21, 1.12)	0.0818	0.1236
Tamoxifen only	155	73	13	17.8	NE	(15.90, NA)	82	28	34.1	37.52	(18.27, NA)	1.28	(0.66, 2.48)	0.4731	0.1236
Prior (neo)-adjuvant CDK4/6															
N	322	163	28	17.2	NE	(18.46, NA)	159	40	25.2	37.52	(25.95, NA)	1.02	(0.63, 1.66)	0.9403	1.0000
Y	3	1	1	100.0	14.78	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	5	18.5	NE	(13.34, NA)	29	8	27.6	NE	(3.98, NA)	1.60	(0.52, 4.91)	0.4187	0.3022
Y	269	137	24	17.5	NE	(15.90, NA)	132	32	24.2	37.52	(25.95, NA)	0.86	(0.50, 1.48)	0.5862	0.3022
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Upset by Hair Loss (MID >=10)															
All Patients	325	164	11	6.7	NE	(6.57, NA)	161	21	13.0	9.63	(7.92, 11.83)	1.69	(0.81, 3.52)	0.1558	NE
Age group (years)															
<65	266	130	11	8.5	NE	(4.21, NA)	136	19	14.0	9.63	(8.34, 12.88)	1.38	(0.65, 2.91)	0.3995	0.0025

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
>=65	59	34	0	0.0	NE	NE	25	2	8.0	3.70	(3.68, NA)	>999.99	(0.00, >999.99)	0.0896	0.0025
Sex															
F	319	163	11	6.7	NE	(6.57, NA)	156	21	13.5	9.63	(7.92, 11.83)	1.69	(0.81, 3.52)	0.1558	1.0000
M	6	1	0	0.0	NE	NE	5	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	6	9.7	NE	(6.57, NA)	58	11	19.0	10.12	(8.34, NA)	1.78	(0.66, 4.83)	0.2556	0.1422
NORTH AMERICA/WESTERN EUROPE	127	64	3	4.7	9.46	(3.75, NA)	63	4	6.3	4.04	(3.71, NA)	2.27	(0.49, 10.42)	0.2803	0.1422
OTHER	78	38	2	5.3	3.71	(2.79, NA)	40	6	15.0	9.49	(3.71, NA)	0.26	(0.04, 1.91)	0.1626	0.1422
Visceral disease (per eCRF)															
N	65	36	1	2.8	NE	(9.43, NA)	29	7	24.1	9.49	(3.71, 10.12)	4.74	(0.58, 38.77)	0.1097	0.1989
Y	260	128	10	7.8	NE	(3.98, NA)	132	14	10.6	9.63	(4.04, 14.75)	1.32	(0.59, 2.99)	0.4956	0.1989
Ethnicity															
HISPANIC OR LATINO	20	10	1	10.0	9.46	(9.46, NA)	10	3	30.0	9.30	(7.92, NA)	3.35	(0.34, 33.36)	0.2769	0.5011
NOT HISPANIC OR LATINO	294	149	10	6.7	NE	(4.21, NA)	145	17	11.7	10.12	(8.34, 14.75)	1.51	(0.69, 3.31)	0.2998	0.5011
NOT REPORTED	5	3	0	0.0	NE	NE	2	1	50.0	3.71	NE	1.00	(1.00, 1.00)	1.0000	0.5011
UNKNOWN	6	2	0	0.0	NE	NE	4	0	0.0	NE	NE	NE	NE	1.0000	0.5011
Race															
Asian	124	63	6	9.5	NE	(6.57, NA)	61	12	19.7	9.63	(8.34, NA)	1.93	(0.72, 5.15)	0.1862	0.5592
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.5592
White	191	97	5	5.2	9.46	(2.79, NA)	94	9	9.6	9.30	(3.71, NA)	1.32	(0.44, 4.00)	0.6171	0.5592
Unknown	8	3	0	0.0	NE	NE	5	0	0.0	NE	NE	NE	NE	1.0000	0.5592
Liver Metastasis at Enrollment															
N	157	73	4	5.5	NE	(3.98, NA)	84	16	19.0	9.40	(4.04, 10.12)	3.30	(1.10, 9.91)	0.0254	0.0646
Y	168	91	7	7.7	6.70	(3.75, NA)	77	5	6.5	11.83	(3.94, NA)	0.76	(0.24, 2.39)	0.6294	0.0646
Number Metastatic Organs at Enrollment															
1	53	32	2	6.2	9.43	(6.57, NA)	21	6	28.6	7.92	(3.68, 11.53)	1.33	(0.25, 6.91)	0.7366	0.9803
2	104	46	3	6.5	NE	(3.65, NA)	58	7	12.1	9.56	(3.71, NA)	1.72	(0.44, 6.64)	0.4240	0.9803
>=3	168	86	6	7.0	NE	(3.94, NA)	82	8	9.8	10.12	(3.94, 14.75)	1.54	(0.53, 4.47)	0.4272	0.9803
ECOG Performance Status at Baseline															
0	206	106	9	8.5	9.46	(4.21, NA)	100	14	14.0	9.23	(3.94, 9.63)	2.04	(0.88, 4.72)	0.0939	0.7676
1	118	58	2	3.4	NE	(2.79, NA)	60	7	11.7	11.83	(4.67, NA)	1.63	(0.34, 7.89)	0.5418	0.7676
Endocrine Resistance (per eCRF)															
Primary	112	58	3	5.2	6.70	(2.79, NA)	54	4	7.4	10.12	(3.78, NA)	0.42	(0.09, 1.94)	0.2534	0.0453
Secondary	212	105	8	7.6	NE	(6.57, NA)	107	17	15.9	9.23	(4.04, 11.83)	2.56	(1.10, 5.95)	0.0240	0.0453
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	4	7.7	NE	(3.65, NA)	52	8	15.4	9.63	(3.78, 12.88)	1.45	(0.43, 4.85)	0.5570	0.8421
POST-MENOPAUSAL	215	111	7	6.3	NE	(3.98, NA)	104	13	12.5	9.49	(4.04, 14.75)	1.78	(0.71, 4.47)	0.2145	0.8421
Hormone receptor status															
ER+/PR-	90	45	3	6.7	NE	(3.65, NA)	45	6	13.3	9.63	(3.68, NA)	1.98	(0.49, 7.96)	0.3240	0.6426

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
ER+/PR+	226	113	8	7.1	NE	(3.98, NA)	113	14	12.4	9.63	(8.34, 14.75)	1.44	(0.60, 3.45)	0.4100	0.6426
Other	9	6	0	0.0	NE	NE	3	1	33.3	3.91	NE	1.00	(1.00, 1.00)	1.0000	0.6426
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	3	15.8	9.46	(3.98, NA)	18	1	5.6	3.91	(3.91, NA)	0.95	(0.10, 9.36)	0.9672	0.6326
Aromatase inhibitor only	131	71	1	1.4	NE	(3.75, NA)	60	7	11.7	11.53	(3.71, NA)	2.08	(0.25, 17.11)	0.4856	0.6326
Tamoxifen only	155	73	7	9.6	NE	(3.94, NA)	82	13	15.9	9.49	(7.92, 12.88)	1.99	(0.78, 5.07)	0.1426	0.6326
Prior (neo)-adjuvant CDK4/6															
N	322	163	11	6.7	NE	(6.57, NA)	159	21	13.2	9.63	(7.92, 11.83)	1.69	(0.81, 3.52)	0.1558	1.0000
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	2	7.4	4.21	(2.79, NA)	29	5	17.2	3.94	(3.68, NA)	2.61	(0.49, 13.79)	0.2437	0.3520
Y	269	137	9	6.6	NE	(6.57, NA)	132	16	12.1	9.63	(8.34, 14.75)	1.48	(0.65, 3.35)	0.3500	0.3520
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Sexual Enjoyment (MID >=10)															
All Patients	325	164	5	3.0	NE	(12.16, NA)	161	13	8.1	20.50	(4.27, NA)	1.67	(0.60, 4.70)	0.3225	NE
Age group (years)															
<65	266	130	3	2.3	NE	(14.29, NA)	136	12	8.8	20.50	(4.83, NA)	1.97	(0.55, 7.01)	0.2859	0.0458
>=65	59	34	2	5.9	12.16	(4.17, NA)	25	1	4.0	2.33	(2.33, NA)	>999.99	(0.00, >999.99)	0.1573	0.0458
Sex															
F	319	163	5	3.1	NE	(12.16, NA)	156	12	7.7	20.50	(4.21, NA)	1.83	(0.64, 5.20)	0.2506	1.0000
M	6	1	0	0.0	NE	NE	5	1	20.0	NE	(4.83, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	1	1.6	NE	(14.98, NA)	58	4	6.9	11.93	(2.33, NA)	4.19	(0.46, 37.92)	0.1716	0.2296
NORTH AMERICA/WESTERN EUROPE	127	64	4	6.2	14.29	(4.17, NA)	63	5	7.9	NE	(4.04, NA)	0.75	(0.20, 2.80)	0.6691	0.2296
OTHER	78	38	0	0.0	NE	NE	40	4	10.0	9.43	(4.21, NA)	>999.99	(0.00, >999.99)	0.5024	0.2296
Visceral disease (per eCRF)															
N	65	36	2	5.6	4.40	(4.17, NA)	29	4	13.8	4.55	(3.88, NA)	1.73	(0.29, 10.41)	0.5457	0.9106
Y	260	128	3	2.3	NE	(12.16, NA)	132	9	6.8	NE	(9.43, NA)	1.77	(0.48, 6.55)	0.3895	0.9106
Ethnicity															
HISPANIC OR LATINO	20	10	0	0.0	NE	NE	10	1	10.0	4.83	NE	>999.99	(0.00, >999.99)	0.3173	0.5437
NOT HISPANIC OR LATINO	294	149	5	3.4	14.98	(12.16, NA)	145	11	7.6	20.50	(4.27, NA)	1.25	(0.43, 3.61)	0.6791	0.5437
NOT REPORTED	5	3	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	0.5437
UNKNOWN	6	2	0	0.0	NE	NE	4	1	25.0	3.88	NE	1.00	(1.00, 1.00)	1.0000	0.5437
Race															
Asian	124	63	1	1.6	NE	(14.98, NA)	61	4	6.6	11.93	(2.33, NA)	4.19	(0.46, 37.92)	0.1716	0.0947
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.0947
White	191	97	4	4.1	14.29	(4.17, NA)	94	7	7.4	NE	(4.83, NA)	0.79	(0.23, 2.69)	0.7004	0.0947
Unknown	8	3	0	0.0	NE	NE	5	2	40.0	7.67	(3.88, NA)	>999.99	(0.00, >999.99)	0.2253	0.0947
Liver Metastasis at Enrollment															

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
N	157	73	2	2.7	NE	(4.17, NA)	84	8	9.5	9.43	(3.88, NA)	2.43	(0.52, 11.45)	0.2412	0.4406
Y	168	91	3	3.3	14.98	(12.16, NA)	77	5	6.5	NE	(4.21, NA)	1.03	(0.24, 4.37)	0.9710	0.4406
Number Metastatic Organs at Enrollment															
1	53	32	2	6.2	12.16	(4.17, NA)	21	3	14.3	3.94	(3.88, NA)	9.48	(0.95, 94.47)	0.0216	0.2107
2	104	46	2	4.3	14.98	(14.29, NA)	58	4	6.9	NE	(4.27, NA)	1.64	(0.28, 9.58)	0.5809	0.2107
>=3	168	86	1	1.2	NE	(4.40, NA)	82	6	7.3	NE	(4.17, NA)	2.26	(0.27, 18.86)	0.4389	0.2107
ECOG Performance Status at Baseline															
0	206	106	4	3.8	NE	(12.16, NA)	100	8	8.0	NE	(4.21, NA)	1.46	(0.44, 4.89)	0.5366	0.9625
1	118	58	1	1.7	4.17	(4.17, NA)	60	5	8.3	9.43	(2.33, NA)	1.23	(0.14, 10.61)	0.8194	0.9625
Endocrine Resistance (per eCRF)															
Primary	112	58	1	1.7	12.16	(12.16, NA)	54	4	7.4	NE	(3.88, NA)	1.66	(0.18, 14.87)	0.6488	0.7278
Secondary	212	105	3	2.9	NE	(4.40, NA)	107	9	8.4	20.50	(4.17, NA)	2.49	(0.67, 9.25)	0.1603	0.7278
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	2	3.8	NE	(4.40, NA)	52	6	11.5	11.47	(3.88, NA)	2.52	(0.50, 12.64)	0.2497	0.6271
POST-MENOPAUSAL	215	111	3	2.7	NE	(4.17, NA)	104	6	5.8	20.50	(4.21, NA)	1.49	(0.37, 5.96)	0.5734	0.6271
Hormone receptor status															
ER+/PR-	90	45	2	4.4	14.98	(12.16, NA)	45	5	11.1	7.87	(3.88, NA)	2.32	(0.45, 12.03)	0.3005	0.5700
ER+/PR+	226	113	3	2.7	NE	(4.17, NA)	113	8	7.1	NE	(4.83, NA)	1.37	(0.36, 5.17)	0.6380	0.5700
Other	9	6	0	0.0	NE	NE	3	0	0.0	NE	NE	NE	NE	1.0000	0.5700
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	2	10.5	NE	(4.17, NA)	18	1	5.6	11.47	NE	3.87	(0.24, 63.34)	0.3072	0.2949
Aromatase inhibitor only	131	71	2	2.8	12.16	(4.40, NA)	60	4	6.7	NE	(3.88, NA)	0.67	(0.12, 3.71)	0.6462	0.2949
Tamoxifen only	155	73	1	1.4	NE	(14.98, NA)	82	8	9.8	20.50	(4.17, NA)	4.10	(0.51, 32.90)	0.1499	0.2949
Prior (neo)-adjuvant CDK4/6															
N	322	163	4	2.5	NE	(12.16, NA)	159	13	8.2	20.50	(4.27, NA)	2.00	(0.65, 6.15)	0.2149	1.0000
Y	3	1	1	100.0	4.40	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	1	3.7	14.29	(14.29, NA)	29	3	10.3	20.50	(4.27, NA)	1.36	(0.12, 15.33)	0.8043	0.9739
Y	269	137	4	2.9	NE	(4.40, NA)	132	10	7.6	NE	(4.17, NA)	1.66	(0.52, 5.30)	0.3843	0.9739
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Sexual Functioning (MID >=10)															
All Patients	325	164	43	26.2	34.46	(15.05, NA)	161	41	25.5	NE	NE	0.68	(0.44, 1.05)	0.0773	NE
Age group (years)															
<65	266	130	38	29.2	15.41	(9.26, NA)	136	37	27.2	NE	NE	0.58	(0.37, 0.91)	0.0163	0.2403
>=65	59	34	5	14.7	NE	NE	25	4	16.0	NE	(9.26, NA)	1.37	(0.37, 5.15)	0.6369	0.2403
Sex															
F	319	163	43	26.4	34.46	(15.05, NA)	156	38	24.4	NE	NE	0.65	(0.42, 1.01)	0.0555	1.0000
M	6	1	0	0.0	NE	NE	5	3	60.0	9.53	(3.75, NA)	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Region															
ASIA	120	62	19	30.6	34.46	(8.08, NA)	58	14	24.1	NE	NE	0.54	(0.27, 1.08)	0.0788	0.2326
NORTH AMERICA/WESTERN EUROPE	127	64	13	20.3	NE	(15.05, NA)	63	15	23.8	NE	(14.98, NA)	1.08	(0.51, 2.26)	0.8458	0.2326
OTHER	78	38	11	28.9	9.53	(3.71, NA)	40	12	30.0	NE	(9.86, NA)	0.45	(0.20, 1.03)	0.0553	0.2326
Visceral disease (per eCRF)															
N	65	36	13	36.1	10.35	(4.24, NA)	29	10	34.5	NE	(4.83, NA)	0.63	(0.27, 1.44)	0.2693	0.9047
Y	260	128	30	23.4	34.46	(15.41, NA)	132	31	23.5	NE	NE	0.71	(0.43, 1.17)	0.1759	0.9047
Ethnicity															
HISPANIC OR LATINO	20	10	1	10.0	NE	(2.10, NA)	10	3	30.0	NE	(3.98, NA)	2.83	(0.29, 27.42)	0.3474	0.2126
NOT HISPANIC OR LATINO	294	149	40	26.8	34.46	(14.92, NA)	145	36	24.8	NE	NE	0.64	(0.40, 1.00)	0.0479	0.2126
NOT REPORTED	5	3	1	33.3	4.63	NE	2	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.1573	0.2126
UNKNOWN	6	2	1	50.0	3.71	NE	4	2	50.0	9.69	(3.78, NA)	<0.01	(0.00, >999.99)	0.1573	0.2126
Race															
Asian	124	63	19	30.2	34.46	(8.08, NA)	61	14	23.0	NE	NE	0.51	(0.26, 1.03)	0.0573	0.5557
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.5557
White	191	97	23	23.7	NE	(10.35, NA)	94	25	26.6	NE	(14.98, NA)	0.81	(0.46, 1.43)	0.4764	0.5557
Unknown	8	3	1	33.3	4.63	NE	5	2	40.0	15.61	(4.96, NA)	<0.01	(0.00, >999.99)	0.0833	0.5557
Liver Metastasis at Enrollment															
N	157	73	20	27.4	NE	(10.35, NA)	84	21	25.0	NE	NE	0.73	(0.40, 1.35)	0.3178	0.8194
Y	168	91	23	25.3	34.46	(9.53, NA)	77	20	26.0	NE	(14.98, NA)	0.64	(0.35, 1.17)	0.1433	0.8194
Number Metastatic Organs at Enrollment															
1	53	32	15	46.9	9.17	(3.94, 15.05)	21	6	28.6	NE	(9.46, NA)	0.31	(0.12, 0.82)	0.0129	0.2050
2	104	46	10	21.7	NE	(9.53, NA)	58	17	29.3	NE	(9.56, NA)	1.06	(0.49, 2.33)	0.8721	0.2050
>=3	168	86	18	20.9	34.46	(15.41, NA)	82	18	22.0	NE	NE	0.73	(0.38, 1.40)	0.3396	0.2050
ECOG Performance Status at Baseline															
0	206	106	28	26.4	34.46	(15.05, NA)	100	31	31.0	NE	(14.98, NA)	0.77	(0.46, 1.29)	0.3244	0.3343
1	118	58	15	25.9	NE	(10.35, NA)	60	10	16.7	NE	NE	0.51	(0.23, 1.13)	0.0913	0.3343
Endocrine Resistance (per eCRF)															
Primary	112	58	13	22.4	NE	(4.17, NA)	54	17	31.5	15.61	(9.49, NA)	0.70	(0.34, 1.46)	0.3526	0.8935
Secondary	212	105	29	27.6	34.46	(15.05, NA)	107	24	22.4	NE	NE	0.64	(0.37, 1.11)	0.1086	0.8935
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	18	34.6	9.53	(4.17, NA)	52	16	30.8	NE	(9.86, NA)	0.43	(0.22, 0.85)	0.0123	0.2695
POST-MENOPAUSAL	215	111	25	22.5	NE	NE	104	22	21.2	NE	NE	0.78	(0.44, 1.39)	0.4035	0.2695
Hormone receptor status															
ER+/PR-	90	45	8	17.8	NE	NE	45	11	24.4	NE	(12.68, NA)	0.92	(0.37, 2.29)	0.8532	0.2858
ER+/PR+	226	113	33	29.2	34.46	(10.35, NA)	113	30	26.5	NE	NE	0.65	(0.40, 1.07)	0.0910	0.2858
Other	9	6	2	33.3	9.26	(3.71, NA)	3	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.2807	0.2858
Prior (neo)-adjuvant endocrine															

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Aromatase inhibitor and tamoxifen	37	19	6	31.6	NE	(3.94, NA)	18	3	16.7	NE	(4.96, NA)	0.47	(0.12, 1.87)	0.2680	0.0111
Aromatase inhibitor only	131	71	10	14.1	NE	NE	60	17	28.3	NE	(9.56, NA)	1.66	(0.76, 3.63)	0.1994	0.0111
Tamoxifen only	155	73	27	37.0	14.92	(4.21, NA)	82	21	25.6	NE	NE	0.38	(0.21, 0.67)	0.0006	0.0111
Prior (neo)-adjuvant CDK4/6															
N	322	163	42	25.8	34.46	(15.05, NA)	159	41	25.8	NE	NE	0.69	(0.45, 1.07)	0.0942	1.0000
Y	3	1	1	100.0	4.40	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	5	18.5	NE	(4.17, NA)	29	9	31.0	12.68	(9.13, NA)	1.42	(0.47, 4.25)	0.5326	0.1735
Y	269	137	38	27.7	34.46	(14.92, NA)	132	32	24.2	NE	NE	0.60	(0.37, 0.96)	0.0330	0.1735
EORTC QLQ-BR23: Time to Unconfirmed Deterioration in Systemic Therapy Side Effects (MID >=10)															
All Patients	325	164	60	36.6	11.76	(9.23, 20.44)	161	91	56.5	10.02	(7.39, 11.93)	1.34	(0.97, 1.86)	0.0805	NE
Age group (years)															
<65	266	130	47	36.2	11.76	(9.23, 21.68)	136	78	57.4	10.12	(7.59, 14.23)	1.29	(0.90, 1.85)	0.1738	0.4077
>=65	59	34	13	38.2	10.61	(4.24, NA)	25	13	52.0	4.37	(3.71, 27.17)	1.72	(0.77, 3.83)	0.1932	0.4077
Sex															
F	319	163	60	36.8	11.76	(9.23, 20.44)	156	87	55.8	10.02	(5.09, 11.93)	1.36	(0.98, 1.89)	0.0701	1.0000
M	6	1	0	0.0	NE	NE	5	4	80.0	14.75	(3.91, NA)	NE	NE	1.0000	1.0000
Region															
ASIA	120	62	25	40.3	10.94	(6.70, NA)	58	32	55.2	11.93	(5.09, 20.67)	1.16	(0.68, 1.97)	0.5866	0.5207
NORTH AMERICA/WESTERN EUROPE	127	64	27	42.2	11.30	(4.40, 20.44)	63	37	58.7	4.24	(3.94, 9.92)	1.81	(1.09, 3.00)	0.0189	0.5207
OTHER	78	38	8	21.1	NE	(9.20, NA)	40	22	55.0	14.23	(8.21, 28.58)	1.33	(0.59, 3.02)	0.5136	0.5207
Visceral disease (per eCRF)															
N	65	36	14	38.9	6.21	(4.17, NA)	29	13	44.8	20.67	(4.86, NA)	0.61	(0.28, 1.34)	0.2134	0.0199
Y	260	128	46	35.9	12.02	(9.23, 21.68)	132	78	59.1	9.30	(4.40, 10.64)	1.63	(1.13, 2.34)	0.0087	0.0199
Ethnicity															
HISPANIC OR LATINO	20	10	4	40.0	14.09	(3.71, NA)	10	6	60.0	9.81	(3.78, NA)	0.90	(0.23, 3.44)	0.8528	0.4671
NOT HISPANIC OR LATINO	294	149	55	36.9	11.30	(9.23, 20.44)	145	83	57.2	10.02	(5.72, 11.93)	1.36	(0.96, 1.91)	0.0825	0.4671
NOT REPORTED	5	3	0	0.0	NE	NE	2	1	50.0	3.94	(3.94, NA)	>999.99	(0.00, >999.99)	0.4795	0.4671
UNKNOWN	6	2	1	50.0	9.20	NE	4	1	25.0	10.64	(10.64, NA)	<0.01	(0.00, >999.99)	0.1573	0.4671
Race															
Asian	124	63	25	39.7	10.94	(6.70, NA)	61	34	55.7	10.84	(4.86, 20.67)	1.22	(0.73, 2.06)	0.4565	0.8746
Black or African American	2	1	1	100.0	17.08	NE	1	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	0.8746
White	191	97	34	35.1	11.30	(9.23, 21.68)	94	57	60.6	9.30	(4.24, 11.33)	1.45	(0.95, 2.22)	0.0891	0.8746
Unknown	8	3	0	0.0	NE	NE	5	0	0.0	NE	NE	NE	NE	1.0000	0.8746
Liver Metastasis at Enrollment															
N	157	73	29	39.7	11.30	(7.46, 24.25)	84	46	54.8	11.93	(7.39, 15.24)	1.26	(0.79, 2.01)	0.3317	0.6571
Y	168	91	31	34.1	11.76	(8.54, 17.08)	77	45	58.4	9.26	(4.40, 10.38)	1.47	(0.93, 2.33)	0.0965	0.6571

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)	
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI					
Number Metastatic Organs at Enrollment																
1	53	32	18	56.2	9.20	(3.94, 15.05)	21	12	57.1	10.84	(3.94, NA)	0.68	(0.33, 1.43)	0.3058	0.0953	
2	104	46	18	39.1	11.30	(5.49, NA)	58	34	58.6	9.20	(3.98, 20.67)	1.31	(0.74, 2.33)	0.3741	0.0953	
>=3	168	86	24	27.9	20.44	(9.23, NA)	82	45	54.9	10.02	(7.59, 14.23)	1.82	(1.11, 2.99)	0.0173	0.0953	
ECOG Performance Status at Baseline																
0	206	106	37	34.9	12.02	(9.20, NA)	100	56	56.0	10.38	(8.21, 14.98)	1.28	(0.84, 1.94)	0.2578	0.7431	
1	118	58	23	39.7	10.94	(4.67, 21.68)	60	35	58.3	7.59	(4.04, 12.88)	1.38	(0.81, 2.34)	0.2317	0.7431	
Endocrine Resistance (per eCRF)																
Primary	112	58	18	31.0	10.61	(6.70, NA)	54	33	61.1	9.33	(4.04, 14.78)	1.32	(0.74, 2.36)	0.3464	0.9366	
Secondary	212	105	41	39.0	15.05	(9.23, 24.25)	107	58	54.2	10.35	(4.86, 14.23)	1.37	(0.92, 2.05)	0.1248	0.9366	
Menopausal Status at Randomization																
NOT POST-MENOPAUSAL	104	52	16	30.8	15.41	(6.70, NA)	52	30	57.7	12.88	(7.59, 15.28)	1.36	(0.74, 2.51)	0.3179	0.9019	
POST-MENOPAUSAL	215	111	44	39.6	10.61	(8.54, 21.68)	104	57	54.8	9.30	(4.24, 10.84)	1.37	(0.92, 2.03)	0.1205	0.9019	
Hormone receptor status																
ER+/PR-	90	45	13	28.9	NE	(8.54, NA)	45	23	51.1	9.69	(3.98, NA)	1.50	(0.76, 2.97)	0.2490	0.7586	
ER+/PR+	226	113	46	40.7	10.61	(7.43, 17.08)	113	67	59.3	10.12	(5.72, 11.93)	1.29	(0.88, 1.87)	0.1928	0.7586	
Other	9	6	1	16.7	NE	(9.20, NA)	3	1	33.3	3.91	(3.91, NA)	>999.99	(0.00, >999.99)	0.2207	0.7586	
Prior (neo)-adjuvant endocrine																
Aromatase inhibitor and tamoxifen	37	19	7	36.8	21.68	(3.94, NA)	18	11	61.1	4.40	(3.68, NA)	1.93	(0.73, 5.10)	0.1730	0.4612	
Aromatase inhibitor only	131	71	26	36.6	9.46	(4.67, NA)	60	30	50.0	10.35	(4.14, 20.67)	1.14	(0.67, 1.92)	0.6422	0.4612	
Tamoxifen only	155	73	27	37.0	15.05	(9.20, NA)	82	50	61.0	10.84	(7.59, 14.75)	1.42	(0.89, 2.27)	0.1397	0.4612	
Prior (neo)-adjuvant CDK4/6																
N	322	163	60	36.8	11.30	(9.23, 20.44)	159	91	57.2	10.02	(7.39, 11.93)	1.32	(0.95, 1.83)	0.0972	1.0000	
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000	
Prior (neo)-adjuvant chemotherapy																
N	56	27	7	25.9	15.41	(9.23, NA)	29	14	48.3	10.35	(3.81, 28.58)	2.06	(0.83, 5.12)	0.1140	0.2551	
Y	269	137	53	38.7	10.94	(8.54, 20.44)	132	77	58.3	10.02	(5.72, 12.88)	1.23	(0.87, 1.75)	0.2556	0.2551	

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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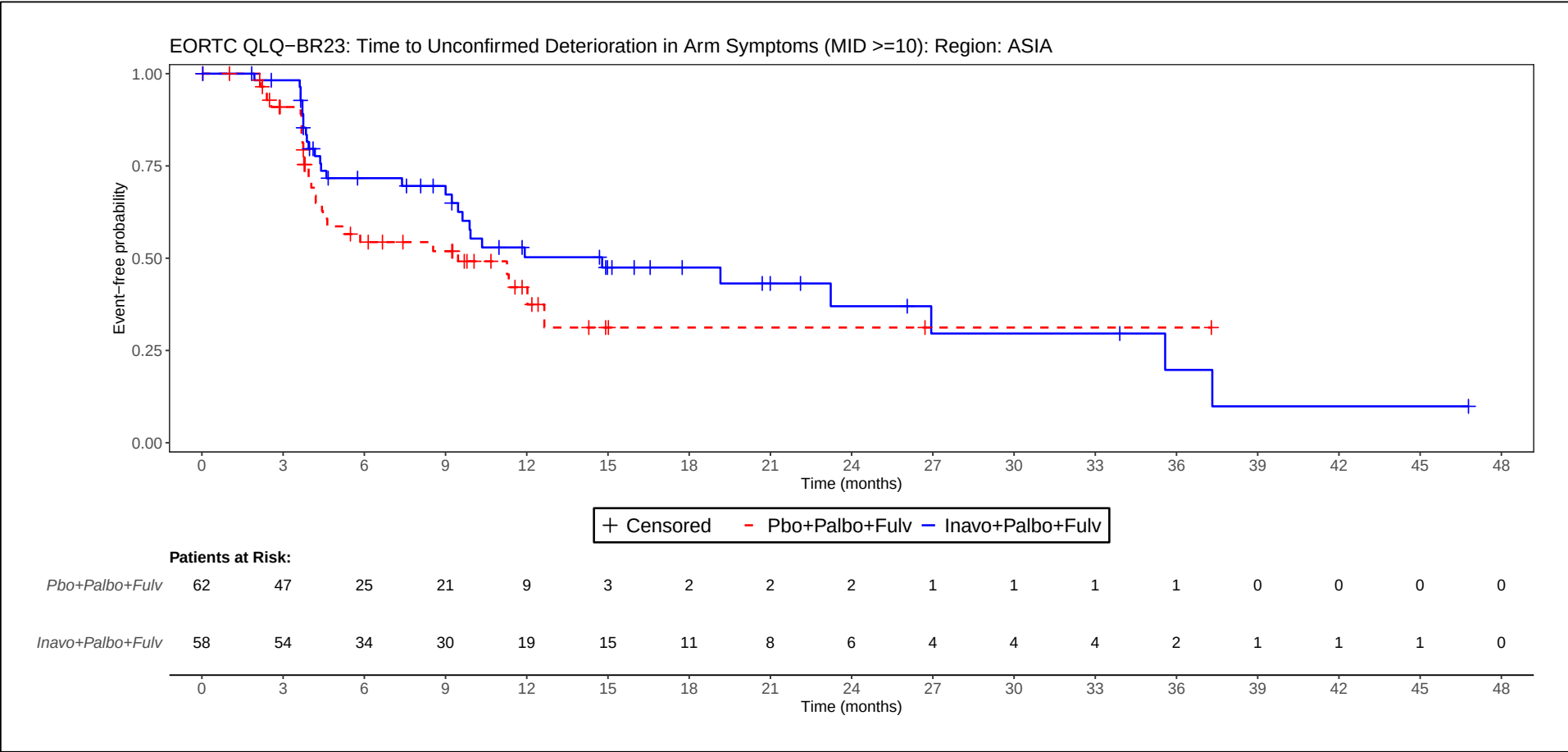
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

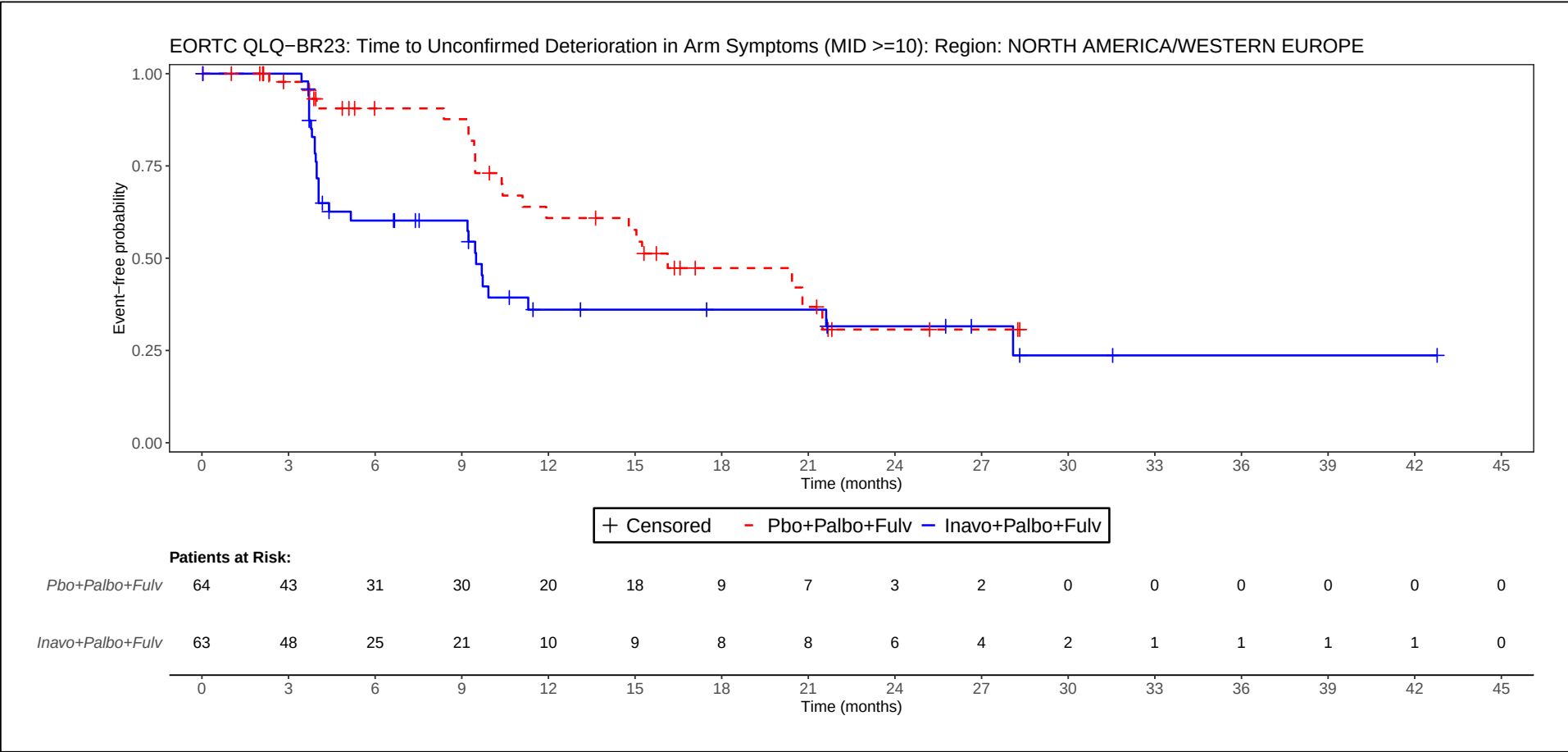
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

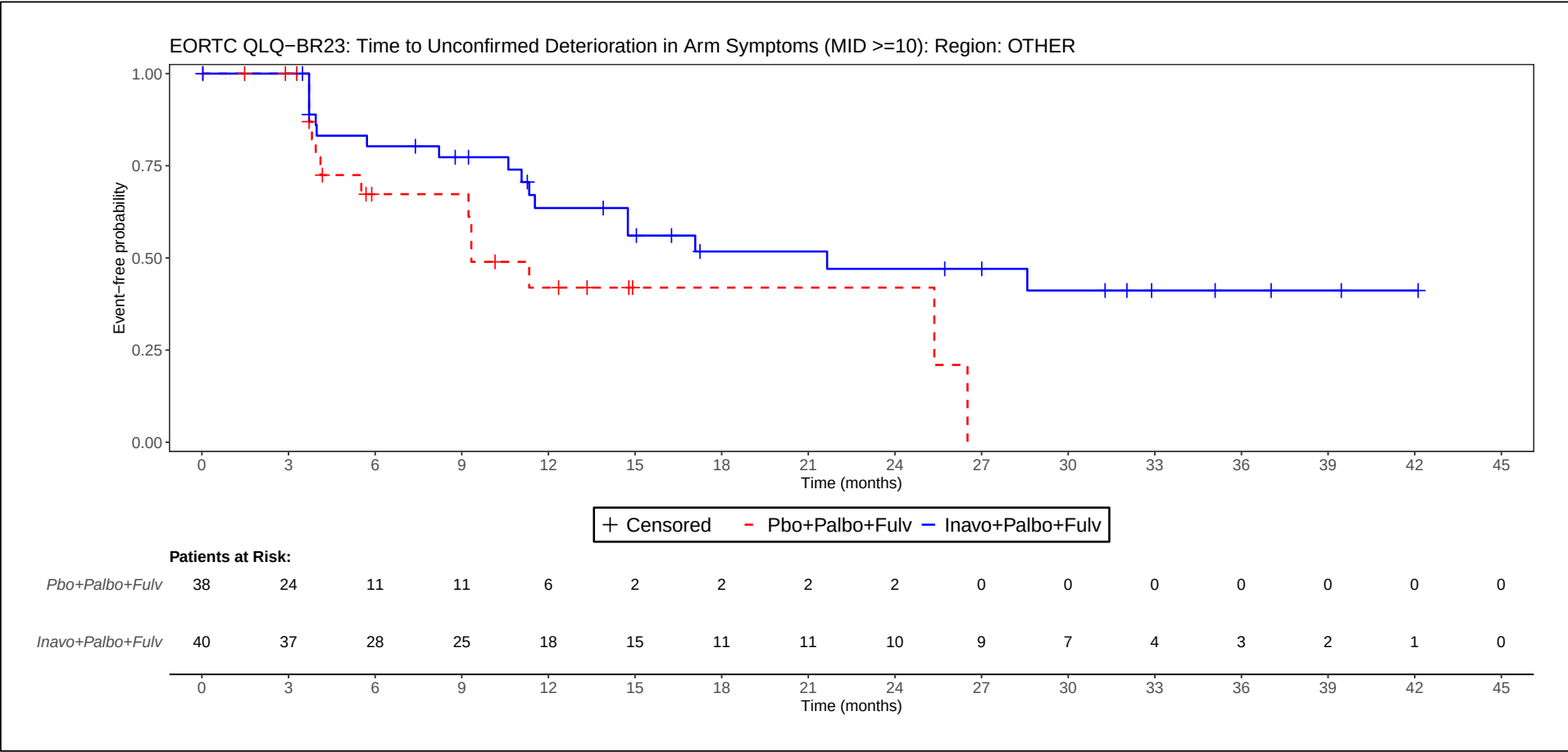
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

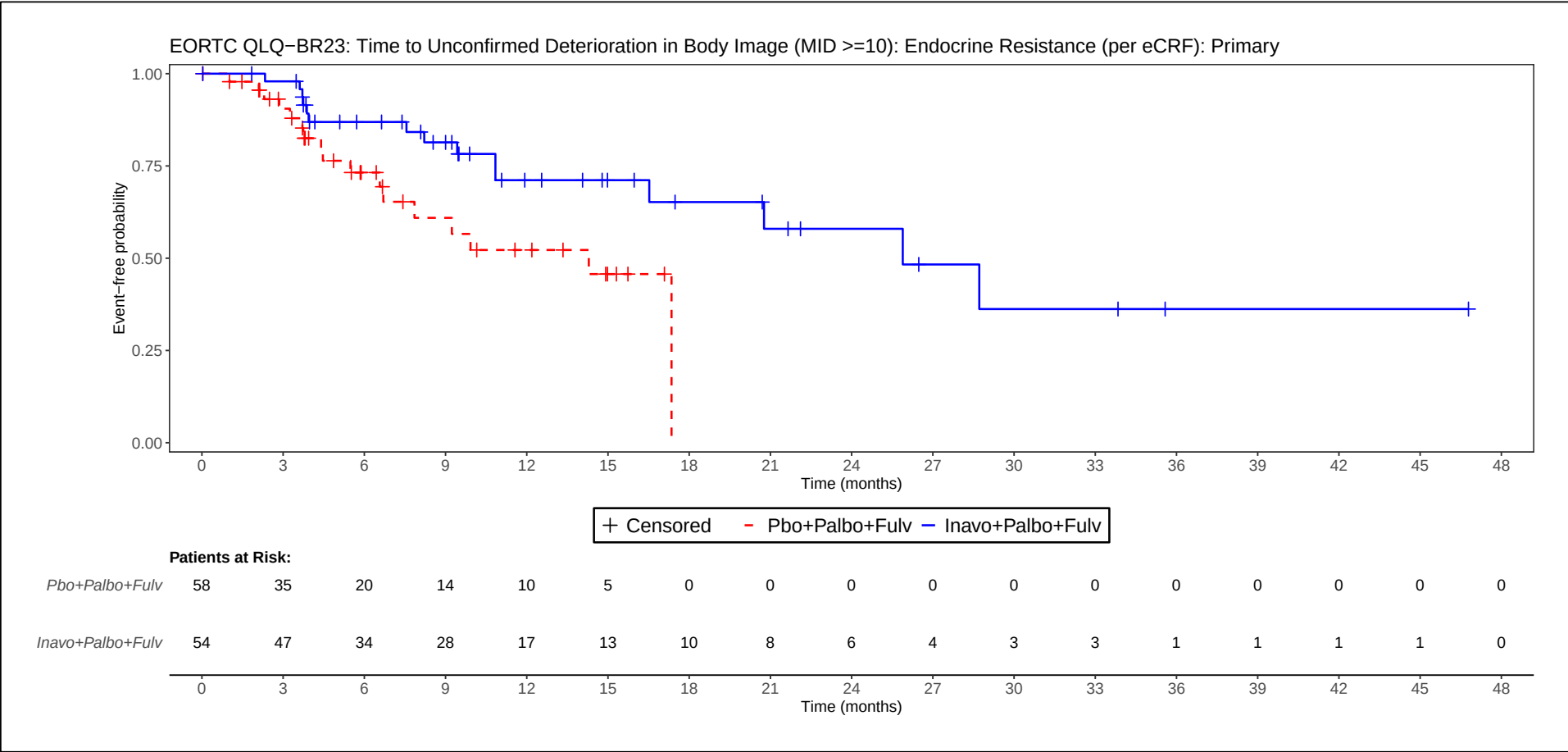
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

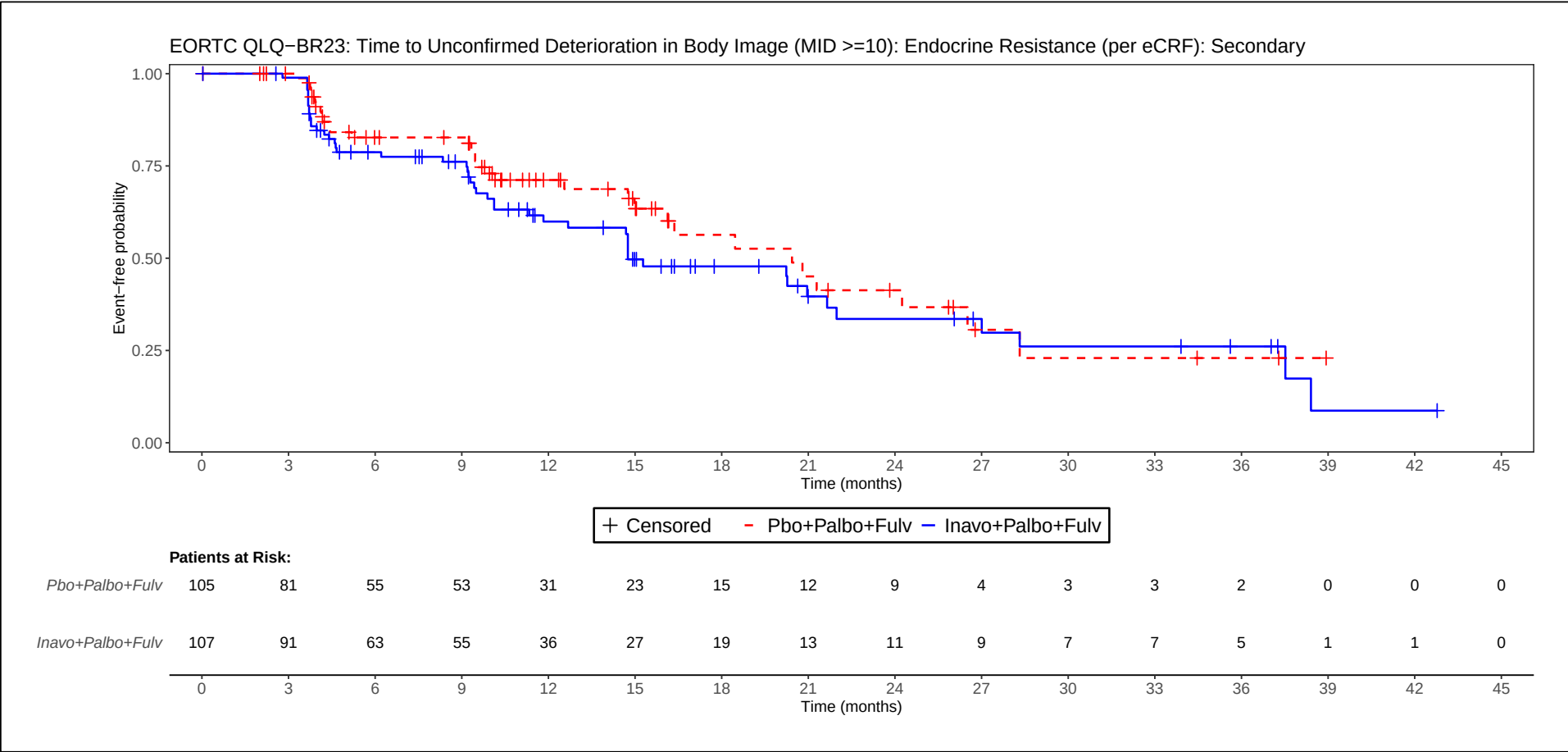
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

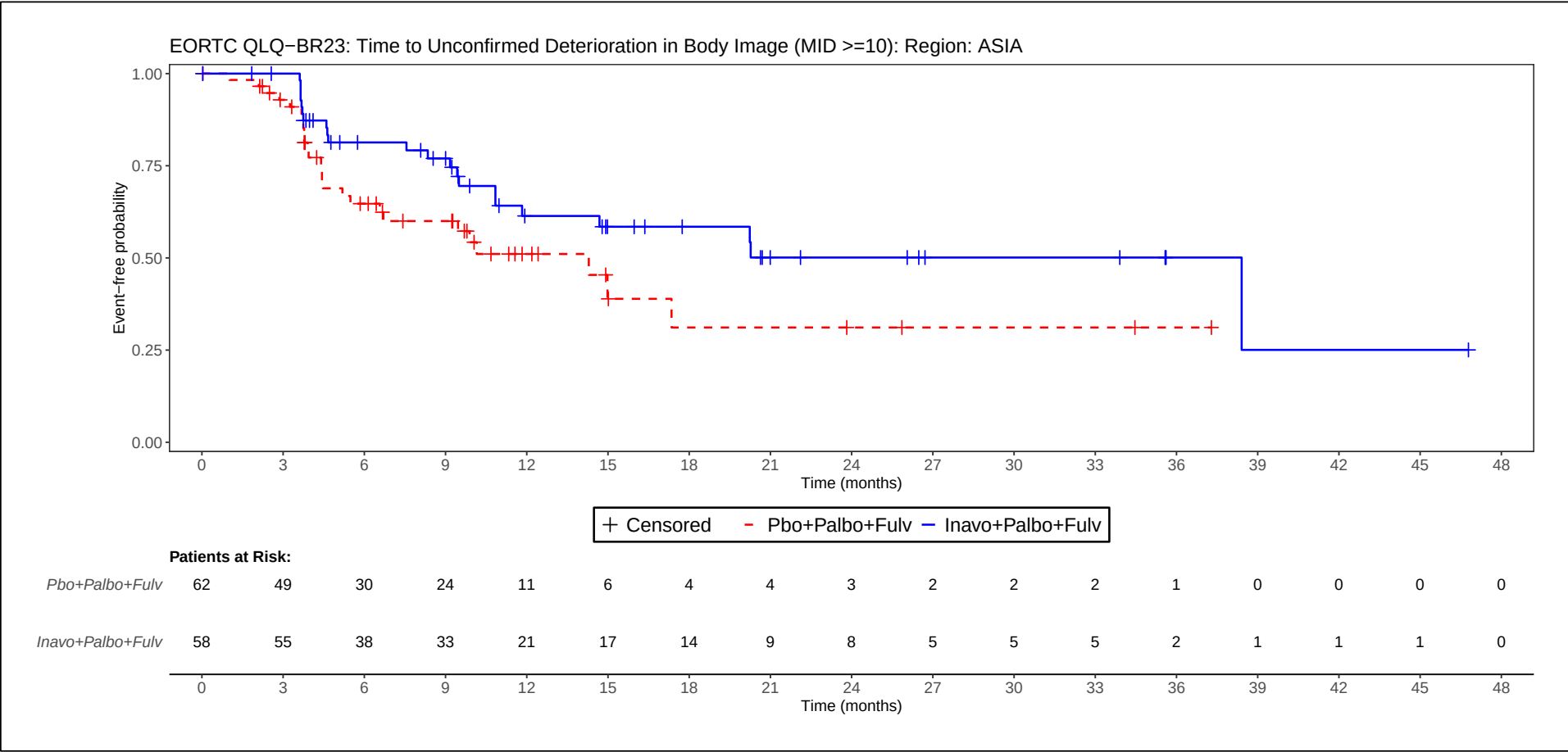
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

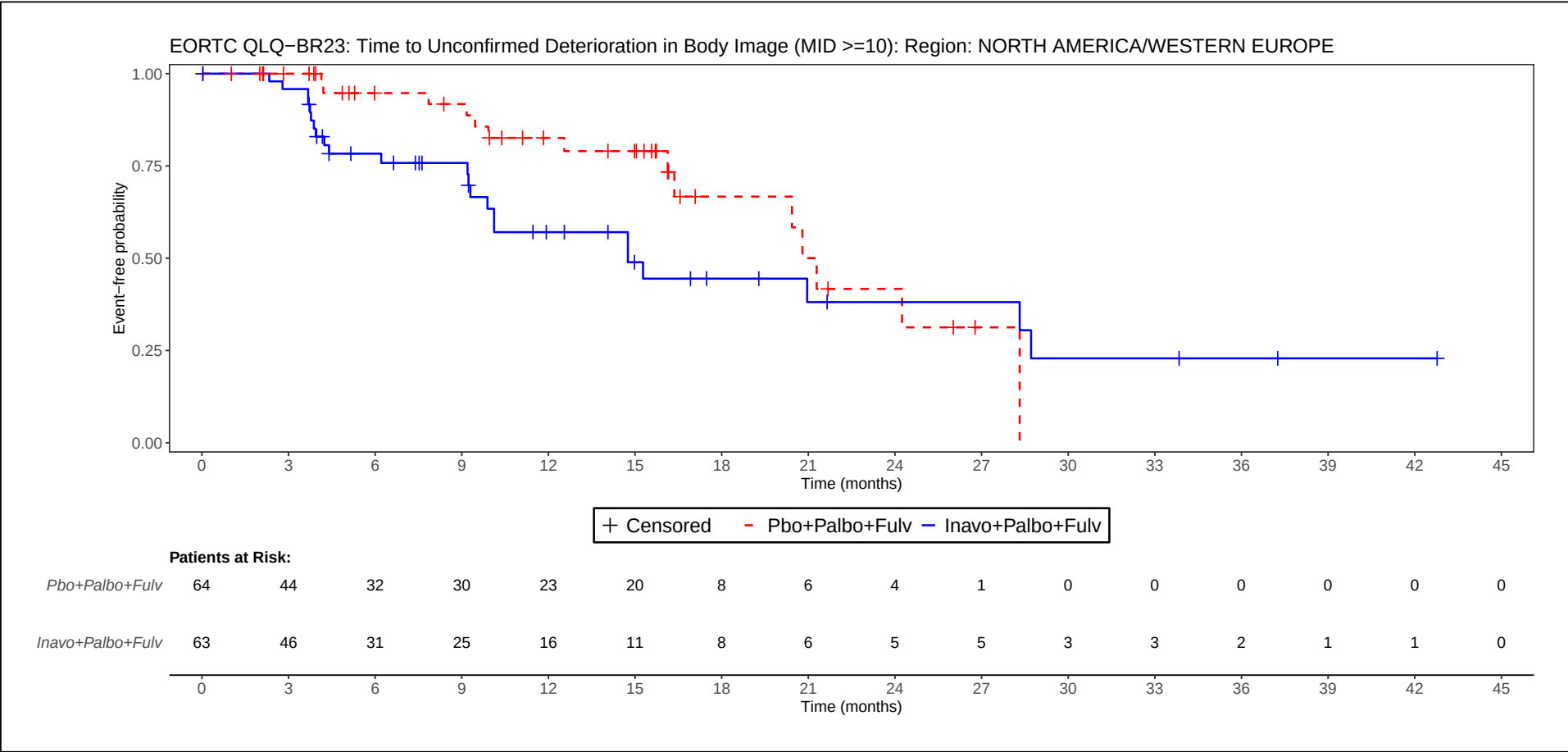
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

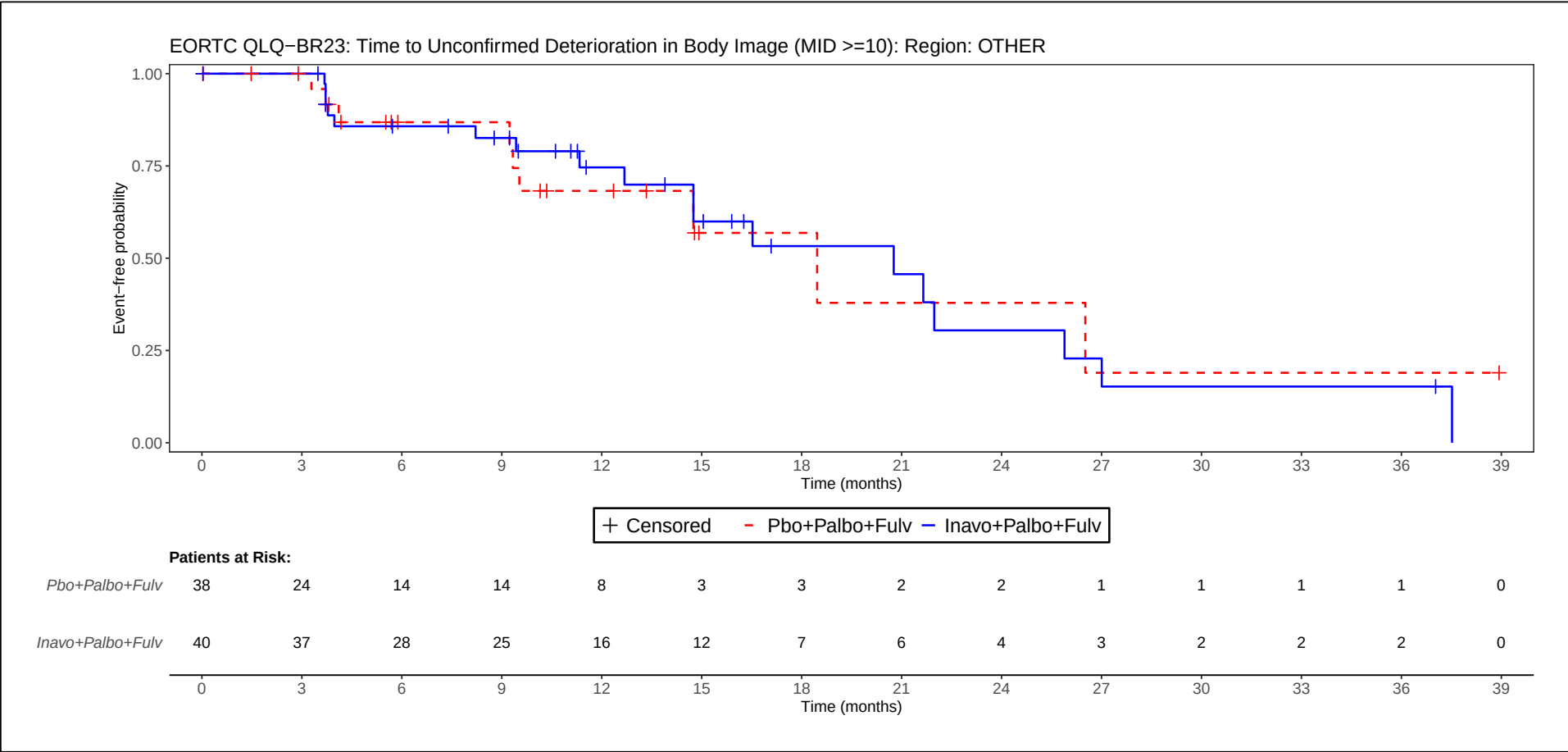
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

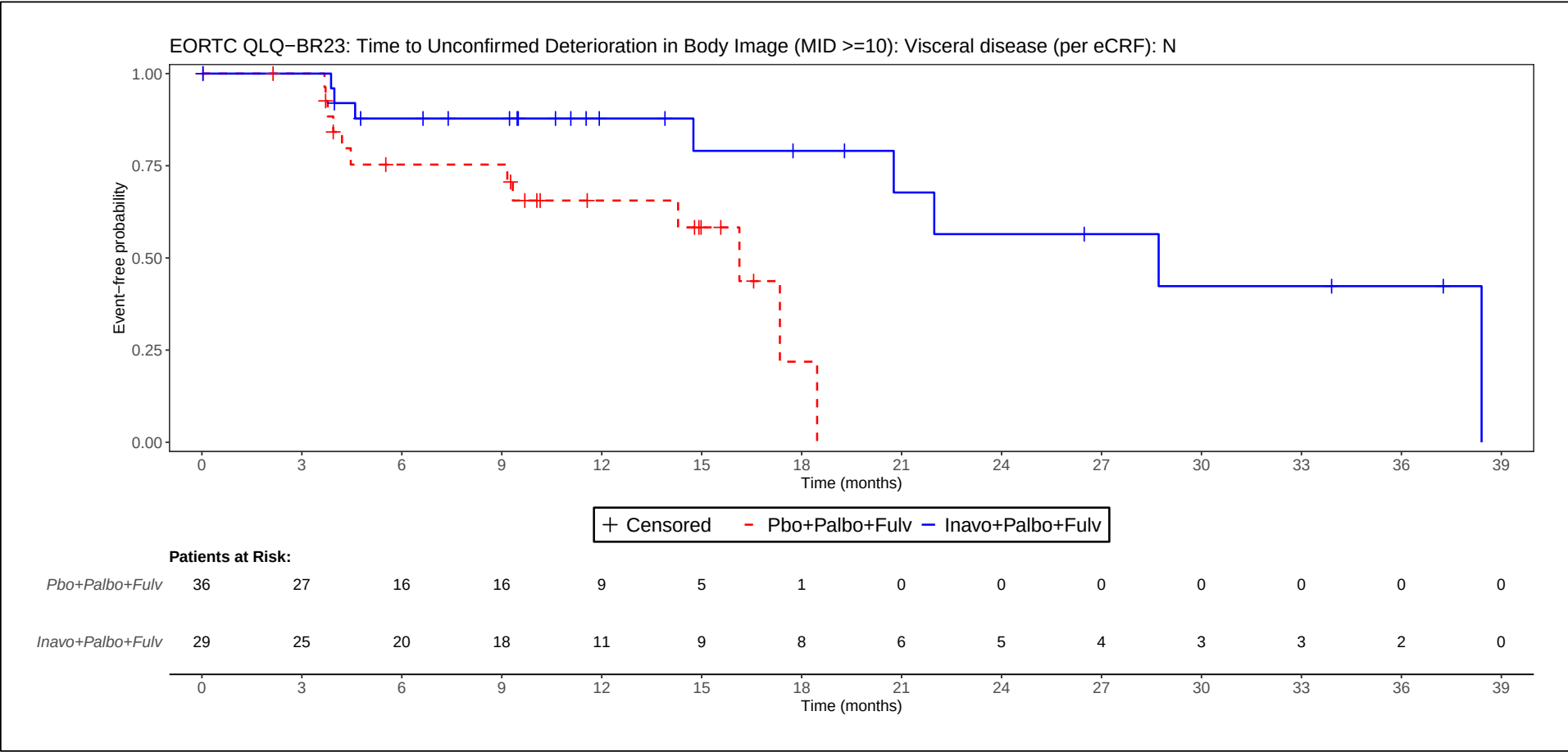
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

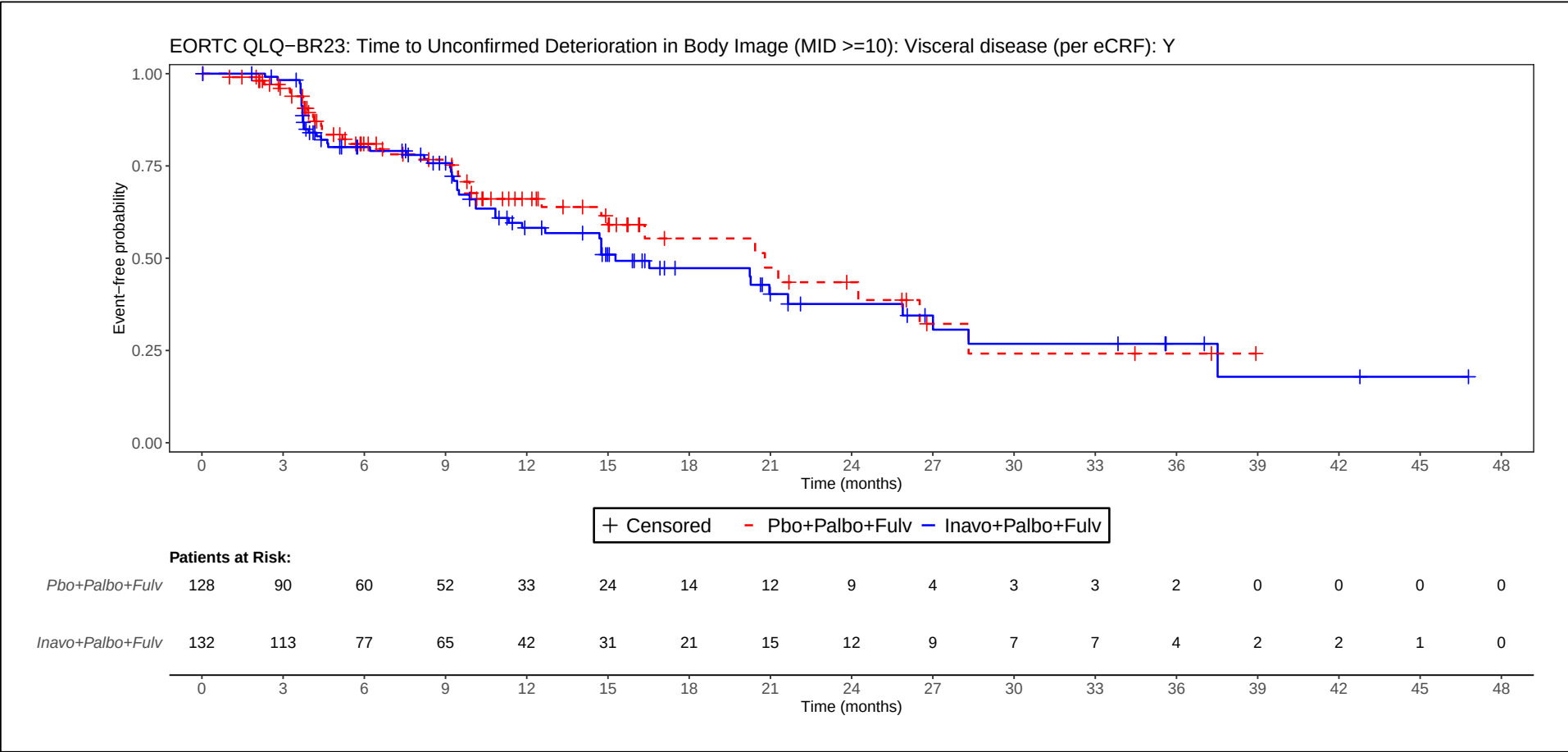
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

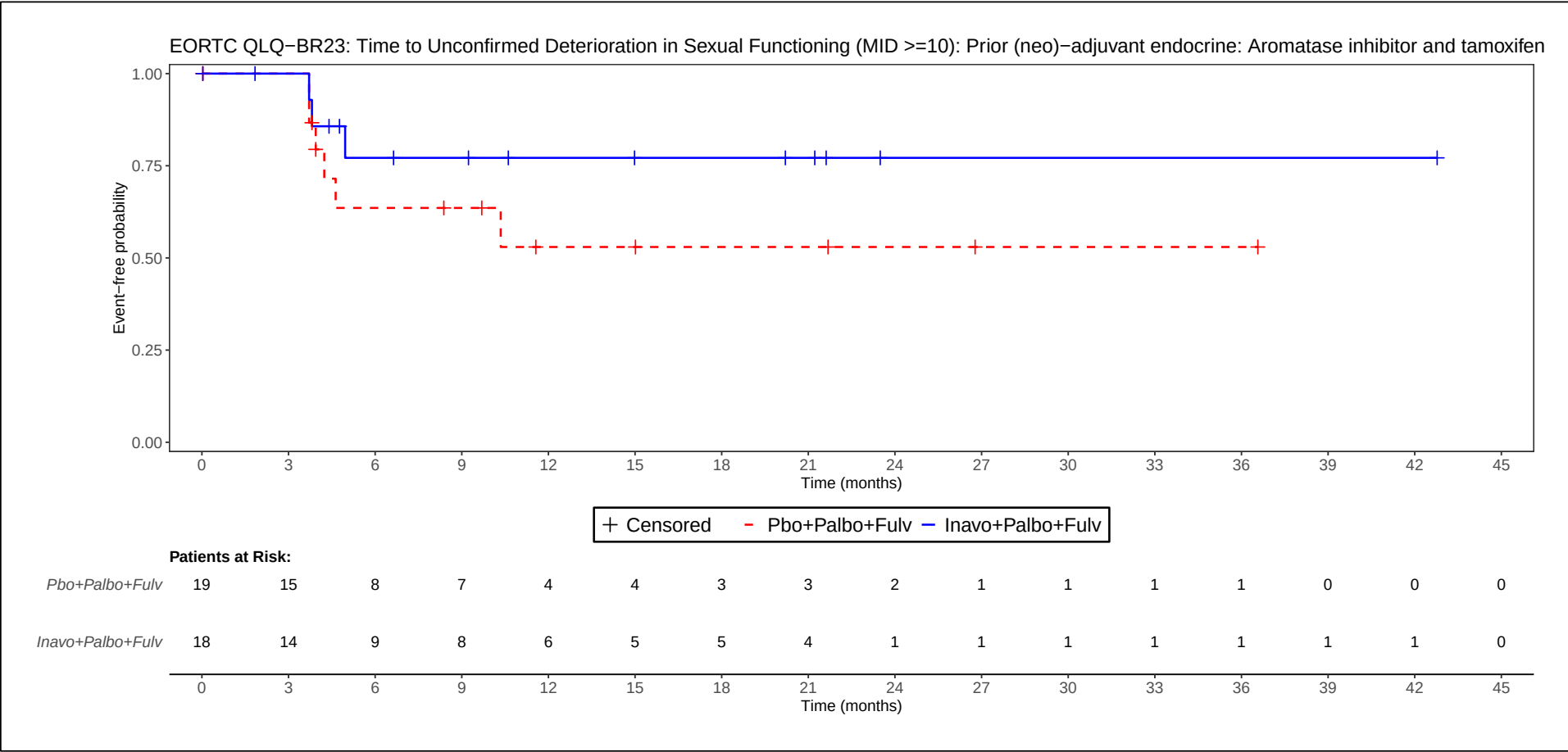
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 0efa981b2a84f5e06c881464de43872934271dc3
18 JUN 2025 17:01 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

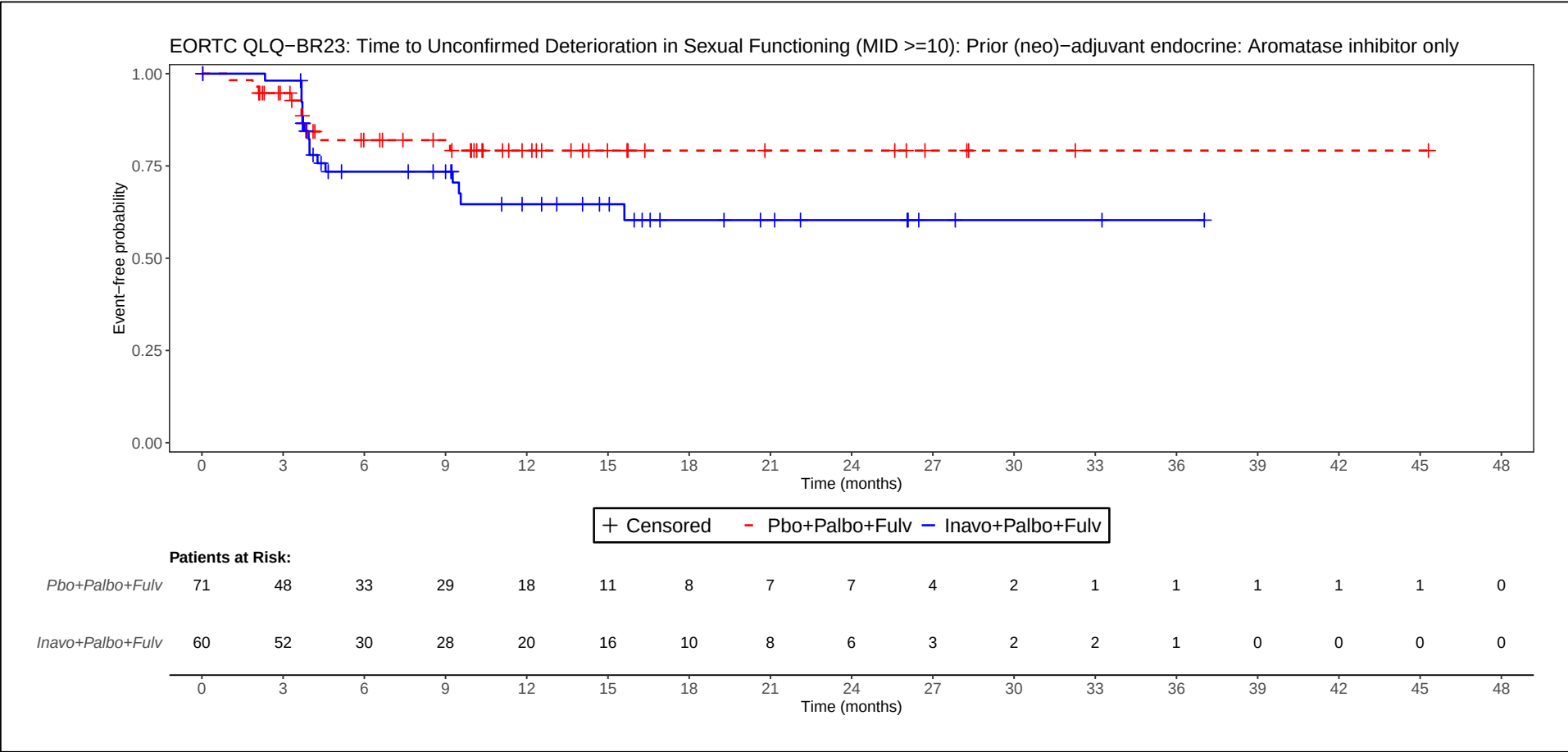
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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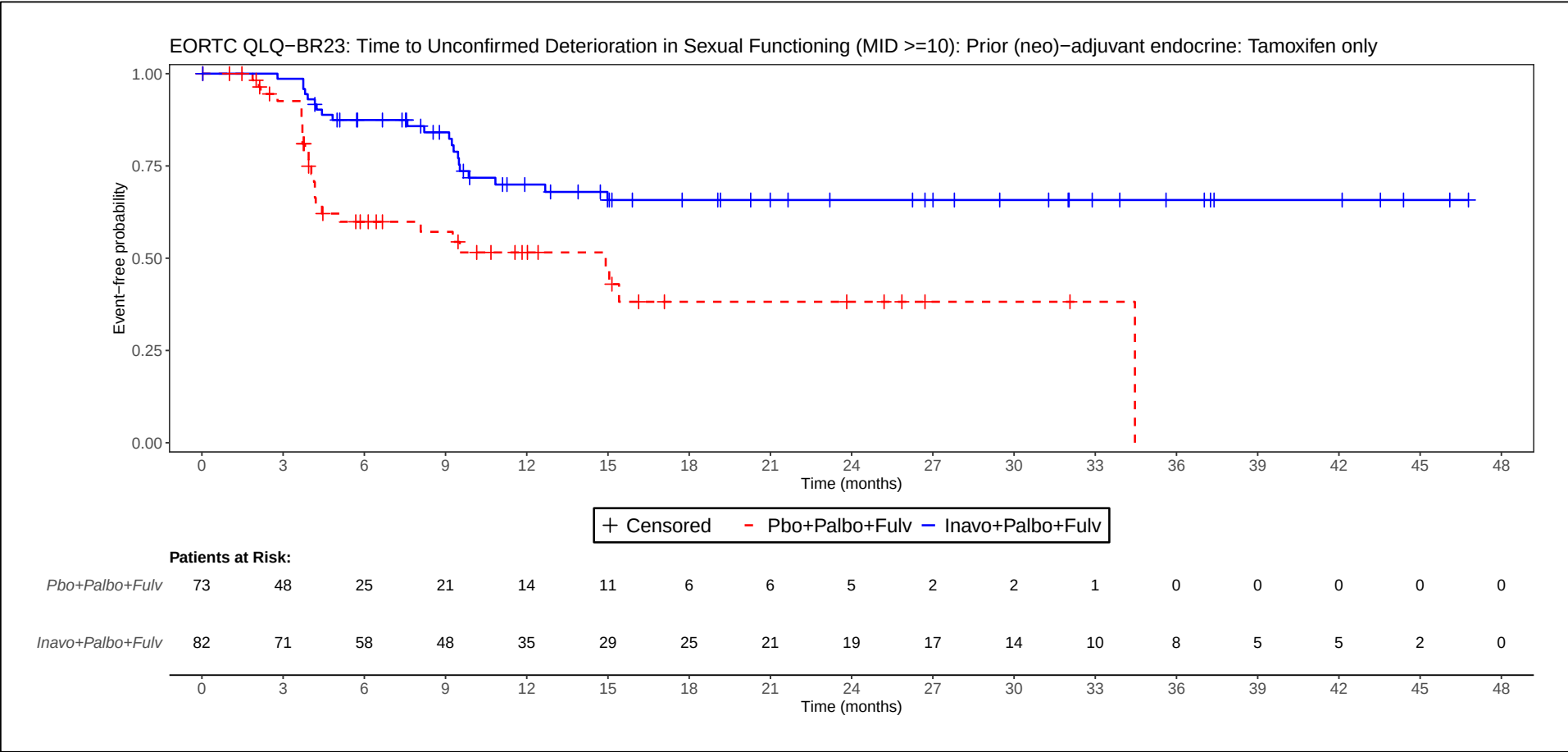
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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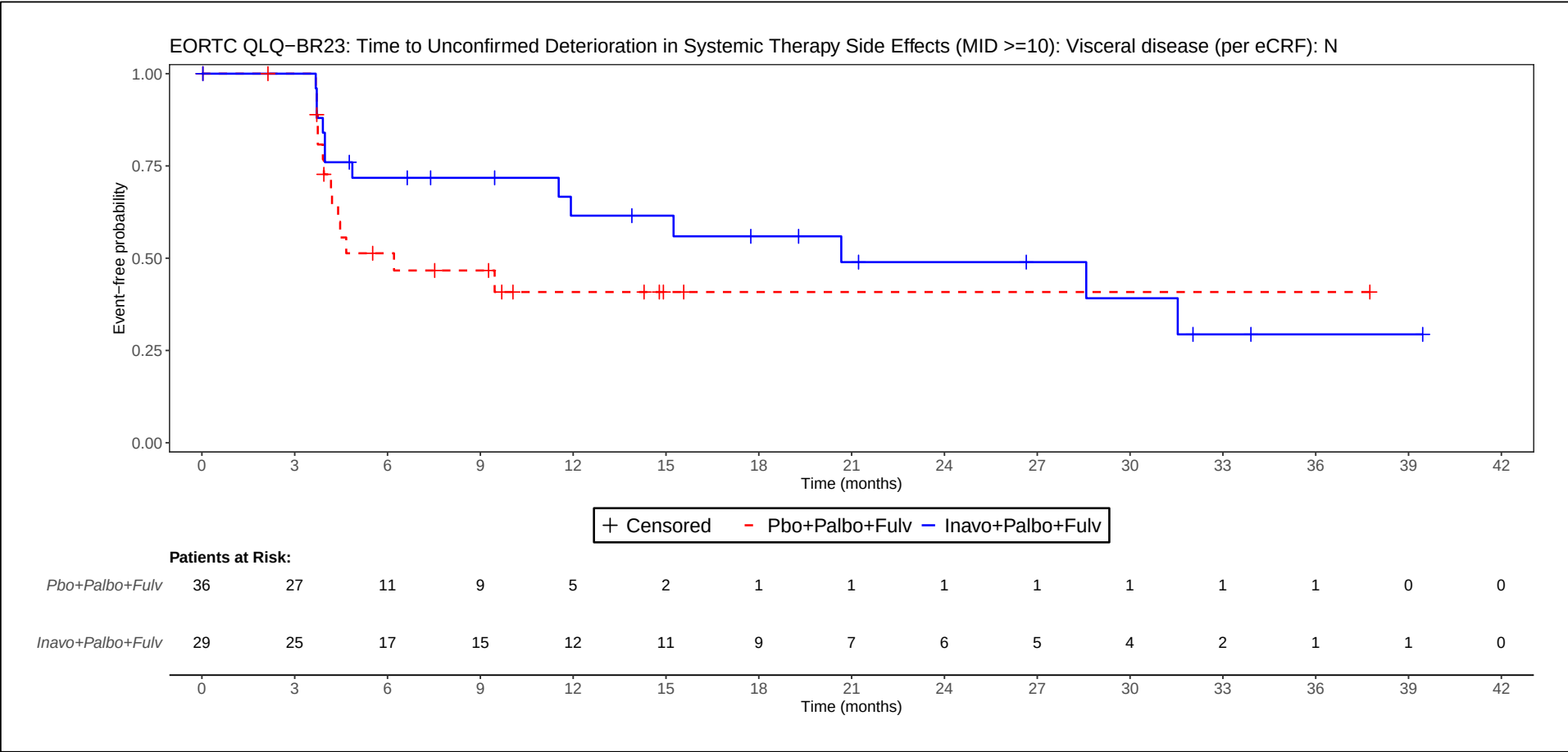
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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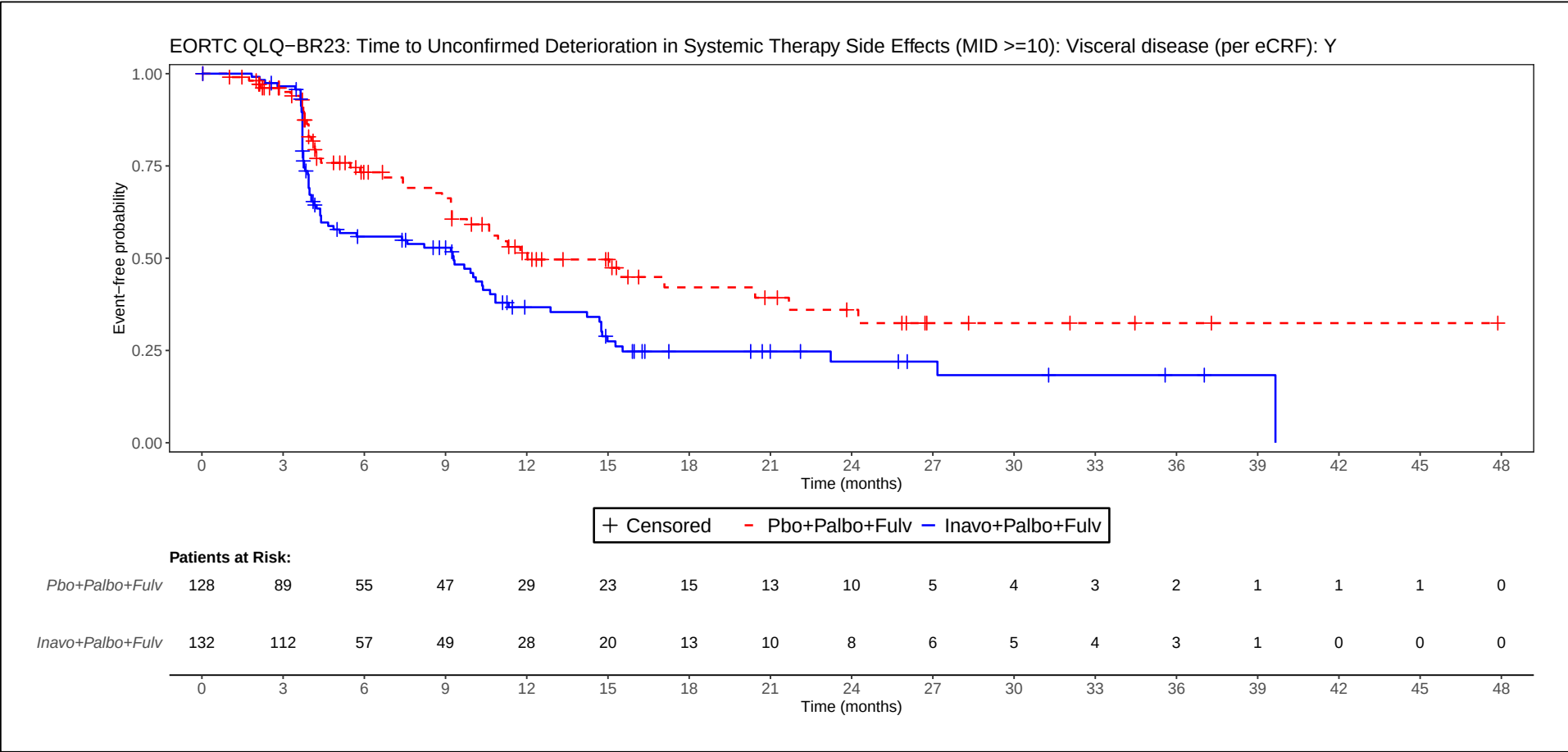
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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18 JUN 2025 17:01 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.2 PRO Items des EORTC QLQ-BR23

2.2.4 MMRM Analyse der PRO Items des EORTC QLQ-BR23

Analysis of MMRM, EORTC QLQ-BR23, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Questionnaire		
Visit		
Statistics	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
EORTC QLQ-BR23: Body image		
Treatment Discontinuation		
n	77	95
Adjusted Mean (SE) of Change from Baseline	-6.431 (2.010)	-0.797 (1.862)
95% CI	(-10.377, -2.486)	(-4.454, 2.860)
Difference in Adjusted Means (SE) of Change from Baseline	-5.634 (2.722)	
95% CI	(-10.980, -0.289)	
p-value (MMRM)	0.0389	
EORTC QLQ-BR23: Sexual functioning		
Treatment Discontinuation		
n	76	93
Adjusted Mean (SE) of Change from Baseline	-1.507 (1.587)	-4.288 (1.487)
95% CI	(-4.624, 1.609)	(-7.208, -1.367)
Difference in Adjusted Means (SE) of Change from Baseline	2.781 (2.161)	
95% CI	(-1.464, 7.025)	
p-value (MMRM)	0.1988	
EORTC QLQ-BR23: Sexual enjoyment		
Treatment Discontinuation		
n	14	12
Adjusted Mean (SE) of Change from Baseline	-10.437 (5.045)	-2.061 (5.860)
95% CI	(-20.452, -0.422)	(-13.718, 9.596)
Difference in Adjusted Means (SE) of Change from Baseline	-8.376 (7.749)	
95% CI	(-23.776, 7.024)	
p-value (MMRM)	0.2827	
EORTC QLQ-BR23: Future perspective		
Treatment Discontinuation		
n	77	95
Adjusted Mean (SE) of Change from Baseline	4.949 (2.855)	6.481 (2.641)
95% CI	(-0.656, 10.555)	(1.296, 11.667)
Difference in Adjusted Means (SE) of Change from Baseline	-1.532 (3.863)	
95% CI	(-9.117, 6.053)	
p-value (MMRM)	0.6918	
EORTC QLQ-BR23: Systemic therapy side effects		
Treatment Discontinuation		
n	77	95
Adjusted Mean (SE) of Change from Baseline	11.592 (1.452)	7.445 (1.373)
95% CI	(8.740, 14.443)	(4.748, 10.143)
Difference in Adjusted Means (SE) of Change from Baseline	4.146 (1.987)	
95% CI	(0.244, 8.049)	
p-value (MMRM)	0.0374	
EORTC QLQ-BR23: Breast symptoms		
Treatment Discontinuation		
n	77	95
Adjusted Mean (SE) of Change from Baseline	-0.376 (1.309)	-1.498 (1.223)
95% CI	(-2.946, 2.193)	(-3.900, 0.905)
Difference in Adjusted Means (SE) of Change from Baseline	1.121 (1.779)	
95% CI	(-2.373, 4.615)	

Questionnaire Visit Statistics	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
p-value (MMRM)	0.5289	
EORTC QLQ-BR23: Arm symptoms		
Treatment Discontinuation		
n	77	95
Adjusted Mean (SE) of Change from Baseline	3.330 (1.744)	-0.996 (1.642)
95% CI	(-0.094, 6.754)	(-4.222, 2.229)
Difference in Adjusted Means (SE) of Change from Baseline	4.326 (2.381)	
95% CI	(-0.351, 9.003)	
p-value (MMRM)	0.0698	
EORTC QLQ-BR23: Upset by hair loss		
Treatment Discontinuation		
n	18	15
Adjusted Mean (SE) of Change from Baseline	8.359 (5.991)	6.764 (6.472)
95% CI	(-3.505, 20.223)	(-6.055, 19.583)
Difference in Adjusted Means (SE) of Change from Baseline	1.595 (8.873)	
95% CI	(-15.978, 19.168)	
p-value (MMRM)	0.8576	

The model includes treatment groups, study visits, baseline value, and stratification factors as fixed effects. Visits that were unscheduled or happened after the assessment of progressive disease during the follow-up period were excluded. Compound symmetry covariance structure was used.
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21 MAY 2025 03:37 GMT

Anhang 4-G1 – Analysen Studie IINAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.3 Subjektiver Gesundheitszustand anhand der EQ-5D VAS

2.3.1 Rücklaufquoten der EQ-5D VAS

Questionnaire Completion by Visit by Scale, EQ-5D-5L, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
EQ-5D-5L: EQ VAS Score			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	155 (94.5%)	304 (93.8%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	141 (91.0%)	152 (94.4%)	293 (92.7%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	134 (89.9%)	130 (89.7%)	264 (89.8%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	126 (90.6%)	102 (86.4%)	228 (88.7%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	103 (88.0%)	73 (86.9%)	176 (87.6%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	92 (92.0%)	57 (86.4%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	40 (87.0%)	113 (89.0%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	69 (93.2%)	30 (76.9%)	99 (87.6%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (82.8%)	24 (77.4%)	77 (81.1%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	51 (87.9%)	20 (76.9%)	71 (84.5%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	38 (86.4%)	17 (77.3%)	55 (83.3%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.5%)	38 (19.2%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)

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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.3 Subjektiver Gesundheitszustand anhand der EQ-5D VAS

2.3.2 Werte und Veränderung gegenüber dem Ausgangswert der EQ-5D VAS

PRO Scores and Change from Baseline by Visit, EQ-5D-5L, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Analysis Visit	Inavo+Palbo+Fulv Value at Visit (N=161)	Inavo+Palbo+Fulv Change from Baseline (N=161)	Pbo+Palbo+Fulv Value at Visit (N=164)	Pbo+Palbo+Fulv Change from Baseline (N=164)
EQ-5D-5L: EQ VAS Score				
BASELINE				
n	149		155	
Mean (SD)	71.4 (20.7)		74.3 (18.8)	
Median	78.0		79.0	
Min - Max	0 - 100		0 - 100	
Cycle 2 Day 1				
n	141	136	152	145
Mean (SD)	73.6 (18.9)	2.3 (17.1)	74.7 (17.4)	-0.0 (15.5)
Median	75.0	0.0	80.0	0.0
Min - Max	10 - 100	-40 - 100	30 - 100	-50 - 41
Cycle 3 Day 1				
n	134	129	130	124
Mean (SD)	74.1 (19.0)	2.8 (17.5)	73.7 (17.0)	-0.5 (16.4)
Median	80.0	0.0	75.5	0.0
Min - Max	6 - 100	-50 - 100	30 - 100	-50 - 40
Cycle 5 Day 1				
n	126	123	102	96
Mean (SD)	74.0 (16.7)	1.6 (16.6)	72.3 (18.9)	-3.3 (20.1)
Median	78.0	0.0	79.5	0.0
Min - Max	30 - 100	-35 - 58	10 - 100	-86 - 40
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	76.0 (16.6)	4.2 (17.2)	77.1 (16.9)	2.2 (15.9)
Median	80.0	0.0	80.0	0.0
Min - Max	23 - 100	-48 - 70	40 - 100	-41 - 39
Cycle 9 Day 1				
n	103	100	73	70
Mean (SD)	74.8 (18.0)	2.6 (17.5)	75.6 (14.9)	1.1 (17.6)
Median	80.0	0.0	80.0	2.0
Min - Max	30 - 100	-65 - 57	38 - 100	-48 - 50
Cycle 11 Day 1				
n	92	88	57	56
Mean (SD)	72.0 (20.8)	-0.3 (19.9)	74.7 (15.4)	0.7 (15.7)
Median	78.0	0.0	79.0	0.0
Min - Max	10 - 100	-90 - 51	40 - 100	-58 - 40
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	76.1 (16.0)	2.1 (18.0)	76.6 (16.5)	2.7 (18.7)
Median	80.0	0.0	80.0	1.0
Min - Max	39 - 99	-50 - 59	29 - 100	-50 - 35
Cycle 15 Day 1				
n	73	69	40	39
Mean (SD)	74.2 (16.0)	1.5 (15.0)	75.6 (17.0)	1.2 (17.6)
Median	80.0	0.0	80.0	0.0
Min - Max	38 - 99	-39 - 49	40 - 100	-47 - 41
Cycle 17 Day 1				
n	69	66	30	29
Mean (SD)	74.1 (17.2)	0.9 (15.7)	74.9 (15.9)	1.6 (15.1)
Median	79.0	0.0	77.5	0.0
Min - Max	40 - 100	-50 - 31	39 - 100	-29 - 34
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	73.3 (17.8)	0.2 (17.4)	77.4 (16.5)	3.0 (17.9)
Median	73.0	0.0	79.5	0.0
Min - Max	39 - 100	-39 - 35	30 - 100	-49 - 34

Analysis Visit	Inavo+Palbo+Fulv	Inavo+Palbo+Fulv	Pbo+Palbo+Fulv	Pbo+Palbo+Fulv
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	74.1 (16.8)	0.9 (16.2)	76.0 (18.3)	4.3 (14.8)
Median	74.0	0.0	80.0	2.0
Min - Max	30 - 100	-39 - 34	39 - 100	-20 - 39
Cycle 23 Day 1				
n	51	48	20	19
Mean (SD)	74.4 (15.4)	2.2 (15.8)	80.3 (10.6)	6.1 (18.1)
Median	74.0	0.5	80.0	4.0
Min - Max	39 - 99	-41 - 34	60 - 100	-28 - 35
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	75.0 (16.4)	3.0 (16.3)	79.3 (15.7)	3.7 (21.7)
Median	79.0	0.0	80.0	1.5
Min - Max	40 - 99	-40 - 39	49 - 100	-39 - 35
Cycle 27 Day 1				
n	38	37	17	16
Mean (SD)	74.0 (17.8)	2.6 (17.0)	80.6 (15.8)	4.8 (24.2)
Median	77.0	3.0	85.0	0.0
Min - Max	42 - 99	-36 - 38	50 - 100	-39 - 40
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	73.8 (16.0)	-0.5 (18.3)	77.0 (13.7)	1.9 (19.9)
Median	76.0	0.5	75.0	-0.5
Min - Max	39 - 99	-41 - 30	50 - 100	-20 - 40
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	74.0 (16.3)	0.9 (15.8)	82.2 (12.0)	12.8 (21.3)
Median	74.0	0.0	80.0	13.0
Min - Max	30 - 98	-40 - 30	60 - 100	-20 - 39
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	76.1 (14.4)	-0.2 (15.1)	82.0 (15.9)	10.1 (18.6)
Median	80.0	-1.0	80.0	15.0
Min - Max	48 - 99	-29 - 30	50 - 98	-30 - 31
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	72.0 (15.4)	-1.2 (17.4)	79.6 (15.6)	9.5 (14.8)
Median	72.5	-1.0	80.0	6.5
Min - Max	50 - 99	-30 - 36	51 - 100	-10 - 37
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	74.3 (16.1)	-3.7 (17.3)	82.3 (14.5)	3.3 (15.4)
Median	75.0	-1.0	80.0	1.0
Min - Max	45 - 99	-34 - 31	60 - 100	-20 - 21
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	72.4 (13.5)	0.8 (19.5)	76.8 (12.3)	5.0 (12.6)
Median	71.5	-4.0	70.0	2.0
Min - Max	40 - 90	-27 - 38	67 - 97	-12 - 19
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	72.5 (14.8)	-3.1 (9.4)	76.8 (15.7)	7.0 (22.9)
Median	72.0	-2.0	77.5	10.5
Min - Max	51 - 98	-18 - 19	57 - 95	-22 - 29
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	78.5 (16.0)	2.2 (19.8)	68.5 (24.3)	-7.8 (29.4)
Median	85.0	-3.0	70.0	-10.0
Min - Max	51 - 97	-21 - 45	39 - 95	-40 - 29

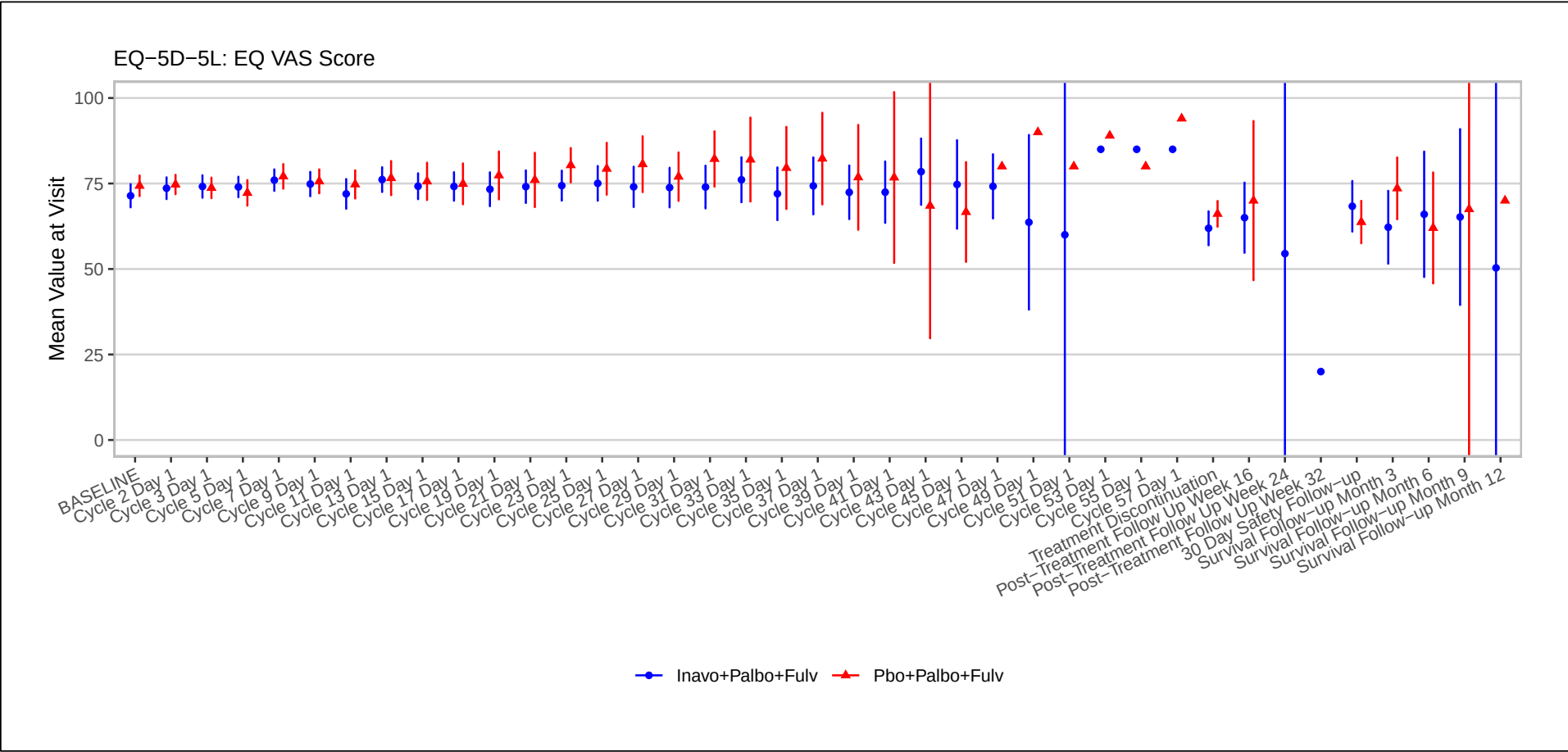
Analysis Visit	Inavo+Palbo+Fulv	Inavo+Palbo+Fulv	Pbo+Palbo+Fulv	Pbo+Palbo+Fulv
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	74.7 (14.0)	-3.3 (14.0)	66.7 (5.9)	5.0 (13.5)
Median	72.0	-6.0	69.0	6.0
Min - Max	56 - 90	-19 - 19	60 - 71	-9 - 18
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	74.2 (8.9)	-8.7 (14.3)	80.0 (0.0)	14.5 (20.5)
Median	71.0	-13.0	80.0	14.5
Min - Max	64 - 89	-20 - 19	80 - 80	0 - 29
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	63.7 (10.3)	-6.0 (12.0)	90.0 (NA)	39.0 (NA)
Median	61.0	-6.0	90.0	39.0
Min - Max	55 - 75	-18 - 6	90 - 90	39 - 39
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	60.0 (14.1)	-20.0 (12.7)	80.0 (NA)	29.0 (NA)
Median	60.0	-20.0	80.0	29.0
Min - Max	50 - 70	-29 - -11	80 - 80	29 - 29
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	85.0 (NA)	4.0 (NA)	89.0 (NA)	38.0 (NA)
Median	85.0	4.0	89.0	38.0
Min - Max	85 - 85	4 - 4	89 - 89	38 - 38
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	85.0 (NA)	4.0 (NA)	80.0 (NA)	29.0 (NA)
Median	85.0	4.0	80.0	29.0
Min - Max	85 - 85	4 - 4	80 - 80	29 - 29
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	85.0 (NA)	4.0 (NA)	94.0 (NA)	43.0 (NA)
Median	85.0	4.0	94.0	43.0
Min - Max	85 - 85	4 - 4	94 - 94	43 - 43
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	61.9 (22.0)	-8.4 (18.7)	66.1 (19.0)	-8.9 (18.0)
Median	68.0	-9.0	69.0	-7.0
Min - Max	8 - 100	-51 - 33	21 - 100	-50 - 35
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	65.0 (13.3)	-7.8 (23.0)	70.0 (18.7)	-5.2 (4.5)
Median	60.0	-10.0	60.0	-6.0
Min - Max	43 - 87	-41 - 29	50 - 90	-10 - 0
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	54.5 (13.4)	-3.0 (24.0)	NE (NE)	NE (NE)
Median	54.5	-3.0	NE	NE
Min - Max	45 - 64	-20 - 14	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	20.0 (NA)	-11.0 (NA)	NE (NE)	NE (NE)
Median	20.0	-11.0	NE	NE

Analysis Visit	Inavo+Palbo+Fulv	Inavo+Palbo+Fulv	Pbo+Palbo+Fulv	Pbo+Palbo+Fulv
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Min - Max	20 - 20	-11 - -11	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	37
Mean (SD)	68.3 (20.4)	-4.5 (22.0)	63.7 (19.3)	-12.7 (21.3)
Median	70.5	-2.0	63.0	-8.0
Min - Max	29 - 97	-44 - 40	15 - 91	-73 - 40
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	62.2 (22.0)	-5.9 (28.1)	73.6 (18.7)	-3.6 (27.9)
Median	69.0	1.0	75.0	3.0
Min - Max	9 - 92	-69 - 42	20 - 100	-70 - 50
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	66.0 (19.8)	7.1 (22.6)	62.0 (13.0)	-1.6 (26.9)
Median	70.0	9.0	60.0	10.0
Min - Max	40 - 88	-34 - 40	50 - 80	-48 - 20
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	65.2 (20.7)	-4.6 (18.5)	67.5 (10.6)	-1.5 (51.6)
Median	60.0	-5.0	67.5	-1.5
Min - Max	45 - 96	-32 - 20	60 - 75	-38 - 35
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	50.3 (30.0)	-14.0 (15.7)	70.0 (NA)	30.0 (NA)
Median	51.0	-11.0	70.0	30.0
Min - Max	20 - 80	-31 - 0	70 - 70	30 - 30

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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Output path:
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15 APR 2025 06:05 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Plot of Mean and 95% Confidence Interval, EQ-5D-5L, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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Git hash: 0efa981b2a84f5e06c881464de43872934271dc3
18 JUN 2025 17:01 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.3 Subjektiver Gesundheitszustand anhand der EQ-5D VAS

2.3.3 Zeit bis zur ersten Verschlechterung der EQ-5D VAS, MID = 15 Punkte

Time to Event Analysis (Efficacy), EQ-5D-5L (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

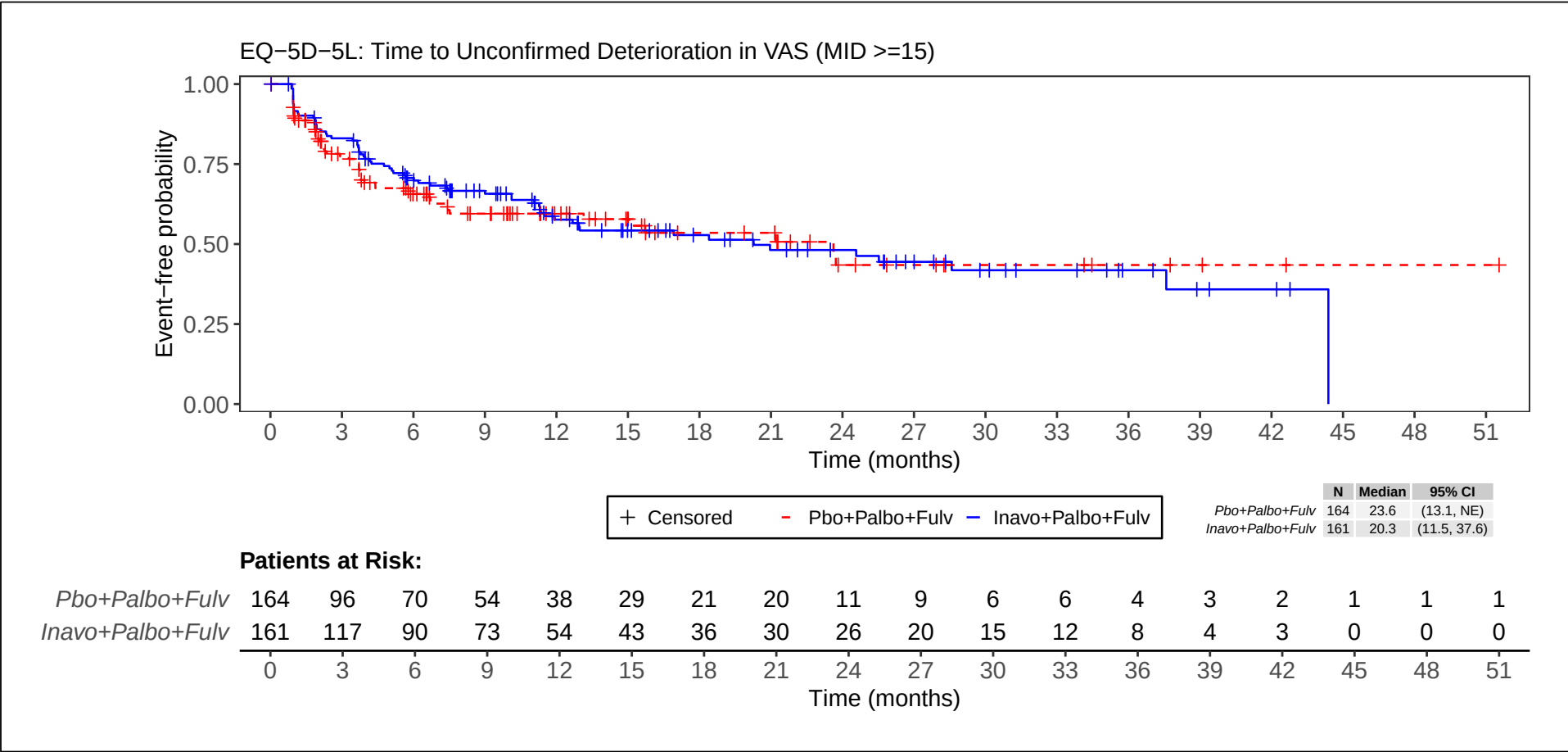
	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
EQ-5D-5L: Time to Unconfirmed Deterioration in VAS (MID >=15)		
Patients with event		
n (%)	67 (41.6%)	58 (35.4%)
Patients without event		
n (%)	94 (58.4%)	106 (64.6%)
Time to Event (Months)		
Median	20.27	23.62
95% CI	(11.53, 37.59)	(13.14, NE)
Range	0.03 - 44.39 {1}	0.03 - 51.55 {2}
Unstratified Analysis		
p-value (log-rank)	0.8223	
Hazard Ratio	0.96	
95% CI	(0.67, 1.37)	
Stratified Analysis		
p-value (log-rank)	0.7865	
Hazard Ratio	0.95	
95% CI	(0.66, 1.38)	

{1} - Censored observation: range minimum
{2} - Censored observations: range minimum & maximum

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ef_tte2.R
Output path:
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x
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
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07 APR 2025 15:47 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Efficacy, EQ-5D-5L (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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17 MAR 2025 23:34 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.3 Subjektiver Gesundheitszustand anhand der EQ-5D VAS

2.3.3 Zeit bis zur ersten Verschlechterung der EQ-5D VAS, MID = 15 Punkte

2.3.3.1 Subgruppenanalyse Zeit bis zur ersten Verschlechterung der EQ-5D VAS, MID = 15 Punkte

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Efficacy), EQ-5D-5L (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOd: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)	
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI					
EQ-5D-5L: Time to Unconfirmed Deterioration in VAS (MID >=15)																
All Patients	325	164	58	35.4	23.62	(13.14, NA)	161	67	41.6	20.27	(11.53, 37.59)	0.96	(0.67, 1.37)	0.8223	NE	
Age group (years)																
<65	266	130	44	33.8	23.62	(13.14, NA)	136	59	43.4	18.40	(11.33, NA)	1.01	(0.68, 1.50)	0.9511	0.5411	
>=65	59	34	14	41.2	7.39	(3.68, NA)	25	8	32.0	28.58	(3.68, NA)	0.74	(0.31, 1.77)	0.4865	0.5411	
Sex																
F	319	163	58	35.6	23.62	(13.14, NA)	156	65	41.7	20.27	(11.53, 37.59)	0.97	(0.68, 1.39)	0.8763	1.0000	
M	6	1	0	0.0	NE	NE	5	2	40.0	NE	(2.37, NA)	NE	NE	1.0000	1.0000	
Region																
ASIA	120	62	27	43.5	21.19	(4.40, NA)	58	30	51.7	12.98	(5.09, NA)	1.00	(0.59, 1.69)	0.9958	0.0993	
NORTH AMERICA/WESTERN EUROPE	127	64	18	28.1	23.62	(15.05, NA)	63	24	38.1	20.27	(5.62, NA)	1.42	(0.77, 2.63)	0.2596	0.0993	
OTHER	78	38	13	34.2	7.52	(3.29, NA)	40	13	32.5	28.58	(12.94, NA)	0.40	(0.18, 0.89)	0.0216	0.0993	
Visceral disease (per eCRF)																
N	65	36	15	41.7	23.62	(3.71, NA)	29	13	44.8	28.58	(4.76, NA)	0.71	(0.33, 1.54)	0.3853	0.4221	
Y	260	128	43	33.6	23.72	(13.14, NA)	132	54	40.9	20.27	(11.33, NA)	1.03	(0.69, 1.54)	0.8891	0.4221	
Ethnicity																
HISPANIC OR LATINO	20	10	4	40.0	23.62	(3.71, NA)	10	4	40.0	5.62	(1.91, NA)	2.80	(0.51, 15.37)	0.2175	0.2264	
NOT HISPANIC OR LATINO	294	149	51	34.2	NE	(7.46, NA)	145	61	42.1	20.27	(11.53, 37.59)	0.98	(0.68, 1.43)	0.9400	0.2264	
NOT REPORTED	5	3	1	33.3	15.74	NE	2	1	50.0	3.71	(3.71, NA)	>999.99	(0.00, >999.99)	0.4795	0.2264	
UNKNOWN	6	2	2	100.0	1.48	(0.95, NA)	4	1	25.0	5.68	(5.68, NA)	<0.01	(0.00, >999.99)	0.0896	0.2264	
Race																
Asian	124	63	27	42.9	21.19	(4.40, NA)	61	31	50.8	12.98	(5.09, NA)	0.99	(0.59, 1.66)	0.9638	0.0776	
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.0776	
White	191	97	29	29.9	23.72	(13.14, NA)	94	36	38.3	24.57	(11.53, NA)	0.98	(0.60, 1.61)	0.9495	0.0776	
Unknown	8	3	2	66.7	8.87	(2.00, NA)	5	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.0624	0.0776	
Liver Metastasis at Enrollment																
N	157	73	28	38.4	23.72	(6.93, NA)	84	35	41.7	28.58	(10.12, NA)	0.97	(0.59, 1.59)	0.9057	0.9962	
Y	168	91	30	33.0	15.74	(6.70, NA)	77	32	41.6	16.92	(11.07, NA)	0.91	(0.55, 1.51)	0.7346	0.9962	
Number Metastatic Organs at Enrollment																
1	53	32	16	50.0	4.40	(3.29, NA)	21	12	57.1	8.76	(2.56, NA)	1.01	(0.47, 2.13)	0.9850	0.2021	
2	104	46	20	43.5	13.14	(3.94, NA)	58	20	34.5	37.59	(10.12, NA)	0.71	(0.38, 1.32)	0.2770	0.2021	
>=3	168	86	22	25.6	NE	(23.62, NA)	82	35	42.7	18.40	(11.33, 28.58)	1.35	(0.79, 2.30)	0.2693	0.2021	
ECOG Performance Status at Baseline																
0	206	106	36	34.0	23.62	(13.14, NA)	100	41	41.0	24.57	(12.68, NA)	0.89	(0.57, 1.41)	0.6210	0.7724	
1	118	58	22	37.9	NE	(3.78, NA)	60	26	43.3	11.93	(6.70, 28.58)	0.97	(0.55, 1.72)	0.9325	0.7724	

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Endocrine Resistance (per eCRF)															
Primary	112	58	20	34.5	7.52	(5.85, NA)	54	18	33.3	28.58	(11.30, NA)	0.64	(0.34, 1.23)	0.1791	0.2254
Secondary	212	105	38	36.2	23.62	(13.14, NA)	107	49	45.8	16.92	(10.12, NA)	1.10	(0.72, 1.69)	0.6544	0.2254
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	18	34.6	15.05	(6.70, NA)	52	20	38.5	44.39	(11.93, NA)	0.77	(0.40, 1.48)	0.4330	0.4375
POST-MENOPAUSAL	215	111	40	36.0	23.62	(7.39, NA)	104	45	43.3	12.94	(11.07, 28.58)	1.06	(0.69, 1.62)	0.7899	0.4375
Hormone receptor status															
ER+/PR-	90	45	17	37.8	15.74	(3.94, NA)	45	17	37.8	16.92	(11.27, NA)	0.74	(0.37, 1.46)	0.3767	0.2293
ER+/PR+	226	113	39	34.5	23.62	(13.14, NA)	113	50	44.2	20.27	(11.07, 37.59)	1.08	(0.71, 1.65)	0.7051	0.2293
Other	9	6	2	33.3	NE	(0.95, NA)	3	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.3431	0.2293
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	7	36.8	15.74	(3.71, NA)	18	8	44.4	10.12	(1.18, NA)	1.18	(0.43, 3.30)	0.7469	0.9146
Aromatase inhibitor only	131	71	25	35.2	23.62	(4.40, NA)	60	25	41.7	16.92	(9.00, NA)	0.93	(0.53, 1.63)	0.8028	0.9146
Tamoxifen only	155	73	26	35.6	23.72	(7.46, NA)	82	34	41.5	25.53	(12.68, NA)	0.95	(0.57, 1.58)	0.8439	0.9146
Prior (neo)-adjuvant CDK4/6															
N	322	163	58	35.6	23.62	(7.52, NA)	159	67	42.1	20.27	(11.53, 37.59)	0.95	(0.67, 1.35)	0.7759	1.0000
Y	3	1	0	0.0	NE	NE	2	0	0.0	NE	NE	NE	NE	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	7	25.9	NE	(6.93, NA)	29	14	48.3	11.53	(3.71, 28.58)	2.00	(0.81, 4.97)	0.1272	0.0570
Y	269	137	51	37.2	21.19	(7.39, NA)	132	53	40.2	24.57	(11.93, NA)	0.82	(0.56, 1.21)	0.3166	0.0570

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_ef_tte_sg.R

Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v5/output/t_ef_tte_sg_VASD_FAS_15NOV2024_41554.docx

Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685

Git hash: 884c7b654f8eaf01b56b221a2c1fd8df1f26a541

07 APR 2025 15:47 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.3 Subjektiver Gesundheitszustand anhand der EQ-5D VAS

2.3.4 MMRM Analyse der EQ-5D VAS

Analysis of MMRM, EQ-5D-5L, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Questionnaire		
Visit		
Statistics	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
EQ-5D-5L: EQ VAS Score		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	-7.791 (1.503)	-8.549 (1.394)
95% CI	(-10.741, -4.841)	(-11.284, -5.814)
Difference in Adjusted Means (SE) of Change from Baseline	0.758 (2.042)	
95% CI	(-3.248, 4.764)	
p-value (MMRM)	0.7106	

The model includes treatment groups, study visits, baseline value, and stratification factors as fixed effects. Visits that were unscheduled or happened after the assessment of progressive disease during the follow-up period were excluded. Compound symmetry covariance structure was used.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_pro_mmr.R
Output path:
/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v10/output/t_pro_mmr_VAS_FAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: b1a1c97d71c5f8414a8ce014f4248054b00f4184
21 MAY 2025 03:36 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.4 Stärkster Schmerz anhand des Brief Pain Inventory-Short Form (BPI-SF)

2.4.1 Rücklaufquoten des PRO Item 3 stärkster Schmerz des BPI-SF

Questionnaire Completion by Visit by Scale, BPI SHORT FORM, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
BPI2-Pain at its Worst in Last Week			
BASELINE			
Number of subjects expected to complete	160 (99.4%)	164 (100%)	324 (99.7%)
Number of subjects completed	149 (93.1%)	155 (94.5%)	304 (93.8%)
Cycle 2 Day 1			
Number of subjects expected to complete	155 (96.3%)	161 (98.2%)	316 (97.2%)
Number of subjects completed	141 (91.0%)	153 (95.0%)	294 (93.0%)
Cycle 3 Day 1			
Number of subjects expected to complete	149 (92.5%)	145 (88.4%)	294 (90.5%)
Number of subjects completed	137 (91.9%)	132 (91.0%)	269 (91.5%)
Cycle 5 Day 1			
Number of subjects expected to complete	139 (86.3%)	118 (72.0%)	257 (79.1%)
Number of subjects completed	127 (91.4%)	102 (86.4%)	229 (89.1%)
Cycle 7 Day 1			
Number of subjects expected to complete	129 (80.1%)	101 (61.6%)	230 (70.8%)
Number of subjects completed	112 (86.8%)	89 (88.1%)	201 (87.4%)
Cycle 9 Day 1			
Number of subjects expected to complete	117 (72.7%)	84 (51.2%)	201 (61.8%)
Number of subjects completed	103 (88.0%)	74 (88.1%)	177 (88.1%)
Cycle 11 Day 1			
Number of subjects expected to complete	100 (62.1%)	66 (40.2%)	166 (51.1%)
Number of subjects completed	92 (92.0%)	57 (86.4%)	149 (89.8%)
Cycle 13 Day 1			
Number of subjects expected to complete	89 (55.3%)	53 (32.3%)	142 (43.7%)
Number of subjects completed	79 (88.8%)	45 (84.9%)	124 (87.3%)
Cycle 15 Day 1			
Number of subjects expected to complete	81 (50.3%)	46 (28.0%)	127 (39.1%)
Number of subjects completed	73 (90.1%)	41 (89.1%)	114 (89.8%)
Cycle 17 Day 1			
Number of subjects expected to complete	74 (46.0%)	39 (23.8%)	113 (34.8%)
Number of subjects completed	70 (94.6%)	30 (76.9%)	100 (88.5%)
Cycle 19 Day 1			
Number of subjects expected to complete	64 (39.8%)	31 (18.9%)	95 (29.2%)
Number of subjects completed	53 (81.5%)	24 (77.4%)	77 (80.2%)
Cycle 21 Day 1			
Number of subjects expected to complete	59 (36.6%)	29 (17.7%)	88 (27.1%)
Number of subjects completed	51 (86.4%)	23 (79.3%)	74 (84.1%)
Cycle 23 Day 1			
Number of subjects expected to complete	58 (36.0%)	26 (15.9%)	84 (25.8%)
Number of subjects completed	52 (89.7%)	20 (76.9%)	72 (85.7%)
Cycle 25 Day 1			
Number of subjects expected to complete	48 (29.8%)	24 (14.6%)	72 (22.2%)
Number of subjects completed	43 (89.6%)	19 (79.2%)	62 (86.1%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 27 Day 1			
Number of subjects expected to complete	44 (27.3%)	22 (13.4%)	66 (20.3%)
Number of subjects completed	38 (86.4%)	17 (77.3%)	55 (83.3%)
Cycle 29 Day 1			
Number of subjects expected to complete	40 (24.8%)	18 (11.0%)	58 (17.8%)
Number of subjects completed	32 (80.0%)	17 (94.4%)	49 (84.5%)
Cycle 31 Day 1			
Number of subjects expected to complete	34 (21.1%)	14 (8.5%)	48 (14.8%)
Number of subjects completed	29 (85.3%)	11 (78.6%)	40 (83.3%)
Cycle 33 Day 1			
Number of subjects expected to complete	27 (16.8%)	10 (6.1%)	37 (11.4%)
Number of subjects completed	21 (77.8%)	9 (90.0%)	30 (81.1%)
Cycle 35 Day 1			
Number of subjects expected to complete	24 (14.9%)	10 (6.1%)	34 (10.5%)
Number of subjects completed	18 (75.0%)	9 (90.0%)	27 (79.4%)
Cycle 37 Day 1			
Number of subjects expected to complete	22 (13.7%)	9 (5.5%)	31 (9.5%)
Number of subjects completed	17 (77.3%)	7 (77.8%)	24 (77.4%)
Cycle 39 Day 1			
Number of subjects expected to complete	18 (11.2%)	8 (4.9%)	26 (8.0%)
Number of subjects completed	14 (77.8%)	5 (62.5%)	19 (73.1%)
Cycle 41 Day 1			
Number of subjects expected to complete	16 (9.9%)	7 (4.3%)	23 (7.1%)
Number of subjects completed	13 (81.2%)	4 (57.1%)	17 (73.9%)
Cycle 43 Day 1			
Number of subjects expected to complete	14 (8.7%)	6 (3.7%)	20 (6.2%)
Number of subjects completed	13 (92.9%)	4 (66.7%)	17 (85.0%)
Cycle 45 Day 1			
Number of subjects expected to complete	11 (6.8%)	4 (2.4%)	15 (4.6%)
Number of subjects completed	7 (63.6%)	3 (75.0%)	10 (66.7%)
Cycle 47 Day 1			
Number of subjects expected to complete	8 (5.0%)	2 (1.2%)	10 (3.1%)
Number of subjects completed	6 (75.0%)	2 (100.0%)	8 (80.0%)
Cycle 49 Day 1			
Number of subjects expected to complete	8 (5.0%)	1 (0.6%)	9 (2.8%)
Number of subjects completed	3 (37.5%)	1 (100.0%)	4 (44.4%)
Cycle 51 Day 1			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	1 (100.0%)	3 (60.0%)
Cycle 53 Day 1			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	1 (50.0%)	1 (100.0%)	2 (66.7%)
Cycle 55 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Cycle 57 Day 1			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Cycle 59 Day 1			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Treatment Discontinuation			
Number of subjects expected to complete	98 (60.9%)	132 (80.5%)	230 (70.8%)
Number of subjects completed	79 (80.6%)	103 (78.0%)	182 (79.1%)
30 Day Safety Follow-up			
Number of subjects expected to complete	38 (23.6%)	45 (27.4%)	83 (25.5%)
Number of subjects completed	32 (84.2%)	40 (88.9%)	72 (86.7%)
Post-Treatment Follow Up Week 16			
Number of subjects expected to complete	10 (6.2%)	6 (3.7%)	16 (4.9%)
Number of subjects completed	9 (90.0%)	5 (83.3%)	14 (87.5%)
Post-Treatment Follow Up Week 24			
Number of subjects expected to complete	4 (2.5%)	1 (0.6%)	5 (1.5%)
Number of subjects completed	2 (50.0%)	0 (0.0%)	2 (40.0%)
Post-Treatment Follow Up Week 32			
Number of subjects expected to complete	3 (1.9%)	1 (0.6%)	4 (1.2%)
Number of subjects completed	1 (33.3%)	0 (0.0%)	1 (25.0%)
Post-Treatment Follow Up Week 40			
Number of subjects expected to complete	1 (0.6%)	1 (0.6%)	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 48			
Number of subjects expected to complete	2 (1.2%)	1 (0.6%)	3 (0.9%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Treatment Follow Up Week 56			
Number of subjects expected to complete	2 (1.2%)	0	2 (0.6%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 72			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 80			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Post-Treatment Follow Up Week 88			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Post-Treatment Follow Up Week 96			
Number of subjects expected to complete	1 (0.6%)	0	1 (0.3%)
Number of subjects completed	0 (0.0%)	0 (NA%)	0 (0.0%)
Survival Follow-up Month 3			
Number of subjects expected to complete	83 (51.6%)	115 (70.1%)	198 (60.9%)
Number of subjects completed	19 (22.9%)	19 (16.4%)	38 (19.1%)
Survival Follow-up Month 6			
Number of subjects expected to complete	71 (44.1%)	91 (55.5%)	162 (49.8%)
Number of subjects completed	7 (9.9%)	5 (5.5%)	12 (7.4%)
Survival Follow-up Month 9			
Number of subjects expected to complete	51 (31.7%)	73 (44.5%)	124 (38.2%)
Number of subjects completed	5 (9.8%)	2 (2.7%)	7 (5.6%)
Survival Follow-up Month 12			
Number of subjects expected to complete	41 (25.5%)	61 (37.2%)	102 (31.4%)
Number of subjects completed	3 (7.3%)	1 (1.6%)	4 (3.9%)
Survival Follow-up Month 15			
Number of subjects expected to complete	36 (22.4%)	49 (29.9%)	85 (26.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 18			
Number of subjects expected to complete	29 (18.0%)	43 (26.2%)	72 (22.2%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 21			
Number of subjects expected to complete	21 (13.0%)	33 (20.1%)	54 (16.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 24			
Number of subjects expected to complete	14 (8.7%)	24 (14.6%)	38 (11.7%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 27			
Number of subjects expected to complete	8 (5.0%)	20 (12.2%)	28 (8.6%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 30			
Number of subjects expected to complete	3 (1.9%)	15 (9.1%)	18 (5.5%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 33			
Number of subjects expected to complete	2 (1.2%)	9 (5.5%)	11 (3.4%)
Number of subjects completed	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 36			
Number of subjects expected to complete	0	6 (3.7%)	6 (1.8%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 39			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 42			
Number of subjects expected to complete	0	3 (1.8%)	3 (0.9%)

Questionnaire Visit	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)
Survival Follow-up Month 45			
Number of subjects expected to complete	0	1 (0.6%)	1 (0.3%)
Number of subjects completed	0 (NA%)	0 (0.0%)	0 (0.0%)

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_qs_compsc.R
Output path:
/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v7/output/t_qs_compsc_BPI_FAS_15NOV2024_41554.d
ocx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: b6027dbd949ffd3bd010747913d30fe0e2c66bc9
14 APR 2025 06:17 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.4 Stärkster Schmerz anhand des Brief Pain Inventory-Short Form (BPI-SF)

2.4.2 Werte und Veränderung gegenüber dem Ausgangswert des PRO Item 3 stärkster Schmerz des BPI-SF

PRO Scores and Change from Baseline by Visit for BPI-SF Worst Pain Item, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: BPI2-Pain at its Worst in Last Week

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
BASELINE				
n	149		155	
Mean (SD)	3.4 (2.7)		3.3 (2.9)	
Median	3.0		3.0	
Min - Max	0 - 10		0 - 10	
Cycle 2 Day 1				
n	141	136	153	146
Mean (SD)	2.9 (2.5)	-0.6 (2.9)	2.6 (2.4)	-0.6 (2.3)
Median	3.0	0.0	2.0	0.0
Min - Max	0 - 10	-10 - 5	0 - 9	-8 - 5
Cycle 3 Day 1				
n	137	132	132	125
Mean (SD)	2.5 (2.4)	-0.9 (3.1)	2.6 (2.5)	-0.7 (2.7)
Median	2.0	-1.0	2.0	0.0
Min - Max	0 - 10	-10 - 6	0 - 8	-9 - 6
Cycle 5 Day 1				
n	127	123	102	96
Mean (SD)	2.7 (2.4)	-0.7 (2.8)	3.1 (2.6)	-0.1 (2.5)
Median	2.0	0.0	3.0	0.0
Min - Max	0 - 10	-10 - 8	0 - 9	-6 - 6
Cycle 7 Day 1				
n	112	107	89	84
Mean (SD)	2.9 (2.8)	-0.6 (3.2)	2.8 (2.7)	-0.3 (3.2)
Median	2.0	-1.0	2.0	0.0
Min - Max	0 - 10	-9 - 8	0 - 10	-8 - 8
Cycle 9 Day 1				
n	103	100	74	71
Mean (SD)	2.5 (2.4)	-0.7 (3.1)	2.6 (2.3)	-0.6 (2.8)
Median	2.0	-0.5	2.0	0.0
Min - Max	0 - 8	-9 - 8	0 - 8	-8 - 7

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:33 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BPI_FAS_15NOV2024_41554.out Page 1 of 7

PRO Scores and Change from Baseline by Visit for BPI-SF Worst Pain Item, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: BPI2-Pain at its Worst in Last Week

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 11 Day 1				
n	92	88	57	56
Mean (SD)	3.0 (2.5)	-0.2 (3.1)	2.5 (2.2)	-0.7 (2.8)
Median	3.0	0.0	2.0	-0.5
Min - Max	0 - 9	-6 - 7	0 - 8	-7 - 7
Cycle 13 Day 1				
n	79	75	45	44
Mean (SD)	2.7 (2.5)	-0.2 (3.3)	2.8 (2.2)	-0.5 (2.5)
Median	2.0	0.0	3.0	0.0
Min - Max	0 - 9	-9 - 8	0 - 9	-5 - 8
Cycle 15 Day 1				
n	73	69	41	40
Mean (SD)	2.4 (2.7)	-0.7 (3.2)	2.5 (2.5)	-0.6 (2.3)
Median	1.0	0.0	2.0	-0.5
Min - Max	0 - 9	-9 - 8	0 - 8	-5 - 5
Cycle 17 Day 1				
n	70	67	30	29
Mean (SD)	2.7 (2.4)	-0.2 (2.7)	3.5 (2.7)	0.2 (2.7)
Median	2.0	0.0	3.0	0.0
Min - Max	0 - 9	-7 - 6	0 - 9	-5 - 5
Cycle 19 Day 1				
n	53	50	24	23
Mean (SD)	2.4 (2.3)	-0.5 (2.8)	3.0 (2.5)	0.1 (2.2)
Median	2.0	0.0	3.0	0.0
Min - Max	0 - 8	-7 - 7	0 - 8	-4 - 5
Cycle 21 Day 1				
n	51	48	23	21
Mean (SD)	2.5 (2.5)	-0.2 (3.1)	2.7 (2.7)	-0.4 (2.5)
Median	2.0	0.0	2.0	0.0
Min - Max	0 - 9	-8 - 8	0 - 9	-5 - 4

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:33 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BPI_FAS_15NOV2024_41554.out Page 2 of 7

PRO Scores and Change from Baseline by Visit for BPI-SF Worst Pain Item, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: BPI2-Pain at its Worst in Last Week

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 23 Day 1				
n	52	49	20	19
Mean (SD)	2.6 (2.4)	-0.3 (2.9)	3.8 (3.2)	0.9 (3.0)
Median	2.0	0.0	3.0	0.0
Min - Max	0 - 8	-8 - 7	0 - 10	-5 - 8
Cycle 25 Day 1				
n	43	42	19	18
Mean (SD)	2.6 (2.7)	-0.4 (2.9)	3.6 (3.2)	0.9 (3.0)
Median	2.0	0.0	2.0	0.0
Min - Max	0 - 9	-7 - 5	0 - 9	-5 - 8
Cycle 27 Day 1				
n	38	37	17	16
Mean (SD)	1.9 (2.4)	-1.1 (2.7)	2.8 (2.9)	0.4 (3.1)
Median	1.0	0.0	2.0	0.0
Min - Max	0 - 7	-7 - 4	0 - 8	-4 - 8
Cycle 29 Day 1				
n	32	32	17	16
Mean (SD)	2.2 (2.4)	-0.5 (3.2)	2.6 (2.9)	-0.4 (2.0)
Median	1.0	0.0	1.0	0.0
Min - Max	0 - 8	-7 - 7	0 - 9	-4 - 3
Cycle 31 Day 1				
n	29	28	11	10
Mean (SD)	2.9 (2.8)	0.5 (3.2)	2.5 (3.1)	-0.4 (2.5)
Median	2.0	0.0	1.0	0.0
Min - Max	0 - 9	-4 - 8	0 - 8	-5 - 3
Cycle 33 Day 1				
n	21	21	9	8
Mean (SD)	1.7 (2.0)	-0.5 (2.3)	2.0 (3.0)	-0.5 (2.4)
Median	1.0	0.0	1.0	0.0
Min - Max	0 - 6	-5 - 4	0 - 9	-4 - 3

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:33 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BPI_FAS_15NOV2024_41554.out Page 3 of 7

PRO Scores and Change from Baseline by Visit for BPI-SF Worst Pain Item, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: BPI2-Pain at its Worst in Last Week

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 35 Day 1				
n	18	17	9	8
Mean (SD)	2.9 (2.6)	0.2 (3.0)	2.7 (3.8)	0.1 (2.5)
Median	2.0	0.0	0.0	0.0
Min - Max	0 - 9	-4 - 9	0 - 10	-4 - 4
Cycle 37 Day 1				
n	17	17	7	6
Mean (SD)	1.9 (2.3)	-0.5 (2.8)	2.4 (3.1)	0.3 (1.9)
Median	1.0	0.0	1.0	0.5
Min - Max	0 - 7	-4 - 6	0 - 8	-3 - 2
Cycle 39 Day 1				
n	14	14	5	5
Mean (SD)	2.5 (2.8)	0.1 (2.3)	3.8 (3.1)	1.6 (2.4)
Median	1.5	0.5	5.0	1.0
Min - Max	0 - 7	-4 - 4	0 - 7	-1 - 5
Cycle 41 Day 1				
n	13	13	4	4
Mean (SD)	2.4 (2.0)	0.2 (2.2)	2.5 (1.7)	1.2 (1.5)
Median	2.0	0.0	3.0	1.0
Min - Max	0 - 6	-4 - 5	0 - 4	0 - 3
Cycle 43 Day 1				
n	13	13	4	4
Mean (SD)	2.4 (2.8)	0.2 (2.6)	3.2 (3.9)	1.0 (1.2)
Median	1.0	0.0	2.5	1.0
Min - Max	0 - 7	-5 - 5	0 - 8	0 - 2
Cycle 45 Day 1				
n	7	7	3	3
Mean (SD)	3.1 (3.2)	1.0 (2.1)	2.7 (4.6)	0.0 (2.0)
Median	4.0	0.0	0.0	0.0
Min - Max	0 - 8	-1 - 4	0 - 8	-2 - 2

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:33 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BPI_FAS_15NOV2024_41554.out Page 4 of 7

PRO Scores and Change from Baseline by Visit for BPI-SF Worst Pain Item, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: BPI2-Pain at its Worst in Last Week

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Cycle 47 Day 1				
n	6	6	2	2
Mean (SD)	2.3 (2.7)	0.7 (2.2)	5.5 (3.5)	2.5 (0.7)
Median	1.5	0.0	5.5	2.5
Min - Max	0 - 6	-1 - 5	3 - 8	2 - 3
Cycle 49 Day 1				
n	3	3	1	1
Mean (SD)	5.0 (1.0)	1.7 (2.9)	0.0 (NA)	0.0 (NA)
Median	5.0	0.0	0.0	0.0
Min - Max	4 - 6	0 - 5	0 - 0	0 - 0
Cycle 51 Day 1				
n	2	2	1	1
Mean (SD)	3.5 (0.7)	1.0 (1.4)	0.0 (NA)	0.0 (NA)
Median	3.5	1.0	0.0	0.0
Min - Max	3 - 4	0 - 2	0 - 0	0 - 0
Cycle 53 Day 1				
n	1	1	1	1
Mean (SD)	1.0 (NA)	-3.0 (NA)	2.0 (NA)	2.0 (NA)
Median	1.0	-3.0	2.0	2.0
Min - Max	1 - 1	-3 - -3	2 - 2	2 - 2
Cycle 55 Day 1				
n	1	1	1	1
Mean (SD)	3.0 (NA)	-1.0 (NA)	0.0 (NA)	0.0 (NA)
Median	3.0	-1.0	0.0	0.0
Min - Max	3 - 3	-1 - -1	0 - 0	0 - 0
Cycle 57 Day 1				
n	1	1	1	1
Mean (SD)	1.0 (NA)	-3.0 (NA)	0.0 (NA)	0.0 (NA)
Median	1.0	-3.0	0.0	0.0
Min - Max	1 - 1	-3 - -3	0 - 0	0 - 0

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:33 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BPI_FAS_15NOV2024_41554.out Page 5 of 7

PRO Scores and Change from Baseline by Visit for BPI-SF Worst Pain Item, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: BPI2-Pain at its Worst in Last Week

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Treatment Discontinuation				
n	79	77	103	96
Mean (SD)	3.8 (2.8)	0.2 (2.8)	3.8 (2.8)	0.4 (2.7)
Median	3.0	0.0	4.0	0.0
Min - Max	0 - 10	-10 - 8	0 - 10	-7 - 8
Post-Treatment Follow Up Week 16				
n	9	9	5	5
Mean (SD)	2.4 (2.5)	-0.7 (2.1)	4.6 (3.4)	2.6 (1.9)
Median	2.0	-1.0	3.0	2.0
Min - Max	0 - 7	-3 - 3	2 - 10	1 - 6
Post-Treatment Follow Up Week 24				
n	2	2	0	0
Mean (SD)	5.0 (1.4)	0.0 (2.8)	NE (NE)	NE (NE)
Median	5.0	0.0	NE	NE
Min - Max	4 - 6	-2 - 2	NE - NE	NE - NE
Post-Treatment Follow Up Week 32				
n	1	1	0	0
Mean (SD)	9.0 (NA)	1.0 (NA)	NE (NE)	NE (NE)
Median	9.0	1.0	NE	NE
Min - Max	9 - 9	1 - 1	NE - NE	NE - NE
30 Day Safety Follow-up				
n	32	31	40	37
Mean (SD)	3.6 (2.9)	-0.1 (3.7)	4.8 (2.5)	0.8 (3.4)
Median	3.0	0.0	4.5	1.0
Min - Max	0 - 9	-8 - 7	0 - 10	-7 - 7
Survival Follow-up Month 3				
n	19	19	19	17
Mean (SD)	2.7 (1.9)	-1.1 (2.0)	3.6 (2.8)	-0.4 (3.1)
Median	3.0	-1.0	3.0	0.0
Min - Max	0 - 6	-4 - 3	0 - 9	-5 - 8

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:33 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BPI_FAS_15NOV2024_41554.out Page 6 of 7

PRO Scores and Change from Baseline by Visit for BPI-SF Worst Pain Item, Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025
 Parameter: BPI2-Pain at its Worst in Last Week

Analysis Visit	Inavo+Palbo+Fulv		Pbo+Palbo+Fulv	
	Value at Visit (N=161)	Change from Baseline (N=161)	Value at Visit (N=164)	Change from Baseline (N=164)
Survival Follow-up Month 6				
n	7	7	5	5
Mean (SD)	4.9 (2.9)	-0.7 (3.3)	4.4 (3.4)	0.2 (2.5)
Median	5.0	-1.0	5.0	0.0
Min - Max	0 - 8	-4 - 4	0 - 8	-2 - 4
Survival Follow-up Month 9				
n	5	5	2	2
Mean (SD)	4.8 (3.5)	0.0 (3.9)	8.5 (0.7)	1.5 (0.7)
Median	5.0	-1.0	8.5	1.5
Min - Max	0 - 9	-4 - 5	8 - 9	1 - 2
Survival Follow-up Month 12				
n	3	3	1	1
Mean (SD)	6.7 (1.5)	0.3 (3.1)	6.0 (NA)	2.0 (NA)
Median	7.0	1.0	6.0	2.0
Min - Max	5 - 8	-3 - 3	6 - 6	2 - 2

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

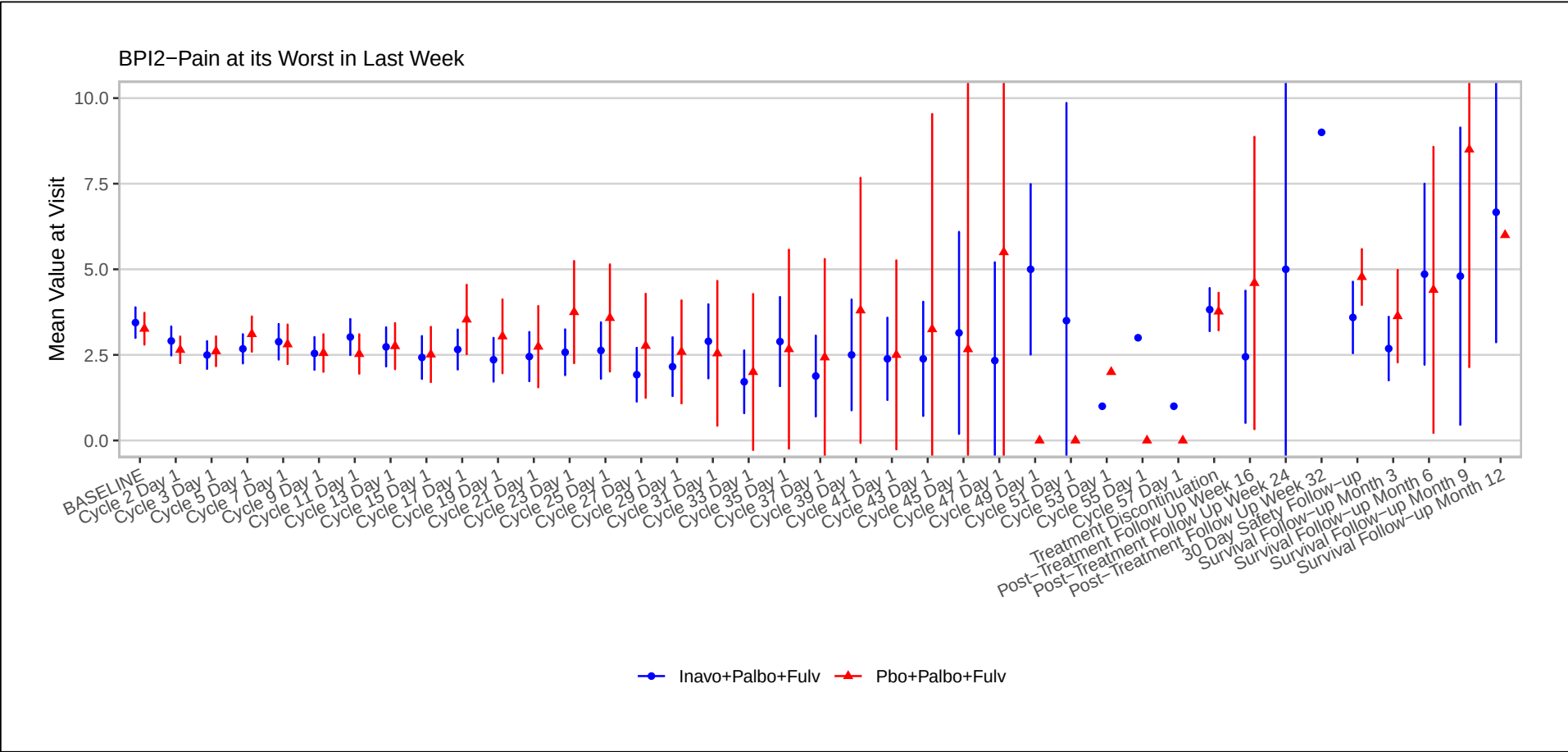
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:33 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/t_qs_cfb_BPI_FAS_15NOV2024_41554.out Page 7 of 7

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Plot of Mean and 95% Confidence Interval, BPI SHORT FORM, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_qs_cfb2.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v14/output/g_qs_cfb2_BPI_FAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 0efa981b2a84f5e06c881464de43872934271dc3
18 JUN 2025 17:00 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.4 Stärkster Schmerz anhand des Brief Pain Inventory-Short Form (BPI-SF)

2.4.3 Zeit bis zur ersten Verschlechterung des PRO Item 3 stärkster Schmerz des BPI-SF, MID $\geq$ 2 Punkte

Time to Event Analysis (Efficacy), BPI SHORT FORM (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

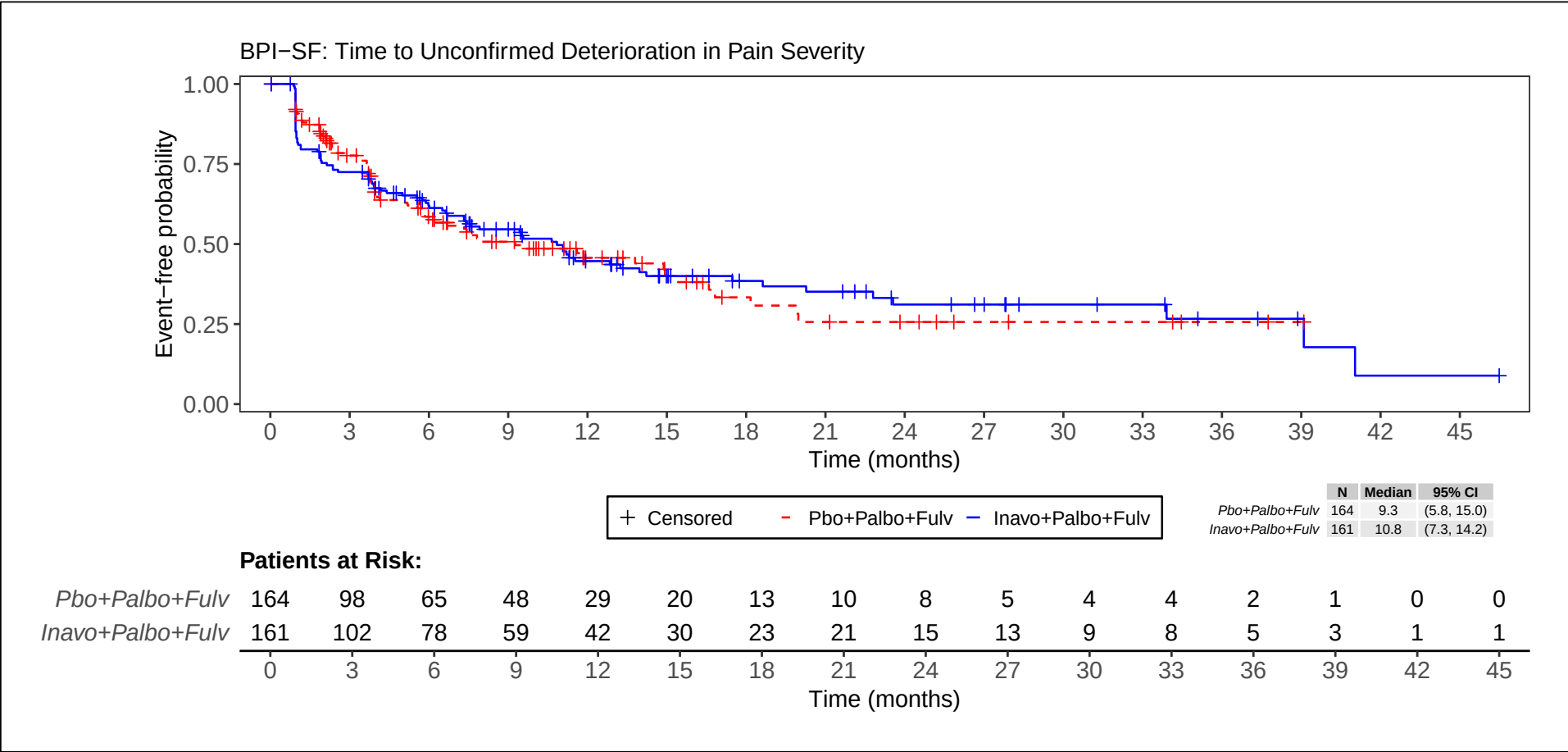
	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
BPI-SF: Time to Unconfirmed Deterioration in Pain Severity		
Patients with event		
n (%)	84 (52.2%)	76 (46.3%)
Patients without event		
n (%)	77 (47.8%)	88 (53.7%)
Time to Event (Months)		
Median	10.84	9.26
95% CI	(7.33, 14.23)	(5.85, 15.05)
Range	0.03 - 46.49 {1}	0.03 - 39.10 {1}
Unstratified Analysis		
p-value (log-rank)	0.9388	
Hazard Ratio	0.99	
95% CI	(0.73, 1.36)	
Stratified Analysis		
p-value (log-rank)	0.6134	
Hazard Ratio	0.92	
95% CI	(0.67, 1.28)	

{1} - Censored observations: range minimum & maximum

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ef_tte2.R
Output path:
/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v5/output/t_ef_tte2_BPID_FAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 884c7b654f8eaf01b56b221a2c1fd8df1f26a541
07 APR 2025 15:47 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Efficacy, BPI SHORT FORM (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ef_km2.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v1/output/g_ef_km2_BPID_FAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 65ba890bf61ac3a2517ff79c20b7283a2af5911f
17 MAR 2025 23:32 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.4 Stärkster Schmerz anhand des Brief Pain Inventory-Short Form (BPI-SF)

2.4.3 Zeit bis zur ersten Verschlechterung des PRO Item 3 stärkster Schmerz des BPI-SF, MID $\geq$ 2 Punkte

2.4.3.1 Subgruppenanalyse Zeit bis zur ersten Verschlechterung des PRO Item 3 stärkster Schmerz des BPI-SF, MID $\geq$ 2 Punkte

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Efficacy), BPI SHORT FORM (Unconfirmed Deterioration), Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)	
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI					
BPI-SF: Time to Unconfirmed Deterioration in Pain Severity																
All Patients	325	164	76	46.3	9.26	(5.85, 15.05)	161	84	52.2	10.84	(7.33, 14.23)	0.99	(0.73, 1.36)	0.9388	NE	
Age group (years)																
<65	266	130	56	43.1	9.66	(6.24, 18.17)	136	72	52.9	11.07	(6.70, 14.23)	1.06	(0.75, 1.51)	0.7603	0.5868	
>=65	59	34	20	58.8	5.75	(2.37, 16.59)	25	12	48.0	7.33	(2.37, 33.91)	0.74	(0.35, 1.56)	0.4186	0.5868	
Sex																
F	319	163	76	46.6	9.26	(5.85, 15.05)	156	81	51.9	10.84	(6.70, 14.23)	1.00	(0.73, 1.38)	0.9854	1.0000	
M	6	1	0	0.0	NE	NE	5	3	60.0	13.24	(2.37, NA)	NE	NE	1.0000	1.0000	
Region																
ASIA	120	62	29	46.8	7.43	(5.75, NA)	58	34	58.6	9.56	(5.98, 18.63)	1.15	(0.69, 1.89)	0.6216	0.3782	
NORTH AMERICA/WESTERN EUROPE	127	64	32	50.0	13.80	(5.09, 16.59)	63	25	39.7	11.30	(4.40, NA)	0.72	(0.42, 1.22)	0.2146	0.3782	
OTHER	78	38	15	39.5	11.73	(2.89, NA)	40	25	62.5	10.84	(1.94, 13.96)	1.25	(0.66, 2.40)	0.5035	0.3782	
Visceral disease (per eCRF)																
N	65	36	17	47.2	7.85	(4.14, NA)	29	18	62.1	11.07	(2.37, 18.63)	1.16	(0.59, 2.27)	0.6603	0.5243	
Y	260	128	59	46.1	9.66	(5.75, 16.59)	132	66	50.0	10.84	(7.33, 14.23)	0.95	(0.67, 1.35)	0.7459	0.5243	
Ethnicity																
HISPANIC OR LATINO	20	10	6	60.0	7.82	(0.95, NA)	10	5	50.0	3.17	(1.02, NA)	0.94	(0.28, 3.10)	0.9157	0.0690	
NOT HISPANIC OR LATINO	294	149	67	45.0	11.60	(6.08, 15.05)	145	77	53.1	11.07	(7.33, 14.23)	1.05	(0.75, 1.46)	0.8213	0.0690	
NOT REPORTED	5	3	1	33.3	1.18	NE	2	1	50.0	0.95	(0.95, NA)	0.71	(0.04, 11.79)	0.8084	0.0690	
UNKNOWN	6	2	2	100.0	1.02	(0.95, NA)	4	1	25.0	10.64	(10.64, NA)	<0.01	(0.00, >999.99)	0.0896	0.0690	
Race																
Asian	124	63	29	46.0	7.43	(5.75, NA)	61	36	59.0	9.56	(5.98, 18.63)	1.14	(0.70, 1.87)	0.6271	0.0069	
Black or African American	2	1	0	0.0	NE	NE	1	0	0.0	NE	NE	NE	NE	1.0000	0.0069	
White	191	97	45	46.4	11.73	(5.09, 15.05)	94	48	51.1	10.84	(5.55, 14.23)	0.98	(0.65, 1.48)	0.9280	0.0069	
Unknown	8	3	2	66.7	1.13	(1.08, NA)	5	0	0.0	NE	NE	<0.01	(0.00, >999.99)	0.0389	0.0069	
Liver Metastasis at Enrollment																
N	157	73	34	46.6	13.80	(5.78, 19.98)	84	47	56.0	11.07	(3.91, 17.48)	1.22	(0.78, 1.89)	0.3894	0.2342	
Y	168	91	42	46.2	7.43	(4.04, 16.82)	77	37	48.1	9.56	(6.70, NA)	0.81	(0.51, 1.27)	0.3291	0.2342	
Number Metastatic Organs at Enrollment																
1	53	32	15	46.9	14.88	(3.75, 19.88)	21	12	57.1	7.05	(0.99, NA)	1.33	(0.60, 2.91)	0.5051	0.3074	
2	104	46	29	63.0	3.94	(3.65, 7.43)	58	31	53.4	6.70	(3.91, 23.56)	0.75	(0.45, 1.25)	0.2603	0.3074	
>=3	168	86	32	37.2	16.59	(7.82, NA)	82	41	50.0	11.30	(7.59, 20.27)	1.09	(0.68, 1.74)	0.7181	0.3074	
ECOG Performance Status at Baseline																
0	206	106	51	48.1	7.85	(5.55, 15.05)	100	57	57.0	9.56	(6.01, 17.48)	0.98	(0.67, 1.43)	0.8807	0.8085	
1	118	58	25	43.1	11.73	(5.09, 19.98)	60	27	45.0	11.20	(5.98, NA)	1.04	(0.60, 1.80)	0.8933	0.8085	

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv					Inavo+Palbo+Fulv					Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	Median (Months)	Median 95% CI	n	Events	%	Median (Months)	Median 95% CI				
Endocrine Resistance (per eCRF)															
Primary	112	58	29	50.0	5.78	(3.32, 7.62)	54	23	42.6	13.24	(6.64, NA)	0.58	(0.33, 1.02)	0.0507	0.0126
Secondary	212	105	47	44.8	13.80	(7.82, 18.17)	107	61	57.0	9.43	(5.88, 13.96)	1.26	(0.86, 1.85)	0.2454	0.0126
Menopausal Status at Randomization															
NOT POST-MENOPAUSAL	104	52	25	48.1	9.66	(3.94, 19.88)	52	30	57.7	9.56	(2.37, 18.63)	1.13	(0.66, 1.93)	0.7089	0.5858
POST-MENOPAUSAL	215	111	51	45.9	7.82	(5.55, 16.59)	104	51	49.0	10.84	(6.64, 22.80)	0.93	(0.63, 1.38)	0.7097	0.5858
Hormone receptor status															
ER+/PR-	90	45	20	44.4	5.78	(3.68, NA)	45	24	53.3	11.07	(5.75, 33.91)	0.81	(0.44, 1.50)	0.4773	0.8131
ER+/PR+	226	113	54	47.8	9.66	(6.74, 16.59)	113	59	52.2	9.56	(5.98, 17.48)	1.04	(0.72, 1.51)	0.8472	0.8131
Other	9	6	2	33.3	NE	(0.95, NA)	3	1	33.3	39.10	NE	<0.01	(0.00, >999.99)	0.3431	0.8131
Prior (neo)-adjuvant endocrine															
Aromatase inhibitor and tamoxifen	37	19	10	52.6	4.14	(1.18, 14.88)	18	10	55.6	7.33	(4.40, NA)	0.55	(0.22, 1.36)	0.1931	0.5998
Aromatase inhibitor only	131	71	34	47.9	7.85	(4.04, 14.98)	60	30	50.0	9.56	(5.75, 11.53)	1.00	(0.61, 1.64)	0.9866	0.5998
Tamoxifen only	155	73	32	43.8	15.05	(5.85, 19.98)	82	44	53.7	12.85	(4.99, 22.80)	1.15	(0.72, 1.82)	0.5852	0.5998
Prior (neo)-adjuvant CDK4/6															
N	322	163	75	46.0	9.26	(5.85, 15.05)	159	84	52.8	10.84	(7.33, 14.23)	1.00	(0.73, 1.37)	0.9574	1.0000
Y	3	1	1	100.0	13.80	NE	2	0	0.0	NE	NE	1.00	(1.00, 1.00)	1.0000	1.0000
Prior (neo)-adjuvant chemotherapy															
N	56	27	11	40.7	14.98	(2.33, NA)	29	12	41.4	11.30	(6.64, NA)	1.02	(0.45, 2.32)	0.9602	0.8714
Y	269	137	65	47.4	9.26	(5.75, 15.05)	132	72	54.5	9.56	(6.01, 17.48)	1.01	(0.72, 1.41)	0.9996	0.8714

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_ef_tte_sg.R

Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v5/output/t_ef_tte_sg_BPID_FAS_15NOV2024_41554.docx

Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685

Git hash: 884c7b654f8eaf01b56b221a2c1fd8df1f26a541

07 APR 2025 15:47 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

2 Patientenberichtete Endpunkte (PRO)

2.4 Stärkster Schmerz anhand des Brief Pain Inventory-Short Form (BPI-SF)

2.4.4 MMRM Analyse des PRO Item 3 stärkster Schmerz des BPI-SF

Analysis of MMRM, BPI SHORT FORM, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Questionnaire		
Visit		
Statistics	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)
BPI2-Pain at its Worst in Last Week		
Treatment Discontinuation		
n	77	96
Adjusted Mean (SE) of Change from Baseline	0.426 (0.241)	0.508 (0.221)
95% CI	(-0.045, 0.898)	(0.074, 0.941)
Difference in Adjusted Means (SE) of Change from Baseline	-0.081 (0.325)	
95% CI	(-0.719, 0.556)	
p-value (MMRM)	0.8029	

The model includes treatment groups, study visits, baseline value, and stratification factors as fixed effects. Visits that were unscheduled or happened after the assessment of progressive disease during the follow-up period were excluded. Compound symmetry covariance structure was used.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_pro_mmr.R
Output path:
/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v10/output/t_pro_mmr_BPI_FAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: b1a1c97d71c5f8414a8ce014f4248054b00f4184
21 MAY 2025 03:36 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.1 Generelle Verträglichkeit

3.1.1 Unerwünschte Ereignisse (UE)

3.1.1.1 Patienten mit Unerwünschten Ereignissen (UE)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

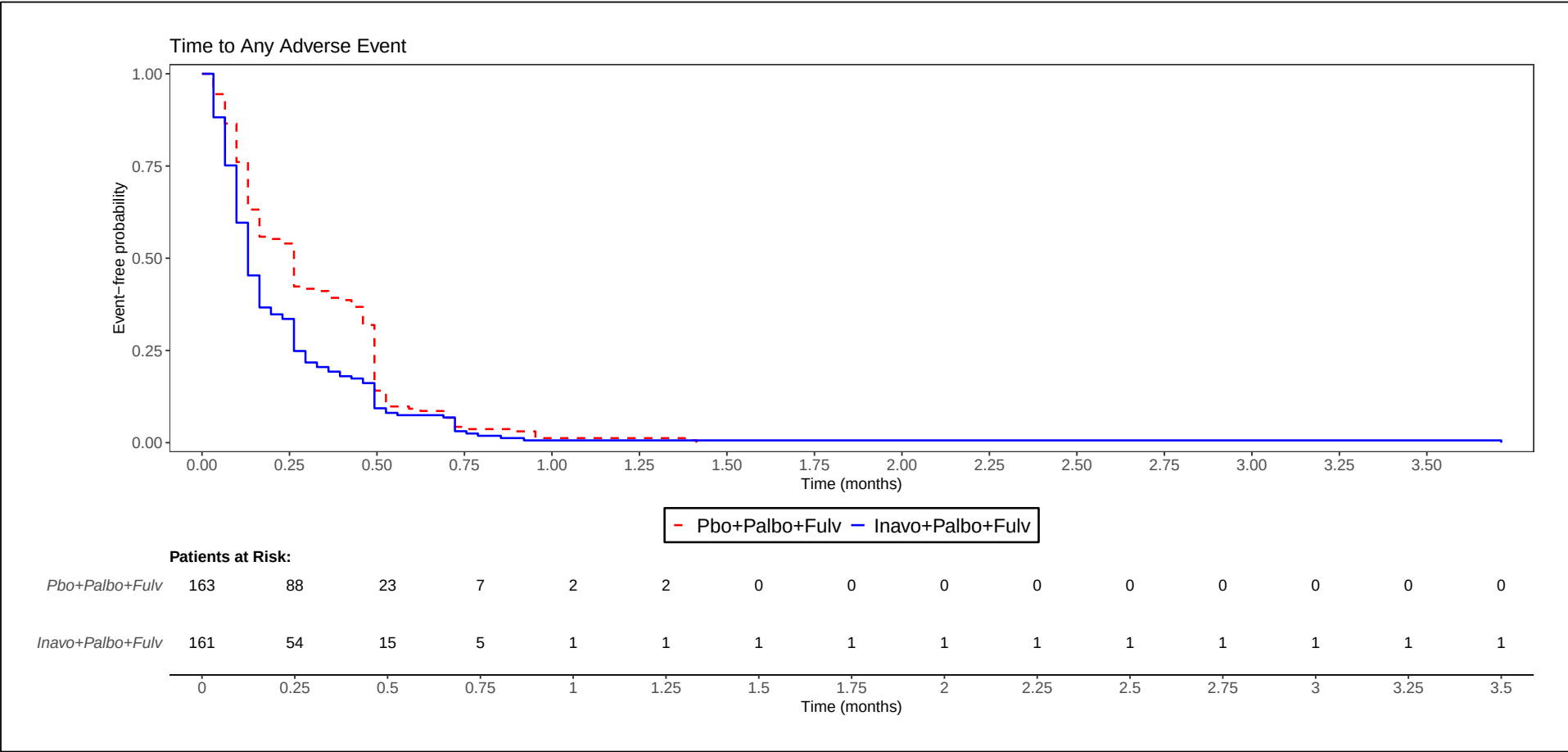
Time to Event Analysis Overall and with Subgroups (Safety), Time to Any Adverse Event, Safety Analysis Set
Protocol: WO41554, CCOd: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to Any Adverse Event											
All Patients	324	163	163	100.0	161	161	100.0	1.41	(1.13, 1.75)	0.0010	NE
Age group (years)											
<65	266	129	129	100.0	137	137	100.0	1.41	(1.11, 1.80)	0.0031	0.9781
>=65	58	34	34	100.0	24	24	100.0	1.38	(0.81, 2.34)	0.1880	0.9781
Sex											
F	318	162	162	100.0	156	156	100.0	1.40	(1.12, 1.75)	0.0013	0.7085
M	6	1	1	100.0	5	5	100.0	0.51	(0.05, 5.74)	0.5826	0.7085
Region											
ASIA	120	62	62	100.0	58	58	100.0	1.69	(1.17, 2.44)	0.0036	0.6648
NORTH AMERICA/WESTERN EUROPE	126	63	63	100.0	63	63	100.0	1.30	(0.91, 1.85)	0.1251	0.6648
OTHER	78	38	38	100.0	40	40	100.0	1.39	(0.88, 2.19)	0.1122	0.6648
Visceral disease (per eCRF)											
N	65	36	36	100.0	29	29	100.0	1.30	(0.78, 2.15)	0.2139	0.6057
Y	259	127	127	100.0	132	132	100.0	1.43	(1.12, 1.83)	0.0027	0.6057
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	52	100.0	52	52	100.0	1.08	(0.73, 1.59)	0.6044	0.1237
POST-MENOPAUSAL	214	110	110	100.0	104	104	100.0	1.55	(1.18, 2.04)	0.0007	0.1237

Men are excluded from the subgroups of "Menopausal Status at Randomization"
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_tte.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_ANYAE_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 8065628e23c1f16f1b9c5c76540f88be90f918fa
08 APR 2025 17:31 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Safety, Time to Any Adverse Event, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_ANYAE_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:14 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.1 Generelle Verträglichkeit

3.1.1 Unerwünschte Ereignisse (UE)

3.1.1.2 Patienten mit schweren unerwünschten Ereignissen (UE $\geq$ Grad 3)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

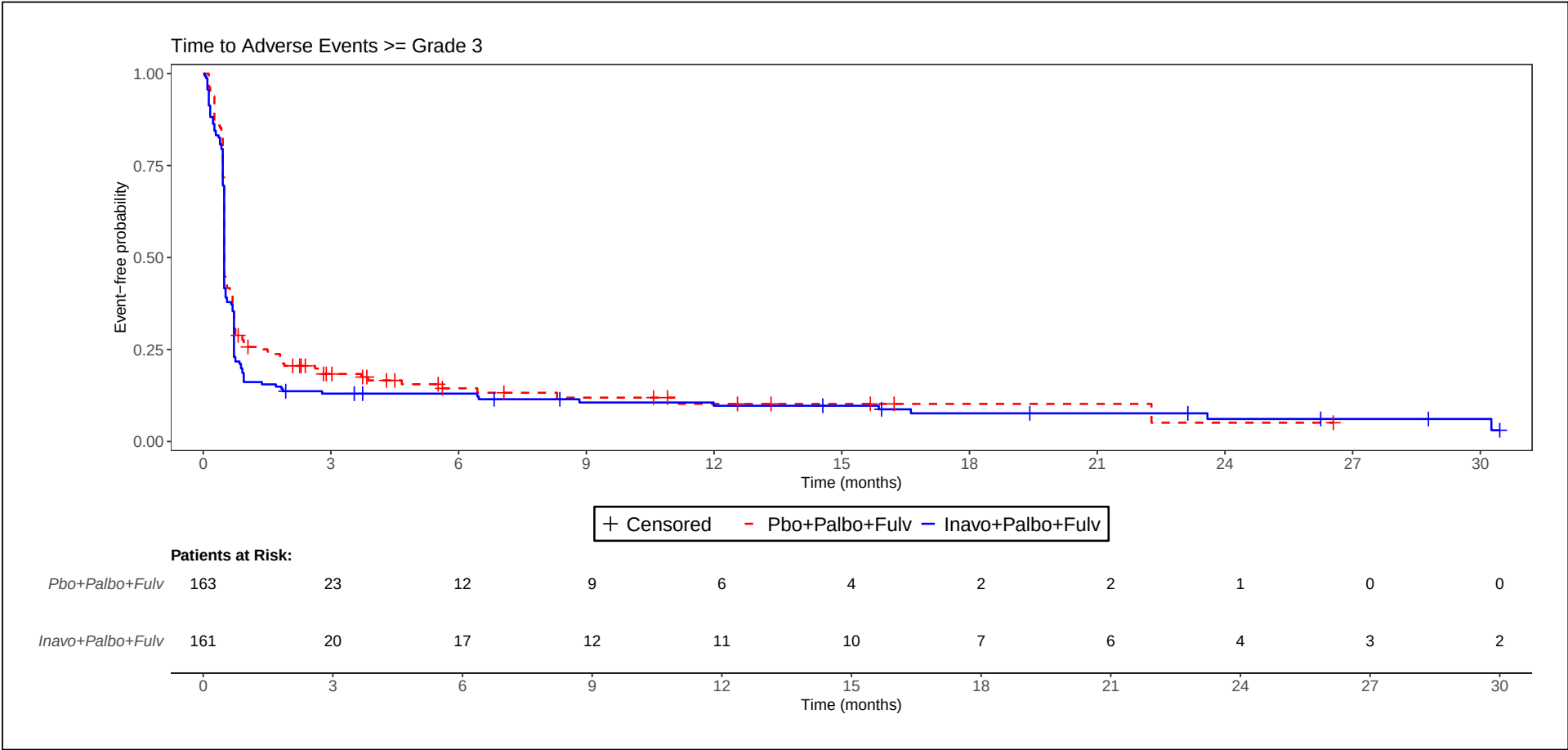
Time to Event Analysis Overall and with Subgroups (Safety), Time to Adverse Events >= Grade 3, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv						
		n	Events	%	n	Events	%	Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
Time to Adverse Events >= Grade 3											
All Patients	324	163	140	85.9	161	148	91.9	1.14	(0.90, 1.44)	0.2755	NE
Age group (years)											
<65	266	129	110	85.3	137	126	92.0	1.10	(0.85, 1.43)	0.5214	0.5061
>=65	58	34	30	88.2	24	22	91.7	1.34	(0.77, 2.33)	0.2284	0.5061
Sex											
F	318	162	139	85.8	156	144	92.3	1.16	(0.92, 1.47)	0.2238	0.3873
M	6	1	1	100.0	5	4	80.0	0.22	(0.01, 3.59)	0.2467	0.3873
Region											
ASIA	120	62	55	88.7	58	57	98.3	1.41	(0.97, 2.06)	0.0868	0.1538
NORTH AMERICA/WESTERN EUROPE	126	63	55	87.3	63	55	87.3	0.90	(0.62, 1.32)	0.5940	0.1538
OTHER	78	38	30	78.9	40	36	90.0	1.28	(0.78, 2.09)	0.3173	0.1538
Visceral disease (per eCRF)											
N	65	36	32	88.9	29	27	93.1	1.00	(0.60, 1.68)	0.9481	0.6374
Y	259	127	108	85.0	132	121	91.7	1.18	(0.91, 1.53)	0.2394	0.6374
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	43	82.7	52	49	94.2	1.15	(0.76, 1.75)	0.5025	0.8834
POST-MENOPAUSAL	214	110	96	87.3	104	95	91.3	1.17	(0.88, 1.56)	0.2825	0.8834

Men are excluded from the subgroups of "Menopausal Status at Randomization"
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_tte.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_AEGE3_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 8065628e23c1f16f1b9c5c76540f88be90f918fa
08 APR 2025 17:31 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Safety, Time to Adverse Events >= Grade 3, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_AEGE3_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:15 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.1 Generelle Verträglichkeit

3.1.1 Unerwünschte Ereignisse (UE)

3.1.1.3 Patienten mit schwerwiegenden unerwünschten Ereignissen (SUE)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

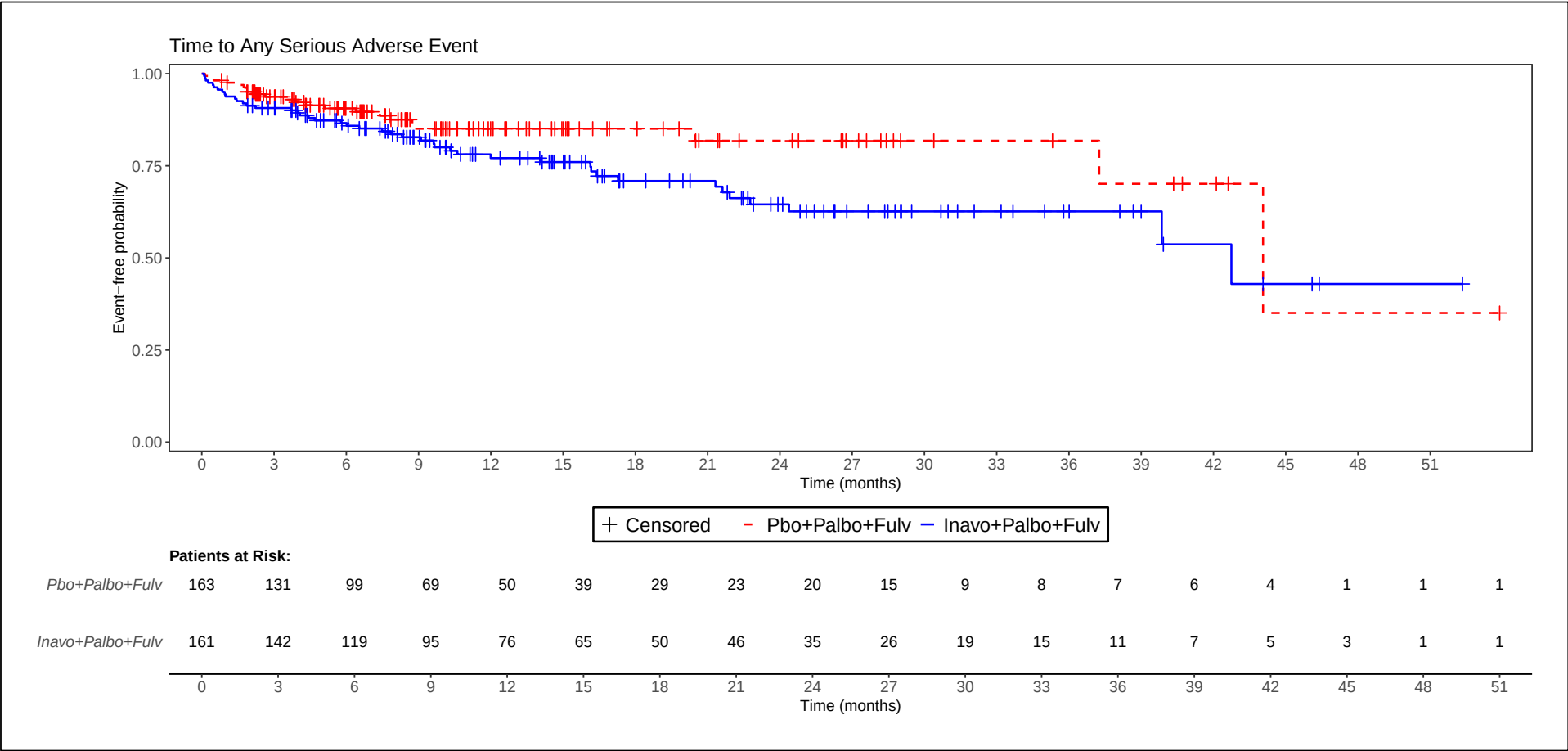
Time to Event Analysis Overall and with Subgroups (Safety), Time to Any Serious Adverse Event, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to Any Serious Adverse Event											
All Patients	324	163	22	13.5	161	44	27.3	1.64	(0.98, 2.74)	0.0579	NE
Age group (years)											
<65	266	129	15	11.6	137	34	24.8	1.58	(0.86, 2.92)	0.1408	0.5276
>=65	58	34	7	20.6	24	10	41.7	2.20	(0.83, 5.77)	0.1020	0.5276
Sex											
F	318	162	22	13.6	156	42	26.9	1.60	(0.95, 2.69)	0.0725	0.3735
M	6	1	0	0.0	5	2	40.0	>999.99	(0.00, >999.99)	0.4658	0.3735
Region											
ASIA	120	62	6	9.7	58	17	29.3	2.35	(0.92, 6.02)	0.0656	0.3734
NORTH AMERICA/WESTERN EUROPE	126	63	9	14.3	63	10	15.9	0.94	(0.38, 2.33)	0.9012	0.3734
OTHER	78	38	7	18.4	40	17	42.5	1.81	(0.74, 4.43)	0.1853	0.3734
Visceral disease (per eCRF)											
N	65	36	6	16.7	29	10	34.5	1.85	(0.66, 5.15)	0.2323	0.8958
Y	259	127	16	12.6	132	34	25.8	1.60	(0.88, 2.91)	0.1185	0.8958
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	13	25.0	8.45	(1.09, 65.85)	0.0155	0.0169
POST-MENOPAUSAL	214	110	21	19.1	104	29	27.9	1.24	(0.71, 2.19)	0.4473	0.0169

Men are excluded from the subgroups of "Menopausal Status at Randomization"
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_tte.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_AESER_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 8065628e23c1f16f1b9c5c76540f88be90f918fa
08 APR 2025 17:31 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

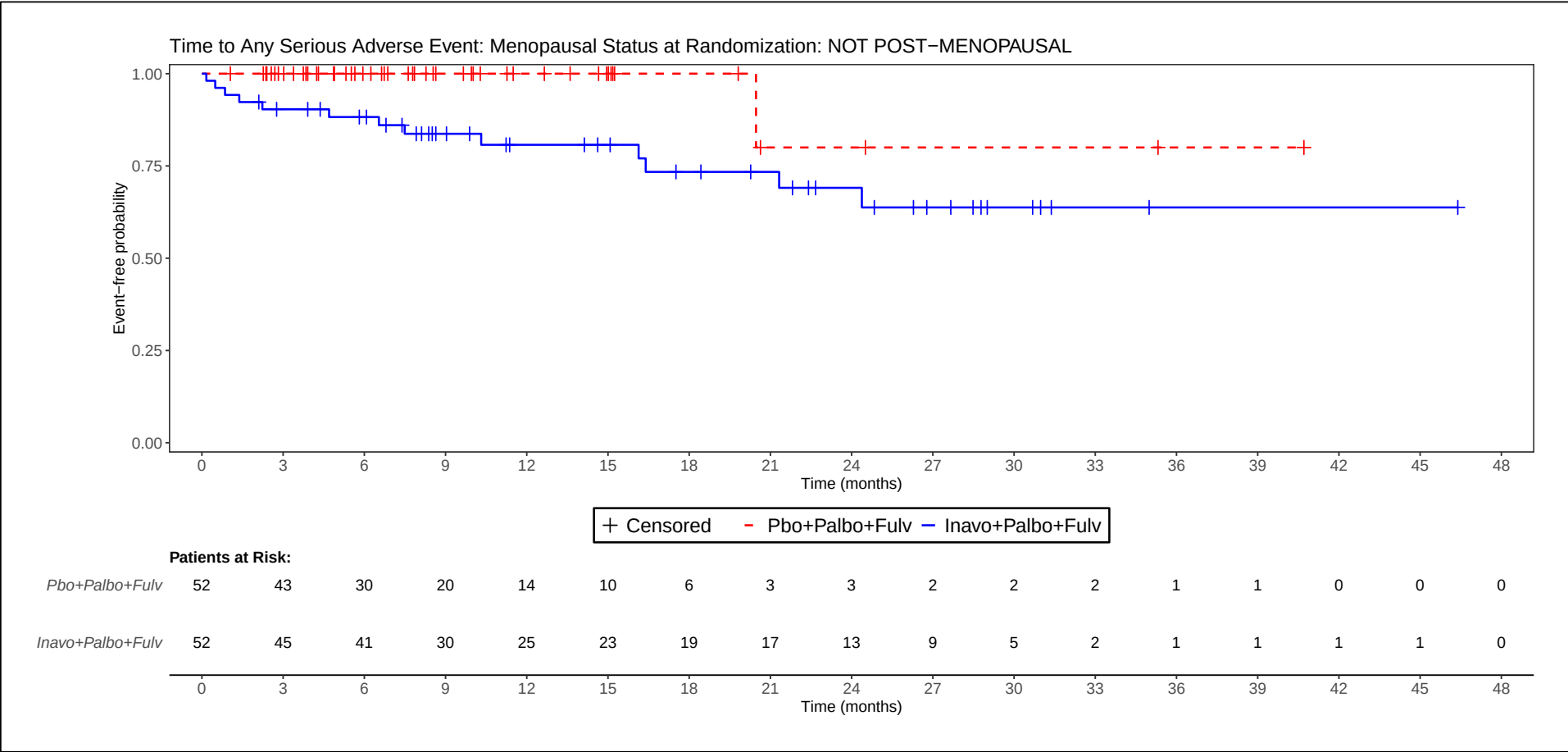
Kaplan Meier Plot for Safety, Time to Any Serious Adverse Event, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_AESER_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:18 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

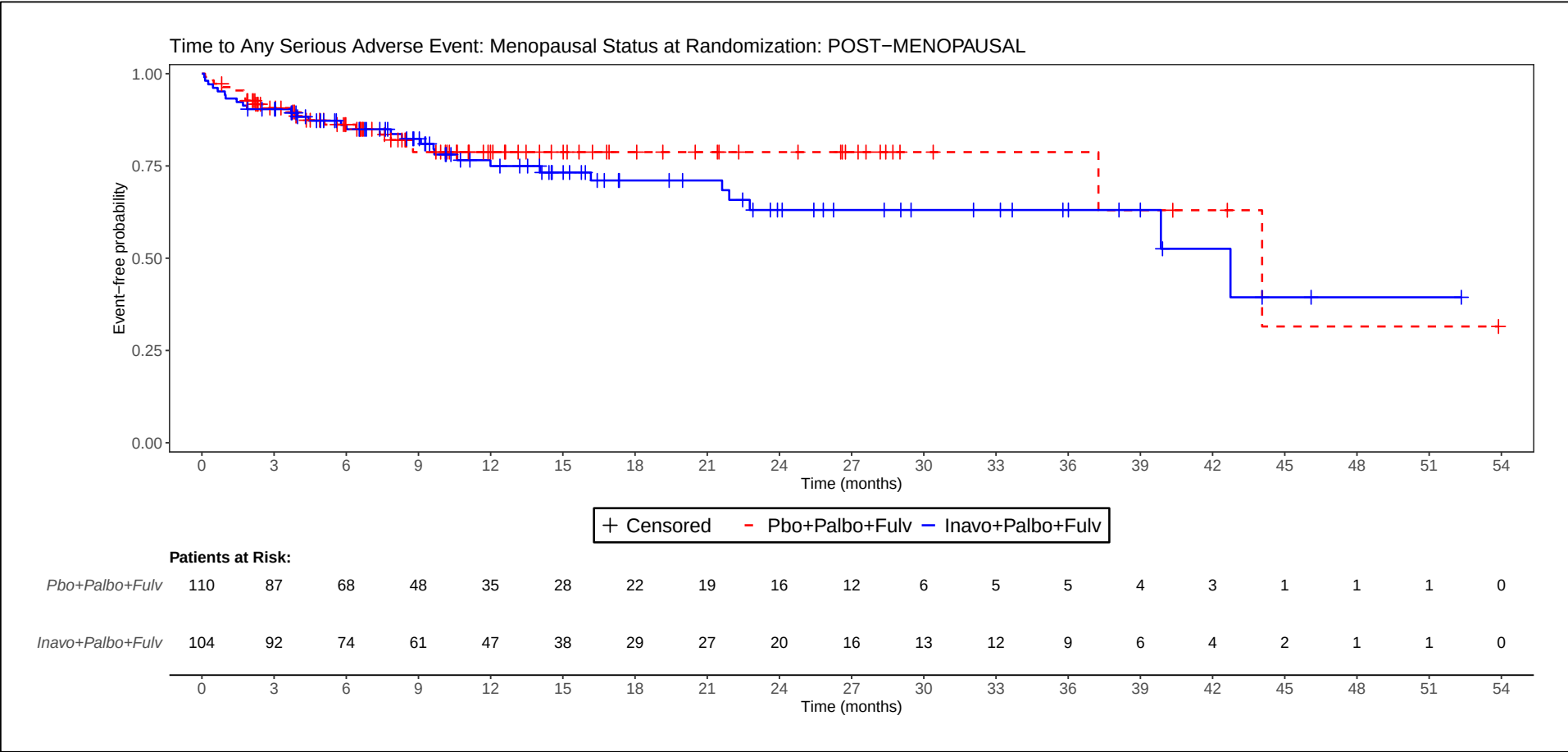
Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_km_signsg.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v14/output/g_km_signsg_AESER_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 0efa981b2a84f5e06c881464de43872934271dc3
18 JUN 2025 17:00 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plots for Subgroups with Significant Interaction Test p-value
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_km_signsg.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v14/output/g_km_signsg_AESER_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 0efa981b2a84f5e06c881464de43872934271dc3
18 JUN 2025 17:00 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.1 Generelle Verträglichkeit

3.1.1 Unerwünschte Ereignisse (UE)

3.1.1.4 Patienten mit unerwünschten Ereignissen Grad 5

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

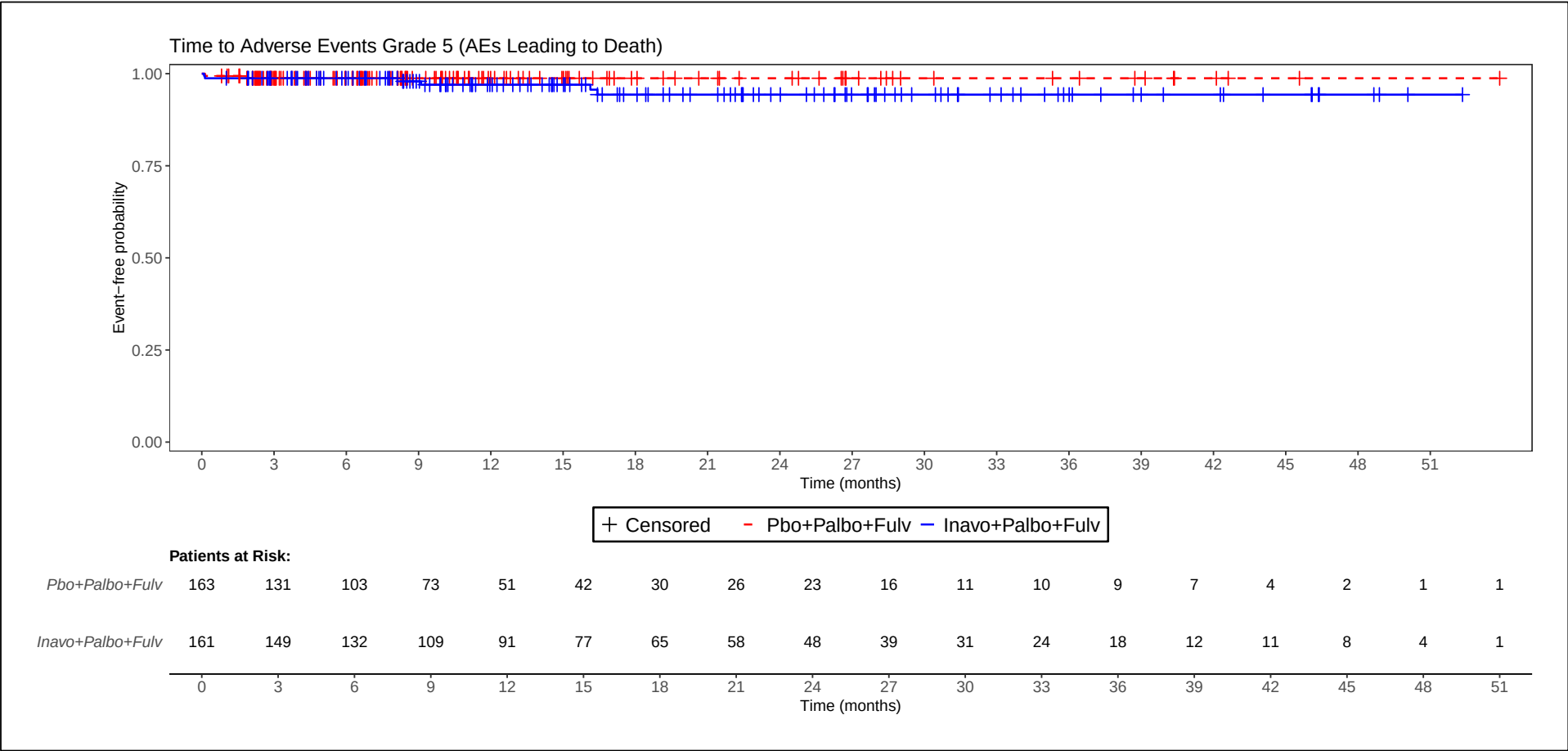
Time to Event Analysis Overall and with Subgroups (Safety), Time to Adverse Events Grade 5 (AEs Leading to Death), Safety Analysis Set
Protocol: WO41554, CCOd: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to Adverse Events Grade 5 (AEs Leading to Death)											
All Patients	324	163	2	1.2	161	6	3.7	2.33	(0.47, 11.72)	0.2892	NE
Age group (years)											
<65	266	129	2	1.6	137	2	1.5	0.60	(0.08, 4.46)	0.6144	0.0271
>=65	58	34	0	0.0	24	4	16.7	>999.99	(0.00, >999.99)	0.0198	0.0271
Sex											
F	318	162	2	1.2	156	6	3.8	2.41	(0.48, 12.08)	0.2709	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	2	3.4	1.35	(0.12, 15.50)	0.8085	0.6865
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	0.6865
OTHER	78	38	1	2.6	40	3	7.5	1.94	(0.19, 19.36)	0.5676	0.6865
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2652	0.3821
Y	259	127	2	1.6	132	5	3.8	1.74	(0.33, 9.12)	0.5063	0.3821
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	0.4757
POST-MENOPAUSAL	214	110	2	1.8	104	5	4.8	2.25	(0.43, 11.69)	0.3204	0.4757

Men are excluded from the subgroups of "Menopausal Status at Randomization"
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Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_AEGR5_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 8065628e23c1f16f1b9c5c76540f88be90f918fa
08 APR 2025 17:31 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Safety, Time to Adverse Events Grade 5 (AEs Leading to Death), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_AEGR5_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:15 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.1 Generelle Verträglichkeit

3.1.1 Unerwünschte Ereignisse (UE)

3.1.1.5 Patienten mit Therapieabbruch aufgrund Unerwünschten Ereignissen (UE)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

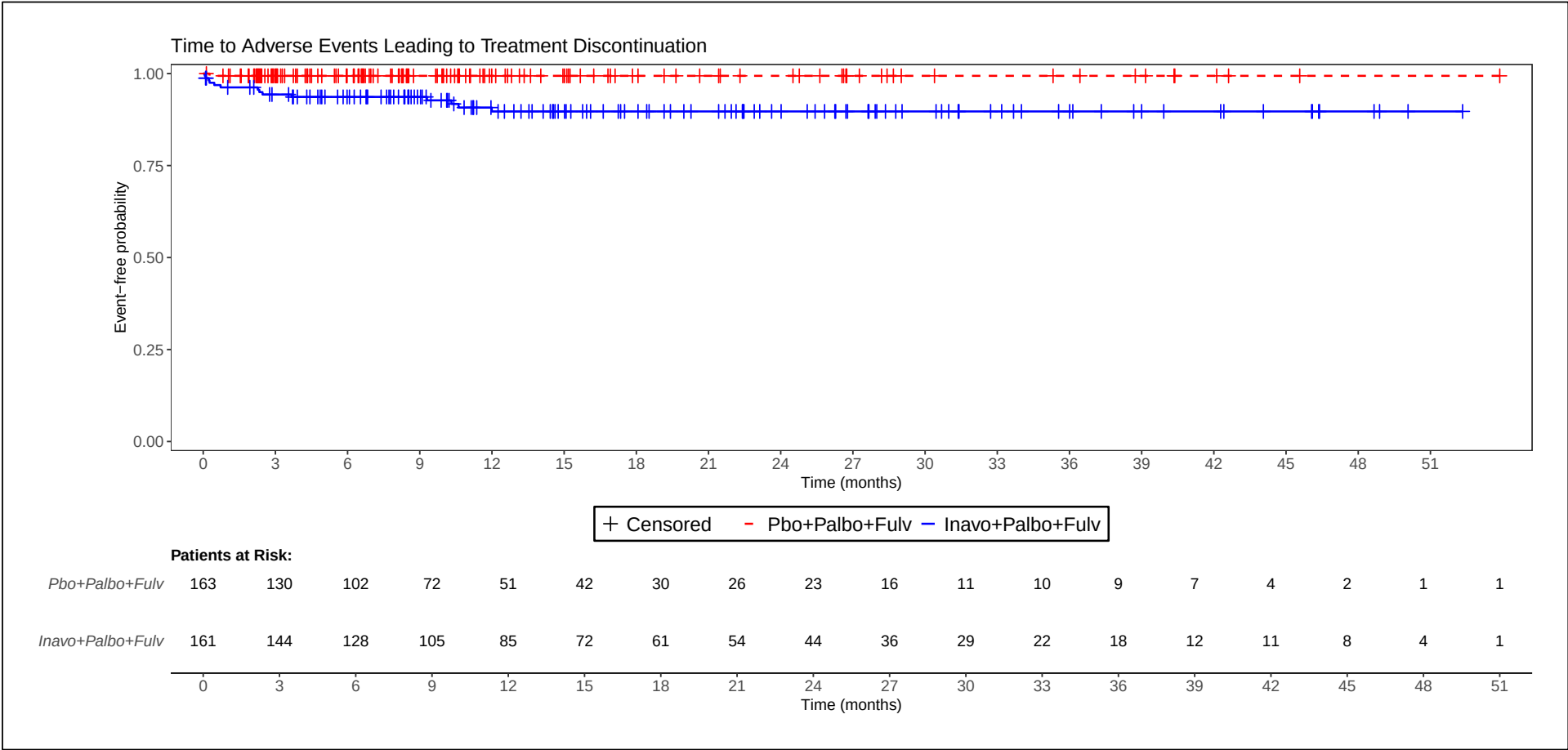
Time to Event Analysis Overall and with Subgroups (Safety), Time to Adverse Events Leading to Treatment Discontinuation, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to Adverse Events Leading to Treatment Discontinuation											
All Patients	324	163	1	0.6	161	14	8.7	12.72	(1.67, 96.95)	0.0015	NE
Age group (years)											
<65	266	129	1	0.8	137	10	7.3	8.11	(1.03, 63.52)	0.0177	0.2966
>=65	58	34	0	0.0	24	4	16.7	>999.99	(0.00, >999.99)	0.0124	0.2966
Sex											
F	318	162	1	0.6	156	14	9.0	13.10	(1.72, 99.80)	0.0013	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	0	0.0	58	3	5.2	>999.99	(0.00, >999.99)	0.0986	0.6179
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	8	12.7	7.71	(0.96, 61.64)	0.0227	0.6179
OTHER	78	38	0	0.0	40	3	7.5	>999.99	(0.00, >999.99)	0.1028	0.6179
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	3	10.3	3.53	(0.37, 34.05)	0.2453	0.1191
Y	259	127	0	0.0	132	11	8.3	>999.99	(0.00, >999.99)	0.0022	0.1191
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	3	5.8	2.58	(0.26, 25.26)	0.3982	0.0814
POST-MENOPAUSAL	214	110	0	0.0	104	11	10.6	>999.99	(0.00, >999.99)	0.0012	0.0814

Men are excluded from the subgroups of "Menopausal Status at Randomization"
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_tte.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_AEDISC_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 8065628e23c1f16f1b9c5c76540f88be90f918fa
08 APR 2025 17:32 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Safety, Time to Adverse Events Leading to Treatment Discontinuation, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_AEDISC_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:15 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.1 Generelle Verträglichkeit

3.1.2 Unerwünschte Ereignisse UE nach Systemorganklassen (SOC) und Preferred Terms (PT)

3.1.2.1 Patienten mit Unerwünschten Ereignissen (UE) nach SOC/PT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis by SOC and PT Overall and with Subgroups (Safety), Adverse Events by SOC and PT, Part 1/3, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Blood and lymphatic system disorders, Any											
All Patients	324	163	120	73.6	161	114	70.8	0.79	(0.61, 1.03)	0.0592	NE
Age group (years)											
<65	266	129	94	72.9	137	98	71.5	0.82	(0.62, 1.09)	0.1328	0.5620
>=65	58	34	26	76.5	24	16	66.7	0.67	(0.36, 1.24)	0.1825	0.5620
Sex											
F	318	162	119	73.5	156	110	70.5	0.80	(0.62, 1.04)	0.0718	0.0838
M	6	1	1	100.0	5	4	80.0	<0.01	(0.00, >999.99)	0.0253	0.0838
Region											
ASIA	120	62	41	66.1	58	42	72.4	1.00	(0.65, 1.54)	0.9670	0.3030
NORTH AMERICA/WESTERN EUROPE	126	63	48	76.2	63	41	65.1	0.66	(0.43, 1.00)	0.0368	0.3030
OTHER	78	38	31	81.6	40	31	77.5	0.76	(0.46, 1.25)	0.2403	0.3030
Visceral disease (per eCRF)											
N	65	36	29	80.6	29	23	79.3	0.91	(0.52, 1.57)	0.6643	0.6052
Y	259	127	91	71.7	132	91	68.9	0.78	(0.58, 1.05)	0.0808	0.6052
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	35	67.3	52	40	76.9	0.97	(0.61, 1.53)	0.8305	0.2736
POST-MENOPAUSAL	214	110	84	76.4	104	70	67.3	0.73	(0.53, 1.01)	0.0434	0.2736
Time to First Blood and lymphatic system disorders, Neutropenia											
All Patients	324	163	89	54.6	161	91	56.5	0.97	(0.72, 1.30)	0.8225	NE
Age group (years)											
<65	266	129	65	50.4	137	78	56.9	1.10	(0.79, 1.54)	0.5985	0.1053
>=65	58	34	24	70.6	24	13	54.2	0.60	(0.31, 1.18)	0.1494	0.1053
Sex											
F	318	162	89	54.9	156	88	56.4	0.96	(0.71, 1.29)	0.7670	0.2064
M	6	1	0	0.0	5	3	60.0	>999.99	(0.00, >999.99)	0.3766	0.2064
Region											
ASIA	120	62	27	43.5	58	30	51.7	1.12	(0.67, 1.90)	0.6733	0.1374
NORTH AMERICA/WESTERN EUROPE	126	63	41	65.1	63	34	54.0	0.69	(0.44, 1.08)	0.1112	0.1374
OTHER	78	38	21	55.3	40	27	67.5	1.34	(0.75, 2.37)	0.3647	0.1374
Visceral disease (per eCRF)											
N	65	36	24	66.7	29	19	65.5	0.95	(0.52, 1.73)	0.8638	0.8966
Y	259	127	65	51.2	132	72	54.5	1.00	(0.71, 1.40)	0.9869	0.8966
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	22	42.3	52	33	63.5	1.46	(0.85, 2.52)	0.1588	0.0481
POST-MENOPAUSAL	214	110	67	60.9	104	55	52.9	0.80	(0.56, 1.14)	0.1884	0.0481
Time to First Blood and lymphatic system disorders, Anaemia											
All Patients	324	163	62	38.0	161	63	39.1	0.83	(0.58, 1.18)	0.3057	NE
Age group (years)											
<65	266	129	50	38.8	137	56	40.9	0.82	(0.56, 1.21)	0.3256	0.8827
>=65	58	34	12	35.3	24	7	29.2	0.76	(0.30, 1.92)	0.5536	0.8827

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	61	37.7	156	62	39.7	0.87	(0.61, 1.24)	0.4387	0.0132
M	6	1	1	100.0	5	1	20.0	<0.01	(0.00, >999.99)	0.0253	0.0132
Region											
ASIA	120	62	24	38.7	58	26	44.8	0.98	(0.56, 1.71)	0.9472	0.6235
NORTH AMERICA/WESTERN EUROPE	126	63	22	34.9	63	18	28.6	0.67	(0.36, 1.26)	0.2134	0.6235
OTHER	78	38	16	42.1	40	19	47.5	0.80	(0.41, 1.57)	0.5129	0.6235
Visceral disease (per eCRF)											
N	65	36	13	36.1	29	14	48.3	1.18	(0.56, 2.52)	0.6480	0.2712
Y	259	127	49	38.6	132	49	37.1	0.76	(0.51, 1.13)	0.1727	0.2712
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	21	40.4	52	21	40.4	0.76	(0.41, 1.41)	0.3787	0.6446
POST-MENOPAUSAL	214	110	40	36.4	104	41	39.4	0.92	(0.59, 1.42)	0.7097	0.6446
Time to First Blood and lymphatic system disorders, Thrombocytopenia											
All Patients	324	163	41	25.2	161	38	23.6	0.95	(0.61, 1.47)	0.7918	NE
Age group (years)											
<65	266	129	29	22.5	137	30	21.9	0.98	(0.59, 1.64)	0.9373	0.9221
>=65	58	34	12	35.3	24	8	33.3	1.02	(0.42, 2.49)	0.9881	0.9221
Sex											
F	318	162	41	25.3	156	36	23.1	0.92	(0.58, 1.43)	0.6865	0.3155
M	6	1	0	0.0	5	2	40.0	>999.99	(0.00, >999.99)	0.5024	0.3155
Region											
ASIA	120	62	16	25.8	58	17	29.3	1.23	(0.62, 2.44)	0.5733	0.0724
NORTH AMERICA/WESTERN EUROPE	126	63	13	20.6	63	16	25.4	1.30	(0.63, 2.70)	0.4792	0.0724
OTHER	78	38	12	31.6	40	5	12.5	0.35	(0.12, 1.01)	0.0394	0.0724
Visceral disease (per eCRF)											
N	65	36	6	16.7	29	10	34.5	2.45	(0.89, 6.75)	0.0796	0.0407
Y	259	127	35	27.6	132	28	21.2	0.74	(0.45, 1.22)	0.2378	0.0407
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	10	19.2	52	14	26.9	1.48	(0.66, 3.35)	0.3492	0.1411
POST-MENOPAUSAL	214	110	31	28.2	104	22	21.2	0.74	(0.43, 1.28)	0.2740	0.1411
Time to First Blood and lymphatic system disorders, Leukopenia											
All Patients	324	163	40	24.5	161	28	17.4	0.63	(0.39, 1.02)	0.0538	NE
Age group (years)											
<65	266	129	32	24.8	137	26	19.0	0.67	(0.40, 1.13)	0.1287	0.4096
>=65	58	34	8	23.5	24	2	8.3	0.33	(0.07, 1.55)	0.1403	0.4096
Sex											
F	318	162	40	24.7	156	28	17.9	0.64	(0.40, 1.05)	0.0703	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	16	25.8	58	12	20.7	0.72	(0.34, 1.53)	0.4015	0.7917
NORTH AMERICA/WESTERN EUROPE	126	63	11	17.5	63	8	12.7	0.63	(0.25, 1.58)	0.3192	0.7917
OTHER	78	38	13	34.2	40	8	20.0	0.52	(0.21, 1.25)	0.1221	0.7917

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	10	27.8	29	7	24.1	0.82	(0.31, 2.14)	0.6704	0.6277
Y	259	127	30	23.6	132	21	15.9	0.58	(0.33, 1.01)	0.0505	0.6277
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	12	23.1	52	12	23.1	0.82	(0.37, 1.84)	0.6245	0.4001
POST-MENOPAUSAL	214	110	28	25.5	104	16	15.4	0.56	(0.30, 1.03)	0.0553	0.4001
Time to First Blood and lymphatic system disorders, Febrile neutropenia											
All Patients	324	163	1	0.6	161	5	3.1	3.86	(0.45, 33.40)	0.1878	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	1.75	(0.18, 17.39)	0.6266	0.2061
>=65	58	34	0	0.0	24	2	8.3	>999.99	(0.00, >999.99)	0.0767	0.2061
Sex											
F	318	162	1	0.6	156	5	3.2	3.97	(0.46, 34.41)	0.1768	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	4	6.9	>999.99	(0.00, >999.99)	0.0790	0.2881
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.94	(0.06, 15.01)	0.9641	0.2881
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.2881
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.82	(0.05, 13.07)	0.8862	0.1252
Y	259	127	0	0.0	132	4	3.0	>999.99	(0.00, >999.99)	0.0804	0.1252
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4547	0.5686
POST-MENOPAUSAL	214	110	1	0.9	104	4	3.8	3.50	(0.39, 31.61)	0.2353	0.5686
Time to First Blood and lymphatic system disorders, Lymphopenia											
All Patients	324	163	5	3.1	161	1	0.6	0.20	(0.02, 1.70)	0.1004	NE
Age group (years)											
<65	266	129	4	3.1	137	1	0.7	0.23	(0.03, 2.02)	0.1455	0.6113
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.6113
Sex											
F	318	162	5	3.1	156	1	0.6	0.20	(0.02, 1.74)	0.1071	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.2513
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.97	(0.06, 15.46)	0.9804	0.2513
OTHER	78	38	4	10.5	40	0	0.0	<0.01	(0.00, >999.99)	0.0381	0.2513
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	0.5744
Y	259	127	4	3.1	132	1	0.8	0.23	(0.03, 2.08)	0.1552	0.5744
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	0	0.0	<0.01	(0.00, >999.99)	0.1553	0.3292
POST-MENOPAUSAL	214	110	3	2.7	104	1	1.0	0.34	(0.04, 3.29)	0.3312	0.3292

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Blood and lymphatic system disorders, Haemolysis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2267	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2004	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2341	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1441	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2712	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2536	1.0000
Time to First Blood and lymphatic system disorders, Myelosuppression											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5428	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5637	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5485	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.6171	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5541	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5930	1.0000
Time to First Blood and lymphatic system disorders, Thrombocytosis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4008	1.0000
Sex											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3264	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3080	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3309	1.0000
Time to First Investigations, Any											
All Patients	324	163	106	65.0	161	118	73.3	1.06	(0.82, 1.38)	0.6665	NE
Age group (years)											
<65	266	129	85	65.9	137	102	74.5	0.98	(0.73, 1.30)	0.8674	0.3366
>=65	58	34	21	61.8	24	16	66.7	1.38	(0.72, 2.65)	0.3417	0.3366
Sex											
F	318	162	105	64.8	156	114	73.1	1.05	(0.81, 1.37)	0.7166	0.6405
M	6	1	1	100.0	5	4	80.0	0.93	(0.09, 9.20)	0.9526	0.6405
Region											
ASIA	120	62	46	74.2	58	50	86.2	1.04	(0.70, 1.56)	0.8494	0.8105
NORTH AMERICA/WESTERN EUROPE	126	63	41	65.1	63	46	73.0	1.18	(0.77, 1.79)	0.4513	0.8105
OTHER	78	38	19	50.0	40	22	55.0	0.96	(0.52, 1.78)	0.9173	0.8105
Visceral disease (per eCRF)											
N	65	36	27	75.0	29	22	75.9	0.86	(0.49, 1.52)	0.6307	0.4640
Y	259	127	79	62.2	132	96	72.7	1.12	(0.83, 1.51)	0.4578	0.4640
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	38	73.1	52	35	67.3	0.68	(0.43, 1.09)	0.1128	0.0233
POST-MENOPAUSAL	214	110	67	60.9	104	79	76.0	1.29	(0.93, 1.79)	0.1289	0.0233
Time to First Investigations, Neutrophil count decreased											
All Patients	324	163	64	39.3	161	64	39.8	0.98	(0.69, 1.39)	0.9341	NE
Age group (years)											
<65	266	129	53	41.1	137	55	40.1	0.90	(0.62, 1.32)	0.6162	0.3971
>=65	58	34	11	32.4	24	9	37.5	1.39	(0.58, 3.36)	0.4547	0.3971
Sex											
F	318	162	63	38.9	156	61	39.1	0.98	(0.69, 1.40)	0.9234	0.3676
M	6	1	1	100.0	5	3	60.0	0.22	(0.01, 3.59)	0.2467	0.3676
Region											
ASIA	120	62	34	54.8	58	30	51.7	0.84	(0.52, 1.38)	0.4922	0.3684
NORTH AMERICA/WESTERN EUROPE	126	63	19	30.2	63	25	39.7	1.38	(0.76, 2.51)	0.2857	0.3684
OTHER	78	38	11	28.9	40	9	22.5	0.78	(0.32, 1.89)	0.5970	0.3684
Visceral disease (per eCRF)											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	13	36.1	29	9	31.0	0.89	(0.38, 2.09)	0.7990	0.8504
Y	259	127	51	40.2	132	55	41.7	0.98	(0.67, 1.44)	0.9393	0.8504
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	26	50.0	52	18	34.6	0.63	(0.34, 1.14)	0.1233	0.0431
POST-MENOPAUSAL	214	110	37	33.6	104	43	41.3	1.27	(0.82, 1.97)	0.2811	0.0431
Time to First Investigations, Platelet count decreased											
All Patients	324	163	38	23.3	161	43	26.7	1.15	(0.74, 1.78)	0.5280	NE
Age group (years)											
<65	266	129	31	24.0	137	36	26.3	1.06	(0.66, 1.72)	0.8028	0.4771
>=65	58	34	7	20.6	24	7	29.2	1.63	(0.57, 4.64)	0.3747	0.4771
Sex											
F	318	162	37	22.8	156	42	26.9	1.19	(0.76, 1.85)	0.4440	0.0658
M	6	1	1	100.0	5	1	20.0	0.22	(0.01, 3.59)	0.2467	0.0658
Region											
ASIA	120	62	18	29.0	58	27	46.6	1.67	(0.92, 3.05)	0.0872	0.2289
NORTH AMERICA/WESTERN EUROPE	126	63	10	15.9	63	8	12.7	0.75	(0.30, 1.92)	0.5512	0.2289
OTHER	78	38	10	26.3	40	8	20.0	0.77	(0.30, 1.97)	0.5878	0.2289
Visceral disease (per eCRF)											
N	65	36	6	16.7	29	7	24.1	1.64	(0.55, 4.88)	0.3655	0.4886
Y	259	127	32	25.2	132	36	27.3	1.05	(0.65, 1.70)	0.8404	0.4886
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	14	26.9	52	10	19.2	0.70	(0.31, 1.58)	0.3878	0.0842
POST-MENOPAUSAL	214	110	23	20.9	104	32	30.8	1.53	(0.89, 2.62)	0.1187	0.0842
Time to First Investigations, White blood cell count decreased											
All Patients	324	163	37	22.7	161	37	23.0	0.90	(0.57, 1.43)	0.6503	NE
Age group (years)											
<65	266	129	35	27.1	137	32	23.4	0.71	(0.44, 1.16)	0.1709	0.0372
>=65	58	34	2	5.9	24	5	20.8	4.16	(0.81, 21.44)	0.0652	0.0372
Sex											
F	318	162	36	22.2	156	36	23.1	0.93	(0.58, 1.48)	0.7451	0.1719
M	6	1	1	100.0	5	1	20.0	<0.01	(0.00, >999.99)	0.0253	0.1719
Region											
ASIA	120	62	22	35.5	58	23	39.7	0.93	(0.51, 1.68)	0.7793	0.9211
NORTH AMERICA/WESTERN EUROPE	126	63	6	9.5	63	6	9.5	1.00	(0.32, 3.10)	0.9964	0.9211
OTHER	78	38	9	23.7	40	8	20.0	0.63	(0.24, 1.69)	0.3647	0.9211
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	4	13.8	1.41	(0.31, 6.41)	0.6542	0.4087
Y	259	127	34	26.8	132	33	25.0	0.82	(0.51, 1.33)	0.4273	0.4087
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	15	28.8	52	15	28.8	0.82	(0.40, 1.70)	0.6002	0.7371
POST-MENOPAUSAL	214	110	21	19.1	104	21	20.2	0.99	(0.54, 1.81)	0.9512	0.7371
Time to First Investigations, Aspartate aminotransferase increased											
All Patients	324	163	32	19.6	161	31	19.3	0.82	(0.50, 1.34)	0.4246	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	26	20.2	137	25	18.2	0.69	(0.40, 1.21)	0.1936	0.1872
>=65	58	34	6	17.6	24	6	25.0	1.57	(0.51, 4.91)	0.4300	0.1872
Sex											
F	318	162	32	19.8	156	30	19.2	0.82	(0.49, 1.35)	0.4292	0.4705
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.4705
Region											
ASIA	120	62	15	24.2	58	15	25.9	0.96	(0.47, 1.98)	0.9132	0.7916
NORTH AMERICA/WESTERN EUROPE	126	63	13	20.6	63	13	20.6	0.82	(0.38, 1.78)	0.6163	0.7916
OTHER	78	38	4	10.5	40	3	7.5	0.64	(0.14, 2.89)	0.5622	0.7916
Visceral disease (per eCRF)											
N	65	36	7	19.4	29	7	24.1	1.07	(0.37, 3.06)	0.8995	0.5313
Y	259	127	25	19.7	132	24	18.2	0.76	(0.43, 1.34)	0.3393	0.5313
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	12	23.1	52	13	25.0	0.83	(0.37, 1.84)	0.6461	0.8494
POST-MENOPAUSAL	214	110	20	18.2	104	17	16.3	0.78	(0.41, 1.50)	0.4568	0.8494
Time to First Investigations, Alanine aminotransferase increased											
All Patients	324	163	27	16.6	161	31	19.3	0.99	(0.59, 1.67)	0.9845	NE
Age group (years)											
<65	266	129	25	19.4	137	25	18.2	0.74	(0.42, 1.29)	0.2834	0.0144
>=65	58	34	2	5.9	24	6	25.0	5.25	(1.06, 26.10)	0.0241	0.0144
Sex											
F	318	162	27	16.7	156	30	19.2	1.00	(0.59, 1.68)	0.9881	0.5109
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.5109
Region											
ASIA	120	62	13	21.0	58	14	24.1	1.02	(0.48, 2.18)	0.9641	0.9918
NORTH AMERICA/WESTERN EUROPE	126	63	11	17.5	63	13	20.6	1.02	(0.45, 2.28)	0.9675	0.9918
OTHER	78	38	3	7.9	40	4	10.0	1.24	(0.28, 5.52)	0.7809	0.9918
Visceral disease (per eCRF)											
N	65	36	6	16.7	29	7	24.1	1.32	(0.44, 3.96)	0.6101	0.5419
Y	259	127	21	16.5	132	24	18.2	0.92	(0.51, 1.67)	0.7909	0.5419
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	10	19.2	52	12	23.1	0.92	(0.39, 2.15)	0.8491	0.9536
POST-MENOPAUSAL	214	110	17	15.5	104	18	17.3	1.02	(0.52, 1.98)	0.9663	0.9536
Time to First Investigations, Weight decreased											
All Patients	324	163	1	0.6	161	31	19.3	26.29	(3.58, 192.90)	<0.0001	NE
Age group (years)											
<65	266	129	1	0.8	137	24	17.5	18.06	(2.44, 133.90)	<0.0001	0.3182
>=65	58	34	0	0.0	24	7	29.2	>999.99	(0.00, >999.99)	0.0007	0.3182
Sex											
F	318	162	1	0.6	156	29	18.6	25.46	(3.46, 187.23)	<0.0001	0.8409
M	6	1	0	0.0	5	2	40.0	>999.99	(0.00, >999.99)	0.4658	0.8409

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	16	27.6	>999.99	(0.00, >999.99)	0.0002	0.3137
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	9	14.3	8.10	(1.02, 64.03)	0.0183	0.3137
OTHER	78	38	0	0.0	40	6	15.0	>999.99	(0.00, >999.99)	0.0443	0.3137
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	4	13.8	>999.99	(0.00, >999.99)	0.0857	0.5498
Y	259	127	1	0.8	132	27	20.5	22.15	(3.01, 163.27)	<0.0001	0.5498
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	9	17.3	>999.99	(0.00, >999.99)	0.0059	0.4212
POST-MENOPAUSAL	214	110	1	0.9	104	20	19.2	18.10	(2.42, 135.26)	<0.0001	0.4212
Time to First Investigations, Blood creatinine increased											
All Patients	324	163	12	7.4	161	9	5.6	0.74	(0.31, 1.77)	0.4987	NE
Age group (years)											
<65	266	129	10	7.8	137	7	5.1	0.63	(0.24, 1.65)	0.3373	0.4139
>=65	58	34	2	5.9	24	2	8.3	1.57	(0.22, 11.19)	0.6474	0.4139
Sex											
F	318	162	12	7.4	156	8	5.1	0.68	(0.28, 1.66)	0.3923	0.4728
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.4728
Region											
ASIA	120	62	7	11.3	58	5	8.6	0.76	(0.24, 2.41)	0.6428	0.8619
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	3	4.8	1.01	(0.20, 4.99)	0.9923	0.8619
OTHER	78	38	2	5.3	40	1	2.5	0.36	(0.03, 4.16)	0.3986	0.8619
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	2	6.9	0.61	(0.11, 3.35)	0.5666	0.7946
Y	259	127	8	6.3	132	7	5.3	0.84	(0.30, 2.31)	0.7284	0.7946
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	1	1.9	0.50	(0.05, 5.51)	0.5624	0.7471
POST-MENOPAUSAL	214	110	10	9.1	104	7	6.7	0.73	(0.28, 1.92)	0.5194	0.7471
Time to First Investigations, Glycosylated haemoglobin increased											
All Patients	324	163	3	1.8	161	15	9.3	4.31	(1.24, 14.97)	0.0123	NE
Age group (years)											
<65	266	129	3	2.3	137	15	10.9	3.83	(1.10, 13.33)	0.0234	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	2	1.2	156	13	8.3	6.07	(1.37, 26.96)	0.0070	0.1973
M	6	1	1	100.0	5	2	40.0	>999.99	(0.00, >999.99)	0.5024	0.1973
Region											
ASIA	120	62	0	0.0	58	8	13.8	>999.99	(0.00, >999.99)	0.0044	0.0304
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	7	11.1	3.10	(0.64, 14.96)	0.1388	0.0304
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2109	0.0304
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	3	10.3	>999.99	(0.00, >999.99)	0.0711	0.2076
Y	259	127	3	2.4	132	12	9.1	3.19	(0.89, 11.36)	0.0594	0.2076

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	6	11.5	>999.99	(0.00, >999.99)	0.0343	0.1502
POST-MENOPAUSAL	214	110	2	1.8	104	7	6.7	3.55	(0.74, 17.08)	0.0918	0.1502
Time to First Investigations, Lymphocyte count decreased											
All Patients	324	163	10	6.1	161	5	3.1	0.43	(0.15, 1.28)	0.1185	NE
Age group (years)											
<65	266	129	9	7.0	137	5	3.6	0.42	(0.14, 1.28)	0.1171	0.4783
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.4783
Sex											
F	318	162	10	6.2	156	5	3.2	0.45	(0.15, 1.31)	0.1319	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	1	1.6	58	2	3.4	2.09	(0.19, 23.08)	0.5364	0.3629
NORTH AMERICA/WESTERN EUROPE	126	63	4	6.3	63	1	1.6	0.24	(0.03, 2.18)	0.1703	0.3629
OTHER	78	38	5	13.2	40	2	5.0	0.24	(0.04, 1.26)	0.0682	0.3629
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.1625	0.2409
Y	259	127	8	6.3	132	5	3.8	0.52	(0.17, 1.60)	0.2464	0.2409
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	1	1.9	0.43	(0.04, 4.81)	0.4820	0.9007
POST-MENOPAUSAL	214	110	8	7.3	104	4	3.8	0.47	(0.14, 1.55)	0.2023	0.9007
Time to First Investigations, Blood bilirubin increased											
All Patients	324	163	5	3.1	161	7	4.3	1.16	(0.36, 3.70)	0.8040	NE
Age group (years)											
<65	266	129	5	3.9	137	6	4.4	0.85	(0.25, 2.86)	0.7963	0.1823
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.1823
Sex											
F	318	162	5	3.1	156	7	4.5	1.19	(0.37, 3.81)	0.7667	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	3	4.8	58	4	6.9	1.32	(0.29, 5.95)	0.7152	0.8933
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.30	(0.11, 14.71)	0.8326	0.8933
OTHER	78	38	1	2.6	40	1	2.5	0.62	(0.04, 10.62)	0.7384	0.8933
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.2657	0.0886
Y	259	127	5	3.9	132	5	3.8	0.85	(0.24, 2.95)	0.7924	0.0886
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	2	3.8	0.59	(0.08, 4.58)	0.6135	0.5733
POST-MENOPAUSAL	214	110	3	2.7	104	5	4.8	1.59	(0.38, 6.72)	0.5219	0.5733
Time to First Investigations, Blood glucose increased											
All Patients	324	163	4	2.5	161	8	5.0	1.77	(0.53, 5.93)	0.3487	NE
Age group (years)											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	4	3.1	137	8	5.8	1.60	(0.48, 5.37)	0.4429	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	4	2.5	156	8	5.1	1.81	(0.54, 6.08)	0.3277	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	3	4.8	58	2	3.4	0.70	(0.12, 4.20)	0.6978	0.1511
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	3	4.8	2.73	(0.28, 26.36)	0.3656	0.1511
OTHER	78	38	0	0.0	40	3	7.5	>999.99	(0.00, >999.99)	0.1243	0.1511
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	3	10.3	3.03	(0.30, 30.06)	0.3222	0.5182
Y	259	127	3	2.4	132	5	3.8	1.42	(0.34, 5.98)	0.6321	0.5182
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	3	5.8	2.75	(0.28, 26.58)	0.3607	0.6765
POST-MENOPAUSAL	214	110	3	2.7	104	5	4.8	1.47	(0.34, 6.27)	0.6031	0.6765
Time to First Investigations, Blood alkaline phosphatase increased											
All Patients	324	163	5	3.1	161	6	3.7	0.96	(0.29, 3.18)	0.9532	NE
Age group (years)											
<65	266	129	5	3.9	137	6	4.4	0.85	(0.26, 2.82)	0.7914	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	5	3.1	156	6	3.8	0.99	(0.30, 3.28)	0.9928	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	2	3.4	0.98	(0.14, 6.98)	0.9850	0.8050
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.66	(0.15, 18.46)	0.6765	0.8050
OTHER	78	38	2	5.3	40	2	5.0	0.57	(0.08, 4.20)	0.5804	0.8050
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.70	(0.04, 11.28)	0.8021	0.9430
Y	259	127	4	3.1	132	5	3.8	1.01	(0.27, 3.77)	0.9905	0.9430
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	3	5.8	0.66	(0.13, 3.40)	0.6167	0.5977
POST-MENOPAUSAL	214	110	2	1.8	104	3	2.9	1.34	(0.22, 8.06)	0.7495	0.5977
Time to First Investigations, Blood insulin increased											
All Patients	324	163	1	0.6	161	10	6.2	8.60	(1.10, 67.36)	0.0137	NE
Age group (years)											
<65	266	129	1	0.8	137	10	7.3	7.62	(0.97, 59.67)	0.0227	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	1	0.6	156	9	5.8	7.78	(0.98, 61.52)	0.0215	0.8098
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.8098
Region											
ASIA	120	62	0	0.0	58	7	12.1	>999.99	(0.00, >999.99)	0.0099	0.0259

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.0920	0.0259
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1923	0.0259
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	0.5998
Y	259	127	1	0.8	132	9	6.8	6.99	(0.88, 55.30)	0.0320	0.5998
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	5	9.6	>999.99	(0.00, >999.99)	0.0636	0.2499
POST-MENOPAUSAL	214	110	1	0.9	104	4	3.8	3.89	(0.43, 34.84)	0.1901	0.2499
Time to First Investigations, Blood cholesterol increased											
All Patients	324	163	3	1.8	161	6	3.7	1.39	(0.35, 5.59)	0.6384	NE
Age group (years)											
<65	266	129	2	1.6	137	6	4.4	1.83	(0.37, 9.09)	0.4538	0.2119
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3743	0.2119
Sex											
F	318	162	3	1.9	156	6	3.8	1.44	(0.36, 5.77)	0.6057	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.1990	0.2109
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	5	7.9	2.16	(0.42, 11.15)	0.3447	0.2109
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4602	0.2109
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3447	0.1578
Y	259	127	2	1.6	132	6	4.5	1.90	(0.38, 9.42)	0.4261	0.1578
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	2	3.8	1.19	(0.11, 13.18)	0.8893	0.8567
POST-MENOPAUSAL	214	110	2	1.8	104	4	3.8	1.57	(0.29, 8.58)	0.6015	0.8567
Time to First Investigations, Electrocardiogram QT prolonged											
All Patients	324	163	1	0.6	161	8	5.0	6.66	(0.83, 53.65)	0.0403	NE
Age group (years)											
<65	266	129	1	0.8	137	8	5.8	5.90	(0.73, 47.64)	0.0596	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	1	0.6	156	8	5.1	6.74	(0.84, 54.47)	0.0389	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	1	1.6	58	6	10.3	4.71	(0.55, 40.62)	0.1206	0.7667
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	0.7667
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4431	0.7667
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	0.5656
Y	259	127	1	0.8	132	7	5.3	5.23	(0.64, 42.85)	0.0861	0.5656
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	3	5.8	1.98	(0.18, 21.88)	0.5687	0.1721

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	5	4.8	>999.99	(0.00, >999.99)	0.0328	0.1721
Time to First Investigations, Amylase increased											
All Patients	324	163	5	3.1	161	3	1.9	0.37	(0.09, 1.59)	0.1658	NE
Age group (years)											
<65	266	129	5	3.9	137	1	0.7	0.13	(0.01, 1.10)	0.0281	0.0047
>=65	58	34	0	0.0	24	2	8.3	>999.99	(0.00, >999.99)	0.1063	0.0047
Sex											
F	318	162	4	2.5	156	3	1.9	0.51	(0.11, 2.35)	0.3796	0.0861
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0455	0.0861
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.58	(0.03, 10.38)	0.7103	0.0996
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.27	(0.11, 14.44)	0.8462	0.0996
OTHER	78	38	3	7.9	40	0	0.0	<0.01	(0.00, >999.99)	0.0239	0.0996
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.39	(0.03, 4.75)	0.4499	0.9887
Y	259	127	3	2.4	132	2	1.5	0.37	(0.06, 2.30)	0.2693	0.9887
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	4	3.6	104	3	2.9	0.53	(0.11, 2.48)	0.4154	1.0000
Time to First Investigations, Blood lactate dehydrogenase increased											
All Patients	324	163	3	1.8	161	4	2.5	1.01	(0.22, 4.57)	0.9898	NE
Age group (years)											
<65	266	129	3	2.3	137	4	2.9	0.88	(0.19, 4.00)	0.8704	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	3	1.9	156	4	2.6	1.04	(0.23, 4.69)	0.9633	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.97	(0.06, 15.49)	0.9812	0.0211
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.1251	0.0211
OTHER	78	38	2	5.3	40	0	0.0	<0.01	(0.00, >999.99)	0.0509	0.0211
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4386	0.2118
Y	259	127	3	2.4	132	3	2.3	0.76	(0.15, 3.76)	0.7313	0.2118
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	3	5.8	>999.99	(0.00, >999.99)	0.2248	0.0343
POST-MENOPAUSAL	214	110	3	2.7	104	1	1.0	0.31	(0.03, 2.98)	0.2821	0.0343
Time to First Investigations, Weight increased											
All Patients	324	163	6	3.7	161	0	0.0	<0.01	(0.00, >999.99)	0.0049	NE
Age group (years)											
<65	266	129	6	4.7	137	0	0.0	<0.01	(0.00, >999.99)	0.0023	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	6	3.7	156	0	0.0	<0.01	(0.00, >999.99)	0.0055	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	5	8.1	58	0	0.0	<0.01	(0.00, >999.99)	0.0079	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2812	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	6	4.7	132	0	0.0	<0.01	(0.00, >999.99)	0.0031	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	0	0.0	<0.01	(0.00, >999.99)	0.0346	1.0000
POST-MENOPAUSAL	214	110	4	3.6	104	0	0.0	<0.01	(0.00, >999.99)	0.0342	1.0000
Time to First Investigations, Gamma-glutamyltransferase increased											
All Patients	324	163	2	1.2	161	3	1.9	1.26	(0.21, 7.65)	0.8021	NE
Age group (years)											
<65	266	129	2	1.6	137	2	1.5	0.68	(0.09, 4.99)	0.7051	0.1750
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.1750
Sex											
F	318	162	2	1.2	156	3	1.9	1.30	(0.21, 7.87)	0.7776	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	1	1.7	0.51	(0.05, 5.58)	0.5706	0.2333
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2179	0.2333
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.2333
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4292	0.2242
Y	259	127	2	1.6	132	2	1.5	0.88	(0.12, 6.26)	0.8979	0.2242
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.44	(0.02, 7.84)	0.5670	0.6308
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	2.06	(0.19, 22.69)	0.5478	0.6308
Time to First Investigations, Blood creatine phosphokinase increased											
All Patients	324	163	2	1.2	161	2	1.2	1.02	(0.14, 7.23)	0.9851	NE
Age group (years)											
<65	266	129	2	1.6	137	2	1.5	0.94	(0.13, 6.68)	0.9514	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	1	0.6	0.52	(0.05, 5.74)	0.5870	0.4240
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.4240
Region											
ASIA	120	62	1	1.6	58	1	1.7	1.07	(0.07, 17.09)	0.9622	0.9998
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	1.01	(0.06, 16.12)	0.9954	0.9998
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.9998

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	0.2264
Y	259	127	1	0.8	132	2	1.5	1.92	(0.17, 21.21)	0.5867	0.2264
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.2949
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	1.06	(0.07, 17.01)	0.9652	0.2949
Time to First Investigations, Lipase increased											
All Patients	324	163	1	0.6	161	3	1.9	2.53	(0.26, 24.78)	0.4111	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.82	(0.16, 20.05)	0.6213	0.3021
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2888	0.3021
Sex											
F	318	162	1	0.6	156	3	1.9	2.60	(0.26, 25.45)	0.3966	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3091	0.7091
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.63	(0.14, 18.36)	0.6909	0.7091
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.7091
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	3	2.3	2.34	(0.24, 22.99)	0.4540	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.0284
POST-MENOPAUSAL	214	110	0	0.0	104	3	2.9	>999.99	(0.00, >999.99)	0.1043	0.0284
Time to First Investigations, SARS-CoV-2 test positive											
All Patients	324	163	2	1.2	161	2	1.2	0.71	(0.10, 5.14)	0.7346	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5485	0.3051
>=65	58	34	2	5.9	24	1	4.2	0.70	(0.06, 7.76)	0.7722	0.3051
Sex											
F	318	162	2	1.2	156	2	1.3	0.73	(0.10, 5.30)	0.7574	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	2	3.2	0.81	(0.11, 5.80)	0.8335	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	2	1.6	132	2	1.5	0.65	(0.09, 4.70)	0.6669	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.80	(0.11, 5.69)	0.8195	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Investigations, Bilirubin conjugated increased											
All Patients	324	163	0	0.0	161	3	1.9	>999.99	(0.00, >999.99)	0.0807	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.0947	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	3	1.9	>999.99	(0.00, >999.99)	0.0768	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.1452	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.0903	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1428	1.0000
Time to First Investigations, Low density lipoprotein increased											
All Patients	324	163	0	0.0	161	3	1.9	>999.99	(0.00, >999.99)	0.1256	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.1523	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	3	1.9	>999.99	(0.00, >999.99)	0.1200	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.0996	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.1440	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.2574	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3416	1.0000
Time to First Investigations, Blood bicarbonate decreased											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.1146	NE
Age group (years)											
<65	266	129	2	1.6	137	0	0.0	<0.01	(0.00, >999.99)	0.0954	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1203	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	2	5.3	40	0	0.0	<0.01	(0.00, >999.99)	0.0745	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	0	0.0	<0.01	(0.00, >999.99)	0.1042	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1360	1.0000
Time to First Investigations, Blood bilirubin unconjugated increased											
All Patients	324	163	1	0.6	161	1	0.6	1.01	(0.06, 16.14)	0.9947	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.92	(0.06, 14.74)	0.9542	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	1.04	(0.06, 16.56)	0.9800	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	1.05	(0.07, 16.83)	0.9711	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.95	(0.06, 15.12)	0.9685	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3221	0.0936
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	0.0936
Time to First Investigations, Blood triglycerides increased											
All Patients	324	163	1	0.6	161	1	0.6	0.75	(0.05, 11.97)	0.8359	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.64	(0.04, 10.24)	0.7492	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.77	(0.05, 12.35)	0.8535	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.92	(0.06, 14.79)	0.9559	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likeli- hood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	1	0.8	132	1	0.8	0.69	(0.04, 11.00)	0.7893	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3950	0.1142
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2589	0.1142
Time to First Investigations, Blood uric acid increased											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.1380	NE
Age group (years)											
<65	266	129	2	1.6	137	0	0.0	<0.01	(0.00, >999.99)	0.1154	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1433	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3295	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2109	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3598	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3060	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2397	0.9999
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3311	0.9999
Time to First Investigations, International normalised ratio increased											
All Patients	324	163	1	0.6	161	1	0.6	0.90	(0.06, 14.37)	0.9398	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.79	(0.05, 12.70)	0.8706	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.92	(0.06, 14.75)	0.9544	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.2451
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3513	0.2451
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2746	0.2451
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.82	(0.05, 13.13)	0.8892	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3384	0.0974
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2998	0.0974
Time to First Investigations, Urinary occult blood positive											
All Patients	324	163	1	0.6	161	1	0.6	1.00	(0.06, 15.99)	0.9999	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.92	(0.06, 14.70)	0.9524	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	1.03	(0.06, 16.40)	0.9857	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	1.04	(0.07, 16.68)	0.9764	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3694	0.1148
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3365	0.1148
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.0982
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3309	0.0982
Time to First Investigations, Aspartate aminotransferase											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2944	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2671	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3006	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2741	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3072	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Investigations, Aspartate aminotransferase decreased											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3028	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3091	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2850	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3050	1.0000
Time to First Investigations, Basophil count increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3651	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4003	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3585	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3413	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3914	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3950	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Investigations, Blood calcium decreased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3377	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3095	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3091	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3326	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3057	1.0000
Time to First Investigations, Blood fibrinogen increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3407	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3706	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3344	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3513	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3617	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3384	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Investigations, Blood phosphorus increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4987	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5525	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4917	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4522	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5204	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Investigations, Blood pressure decreased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4036	NE
Age group (years)											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4292	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3964	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3409	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3281	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3711	1.0000
Time to First Investigations, Blood pressure increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3377	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3095	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3057	1.0000
Time to First Investigations, Blood urea increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4433	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2429	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4353	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4363	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3865	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4045	1.0000
Time to First Investigations, Carbon dioxide increased											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Investigations, Electrocardiogram T wave abnormal											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3584	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2453	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3520	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3413	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3858	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3416	1.0000
Time to First Investigations, Glomerular filtration rate decreased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4214	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4555	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3545	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3711	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Investigations, Glucose urine present											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3570	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3827	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3506	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3418	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2673	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3364	1.0000
Time to First Investigations, Haemoglobin decreased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Investigations, Human chorionic gonadotropin increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5089	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5596	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5019	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5403	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5127	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6276	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Investigations, Insulin C-peptide increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First Investigations, Intestinal transit time increased											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3264	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3694	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Investigations, Lymphocyte count increased											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2990	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3266	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3046	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3060	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3311	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Investigations, Platelet count increased											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1266	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0833	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1327	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1025	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1410	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1747	1.0000
Time to First Investigations, Prothrombin time prolonged											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3407	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3706	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3344	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3513	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3617	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3384	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Investigations, Reticulocyte count increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3358	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3080	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3306	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Investigations, Transaminases increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Investigations, White blood cells urine positive											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3954	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4271	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3884	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4193	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4247	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4404	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Any											
All Patients	324	163	85	52.1	161	131	81.4	2.21	(1.68, 2.91)	<0.0001	NE
Age group (years)											
<65	266	129	63	48.8	137	116	84.7	2.57	(1.89, 3.50)	<0.0001	0.0185
>=65	58	34	22	64.7	24	15	62.5	1.09	(0.56, 2.13)	0.7950	0.0185
Sex											
F	318	162	84	51.9	156	126	80.8	2.23	(1.69, 2.95)	<0.0001	0.6259
M	6	1	1	100.0	5	5	100.0	0.93	(0.09, 9.20)	0.9526	0.6259
Region											
ASIA	120	62	31	50.0	58	49	84.5	2.82	(1.79, 4.44)	<0.0001	0.5197
NORTH AMERICA/WESTERN EUROPE	126	63	42	66.7	63	55	87.3	1.91	(1.28, 2.87)	0.0016	0.5197
OTHER	78	38	12	31.6	40	27	67.5	2.35	(1.18, 4.66)	0.0121	0.5197
Visceral disease (per eCRF)											
N	65	36	20	55.6	29	23	79.3	1.80	(0.99, 3.29)	0.0519	0.3853
Y	259	127	65	51.2	132	108	81.8	2.31	(1.70, 3.16)	<0.0001	0.3853
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	25	48.1	52	43	82.7	2.60	(1.58, 4.27)	0.0001	0.3556
POST-MENOPAUSAL	214	110	59	53.6	104	83	79.8	2.07	(1.48, 2.89)	<0.0001	0.3556
Time to First Gastrointestinal disorders, Diarrhoea											
All Patients	324	163	26	16.0	161	84	52.2	3.72	(2.40, 5.79)	<0.0001	NE
Age group (years)											
<65	266	129	17	13.2	137	75	54.7	4.71	(2.78, 7.98)	<0.0001	0.0551
>=65	58	34	9	26.5	24	9	37.5	1.66	(0.65, 4.19)	0.2750	0.0551
Sex											
F	318	162	26	16.0	156	81	51.9	3.69	(2.37, 5.74)	<0.0001	0.4683
M	6	1	0	0.0	5	3	60.0	>999.99	(0.00, >999.99)	0.3766	0.4683
Region											
ASIA	120	62	6	9.7	58	28	48.3	5.36	(2.21, 12.97)	<0.0001	0.4607
NORTH AMERICA/WESTERN EUROPE	126	63	17	27.0	63	39	61.9	3.04	(1.72, 5.38)	<0.0001	0.4607
OTHER	78	38	3	7.9	40	17	42.5	4.96	(1.44, 17.09)	0.0050	0.4607
Visceral disease (per eCRF)											
N	65	36	5	13.9	29	15	51.7	4.45	(1.61, 12.27)	0.0016	0.7153
Y	259	127	21	16.5	132	69	52.3	3.54	(2.17, 5.77)	<0.0001	0.7153
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	26	50.0	9.06	(2.74, 30.00)	<0.0001	0.0508
POST-MENOPAUSAL	214	110	23	20.9	104	55	52.9	3.01	(1.85, 4.90)	<0.0001	0.0508
Time to First Gastrointestinal disorders, Stomatitis											
All Patients	324	163	30	18.4	161	57	35.4	2.07	(1.33, 3.22)	0.0010	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	22	17.1	137	52	38.0	2.36	(1.43, 3.89)	0.0005	0.1599
>=65	58	34	8	23.5	24	5	20.8	1.05	(0.34, 3.20)	0.9500	0.1599
Sex											
F	318	162	29	17.9	156	57	36.5	2.23	(1.43, 3.49)	0.0003	0.0281
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.1573	0.0281
Region											
ASIA	120	62	13	21.0	58	27	46.6	2.66	(1.37, 5.17)	0.0027	0.2537
NORTH AMERICA/WESTERN EUROPE	126	63	14	22.2	63	18	28.6	1.35	(0.67, 2.71)	0.4055	0.2537
OTHER	78	38	3	7.9	40	12	30.0	3.55	(1.00, 12.66)	0.0373	0.2537
Visceral disease (per eCRF)											
N	65	36	7	19.4	29	11	37.9	2.26	(0.88, 5.83)	0.0819	0.9378
Y	259	127	23	18.1	132	46	34.8	2.04	(1.24, 3.37)	0.0044	0.9378
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	11	21.2	52	21	40.4	1.99	(0.96, 4.15)	0.0602	0.7604
POST-MENOPAUSAL	214	110	18	16.4	104	36	34.6	2.36	(1.34, 4.16)	0.0022	0.7604
Time to First Gastrointestinal disorders, Nausea											
All Patients	324	163	32	19.6	161	47	29.2	1.32	(0.84, 2.08)	0.2357	NE
Age group (years)											
<65	266	129	20	15.5	137	42	30.7	1.77	(1.03, 3.03)	0.0355	0.0294
>=65	58	34	12	35.3	24	5	20.8	0.49	(0.17, 1.41)	0.1778	0.0294
Sex											
F	318	162	32	19.8	156	47	30.1	1.36	(0.86, 2.14)	0.1860	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	4	6.5	58	14	24.1	3.29	(1.07, 10.07)	0.0277	0.1014
NORTH AMERICA/WESTERN EUROPE	126	63	21	33.3	63	25	39.7	1.13	(0.63, 2.03)	0.7025	0.1014
OTHER	78	38	7	18.4	40	8	20.0	0.79	(0.28, 2.26)	0.6629	0.1014
Visceral disease (per eCRF)											
N	65	36	12	33.3	29	5	17.2	0.39	(0.13, 1.14)	0.0755	0.0106
Y	259	127	20	15.7	132	42	31.8	1.82	(1.07, 3.12)	0.0265	0.0106
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	5	9.6	52	16	30.8	3.12	(1.13, 8.57)	0.0201	0.0545
POST-MENOPAUSAL	214	110	27	24.5	104	31	29.8	1.04	(0.62, 1.75)	0.8928	0.0545
Time to First Gastrointestinal disorders, Constipation											
All Patients	324	163	25	15.3	161	26	16.1	0.91	(0.52, 1.58)	0.7297	NE
Age group (years)											
<65	266	129	21	16.3	137	26	19.0	0.96	(0.54, 1.72)	0.8989	0.0455
>=65	58	34	4	11.8	24	0	0.0	<0.01	(0.00, >999.99)	0.0955	0.0455
Sex											
F	318	162	24	14.8	156	26	16.7	0.98	(0.56, 1.71)	0.9406	0.0356
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0253	0.0356

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	9	14.5	58	5	8.6	0.48	(0.16, 1.44)	0.1803	0.2742
NORTH AMERICA/WESTERN EUROPE	126	63	14	22.2	63	16	25.4	1.02	(0.50, 2.10)	0.9567	0.2742
OTHER	78	38	2	5.3	40	5	12.5	2.17	(0.42, 11.28)	0.3465	0.2742
Visceral disease (per eCRF)											
N	65	36	7	19.4	29	4	13.8	0.56	(0.16, 1.95)	0.3572	0.4664
Y	259	127	18	14.2	132	22	16.7	1.03	(0.55, 1.92)	0.9331	0.4664
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	5	9.6	52	8	15.4	1.35	(0.44, 4.19)	0.5987	0.4836
POST-MENOPAUSAL	214	110	19	17.3	104	18	17.3	0.88	(0.46, 1.68)	0.6932	0.4836
Time to First Gastrointestinal disorders, Vomiting											
All Patients	324	163	10	6.1	161	26	16.1	2.43	(1.17, 5.05)	0.0139	NE
Age group (years)											
<65	266	129	7	5.4	137	23	16.8	2.71	(1.16, 6.34)	0.0165	0.5542
>=65	58	34	3	8.8	24	3	12.5	1.66	(0.33, 8.23)	0.5313	0.5542
Sex											
F	318	162	10	6.2	156	25	16.0	2.44	(1.17, 5.09)	0.0140	0.6771
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6171	0.6771
Region											
ASIA	120	62	2	3.2	58	8	13.8	4.12	(0.87, 19.46)	0.0521	0.4545
NORTH AMERICA/WESTERN EUROPE	126	63	8	12.7	63	16	25.4	2.05	(0.88, 4.79)	0.0909	0.4545
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2144	0.4545
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	4	13.8	2.07	(0.37, 11.45)	0.3949	0.9912
Y	259	127	8	6.3	132	22	16.7	2.44	(1.09, 5.49)	0.0258	0.9912
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	9	17.3	>999.99	(0.00, >999.99)	0.0049	0.0095
POST-MENOPAUSAL	214	110	10	9.1	104	16	15.4	1.62	(0.74, 3.59)	0.2258	0.0095
Time to First Gastrointestinal disorders, Abdominal pain											
All Patients	324	163	12	7.4	161	18	11.2	1.27	(0.61, 2.65)	0.5261	NE
Age group (years)											
<65	266	129	8	6.2	137	17	12.4	1.62	(0.70, 3.79)	0.2581	0.1545
>=65	58	34	4	11.8	24	1	4.2	0.32	(0.04, 2.90)	0.2875	0.1545
Sex											
F	318	162	12	7.4	156	18	11.5	1.29	(0.62, 2.70)	0.4949	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	3	4.8	58	7	12.1	2.13	(0.55, 8.27)	0.2636	0.4458
NORTH AMERICA/WESTERN EUROPE	126	63	9	14.3	63	10	15.9	0.95	(0.38, 2.37)	0.9165	0.4458
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4241	0.4458
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.42	(0.04, 4.95)	0.4773	0.4530
Y	259	127	10	7.9	132	17	12.9	1.38	(0.63, 3.01)	0.4233	0.4530

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	5	9.6	52	8	15.4	1.41	(0.46, 4.33)	0.5454	0.8856
POST-MENOPAUSAL	214	110	7	6.4	104	10	9.6	1.18	(0.44, 3.16)	0.7367	0.8856
Time to First Gastrointestinal disorders, Abdominal pain upper											
All Patients	324	163	12	7.4	161	14	8.7	1.00	(0.46, 2.16)	0.9953	NE
Age group (years)											
<65	266	129	9	7.0	137	13	9.5	1.09	(0.46, 2.56)	0.8447	0.5229
>=65	58	34	3	8.8	24	1	4.2	0.48	(0.05, 4.62)	0.5159	0.5229
Sex											
F	318	162	12	7.4	156	14	9.0	1.03	(0.47, 2.23)	0.9474	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	7	12.1	3.53	(0.73, 17.02)	0.0939	0.0921
NORTH AMERICA/WESTERN EUROPE	126	63	9	14.3	63	7	11.1	0.70	(0.26, 1.87)	0.4714	0.0921
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2109	0.0921
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	2	6.9	0.53	(0.10, 2.94)	0.4593	0.4508
Y	259	127	8	6.3	132	12	9.1	1.22	(0.50, 2.98)	0.6697	0.4508
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	4	7.7	1.52	(0.28, 8.36)	0.6269	0.5761
POST-MENOPAUSAL	214	110	10	9.1	104	10	9.6	0.92	(0.38, 2.23)	0.8622	0.5761
Time to First Gastrointestinal disorders, Dyspepsia											
All Patients	324	163	4	2.5	161	14	8.7	3.31	(1.09, 10.09)	0.0254	NE
Age group (years)											
<65	266	129	4	3.1	137	13	9.5	2.75	(0.89, 8.48)	0.0654	0.3577
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.3577
Sex											
F	318	162	4	2.5	156	14	9.0	3.41	(1.12, 10.37)	0.0218	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	2	3.2	58	6	10.3	2.63	(0.53, 13.14)	0.2219	0.6176
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	6	9.5	3.02	(0.61, 14.98)	0.1543	0.6176
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.1628	0.6176
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2618	0.4189
Y	259	127	4	3.1	132	13	9.8	2.90	(0.94, 8.91)	0.0517	0.4189
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	7	13.5	6.50	(0.80, 53.01)	0.0445	0.3844
POST-MENOPAUSAL	214	110	3	2.7	104	7	6.7	2.29	(0.59, 8.89)	0.2175	0.3844
Time to First Gastrointestinal disorders, Gastrooesophageal reflux disease											
All Patients	324	163	2	1.2	161	14	8.7	6.29	(1.42, 27.78)	0.0055	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	1	0.8	137	13	9.5	10.26	(1.34, 78.87)	0.0057	0.2626
>=65	58	34	1	2.9	24	1	4.2	1.48	(0.09, 23.72)	0.7790	0.2626
Sex											
F	318	162	2	1.2	156	14	9.0	6.46	(1.46, 28.56)	0.0047	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	0	0.0	58	6	10.3	>999.99	(0.00, >999.99)	0.0182	0.3450
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	8	12.7	3.68	(0.78, 17.43)	0.0784	0.3450
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.3450
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2652	0.5461
Y	259	127	2	1.6	132	13	9.8	5.37	(1.21, 23.92)	0.0136	0.5461
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	6	11.5	>999.99	(0.00, >999.99)	0.0162	0.1695
POST-MENOPAUSAL	214	110	2	1.8	104	8	7.7	3.66	(0.77, 17.34)	0.0804	0.1695
Time to First Gastrointestinal disorders, Dry mouth											
All Patients	324	163	5	3.1	161	9	5.6	1.77	(0.59, 5.28)	0.3004	NE
Age group (years)											
<65	266	129	4	3.1	137	9	6.6	2.03	(0.62, 6.59)	0.2308	0.2013
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.2013
Sex											
F	318	162	5	3.1	156	8	5.1	1.64	(0.54, 5.02)	0.3810	0.6319
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.6319
Region											
ASIA	120	62	2	3.2	58	2	3.4	1.05	(0.15, 7.43)	0.9673	0.1876
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	6	9.5	5.97	(0.72, 49.57)	0.0595	0.1876
OTHER	78	38	2	5.3	40	1	2.5	0.47	(0.04, 5.19)	0.5282	0.1876
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	0	0.0	<0.01	(0.00, >999.99)	0.1221	0.0091
Y	259	127	2	1.6	132	9	6.8	4.20	(0.91, 19.47)	0.0458	0.0091
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	3	5.8	1.02	(0.21, 5.05)	0.9836	0.4002
POST-MENOPAUSAL	214	110	2	1.8	104	5	4.8	2.56	(0.50, 13.22)	0.2432	0.4002
Time to First Gastrointestinal disorders, Haemorrhoids											
All Patients	324	163	3	1.8	161	11	6.8	2.96	(0.82, 10.70)	0.0824	NE
Age group (years)											
<65	266	129	3	2.3	137	11	8.0	2.61	(0.72, 9.46)	0.1290	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	3	1.9	156	10	6.4	2.74	(0.75, 10.06)	0.1130	0.6737
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.6737
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.2048	0.5143

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	7	11.1	3.02	(0.62, 14.71)	0.1514	0.5143
OTHER	78	38	1	2.6	40	2	5.0	1.46	(0.13, 16.94)	0.7593	0.5143
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.47	(0.04, 5.34)	0.5333	0.0712
Y	259	127	1	0.8	132	10	7.6	7.75	(0.99, 60.83)	0.0214	0.0712
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	6	11.5	>999.99	(0.00, >999.99)	0.0357	0.0409
POST-MENOPAUSAL	214	110	3	2.7	104	4	3.8	1.23	(0.27, 5.52)	0.7864	0.0409
Time to First Gastrointestinal disorders, Toothache											
All Patients	324	163	4	2.5	161	10	6.2	1.93	(0.60, 6.20)	0.2626	NE
Age group (years)											
<65	266	129	3	2.3	137	10	7.3	2.30	(0.63, 8.46)	0.1969	0.1712
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3743	0.1712
Sex											
F	318	162	4	2.5	156	9	5.8	1.73	(0.53, 5.66)	0.3605	0.6054
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.6054
Region											
ASIA	120	62	1	1.6	58	5	8.6	4.48	(0.52, 38.73)	0.1358	0.1847
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	5	7.9	1.98	(0.38, 10.28)	0.4091	0.1847
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1757	0.1847
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.59	(0.04, 9.71)	0.7119	0.6300
Y	259	127	3	2.4	132	9	6.8	2.28	(0.61, 8.47)	0.2062	0.6300
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	3	5.8	>999.99	(0.00, >999.99)	0.1911	0.1415
POST-MENOPAUSAL	214	110	4	3.6	104	6	5.8	1.29	(0.36, 4.59)	0.6977	0.1415
Time to First Gastrointestinal disorders, Aphthous ulcer											
All Patients	324	163	3	1.8	161	8	5.0	2.51	(0.66, 9.47)	0.1605	NE
Age group (years)											
<65	266	129	1	0.8	137	7	5.1	5.75	(0.70, 46.83)	0.0647	0.1778
>=65	58	34	2	5.9	24	1	4.2	0.78	(0.07, 8.59)	0.8354	0.1778
Sex											
F	318	162	3	1.9	156	8	5.1	2.58	(0.68, 9.74)	0.1473	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.81	(0.05, 13.24)	0.8831	0.7427
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	7	11.1	3.48	(0.72, 16.78)	0.0967	0.7427
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.7427
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2528	0.3467
Y	259	127	3	2.4	132	7	5.3	2.05	(0.53, 7.95)	0.2892	0.3467
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	4	7.7	>999.99	(0.00, >999.99)	0.0463	0.0765

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihoood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	3	2.7	104	4	3.8	1.30	(0.29, 5.84)	0.7283	0.0765
Time to First Gastrointestinal disorders, Flatulence											
All Patients	324	163	4	2.5	161	6	3.7	1.14	(0.32, 4.10)	0.8427	NE
Age group (years)											
<65	266	129	4	3.1	137	5	3.6	0.79	(0.21, 3.03)	0.7330	0.1651
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.1651
Sex											
F	318	162	4	2.5	156	6	3.8	1.15	(0.32, 4.15)	0.8332	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.2977
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	6	9.5	1.78	(0.44, 7.18)	0.4098	0.2977
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1432	0.2977
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.0565	0.0455
Y	259	127	2	1.6	132	6	4.5	2.32	(0.46, 11.70)	0.2927	0.0455
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6336	0.3358
POST-MENOPAUSAL	214	110	4	3.6	104	5	4.8	1.08	(0.29, 4.08)	0.9094	0.3358
Time to First Gastrointestinal disorders, Gingival pain											
All Patients	324	163	1	0.6	161	7	4.3	5.92	(0.72, 48.45)	0.0602	NE
Age group (years)											
<65	266	129	1	0.8	137	7	5.1	5.23	(0.64, 42.89)	0.0863	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	1	0.6	156	7	4.5	6.09	(0.74, 49.83)	0.0553	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3537	0.7513
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	5	7.9	4.37	(0.51, 37.67)	0.1438	0.7513
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3600	0.7513
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	2	6.9	2.22	(0.20, 24.81)	0.5068	0.1808
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0493	0.1808
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6464	0.6245
POST-MENOPAUSAL	214	110	1	0.9	104	6	5.8	5.88	(0.71, 48.88)	0.0630	0.6245
Time to First Gastrointestinal disorders, Abdominal distension											
All Patients	324	163	3	1.8	161	4	2.5	1.09	(0.24, 4.91)	0.9105	NE
Age group (years)											
<65	266	129	3	2.3	137	4	2.9	0.95	(0.21, 4.30)	0.9498	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	3	1.9	156	4	2.6	1.09	(0.24, 4.94)	0.9089	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.1659	0.2382
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	1	1.6	0.40	(0.04, 4.41)	0.4377	0.2382
OTHER	78	38	1	2.6	40	1	2.5	0.80	(0.05, 12.97)	0.8751	0.2382
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.0833	0.1948
Y	259	127	2	1.6	132	4	3.0	1.61	(0.29, 8.83)	0.5801	0.1948
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	2	3.8	1.39	(0.12, 15.61)	0.7882	0.7633
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.89	(0.12, 6.42)	0.9061	0.7633
Time to First Gastrointestinal disorders, Mouth ulceration											
All Patients	324	163	2	1.2	161	5	3.1	1.92	(0.36, 10.08)	0.4359	NE
Age group (years)											
<65	266	129	2	1.6	137	5	3.6	1.68	(0.32, 8.89)	0.5400	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	5	3.2	1.92	(0.36, 10.16)	0.4374	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	2	3.4	0.96	(0.13, 6.80)	0.9645	0.2573
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.2573
OTHER	78	38	0	0.0	40	3	7.5	>999.99	(0.00, >999.99)	0.1725	0.2573
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.65	(0.03, 12.16)	0.7722	0.5124
Y	259	127	1	0.8	132	4	3.0	3.22	(0.36, 29.16)	0.2720	0.5124
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	3	5.8	>999.99	(0.00, >999.99)	0.0994	0.1016
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.65	(0.09, 4.83)	0.6709	0.1016
Time to First Gastrointestinal disorders, Odynophagia											
All Patients	324	163	2	1.2	161	5	3.1	1.94	(0.37, 10.16)	0.4265	NE
Age group (years)											
<65	266	129	2	1.6	137	4	2.9	1.25	(0.22, 7.04)	0.7997	0.2607
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.2607
Sex											
F	318	162	2	1.2	156	4	2.6	1.70	(0.31, 9.44)	0.5384	0.6170
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.6170
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	5	7.9	2.15	(0.41, 11.20)	0.3503	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	3	10.3	2.90	(0.29, 28.58)	0.3406	0.6516
Y	259	127	1	0.8	132	2	1.5	1.67	(0.15, 18.66)	0.6727	0.6516
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	2	3.8	0.82	(0.11, 5.96)	0.8467	0.1220
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.2026	0.1220
Time to First Gastrointestinal disorders, Oral pain											
All Patients	324	163	1	0.6	161	6	3.7	5.95	(0.72, 49.46)	0.0604	NE
Age group (years)											
<65	266	129	1	0.8	137	6	4.4	5.42	(0.65, 45.03)	0.0793	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	1	0.6	156	6	3.8	6.11	(0.74, 50.79)	0.0558	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.1637	0.6841
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	4	6.3	4.07	(0.45, 36.38)	0.1738	0.6841
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.6841
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	1.27	(0.08, 20.27)	0.8665	0.1110
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0324	0.1110
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	1.01	(0.06, 16.14)	0.9945	0.0772
POST-MENOPAUSAL	214	110	0	0.0	104	5	4.8	>999.99	(0.00, >999.99)	0.0220	0.0772
Time to First Gastrointestinal disorders, Anal fissure											
All Patients	324	163	1	0.6	161	4	2.5	3.50	(0.39, 31.41)	0.2331	NE
Age group (years)											
<65	266	129	1	0.8	137	4	2.9	3.10	(0.35, 27.90)	0.2868	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	3	1.9	2.83	(0.29, 27.28)	0.3464	0.7116
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.7116
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.8090
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	3	4.8	2.76	(0.29, 26.58)	0.3584	0.8090
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	0.8090
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	1	0.8	132	4	3.0	3.20	(0.36, 28.76)	0.2728	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.4393
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.95	(0.18, 21.51)	0.5790	0.4393

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Gastrointestinal disorders, Dental caries											
All Patients	324	163	3	1.8	161	2	1.2	0.47	(0.08, 2.85)	0.4031	NE
Age group (years)											
<65	266	129	2	1.6	137	2	1.5	0.57	(0.08, 4.02)	0.5638	0.4142
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.4142
Sex											
F	318	162	3	1.9	156	2	1.3	0.49	(0.08, 2.94)	0.4245	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.2662	0.0352
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	0	0.0	<0.01	(0.00, >999.99)	0.1291	0.0352
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1441	0.0352
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.81	(0.05, 12.91)	0.8797	0.5942
Y	259	127	2	1.6	132	1	0.8	0.36	(0.03, 3.98)	0.3827	0.5942
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.57	(0.04, 9.10)	0.6865	0.8317
POST-MENOPAUSAL	214	110	2	1.8	104	1	1.0	0.42	(0.04, 4.66)	0.4661	0.8317
Time to First Gastrointestinal disorders, Dysphagia											
All Patients	324	163	1	0.6	161	3	1.9	2.32	(0.24, 22.32)	0.4531	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	2.03	(0.21, 19.56)	0.5310	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	3	1.9	2.39	(0.25, 23.01)	0.4359	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	3	4.8	2.76	(0.29, 26.52)	0.3596	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	3	2.3	2.12	(0.22, 20.38)	0.5057	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	3	2.9	2.61	(0.27, 25.09)	0.3883	1.0000
Time to First Gastrointestinal disorders, Gastritis											
All Patients	324	163	2	1.2	161	1	0.6	0.29	(0.03, 3.36)	0.2958	NE
Age group (years)											
<65	266	129	2	1.6	137	1	0.7	0.24	(0.02, 2.86)	0.2290	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	2	1.2	156	1	0.6	0.29	(0.03, 3.41)	0.3013	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2059	0.1715
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.0679	0.1715
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3372	0.1715
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.71	(0.04, 13.01)	0.8149	0.2774
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1844	0.2774
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.1573	0.3255
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.55	(0.03, 9.98)	0.6839	0.3255
Time to First Gastrointestinal disorders, Proctalgia											
All Patients	324	163	1	0.6	161	2	1.2	1.76	(0.16, 19.52)	0.6389	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.58	(0.14, 17.48)	0.7078	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.81	(0.16, 20.06)	0.6223	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.1647
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2857	0.1647
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2064	0.1647
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	2	1.5	1.62	(0.15, 17.90)	0.6931	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.3287
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.89	(0.06, 14.30)	0.9371	0.3287
Time to First Gastrointestinal disorders, Anal fistula											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2666	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3068	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5298	0.9999
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.9999
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3469	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5351	1.0000
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likeli- hood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2847	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5050	1.0000
Time to First Gastrointestinal disorders, Anorectal discomfort											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2476	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2854	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2448	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3090	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5351	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2626	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6015	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3126	1.0000
Time to First Gastrointestinal disorders, Haematochezia											
All Patients	324	163	1	0.6	161	1	0.6	0.66	(0.04, 10.49)	0.7633	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.58	(0.04, 9.29)	0.6969	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.62	(0.04, 10.02)	0.7357	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.78	(0.05, 12.53)	0.8589	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2207	0.1117
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4254	0.1117
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.60	(0.04, 9.91)	0.7206	1.0000
Time to First Gastrointestinal disorders, Lip ulceration											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2267	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2552	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2205	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.2297	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2417	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.2695	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Periodontal disease											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2265	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4003	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2429	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2192	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.2282	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2470	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1932	1.0000
Time to First Gastrointestinal disorders, Rectal haemorrhage											
All Patients	324	163	1	0.6	161	1	0.6	0.93	(0.06, 14.88)	0.9579	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2463	0.0630
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.0630
Sex											
F	318	162	1	0.6	156	1	0.6	0.95	(0.06, 15.28)	0.9729	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2877	0.2493
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	0.2493
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.2493
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.85	(0.05, 13.66)	0.9091	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.99	(0.06, 15.91)	0.9964	1.0000
Time to First Gastrointestinal disorders, Abdominal discomfort											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3264	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3080	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Abdominal hernia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3689	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4084	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3621	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4241	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3967	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3355	1.0000
Time to First Gastrointestinal disorders, Abdominal pain lower											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Gastrointestinal disorders, Abdominal rigidity											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2364	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2051	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2431	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2864	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3268	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.1984	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Abdominal tenderness											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Gastrointestinal disorders, Anal erythema											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Anal haemorrhage											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.0973	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0679	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.0932	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.0973	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.0771	1.0000
Time to First Gastrointestinal disorders, Anal inflammation											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2566	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4193	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2636	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2918	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2304	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2855	1.0000
Time to First Gastrointestinal disorders, Anal pruritus											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5164	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5677	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5101	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5329	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5224	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6374	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Angular cheilitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3645	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3576	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3423	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3908	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4093	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Anorectal disorder											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3484	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3786	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3420	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3519	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3745	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3613	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Ascites											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Gastrointestinal disorders, Cheilitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3421	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3702	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3359	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3468	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3632	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3379	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Cheilosis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4510	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4882	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4423	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3890	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3954	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4795	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Chronic gastritis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3638	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4011	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3570	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3545	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3922	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4021	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Coating in mouth											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3319	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3082	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3037	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Gastrointestinal disorders, Diverticulum intestinal											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2969	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3251	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3865	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Eructation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4033	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2604	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3965	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4193	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4319	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3757	1.0000
Time to First Gastrointestinal disorders, Faeces pale											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1757	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1380	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1839	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2457	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2034	1.0000
Time to First Gastrointestinal disorders, Food poisoning											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2767	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2482	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2833	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2987	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3674	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2482	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Gastric ulcer											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4264	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4623	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4180	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3627	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likeli- hood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4425	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3813	1.0000
Time to First Gastrointestinal disorders, Gastrointestinal disorder											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4066	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4426	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3985	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3372	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4227	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4431	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Gastrointestinal haemorrhage											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4857	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5338	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4762	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5186	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5040	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Gingival erythema											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3205	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3442	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3141	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3254	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3390	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3076	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Gingival recession											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3426	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3729	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3363	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3559	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2618	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3326	1.0000
Time to First Gastrointestinal disorders, Glossitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Gastrointestinal disorders, Glossodynia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Gastrointestinal disorders, Haemorrhoids thrombosed											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3416	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3126	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3365	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Hiatus hernia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3205	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3442	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3141	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3372	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3173	1.0000
Time to First Gastrointestinal disorders, Intestinal obstruction											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Gastrointestinal disorders, Intestinal perforation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4264	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4623	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4180	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3627	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4425	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3813	1.0000
Time to First Gastrointestinal disorders, Lip oedema											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1967	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2049	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2059	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1814	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.1441	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Loose tooth											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1353	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3458	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1416	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1662	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1138	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1967	1.0000
Time to First Gastrointestinal disorders, Oesophageal pain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Oesophageal stenosis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2925	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2645	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2988	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2879	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2714	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihoood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2998	1.0000
Time to First Gastrointestinal disorders, Oesophagitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Gastrointestinal disorders, Proctitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5271	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5804	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5298	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5351	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5338	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5050	1.0000
Time to First Gastrointestinal disorders, Salivary hypersecretion											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3590	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3852	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3525	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3490	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2673	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3800	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Tongue pruritus											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3110	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Gastrointestinal disorders, Tooth loss											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4842	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5371	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4795	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4561	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4920	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5930	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First General disorders and administration site conditions, Any											
All Patients	324	163	88	54.0	161	97	60.2	1.03	(0.77, 1.38)	0.8538	NE
Age group (years)											
<65	266	129	69	53.5	137	84	61.3	1.06	(0.77, 1.46)	0.7323	0.6390
>=65	58	34	19	55.9	24	13	54.2	0.83	(0.41, 1.70)	0.6178	0.6390
Sex											
F	318	162	87	53.7	156	93	59.6	1.04	(0.77, 1.40)	0.8042	0.3991
M	6	1	1	100.0	5	4	80.0	0.22	(0.01, 3.59)	0.2467	0.3991
Region											
ASIA	120	62	27	43.5	58	31	53.4	1.06	(0.63, 1.80)	0.8165	0.7338
NORTH AMERICA/WESTERN EUROPE	126	63	42	66.7	63	45	71.4	1.15	(0.75, 1.75)	0.5245	0.7338
OTHER	78	38	19	50.0	40	21	52.5	0.77	(0.41, 1.47)	0.4344	0.7338
Visceral disease (per eCRF)											
N	65	36	24	66.7	29	14	48.3	0.57	(0.29, 1.12)	0.0973	0.0197
Y	259	127	64	50.4	132	83	62.9	1.21	(0.87, 1.68)	0.2573	0.0197
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	28	53.8	52	32	61.5	1.06	(0.63, 1.76)	0.8330	0.9499
POST-MENOPAUSAL	214	110	59	53.6	104	61	58.7	1.04	(0.72, 1.50)	0.8379	0.9499
Time to First General disorders and administration site conditions, Fatigue											
All Patients	324	163	24	14.7	161	46	28.6	1.76	(1.07, 2.89)	0.0239	NE
Age group (years)											
<65	266	129	19	14.7	137	42	30.7	1.87	(1.08, 3.23)	0.0225	0.5236
>=65	58	34	5	14.7	24	4	16.7	1.17	(0.31, 4.35)	0.8173	0.5236
Sex											
F	318	162	24	14.8	156	45	28.8	1.78	(1.08, 2.92)	0.0222	0.5764
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.5764
Region											
ASIA	120	62	2	3.2	58	13	22.4	6.13	(1.37, 27.43)	0.0070	0.0089
NORTH AMERICA/WESTERN EUROPE	126	63	10	15.9	63	23	36.5	2.24	(1.06, 4.72)	0.0293	0.0089
OTHER	78	38	12	31.6	40	10	25.0	0.62	(0.26, 1.44)	0.2649	0.0089
Visceral disease (per eCRF)											
N	65	36	6	16.7	29	3	10.3	0.52	(0.13, 2.12)	0.3565	0.0516
Y	259	127	18	14.2	132	43	32.6	2.11	(1.22, 3.68)	0.0067	0.0516
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	9	17.3	52	13	25.0	1.03	(0.43, 2.45)	0.9494	0.2369
POST-MENOPAUSAL	214	110	15	13.6	104	32	30.8	2.26	(1.22, 4.18)	0.0076	0.2369

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First General disorders and administration site conditions, Mucosal inflammation											
All Patients	324	163	19	11.7	161	33	20.5	1.74	(0.99, 3.07)	0.0525	NE
Age group (years)											
<65	266	129	14	10.9	137	30	21.9	1.95	(1.03, 3.69)	0.0364	0.3328
>=65	58	34	5	14.7	24	3	12.5	0.93	(0.22, 3.92)	0.9251	0.3328
Sex											
F	318	162	19	11.7	156	31	19.9	1.69	(0.95, 3.00)	0.0701	0.4631
M	6	1	0	0.0	5	2	40.0	>999.99	(0.00, >999.99)	0.5024	0.4631
Region											
ASIA	120	62	8	12.9	58	10	17.2	1.29	(0.51, 3.29)	0.5909	0.5716
NORTH AMERICA/WESTERN EUROPE	126	63	9	14.3	63	16	25.4	1.84	(0.81, 4.18)	0.1394	0.5716
OTHER	78	38	2	5.3	40	7	17.5	3.15	(0.65, 15.35)	0.1342	0.5716
Visceral disease (per eCRF)											
N	65	36	7	19.4	29	8	27.6	1.54	(0.56, 4.26)	0.3967	0.6045
Y	259	127	12	9.4	132	25	18.9	1.93	(0.97, 3.85)	0.0589	0.6045
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	6	11.5	52	10	19.2	1.55	(0.56, 4.29)	0.3986	0.8984
POST-MENOPAUSAL	214	110	13	11.8	104	21	20.2	1.79	(0.89, 3.57)	0.0970	0.8984
Time to First General disorders and administration site conditions, Asthenia											
All Patients	324	163	23	14.1	161	27	16.8	1.02	(0.58, 1.79)	0.9419	NE
Age group (years)											
<65	266	129	15	11.6	137	22	16.1	1.16	(0.60, 2.25)	0.6624	0.6005
>=65	58	34	8	23.5	24	5	20.8	0.82	(0.27, 2.54)	0.7350	0.6005
Sex											
F	318	162	23	14.2	156	26	16.7	1.00	(0.57, 1.76)	0.9961	0.4796
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.4796
Region											
ASIA	120	62	0	0.0	58	3	5.2	>999.99	(0.00, >999.99)	0.1364	0.1145
NORTH AMERICA/WESTERN EUROPE	126	63	16	25.4	63	14	22.2	0.84	(0.41, 1.73)	0.6398	0.1145
OTHER	78	38	7	18.4	40	10	25.0	0.89	(0.33, 2.41)	0.8254	0.1145
Visceral disease (per eCRF)											
N	65	36	8	22.2	29	6	20.7	0.93	(0.32, 2.69)	0.8920	0.5682
Y	259	127	15	11.8	132	21	15.9	1.12	(0.58, 2.19)	0.7350	0.5682
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	6	11.5	52	9	17.3	1.33	(0.47, 3.75)	0.5910	0.5097
POST-MENOPAUSAL	214	110	17	15.5	104	17	16.3	0.90	(0.46, 1.78)	0.7601	0.5097
Time to First General disorders and administration site conditions, Pyrexia											
All Patients	324	163	16	9.8	161	18	11.2	0.86	(0.43, 1.71)	0.6701	NE
Age group (years)											
<65	266	129	13	10.1	137	18	13.1	0.97	(0.47, 2.00)	0.9273	0.0878
>=65	58	34	3	8.8	24	0	0.0	<0.01	(0.00, >999.99)	0.1225	0.0878

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	15	9.3	156	17	10.9	0.90	(0.45, 1.83)	0.7811	0.3399
M	6	1	1	100.0	5	1	20.0	0.22	(0.01, 3.59)	0.2467	0.3399
Region											
ASIA	120	62	4	6.5	58	9	15.5	1.92	(0.58, 6.28)	0.2741	0.0771
NORTH AMERICA/WESTERN EUROPE	126	63	12	19.0	63	7	11.1	0.41	(0.15, 1.12)	0.0726	0.0771
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2181	0.0771
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	2	6.9	0.45	(0.08, 2.48)	0.3443	0.4179
Y	259	127	12	9.4	132	16	12.1	0.99	(0.46, 2.11)	0.9762	0.4179
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	4	7.7	52	10	19.2	2.01	(0.62, 6.47)	0.2334	0.0836
POST-MENOPAUSAL	214	110	11	10.0	104	7	6.7	0.49	(0.19, 1.30)	0.1433	0.0836
Time to First General disorders and administration site conditions, Oedema peripheral											
All Patients	324	163	6	3.7	161	12	7.5	1.70	(0.64, 4.57)	0.2844	NE
Age group (years)											
<65	266	129	4	3.1	137	12	8.8	2.23	(0.71, 6.98)	0.1574	0.0673
>=65	58	34	2	5.9	24	0	0.0	<0.01	(0.00, >999.99)	0.2517	0.0673
Sex											
F	318	162	6	3.7	156	12	7.7	1.75	(0.65, 4.69)	0.2608	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	3	4.8	58	6	10.3	1.67	(0.41, 6.85)	0.4688	0.4229
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	4	6.3	1.16	(0.26, 5.23)	0.8429	0.4229
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.1975	0.4229
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.62	(0.06, 6.89)	0.6983	0.2905
Y	259	127	4	3.1	132	11	8.3	2.10	(0.67, 6.66)	0.1956	0.2905
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	4	7.7	1.72	(0.31, 9.51)	0.5304	0.9205
POST-MENOPAUSAL	214	110	4	3.6	104	8	7.7	1.80	(0.54, 6.02)	0.3336	0.9205
Time to First General disorders and administration site conditions, Pain											
All Patients	324	163	8	4.9	161	7	4.3	0.64	(0.23, 1.78)	0.3885	NE
Age group (years)											
<65	266	129	7	5.4	137	6	4.4	0.54	(0.18, 1.62)	0.2656	0.5570
>=65	58	34	1	2.9	24	1	4.2	1.33	(0.08, 21.37)	0.8421	0.5570
Sex											
F	318	162	8	4.9	156	7	4.5	0.66	(0.24, 1.83)	0.4231	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	3	4.8	58	2	3.4	0.44	(0.07, 2.69)	0.3641	0.5920
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	3	4.8	1.39	(0.23, 8.31)	0.7188	0.5920

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	3	7.9	40	2	5.0	0.34	(0.06, 2.08)	0.2222	0.5920
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	2	6.9	0.38	(0.07, 2.12)	0.2537	0.5454
Y	259	127	4	3.1	132	5	3.8	0.95	(0.25, 3.55)	0.9379	0.5454
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	1	1.9	0.37	(0.03, 4.29)	0.4128	0.4526
POST-MENOPAUSAL	214	110	6	5.5	104	6	5.8	0.82	(0.26, 2.54)	0.7261	0.4526
Time to First General disorders and administration site conditions, Chest pain											
All Patients	324	163	8	4.9	161	4	2.5	0.40	(0.12, 1.35)	0.1273	NE
Age group (years)											
<65	266	129	6	4.7	137	3	2.2	0.34	(0.09, 1.40)	0.1190	0.6197
>=65	58	34	2	5.9	24	1	4.2	0.69	(0.06, 7.63)	0.7591	0.6197
Sex											
F	318	162	8	4.9	156	4	2.6	0.41	(0.12, 1.38)	0.1380	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	3	4.8	58	3	5.2	0.79	(0.16, 3.97)	0.7718	0.4355
NORTH AMERICA/WESTERN EUROPE	126	63	5	7.9	63	1	1.6	0.18	(0.02, 1.56)	0.0806	0.4355
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.4355
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	0	0.0	<0.01	(0.00, >999.99)	0.1152	0.1277
Y	259	127	5	3.9	132	4	3.0	0.59	(0.16, 2.22)	0.4304	0.1277
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	2	3.8	0.79	(0.11, 5.65)	0.8143	0.3947
POST-MENOPAUSAL	214	110	6	5.5	104	2	1.9	0.26	(0.05, 1.34)	0.0855	0.3947
Time to First General disorders and administration site conditions, Chills											
All Patients	324	163	3	1.8	161	3	1.9	0.84	(0.17, 4.18)	0.8315	NE
Age group (years)											
<65	266	129	3	2.3	137	3	2.2	0.75	(0.15, 3.72)	0.7203	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	3	1.9	1.26	(0.21, 7.57)	0.8003	0.0129
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0253	0.0129
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	3	4.8	0.91	(0.18, 4.54)	0.9127	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3268	0.2711
Y	259	127	2	1.6	132	3	2.3	1.20	(0.20, 7.21)	0.8438	0.2711
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4404	0.3108

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.93	(0.13, 6.62)	0.9421	0.3108
Time to First General disorders and administration site conditions, Influenza like illness											
All Patients	324	163	3	1.8	161	2	1.2	0.45	(0.07, 2.76)	0.3769	NE
Age group (years)											
<65	266	129	3	2.3	137	1	0.7	0.21	(0.02, 2.10)	0.1468	0.0708
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.3428	0.0708
Sex											
F	318	162	3	1.9	156	2	1.3	0.46	(0.08, 2.84)	0.3940	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.1822
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.32	(0.12, 14.91)	0.8239	0.1822
OTHER	78	38	2	5.3	40	0	0.0	<0.01	(0.00, >999.99)	0.0744	0.1822
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	3	2.4	132	2	1.5	0.42	(0.07, 2.59)	0.3383	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6095	0.1726
POST-MENOPAUSAL	214	110	3	2.7	104	1	1.0	0.28	(0.03, 2.69)	0.2372	0.1726
Time to First General disorders and administration site conditions, Malaise											
All Patients	324	163	3	1.8	161	2	1.2	0.52	(0.08, 3.15)	0.4671	NE
Age group (years)											
<65	266	129	3	2.3	137	1	0.7	0.23	(0.02, 2.28)	0.1731	0.0806
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2604	0.0806
Sex											
F	318	162	3	1.9	156	2	1.3	0.53	(0.09, 3.24)	0.4864	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	2	3.4	0.91	(0.13, 6.55)	0.9289	0.5621
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1797	0.5621
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.5621
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.1266	0.1240
Y	259	127	1	0.8	132	2	1.5	1.64	(0.15, 18.25)	0.6840	0.1240
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	1.01	(0.06, 16.15)	0.9943	0.7970
POST-MENOPAUSAL	214	110	2	1.8	104	1	1.0	0.38	(0.03, 4.26)	0.4175	0.7970
Time to First General disorders and administration site conditions, Axillary pain											
All Patients	324	163	2	1.2	161	2	1.2	0.66	(0.09, 4.78)	0.6757	NE
Age group (years)											
<65	266	129	2	1.6	137	2	1.5	0.58	(0.08, 4.23)	0.5888	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	2	1.2	156	2	1.3	0.67	(0.09, 4.87)	0.6876	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.78	(0.05, 12.66)	0.8608	0.2219
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3428	0.2219
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1380	0.2219
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2618	0.1509
Y	259	127	2	1.6	132	1	0.8	0.27	(0.02, 3.02)	0.2538	0.1509
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.66	(0.09, 4.95)	0.6844	1.0000
Time to First General disorders and administration site conditions, Injection site pain											
All Patients	324	163	3	1.8	161	1	0.6	0.33	(0.03, 3.19)	0.3145	NE
Age group (years)											
<65	266	129	3	2.3	137	1	0.7	0.30	(0.03, 2.93)	0.2745	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	3	1.9	156	1	0.6	0.34	(0.04, 3.27)	0.3269	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	1	1.6	0.32	(0.03, 3.11)	0.3025	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	3	2.4	132	1	0.8	0.31	(0.03, 2.99)	0.2841	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	0	0.0	<0.01	(0.00, >999.99)	0.1552	0.1818
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	1.04	(0.06, 16.60)	0.9787	0.1818
Time to First General disorders and administration site conditions, Peripheral swelling											
All Patients	324	163	1	0.6	161	3	1.9	1.86	(0.19, 18.33)	0.5908	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	1.58	(0.16, 15.73)	0.6954	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	3	1.9	1.79	(0.18, 17.95)	0.6148	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.6377
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	0.6377

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	1	2.6	40	2	5.0	1.00	(0.09, 11.05)	1.0000	0.6377
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.5637	0.4054
Y	259	127	1	0.8	132	2	1.5	1.33	(0.12, 14.99)	0.8152	0.4054
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	3	2.9	1.87	(0.19, 18.77)	0.5879	1.0000
Time to First General disorders and administration site conditions, Chest discomfort											
All Patients	324	163	2	1.2	161	1	0.6	0.41	(0.04, 4.59)	0.4525	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.65	(0.04, 10.80)	0.7603	0.4117
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.4117
Sex											
F	318	162	2	1.2	156	1	0.6	0.42	(0.04, 4.73)	0.4695	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	1	1.6	0.45	(0.04, 5.01)	0.5071	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	1.00	(0.06, 16.45)	1.0000	0.2566
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3040	0.2566
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	1	1.0	0.44	(0.04, 4.95)	0.4969	1.0000
Time to First General disorders and administration site conditions, Injection site erythema											
All Patients	324	163	1	0.6	161	2	1.2	1.87	(0.17, 20.65)	0.6054	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.69	(0.15, 18.72)	0.6662	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.92	(0.17, 21.21)	0.5895	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3698	0.1540
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.1540
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	0.1540
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.1175	0.0382
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3080	0.0382
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	2	3.8	1.76	(0.16, 19.55)	0.6417	0.9999

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	0.9999
Time to First General disorders and administration site conditions, Oedema											
All Patients	324	163	0	0.0	161	3	1.9	>999.99	(0.00, >999.99)	0.1910	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.2350	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2769	0.9999
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.9999
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5186	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3865	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.3030	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.3988	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First General disorders and administration site conditions, Ill-defined disorder											
All Patients	324	163	1	0.6	161	1	0.6	0.69	(0.04, 11.15)	0.7906	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.60	(0.04, 9.72)	0.7130	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.71	(0.04, 11.51)	0.8085	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.82	(0.05, 13.06)	0.8858	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2705	0.1306
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3871	0.1306
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.76	(0.05, 12.29)	0.8476	1.0000
Time to First General disorders and administration site conditions, Injection site bruising											
All Patients	324	163	1	0.6	161	1	0.6	1.02	(0.06, 16.24)	0.9912	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.93	(0.06, 14.87)	0.9591	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	1.04	(0.07, 16.67)	0.9765	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	1.02	(0.06, 16.25)	0.9909	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3865	0.1161
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	0.1161
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.0922
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	0.0922
Time to First General disorders and administration site conditions, Catheter site pain											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3220	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3255	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2981	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3243	1.0000
Time to First General disorders and administration site conditions, Death											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4088	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4008	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5016	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4254	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3819	1.0000
Time to First General disorders and administration site conditions, Facial pain											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2683	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2301	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2751	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2850	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3613	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2994	1.0000
Time to First General disorders and administration site conditions, Gait disturbance											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First General disorders and administration site conditions, Hyperthermia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4022	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4296	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3953	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3511	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4297	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3726	1.0000
Time to First General disorders and administration site conditions, Injection site discomfort											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First General disorders and administration site conditions, Injection site pruritus											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3188	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2969	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3251	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3255	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3021	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3289	1.0000
Time to First General disorders and administration site conditions, Injection site reaction											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4177	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4541	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4094	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4386	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4367	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4862	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First General disorders and administration site conditions, Localised oedema											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5019	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5465	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4939	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5002	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5091	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6056	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First General disorders and administration site conditions, Mass											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4419	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4795	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4334	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3841	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4622	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4063	1.0000
Time to First General disorders and administration site conditions, Non-cardiac chest pain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3319	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3014	1.0000
Time to First General disorders and administration site conditions, Soft tissue inflammation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3584	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3821	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3520	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3954	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3858	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3736	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First General disorders and administration site conditions, Swelling face											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1459	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1025	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1543	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.1213	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1277	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2049	1.0000
Time to First General disorders and administration site conditions, Systemic inflammatory response syndrome											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2518	NE

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2187	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2587	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2918	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3359	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2100	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First General disorders and administration site conditions, Thirst											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First General disorders and administration site conditions, Unevaluable event											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1432	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0981	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1498	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1742	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1294	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.0455	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First General disorders and administration site conditions, Xerosis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Metabolism and nutrition disorders, Any											
All Patients	324	163	63	38.7	161	119	73.9	2.54	(1.87, 3.45)	<0.0001	NE
Age group (years)											
<65	266	129	52	40.3	137	102	74.5	2.41	(1.72, 3.37)	<0.0001	0.3870
>=65	58	34	11	32.4	24	17	70.8	3.26	(1.52, 7.01)	0.0015	0.3870
Sex											
F	318	162	62	38.3	156	115	73.7	2.56	(1.88, 3.50)	<0.0001	0.4423
M	6	1	1	100.0	5	4	80.0	0.93	(0.09, 9.20)	0.9526	0.4423
Region											
ASIA	120	62	23	37.1	58	48	82.8	3.14	(1.91, 5.18)	<0.0001	0.5725
NORTH AMERICA/WESTERN EUROPE	126	63	26	41.3	63	45	71.4	2.31	(1.42, 3.75)	0.0006	0.5725
OTHER	78	38	14	36.8	40	26	65.0	2.18	(1.13, 4.21)	0.0183	0.5725
Visceral disease (per eCRF)											
N	65	36	16	44.4	29	22	75.9	2.94	(1.52, 5.70)	0.0009	0.8630
Y	259	127	47	37.0	132	97	73.5	2.52	(1.77, 3.57)	<0.0001	0.8630

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	13	25.0	52	36	69.2	3.82	(2.02, 7.23)	<0.0001	0.2247
POST-MENOPAUSAL	214	110	49	44.5	104	79	76.0	2.29	(1.60, 3.29)	<0.0001	0.2247
Time to First Metabolism and nutrition disorders, Hyperglycaemia											
All Patients	324	163	15	9.2	161	91	56.5	7.76	(4.49, 13.41)	<0.0001	NE
Age group (years)											
<65	266	129	13	10.1	137	78	56.9	6.84	(3.80, 12.31)	<0.0001	0.3253
>=65	58	34	2	5.9	24	13	54.2	14.09	(3.16, 62.88)	<0.0001	0.3253
Sex											
F	318	162	15	9.3	156	87	55.8	7.56	(4.36, 13.09)	<0.0001	0.4960
M	6	1	0	0.0	5	4	80.0	>999.99	(0.00, >999.99)	0.2591	0.4960
Region											
ASIA	120	62	4	6.5	58	36	62.1	12.43	(4.41, 34.98)	<0.0001	0.0878
NORTH AMERICA/WESTERN EUROPE	126	63	4	6.3	63	34	54.0	11.00	(3.90, 31.02)	<0.0001	0.0878
OTHER	78	38	7	18.4	40	21	52.5	3.38	(1.43, 8.01)	0.0035	0.0878
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	19	65.5	12.88	(3.79, 43.72)	<0.0001	0.4110
Y	259	127	12	9.4	132	72	54.5	6.87	(3.72, 12.68)	<0.0001	0.4110
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	27	51.9	32.25	(4.36, 238.28)	<0.0001	0.0586
POST-MENOPAUSAL	214	110	14	12.7	104	60	57.7	6.04	(3.37, 10.82)	<0.0001	0.0586
Time to First Metabolism and nutrition disorders, Decreased appetite											
All Patients	324	163	18	11.0	161	44	27.3	2.30	(1.33, 3.99)	0.0023	NE
Age group (years)											
<65	266	129	12	9.3	137	33	24.1	2.36	(1.21, 4.57)	0.0091	0.7359
>=65	58	34	6	17.6	24	11	45.8	2.86	(1.05, 7.74)	0.0308	0.7359
Sex											
F	318	162	18	11.1	156	44	28.2	2.38	(1.37, 4.12)	0.0015	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	6	9.7	58	15	25.9	2.48	(0.96, 6.41)	0.0530	0.8979
NORTH AMERICA/WESTERN EUROPE	126	63	10	15.9	63	21	33.3	2.12	(1.00, 4.51)	0.0453	0.8979
OTHER	78	38	2	5.3	40	8	20.0	2.99	(0.63, 14.28)	0.1502	0.8979
Visceral disease (per eCRF)											
N	65	36	6	16.7	29	8	27.6	1.54	(0.53, 4.49)	0.4282	0.4316
Y	259	127	12	9.4	132	36	27.3	2.66	(1.38, 5.12)	0.0023	0.4316
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	11	21.2	3.70	(1.03, 13.29)	0.0312	0.5670
POST-MENOPAUSAL	214	110	15	13.6	104	33	31.7	2.19	(1.19, 4.03)	0.0101	0.5670
Time to First Metabolism and nutrition disorders, Hypokalaemia											
All Patients	324	163	13	8.0	161	27	16.8	1.95	(1.00, 3.79)	0.0459	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	11	8.5	137	22	16.1	1.71	(0.82, 3.54)	0.1449	0.3152
>=65	58	34	2	5.9	24	5	20.8	4.04	(0.78, 20.90)	0.0714	0.3152
Sex											
F	318	162	13	8.0	156	26	16.7	1.91	(0.98, 3.73)	0.0546	0.5914
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.5914
Region											
ASIA	120	62	8	12.9	58	20	34.5	2.60	(1.14, 5.94)	0.0185	0.0895
NORTH AMERICA/WESTERN EUROPE	126	63	5	7.9	63	4	6.3	0.70	(0.18, 2.65)	0.5909	0.0895
OTHER	78	38	0	0.0	40	3	7.5	>999.99	(0.00, >999.99)	0.1267	0.0895
Visceral disease (per eCRF)											
N	65	36	5	13.9	29	3	10.3	0.58	(0.13, 2.47)	0.4529	0.0925
Y	259	127	8	6.3	132	24	18.2	2.76	(1.24, 6.17)	0.0097	0.0925
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	5	9.6	52	10	19.2	1.68	(0.57, 4.98)	0.3444	0.8403
POST-MENOPAUSAL	214	110	8	7.3	104	16	15.4	2.01	(0.86, 4.73)	0.1012	0.8403
Time to First Metabolism and nutrition disorders, Hypocalcaemia											
All Patients	324	163	4	2.5	161	14	8.7	3.47	(1.14, 10.56)	0.0197	NE
Age group (years)											
<65	266	129	4	3.1	137	14	10.2	3.16	(1.04, 9.62)	0.0327	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	4	2.5	156	14	9.0	3.57	(1.17, 10.86)	0.0168	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	0	0.0	58	6	10.3	>999.99	(0.00, >999.99)	0.0157	0.1238
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	5	7.9	1.72	(0.41, 7.18)	0.4538	0.1238
OTHER	78	38	1	2.6	40	3	7.5	2.59	(0.27, 25.04)	0.3929	0.1238
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	3	10.3	3.39	(0.34, 33.44)	0.2694	0.9358
Y	259	127	3	2.4	132	11	8.3	3.50	(0.98, 12.57)	0.0399	0.9358
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	6	11.5	5.53	(0.66, 46.47)	0.0773	0.5385
POST-MENOPAUSAL	214	110	3	2.7	104	8	7.7	2.85	(0.76, 10.75)	0.1053	0.5385
Time to First Metabolism and nutrition disorders, Hyponatraemia											
All Patients	324	163	5	3.1	161	10	6.2	1.38	(0.47, 4.11)	0.5576	NE
Age group (years)											
<65	266	129	4	3.1	137	7	5.1	1.08	(0.31, 3.79)	0.9059	0.2545
>=65	58	34	1	2.9	24	3	12.5	4.16	(0.43, 40.08)	0.1805	0.2545
Sex											
F	318	162	5	3.1	156	10	6.4	1.42	(0.48, 4.22)	0.5258	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	3	4.8	58	7	12.1	1.54	(0.39, 6.13)	0.5345	0.7887

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.32	(0.12, 14.99)	0.8201	0.7887
OTHER	78	38	1	2.6	40	1	2.5	0.82	(0.05, 13.21)	0.8869	0.7887
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	3	10.3	0.77	(0.15, 3.94)	0.7560	0.3797
Y	259	127	2	1.6	132	7	5.3	2.49	(0.51, 12.19)	0.2463	0.3797
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	2	3.8	0.49	(0.06, 3.93)	0.4943	0.2629
POST-MENOPAUSAL	214	110	3	2.7	104	8	7.7	2.12	(0.56, 8.09)	0.2589	0.2629
Time to First Metabolism and nutrition disorders, Hypertriglyceridaemia											
All Patients	324	163	7	4.3	161	3	1.9	0.33	(0.08, 1.28)	0.0911	NE
Age group (years)											
<65	266	129	6	4.7	137	3	2.2	0.34	(0.08, 1.38)	0.1144	0.5229
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3743	0.5229
Sex											
F	318	162	7	4.3	156	3	1.9	0.34	(0.09, 1.32)	0.1010	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	4	6.5	58	2	3.4	0.43	(0.08, 2.35)	0.3138	0.6304
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	1	1.6	0.43	(0.04, 4.74)	0.4779	0.6304
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.0943	0.6304
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	0	0.0	<0.01	(0.00, >999.99)	0.0813	0.1429
Y	259	127	4	3.1	132	3	2.3	0.54	(0.12, 2.45)	0.4205	0.1429
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5002	0.1205
POST-MENOPAUSAL	214	110	7	6.4	104	2	1.9	0.24	(0.05, 1.18)	0.0574	0.1205
Time to First Metabolism and nutrition disorders, Hypoalbuminaemia											
All Patients	324	163	4	2.5	161	5	3.1	1.10	(0.29, 4.12)	0.8921	NE
Age group (years)											
<65	266	129	4	3.1	137	5	3.6	0.98	(0.26, 3.69)	0.9763	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	4	2.5	156	5	3.2	1.13	(0.30, 4.23)	0.8585	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	4	6.9	1.81	(0.33, 10.04)	0.4896	0.3672
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	0.3672
OTHER	78	38	1	2.6	40	1	2.5	0.69	(0.04, 11.46)	0.7927	0.3672
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	2	6.9	1.83	(0.16, 20.83)	0.6201	0.4805
Y	259	127	3	2.4	132	3	2.3	0.90	(0.18, 4.48)	0.8991	0.4805
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	3	5.8	2.35	(0.23, 23.59)	0.4563	0.3330

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	3	2.7	104	2	1.9	0.65	(0.11, 3.90)	0.6344	0.3330
Time to First Metabolism and nutrition disorders, Hyperkalaemia											
All Patients	324	163	5	3.1	161	3	1.9	0.47	(0.11, 2.02)	0.3006	NE
Age group (years)											
<65	266	129	3	2.3	137	3	2.2	0.77	(0.15, 3.89)	0.7491	0.2539
>=65	58	34	2	5.9	24	0	0.0	<0.01	(0.00, >999.99)	0.2517	0.2539
Sex											
F	318	162	5	3.1	156	3	1.9	0.48	(0.11, 2.06)	0.3120	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	2	3.4	0.65	(0.09, 4.79)	0.6664	0.2825
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	1.02	(0.06, 16.25)	0.9908	0.2825
OTHER	78	38	2	5.3	40	0	0.0	<0.01	(0.00, >999.99)	0.1467	0.2825
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.1367	0.1650
Y	259	127	3	2.4	132	3	2.3	0.80	(0.16, 4.03)	0.7882	0.1650
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.90	(0.06, 14.45)	0.9398	0.6531
POST-MENOPAUSAL	214	110	4	3.6	104	2	1.9	0.38	(0.07, 2.15)	0.2549	0.6531
Time to First Metabolism and nutrition disorders, Hypomagnesaemia											
All Patients	324	163	3	1.8	161	5	3.1	1.37	(0.32, 5.83)	0.6656	NE
Age group (years)											
<65	266	129	3	2.3	137	4	2.9	0.93	(0.20, 4.23)	0.9238	0.1901
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.1901
Sex											
F	318	162	3	1.9	156	5	3.2	1.41	(0.33, 5.97)	0.6426	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5127	0.5574
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	3	4.8	1.43	(0.24, 8.57)	0.6933	0.5574
OTHER	78	38	1	2.6	40	1	2.5	0.65	(0.04, 10.96)	0.7608	0.5574
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.54	(0.05, 6.10)	0.6136	0.2627
Y	259	127	1	0.8	132	4	3.0	3.01	(0.33, 27.37)	0.3036	0.2627
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.3077
POST-MENOPAUSAL	214	110	3	2.7	104	4	3.8	1.09	(0.24, 5.01)	0.9089	0.3077
Time to First Metabolism and nutrition disorders, Hypercalcaemia											
All Patients	324	163	6	3.7	161	1	0.6	0.13	(0.02, 1.13)	0.0309	NE
Age group (years)											
<65	266	129	5	3.9	137	1	0.7	0.14	(0.02, 1.19)	0.0367	0.6627
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.6627

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	6	3.7	156	1	0.6	0.14	(0.02, 1.16)	0.0339	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	2	3.2	58	0	0.0	<0.01	(0.00, >999.99)	0.1661	0.5868
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3134	0.5868
OTHER	78	38	3	7.9	40	1	2.5	0.19	(0.02, 1.92)	0.1212	0.5868
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.0801	0.4425
Y	259	127	4	3.1	132	1	0.8	0.23	(0.03, 2.09)	0.1554	0.4425
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	0.9999
POST-MENOPAUSAL	214	110	6	5.5	104	1	1.0	0.15	(0.02, 1.23)	0.0409	0.9999
Time to First Metabolism and nutrition disorders, Hypophosphataemia											
All Patients	324	163	2	1.2	161	5	3.1	2.35	(0.45, 12.19)	0.2958	NE
Age group (years)											
<65	266	129	2	1.6	137	5	3.6	2.14	(0.41, 11.12)	0.3556	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	5	3.2	2.41	(0.46, 12.52)	0.2796	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	3	5.2	2.74	(0.28, 26.84)	0.3670	0.1279
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.1523	0.1279
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3042	0.1279
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	5	3.8	2.20	(0.42, 11.45)	0.3352	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	3	5.8	2.49	(0.25, 24.54)	0.4182	0.8550
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	2.13	(0.19, 23.51)	0.5269	0.8550
Time to First Metabolism and nutrition disorders, Dehydration											
All Patients	324	163	2	1.2	161	4	2.5	1.90	(0.35, 10.43)	0.4508	NE
Age group (years)											
<65	266	129	2	1.6	137	4	2.9	1.72	(0.31, 9.45)	0.5264	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	4	2.6	1.96	(0.36, 10.72)	0.4311	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	4	6.3	1.98	(0.36, 10.84)	0.4199	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	0.2827
Y	259	127	2	1.6	132	3	2.3	1.31	(0.22, 7.89)	0.7672	0.2827
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	4	3.8	2.01	(0.37, 11.02)	0.4107	1.0000
Time to First Metabolism and nutrition disorders, Hyperphosphataemia											
All Patients	324	163	2	1.2	161	2	1.2	0.74	(0.10, 5.38)	0.7682	NE
Age group (years)											
<65	266	129	2	1.6	137	2	1.5	0.65	(0.09, 4.70)	0.6644	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.51	(0.13, 17.03)	0.7365	0.0187
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0253	0.0187
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.9906
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.72	(0.04, 11.74)	0.8173	0.9906
OTHER	78	38	1	2.6	40	1	2.5	0.76	(0.05, 12.33)	0.8450	0.9906
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3359	0.2412
Y	259	127	1	0.8	132	2	1.5	1.37	(0.12, 15.51)	0.7978	0.2412
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6095	0.3569
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.95	(0.06, 15.21)	0.9705	0.3569
Time to First Metabolism and nutrition disorders, Type 2 diabetes mellitus											
All Patients	324	163	0	0.0	161	4	2.5	>999.99	(0.00, >999.99)	0.0662	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.0799	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	4	2.6	>999.99	(0.00, >999.99)	0.0637	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	4	10.0	>999.99	(0.00, >999.99)	0.0659	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.2103	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.1646	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	4	3.8	>999.99	(0.00, >999.99)	0.0625	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Metabolism and nutrition disorders, Glucose tolerance impaired											
All Patients	324	163	1	0.6	161	2	1.2	1.36	(0.12, 15.63)	0.8052	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.21	(0.11, 13.97)	0.8764	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.38	(0.12, 15.91)	0.7974	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3831	0.5431
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.5431
OTHER	78	38	1	2.6	40	1	2.5	0.63	(0.04, 10.65)	0.7456	0.5431
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	2	1.5	1.26	(0.11, 14.43)	0.8543	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.87	(0.05, 13.95)	0.9191	0.3500
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3526	0.3500
Time to First Metabolism and nutrition disorders, Hypercholesterolaemia											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.1082	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1802	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1138	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	0	0.0	<0.01	(0.00, >999.99)	0.1349	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	0	0.0	<0.01	(0.00, >999.99)	0.0968	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1280	1.0000
Time to First Metabolism and nutrition disorders, Hyperinsulinaemia											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1560	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.1753	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1507	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3090	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.1531	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Metabolism and nutrition disorders, Hyperlipidaemia											
All Patients	324	163	1	0.6	161	1	0.6	0.76	(0.05, 12.24)	0.8482	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.68	(0.04, 10.98)	0.7874	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.78	(0.05, 12.59)	0.8637	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.2125
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3532	0.2125
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1757	0.2125
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.1290
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3858	0.1290
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.84	(0.05, 13.49)	0.9034	1.0000
Time to First Metabolism and nutrition disorders, Hypermagnesaemia											
All Patients	324	163	1	0.6	161	1	0.6	0.92	(0.06, 14.69)	0.9501	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	0.1454
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4561	0.1454
Sex											
F	318	162	1	0.6	156	1	0.6	0.94	(0.06, 15.10)	0.9655	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	0.2496
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2924	0.2496
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.2496
Visceral disease (per eCRF)											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3613	0.1206
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	0.1206
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	1.00	(0.06, 16.04)	0.9988	1.0000
Time to First Metabolism and nutrition disorders, Hyperuricaemia											
All Patients	324	163	1	0.6	161	1	0.6	0.69	(0.04, 11.62)	0.7954	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0870	0.0460
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2240	0.0460
Sex											
F	318	162	1	0.6	156	1	0.6	0.70	(0.04, 11.80)	0.8018	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.70	(0.04, 11.94)	0.8061	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	0.0773
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1213	0.0773
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.79	(0.05, 13.05)	0.8697	1.0000
Time to First Metabolism and nutrition disorders, Hypoglycaemia											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2138	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2428	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2067	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3367	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3378	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2327	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3736	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3711	1.0000
Time to First Metabolism and nutrition disorders, Insulin resistance											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1928	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2156	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1868	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3563	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2110	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.2110	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Metabolism and nutrition disorders, Diabetes mellitus											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3559	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2367	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3496	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3778	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2528	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3411	1.0000
Time to First Metabolism and nutrition disorders, Histamine intolerance											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Metabolism and nutrition disorders, Hypernatraemia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2969	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3251	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3021	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Metabolism and nutrition disorders, Iron deficiency											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1069	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4386	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1040	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1069	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1336	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1242	1.0000
Time to First Metabolism and nutrition disorders, Lactic acidosis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4362	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4769	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3819	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3743	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Metabolism and nutrition disorders, Polydipsia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3651	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4003	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3585	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4241	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3914	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3950	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Metabolism and nutrition disorders, Tetany											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3188	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3416	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3126	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3103	1.0000
Time to First Metabolism and nutrition disorders, Vitamin B12 deficiency											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4927	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5289	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4864	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4561	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5101	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4349	1.0000
Time to First Metabolism and nutrition disorders, Vitamin C deficiency											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000

Men are excluded from the subgroups of "Menopausal Status at Randomization"
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_tte.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_SPT_P1_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 8065628e23c1f16f1b9c5c76540f88be90f918fa
08 APR 2025 19:27 GMT

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Time to Event Analysis by SOC and PT Overall and with Subgroups (Safety), Adverse Events by SOC and PT, Part 2/3, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Infections and infestations, Any											
All Patients	324	163	62	38.0	161	99	61.5	1.45	(1.05, 1.99)	0.0223	NE
Age group (years)											
<65	266	129	45	34.9	137	87	63.5	1.63	(1.13, 2.34)	0.0076	0.2651
>=65	58	34	17	50.0	24	12	50.0	0.87	(0.41, 1.85)	0.7225	0.2651
Sex											
F	318	162	62	38.3	156	94	60.3	1.43	(1.04, 1.97)	0.0288	0.1150
M	6	1	0	0.0	5	5	100.0	>999.99	(0.00, >999.99)	0.1386	0.1150
Region											
ASIA	120	62	20	32.3	58	33	56.9	1.70	(0.97, 2.96)	0.0605	0.6754
NORTH AMERICA/WESTERN EUROPE	126	63	28	44.4	63	43	68.3	1.43	(0.88, 2.31)	0.1431	0.6754
OTHER	78	38	14	36.8	40	23	57.5	1.15	(0.59, 2.25)	0.6781	0.6754
Visceral disease (per eCRF)											
N	65	36	15	41.7	29	20	69.0	1.75	(0.89, 3.42)	0.1006	0.4727
Y	259	127	47	37.0	132	79	59.8	1.38	(0.96, 1.98)	0.0819	0.4727
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	20	38.5	52	38	73.1	1.97	(1.13, 3.43)	0.0141	0.2033
POST-MENOPAUSAL	214	110	42	38.2	104	56	53.8	1.23	(0.82, 1.84)	0.3188	0.2033
Time to First Infections and infestations, COVID-19											
All Patients	324	163	18	11.0	161	39	24.2	1.64	(0.94, 2.87)	0.0814	NE
Age group (years)											
<65	266	129	13	10.1	137	34	24.8	1.71	(0.90, 3.25)	0.0992	0.8385
>=65	58	34	5	14.7	24	5	20.8	1.39	(0.40, 4.82)	0.6009	0.8385
Sex											
F	318	162	18	11.1	156	37	23.7	1.62	(0.92, 2.85)	0.0921	0.4297
M	6	1	0	0.0	5	2	40.0	>999.99	(0.00, >999.99)	0.4658	0.4297
Region											
ASIA	120	62	7	11.3	58	14	24.1	1.50	(0.60, 3.75)	0.3804	0.6195
NORTH AMERICA/WESTERN EUROPE	126	63	9	14.3	63	15	23.8	1.43	(0.62, 3.29)	0.3985	0.6195
OTHER	78	38	2	5.3	40	10	25.0	2.96	(0.64, 13.58)	0.1437	0.6195
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	10	34.5	3.40	(0.93, 12.40)	0.0489	0.1378
Y	259	127	15	11.8	132	29	22.0	1.33	(0.71, 2.48)	0.3773	0.1378
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	6	11.5	52	13	25.0	1.40	(0.52, 3.76)	0.5008	0.7247
POST-MENOPAUSAL	214	110	12	10.9	104	24	23.1	1.74	(0.87, 3.48)	0.1155	0.7247
Time to First Infections and infestations, Urinary tract infection											
All Patients	324	163	15	9.2	161	28	17.4	1.50	(0.80, 2.82)	0.2040	NE
Age group (years)											
<65	266	129	8	6.2	137	26	19.0	2.46	(1.11, 5.45)	0.0225	0.0305
>=65	58	34	7	20.6	24	2	8.3	0.36	(0.07, 1.72)	0.1799	0.0305

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	15	9.3	156	28	17.9	1.55	(0.83, 2.92)	0.1696	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	5	8.1	58	10	17.2	1.93	(0.66, 5.67)	0.2252	0.8665
NORTH AMERICA/WESTERN EUROPE	126	63	8	12.7	63	12	19.0	1.25	(0.51, 3.08)	0.6214	0.8665
OTHER	78	38	2	5.3	40	6	15.0	1.60	(0.31, 8.09)	0.5693	0.8665
Visceral disease (per eCRF)											
N	65	36	7	19.4	29	4	13.8	0.45	(0.13, 1.59)	0.2064	0.0466
Y	259	127	8	6.3	132	24	18.2	2.41	(1.08, 5.38)	0.0270	0.0466
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	13	25.0	10.27	(1.33, 79.26)	0.0059	0.0057
POST-MENOPAUSAL	214	110	14	12.7	104	15	14.4	0.91	(0.44, 1.90)	0.8066	0.0057
Time to First Infections and infestations, Upper respiratory tract infection											
All Patients	324	163	9	5.5	161	17	10.6	1.34	(0.59, 3.04)	0.4784	NE
Age group (years)											
<65	266	129	8	6.2	137	14	10.2	1.10	(0.46, 2.66)	0.8329	0.2319
>=65	58	34	1	2.9	24	3	12.5	4.03	(0.42, 38.97)	0.1929	0.2319
Sex											
F	318	162	9	5.6	156	16	10.3	1.31	(0.57, 2.99)	0.5237	0.4952
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6171	0.4952
Region											
ASIA	120	62	5	8.1	58	6	10.3	1.01	(0.30, 3.34)	0.9882	0.6854
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	5	7.9	1.76	(0.34, 9.27)	0.4979	0.6854
OTHER	78	38	2	5.3	40	6	15.0	1.80	(0.36, 9.10)	0.4700	0.6854
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	5	17.2	2.27	(0.44, 11.85)	0.3170	0.3895
Y	259	127	7	5.5	132	12	9.1	1.12	(0.44, 2.88)	0.8120	0.3895
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	5	9.6	52	6	11.5	0.86	(0.25, 2.90)	0.8056	0.3327
POST-MENOPAUSAL	214	110	4	3.6	104	10	9.6	1.75	(0.54, 5.67)	0.3464	0.3327
Time to First Infections and infestations, Influenza											
All Patients	324	163	4	2.5	161	8	5.0	1.29	(0.39, 4.34)	0.6759	NE
Age group (years)											
<65	266	129	3	2.3	137	8	5.8	1.53	(0.40, 5.86)	0.5279	0.2444
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3458	0.2444
Sex											
F	318	162	4	2.5	156	8	5.1	1.32	(0.39, 4.43)	0.6524	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	3	5.2	1.98	(0.20, 19.40)	0.5510	0.7526
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	2	3.2	0.68	(0.09, 4.87)	0.6952	0.7526
OTHER	78	38	1	2.6	40	3	7.5	1.73	(0.18, 16.73)	0.6291	0.7526

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	2	6.9	1.39	(0.12, 16.12)	0.7929	0.8411
Y	259	127	3	2.4	132	6	4.5	1.20	(0.30, 4.86)	0.7968	0.8411
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	3	5.8	2.01	(0.20, 20.02)	0.5429	0.7433
POST-MENOPAUSAL	214	110	3	2.7	104	5	4.8	1.18	(0.28, 5.00)	0.8248	0.7433
Time to First Infections and infestations, Nasopharyngitis											
All Patients	324	163	5	3.1	161	6	3.7	0.74	(0.22, 2.44)	0.6155	NE
Age group (years)											
<65	266	129	4	3.1	137	6	4.4	0.81	(0.22, 2.91)	0.7429	0.3571
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3613	0.3571
Sex											
F	318	162	5	3.1	156	5	3.2	0.61	(0.17, 2.12)	0.4289	0.3276
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.3276
Region											
ASIA	120	62	2	3.2	58	3	5.2	0.96	(0.16, 5.75)	0.9599	0.0850
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	3	4.8	2.65	(0.28, 25.56)	0.3796	0.0850
OTHER	78	38	2	5.3	40	0	0.0	<0.01	(0.00, >999.99)	0.0344	0.0850
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4081	0.2127
Y	259	127	5	3.9	132	5	3.8	0.57	(0.16, 2.00)	0.3742	0.2127
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	2	3.8	0.67	(0.09, 4.83)	0.6859	0.8775
POST-MENOPAUSAL	214	110	3	2.7	104	3	2.9	0.59	(0.11, 3.03)	0.5184	0.8775
Time to First Infections and infestations, Pneumonia											
All Patients	324	163	3	1.8	161	8	5.0	1.92	(0.50, 7.32)	0.3329	NE
Age group (years)											
<65	266	129	3	2.3	137	7	5.1	1.53	(0.39, 6.03)	0.5373	0.2602
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.3173	0.2602
Sex											
F	318	162	3	1.9	156	7	4.5	1.75	(0.44, 6.86)	0.4182	0.5360
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.5360
Region											
ASIA	120	62	1	1.6	58	2	3.4	2.06	(0.19, 22.70)	0.5472	0.2759
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.1495	0.2759
OTHER	78	38	2	5.3	40	3	7.5	1.01	(0.17, 6.10)	0.9905	0.2759
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	3	10.3	>999.99	(0.00, >999.99)	0.0922	0.0843
Y	259	127	3	2.4	132	5	3.8	1.10	(0.26, 4.67)	0.8986	0.0843
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	2	3.8	1.63	(0.15, 18.27)	0.6881	0.8443
POST-MENOPAUSAL	214	110	2	1.8	104	5	4.8	1.81	(0.34, 9.57)	0.4767	0.8443

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Infections and infestations, Conjunctivitis											
All Patients	324	163	1	0.6	161	6	3.7	5.30	(0.64, 44.19)	0.0844	NE
Age group (years)											
<65	266	129	1	0.8	137	6	4.4	4.78	(0.57, 39.84)	0.1107	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	1	0.6	156	6	3.8	5.45	(0.65, 45.43)	0.0782	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3128	0.0520
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	6	9.5	>999.99	(0.00, >999.99)	0.0150	0.0520
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.0520
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	1.27	(0.08, 20.37)	0.8637	0.1168
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0482	0.1168
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.2110	0.4131
POST-MENOPAUSAL	214	110	1	0.9	104	4	3.8	3.78	(0.42, 33.93)	0.2012	0.4131
Time to First Infections and infestations, Cystitis											
All Patients	324	163	2	1.2	161	4	2.5	1.35	(0.24, 7.48)	0.7315	NE
Age group (years)											
<65	266	129	1	0.8	137	4	2.9	2.20	(0.24, 20.05)	0.4762	0.1983
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4142	0.1983
Sex											
F	318	162	2	1.2	156	4	2.6	1.39	(0.25, 7.71)	0.7050	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.3254	0.3805
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	2	3.2	0.80	(0.11, 5.73)	0.8246	0.3805
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.3805
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	4	3.0	1.22	(0.22, 6.78)	0.8185	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.2402	0.1931
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.75	(0.10, 5.38)	0.7677	0.1931
Time to First Infections and infestations, Cellulitis											
All Patients	324	163	0	0.0	161	5	3.1	>999.99	(0.00, >999.99)	0.0854	NE
Age group (years)											
<65	266	129	0	0.0	137	5	3.6	>999.99	(0.00, >999.99)	0.1152	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	5	3.2	>999.99	(0.00, >999.99)	0.0831	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	3	5.2	>999.99	(0.00, >999.99)	0.1377	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5465	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5351	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4795	1.0000
Y	259	127	0	0.0	132	4	3.0	>999.99	(0.00, >999.99)	0.1226	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	4	3.8	>999.99	(0.00, >999.99)	0.1396	1.0000
Time to First Infections and infestations, Herpes zoster											
All Patients	324	163	2	1.2	161	3	1.9	0.76	(0.13, 4.56)	0.7622	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	1.28	(0.13, 12.40)	0.8301	0.2809
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3458	0.2809
Sex											
F	318	162	2	1.2	156	3	1.9	0.78	(0.13, 4.71)	0.7888	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	3	5.2	>999.99	(0.00, >999.99)	0.2207	0.0321
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1662	0.0321
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1432	0.0321
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	3	2.3	0.69	(0.11, 4.14)	0.6814	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	0.3827
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.62	(0.09, 4.45)	0.6354	0.3827
Time to First Infections and infestations, Sinusitis											
All Patients	324	163	2	1.2	161	3	1.9	0.81	(0.13, 4.87)	0.8175	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	1.38	(0.14, 13.39)	0.7794	0.2517
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.2517
Sex											
F	318	162	2	1.2	156	3	1.9	0.84	(0.14, 5.03)	0.8453	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.7849
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.56	(0.14, 17.25)	0.7142	0.7849
OTHER	78	38	1	2.6	40	1	2.5	0.36	(0.02, 5.77)	0.4512	0.7849
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	3	2.3	0.75	(0.12, 4.48)	0.7477	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	2	3.8	0.65	(0.06, 7.25)	0.7227	0.9773
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.74	(0.05, 11.88)	0.8314	0.9773
Time to First Infections and infestations, Skin infection											
All Patients	324	163	1	0.6	161	4	2.5	2.19	(0.24, 19.83)	0.4749	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.1670	0.0746
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3613	0.0746
Sex											
F	318	162	1	0.6	156	4	2.6	2.11	(0.23, 19.19)	0.4994	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.3413	0.4157
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.56	(0.03, 9.03)	0.6784	0.4157
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4795	0.4157
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	4	3.0	2.12	(0.23, 19.14)	0.4944	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.3736	0.3365
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.11	(0.10, 12.27)	0.9345	0.3365
Time to First Infections and infestations, Gingivitis											
All Patients	324	163	1	0.6	161	3	1.9	2.48	(0.25, 24.59)	0.4229	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.31	(0.11, 15.50)	0.8318	0.2404
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.2404
Sex											
F	318	162	1	0.6	156	3	1.9	2.44	(0.24, 24.55)	0.4359	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	2	3.4	1.06	(0.07, 16.98)	0.9660	0.6606
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	0.6606
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.6606
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.67	(0.04, 12.61)	0.7860	0.2096
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.1646	0.2096
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	NE	NE	1.0000	0.4068
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	2.12	(0.19, 23.37)	0.5304	0.4068
Time to First Infections and infestations, Lower respiratory tract infection											
All Patients	324	163	3	1.8	161	1	0.6	0.19	(0.02, 1.90)	0.1190	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.59	(0.03, 10.01)	0.7100	0.3001
>=65	58	34	2	5.9	24	0	0.0	<0.01	(0.00, >999.99)	0.1761	0.3001
Sex											
F	318	162	3	1.9	156	1	0.6	0.20	(0.02, 1.95)	0.1260	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.4989
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	0	0.0	<0.01	(0.00, >999.99)	0.0921	0.4989
OTHER	78	38	1	2.6	40	1	2.5	0.39	(0.02, 6.28)	0.4904	0.4989
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.66	(0.04, 11.06)	0.7708	0.1592
Y	259	127	2	1.6	132	0	0.0	<0.01	(0.00, >999.99)	0.0669	0.1592
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	0.9999
POST-MENOPAUSAL	214	110	3	2.7	104	1	1.0	0.23	(0.02, 2.25)	0.1699	0.9999
Time to First Infections and infestations, Periodontitis											
All Patients	324	163	1	0.6	161	3	1.9	1.87	(0.19, 18.43)	0.5882	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	0.98	(0.08, 11.50)	0.9874	0.2696
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2604	0.2696
Sex											
F	318	162	1	0.6	156	3	1.9	1.90	(0.19, 18.83)	0.5762	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.3235	0.3996
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.3996
OTHER	78	38	1	2.6	40	1	2.5	0.64	(0.04, 10.84)	0.7582	0.3996
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	3	2.3	1.72	(0.17, 16.99)	0.6378	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6095	0.4645
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.46	(0.13, 16.61)	0.7589	0.4645
Time to First Infections and infestations, Pharyngitis											
All Patients	324	163	1	0.6	161	3	1.9	1.58	(0.16, 15.46)	0.6921	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	1.27	(0.13, 12.49)	0.8390	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	3	1.9	1.61	(0.16, 15.81)	0.6785	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	1	1.6	58	2	3.4	0.96	(0.08, 11.14)	0.9714	0.7163
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.7163
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5083	0.7163
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	3	2.3	1.44	(0.15, 14.08)	0.7518	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	0.5000
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.26	(0.11, 14.27)	0.8493	0.5000
Time to First Infections and infestations, Respiratory tract infection											
All Patients	324	163	0	0.0	161	4	2.5	>999.99	(0.00, >999.99)	0.1307	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.1695	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	4	2.6	>999.99	(0.00, >999.99)	0.1274	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2664	1.0000
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.3134	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.2089	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.3105	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4795	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	3	2.9	>999.99	(0.00, >999.99)	0.1910	1.0000
Time to First Infections and infestations, Tooth infection											
All Patients	324	163	2	1.2	161	2	1.2	0.67	(0.09, 4.90)	0.6923	NE
Age group (years)											
<65	266	129	2	1.6	137	2	1.5	0.58	(0.08, 4.27)	0.5910	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	2	1.3	0.68	(0.09, 5.00)	0.7058	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	2	3.2	0.66	(0.09, 4.99)	0.6813	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1266	0.2223
Y	259	127	1	0.8	132	2	1.5	1.47	(0.13, 16.34)	0.7538	0.2223

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5002	0.1742
POST-MENOPAUSAL	214	110	2	1.8	104	1	1.0	0.32	(0.03, 3.81)	0.3427	0.1742
Time to First Infections and infestations, Bacteriuria											
All Patients	324	163	2	1.2	161	1	0.6	0.36	(0.03, 4.19)	0.3976	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.51	(0.03, 9.16)	0.6441	0.4501
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.4501
Sex											
F	318	162	2	1.2	156	1	0.6	0.36	(0.03, 4.26)	0.4042	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	1	1.6	0.35	(0.03, 4.07)	0.3814	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	2	1.6	132	1	0.8	0.32	(0.03, 3.79)	0.3456	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6310	0.0586
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1663	0.0586
Time to First Infections and infestations, Gastroenteritis											
All Patients	324	163	1	0.6	161	2	1.2	1.63	(0.14, 18.48)	0.6919	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.45	(0.13, 16.60)	0.7642	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.68	(0.15, 19.03)	0.6729	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	0.5974
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.79	(0.05, 12.85)	0.8652	0.5974
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.5974
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	2	1.5	1.53	(0.13, 17.41)	0.7289	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.1553	0.0609
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2123	0.0609
Time to First Infections and infestations, Hordeolum											
All Patients	324	163	2	1.2	161	1	0.6	0.38	(0.03, 4.25)	0.4143	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	2	1.6	137	1	0.7	0.33	(0.03, 3.67)	0.3403	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	1	0.6	0.39	(0.03, 4.39)	0.4312	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	1	1.6	0.44	(0.04, 4.86)	0.4898	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.95	(0.06, 15.46)	0.9705	0.2497
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	0.2497
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	0	0.0	<0.01	(0.00, >999.99)	0.1119	0.0407
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4216	0.0407
Time to First Infections and infestations, Localised infection											
All Patients	324	163	1	0.6	161	2	1.2	1.49	(0.13, 16.68)	0.7436	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.30	(0.12, 14.60)	0.8317	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.54	(0.14, 17.21)	0.7237	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.76	(0.16, 19.50)	0.6396	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.80	(0.05, 12.78)	0.8729	0.3531
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3326	0.3531
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.64	(0.15, 18.28)	0.6835	1.0000
Time to First Infections and infestations, Oral herpes											
All Patients	324	163	1	0.6	161	2	1.2	1.79	(0.16, 19.96)	0.6304	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.63	(0.15, 18.16)	0.6890	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.84	(0.17, 20.51)	0.6138	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.95	(0.18, 21.53)	0.5788	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	2	1.5	1.69	(0.15, 18.85)	0.6651	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.76	(0.05, 12.52)	0.8498	0.2883
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	0.2883
Time to First Infections and infestations, Paronychia											
All Patients	324	163	0	0.0	161	3	1.9	>999.99	(0.00, >999.99)	0.1515	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.1832	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	3	1.9	>999.99	(0.00, >999.99)	0.1450	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.1094	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.1731	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4956	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1899	1.0000
Time to First Infections and infestations, Respiratory tract infection viral											
All Patients	324	163	1	0.6	161	2	1.2	1.70	(0.15, 19.08)	0.6641	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.51	(0.13, 17.12)	0.7356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.75	(0.16, 19.63)	0.6464	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	2	5.0	1.41	(0.12, 16.51)	0.7811	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.1540	0.0395
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	0.0395
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.0449

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1911	0.0449
Time to First Infections and infestations, Tooth abscess											
All Patients	324	163	1	0.6	161	2	1.2	1.57	(0.14, 17.78)	0.7157	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.36	(0.12, 15.66)	0.8033	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.61	(0.14, 18.28)	0.6984	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.63	(0.14, 18.27)	0.6913	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	2	1.5	1.45	(0.13, 16.51)	0.7615	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3076	0.3295
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.77	(0.05, 12.54)	0.8540	0.3295
Time to First Infections and infestations, Candida infection											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2150	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5002	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2082	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5485	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3954	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4317	1.0000
Time to First Infections and infestations, Folliculitis											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2220	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2510	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2151	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2744	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4895	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4328	1.0000
Time to First Infections and infestations, Furuncle											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2627	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3110	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2557	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.3005	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2733	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5271	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4093	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4386	1.0000
Time to First Infections and infestations, Osteomyelitis											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.3282	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3752	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.3193	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5097	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5083	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4533	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5113	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.4651	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Viral infection											
All Patients	324	163	1	0.6	161	1	0.6	0.64	(0.04, 10.99)	0.7591	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	1	4.2	1.76	(0.11, 28.27)	0.6867	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.65	(0.04, 11.10)	0.7617	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.2493
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3212	0.2493
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1573	0.2493
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.62	(0.04, 10.44)	0.7355	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.57	(0.03, 10.30)	0.7007	1.0000
Time to First Infections and infestations, Vulvitis											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.3214	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3681	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.3120	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2713	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4795	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4895	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6056	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4328	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Infections and infestations, Vulvovaginal mycotic infection											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2148	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2434	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2079	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.1828	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2320	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4317	1.0000
Time to First Infections and infestations, Abscess											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3781	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4102	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3711	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3763	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4044	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3492	1.0000
Time to First Infections and infestations, Anal abscess											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4214	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4555	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4130	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3545	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4357	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5002	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Asymptomatic bacteriuria											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5514	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5930	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5571	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5839	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5553	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5812	1.0000
Time to First Infections and infestations, Breast cellulitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5002	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5371	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5023	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4795	1.0000
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4795	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5525	1.0000
Time to First Infections and infestations, Bronchitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4602	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5034	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4505	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3948	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4759	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4167	1.0000
Time to First Infections and infestations, COVID-19 pneumonia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3220	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3042	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2981	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3243	1.0000
Time to First Infections and infestations, Clostridium difficile colitis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2217	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4008	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2294	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1367	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2819	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2494	1.0000
Time to First Infections and infestations, Conjunctivitis viral											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Infections and infestations, Device related infection											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3580	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3865	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3513	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4142	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3838	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3865	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Erysipelas											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4033	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4304	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3965	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4602	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4319	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3757	1.0000
Time to First Infections and infestations, Gastroenteritis norovirus											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4795	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5186	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5186	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4386	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4561	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4795	1.0000
Time to First Infections and infestations, Gastroenteritis viral											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3954	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4271	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3884	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3388	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4247	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4404	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Genital herpes											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5039	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5637	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5002	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5127	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5186	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4516	1.0000
Time to First Infections and infestations, Herpes simplex											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2806	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2537	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2870	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3032	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2527	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2673	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Herpes simplex reactivation											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2260	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1928	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2340	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2974	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2096	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2528	1.0000
Time to First Infections and infestations, Infection											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2393	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2079	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2463	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2156	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2103	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2703	1.0000
Time to First Infections and infestations, Injection site infection											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5465	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.6015	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.6015	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4795	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.5637	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5637	1.0000
Time to First Infections and infestations, Lung abscess											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3638	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4011	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3570	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4241	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3922	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3350	1.0000
Time to First Infections and infestations, Nail infection											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3416	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3126	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3365	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3103	1.0000
Time to First Infections and infestations, Oesophageal candidiasis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4692	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2963	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4607	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5892	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4895	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4328	1.0000
Time to First Infections and infestations, Onychomycosis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3689	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4084	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3621	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3423	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3967	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4167	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Pericoronitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3596	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3884	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3531	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3469	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3858	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3865	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Pneumonia viral											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3220	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3042	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3865	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Pulpitis dental											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2649	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4475	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2718	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2871	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2393	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2957	1.0000
Time to First Infections and infestations, Pustule											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2207	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1938	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2278	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2092	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2069	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2503	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Infections and infestations, Pyuria											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3358	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3080	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3306	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First Infections and infestations, Rash pustular											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4153	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4440	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4078	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3555	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4302	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4450	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Rhinitis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1444	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1052	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1482	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1757	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1894	1.0000
Time to First Infections and infestations, Rotavirus infection											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2995	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2715	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3057	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2966	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3729	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Sialoadenitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.6374	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.6374	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.6374	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.7055	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5930	1.0000
Time to First Infections and infestations, Soft tissue infection											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5186	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5820	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5211	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5351	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4795	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5154	1.0000
Time to First Infections and infestations, Tracheobronchitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4888	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5371	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4844	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5271	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4979	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6056	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Urethritis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3580	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3865	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3513	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3469	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3838	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3865	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Vaginal infection											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3590	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3852	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3525	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4047	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3845	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3800	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Infections and infestations, Viral upper respiratory tract infection											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4142	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4457	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4936	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3634	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3876	1.0000
Time to First Infections and infestations, Wound infection											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2969	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3251	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3021	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3289	1.0000
Time to First Skin and subcutaneous tissue disorders, Any											
All Patients	324	163	57	35.0	161	79	49.1	1.31	(0.93, 1.84)	0.1212	NE
Age group (years)											
<65	266	129	45	34.9	137	70	51.1	1.33	(0.92, 1.94)	0.1330	0.6228
>=65	58	34	12	35.3	24	9	37.5	1.08	(0.46, 2.57)	0.8577	0.6228
Sex											
F	318	162	56	34.6	156	79	50.6	1.40	(0.99, 1.97)	0.0528	0.0193
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0253	0.0193
Region											
ASIA	120	62	23	37.1	58	27	46.6	1.06	(0.60, 1.86)	0.8429	0.2819
NORTH AMERICA/WESTERN EUROPE	126	63	28	44.4	63	35	55.6	1.29	(0.78, 2.12)	0.3142	0.2819
OTHER	78	38	6	15.8	40	17	42.5	2.45	(0.96, 6.22)	0.0525	0.2819
Visceral disease (per eCRF)											
N	65	36	18	50.0	29	13	44.8	0.80	(0.39, 1.63)	0.5306	0.0702
Y	259	127	39	30.7	132	66	50.0	1.56	(1.05, 2.33)	0.0261	0.0702

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	19	36.5	52	26	50.0	1.13	(0.62, 2.06)	0.6902	0.5284
POST-MENOPAUSAL	214	110	37	33.6	104	53	51.0	1.52	(1.00, 2.31)	0.0497	0.5284
Time to First Skin and subcutaneous tissue disorders, Rash											
All Patients	324	163	23	14.1	161	27	16.8	1.07	(0.61, 1.87)	0.8131	NE
Age group (years)											
<65	266	129	18	14.0	137	25	18.2	1.13	(0.62, 2.09)	0.6869	0.4372
>=65	58	34	5	14.7	24	2	8.3	0.60	(0.12, 3.10)	0.5363	0.4372
Sex											
F	318	162	23	14.2	156	27	17.3	1.10	(0.63, 1.93)	0.7331	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	12	19.4	58	10	17.2	0.74	(0.32, 1.72)	0.4818	0.4770
NORTH AMERICA/WESTERN EUROPE	126	63	9	14.3	63	12	19.0	1.30	(0.55, 3.10)	0.5418	0.4770
OTHER	78	38	2	5.3	40	5	12.5	2.17	(0.42, 11.26)	0.3435	0.4770
Visceral disease (per eCRF)											
N	65	36	7	19.4	29	5	17.2	0.78	(0.24, 2.48)	0.6776	0.5388
Y	259	127	16	12.6	132	22	16.7	1.20	(0.63, 2.28)	0.5875	0.5388
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	7	13.5	52	11	21.2	1.32	(0.50, 3.45)	0.5691	0.5534
POST-MENOPAUSAL	214	110	16	14.5	104	16	15.4	0.99	(0.49, 1.98)	0.9797	0.5534
Time to First Skin and subcutaneous tissue disorders, Alopecia											
All Patients	324	163	12	7.4	161	29	18.0	2.05	(1.04, 4.02)	0.0332	NE
Age group (years)											
<65	266	129	9	7.0	137	27	19.7	2.25	(1.06, 4.80)	0.0309	0.3734
>=65	58	34	3	8.8	24	2	8.3	0.99	(0.16, 5.93)	0.9900	0.3734
Sex											
F	318	162	12	7.4	156	29	18.6	2.12	(1.08, 4.15)	0.0259	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	3	4.8	58	9	15.5	2.65	(0.72, 9.81)	0.1297	0.7646
NORTH AMERICA/WESTERN EUROPE	126	63	8	12.7	63	15	23.8	1.72	(0.73, 4.07)	0.2092	0.7646
OTHER	78	38	1	2.6	40	5	12.5	3.55	(0.41, 30.83)	0.2207	0.7646
Visceral disease (per eCRF)											
N	65	36	6	16.7	29	4	13.8	0.69	(0.19, 2.46)	0.5634	0.0440
Y	259	127	6	4.7	132	25	18.9	3.31	(1.36, 8.08)	0.0053	0.0440
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	9	17.3	6.77	(0.85, 53.82)	0.0370	0.1331
POST-MENOPAUSAL	214	110	11	10.0	104	20	19.2	1.68	(0.81, 3.52)	0.1614	0.1331
Time to First Skin and subcutaneous tissue disorders, Dry skin											
All Patients	324	163	9	5.5	161	20	12.4	2.14	(0.97, 4.70)	0.0531	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	5	3.9	137	17	12.4	2.98	(1.10, 8.08)	0.0246	0.2972
>=65	58	34	4	11.8	24	3	12.5	1.18	(0.26, 5.28)	0.8282	0.2972
Sex											
F	318	162	8	4.9	156	20	12.8	2.49	(1.10, 5.66)	0.0244	0.0170
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0253	0.0170
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.1665	0.1519
NORTH AMERICA/WESTERN EUROPE	126	63	9	14.3	63	15	23.8	1.71	(0.75, 3.92)	0.1978	0.1519
OTHER	78	38	0	0.0	40	3	7.5	>999.99	(0.00, >999.99)	0.1300	0.1519
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	3	10.3	1.14	(0.23, 5.70)	0.8709	0.4237
Y	259	127	6	4.7	132	17	12.9	2.60	(1.02, 6.60)	0.0372	0.4237
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	6	11.5	5.90	(0.71, 49.21)	0.0631	0.3368
POST-MENOPAUSAL	214	110	7	6.4	104	14	13.5	2.01	(0.81, 4.98)	0.1252	0.3368
Time to First Skin and subcutaneous tissue disorders, Pruritus											
All Patients	324	163	14	8.6	161	13	8.1	0.77	(0.36, 1.65)	0.5010	NE
Age group (years)											
<65	266	129	10	7.8	137	12	8.8	0.88	(0.38, 2.05)	0.7632	0.3778
>=65	58	34	4	11.8	24	1	4.2	0.35	(0.04, 3.19)	0.3334	0.3778
Sex											
F	318	162	14	8.6	156	13	8.3	0.79	(0.37, 1.70)	0.5502	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	5	8.1	58	4	6.9	0.75	(0.20, 2.83)	0.6773	0.5590
NORTH AMERICA/WESTERN EUROPE	126	63	8	12.7	63	6	9.5	0.62	(0.21, 1.80)	0.3741	0.5590
OTHER	78	38	1	2.6	40	3	7.5	2.30	(0.24, 22.53)	0.4611	0.5590
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	1	3.4	0.32	(0.04, 2.85)	0.2794	0.2447
Y	259	127	10	7.9	132	12	9.1	0.90	(0.38, 2.09)	0.7992	0.2447
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	6	11.5	52	5	9.6	0.63	(0.19, 2.11)	0.4471	0.6214
POST-MENOPAUSAL	214	110	8	7.3	104	8	7.7	0.91	(0.34, 2.44)	0.8521	0.6214
Time to First Skin and subcutaneous tissue disorders, Rash maculo-papular											
All Patients	324	163	5	3.1	161	8	5.0	1.53	(0.50, 4.71)	0.4532	NE
Age group (years)											
<65	266	129	4	3.1	137	8	5.8	1.74	(0.52, 5.81)	0.3632	0.2343
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.2343
Sex											
F	318	162	5	3.1	156	8	5.1	1.57	(0.51, 4.82)	0.4275	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
ASIA	120	62	2	3.2	58	2	3.4	1.05	(0.15, 7.47)	0.9592	0.5179
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	4	6.3	4.09	(0.46, 36.57)	0.1722	0.5179
OTHER	78	38	2	5.3	40	2	5.0	0.85	(0.12, 6.11)	0.8697	0.5179
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	1	3.4	0.43	(0.04, 4.14)	0.4530	0.1061
Y	259	127	2	1.6	132	7	5.3	3.09	(0.64, 14.99)	0.1395	0.1061
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.1477
POST-MENOPAUSAL	214	110	4	3.6	104	8	7.7	2.00	(0.60, 6.70)	0.2511	0.1477
Time to First Skin and subcutaneous tissue disorders, Nail disorder											
All Patients	324	163	1	0.6	161	6	3.7	5.14	(0.62, 42.77)	0.0914	NE
Age group (years)											
<65	266	129	0	0.0	137	6	4.4	>999.99	(0.00, >999.99)	0.0362	0.0322
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.0322
Sex											
F	318	162	1	0.6	156	6	3.8	5.29	(0.64, 44.00)	0.0847	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3537	0.8536
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	5	7.9	4.78	(0.56, 40.90)	0.1148	0.8536
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.8536
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	1	0.8	132	6	4.5	4.69	(0.56, 39.02)	0.1154	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	0.9999
POST-MENOPAUSAL	214	110	1	0.9	104	6	5.8	5.70	(0.69, 47.35)	0.0686	0.9999
Time to First Skin and subcutaneous tissue disorders, Palmar-plantar erythrodysaesthesia syndrome											
All Patients	324	163	2	1.2	161	4	2.5	1.35	(0.24, 7.46)	0.7304	NE
Age group (years)											
<65	266	129	1	0.8	137	4	2.9	2.13	(0.24, 19.18)	0.4915	0.1944
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.1944
Sex											
F	318	162	2	1.2	156	4	2.6	1.39	(0.25, 7.69)	0.7044	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.94	(0.06, 15.09)	0.9651	0.7646
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	3	4.8	2.29	(0.24, 22.12)	0.4628	0.7646
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.7646
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.50	(0.05, 5.61)	0.5704	0.0722
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.1880	0.0722

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99 1.20	(0.00, >999.99) (0.20, 7.26)	0.5930 0.8390	0.3901 0.3901
POST-MENOPAUSAL	214	110	2	1.8	104	3	2.9				
Time to First Skin and subcutaneous tissue disorders, Rash pruritic											
All Patients	324	163	2	1.2	161	4	2.5	1.84	(0.33, 10.13)	0.4781	NE
Age group (years)											
<65	266	129	1	0.8	137	4	2.9	3.25	(0.36, 29.48)	0.2679	0.1846
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.1846
Sex											
F	318	162	2	1.2	156	4	2.6	1.87	(0.34, 10.31)	0.4674	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	1	1.6	58	2	3.4	1.89	(0.17, 20.97)	0.5986	0.6280
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	1.01	(0.06, 16.12)	0.9955	0.6280
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	0.6280
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	4	3.0	1.72	(0.31, 9.50)	0.5269	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	1.02	(0.06, 16.31)	0.9887	0.5880
POST-MENOPAUSAL	214	110	1	0.9	104	3	2.9	2.66	(0.27, 26.18)	0.3854	0.5880
Time to First Skin and subcutaneous tissue disorders, Hyperhidrosis											
All Patients	324	163	3	1.8	161	1	0.6	0.34	(0.04, 3.24)	0.3234	NE
Age group (years)											
<65	266	129	2	1.6	137	1	0.7	0.47	(0.04, 5.14)	0.5226	0.4933
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.4933
Sex											
F	318	162	3	1.9	156	1	0.6	0.35	(0.04, 3.33)	0.3361	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	0.1003
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	0	0.0	<0.01	(0.00, >999.99)	0.1573	0.1003
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3110	0.1003
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3865	0.4633
Y	259	127	2	1.6	132	1	0.8	0.48	(0.04, 5.29)	0.5395	0.4633
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	1.01	(0.06, 16.15)	0.9944	0.1944
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1703	0.1944
Time to First Skin and subcutaneous tissue disorders, Dermatitis acneiform											
All Patients	324	163	1	0.6	161	2	1.2	1.90	(0.17, 21.05)	0.5933	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	1	0.8	137	2	1.5	1.70	(0.15, 18.89)	0.6601	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.96	(0.18, 21.62)	0.5774	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3496	0.1526
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	0.1526
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	0.1526
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.1113	0.0366
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3060	0.0366
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4093	0.3284
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	1.07	(0.07, 17.09)	0.9624	0.3284
Time to First Skin and subcutaneous tissue disorders, Erythema											
All Patients	324	163	1	0.6	161	2	1.2	1.09	(0.10, 12.14)	0.9419	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3669	0.0928
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3476	0.0928
Sex											
F	318	162	1	0.6	156	2	1.3	1.13	(0.10, 12.56)	0.9201	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.39	(0.13, 15.52)	0.7858	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4328	0.2483
Y	259	127	1	0.8	132	1	0.8	0.54	(0.03, 8.71)	0.6599	0.2483
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6080	0.3787
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.68	(0.04, 10.85)	0.7803	0.3787
Time to First Skin and subcutaneous tissue disorders, Rash papular											
All Patients	324	163	1	0.6	161	2	1.2	1.60	(0.14, 18.29)	0.7014	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.42	(0.12, 16.40)	0.7764	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.65	(0.14, 18.81)	0.6833	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	0.1330

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5002	0.1330
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3046	0.1330
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	0.0583
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2403	0.0583
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.52	(0.03, 9.62)	0.6536	0.2751
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	0.2751
Time to First Skin and subcutaneous tissue disorders, Urticaria											
All Patients	324	163	0	0.0	161	3	1.9	>999.99	(0.00, >999.99)	0.2087	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.2549	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	3	1.9	>999.99	(0.00, >999.99)	0.2009	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5541	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2475	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.2272	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5002	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.2668	1.0000
Time to First Skin and subcutaneous tissue disorders, Blister											
All Patients	324	163	1	0.6	161	1	0.6	0.61	(0.04, 10.06)	0.7241	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.51	(0.03, 8.56)	0.6315	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.62	(0.04, 10.35)	0.7402	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.66	(0.04, 10.88)	0.7715	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2673	0.0781
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1222	0.0781
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3800	0.1200

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1747	0.1200
Time to First Skin and subcutaneous tissue disorders, Dermal cyst											
All Patients	324	163	1	0.6	161	1	0.6	0.51	(0.03, 8.37)	0.6331	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.41	(0.03, 6.83)	0.5249	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.52	(0.03, 8.50)	0.6395	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.64	(0.04, 10.50)	0.7493	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.48	(0.03, 7.87)	0.6024	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6015	0.1254
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2579	0.1254
Time to First Skin and subcutaneous tissue disorders, Eczema											
All Patients	324	163	1	0.6	161	1	0.6	0.73	(0.04, 12.04)	0.8220	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.63	(0.04, 10.55)	0.7443	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.75	(0.05, 12.40)	0.8391	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3255	0.2694
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.2694
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5485	0.2694
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.67	(0.04, 11.08)	0.7751	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5127	0.1063
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3289	0.1063
Time to First Skin and subcutaneous tissue disorders, Nail discolouration											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2775	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3159	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2711	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4795	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3409	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2941	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6056	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3751	1.0000
Time to First Skin and subcutaneous tissue disorders, Night sweats											
All Patients	324	163	1	0.6	161	1	0.6	0.84	(0.05, 13.61)	0.9026	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.76	(0.05, 12.36)	0.8471	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.86	(0.05, 13.99)	0.9180	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.93	(0.06, 14.88)	0.9580	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	0.1195
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4297	0.1195
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.91	(0.06, 14.73)	0.9494	1.0000
Time to First Skin and subcutaneous tissue disorders, Onycholysis											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2413	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2795	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2337	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2198	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2614	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.2087	1.0000
Time to First Skin and subcutaneous tissue disorders, Pain of skin											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1760	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2032	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1702	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3423	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3238	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.1953	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3323	1.0000
Time to First Skin and subcutaneous tissue disorders, Papulopustular rosacea											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.3288	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3908	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.3196	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2644	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.3503	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.2639	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Skin and subcutaneous tissue disorders, Rash erythematous											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1651	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.1867	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1597	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3173	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3606	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3373	1.0000
Time to First Skin and subcutaneous tissue disorders, Skin ulcer											
All Patients	324	163	1	0.6	161	1	0.6	0.52	(0.03, 8.34)	0.6385	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0956	0.0440
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2593	0.0440
Sex											
F	318	162	1	0.6	156	1	0.6	0.54	(0.03, 8.65)	0.6578	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.0995	0.2047
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3768	0.2047
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.2047
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.48	(0.03, 7.66)	0.5933	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.0513	0.0660
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4204	0.0660
Time to First Skin and subcutaneous tissue disorders, Xeroderma											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1535	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3319	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1482	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.1540	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1439	1.0000
Time to First Skin and subcutaneous tissue disorders, Acne											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3416	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3126	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3365	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Skin and subcutaneous tissue disorders, Dermatitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4916	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5403	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4827	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5186	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5115	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4302	1.0000
Time to First Skin and subcutaneous tissue disorders, Dermatitis bullous											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First Skin and subcutaneous tissue disorders, Dermatitis contact											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4120	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4503	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4038	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4406	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3657	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4669	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Skin and subcutaneous tissue disorders, Erythema multiforme											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4227	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4576	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4142	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3627	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4376	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5002	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Skin and subcutaneous tissue disorders, Lichen sclerosis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1437	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3458	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1501	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1655	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1213	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1987	1.0000
Time to First Skin and subcutaneous tissue disorders, Nail bed inflammation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3630	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3976	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3563	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3413	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3886	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3950	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Skin and subcutaneous tissue disorders, Nail dystrophy											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3697	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4074	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3628	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3476	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3954	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4117	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Skin and subcutaneous tissue disorders, Onychoclasia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3061	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2801	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3124	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3051	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2893	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3100	1.0000
Time to First Skin and subcutaneous tissue disorders, Palmar erythema											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3377	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3095	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3326	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3057	1.0000
Time to First Skin and subcutaneous tissue disorders, Psoriasis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3220	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3255	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2981	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3243	1.0000
Time to First Skin and subcutaneous tissue disorders, Rosacea											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5009	NE
Age group (years)											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5501	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4945	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4708	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5229	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4366	1.0000
Time to First Skin and subcutaneous tissue disorders, Sensitive skin											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4649	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5064	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4566	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3890	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4858	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4317	1.0000
Time to First Skin and subcutaneous tissue disorders, Skin discolouration											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2695	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2344	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2762	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2809	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2433	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2397	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Skin and subcutaneous tissue disorders, Skin exfoliation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3584	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3821	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3520	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3954	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3858	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3416	1.0000
Time to First Skin and subcutaneous tissue disorders, Skin fissures											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3358	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3080	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3306	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First Skin and subcutaneous tissue disorders, Skin lesion											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1360	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3458	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1422	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1742	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1859	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1904	1.0000
Time to First Skin and subcutaneous tissue disorders, Skin reaction											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2566	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2247	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2636	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2583	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2304	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2855	1.0000
Time to First Skin and subcutaneous tissue disorders, Vitiligo											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1374	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0943	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1432	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1306	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1175	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.0359	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Musculoskeletal and connective tissue disorders, Any											
All Patients	324	163	58	35.6	161	72	44.7	1.04	(0.73, 1.47)	0.8243	NE
Age group (years)											
<65	266	129	42	32.6	137	65	47.4	1.22	(0.83, 1.81)	0.3092	0.0690
>=65	58	34	16	47.1	24	7	29.2	0.49	(0.20, 1.19)	0.1084	0.0690
Sex											
F	318	162	57	35.2	156	69	44.2	1.06	(0.75, 1.51)	0.7385	0.4138
M	6	1	1	100.0	5	3	60.0	0.22	(0.01, 3.59)	0.2467	0.4138
Region											
ASIA	120	62	15	24.2	58	17	29.3	0.83	(0.41, 1.69)	0.6104	0.8770
NORTH AMERICA/WESTERN EUROPE	126	63	33	52.4	63	42	66.7	1.14	(0.72, 1.81)	0.5617	0.8770
OTHER	78	38	10	26.3	40	13	32.5	0.96	(0.42, 2.22)	0.9236	0.8770
Visceral disease (per eCRF)											
N	65	36	19	52.8	29	14	48.3	0.49	(0.23, 1.05)	0.0630	0.1479
Y	259	127	39	30.7	132	58	43.9	1.26	(0.84, 1.90)	0.2642	0.1479
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	15	28.8	52	24	46.2	1.30	(0.68, 2.48)	0.4290	0.4016
POST-MENOPAUSAL	214	110	42	38.2	104	45	43.3	0.99	(0.65, 1.51)	0.9569	0.4016
Time to First Musculoskeletal and connective tissue disorders, Arthralgia											
All Patients	324	163	25	15.3	161	22	13.7	0.60	(0.33, 1.07)	0.0792	NE
Age group (years)											
<65	266	129	18	14.0	137	20	14.6	0.67	(0.35, 1.27)	0.2173	0.5236
>=65	58	34	7	20.6	24	2	8.3	0.36	(0.07, 1.75)	0.1877	0.5236
Sex											
F	318	162	24	14.8	156	22	14.1	0.65	(0.36, 1.17)	0.1489	0.0379
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0253	0.0379
Region											
ASIA	120	62	5	8.1	58	5	8.6	0.46	(0.12, 1.75)	0.2446	0.4668
NORTH AMERICA/WESTERN EUROPE	126	63	18	28.6	63	12	19.0	0.54	(0.26, 1.12)	0.0913	0.4668
OTHER	78	38	2	5.3	40	5	12.5	1.58	(0.30, 8.32)	0.5831	0.4668

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	9	25.0	29	2	6.9	0.07	(<0.01, 0.60)	0.0019	0.0395
Y	259	127	16	12.6	132	20	15.2	0.85	(0.44, 1.65)	0.6338	0.0395
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	6	11.5	52	6	11.5	0.55	(0.17, 1.74)	0.2989	0.9269
POST-MENOPAUSAL	214	110	18	16.4	104	16	15.4	0.68	(0.34, 1.35)	0.2676	0.9269
Time to First Musculoskeletal and connective tissue disorders, Back pain											
All Patients	324	163	18	11.0	161	23	14.3	0.99	(0.53, 1.86)	0.9852	NE
Age group (years)											
<65	266	129	14	10.9	137	20	14.6	0.98	(0.49, 1.95)	0.9448	0.9974
>=65	58	34	4	11.8	24	3	12.5	0.98	(0.22, 4.46)	0.9834	0.9974
Sex											
F	318	162	18	11.1	156	23	14.7	1.02	(0.55, 1.91)	0.9470	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	5	8.1	58	7	12.1	1.03	(0.32, 3.32)	0.9582	0.5001
NORTH AMERICA/WESTERN EUROPE	126	63	9	14.3	63	13	20.6	1.31	(0.56, 3.07)	0.5385	0.5001
OTHER	78	38	4	10.5	40	3	7.5	0.42	(0.09, 1.96)	0.2558	0.5001
Visceral disease (per eCRF)											
N	65	36	6	16.7	29	3	10.3	0.34	(0.08, 1.46)	0.1321	0.2064
Y	259	127	12	9.4	132	20	15.2	1.27	(0.62, 2.62)	0.5089	0.2064
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	5	9.6	52	11	21.2	1.62	(0.56, 4.72)	0.3737	0.1876
POST-MENOPAUSAL	214	110	13	11.8	104	12	11.5	0.76	(0.34, 1.69)	0.5021	0.1876
Time to First Musculoskeletal and connective tissue disorders, Muscle spasms											
All Patients	324	163	7	4.3	161	20	12.4	2.38	(1.00, 5.67)	0.0427	NE
Age group (years)											
<65	266	129	4	3.1	137	20	14.6	3.77	(1.28, 11.10)	0.0097	0.0093
>=65	58	34	3	8.8	24	0	0.0	<0.01	(0.00, >999.99)	0.1298	0.0093
Sex											
F	318	162	6	3.7	156	20	12.8	2.92	(1.17, 7.30)	0.0165	0.0215
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0455	0.0215
Region											
ASIA	120	62	1	1.6	58	3	5.2	2.13	(0.21, 21.14)	0.5090	0.1494
NORTH AMERICA/WESTERN EUROPE	126	63	6	9.5	63	11	17.5	1.68	(0.62, 4.58)	0.3013	0.1494
OTHER	78	38	0	0.0	40	6	15.0	>999.99	(0.00, >999.99)	0.0335	0.1494
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	3	10.3	>999.99	(0.00, >999.99)	0.0953	0.1216
Y	259	127	7	5.5	132	17	12.9	1.89	(0.78, 4.59)	0.1523	0.1216
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	7	13.5	2.85	(0.58, 13.88)	0.1771	0.9361
POST-MENOPAUSAL	214	110	4	3.6	104	13	12.5	2.97	(0.96, 9.14)	0.0471	0.9361

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Musculoskeletal and connective tissue disorders, Pain in extremity											
All Patients	324	163	10	6.1	161	11	6.8	0.81	(0.34, 1.93)	0.6266	NE
Age group (years)											
<65	266	129	7	5.4	137	10	7.3	0.90	(0.33, 2.40)	0.8259	0.5319
>=65	58	34	3	8.8	24	1	4.2	0.47	(0.05, 4.56)	0.5067	0.5319
Sex											
F	318	162	9	5.6	156	10	6.4	0.89	(0.36, 2.21)	0.8010	0.1472
M	6	1	1	100.0	5	1	20.0	<0.01	(0.00, >999.99)	0.0253	0.1472
Region											
ASIA	120	62	1	1.6	58	2	3.4	1.40	(0.12, 16.01)	0.7845	0.8600
NORTH AMERICA/WESTERN EUROPE	126	63	8	12.7	63	8	12.7	0.79	(0.28, 2.20)	0.6540	0.8600
OTHER	78	38	1	2.6	40	1	2.5	0.41	(0.03, 6.49)	0.5090	0.8600
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	2	6.9	0.36	(0.05, 2.45)	0.2806	0.6905
Y	259	127	7	5.5	132	9	6.8	0.95	(0.35, 2.58)	0.9180	0.6905
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	4	7.7	0.64	(0.13, 3.03)	0.5698	0.9911
POST-MENOPAUSAL	214	110	6	5.5	104	6	5.8	0.93	(0.30, 2.92)	0.9055	0.9911
Time to First Musculoskeletal and connective tissue disorders, Myalgia											
All Patients	324	163	9	5.5	161	10	6.2	0.86	(0.35, 2.14)	0.7459	NE
Age group (years)											
<65	266	129	7	5.4	137	9	6.6	0.88	(0.32, 2.40)	0.7998	0.8941
>=65	58	34	2	5.9	24	1	4.2	0.77	(0.07, 8.46)	0.8274	0.8941
Sex											
F	318	162	9	5.6	156	10	6.4	0.88	(0.35, 2.20)	0.7865	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	3	4.8	58	3	5.2	0.74	(0.15, 3.78)	0.7193	0.2647
NORTH AMERICA/WESTERN EUROPE	126	63	6	9.5	63	5	7.9	0.65	(0.20, 2.18)	0.4846	0.2647
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2067	0.2647
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	2	6.9	0.62	(0.11, 3.39)	0.5777	0.4427
Y	259	127	5	3.9	132	8	6.1	1.03	(0.33, 3.21)	0.9659	0.4427
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	5	9.6	52	3	5.8	0.41	(0.09, 1.83)	0.2307	0.2075
POST-MENOPAUSAL	214	110	4	3.6	104	7	6.7	1.55	(0.45, 5.36)	0.4857	0.2075
Time to First Musculoskeletal and connective tissue disorders, Musculoskeletal pain											
All Patients	324	163	6	3.7	161	5	3.1	0.77	(0.23, 2.52)	0.6617	NE
Age group (years)											
<65	266	129	5	3.9	137	5	3.6	0.86	(0.25, 2.98)	0.8126	0.3534
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3743	0.3534

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	6	3.7	156	4	2.6	0.62	(0.17, 2.21)	0.4584	0.4456
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.4456
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.4579
NORTH AMERICA/WESTERN EUROPE	126	63	6	9.5	63	4	6.3	0.63	(0.18, 2.25)	0.4792	0.4579
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3297	0.4579
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.1796	0.1349
Y	259	127	4	3.1	132	5	3.8	1.10	(0.29, 4.10)	0.8909	0.1349
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.2722
POST-MENOPAUSAL	214	110	5	4.5	104	4	3.8	0.77	(0.21, 2.89)	0.7015	0.2722
Time to First Musculoskeletal and connective tissue disorders, Musculoskeletal chest pain											
All Patients	324	163	5	3.1	161	5	3.1	0.66	(0.19, 2.31)	0.5128	NE
Age group (years)											
<65	266	129	4	3.1	137	5	3.6	0.72	(0.19, 2.73)	0.6301	0.4138
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3754	0.4138
Sex											
F	318	162	5	3.1	156	5	3.2	0.66	(0.19, 2.33)	0.5196	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	2	3.4	1.73	(0.16, 19.12)	0.6493	0.3653
NORTH AMERICA/WESTERN EUROPE	126	63	4	6.3	63	2	3.2	0.34	(0.06, 1.90)	0.2002	0.3653
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5127	0.3653
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.42	(0.03, 6.75)	0.5290	0.8690
Y	259	127	4	3.1	132	4	3.0	0.68	(0.17, 2.71)	0.5778	0.8690
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	2	3.8	0.75	(0.11, 5.34)	0.7737	0.9941
POST-MENOPAUSAL	214	110	3	2.7	104	3	2.9	0.55	(0.11, 2.82)	0.4719	0.9941
Time to First Musculoskeletal and connective tissue disorders, Bone pain											
All Patients	324	163	6	3.7	161	3	1.9	0.46	(0.11, 1.85)	0.2624	NE
Age group (years)											
<65	266	129	4	3.1	137	3	2.2	0.61	(0.14, 2.76)	0.5198	0.2637
>=65	58	34	2	5.9	24	0	0.0	<0.01	(0.00, >999.99)	0.2517	0.2637
Sex											
F	318	162	6	3.7	156	2	1.3	0.32	(0.06, 1.57)	0.1373	0.3358
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.3358
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.0727
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	3	4.8	1.46	(0.24, 8.73)	0.6786	0.0727

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	4	10.5	40	0	0.0	<0.01	(0.00, >999.99)	0.0163	0.0727
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	0	0.0	<0.01	(0.00, >999.99)	0.0945	0.1097
Y	259	127	3	2.4	132	3	2.3	0.93	(0.19, 4.59)	0.9254	0.1097
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	1	1.9	0.50	(0.05, 5.55)	0.5671	0.6992
POST-MENOPAUSAL	214	110	4	3.6	104	1	1.0	0.24	(0.03, 2.14)	0.1632	0.6992
Time to First Musculoskeletal and connective tissue disorders, Flank pain											
All Patients	324	163	1	0.6	161	4	2.5	2.66	(0.29, 24.09)	0.3670	NE
Age group (years)											
<65	266	129	1	0.8	137	4	2.9	2.26	(0.25, 20.59)	0.4590	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	4	2.6	2.74	(0.30, 24.80)	0.3515	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2877	0.0831
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.1391	0.0831
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5083	0.0831
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4497	0.4123
Y	259	127	1	0.8	132	3	2.3	1.96	(0.20, 19.00)	0.5550	0.4123
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	4	3.8	3.08	(0.34, 27.76)	0.2910	1.0000
Time to First Musculoskeletal and connective tissue disorders, Osteonecrosis of jaw											
All Patients	324	163	0	0.0	161	5	3.1	>999.99	(0.00, >999.99)	0.0886	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.1742	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2733	1.0000
Sex											
F	318	162	0	0.0	156	4	2.6	>999.99	(0.00, >999.99)	0.1129	0.9999
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.4795	0.9999
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5097	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.1377	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5892	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	3	10.3	>999.99	(0.00, >999.99)	0.1676	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2580	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6095	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	3	2.9	>999.99	(0.00, >999.99)	0.1350	1.0000
Time to First Musculoskeletal and connective tissue disorders, Pain in jaw											
All Patients	324	163	1	0.6	161	4	2.5	2.81	(0.31, 25.56)	0.3391	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.1250	0.0511
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4475	0.0511
Sex											
F	318	162	1	0.6	156	3	1.9	2.36	(0.24, 23.08)	0.4458	0.6671
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6171	0.6671
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.8100
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	3	4.8	2.50	(0.26, 24.35)	0.4141	0.8100
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5211	0.8100
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.2650	0.2176
Y	259	127	1	0.8	132	2	1.5	1.61	(0.15, 17.75)	0.6968	0.2176
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	3	2.9	2.60	(0.27, 25.22)	0.3920	1.0000
Time to First Musculoskeletal and connective tissue disorders, Groin pain											
All Patients	324	163	0	0.0	161	4	2.5	>999.99	(0.00, >999.99)	0.1203	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.2094	0.9999
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2963	0.9999
Sex											
F	318	162	0	0.0	156	4	2.6	>999.99	(0.00, >999.99)	0.1166	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	4	6.3	>999.99	(0.00, >999.99)	0.0861	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	4	3.0	>999.99	(0.00, >999.99)	0.1311	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	0.9999
POST-MENOPAUSAL	214	110	0	0.0	104	4	3.8	>999.99	(0.00, >999.99)	0.1029	0.9999
Time to First Musculoskeletal and connective tissue disorders, Neck pain											
All Patients	324	163	1	0.6	161	2	1.2	1.66	(0.15, 18.48)	0.6748	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.48	(0.13, 16.48)	0.7475	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	1	0.6	156	2	1.3	1.72	(0.15, 19.04)	0.6564	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.90	(0.17, 20.99)	0.5932	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2781	0.0674
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.1943	0.0674
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.85	(0.17, 20.43)	0.6109	1.0000
Time to First Musculoskeletal and connective tissue disorders, Pathological fracture											
All Patients	324	163	2	1.2	161	1	0.6	0.39	(0.03, 4.45)	0.4353	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.90	(0.06, 14.34)	0.9385	0.4207
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3613	0.4207
Sex											
F	318	162	2	1.2	156	1	0.6	0.41	(0.04, 4.59)	0.4520	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.70	(0.04, 11.73)	0.8024	0.5470
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.5470
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3042	0.5470
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2278	0.3592
Y	259	127	1	0.8	132	1	0.8	0.92	(0.06, 14.64)	0.9503	0.3592
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.0587
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1163	0.0587
Time to First Musculoskeletal and connective tissue disorders, Joint stiffness											
All Patients	324	163	1	0.6	161	1	0.6	0.86	(0.05, 13.72)	0.9132	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.74	(0.05, 11.93)	0.8343	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.88	(0.06, 14.10)	0.9286	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.88	(0.05, 14.00)	0.9251	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3729	0.1245
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3908	0.1245
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2913	0.0843
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3323	0.0843
Time to First Musculoskeletal and connective tissue disorders, Muscle discomfort											
All Patients	324	163	1	0.6	161	1	0.6	0.61	(0.04, 10.09)	0.7280	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5598	0.1549
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3894	0.1549
Sex											
F	318	162	1	0.6	156	1	0.6	0.63	(0.04, 10.39)	0.7437	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.66	(0.04, 10.74)	0.7684	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3747	0.1249
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5271	0.1249
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.73	(0.04, 11.81)	0.8232	1.0000
Time to First Musculoskeletal and connective tissue disorders, Muscle tightness											
All Patients	324	163	1	0.6	161	1	0.6	0.91	(0.06, 14.61)	0.9470	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4003	0.1414
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.1414
Sex											
F	318	162	1	0.6	156	1	0.6	0.93	(0.06, 15.01)	0.9620	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.2727
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	0.2727
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4241	0.2727
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	0.1193
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3914	0.1193
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3950	0.1045

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	0.1045
Time to First Musculoskeletal and connective tissue disorders, Muscular weakness											
All Patients	324	163	1	0.6	161	1	0.6	0.99	(0.06, 15.83)	0.9945	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3396	0.1321
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.1321
Sex											
F	318	162	1	0.6	156	1	0.6	1.02	(0.06, 16.25)	0.9908	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3258	0.2554
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	0.2554
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.2554
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	0.0742
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2914	0.0742
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.0946
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3125	0.0946
Time to First Musculoskeletal and connective tissue disorders, Musculoskeletal stiffness											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.1393	NE
Age group (years)											
<65	266	129	2	1.6	137	0	0.0	<0.01	(0.00, >999.99)	0.1187	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1446	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2987	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2974	1.0000
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.2114	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3221	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3004	1.0000
Time to First Musculoskeletal and connective tissue disorders, Sacral pain											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.1358	NE
Age group (years)											
<65	266	129	2	1.6	137	0	0.0	<0.01	(0.00, >999.99)	0.1124	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1412	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2871	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3110	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	2	1.6	132	0	0.0	<0.01	(0.00, >999.99)	0.1197	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1546	1.0000
Time to First Musculoskeletal and connective tissue disorders, Arthritis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2926	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3221	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2978	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3221	1.0000
Time to First Musculoskeletal and connective tissue disorders, Coccodynia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3377	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3095	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3326	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3057	1.0000
Time to First Musculoskeletal and connective tissue disorders, Exostosis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4669	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5211	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4795	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4795	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4386	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5127	1.0000
Time to First Musculoskeletal and connective tissue disorders, Extremity contracture											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3189	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3420	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3126	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3126	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Musculoskeletal and connective tissue disorders, Hypercreatinemia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Musculoskeletal and connective tissue disorders, Joint effusion											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2969	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3251	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3021	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3289	1.0000
Time to First Musculoskeletal and connective tissue disorders, Joint swelling											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5465	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5839	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5514	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5839	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5716	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4795	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Musculoskeletal and connective tissue disorders, Limb discomfort											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4649	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5064	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4566	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4936	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4858	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5127	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Musculoskeletal and connective tissue disorders, Mobility decreased											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Musculoskeletal and connective tissue disorders, Muscle contracture											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Musculoskeletal and connective tissue disorders, Muscle fibrosis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2730	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3894	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2793	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2733	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3747	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2879	1.0000
Time to First Musculoskeletal and connective tissue disorders, Muscle twitching											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3559	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3810	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3496	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3613	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3846	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3411	1.0000
Time to First Musculoskeletal and connective tissue disorders, Osteoarthritis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4855	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5403	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4763	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4183	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5032	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Musculoskeletal and connective tissue disorders, Osteonecrosis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5009	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5501	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4945	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4708	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5229	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4366	1.0000
Time to First Musculoskeletal and connective tissue disorders, Osteopenia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1998	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1621	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2079	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2549	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2415	1.0000
Time to First Musculoskeletal and connective tissue disorders, Osteoporosis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1393	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0923	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1458	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.0910	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1197	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1967	1.0000
Time to First Musculoskeletal and connective tissue disorders, Periarthritis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3295	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Musculoskeletal and connective tissue disorders, Plantar fasciitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3752	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4092	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3683	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4319	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2899	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3487	1.0000
Time to First Musculoskeletal and connective tissue disorders, Rotator cuff syndrome											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4898	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5308	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4831	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4631	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5071	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6015	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Musculoskeletal and connective tissue disorders, Spinal osteoarthritis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2136	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1802	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2219	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2801	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1995	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2596	1.0000
Time to First Musculoskeletal and connective tissue disorders, Temporomandibular pain and dysfunction syndrome											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1544	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1109	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1635	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2123	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2059	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2153	1.0000
Time to First Nervous system disorders, Any											
All Patients	324	163	45	27.6	161	66	41.0	1.44	(0.98, 2.10)	0.0619	NE
Age group (years)											
<65	266	129	31	24.0	137	62	45.3	1.90	(1.23, 2.93)	0.0032	0.0014
>=65	58	34	14	41.2	24	4	16.7	0.34	(0.11, 1.03)	0.0451	0.0014
Sex											
F	318	162	44	27.2	156	64	41.0	1.48	(1.01, 2.18)	0.0443	0.0951
M	6	1	1	100.0	5	2	40.0	0.22	(0.01, 3.59)	0.2467	0.0951
Region											
ASIA	120	62	15	24.2	58	22	37.9	1.40	(0.72, 2.70)	0.3191	0.8321
NORTH AMERICA/WESTERN EUROPE	126	63	24	38.1	63	31	49.2	1.36	(0.80, 2.32)	0.2615	0.8321
OTHER	78	38	6	15.8	40	13	32.5	2.01	(0.76, 5.33)	0.1521	0.8321
Visceral disease (per eCRF)											
N	65	36	15	41.7	29	10	34.5	0.73	(0.32, 1.64)	0.4412	0.0706
Y	259	127	30	23.6	132	56	42.4	1.77	(1.13, 2.76)	0.0112	0.0706
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	13	25.0	52	23	44.2	1.90	(0.96, 3.76)	0.0607	0.3804
POST-MENOPAUSAL	214	110	31	28.2	104	41	39.4	1.30	(0.81, 2.08)	0.2688	0.3804
Time to First Nervous system disorders, Headache											
All Patients	324	163	23	14.1	161	39	24.2	1.50	(0.89, 2.51)	0.1237	NE
Age group (years)											
<65	266	129	16	12.4	137	37	27.0	1.90	(1.05, 3.42)	0.0307	0.0301
>=65	58	34	7	20.6	24	2	8.3	0.36	(0.07, 1.75)	0.1870	0.0301
Sex											
F	318	162	22	13.6	156	39	25.0	1.63	(0.97, 2.76)	0.0638	0.0351
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0253	0.0351
Region											
ASIA	120	62	4	6.5	58	11	19.0	2.42	(0.77, 7.66)	0.1206	0.3819

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	15	23.8	63	18	28.6	1.10	(0.55, 2.18)	0.7893	0.3819
OTHER	78	38	4	10.5	40	10	25.0	2.16	(0.67, 6.95)	0.1858	0.3819
Visceral disease (per eCRF)											
N	65	36	8	22.2	29	7	24.1	0.99	(0.36, 2.74)	0.9810	0.3535
Y	259	127	15	11.8	132	32	24.2	1.77	(0.95, 3.27)	0.0666	0.3535
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	6	11.5	52	14	26.9	2.07	(0.79, 5.44)	0.1305	0.5003
POST-MENOPAUSAL	214	110	16	14.5	104	25	24.0	1.44	(0.77, 2.71)	0.2517	0.5003
Time to First Nervous system disorders, Dizziness											
All Patients	324	163	14	8.6	161	15	9.3	0.82	(0.39, 1.73)	0.6089	NE
Age group (years)											
<65	266	129	9	7.0	137	15	10.9	1.15	(0.49, 2.67)	0.7462	0.0175
>=65	58	34	5	14.7	24	0	0.0	<0.01	(0.00, >999.99)	0.0639	0.0175
Sex											
F	318	162	13	8.0	156	14	9.0	0.87	(0.40, 1.88)	0.7199	0.0709
M	6	1	1	100.0	5	1	20.0	<0.01	(0.00, >999.99)	0.0253	0.0709
Region											
ASIA	120	62	9	14.5	58	8	13.8	0.75	(0.29, 1.96)	0.5514	0.8203
NORTH AMERICA/WESTERN EUROPE	126	63	4	6.3	63	6	9.5	1.05	(0.28, 3.97)	0.9417	0.8203
OTHER	78	38	1	2.6	40	1	2.5	0.77	(0.05, 12.41)	0.8515	0.8203
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	1	3.4	0.30	(0.03, 2.65)	0.2455	0.1815
Y	259	127	10	7.9	132	14	10.6	0.98	(0.43, 2.24)	0.9664	0.1815
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	4	7.7	52	4	7.7	0.97	(0.24, 3.88)	0.9647	0.8655
POST-MENOPAUSAL	214	110	9	8.2	104	10	9.6	0.84	(0.34, 2.12)	0.7158	0.8655
Time to First Nervous system disorders, Dysgeusia											
All Patients	324	163	6	3.7	161	14	8.7	2.27	(0.87, 5.92)	0.0845	NE
Age group (years)											
<65	266	129	3	2.3	137	13	9.5	3.83	(1.09, 13.45)	0.0244	0.0901
>=65	58	34	3	8.8	24	1	4.2	0.50	(0.05, 4.85)	0.5451	0.0901
Sex											
F	318	162	6	3.7	156	13	8.3	2.15	(0.82, 5.66)	0.1130	0.6534
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.6534
Region											
ASIA	120	62	2	3.2	58	1	1.7	0.46	(0.04, 5.06)	0.5131	0.2098
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	12	19.0	4.19	(1.18, 14.85)	0.0158	0.2098
OTHER	78	38	1	2.6	40	1	2.5	0.99	(0.06, 15.78)	0.9927	0.2098
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	2	6.9	1.25	(0.18, 8.91)	0.8204	0.5034
Y	259	127	4	3.1	132	12	9.1	2.75	(0.88, 8.53)	0.0688	0.5034
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	4	7.7	>999.99	(0.00, >999.99)	0.0634	0.0709

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	6	5.5	104	9	8.7	1.56	(0.55, 4.39)	0.3971	0.0709
Time to First Nervous system disorders, Hypoaesthesia											
All Patients	324	163	5	3.1	161	4	2.5	0.53	(0.14, 2.01)	0.3455	NE
Age group (years)											
<65	266	129	5	3.9	137	4	2.9	0.45	(0.12, 1.71)	0.2313	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	5	3.1	156	4	2.6	0.55	(0.15, 2.07)	0.3714	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	4	6.5	58	1	1.7	0.15	(0.02, 1.37)	0.0539	0.1786
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	3	4.8	2.46	(0.25, 23.81)	0.4228	0.1786
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.1786
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.49	(0.04, 5.54)	0.5569	0.8464
Y	259	127	3	2.4	132	3	2.3	0.60	(0.12, 2.99)	0.5280	0.8464
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	0	0.0	<0.01	(0.00, >999.99)	0.0073	0.0147
POST-MENOPAUSAL	214	110	2	1.8	104	4	3.8	1.70	(0.31, 9.28)	0.5381	0.0147
Time to First Nervous system disorders, Disturbance in attention											
All Patients	324	163	1	0.6	161	5	3.1	4.76	(0.55, 40.82)	0.1165	NE
Age group (years)											
<65	266	129	1	0.8	137	4	2.9	3.39	(0.38, 30.47)	0.2466	0.4284
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.4284
Sex											
F	318	162	1	0.6	156	5	3.2	4.89	(0.57, 41.91)	0.1092	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	5	7.9	4.96	(0.58, 42.49)	0.1047	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	1.30	(0.08, 20.73)	0.8538	0.1390
Y	259	127	0	0.0	132	4	3.0	>999.99	(0.00, >999.99)	0.0615	0.1390
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	2	3.8	1.97	(0.18, 21.73)	0.5727	0.1949
POST-MENOPAUSAL	214	110	0	0.0	104	3	2.9	>999.99	(0.00, >999.99)	0.0864	0.1949
Time to First Nervous system disorders, Paraesthesia											
All Patients	324	163	2	1.2	161	3	1.9	1.08	(0.18, 6.53)	0.9366	NE
Age group (years)											
<65	266	129	2	1.6	137	3	2.2	0.94	(0.15, 5.74)	0.9477	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	2	1.2	156	3	1.9	1.11	(0.18, 6.73)	0.9105	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2059	0.2418
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.86	(0.17, 20.50)	0.6080	0.2418
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5083	0.2418
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3865	0.1692
Y	259	127	1	0.8	132	3	2.3	1.83	(0.19, 17.79)	0.5950	0.1692
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	3	2.9	1.22	(0.20, 7.37)	0.8254	1.0000
Time to First Nervous system disorders, Peripheral sensory neuropathy											
All Patients	324	163	0	0.0	161	4	2.5	>999.99	(0.00, >999.99)	0.0539	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.0675	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	4	2.6	>999.99	(0.00, >999.99)	0.0507	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	3	5.2	>999.99	(0.00, >999.99)	0.0906	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	4	3.0	>999.99	(0.00, >999.99)	0.0642	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.2026	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1484	1.0000
Time to First Nervous system disorders, Amnesia											
All Patients	324	163	1	0.6	161	2	1.2	1.35	(0.12, 15.43)	0.8062	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2206	0.0882
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.0882
Sex											
F	318	162	1	0.6	156	2	1.3	1.40	(0.12, 15.89)	0.7874	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.6534
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.70	(0.04, 11.71)	0.8011	0.6534
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4936	0.6534

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	2	1.5	1.29	(0.11, 14.64)	0.8378	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4497	0.3514
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.76	(0.05, 12.60)	0.8465	0.3514
Time to First Nervous system disorders, Memory impairment											
All Patients	324	163	1	0.6	161	2	1.2	1.30	(0.12, 14.51)	0.8316	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3272	0.0977
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4414	0.0977
Sex											
F	318	162	1	0.6	156	2	1.3	1.34	(0.12, 15.01)	0.8093	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.60	(0.14, 17.85)	0.6985	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4533	0.2607
Y	259	127	1	0.8	132	1	0.8	0.69	(0.04, 11.00)	0.7893	0.2607
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.54	(0.14, 17.12)	0.7221	1.0000
Time to First Nervous system disorders, Migraine											
All Patients	324	163	1	0.6	161	2	1.2	1.91	(0.17, 21.14)	0.5899	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.73	(0.16, 19.16)	0.6493	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.97	(0.18, 21.71)	0.5743	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.5658
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	0.5658
OTHER	78	38	1	2.6	40	1	2.5	0.81	(0.05, 13.01)	0.8794	0.5658
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	1.28	(0.08, 20.51)	0.8598	0.3698
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3345	0.3698
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	2.04	(0.18, 22.51)	0.5522	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Nervous system disorders, Syncope											
All Patients	324	163	2	1.2	161	1	0.6	0.45	(0.04, 4.98)	0.5017	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.94	(0.06, 14.99)	0.9637	0.3996
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3743	0.3996
Sex											
F	318	162	2	1.2	156	1	0.6	0.46	(0.04, 5.11)	0.5169	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.1633
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	0	0.0	<0.01	(0.00, >999.99)	0.1421	0.1633
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	0.1633
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	1	0.8	0.41	(0.04, 4.63)	0.4605	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.0561
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1384	0.0561
Time to First Nervous system disorders, Ageusia											
All Patients	324	163	1	0.6	161	1	0.6	0.69	(0.04, 11.58)	0.7926	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.59	(0.03, 10.17)	0.7152	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.70	(0.04, 11.90)	0.8076	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.71	(0.04, 11.90)	0.8129	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1967	0.1117
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	0.1117
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.81	(0.05, 13.31)	0.8831	1.0000
Time to First Nervous system disorders, Dysaesthesia											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1933	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2171	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1872	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.1665	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2127	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4483	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3103	1.0000
Time to First Nervous system disorders, Presyncope											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.3443	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3707	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.3383	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2702	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.3767	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First Nervous system disorders, Taste disorder											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1528	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.1700	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1475	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3012	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.1646	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Nervous system disorders, Anosmia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1410	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1025	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1470	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1967	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2024	1.0000
Time to First Nervous system disorders, Ataxia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4076	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4443	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3994	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4268	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4199	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3747	1.0000
Time to First Nervous system disorders, Axonal neuropathy											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4969	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5403	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4905	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4795	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5169	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4328	1.0000
Time to First Nervous system disorders, Brain fog											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Nervous system disorders, Burning sensation											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2594	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2256	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0253	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2871	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2345	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Nervous system disorders, Cerebral haemorrhage											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4889	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5305	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4795	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5541	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5002	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4281	1.0000
Time to First Nervous system disorders, Cerebrovascular accident											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3082	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2652	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3037	1.0000
Time to First Nervous system disorders, Cranial nerve paralysis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2723	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2424	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2789	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2871	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3598	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3002	1.0000
Time to First Nervous system disorders, Dysarthria											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3173	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3396	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3111	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Nervous system disorders, Encephalopathy											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4535	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4910	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4450	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5563	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4672	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4795	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Nervous system disorders, Haemorrhage intracranial											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First Nervous system disorders, Hemianopia homonymous											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4007	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4271	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3938	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3503	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4283	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3719	1.0000
Time to First Nervous system disorders, Hemiparesis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3655	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4031	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3588	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3367	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2749	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4021	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Nervous system disorders, Hyperaesthesia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1365	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0973	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1438	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1380	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1824	1.0000
Time to First Nervous system disorders, Lateropulsion											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Nervous system disorders, Lethargy											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2762	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2525	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2826	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2934	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2489	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2611	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Nervous system disorders, Loss of consciousness											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1998	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1621	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2079	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1201	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1859	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2415	1.0000
Time to First Nervous system disorders, Neuropathy peripheral											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3319	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3082	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3297	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Nervous system disorders, Sciatica											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1266	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0833	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1327	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1482	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1222	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1747	1.0000
Time to First Nervous system disorders, Seizure											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3540	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3810	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3477	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3314	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3820	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3674	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Nervous system disorders, Somnolence											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Nervous system disorders, Tension headache											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4795	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5201	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4727	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4275	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4922	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6095	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Any											
All Patients	324	163	38	23.3	161	57	35.4	1.30	(0.86, 1.97)	0.2088	NE
Age group (years)											
<65	266	129	27	20.9	137	49	35.8	1.43	(0.89, 2.30)	0.1343	0.5248
>=65	58	34	11	32.4	24	8	33.3	0.97	(0.39, 2.44)	0.9567	0.5248
Sex											
F	318	162	37	22.8	156	53	34.0	1.26	(0.82, 1.92)	0.2871	0.7890
M	6	1	1	100.0	5	4	80.0	1.69	(0.18, 16.13)	0.6458	0.7890
Region											
ASIA	120	62	8	12.9	58	21	36.2	2.43	(1.07, 5.50)	0.0281	0.0947
NORTH AMERICA/WESTERN EUROPE	126	63	23	36.5	63	30	47.6	1.28	(0.74, 2.20)	0.3810	0.0947
OTHER	78	38	7	18.4	40	6	15.0	0.52	(0.17, 1.59)	0.2484	0.0947
Visceral disease (per eCRF)											
N	65	36	12	33.3	29	6	20.7	0.50	(0.18, 1.34)	0.1583	0.0198
Y	259	127	26	20.5	132	51	38.6	1.65	(1.03, 2.65)	0.0366	0.0198
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	7	13.5	52	20	38.5	2.58	(1.08, 6.13)	0.0265	0.0555
POST-MENOPAUSAL	214	110	30	27.3	104	33	31.7	0.96	(0.58, 1.58)	0.8728	0.0555
Time to First Respiratory, thoracic and mediastinal disorders, Cough											
All Patients	324	163	13	8.0	161	24	14.9	1.29	(0.65, 2.56)	0.4598	NE
Age group (years)											
<65	266	129	9	7.0	137	22	16.1	1.49	(0.68, 3.26)	0.3210	0.3614
>=65	58	34	4	11.8	24	2	8.3	0.64	(0.12, 3.53)	0.6100	0.3614
Sex											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	12	7.4	156	23	14.7	1.42	(0.70, 2.88)	0.3229	0.1626
M	6	1	1	100.0	5	1	20.0	0.29	(0.02, 4.65)	0.3508	0.1626
Region											
ASIA	120	62	3	4.8	58	8	13.8	2.17	(0.57, 8.23)	0.2436	0.7822
NORTH AMERICA/WESTERN EUROPE	126	63	9	14.3	63	14	22.2	0.98	(0.41, 2.35)	0.9687	0.7822
OTHER	78	38	1	2.6	40	2	5.0	1.11	(0.10, 12.35)	0.9311	0.7822
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	1	3.4	0.21	(0.02, 1.90)	0.1269	0.0503
Y	259	127	9	7.1	132	23	17.4	1.68	(0.77, 3.66)	0.1848	0.0503
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	8	15.4	1.99	(0.53, 7.56)	0.3015	0.6322
POST-MENOPAUSAL	214	110	9	8.2	104	15	14.4	1.28	(0.56, 2.96)	0.5580	0.6322
Time to First Respiratory, thoracic and mediastinal disorders, Dyspnoea											
All Patients	324	163	9	5.5	161	15	9.3	1.32	(0.58, 3.04)	0.5099	NE
Age group (years)											
<65	266	129	8	6.2	137	12	8.8	1.03	(0.42, 2.54)	0.9516	0.2082
>=65	58	34	1	2.9	24	3	12.5	4.55	(0.47, 43.93)	0.1509	0.2082
Sex											
F	318	162	9	5.6	156	15	9.6	1.36	(0.59, 3.13)	0.4662	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	5	8.6	3.78	(0.44, 32.64)	0.1942	0.1040
NORTH AMERICA/WESTERN EUROPE	126	63	5	7.9	63	9	14.3	1.57	(0.53, 4.72)	0.4149	0.1040
OTHER	78	38	3	7.9	40	1	2.5	0.28	(0.03, 2.71)	0.2403	0.1040
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.62	(0.06, 6.80)	0.6903	0.3746
Y	259	127	7	5.5	132	14	10.6	1.46	(0.59, 3.65)	0.4122	0.3746
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	4	7.7	2.90	(0.31, 26.84)	0.3265	0.4888
POST-MENOPAUSAL	214	110	8	7.3	104	11	10.6	1.24	(0.50, 3.08)	0.6510	0.4888
Time to First Respiratory, thoracic and mediastinal disorders, Oropharyngeal pain											
All Patients	324	163	5	3.1	161	10	6.2	1.76	(0.60, 5.17)	0.2995	NE
Age group (years)											
<65	266	129	5	3.9	137	10	7.3	1.58	(0.53, 4.64)	0.4061	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	4	2.5	156	9	5.8	2.08	(0.64, 6.79)	0.2139	0.1587
M	6	1	1	100.0	5	1	20.0	0.22	(0.01, 3.59)	0.2467	0.1587
Region											
ASIA	120	62	2	3.2	58	5	8.6	2.68	(0.52, 13.81)	0.2206	0.3264
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	3	4.8	0.83	(0.17, 4.14)	0.8185	0.3264
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.3048	0.3264

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3865	0.1597
Y	259	127	4	3.1	132	10	7.6	2.04	(0.64, 6.53)	0.2220	0.1597
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	6	11.5	>999.99	(0.00, >999.99)	0.0181	0.0125
POST-MENOPAUSAL	214	110	4	3.6	104	3	2.9	0.70	(0.15, 3.12)	0.6330	0.0125
Time to First Respiratory, thoracic and mediastinal disorders, Epistaxis											
All Patients	324	163	6	3.7	161	8	5.0	1.12	(0.39, 3.27)	0.8297	NE
Age group (years)											
<65	266	129	5	3.9	137	7	5.1	1.09	(0.34, 3.46)	0.8839	0.8295
>=65	58	34	1	2.9	24	1	4.2	1.33	(0.08, 21.42)	0.8405	0.8295
Sex											
F	318	162	6	3.7	156	7	4.5	0.99	(0.33, 2.97)	0.9831	0.5085
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.5085
Region											
ASIA	120	62	1	1.6	58	1	1.7	1.02	(0.06, 16.26)	0.9909	0.9718
NORTH AMERICA/WESTERN EUROPE	126	63	5	7.9	63	7	11.1	1.24	(0.39, 3.95)	0.7143	0.9718
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.9718
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	1	3.4	0.23	(0.03, 2.13)	0.1623	0.0524
Y	259	127	2	1.6	132	7	5.3	2.96	(0.61, 14.34)	0.1578	0.0524
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	3	5.8	2.69	(0.28, 25.93)	0.3734	0.3658
POST-MENOPAUSAL	214	110	5	4.5	104	4	3.8	0.69	(0.18, 2.60)	0.5804	0.3658
Time to First Respiratory, thoracic and mediastinal disorders, Nasal congestion											
All Patients	324	163	4	2.5	161	7	4.3	1.14	(0.33, 3.93)	0.8384	NE
Age group (years)											
<65	266	129	4	3.1	137	6	4.4	0.82	(0.23, 2.96)	0.7598	0.1746
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2429	0.1746
Sex											
F	318	162	3	1.9	156	7	4.5	1.62	(0.42, 6.33)	0.4832	0.0578
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.1573	0.0578
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2934	0.2312
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	6	9.5	1.45	(0.36, 5.87)	0.6003	0.2312
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5201	0.2312
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	1	3.4	0.28	(0.03, 2.81)	0.2533	0.0687
Y	259	127	1	0.8	132	6	4.5	3.63	(0.44, 30.32)	0.2024	0.0687
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.76	(0.05, 12.42)	0.8442	0.3649
POST-MENOPAUSAL	214	110	2	1.8	104	6	5.8	2.26	(0.45, 11.27)	0.3052	0.3649

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Respiratory, thoracic and mediastinal disorders, Rhinorrhoea											
All Patients	324	163	4	2.5	161	7	4.3	1.12	(0.31, 3.97)	0.8626	NE
Age group (years)											
<65	266	129	3	2.3	137	6	4.4	0.99	(0.24, 4.17)	0.9938	0.8936
>=65	58	34	1	2.9	24	1	4.2	1.52	(0.10, 24.34)	0.7646	0.8936
Sex											
F	318	162	3	1.9	156	7	4.5	1.62	(0.40, 6.50)	0.4914	0.0351
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0455	0.0351
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	4	6.3	63	7	11.1	1.13	(0.31, 4.12)	0.8492	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.0905	0.0403
Y	259	127	2	1.6	132	7	5.3	2.25	(0.45, 11.17)	0.3099	0.0403
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6310	0.4195
POST-MENOPAUSAL	214	110	3	2.7	104	6	5.8	1.57	(0.38, 6.47)	0.5323	0.4195
Time to First Respiratory, thoracic and mediastinal disorders, Pneumonitis											
All Patients	324	163	2	1.2	161	5	3.1	2.11	(0.41, 10.96)	0.3644	NE
Age group (years)											
<65	266	129	1	0.8	137	5	3.6	3.67	(0.42, 31.67)	0.2066	0.1441
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.1441
Sex											
F	318	162	2	1.2	156	2	1.3	0.98	(0.14, 6.99)	0.9870	0.2630
M	6	1	0	0.0	5	3	60.0	>999.99	(0.00, >999.99)	0.3322	0.2630
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.97	(0.06, 15.47)	0.9805	0.6052
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	3	4.8	2.45	(0.25, 23.80)	0.4239	0.6052
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	0.6052
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	3	10.3	3.79	(0.39, 36.47)	0.2144	0.6290
Y	259	127	1	0.8	132	2	1.5	1.36	(0.12, 15.41)	0.8034	0.6290
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.87	(0.05, 13.95)	0.9191	0.9702
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	1.03	(0.06, 16.46)	0.9835	0.9702
Time to First Respiratory, thoracic and mediastinal disorders, Nasal dryness											
All Patients	324	163	0	0.0	161	5	3.1	>999.99	(0.00, >999.99)	0.0357	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.0855	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	5	3.2	>999.99	(0.00, >999.99)	0.0332	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	5	7.9	>999.99	(0.00, >999.99)	0.0278	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0443	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.2094	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	3	2.9	>999.99	(0.00, >999.99)	0.0860	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Pleural effusion											
All Patients	324	163	2	1.2	161	3	1.9	1.20	(0.20, 7.25)	0.8429	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	2.26	(0.23, 21.97)	0.4716	0.2285
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3918	0.2285
Sex											
F	318	162	2	1.2	156	3	1.9	1.24	(0.20, 7.47)	0.8171	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.94	(0.06, 15.12)	0.9671	0.1061
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.1830	0.1061
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1353	0.1061
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	3	2.3	1.11	(0.18, 6.71)	0.9103	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.3117
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.84	(0.12, 6.00)	0.8622	0.3117
Time to First Respiratory, thoracic and mediastinal disorders, Rhinitis allergic											
All Patients	324	163	0	0.0	161	5	3.1	>999.99	(0.00, >999.99)	0.0453	NE
Age group (years)											
<65	266	129	0	0.0	137	5	3.6	>999.99	(0.00, >999.99)	0.0600	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	5	3.2	>999.99	(0.00, >999.99)	0.0421	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	4	6.9	>999.99	(0.00, >999.99)	0.0819	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0543	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.1860	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	3	2.9	>999.99	(0.00, >999.99)	0.1228	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Pneumothorax											
All Patients	324	163	0	0.0	161	3	1.9	>999.99	(0.00, >999.99)	0.1039	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.1288	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	3	1.9	>999.99	(0.00, >999.99)	0.0991	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.1677	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3423	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.1212	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.1944	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3323	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Productive cough											
All Patients	324	163	1	0.6	161	2	1.2	1.01	(0.08, 12.27)	0.9958	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	0.89	(0.07, 10.84)	0.9271	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2724	0.0270
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0455	0.0270
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	0.6897
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.43	(0.03, 7.11)	0.5476	0.6897
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.6897
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	2	1.5	0.86	(0.07, 10.97)	0.9072	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5930	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Respiratory, thoracic and mediastinal disorders, Pulmonary embolism											
All Patients	324	163	3	1.8	161	0	0.0	<0.01	(0.00, >999.99)	0.0382	NE
Age group (years)											
<65	266	129	2	1.6	137	0	0.0	<0.01	(0.00, >999.99)	0.0753	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3819	1.0000
Sex											
F	318	162	3	1.9	156	0	0.0	<0.01	(0.00, >999.99)	0.0415	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	0	0.0	<0.01	(0.00, >999.99)	0.1274	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1306	1.0000
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.1643	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	3	2.7	104	0	0.0	<0.01	(0.00, >999.99)	0.0486	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Dysphonia											
All Patients	324	163	1	0.6	161	1	0.6	0.59	(0.04, 9.64)	0.7056	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2236	0.0487
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2888	0.0487
Sex											
F	318	162	1	0.6	156	1	0.6	0.60	(0.04, 9.94)	0.7217	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5541	0.2312
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.2312
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1967	0.2312
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.52	(0.03, 8.62)	0.6455	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.71	(0.04, 11.51)	0.8075	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Dyspnoea exertional											
All Patients	324	163	1	0.6	161	1	0.6	0.70	(0.04, 11.71)	0.8007	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.61	(0.04, 10.40)	0.7314	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	1	0.6	156	1	0.6	0.70	(0.04, 11.88)	0.8066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	0.2553
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1138	0.2553
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.2553
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1573	0.1003
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	0.1003
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.0669
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1025	0.0669
Time to First Respiratory, thoracic and mediastinal disorders, Nasal inflammation											
All Patients	324	163	1	0.6	161	1	0.6	1.00	(0.06, 16.04)	0.9983	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.92	(0.06, 14.64)	0.9502	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	1.03	(0.06, 16.45)	0.9838	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.99	(0.06, 15.86)	0.9953	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	1.29	(0.08, 20.64)	0.8563	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	1.04	(0.07, 16.69)	0.9758	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Upper-airway cough syndrome											
All Patients	324	163	1	0.6	161	1	0.6	0.82	(0.05, 13.33)	0.8899	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.75	(0.05, 12.21)	0.8396	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.84	(0.05, 13.71)	0.9056	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.94	(0.06, 15.03)	0.9643	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.78	(0.05, 12.62)	0.8589	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.89	(0.06, 14.44)	0.9375	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Aponia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2730	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2488	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2793	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2733	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2450	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2879	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Asthma											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2978	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3041	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2966	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2785	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2999	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Respiratory, thoracic and mediastinal disorders, Bronchiectasis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4419	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4795	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4334	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4292	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4622	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4945	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Bronchospasm											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5186	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5553	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5224	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4795	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5211	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5741	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Dry throat											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3368	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3653	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3306	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3380	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2618	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3347	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Hypoventilation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3377	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3095	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3326	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3057	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Laryngeal haemorrhage											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4933	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.3173	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4892	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4795	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5036	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4461	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Lower respiratory tract congestion											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Pharyngeal erythema											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1944	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3918	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2024	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2528	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1786	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2343	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Pharyngeal inflammation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3416	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3126	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3103	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Pulmonary thrombosis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Pulmonary venous thrombosis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3220	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3255	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2981	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Reflux laryngitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4362	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4769	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4276	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4292	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4543	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4005	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Respiratory disorder											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4008	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3264	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3049	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3080	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3309	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Sinus congestion											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Throat irritation											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2695	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2344	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2762	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2934	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3598	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2397	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Respiratory, thoracic and mediastinal disorders, Wheezing											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2087	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3918	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2169	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2719	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1929	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2534	1.0000

Men are excluded from the subgroups of "Menopausal Status at Randomization"
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_tte.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_SPT_P2_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 8065628e23c1f16f1b9c5c76540f88be90f918fa
08 APR 2025 20:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis by SOC and PT Overall and with Subgroups (Safety), Adverse Events by SOC and PT, Part 3/3, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Eye disorders, Any											
All Patients	324	163	25	15.3	161	40	24.8	1.44	(0.87, 2.37)	0.1555	NE
Age group (years)											
<65	266	129	22	17.1	137	36	26.3	1.28	(0.75, 2.18)	0.3712	0.5058
>=65	58	34	3	8.8	24	4	16.7	2.23	(0.50, 9.97)	0.2820	0.5058
Sex											
F	318	162	25	15.4	156	40	25.6	1.49	(0.90, 2.46)	0.1196	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	10	16.1	58	9	15.5	0.73	(0.29, 1.80)	0.4890	0.2394
NORTH AMERICA/WESTERN EUROPE	126	63	10	15.9	63	20	31.7	2.15	(1.00, 4.60)	0.0441	0.2394
OTHER	78	38	5	13.2	40	11	27.5	1.53	(0.53, 4.43)	0.4316	0.2394
Visceral disease (per eCRF)											
N	65	36	7	19.4	29	4	13.8	0.66	(0.19, 2.29)	0.5143	0.1586
Y	259	127	18	14.2	132	36	27.3	1.69	(0.96, 2.97)	0.0690	0.1586
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	11	21.2	52	14	26.9	0.97	(0.44, 2.16)	0.9446	0.2606
POST-MENOPAUSAL	214	110	14	12.7	104	26	25.0	1.88	(0.98, 3.60)	0.0537	0.2606
Time to First Eye disorders, Dry eye											
All Patients	324	163	7	4.3	161	14	8.7	1.66	(0.67, 4.14)	0.2691	NE
Age group (years)											
<65	266	129	7	5.4	137	13	9.5	1.35	(0.54, 3.42)	0.5190	0.2363
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2131	0.2363
Sex											
F	318	162	7	4.3	156	14	9.0	1.71	(0.69, 4.26)	0.2418	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	1	1.7	0.43	(0.04, 4.81)	0.4844	0.3630
NORTH AMERICA/WESTERN EUROPE	126	63	4	6.3	63	8	12.7	1.81	(0.54, 6.02)	0.3297	0.3630
OTHER	78	38	1	2.6	40	5	12.5	3.56	(0.41, 30.71)	0.2188	0.3630
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	1	3.4	0.29	(0.03, 2.62)	0.2408	0.0287
Y	259	127	3	2.4	132	13	9.8	3.36	(0.95, 11.84)	0.0456	0.0287
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	4	7.7	1.00	(0.22, 4.49)	0.9992	0.4099
POST-MENOPAUSAL	214	110	4	3.6	104	10	9.6	2.25	(0.70, 7.21)	0.1596	0.4099
Time to First Eye disorders, Vision blurred											
All Patients	324	163	2	1.2	161	8	5.0	3.46	(0.73, 16.44)	0.0973	NE
Age group (years)											
<65	266	129	2	1.6	137	8	5.8	3.09	(0.65, 14.73)	0.1371	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	2	1.2	156	8	5.1	3.55	(0.75, 16.88)	0.0898	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3132	0.6347
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	6	9.5	2.88	(0.58, 14.32)	0.1758	0.6347
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5351	0.6347
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	2	1.6	132	8	6.1	3.24	(0.68, 15.39)	0.1186	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	3	5.8	2.10	(0.21, 21.06)	0.5209	0.6722
POST-MENOPAUSAL	214	110	1	0.9	104	5	4.8	4.92	(0.57, 42.26)	0.1082	0.6722
Time to First Eye disorders, Cataract											
All Patients	324	163	2	1.2	161	4	2.5	1.56	(0.28, 8.54)	0.6075	NE
Age group (years)											
<65	266	129	2	1.6	137	3	2.2	0.97	(0.16, 5.88)	0.9745	0.1904
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2076	0.1904
Sex											
F	318	162	2	1.2	156	4	2.6	1.60	(0.29, 8.79)	0.5846	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	2	3.4	1.74	(0.16, 19.23)	0.6457	0.9848
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.9848
OTHER	78	38	1	2.6	40	2	5.0	1.19	(0.11, 13.26)	0.8892	0.9848
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2749	0.2652
Y	259	127	2	1.6	132	3	2.3	1.04	(0.17, 6.24)	0.9688	0.2652
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.3141	0.1879
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.93	(0.13, 6.63)	0.9455	0.1879
Time to First Eye disorders, Lacrimation increased											
All Patients	324	163	1	0.6	161	5	3.1	3.72	(0.43, 32.31)	0.2022	NE
Age group (years)											
<65	266	129	1	0.8	137	4	2.9	2.41	(0.26, 21.97)	0.4224	0.3863
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.3863
Sex											
F	318	162	1	0.6	156	5	3.2	3.81	(0.44, 33.12)	0.1934	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.8436
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	4	6.3	2.95	(0.31, 27.61)	0.3223	0.8436
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4241	0.8436

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2482	0.0236
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0562	0.0236
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.5294
POST-MENOPAUSAL	214	110	1	0.9	104	4	3.8	2.93	(0.32, 26.91)	0.3214	0.5294
Time to First Eye disorders, Conjunctivitis allergic											
All Patients	324	163	1	0.6	161	2	1.2	1.34	(0.12, 15.09)	0.8111	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.12	(0.10, 12.71)	0.9253	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.38	(0.12, 15.55)	0.7917	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	2	3.4	1.41	(0.13, 15.86)	0.7799	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2733	0.2504
Y	259	127	1	0.8	132	1	0.8	0.55	(0.03, 9.00)	0.6712	0.2504
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.69	(0.04, 11.02)	0.7912	0.2503
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4547	0.2503
Time to First Eye disorders, Eye pruritus											
All Patients	324	163	0	0.0	161	3	1.9	>999.99	(0.00, >999.99)	0.0804	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.1700	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	3	1.9	>999.99	(0.00, >999.99)	0.0765	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.0799	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.0894	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	3	2.9	>999.99	(0.00, >999.99)	0.0733	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Eye disorders, Punctate keratitis											
All Patients	324	163	1	0.6	161	2	1.2	1.63	(0.15, 17.95)	0.6878	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2378	0.0976
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4561	0.0976
Sex											
F	318	162	1	0.6	156	2	1.3	1.67	(0.15, 18.47)	0.6704	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3537	0.6018
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.89	(0.06, 14.27)	0.9358	0.6018
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.6018
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	2	1.5	1.46	(0.13, 16.07)	0.7571	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.2372	0.0618
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2968	0.0618
Time to First Eye disorders, Visual acuity reduced											
All Patients	324	163	2	1.2	161	1	0.6	0.42	(0.04, 4.75)	0.4737	NE
Age group (years)											
<65	266	129	2	1.6	137	1	0.7	0.38	(0.03, 4.24)	0.4118	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	1	0.6	0.44	(0.04, 4.89)	0.4898	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	0	0.0	<0.01	(0.00, >999.99)	0.1096	0.1700
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.1700
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	0.1700
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	0.0399
Y	259	127	2	1.6	132	0	0.0	<0.01	(0.00, >999.99)	0.0975	0.0399
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.2777
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.89	(0.05, 14.36)	0.9337	0.2777
Time to First Eye disorders, Xerophthalmia											
All Patients	324	163	0	0.0	161	3	1.9	>999.99	(0.00, >999.99)	0.1274	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.1493	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	3	1.9	>999.99	(0.00, >999.99)	0.1218	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.0975	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.1406	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5002	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1745	1.0000
Time to First Eye disorders, Blepharitis											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.1225	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2537	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4561	1.0000
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1276	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2980	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2568	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3819	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2425	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2673	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2968	1.0000
Time to First Eye disorders, Epiretinal membrane											
All Patients	324	163	1	0.6	161	1	0.6	0.75	(0.05, 12.09)	0.8369	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.65	(0.04, 10.53)	0.7588	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.77	(0.05, 12.47)	0.8541	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.1990	0.2866
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.2866
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3600	0.2866
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.70	(0.04, 11.23)	0.7967	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.83	(0.05, 13.37)	0.8971	1.0000
Time to First Eye disorders, Myopia											
All Patients	324	163	1	0.6	161	1	0.6	0.91	(0.06, 14.63)	0.9480	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.81	(0.05, 13.02)	0.8813	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.94	(0.06, 15.02)	0.9632	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	1	2.5	0.80	(0.05, 12.96)	0.8749	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	0.0724
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2433	0.0724
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2397	0.0875
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3057	0.0875
Time to First Eye disorders, Photophobia											
All Patients	324	163	1	0.6	161	1	0.6	0.75	(0.05, 12.33)	0.8369	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.65	(0.04, 10.84)	0.7603	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.77	(0.05, 12.74)	0.8558	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.1649	0.2341
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	0.2341
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.2341
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.70	(0.04, 11.58)	0.8017	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.63	(0.04, 10.88)	0.7505	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Eye disorders, Photopsia											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2304	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2647	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2240	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2153	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5271	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1974	1.0000
Time to First Eye disorders, Retinal vascular disorder											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1763	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2021	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1705	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2033	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.1956	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1609	1.0000
Time to First Eye disorders, Visual impairment											
All Patients	324	163	1	0.6	161	1	0.6	0.89	(0.06, 14.38)	0.9376	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.79	(0.05, 12.73)	0.8673	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.92	(0.06, 14.78)	0.9528	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3613	0.2498
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	0.2498
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.2498
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.82	(0.05, 13.23)	0.8892	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.98	(0.06, 15.66)	0.9872	1.0000
Time to First Eye disorders, Vitreous floaters											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2909	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3416	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2828	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2331	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.3106	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.2400	1.0000
Time to First Eye disorders, Chalazion											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2691	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2317	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2758	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2109	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2425	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2327	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Eye disorders, Conjunctival haemorrhage											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2217	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1881	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2294	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2024	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2043	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.1859	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Eye disorders, Dacryoadenitis acquired											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2762	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3894	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2826	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2815	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2489	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
Time to First Eye disorders, Diplopia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2926	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3221	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2978	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3221	1.0000
Time to First Eye disorders, Eye discharge											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1998	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1621	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2079	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2549	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2415	1.0000
Time to First Eye disorders, Eye disorder											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5097	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5465	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5127	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5637	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5083	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5637	1.0000
Time to First Eye disorders, Eye haemorrhage											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3082	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3037	1.0000
Time to First Eye disorders, Eye irritation											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2173	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4070	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2254	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1432	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2801	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2579	1.0000
Time to First Eye disorders, Eye swelling											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3386	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3657	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3324	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3468	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3587	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3349	1.0000
Time to First Eye disorders, Eyelid oedema											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2920	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2617	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2984	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3128	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3729	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3020	1.0000
Time to First Eye disorders, Eyelid pain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3438	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3725	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3376	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3261	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3655	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3433	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Eye disorders, Hypoaesthesia eye											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3377	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3095	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3238	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3057	1.0000
Time to First Eye disorders, Keratitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3651	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4003	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3585	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4241	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3914	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3950	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Eye disorders, Keratopathy											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3689	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4084	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3621	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3613	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3967	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3355	1.0000
Time to First Eye disorders, Macular hole											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2036	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1668	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2118	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.1990	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1908	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2469	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Eye disorders, Ocular hyperaemia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3082	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3037	1.0000
Time to First Eye disorders, Ocular toxicity											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3590	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3852	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3525	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3490	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3845	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3393	1.0000
Time to First Eye disorders, Periorbital oedema											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2701	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2320	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2770	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2850	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2439	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2255	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Eye disorders, Presbyopia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4855	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5403	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4763	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5637	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5032	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Eye disorders, Retinal haemorrhage											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5032	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5598	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4962	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5439	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5271	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4386	1.0000
Time to First Psychiatric disorders, Any											
All Patients	324	163	21	12.9	161	30	18.6	1.14	(0.65, 2.01)	0.6405	NE
Age group (years)											
<65	266	129	19	14.7	137	27	19.7	0.98	(0.54, 1.77)	0.9430	0.4312
>=65	58	34	2	5.9	24	3	12.5	2.22	(0.37, 13.30)	0.3693	0.4312
Sex											
F	318	162	21	13.0	156	29	18.6	1.15	(0.65, 2.02)	0.6341	0.5417
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6171	0.5417
Region											
ASIA	120	62	8	12.9	58	10	17.2	1.08	(0.42, 2.77)	0.8707	0.1675
NORTH AMERICA/WESTERN EUROPE	126	63	9	14.3	63	18	28.6	1.74	(0.78, 3.89)	0.1686	0.1675
OTHER	78	38	4	10.5	40	2	5.0	0.29	(0.05, 1.66)	0.1440	0.1675
Visceral disease (per eCRF)											
N	65	36	6	16.7	29	4	13.8	0.66	(0.18, 2.37)	0.5197	0.2713
Y	259	127	15	11.8	132	26	19.7	1.33	(0.70, 2.52)	0.3843	0.2713
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	10	19.2	52	8	15.4	0.46	(0.18, 1.21)	0.1100	0.0486
POST-MENOPAUSAL	214	110	11	10.0	104	21	20.2	1.79	(0.86, 3.73)	0.1128	0.0486
Time to First Psychiatric disorders, Insomnia											
All Patients	324	163	14	8.6	161	21	13.0	1.19	(0.60, 2.35)	0.6243	NE
Age group (years)											
<65	266	129	13	10.1	137	19	13.9	0.98	(0.48, 2.01)	0.9616	0.4166
>=65	58	34	1	2.9	24	2	8.3	2.99	(0.27, 32.99)	0.3475	0.4166
Sex											
F	318	162	14	8.6	156	20	12.8	1.18	(0.59, 2.35)	0.6464	0.5333
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6171	0.5333
Region											
ASIA	120	62	7	11.3	58	9	15.5	1.07	(0.39, 2.93)	0.8877	0.0694
NORTH AMERICA/WESTERN EUROPE	126	63	5	7.9	63	12	19.0	1.94	(0.68, 5.55)	0.2075	0.0694
OTHER	78	38	2	5.3	40	0	0.0	<0.01	(0.00, >999.99)	0.1464	0.0694
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	4	13.8	0.85	(0.21, 3.52)	0.8247	0.6741
Y	259	127	10	7.9	132	17	12.9	1.33	(0.60, 2.92)	0.4787	0.6741
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	8	15.4	52	3	5.8	0.22	(0.06, 0.90)	0.0234	0.0021
POST-MENOPAUSAL	214	110	6	5.5	104	17	16.3	2.59	(1.02, 6.59)	0.0387	0.0021
Time to First Psychiatric disorders, Anxiety											
All Patients	324	163	5	3.1	161	4	2.5	0.58	(0.15, 2.20)	0.4176	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	4	3.1	137	4	2.9	0.61	(0.15, 2.50)	0.4890	0.3913
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.3913
Sex											
F	318	162	5	3.1	156	4	2.6	0.59	(0.16, 2.25)	0.4376	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3085	0.2230
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	4	6.3	1.00	(0.22, 4.56)	0.9963	0.2230
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1380	0.2230
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.49	(0.04, 5.50)	0.5520	0.8151
Y	259	127	3	2.4	132	3	2.3	0.66	(0.13, 3.38)	0.6202	0.8151
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	2	3.8	0.85	(0.07, 9.75)	0.8955	0.3896
POST-MENOPAUSAL	214	110	4	3.6	104	2	1.9	0.46	(0.08, 2.52)	0.3604	0.3896
Time to First Psychiatric disorders, Depression											
All Patients	324	163	4	2.5	161	2	1.2	0.34	(0.06, 1.92)	0.2038	NE
Age group (years)											
<65	266	129	4	3.1	137	2	1.5	0.29	(0.05, 1.64)	0.1390	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	4	2.5	156	2	1.3	0.35	(0.06, 1.95)	0.2108	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.2808
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	2	3.2	0.69	(0.09, 5.11)	0.7171	0.2808
OTHER	78	38	2	5.3	40	0	0.0	<0.01	(0.00, >999.99)	0.0726	0.2808
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1573	0.3810
Y	259	127	3	2.4	132	2	1.5	0.48	(0.08, 2.92)	0.4123	0.3810
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.47	(0.02, 9.40)	0.6180	0.5370
POST-MENOPAUSAL	214	110	3	2.7	104	1	1.0	0.22	(0.02, 2.29)	0.1726	0.5370
Time to First Psychiatric disorders, Disorientation											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2059	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2366	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1997	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.1888	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2312	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1862	1.0000
Time to First Psychiatric disorders, Emotional distress											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.3008	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5455	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2429	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2923	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2541	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4497	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4543	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4005	1.0000
Time to First Psychiatric disorders, Mood altered											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.3330	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3859	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.3254	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2979	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4497	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5154	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.4691	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Psychiatric disorders, Bruxism											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4718	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5108	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4635	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3890	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4927	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5233	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Psychiatric disorders, Daydreaming											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4142	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4457	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4936	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4292	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4497	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Psychiatric disorders, Depressed mood											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3264	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3694	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3309	1.0000
Time to First Psychiatric disorders, Hallucination											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3689	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4084	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3621	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3423	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3967	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3355	1.0000
Time to First Psychiatric disorders, Irritability											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3358	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3080	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First Psychiatric disorders, Mixed anxiety and depressive disorder											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4646	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5071	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4561	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5485	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4827	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5050	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Psychiatric disorders, Panic attack											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4940	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5428	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4872	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4708	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4227	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihoood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Psychiatric disorders, Restlessness											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3596	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3884	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3531	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3469	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3858	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3369	1.0000
Time to First Psychiatric disorders, Suicidal ideation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3377	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3095	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3091	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3326	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Vascular disorders, Any											
All Patients	324	163	16	9.8	161	32	19.9	1.71	(0.94, 3.13)	0.0780	NE
Age group (years)											
<65	266	129	14	10.9	137	28	20.4	1.53	(0.80, 2.92)	0.1985	0.4034
>=65	58	34	2	5.9	24	4	16.7	3.03	(0.55, 16.56)	0.1781	0.4034

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	16	9.9	156	31	19.9	1.68	(0.92, 3.09)	0.0907	0.5359
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.5359
Region											
ASIA	120	62	5	8.1	58	7	12.1	1.07	(0.34, 3.44)	0.9029	0.4737
NORTH AMERICA/WESTERN EUROPE	126	63	8	12.7	63	20	31.7	2.56	(1.13, 5.83)	0.0201	0.4737
OTHER	78	38	3	7.9	40	5	12.5	1.20	(0.28, 5.12)	0.8087	0.4737
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	6	20.7	1.68	(0.47, 6.08)	0.4210	0.9849
Y	259	127	12	9.4	132	26	19.7	1.71	(0.86, 3.41)	0.1199	0.9849
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	5	9.6	52	10	19.2	1.64	(0.55, 4.85)	0.3666	0.9873
POST-MENOPAUSAL	214	110	11	10.0	104	21	20.2	1.65	(0.79, 3.45)	0.1820	0.9873
Time to First Vascular disorders, Hot flush											
All Patients	324	163	5	3.1	161	10	6.2	1.89	(0.64, 5.54)	0.2391	NE
Age group (years)											
<65	266	129	5	3.9	137	10	7.3	1.70	(0.58, 5.00)	0.3267	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	5	3.1	156	9	5.8	1.72	(0.58, 5.16)	0.3238	0.6055
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.6055
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.3408
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	9	14.3	2.92	(0.79, 10.82)	0.0923	0.3408
OTHER	78	38	2	5.3	40	1	2.5	0.46	(0.04, 5.13)	0.5213	0.3408
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	2	6.9	2.60	(0.24, 28.69)	0.4176	0.8086
Y	259	127	4	3.1	132	8	6.1	1.75	(0.53, 5.85)	0.3527	0.8086
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	4	7.7	1.58	(0.28, 8.80)	0.5997	0.9394
POST-MENOPAUSAL	214	110	3	2.7	104	5	4.8	1.73	(0.41, 7.25)	0.4464	0.9394
Time to First Vascular disorders, Lymphoedema											
All Patients	324	163	4	2.5	161	8	5.0	1.52	(0.45, 5.06)	0.4943	NE
Age group (years)											
<65	266	129	3	2.3	137	8	5.8	1.75	(0.46, 6.65)	0.4035	0.2372
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4142	0.2372
Sex											
F	318	162	4	2.5	156	8	5.1	1.54	(0.46, 5.15)	0.4779	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	3	4.8	58	4	6.9	1.07	(0.24, 4.81)	0.9292	0.6963
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	4	6.3	3.03	(0.33, 27.45)	0.3008	0.6963
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.6963

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.81	(0.05, 13.60)	0.8812	0.7105
Y	259	127	3	2.4	132	7	5.3	1.70	(0.44, 6.59)	0.4377	0.7105
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	3	5.8	1.83	(0.18, 18.22)	0.6010	0.6534
POST-MENOPAUSAL	214	110	3	2.7	104	5	4.8	1.30	(0.31, 5.51)	0.7222	0.6534
Time to First Vascular disorders, Hypertension											
All Patients	324	163	3	1.8	161	5	3.1	1.19	(0.28, 5.10)	0.8126	NE
Age group (years)											
<65	266	129	3	2.3	137	3	2.2	0.67	(0.13, 3.40)	0.6241	0.0509
>=65	58	34	0	0.0	24	2	8.3	>999.99	(0.00, >999.99)	0.1265	0.0509
Sex											
F	318	162	3	1.9	156	5	3.2	1.21	(0.28, 5.21)	0.7941	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5637	0.2489
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	3	4.8	2.57	(0.27, 24.73)	0.3959	0.2489
OTHER	78	38	2	5.3	40	1	2.5	0.34	(0.03, 3.97)	0.3709	0.2489
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.5403	0.2632
Y	259	127	3	2.4	132	4	3.0	0.97	(0.21, 4.37)	0.9635	0.2632
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.2595	0.1351
POST-MENOPAUSAL	214	110	3	2.7	104	3	2.9	0.70	(0.13, 3.64)	0.6688	0.1351
Time to First Vascular disorders, Thrombosis											
All Patients	324	163	0	0.0	161	4	2.5	>999.99	(0.00, >999.99)	0.0785	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.0945	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	4	2.6	>999.99	(0.00, >999.99)	0.0758	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.0958	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5186	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2599	1.0000
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.1486	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	3	2.9	>999.99	(0.00, >999.99)	0.1471	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Vascular disorders, Hypotension											
All Patients	324	163	1	0.6	161	2	1.2	1.05	(0.09, 12.79)	0.9666	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	0.95	(0.08, 11.46)	0.9686	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.08	(0.09, 13.14)	0.9517	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.6223
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.50	(0.03, 8.41)	0.6220	0.6223
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	0.6223
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.96	(0.06, 15.86)	0.9793	0.3749
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.7055	0.3749
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.65	(0.04, 11.14)	0.7681	0.2647
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5930	0.2647
Time to First Vascular disorders, Deep vein thrombosis											
All Patients	324	163	1	0.6	161	1	0.6	0.59	(0.04, 9.66)	0.7101	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0949	0.0476
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2259	0.0476
Sex											
F	318	162	1	0.6	156	1	0.6	0.61	(0.04, 9.96)	0.7268	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.2827
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1655	0.2827
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4363	0.2827
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1859	0.1187
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4120	0.1187
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.72	(0.04, 11.55)	0.8132	1.0000
Time to First Vascular disorders, Flushing											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1746	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.1978	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1689	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.1658	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.1921	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1576	1.0000
Time to First Vascular disorders, Haematoma											
All Patients	324	163	1	0.6	161	1	0.6	0.88	(0.05, 14.02)	0.9248	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4003	0.1456
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.1456
Sex											
F	318	162	1	0.6	156	1	0.6	0.90	(0.06, 14.40)	0.9399	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.91	(0.06, 14.56)	0.9470	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2749	0.0727
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2850	0.0727
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3950	0.1007
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3050	0.1007
Time to First Vascular disorders, Phlebitis											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1646	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2100	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1591	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.1521	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likeli- hood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.1799	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3324	1.0000
Time to First Vascular disorders, Arteriosclerosis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4060	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2604	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3992	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3563	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4319	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3757	1.0000
Time to First Vascular disorders, Blood pressure fluctuation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4166	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4491	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3466	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4310	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3740	1.0000
Time to First Vascular disorders, Embolism											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4000	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2604	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3927	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4862	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4240	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3671	1.0000
Time to First Vascular disorders, Orthostatic hypotension											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Vascular disorders, Peripheral venous disease											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3584	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3821	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3520	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3532	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3858	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3416	1.0000
Time to First Vascular disorders, Phlebosclerosis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1415	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1044	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1473	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.1294	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1242	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1967	1.0000
Time to First Vascular disorders, Raynaud's phenomenon											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4927	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5289	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4864	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4561	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5101	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6095	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Vascular disorders, Thrombophlebitis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2925	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2645	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2988	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3085	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2714	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2967	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Vascular disorders, Vascular rupture											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Renal and urinary disorders, Any											
All Patients	324	163	14	8.6	161	20	12.4	1.10	(0.55, 2.19)	0.7838	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	11	8.5	137	18	13.1	1.12	(0.52, 2.39)	0.7727	0.8090
>=65	58	34	3	8.8	24	2	8.3	0.90	(0.15, 5.43)	0.9093	0.8090
Sex											
F	318	162	14	8.6	156	20	12.8	1.14	(0.57, 2.26)	0.7169	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	6	9.7	58	7	12.1	1.12	(0.37, 3.37)	0.8336	0.1765
NORTH AMERICA/WESTERN EUROPE	126	63	7	11.1	63	6	9.5	0.66	(0.22, 1.98)	0.4526	0.1765
OTHER	78	38	1	2.6	40	7	17.5	4.16	(0.50, 34.32)	0.1516	0.1765
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	2	6.9	0.53	(0.08, 3.30)	0.4875	0.5402
Y	259	127	11	8.7	132	18	13.6	1.18	(0.55, 2.52)	0.6706	0.5402
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	4	7.7	52	8	15.4	1.60	(0.47, 5.44)	0.4454	0.6515
POST-MENOPAUSAL	214	110	10	9.1	104	12	11.5	0.97	(0.42, 2.26)	0.9405	0.6515
Time to First Renal and urinary disorders, Dysuria											
All Patients	324	163	6	3.7	161	2	1.2	0.22	(0.04, 1.13)	0.0490	NE
Age group (years)											
<65	266	129	4	3.1	137	1	0.7	0.16	(0.02, 1.46)	0.0657	0.3652
>=65	58	34	2	5.9	24	1	4.2	0.66	(0.06, 7.36)	0.7364	0.3652
Sex											
F	318	162	6	3.7	156	2	1.3	0.23	(0.05, 1.16)	0.0533	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	2	3.2	58	0	0.0	<0.01	(0.00, >999.99)	0.1550	0.1077
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	0	0.0	<0.01	(0.00, >999.99)	0.0402	0.1077
OTHER	78	38	1	2.6	40	2	5.0	1.00	(0.08, 11.88)	0.9980	0.1077
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	0	0.0	<0.01	(0.00, >999.99)	0.0241	0.1535
Y	259	127	3	2.4	132	2	1.5	0.46	(0.08, 2.84)	0.3955	0.1535
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.97	(0.06, 15.49)	0.9818	0.3548
POST-MENOPAUSAL	214	110	5	4.5	104	1	1.0	0.12	(0.01, 1.08)	0.0262	0.3548
Time to First Renal and urinary disorders, Haematuria											
All Patients	324	163	3	1.8	161	2	1.2	0.51	(0.08, 3.09)	0.4545	NE
Age group (years)											
<65	266	129	2	1.6	137	2	1.5	0.63	(0.09, 4.61)	0.6480	0.3900
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.3900
Sex											
F	318	162	3	1.9	156	2	1.3	0.52	(0.09, 3.18)	0.4743	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	2	3.2	58	1	1.7	0.50	(0.05, 5.50)	0.5617	0.9222

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.68	(0.04, 11.12)	0.7874	0.9222
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.9222
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	3	2.4	132	2	1.5	0.47	(0.08, 2.84)	0.3970	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.1594
POST-MENOPAUSAL	214	110	3	2.7	104	1	1.0	0.27	(0.03, 2.60)	0.2239	0.1594
Time to First Renal and urinary disorders, Micturition urgency											
All Patients	324	163	1	0.6	161	4	2.5	2.72	(0.30, 24.63)	0.3550	NE
Age group (years)											
<65	266	129	1	0.8	137	4	2.9	2.31	(0.25, 20.99)	0.4459	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	4	2.6	2.81	(0.31, 25.49)	0.3367	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.70	(0.04, 11.83)	0.8020	0.3505
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3819	0.3505
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.3174	0.3505
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2733	0.4123
Y	259	127	1	0.8	132	3	2.3	1.77	(0.18, 17.36)	0.6180	0.4123
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	3	5.8	1.48	(0.14, 15.23)	0.7396	0.4131
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3352	0.4131
Time to First Renal and urinary disorders, Proteinuria											
All Patients	324	163	1	0.6	161	4	2.5	2.84	(0.32, 25.62)	0.3304	NE
Age group (years)											
<65	266	129	1	0.8	137	4	2.9	2.50	(0.28, 22.60)	0.3982	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	4	2.6	2.93	(0.33, 26.43)	0.3147	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.81	(0.05, 13.24)	0.8831	0.3002
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2046	0.3002
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4872	0.3002
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3566	0.4093
Y	259	127	1	0.8	132	3	2.3	1.96	(0.20, 19.05)	0.5556	0.4093
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.0187

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	4	3.8	>999.99	(0.00, >999.99)	0.0815	0.0187
Time to First Renal and urinary disorders, Pollakiuria											
All Patients	324	163	1	0.6	161	2	1.2	1.65	(0.15, 18.60)	0.6831	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.45	(0.13, 16.55)	0.7619	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.70	(0.15, 19.16)	0.6642	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.70	(0.04, 11.83)	0.8020	0.5777
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	0.5777
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.5777
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	2	1.5	1.53	(0.14, 17.34)	0.7274	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	2	3.8	1.52	(0.13, 17.73)	0.7370	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Renal and urinary disorders, Urinary incontinence											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.1478	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4142	1.0000
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1530	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	0	0.0	<0.01	(0.00, >999.99)	0.1443	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	2	1.6	132	0	0.0	<0.01	(0.00, >999.99)	0.1330	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2998	1.0000
Time to First Renal and urinary disorders, Acute kidney injury											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Renal and urinary disorders, Bladder irritation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3407	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3706	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3344	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3534	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2618	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3324	1.0000
Time to First Renal and urinary disorders, Bladder pain											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3264	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3080	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3309	1.0000
Time to First Renal and urinary disorders, Glycosuria											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3377	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3095	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3091	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3326	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3057	1.0000
Time to First Renal and urinary disorders, Ketonuria											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3358	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3080	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3306	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Renal and urinary disorders, Leukocyturia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3220	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3255	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2981	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3243	1.0000
Time to First Renal and urinary disorders, Nephrolithiasis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4975	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5465	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4909	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5083	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5186	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4366	1.0000
Time to First Renal and urinary disorders, Polyuria											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3651	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4003	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3585	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4241	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3914	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3950	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Renal and urinary disorders, Renal colic											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1437	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1003	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1501	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1655	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1213	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1987	1.0000
Time to First Renal and urinary disorders, Urethral disorder											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3596	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3884	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3531	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4142	1.0000
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2673	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3369	1.0000
Time to First Renal and urinary disorders, Urinary tract disorder											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5032	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5598	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4962	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4701	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5271	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4386	1.0000
Time to First Renal and urinary disorders, Urine abnormality											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3377	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3095	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3091	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3326	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Injury, poisoning and procedural complications, Any											
All Patients	324	163	9	5.5	161	24	14.9	1.86	(0.86, 4.03)	0.1110	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	7	5.4	137	22	16.1	1.88	(0.79, 4.45)	0.1450	0.7990
>=65	58	34	2	5.9	24	2	8.3	1.42	(0.20, 10.18)	0.7289	0.7990
Sex											
F	318	162	8	4.9	156	24	15.4	2.20	(0.98, 4.92)	0.0502	0.0276
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0833	0.0276
Region											
ASIA	120	62	1	1.6	58	8	13.8	5.97	(0.74, 48.09)	0.0566	0.2823
NORTH AMERICA/WESTERN EUROPE	126	63	5	7.9	63	11	17.5	1.96	(0.68, 5.67)	0.2029	0.2823
OTHER	78	38	3	7.9	40	5	12.5	0.68	(0.16, 2.93)	0.6020	0.2823
Visceral disease (per eCRF)											
N	65	36	5	13.9	29	5	17.2	0.82	(0.23, 2.93)	0.7674	0.1284
Y	259	127	4	3.1	132	19	14.4	3.20	(1.08, 9.47)	0.0262	0.1284
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	10	19.2	>999.99	(0.00, >999.99)	0.0124	0.0091
POST-MENOPAUSAL	214	110	8	7.3	104	14	13.5	1.32	(0.55, 3.18)	0.5359	0.0091
Time to First Injury, poisoning and procedural complications, Contusion											
All Patients	324	163	0	0.0	161	5	3.1	>999.99	(0.00, >999.99)	0.0390	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.0913	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	5	3.2	>999.99	(0.00, >999.99)	0.0364	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.2308	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.0850	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	4	3.0	>999.99	(0.00, >999.99)	0.0846	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	3	5.8	>999.99	(0.00, >999.99)	0.1346	0.9999
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1576	0.9999
Time to First Injury, poisoning and procedural complications, Fall											
All Patients	324	163	1	0.6	161	4	2.5	2.35	(0.25, 21.68)	0.4380	NE
Age group (years)											
<65	266	129	1	0.8	137	4	2.9	2.03	(0.22, 18.74)	0.5230	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	4	2.6	>999.99	(0.00, >999.99)	0.1083	0.0106
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0833	0.0106

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.8194
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	3	4.8	2.45	(0.25, 23.71)	0.4239	0.8194
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4795	0.8194
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4795	0.4002
Y	259	127	1	0.8	132	3	2.3	1.91	(0.20, 18.45)	0.5715	0.4002
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4497	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	3	2.9	>999.99	(0.00, >999.99)	0.1495	1.0000
Time to First Injury, poisoning and procedural complications, Accidental overdose											
All Patients	324	163	2	1.2	161	2	1.2	0.74	(0.10, 5.40)	0.7648	NE
Age group (years)											
<65	266	129	2	1.6	137	2	1.5	0.63	(0.09, 4.65)	0.6475	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	2	1.3	0.75	(0.10, 5.51)	0.7787	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.59	(0.03, 10.50)	0.7150	0.9998
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.89	(0.06, 14.28)	0.9362	0.9998
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.9998
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3865	0.2311
Y	259	127	1	0.8	132	2	1.5	1.26	(0.11, 14.21)	0.8521	0.2311
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6015	0.2111
POST-MENOPAUSAL	214	110	2	1.8	104	1	1.0	0.48	(0.04, 5.32)	0.5424	0.2111
Time to First Injury, poisoning and procedural complications, Skin abrasion											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2411	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2724	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2337	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.1832	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2644	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4497	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3757	1.0000
Time to First Injury, poisoning and procedural complications, Animal bite											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Injury, poisoning and procedural complications, Ankle fracture											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5127	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5637	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5060	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5403	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5176	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4613	1.0000
Time to First Injury, poisoning and procedural complications, Arthropod bite											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3645	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3576	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3423	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3908	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3323	1.0000
Time to First Injury, poisoning and procedural complications, Eyelid injury											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3623	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3923	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3557	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3476	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3872	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Injury, poisoning and procedural complications, Femur fracture											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1353	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0863	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1416	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1306	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2024	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1967	1.0000
Time to First Injury, poisoning and procedural complications, Foot fracture											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3651	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4003	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3585	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3537	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3914	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3950	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Injury, poisoning and procedural complications, Foreign body											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1374	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0943	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1432	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1655	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1175	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1987	1.0000
Time to First Injury, poisoning and procedural complications, Humerus fracture											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2325	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2055	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2395	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2835	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3276	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2620	1.0000
Time to First Injury, poisoning and procedural complications, Ilium fracture											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4939	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5501	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4897	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5271	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5050	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6434	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Injury, poisoning and procedural complications, Immunisation reaction											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1380	NE

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4795	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1360	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1306	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.0923	1.0000
Time to First Injury, poisoning and procedural complications, Implantation complication											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1737	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3576	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1818	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2457	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2528	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2034	1.0000
Time to First Injury, poisoning and procedural complications, Jaw fracture											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5127	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5637	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5060	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5403	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4969	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4613	1.0000
Time to First Injury, poisoning and procedural complications, Ligament sprain											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1438	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0943	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0833	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1797	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1336	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Injury, poisoning and procedural complications, Limb injury											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3645	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3576	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3423	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3908	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3323	1.0000
Time to First Injury, poisoning and procedural complications, Meniscus injury											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1737	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1349	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1818	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2457	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2528	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2034	1.0000
Time to First Injury, poisoning and procedural complications, Muscle strain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4602	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5002	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4517	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4795	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4795	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4956	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Injury, poisoning and procedural complications, Periorbital haematoma											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Injury, poisoning and procedural complications, Post procedural fistula											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4933	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5371	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4892	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4795	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5036	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4461	1.0000
Time to First Injury, poisoning and procedural complications, Postoperative hypertension											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4054	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4419	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3971	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3378	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4171	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3711	1.0000
Time to First Injury, poisoning and procedural complications, Procedural headache											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5019	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5465	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4939	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5002	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5091	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4533	1.0000
Time to First Injury, poisoning and procedural complications, Rib fracture											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4060	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4338	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3992	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4272	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4319	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4497	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Injury, poisoning and procedural complications, Road traffic accident											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3645	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3576	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3423	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3908	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3323	1.0000
Time to First Injury, poisoning and procedural complications, Skin laceration											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Injury, poisoning and procedural complications, Snake bite											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5032	NE

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5598	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4962	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5439	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4328	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6464	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Injury, poisoning and procedural complications, Tooth fracture											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1894	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1522	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1976	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.0943	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1684	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2227	1.0000
Time to First Injury, poisoning and procedural complications, Transfusion reaction											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4561	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4937	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4477	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4533	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4704	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4795	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Injury, poisoning and procedural complications, Wound											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4076	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4443	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3994	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4268	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4199	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3747	1.0000
Time to First Injury, poisoning and procedural complications, Wrist fracture											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4602	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2733	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4505	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3948	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4759	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4167	1.0000
Time to First Cardiac disorders, Any											
All Patients	324	163	15	9.2	161	15	9.3	0.74	(0.36, 1.53)	0.4152	NE
Age group (years)											
<65	266	129	10	7.8	137	13	9.5	0.86	(0.37, 2.01)	0.7337	0.6343
>=65	58	34	5	14.7	24	2	8.3	0.53	(0.10, 2.75)	0.4433	0.6343
Sex											
F	318	162	15	9.3	156	14	9.0	0.70	(0.33, 1.48)	0.3462	0.4269
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.4269
Region											
ASIA	120	62	3	4.8	58	4	6.9	1.19	(0.26, 5.42)	0.8212	0.6826
NORTH AMERICA/WESTERN EUROPE	126	63	8	12.7	63	5	7.9	0.51	(0.17, 1.58)	0.2363	0.6826
OTHER	78	38	4	10.5	40	6	15.0	0.85	(0.23, 3.09)	0.7999	0.6826
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.5403	0.1810
Y	259	127	15	11.8	132	14	10.6	0.64	(0.30, 1.35)	0.2368	0.1810
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	5	9.6	52	5	9.6	0.66	(0.18, 2.41)	0.5261	0.8968
POST-MENOPAUSAL	214	110	10	9.1	104	9	8.7	0.69	(0.27, 1.74)	0.4286	0.8968
Time to First Cardiac disorders, Sinus tachycardia											
All Patients	324	163	3	1.8	161	5	3.1	1.15	(0.27, 4.97)	0.8520	NE
Age group (years)											
<65	266	129	2	1.6	137	5	3.6	1.52	(0.28, 8.16)	0.6204	0.2525
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4193	0.2525
Sex											
F	318	162	3	1.9	156	4	2.6	0.90	(0.19, 4.23)	0.8982	0.5181
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.5181
Region											
ASIA	120	62	1	1.6	58	2	3.4	1.99	(0.18, 22.04)	0.5657	0.9573
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.55	(0.03, 9.54)	0.6759	0.9573
OTHER	78	38	1	2.6	40	2	5.0	1.03	(0.09, 12.04)	0.9832	0.9573
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	3	2.4	132	5	3.8	1.04	(0.24, 4.53)	0.9628	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	3	5.8	1.77	(0.17, 18.49)	0.6280	0.3415
POST-MENOPAUSAL	214	110	2	1.8	104	1	1.0	0.31	(0.03, 3.72)	0.3311	0.3415
Time to First Cardiac disorders, Palpitations											
All Patients	324	163	2	1.2	161	3	1.9	1.42	(0.24, 8.53)	0.6976	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	2	1.6	137	3	2.2	1.28	(0.21, 7.67)	0.7871	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	3	1.9	1.46	(0.24, 8.76)	0.6760	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3295	0.2434
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.94	(0.18, 21.42)	0.5814	0.2434
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4142	0.2434
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	3	2.3	1.32	(0.22, 7.90)	0.7622	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.1235
POST-MENOPAUSAL	214	110	1	0.9	104	3	2.9	2.99	(0.31, 28.81)	0.3183	0.1235
Time to First Cardiac disorders, Bradycardia											
All Patients	324	163	4	2.5	161	0	0.0	<0.01	(0.00, >999.99)	0.0304	NE
Age group (years)											
<65	266	129	2	1.6	137	0	0.0	<0.01	(0.00, >999.99)	0.1243	1.0000
>=65	58	34	2	5.9	24	0	0.0	<0.01	(0.00, >999.99)	0.2402	1.0000
Sex											
F	318	162	4	2.5	156	0	0.0	<0.01	(0.00, >999.99)	0.0328	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	0	0.0	<0.01	(0.00, >999.99)	0.0754	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1353	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	4	3.1	132	0	0.0	<0.01	(0.00, >999.99)	0.0245	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	3	2.7	104	0	0.0	<0.01	(0.00, >999.99)	0.0676	1.0000
Time to First Cardiac disorders, Tachycardia											
All Patients	324	163	0	0.0	161	3	1.9	>999.99	(0.00, >999.99)	0.1302	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.1547	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	3	1.9	>999.99	(0.00, >999.99)	0.1251	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likeli- hood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2349	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3297	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.1470	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.2183	1.0000
Time to First Cardiac disorders, Acute coronary syndrome											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2239	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5305	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2240	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2165	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2615	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2389	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1926	1.0000
Time to First Cardiac disorders, Atrial fibrillation											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.0986	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	2	5.9	24	0	0.0	<0.01	(0.00, >999.99)	0.2368	1.0000
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1037	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	0	0.0	<0.01	(0.00, >999.99)	0.1311	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	0	0.0	<0.01	(0.00, >999.99)	0.0842	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1169	1.0000
Time to First Cardiac disorders, Sinus bradycardia											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.0526	NE
Age group (years)											
<65	266	129	2	1.6	137	0	0.0	<0.01	(0.00, >999.99)	0.0332	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.0572	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2636	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1138	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	0	0.0	<0.01	(0.00, >999.99)	0.0464	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.1380	0.9999
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1894	0.9999
Time to First Cardiac disorders, Angina pectoris											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3173	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3396	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3111	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3091	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3345	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Cardiac disorders, Atrial flutter											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3426	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3729	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3363	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3559	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3644	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3326	1.0000
Time to First Cardiac disorders, Cardiac arrest											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3280	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3080	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3332	1.0000
Time to First Cardiac disorders, Cardiomyopathy											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2123	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3918	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2207	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1353	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1977	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2585	1.0000
Time to First Cardiac disorders, Left ventricular hypertrophy											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4549	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4964	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4450	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3838	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4759	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4167	1.0000
Time to First Cardiac disorders, Supraventricular extrasystoles											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5514	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.3173	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5571	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5637	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.5403	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5812	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Cardiac disorders, Wolff-Parkinson-White syndrome											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2701	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2320	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2770	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2109	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2439	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2255	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Reproductive system and breast disorders, Any											
All Patients	324	163	16	9.8	161	14	8.7	0.70	(0.34, 1.45)	0.3391	NE
Age group (years)											
<65	266	129	14	10.9	137	12	8.8	0.61	(0.28, 1.33)	0.2091	0.4399
>=65	58	34	2	5.9	24	2	8.3	1.38	(0.19, 9.82)	0.7498	0.4399
Sex											
F	318	162	15	9.3	156	14	9.0	0.79	(0.38, 1.64)	0.5184	0.0341
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0253	0.0341
Region											
ASIA	120	62	3	4.8	58	1	1.7	0.22	(0.02, 2.18)	0.1584	0.4100
NORTH AMERICA/WESTERN EUROPE	126	63	9	14.3	63	10	15.9	1.05	(0.42, 2.58)	0.9221	0.4100
OTHER	78	38	4	10.5	40	3	7.5	0.47	(0.10, 2.19)	0.3279	0.4100
Visceral disease (per eCRF)											
N	65	36	6	16.7	29	2	6.9	0.27	(0.05, 1.40)	0.0984	0.2334
Y	259	127	10	7.9	132	12	9.1	0.94	(0.40, 2.19)	0.8845	0.2334
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	9	17.3	52	7	13.5	0.59	(0.22, 1.61)	0.2984	0.4040
POST-MENOPAUSAL	214	110	6	5.5	104	7	6.7	1.01	(0.34, 3.04)	0.9794	0.4040
Time to First Reproductive system and breast disorders, Breast pain											
All Patients	324	163	6	3.7	161	1	0.6	0.14	(0.02, 1.19)	0.0361	NE
Age group (years)											
<65	266	129	5	3.9	137	1	0.7	0.16	(0.02, 1.38)	0.0564	0.6579
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3613	0.6579
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	6	3.7	156	1	0.6	0.15	(0.02, 1.22)	0.0396	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3085	0.0663
NORTH AMERICA/WESTERN EUROPE	126	63	5	7.9	63	0	0.0	<0.01	(0.00, >999.99)	0.0184	0.0663
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	0.0663
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.53	(0.05, 5.92)	0.5979	0.1286
Y	259	127	4	3.1	132	0	0.0	<0.01	(0.00, >999.99)	0.0268	0.1286
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	4	7.7	52	0	0.0	<0.01	(0.00, >999.99)	0.0405	0.1432
POST-MENOPAUSAL	214	110	2	1.8	104	1	1.0	0.42	(0.04, 4.65)	0.4646	0.1432
Time to First Reproductive system and breast disorders, Vulvovaginal dryness											
All Patients	324	163	1	0.6	161	6	3.7	5.38	(0.64, 44.96)	0.0820	NE
Age group (years)											
<65	266	129	1	0.8	137	6	4.4	4.87	(0.58, 40.79)	0.1064	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	1	0.6	156	6	3.8	5.53	(0.66, 46.24)	0.0759	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.8738
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	5	7.9	4.95	(0.58, 42.39)	0.1057	0.8738
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4936	0.8738
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	1.03	(0.06, 16.76)	0.9831	0.1073
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0382	0.1073
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	2	3.8	2.00	(0.18, 22.06)	0.5635	0.1505
POST-MENOPAUSAL	214	110	0	0.0	104	4	3.8	>999.99	(0.00, >999.99)	0.0610	0.1505
Time to First Reproductive system and breast disorders, Vulvovaginal pruritus											
All Patients	324	163	0	0.0	161	4	2.5	>999.99	(0.00, >999.99)	0.0491	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.1078	0.9999
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.9999
Sex											
F	318	162	0	0.0	156	4	2.6	>999.99	(0.00, >999.99)	0.0462	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	4	6.3	>999.99	(0.00, >999.99)	0.0453	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	4	3.0	>999.99	(0.00, >999.99)	0.0575	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	3	5.8	>999.99	(0.00, >999.99)	0.0781	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3406	1.0000
Time to First Reproductive system and breast disorders, Pelvic pain											
All Patients	324	163	3	1.8	161	0	0.0	<0.01	(0.00, >999.99)	0.0315	NE
Age group (years)											
<65	266	129	3	2.3	137	0	0.0	<0.01	(0.00, >999.99)	0.0203	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	3	1.9	156	0	0.0	<0.01	(0.00, >999.99)	0.0344	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.1294	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	0	0.0	<0.01	(0.00, >999.99)	0.1241	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.1287	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2032	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	0	0.0	<0.01	(0.00, >999.99)	0.0108	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Reproductive system and breast disorders, Vaginal haemorrhage											
All Patients	324	163	1	0.6	161	1	0.6	0.92	(0.06, 14.82)	0.9555	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2488	0.0658
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.0658
Sex											
F	318	162	1	0.6	156	1	0.6	0.95	(0.06, 15.21)	0.9702	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.93	(0.06, 14.88)	0.9579	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.84	(0.05, 13.56)	0.9044	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2611	0.0913
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	0.0913

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Reproductive system and breast disorders, Atrophic vulvovaginitis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1573	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1637	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2076	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1454	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2178	1.0000
Time to First Reproductive system and breast disorders, Breast induration											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3580	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3865	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3513	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3359	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3838	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3865	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Reproductive system and breast disorders, Coital bleeding											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Reproductive system and breast disorders, Endometrial hyperplasia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3110	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Reproductive system and breast disorders, Erectile dysfunction											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2364	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2051	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0253	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2864	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2094	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Reproductive system and breast disorders, Genital erythema											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4743	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5146	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4659	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4872	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4964	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5233	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Reproductive system and breast disorders, Genital odour											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3264	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3049	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3694	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Reproductive system and breast disorders, Hyperreactio luteinalis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2779	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2544	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2843	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2393	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2508	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2611	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Reproductive system and breast disorders, Intermenstrual bleeding											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3295	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Reproductive system and breast disorders, Pelvic fluid collection											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2762	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2525	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2826	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2393	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2489	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
Time to First Reproductive system and breast disorders, Uterine polyp											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1365	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0973	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1438	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1380	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1824	1.0000
Time to First Reproductive system and breast disorders, Vulvovaginal discomfort											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4578	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4996	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4481	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5637	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4795	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5071	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Ear and labyrinth disorders, Any											
All Patients	324	163	7	4.3	161	7	4.3	0.71	(0.24, 2.05)	0.5232	NE
Age group (years)											
<65	266	129	5	3.9	137	7	5.1	0.86	(0.27, 2.77)	0.8033	0.1712
>=65	58	34	2	5.9	24	0	0.0	<0.01	(0.00, >999.99)	0.2402	0.1712
Sex											
F	318	162	7	4.3	156	7	4.5	0.73	(0.25, 2.10)	0.5544	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	4	6.5	58	4	6.9	0.67	(0.16, 2.81)	0.5858	0.3902
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	3	4.8	1.20	(0.20, 7.25)	0.8453	0.3902
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1432	0.3902
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	2	6.9	0.89	(0.12, 6.57)	0.9129	0.7995
Y	259	127	5	3.9	132	5	3.8	0.68	(0.19, 2.38)	0.5435	0.7995
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	4	7.7	52	3	5.8	0.41	(0.08, 1.99)	0.2580	0.4274
POST-MENOPAUSAL	214	110	3	2.7	104	4	3.8	1.03	(0.23, 4.65)	0.9741	0.4274
Time to First Ear and labyrinth disorders, Vertigo											
All Patients	324	163	5	3.1	161	3	1.9	0.44	(0.10, 1.89)	0.2583	NE
Age group (years)											
<65	266	129	3	2.3	137	3	2.2	0.65	(0.13, 3.33)	0.6050	0.2295
>=65	58	34	2	5.9	24	0	0.0	<0.01	(0.00, >999.99)	0.2402	0.2295
Sex											
F	318	162	5	3.1	156	3	1.9	0.46	(0.11, 1.94)	0.2761	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	2	3.4	0.82	(0.11, 6.02)	0.8465	0.4959
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	1	1.6	0.36	(0.03, 4.08)	0.3886	0.4959
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1432	0.4959
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.1619	0.1645
Y	259	127	3	2.4	132	3	2.3	0.70	(0.14, 3.52)	0.6606	0.1645
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	1	1.9	0.30	(0.02, 3.74)	0.3304	0.7315
POST-MENOPAUSAL	214	110	3	2.7	104	2	1.9	0.55	(0.09, 3.32)	0.5073	0.7315

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Ear and labyrinth disorders, Tinnitus											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2726	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3219	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2694	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5637	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3476	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2815	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5271	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4167	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4969	1.0000
Time to First Ear and labyrinth disorders, Cerumen impaction											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5009	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5501	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4945	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5316	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4386	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6336	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Ear and labyrinth disorders, Ear discomfort											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2747	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2457	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2813	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2824	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2482	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2416	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Ear and labyrinth disorders, Ear pain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3580	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3865	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3513	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3359	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3838	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3342	1.0000
Time to First Ear and labyrinth disorders, Middle ear inflammation											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3157	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2924	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3221	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3299	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2976	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3270	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Hepatobiliary disorders, Any											
All Patients	324	163	7	4.3	161	2	1.2	0.21	(0.04, 1.03)	0.0341	NE
Age group (years)											
<65	266	129	6	4.7	137	2	1.5	0.21	(0.04, 1.07)	0.0403	0.6093
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4193	0.6093
Sex											
F	318	162	7	4.3	156	1	0.6	0.10	(0.01, 0.85)	0.0103	0.1365
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.1365
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.4873
NORTH AMERICA/WESTERN EUROPE	126	63	5	7.9	63	2	3.2	0.29	(0.05, 1.56)	0.1286	0.4873
OTHER	78	38	2	5.3	40	0	0.0	<0.01	(0.00, >999.99)	0.1178	0.4873
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.36	(0.03, 4.12)	0.3900	0.4521
Y	259	127	5	3.9	132	1	0.8	0.15	(0.02, 1.33)	0.0503	0.4521
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.1757	0.5953
POST-MENOPAUSAL	214	110	6	5.5	104	1	1.0	0.12	(0.01, 1.03)	0.0232	0.5953
Time to First Hepatobiliary disorders, Hypertransaminaemia											
All Patients	324	163	3	1.8	161	2	1.2	0.44	(0.07, 2.66)	0.3556	NE
Age group (years)											
<65	266	129	3	2.3	137	2	1.5	0.37	(0.06, 2.28)	0.2677	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	3	1.9	156	1	0.6	0.20	(0.02, 1.97)	0.1289	0.2285
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.2285
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	2	3.2	0.45	(0.07, 2.82)	0.3838	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.36	(0.03, 4.12)	0.3900	0.8203
Y	259	127	1	0.8	132	1	0.8	0.73	(0.05, 11.73)	0.8224	0.8203
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.1757	0.4199
POST-MENOPAUSAL	214	110	2	1.8	104	1	1.0	0.28	(0.02, 3.26)	0.2808	0.4199
Time to First Hepatobiliary disorders, Hepatic pain											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.1395	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	2	1.6	137	0	0.0	<0.01	(0.00, >999.99)	0.1210	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1447	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	2	5.3	40	0	0.0	<0.01	(0.00, >999.99)	0.1178	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	2	1.6	132	0	0.0	<0.01	(0.00, >999.99)	0.1213	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1503	1.0000
Time to First Hepatobiliary disorders, Bile duct stone											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.0339	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0339	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.0339	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.0833	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.0614	1.0000
Time to First Hepatobiliary disorders, Cholelithiasis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2566	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4193	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2636	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2918	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2304	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2855	1.0000
Time to First Hepatobiliary disorders, Hyperbilirubinaemia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3220	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2981	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3243	1.0000
Time to First Immune system disorders, Any											
All Patients	324	163	4	2.5	161	5	3.1	0.83	(0.22, 3.12)	0.7787	NE
Age group (years)											
<65	266	129	3	2.3	137	4	2.9	0.77	(0.17, 3.51)	0.7328	0.6858
>=65	58	34	1	2.9	24	1	4.2	1.40	(0.09, 22.50)	0.8103	0.6858
Sex											
F	318	162	4	2.5	156	5	3.2	0.84	(0.22, 3.16)	0.7924	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	2	3.4	1.65	(0.15, 18.83)	0.6822	0.7352
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	1	1.6	0.34	(0.03, 3.82)	0.3581	0.7352
OTHER	78	38	1	2.6	40	2	5.0	1.02	(0.09, 11.32)	0.9883	0.7352
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.1110	0.0652
Y	259	127	4	3.1	132	3	2.3	0.42	(0.09, 1.90)	0.2449	0.0652

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.2828	0.1180
POST-MENOPAUSAL	214	110	4	3.6	104	3	2.9	0.53	(0.12, 2.40)	0.4034	0.1180
Time to First Immune system disorders, Contrast media allergy											
All Patients	324	163	2	1.2	161	3	1.9	1.11	(0.18, 6.75)	0.9083	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.46	(0.13, 16.58)	0.7574	0.9617
>=65	58	34	1	2.9	24	1	4.2	1.40	(0.09, 22.50)	0.8103	0.9617
Sex											
F	318	162	2	1.2	156	3	1.9	1.15	(0.19, 6.96)	0.8809	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	2	3.4	1.65	(0.15, 18.83)	0.6822	0.2787
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2974	0.2787
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5201	0.2787
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	0.2198
Y	259	127	2	1.6	132	2	1.5	0.62	(0.09, 4.50)	0.6367	0.2198
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.3021
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.75	(0.11, 5.40)	0.7775	0.3021
Time to First Immune system disorders, Hypersensitivity											
All Patients	324	163	1	0.6	161	1	0.6	0.66	(0.04, 10.67)	0.7669	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.56	(0.03, 9.12)	0.6819	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.62	(0.04, 10.18)	0.7342	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	1	2.5	0.56	(0.03, 9.00)	0.6787	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2815	0.0944
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1967	0.0944
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.64	(0.04, 10.76)	0.7582	1.0000
Time to First Immune system disorders, Seasonal allergy											
All Patients	324	163	1	0.6	161	1	0.6	0.52	(0.03, 8.46)	0.6418	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	1	0.8	137	1	0.7	0.42	(0.03, 6.81)	0.5259	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.54	(0.03, 8.75)	0.6596	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.63	(0.04, 10.33)	0.7437	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.47	(0.03, 7.68)	0.5894	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6464	0.1456
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2534	0.1456
Time to First Endocrine disorders, Any											
All Patients	324	163	2	1.2	161	5	3.1	1.83	(0.35, 9.61)	0.4676	NE
Age group (years)											
<65	266	129	0	0.0	137	5	3.6	>999.99	(0.00, >999.99)	0.0638	0.0106
>=65	58	34	2	5.9	24	0	0.0	<0.01	(0.00, >999.99)	0.2317	0.0106
Sex											
F	318	162	2	1.2	156	5	3.2	1.89	(0.36, 9.90)	0.4445	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.6455
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	4	6.3	3.14	(0.34, 28.60)	0.2852	0.6455
OTHER	78	38	1	2.6	40	1	2.5	0.63	(0.04, 10.63)	0.7439	0.6455
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.1716	0.1620
Y	259	127	2	1.6	132	3	2.3	1.04	(0.17, 6.33)	0.9675	0.1620
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6056	0.4468
POST-MENOPAUSAL	214	110	2	1.8	104	4	3.8	1.77	(0.32, 9.74)	0.5054	0.4468
Time to First Endocrine disorders, Hypothyroidism											
All Patients	324	163	1	0.6	161	2	1.2	1.35	(0.12, 15.30)	0.8073	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2616	0.0870
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3918	0.0870
Sex											
F	318	162	1	0.6	156	2	1.3	1.39	(0.12, 15.77)	0.7882	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.1154

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2209	0.1154
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1201	0.1154
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4386	0.2626
Y	259	127	1	0.8	132	1	0.8	0.74	(0.05, 12.07)	0.8339	0.2626
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.58	(0.14, 17.66)	0.7078	1.0000
Time to First Endocrine disorders, Hyperthyroidism											
All Patients	324	163	1	0.6	161	1	0.6	0.84	(0.05, 13.53)	0.8992	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	0.1469
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.1469
Sex											
F	318	162	1	0.6	156	1	0.6	0.86	(0.05, 13.94)	0.9163	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.98	(0.06, 15.67)	0.9884	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.79	(0.05, 12.79)	0.8680	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.93	(0.06, 14.92)	0.9577	1.0000
Time to First Endocrine disorders, Cushingoid											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5019	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5465	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4939	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5002	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5091	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6056	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likeli- hood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Endocrine disorders, Thyroid disorder											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3416	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3126	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3103	1.0000
Time to First Endocrine disorders, Thyroid mass											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3416	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3126	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3103	1.0000
Time to First Surgical and medical procedures, Any											
All Patients	324	163	3	1.8	161	0	0.0	<0.01	(0.00, >999.99)	0.0188	NE
Age group (years)											
<65	266	129	2	1.6	137	0	0.0	<0.01	(0.00, >999.99)	0.0373	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3613	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.0762	0.9999
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0455	0.9999
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	0	0.0	<0.01	(0.00, >999.99)	0.0300	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	3	2.4	132	0	0.0	<0.01	(0.00, >999.99)	0.0131	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.1897	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2182	1.0000
Time to First Surgical and medical procedures, Influenza immunisation											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1757	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3613	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1851	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2399	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1607	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2182	1.0000
Time to First Surgical and medical procedures, Mammoplasty											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2356	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2039	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2424	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2858	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2081	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.1897	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Surgical and medical procedures, Tooth extraction											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1405	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0973	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	1	100.0	5	0	0.0	<0.01	(0.00, >999.99)	0.0455	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1655	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1213	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Neoplasms benign, malignant and unspecified (incl cysts and polyps), Any											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2388	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2759	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2306	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.2579	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.1896	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4547	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3747	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Neoplasms benign, malignant and unspecified (incl cysts and polyps), Cancer pain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4076	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4443	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3994	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4268	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3657	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4547	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Neoplasms benign, malignant and unspecified (incl cysts and polyps), Transitional cell carcinoma											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4044	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4402	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3961	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4268	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3527	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3747	1.0000
Time to First Product issues, Any											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2747	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2457	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2813	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2207	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3674	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3004	1.0000
Time to First Product issues, Device dislocation											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2747	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2457	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2813	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2207	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3674	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3004	1.0000

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_ae_tte.R

Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_SPT_P3_SAS_15NOV2024_41554.docx

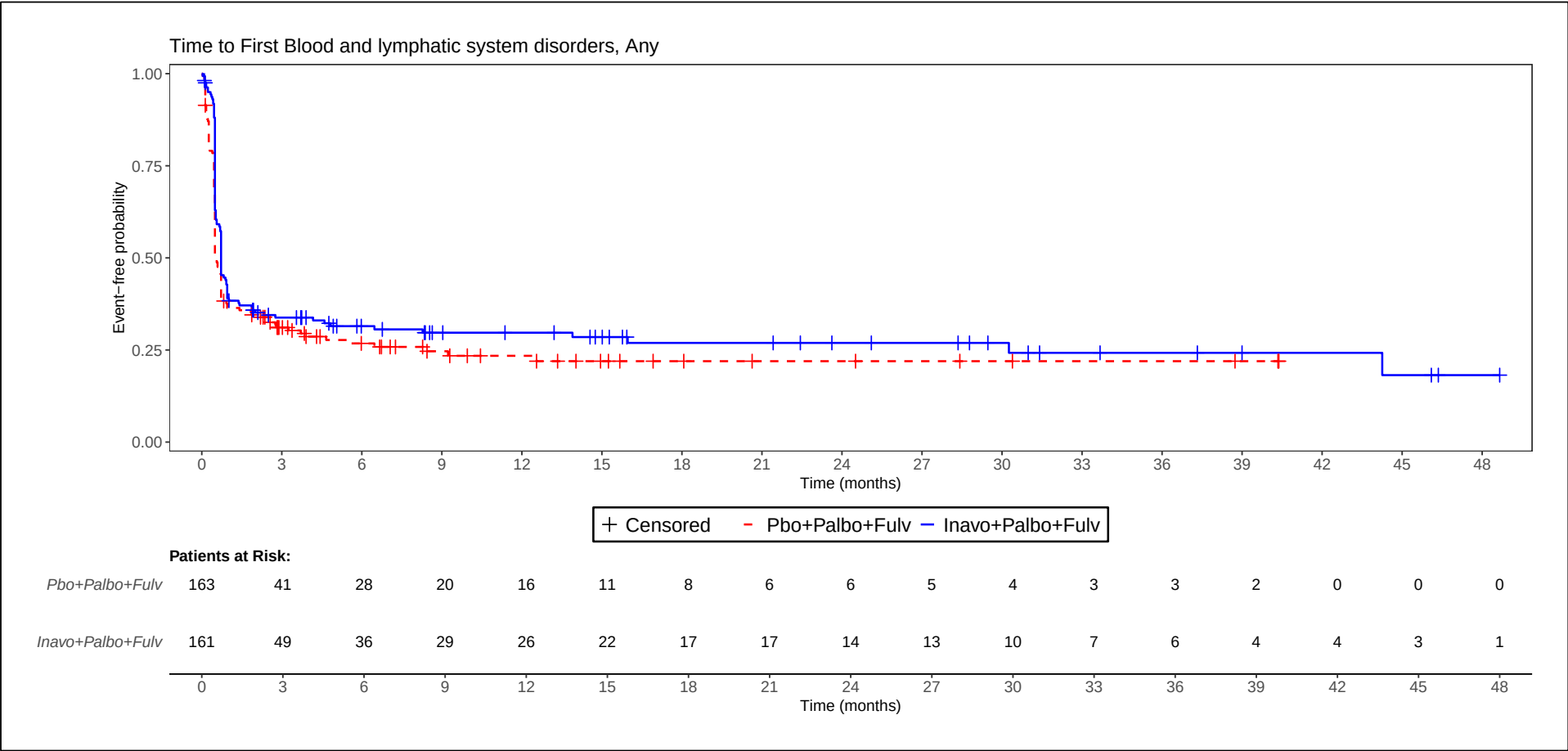
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Git hash: 8065628e23c1f16f1b9c5c76540f88be90f918fa

08 APR 2025 19:07 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

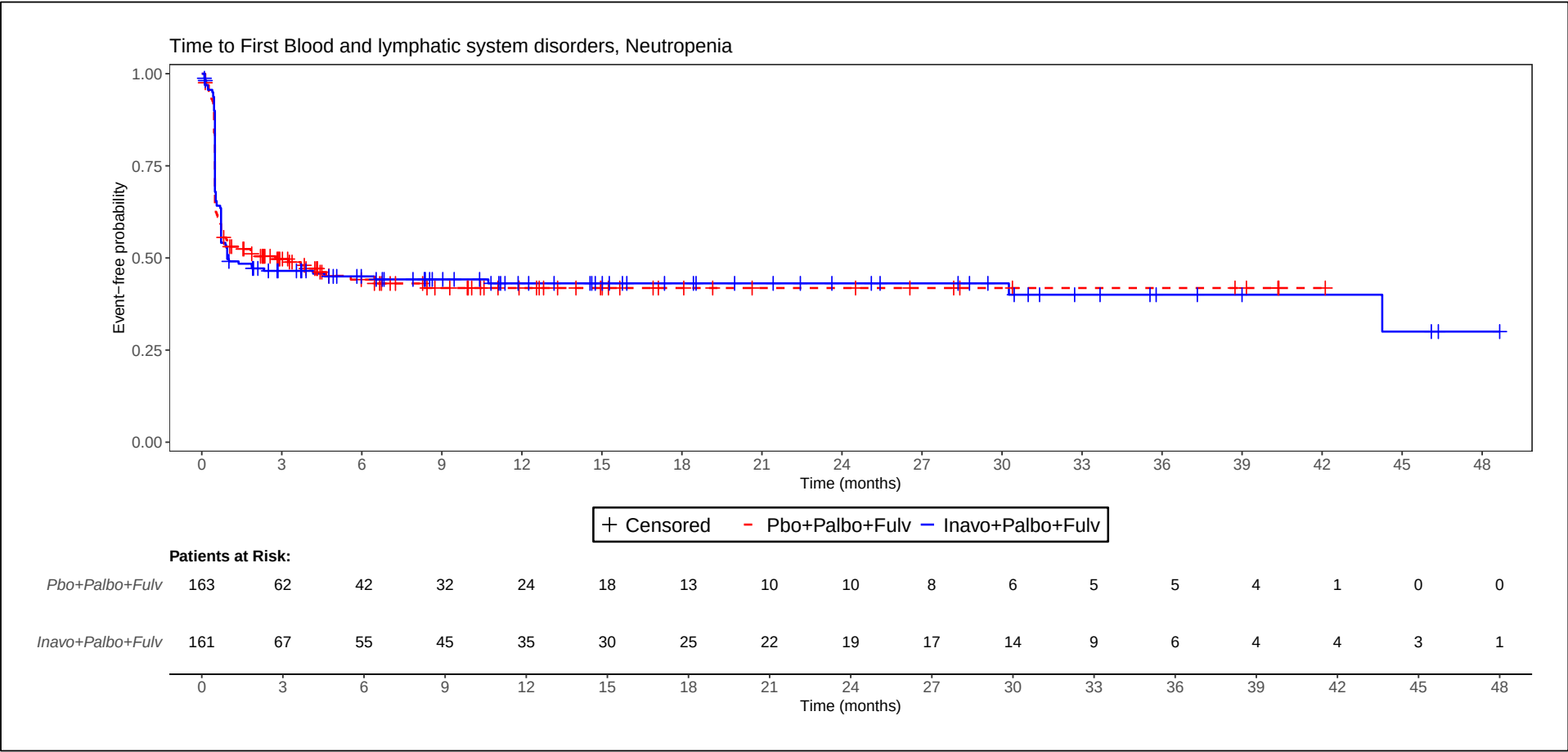
Kaplan Meier Plot for Safety, Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_SPT_SAS_15NOV2024_41554.pdf
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31 MAR 2025 06:22 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

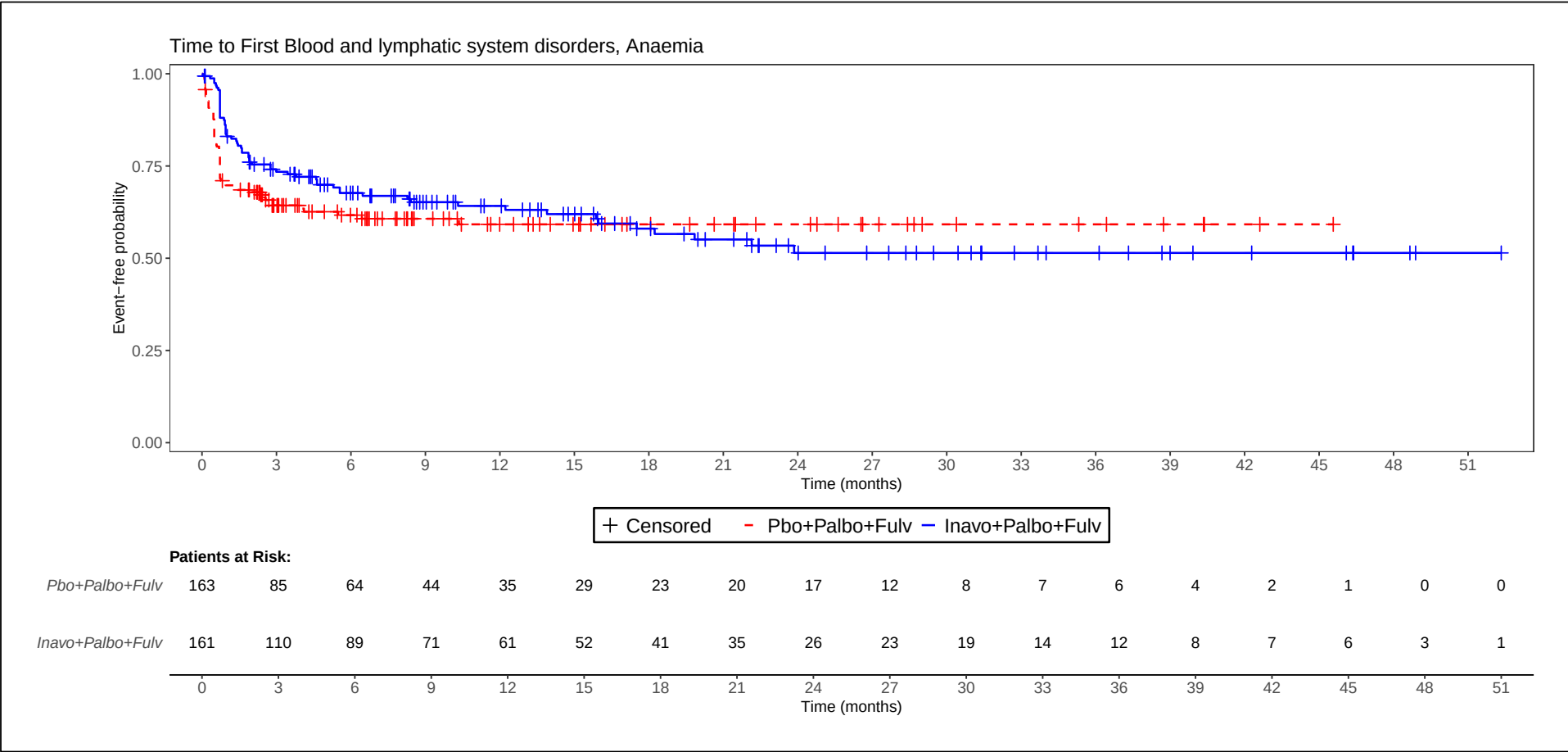
Kaplan Meier Plot for Safety, Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_SPT_SAS_15NOV2024_41554.pdf
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

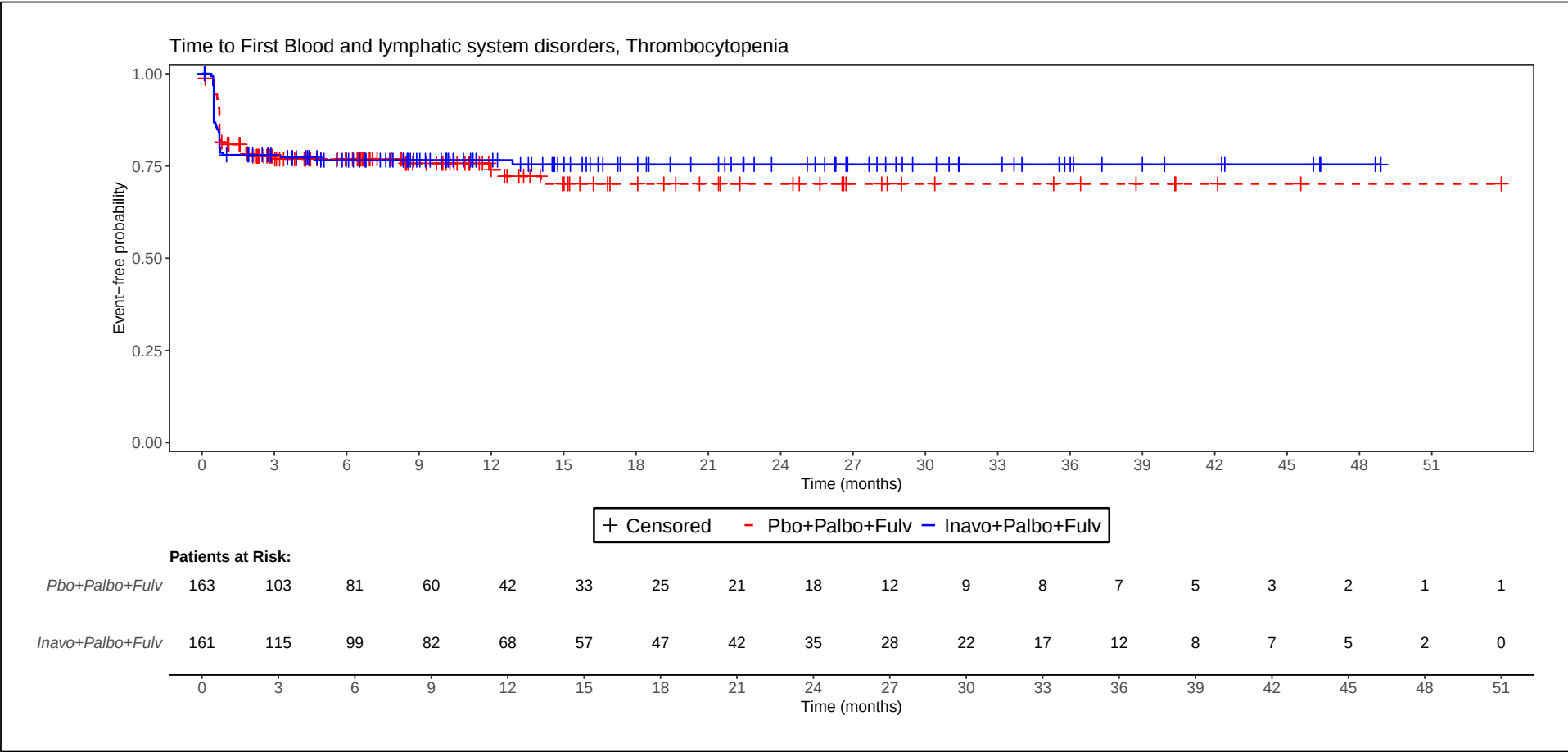
Kaplan Meier Plot for Safety, Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

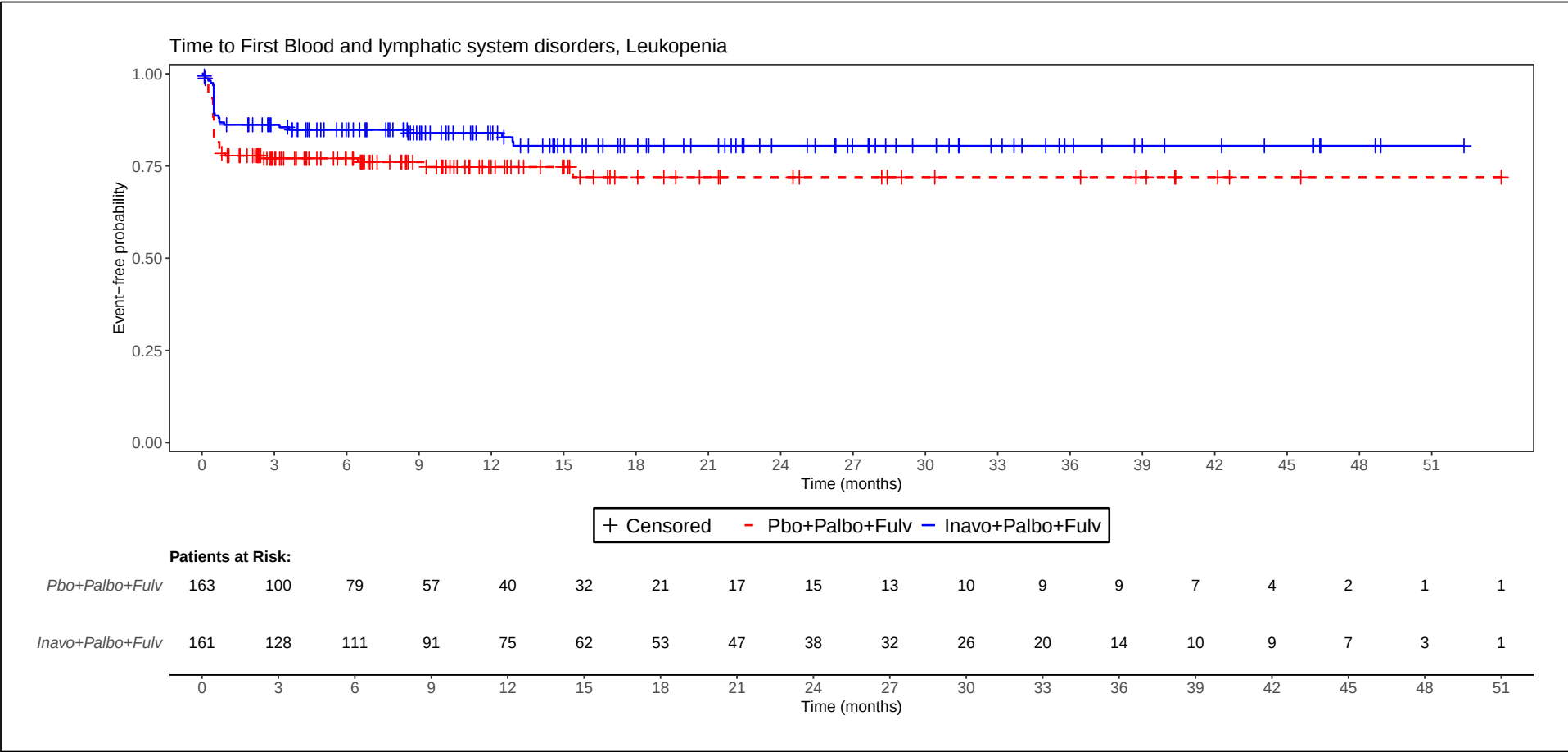
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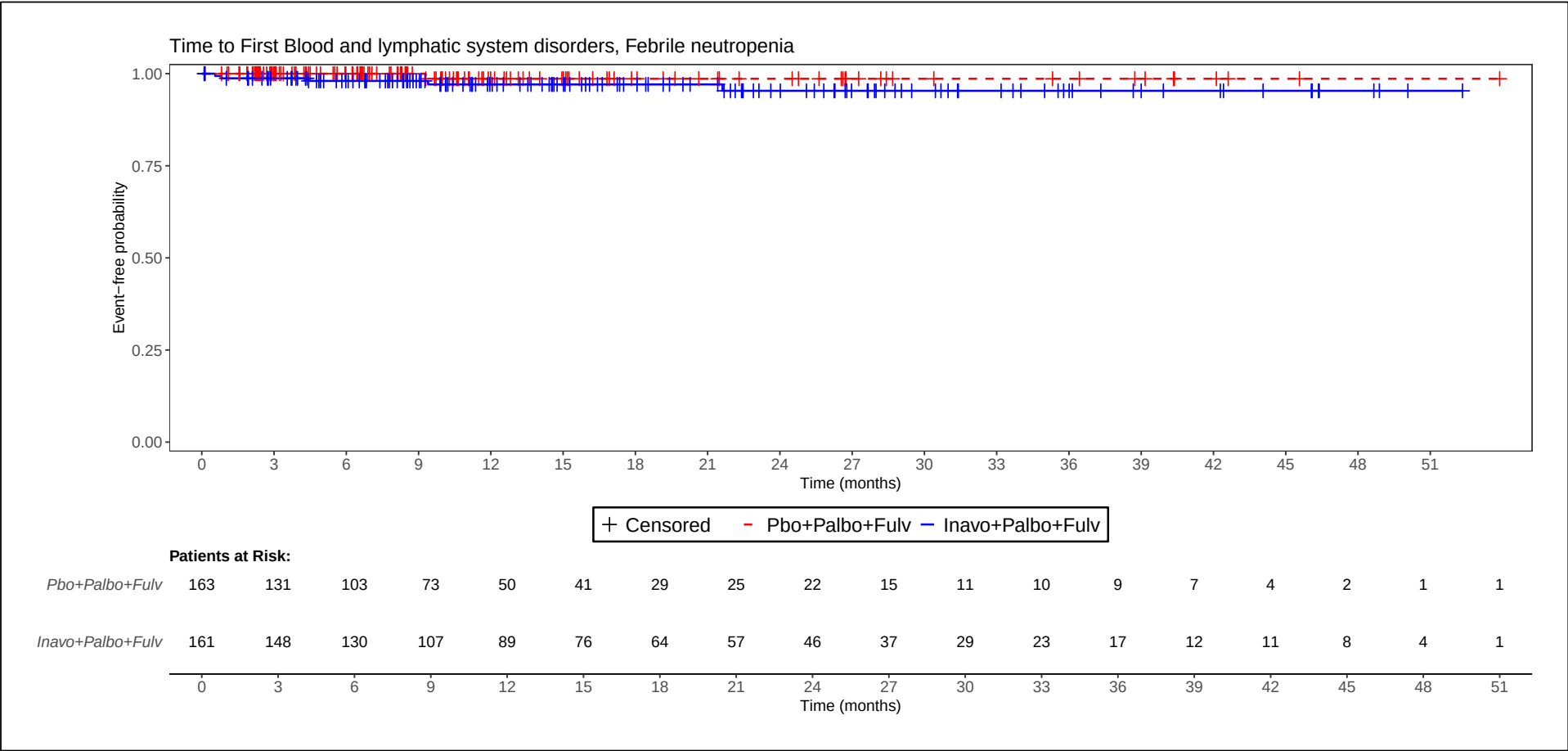
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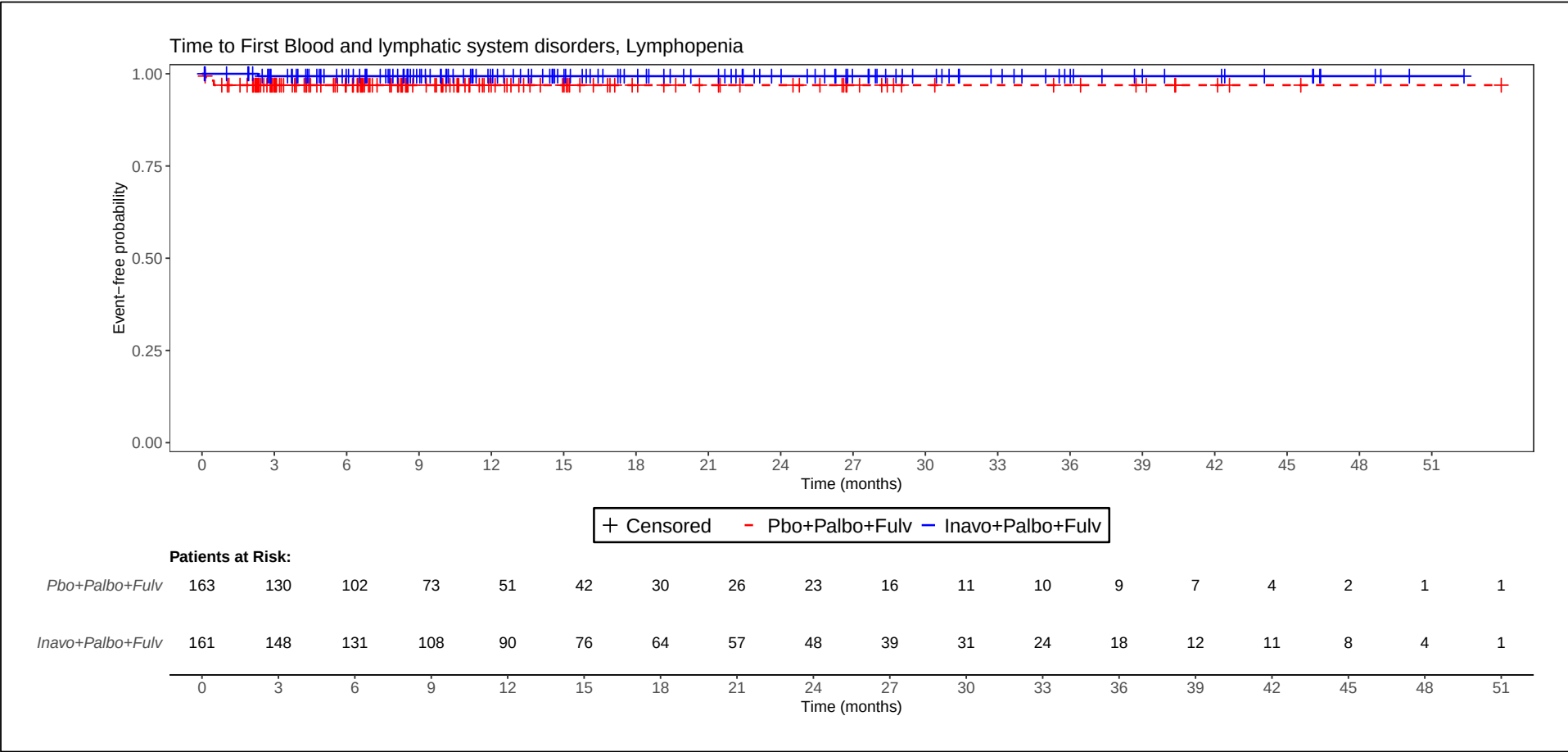
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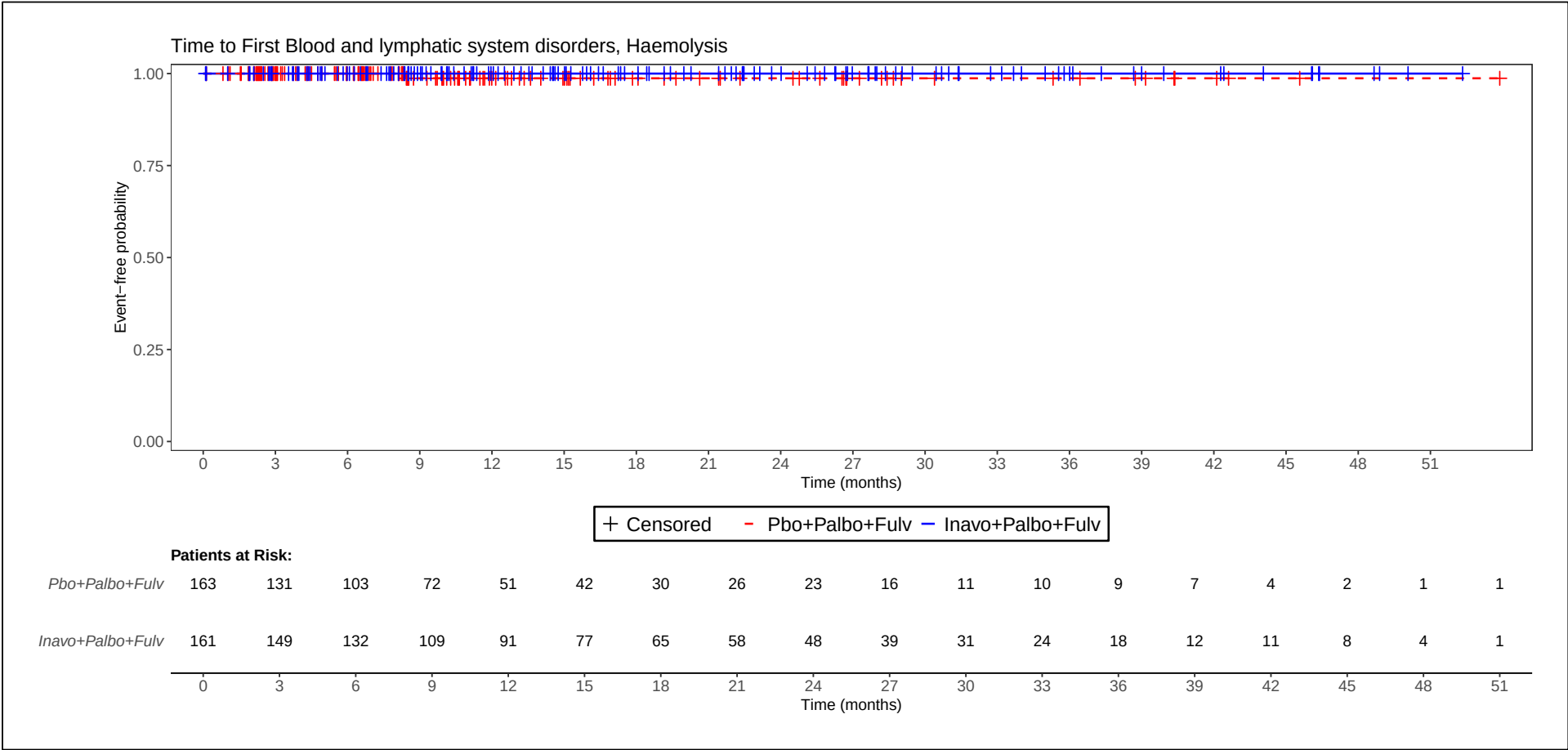
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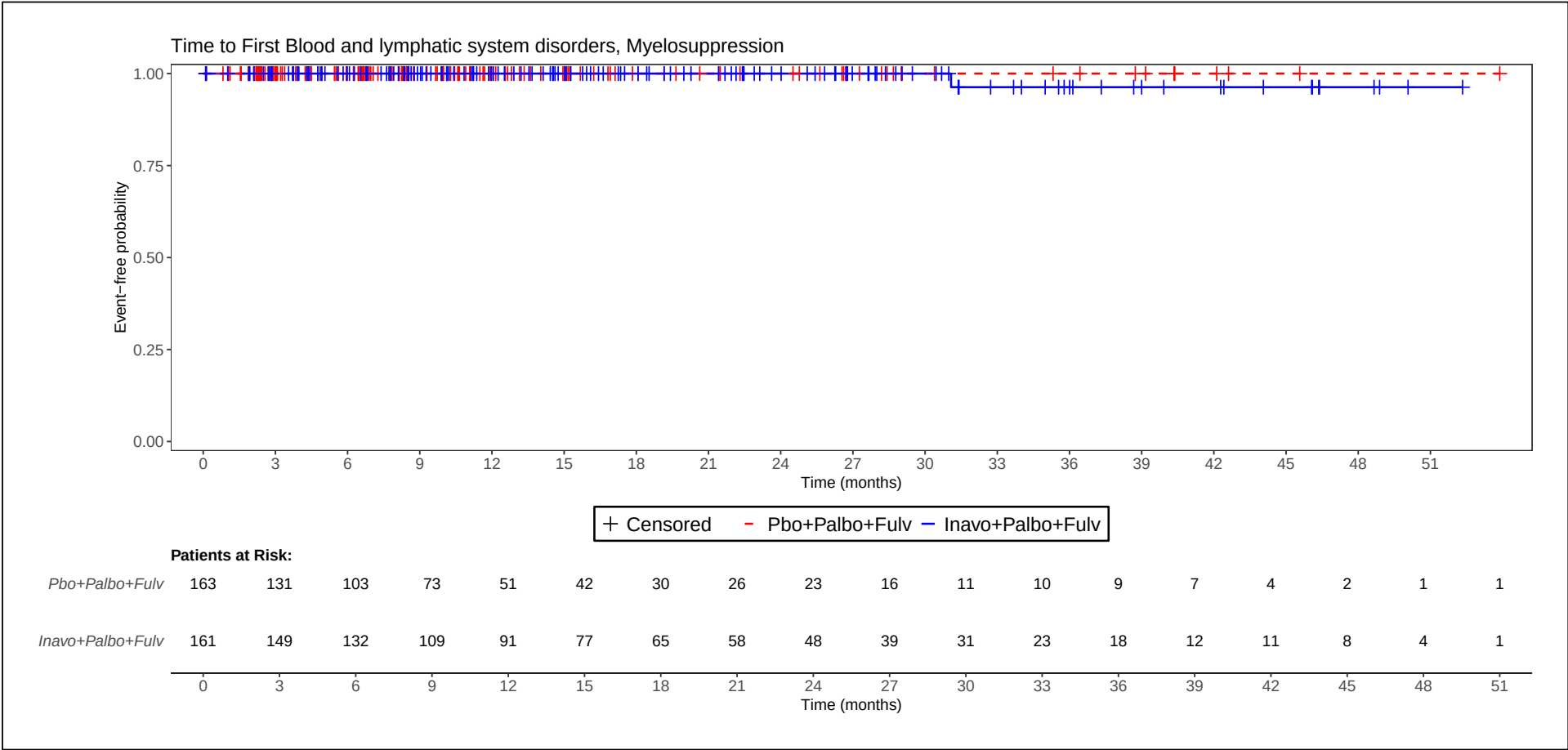
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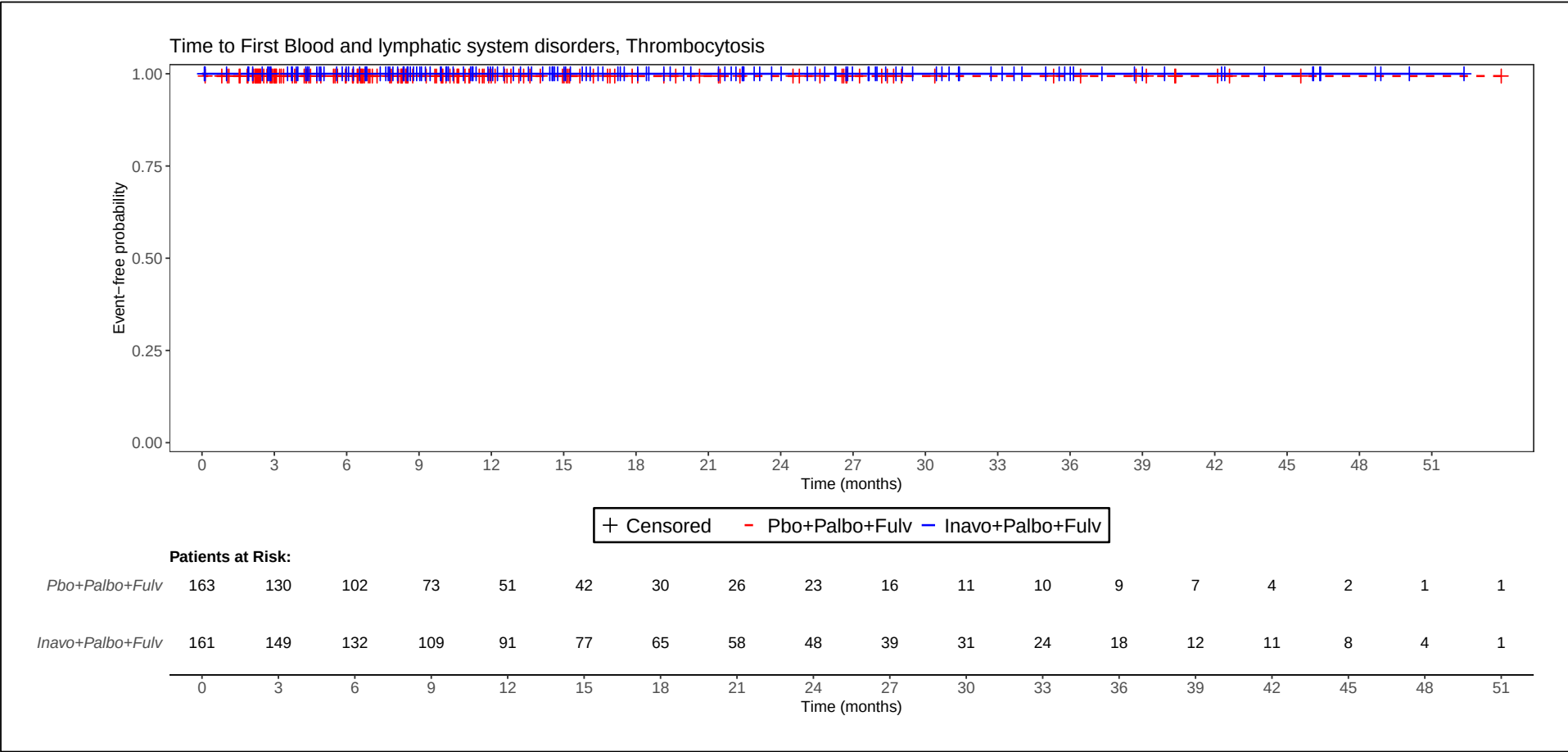
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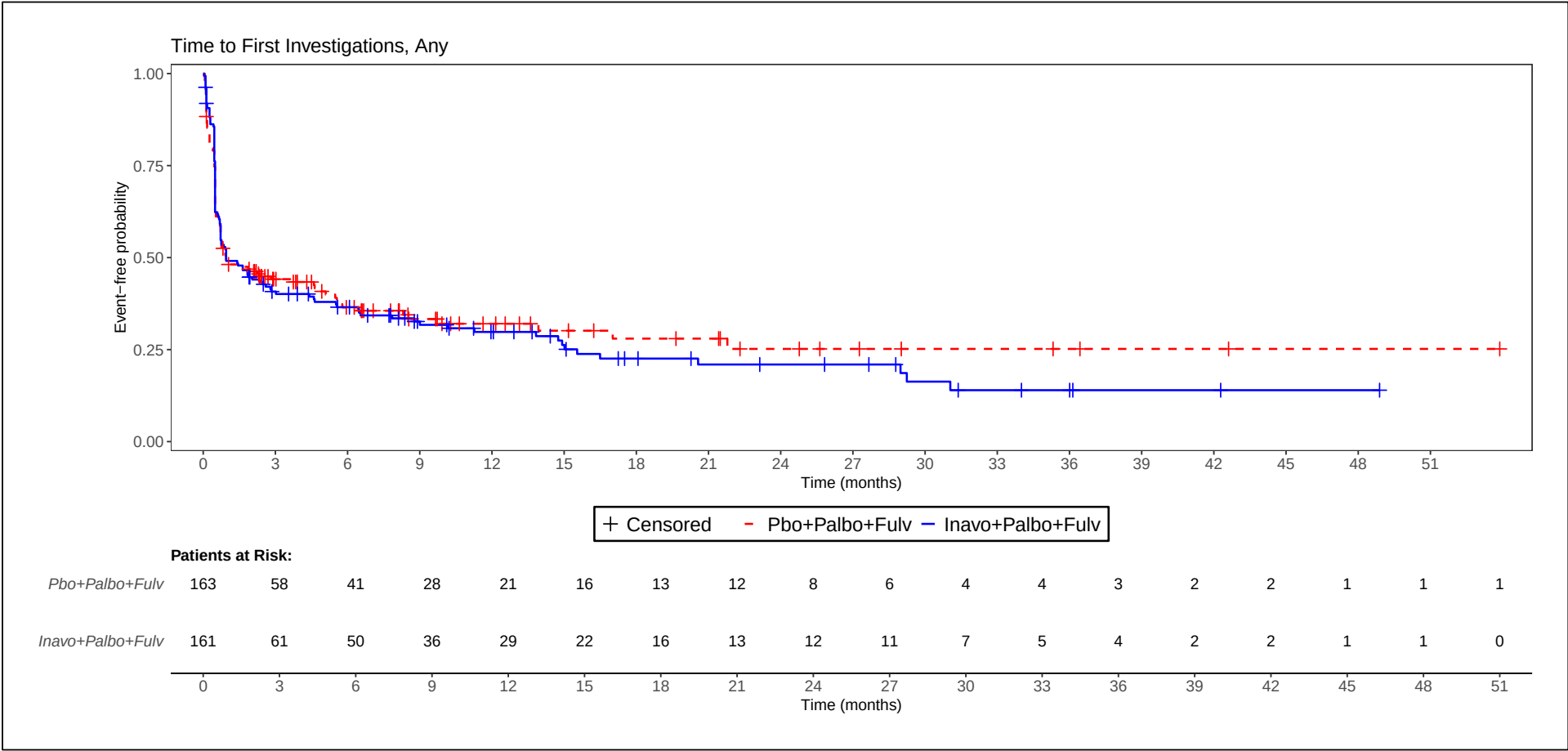
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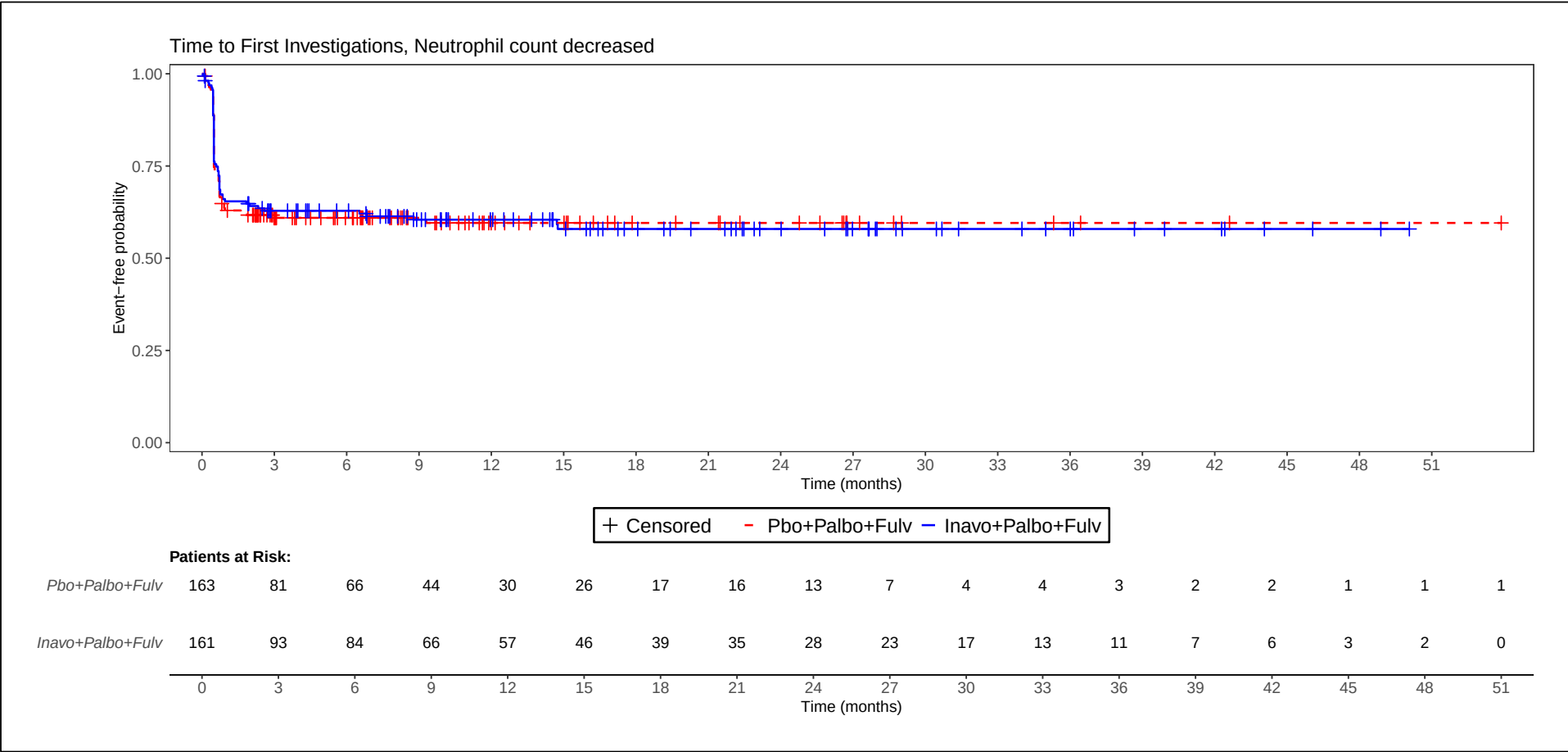
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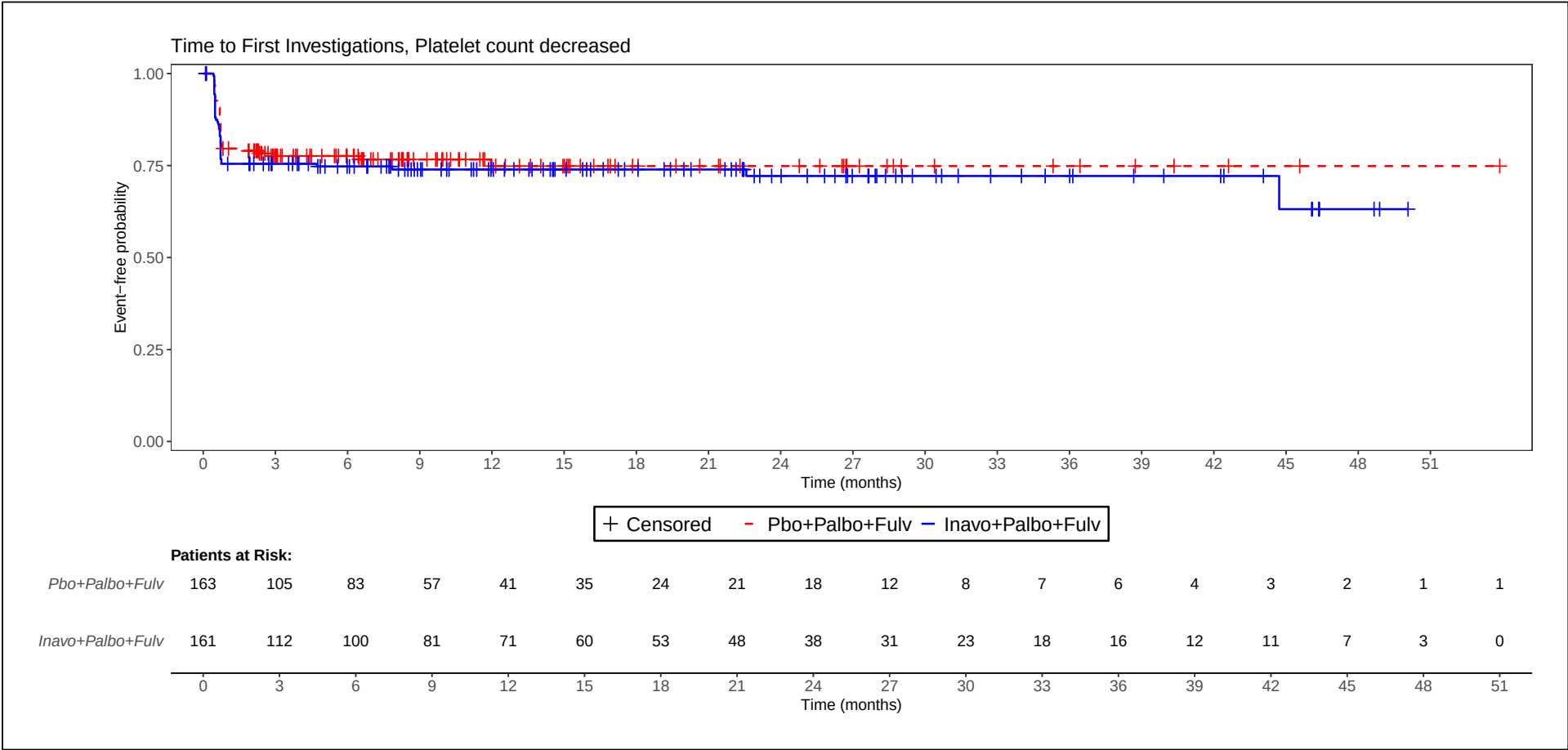
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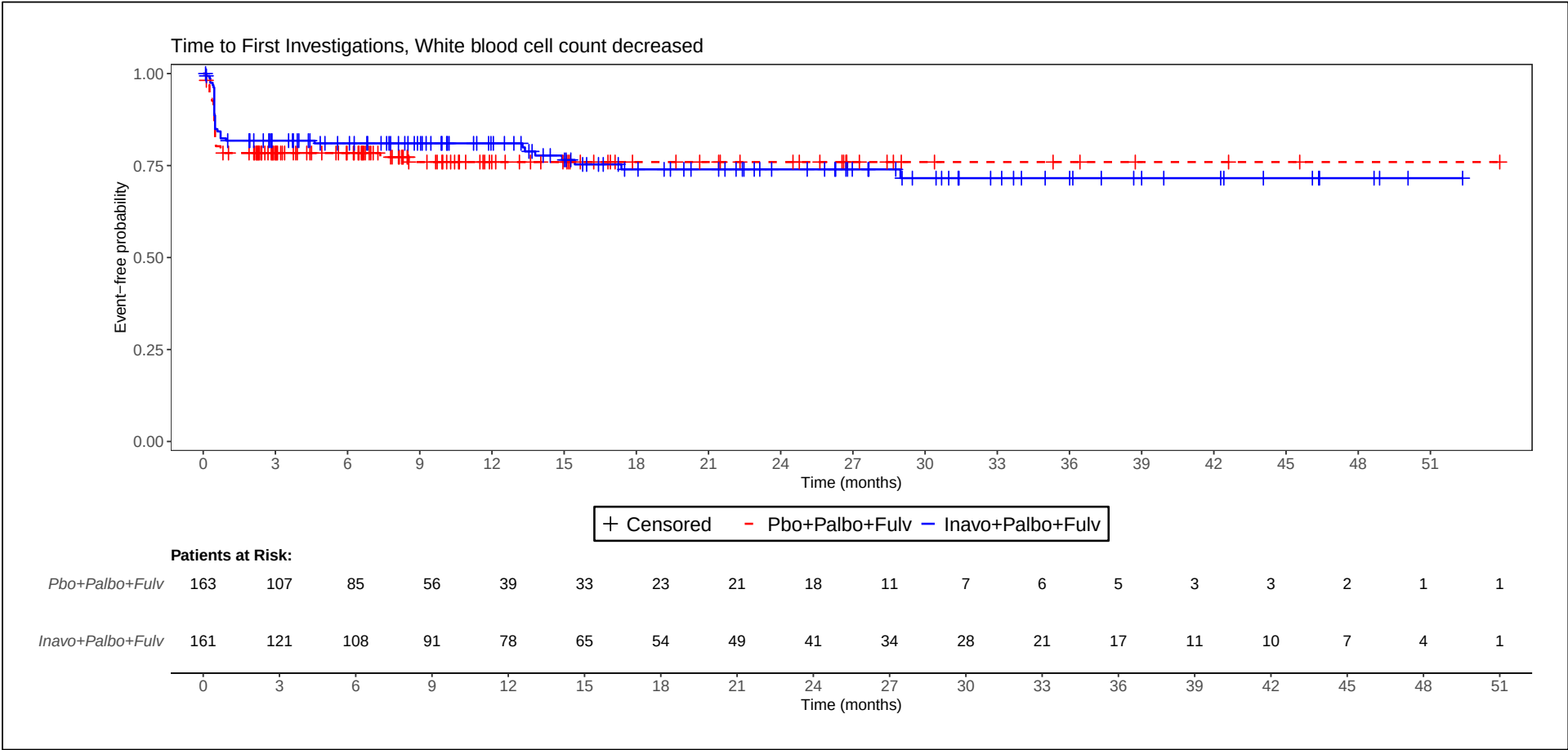
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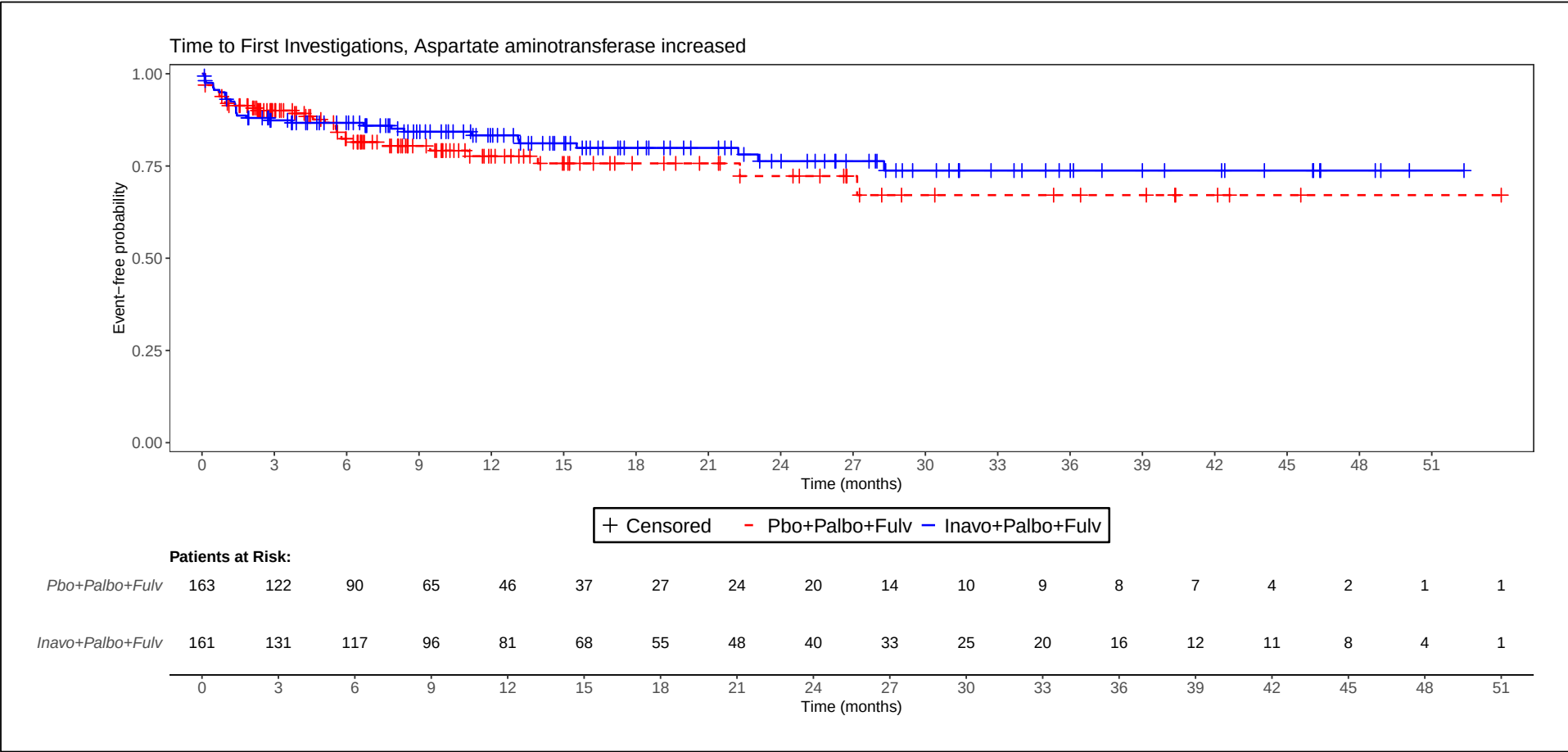
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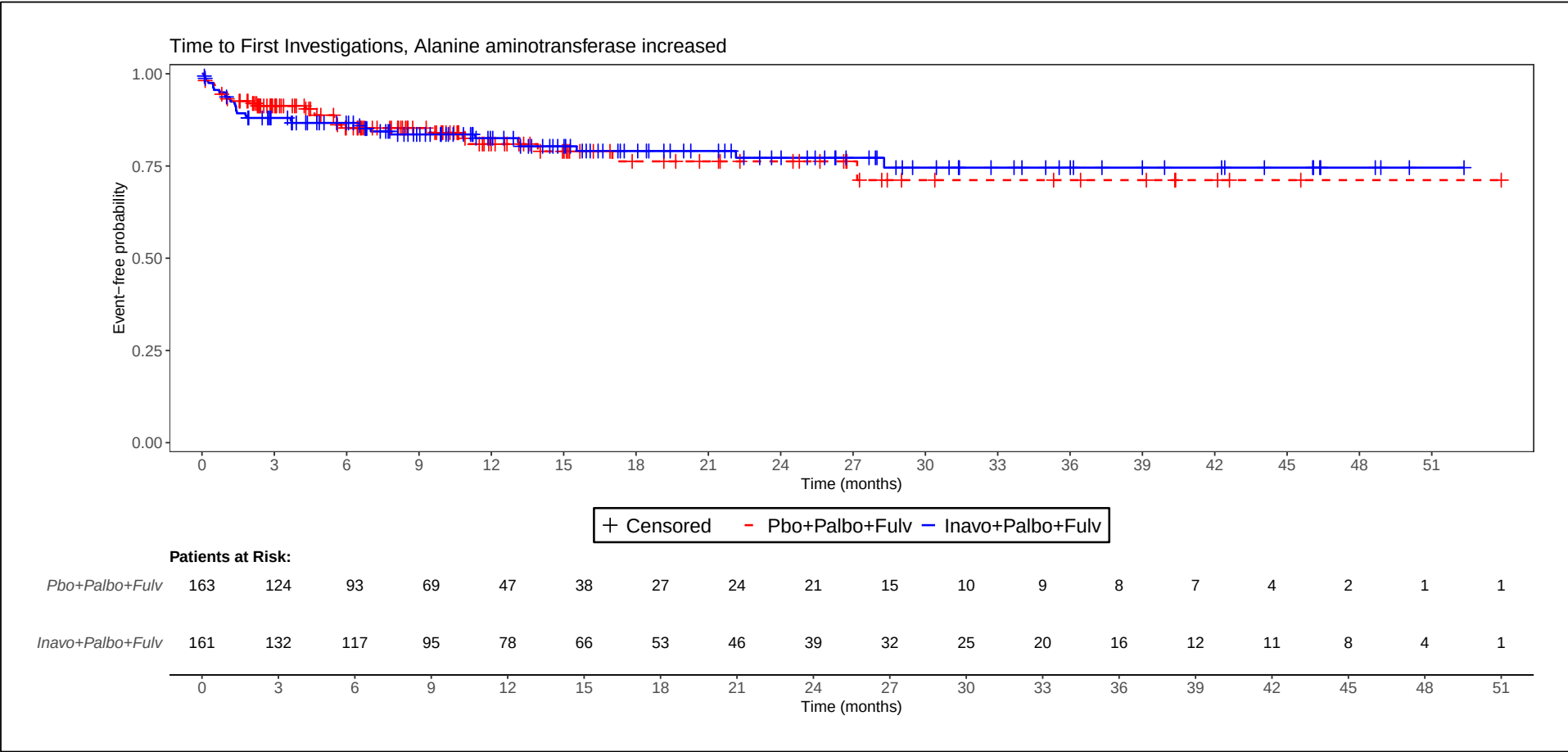
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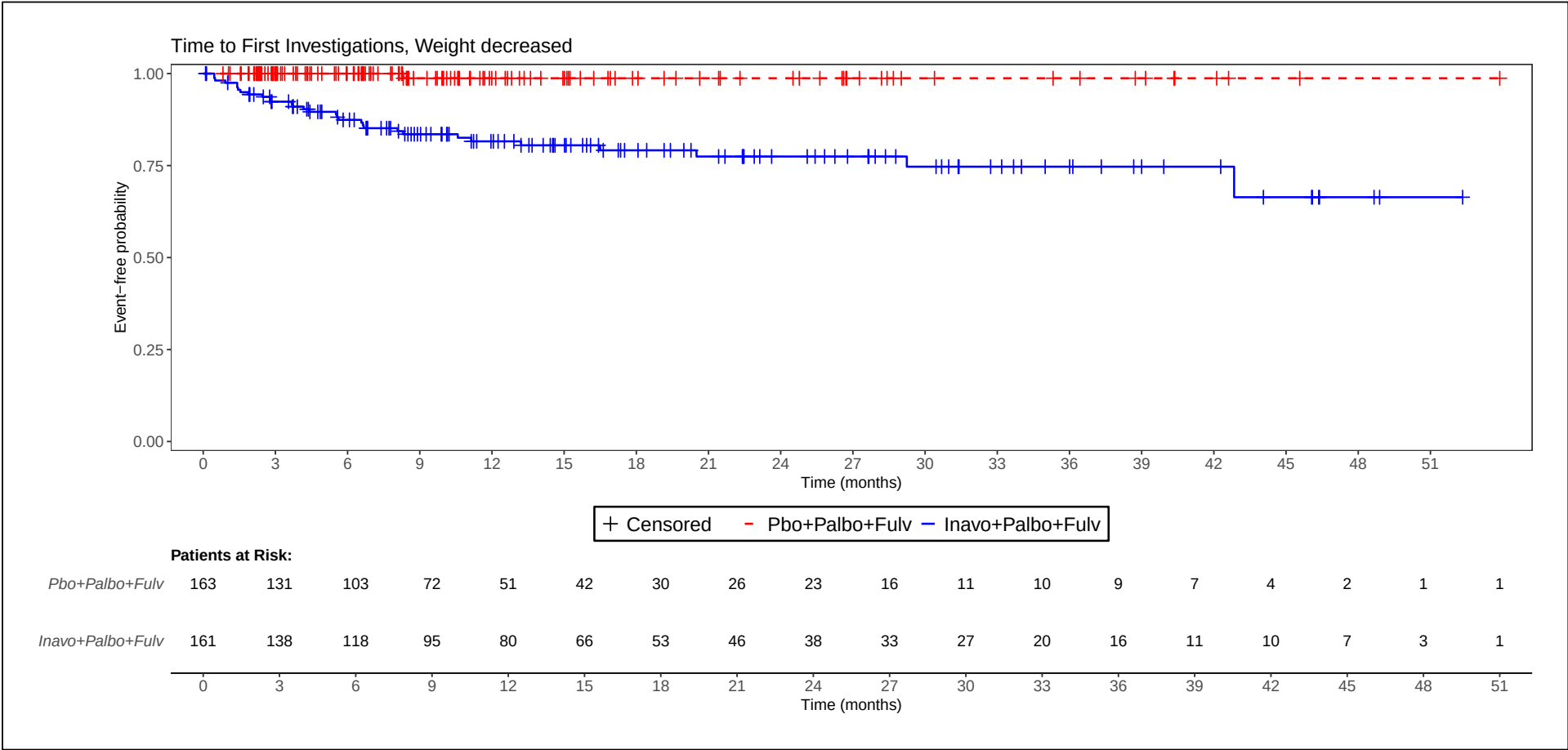
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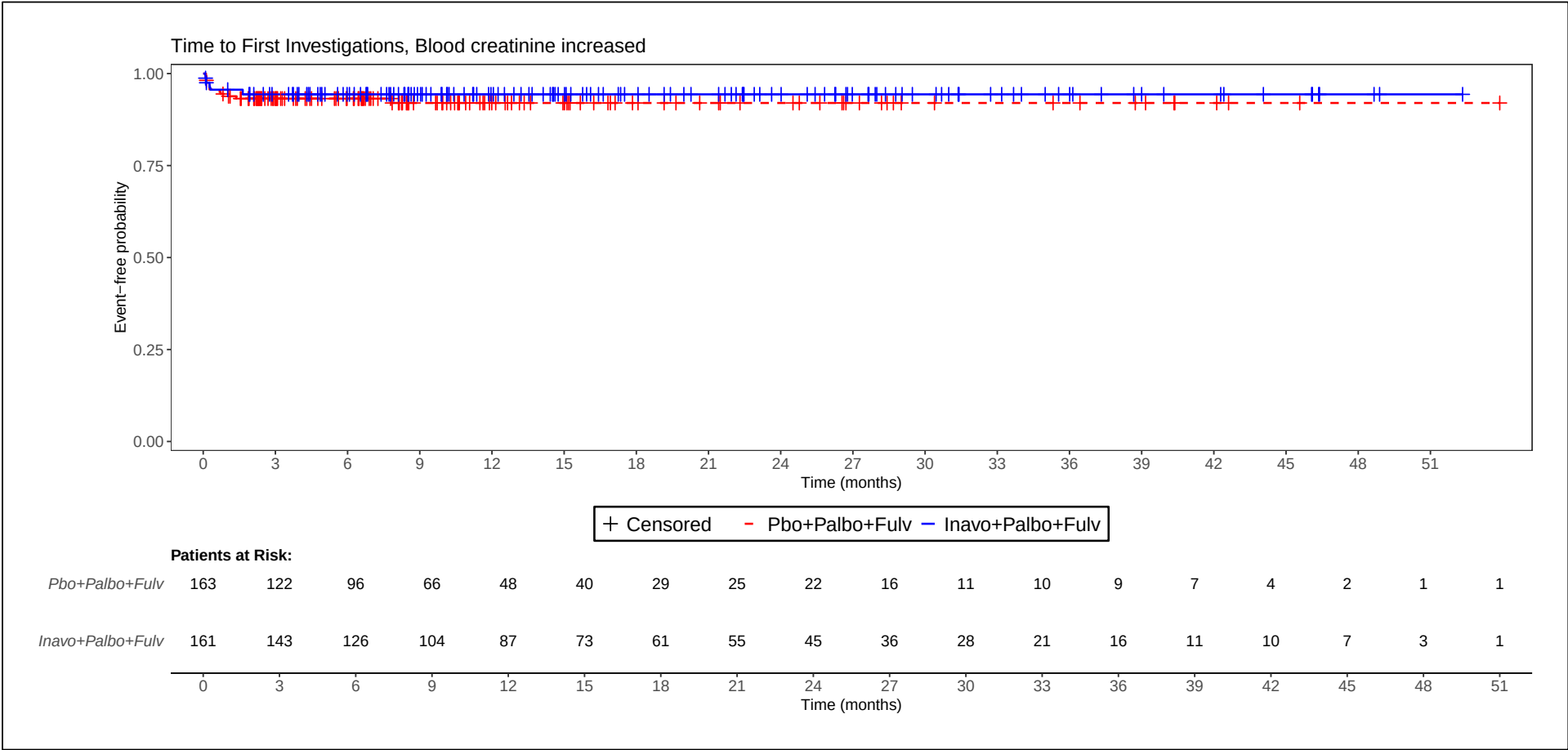
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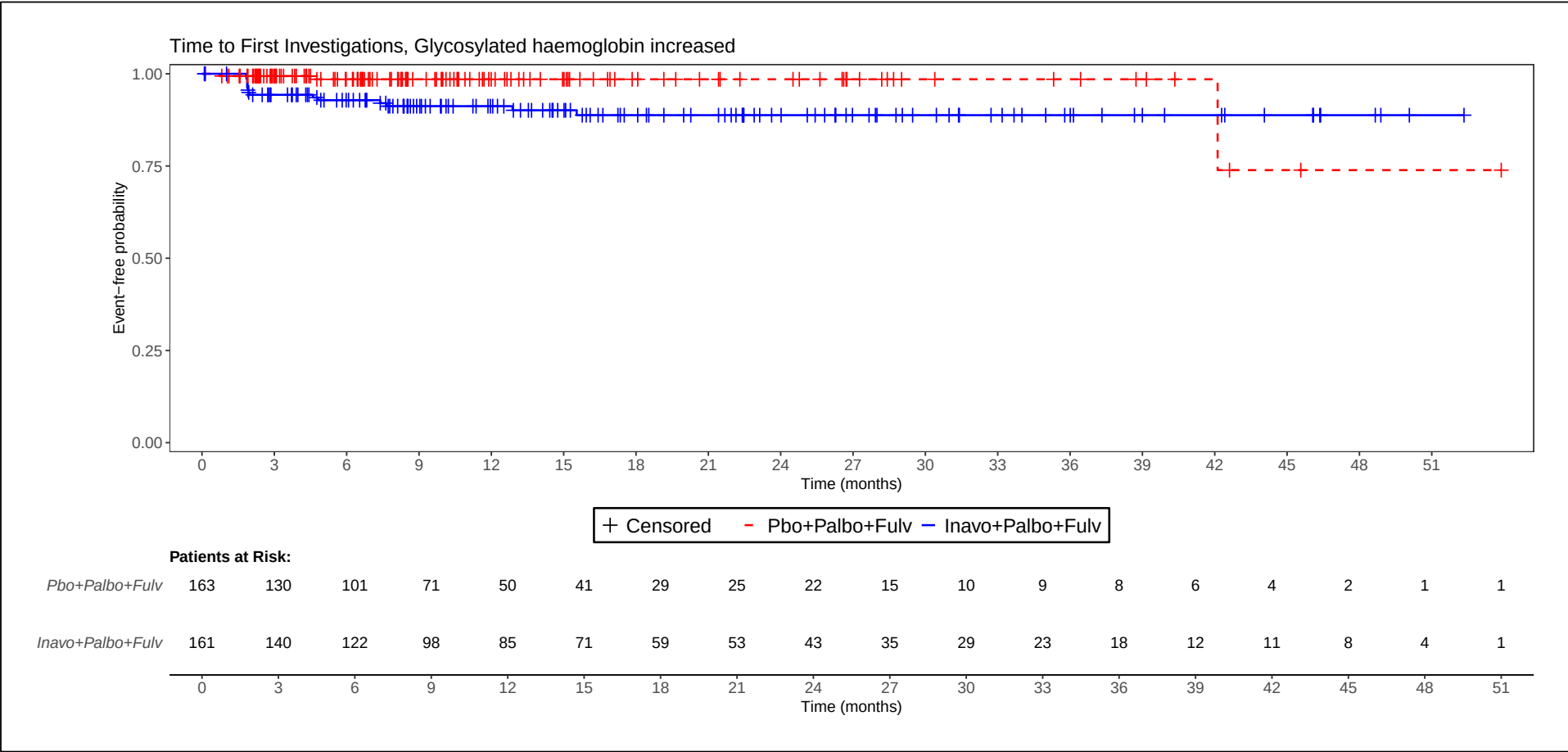
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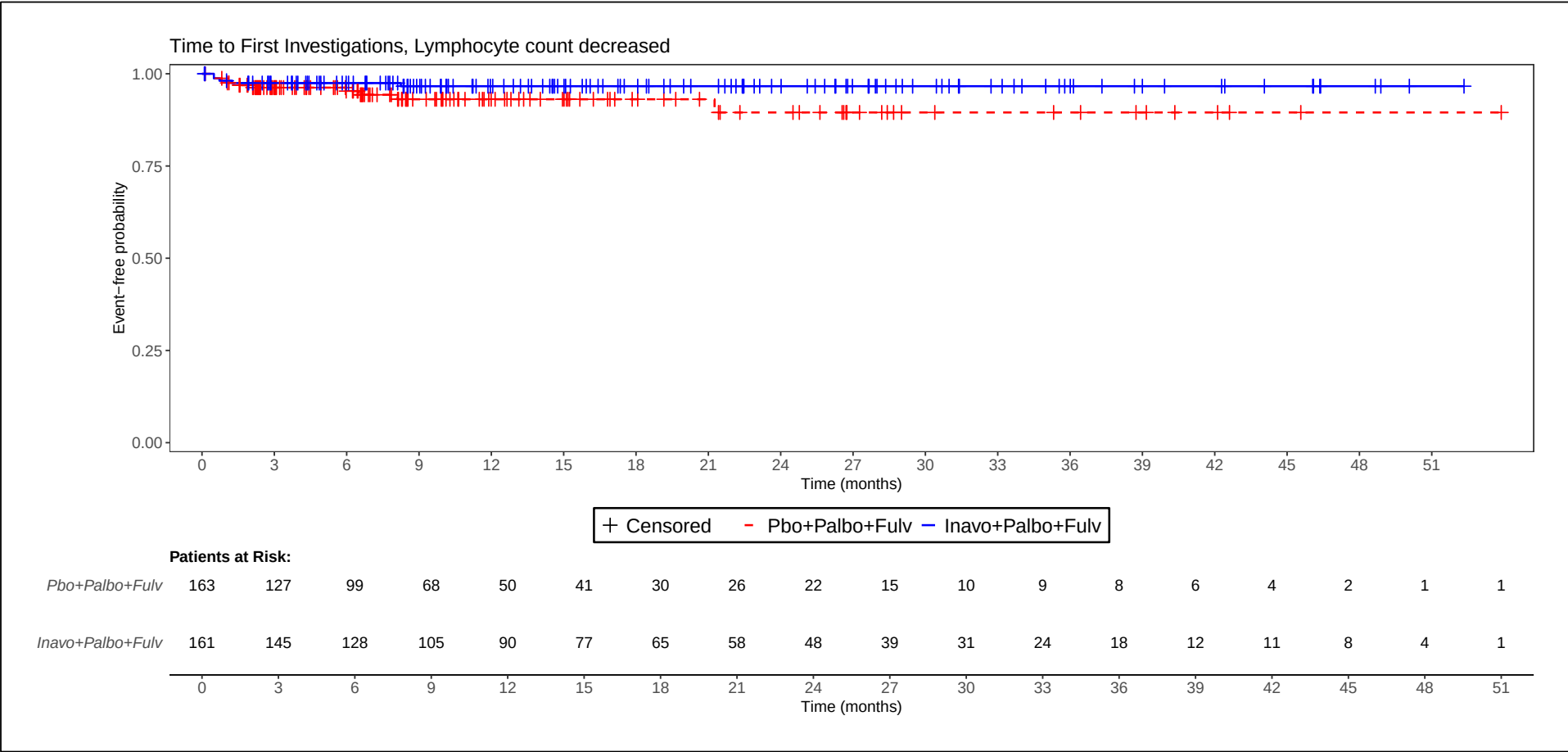
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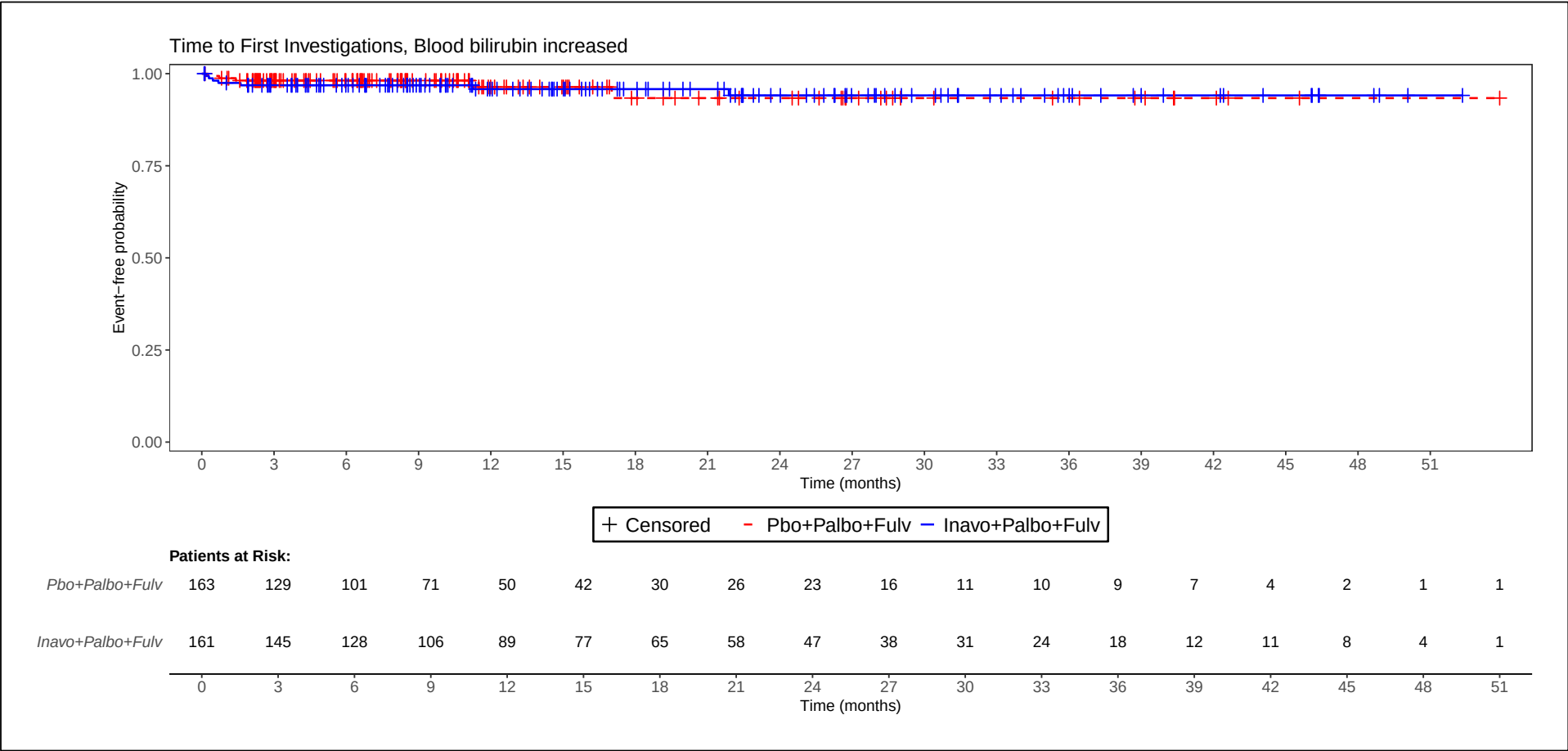
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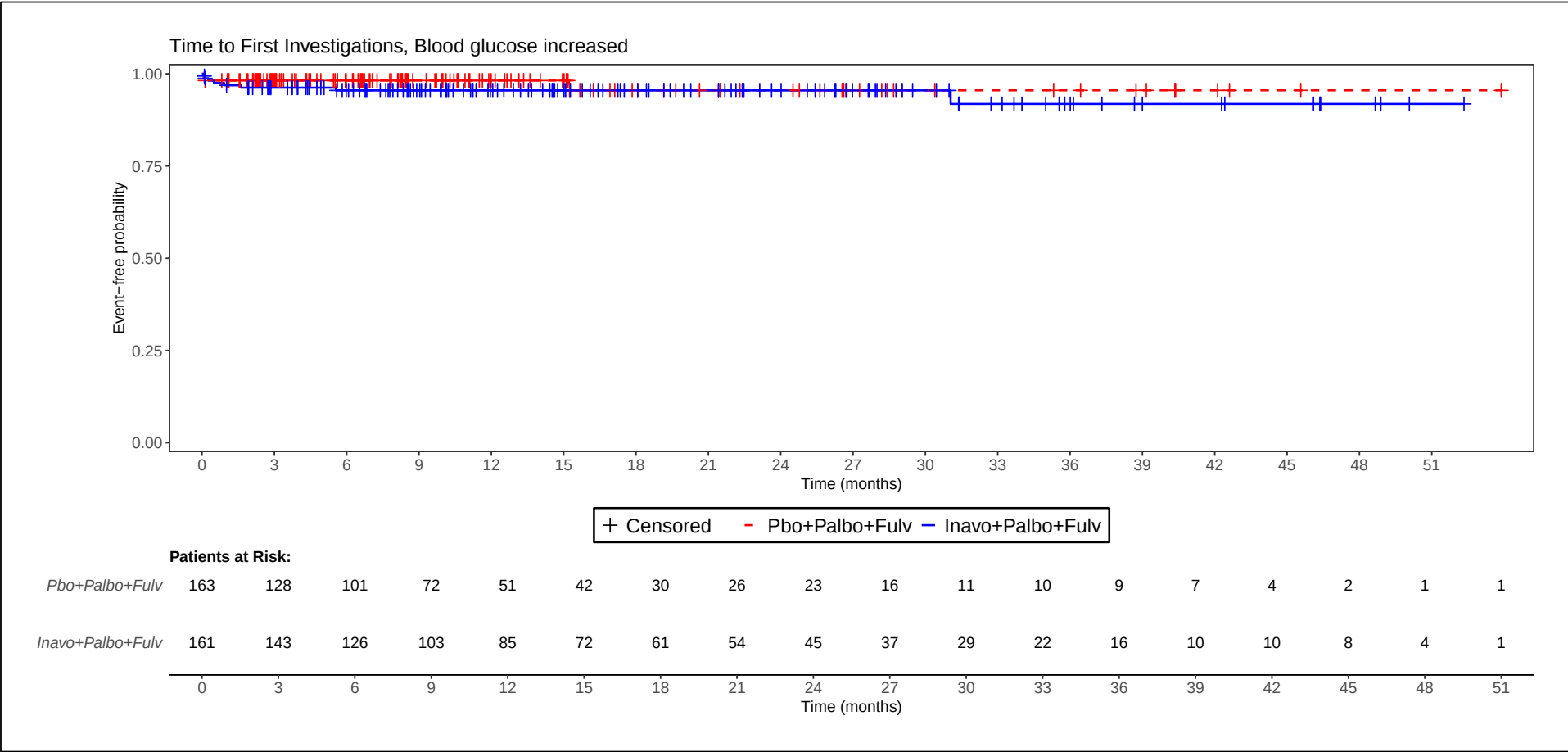
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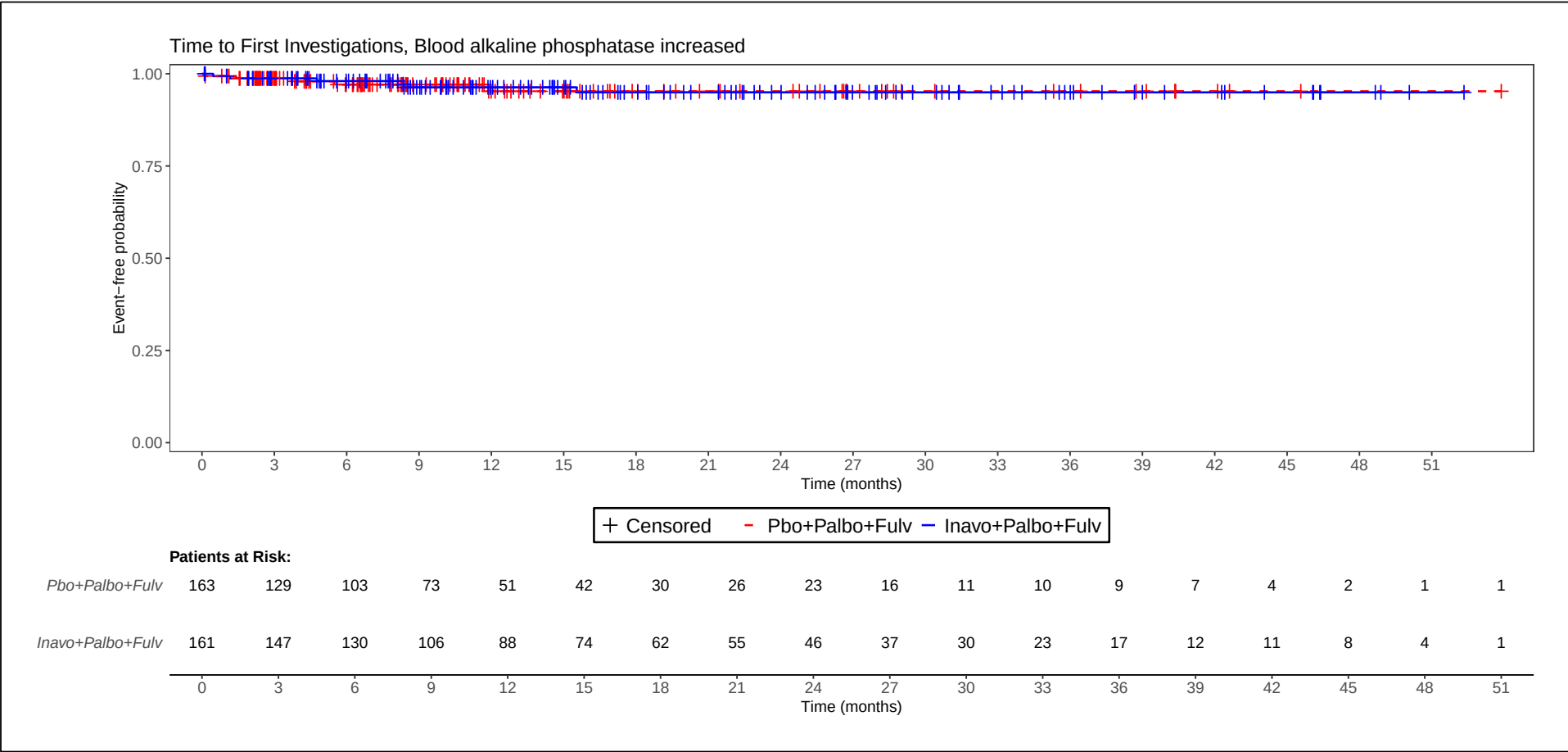
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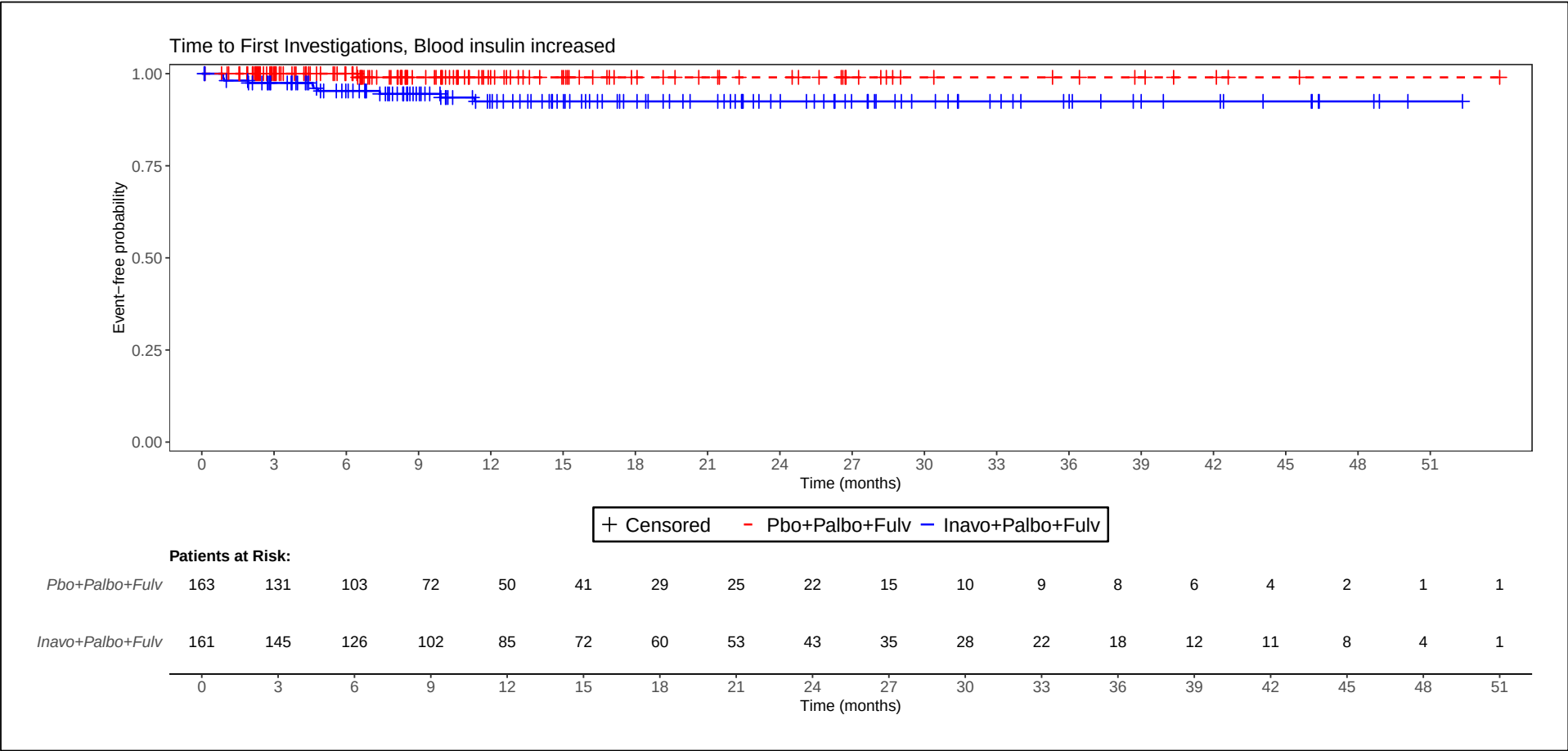
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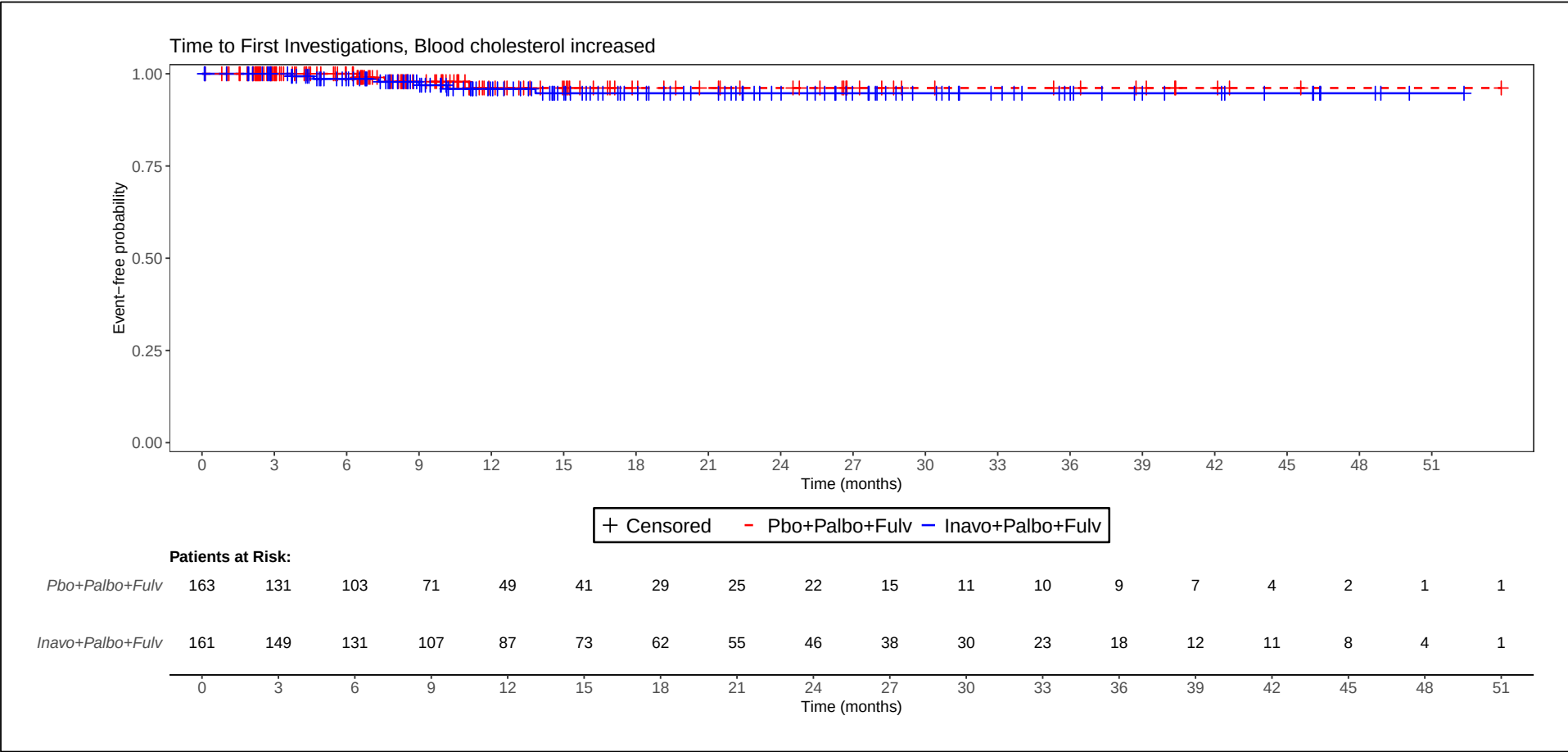
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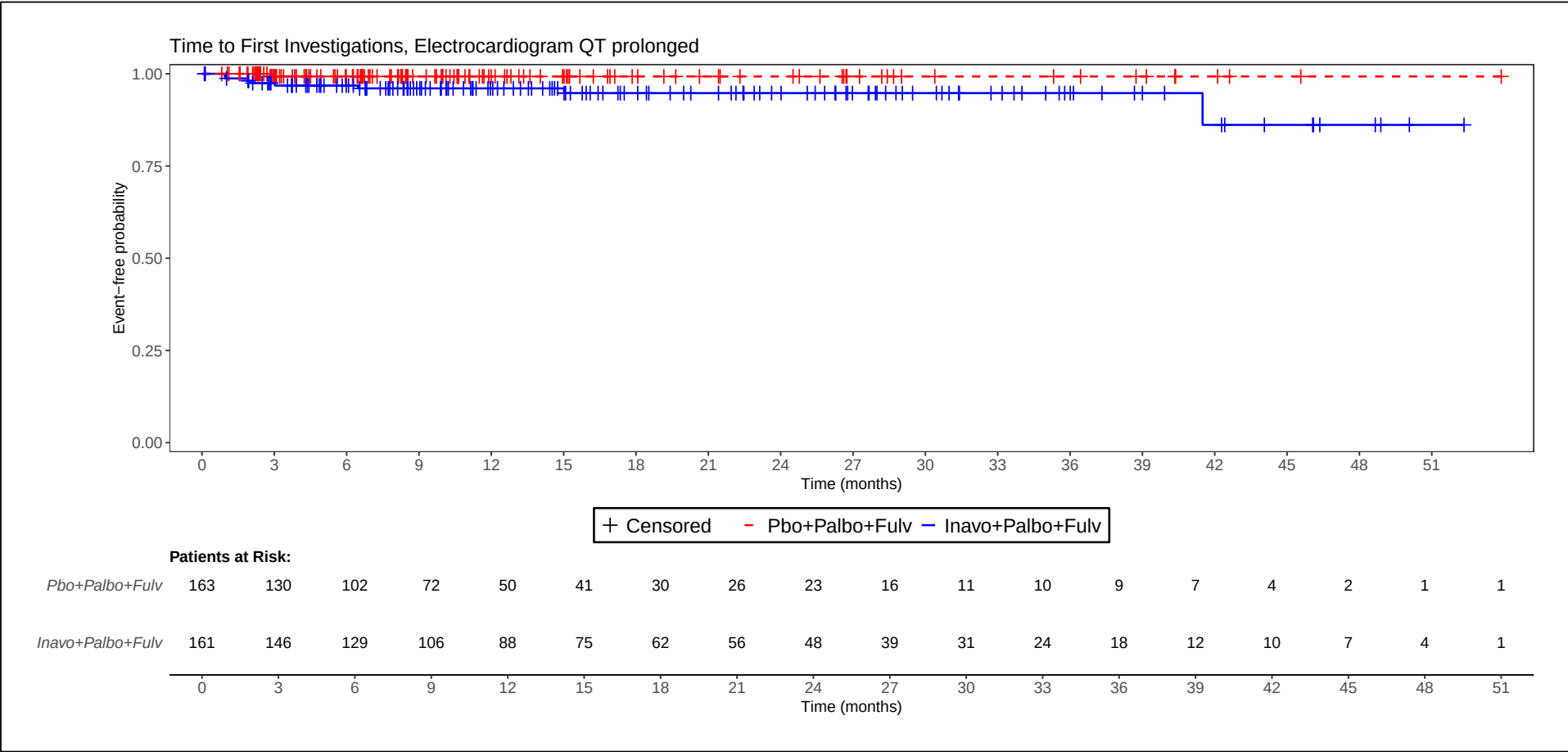
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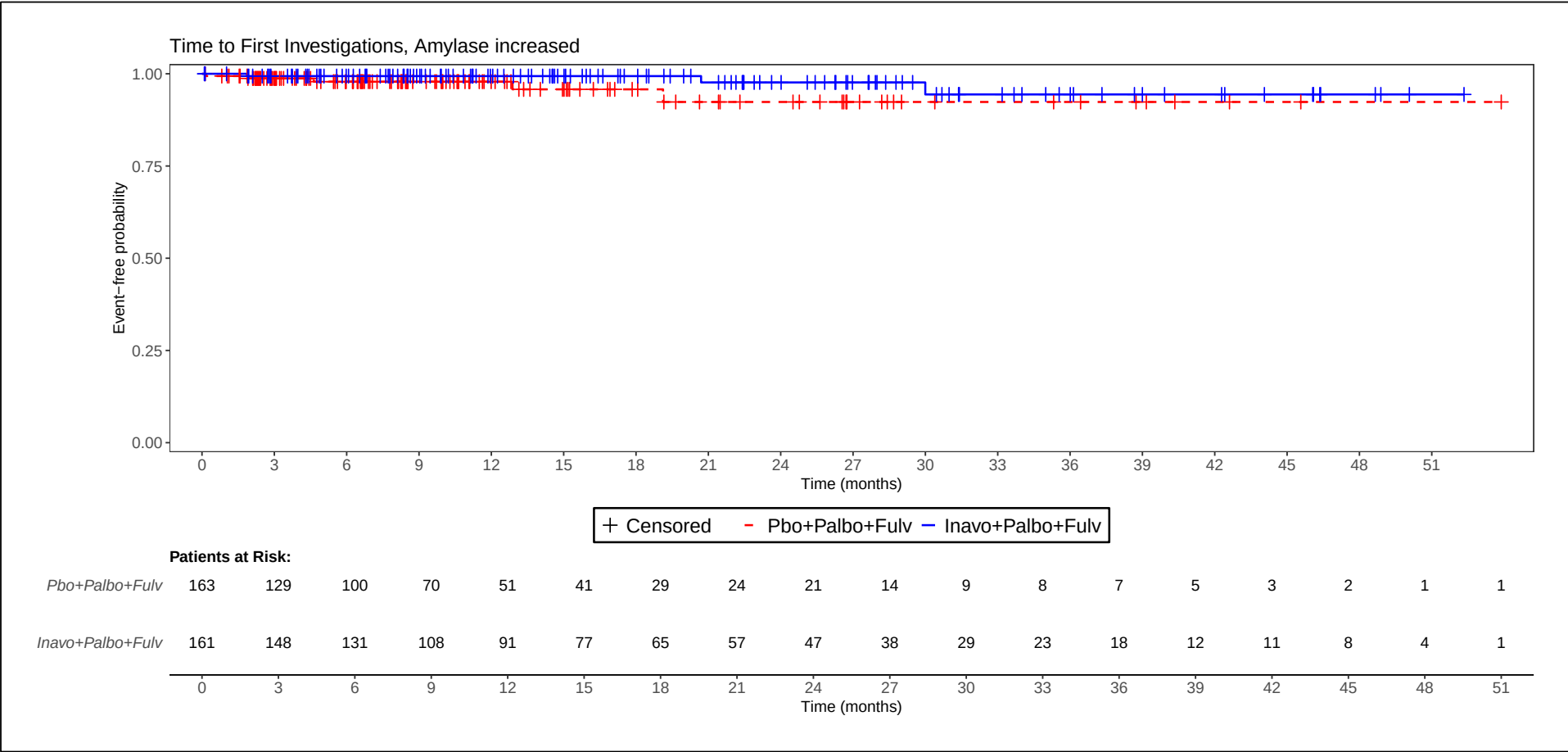
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

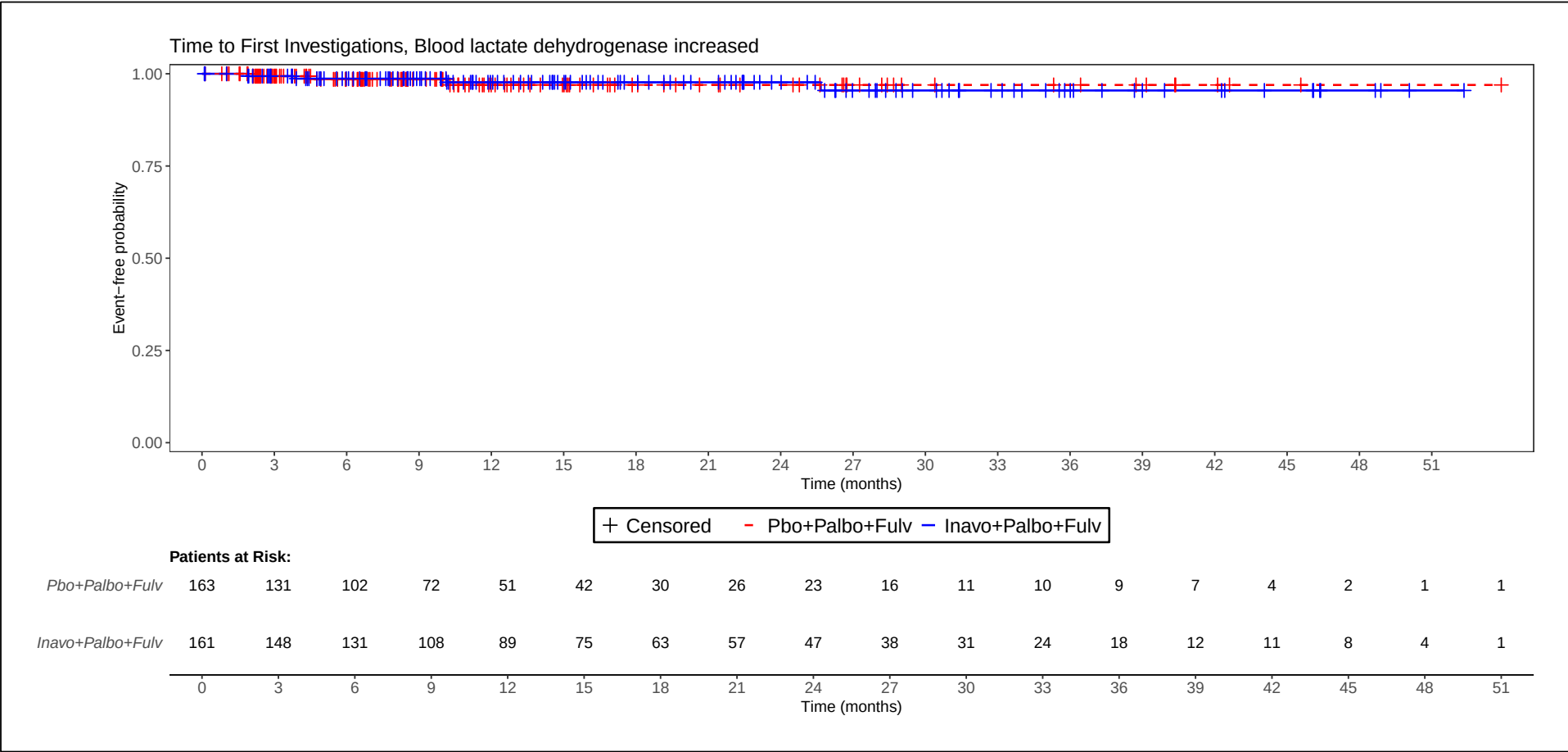
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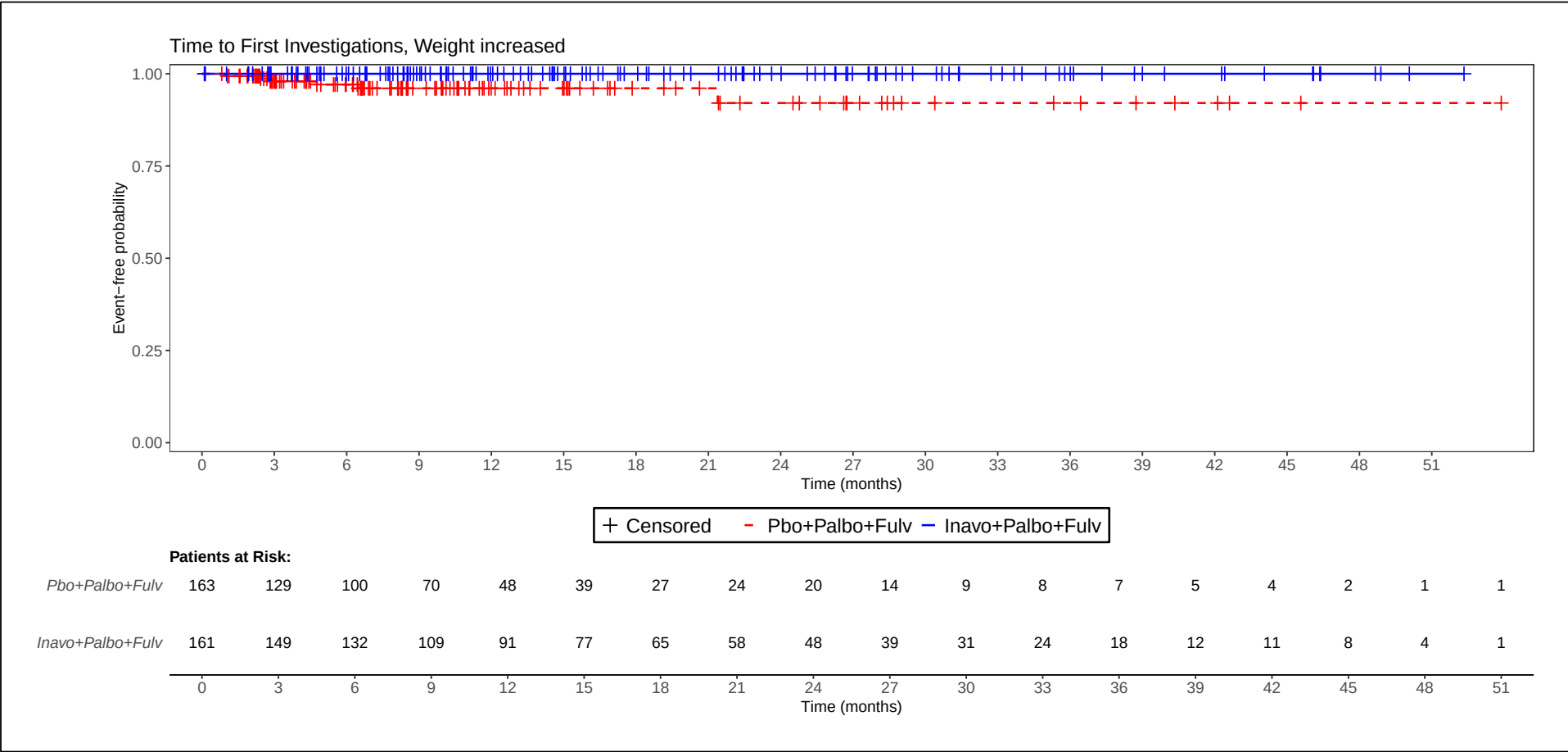
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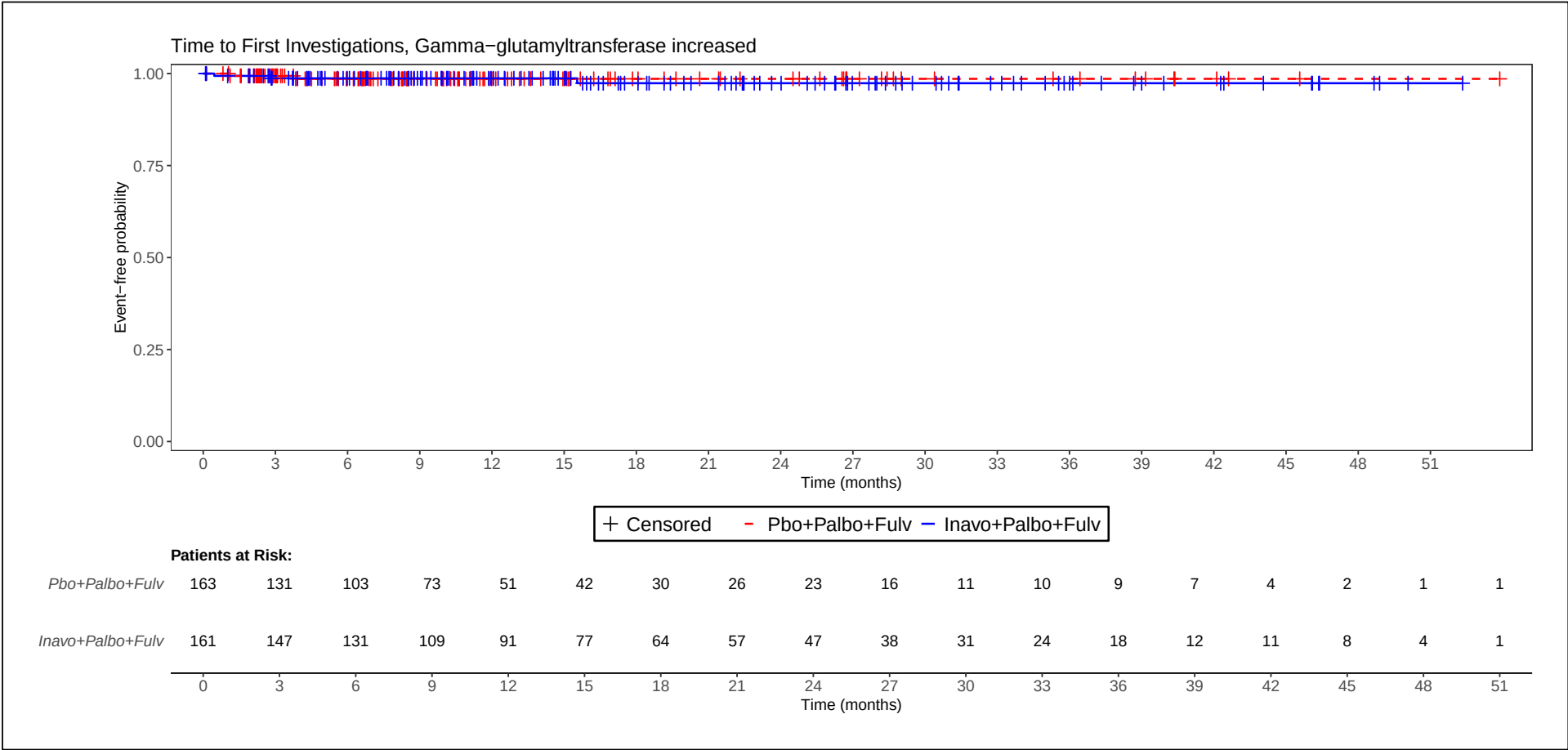
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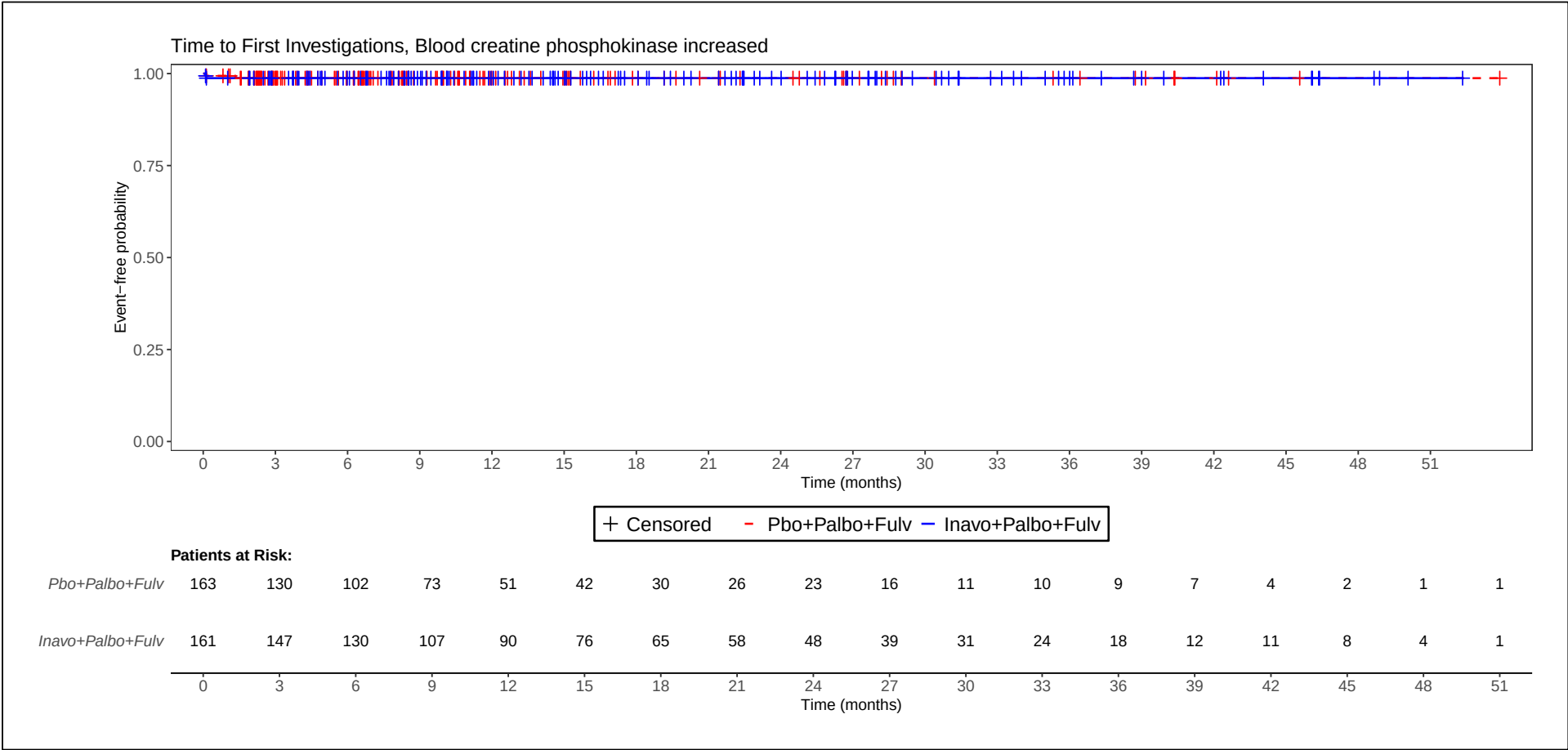
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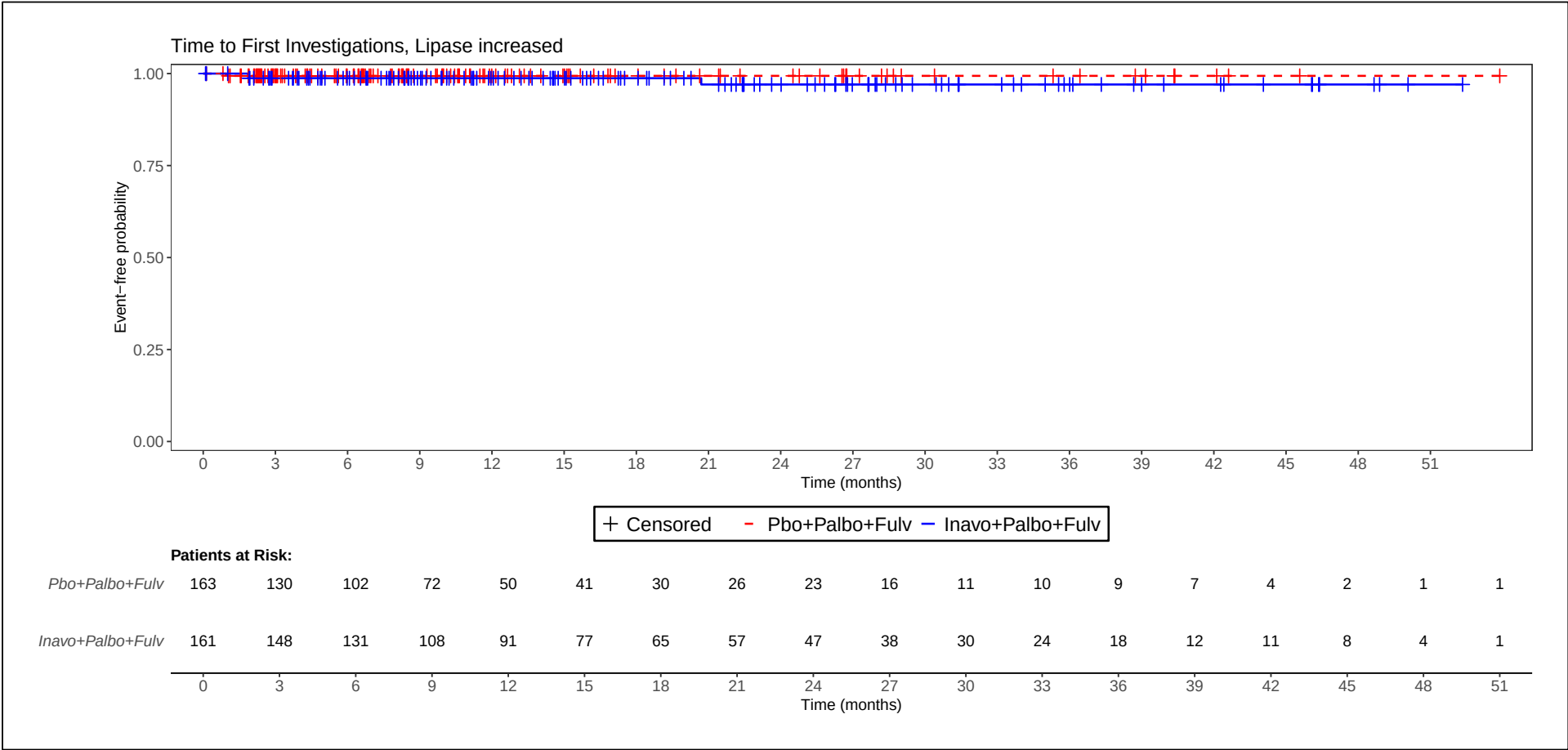
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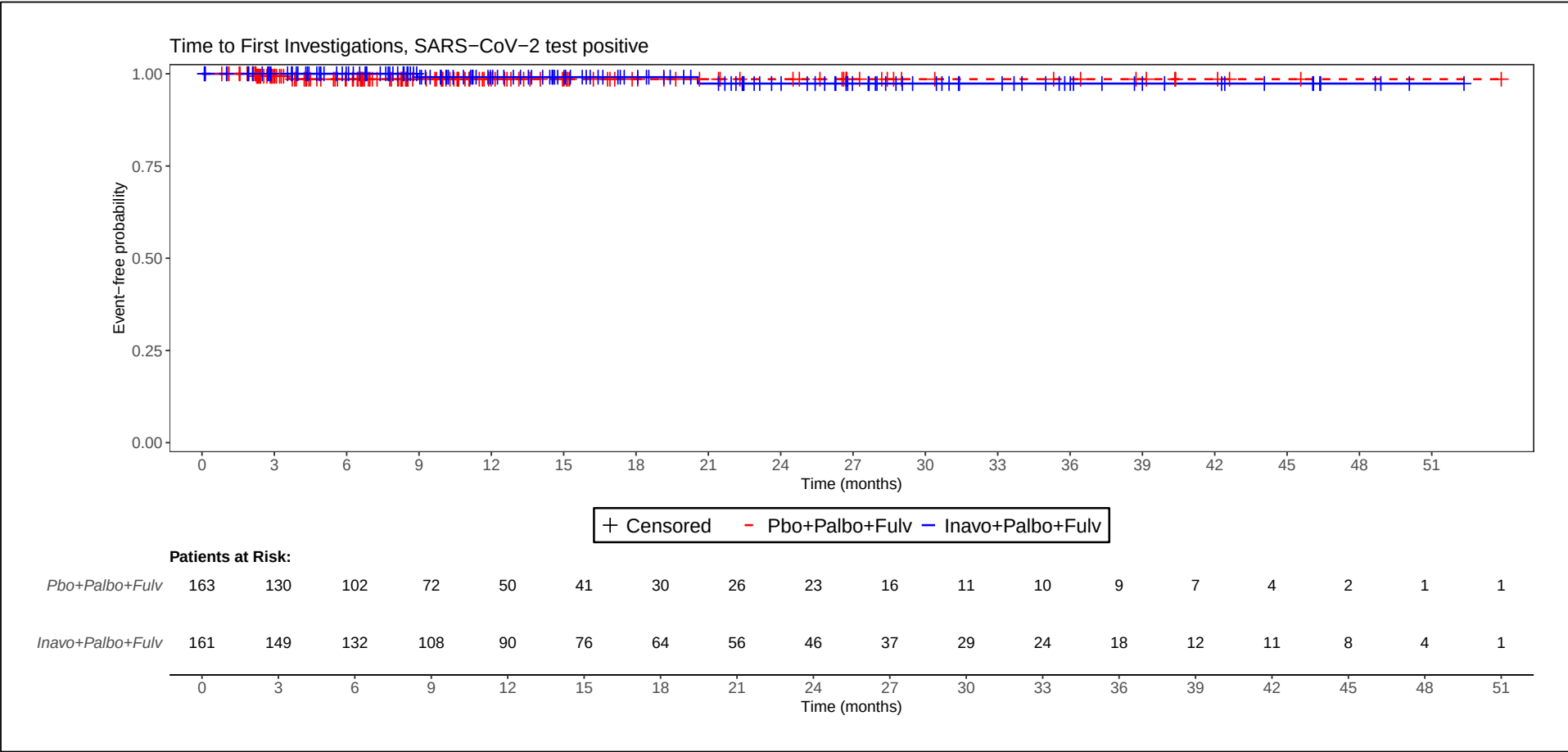
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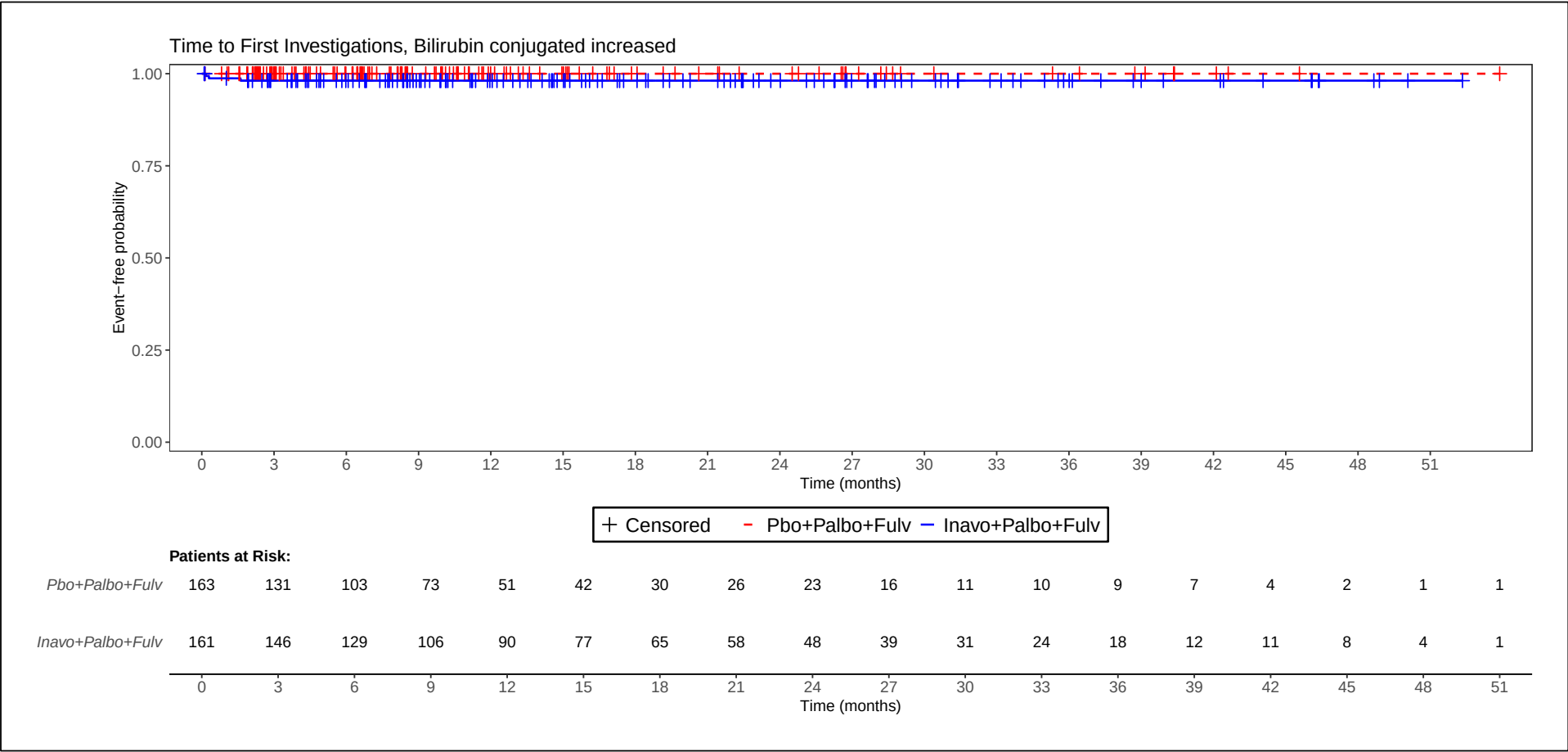
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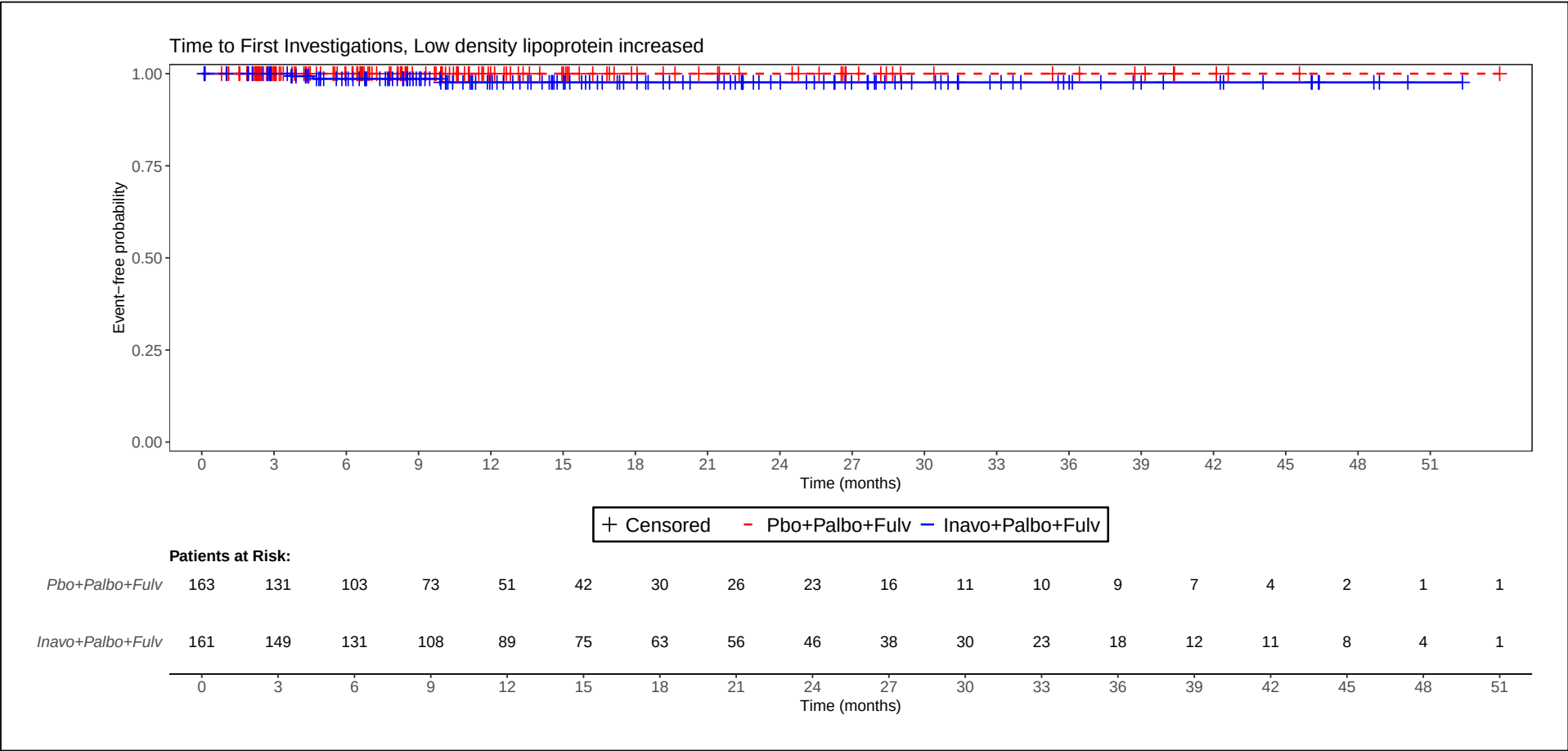
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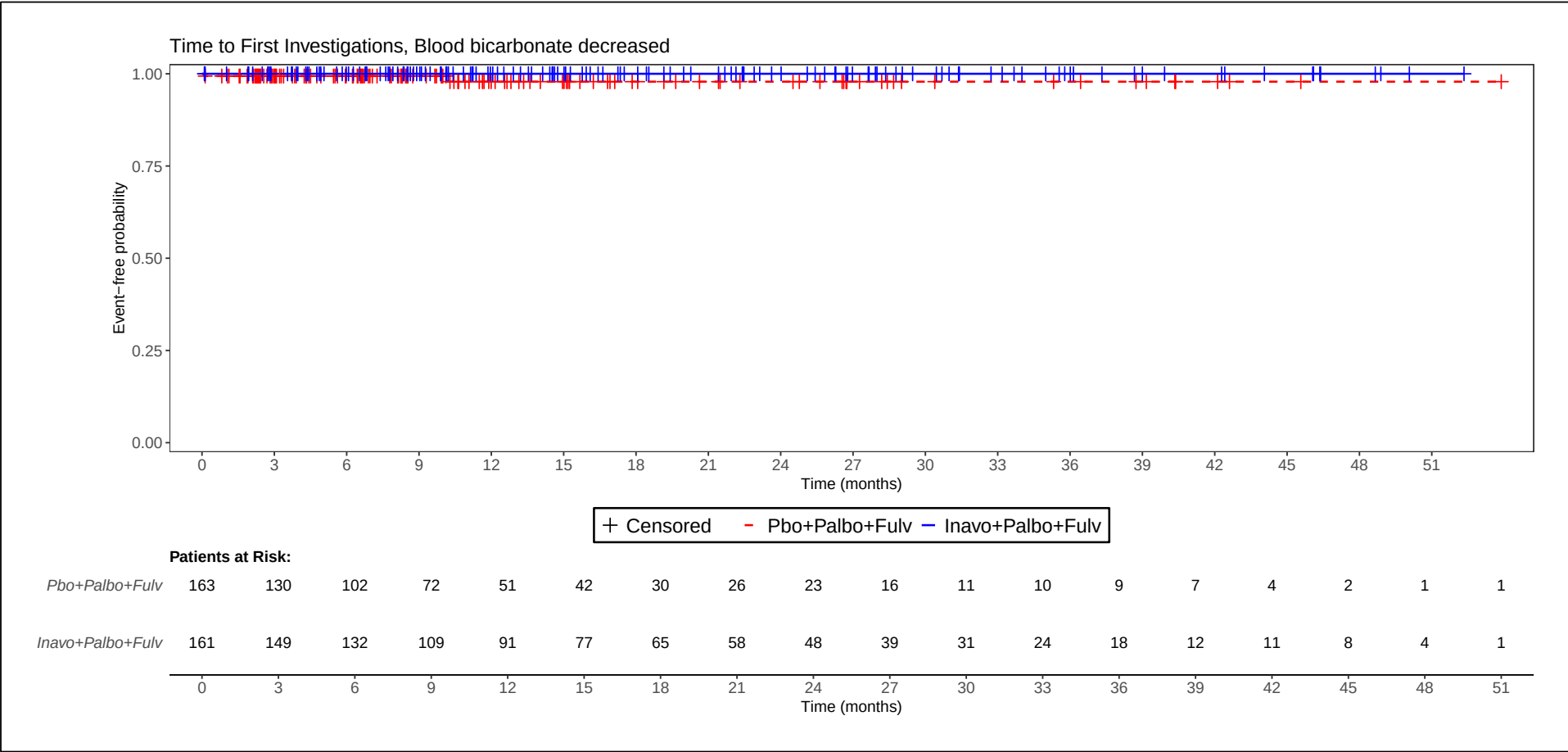
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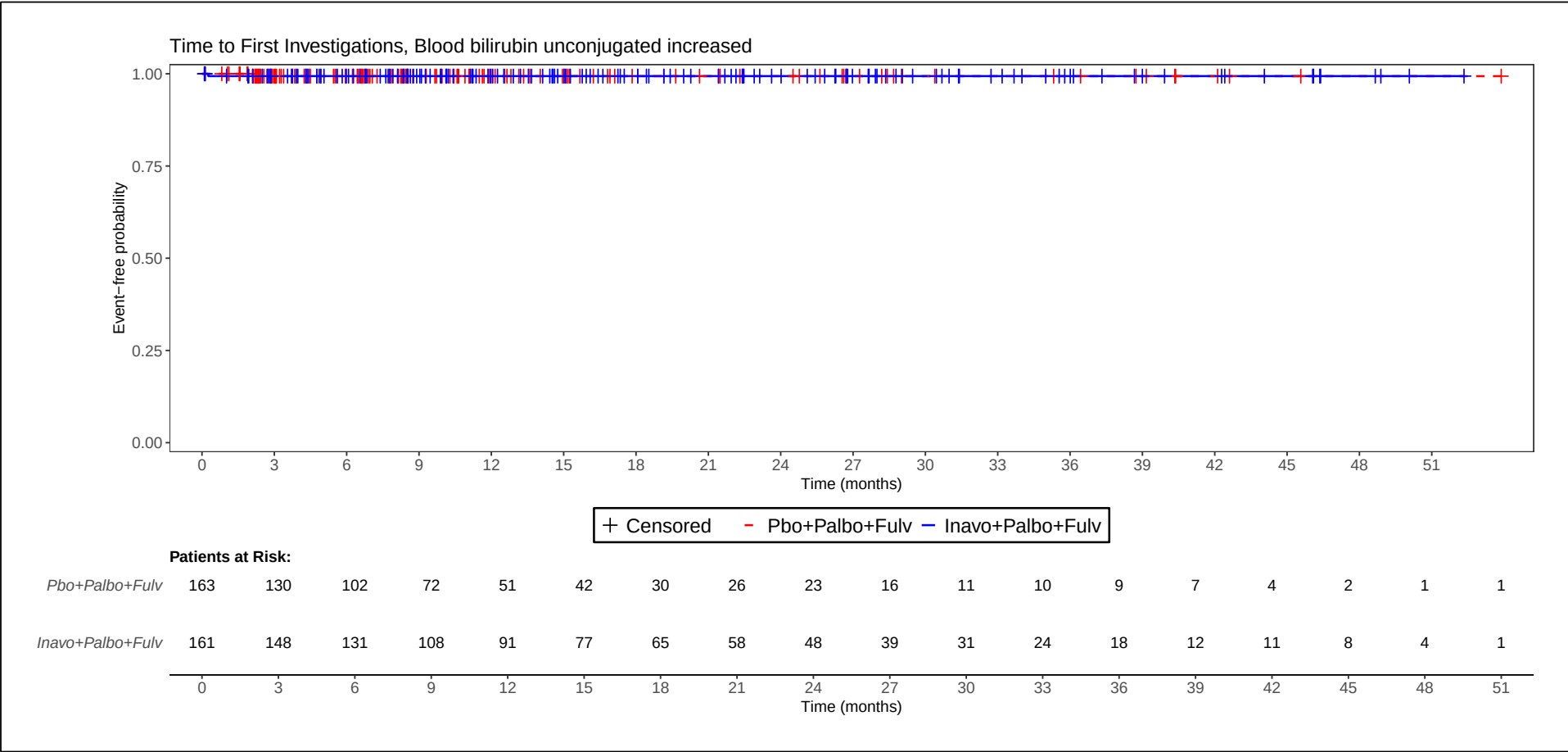
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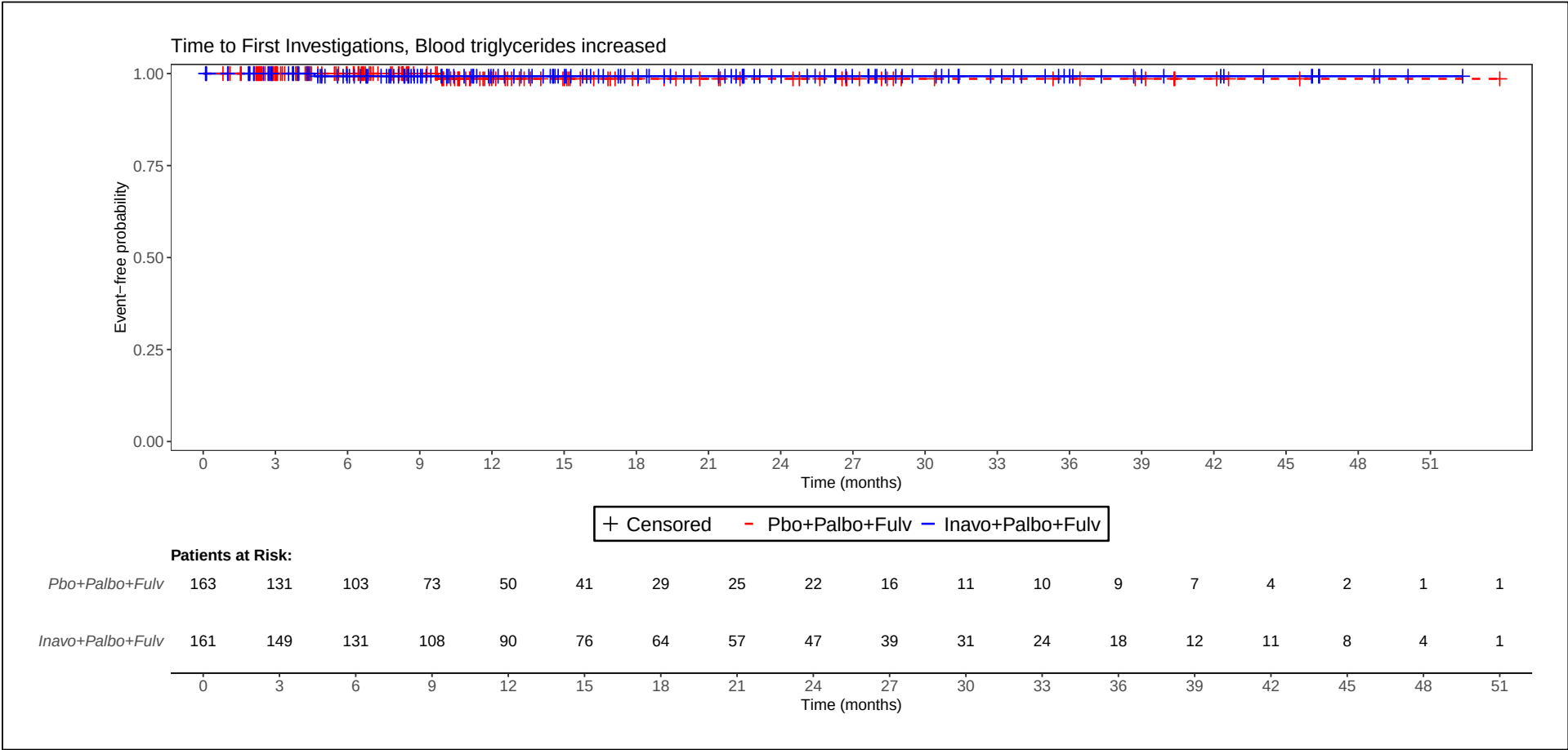
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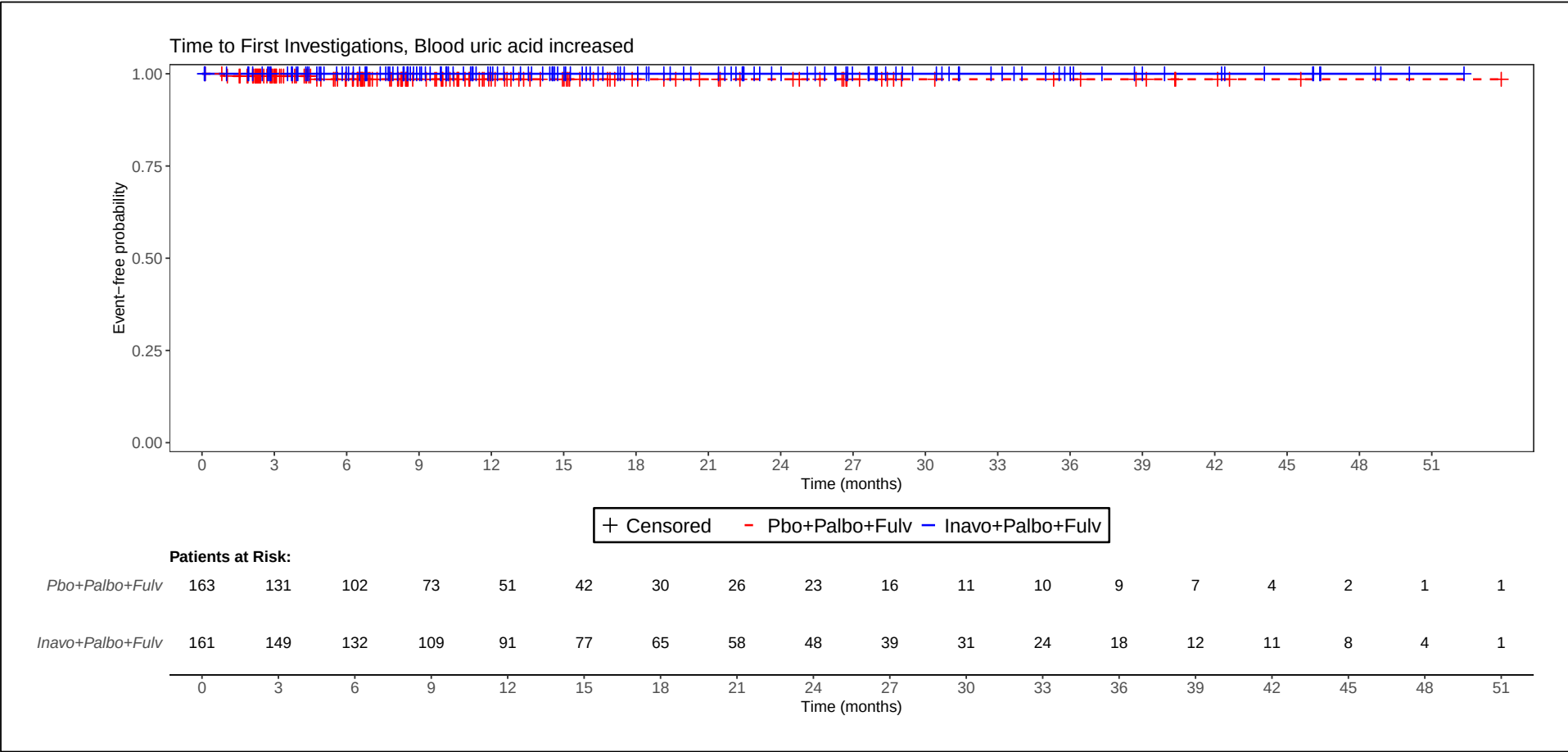
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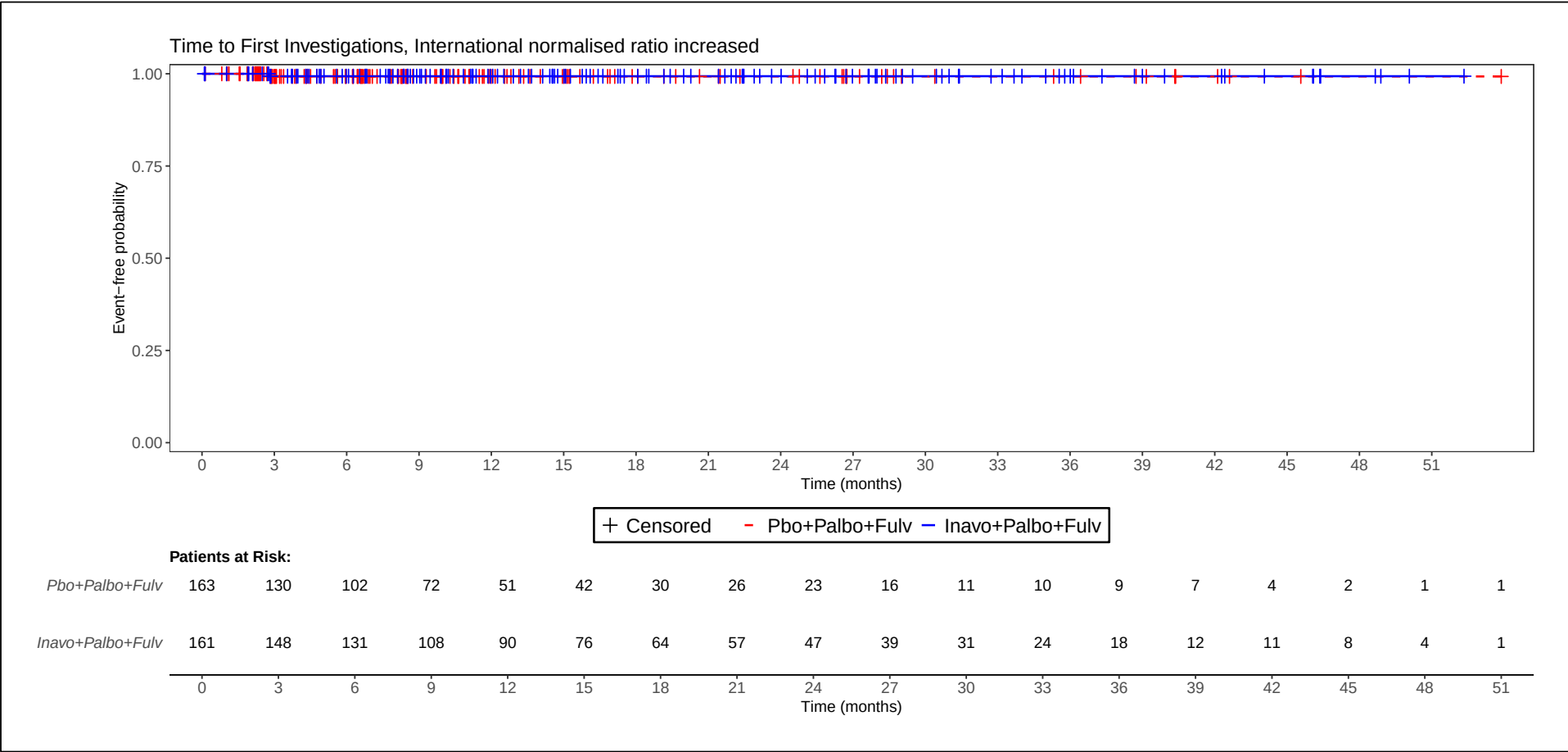
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

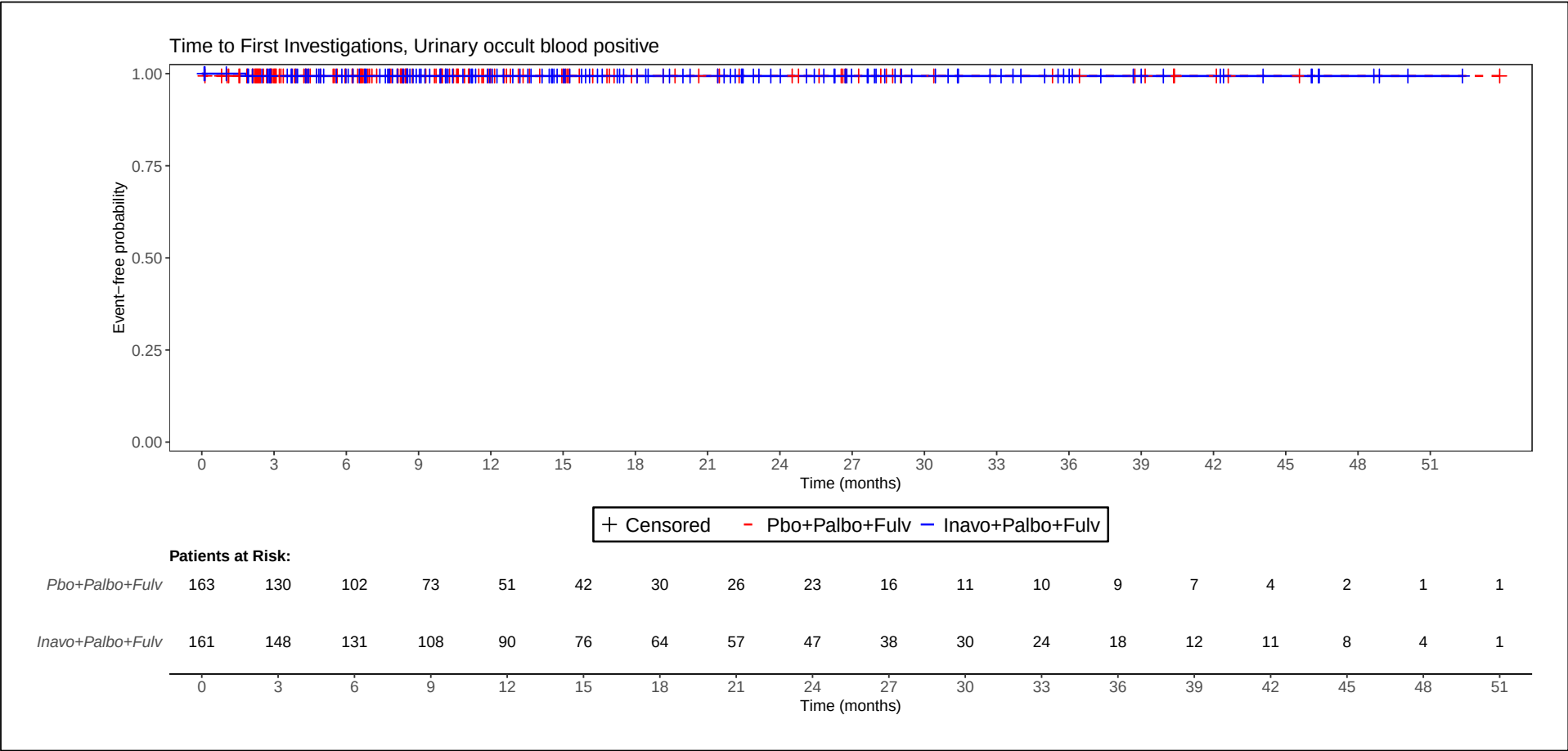
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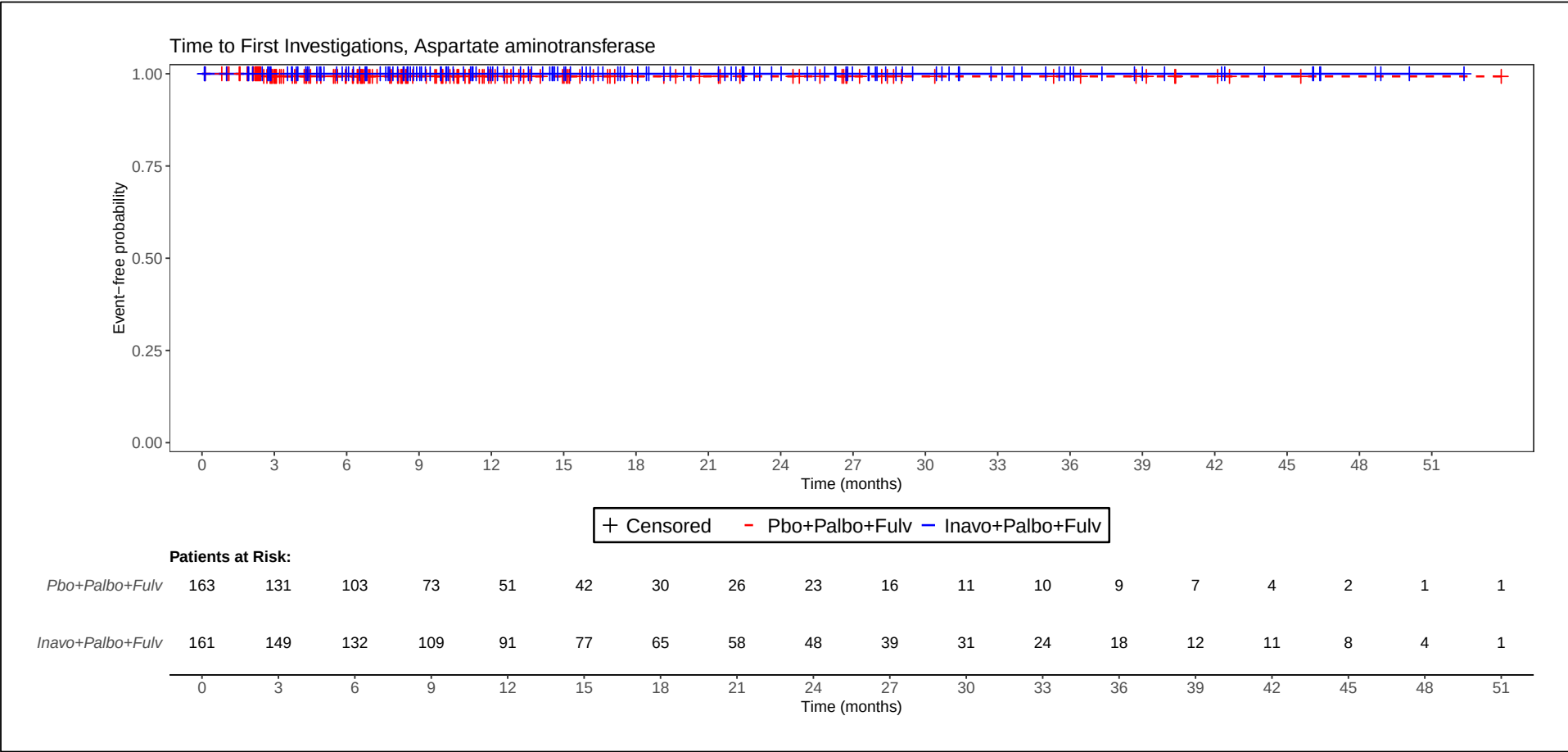
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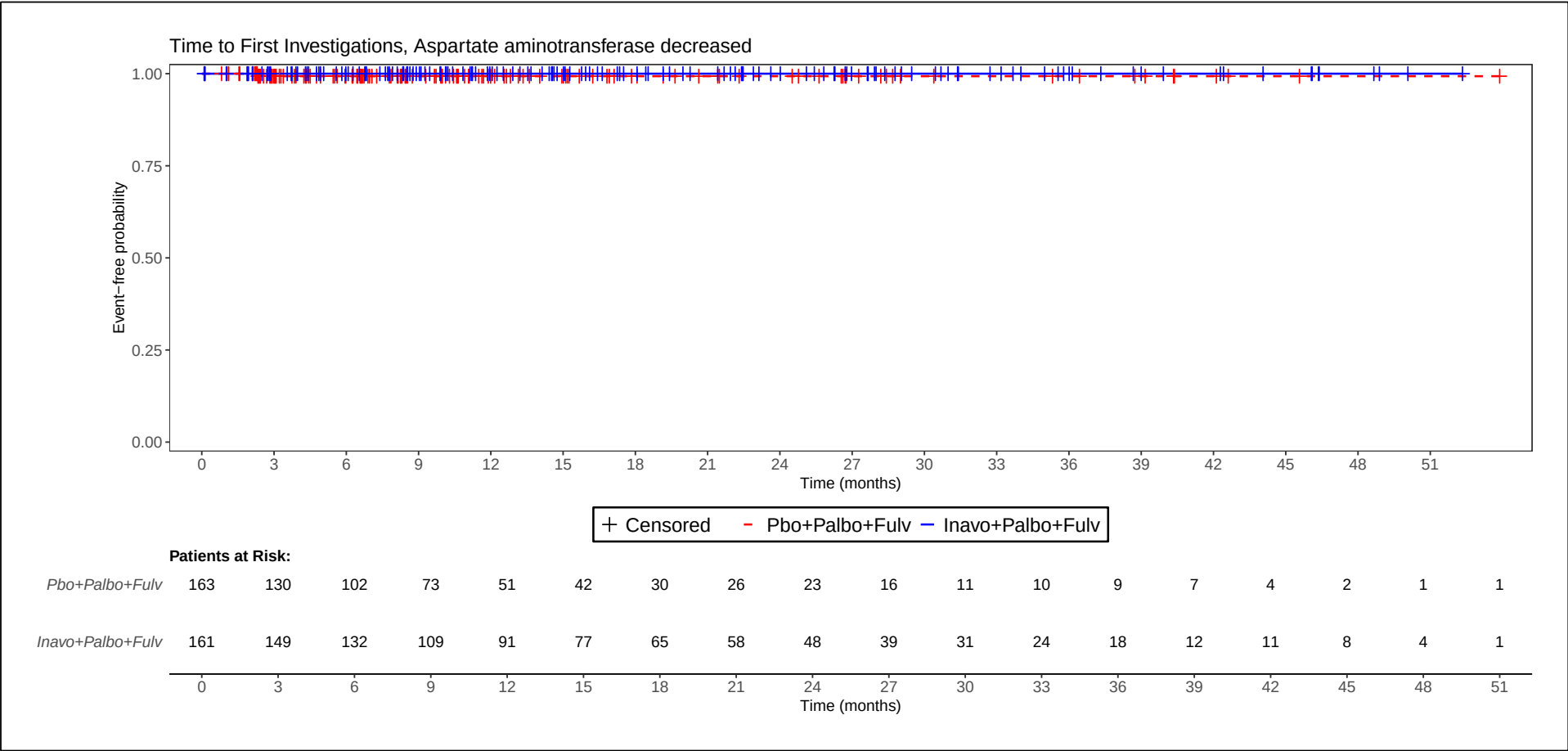
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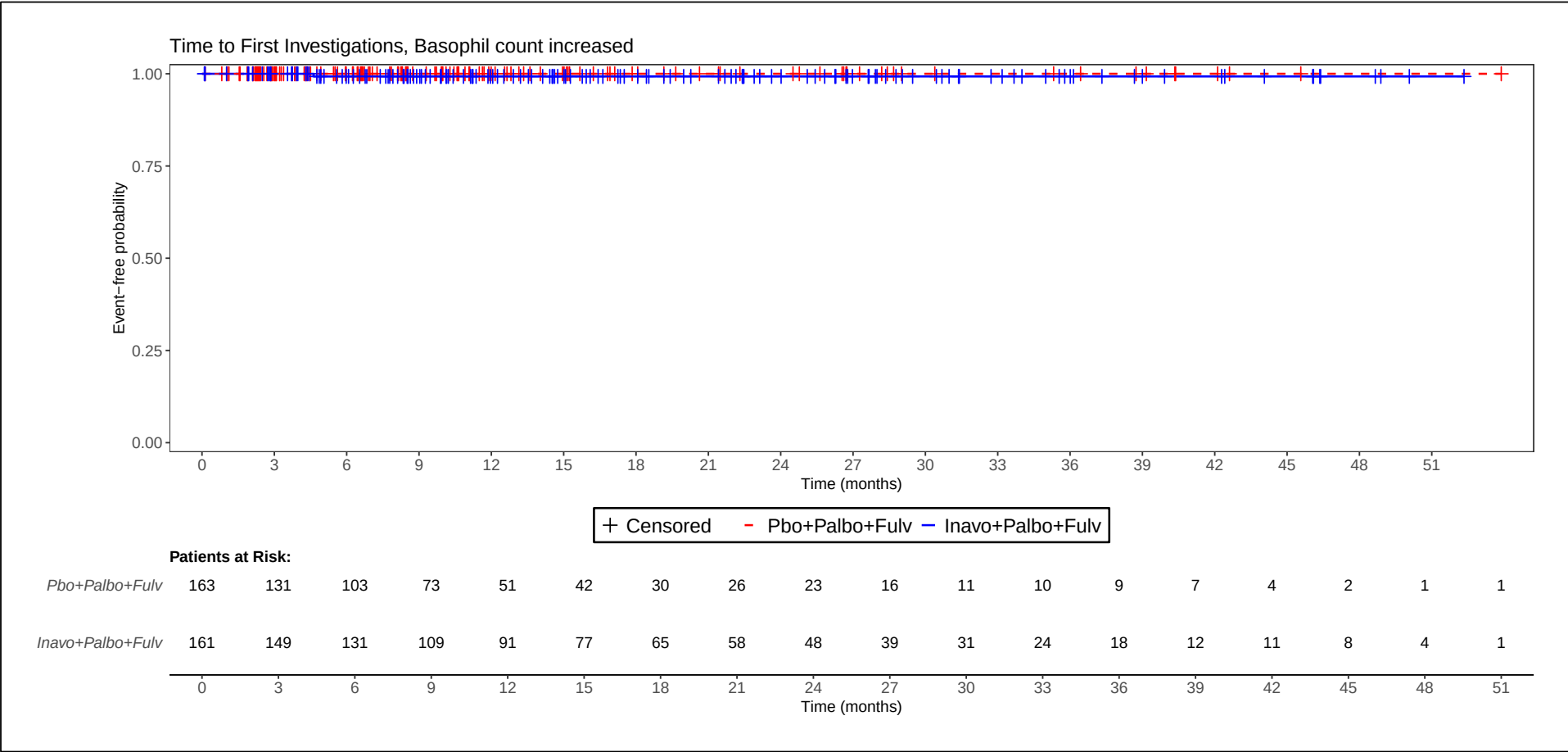
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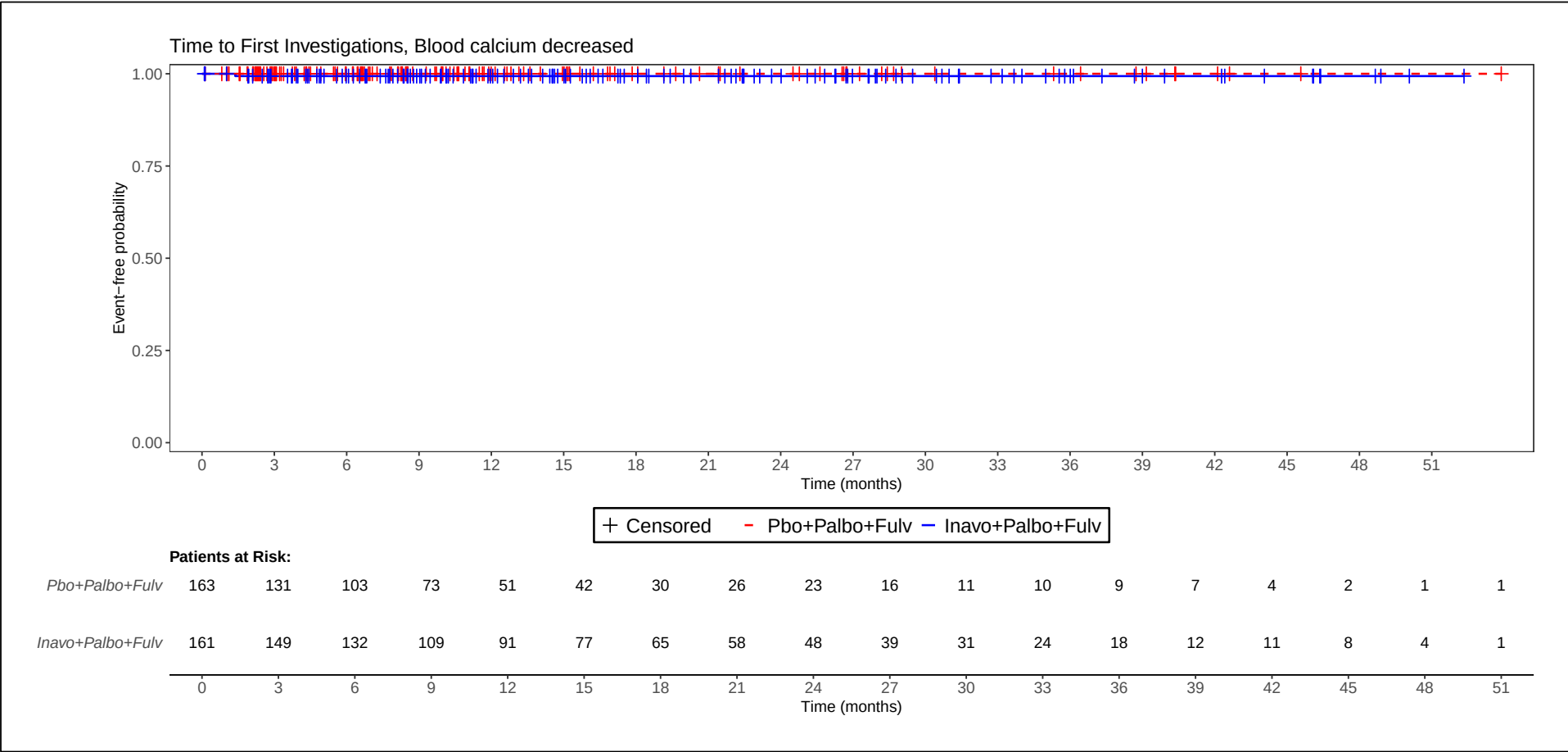
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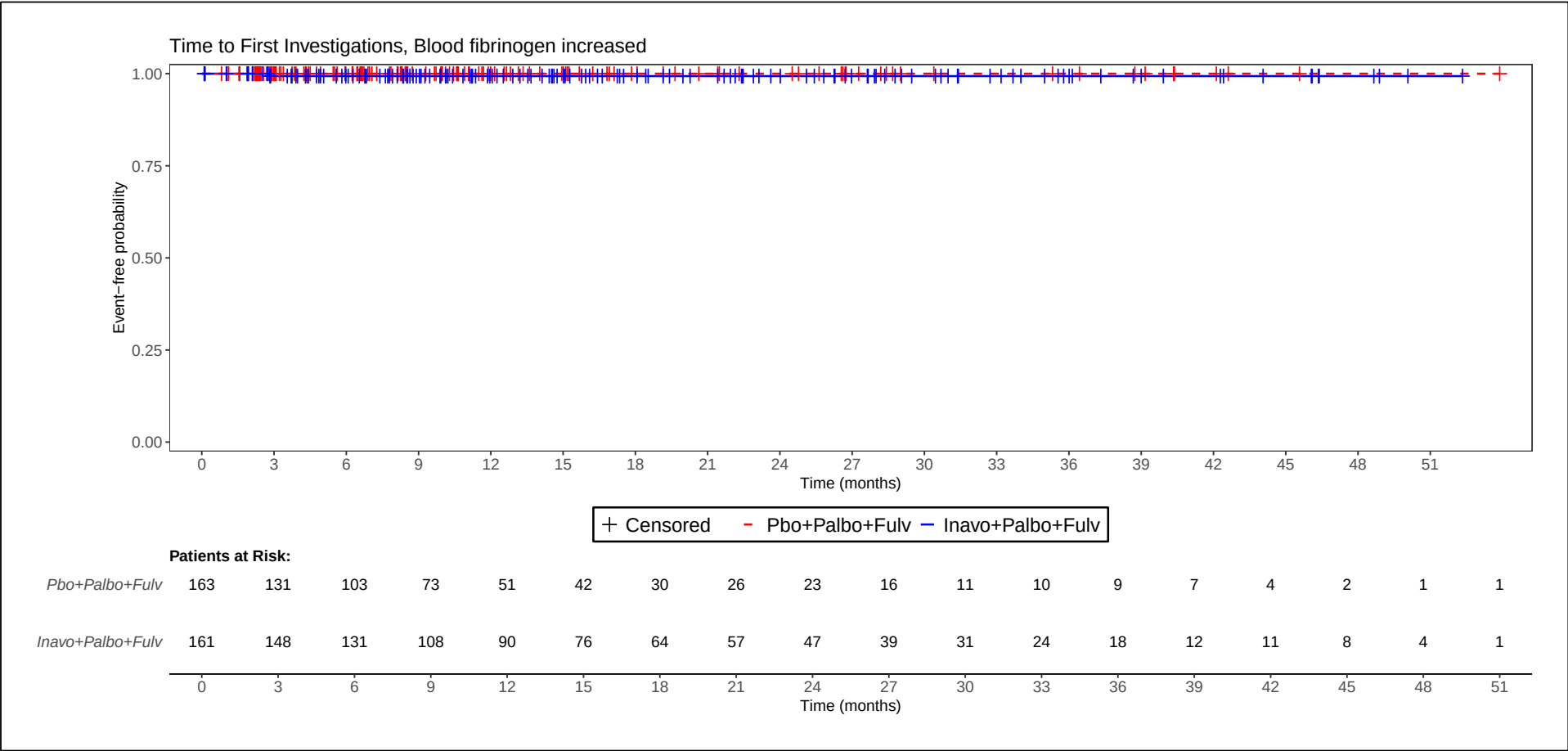
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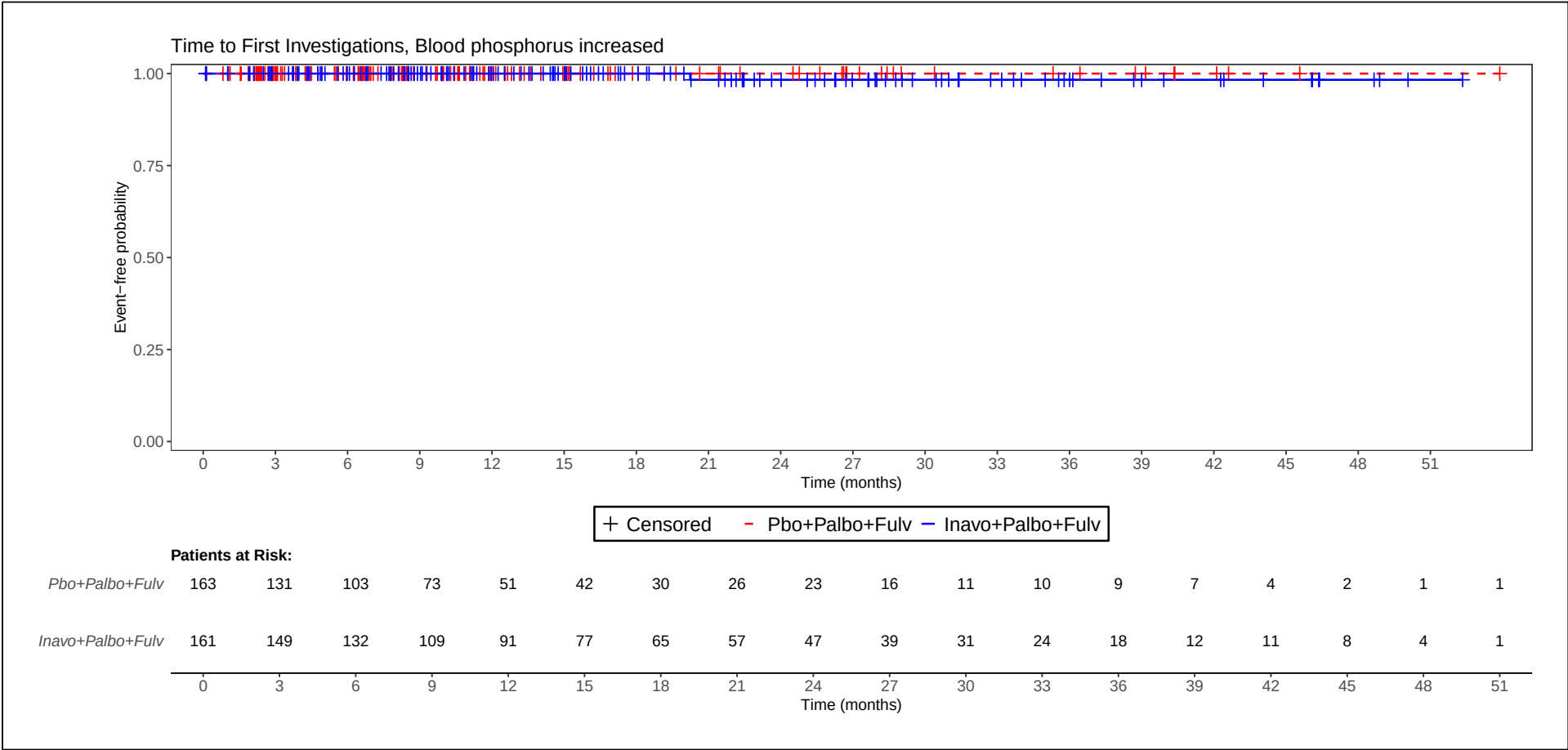
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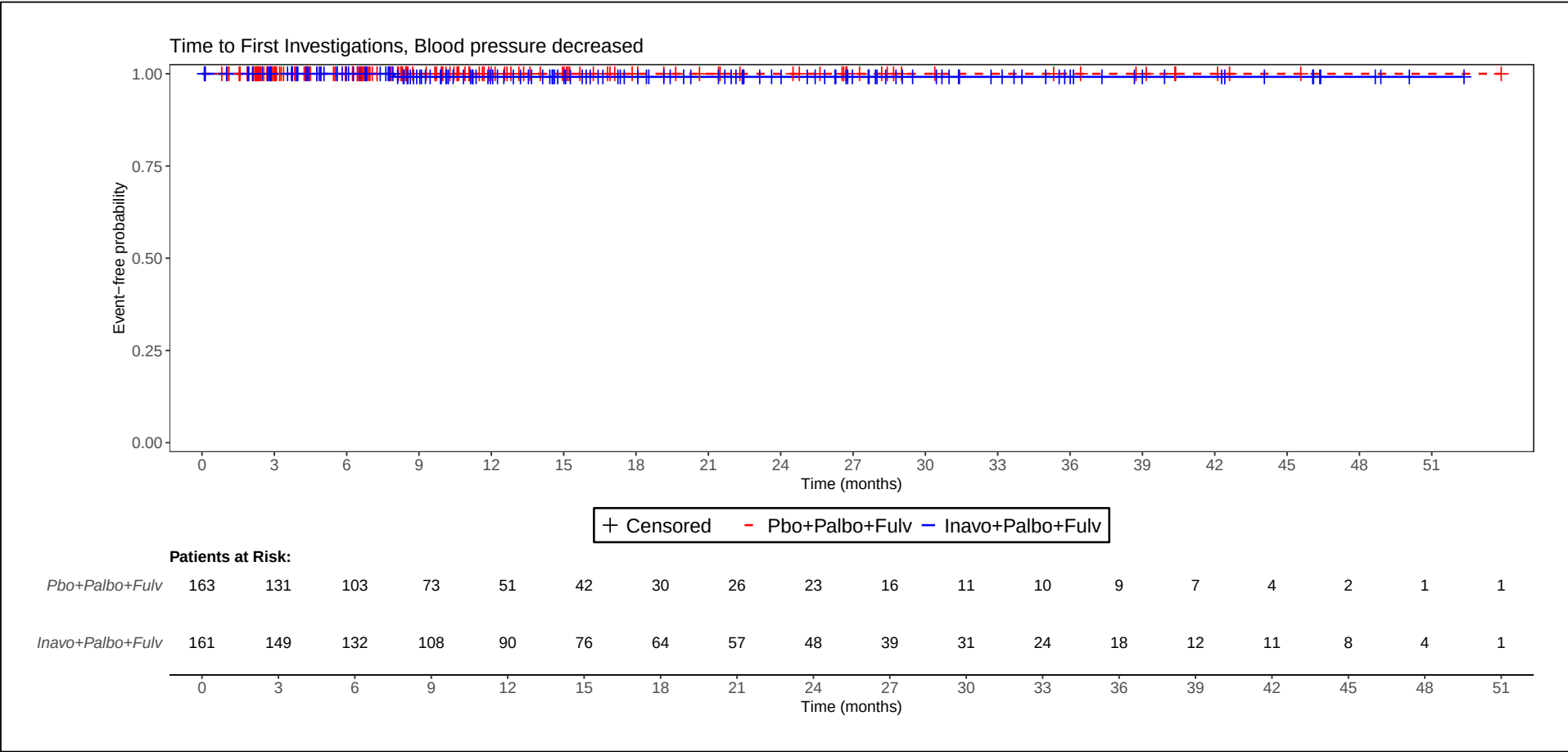
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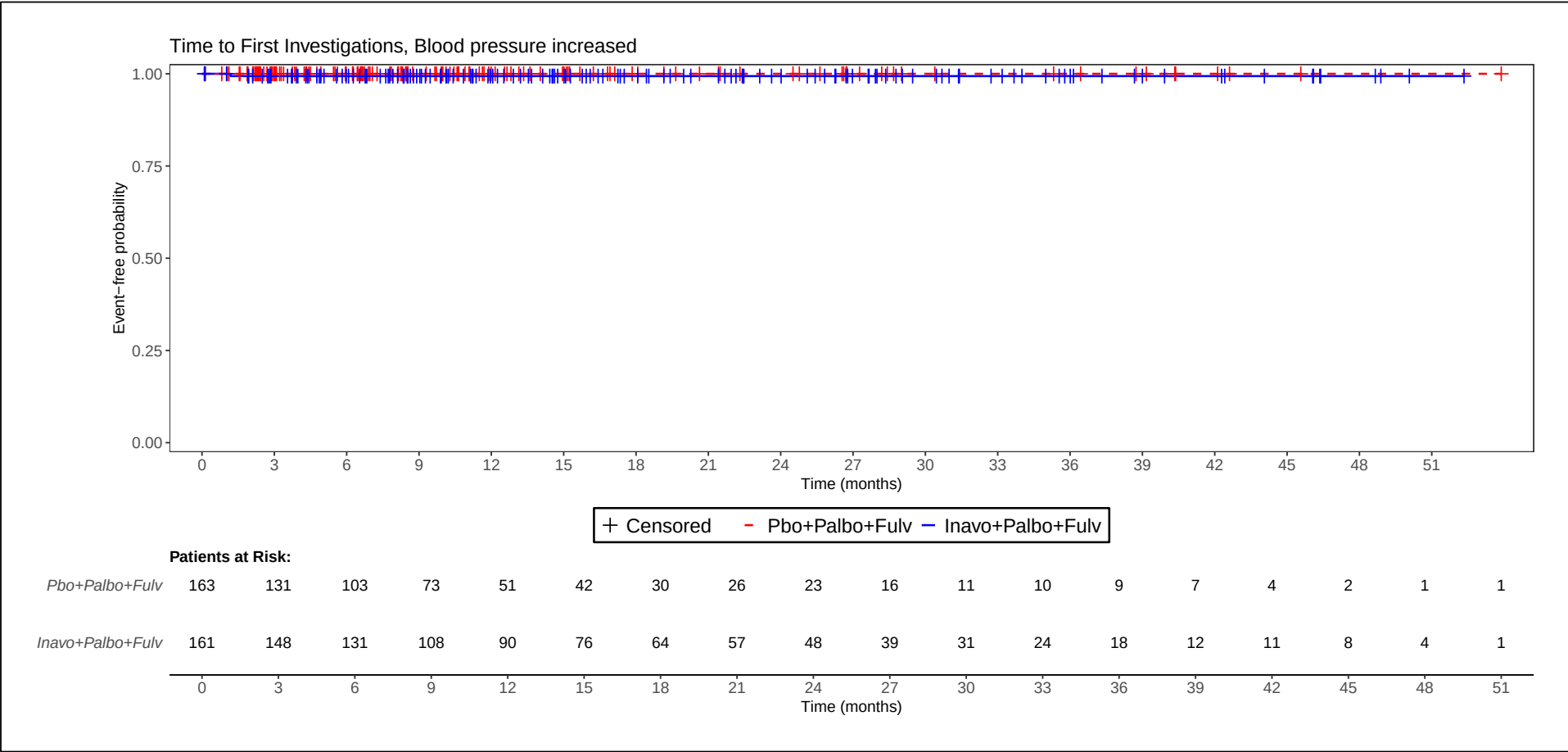
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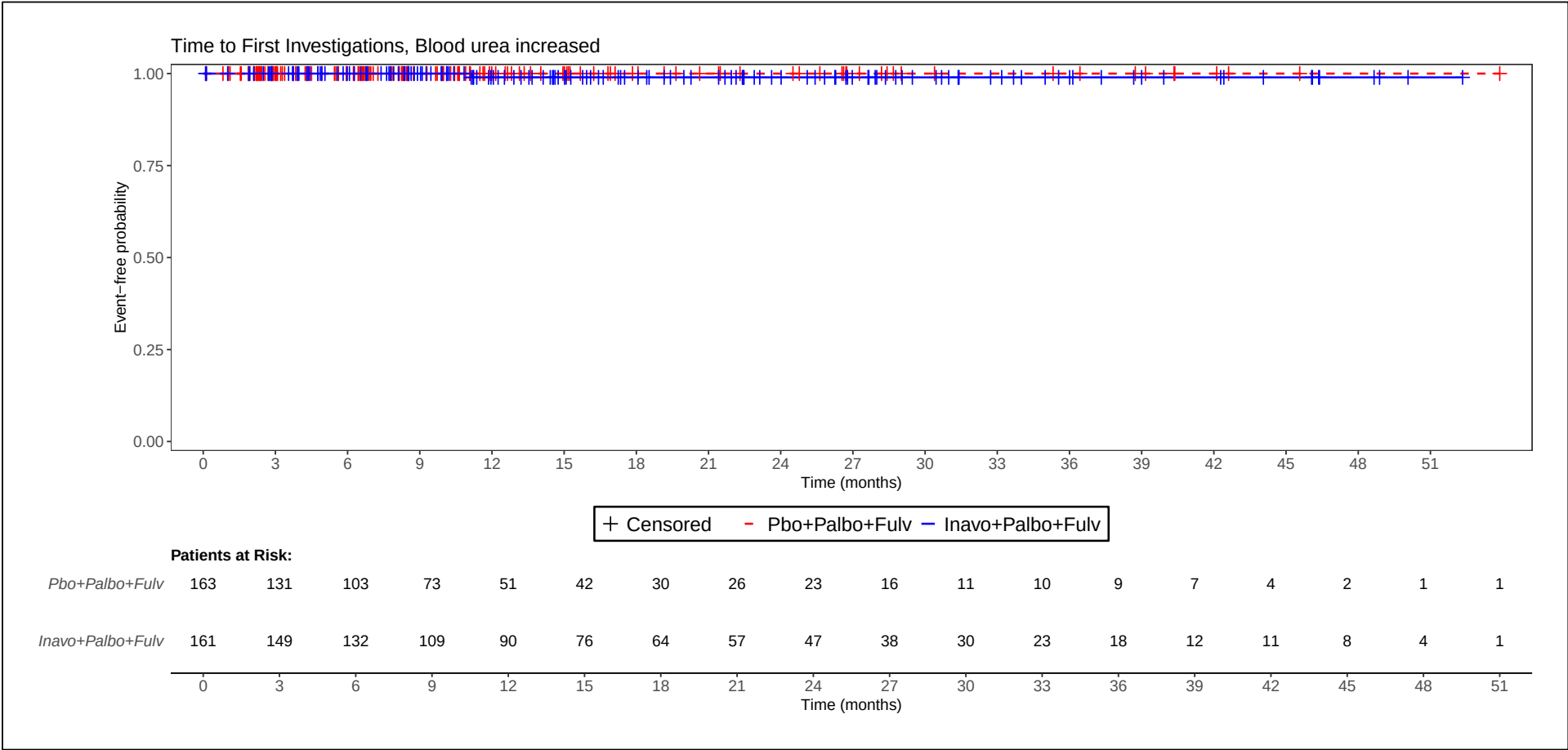
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

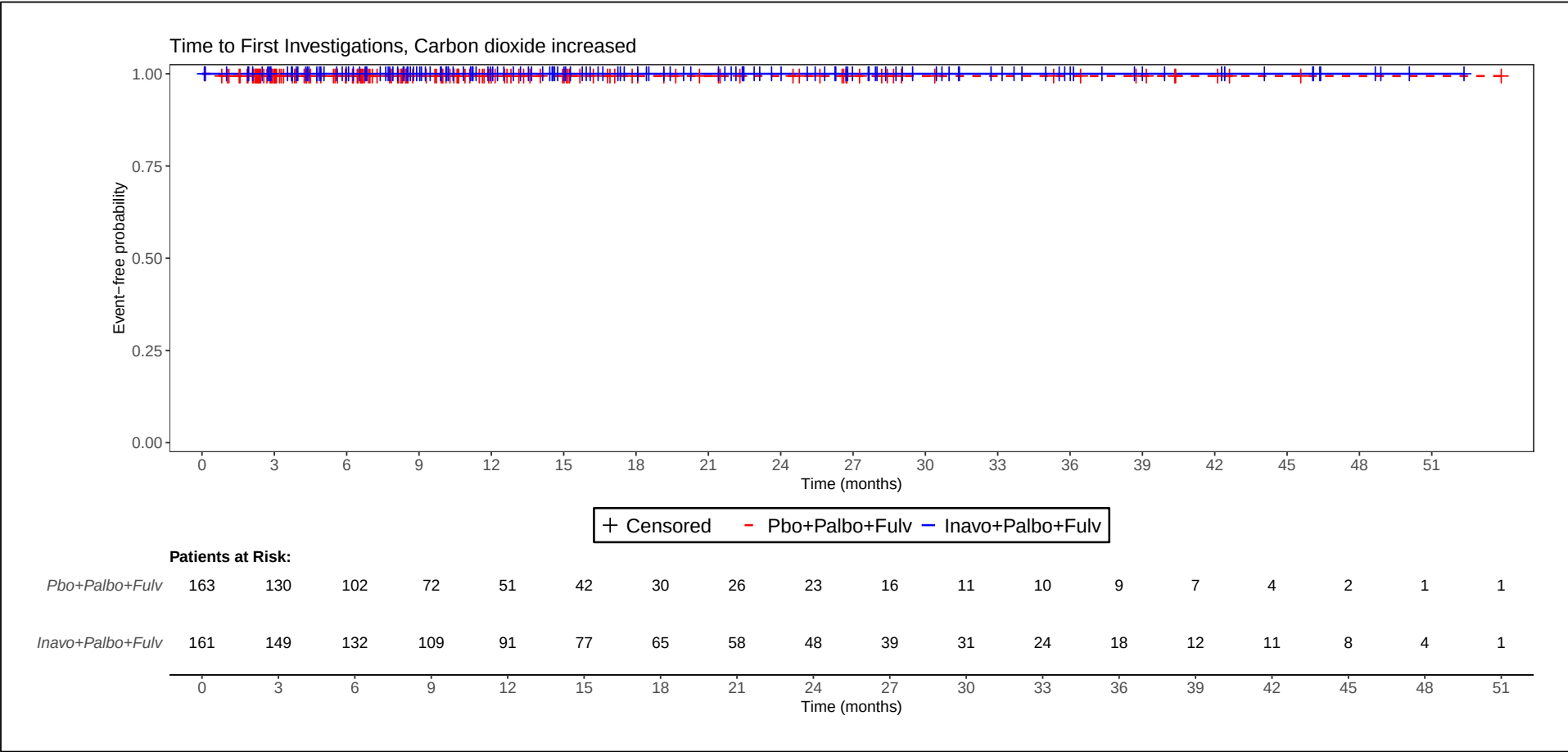
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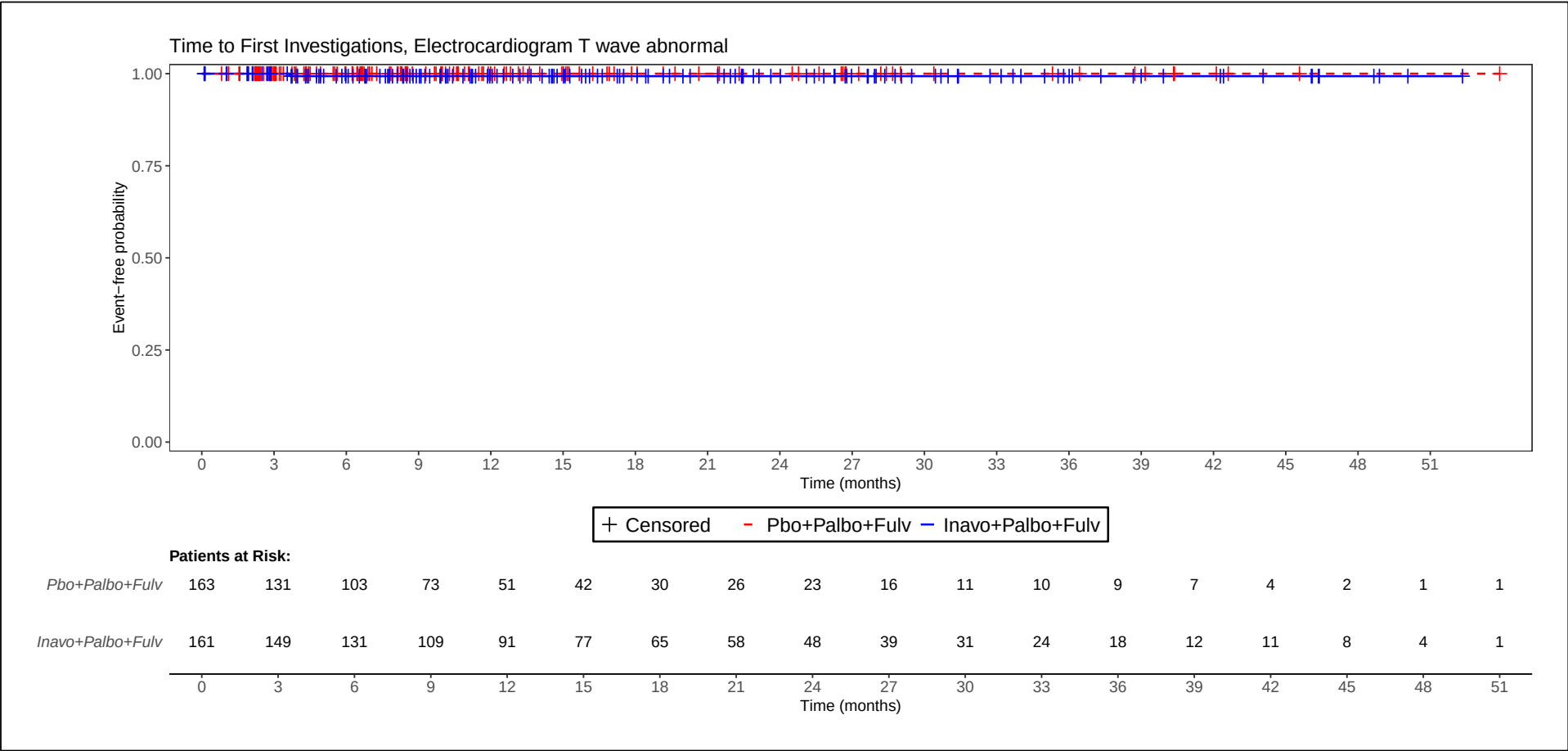
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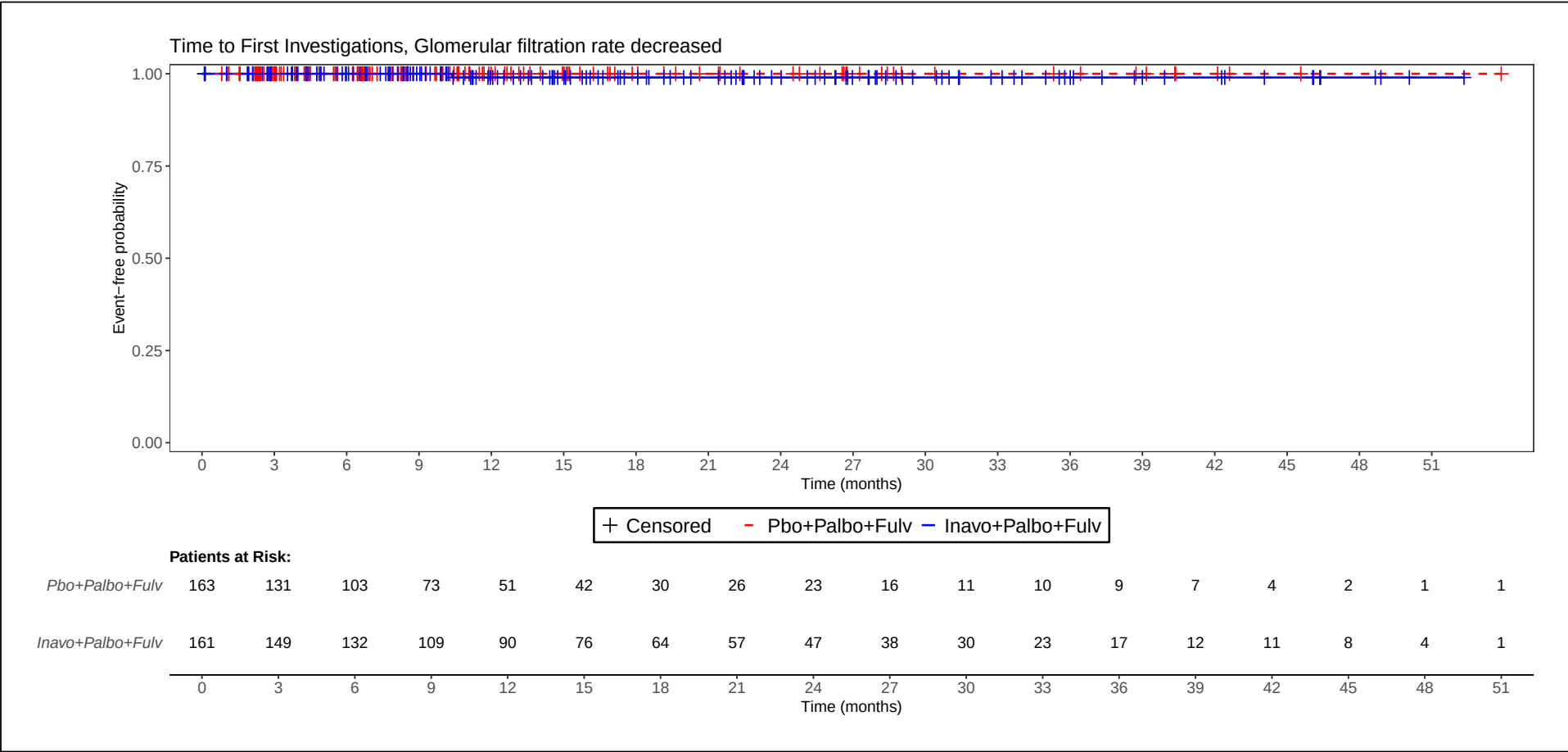
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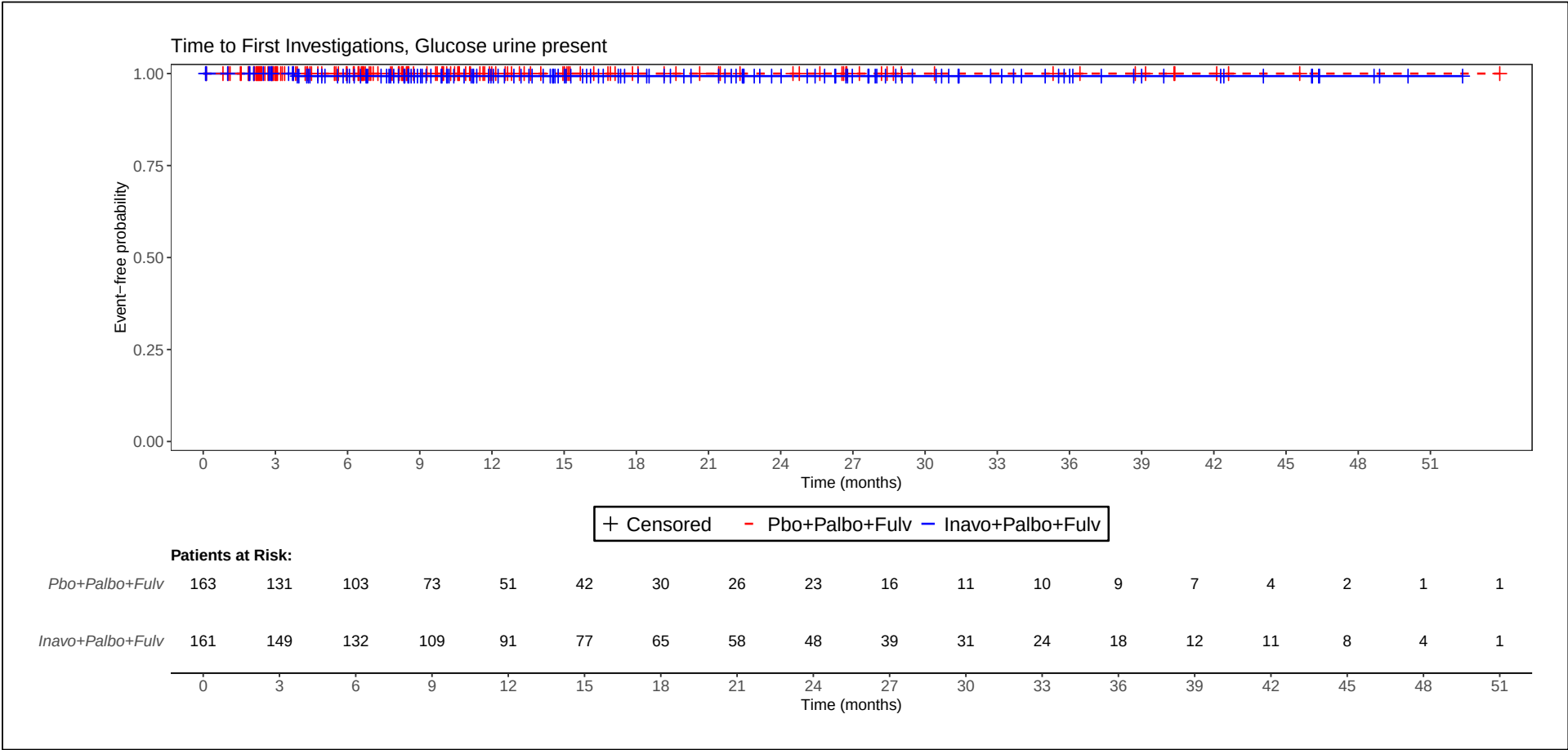
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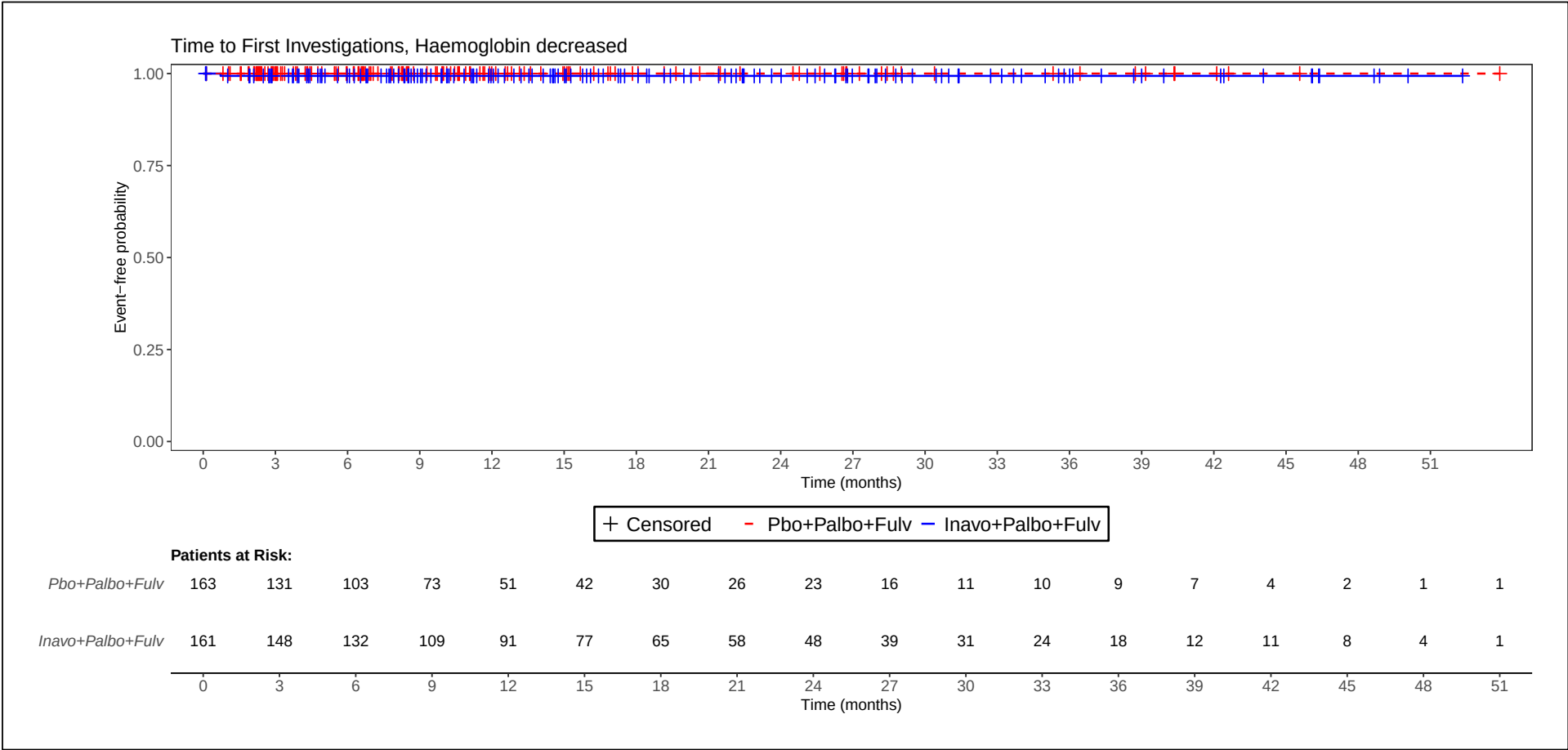
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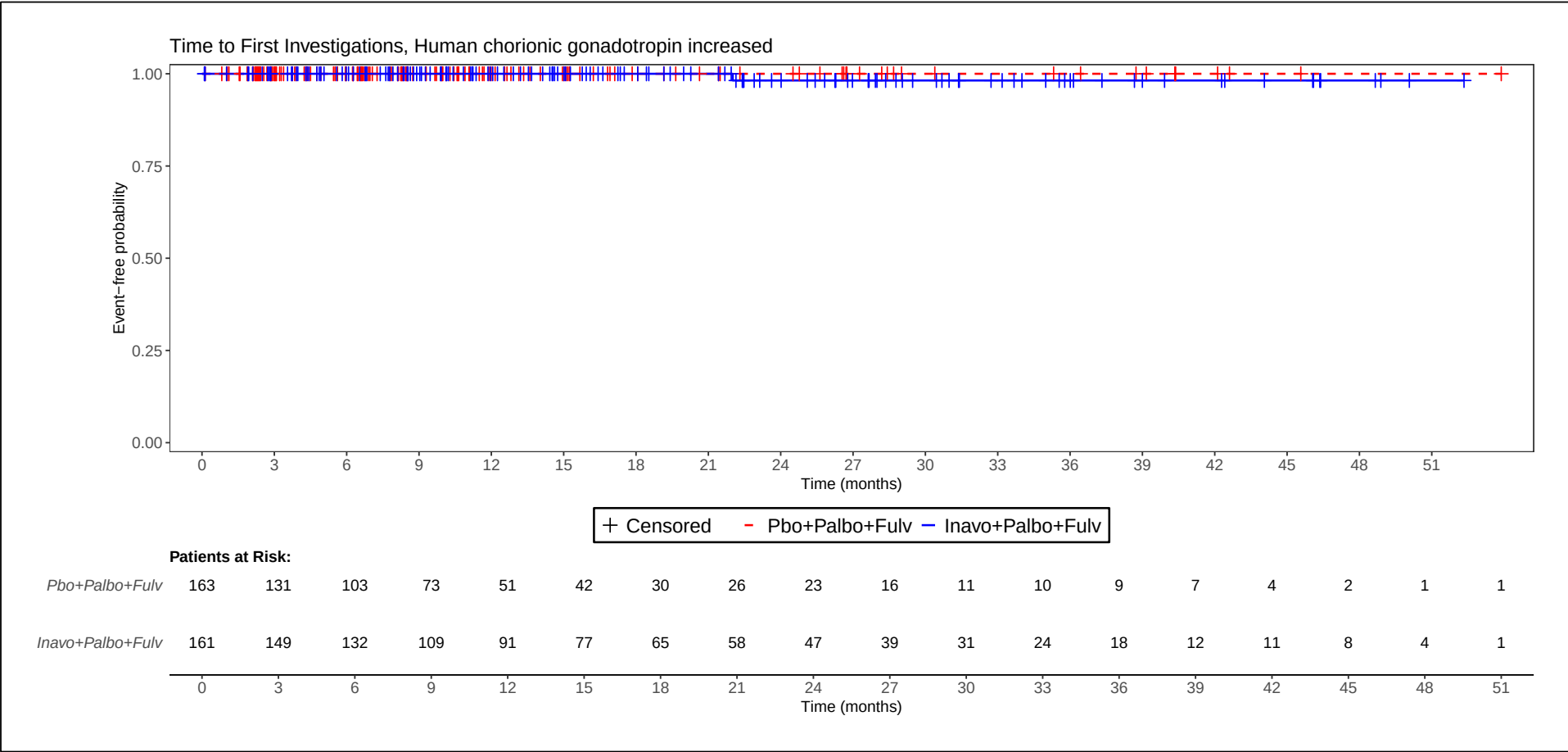
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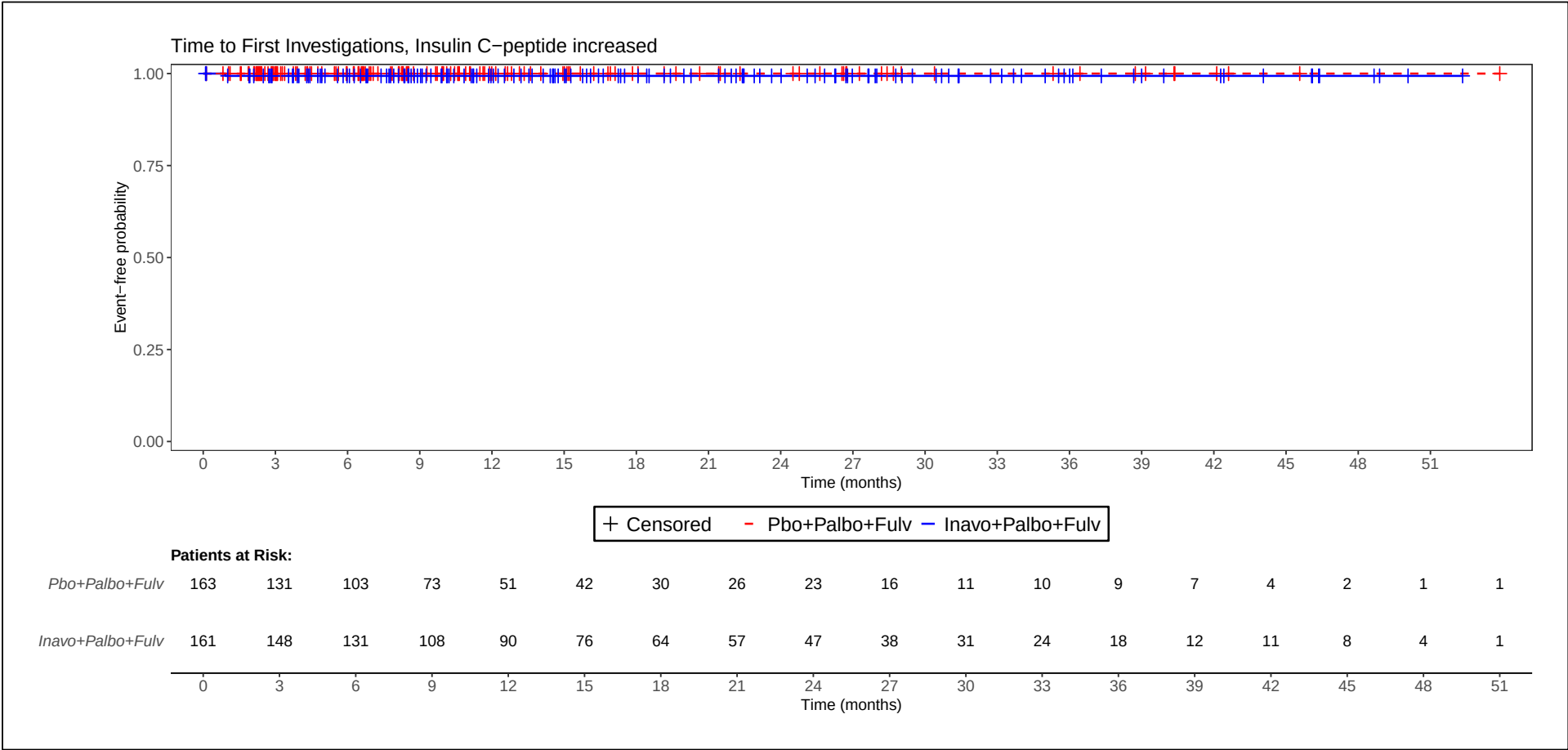
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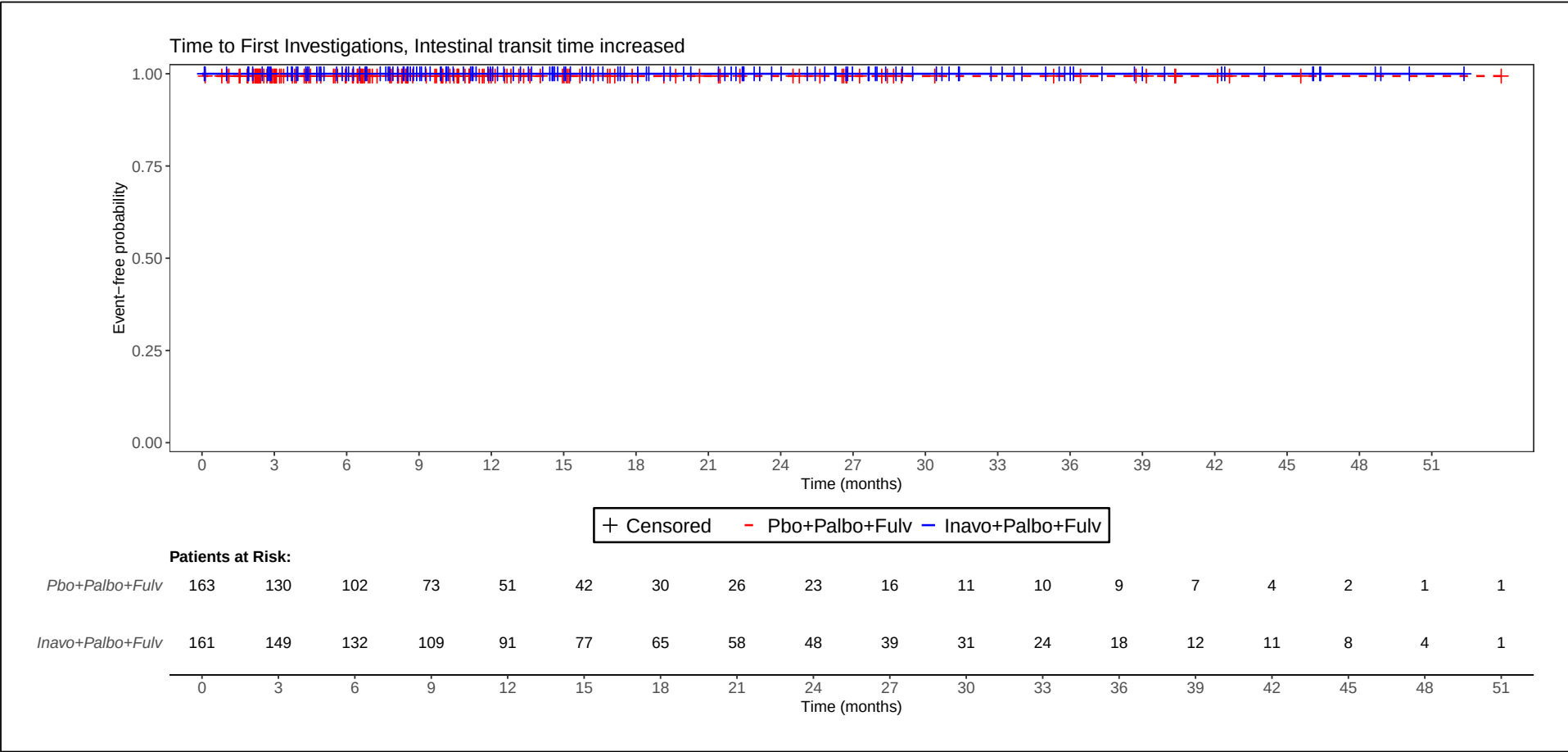
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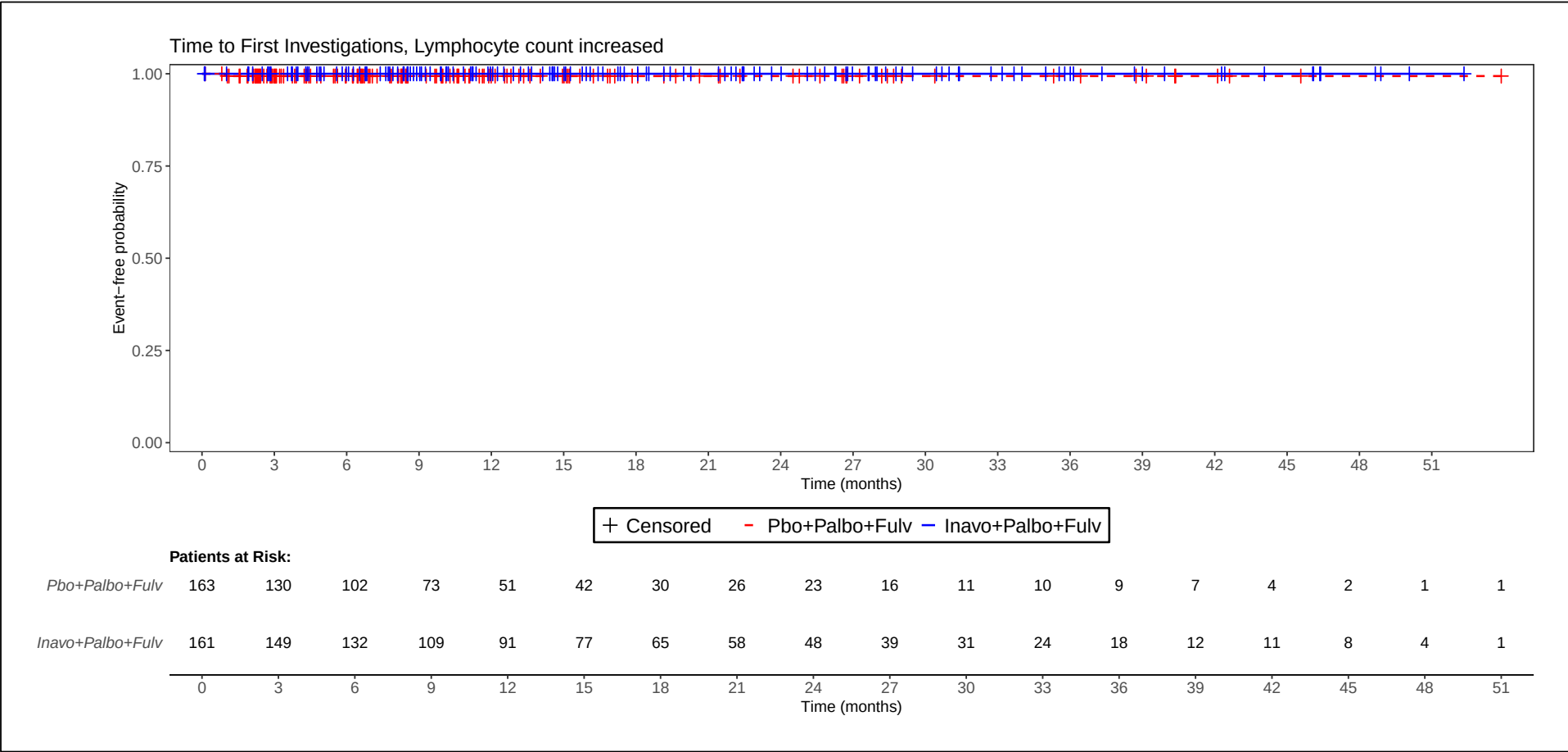
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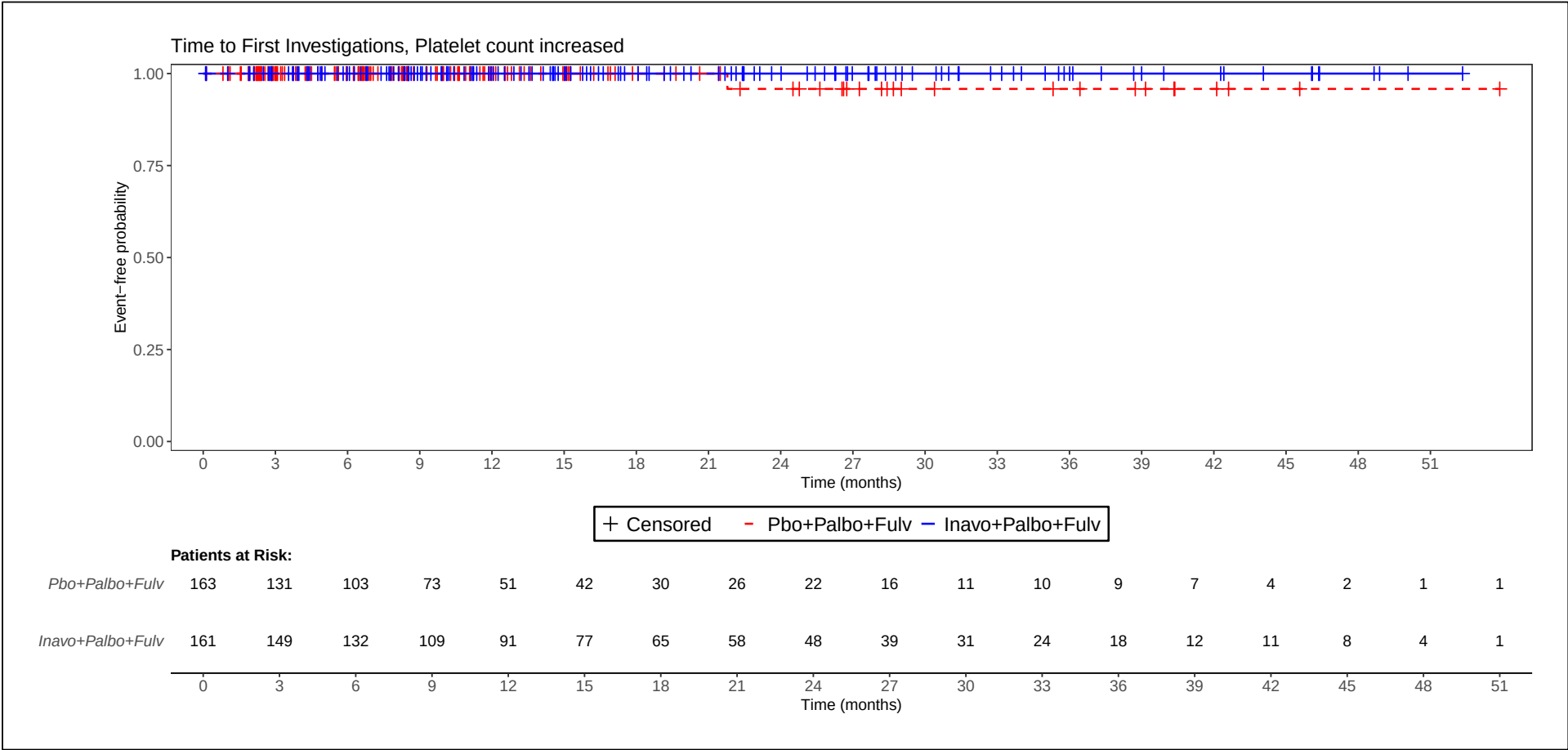
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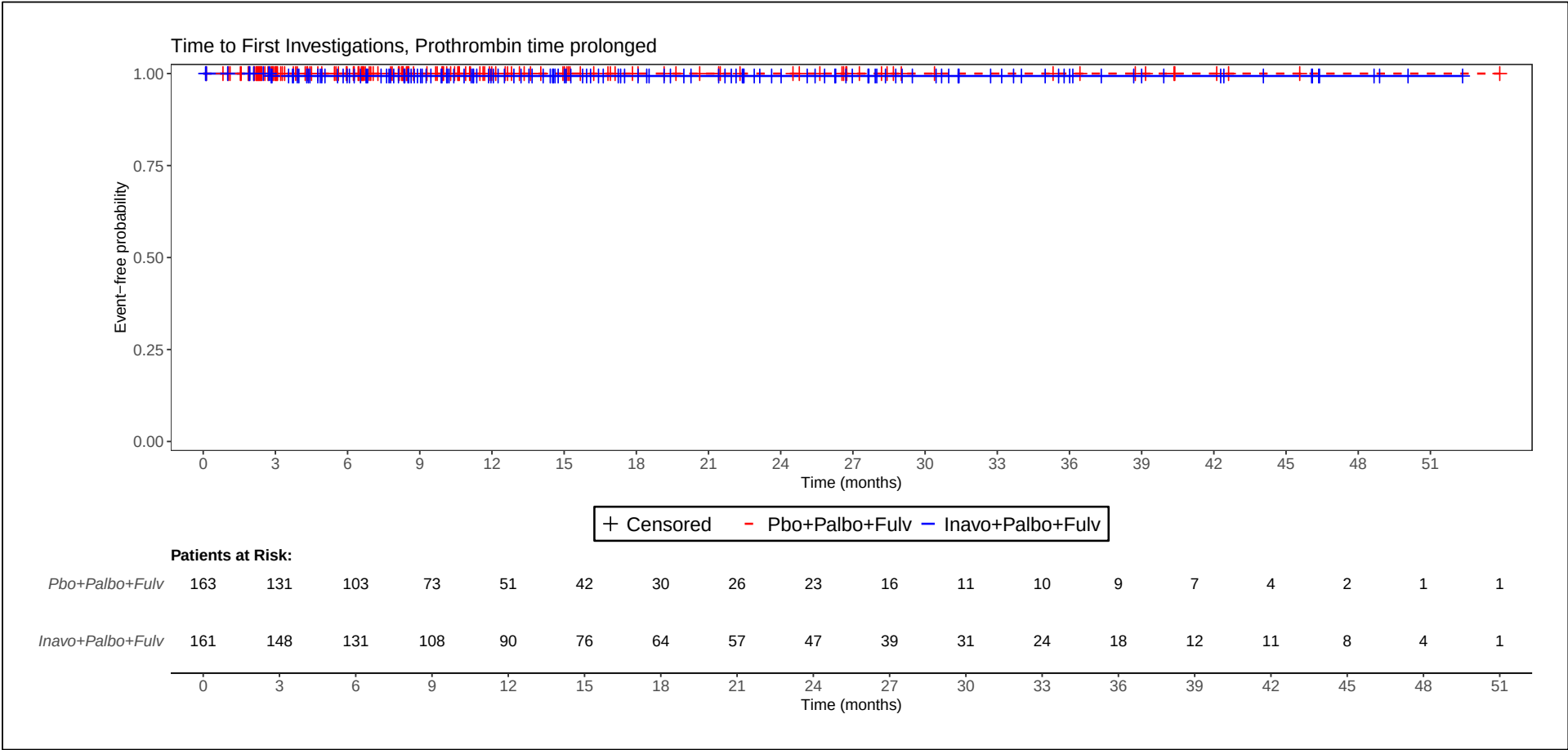
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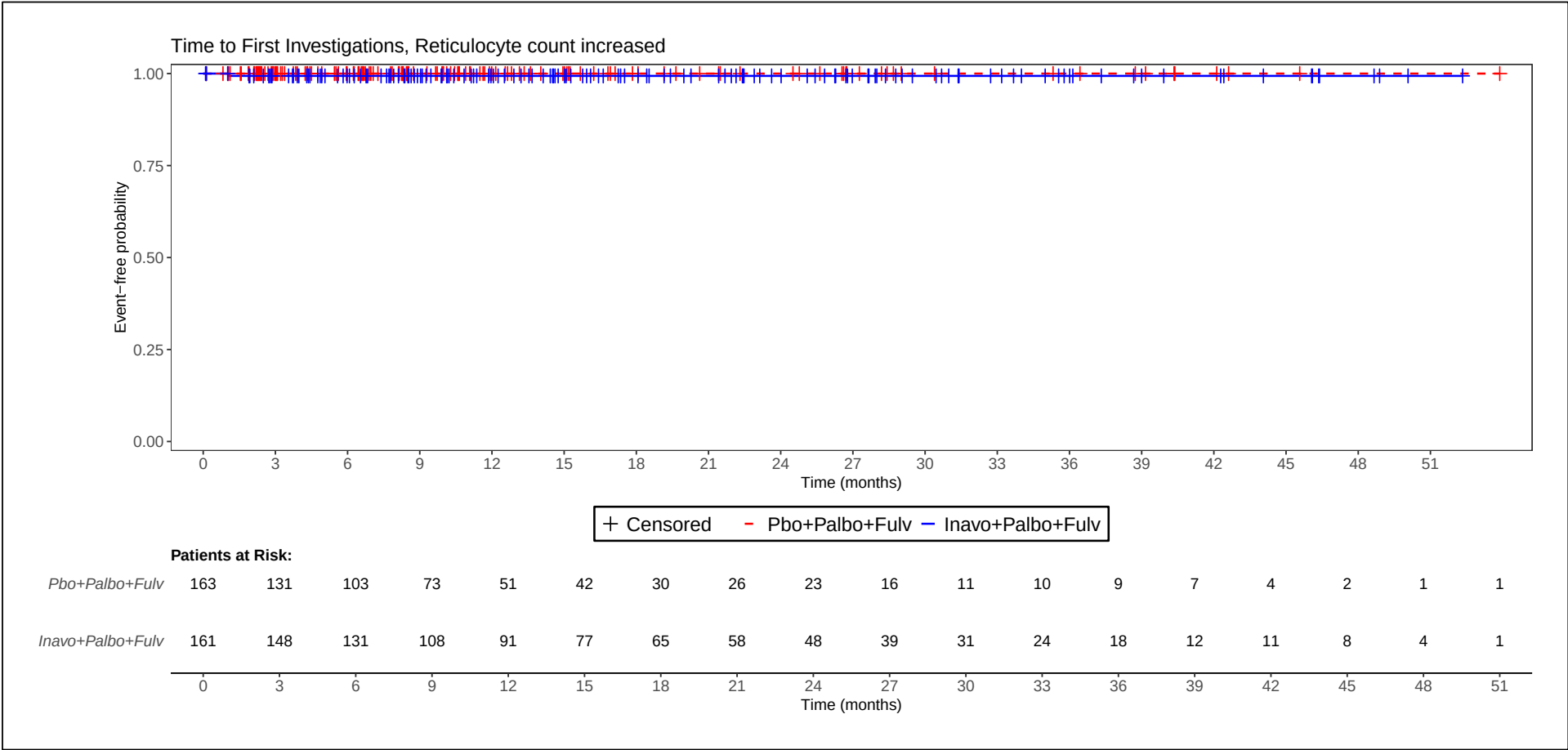
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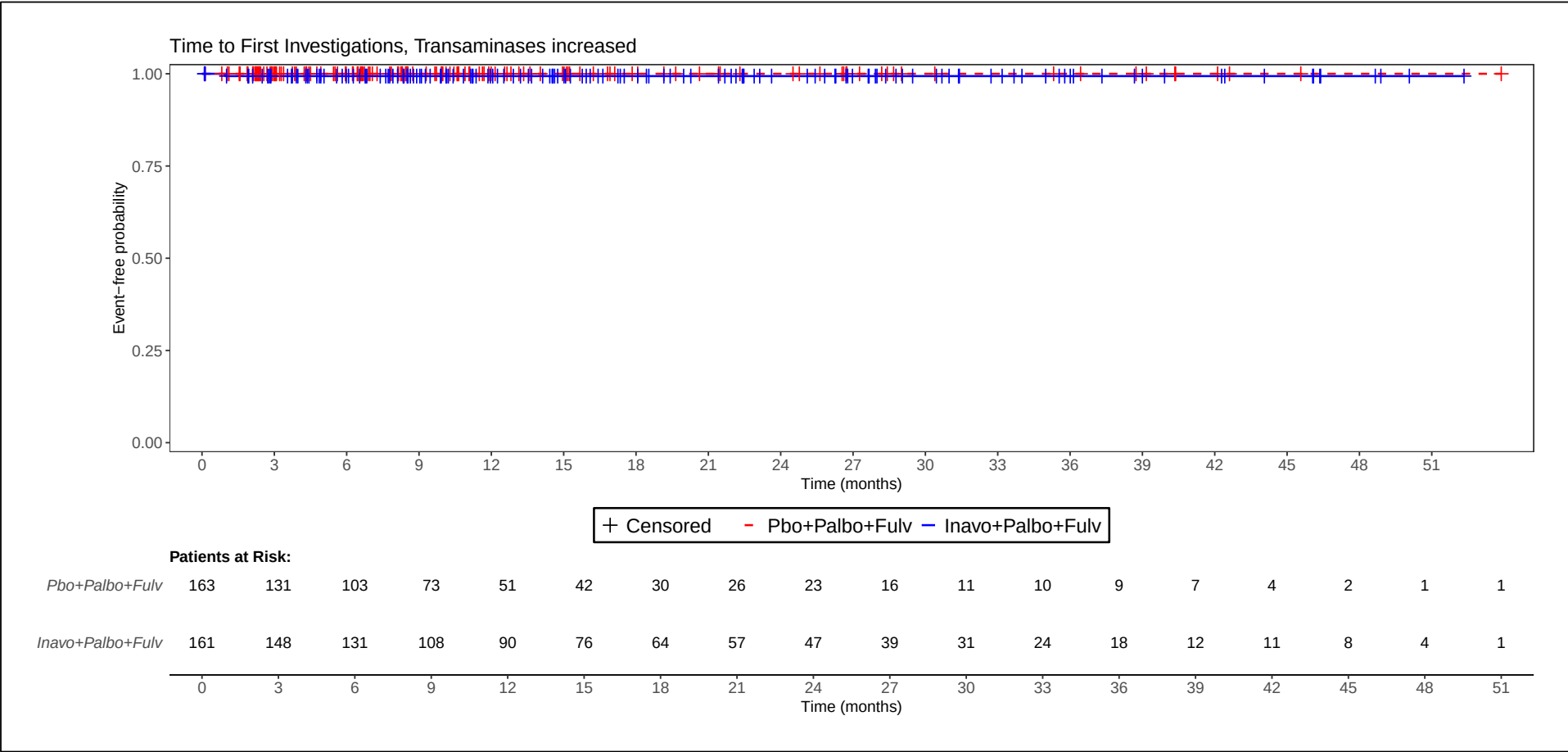
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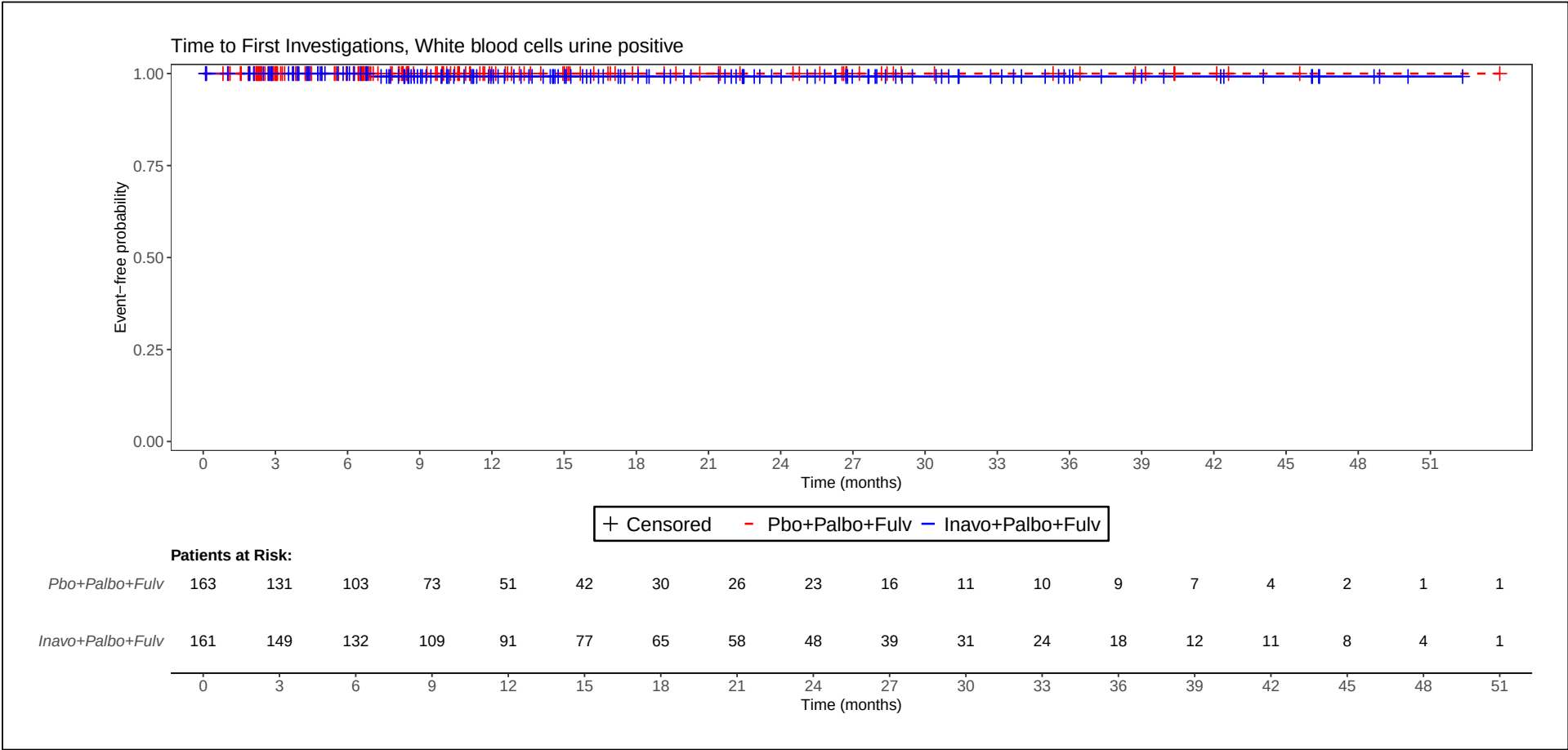
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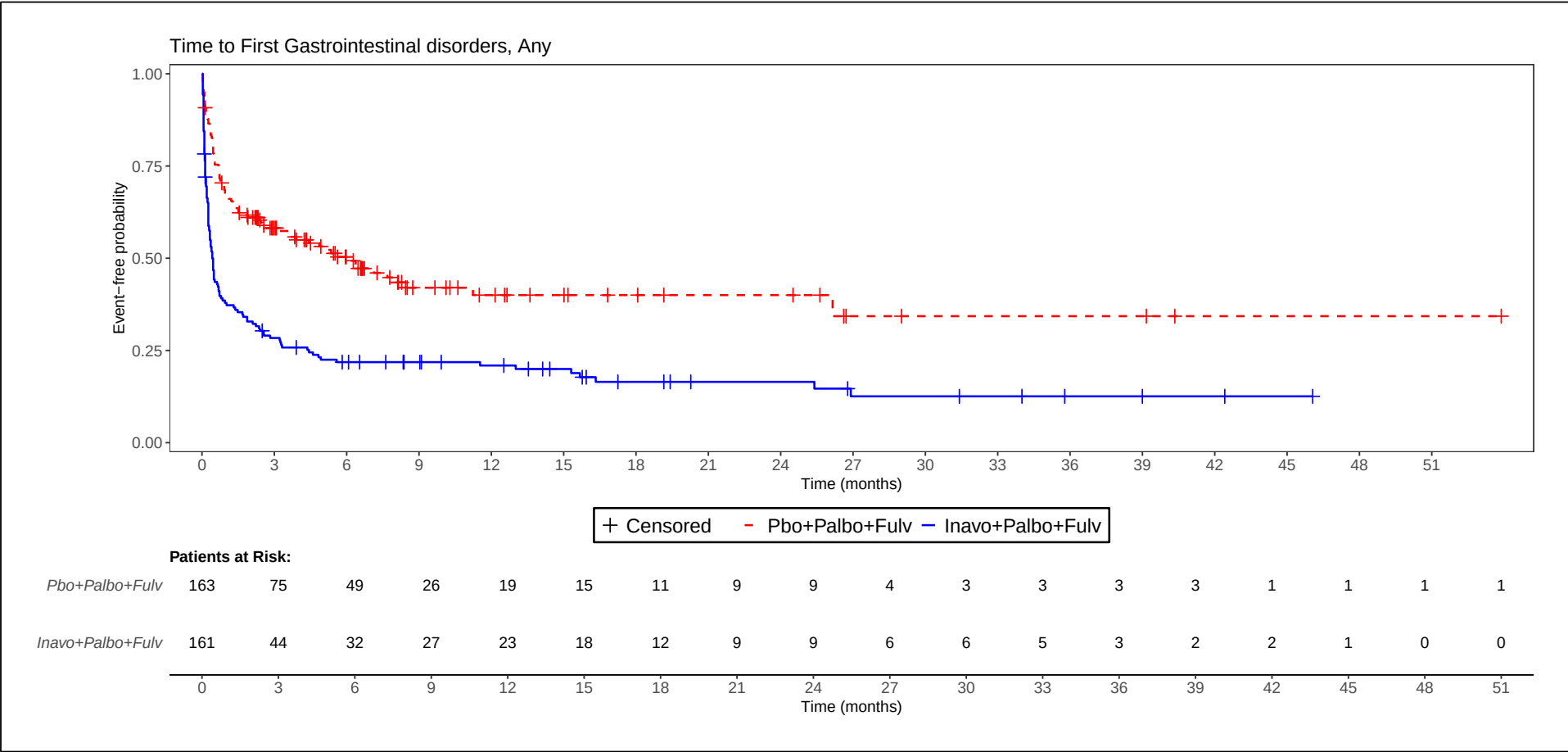
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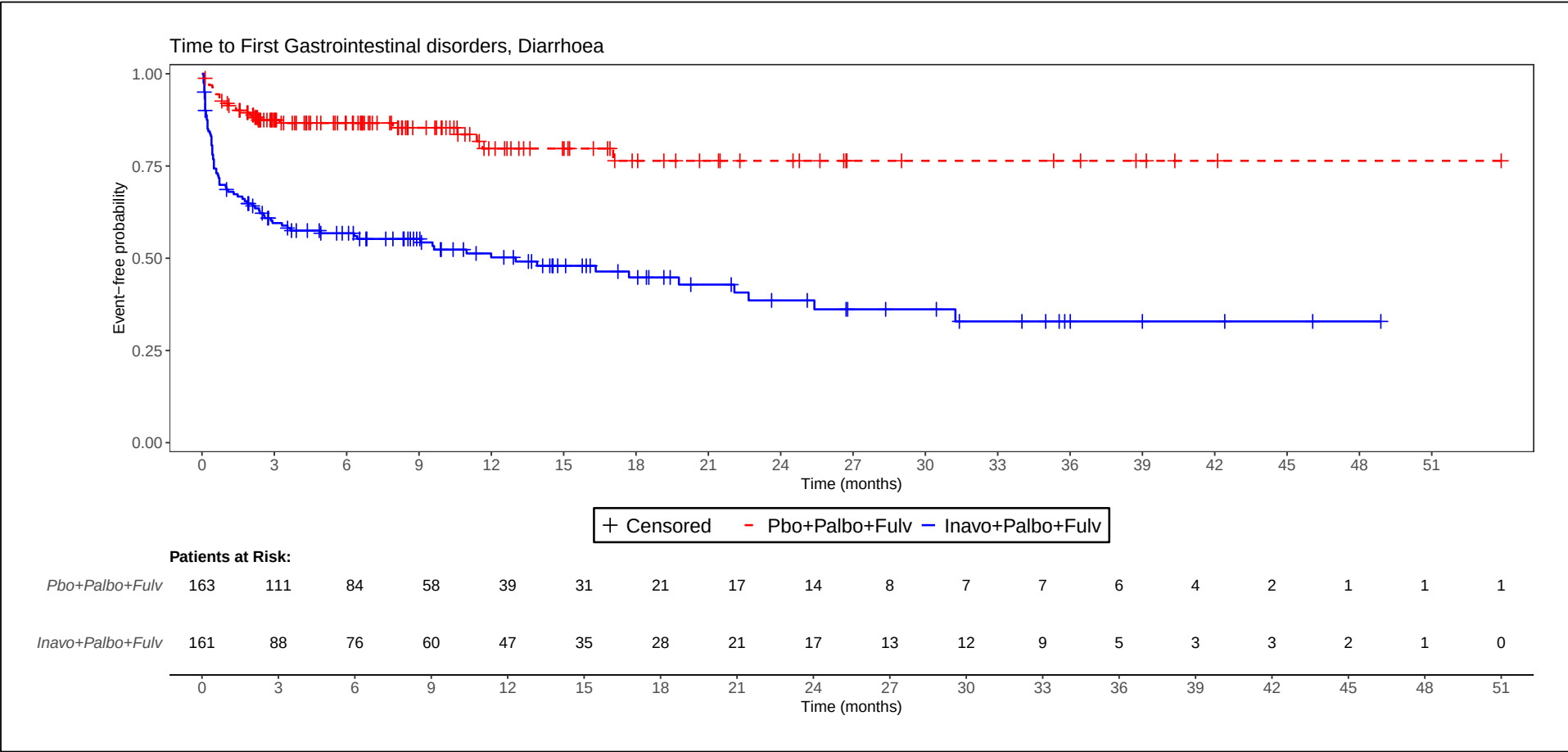
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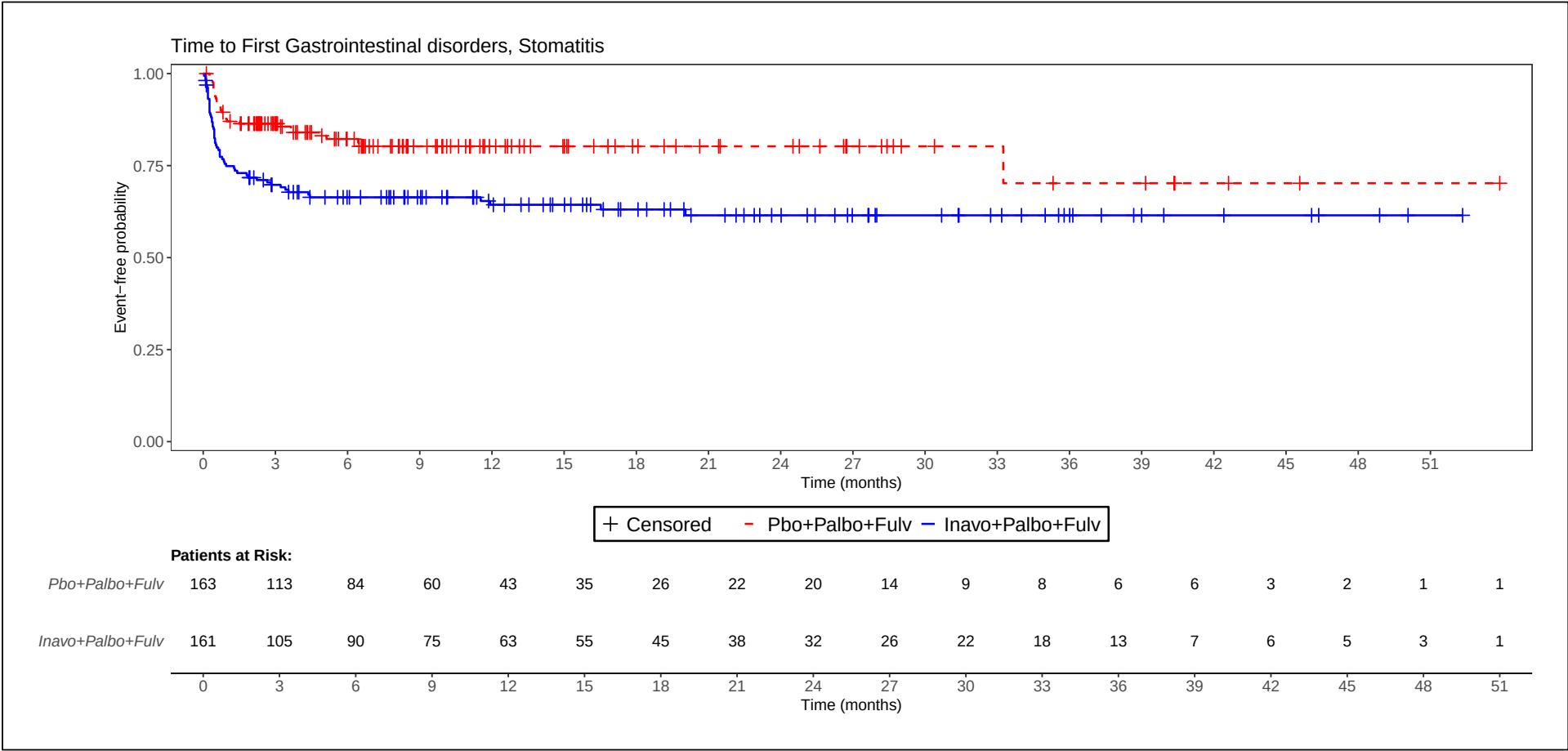
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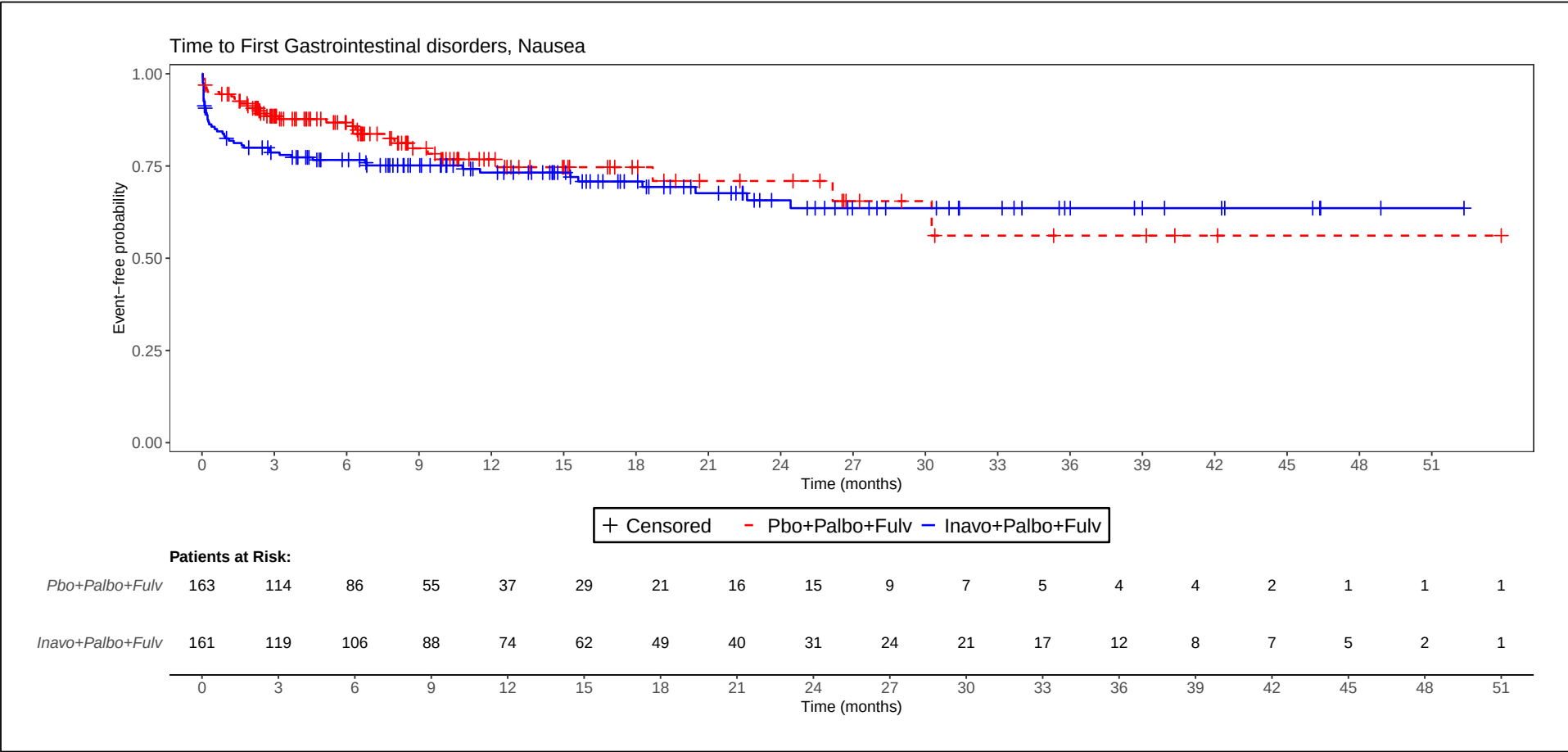
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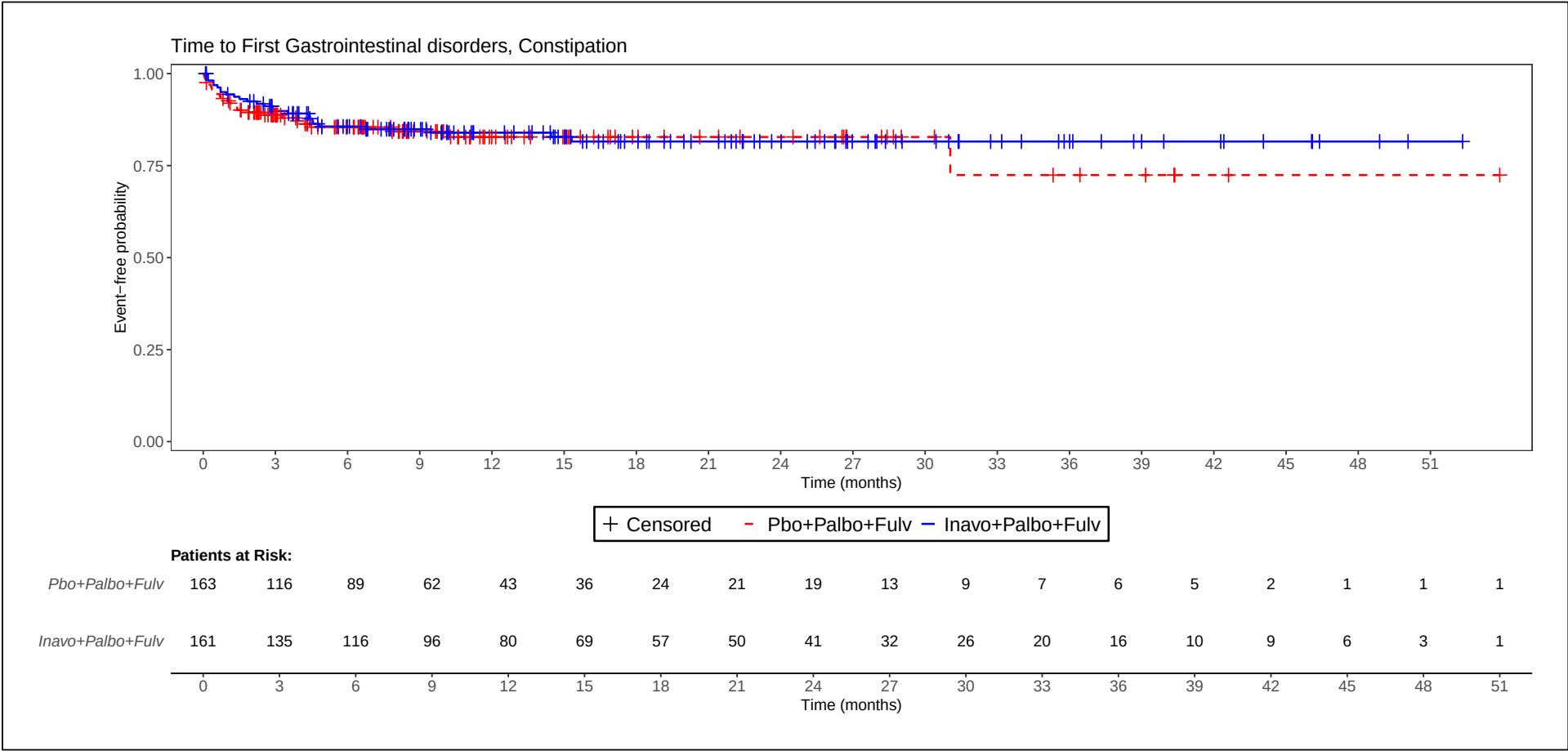
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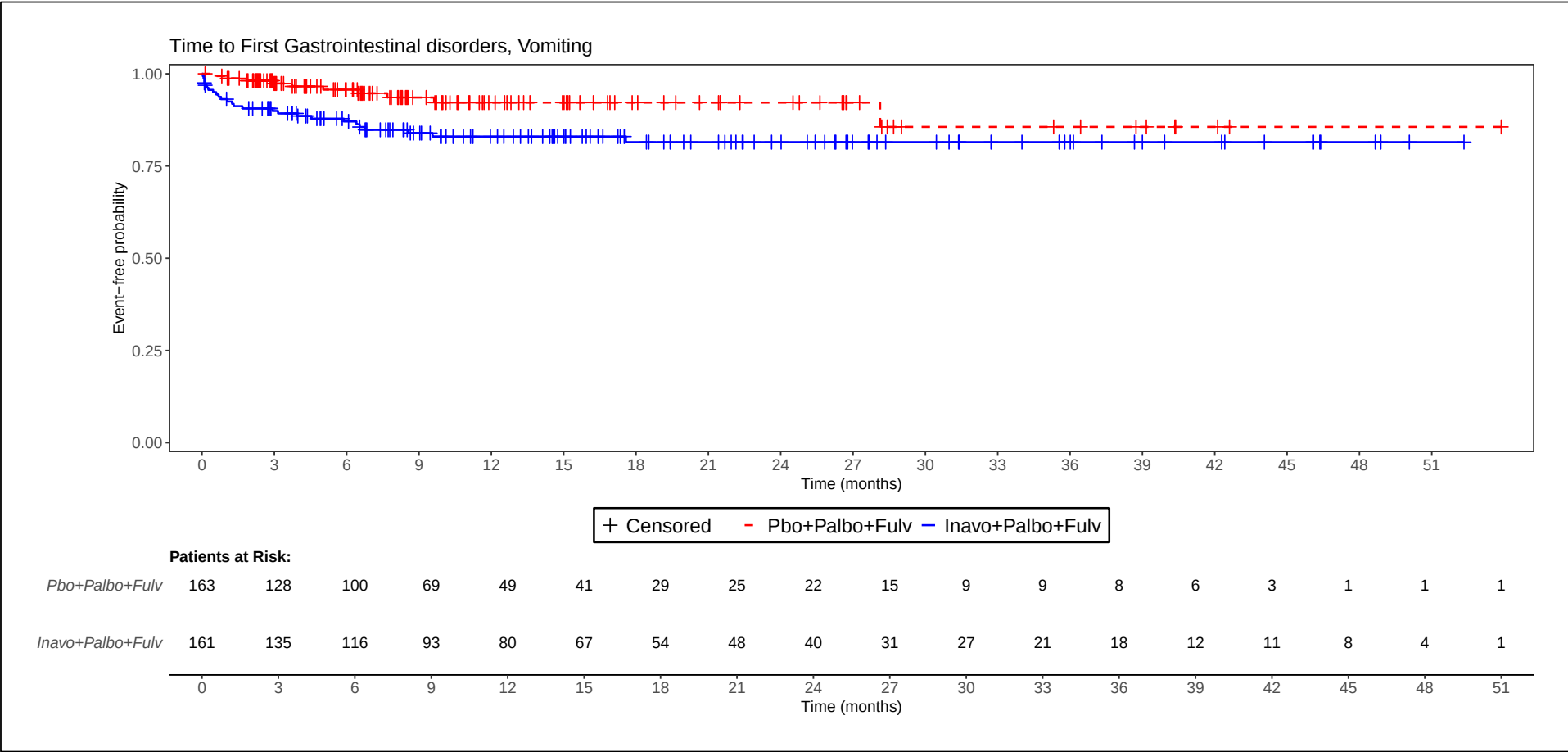
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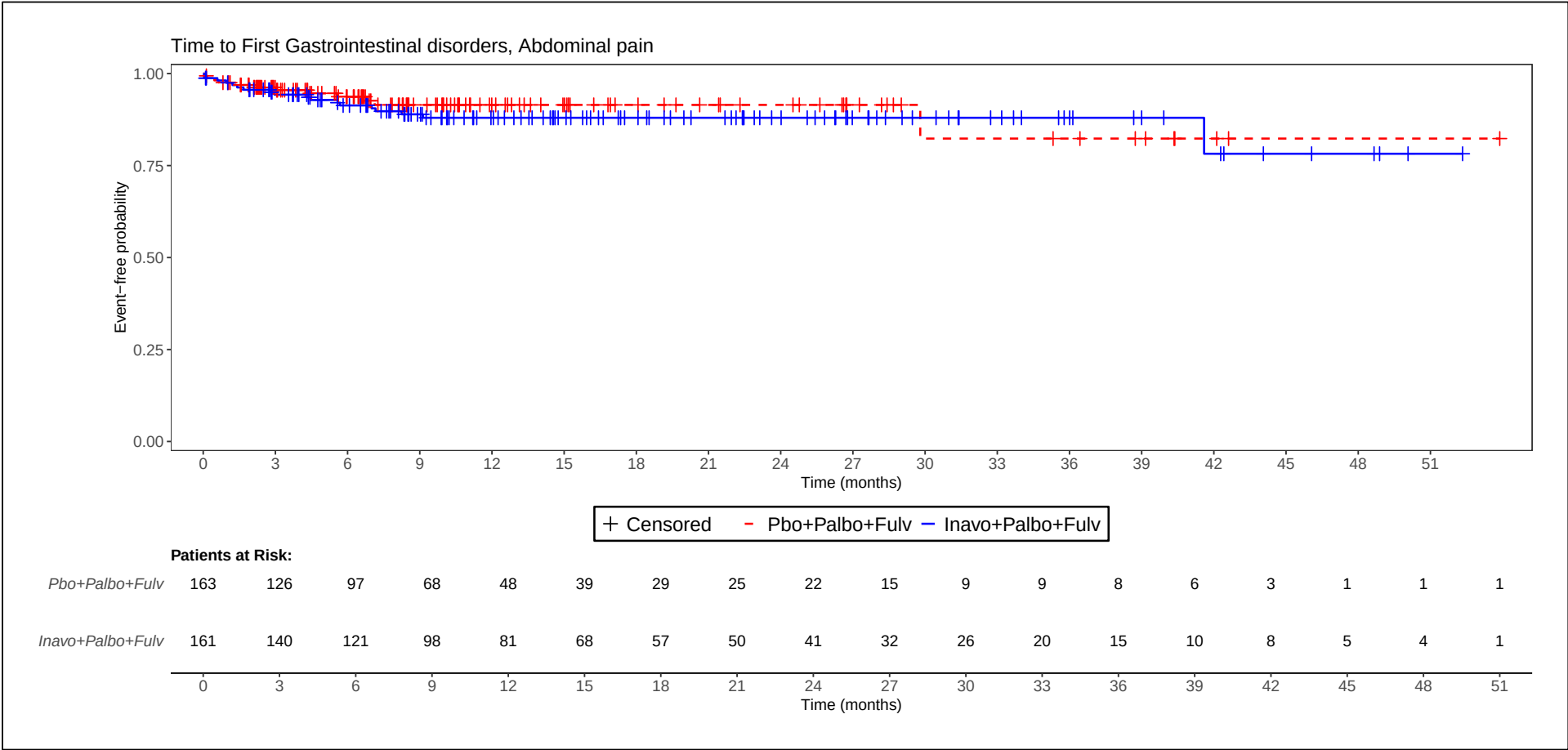
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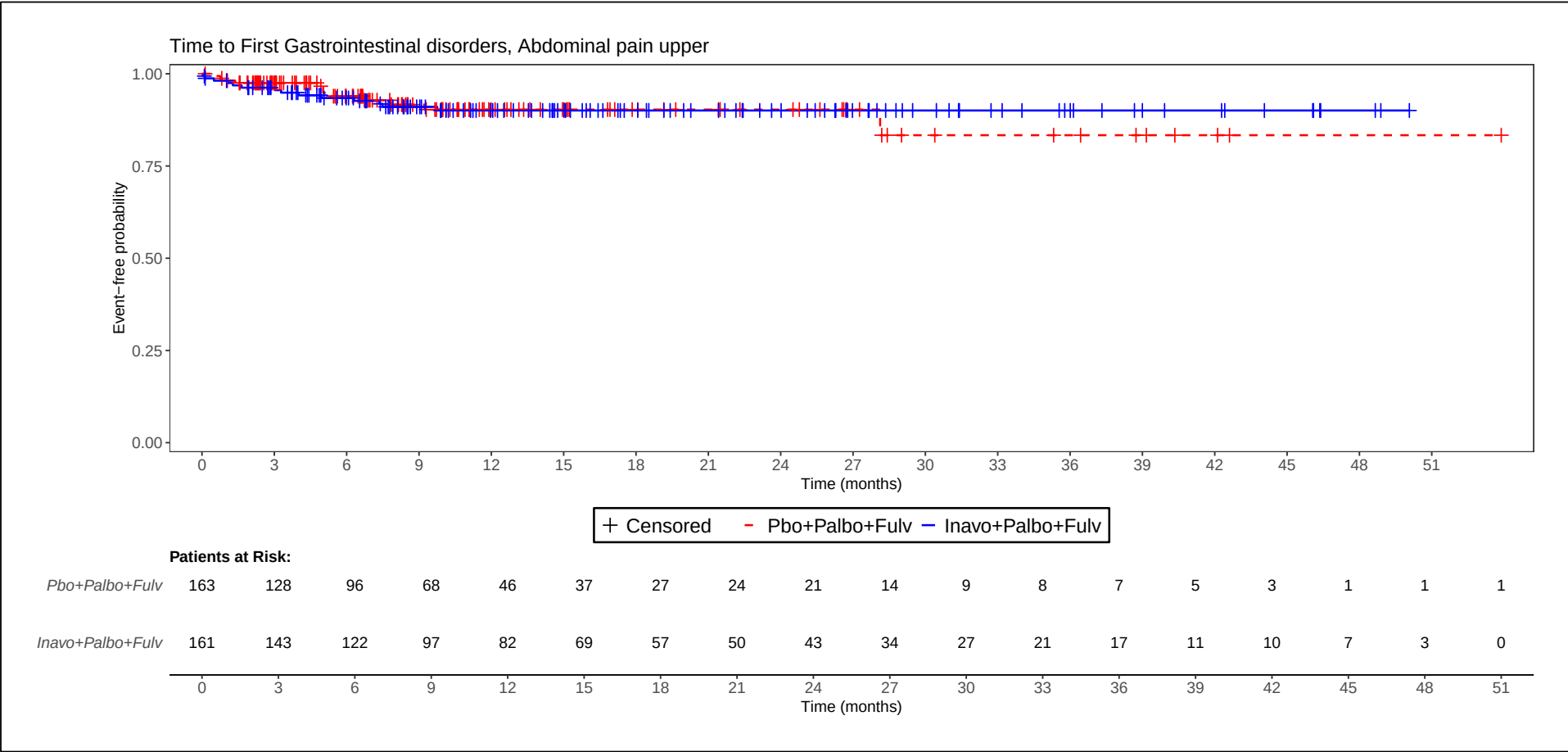
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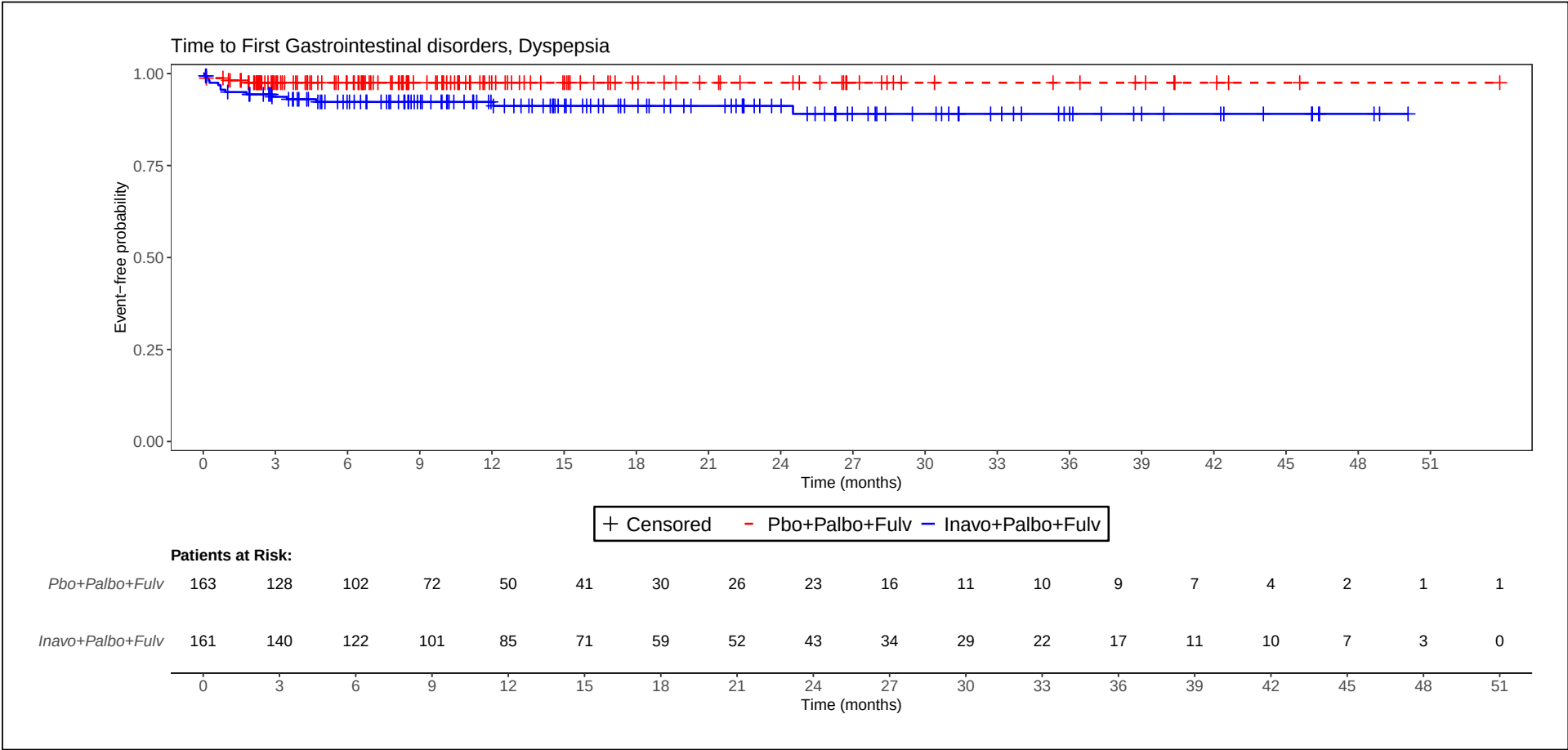
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

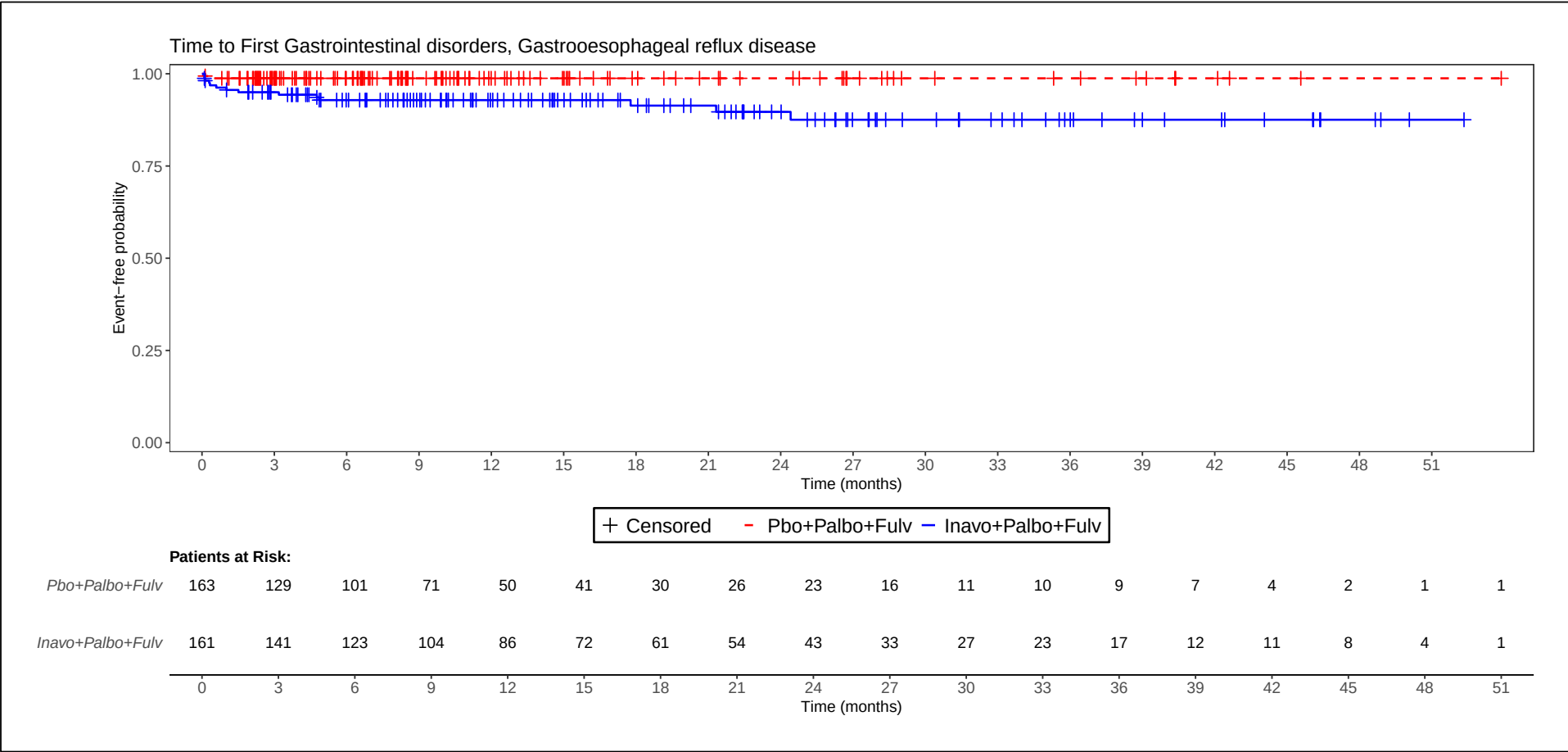
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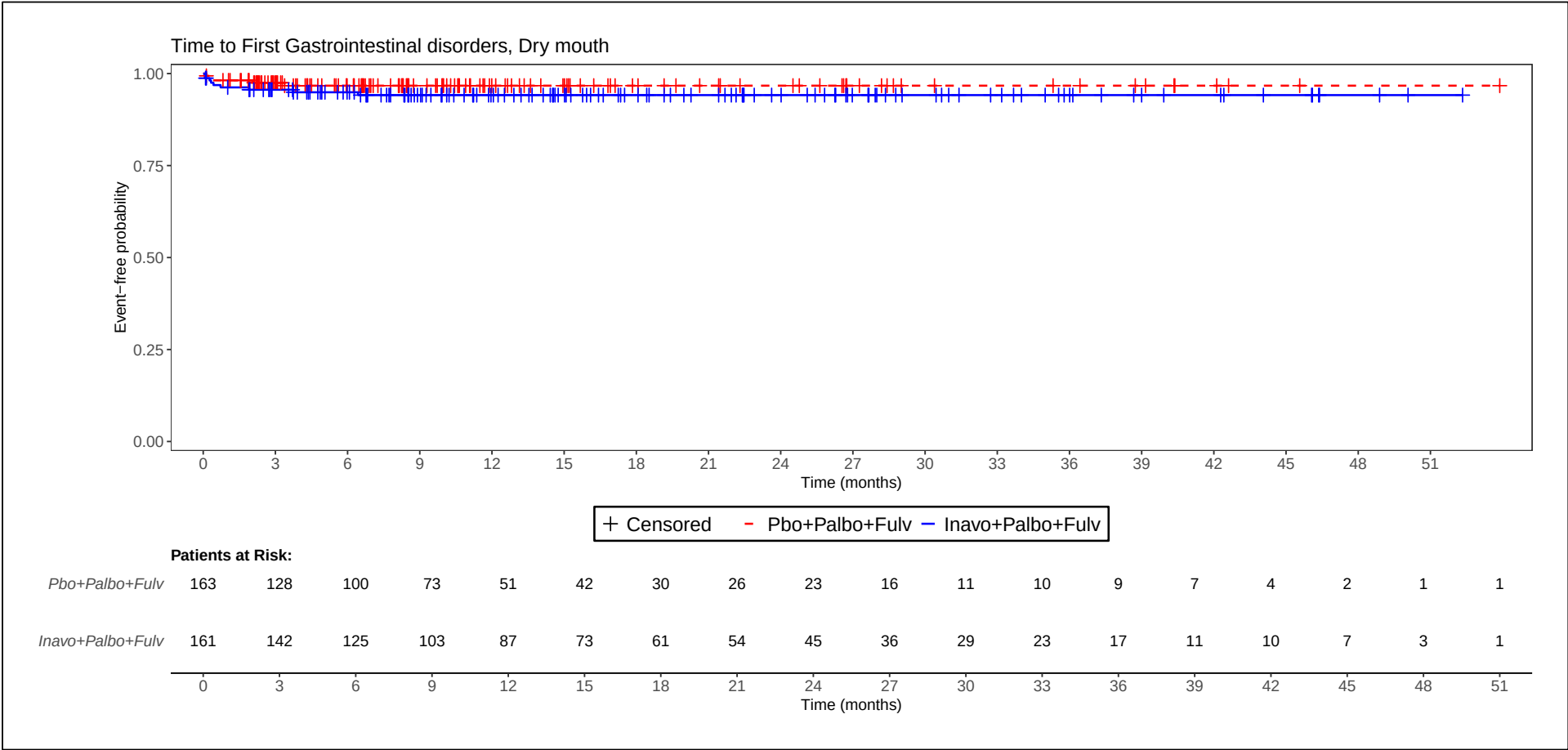
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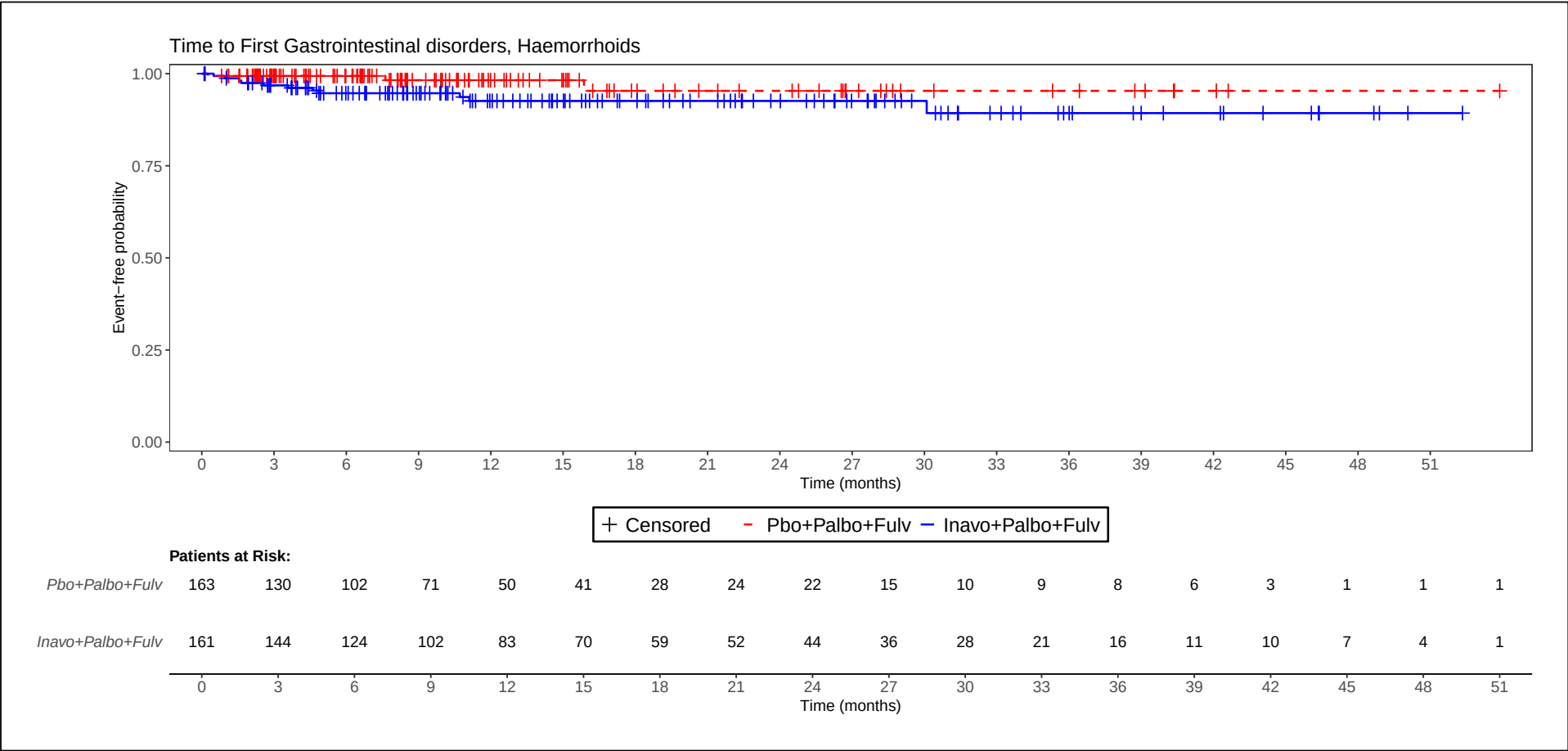
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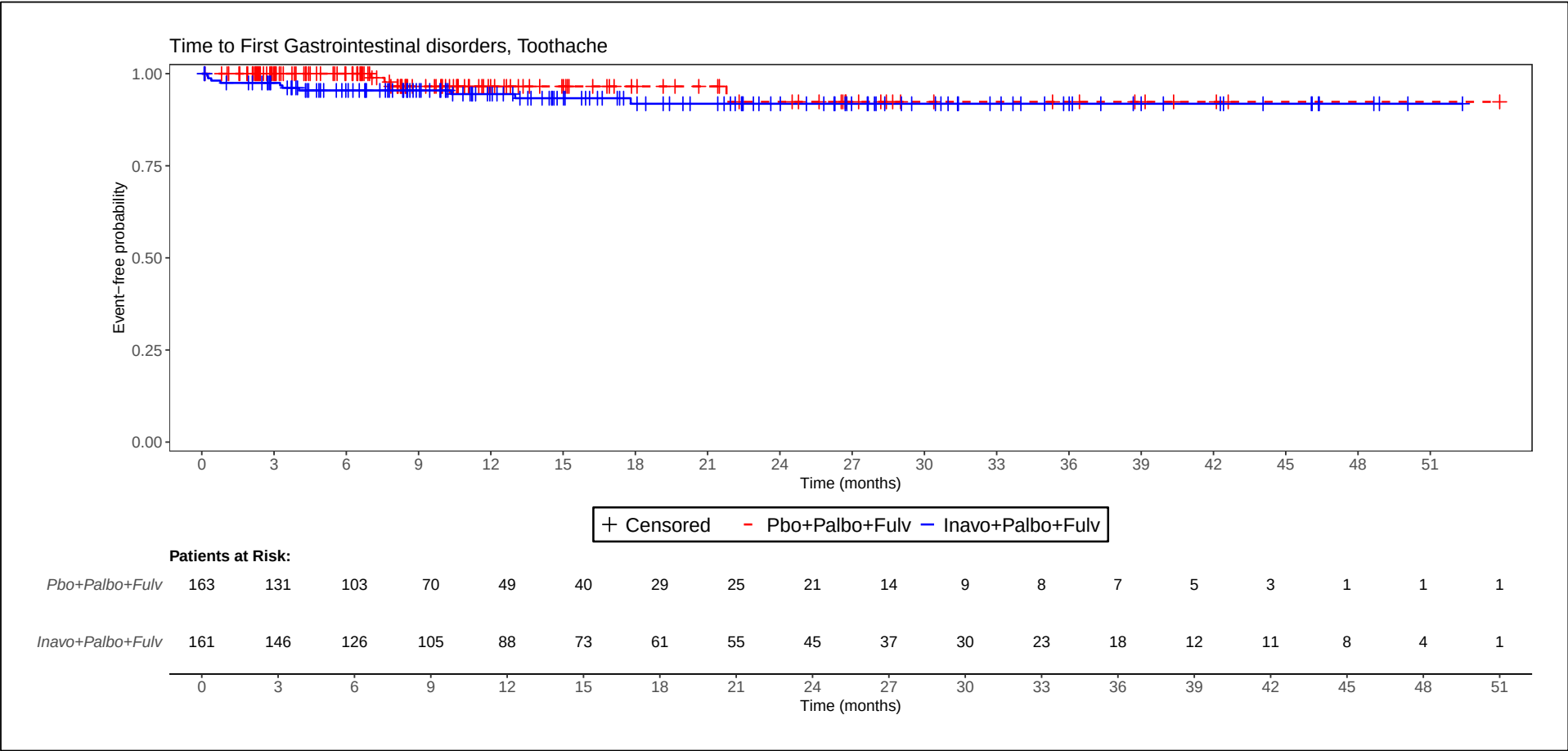
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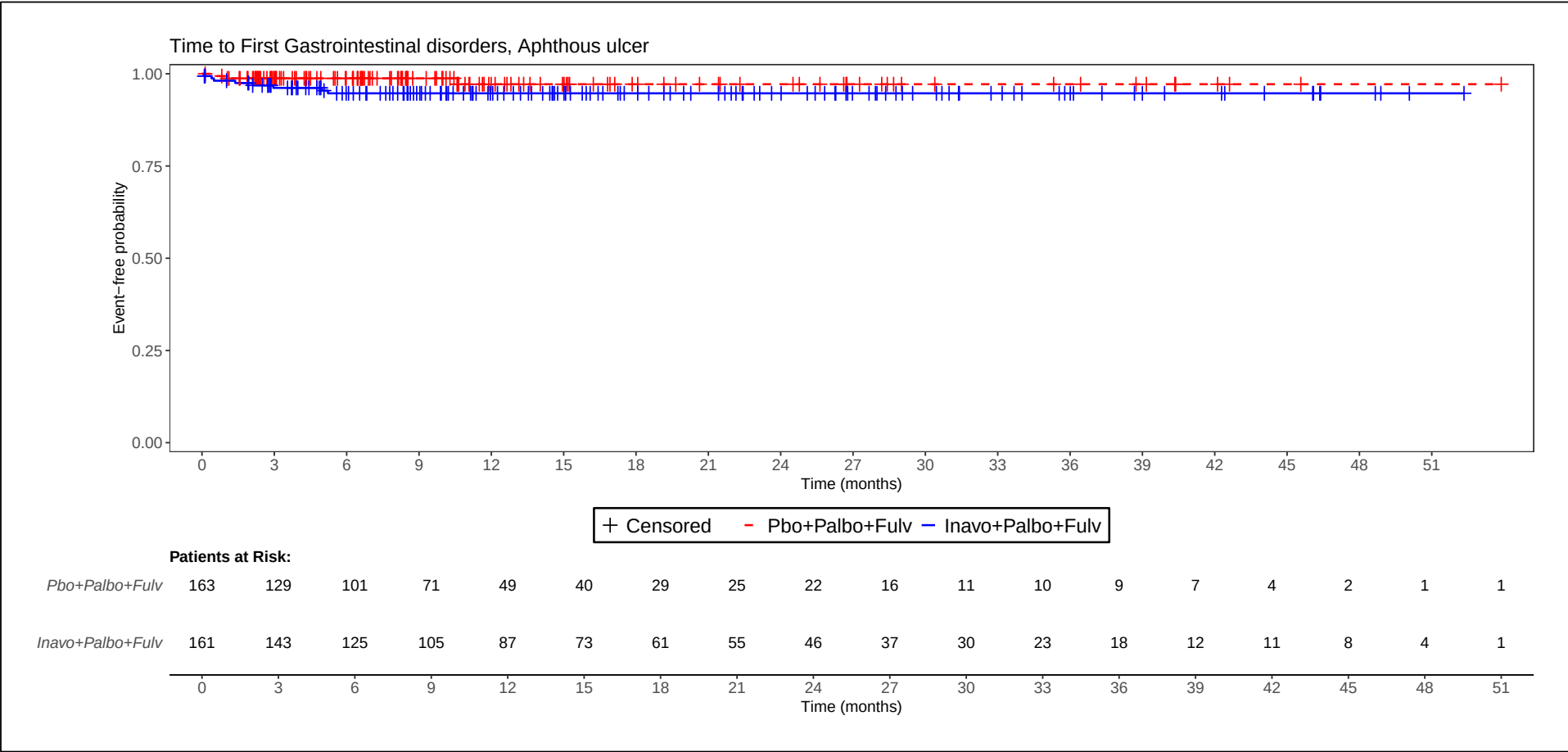
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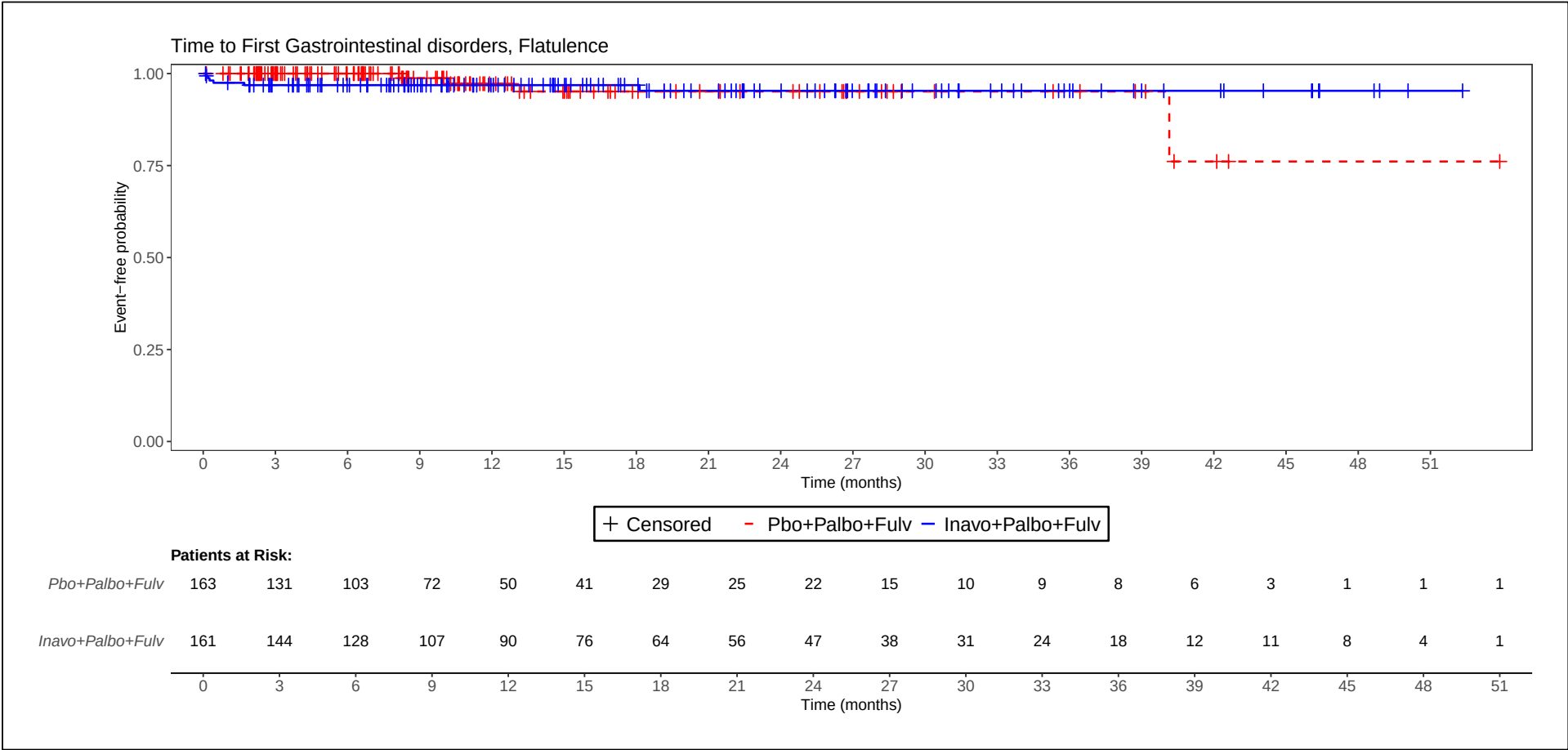
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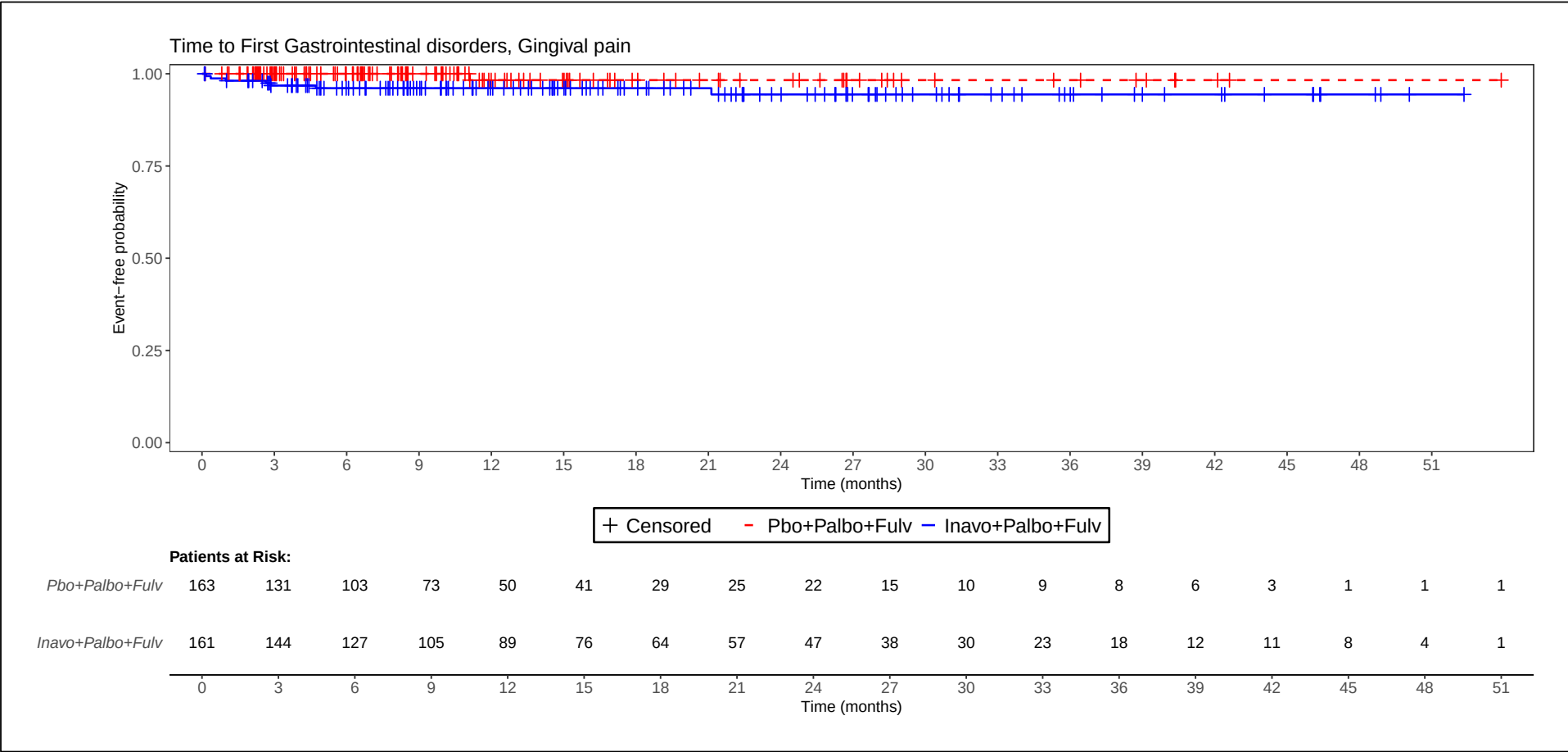
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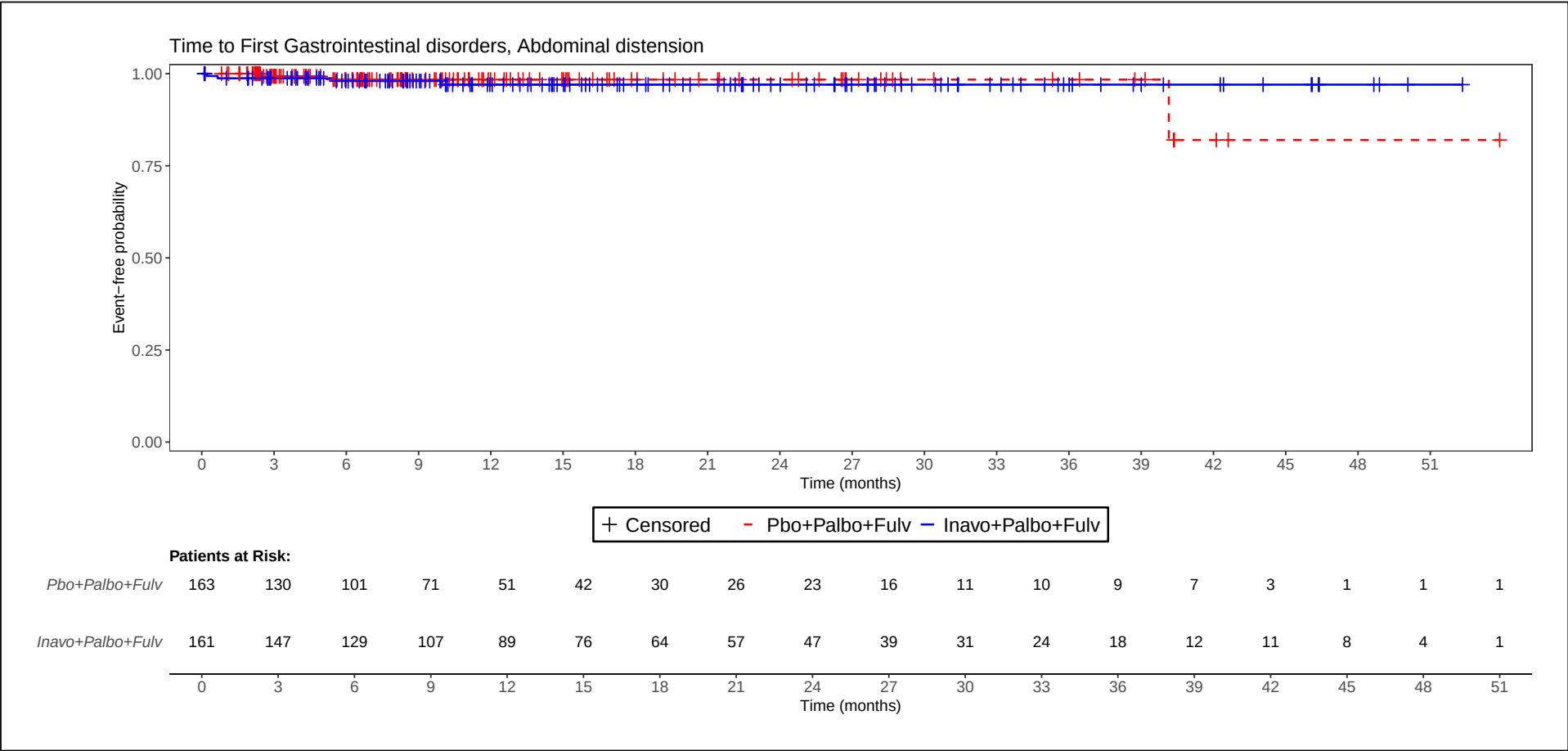
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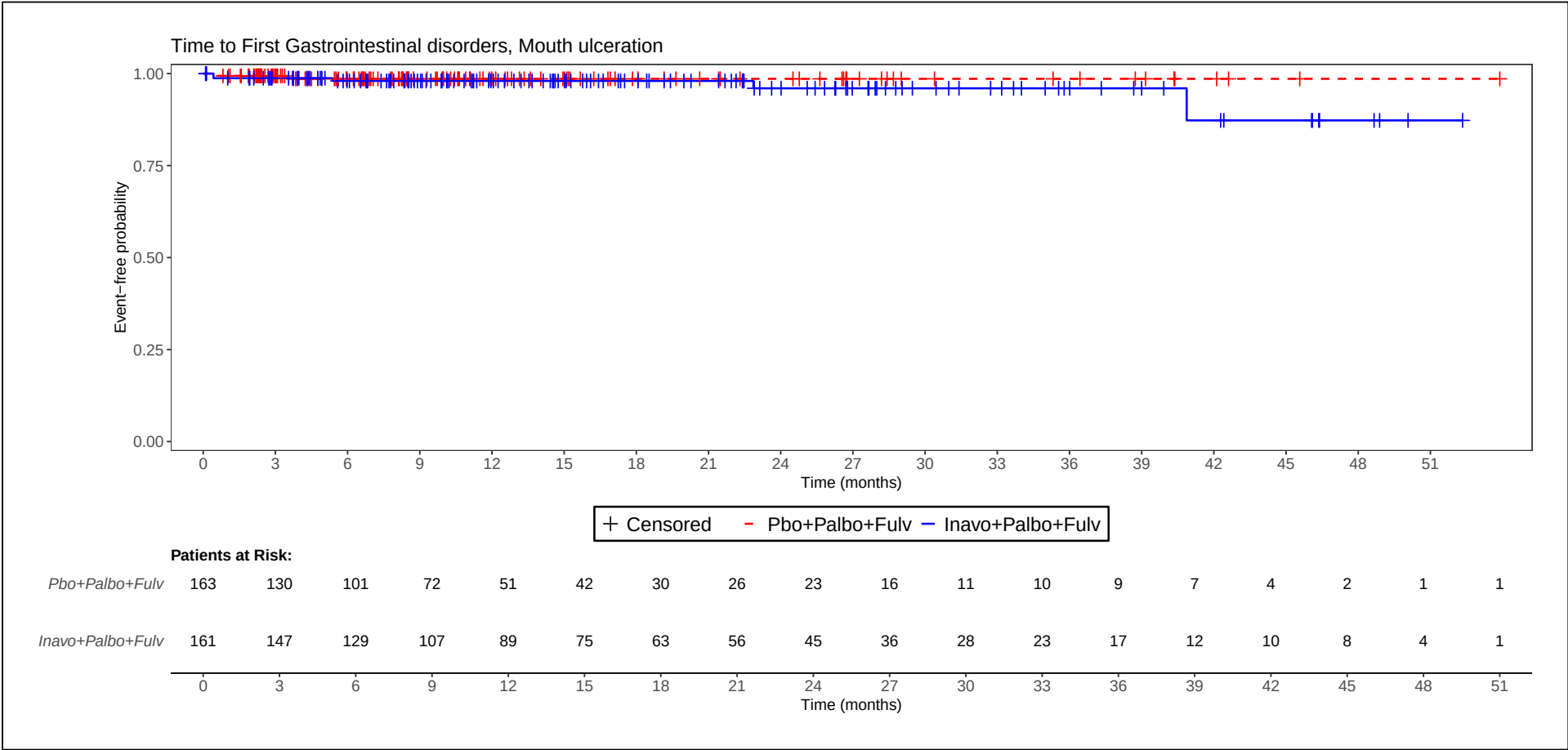
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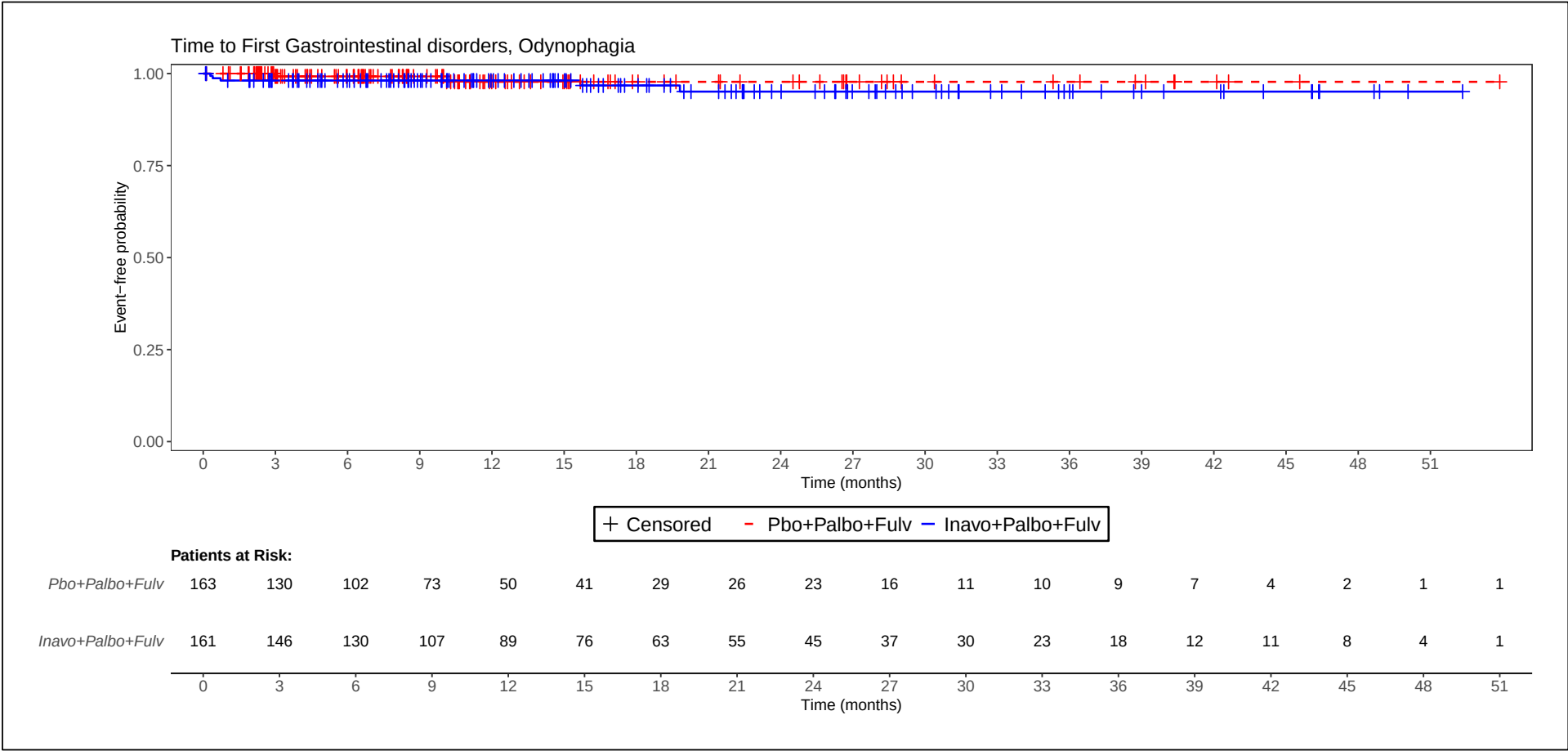
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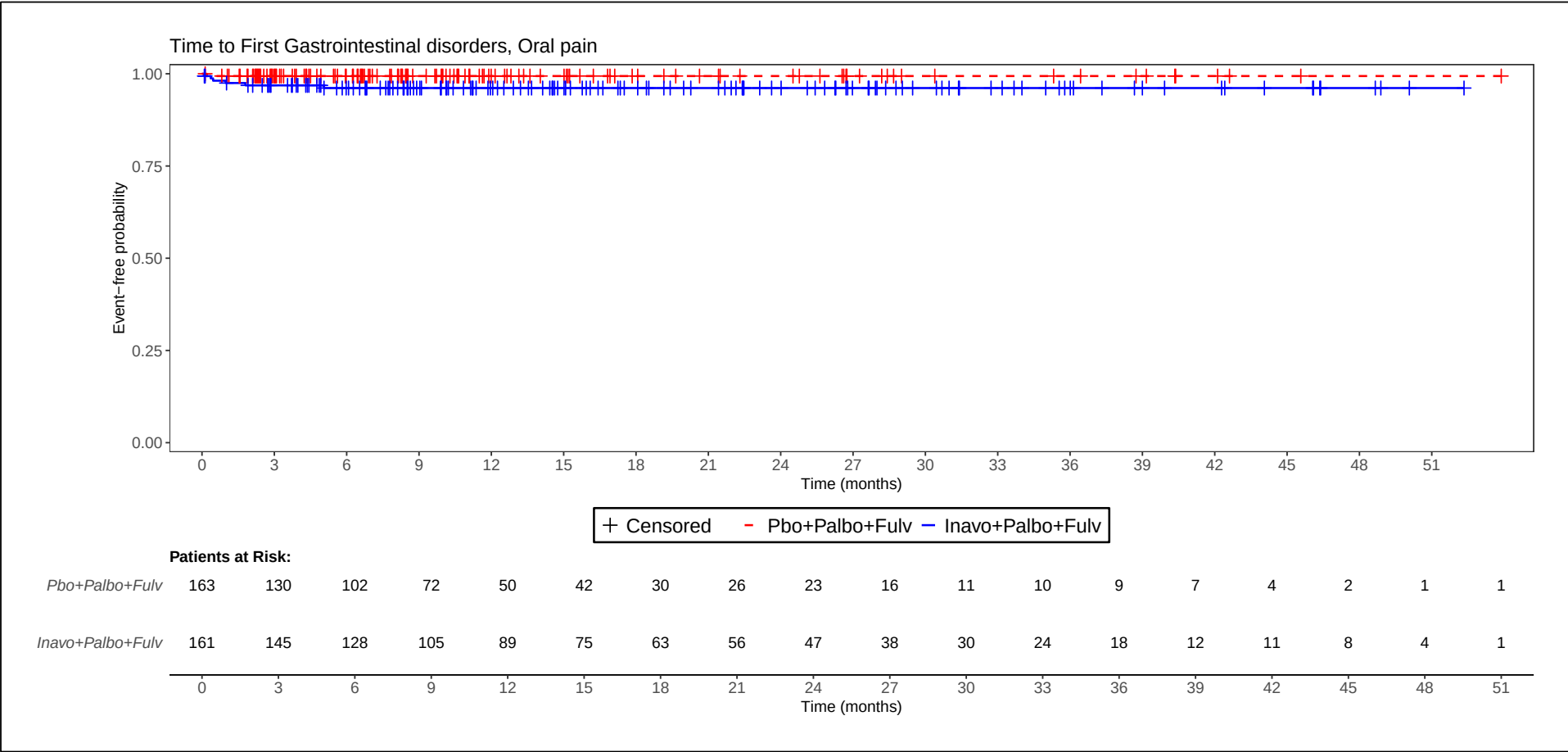
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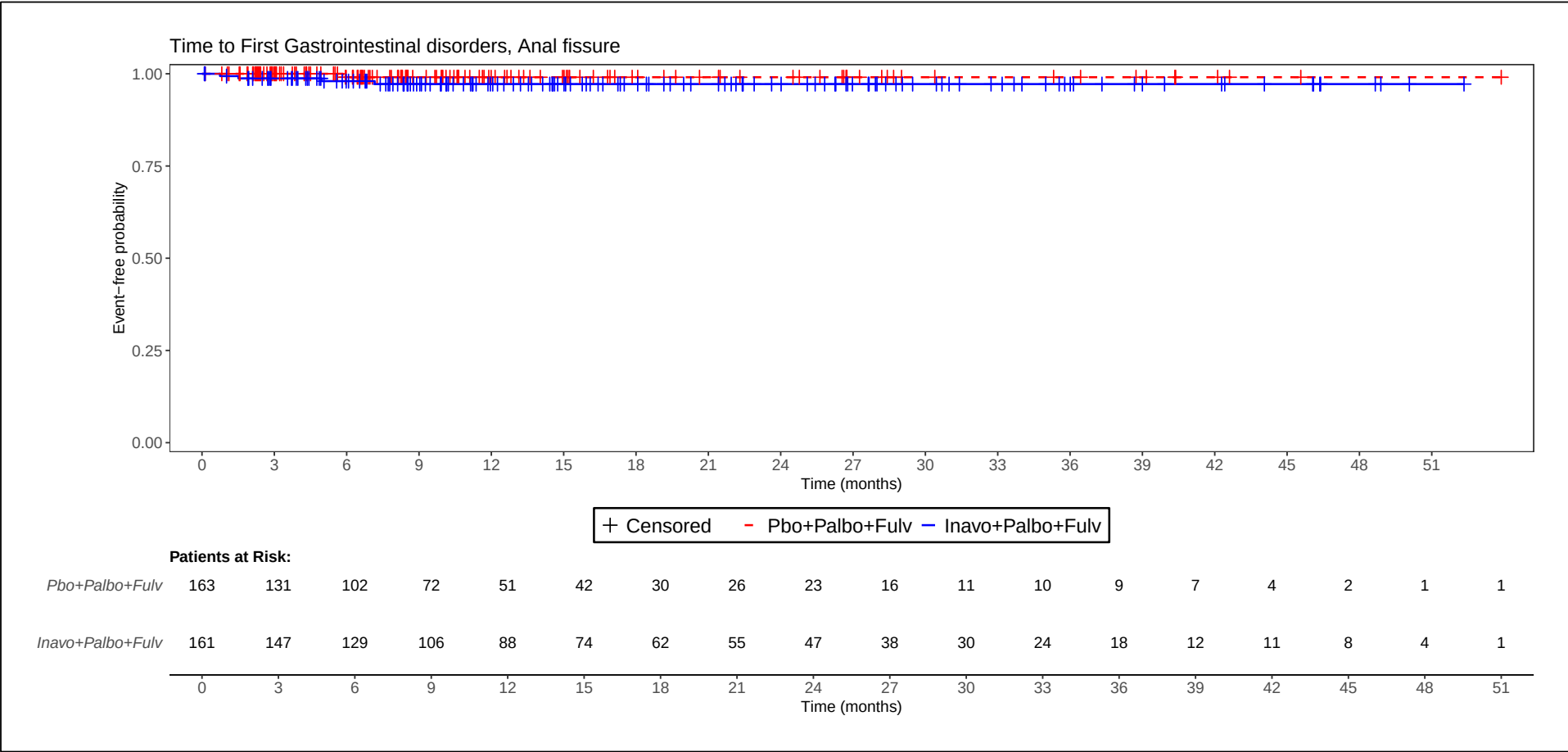
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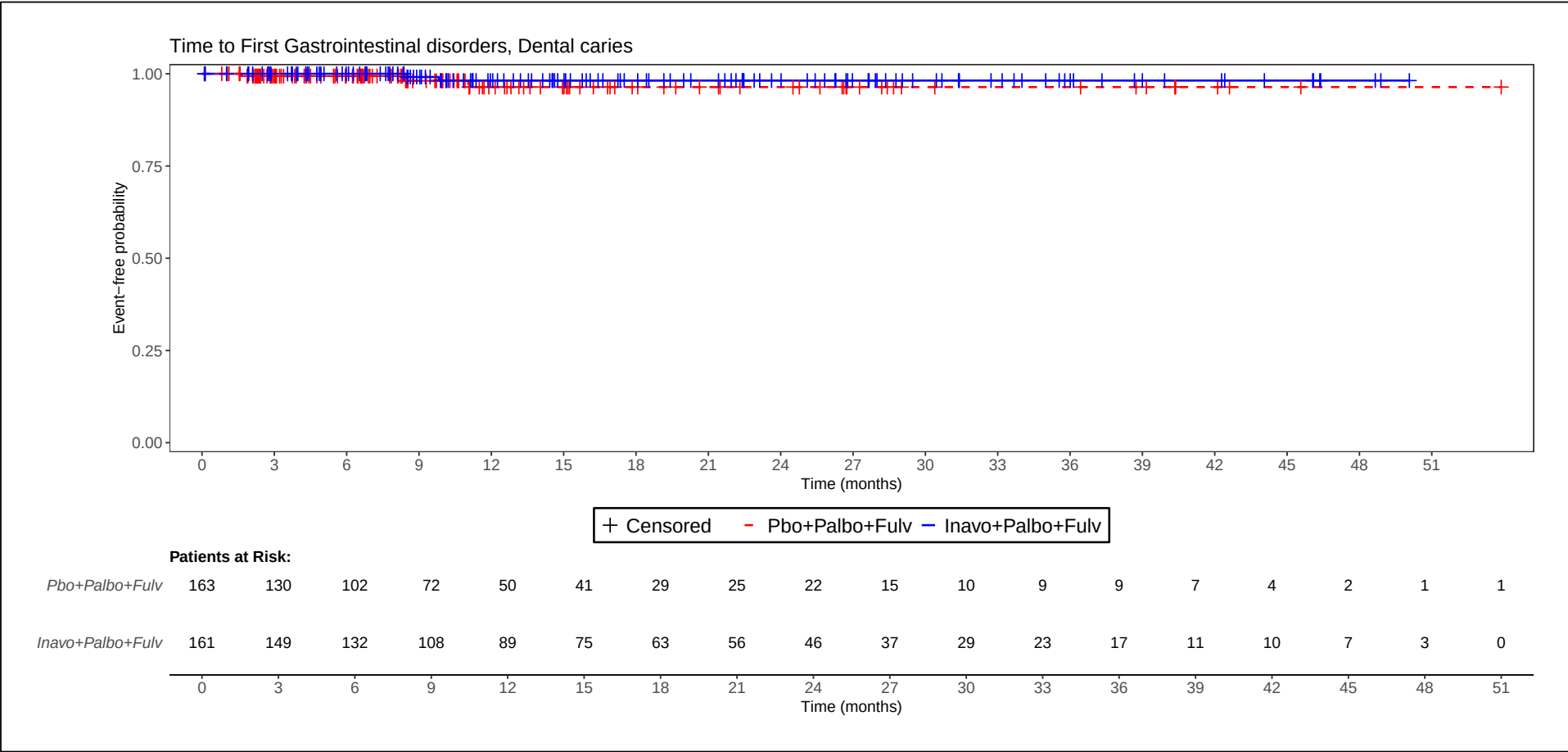
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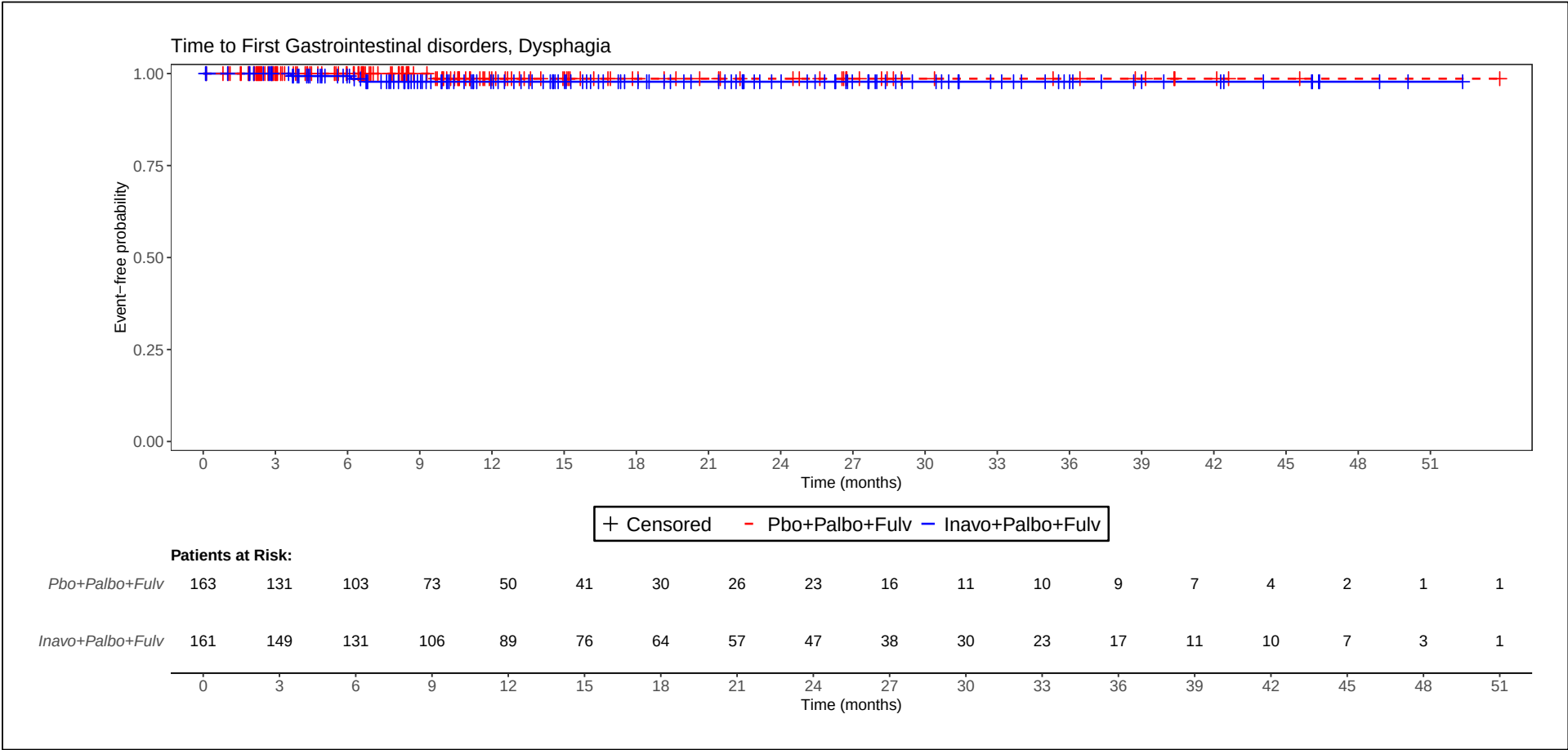
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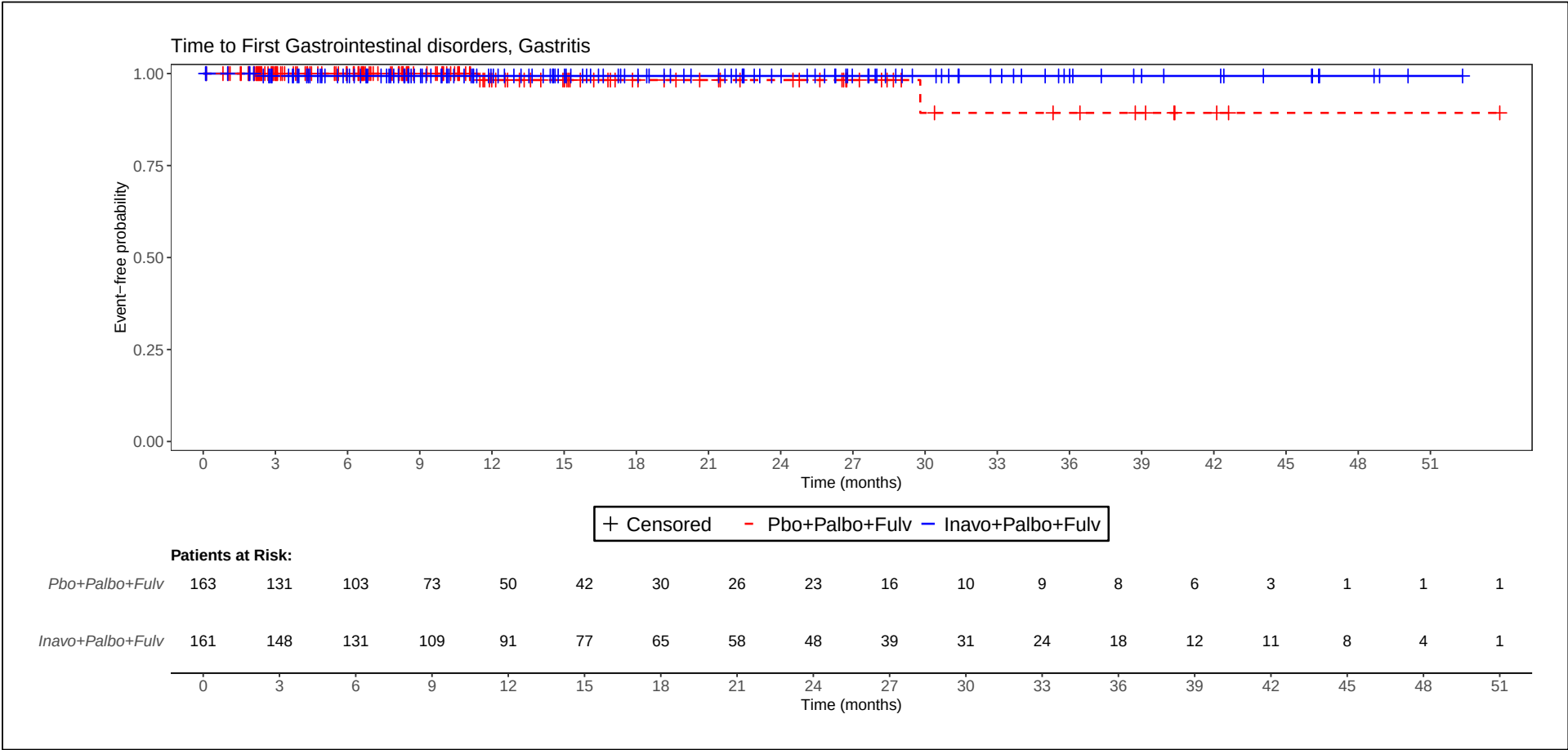
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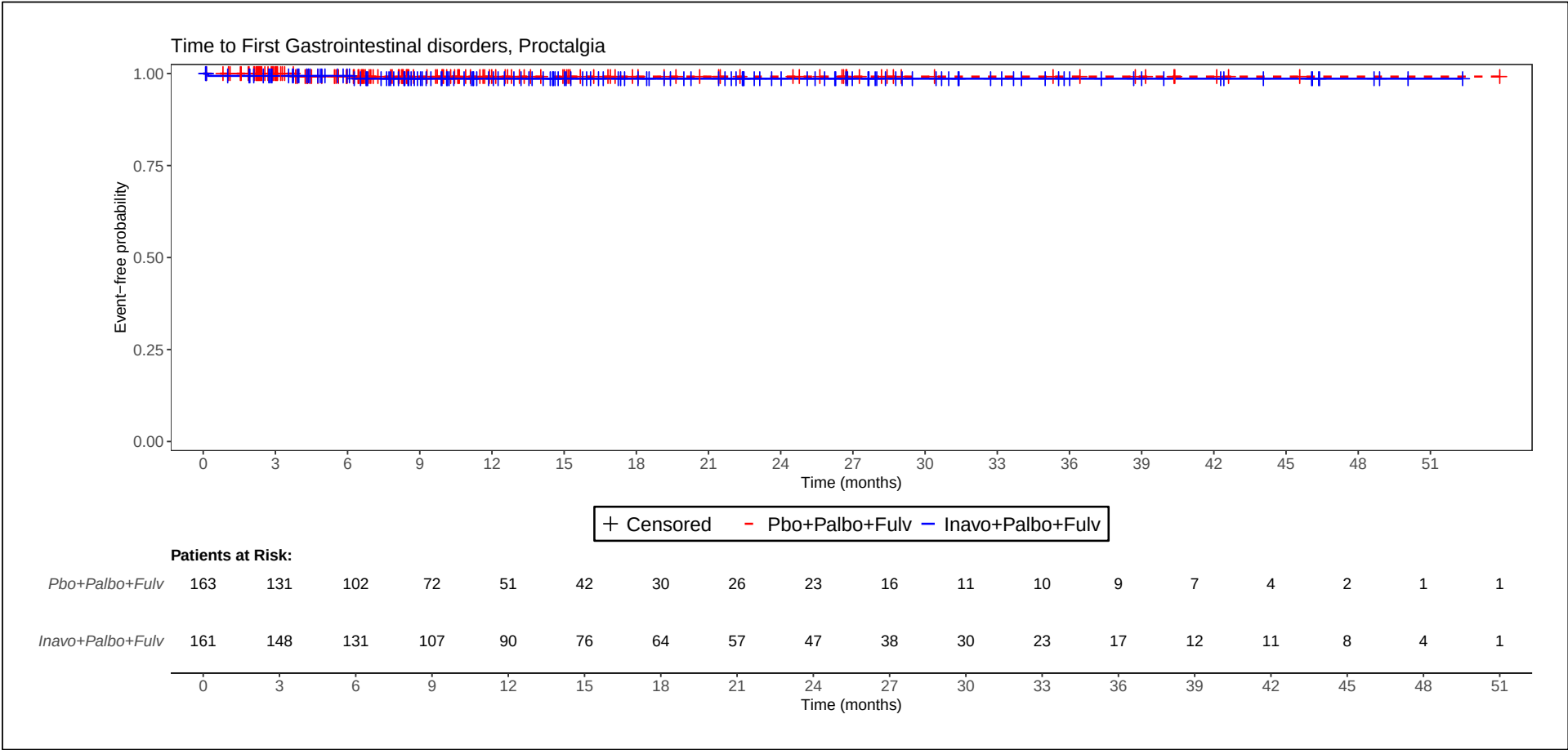
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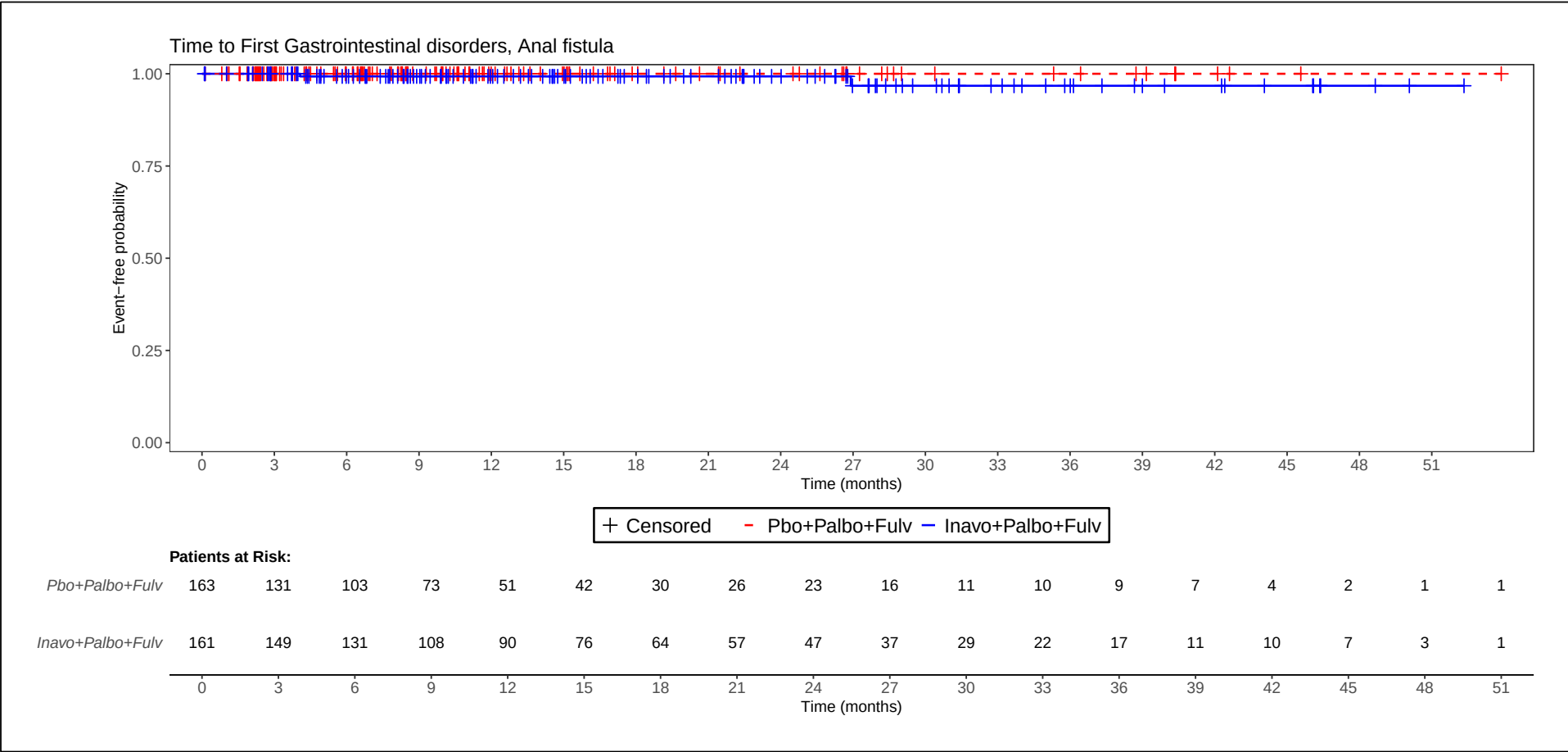
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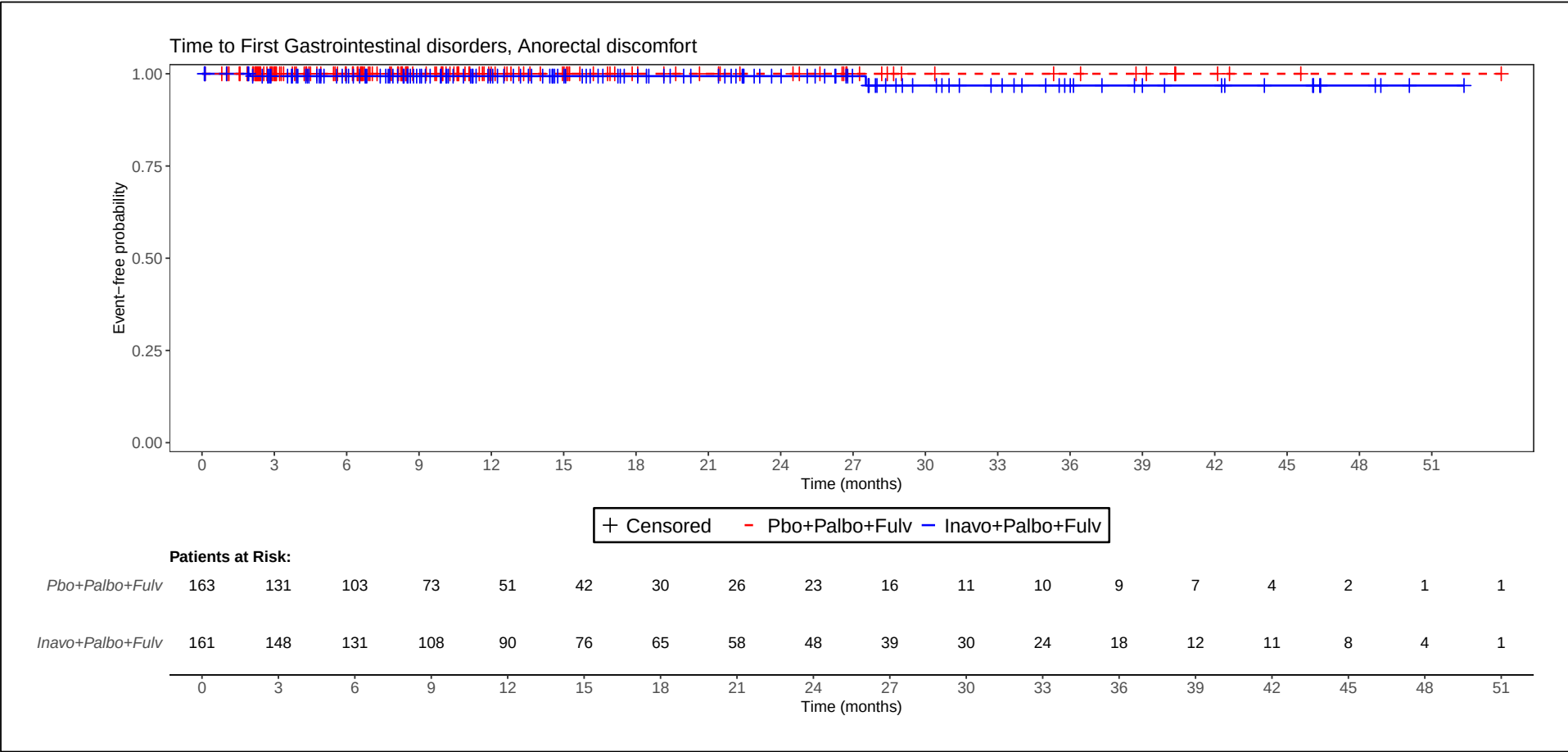
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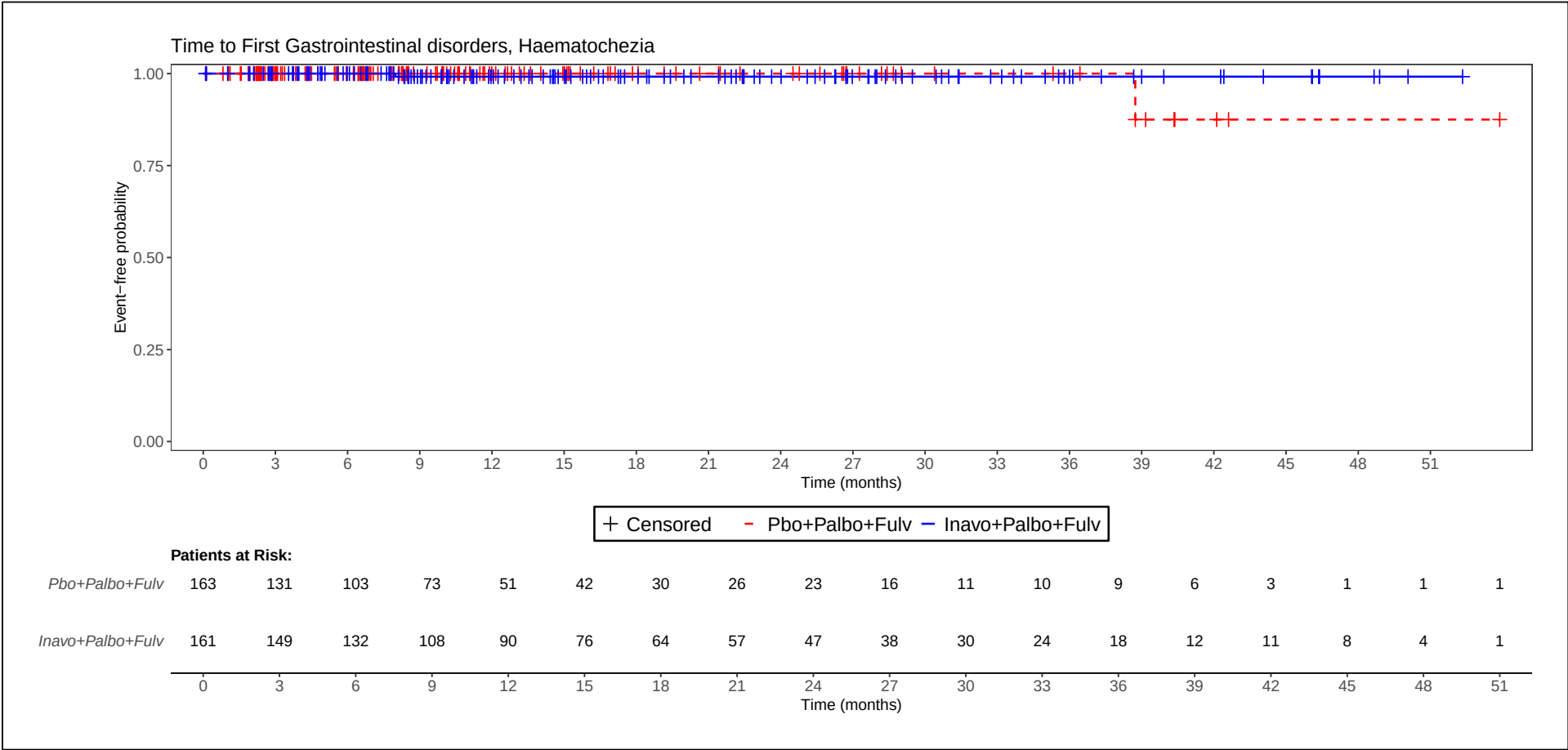
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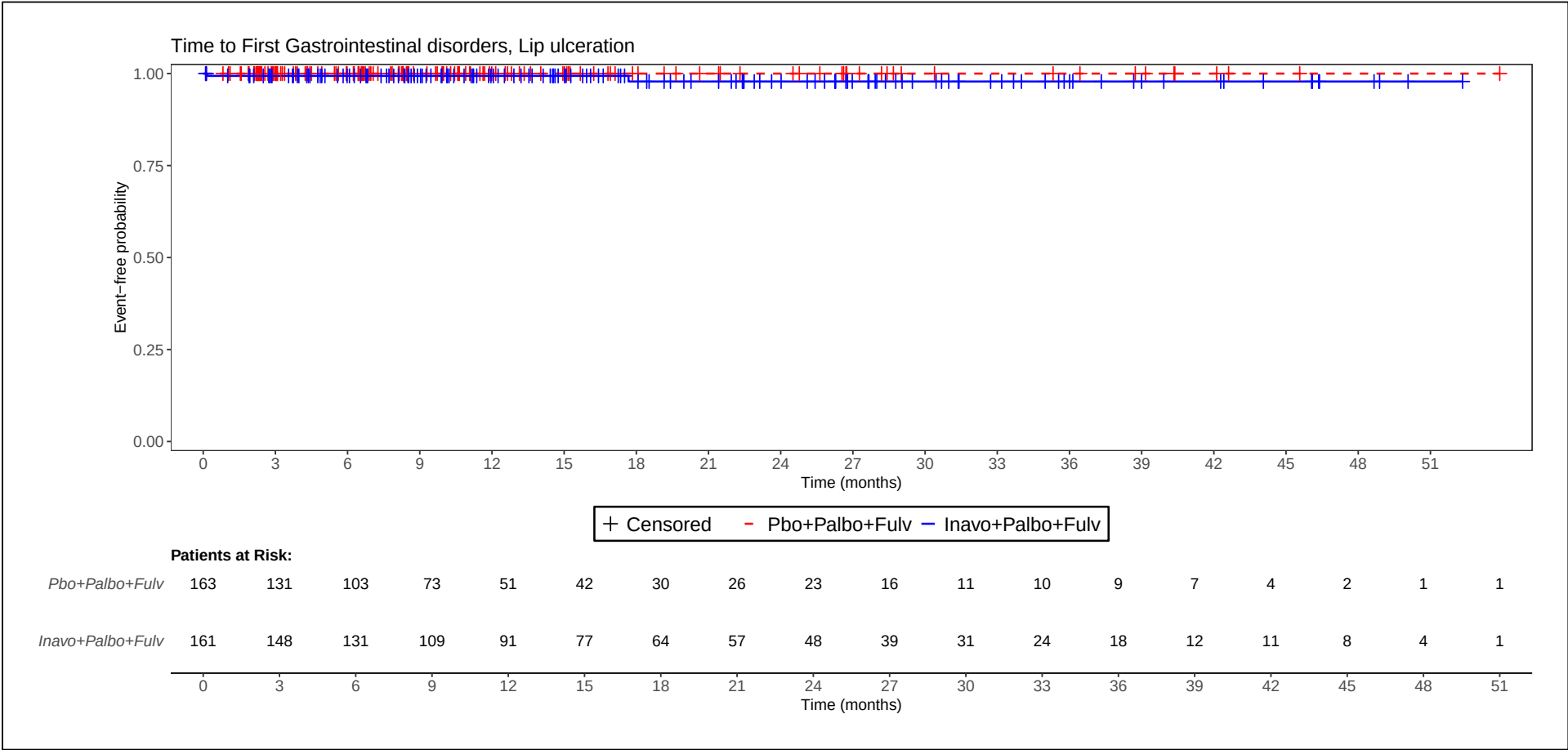
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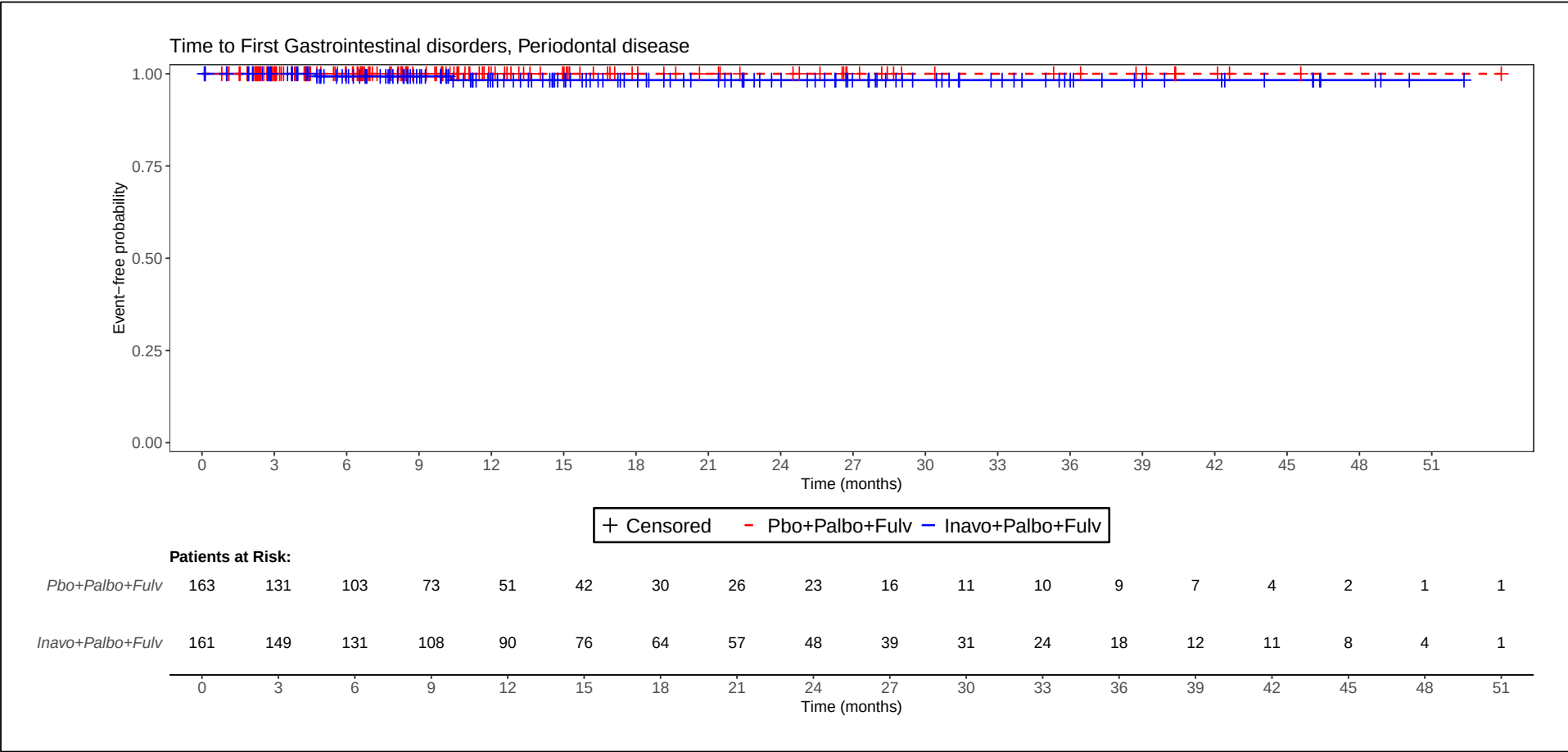
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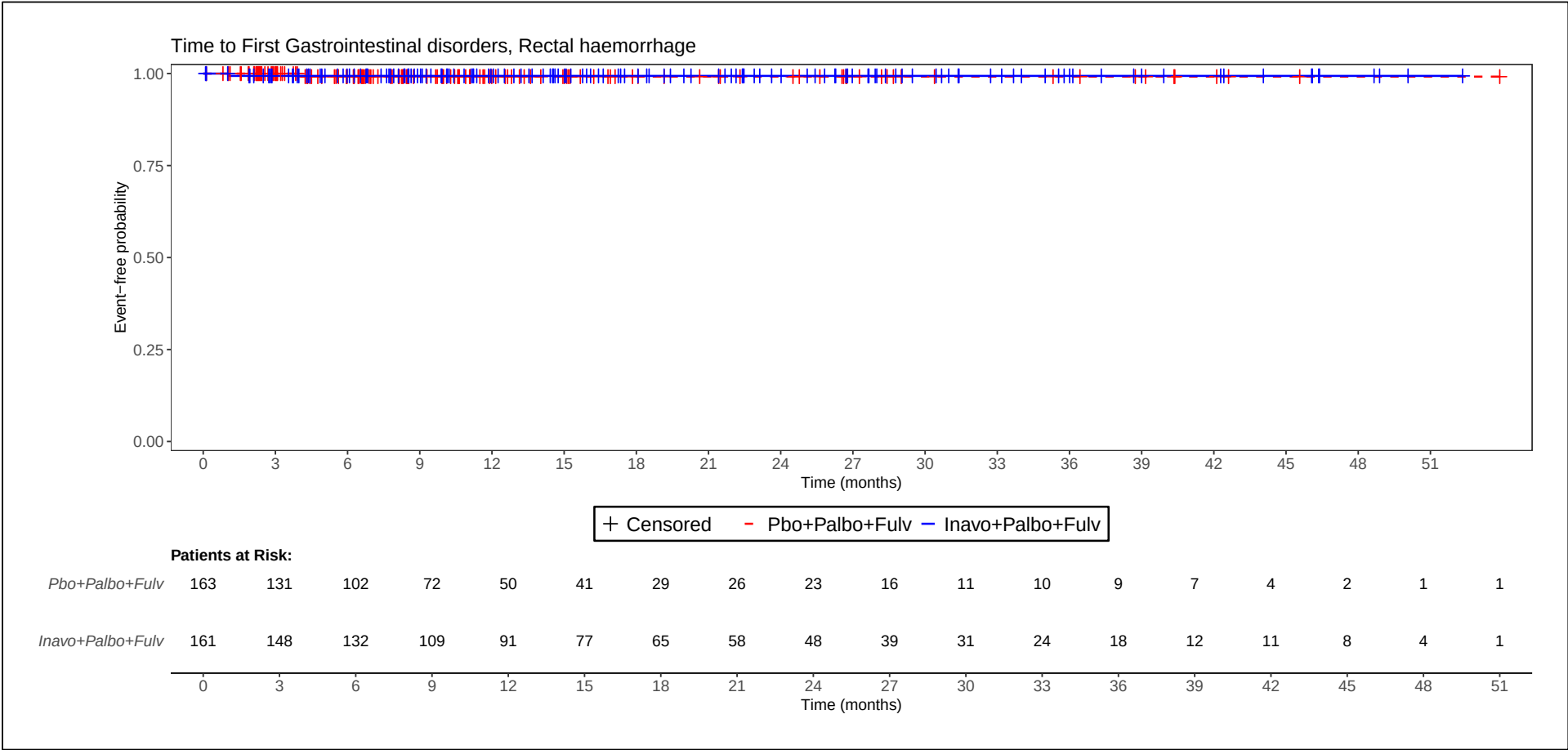
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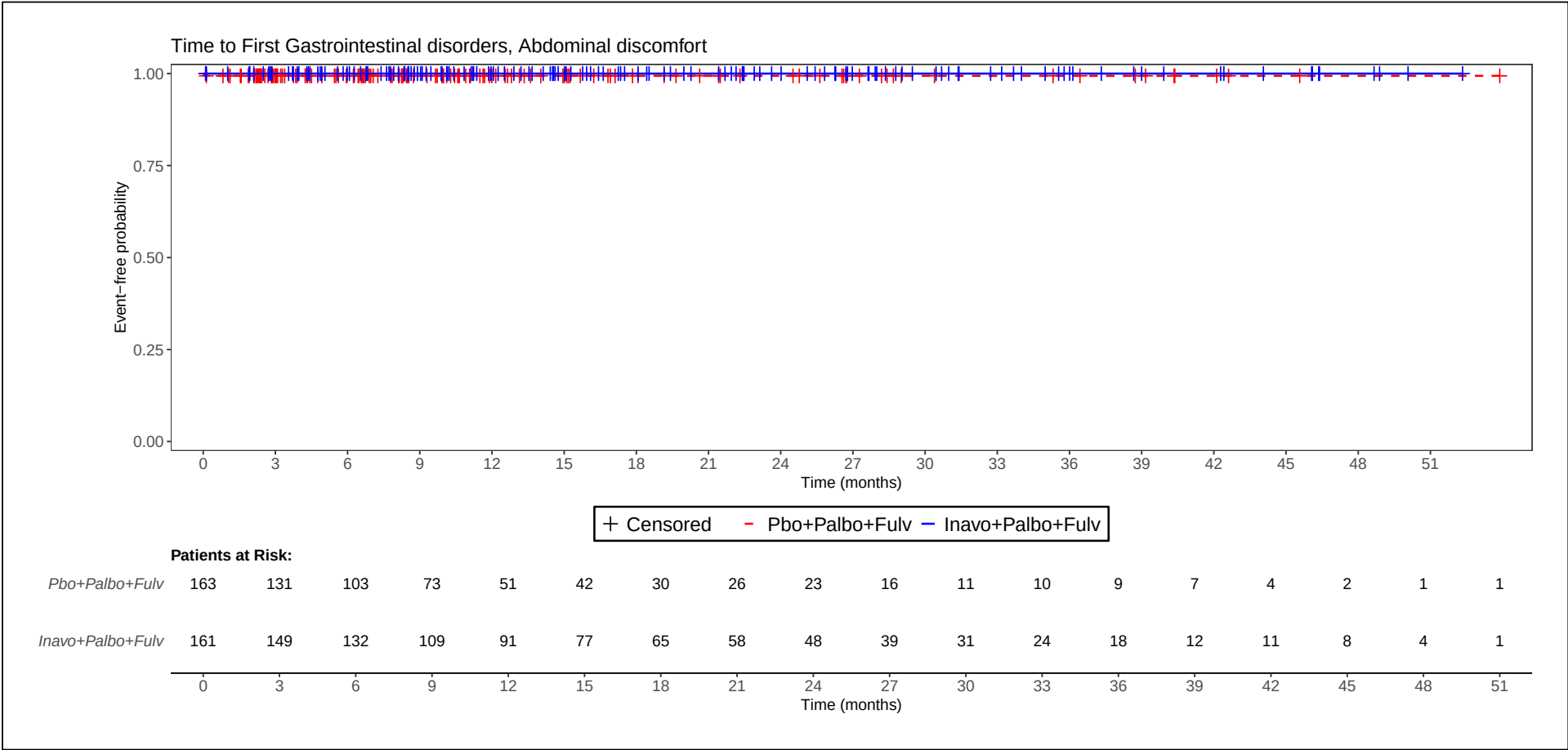
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

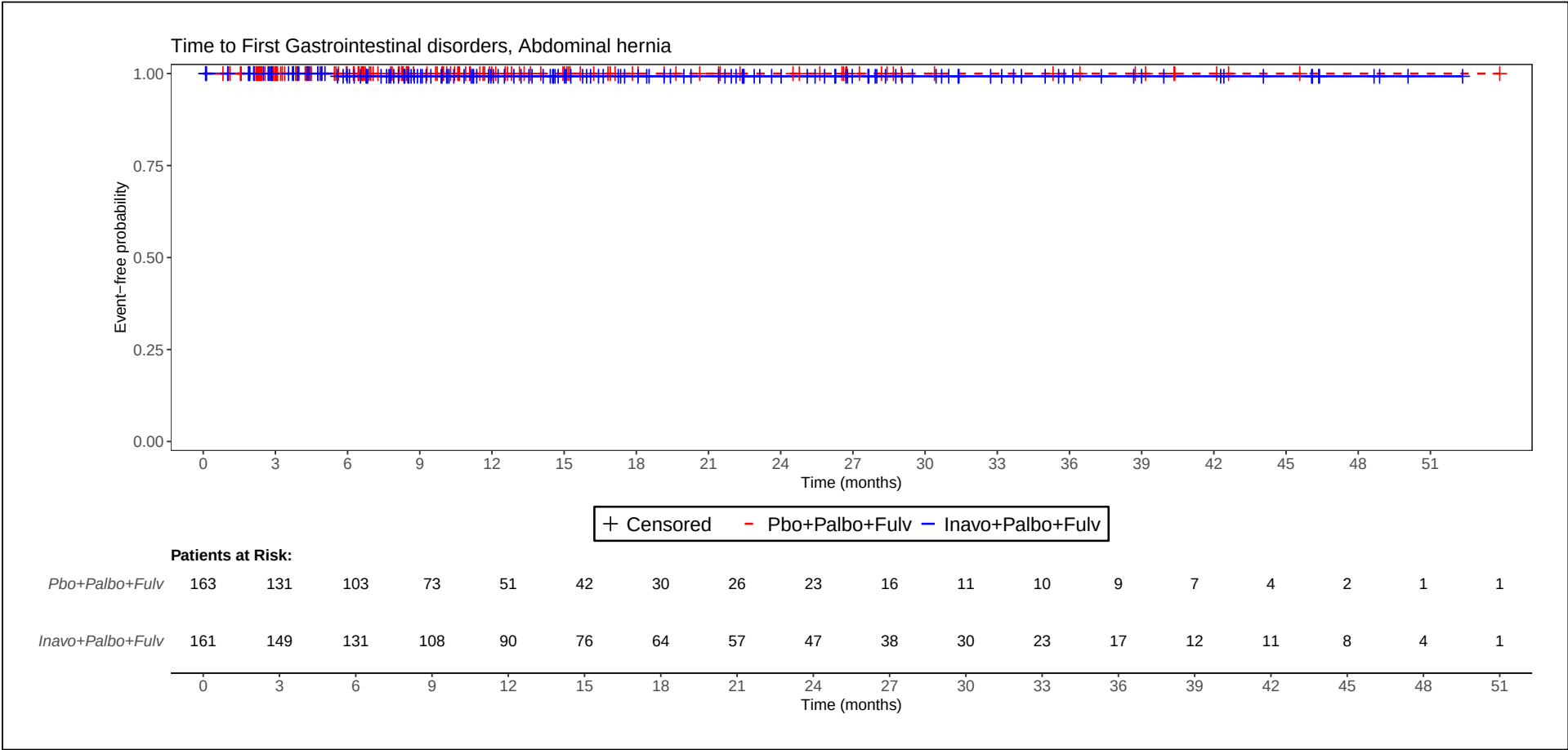
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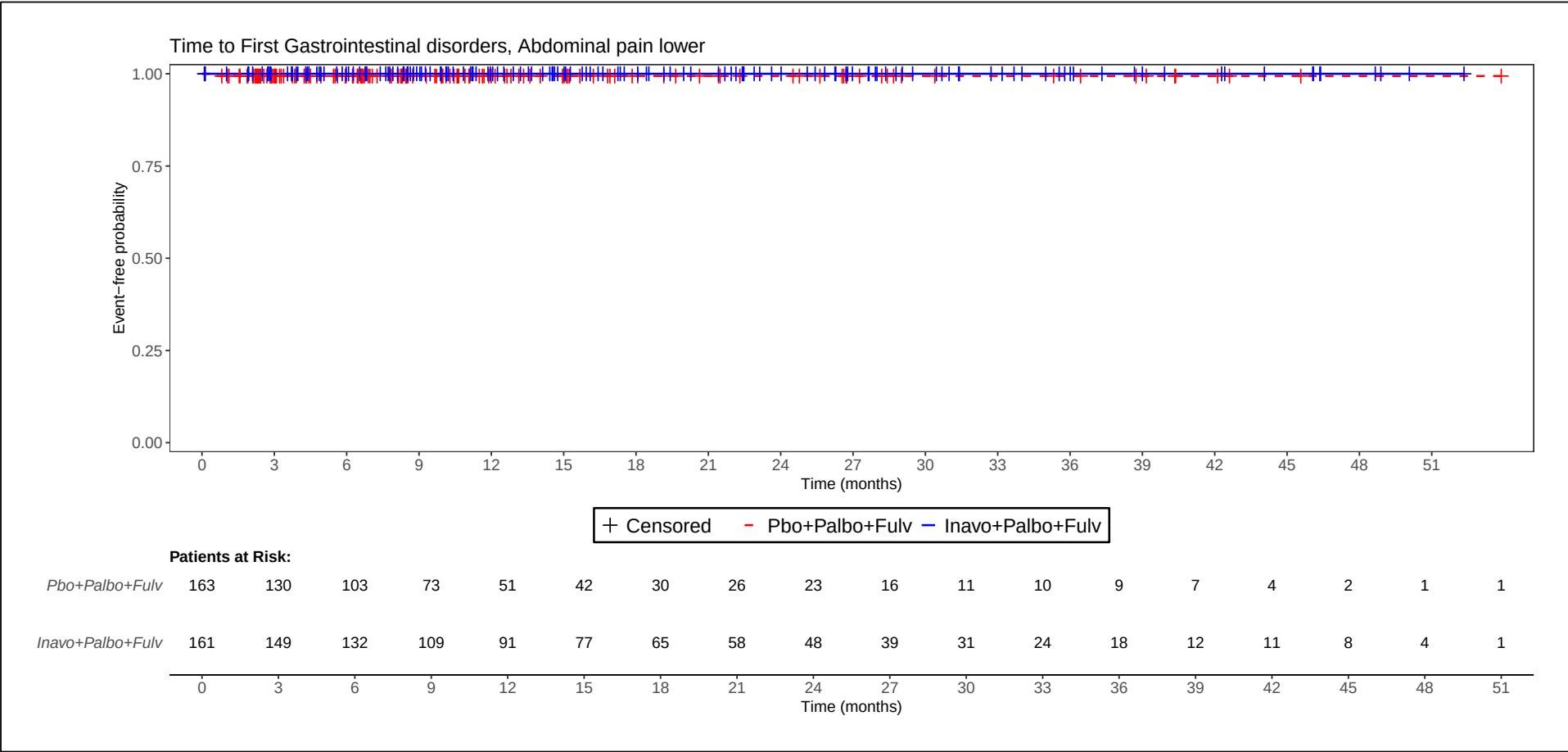
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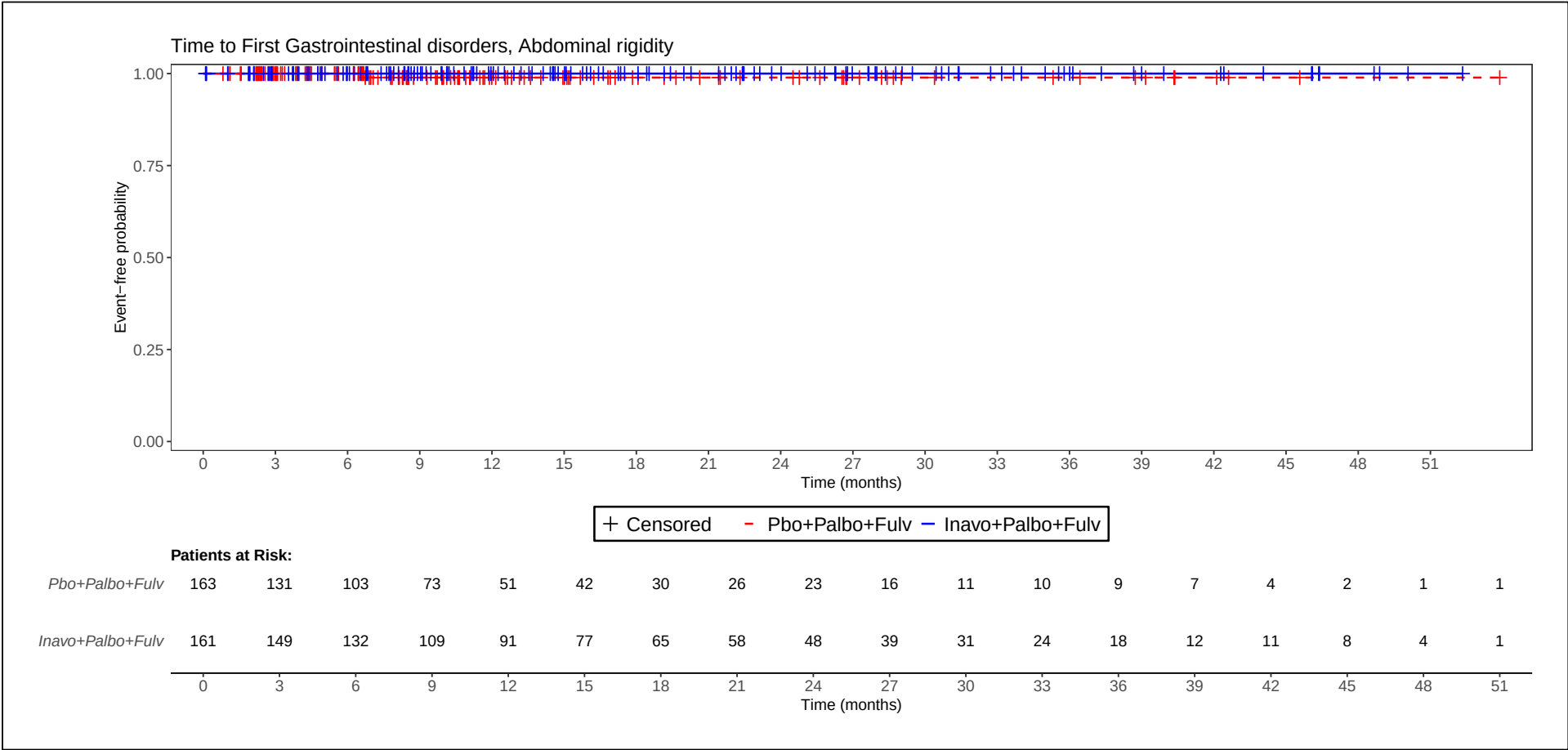
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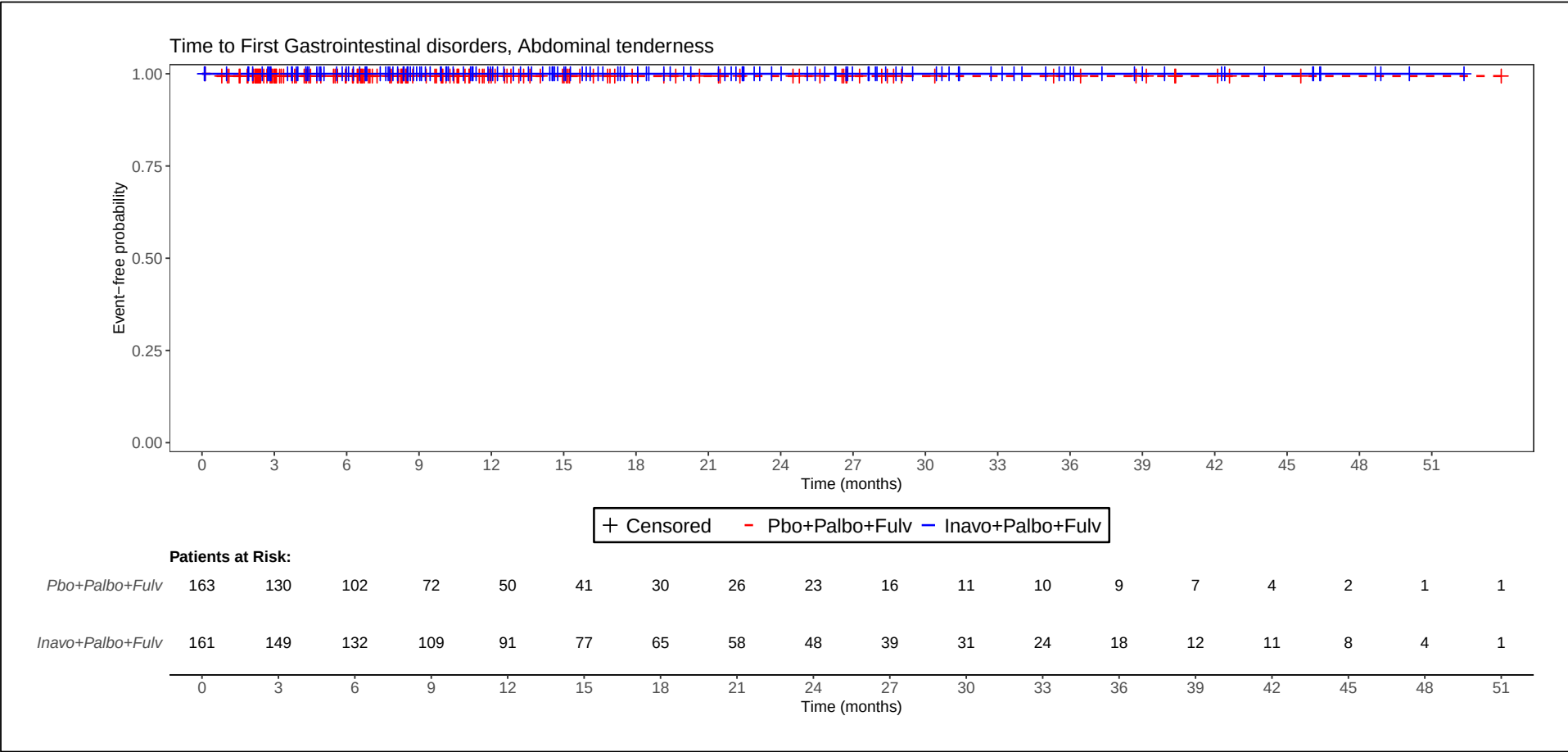
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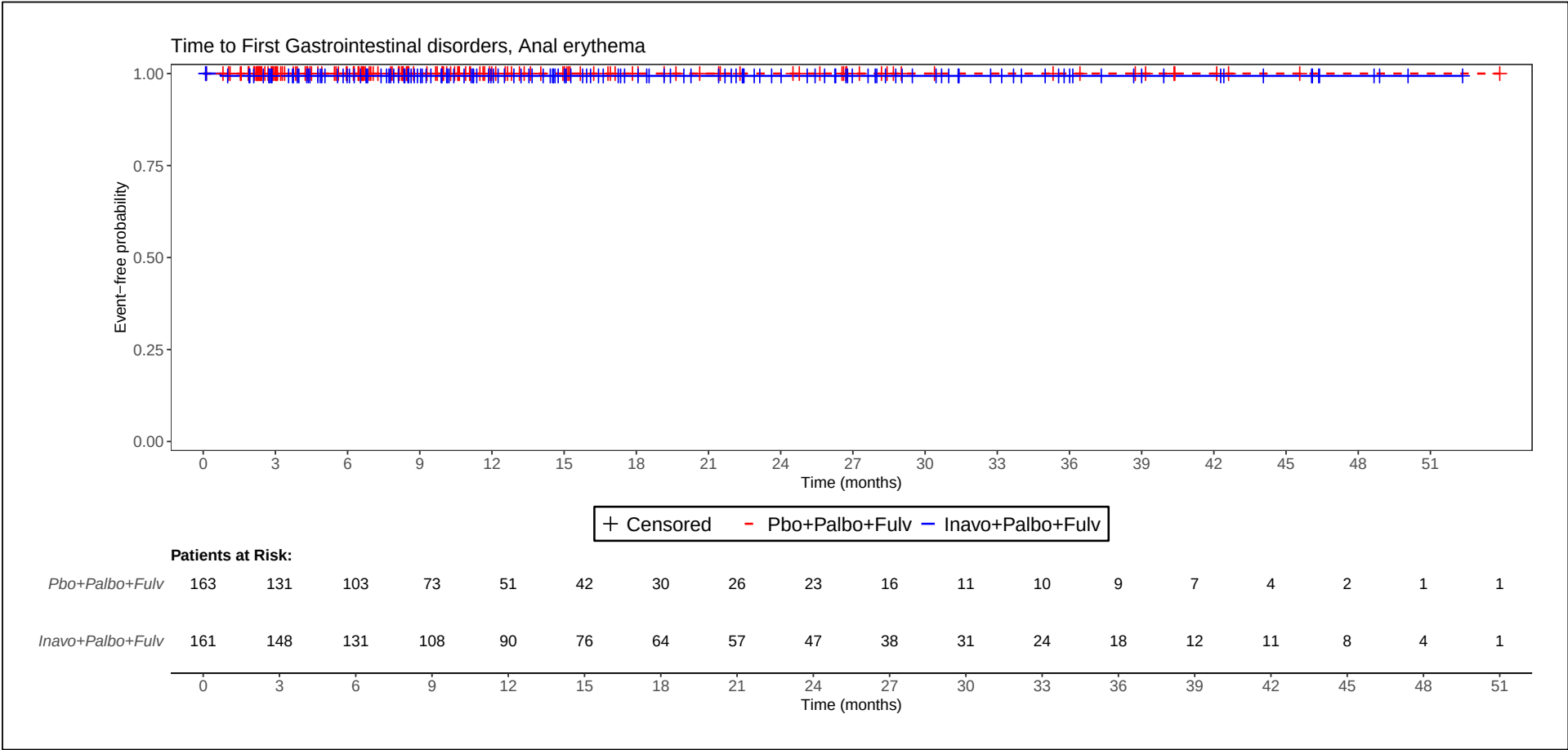
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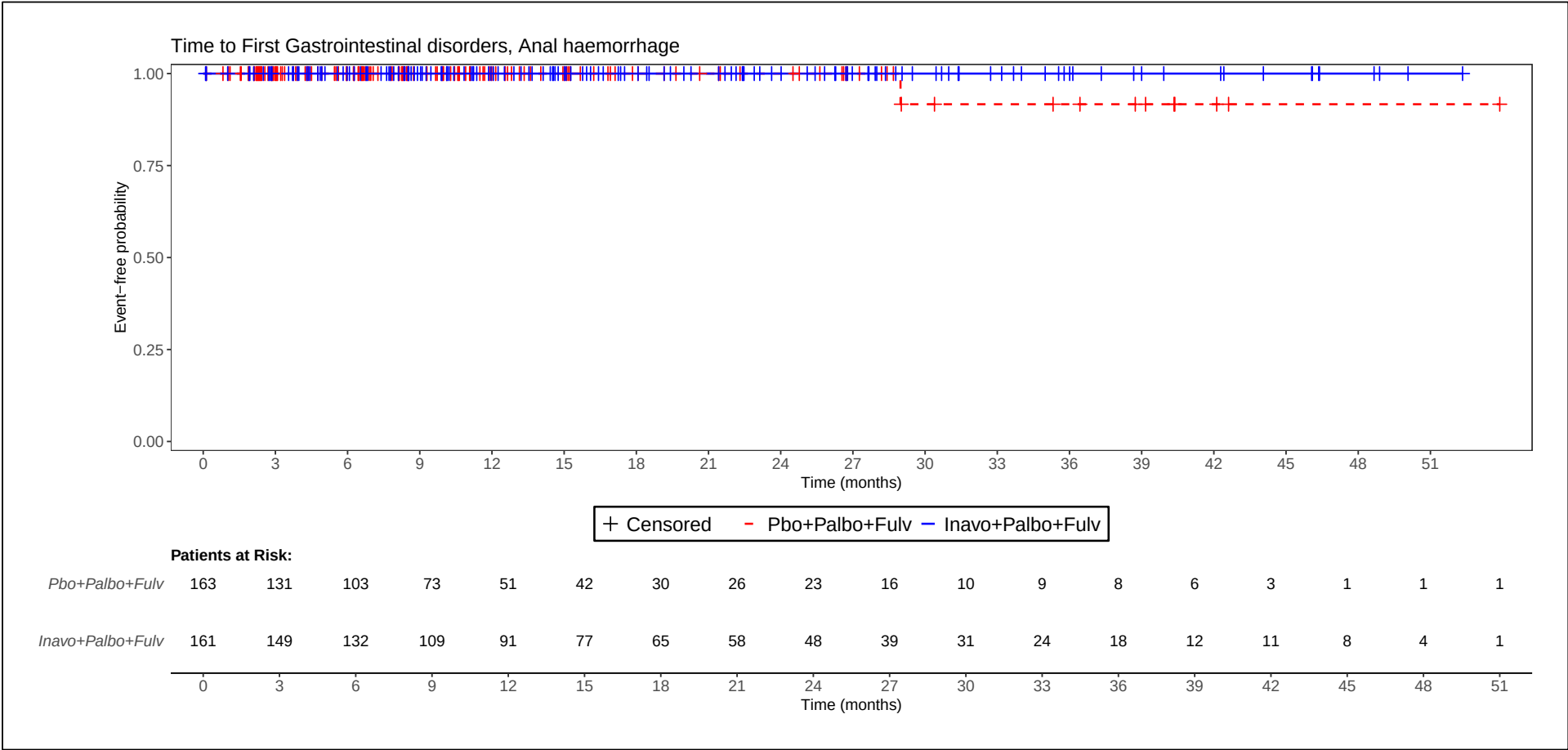
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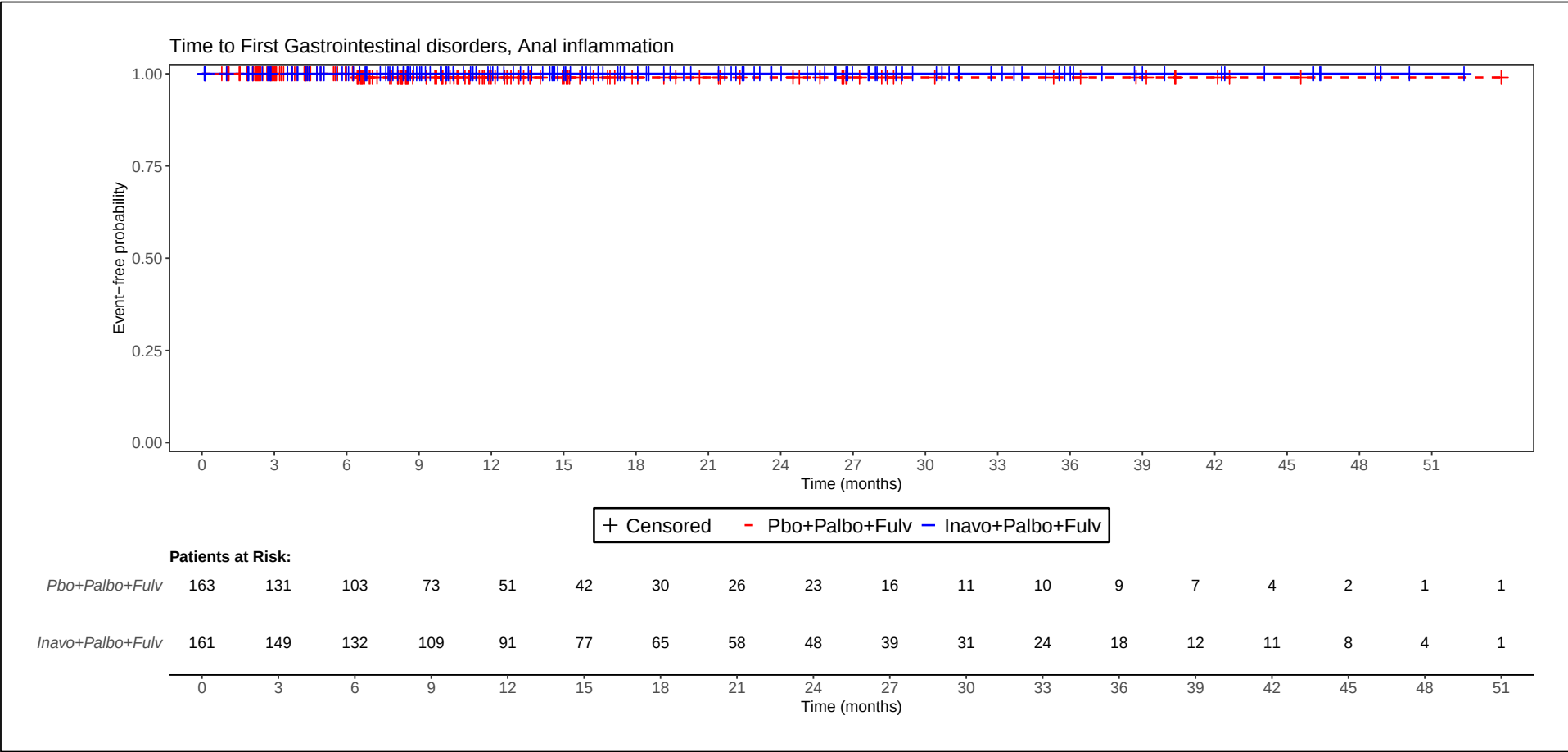
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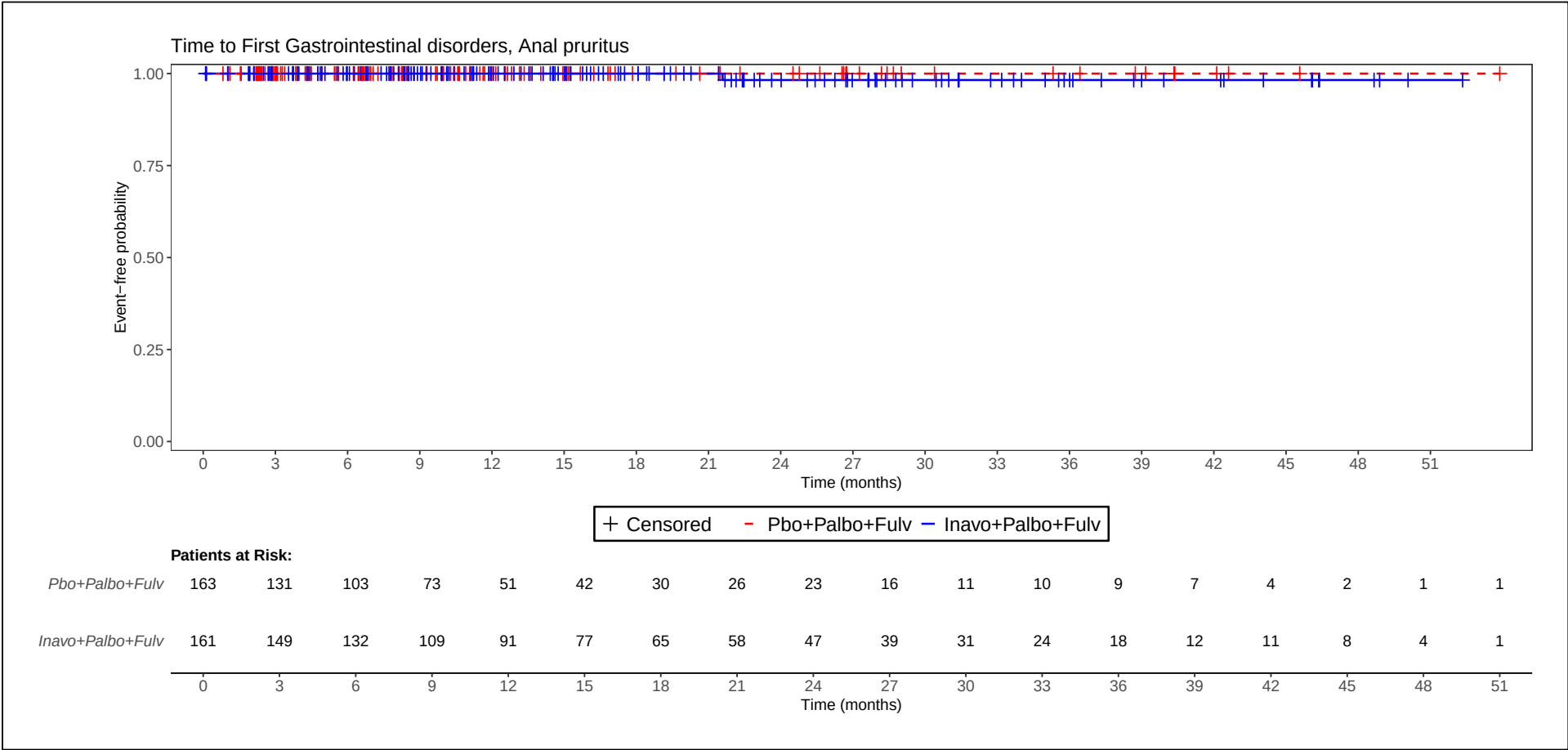
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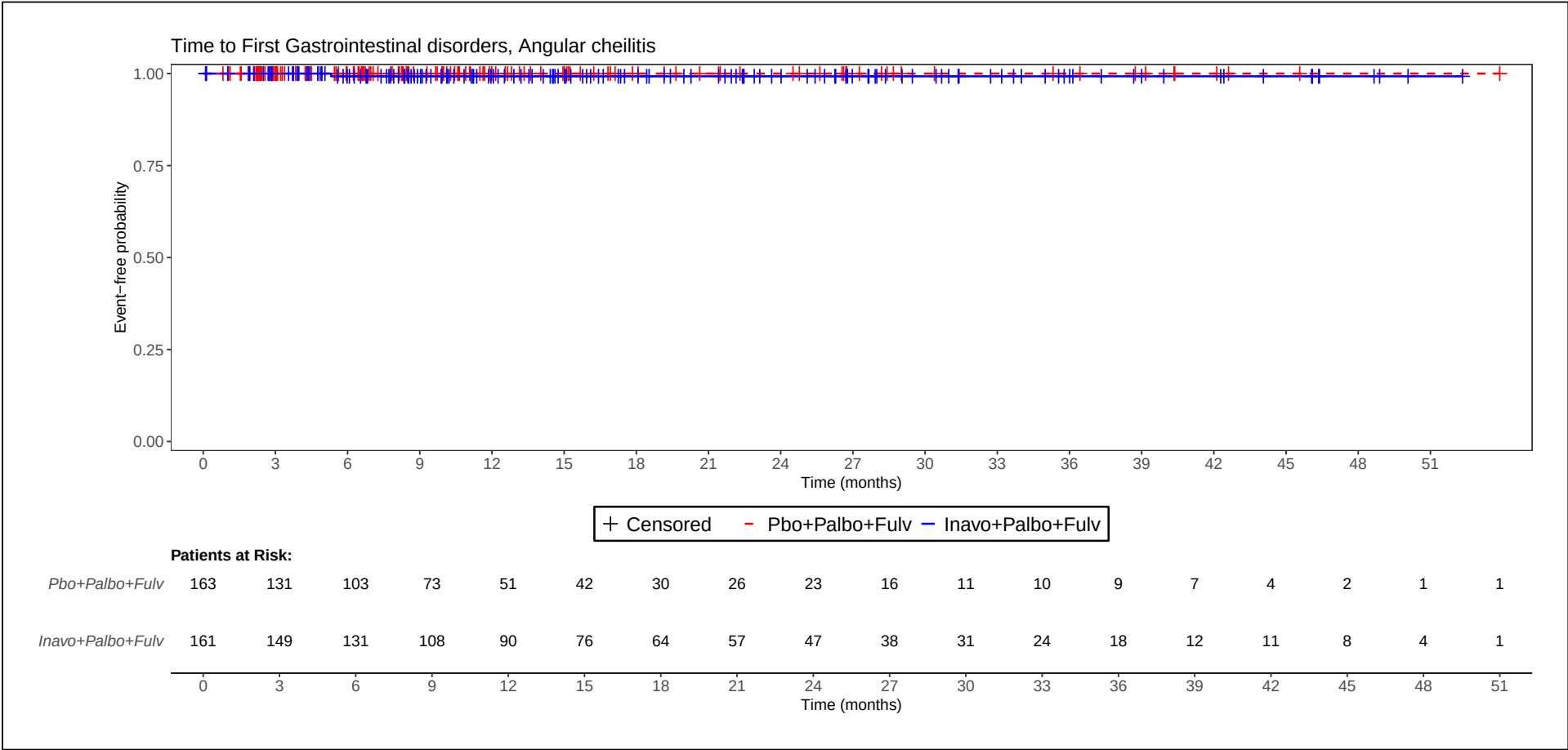
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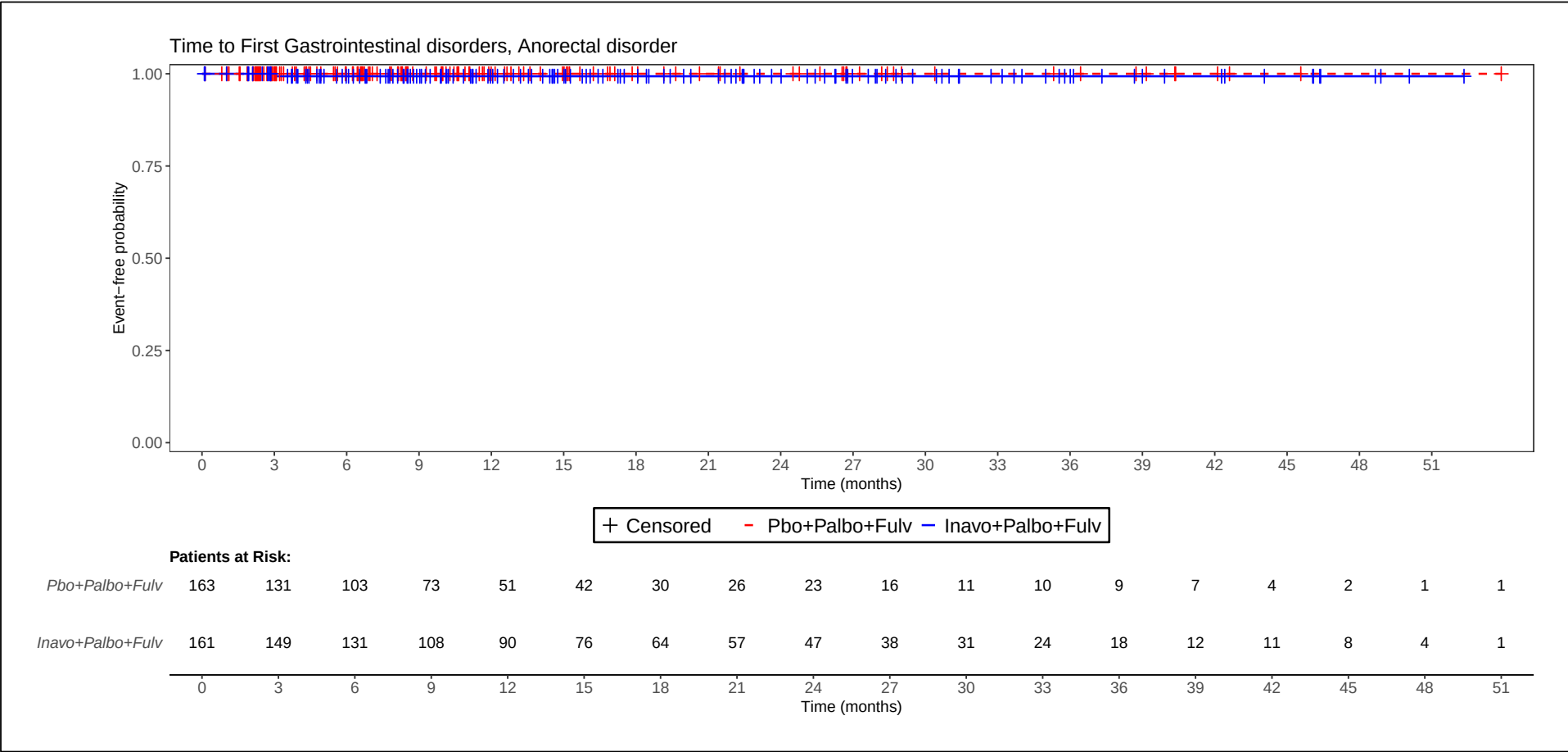
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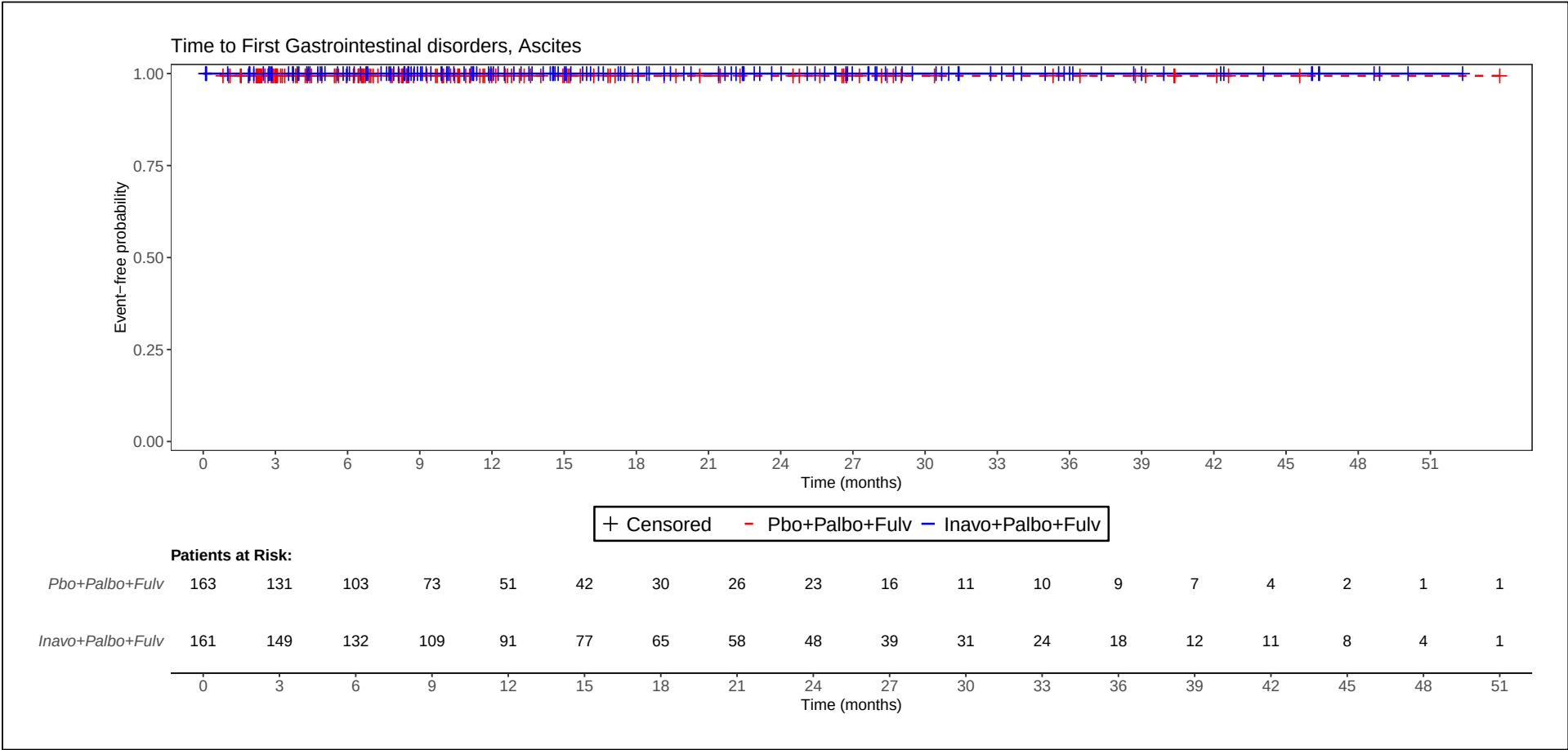
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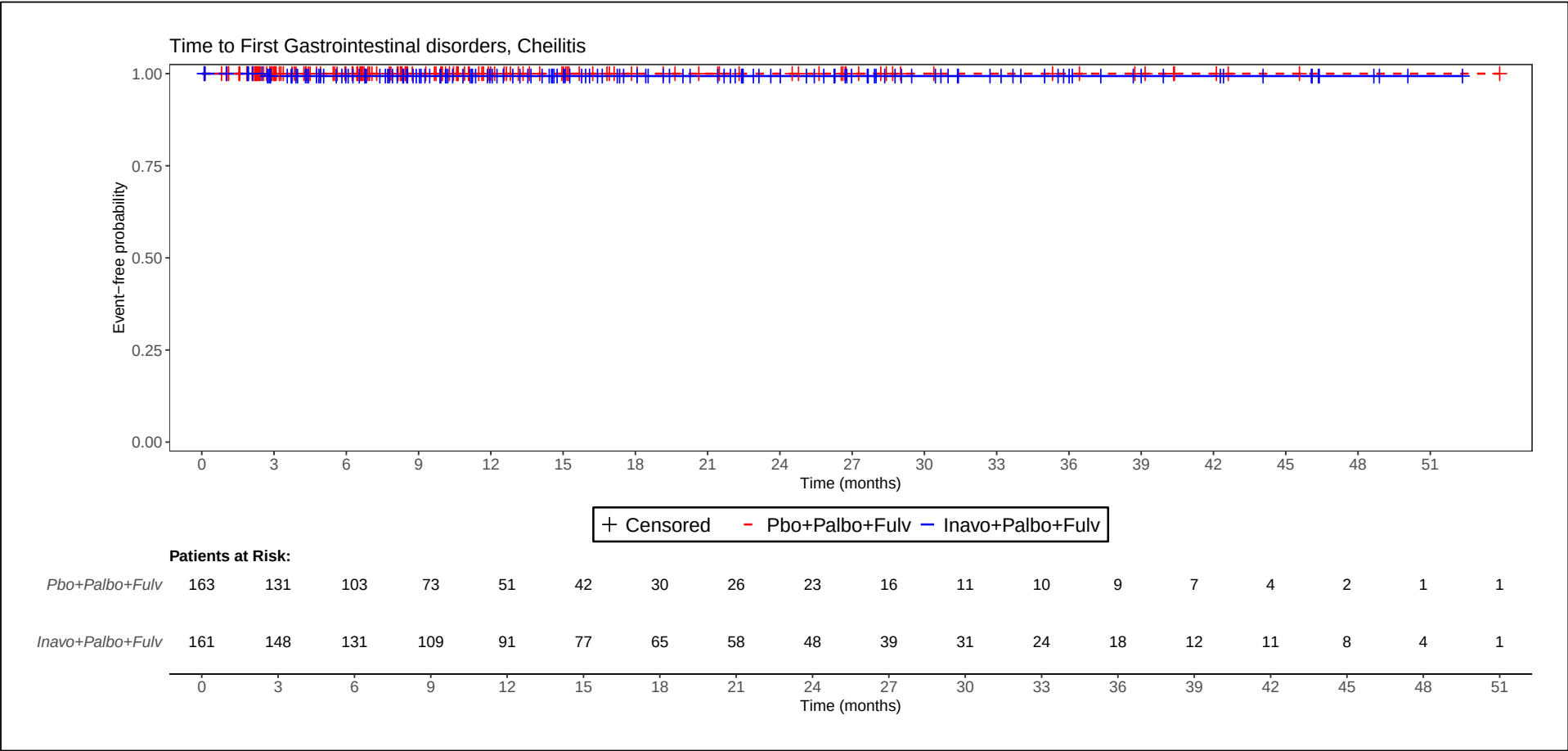
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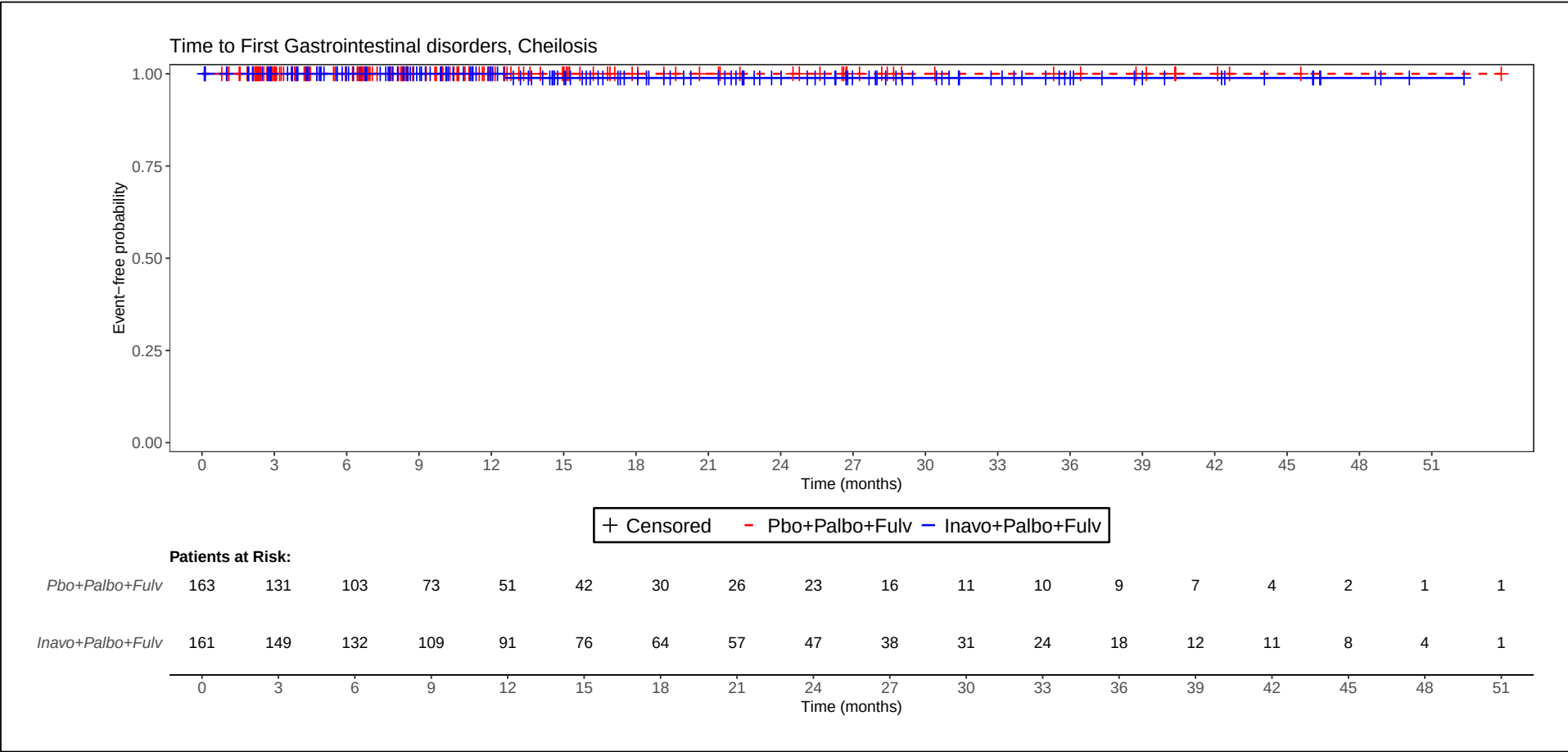
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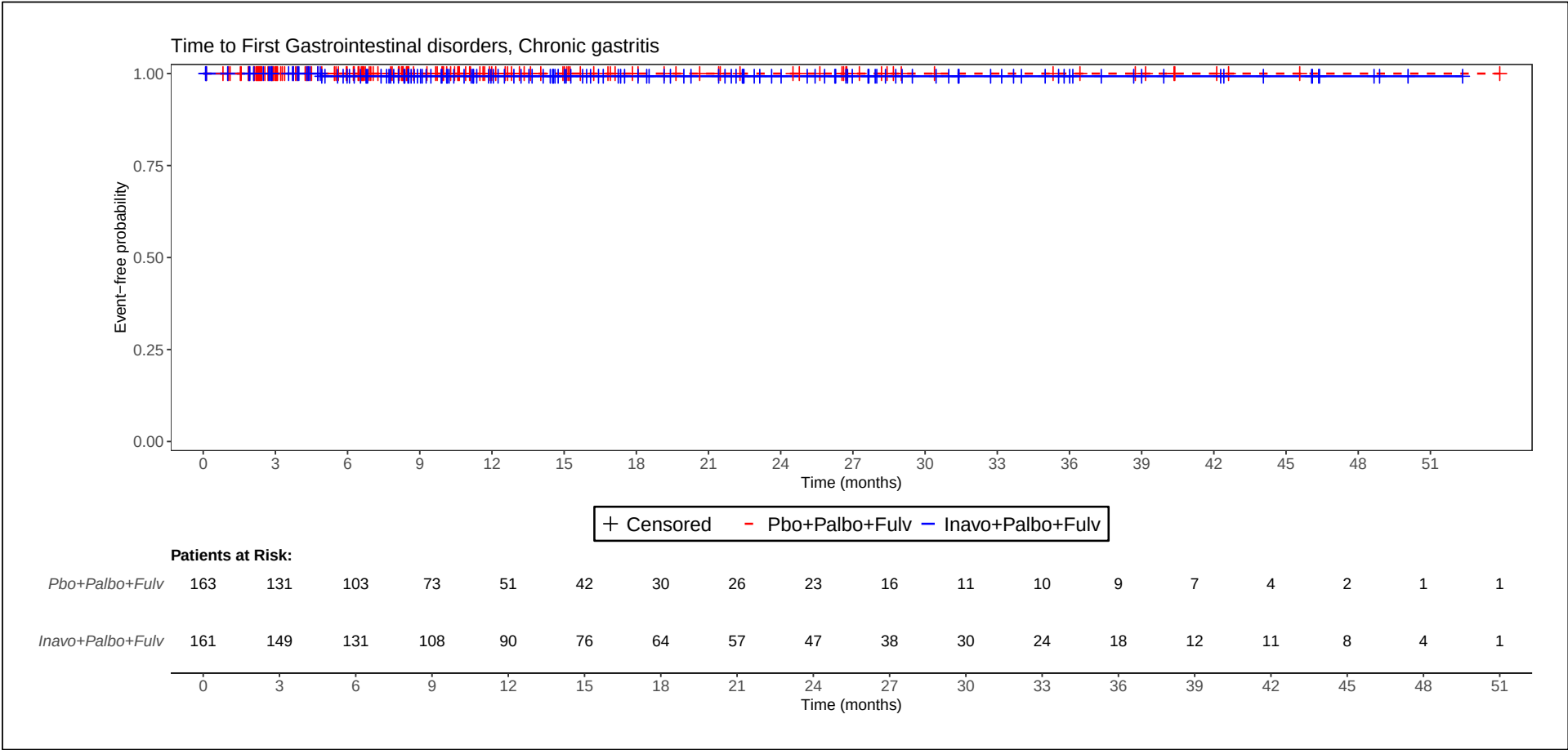
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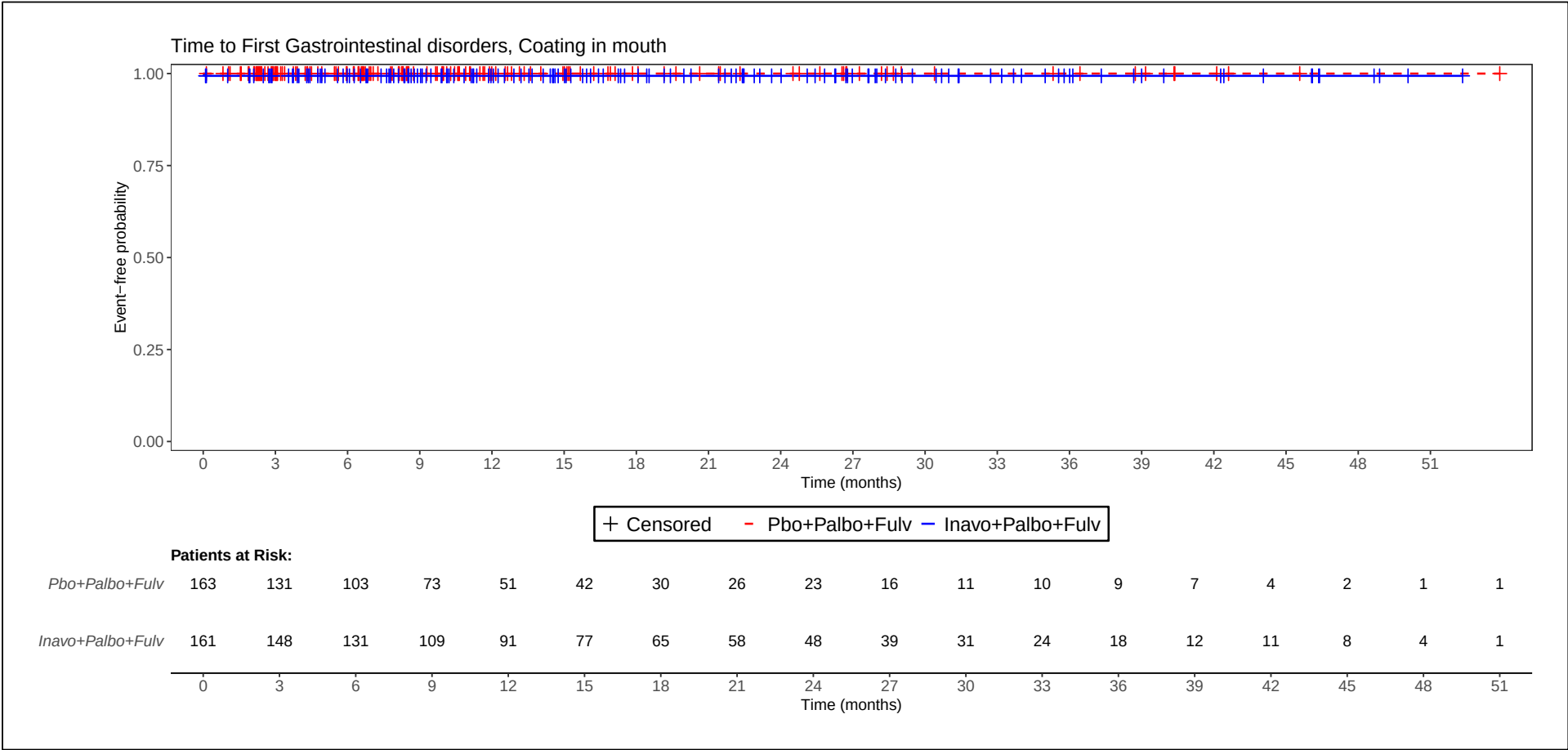
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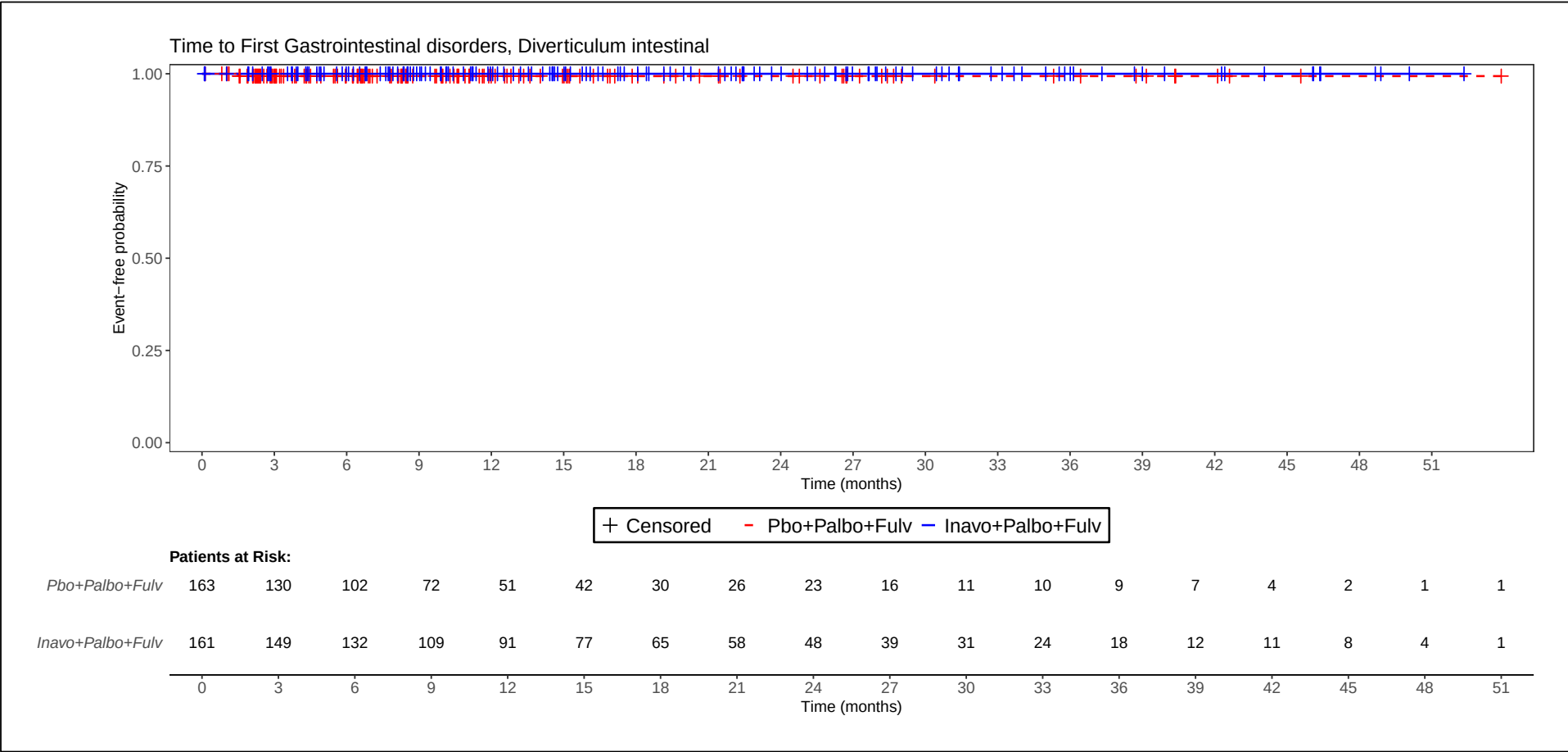
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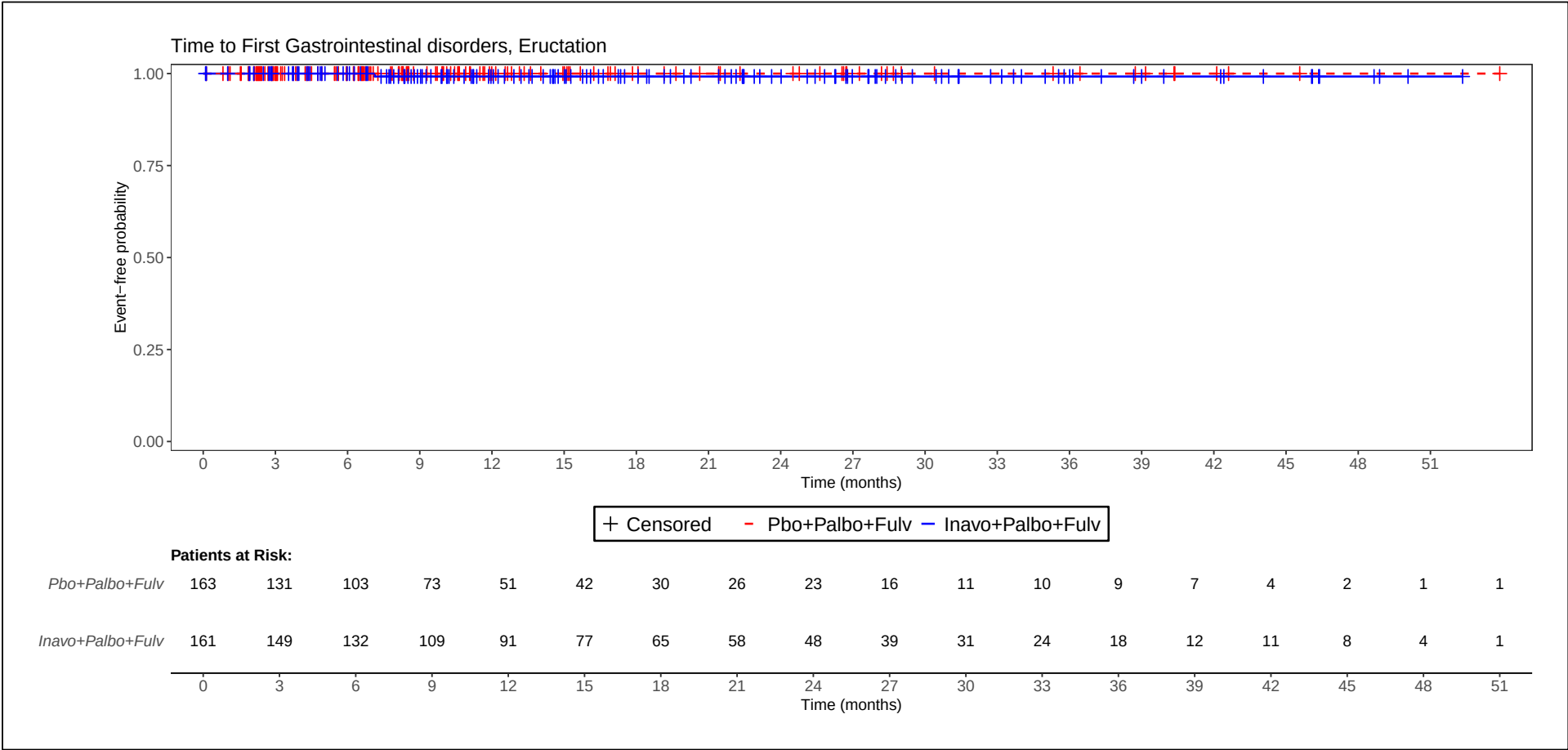
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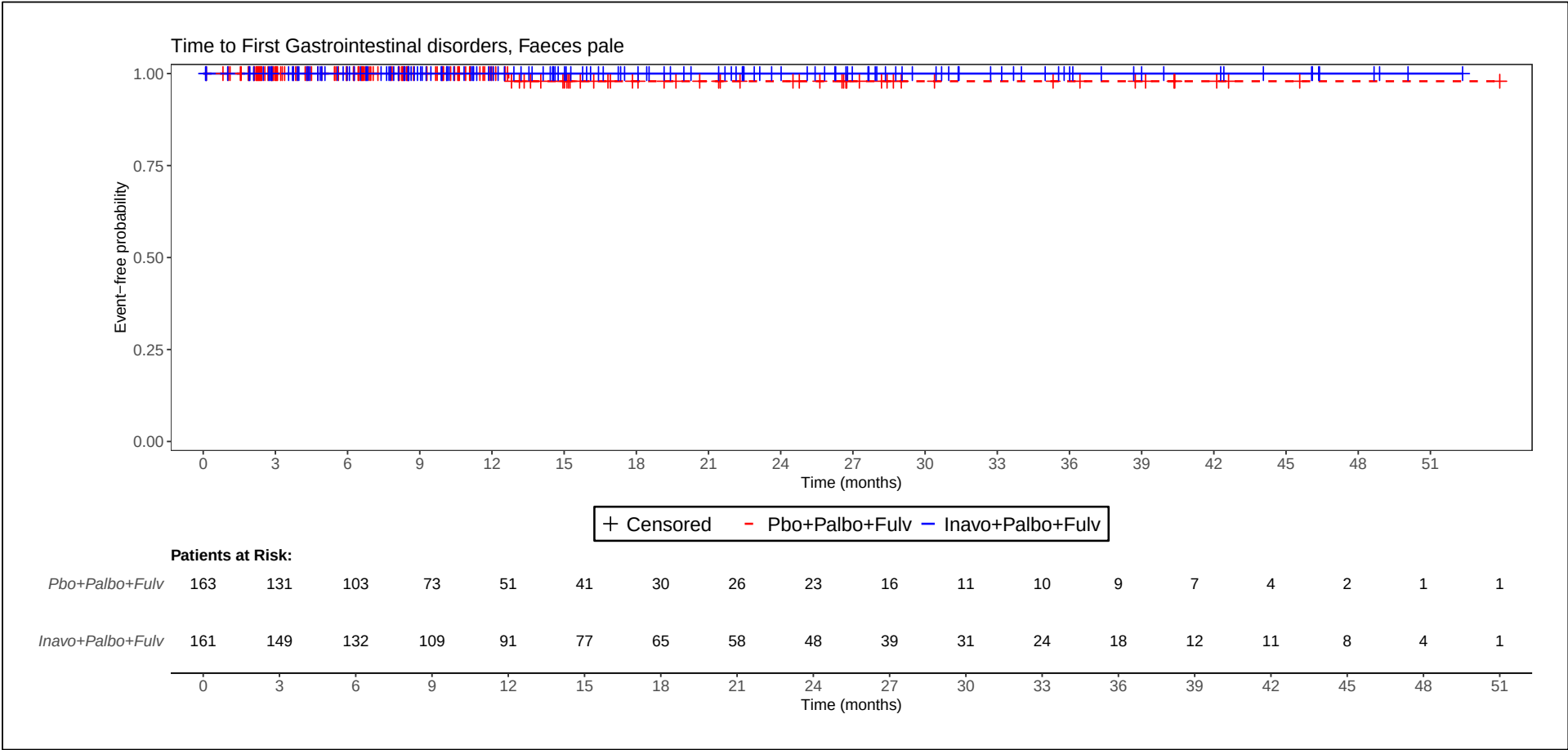
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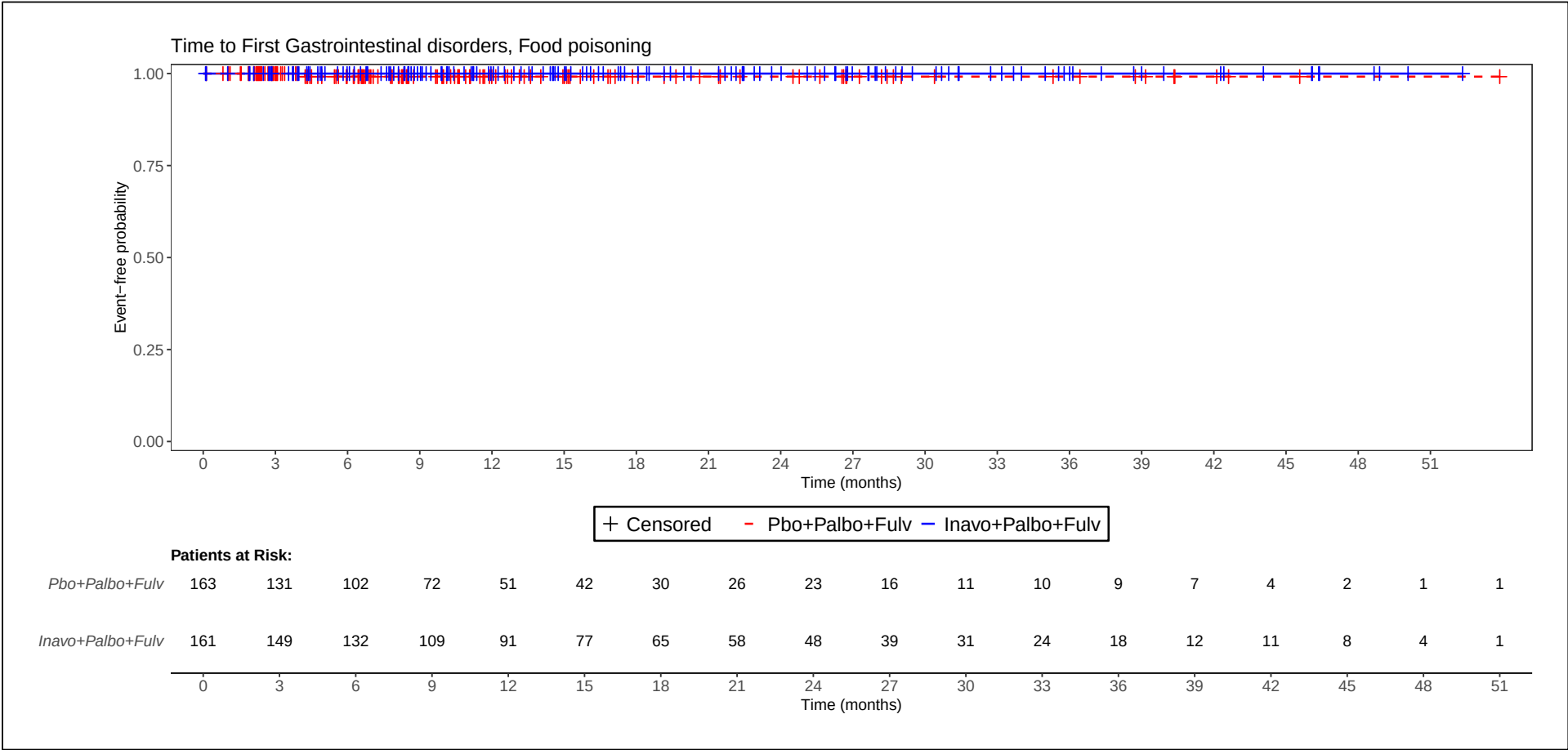
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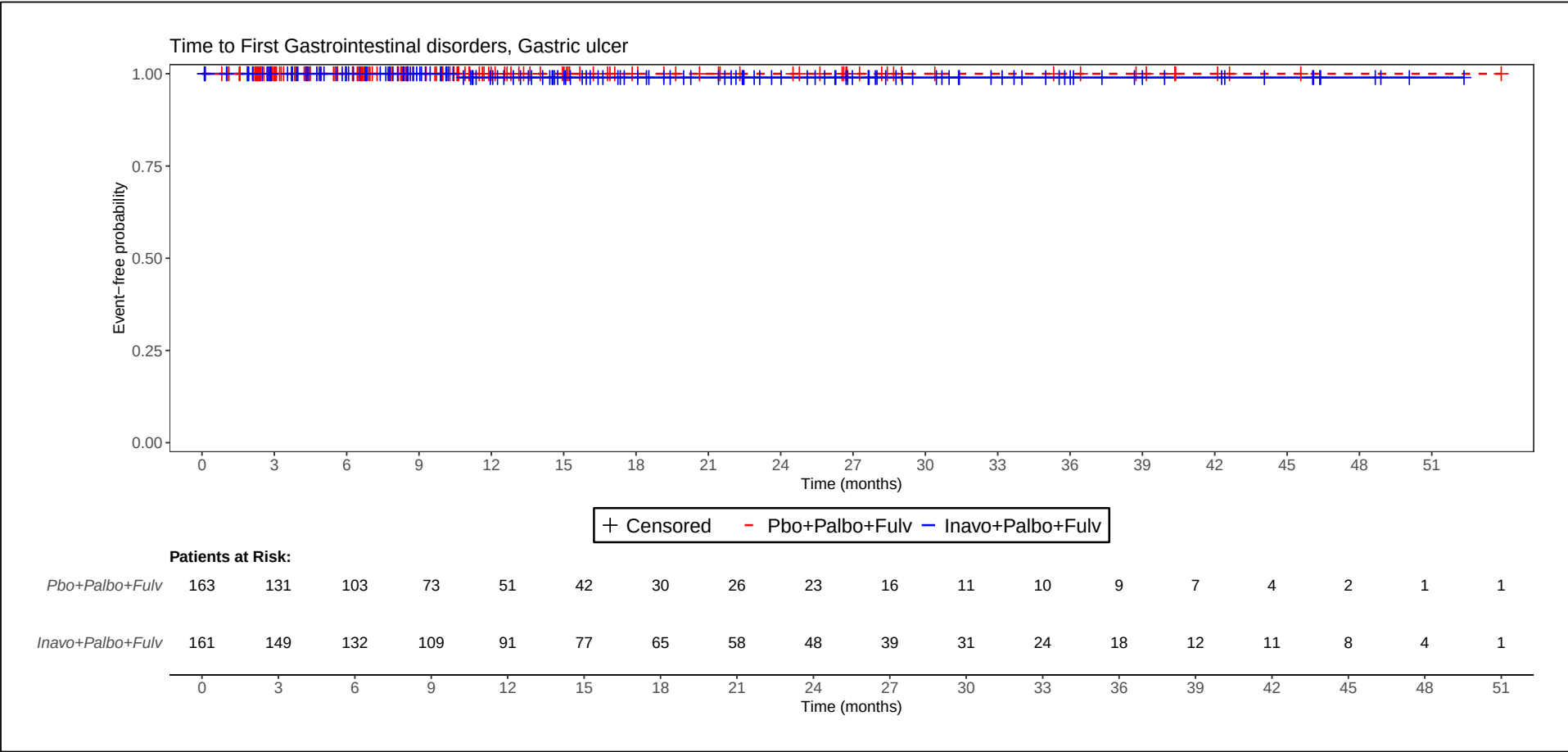
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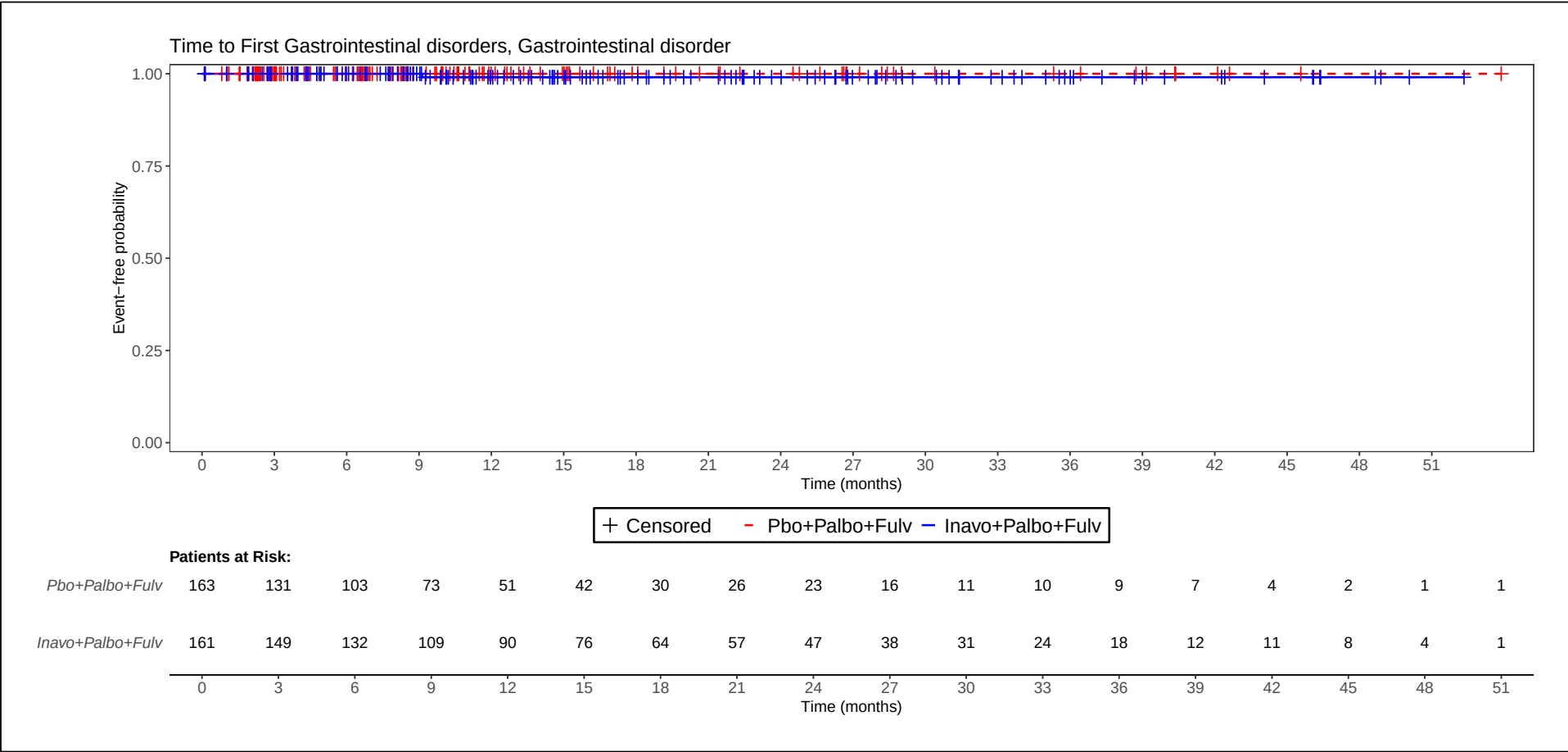
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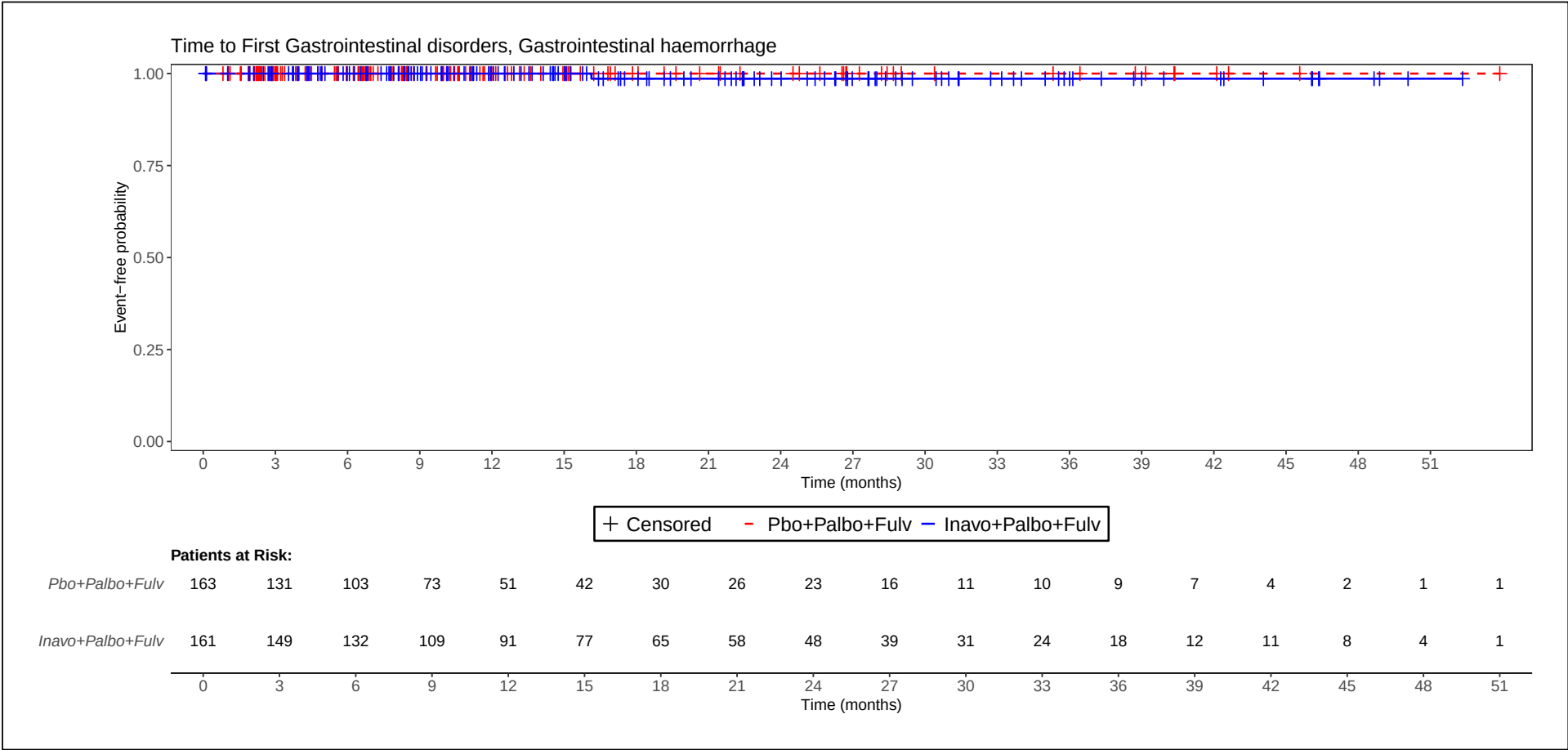
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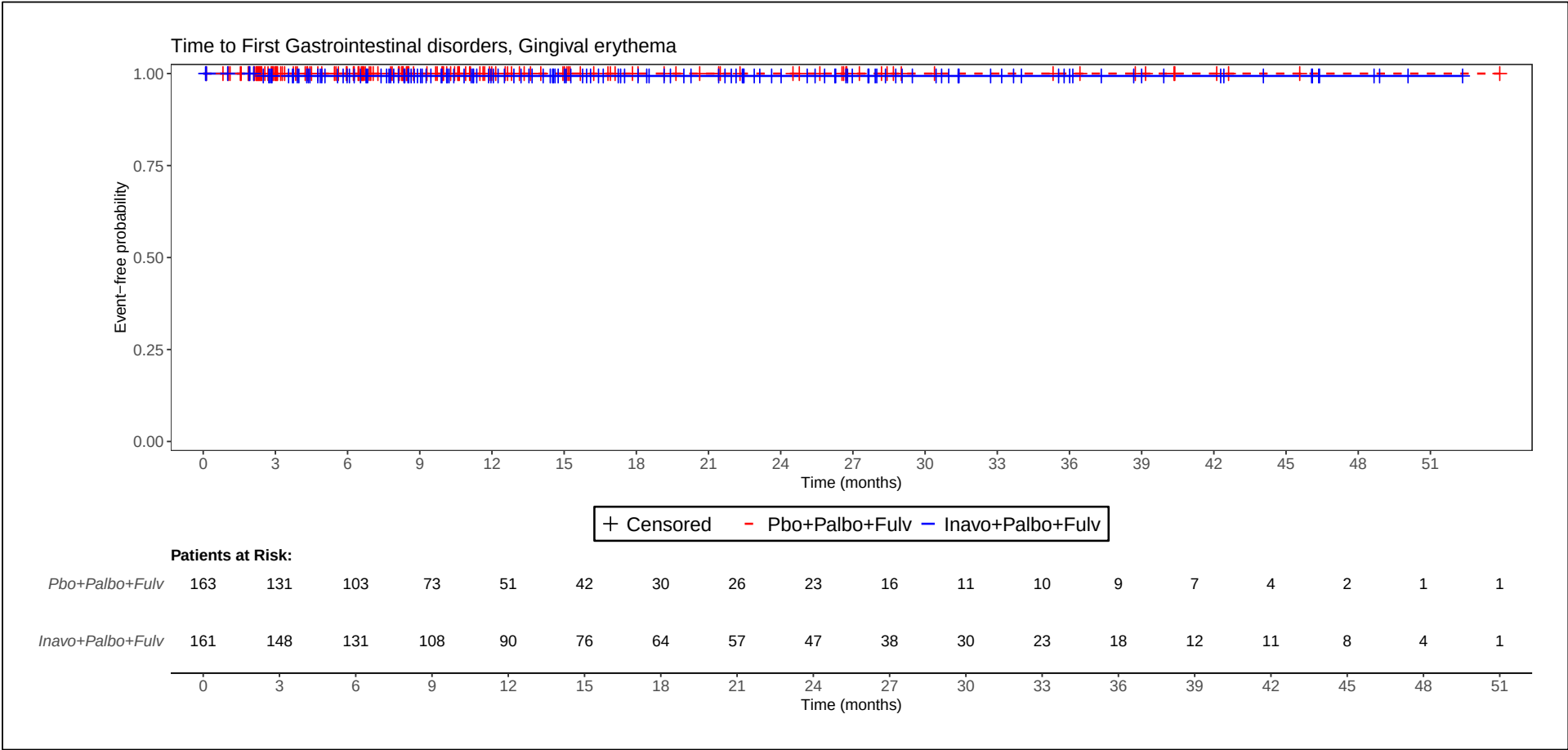
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

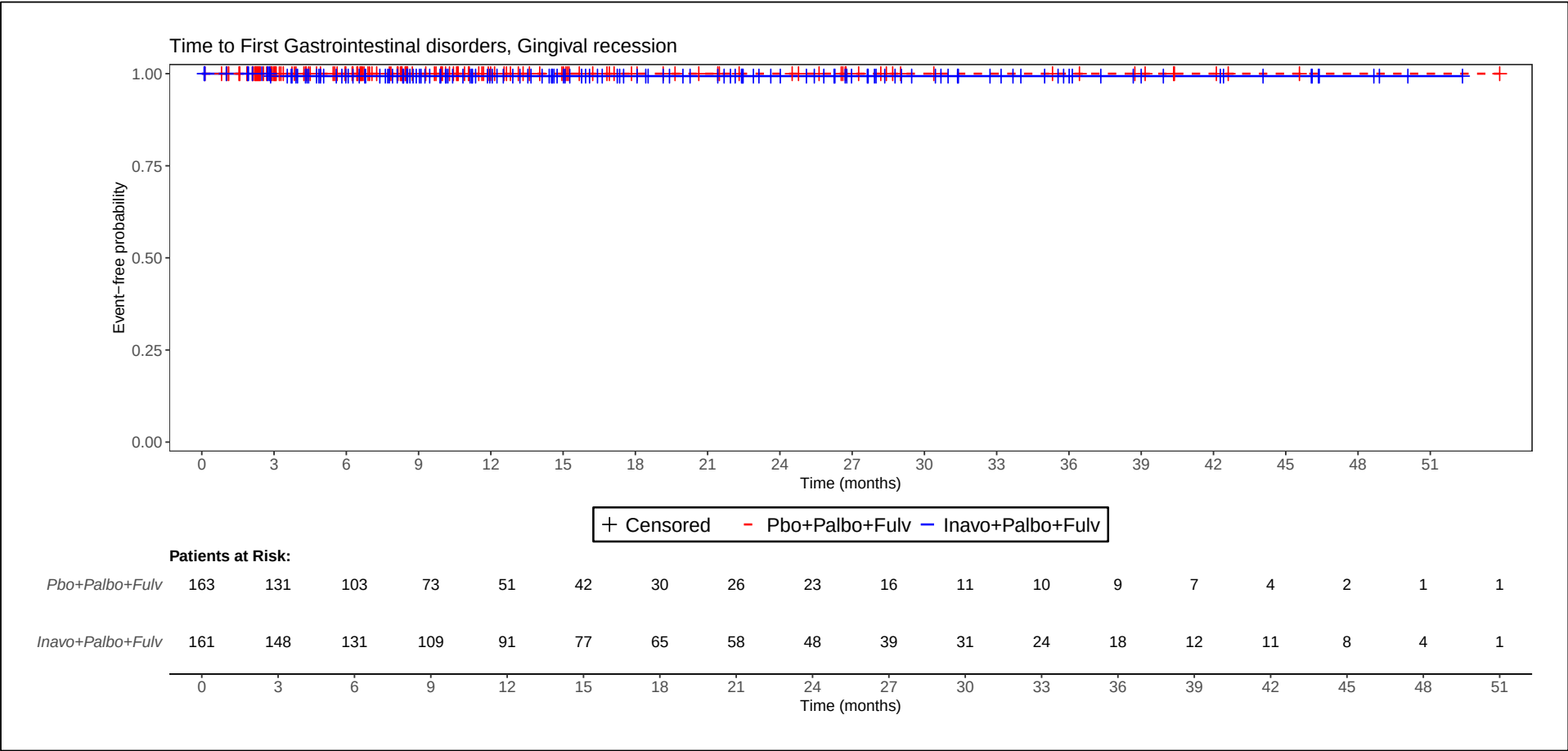
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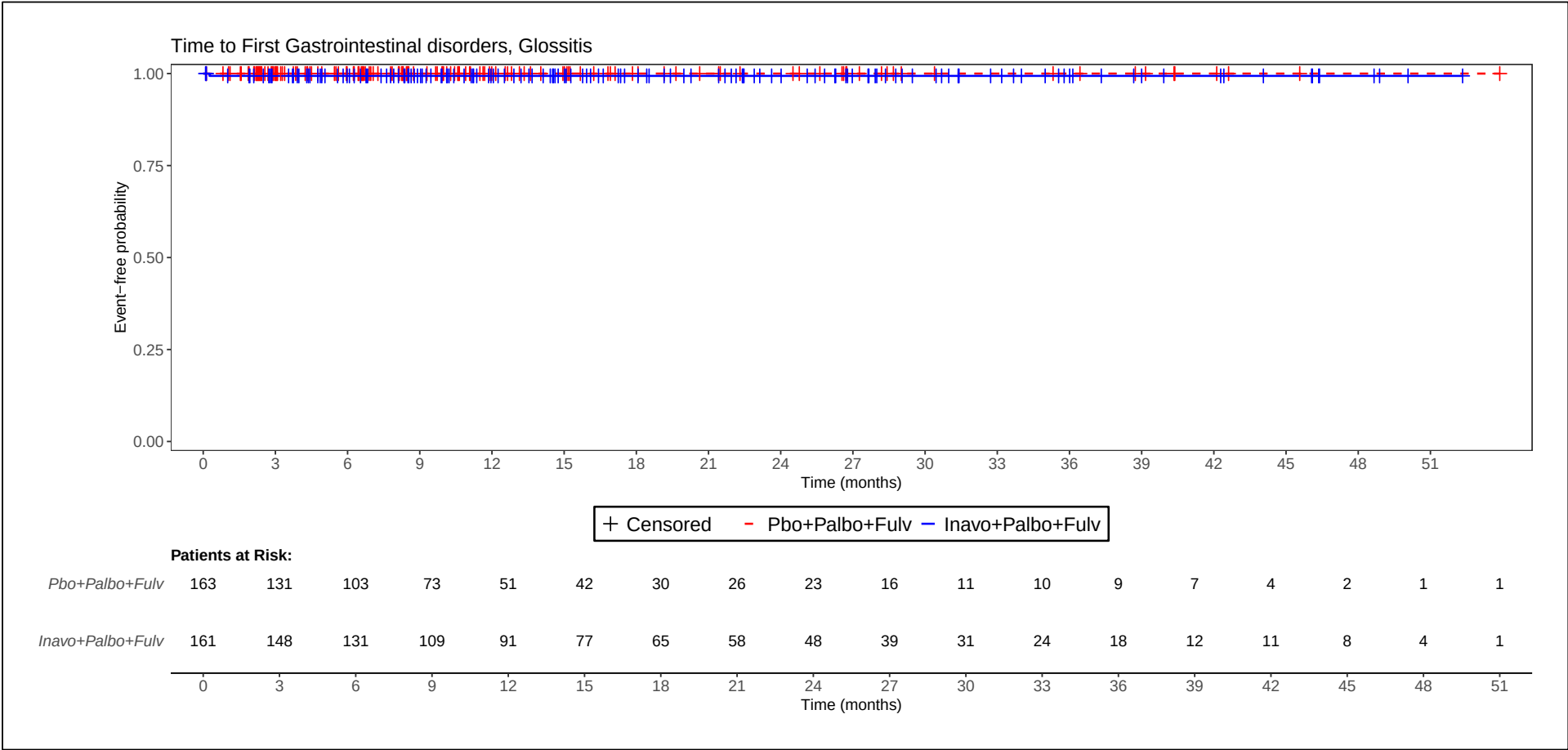
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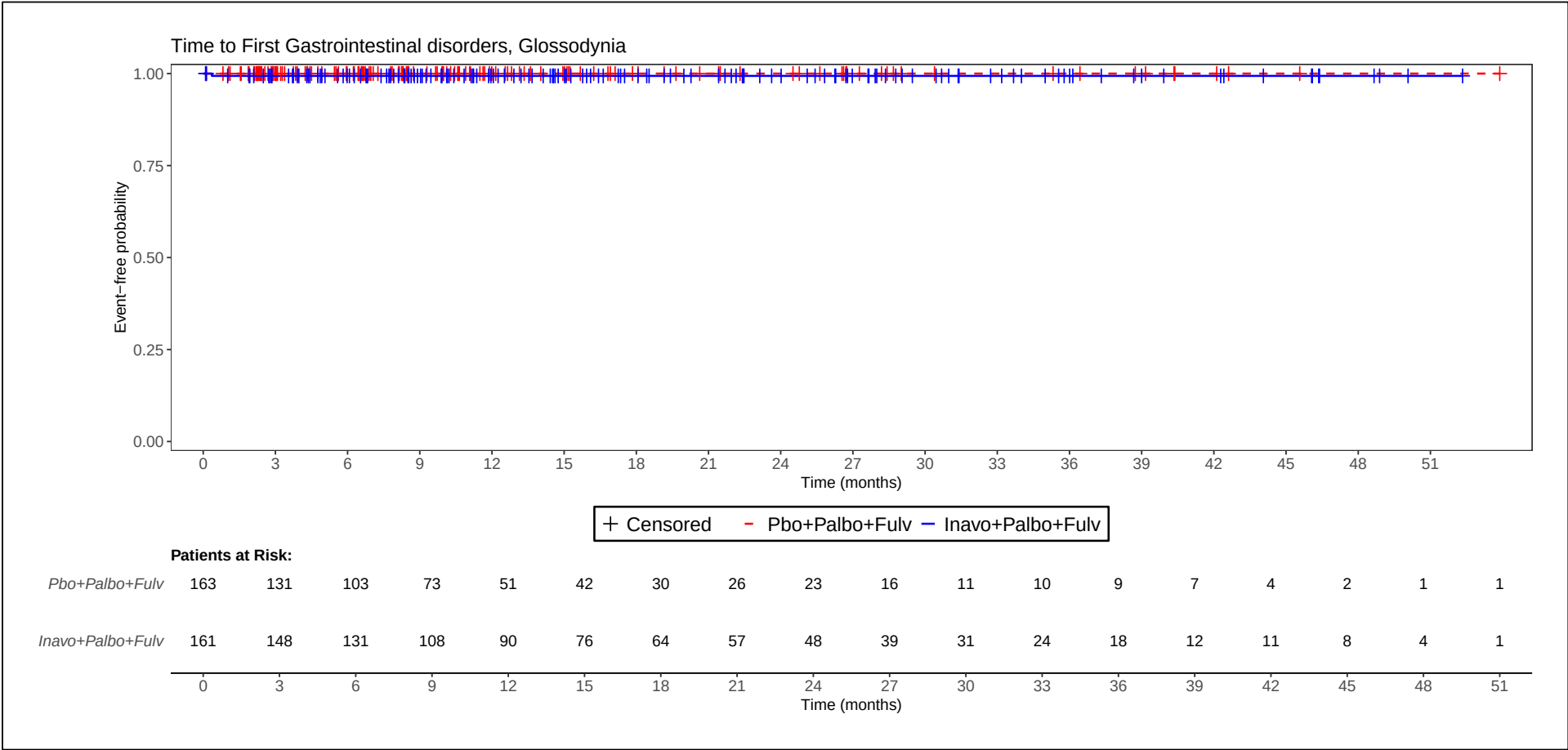
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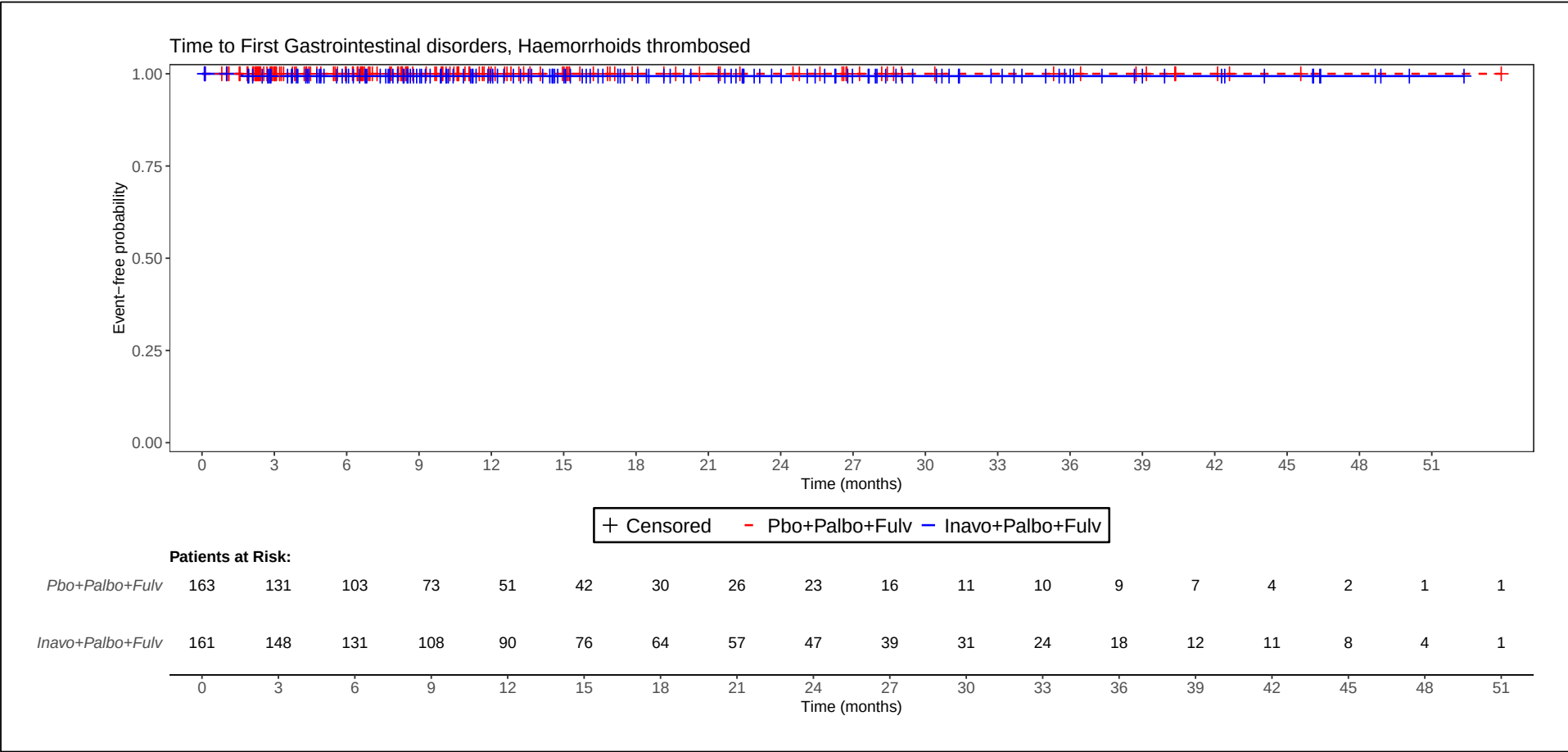
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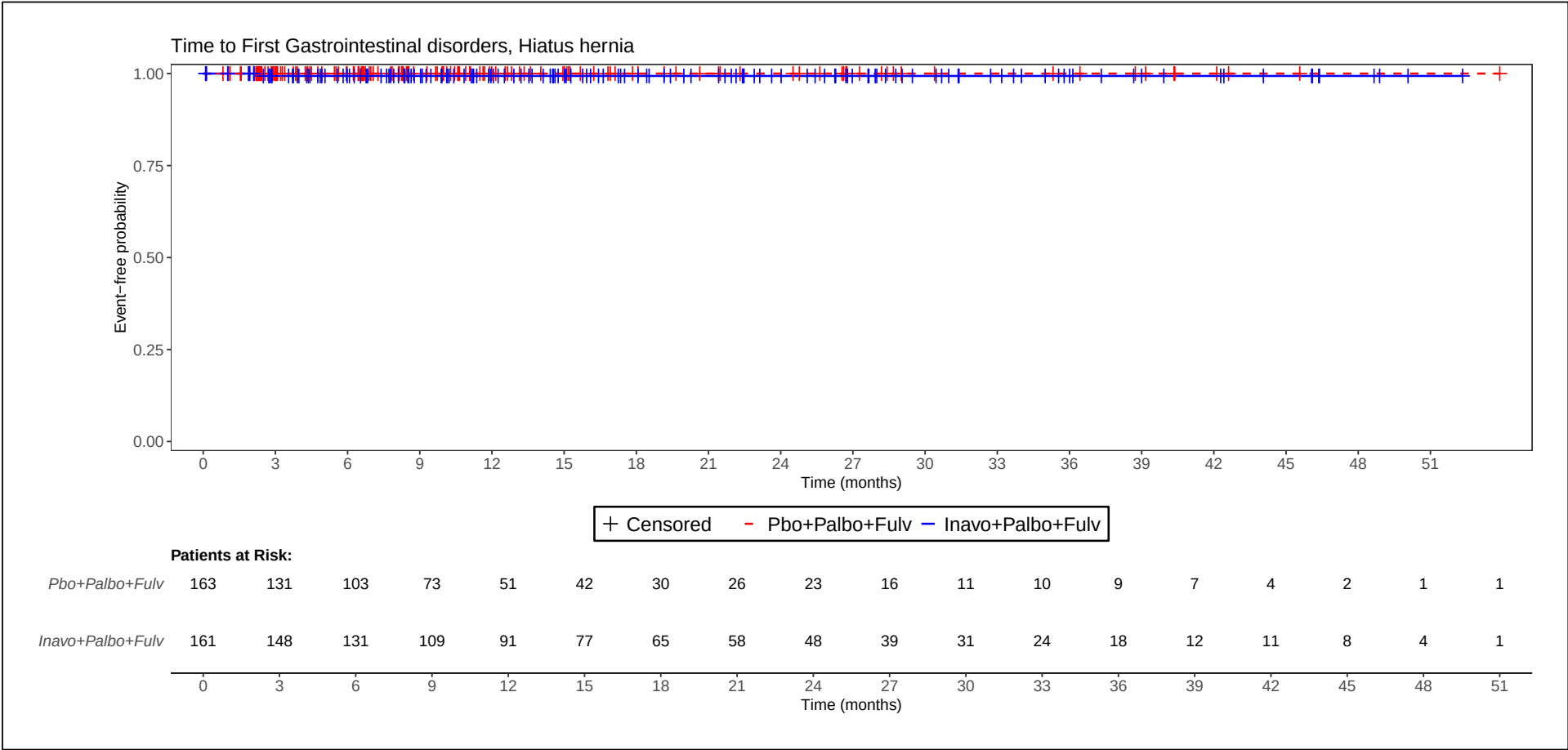
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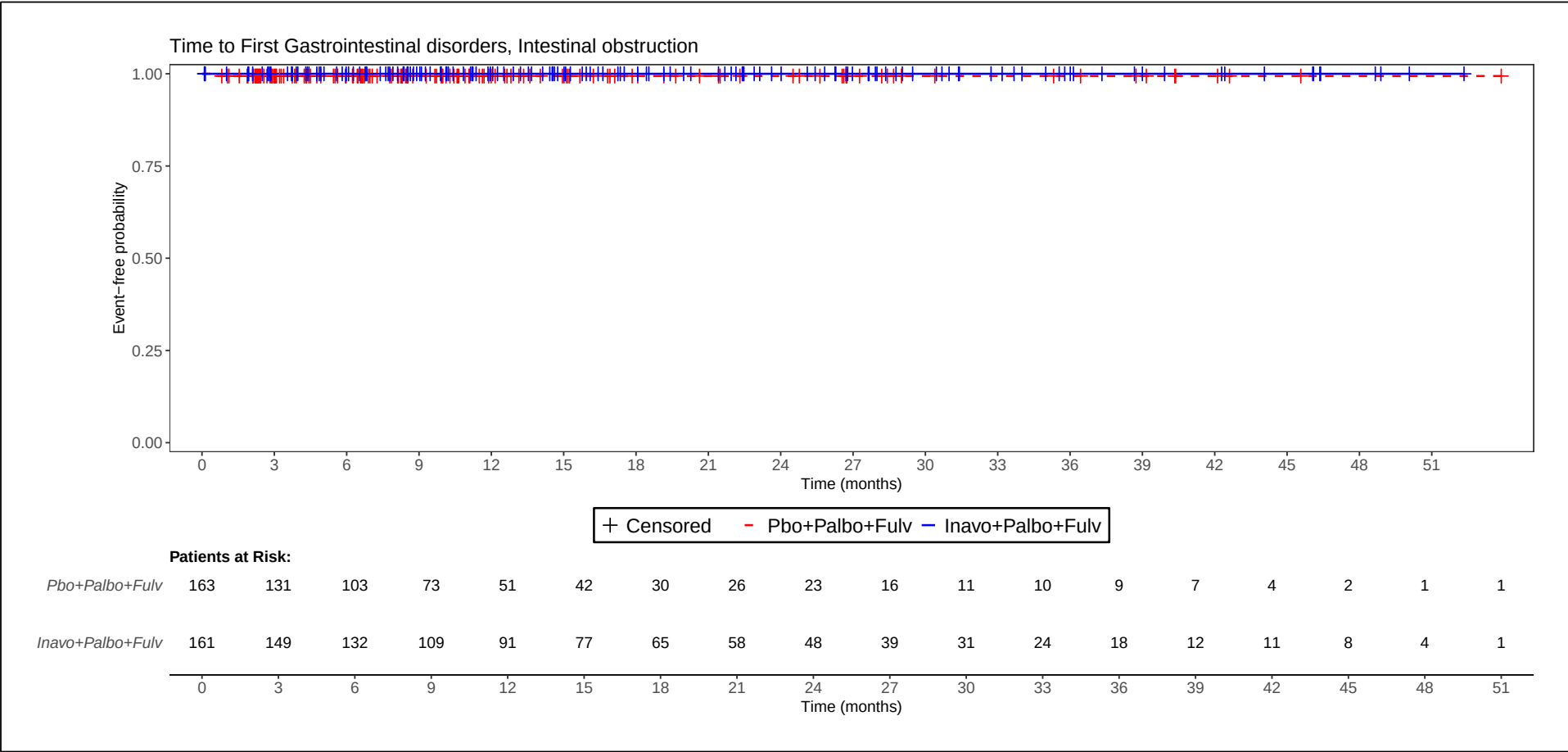
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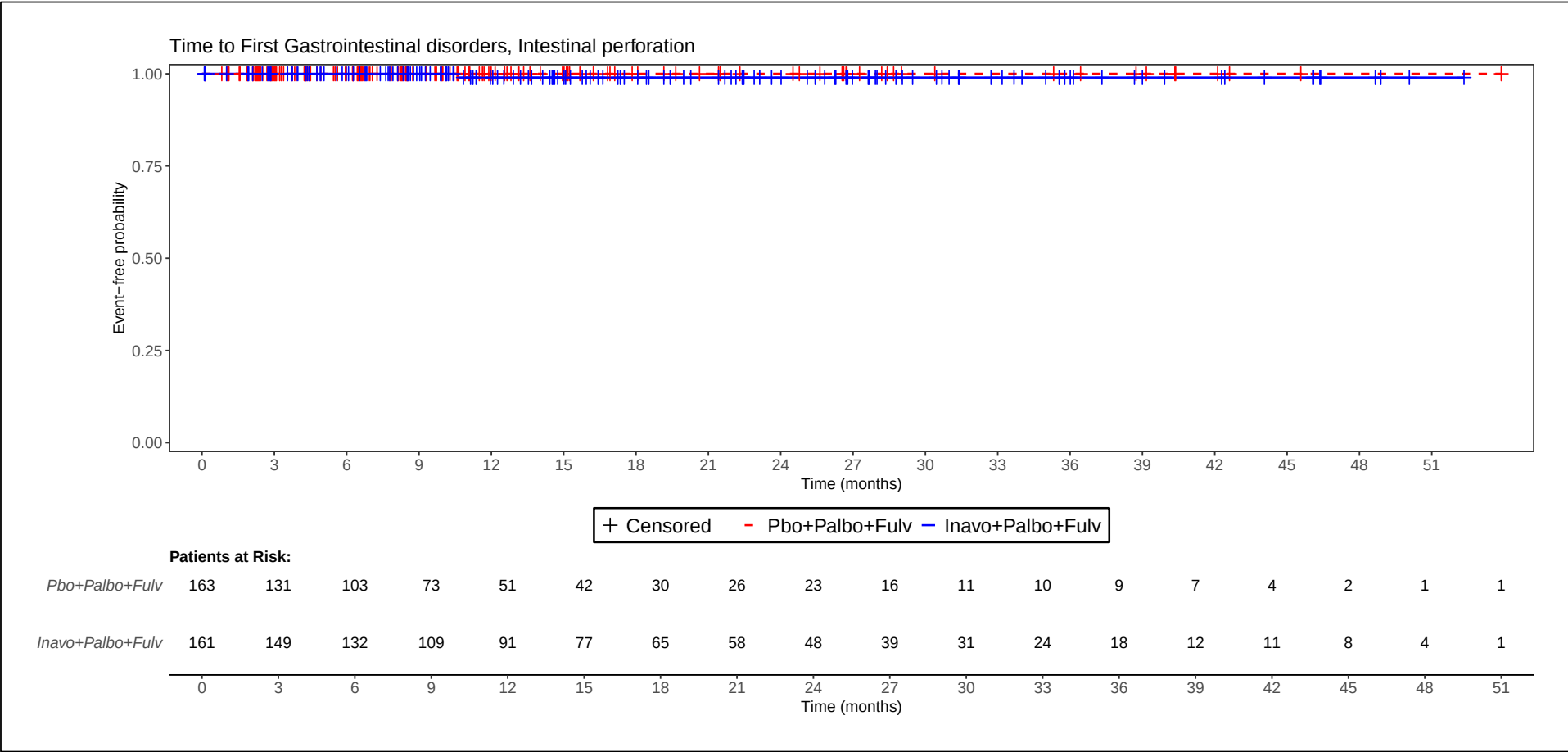
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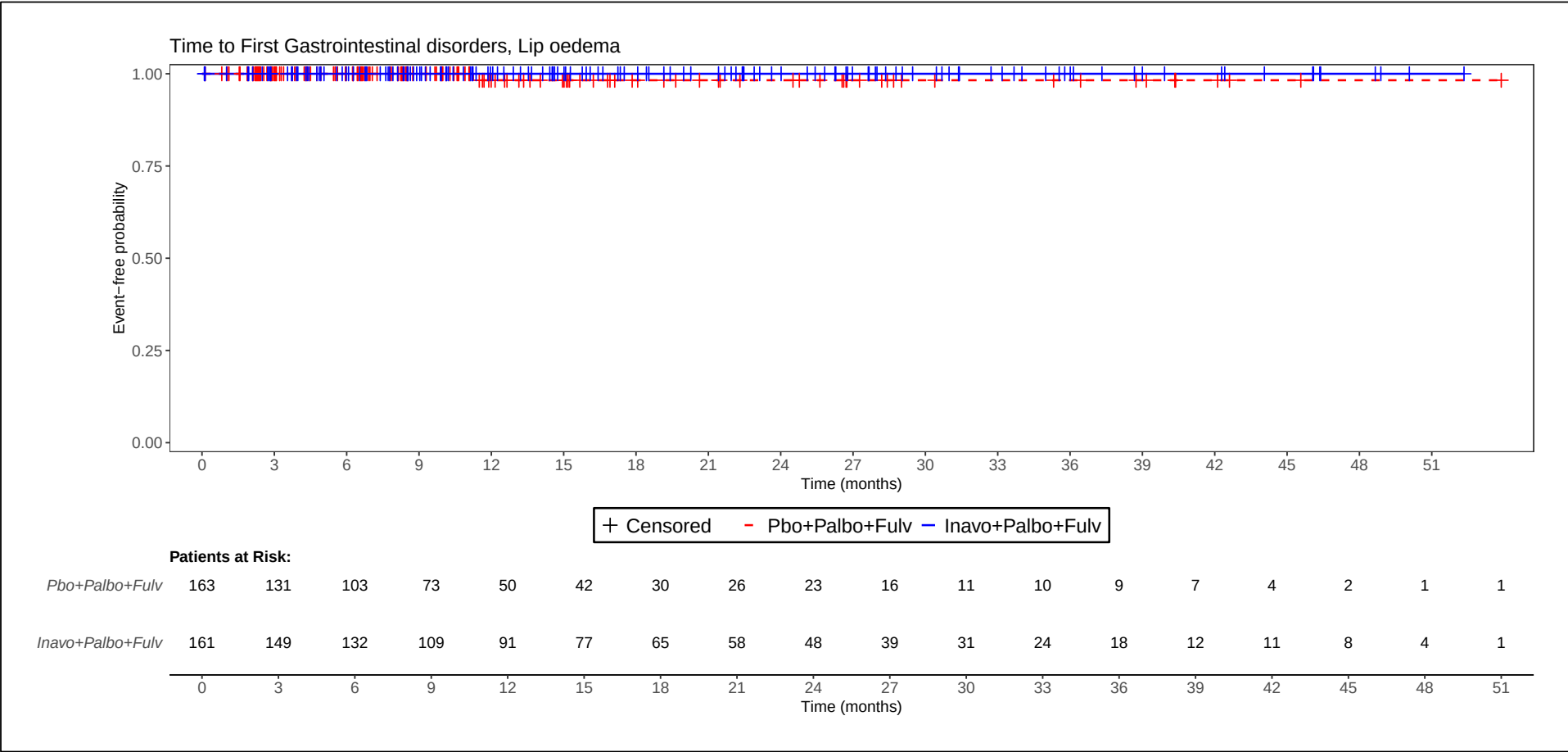
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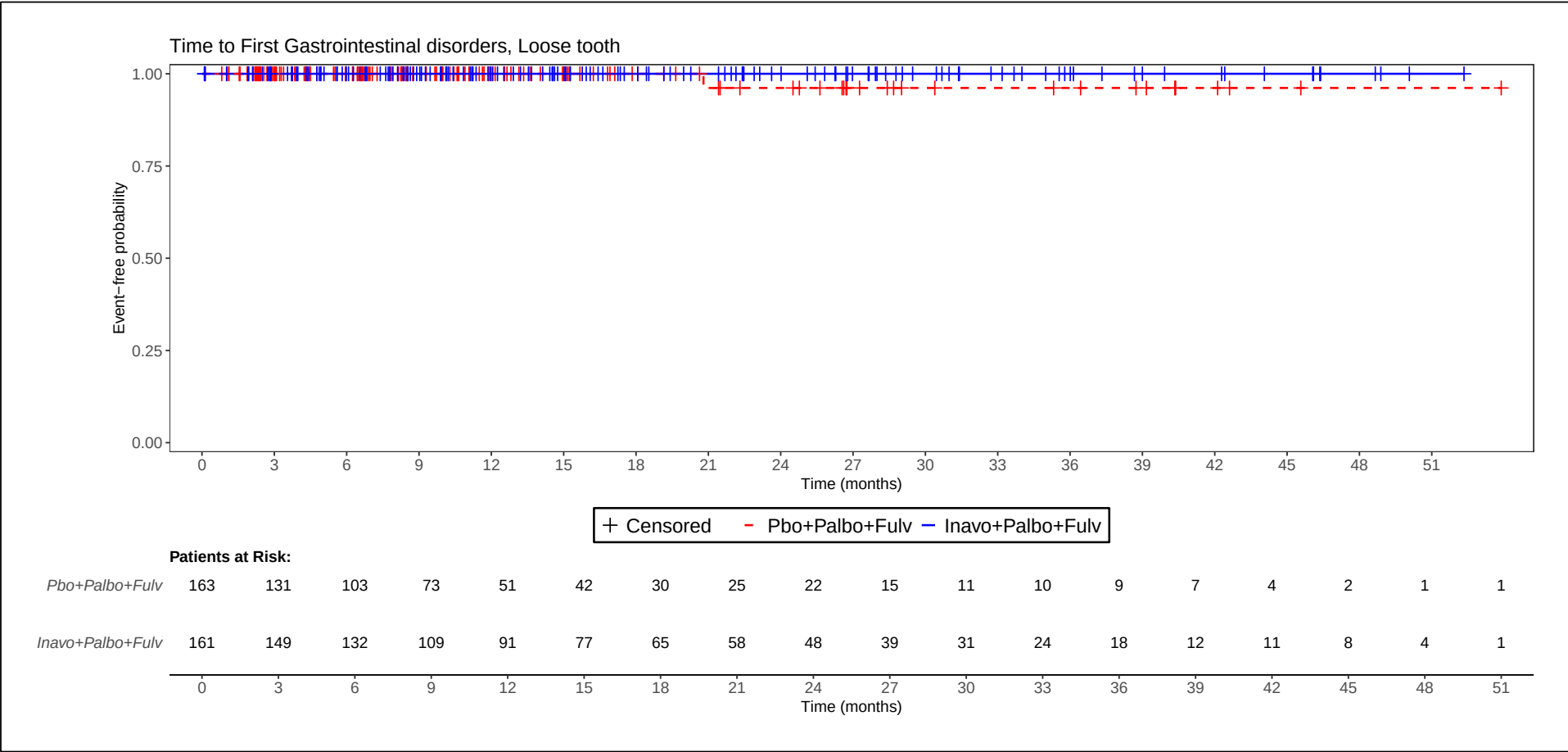
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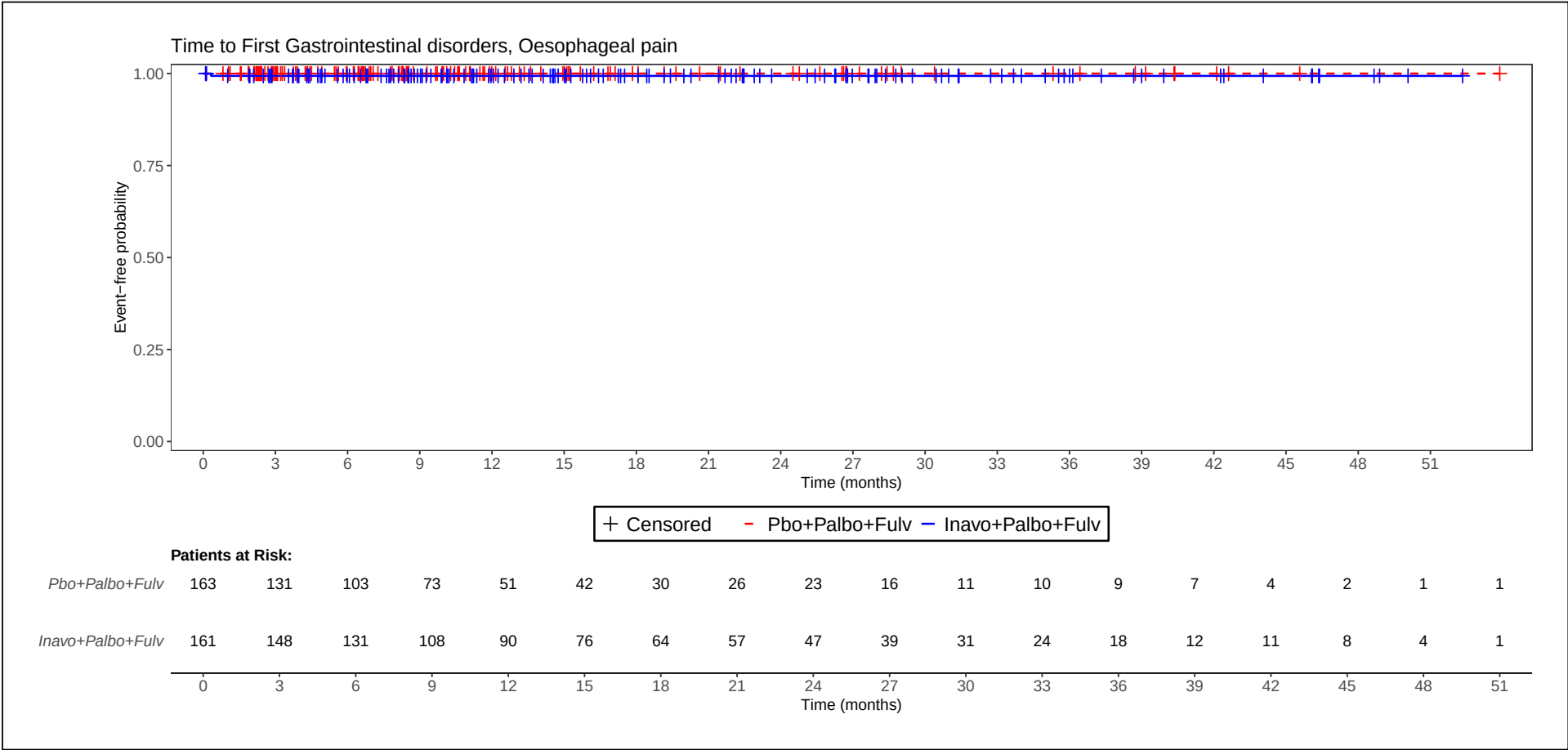
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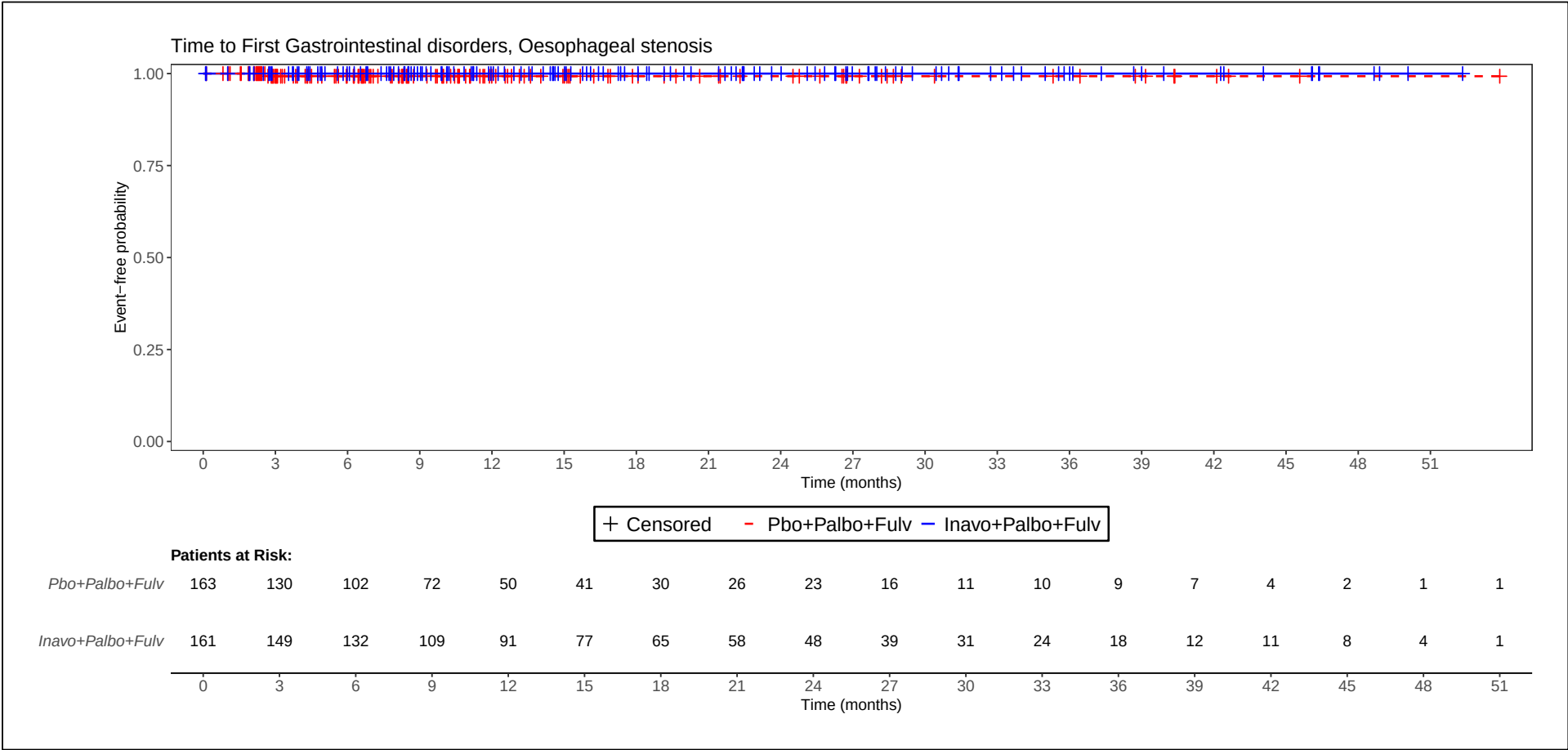
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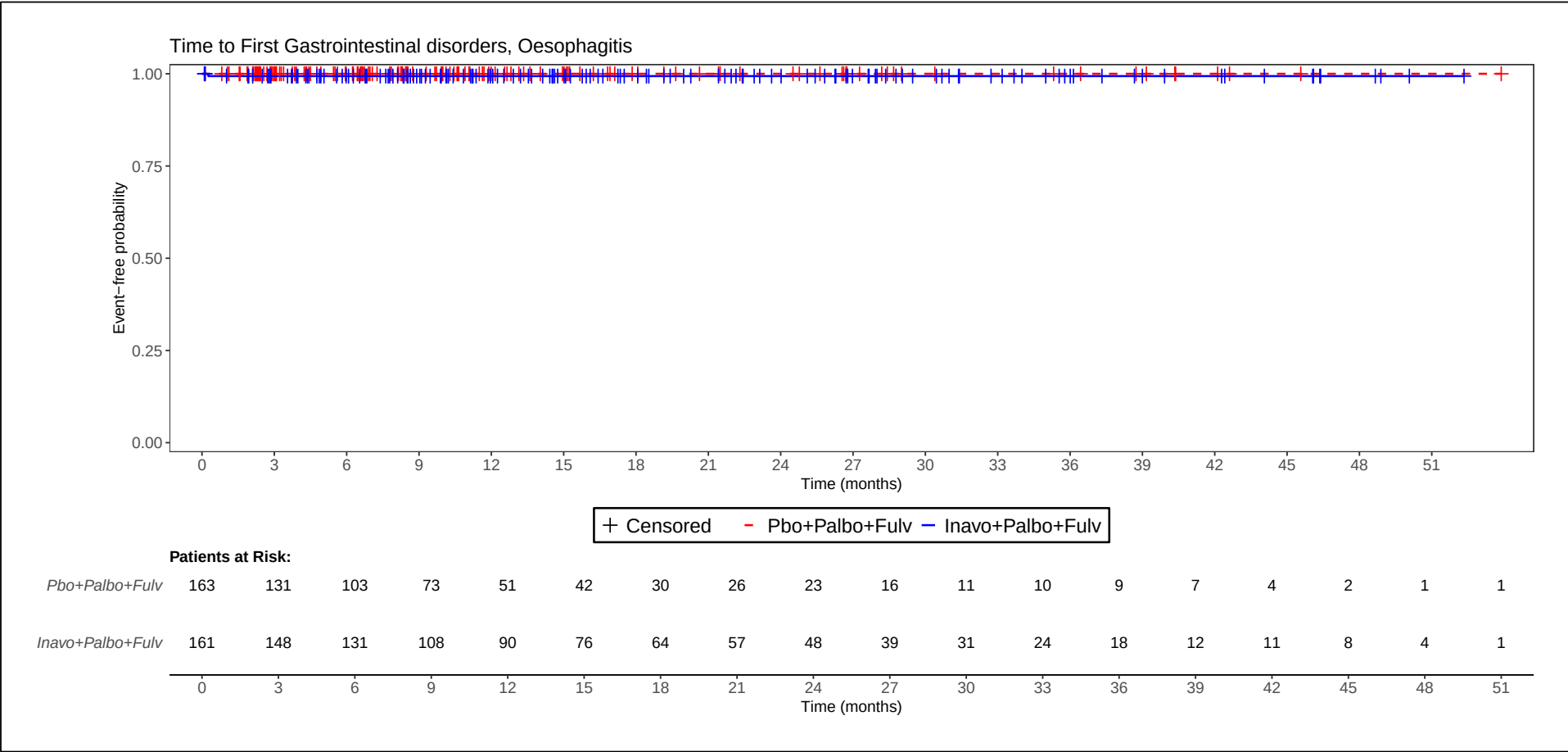
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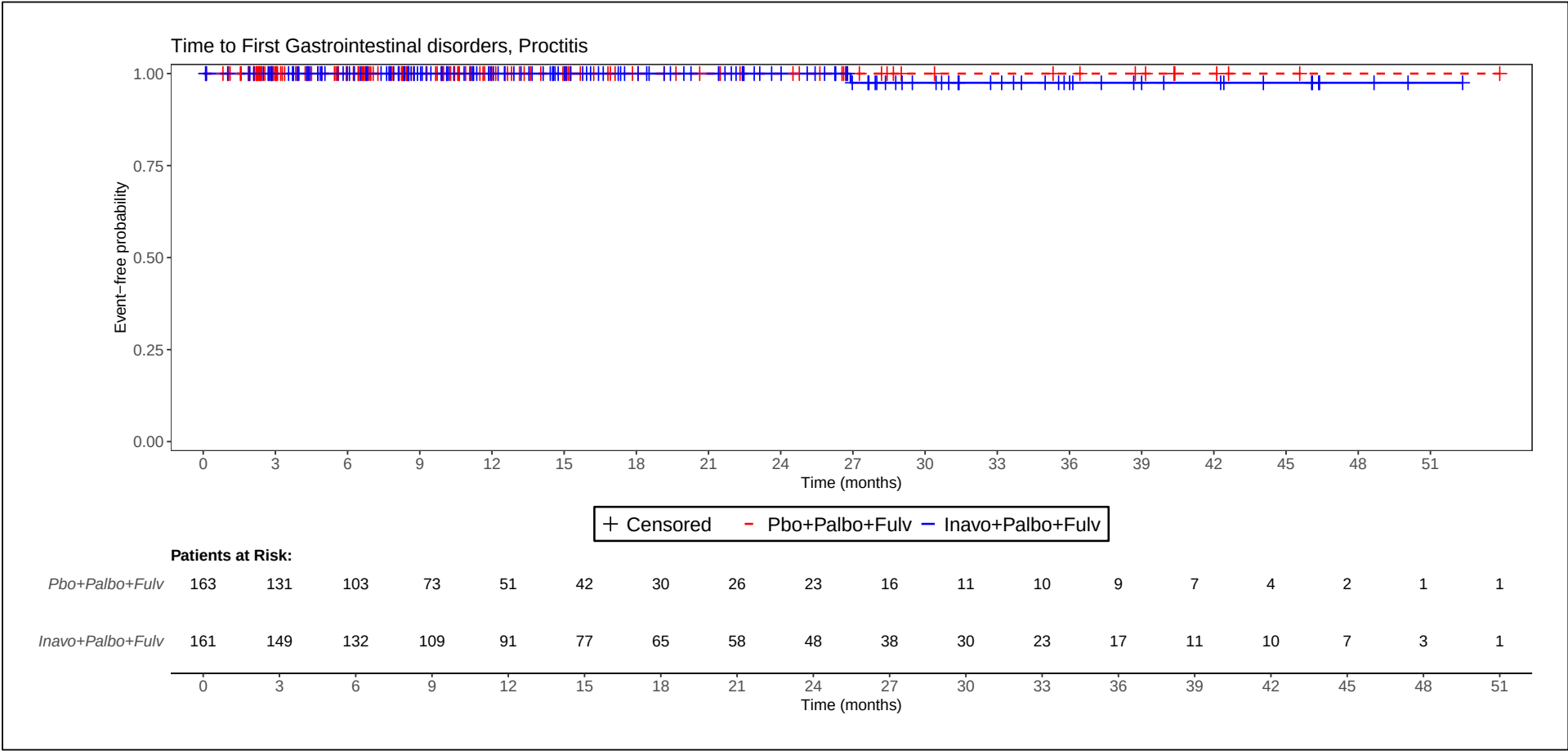
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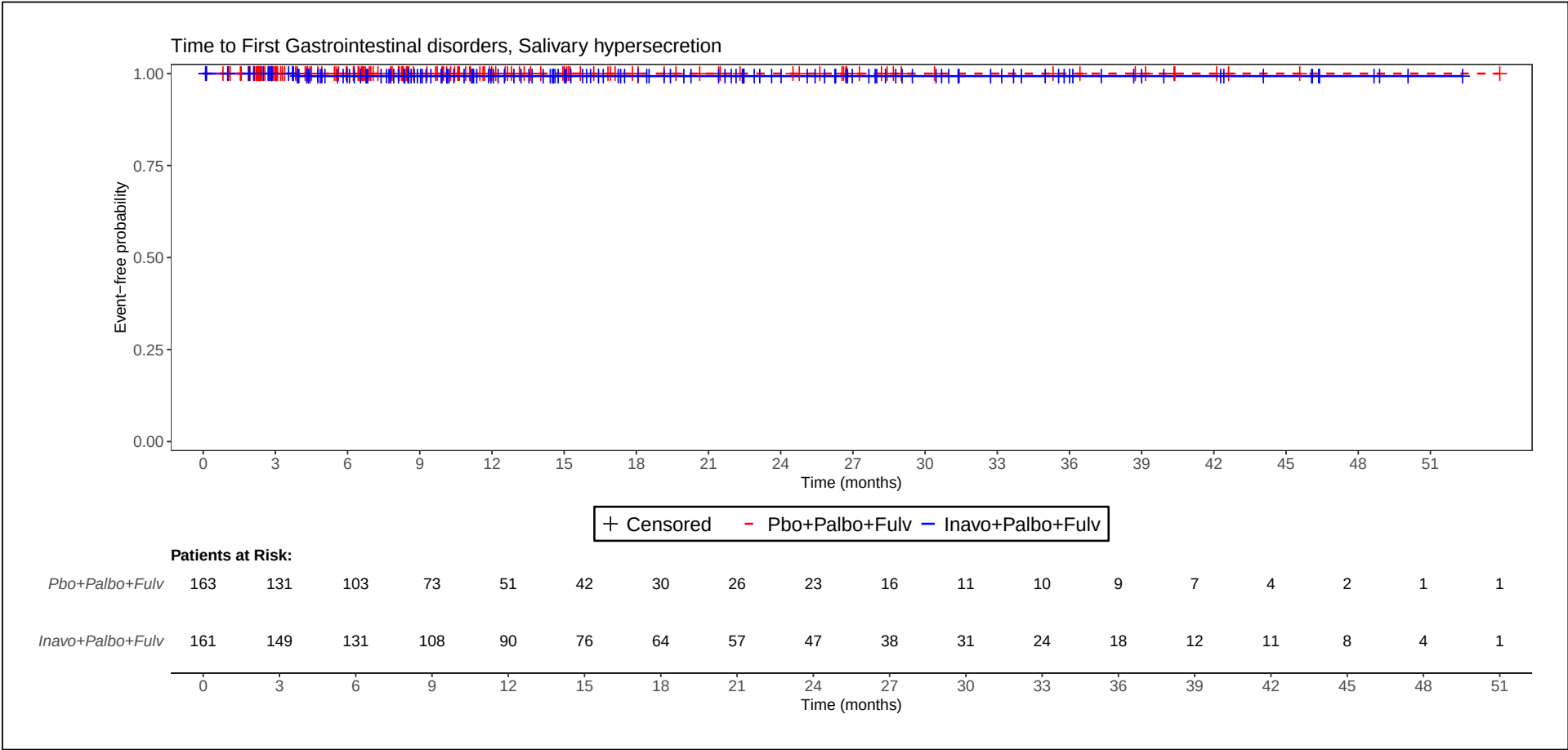
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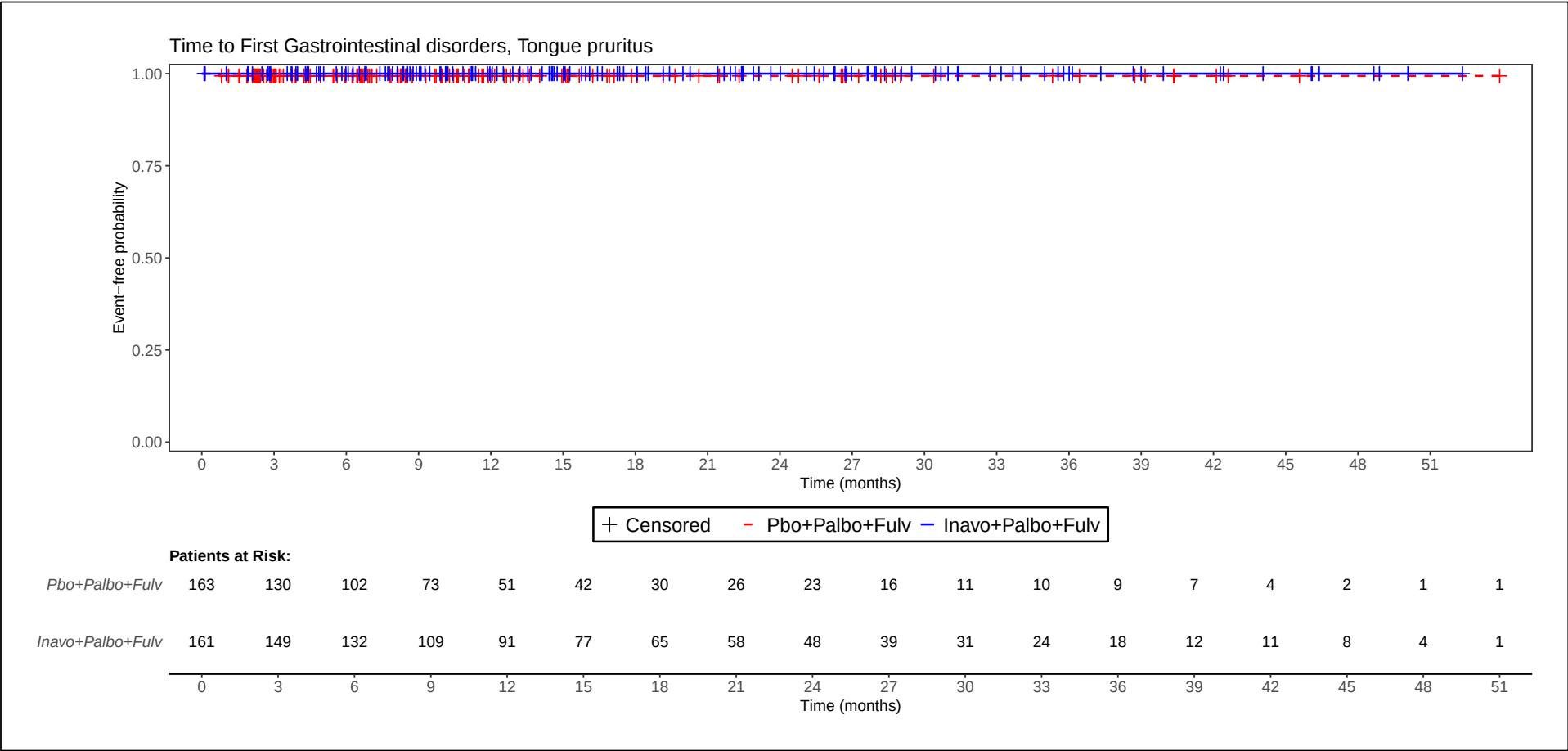
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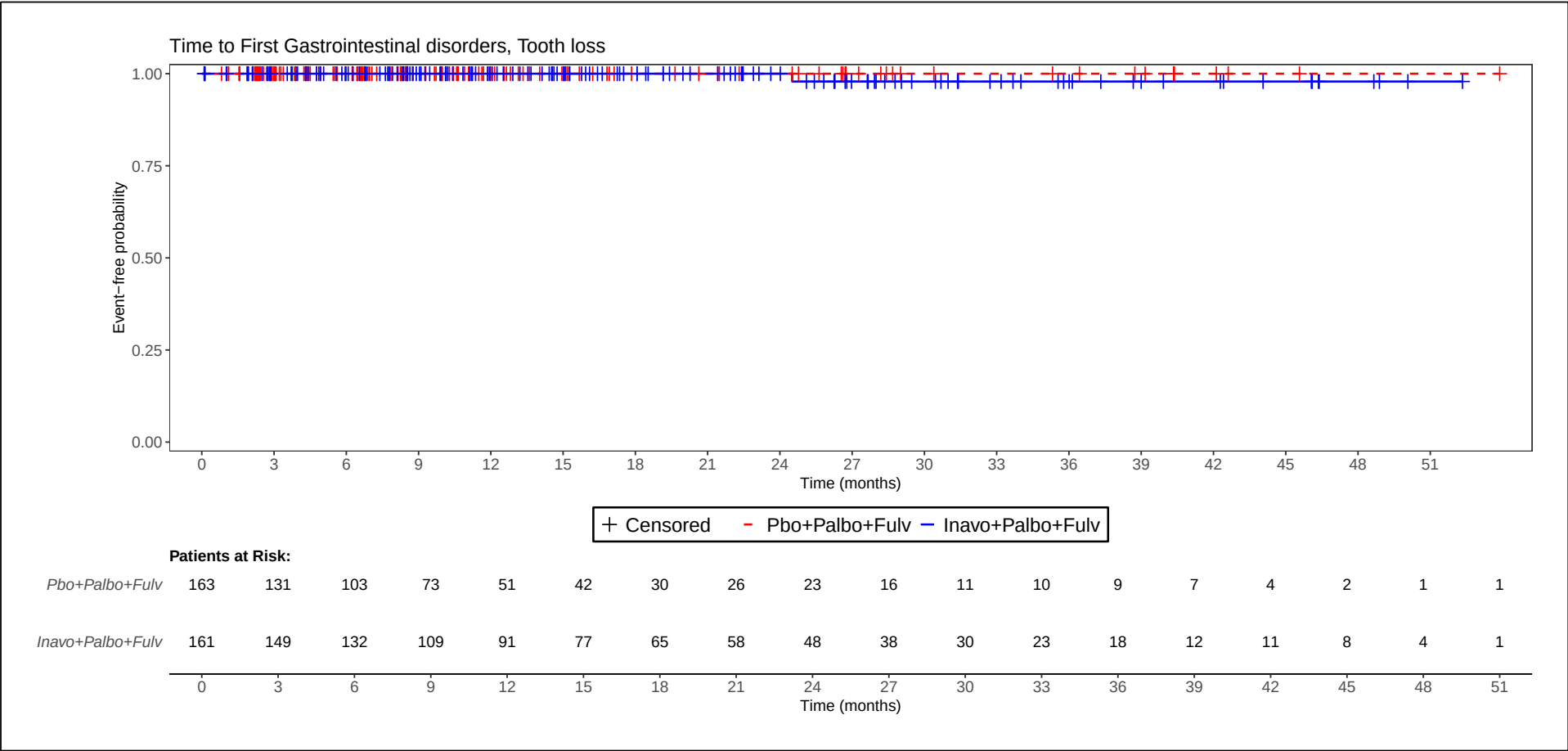
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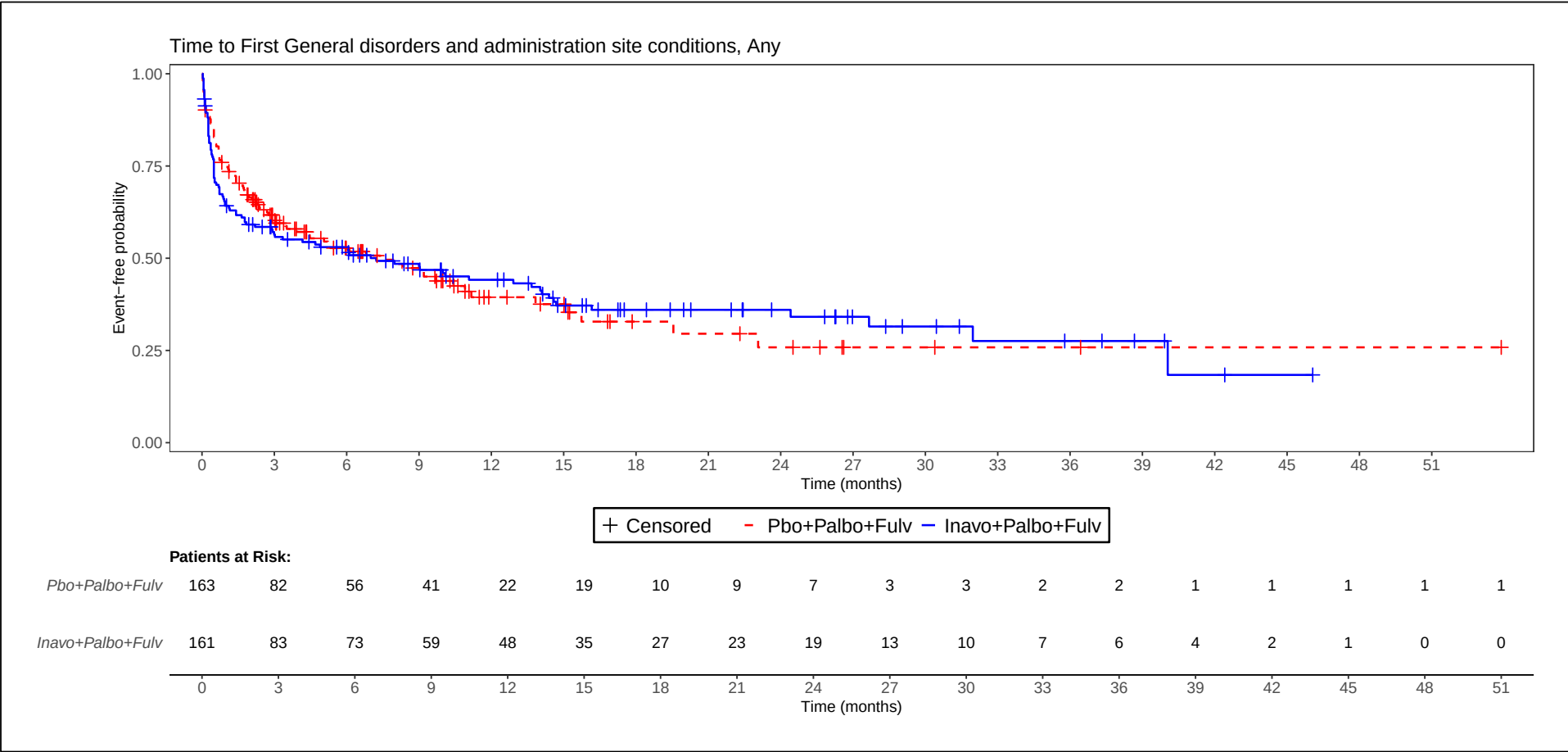
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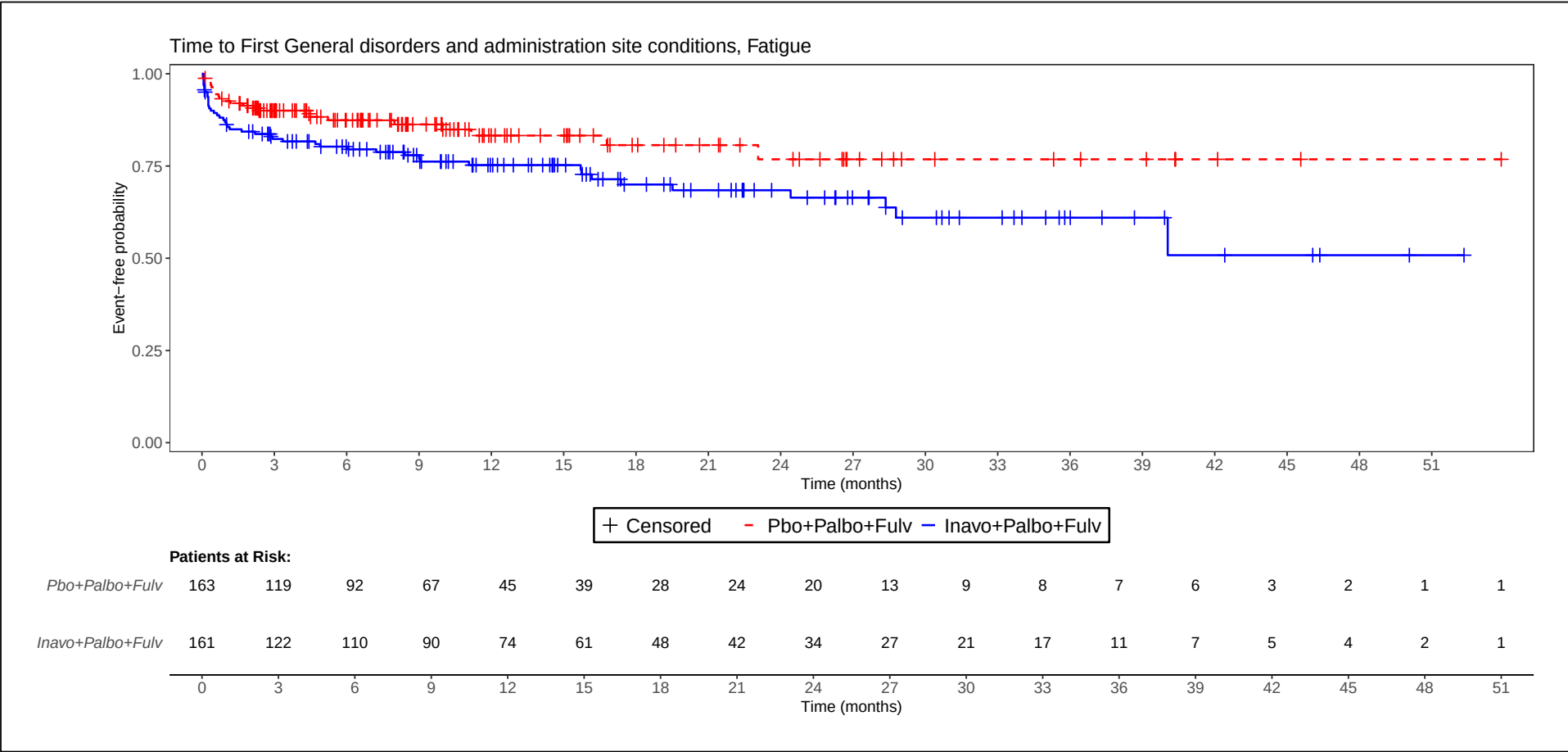
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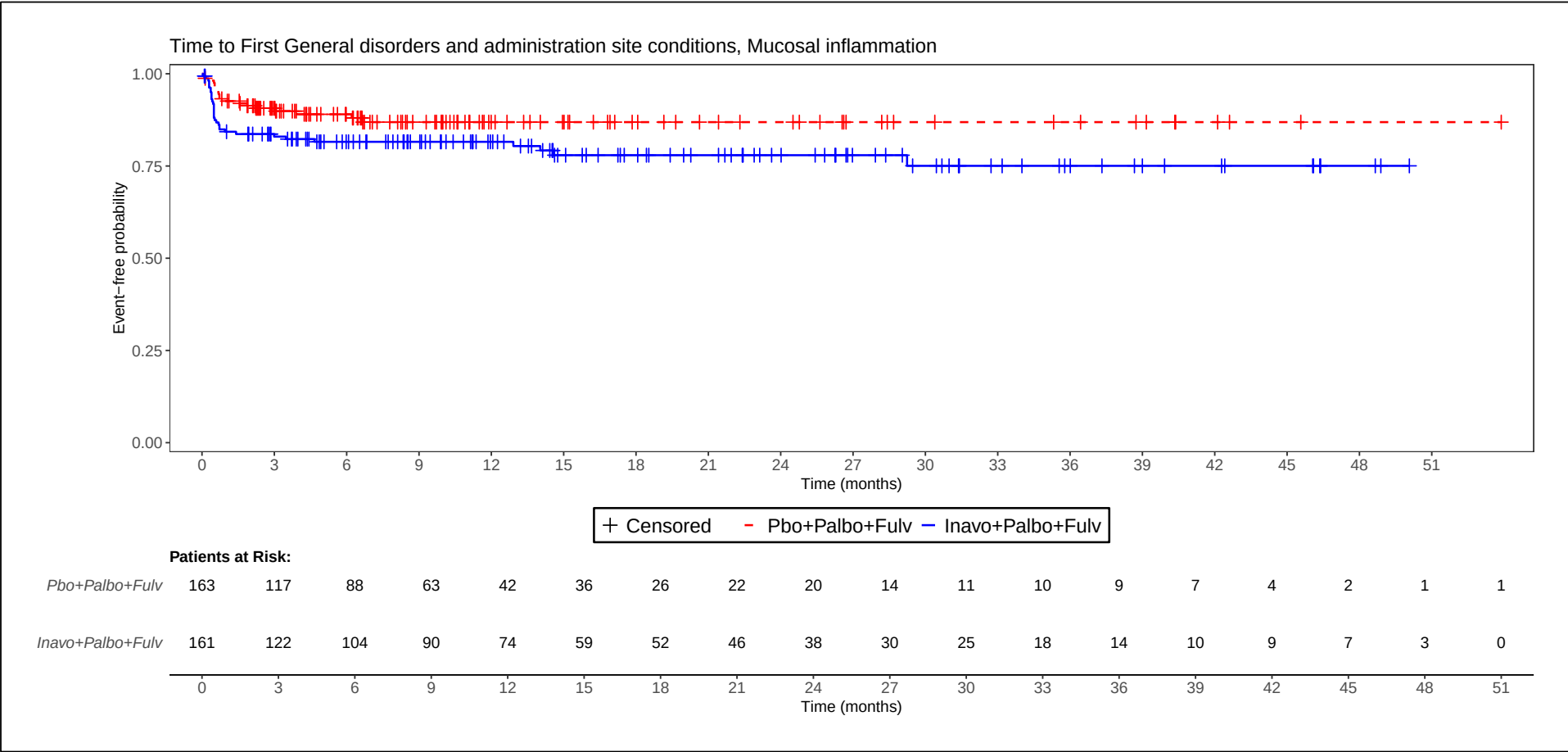
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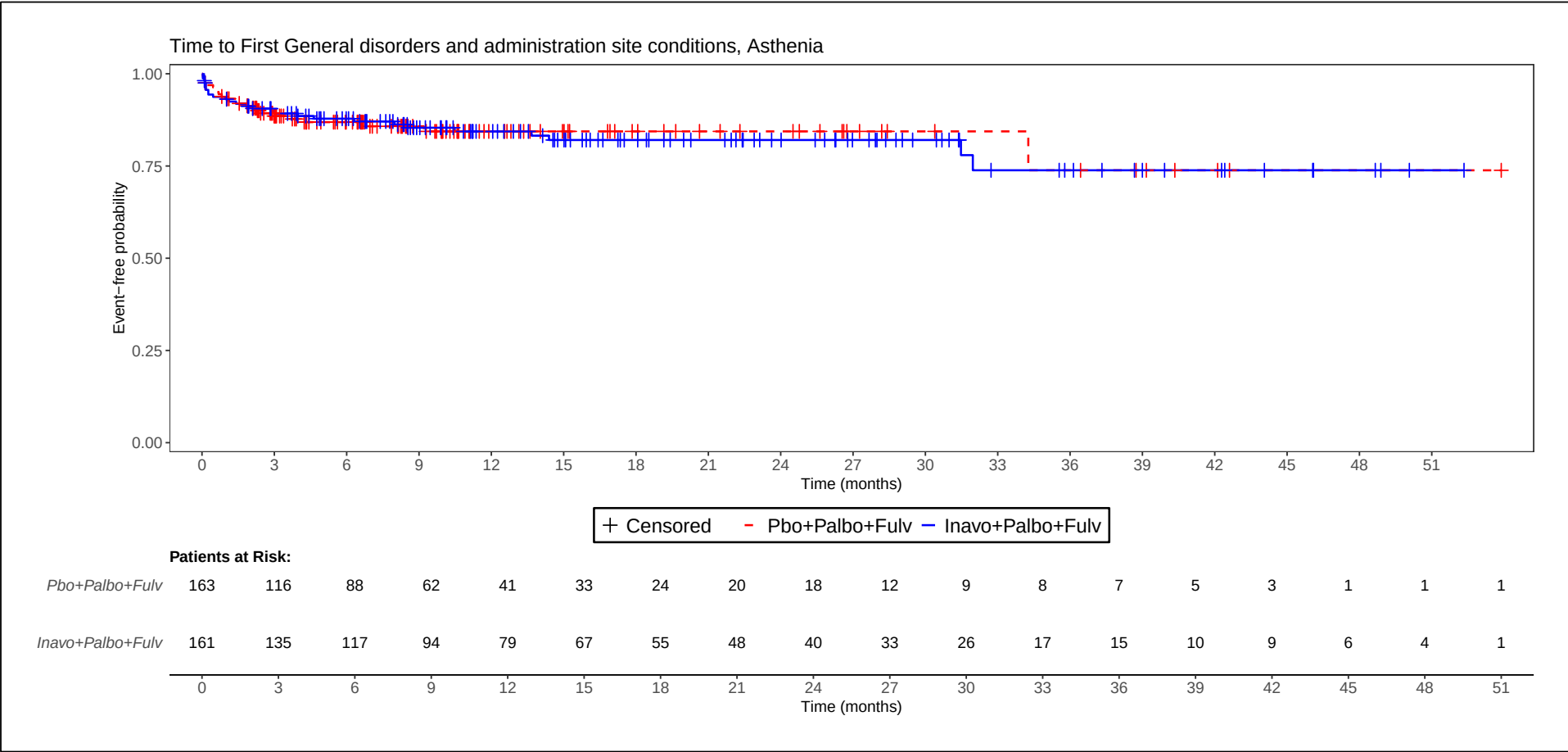
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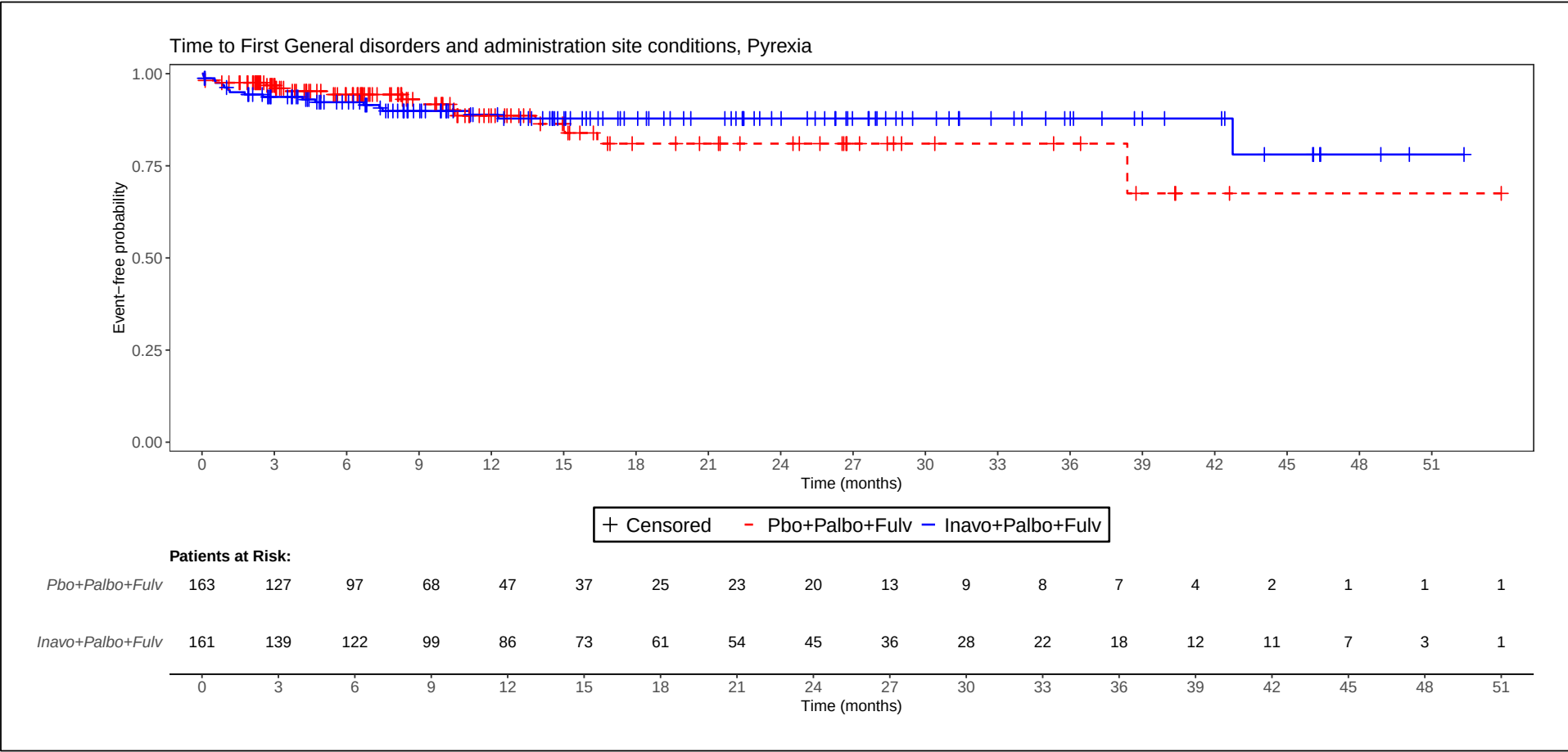
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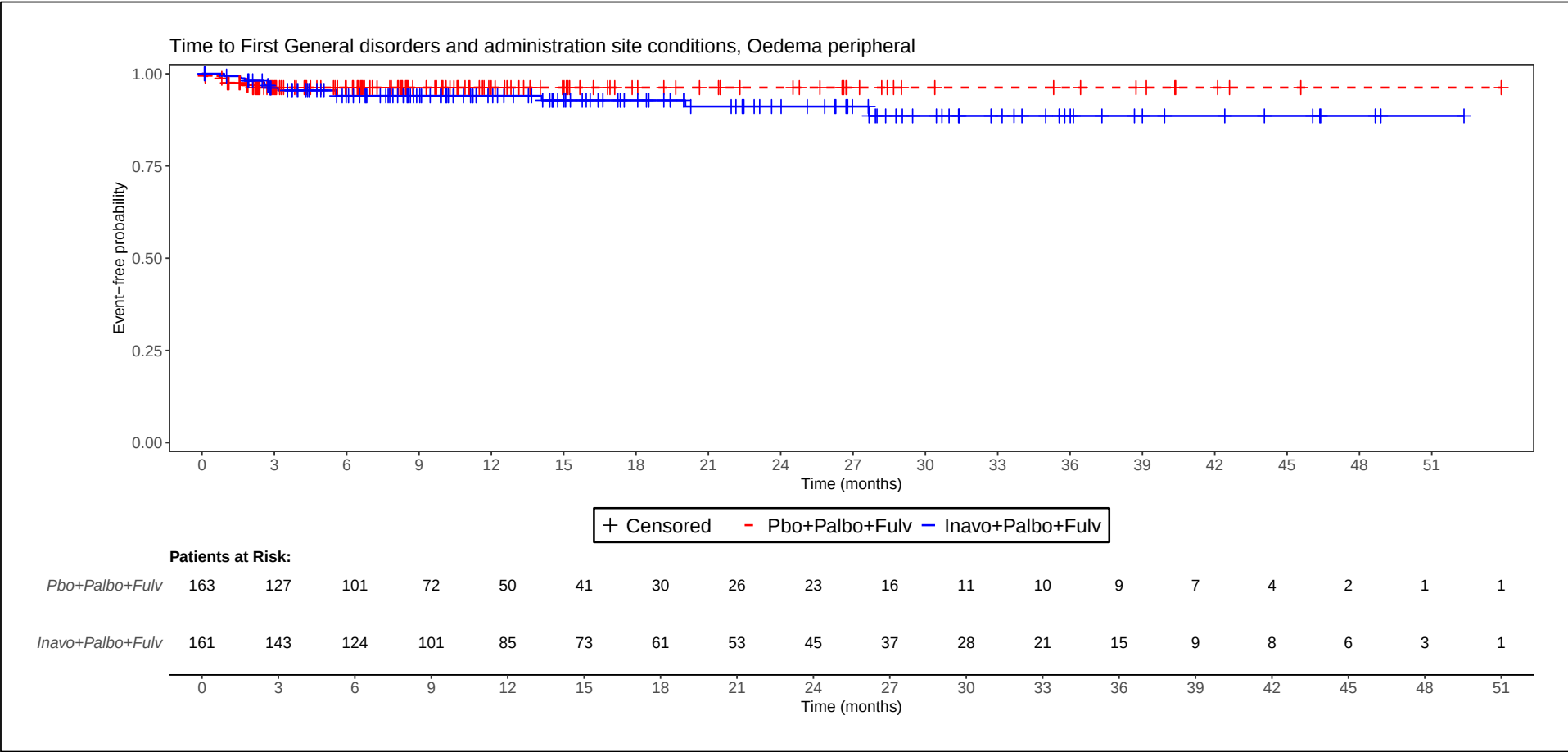
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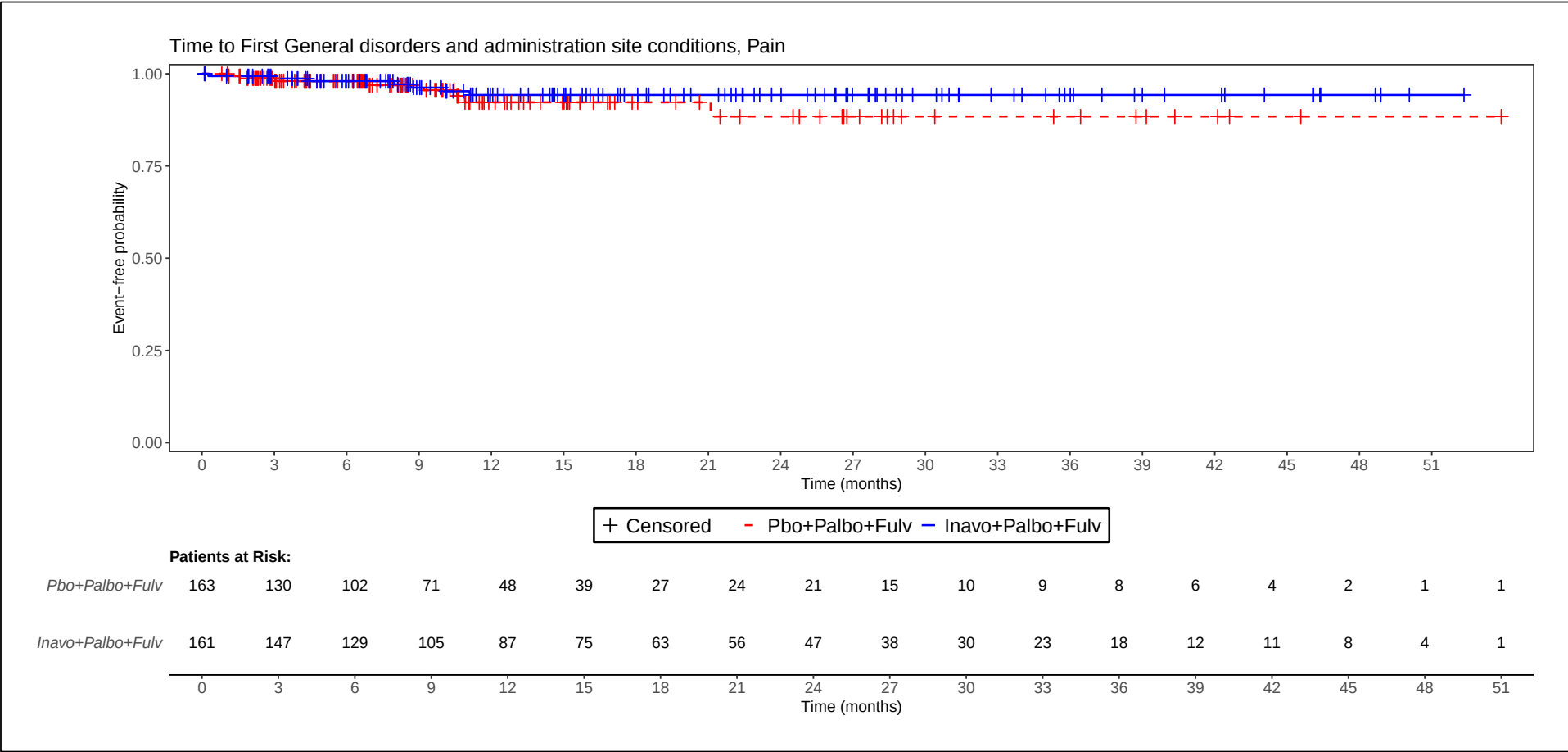
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

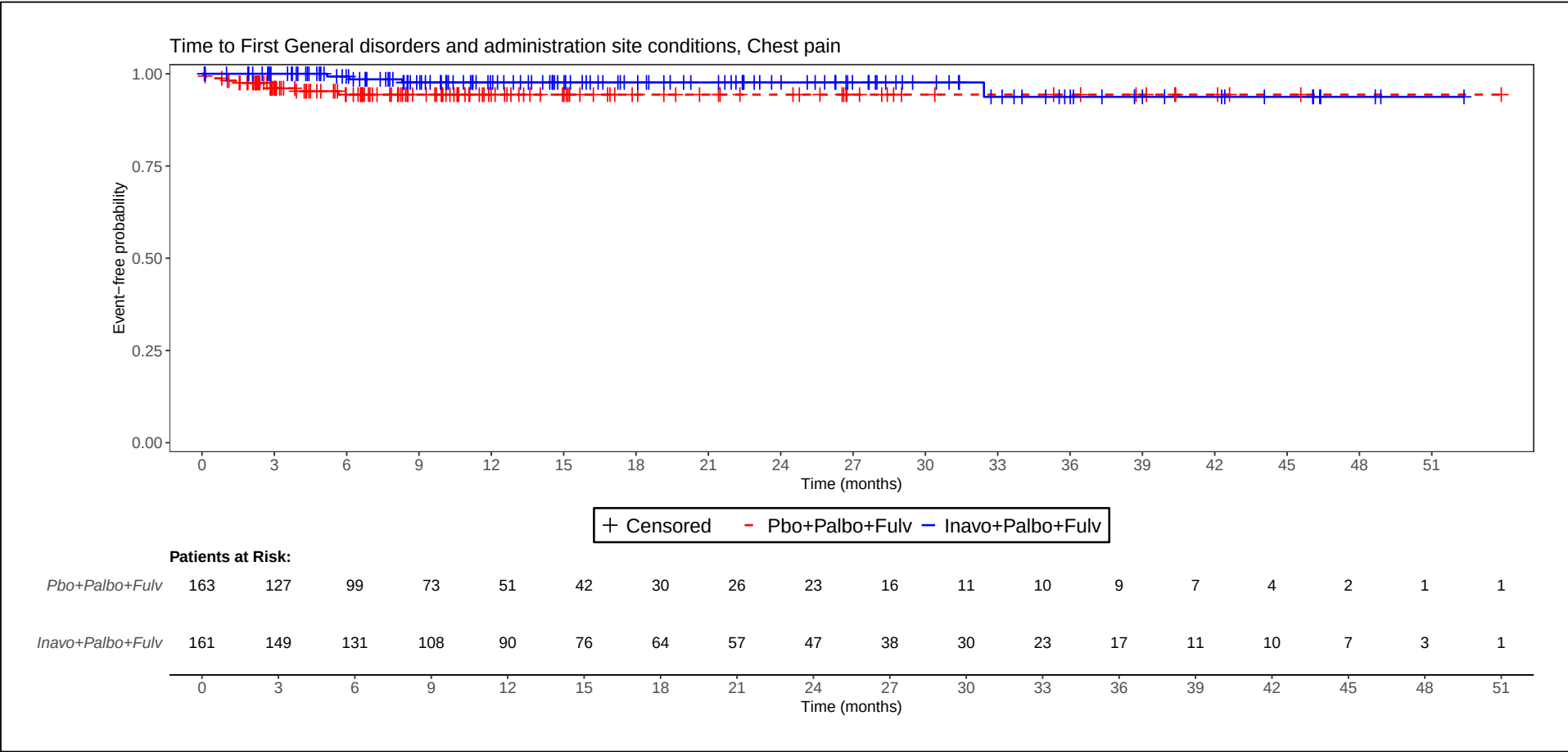
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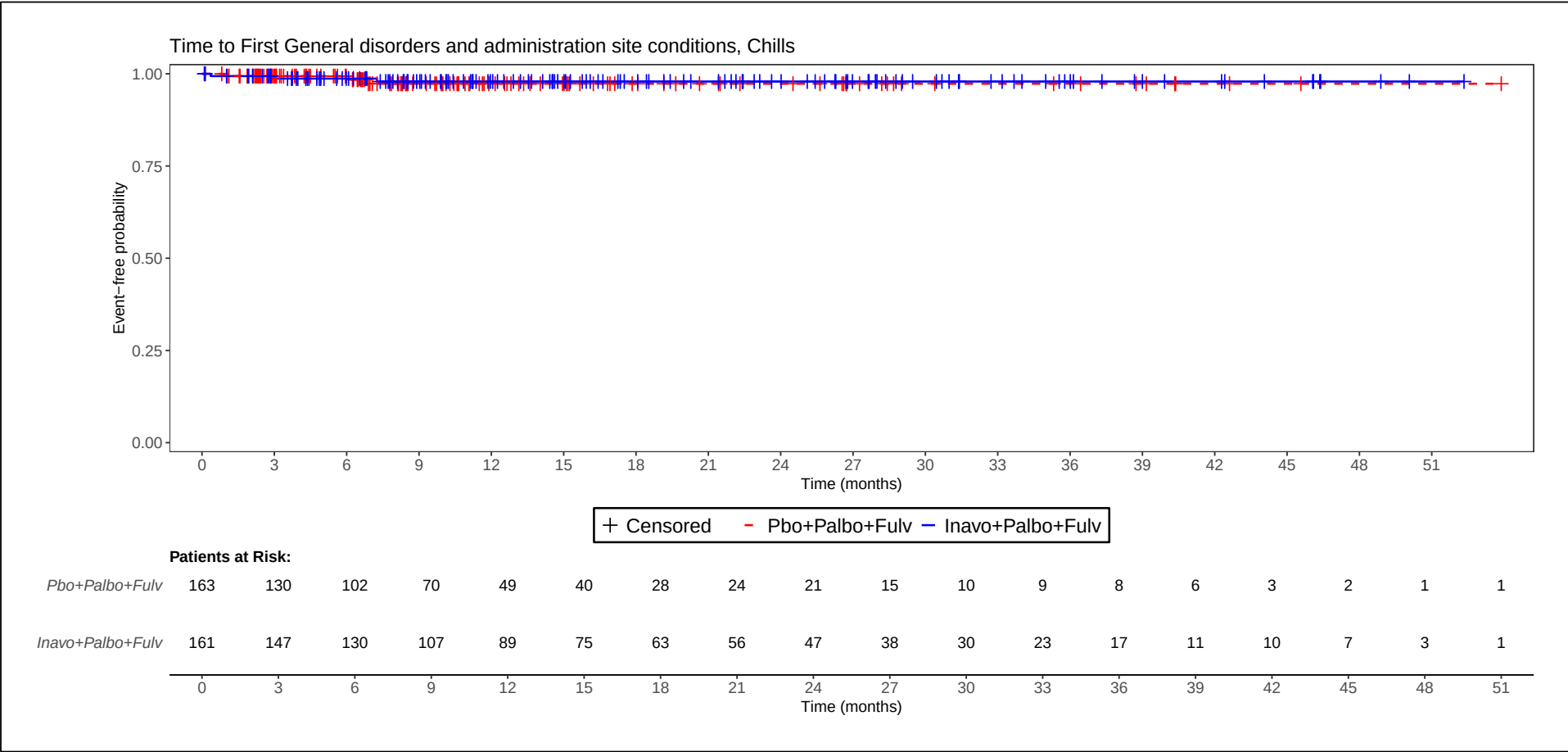
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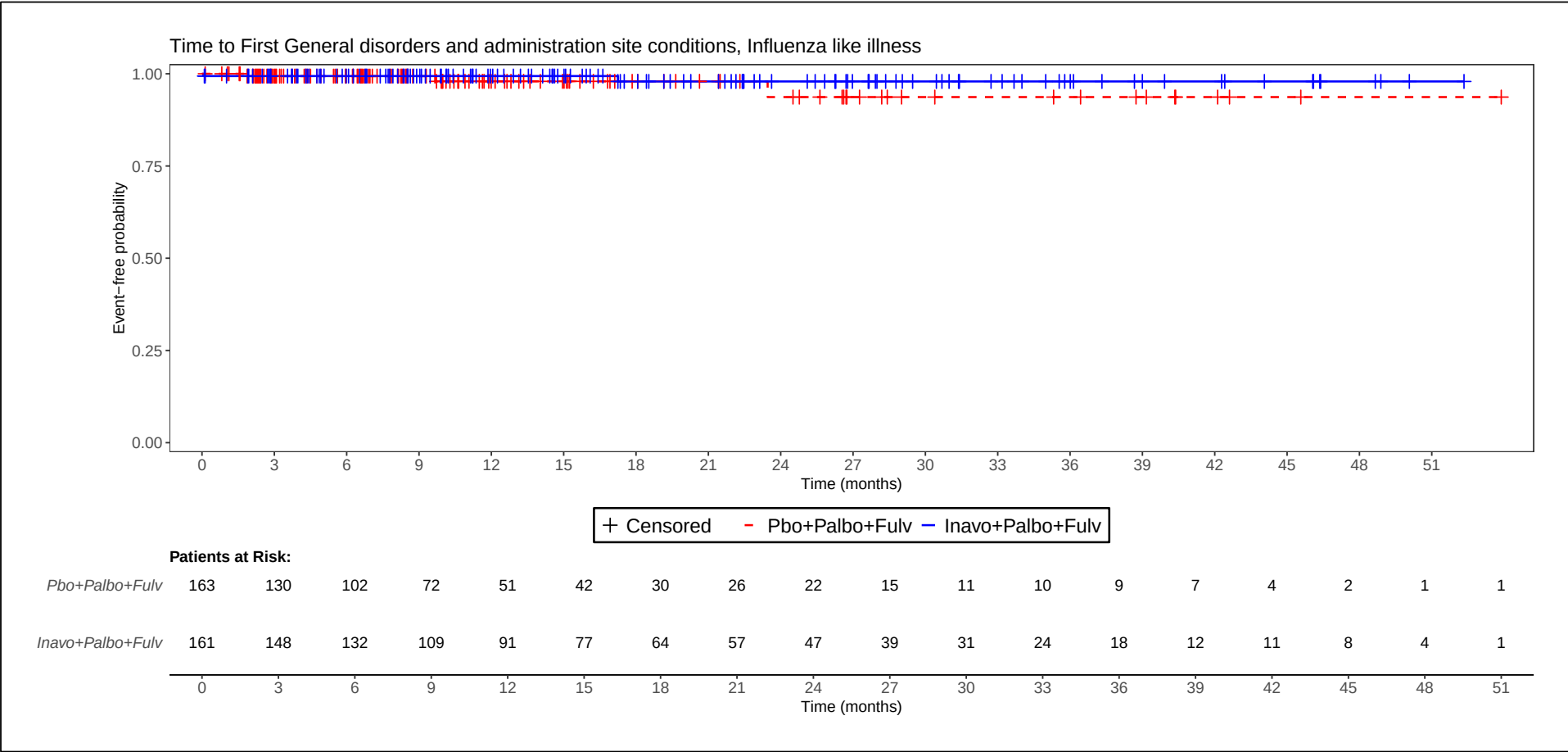
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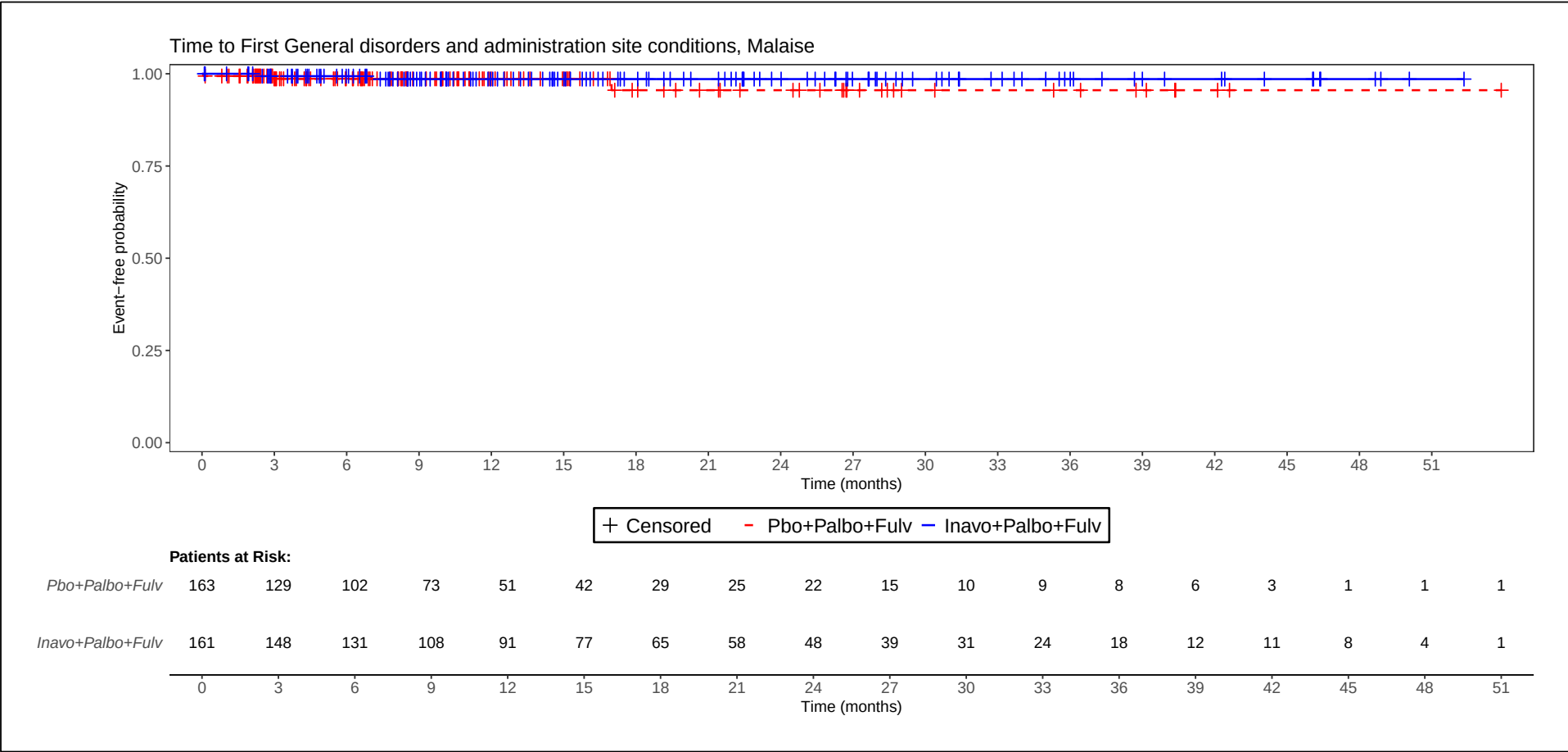
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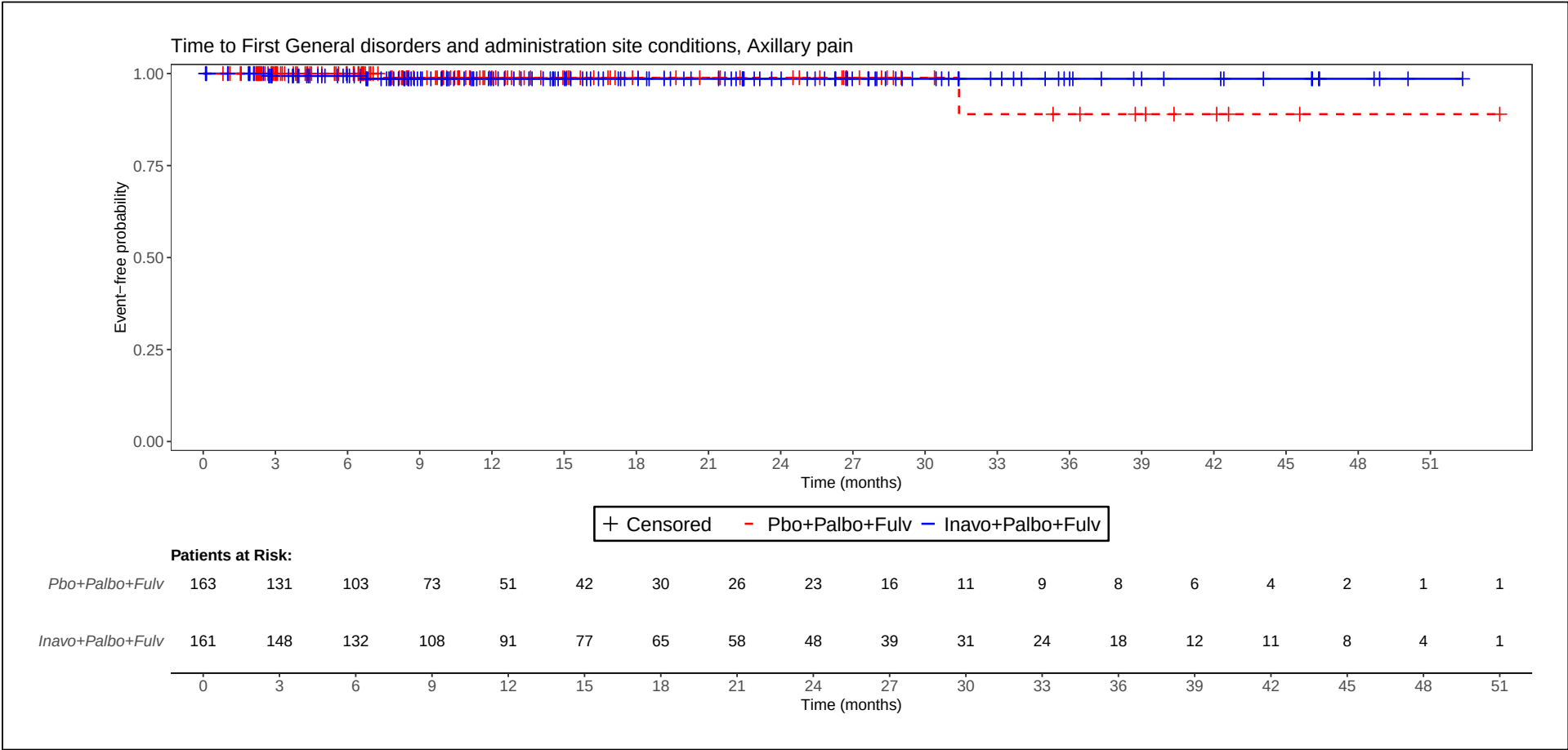
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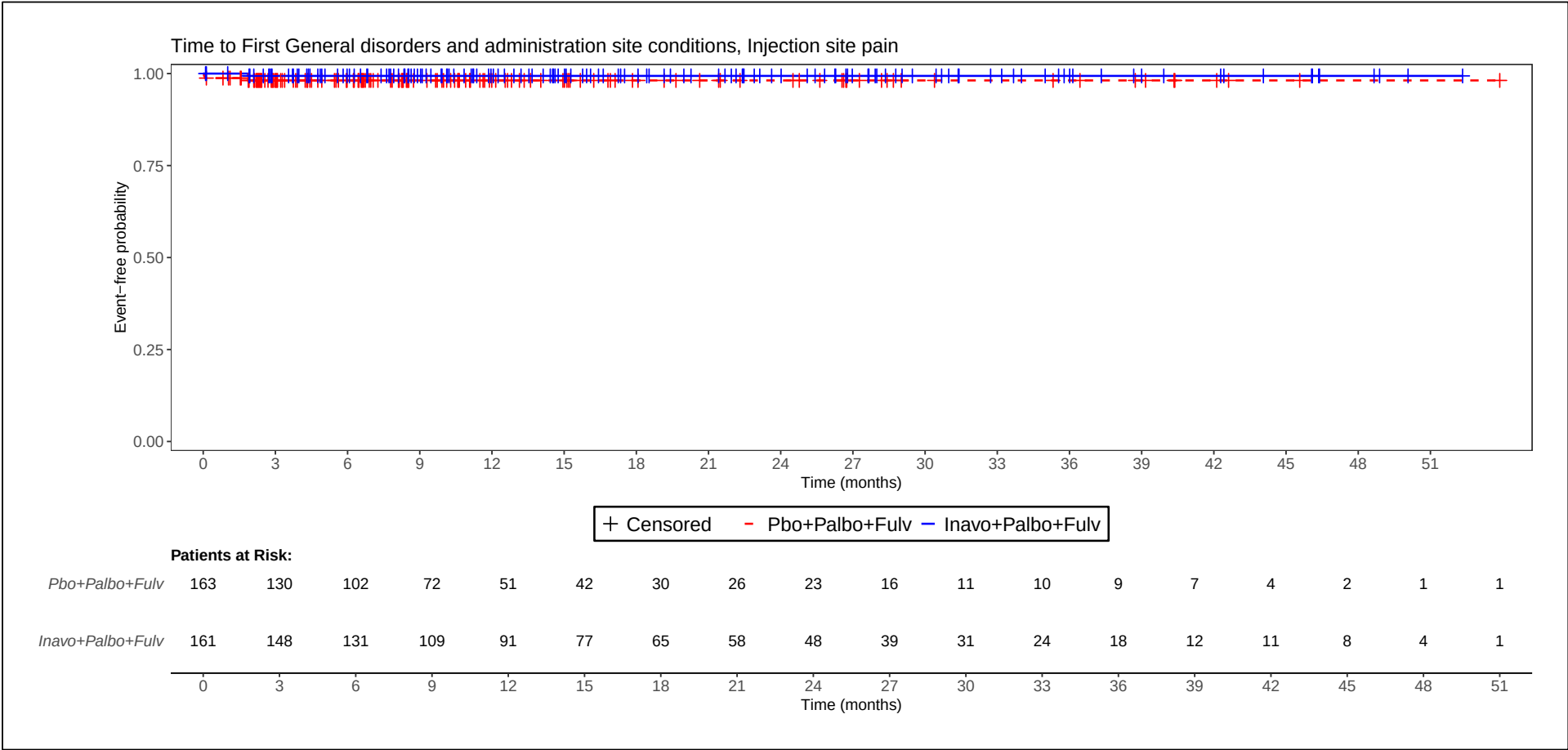
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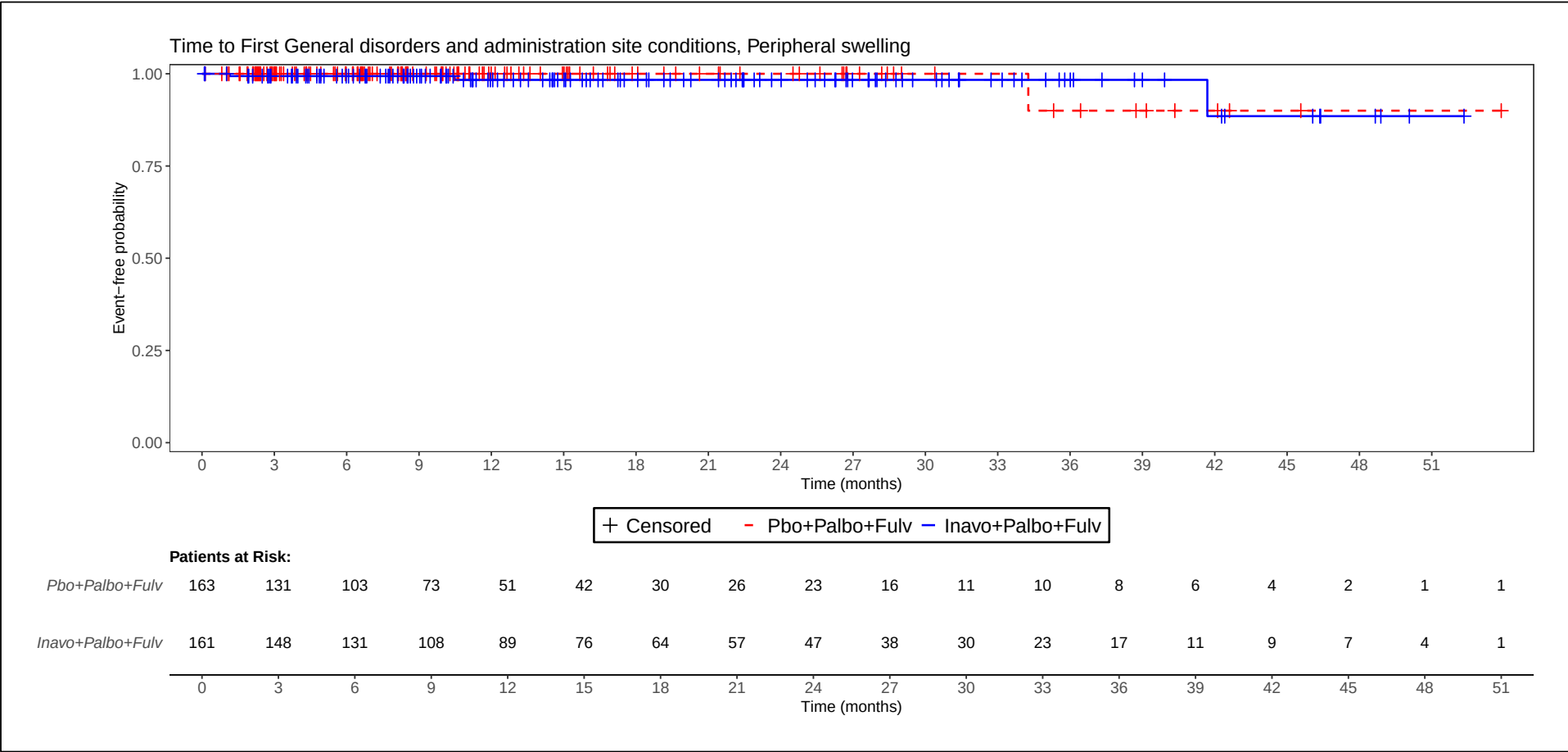
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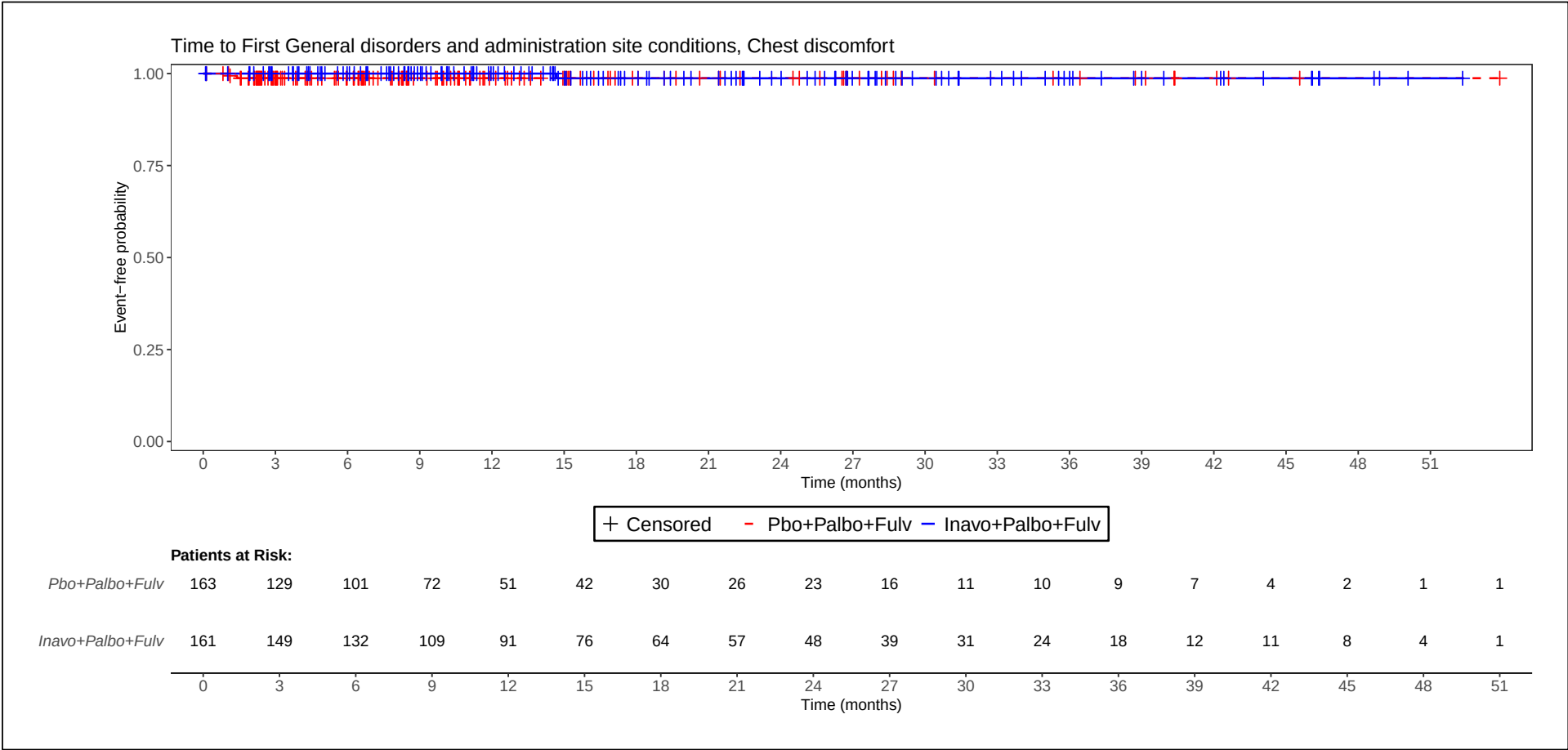
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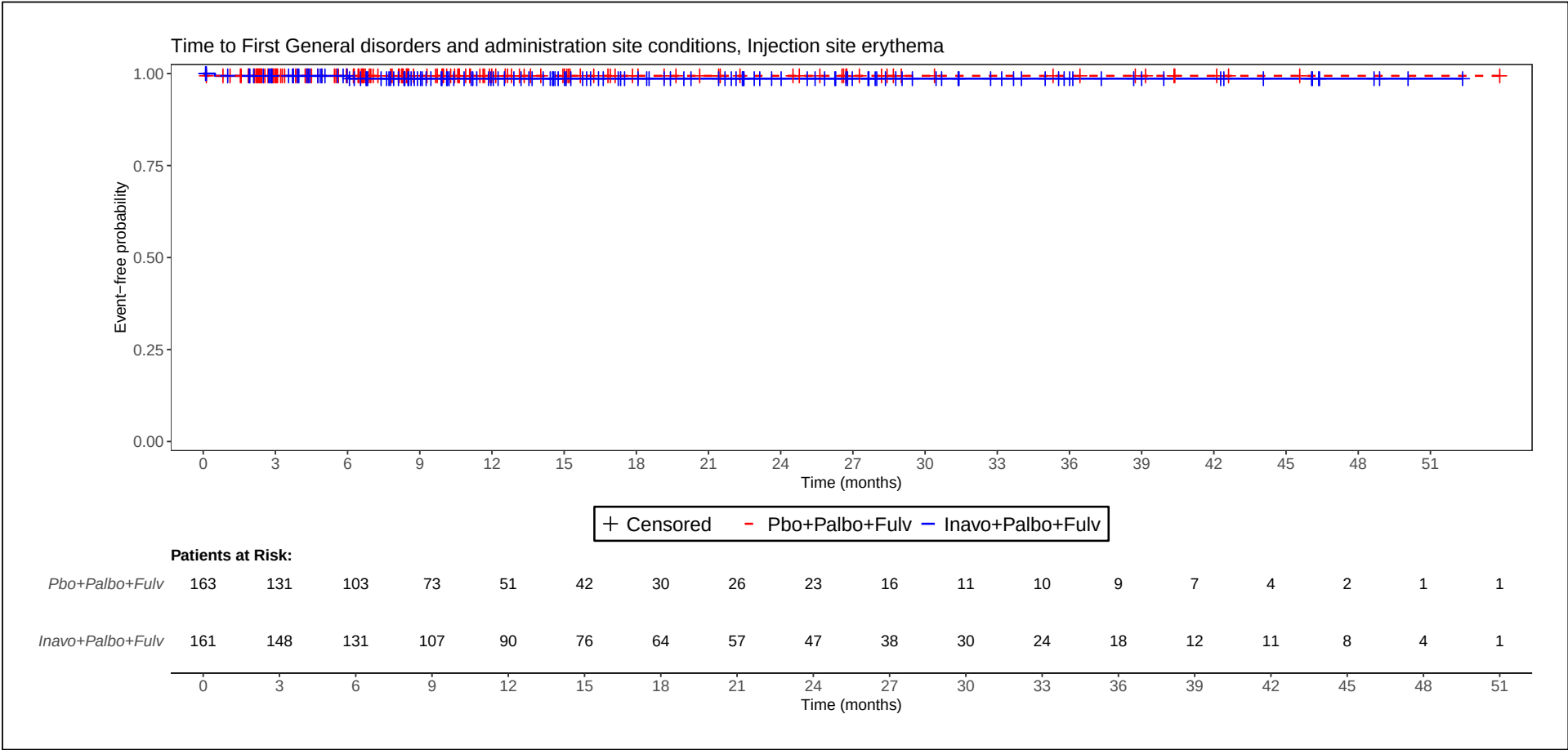
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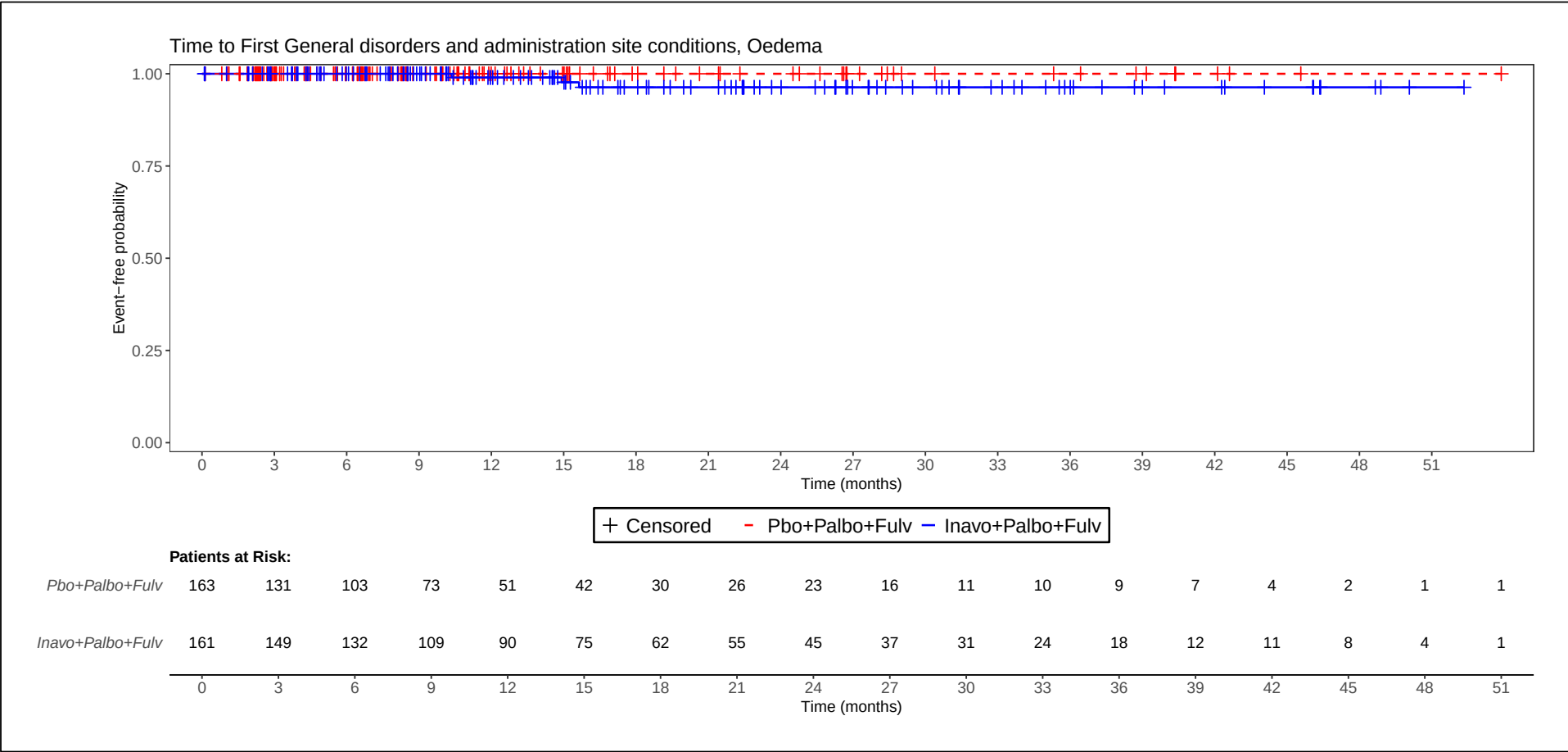
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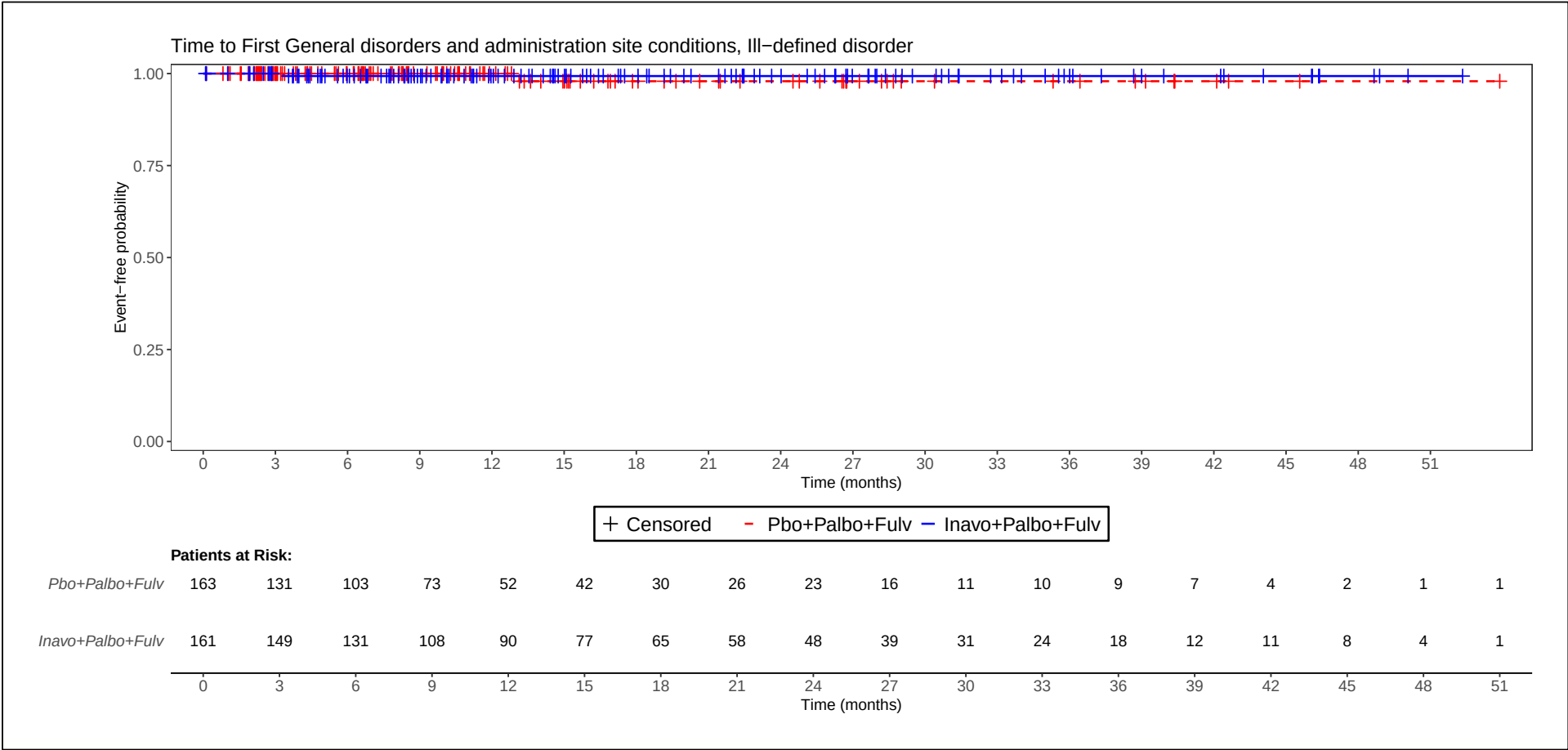
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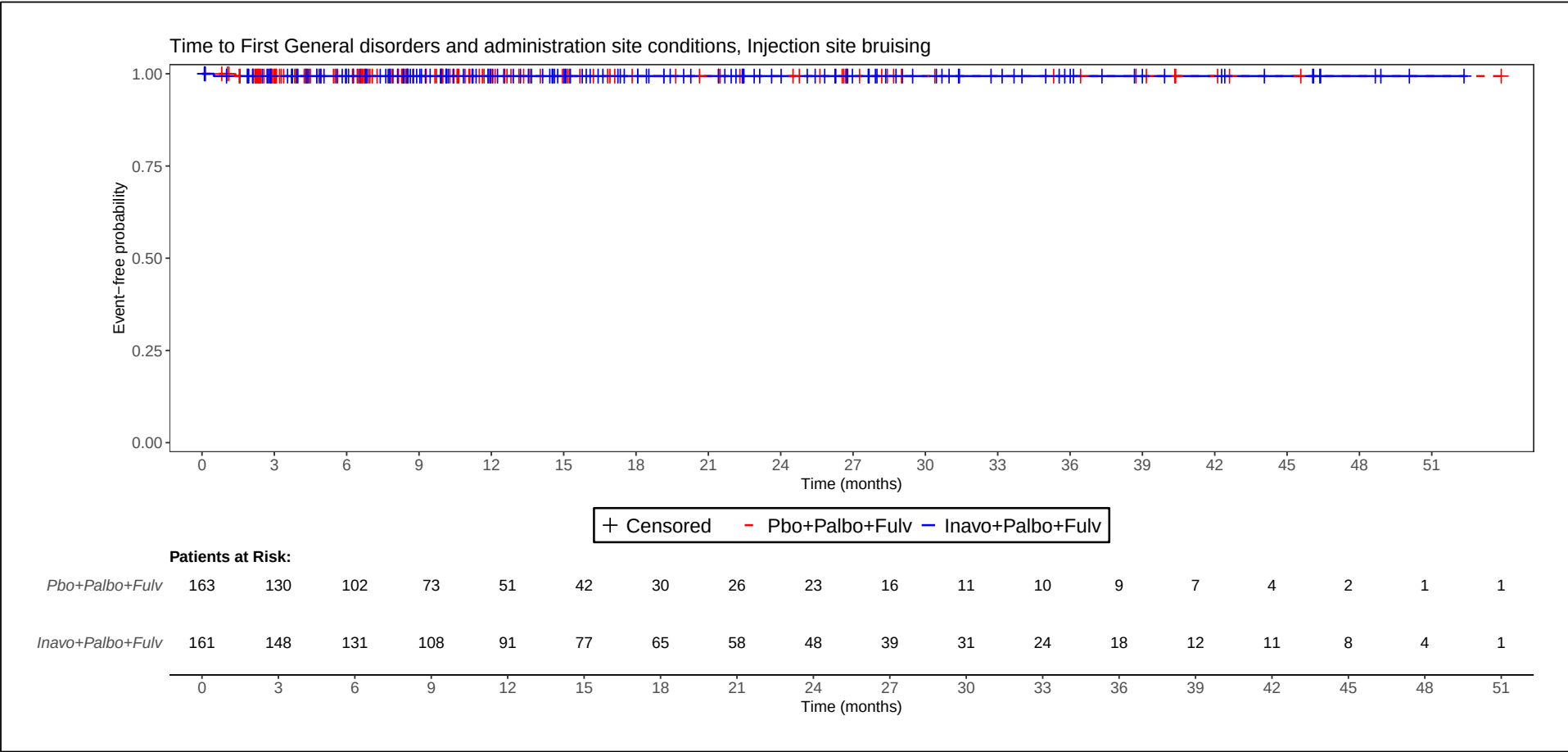
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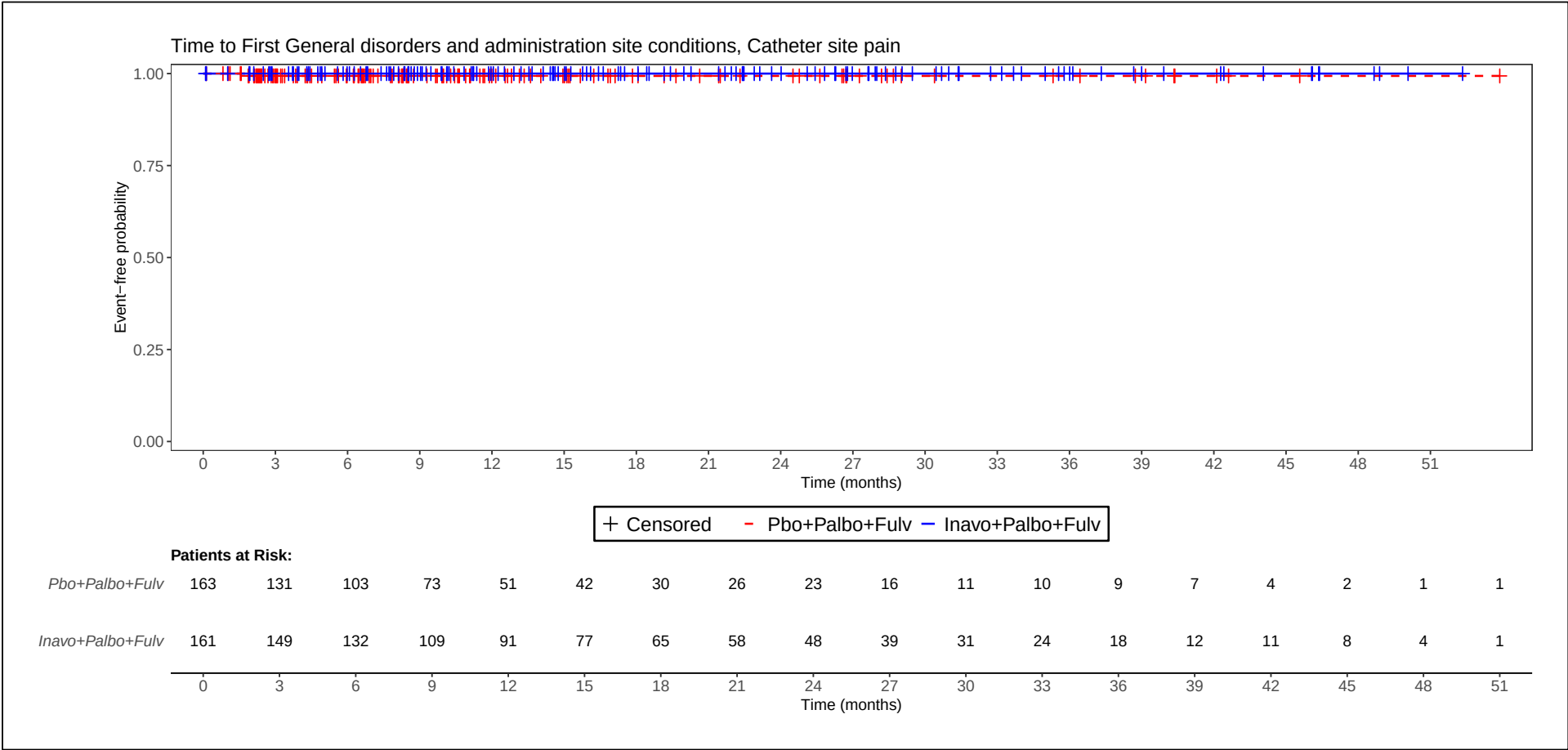
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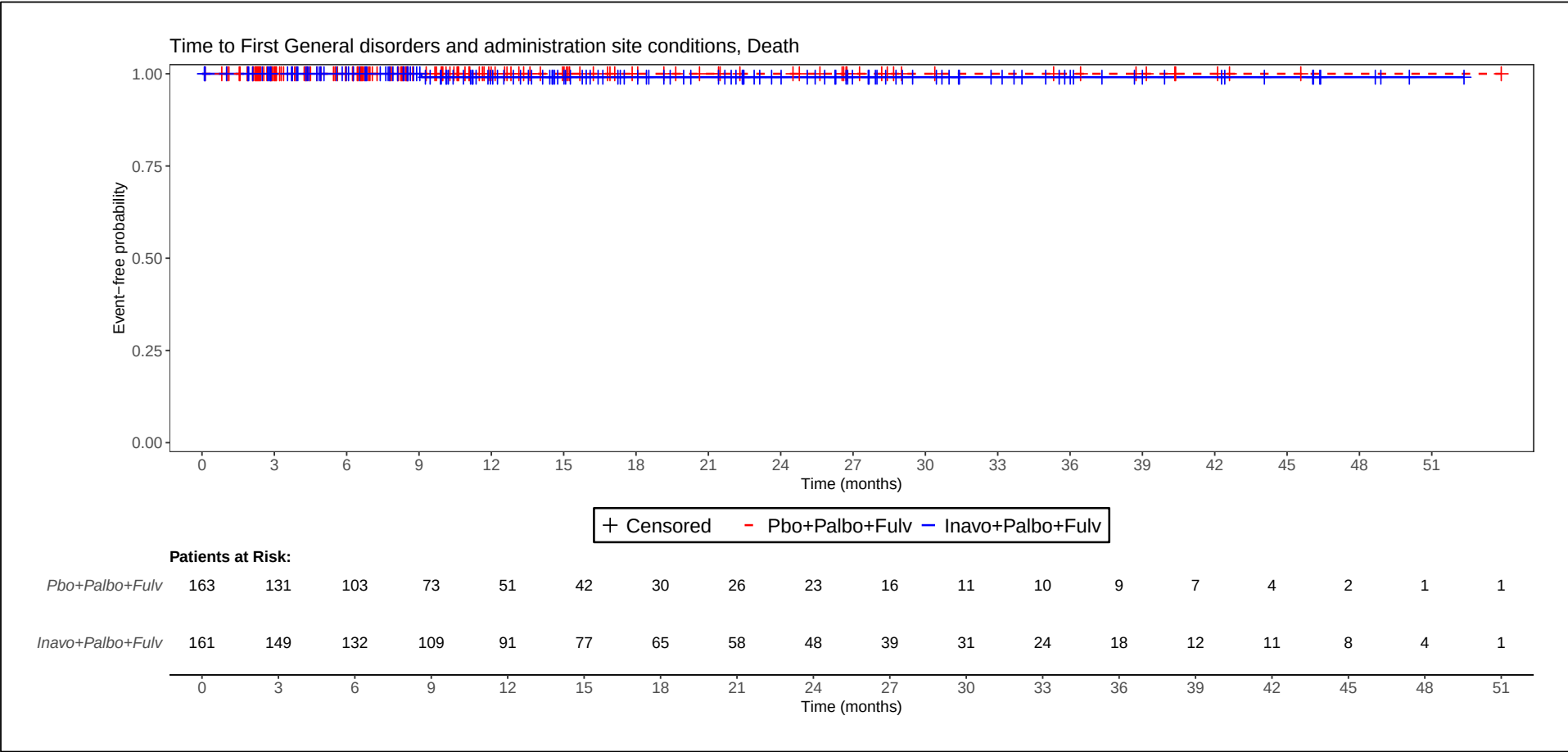
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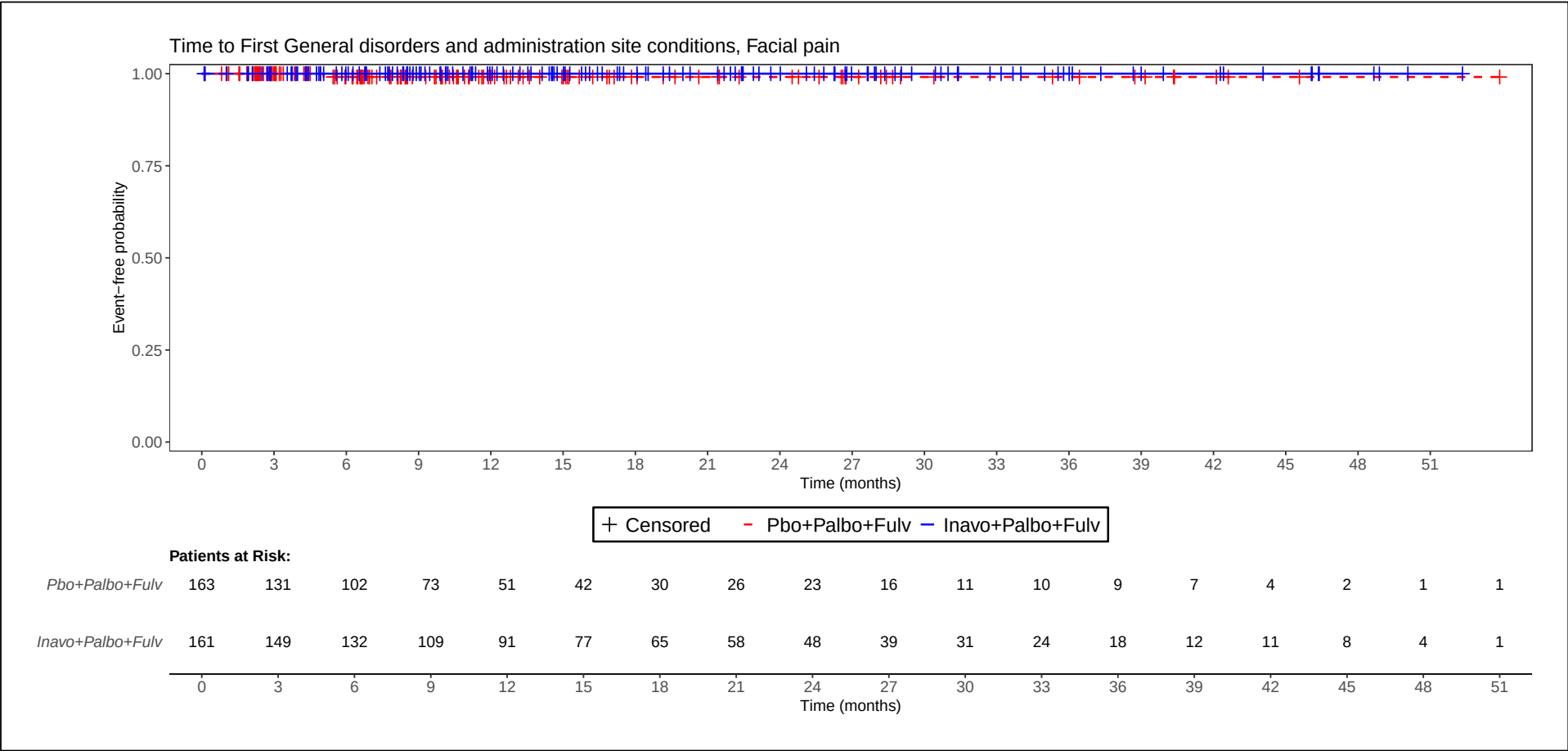
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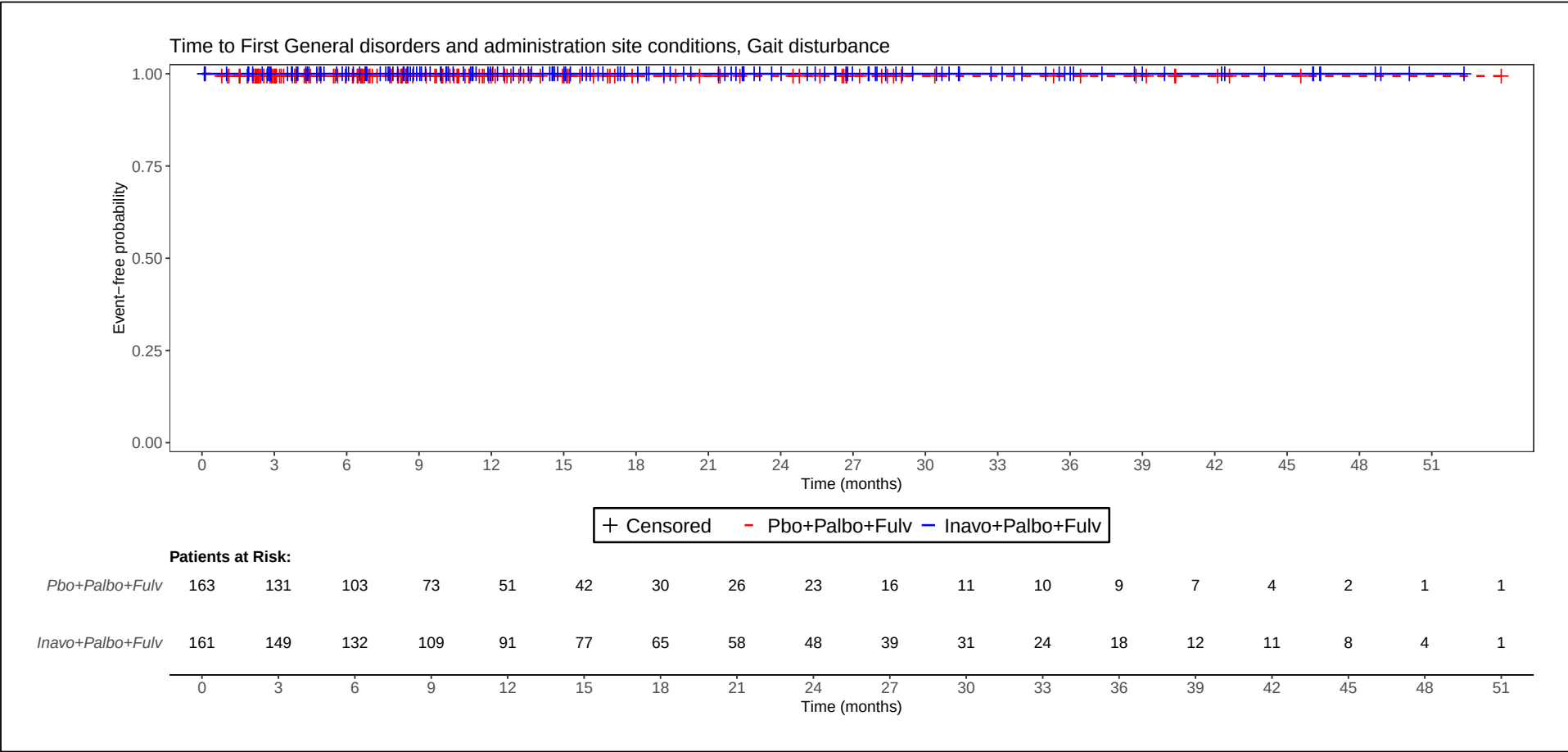
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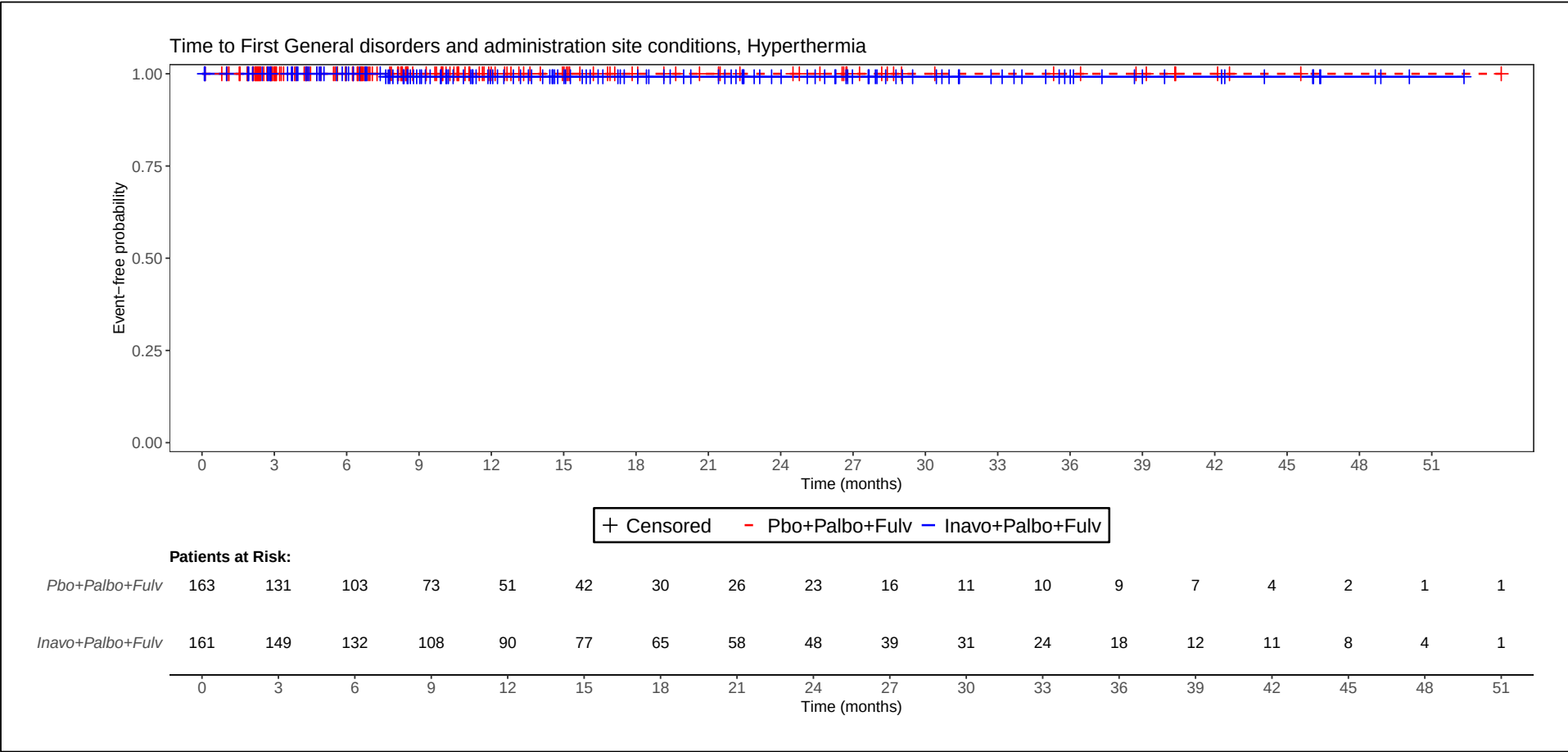
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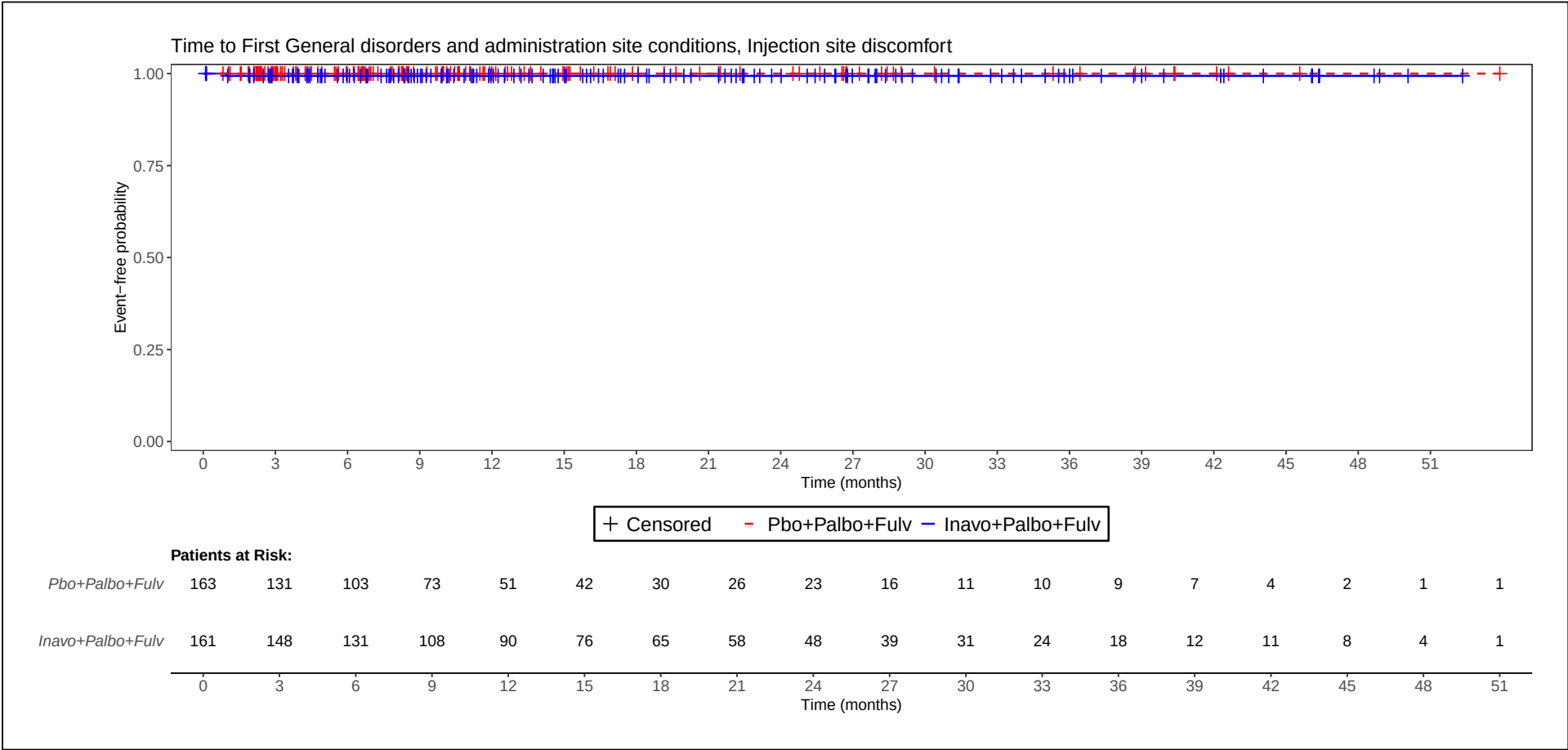
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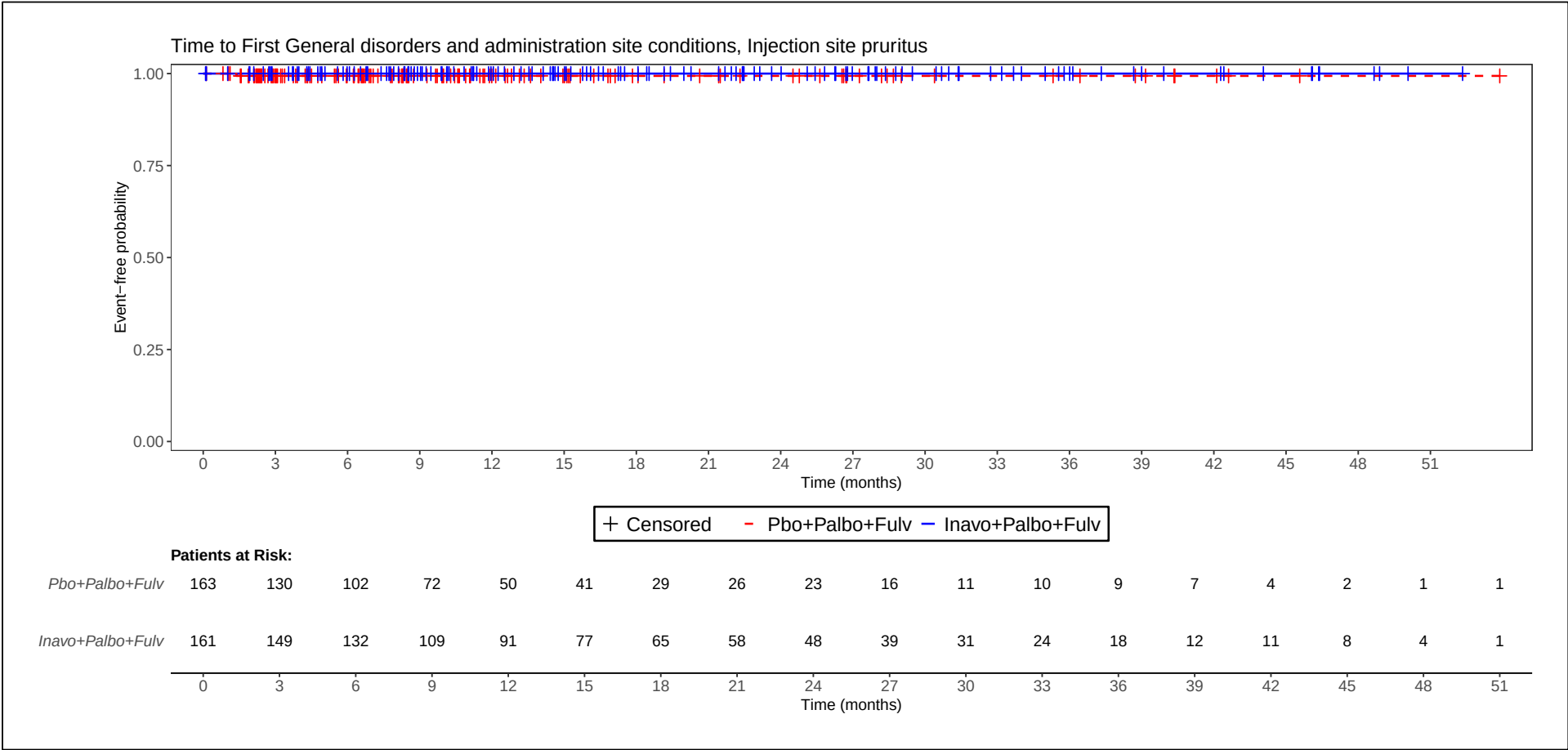
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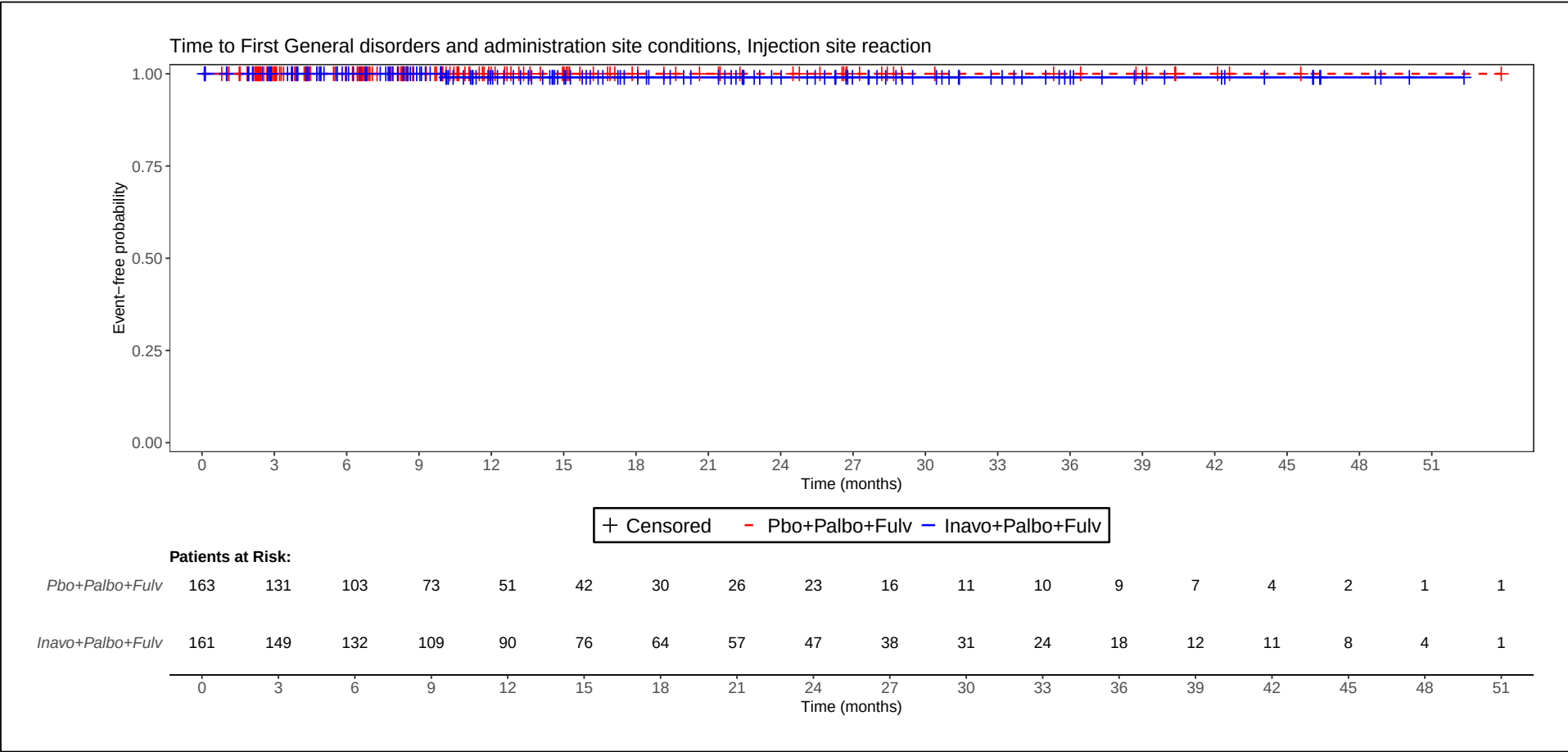
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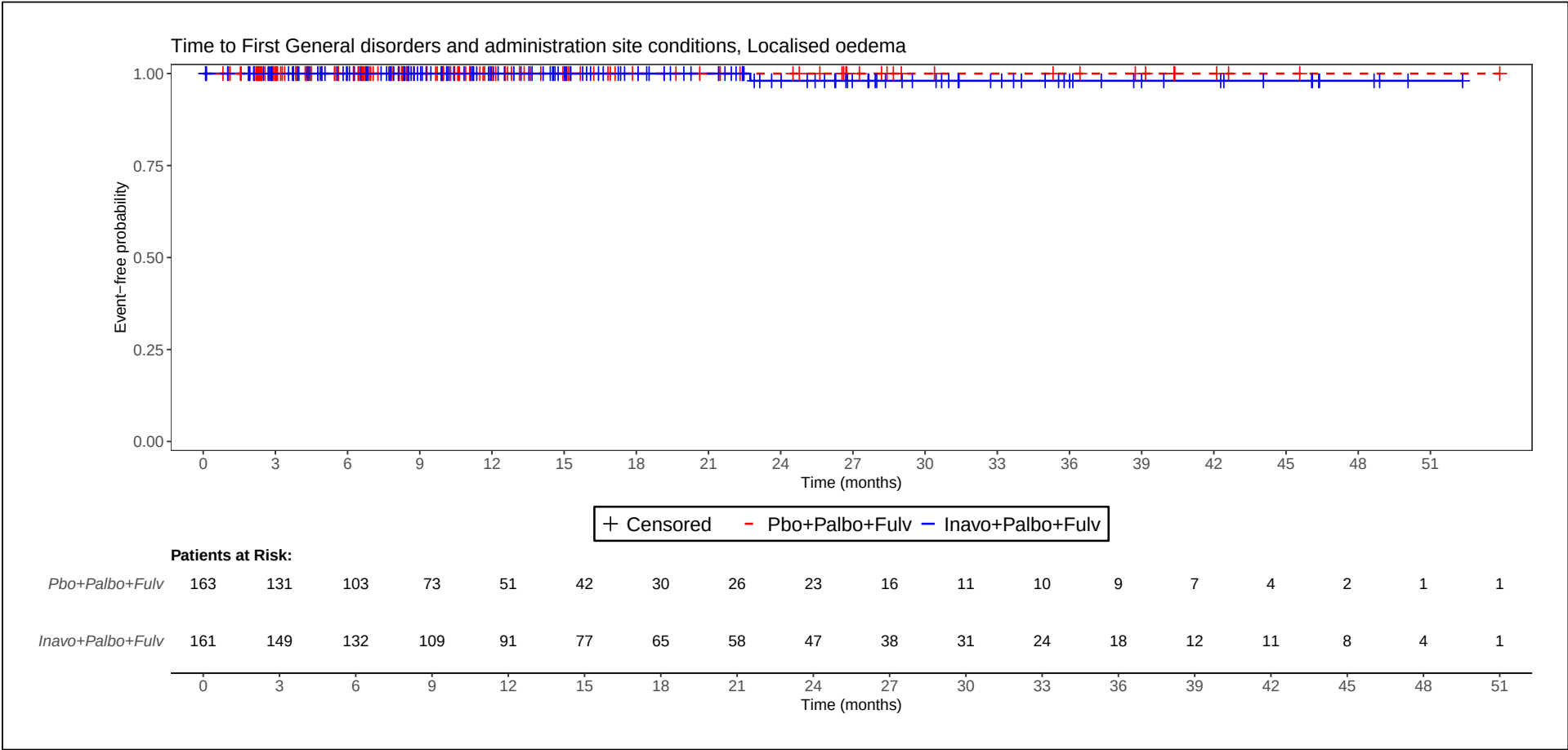
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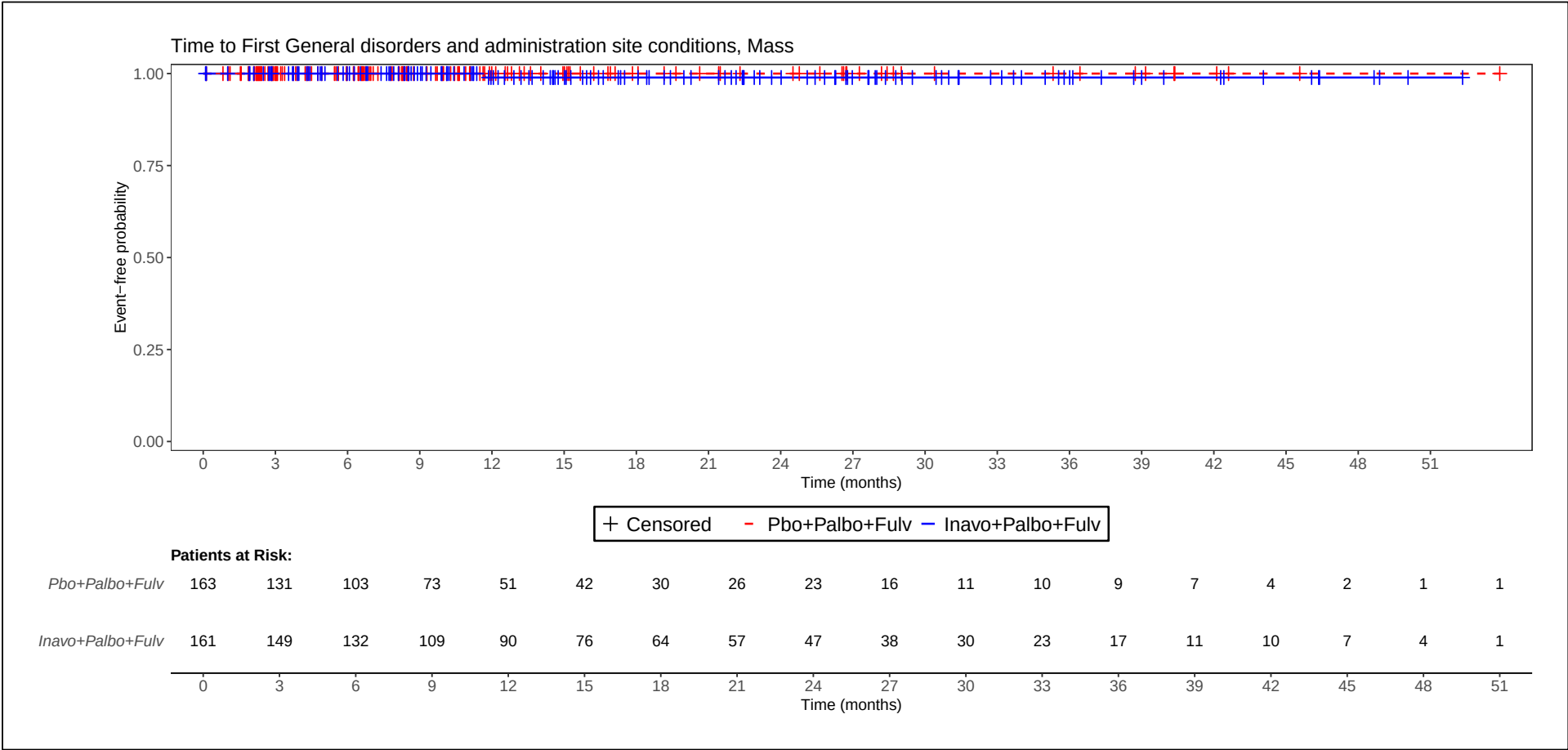
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

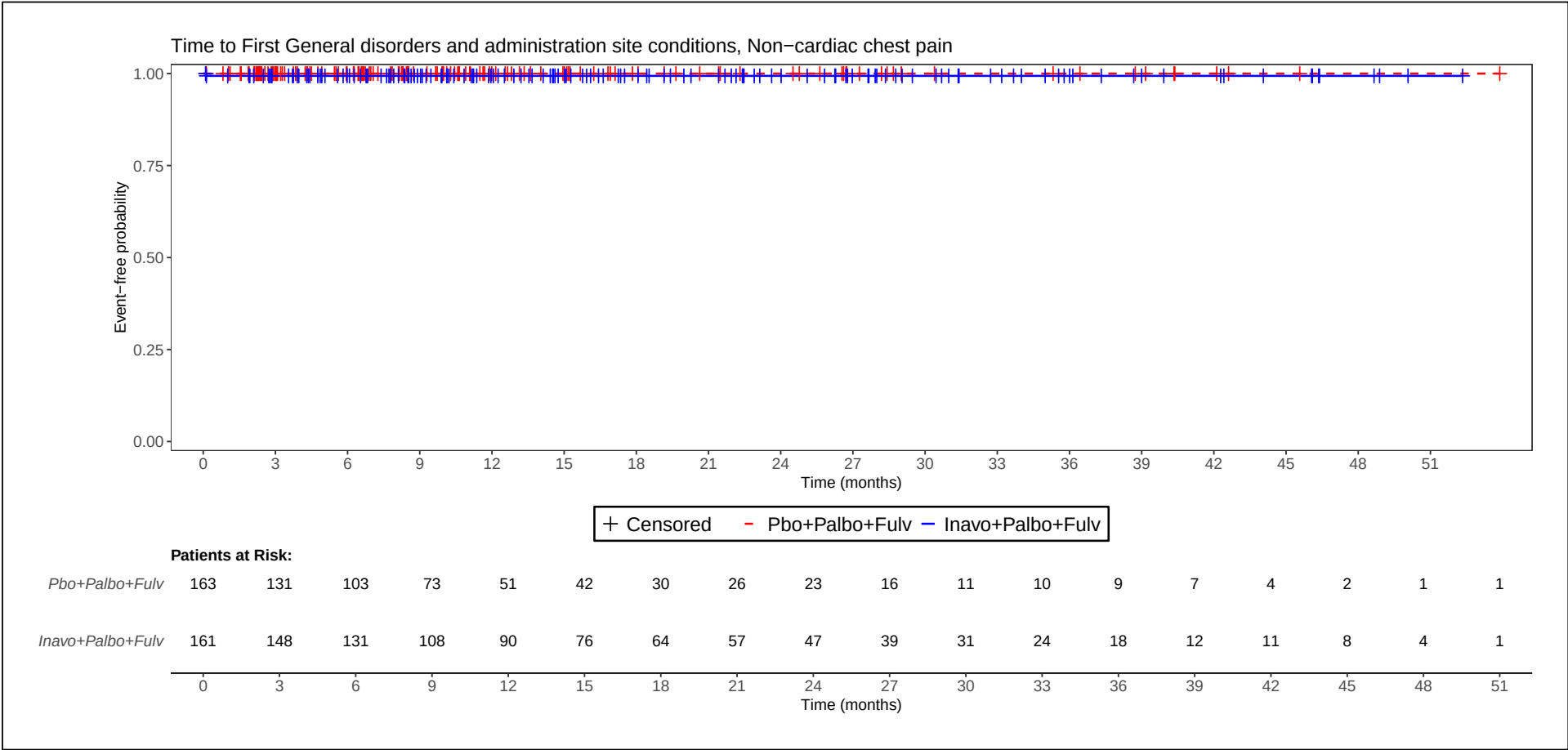
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

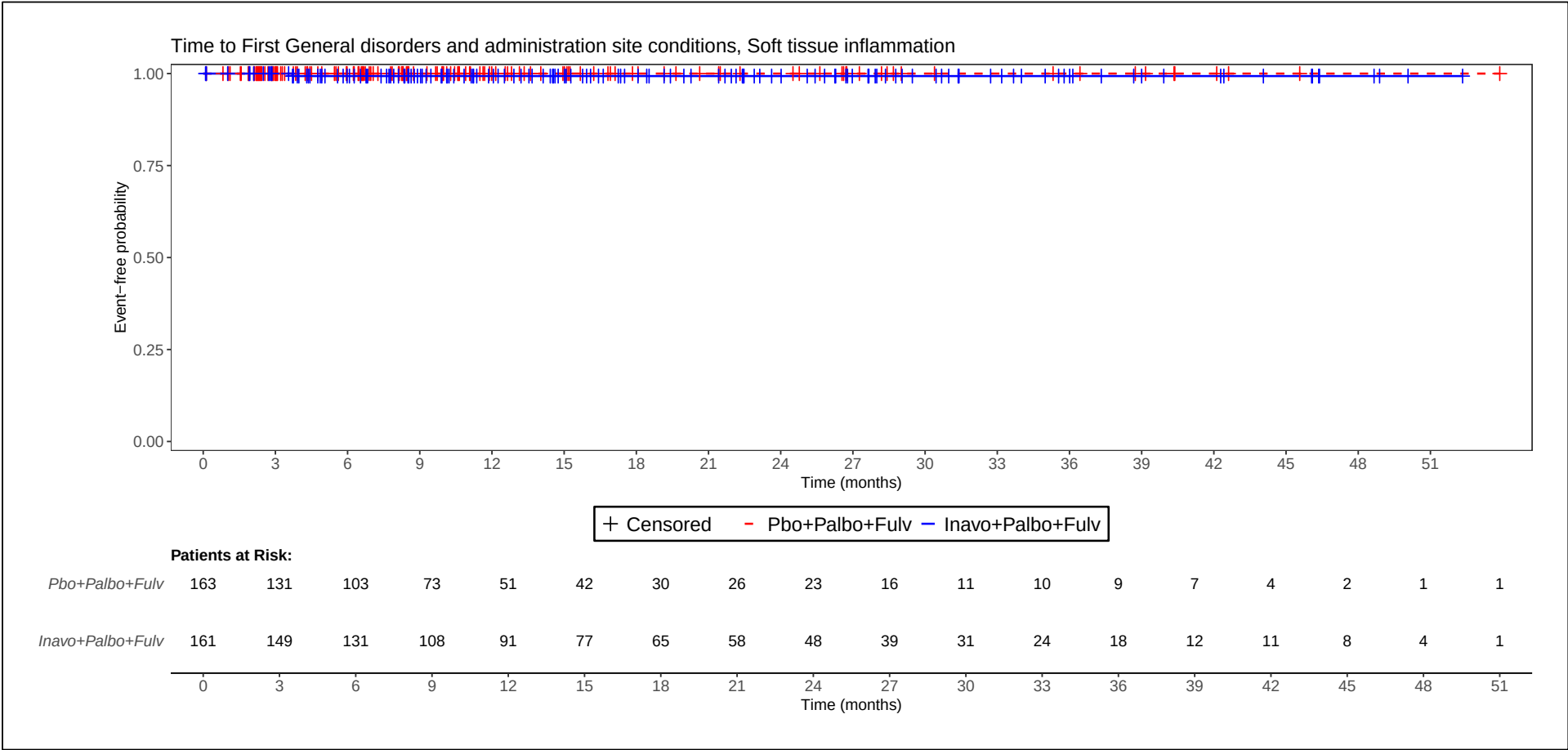
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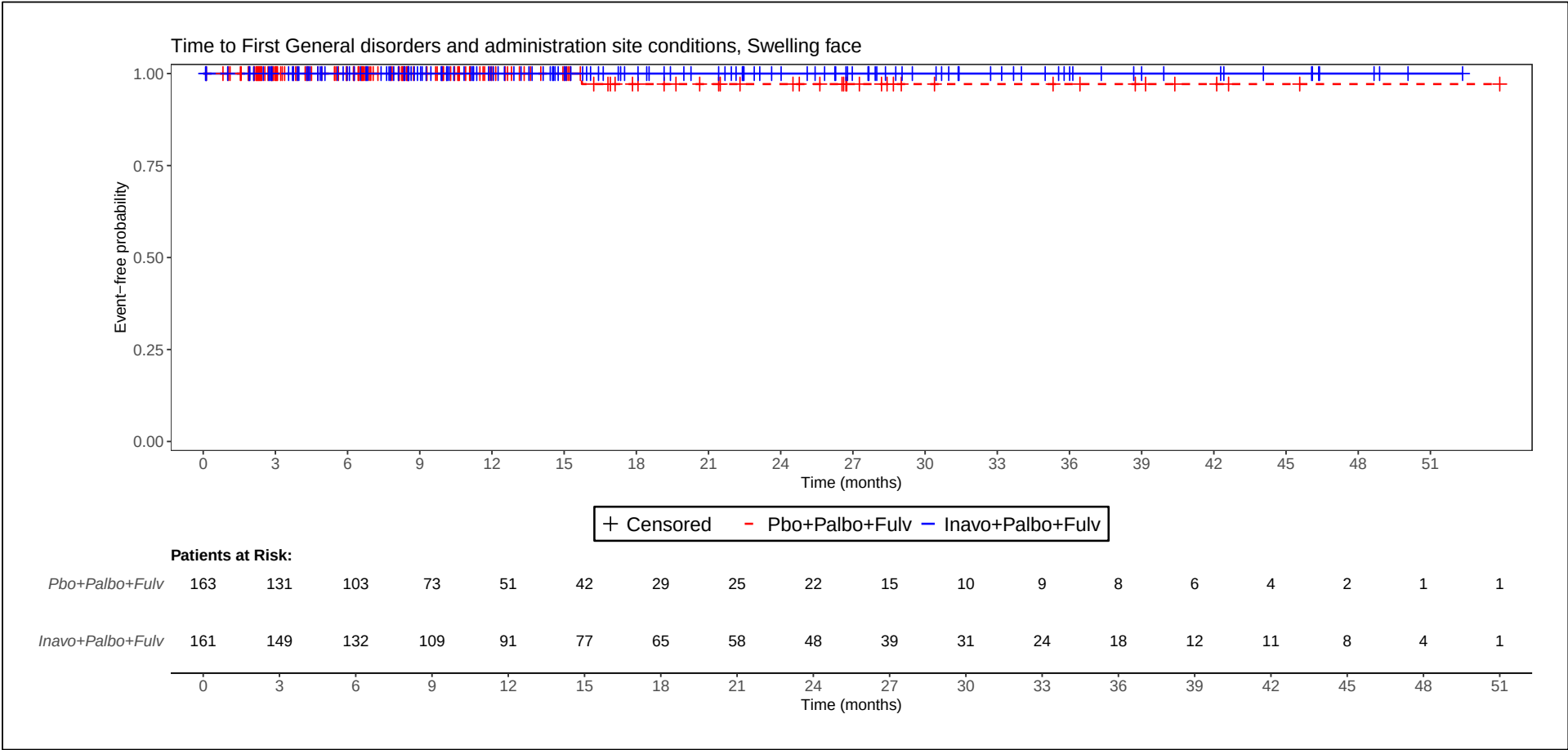
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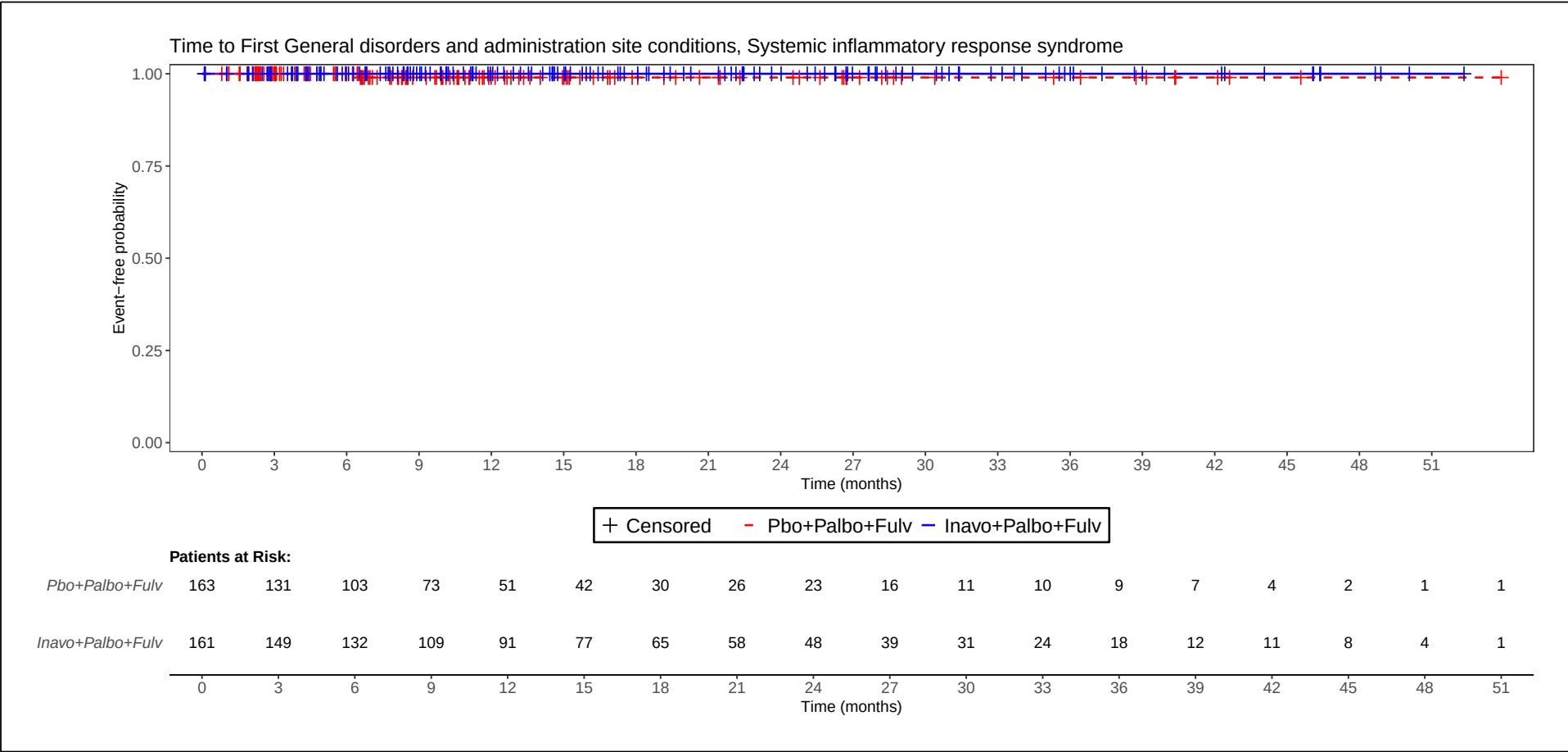
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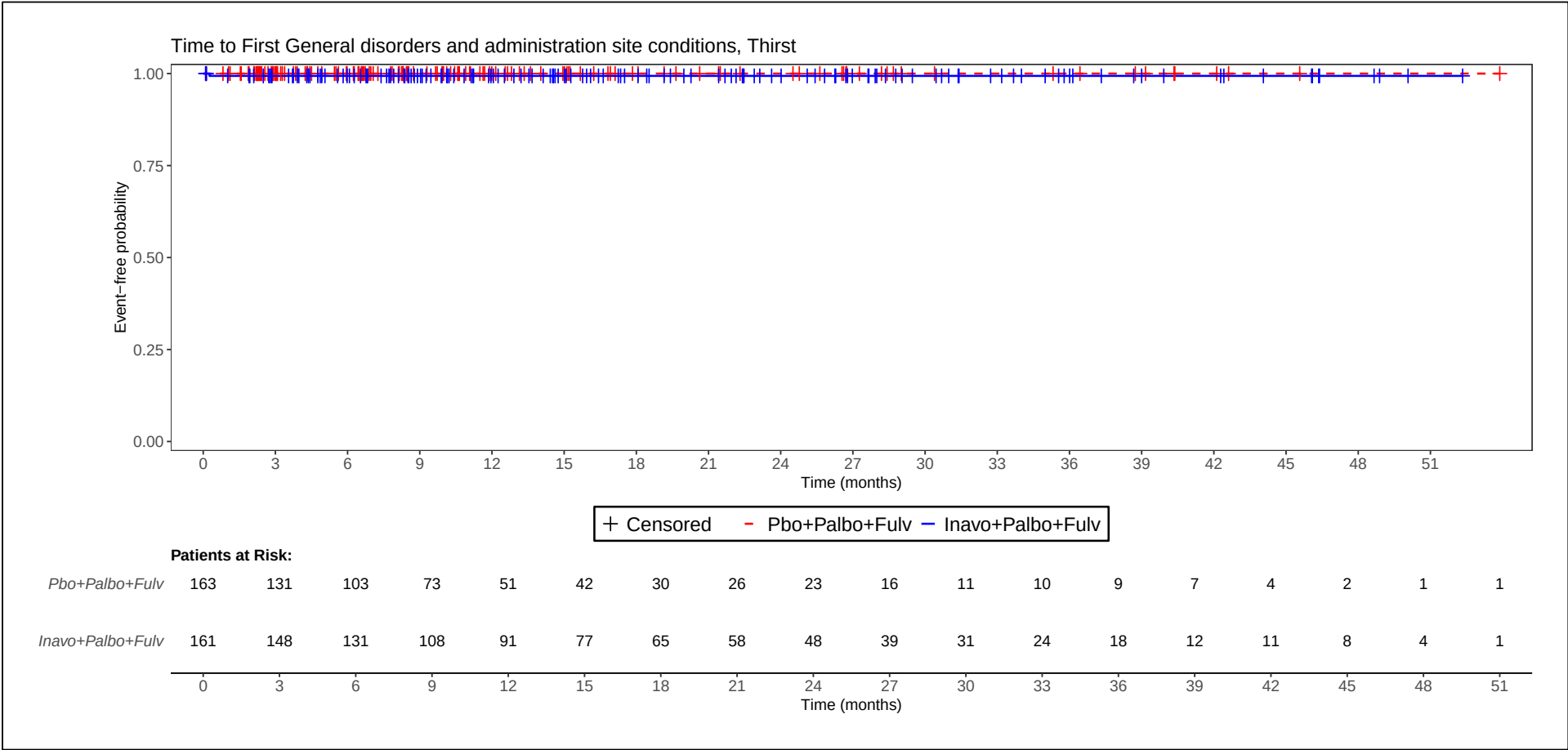
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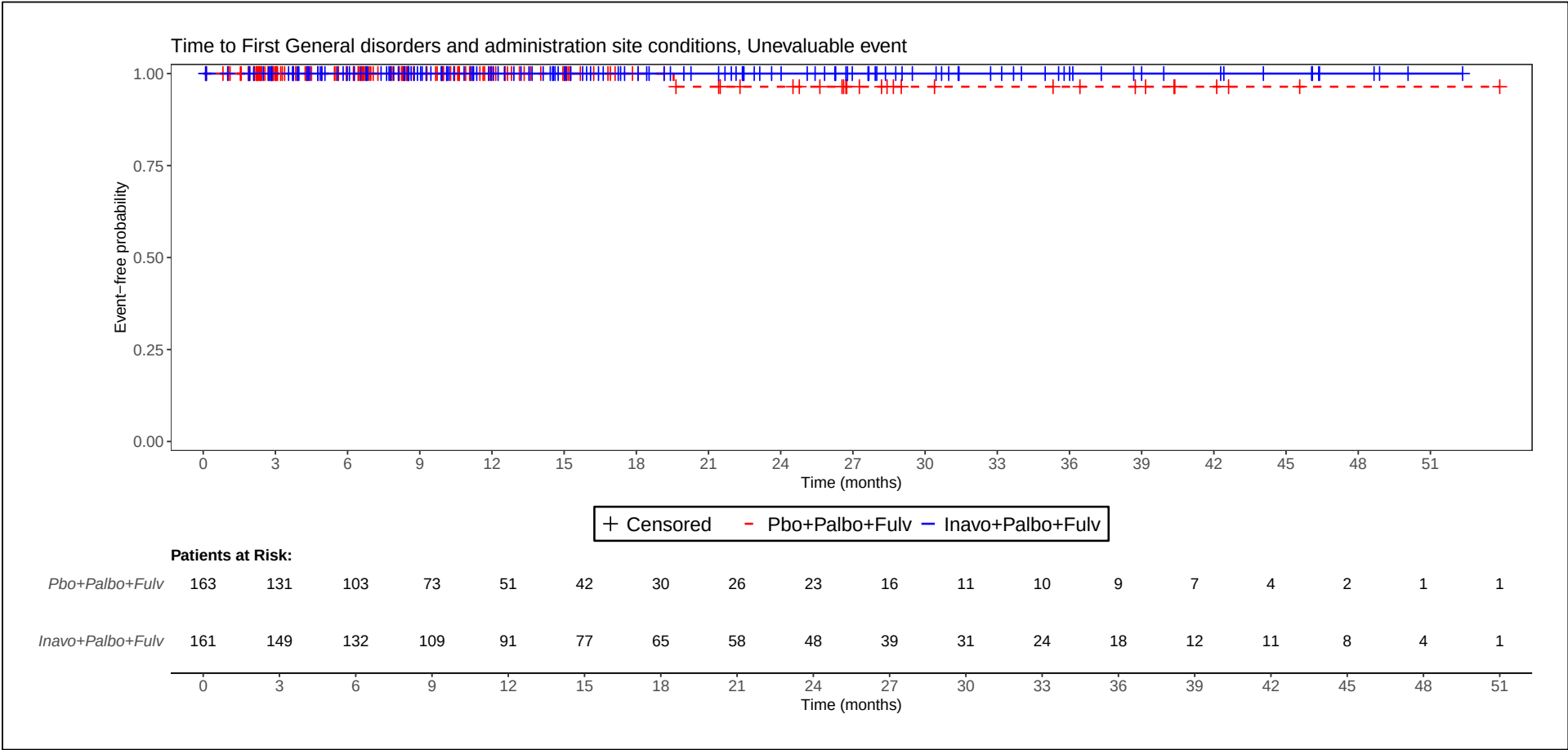
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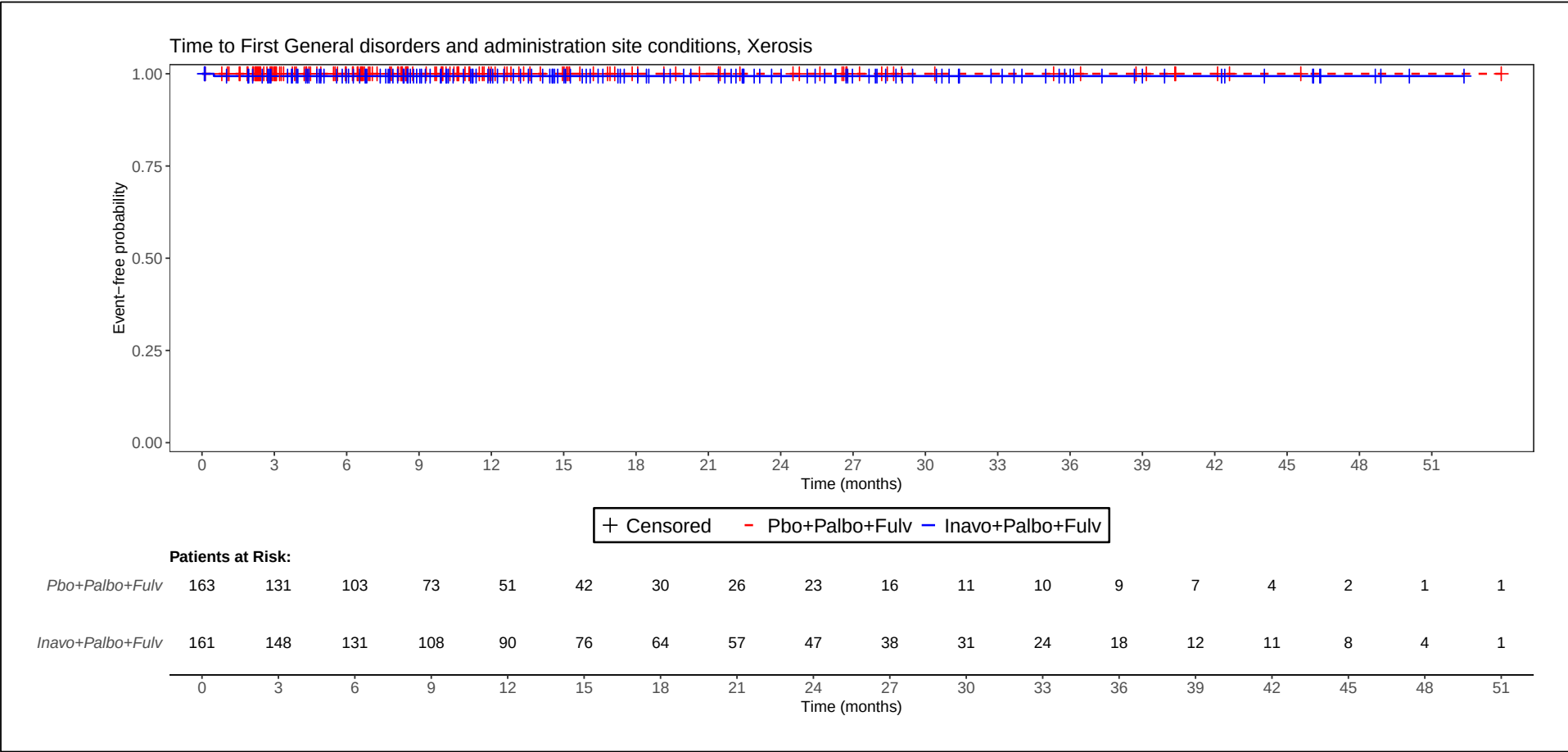
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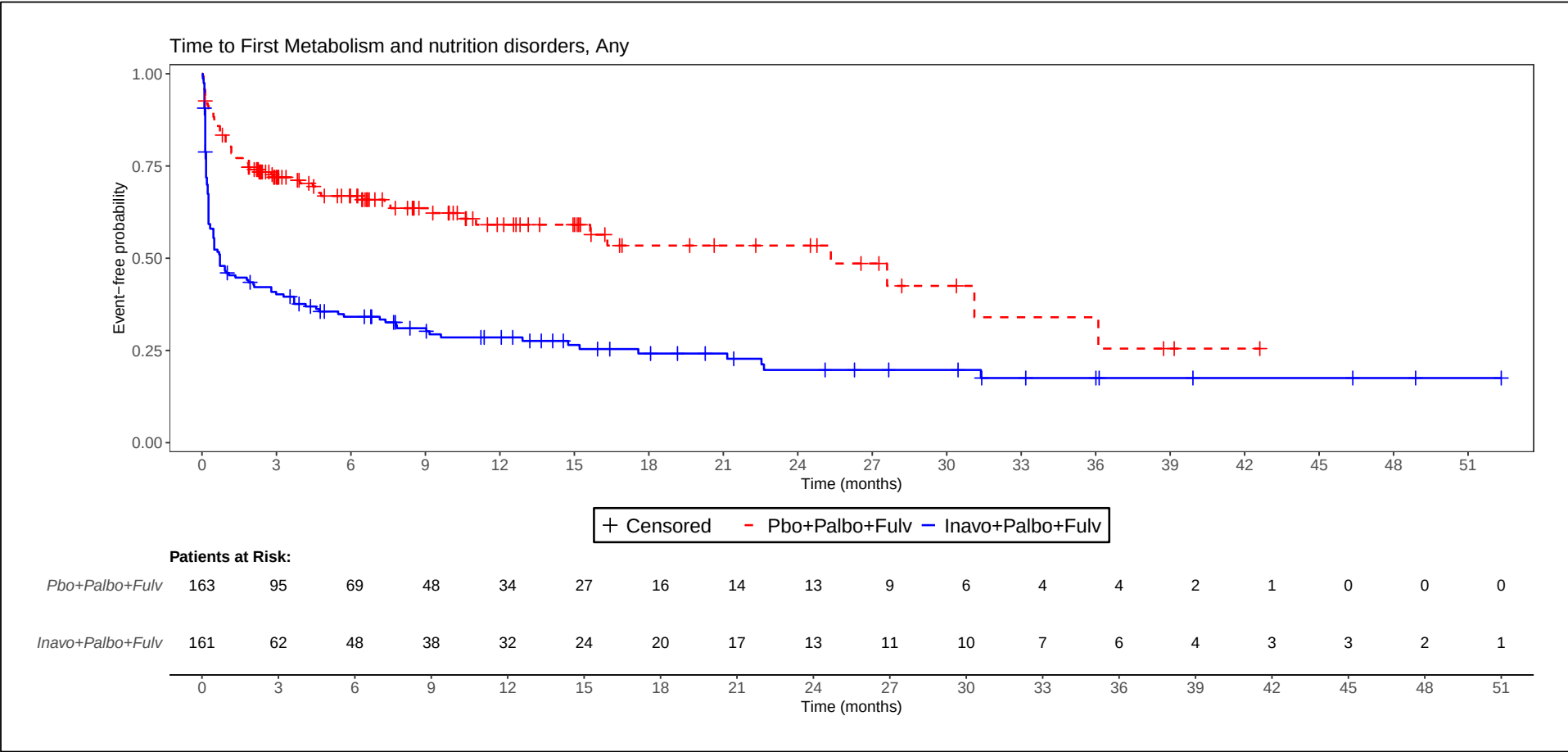
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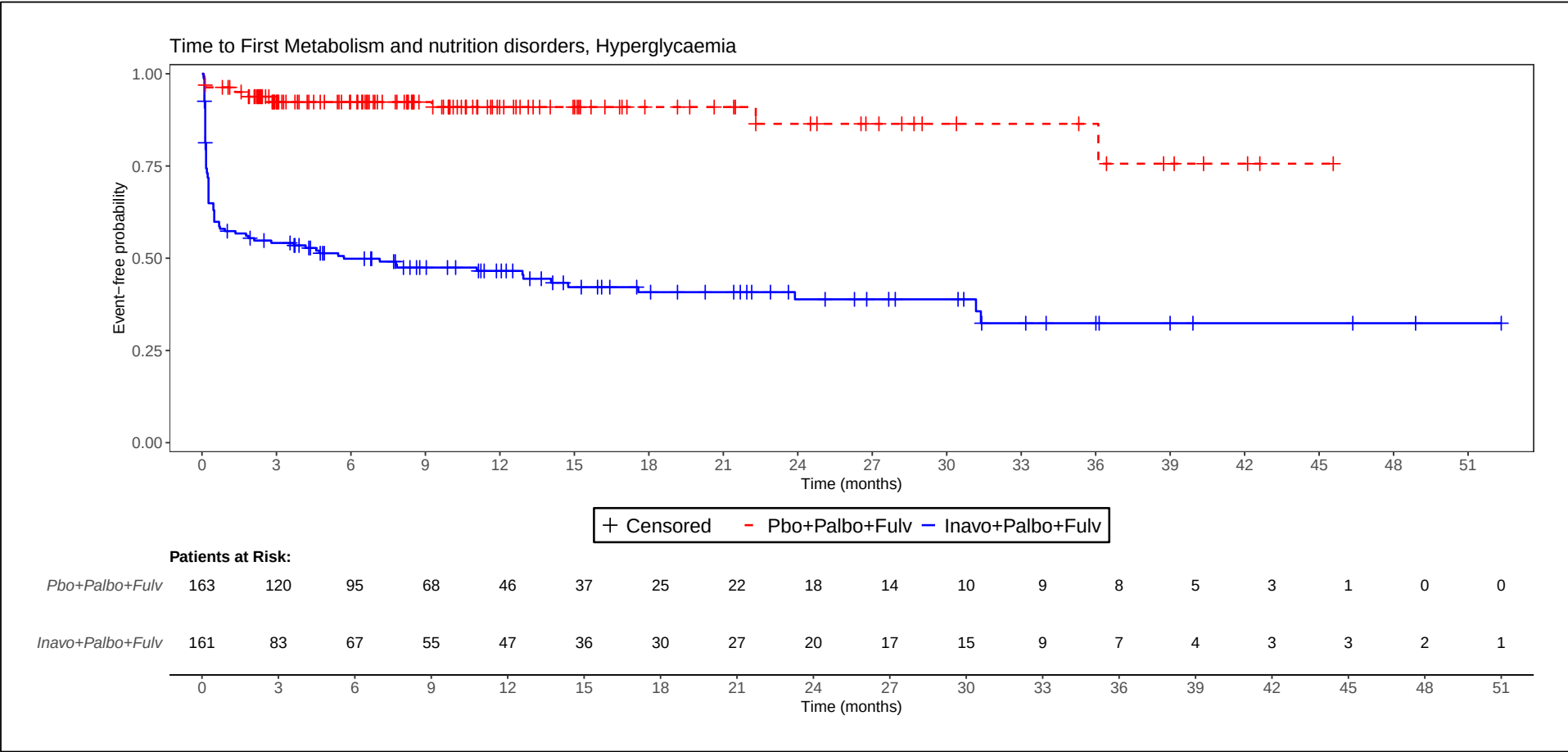
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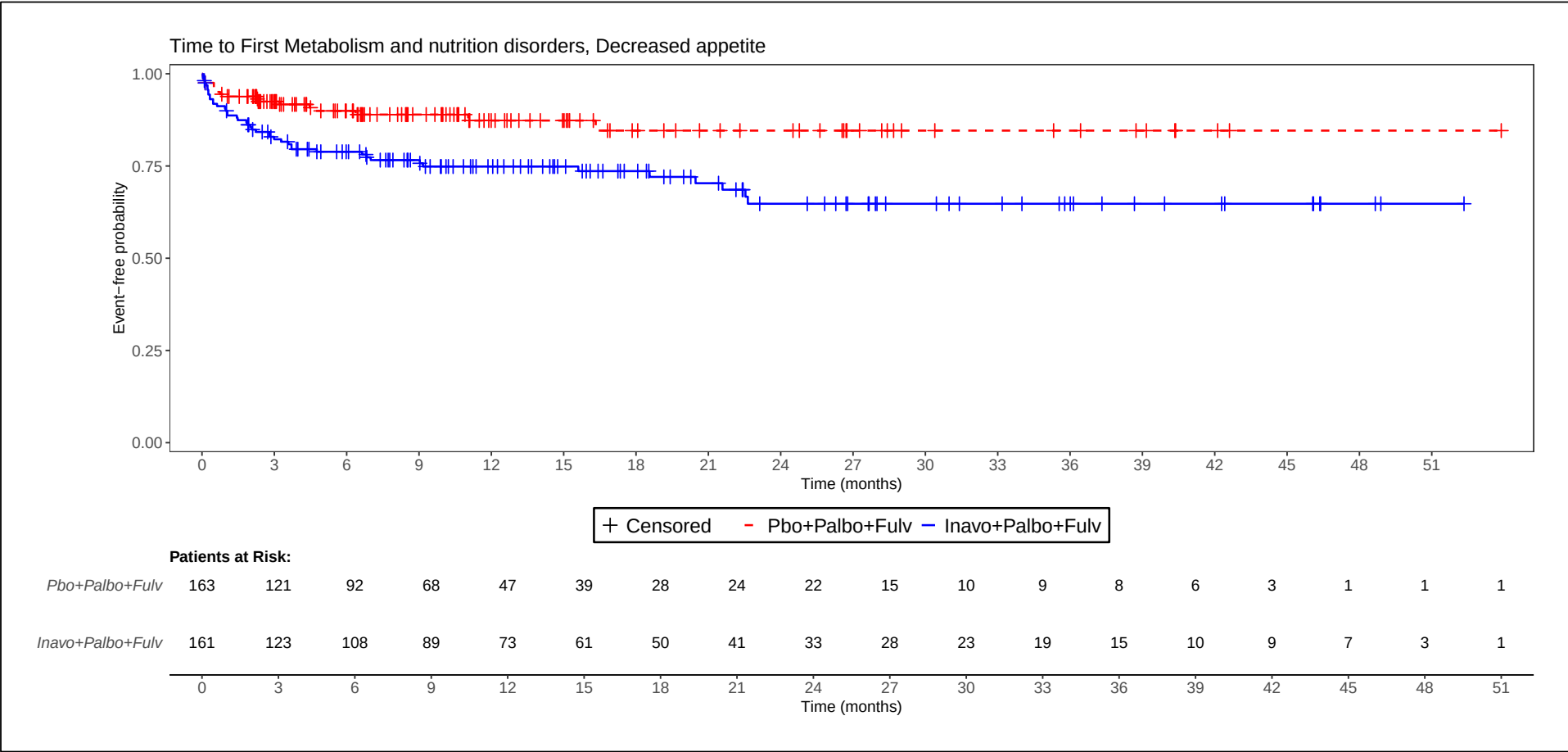
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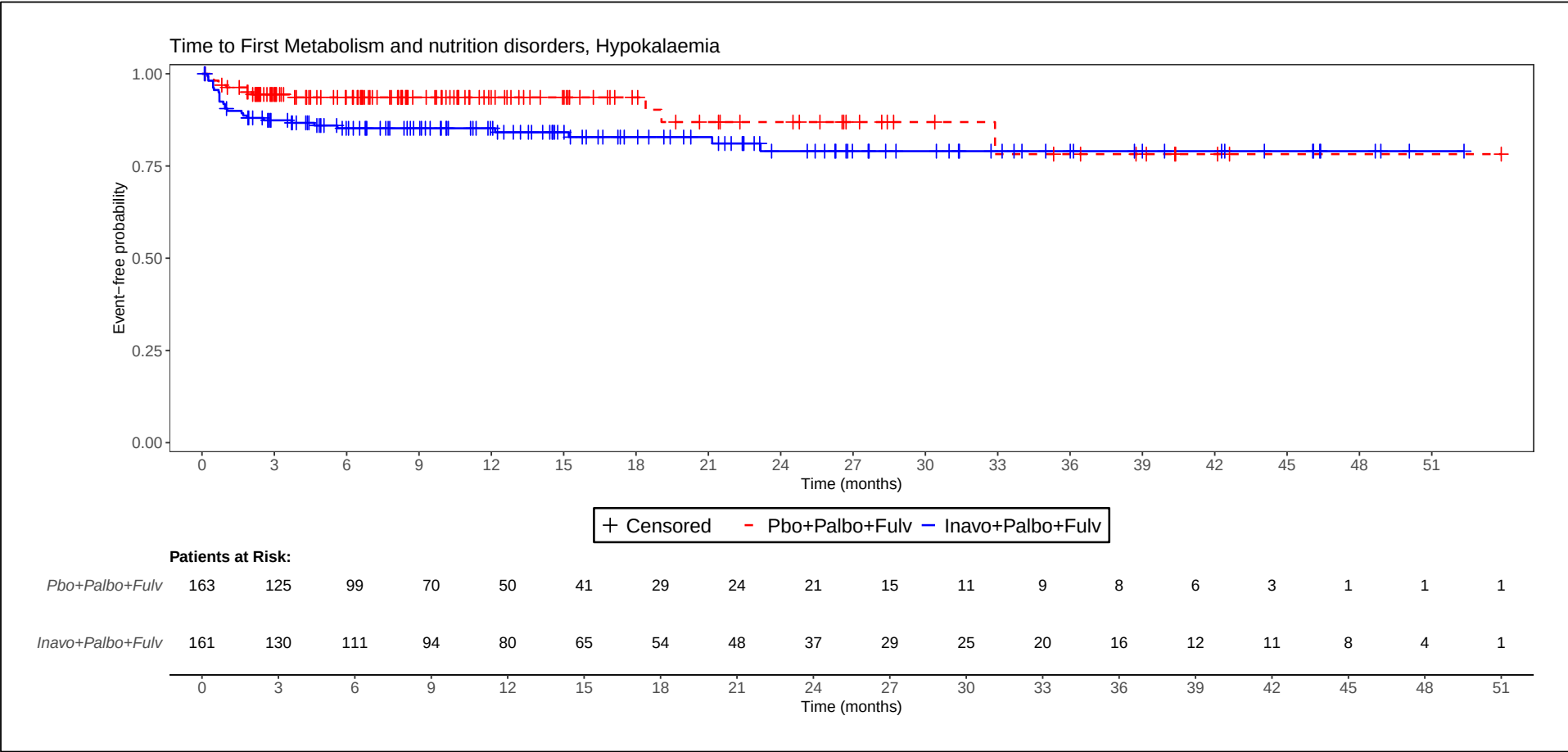
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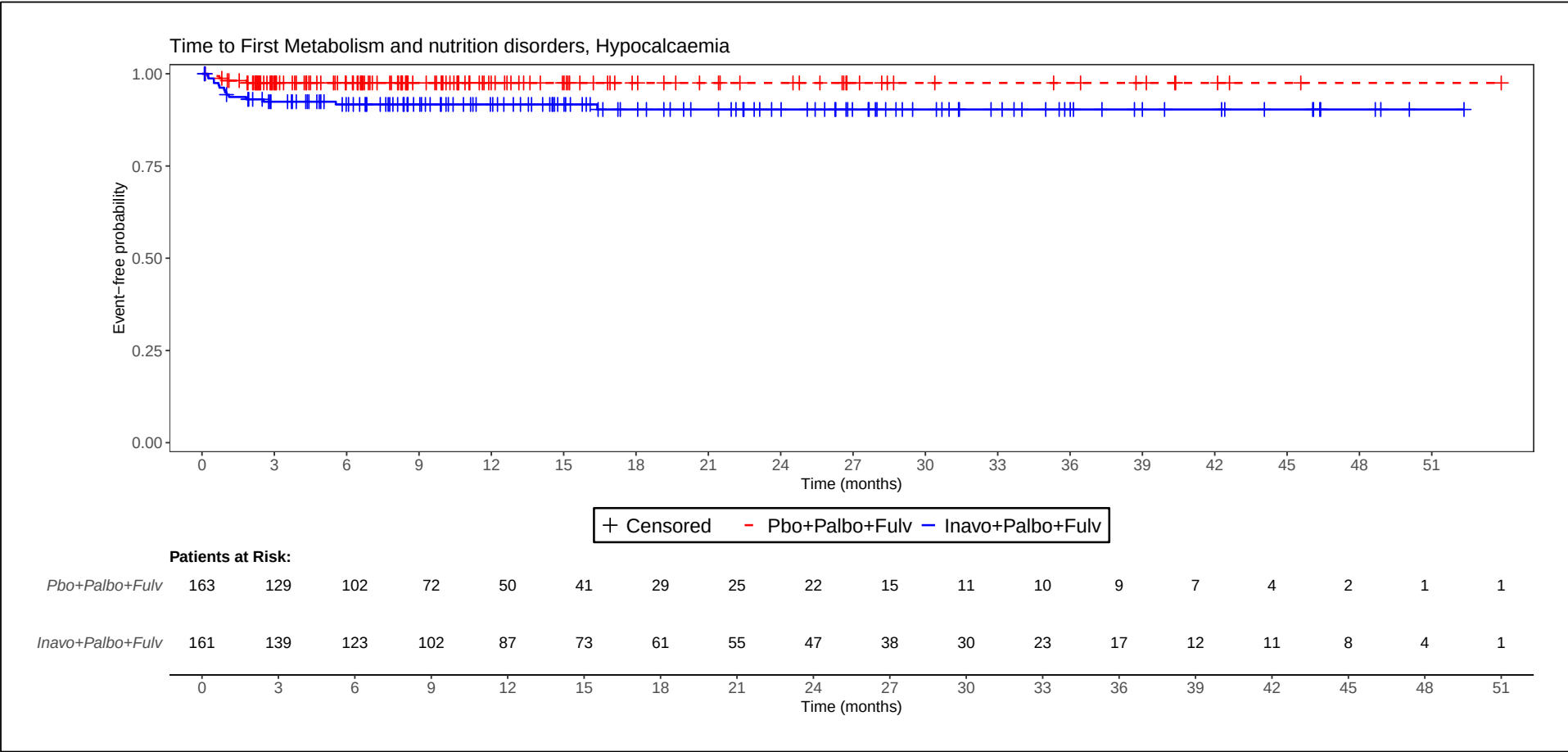
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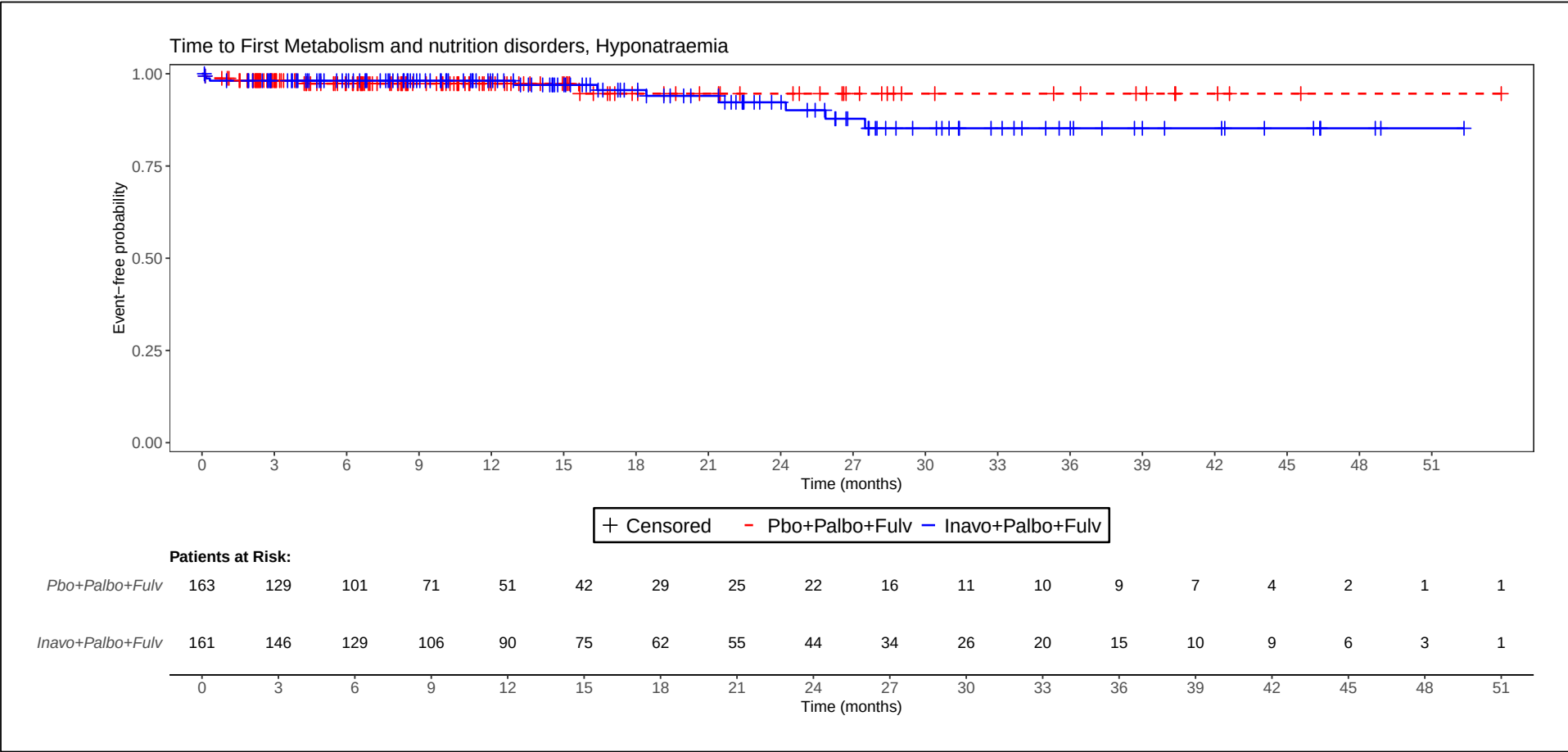
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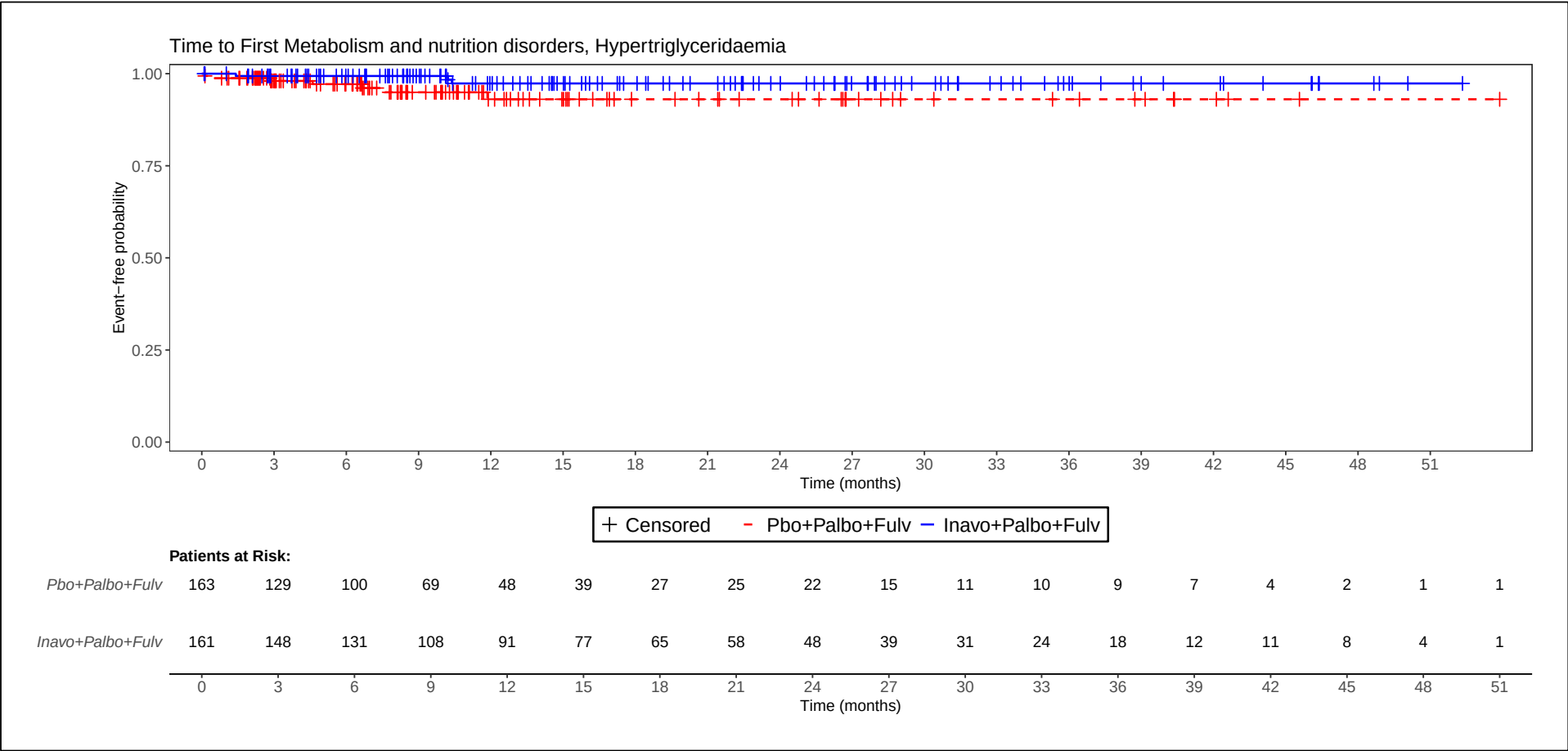
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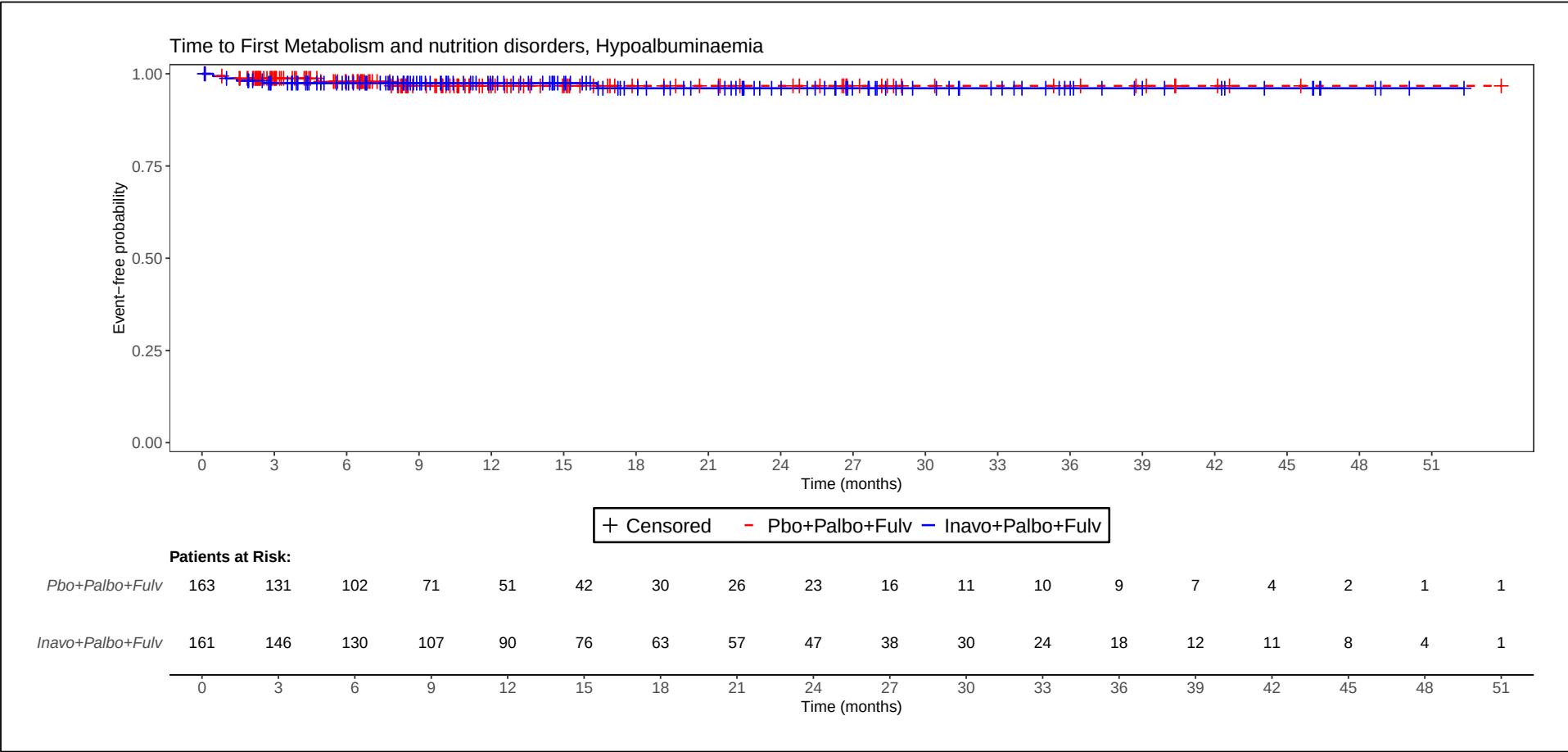
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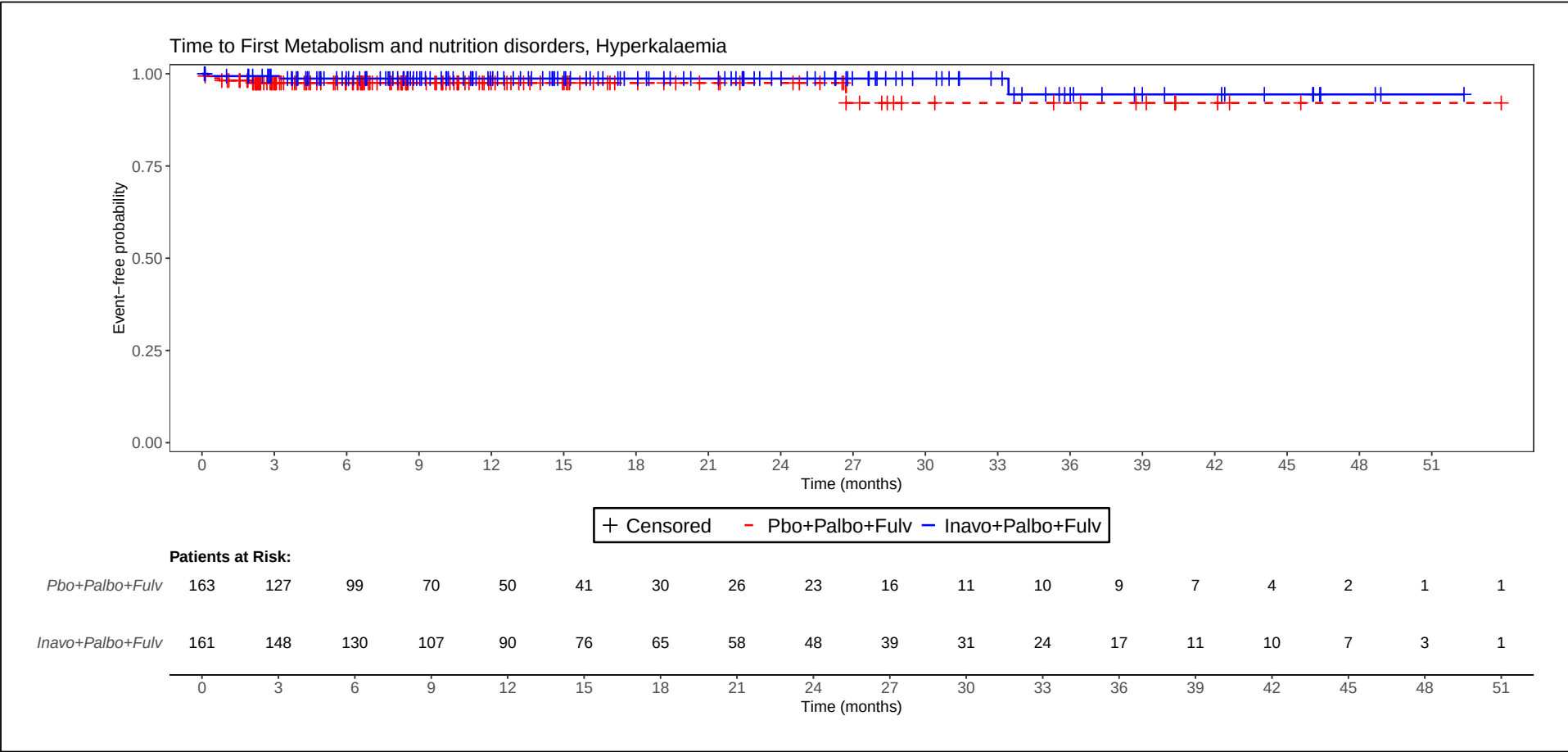
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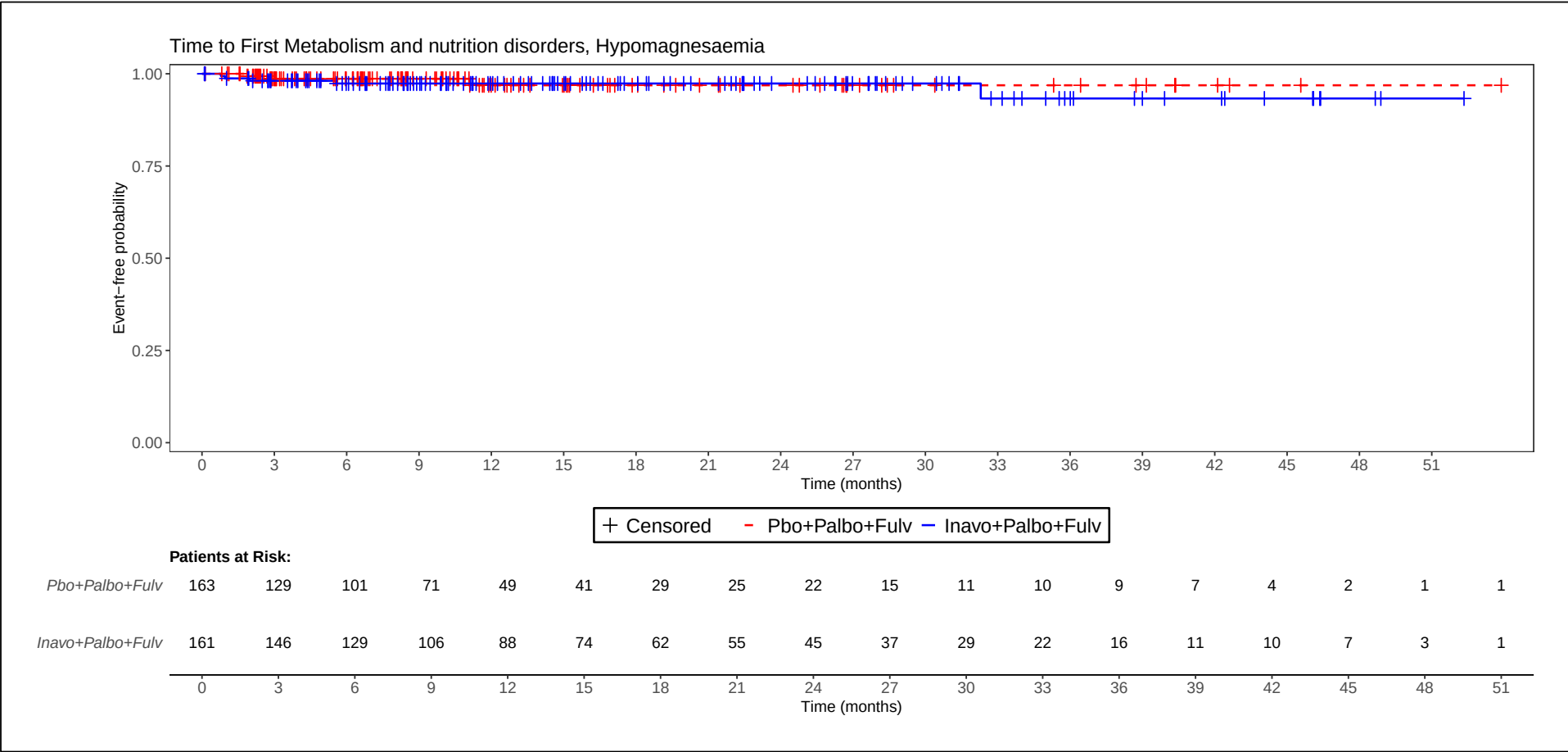
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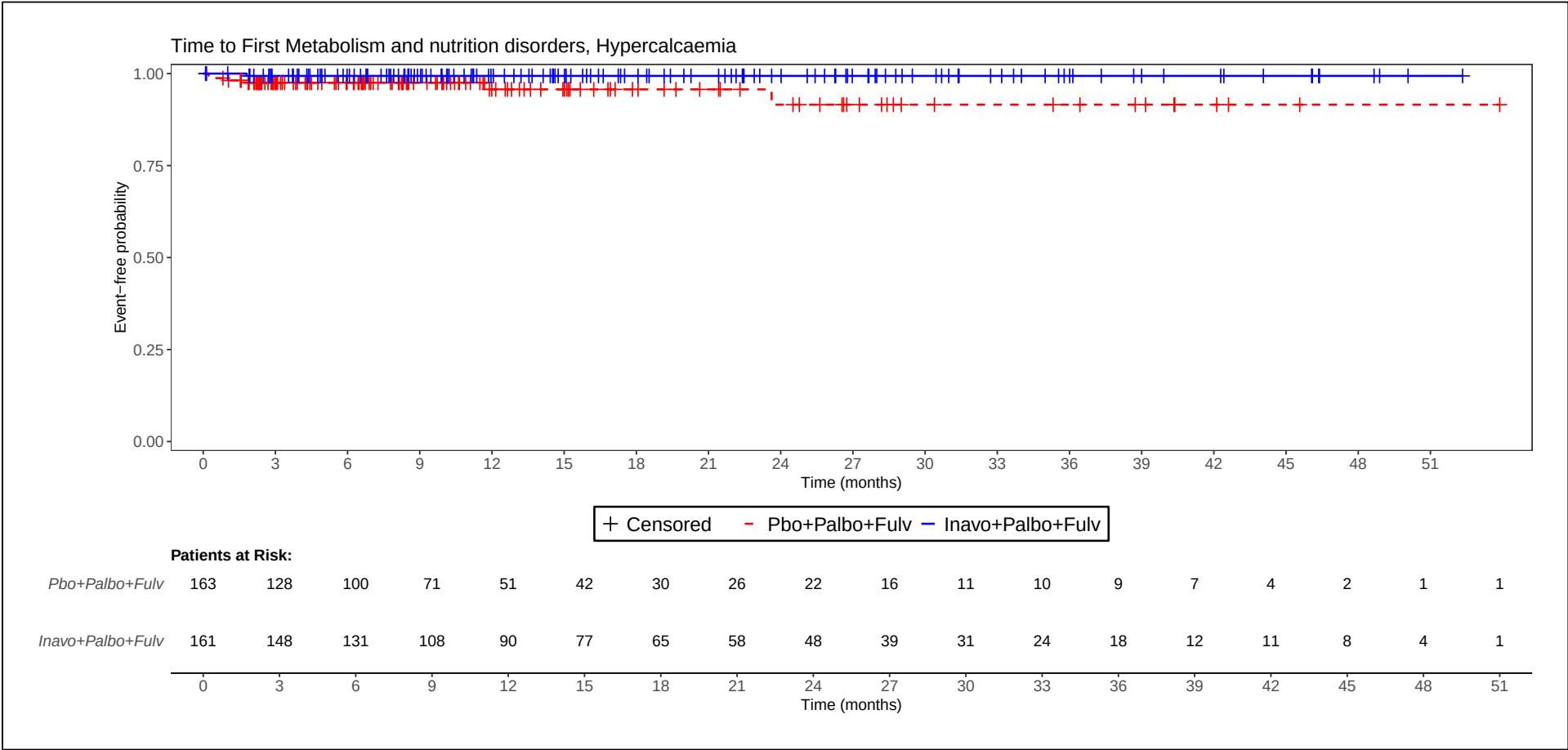
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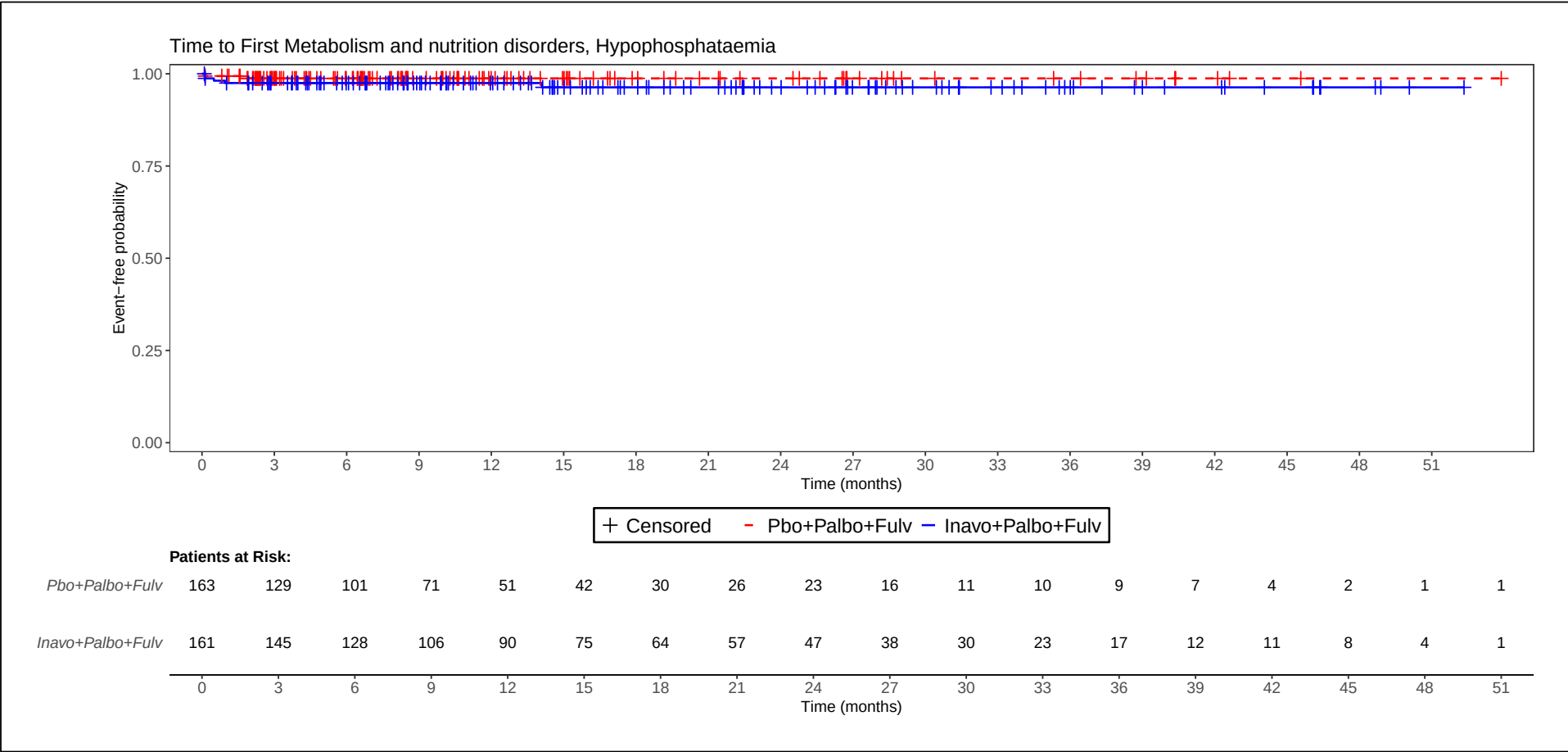
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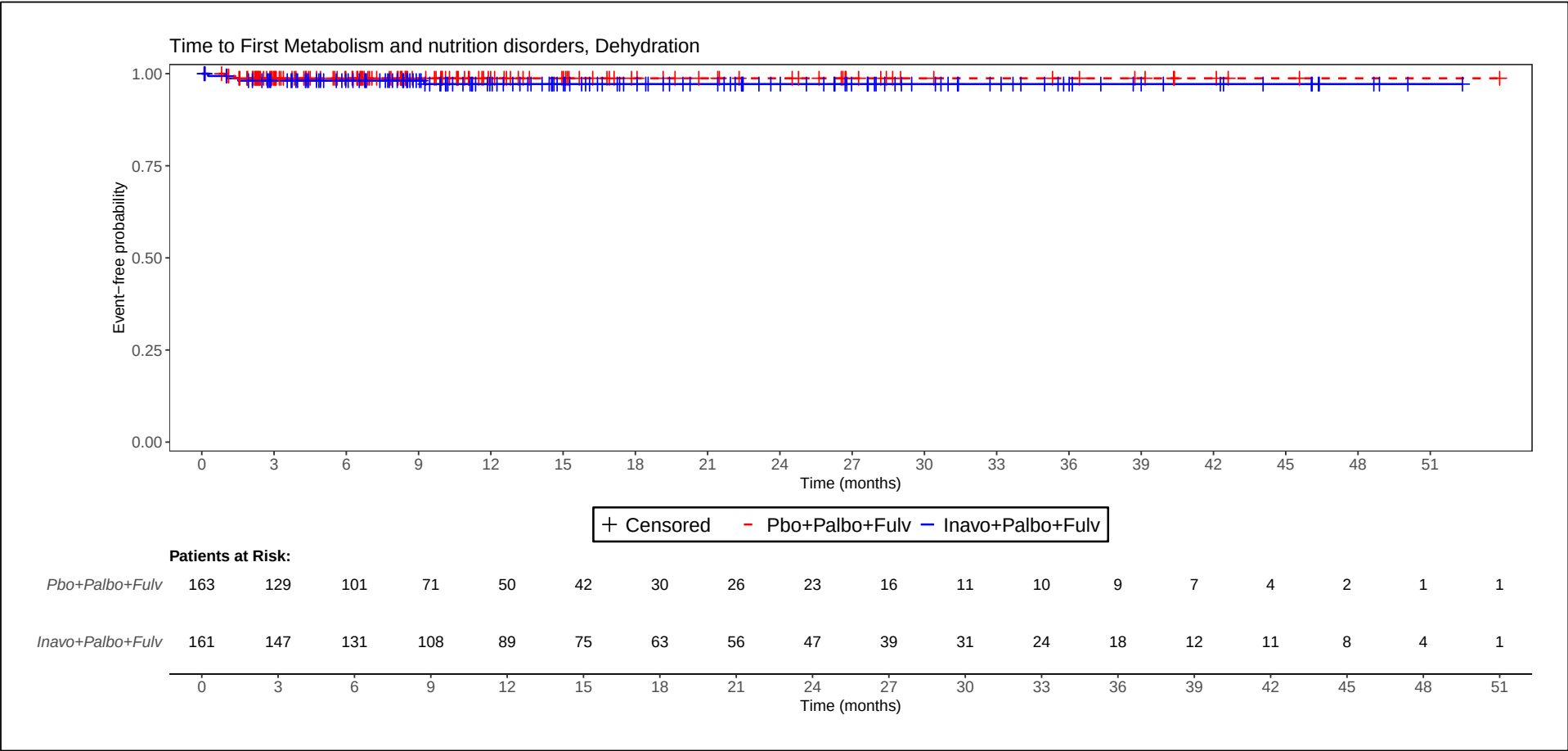
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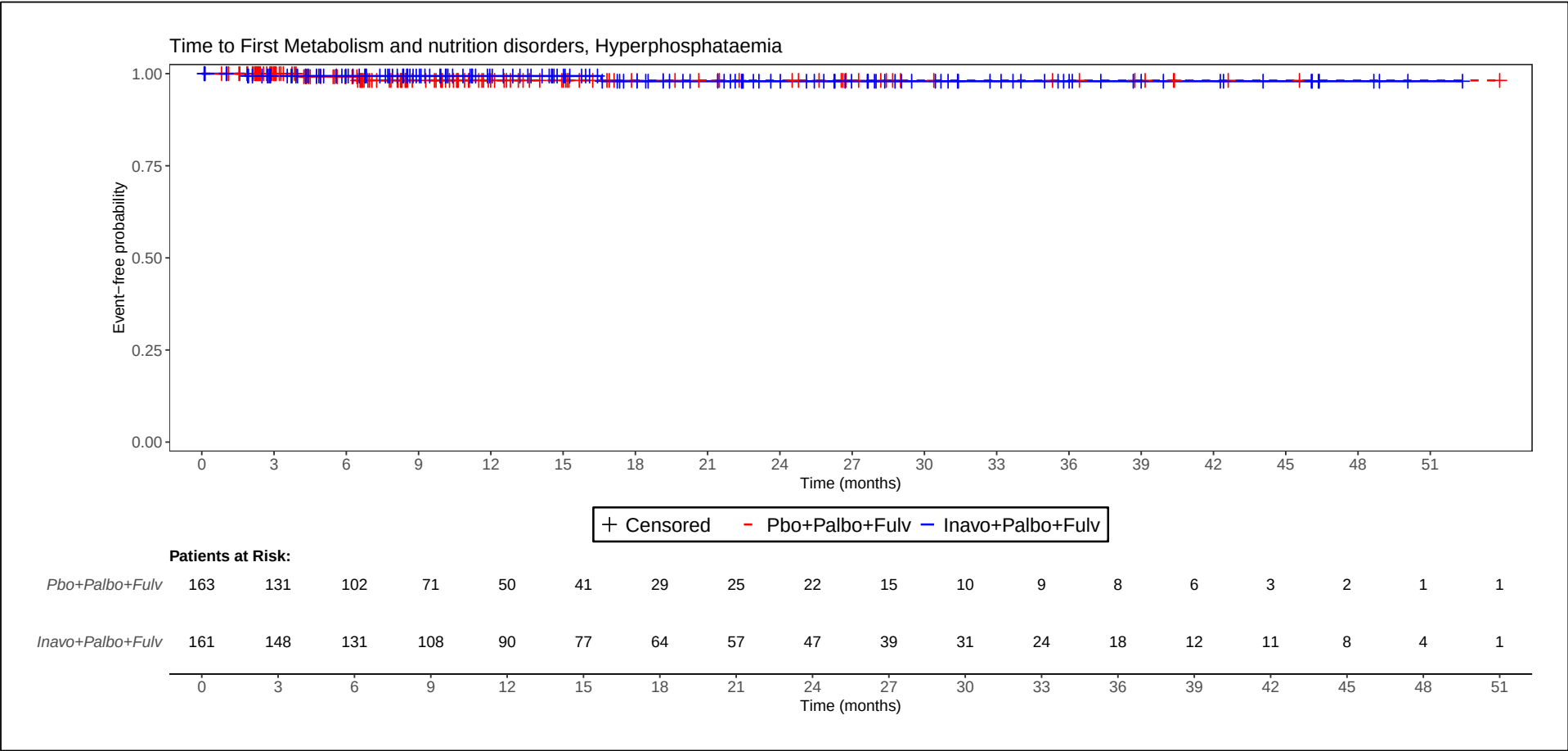
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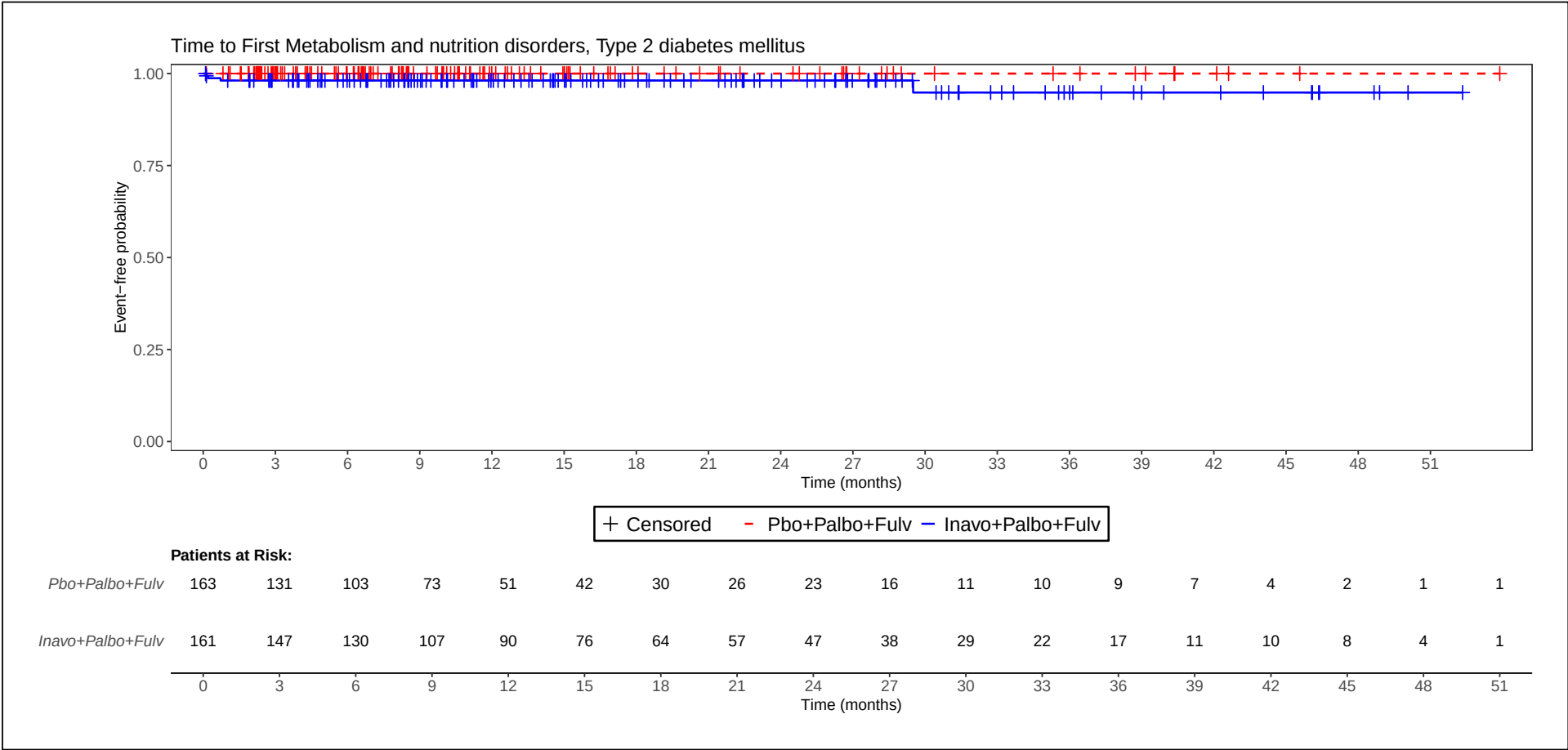
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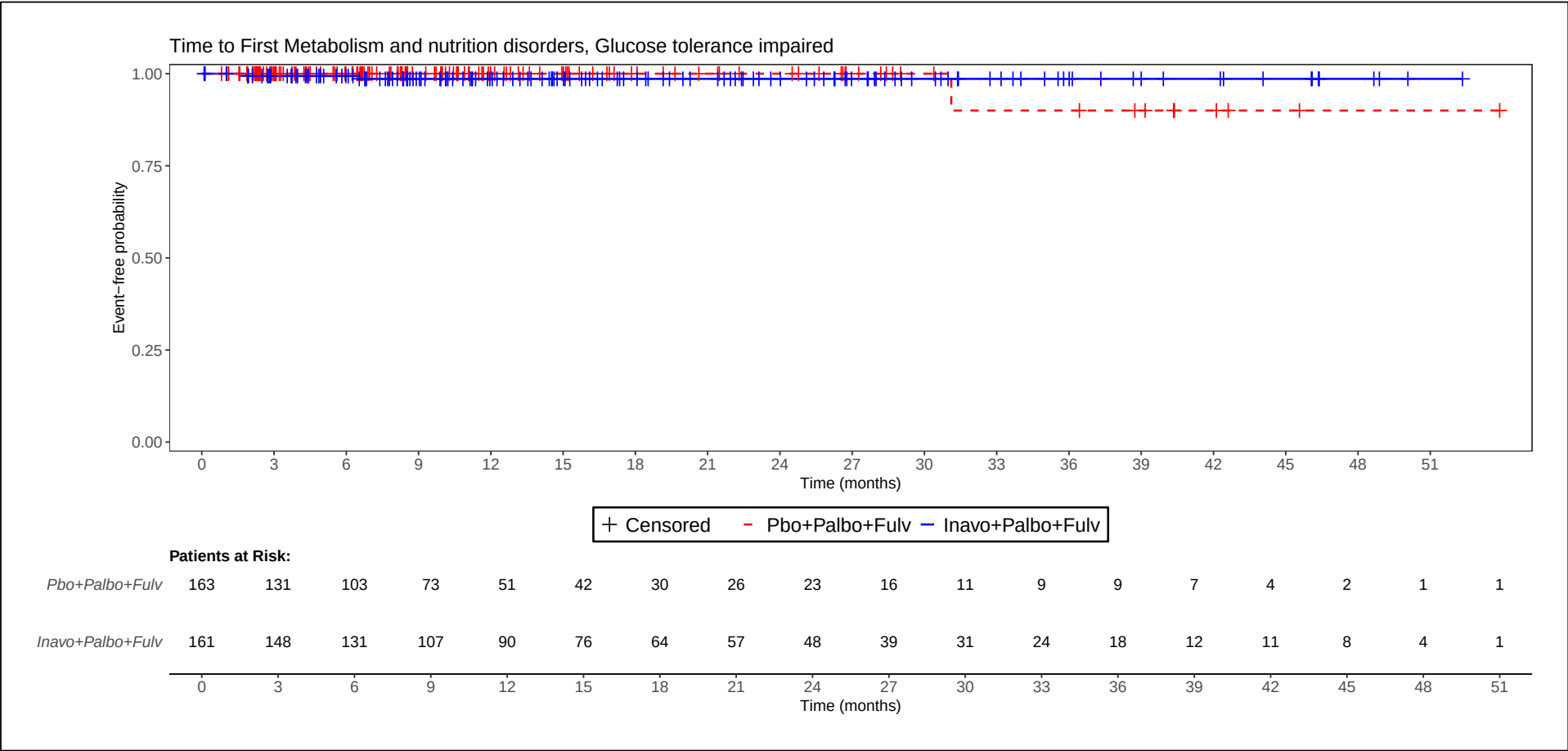
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

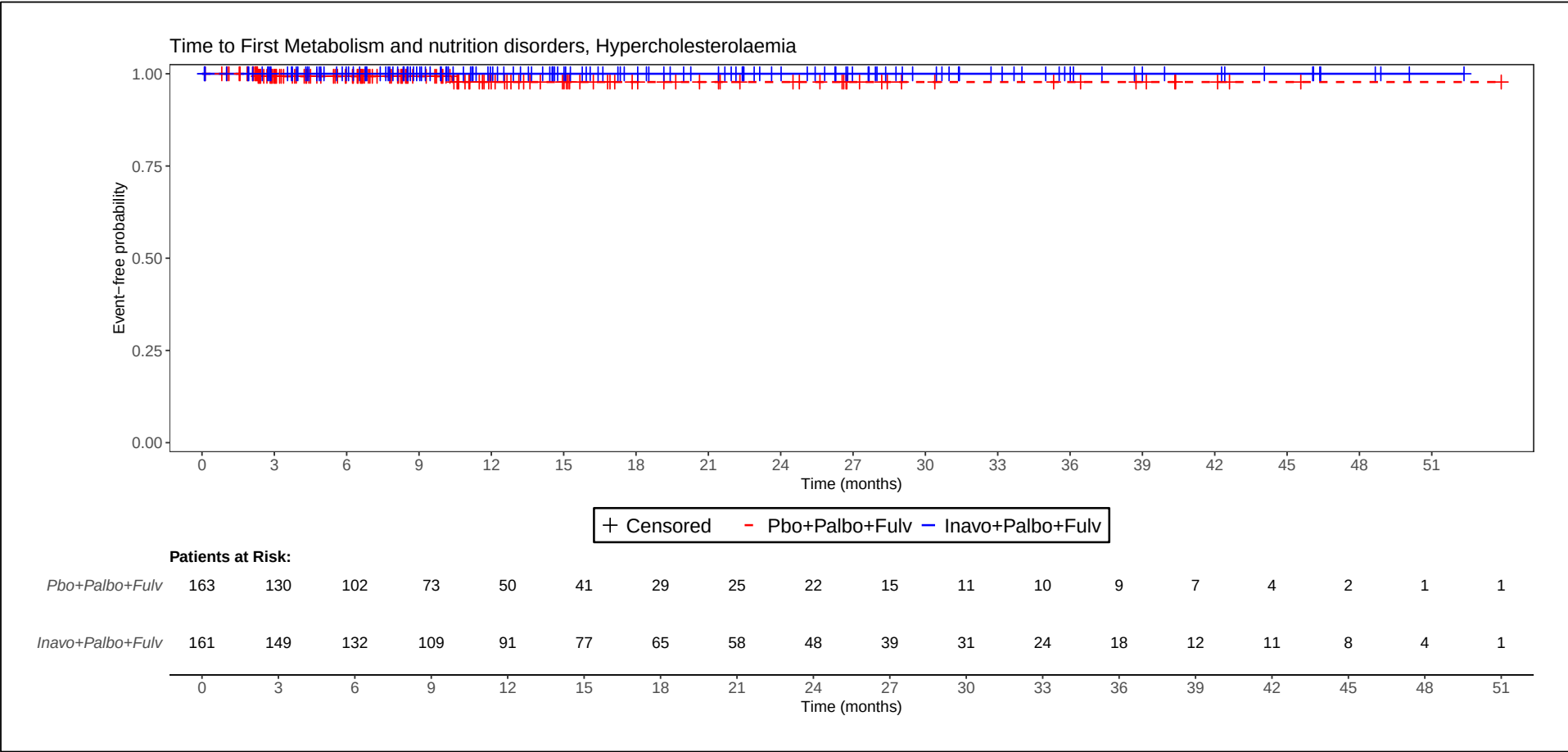
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

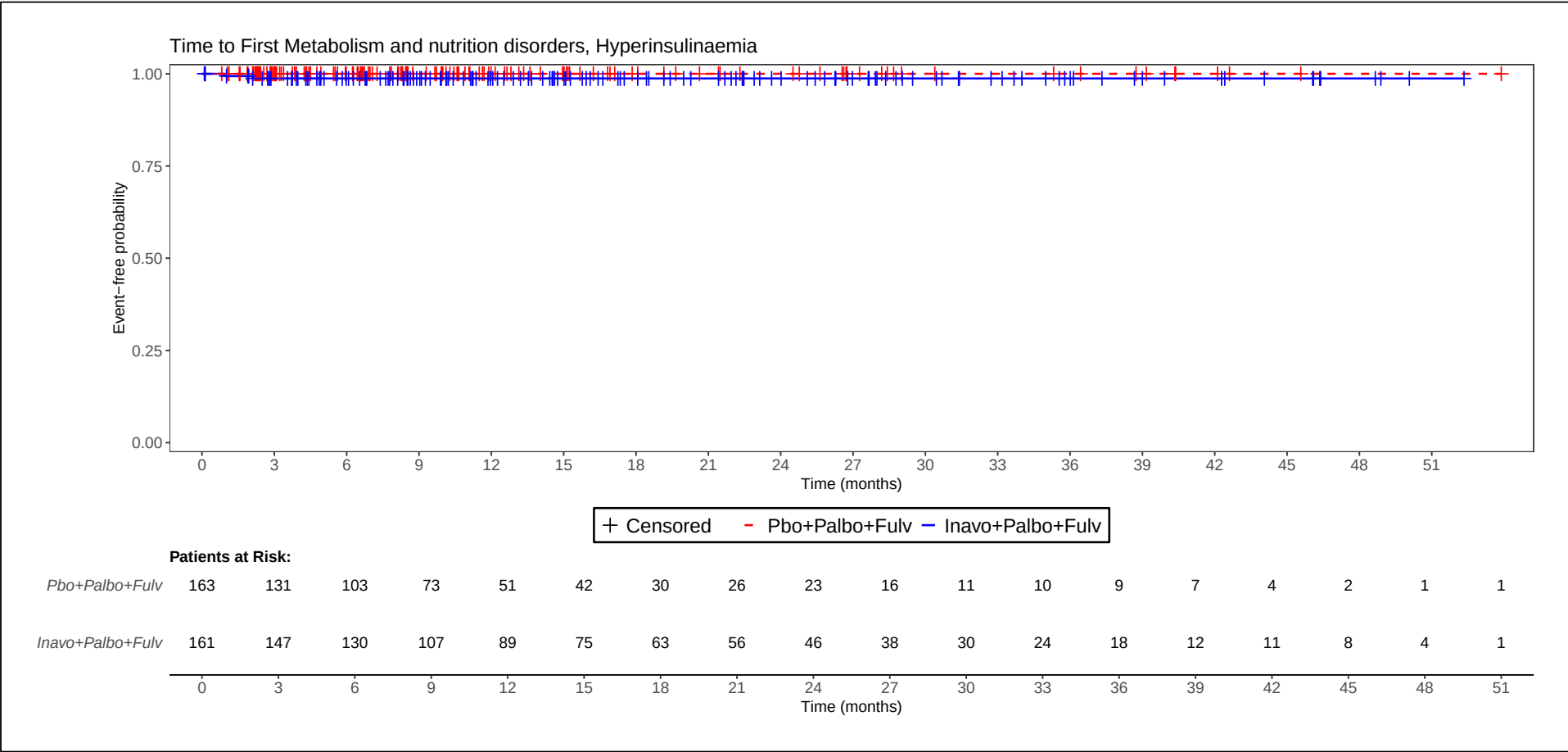
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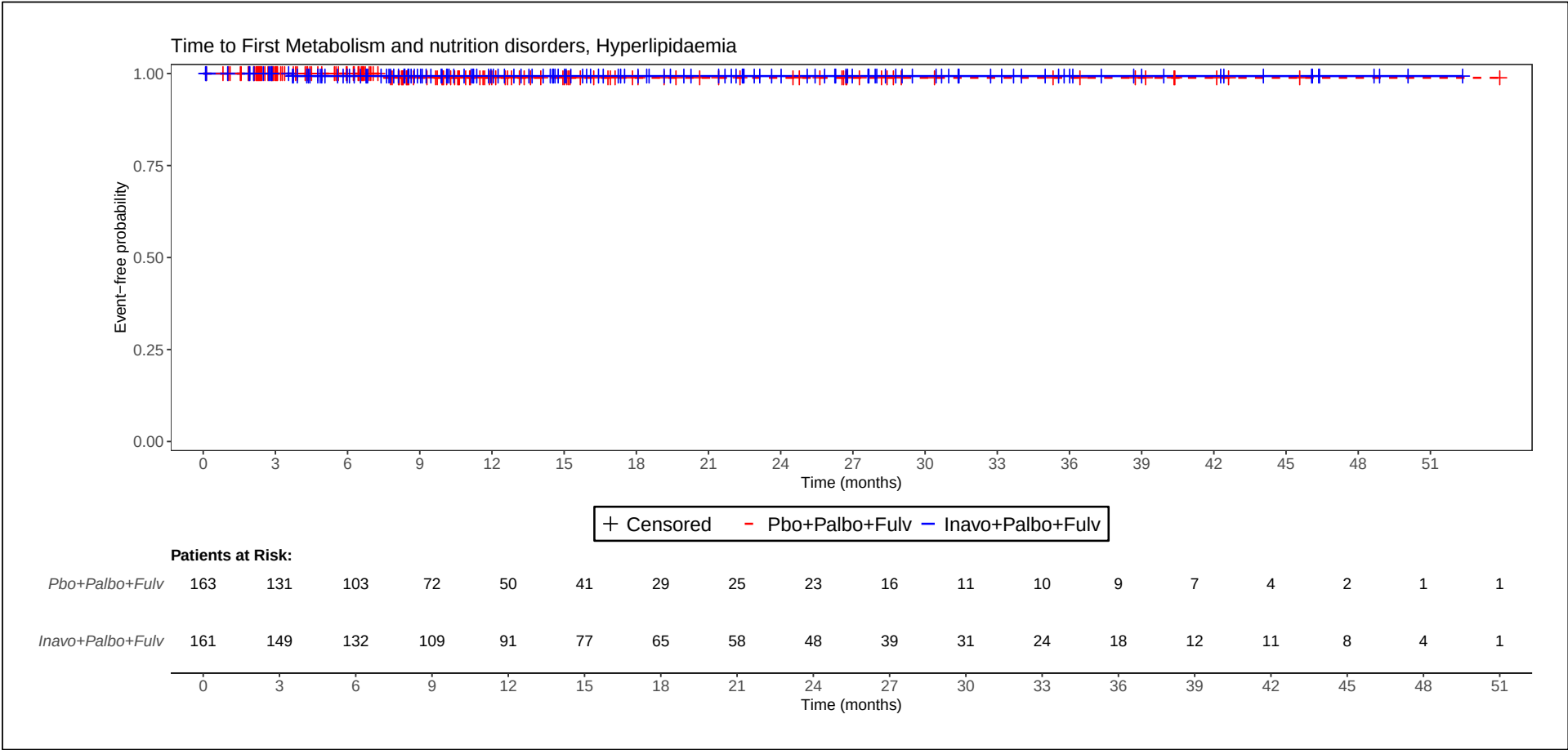
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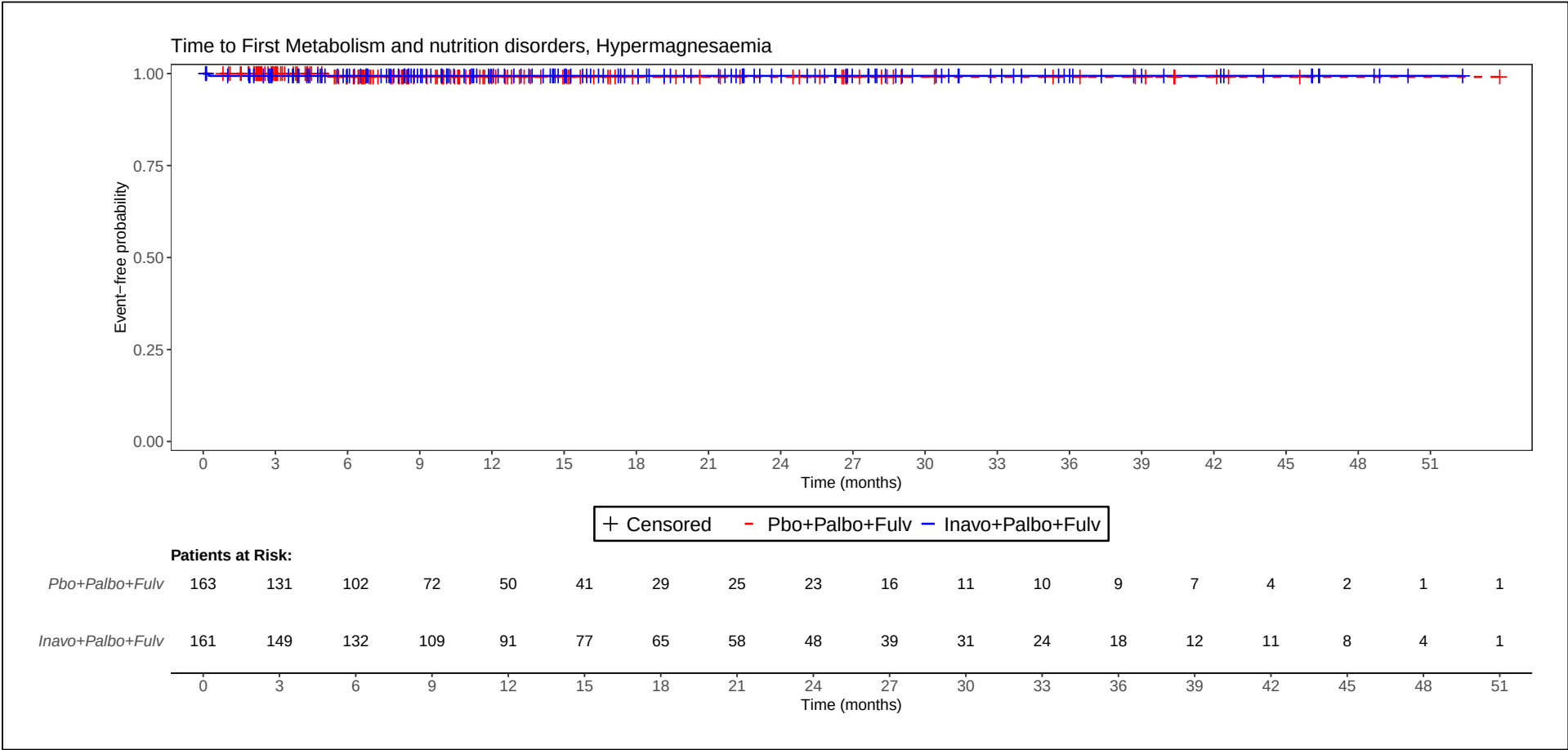
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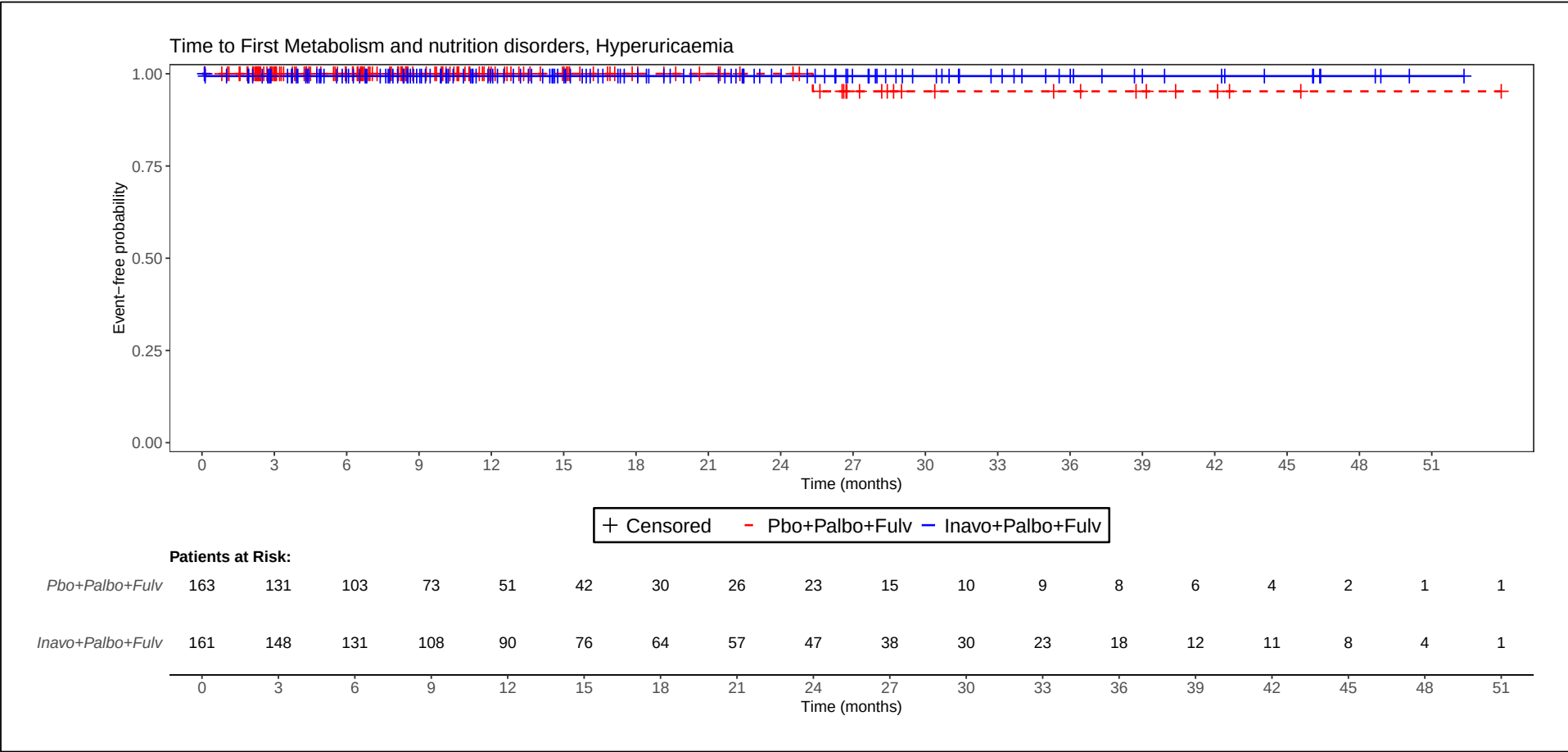
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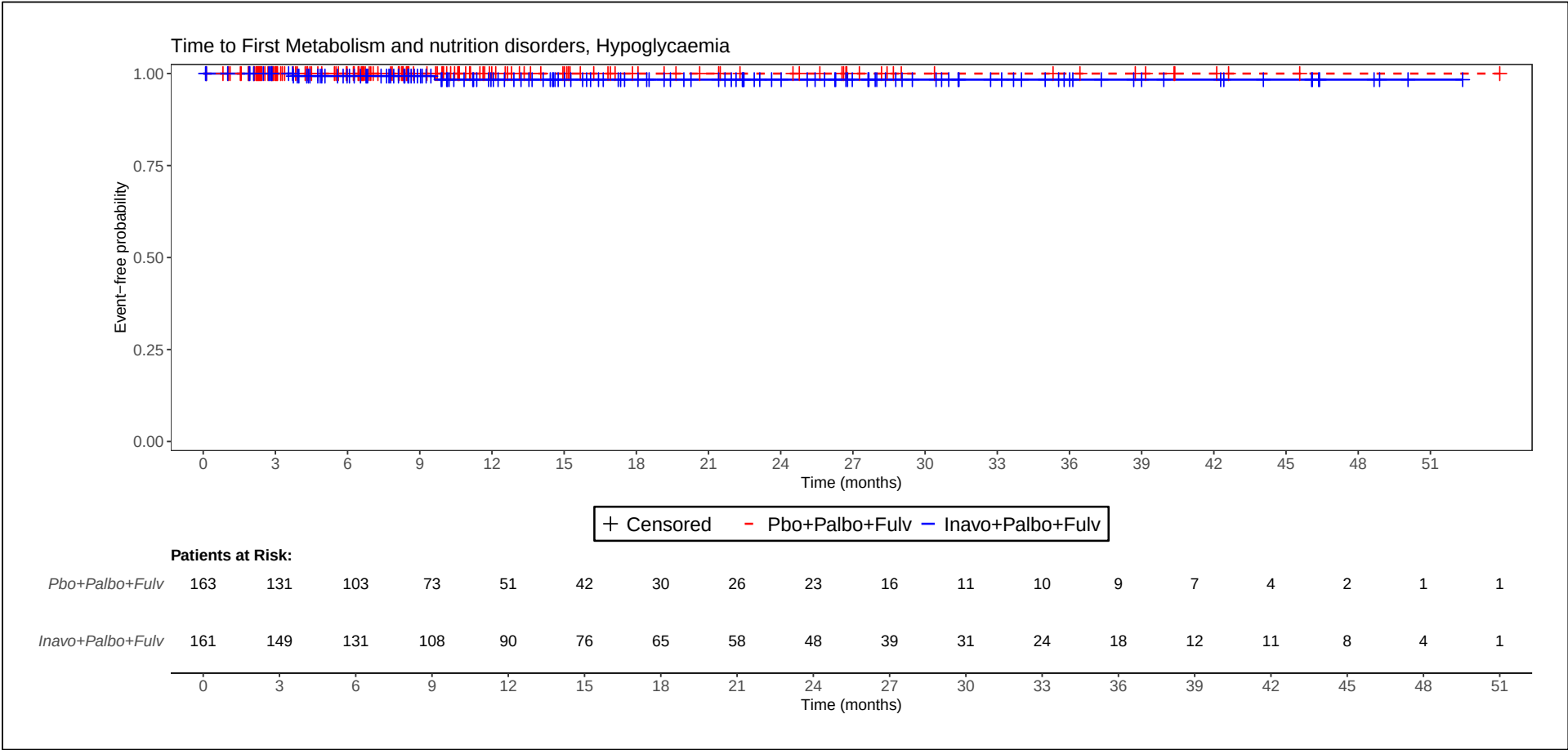
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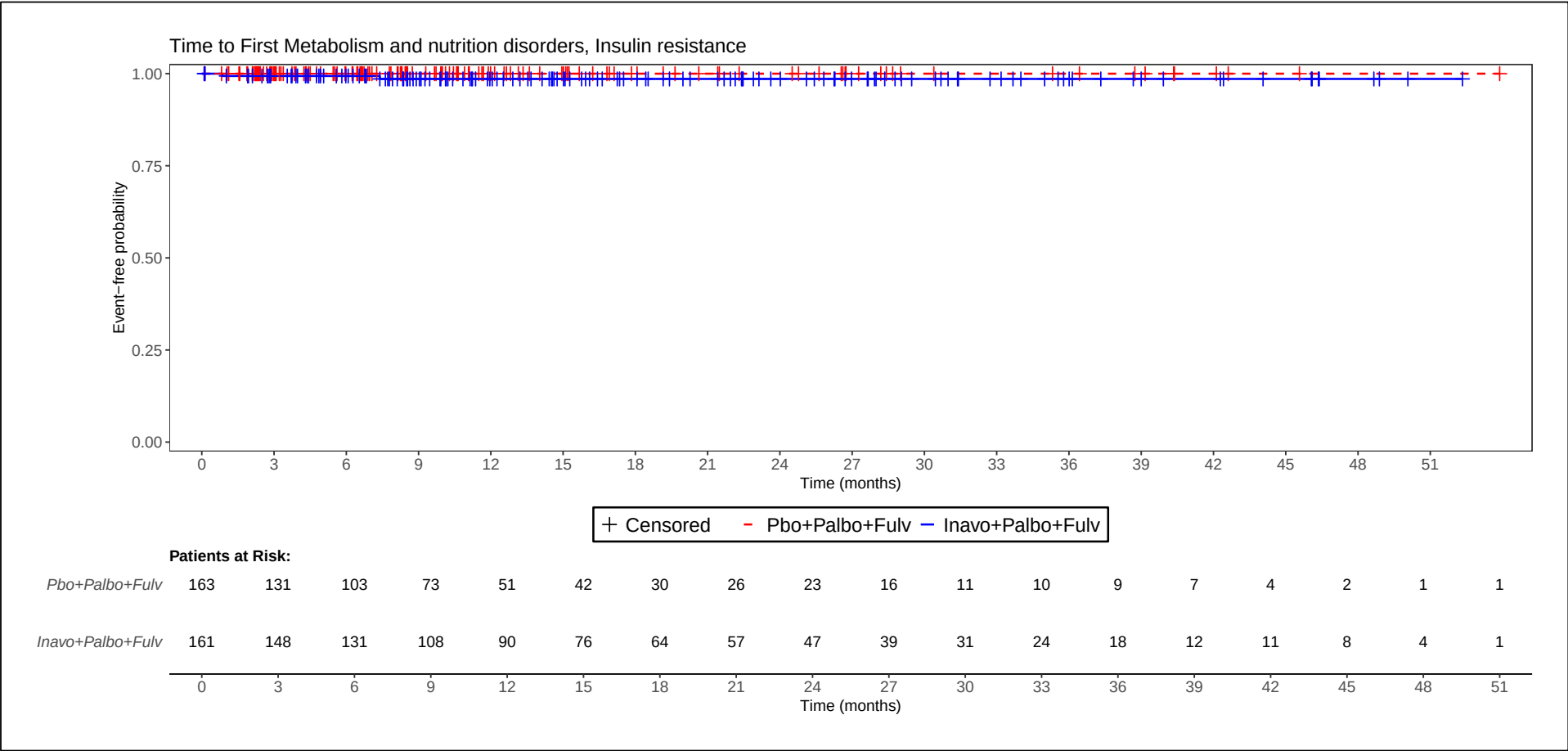
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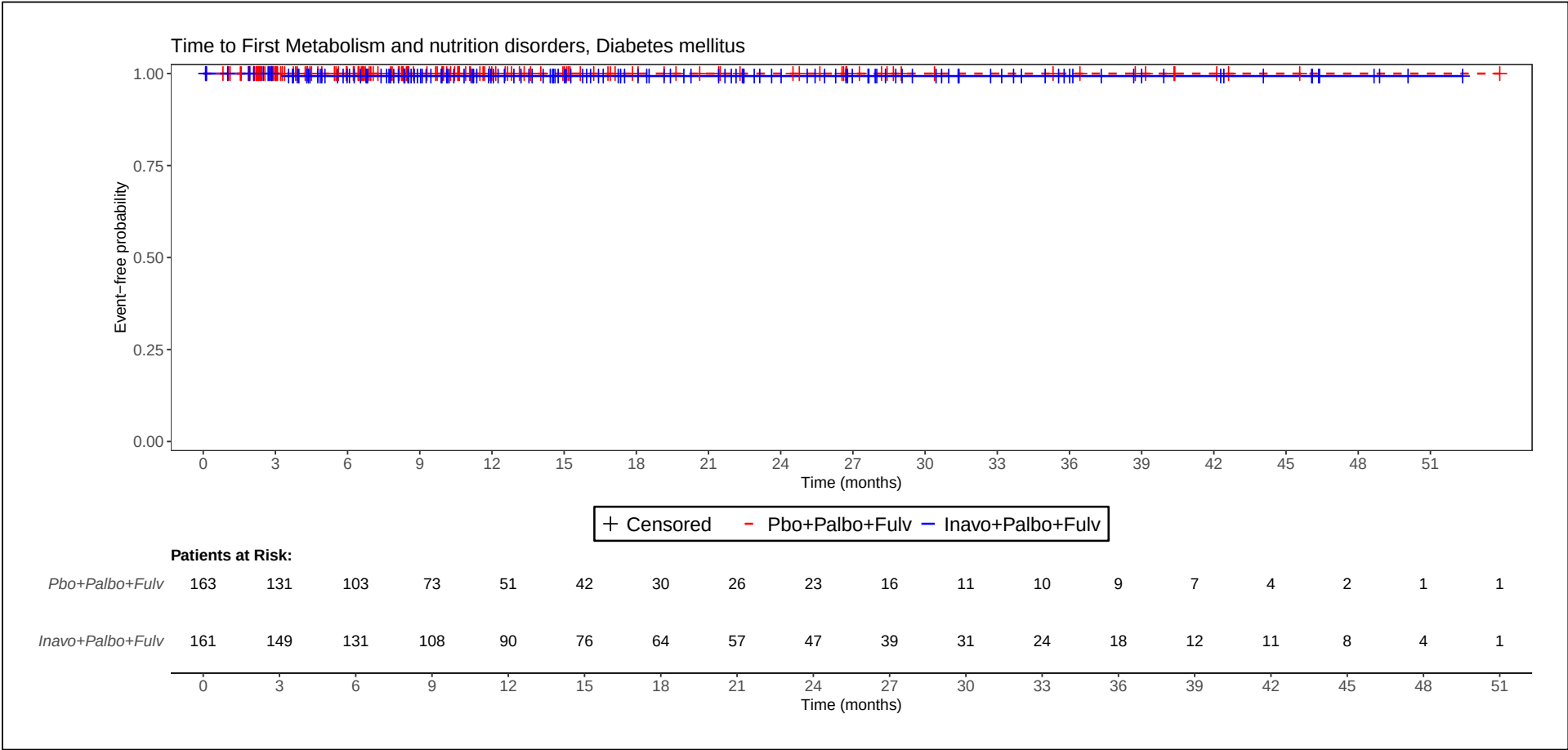
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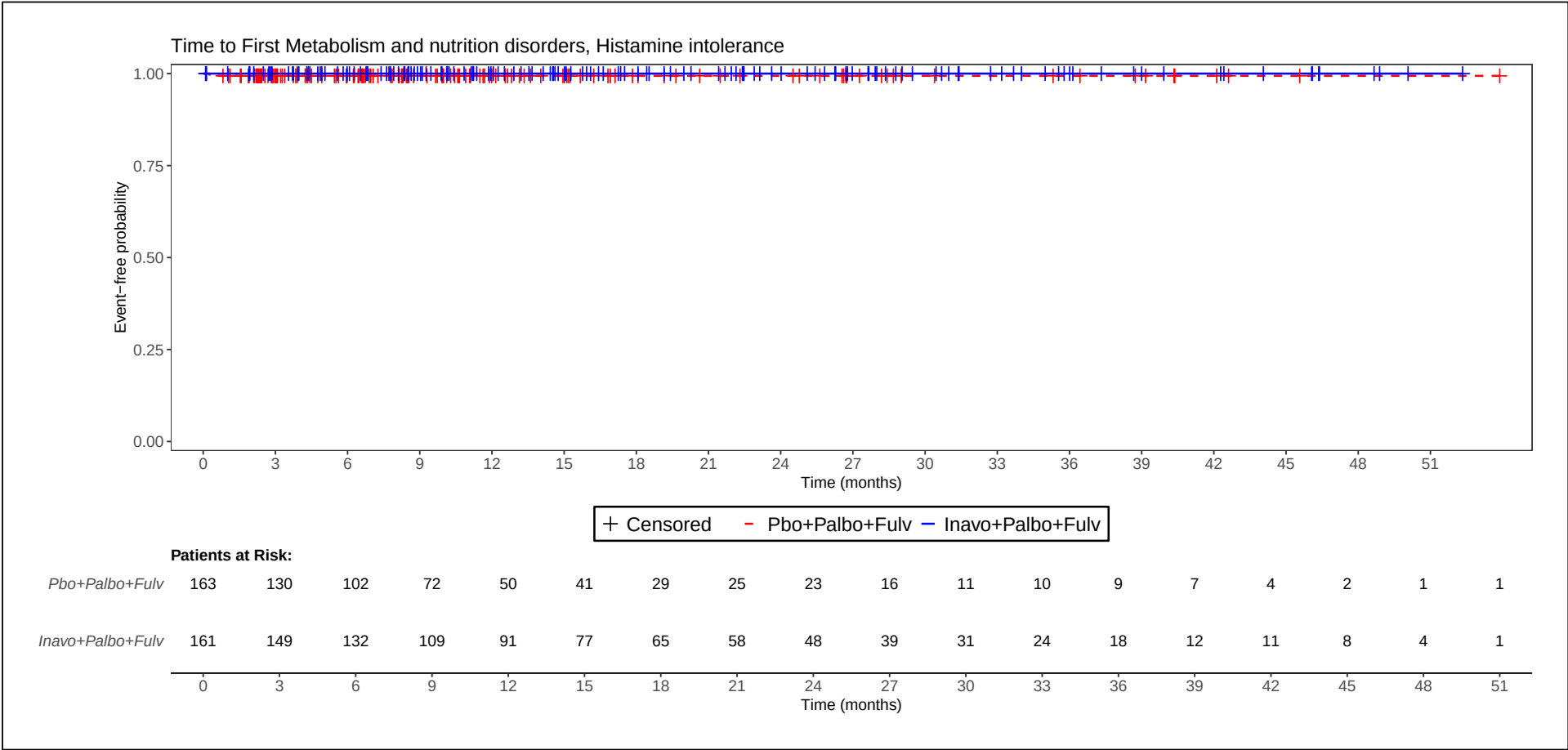
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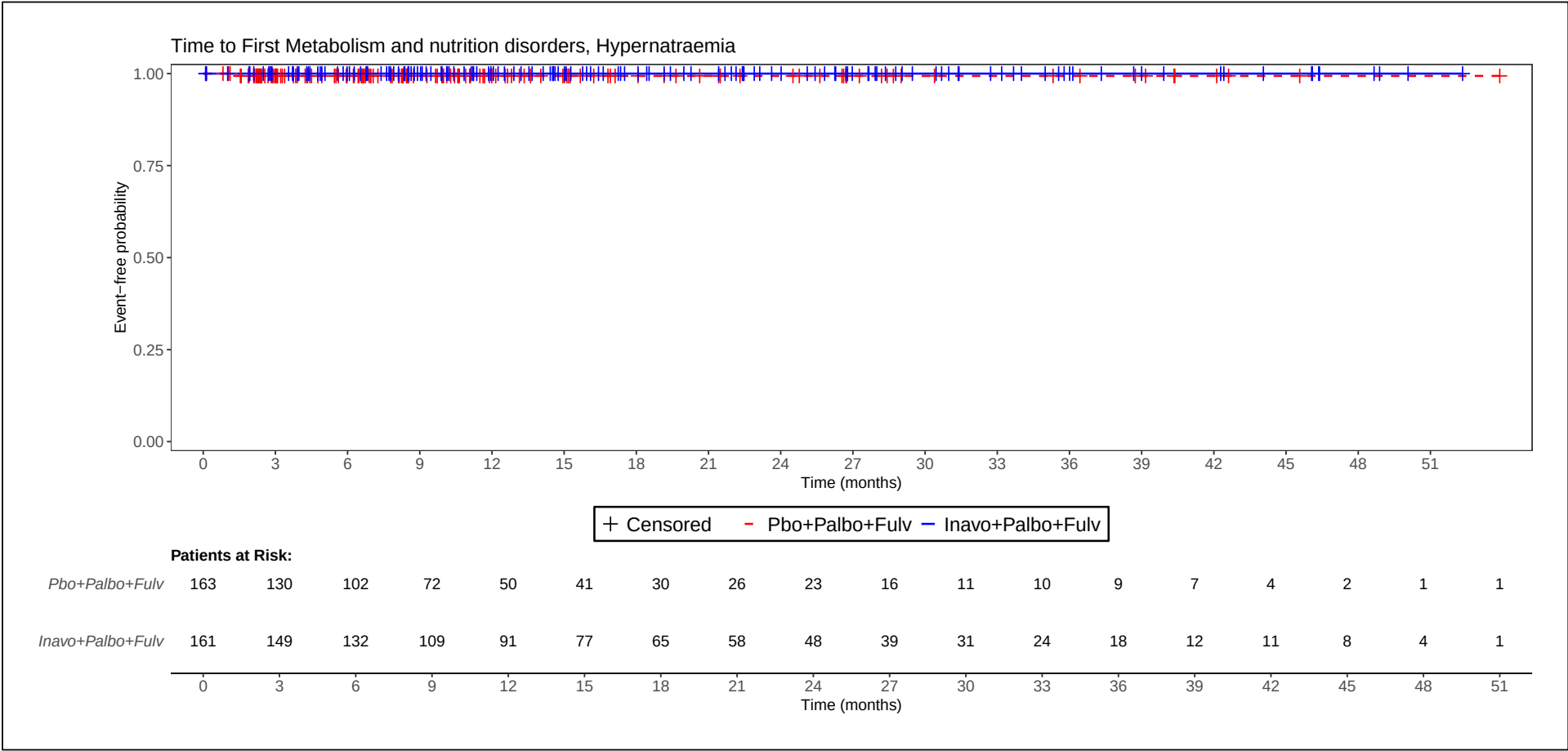
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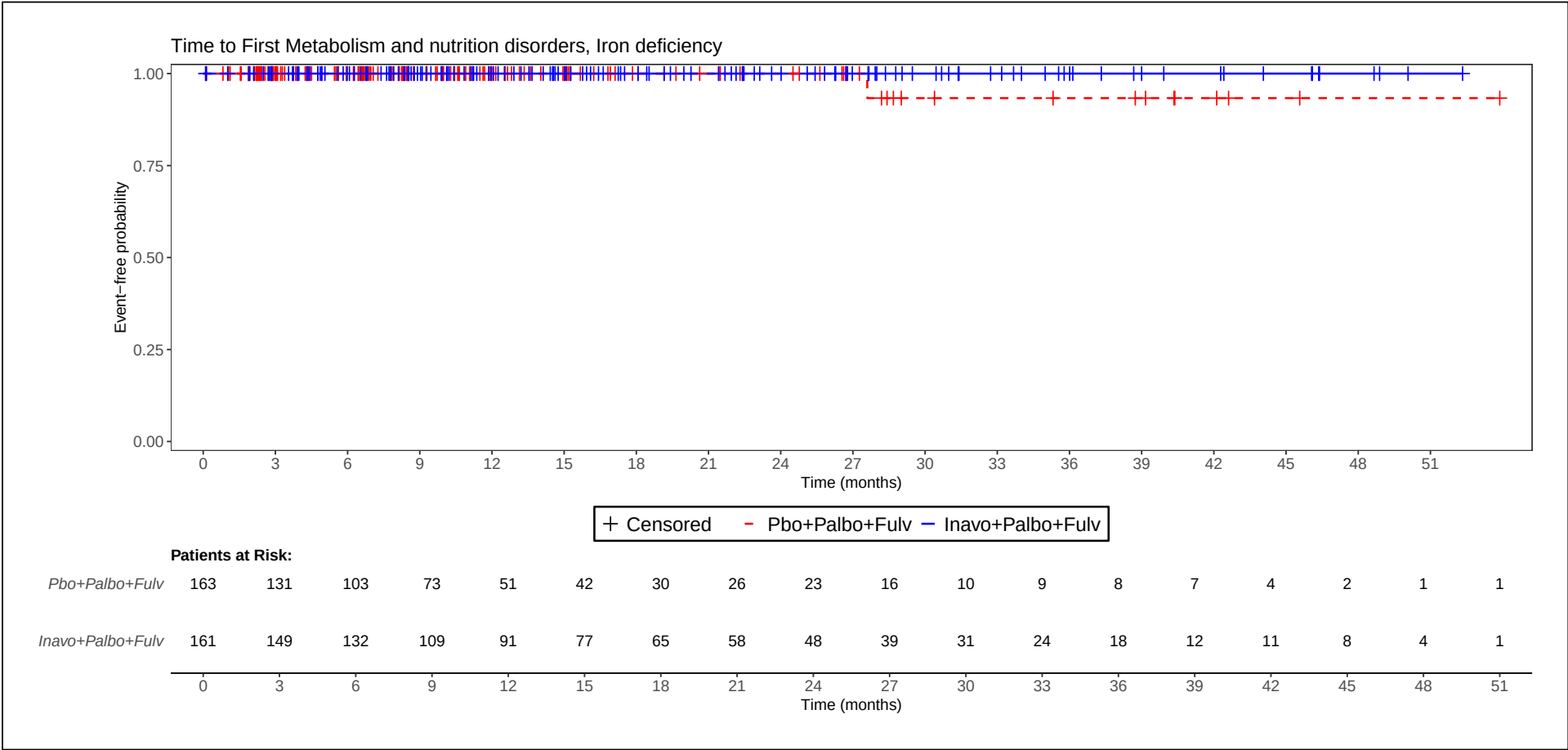
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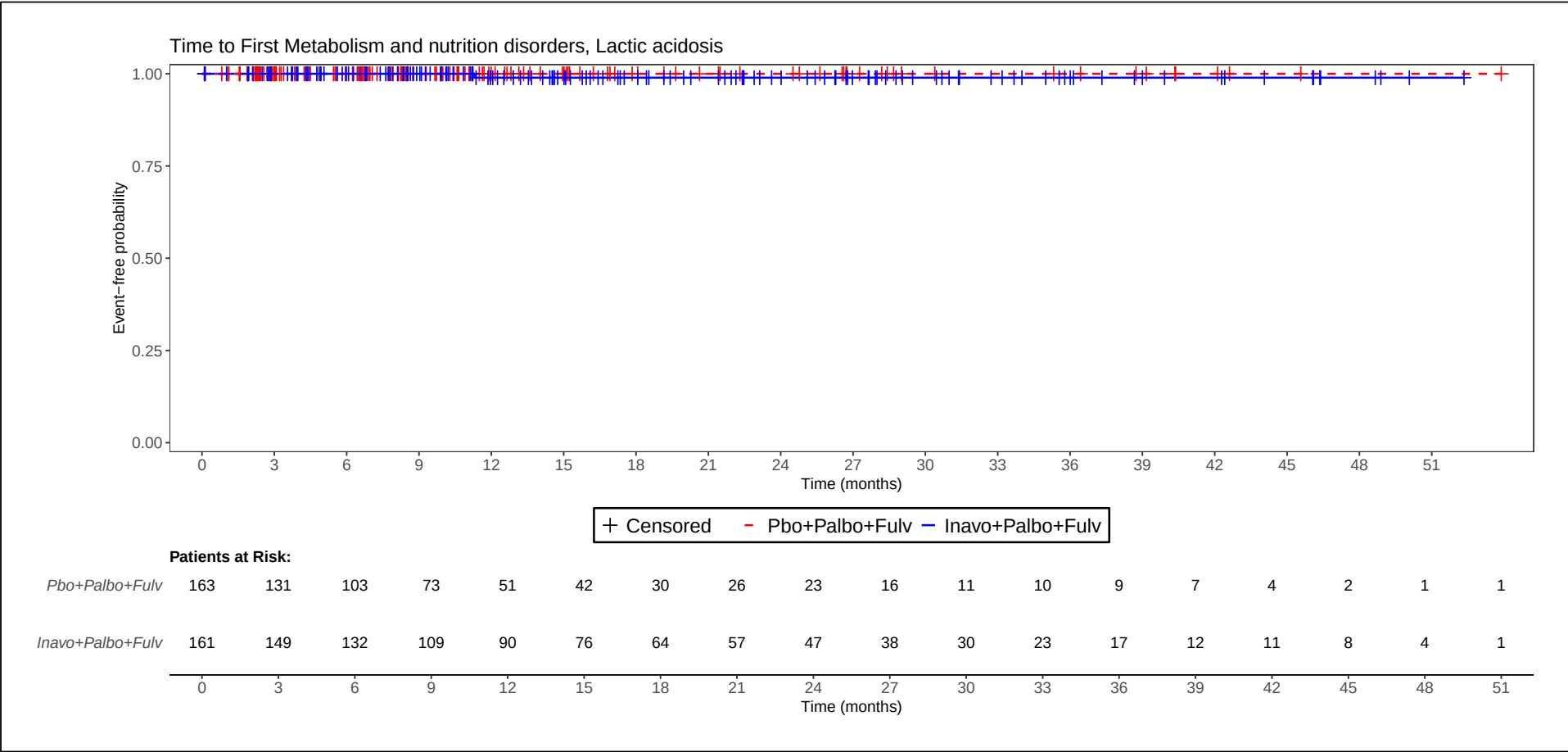
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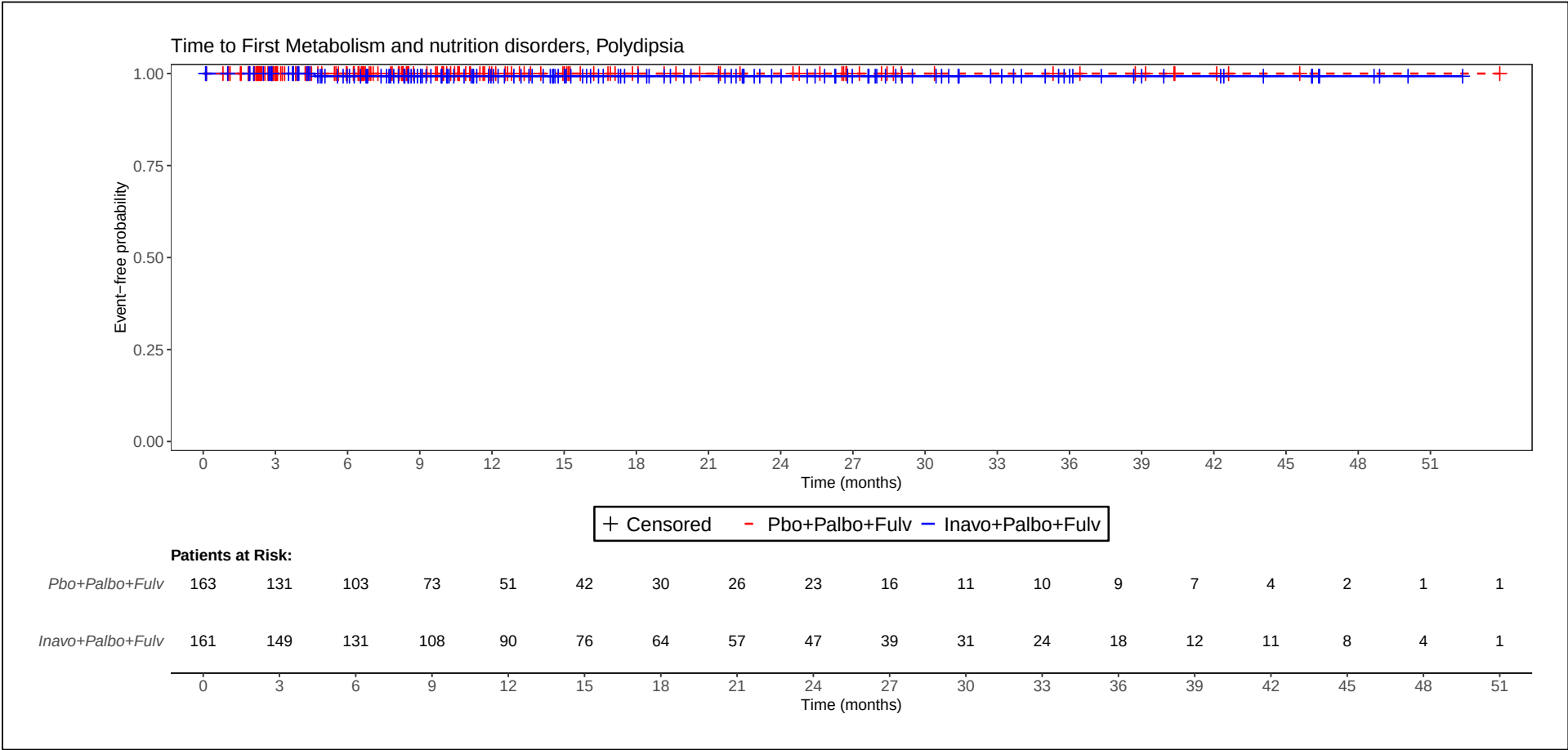
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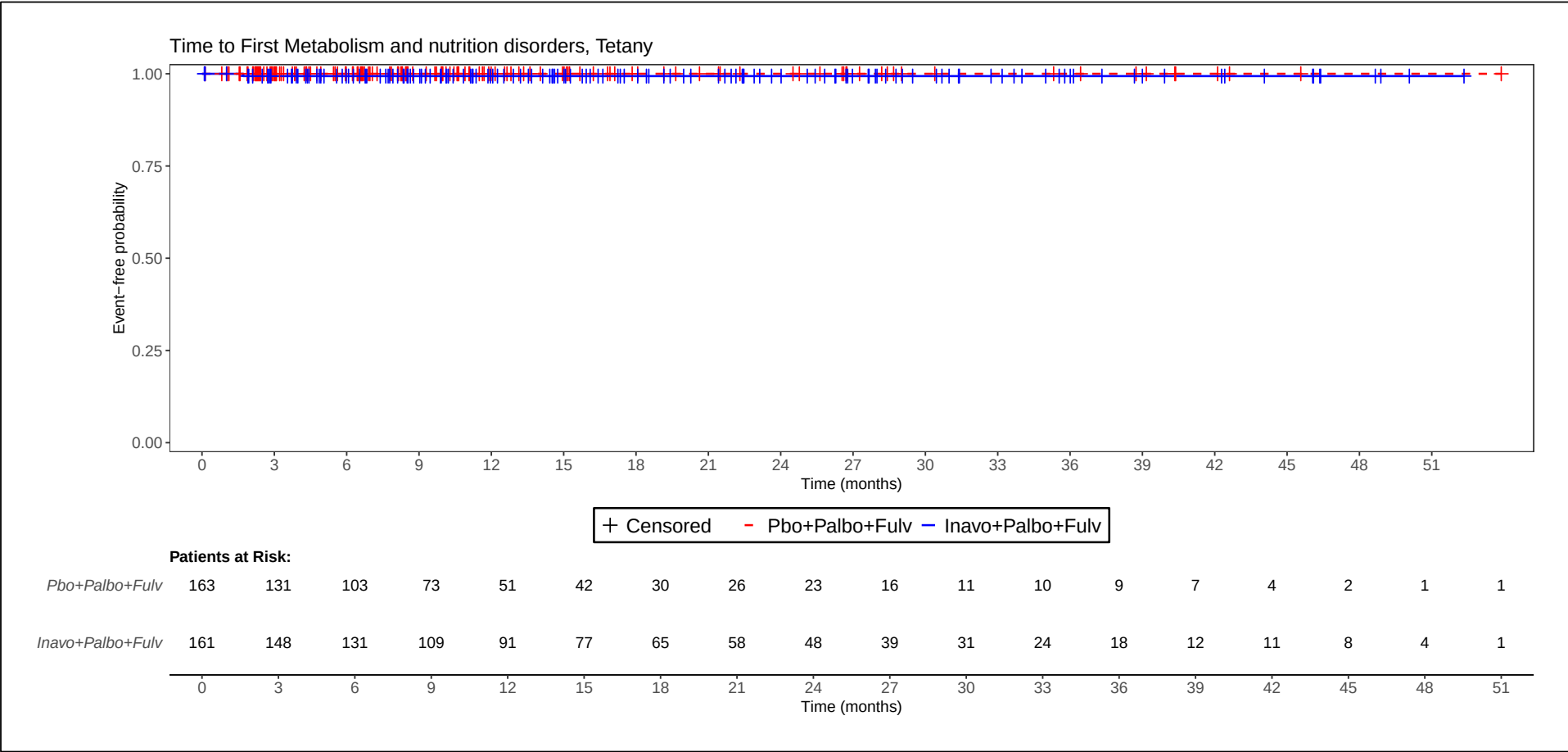
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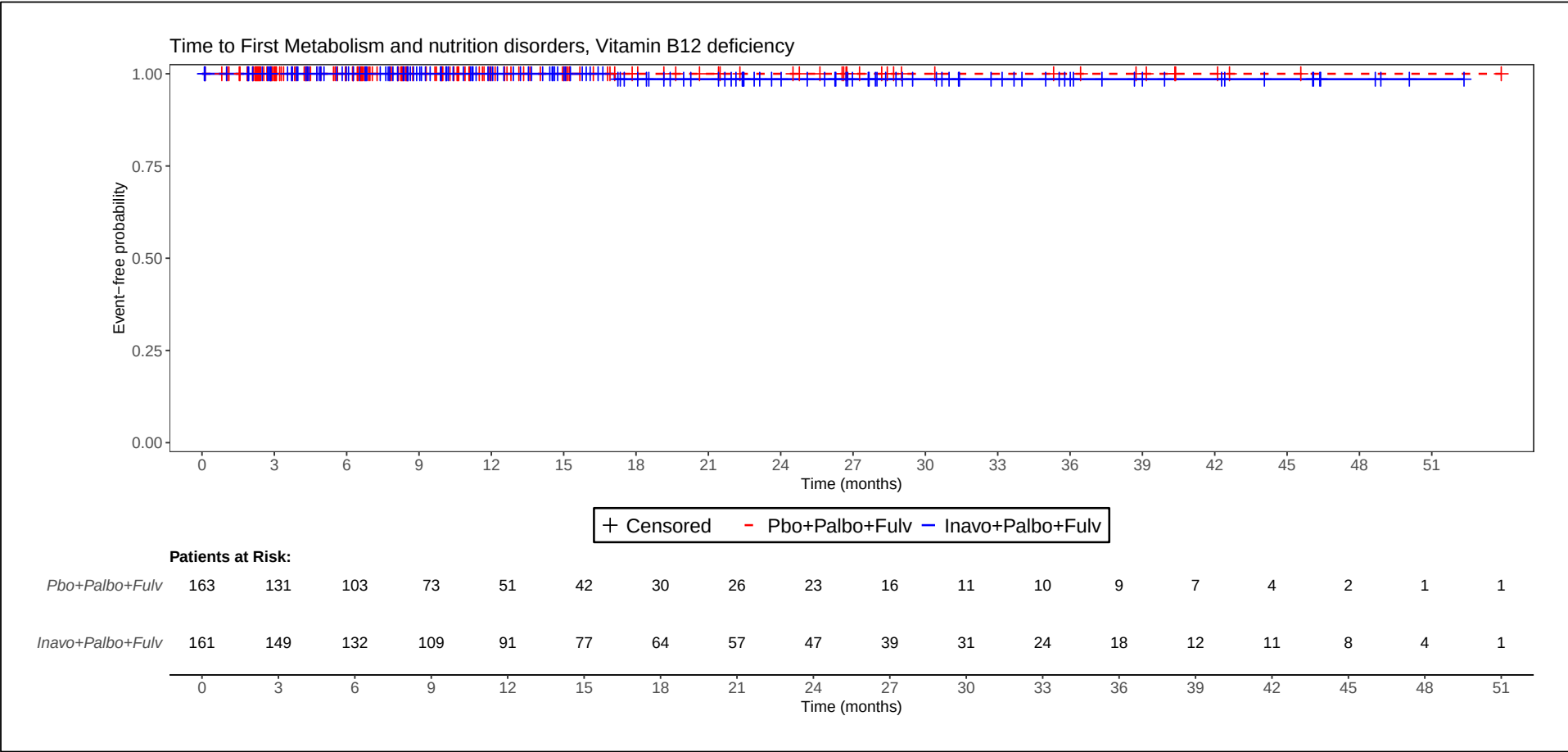
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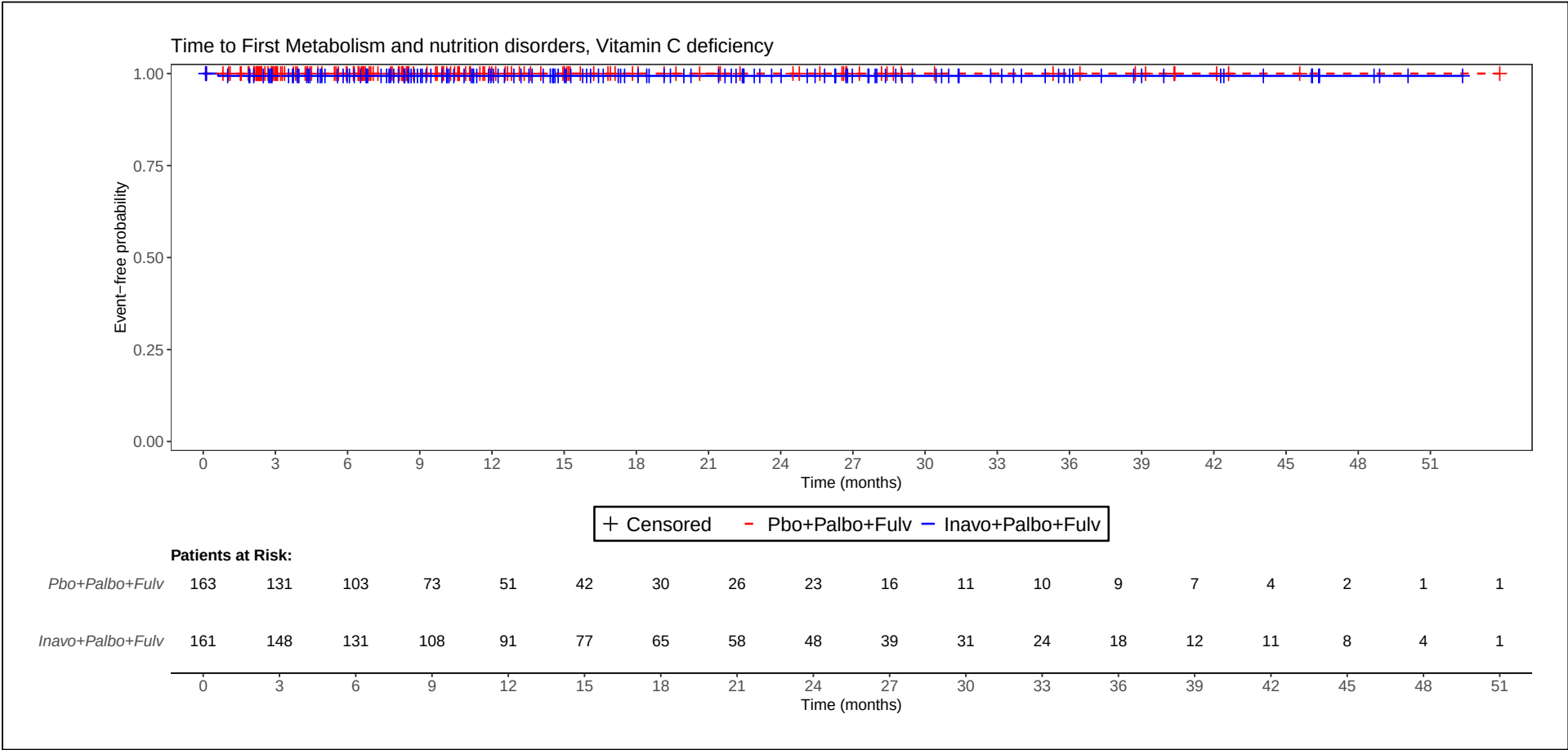
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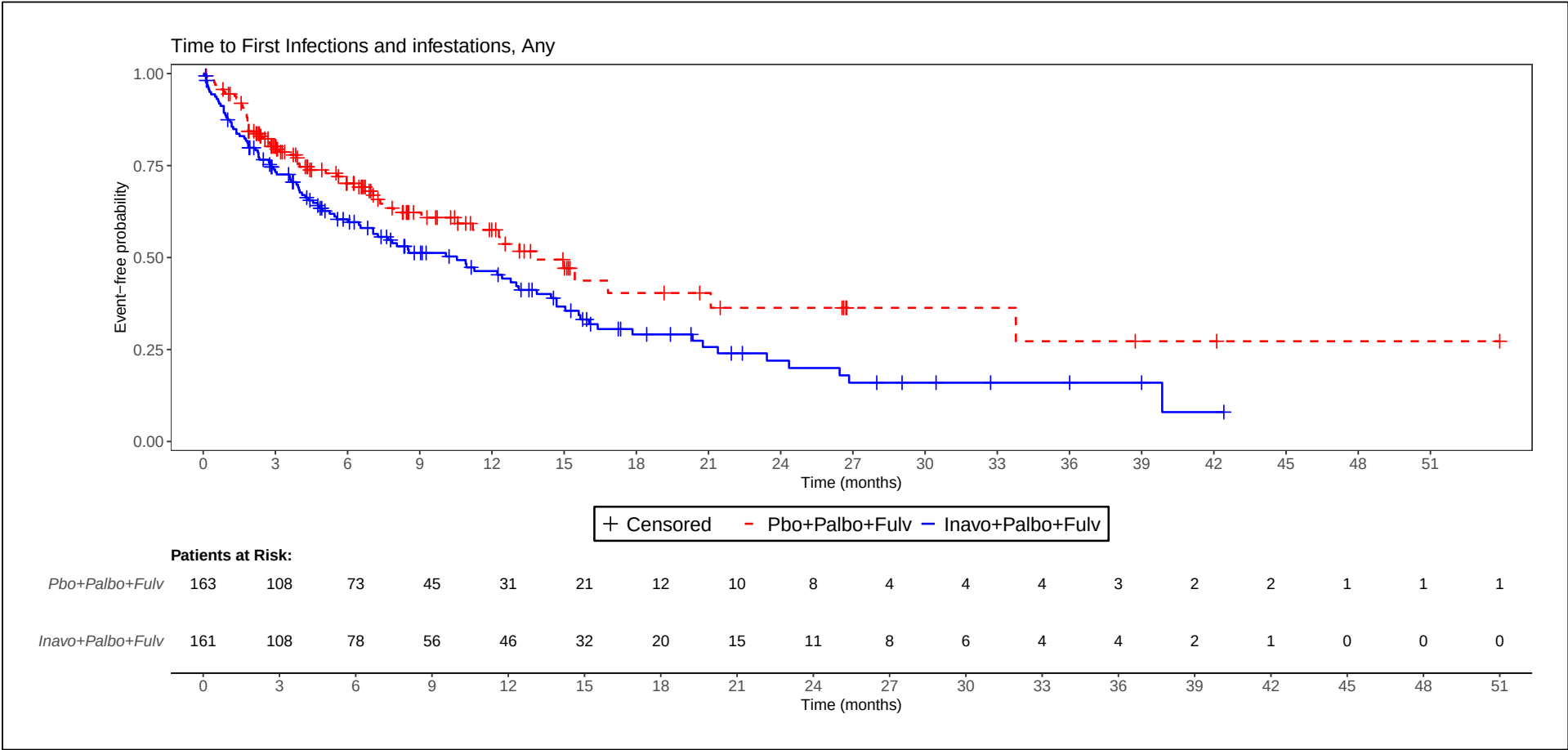
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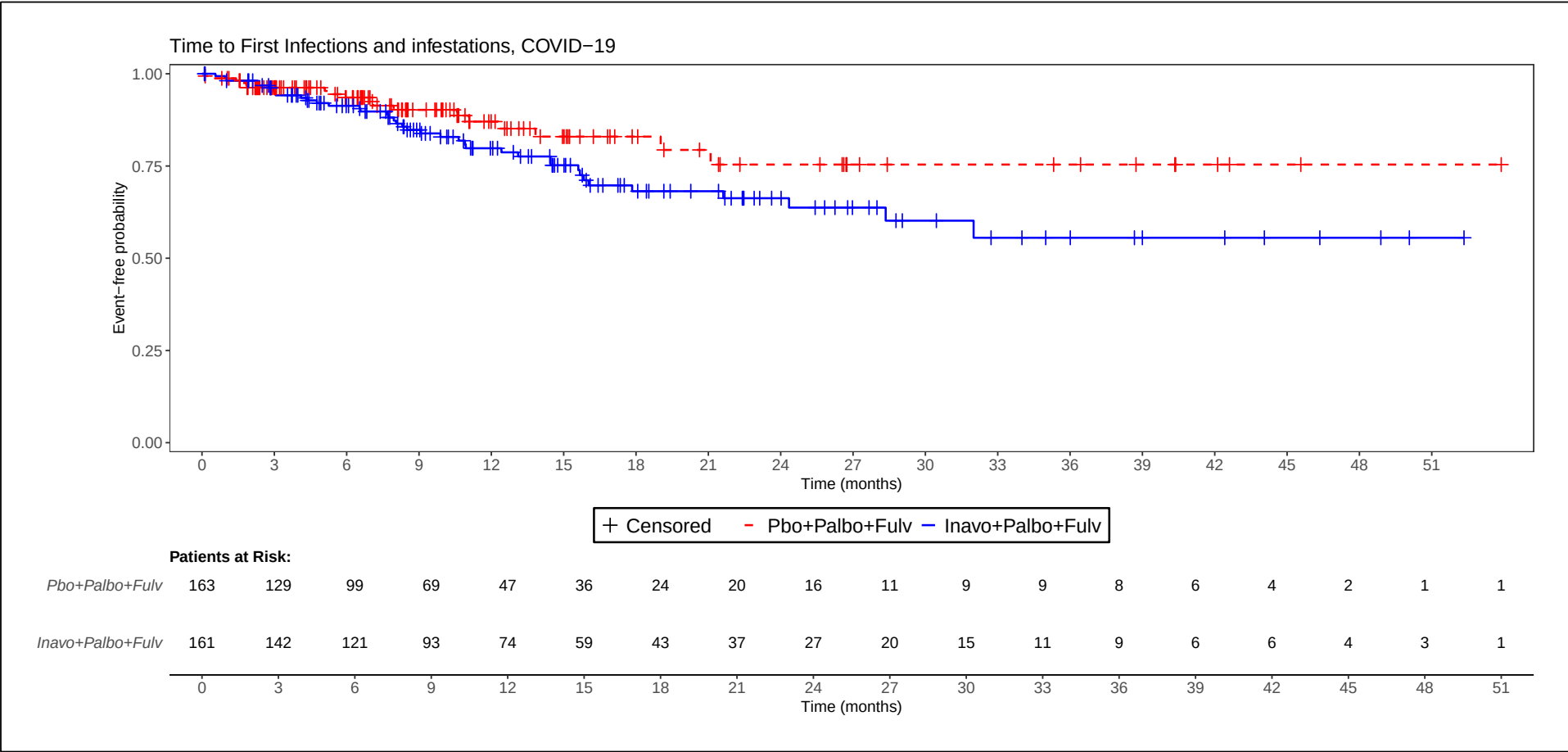
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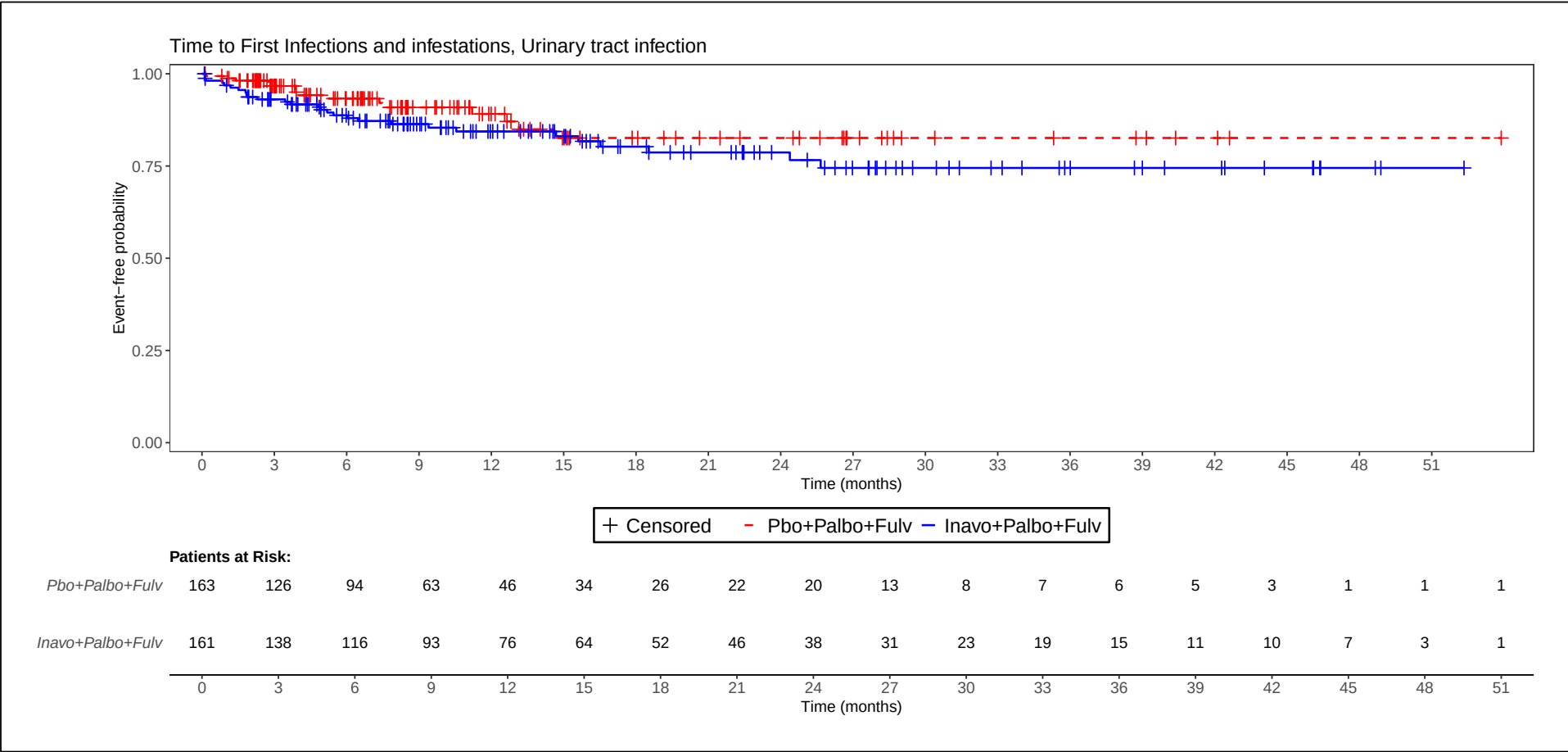
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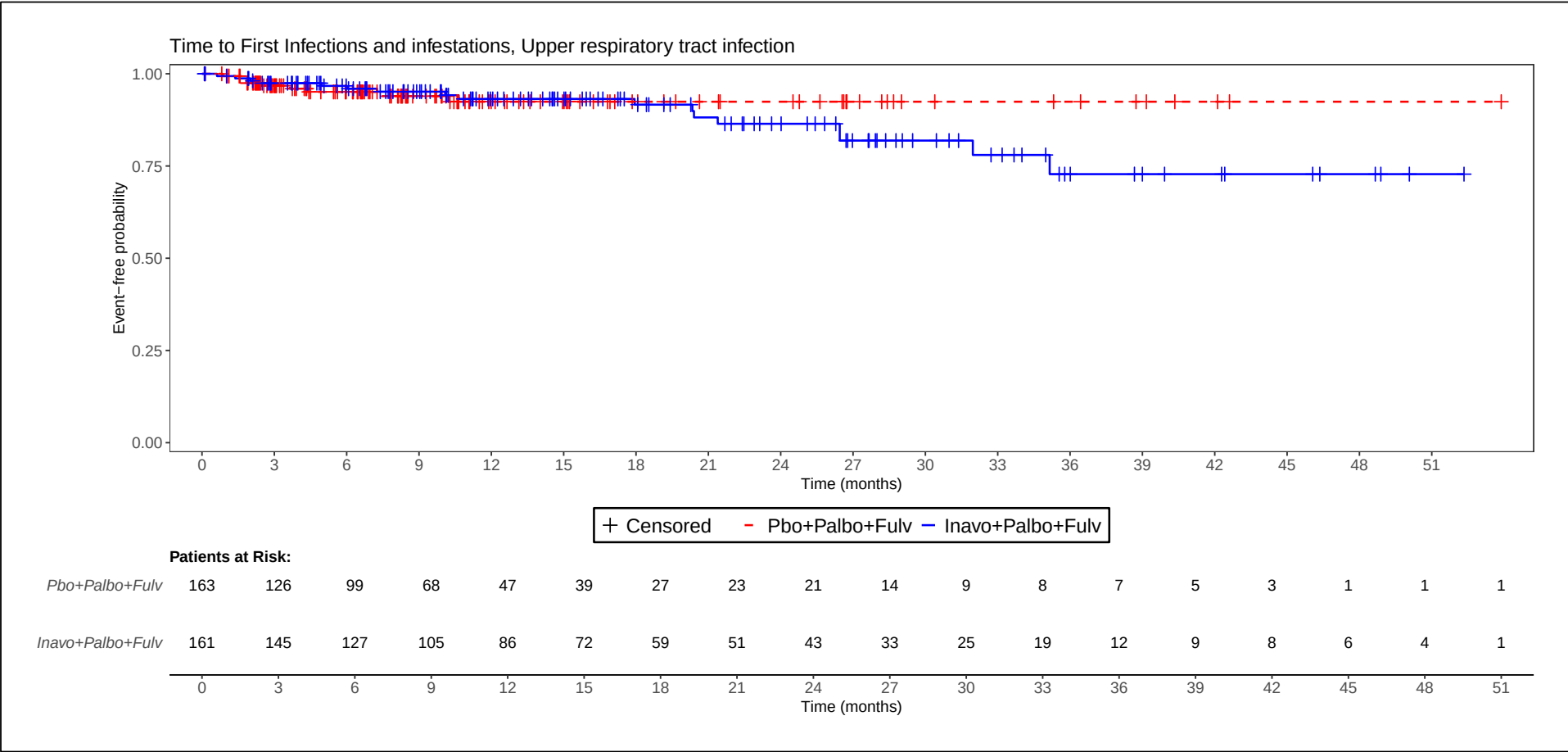
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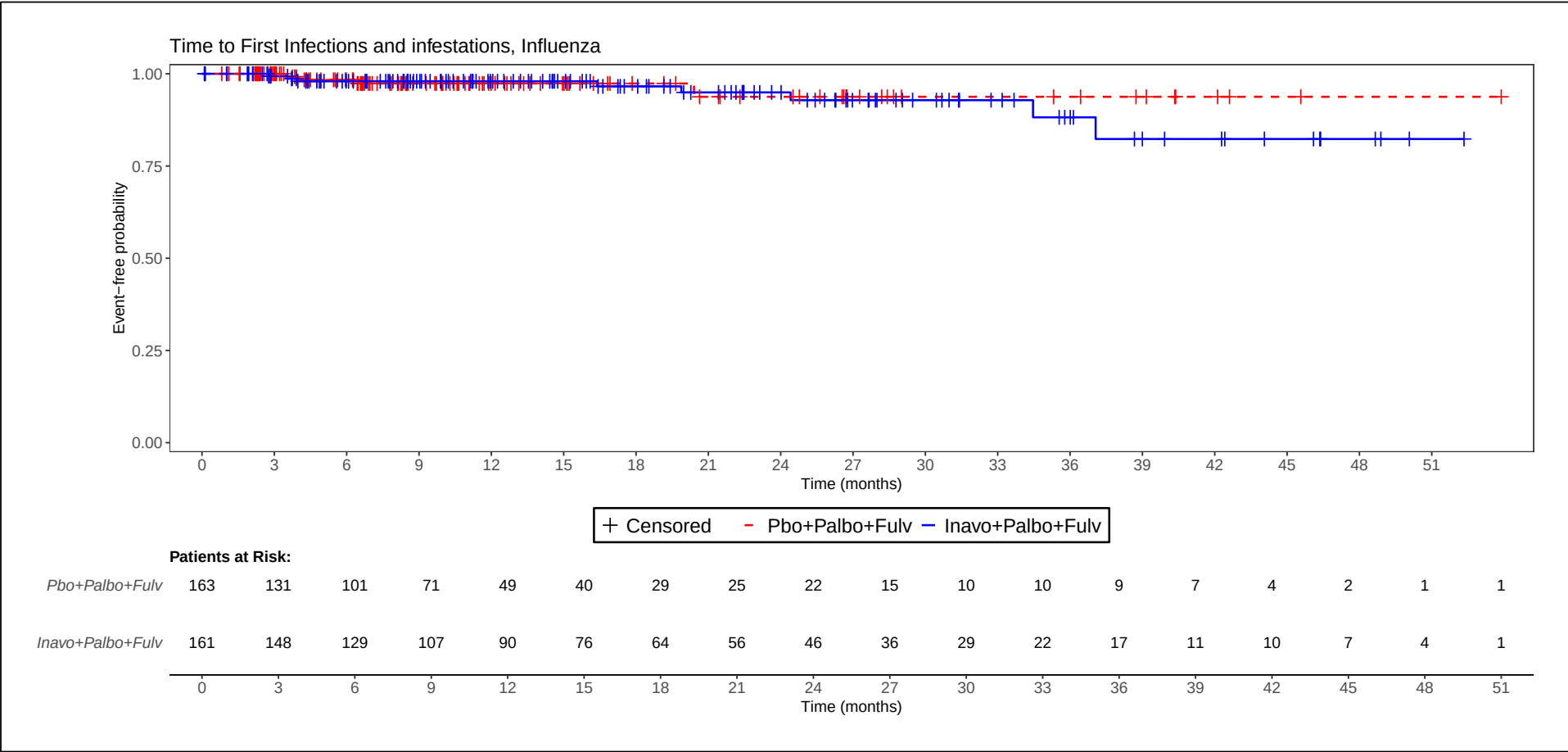
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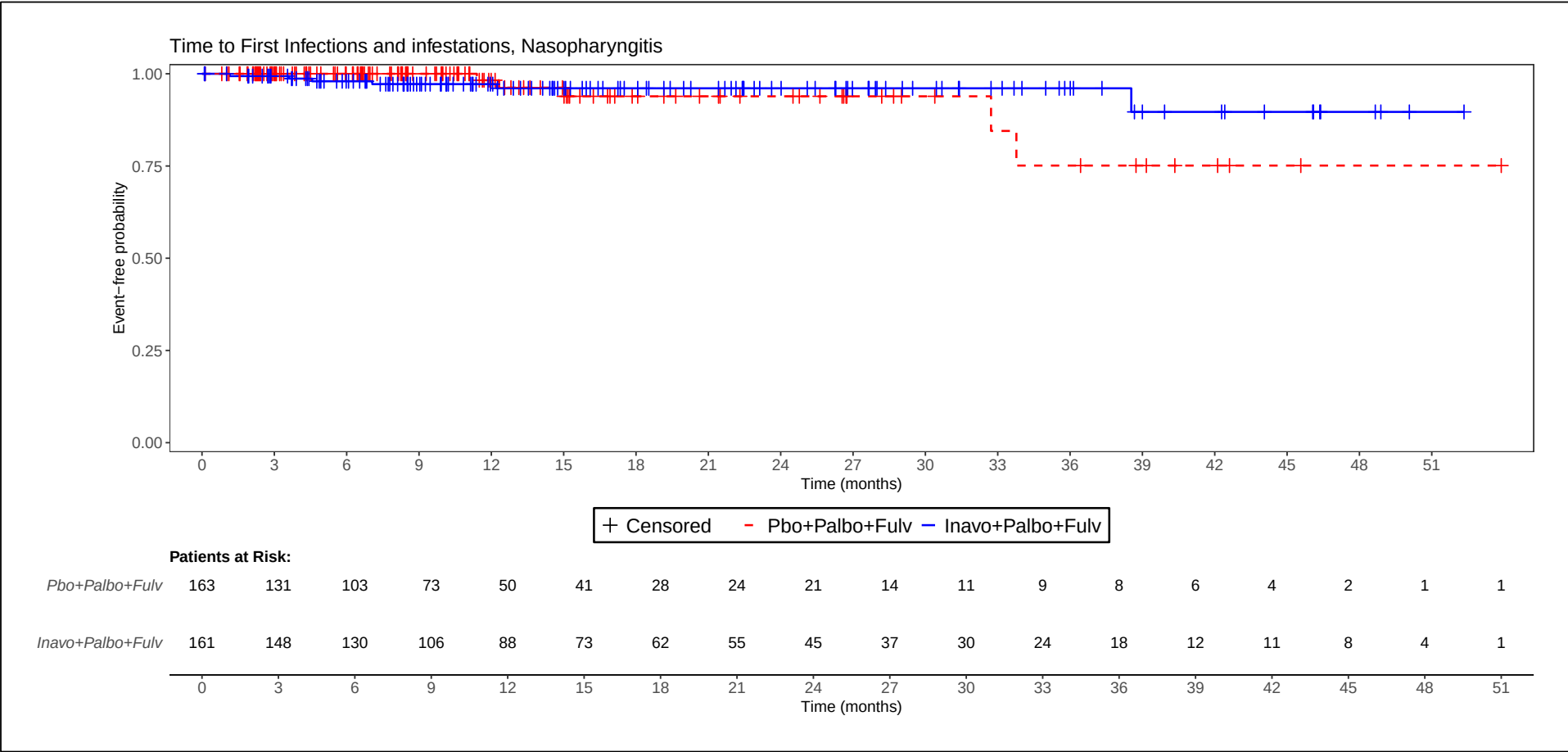
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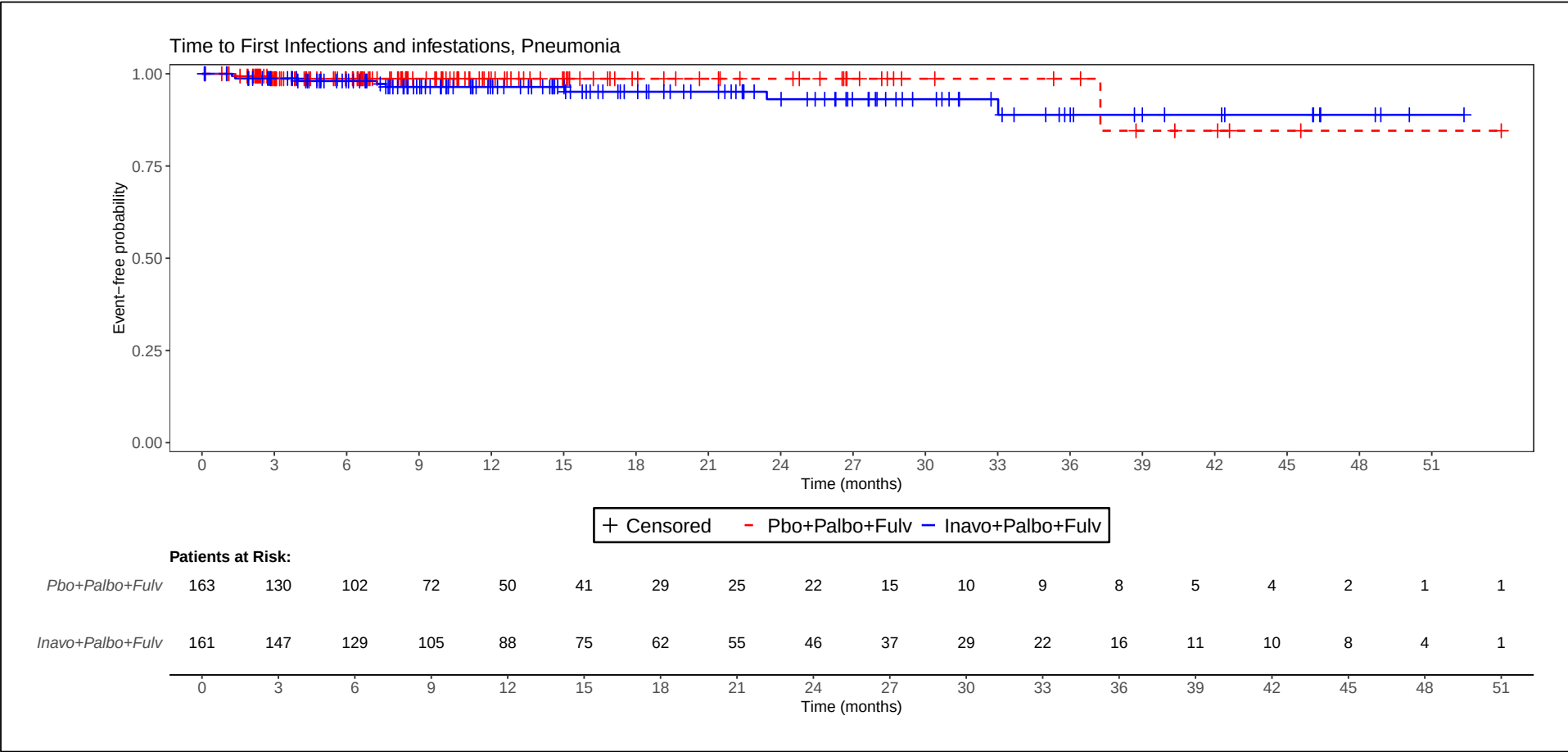
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

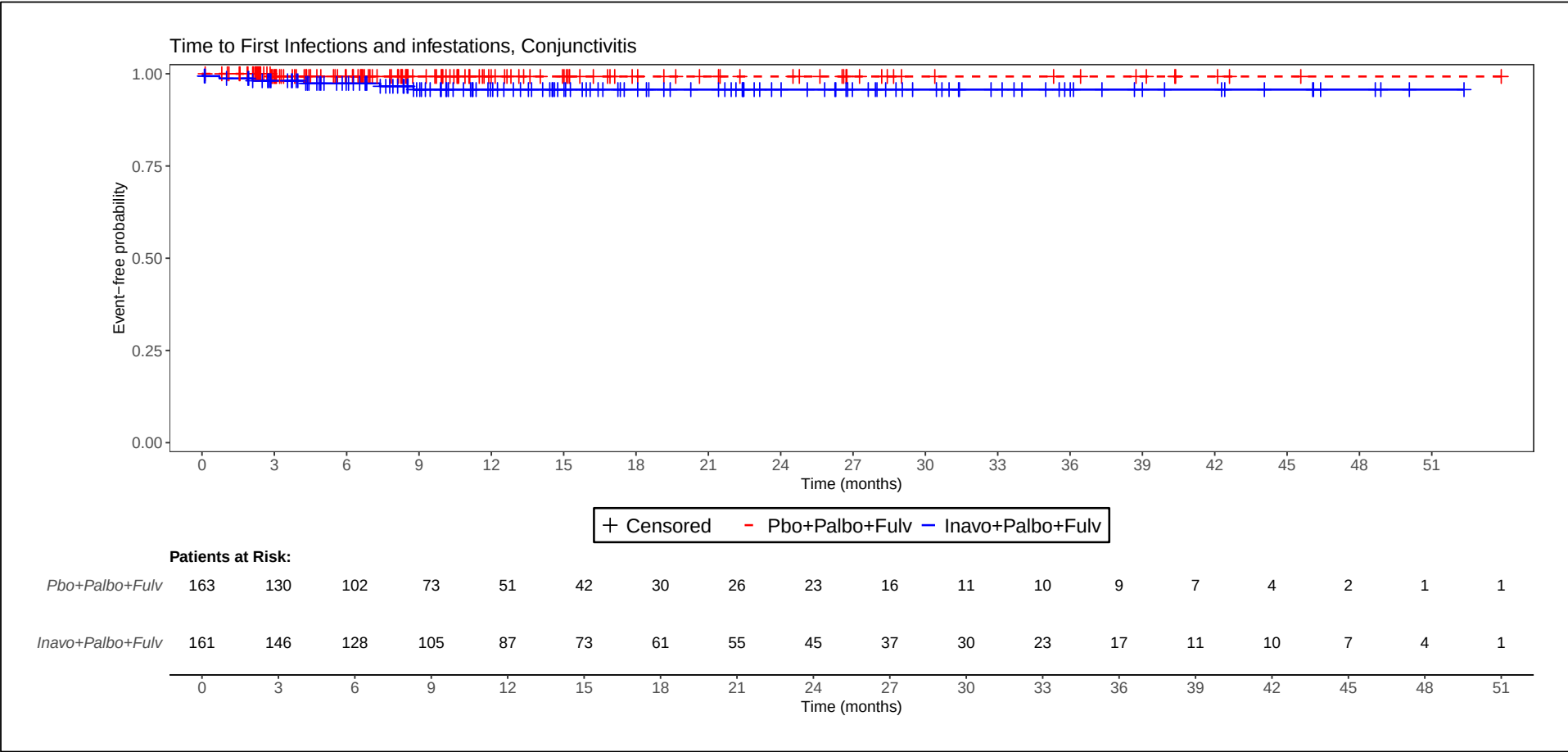
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

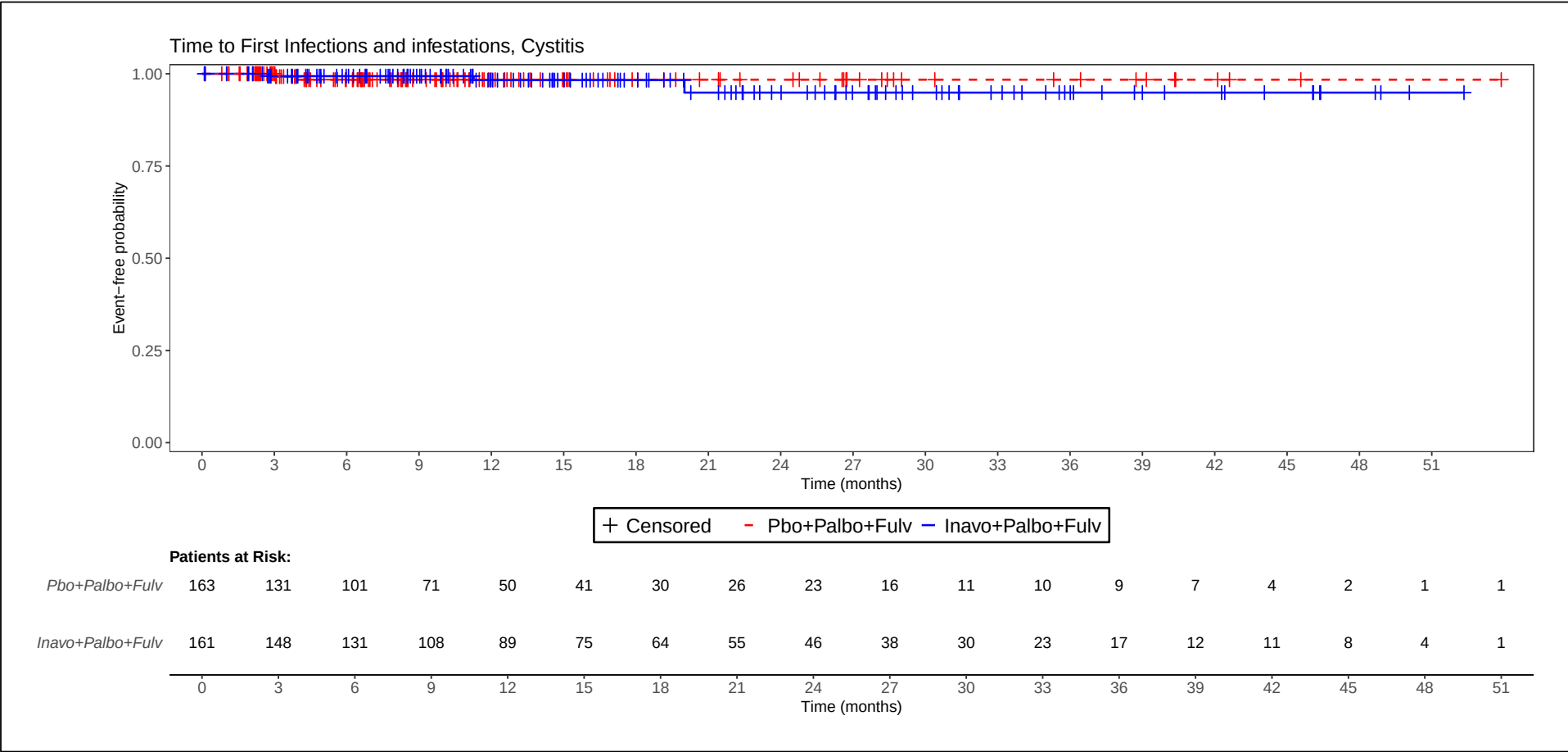
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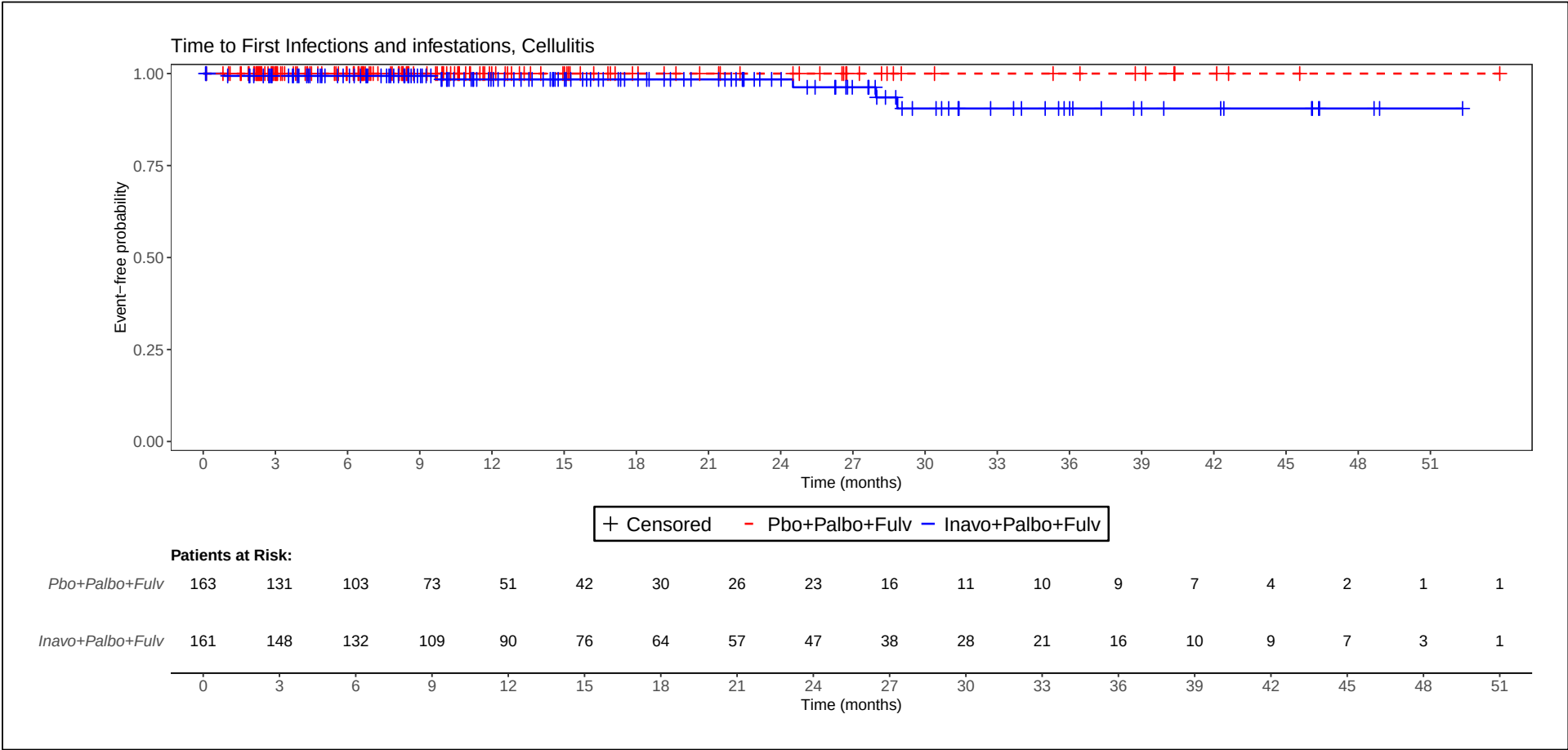
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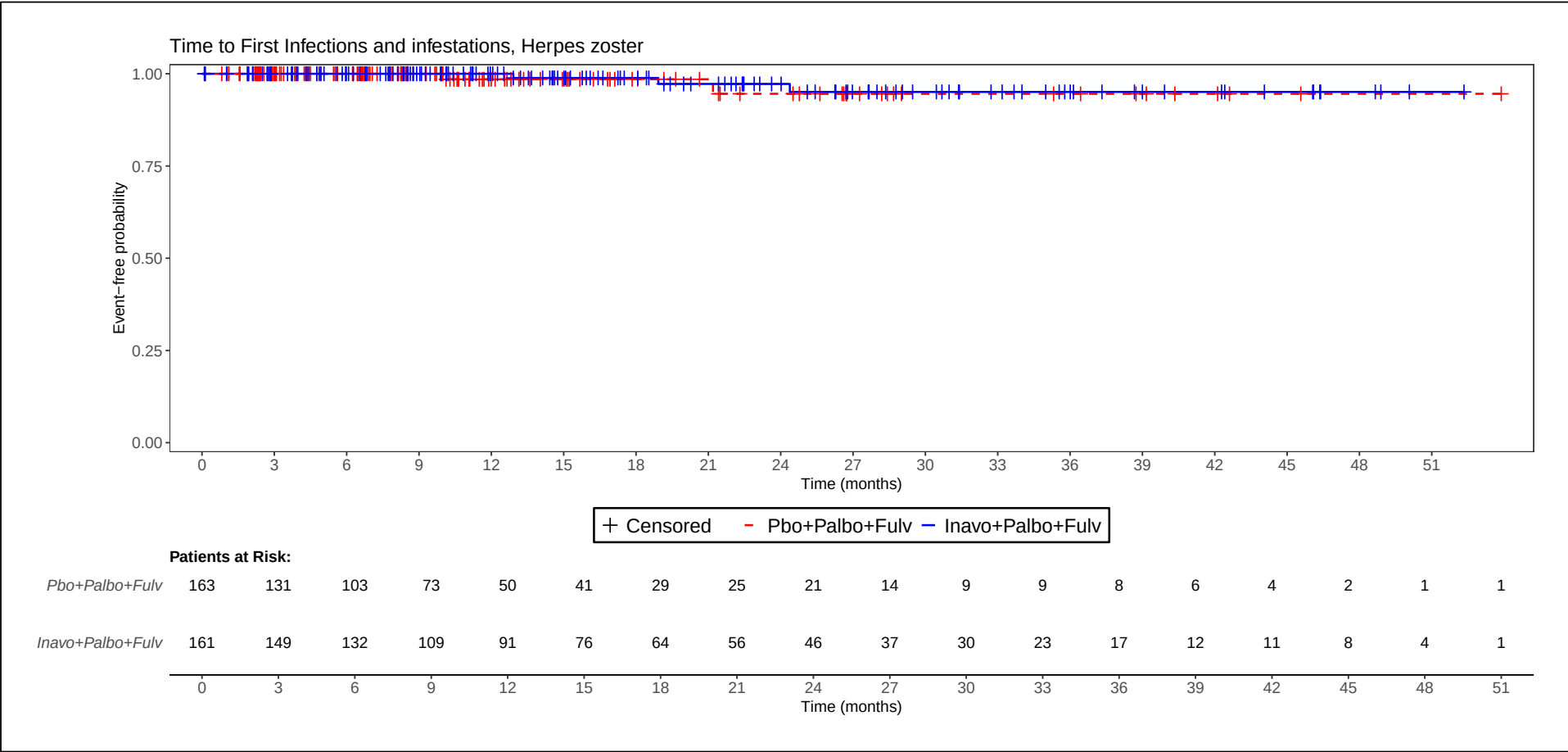
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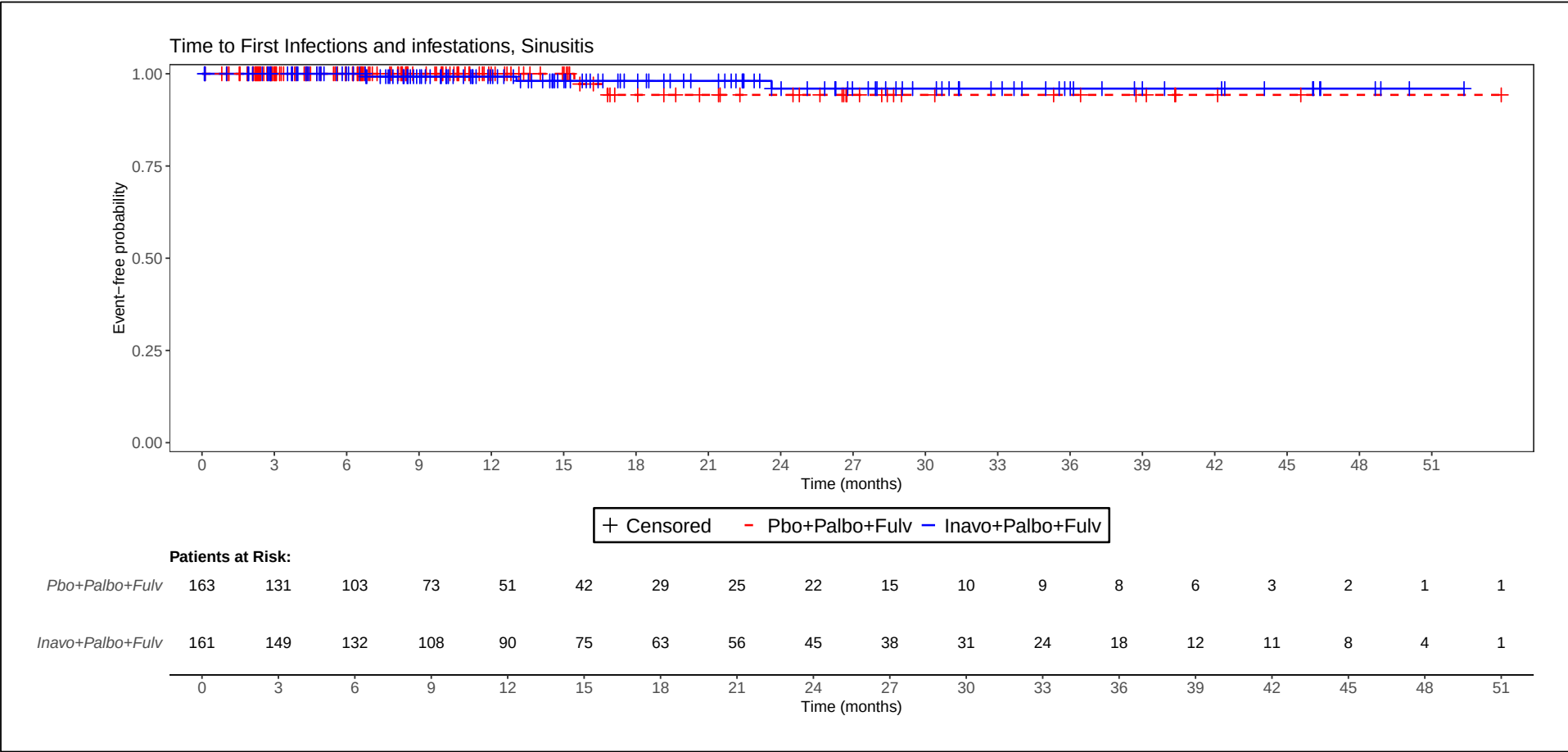
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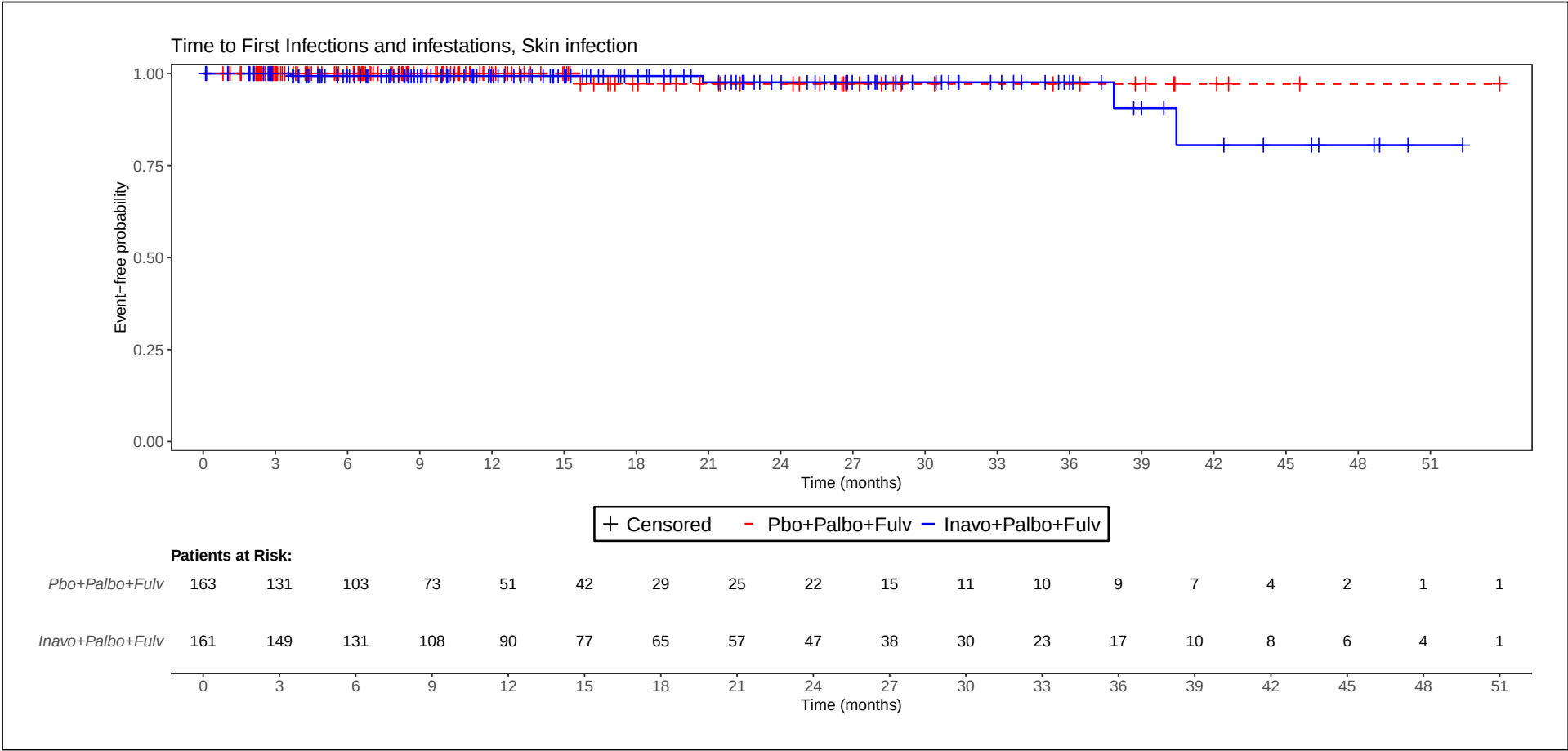
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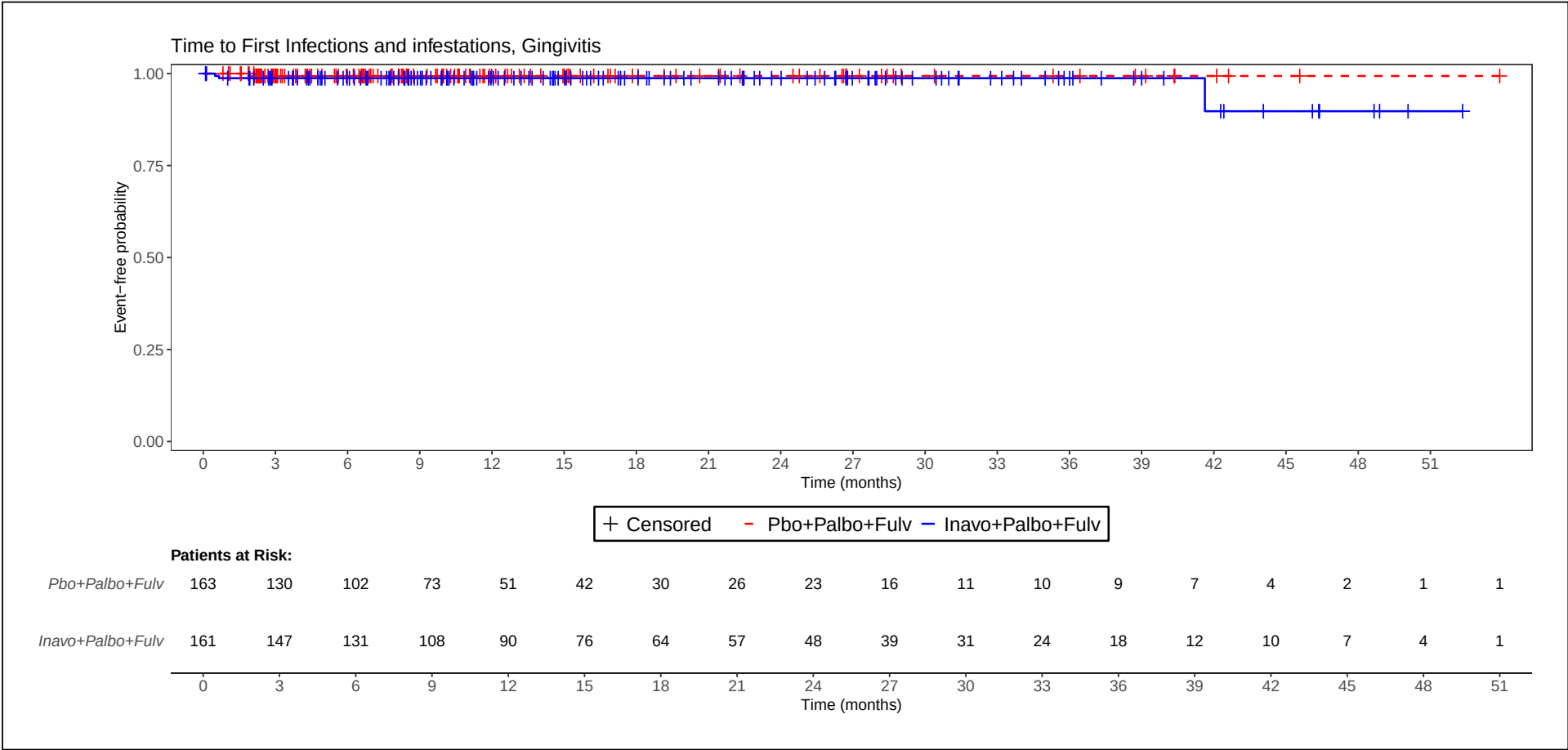
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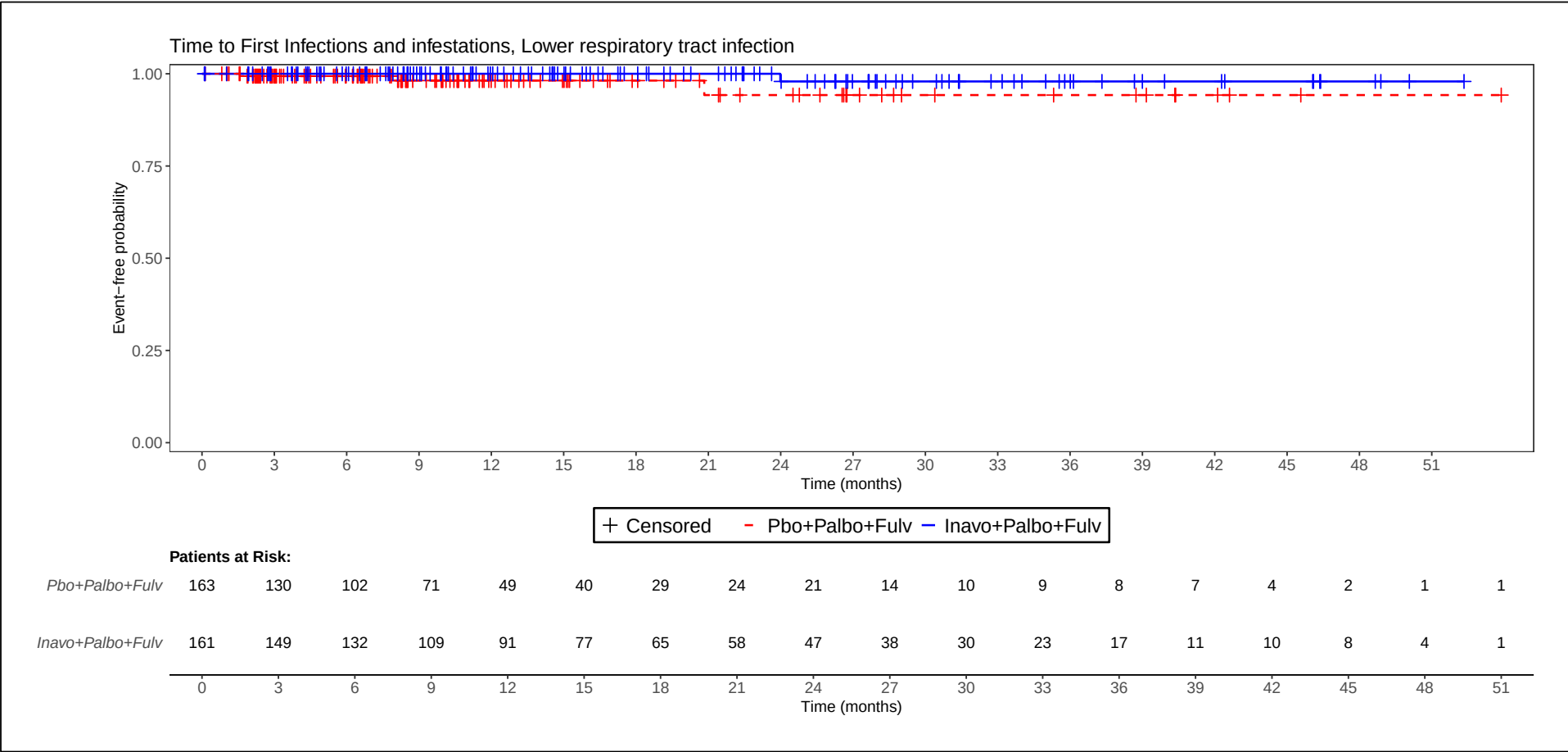
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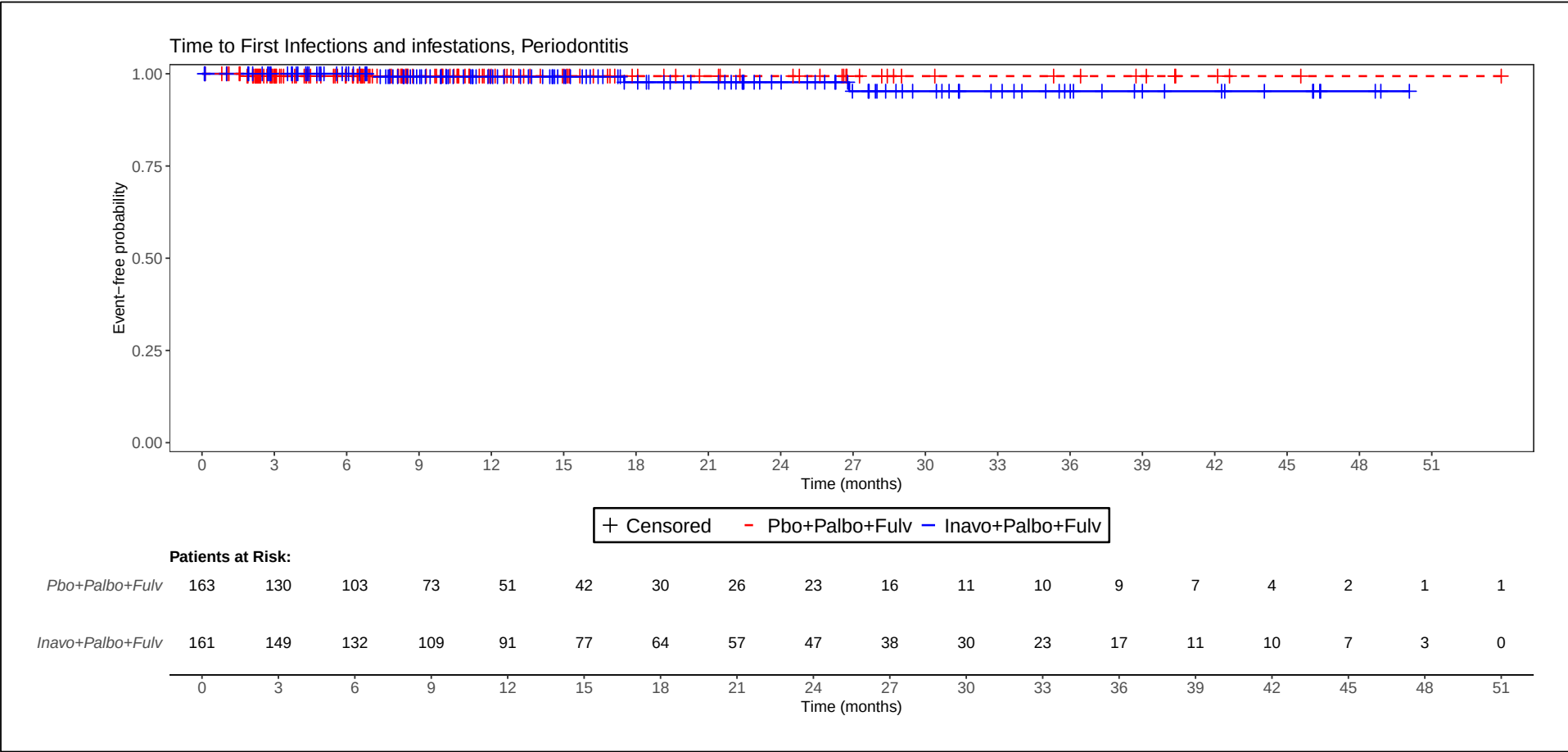
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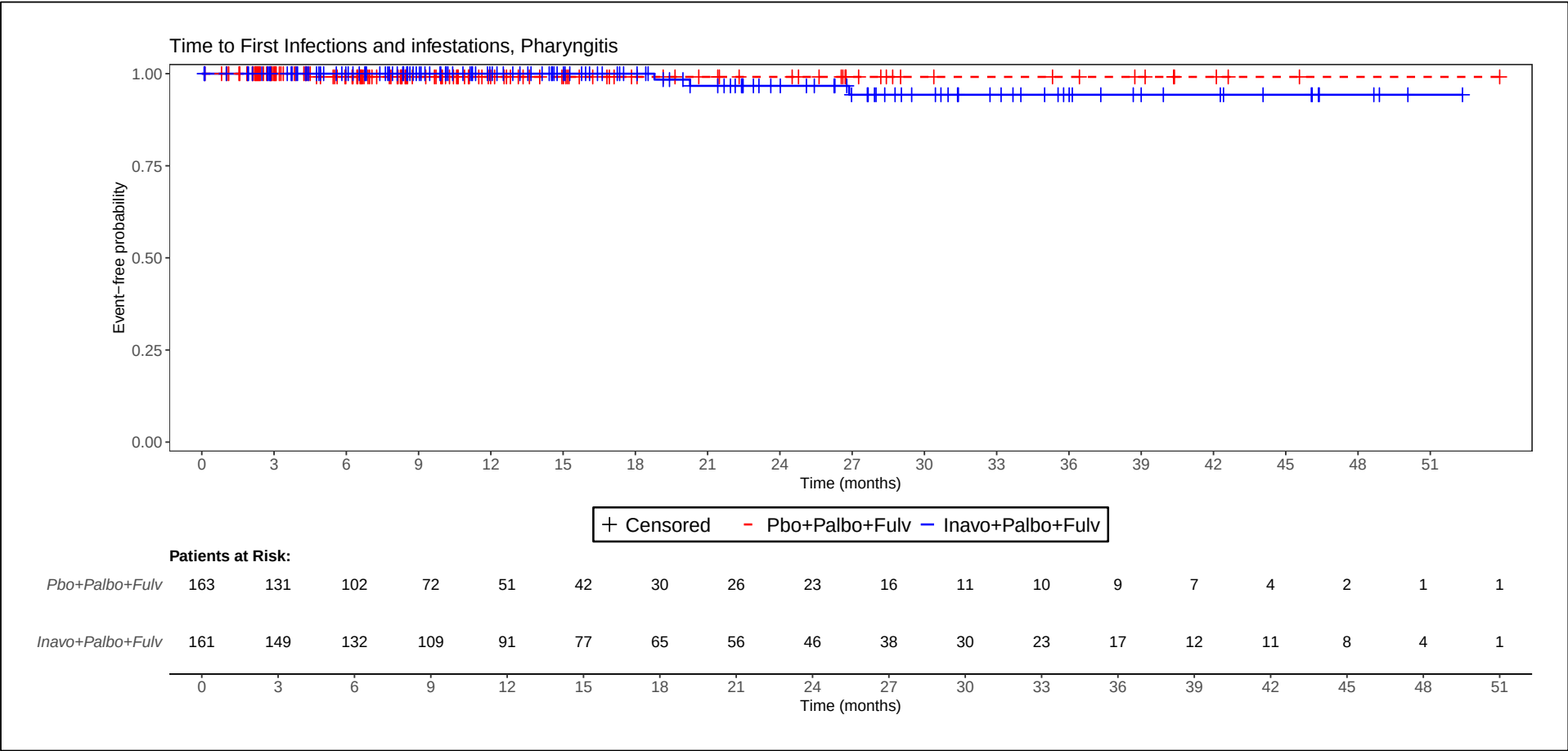
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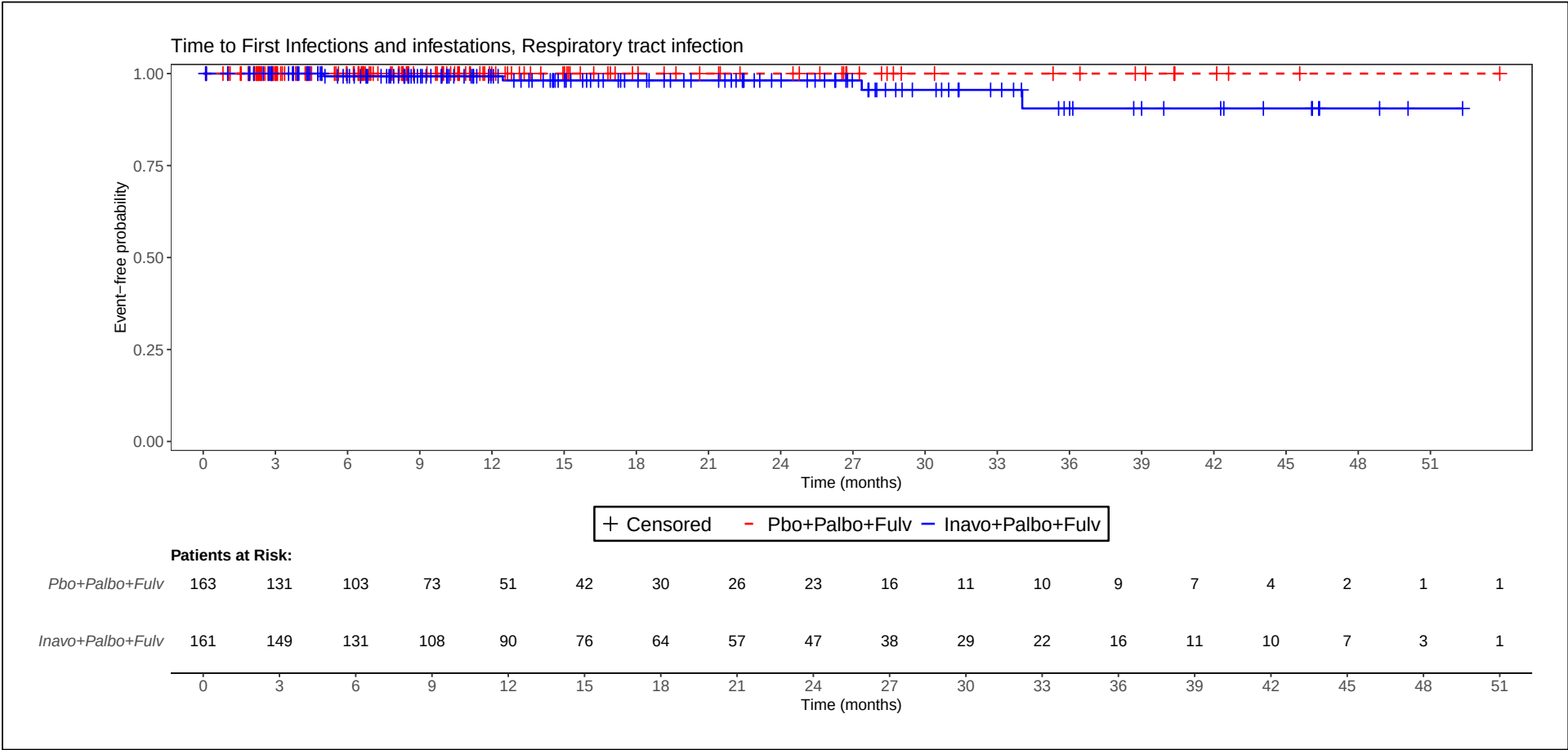
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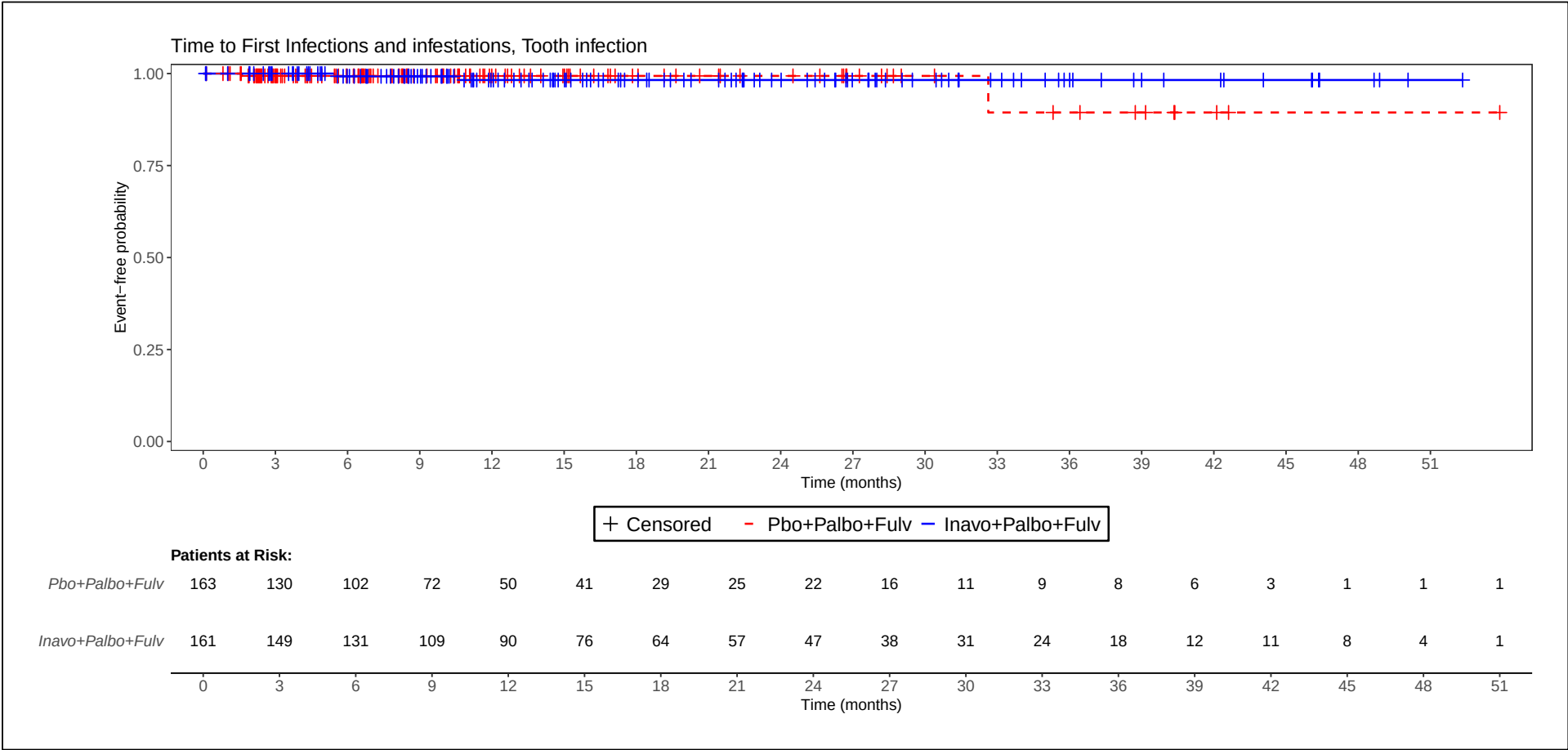
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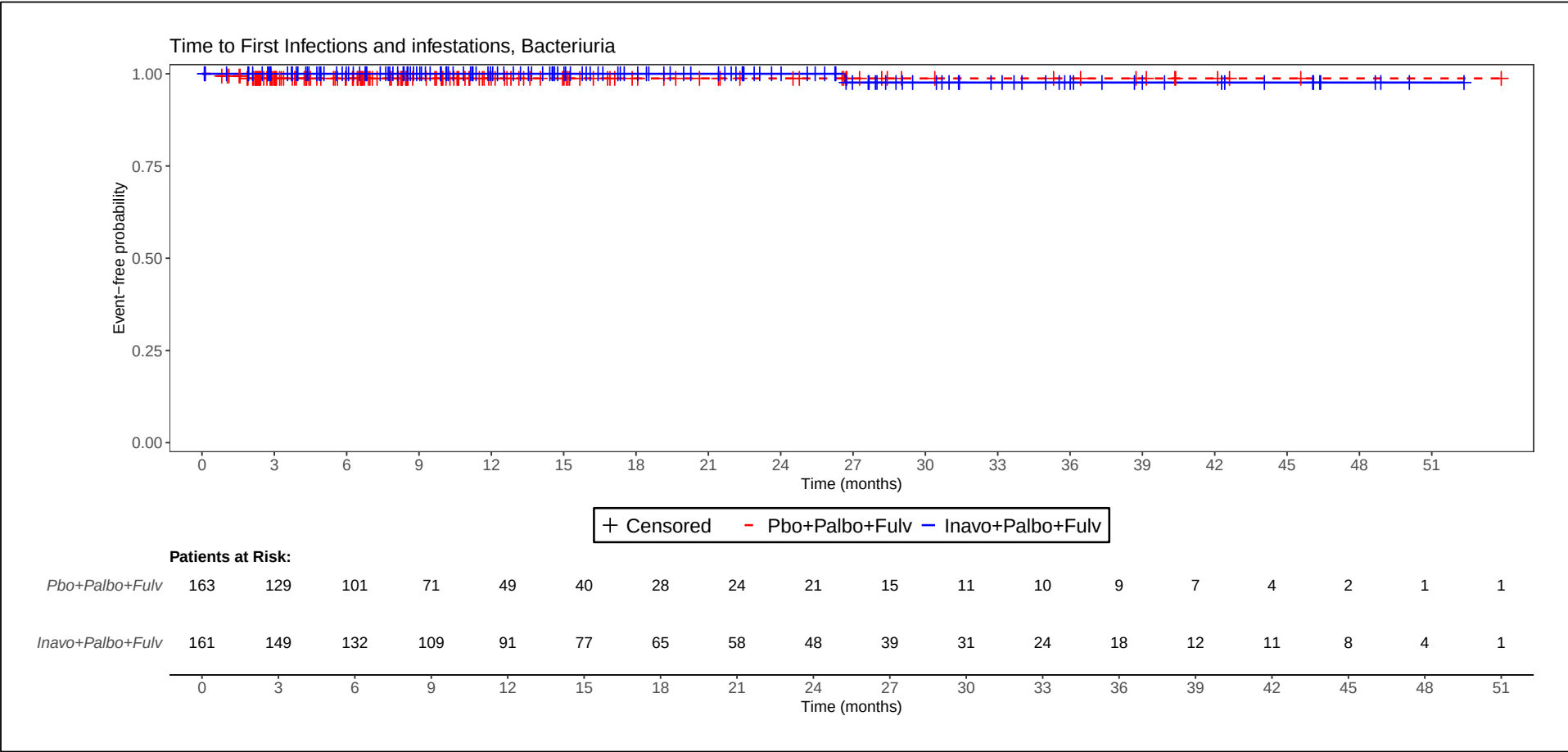
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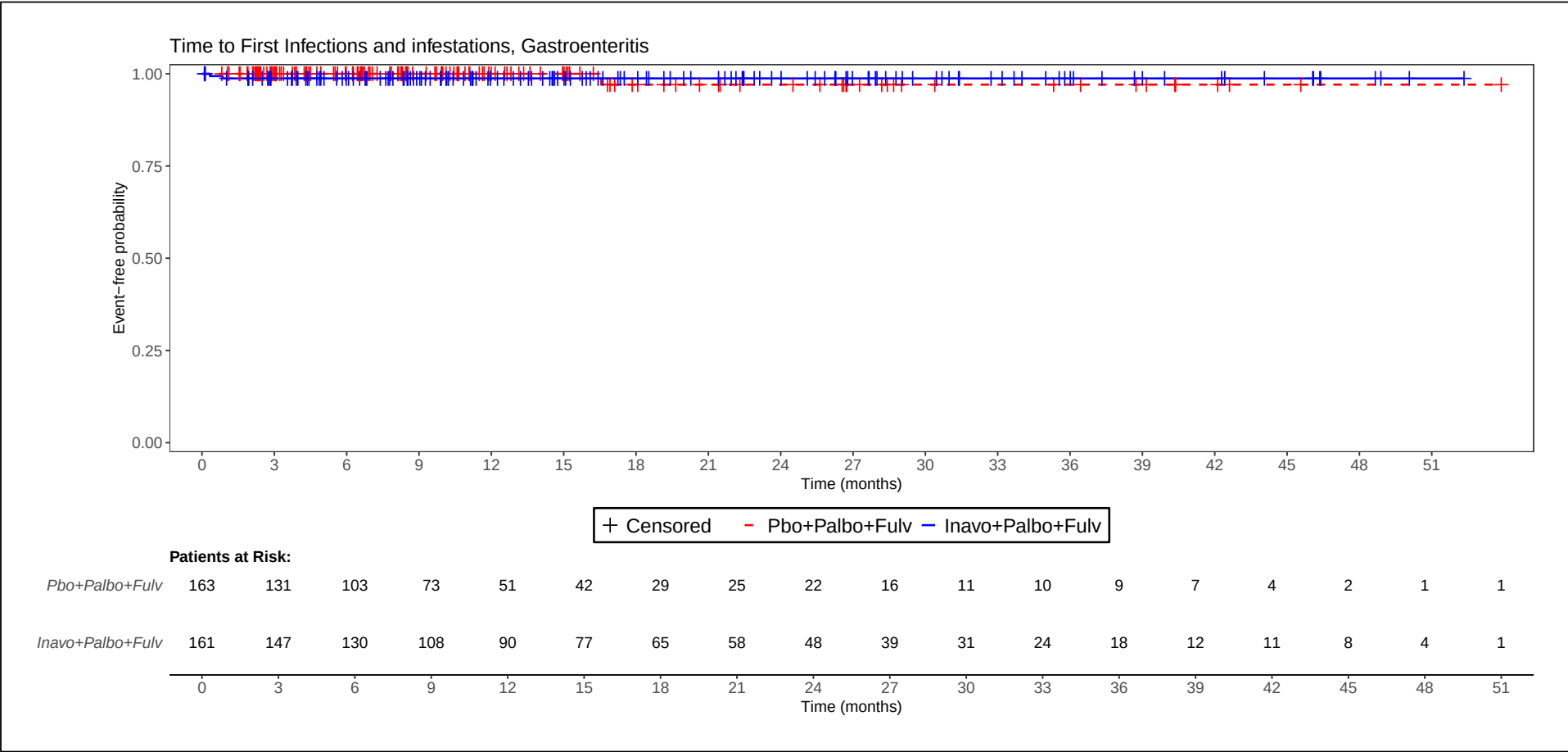
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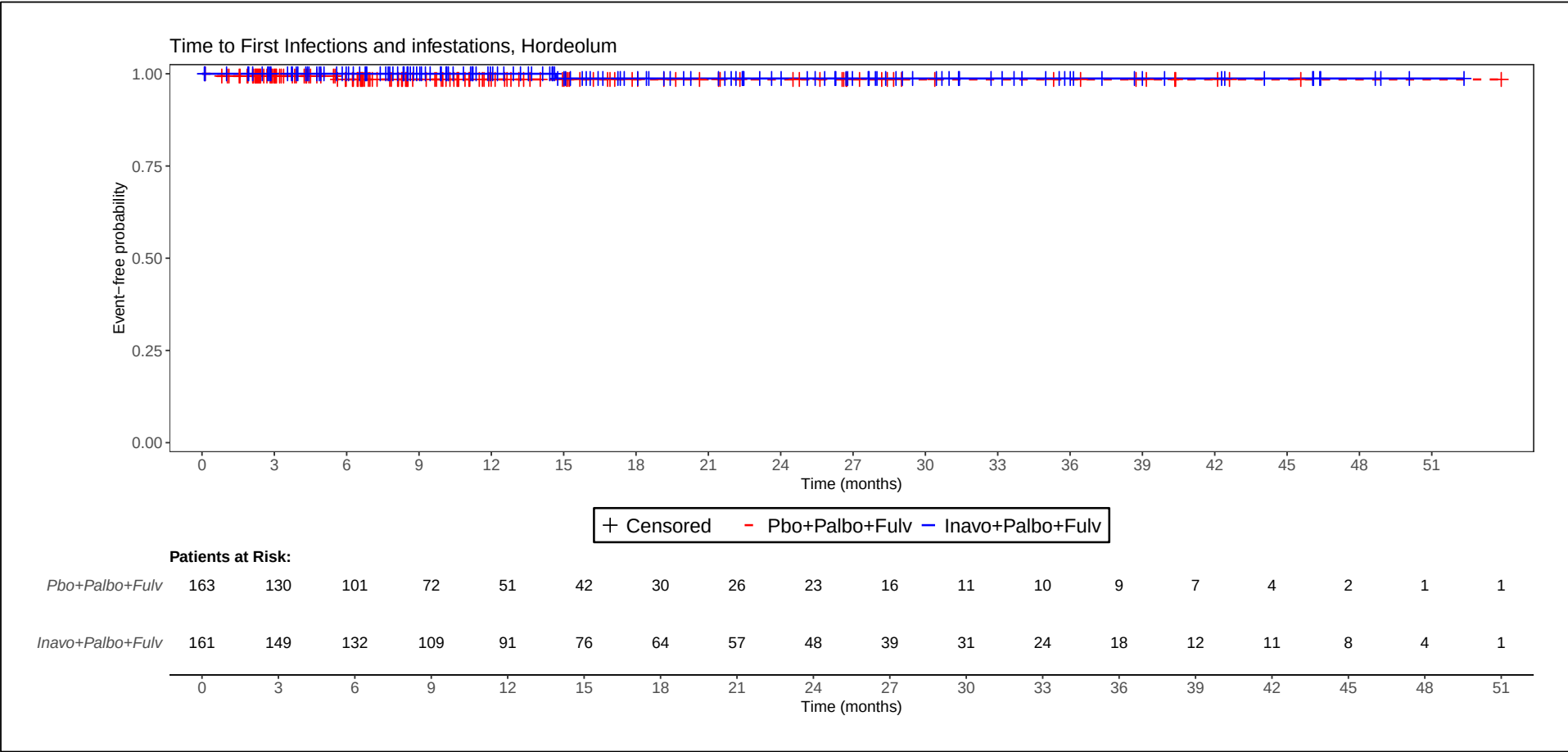
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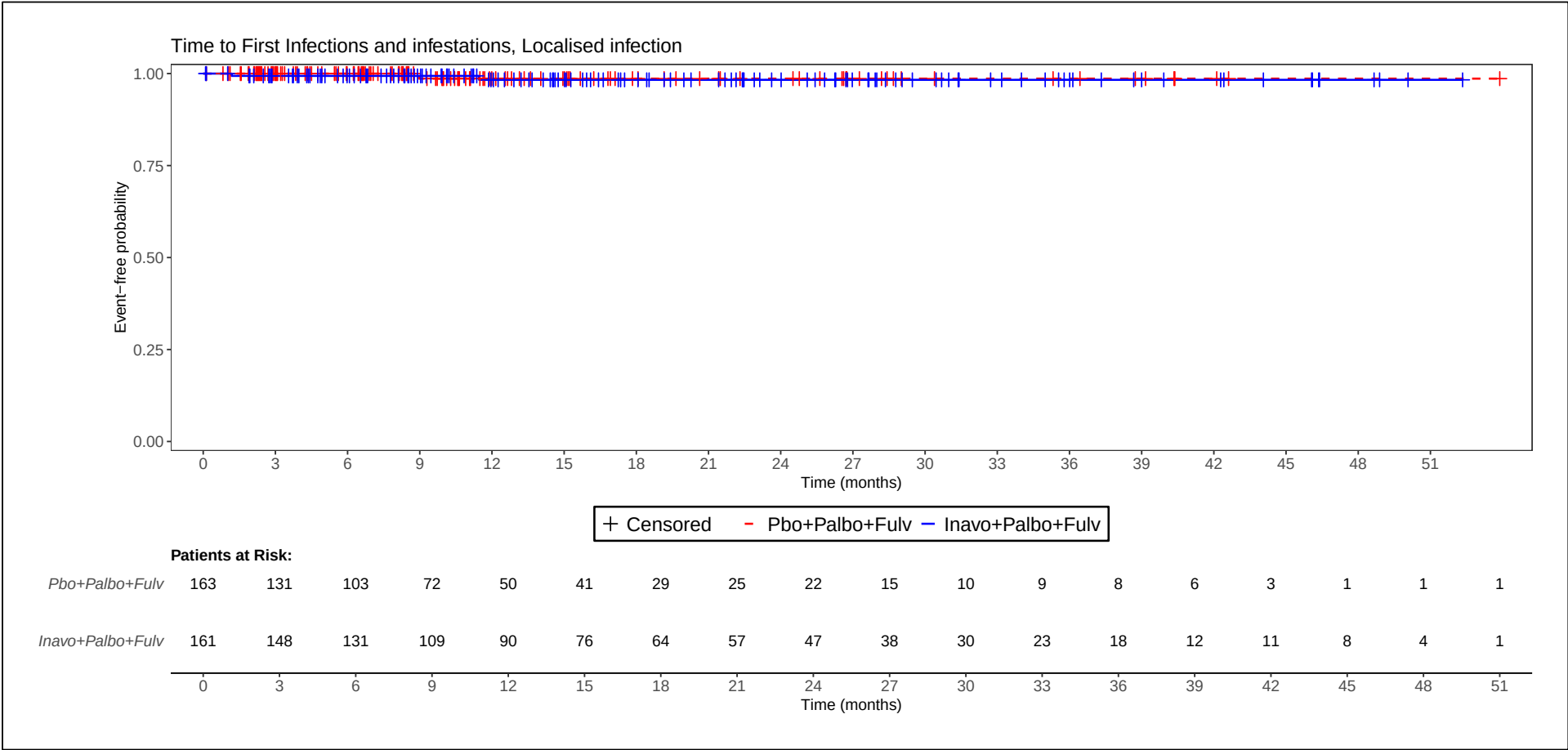
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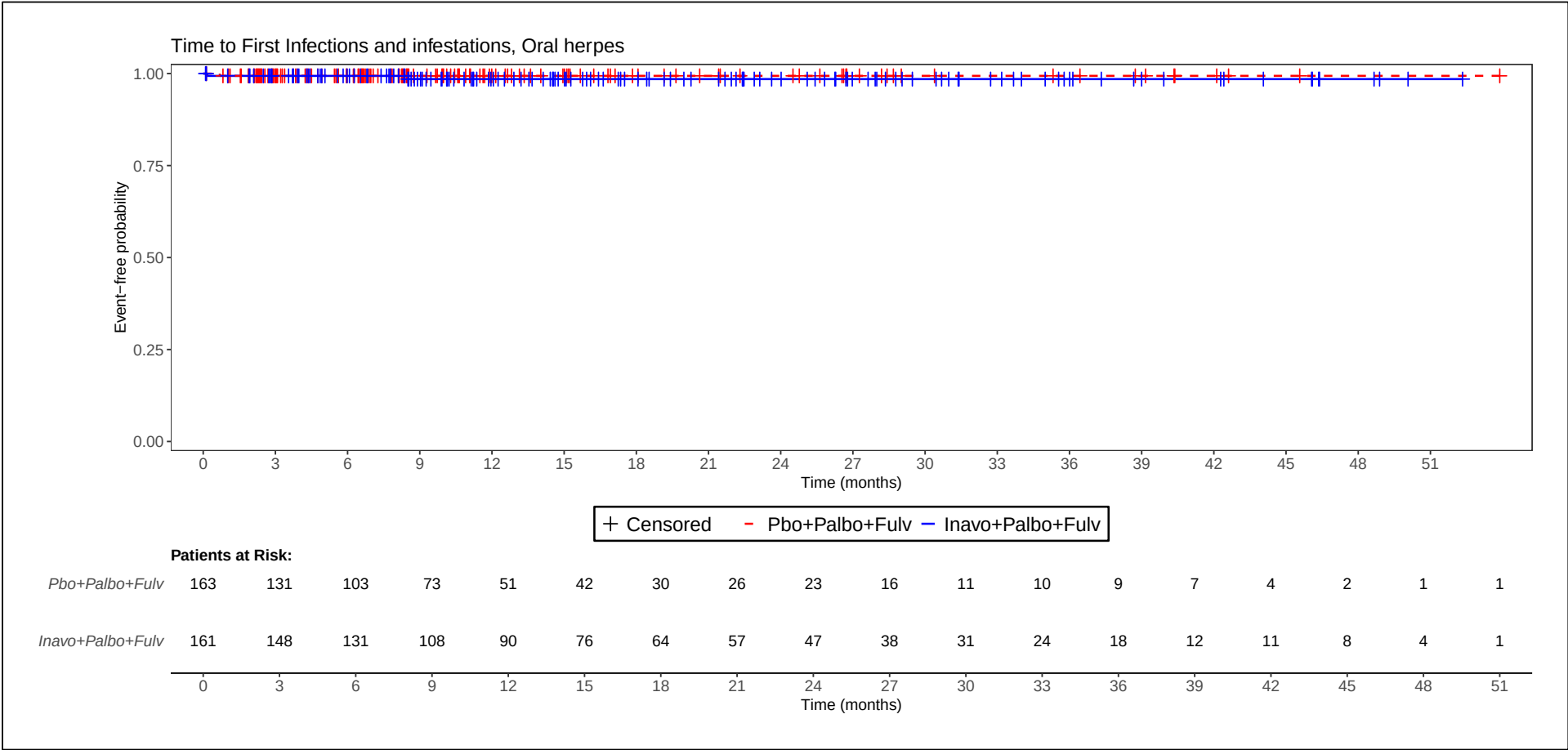
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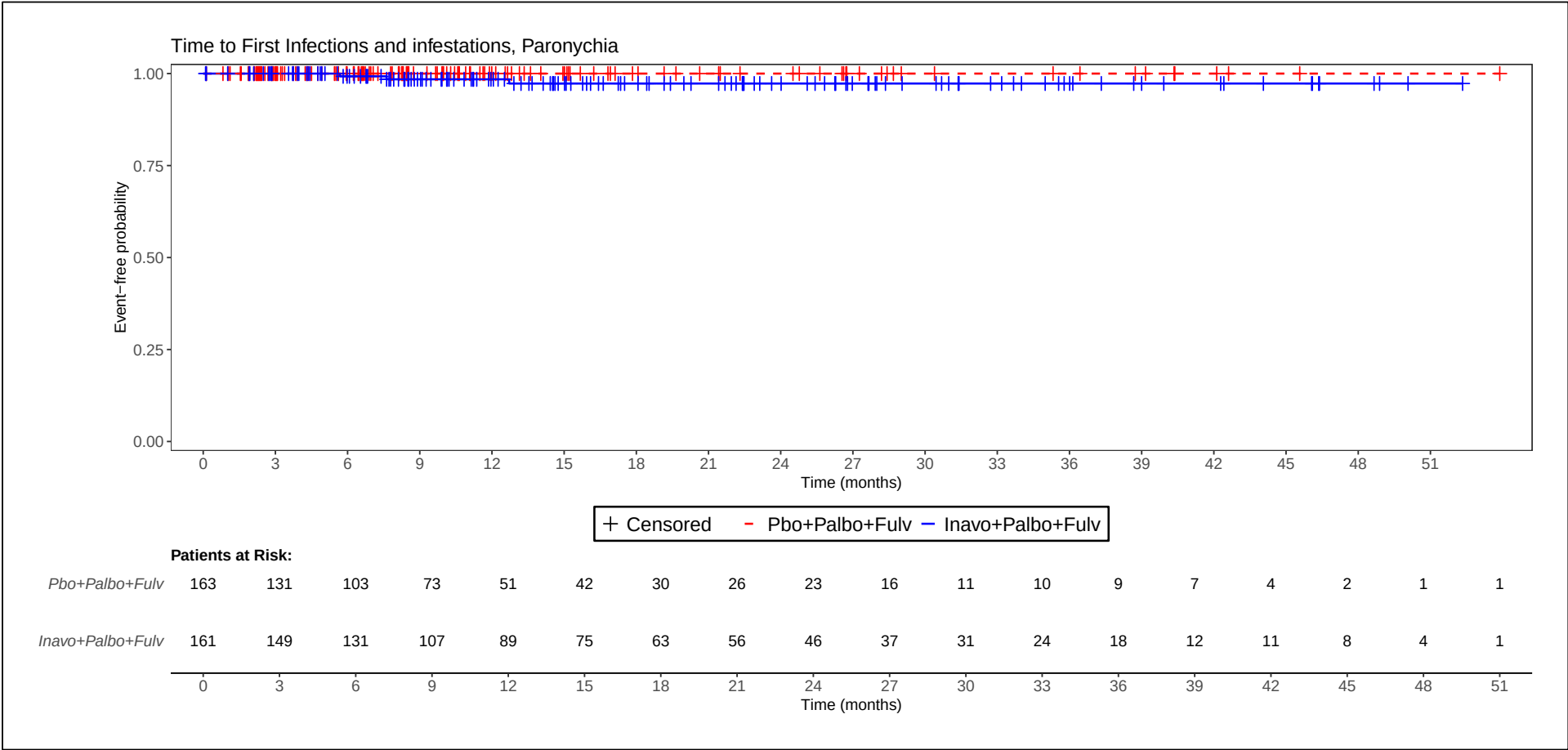
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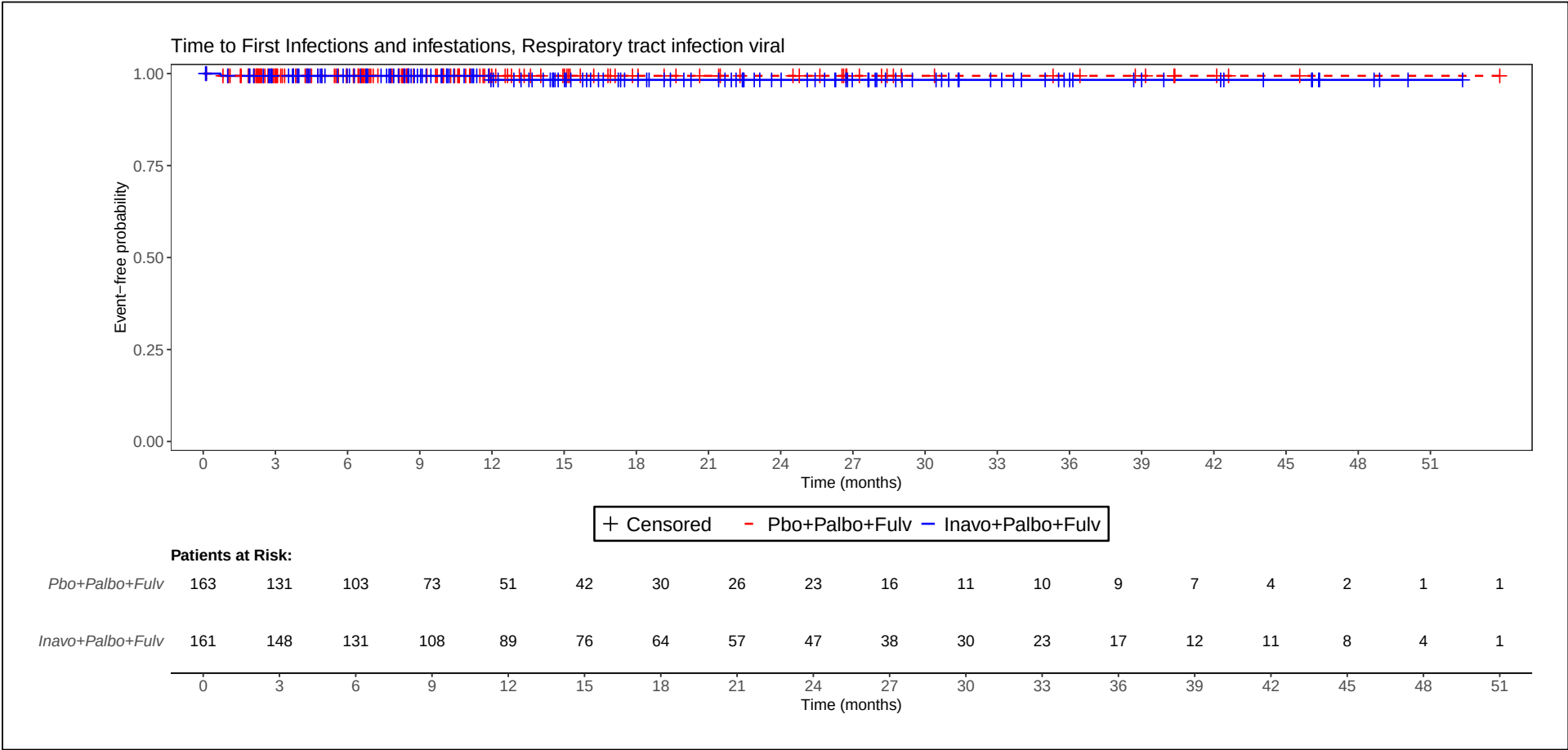
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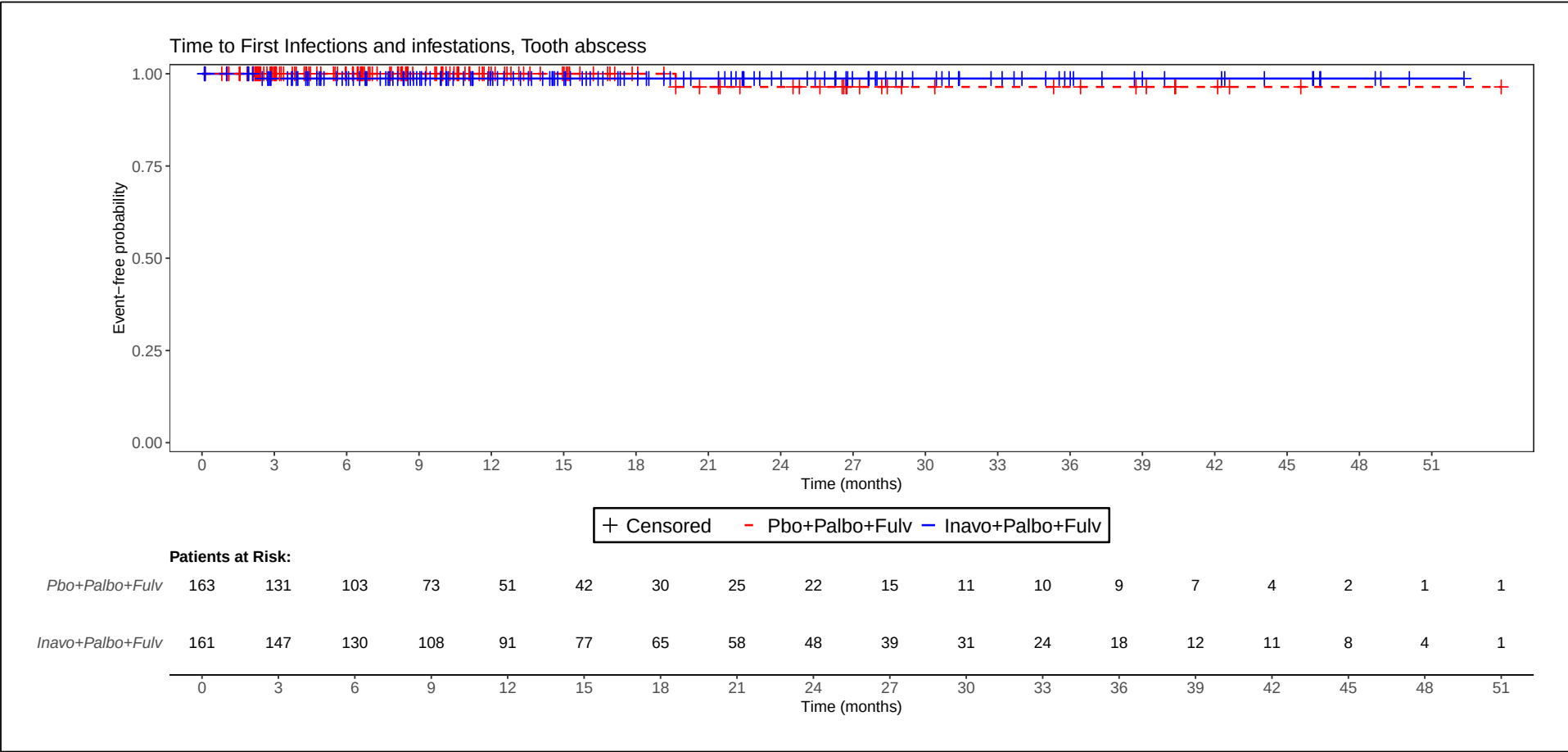
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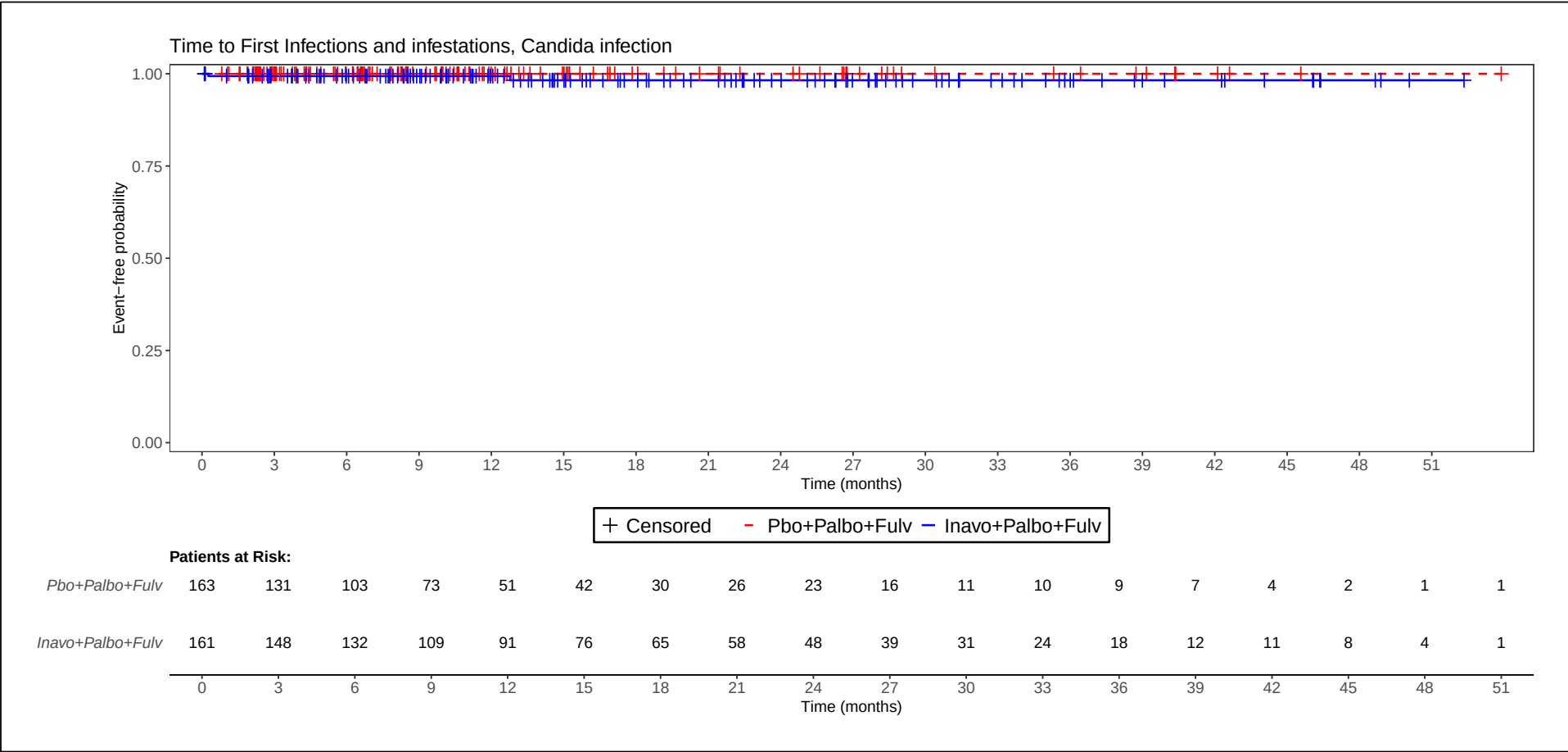
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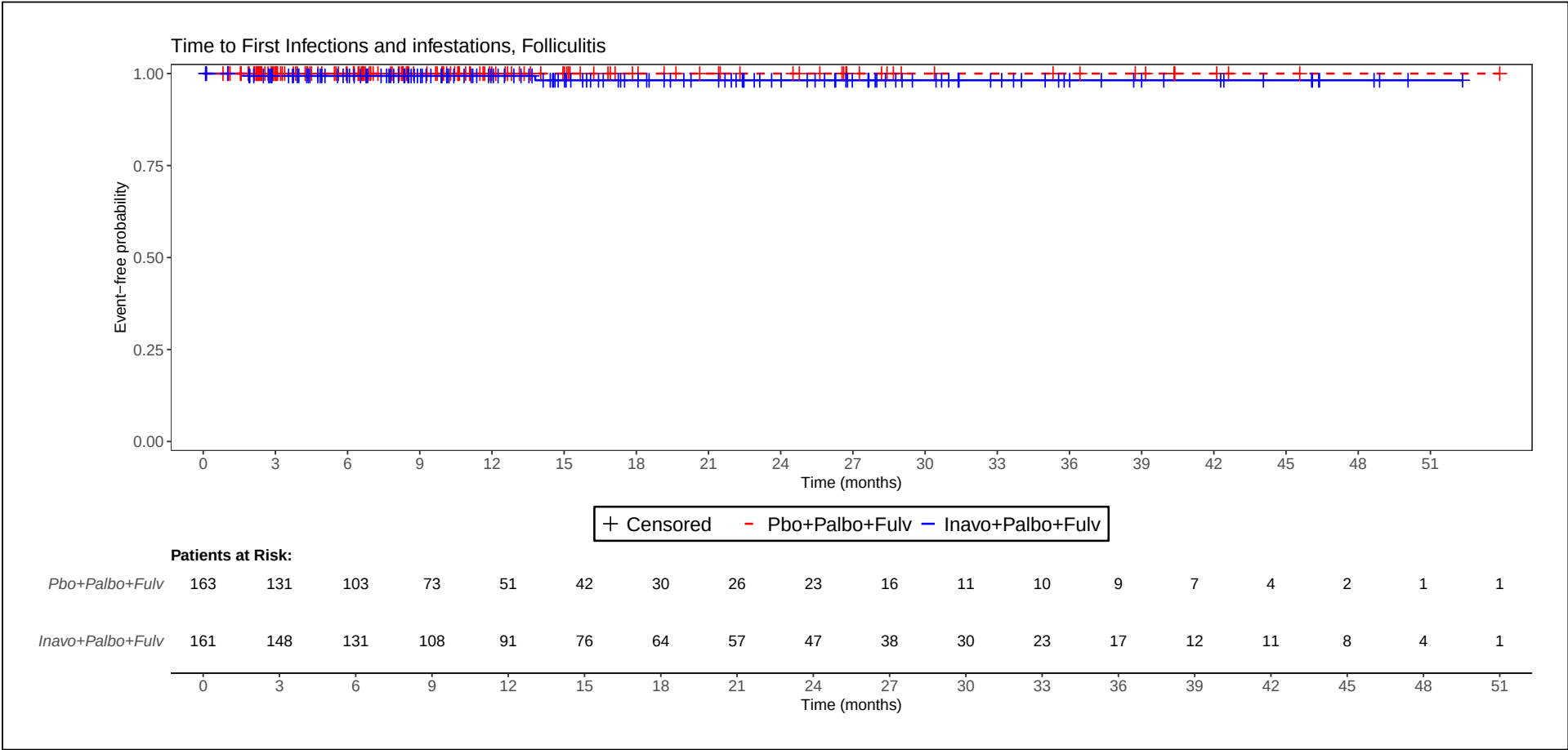
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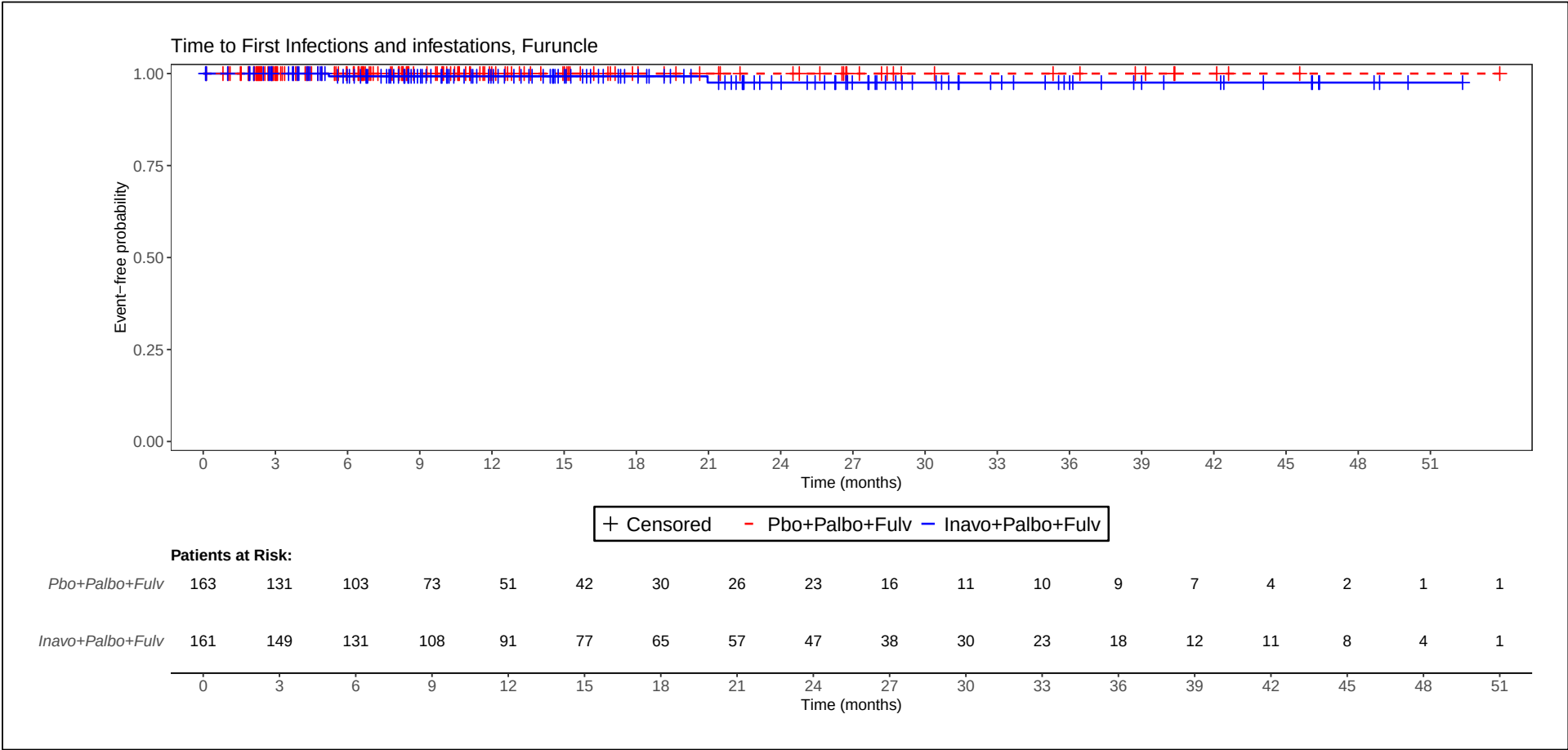
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

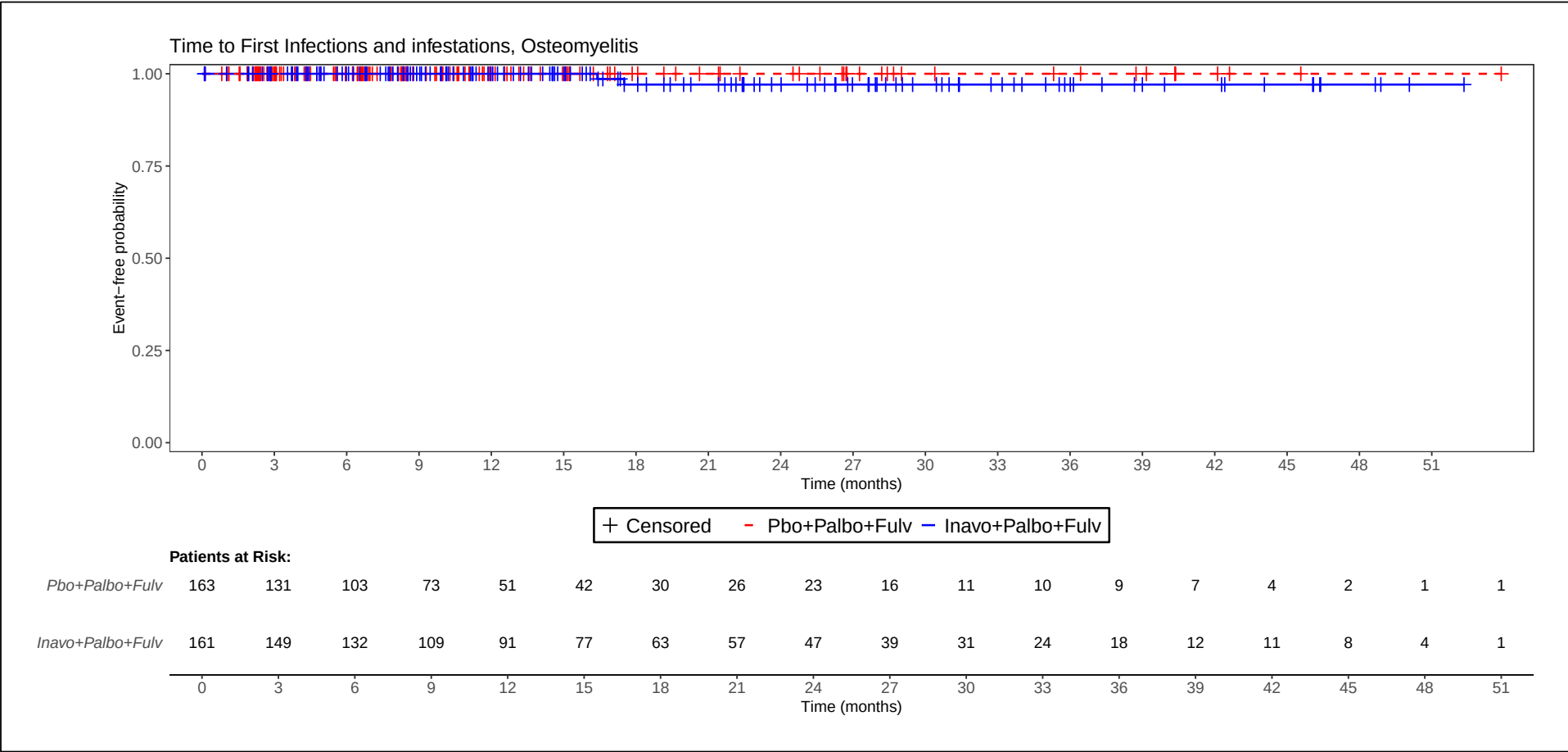
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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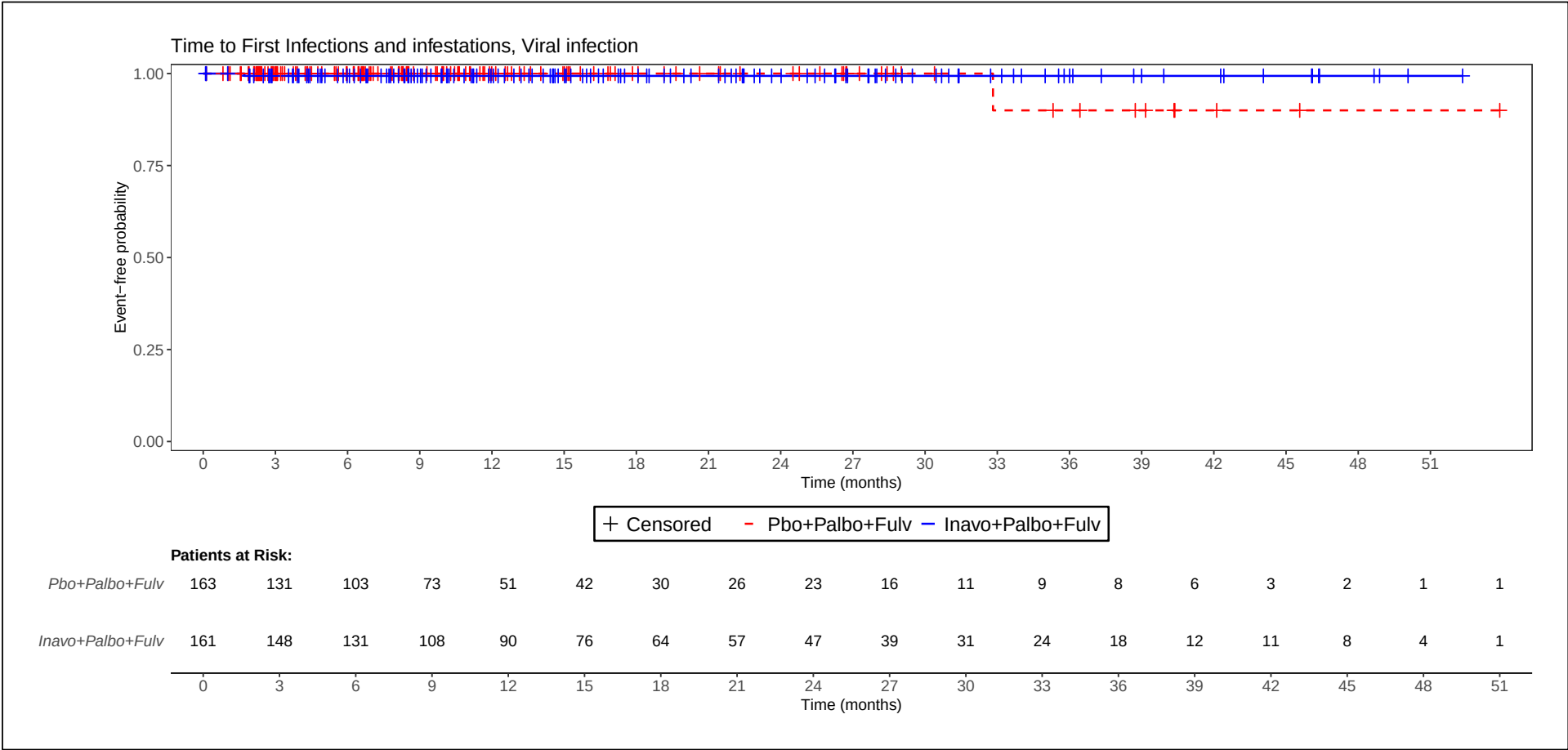
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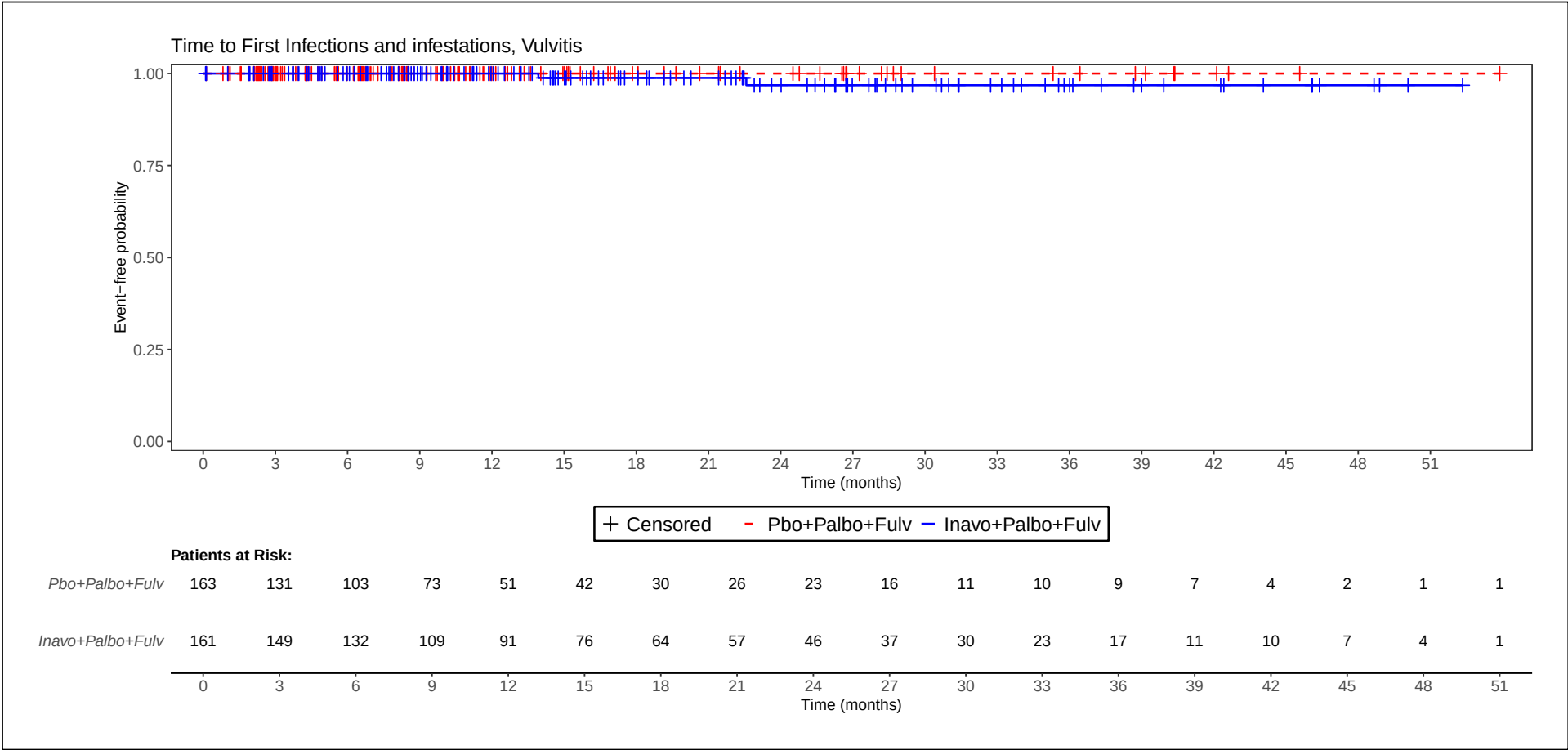
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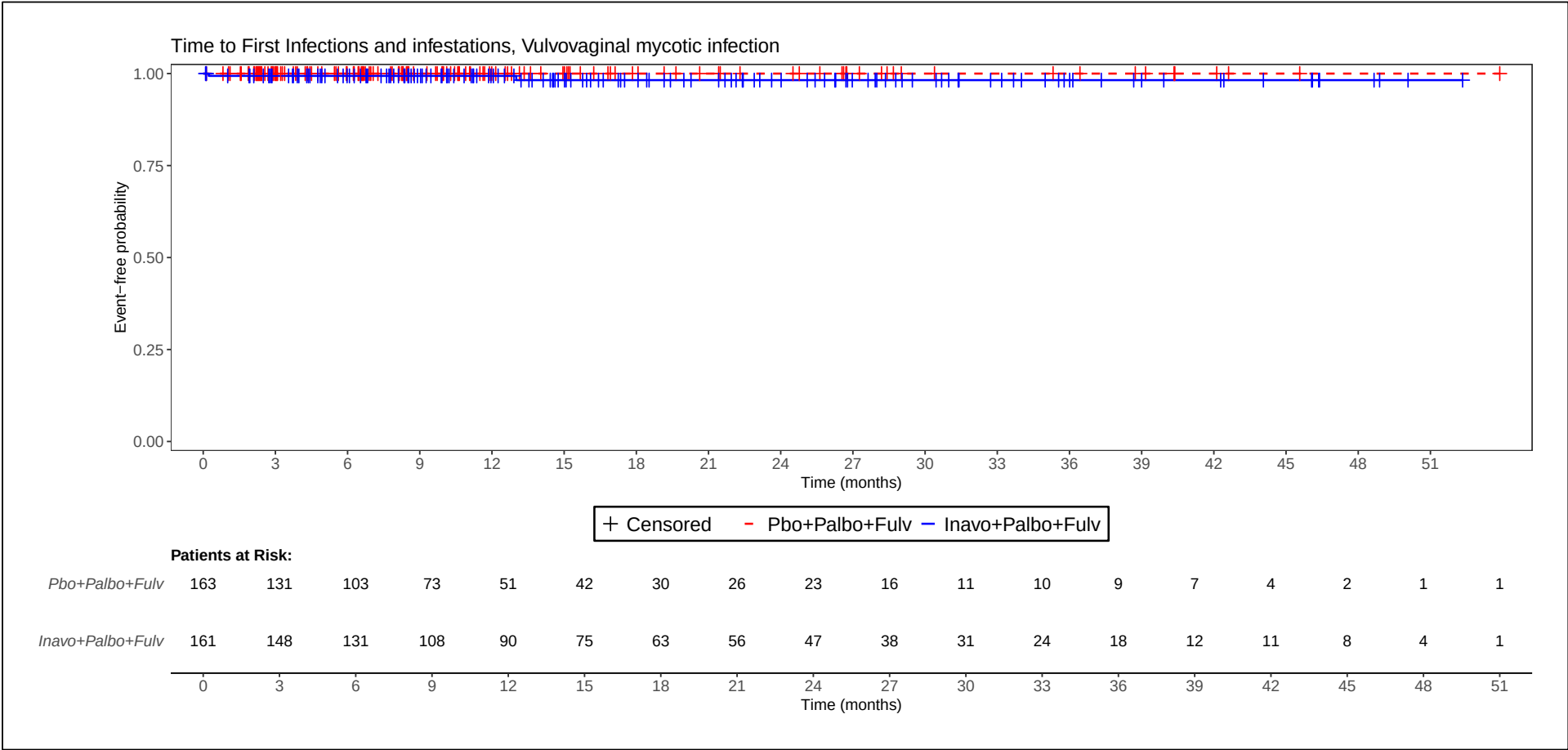
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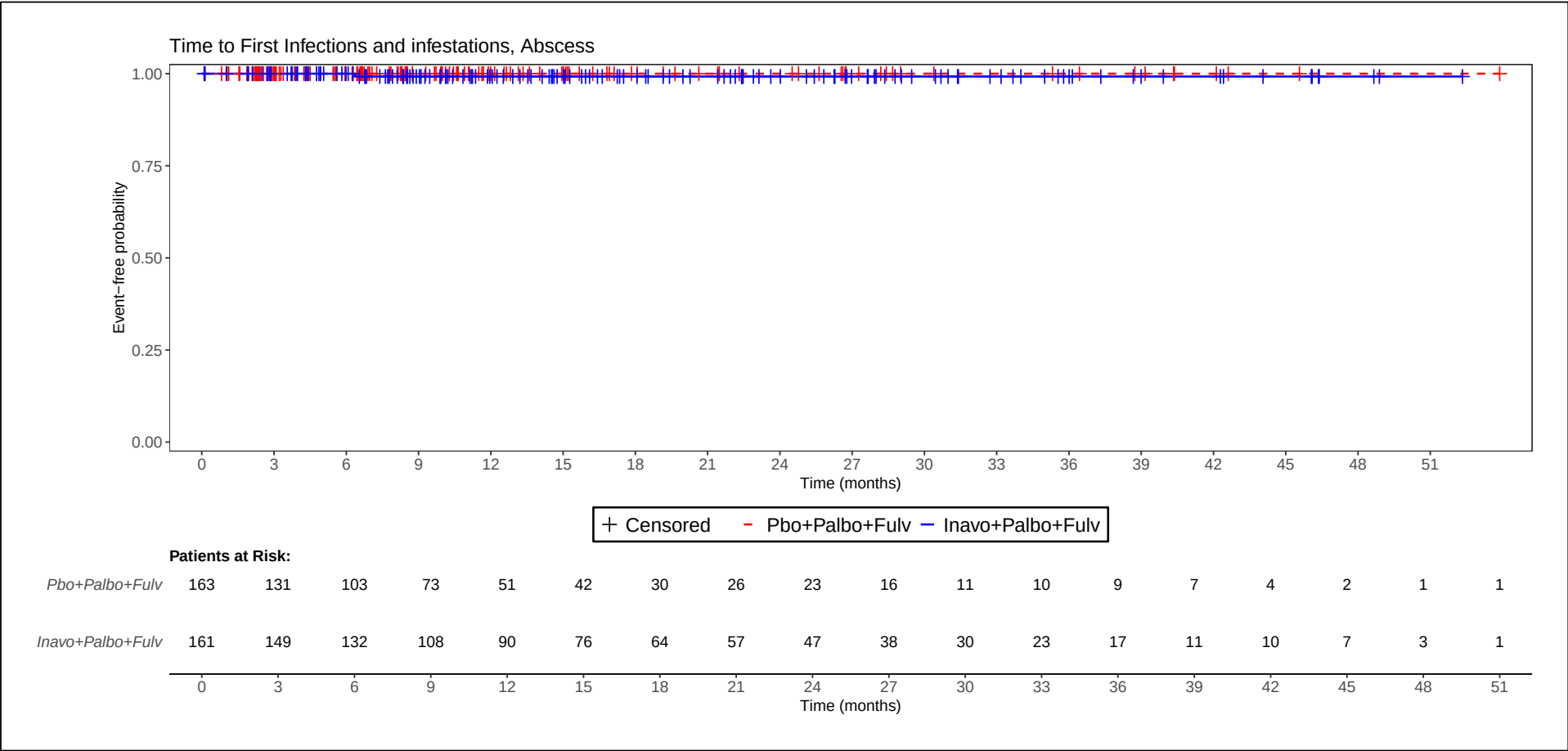
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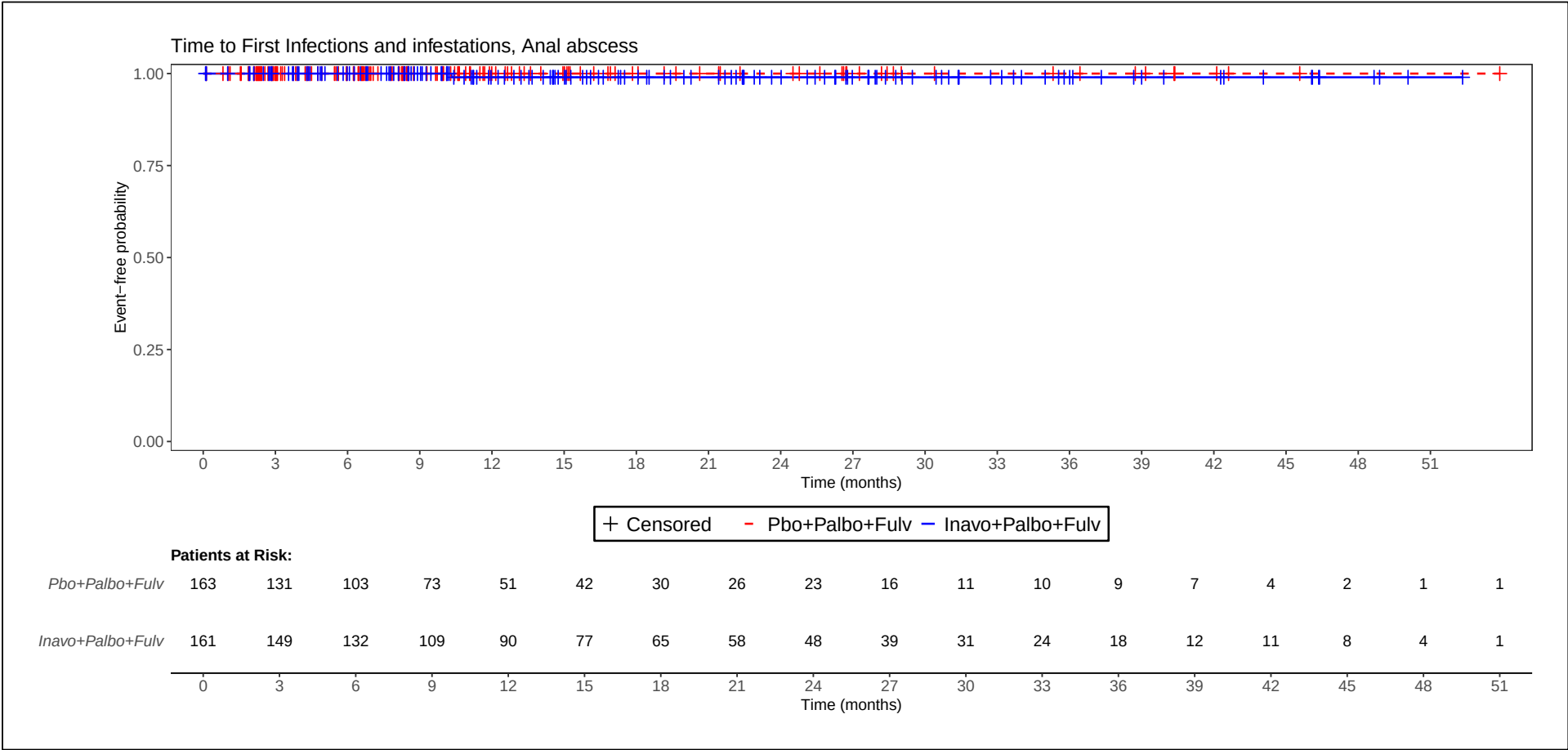
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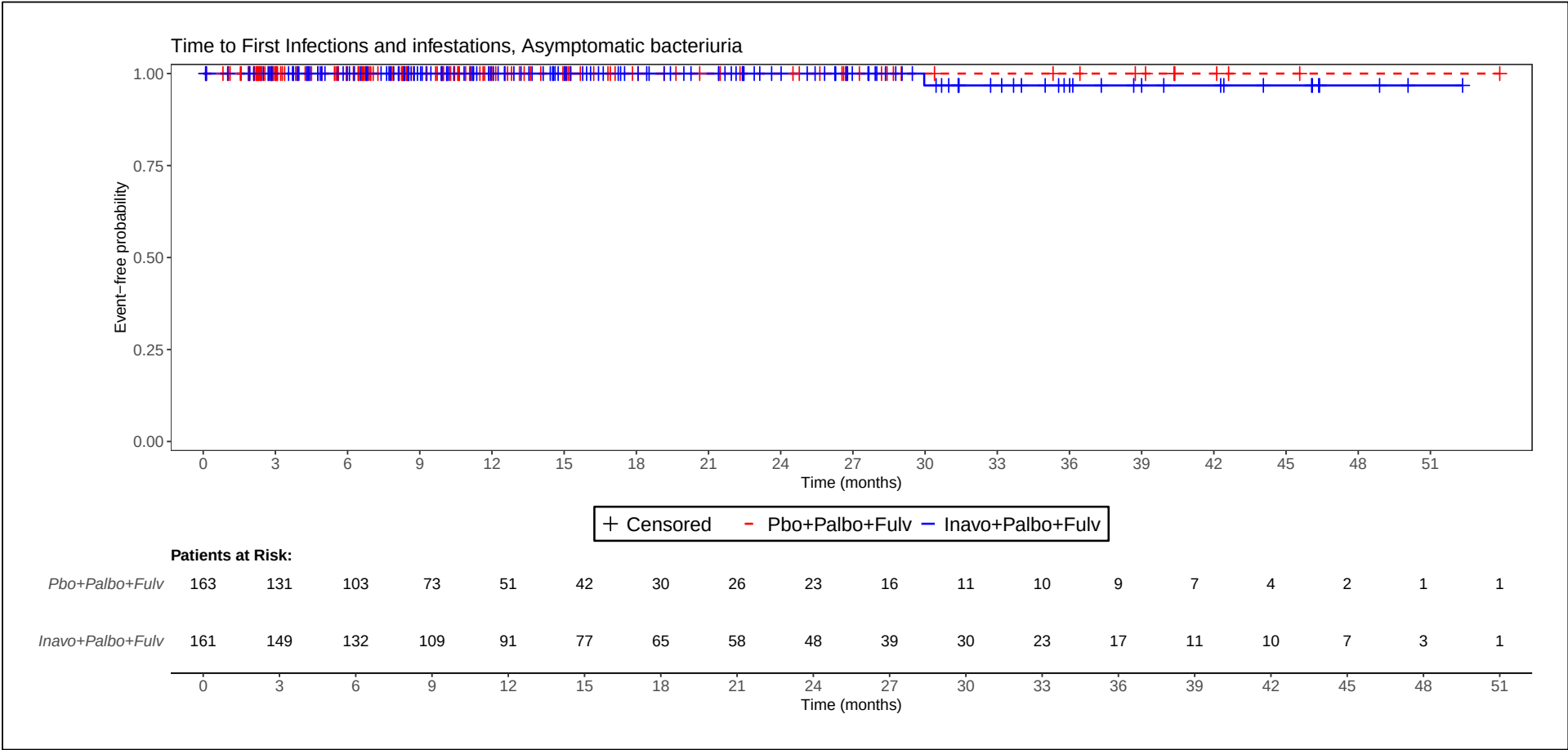
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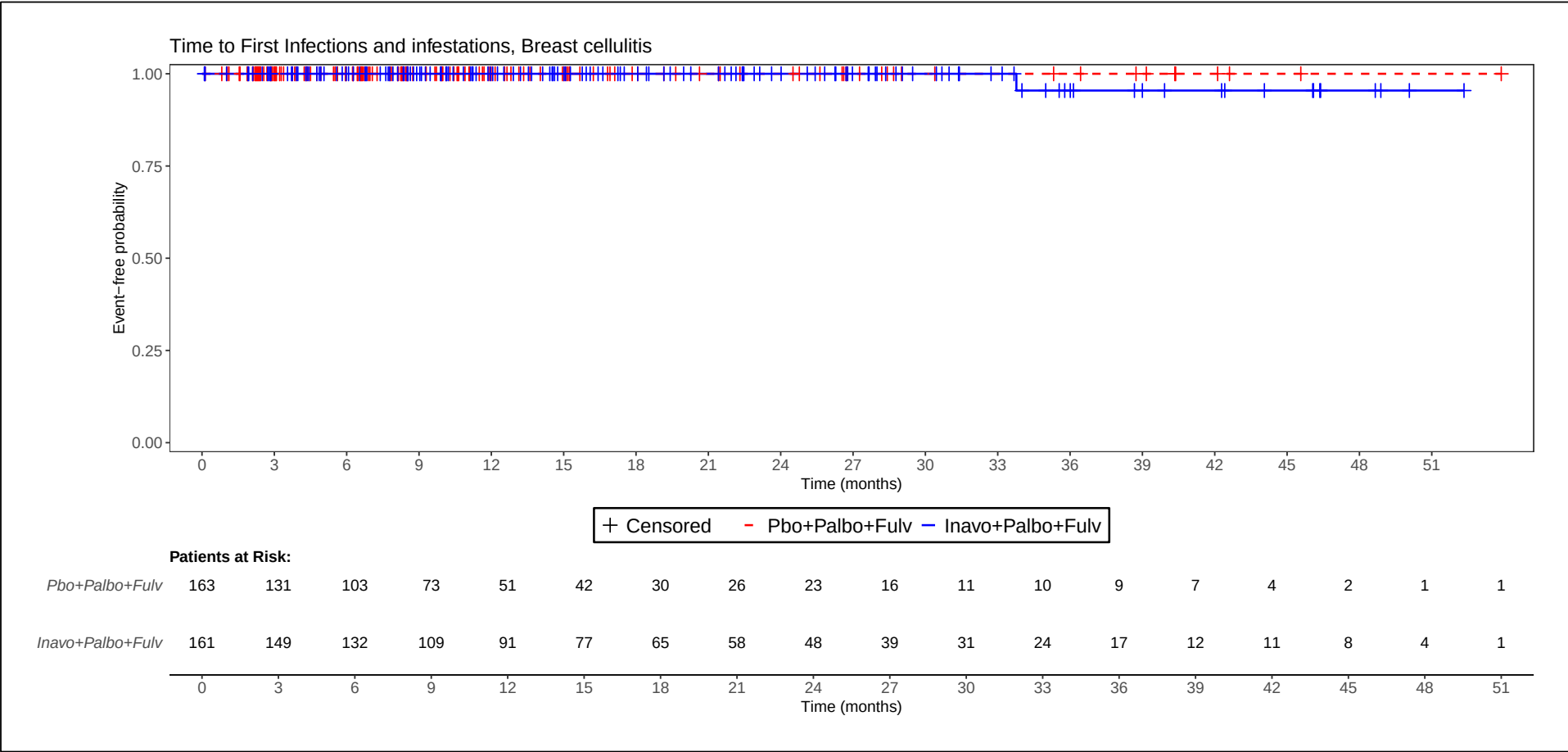
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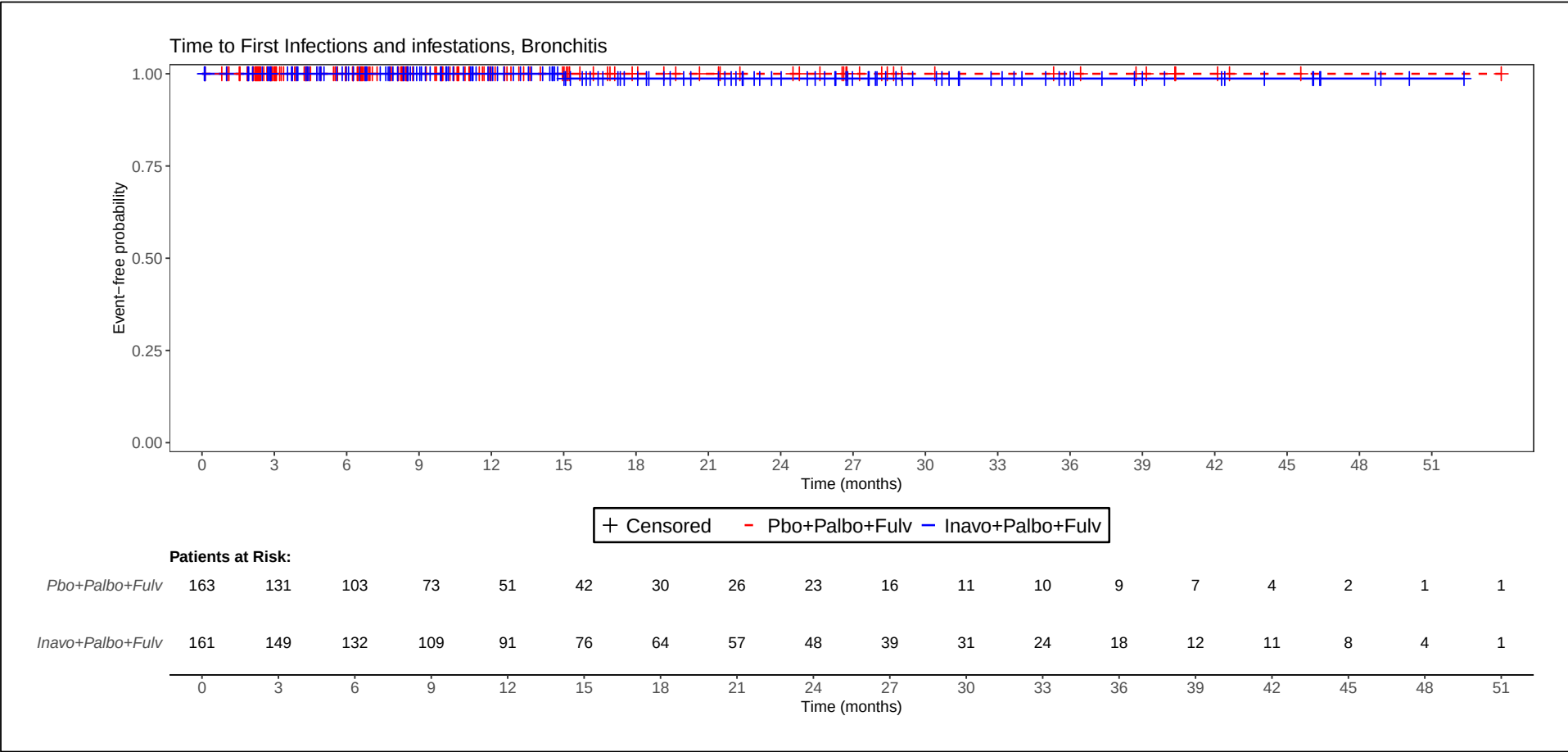
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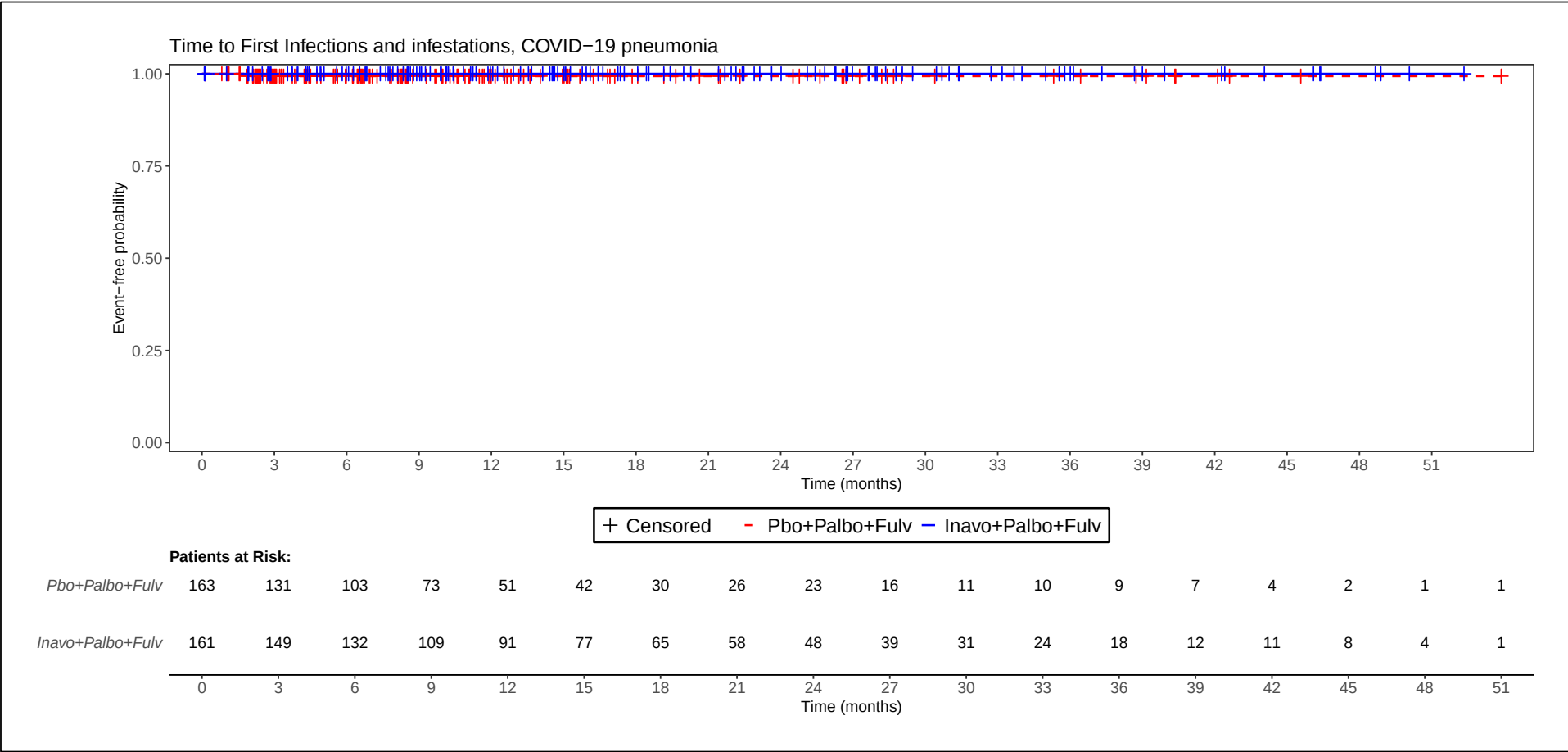
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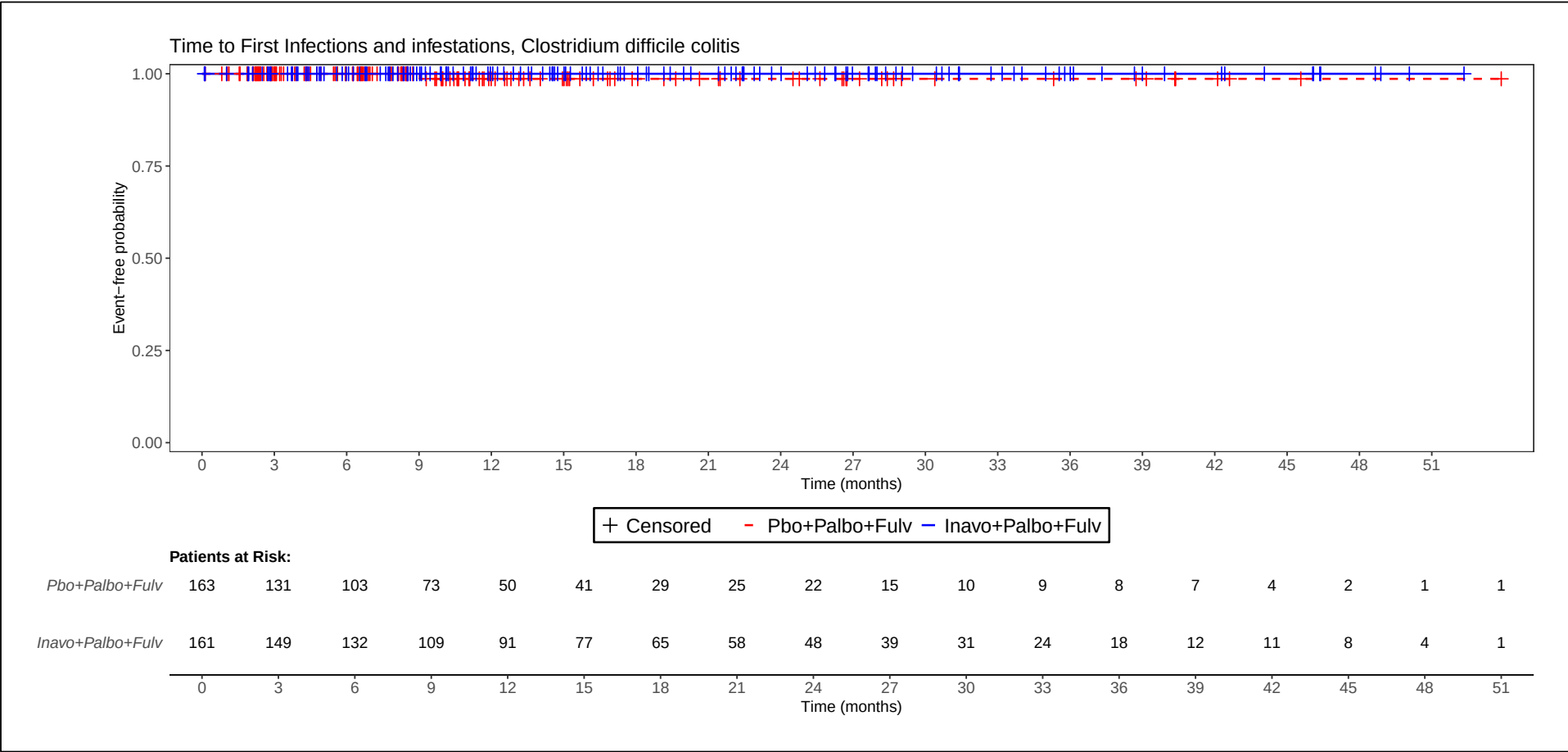
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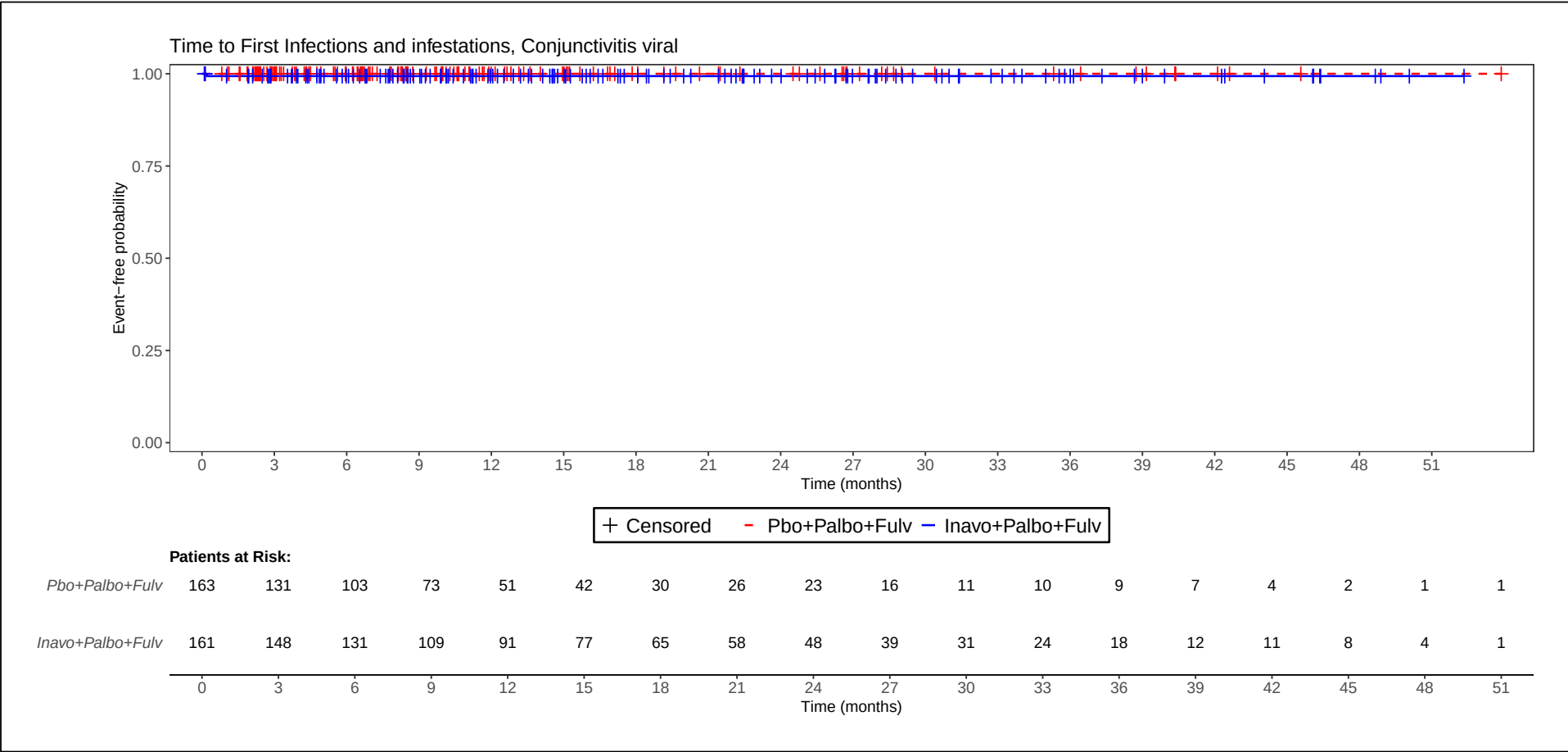
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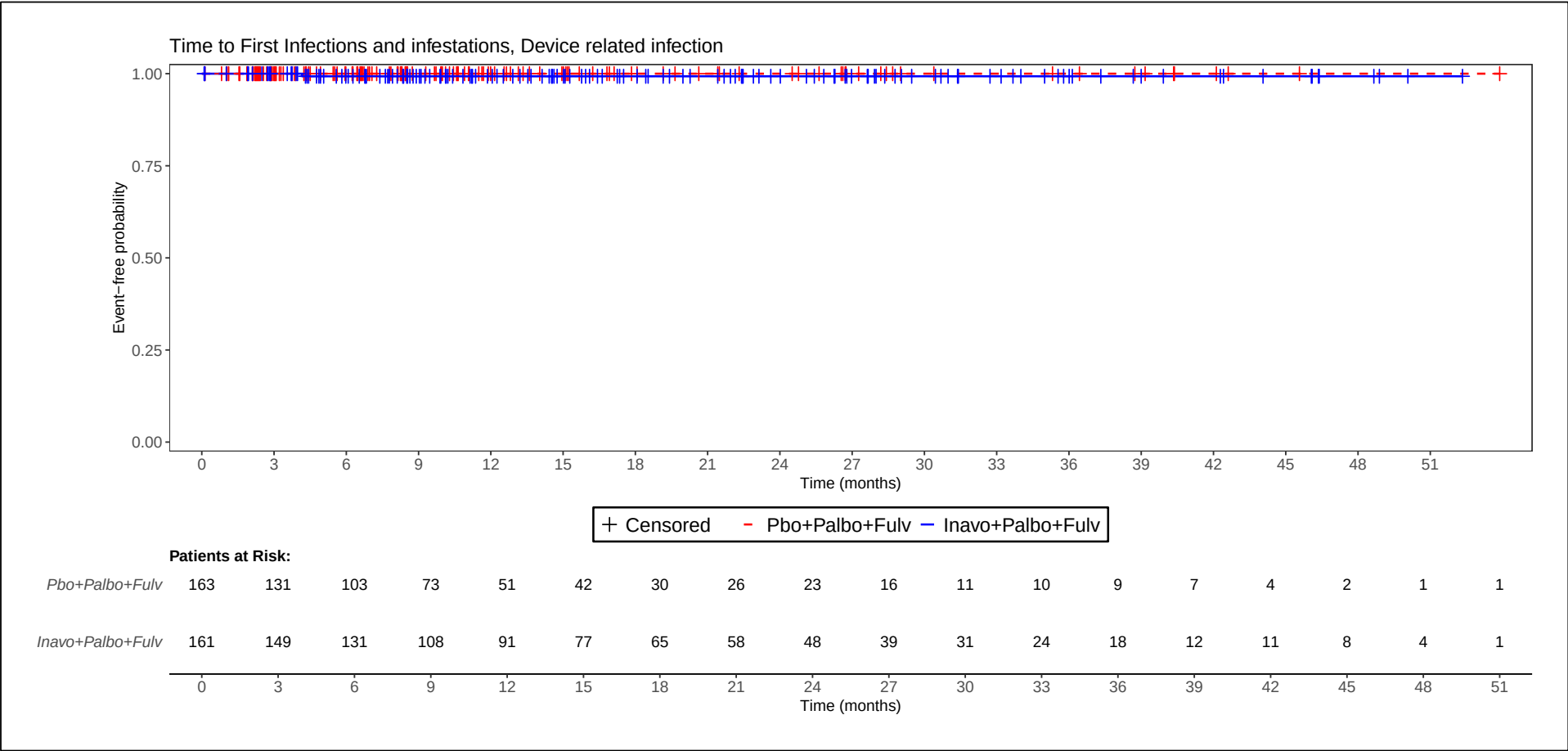
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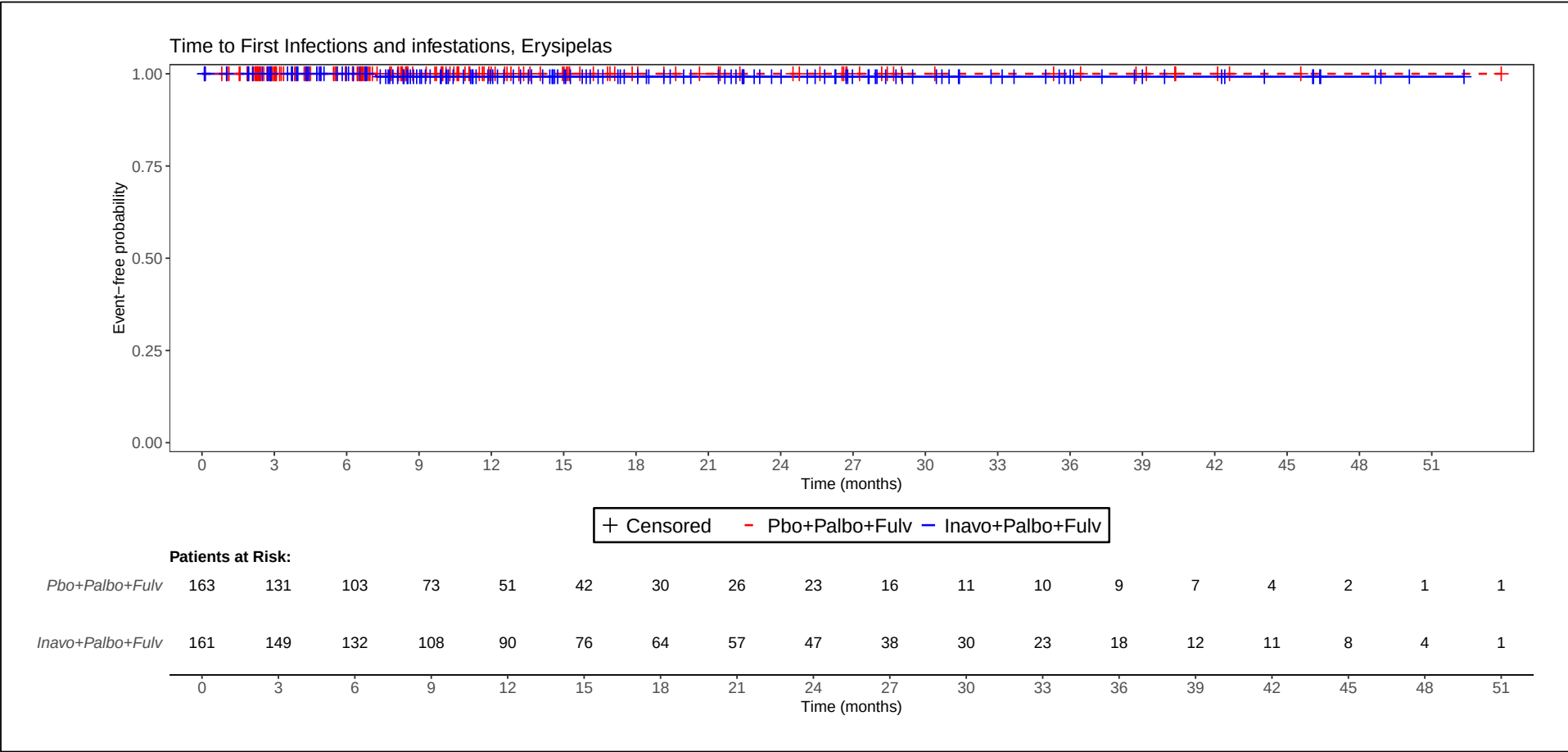
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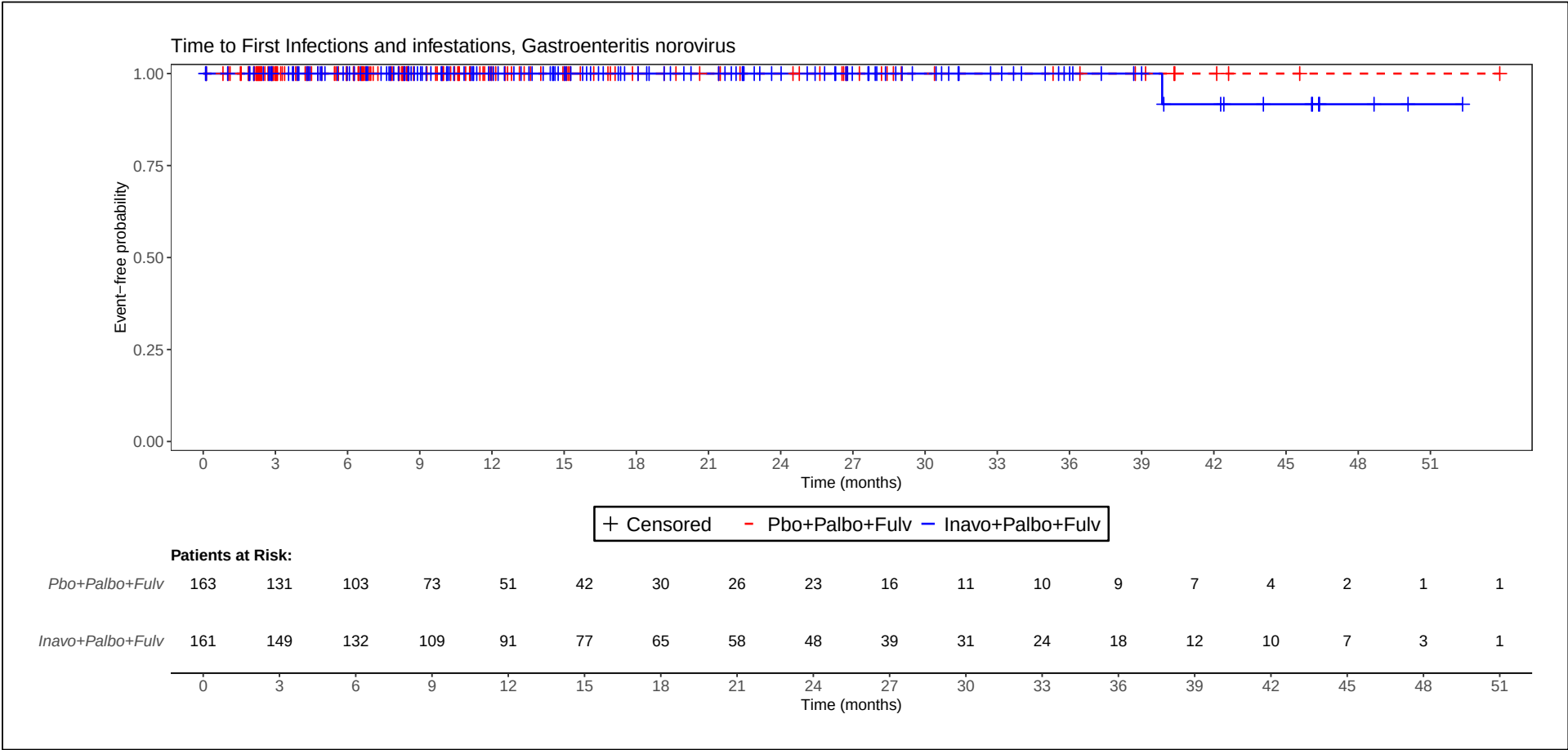
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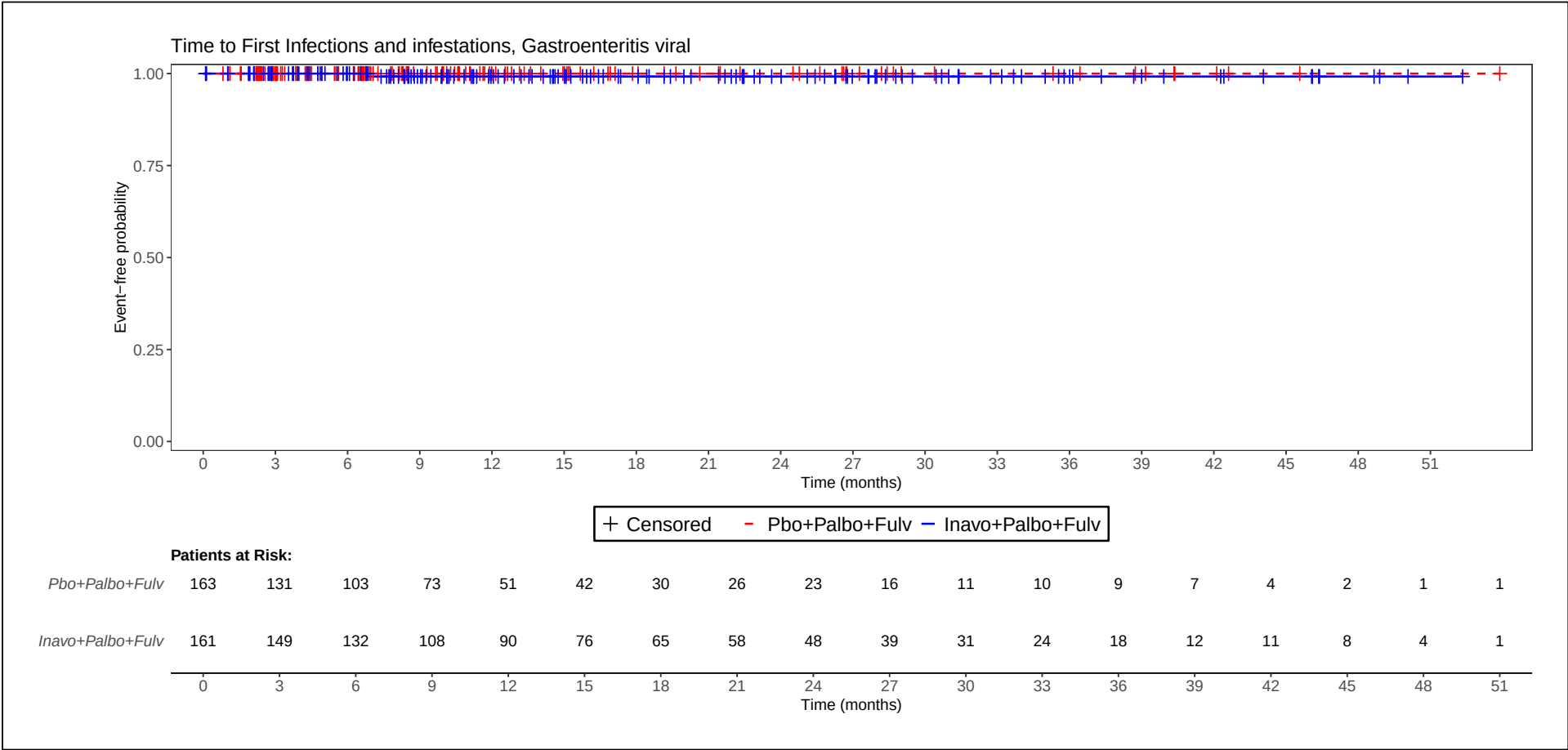
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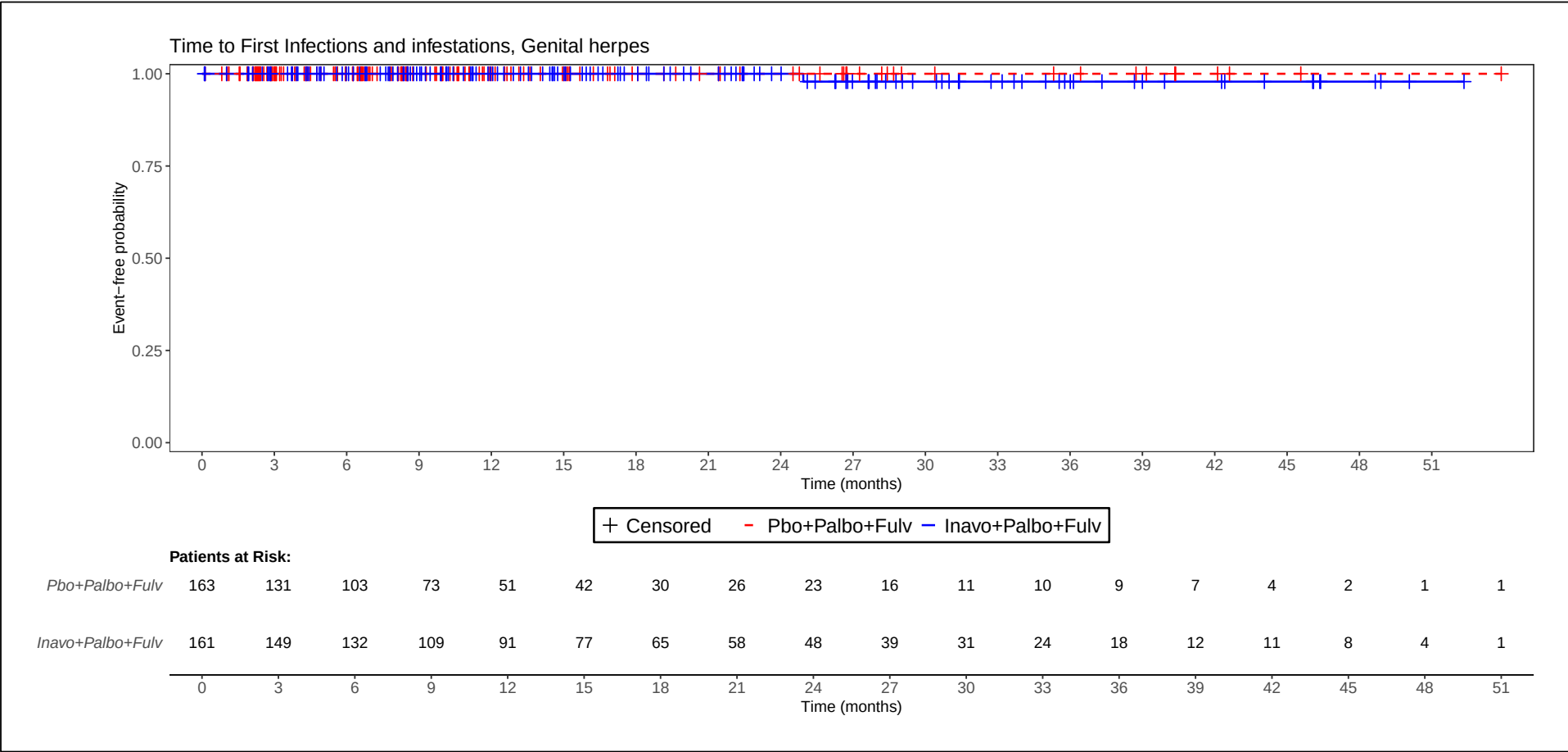
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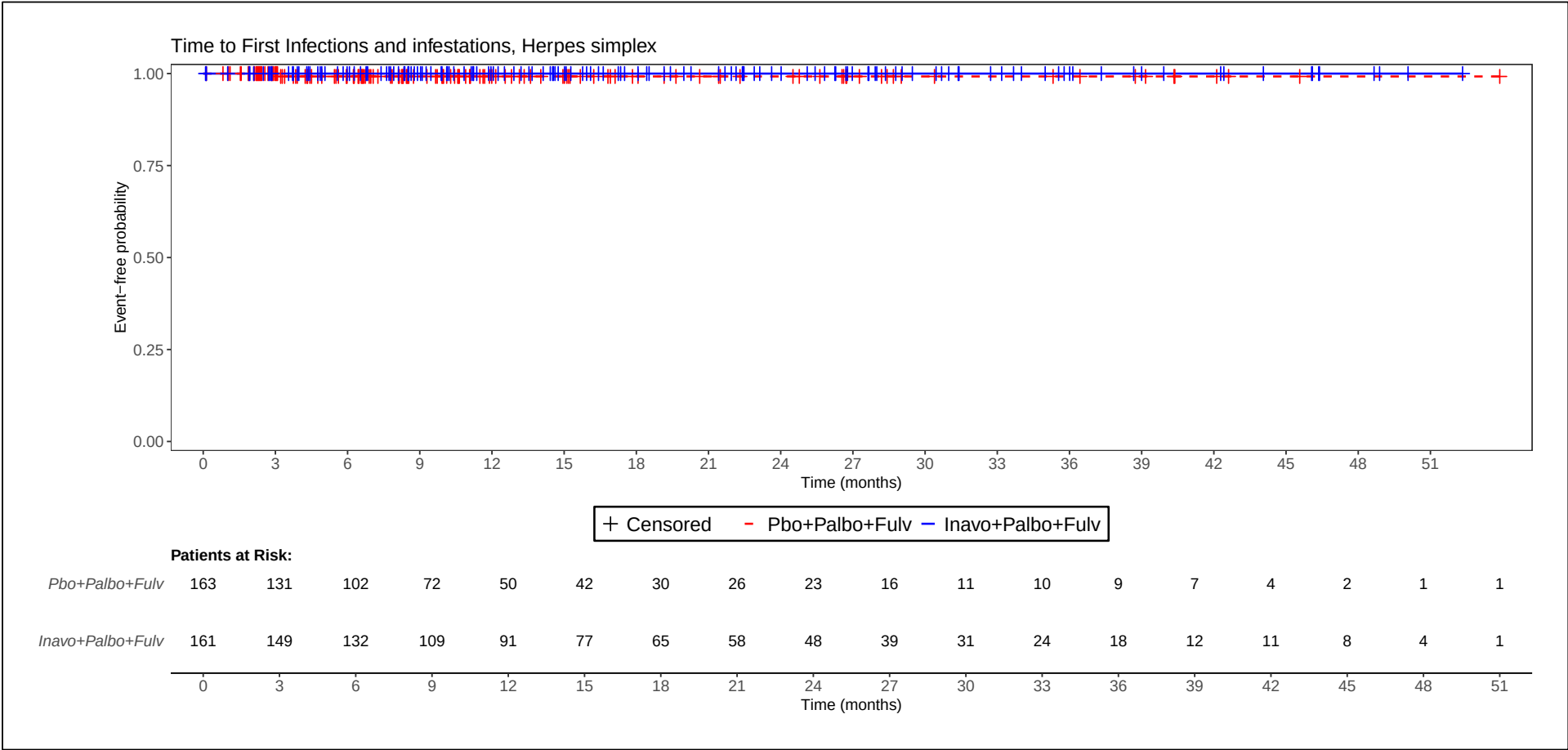
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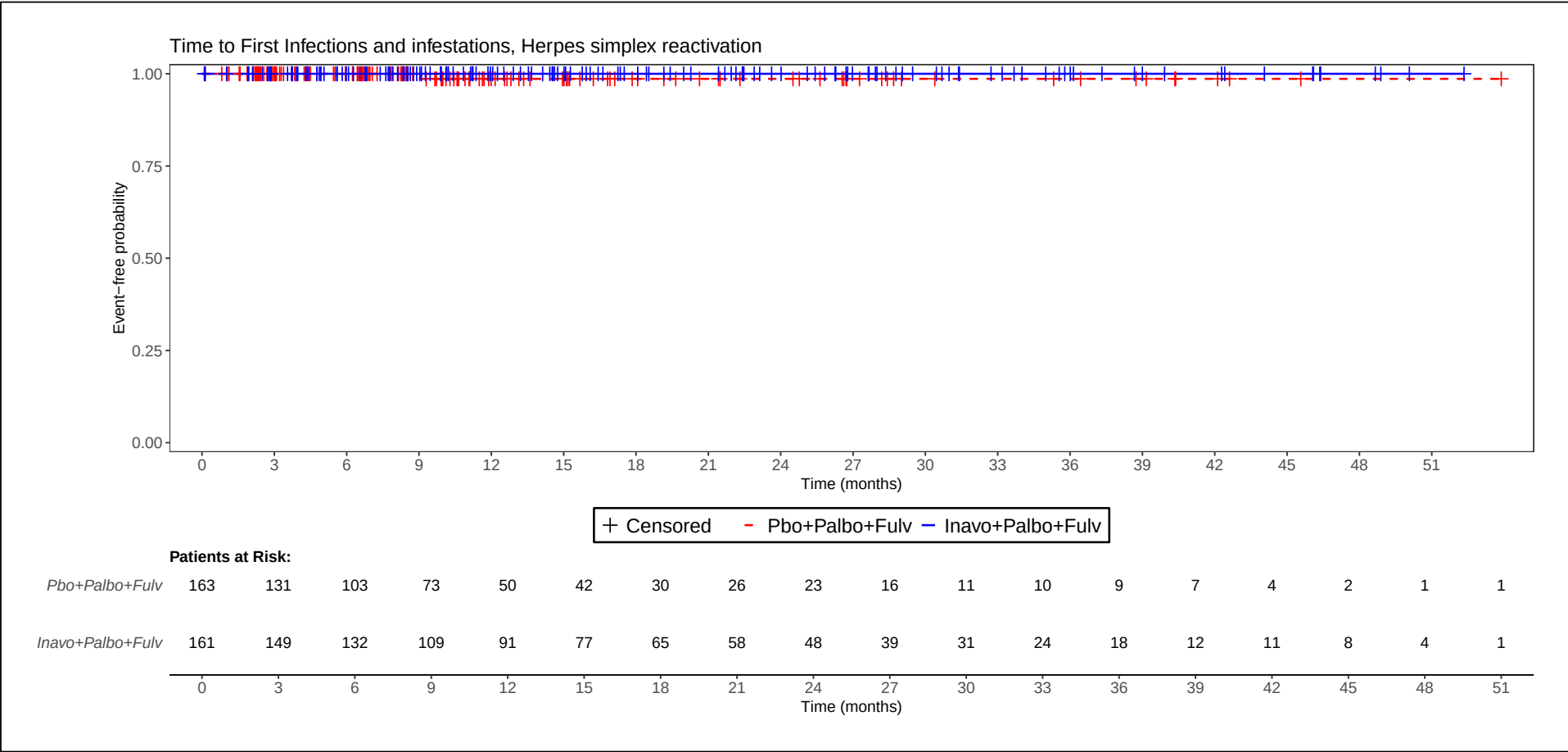
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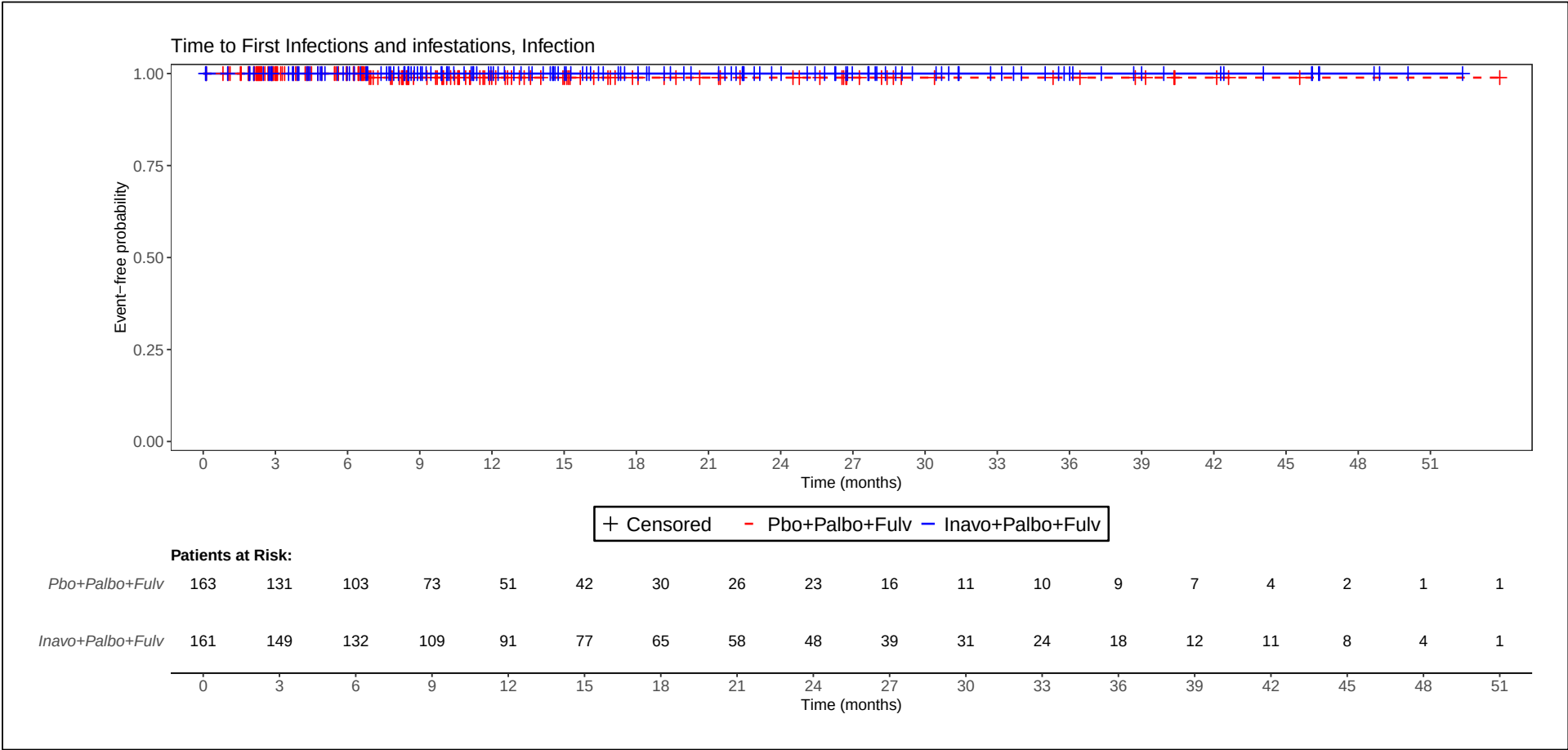
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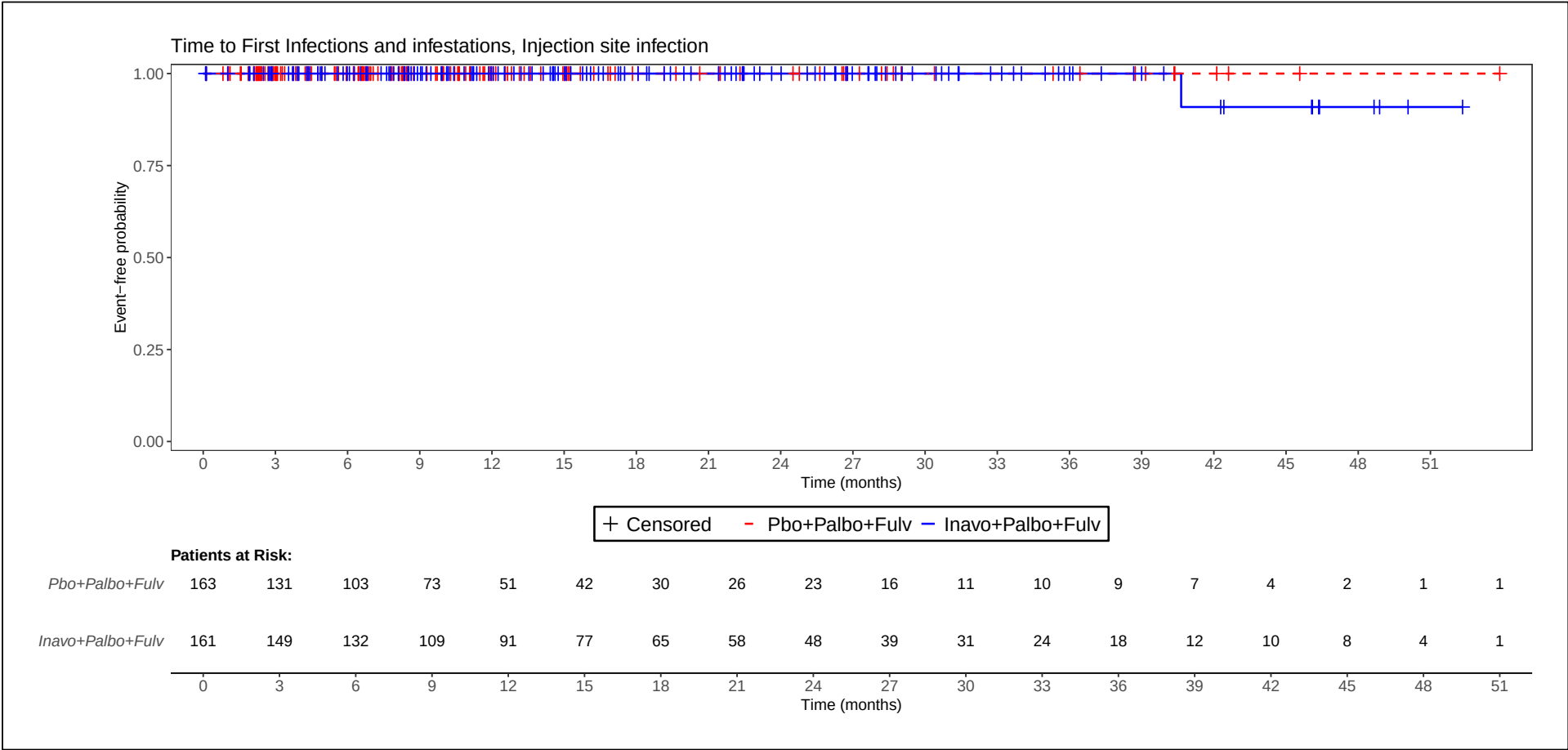
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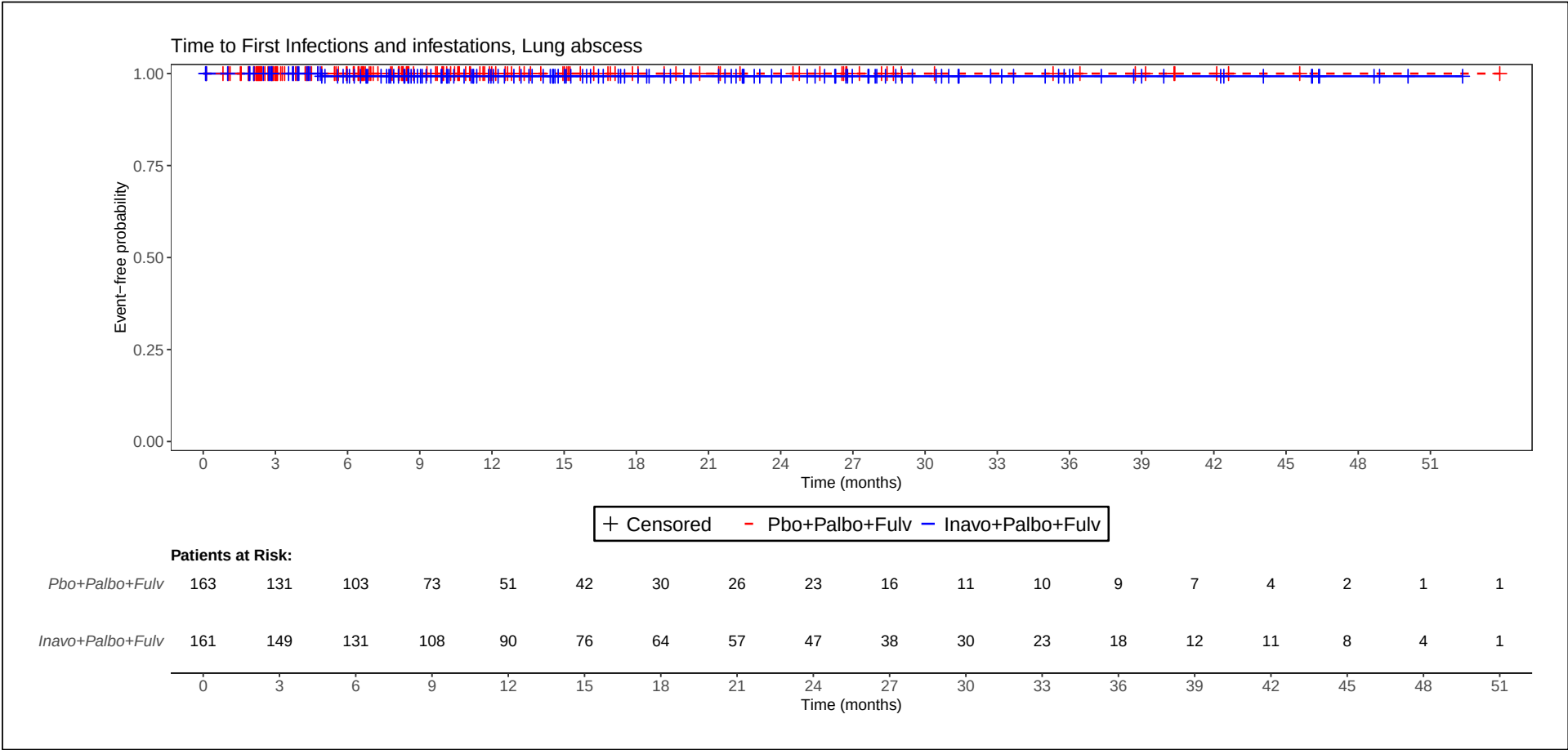
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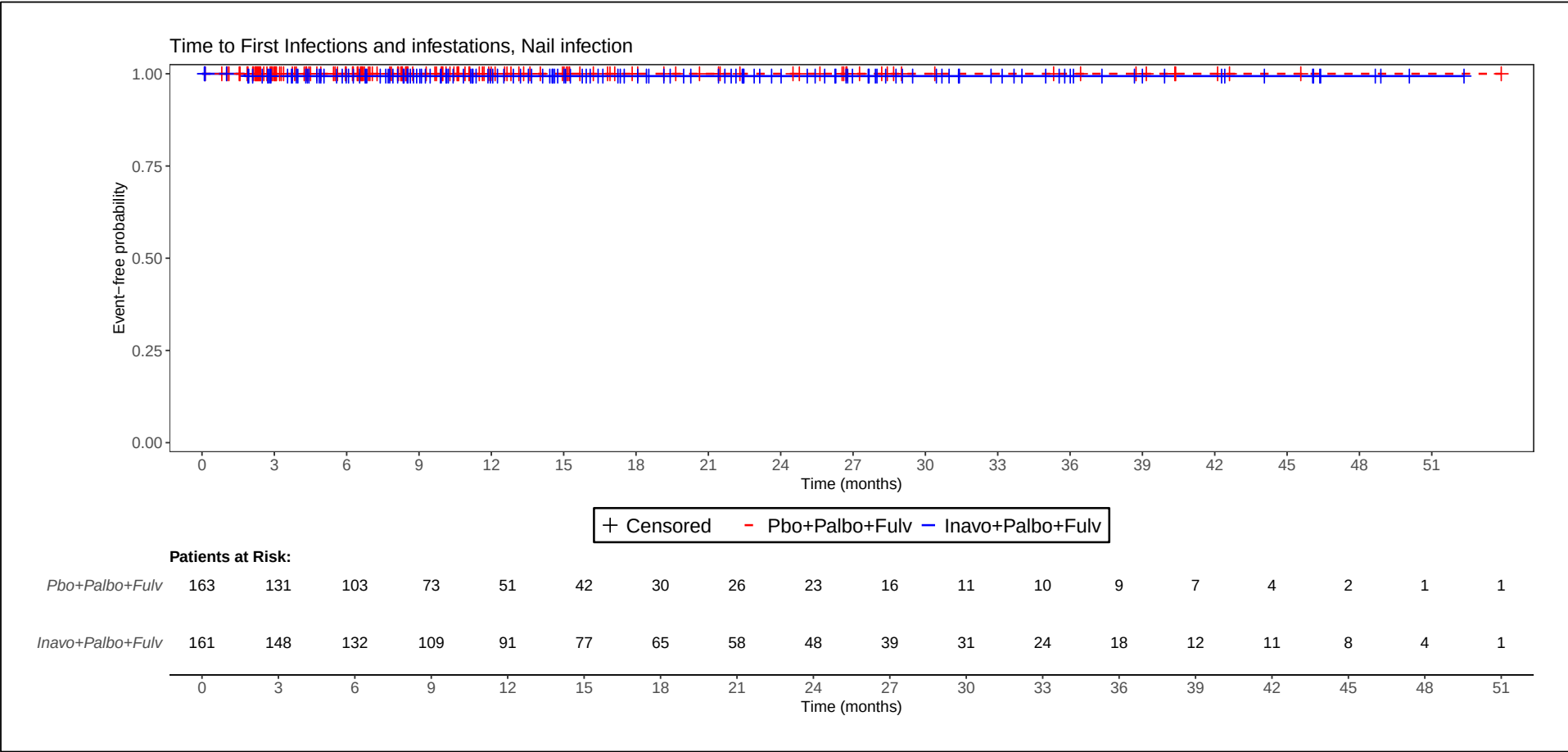
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

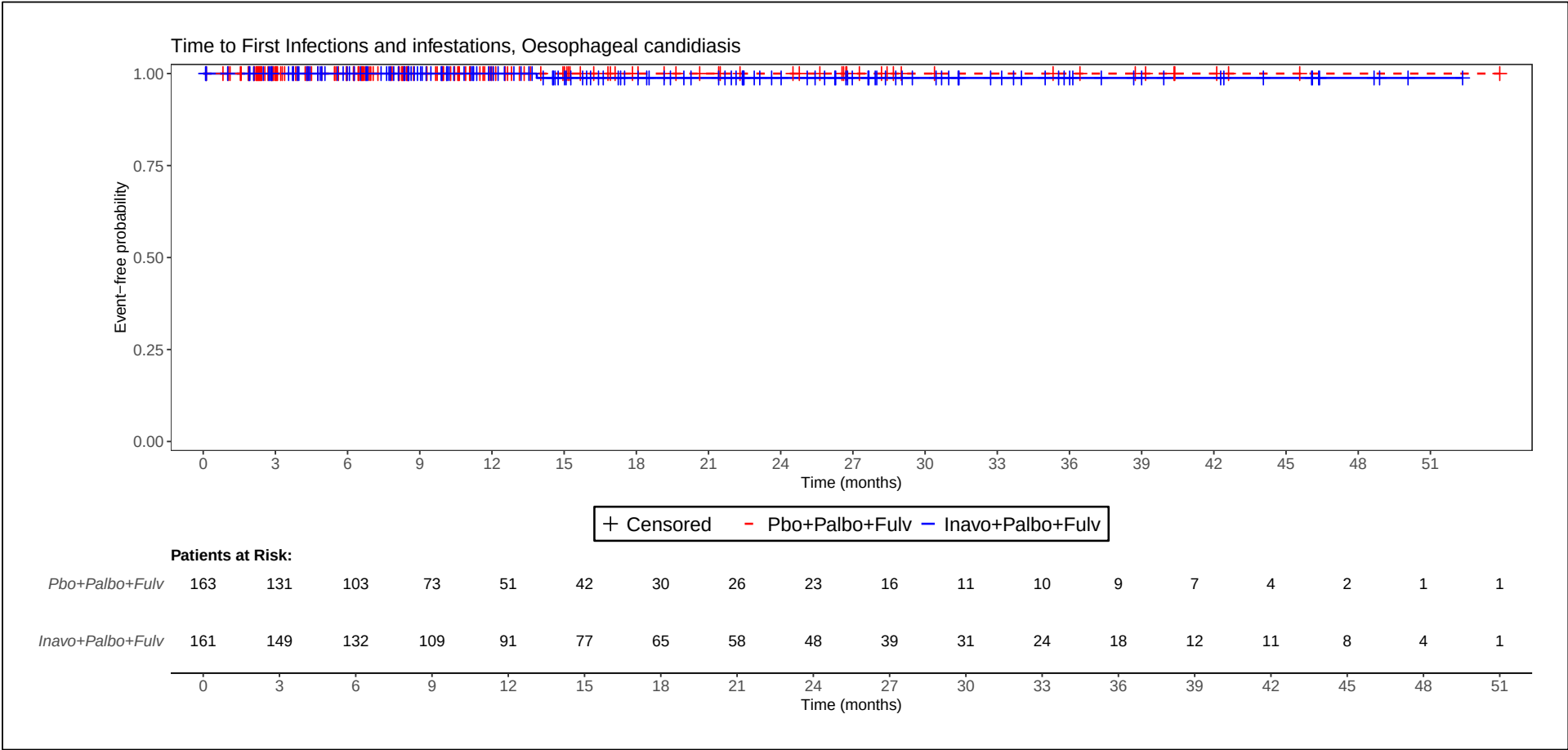
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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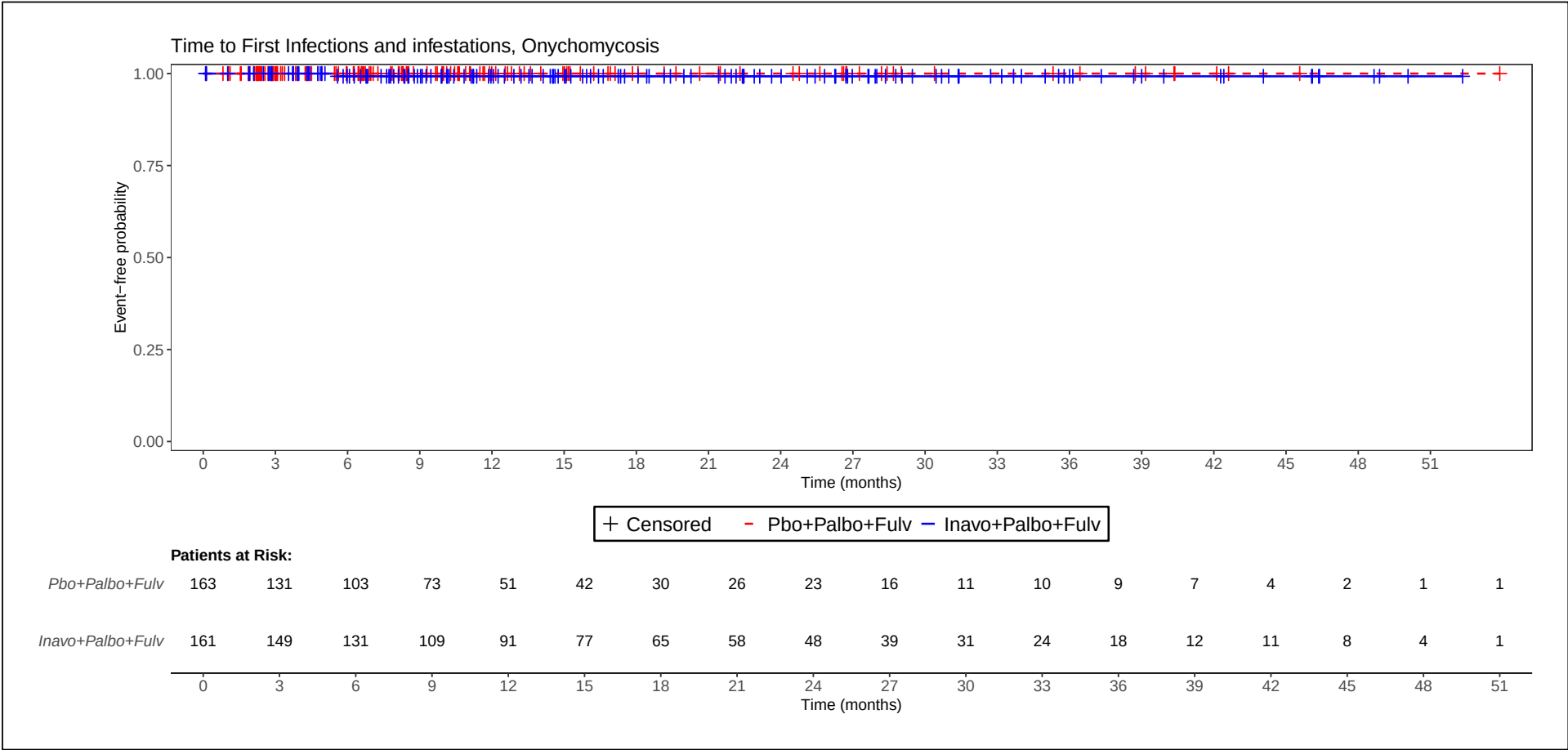
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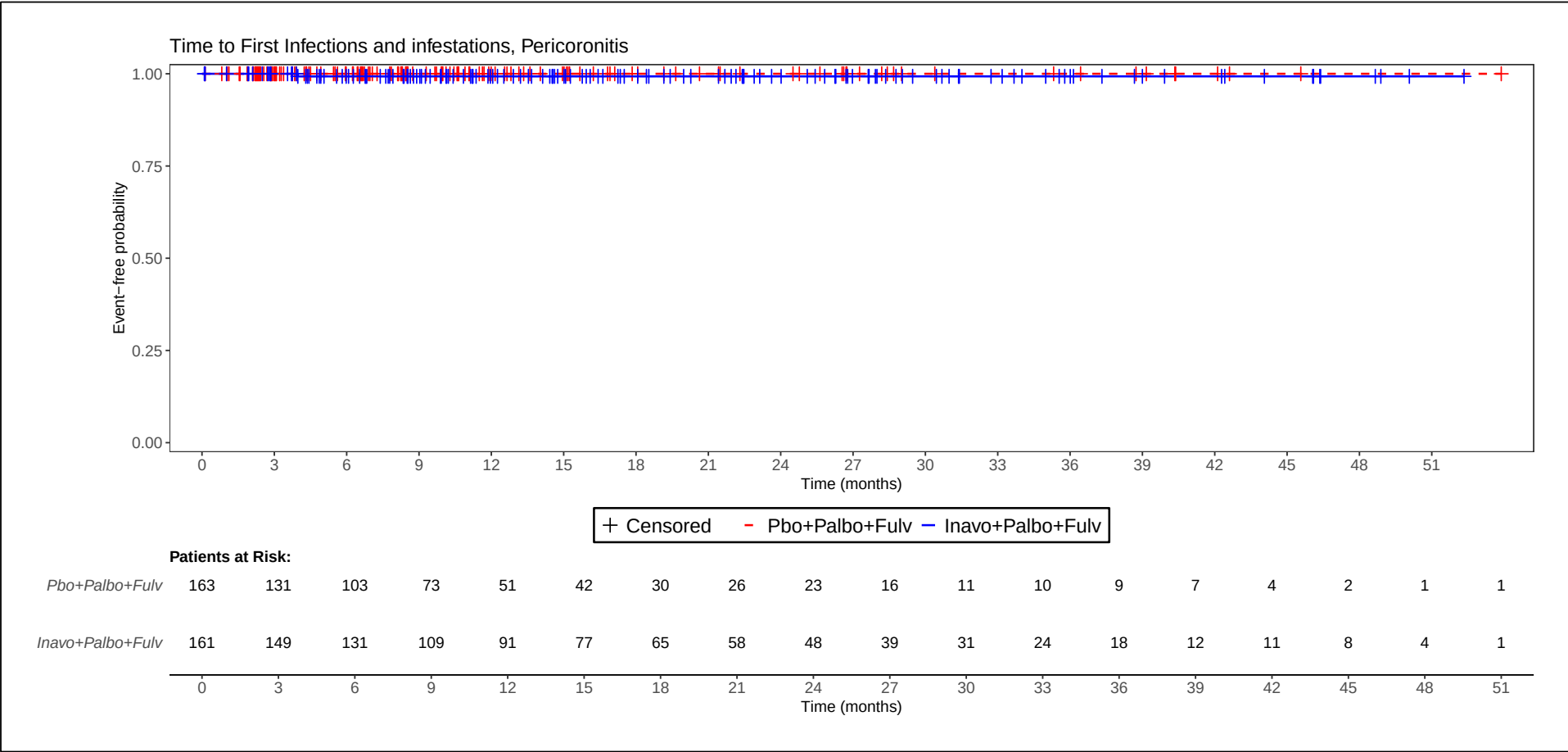
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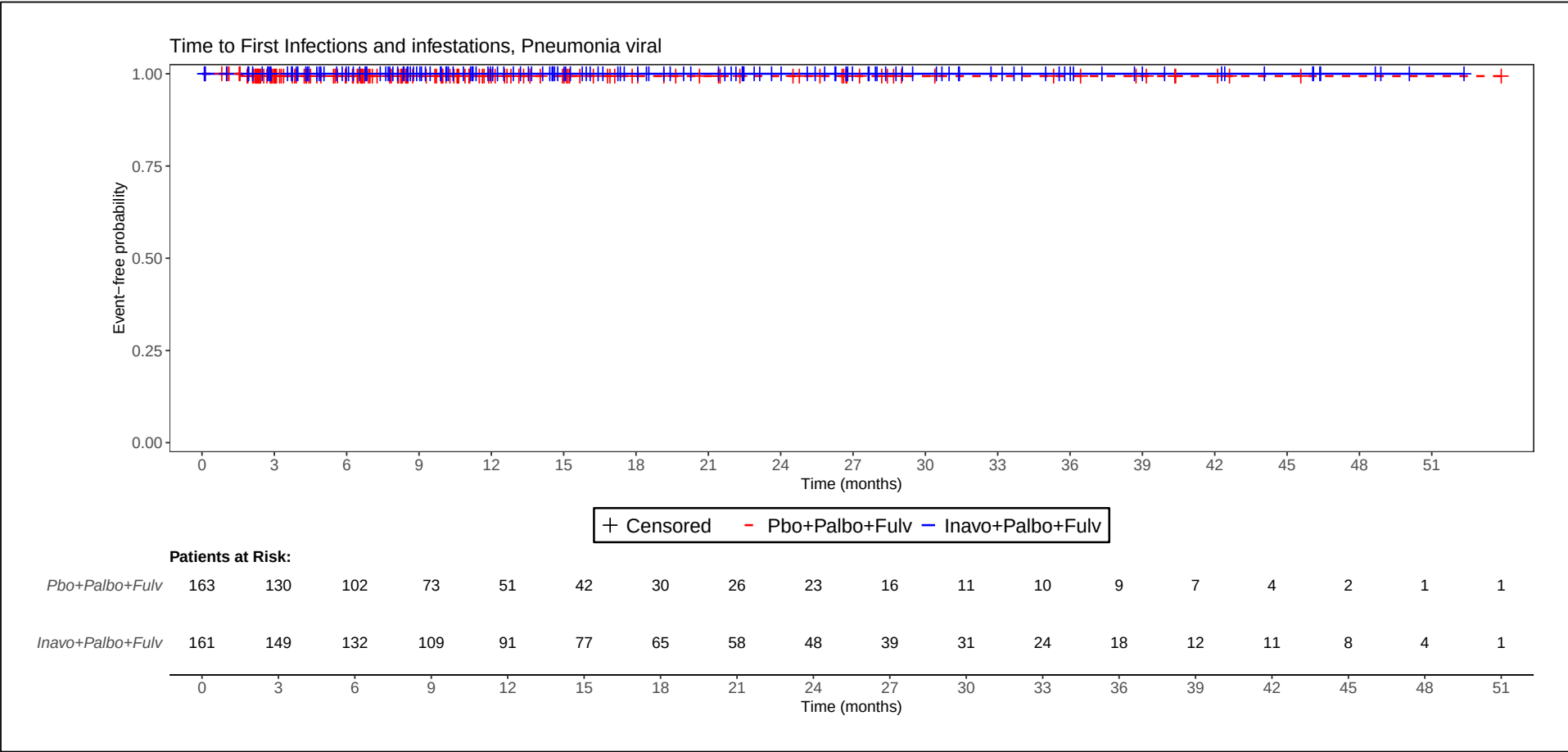
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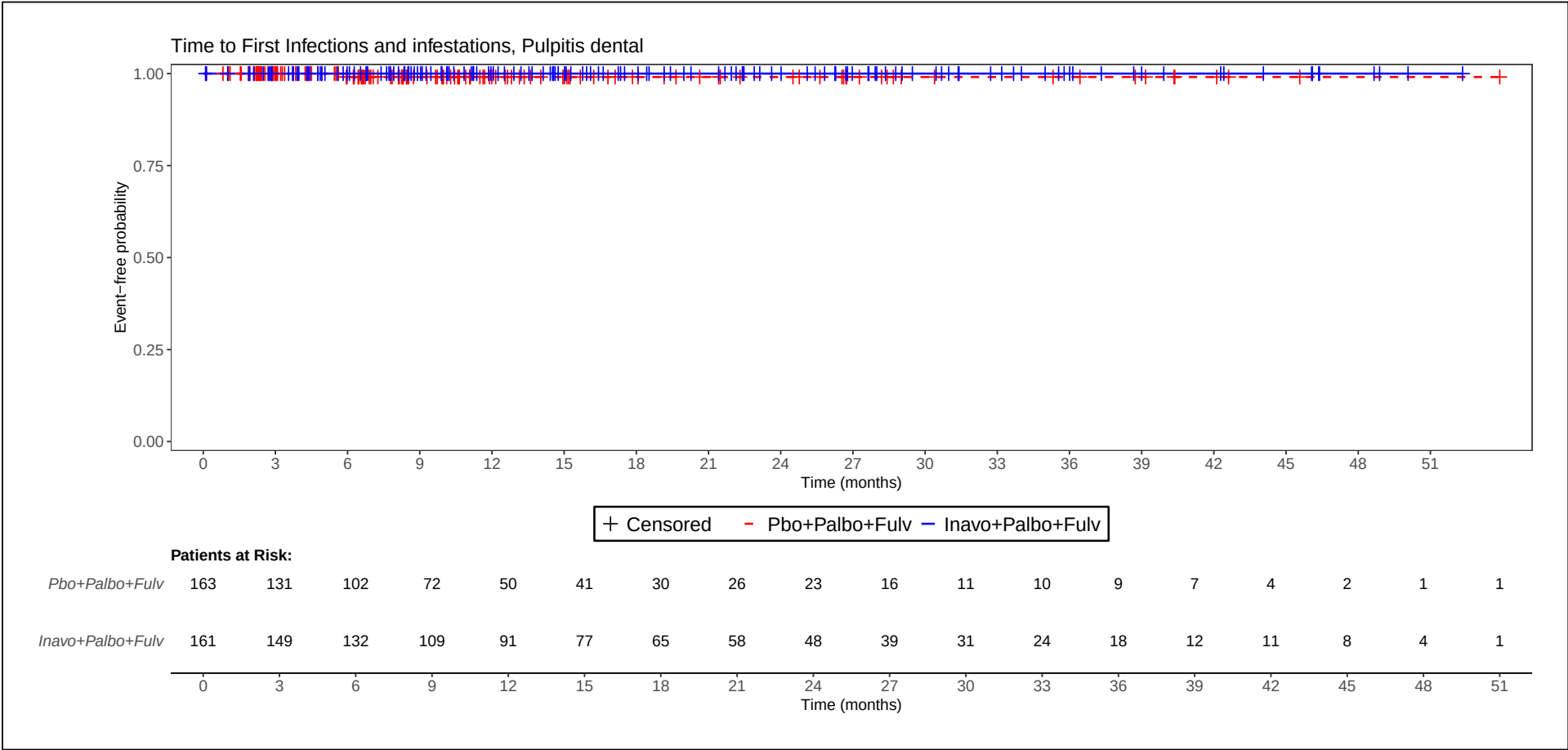
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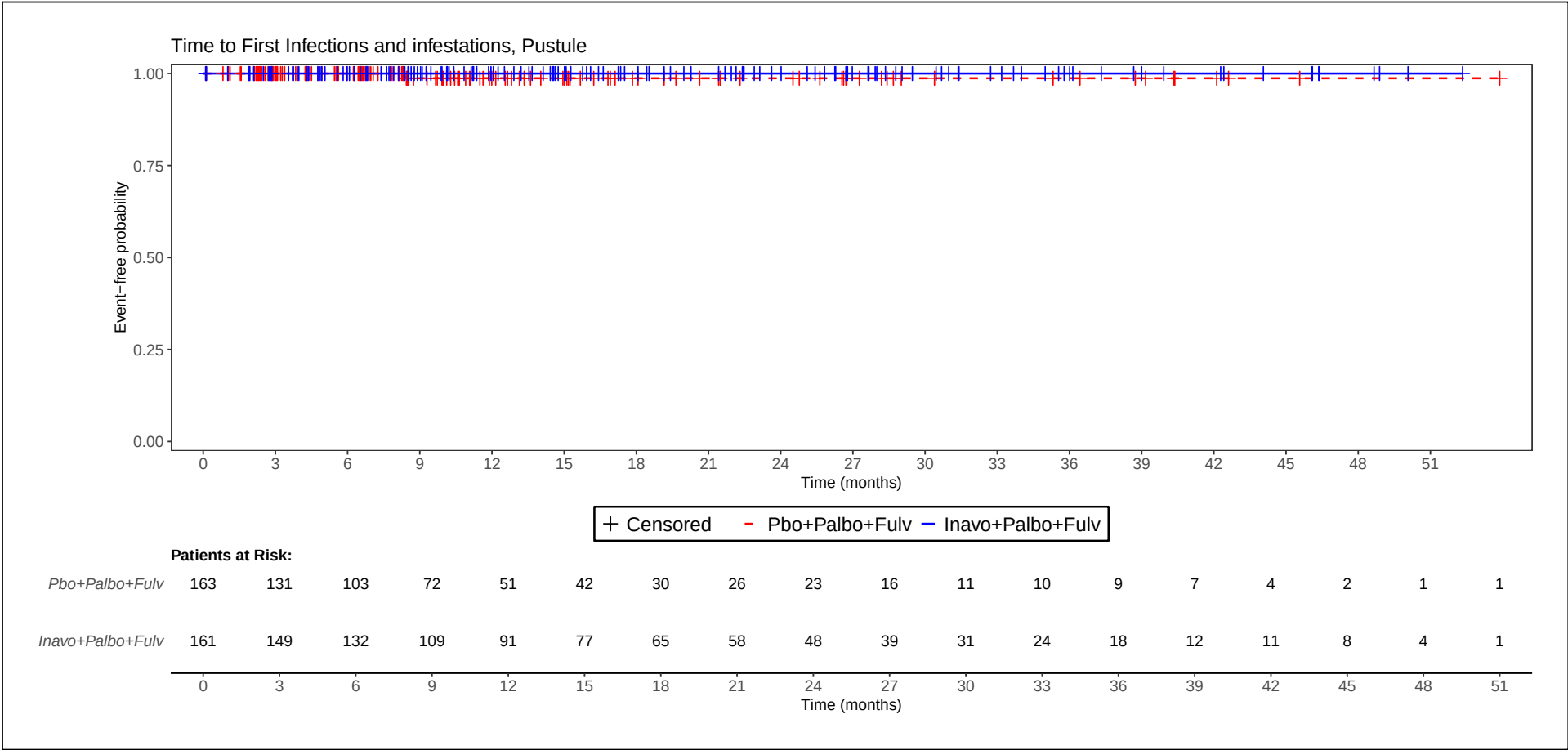
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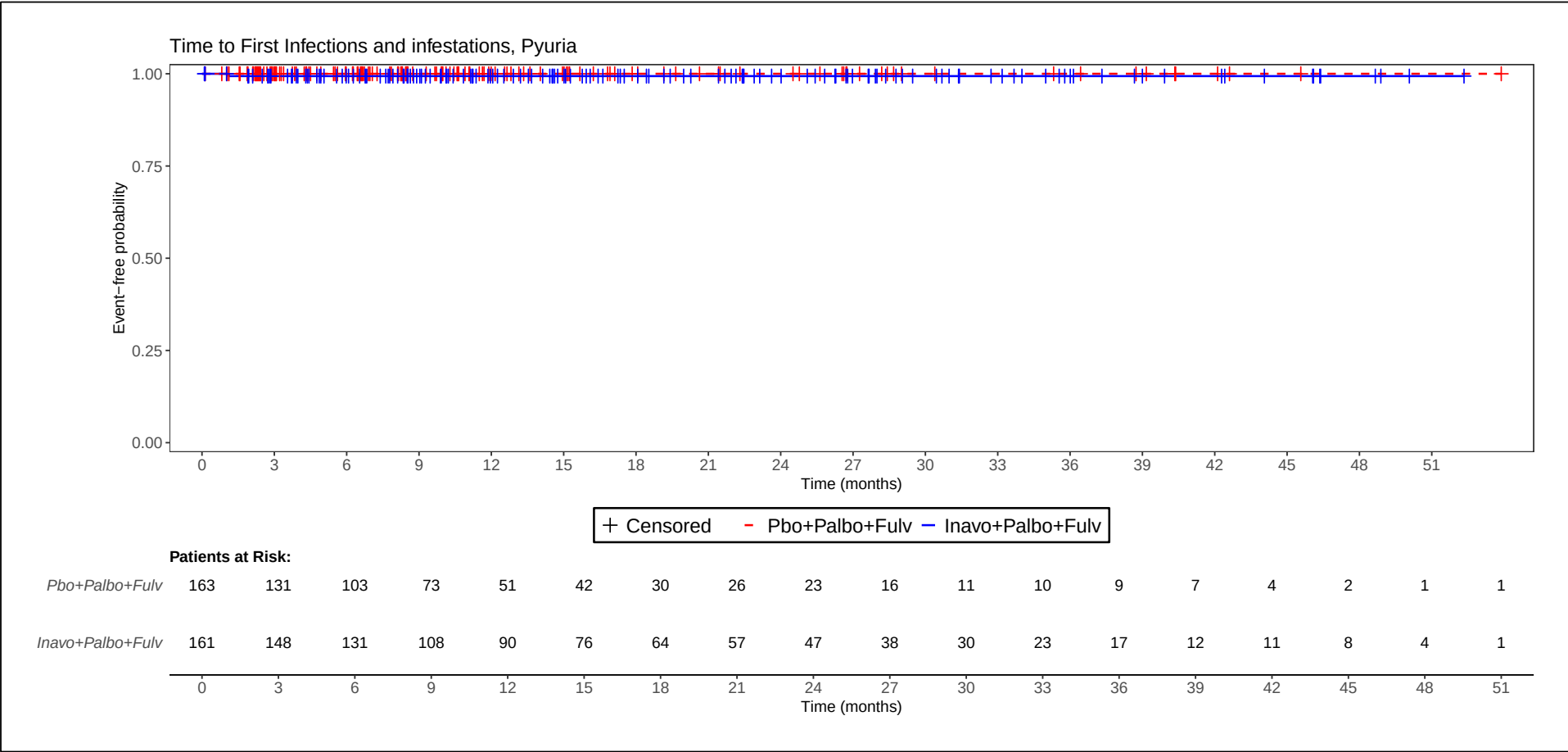
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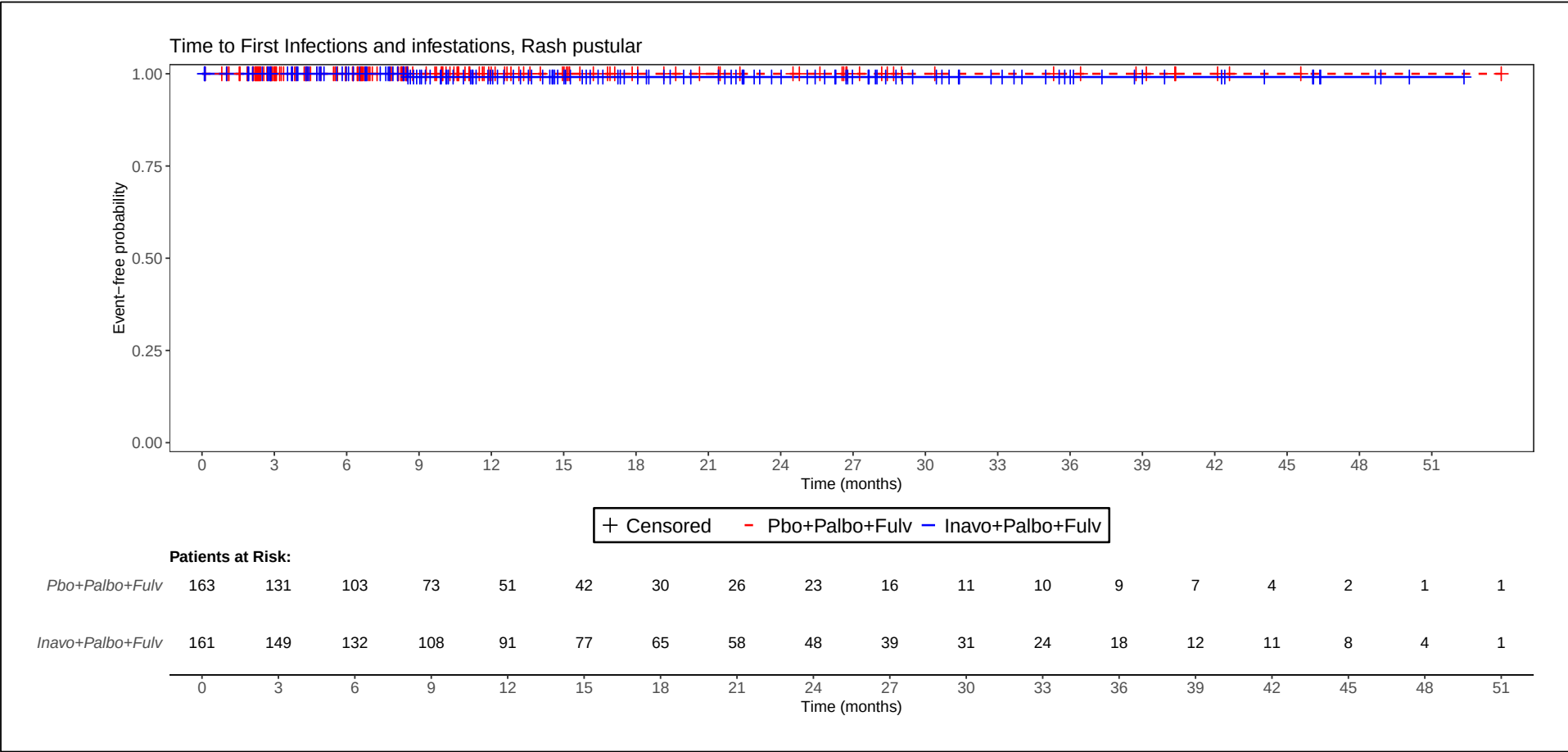
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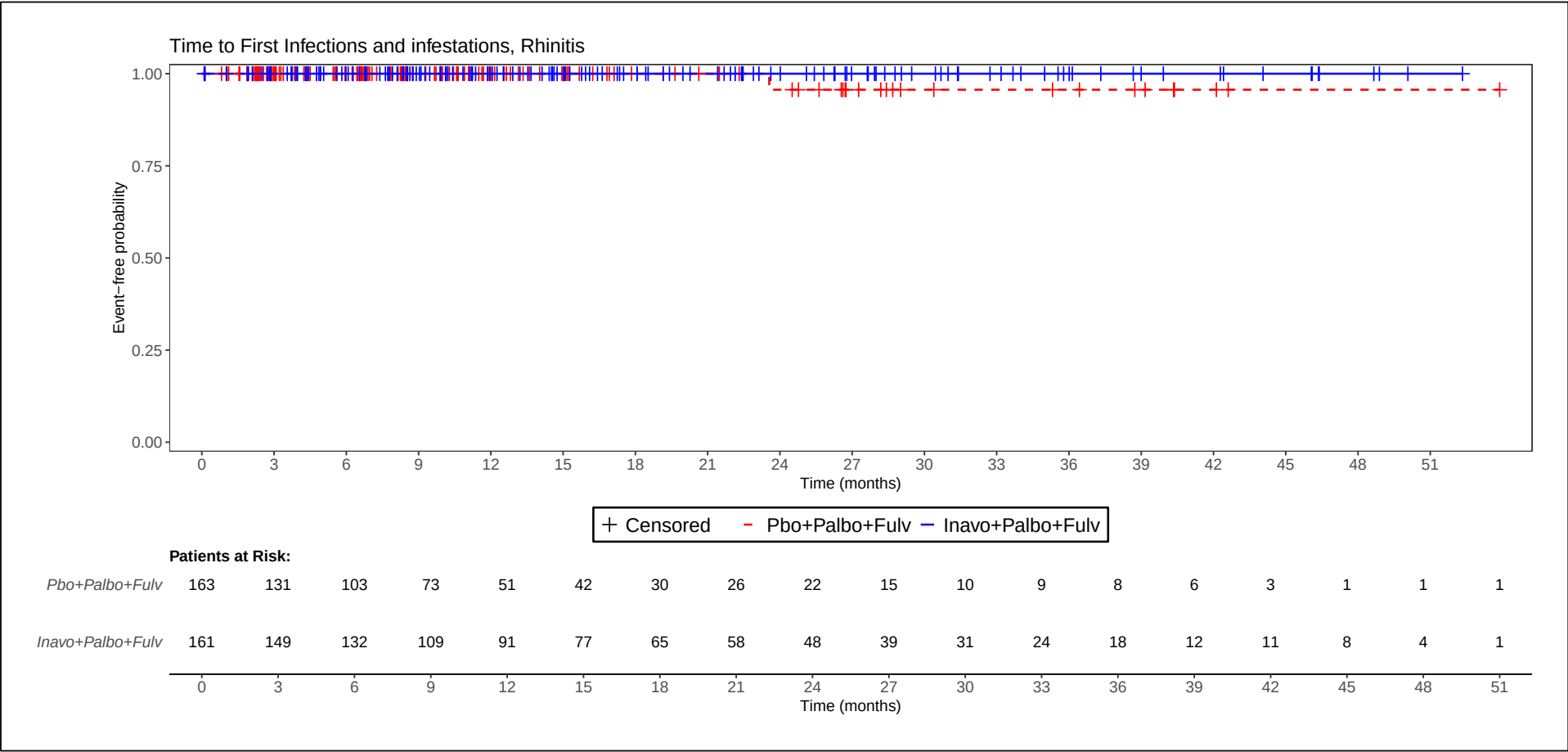
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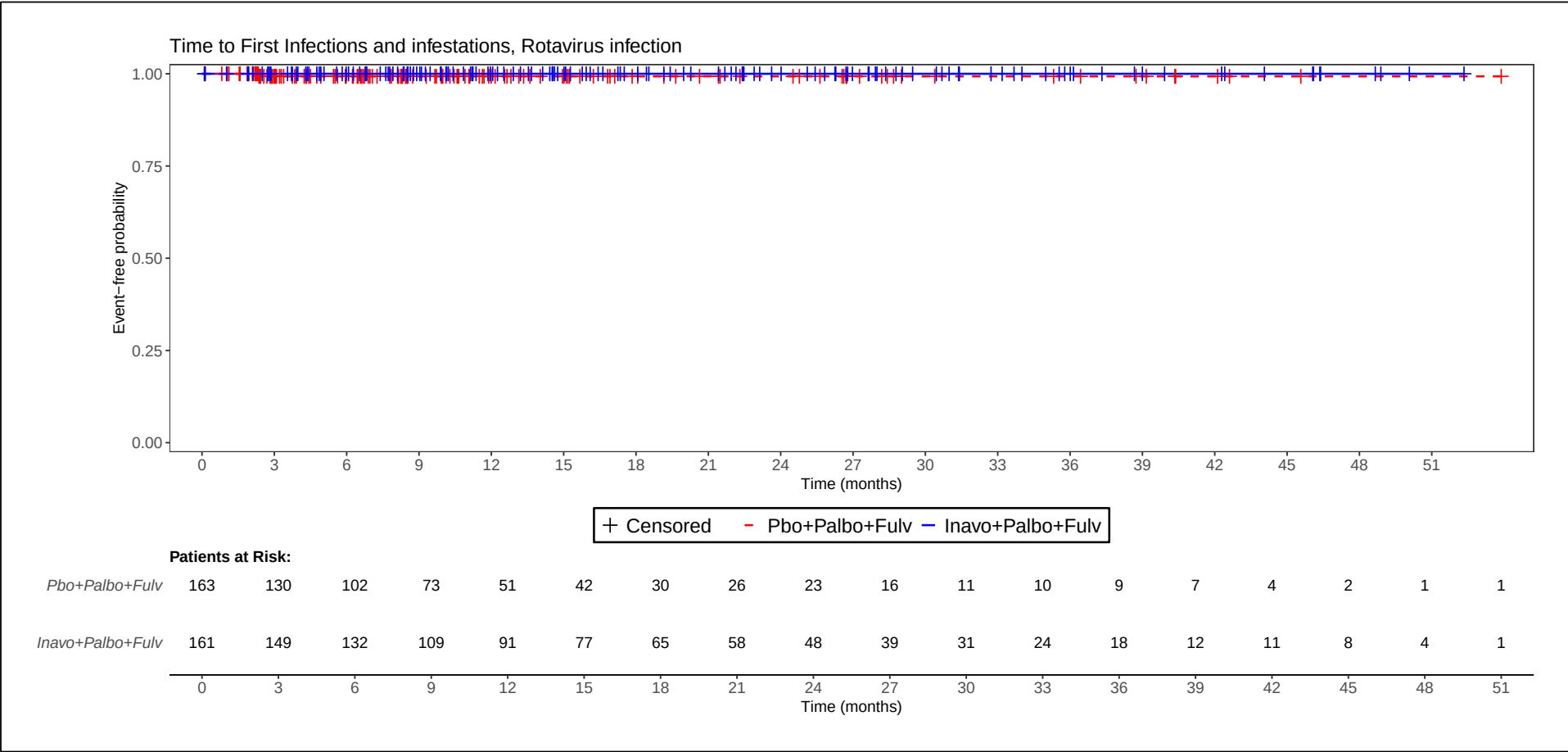
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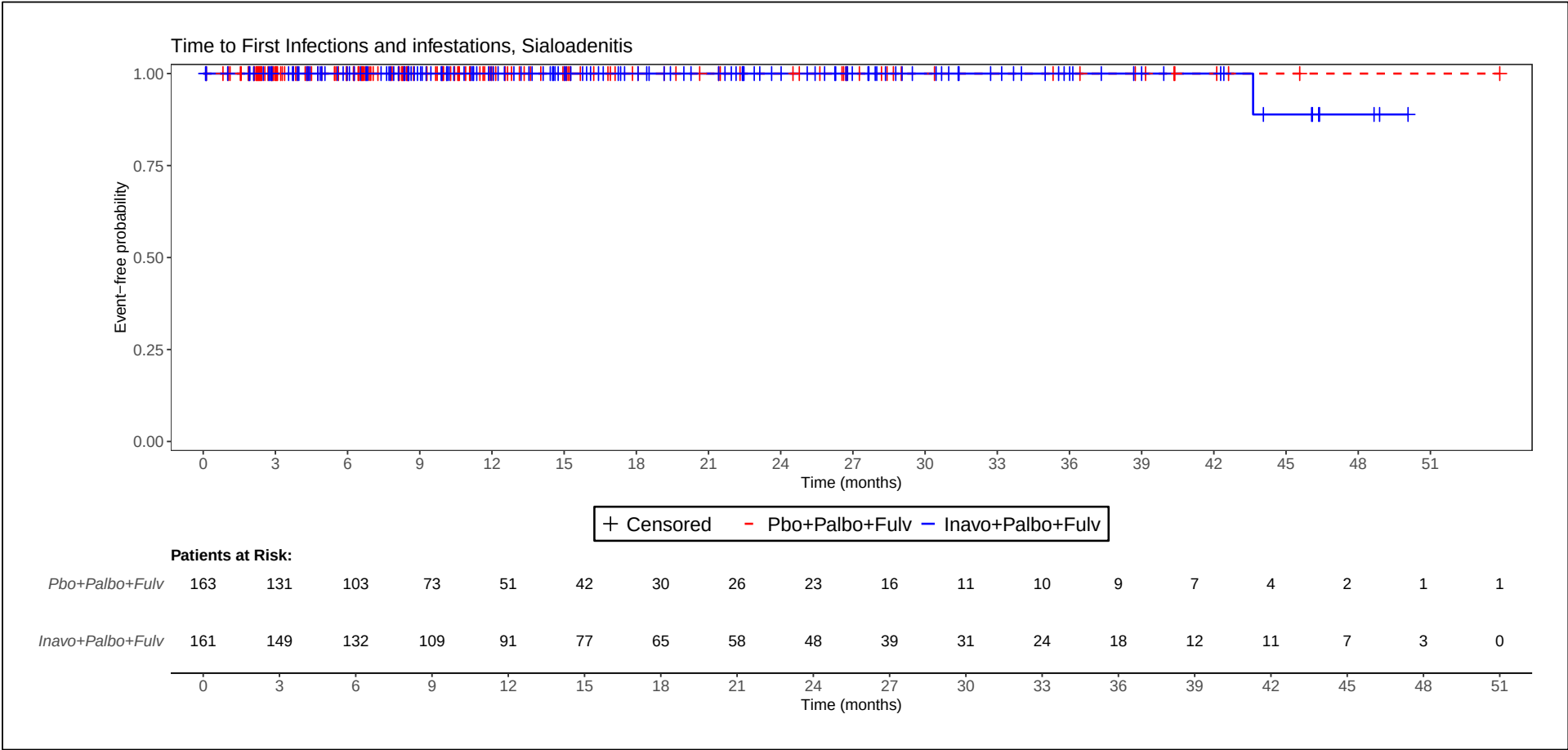
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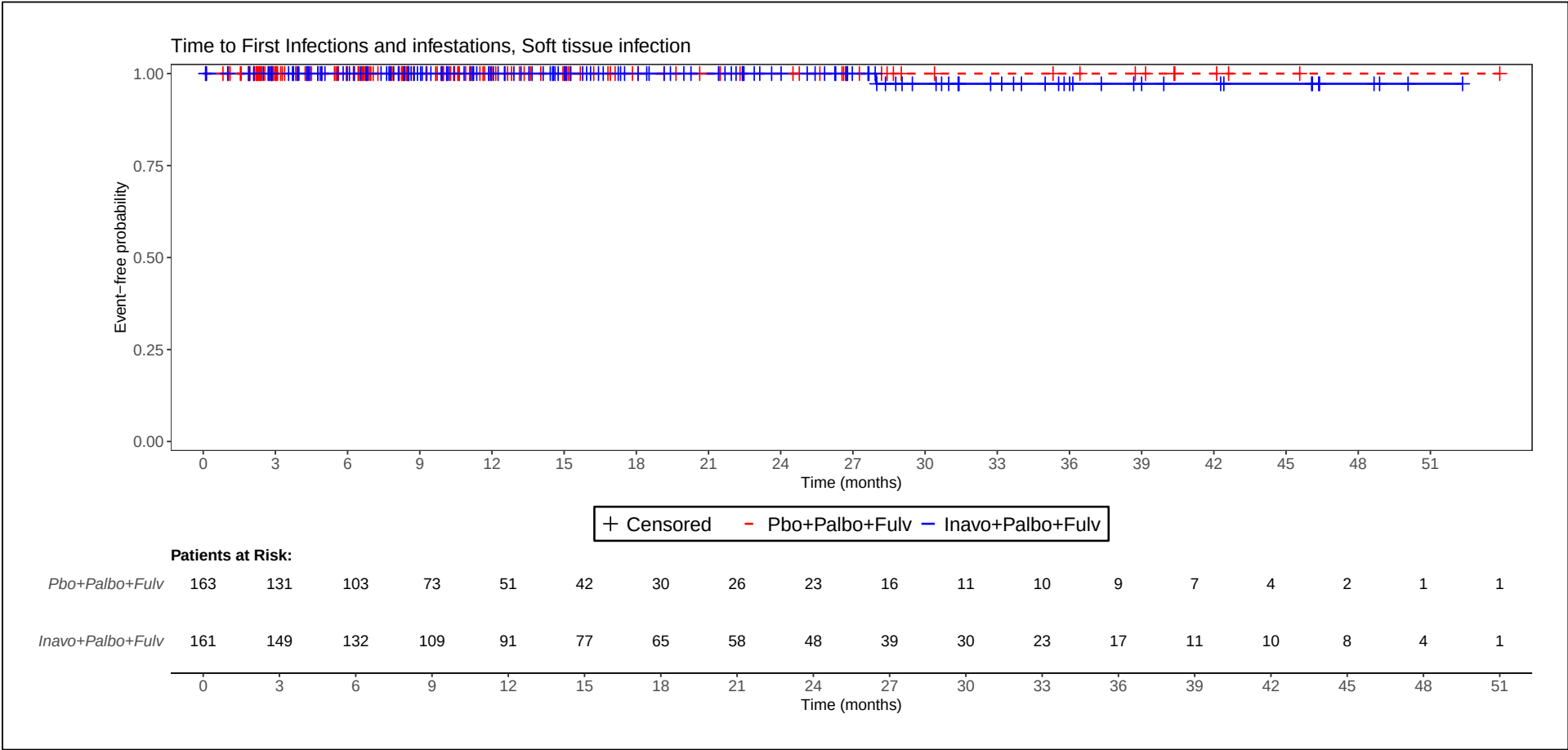
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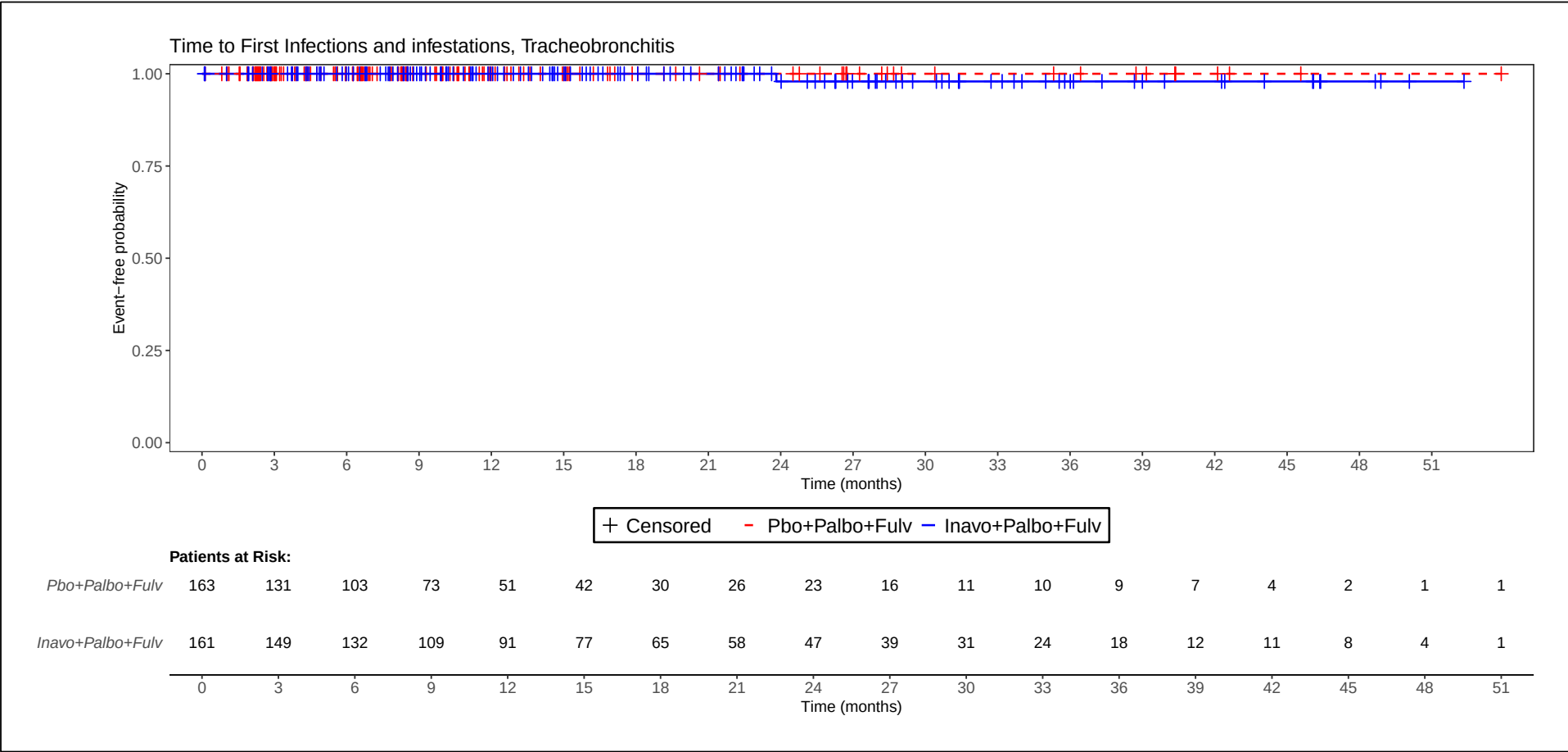
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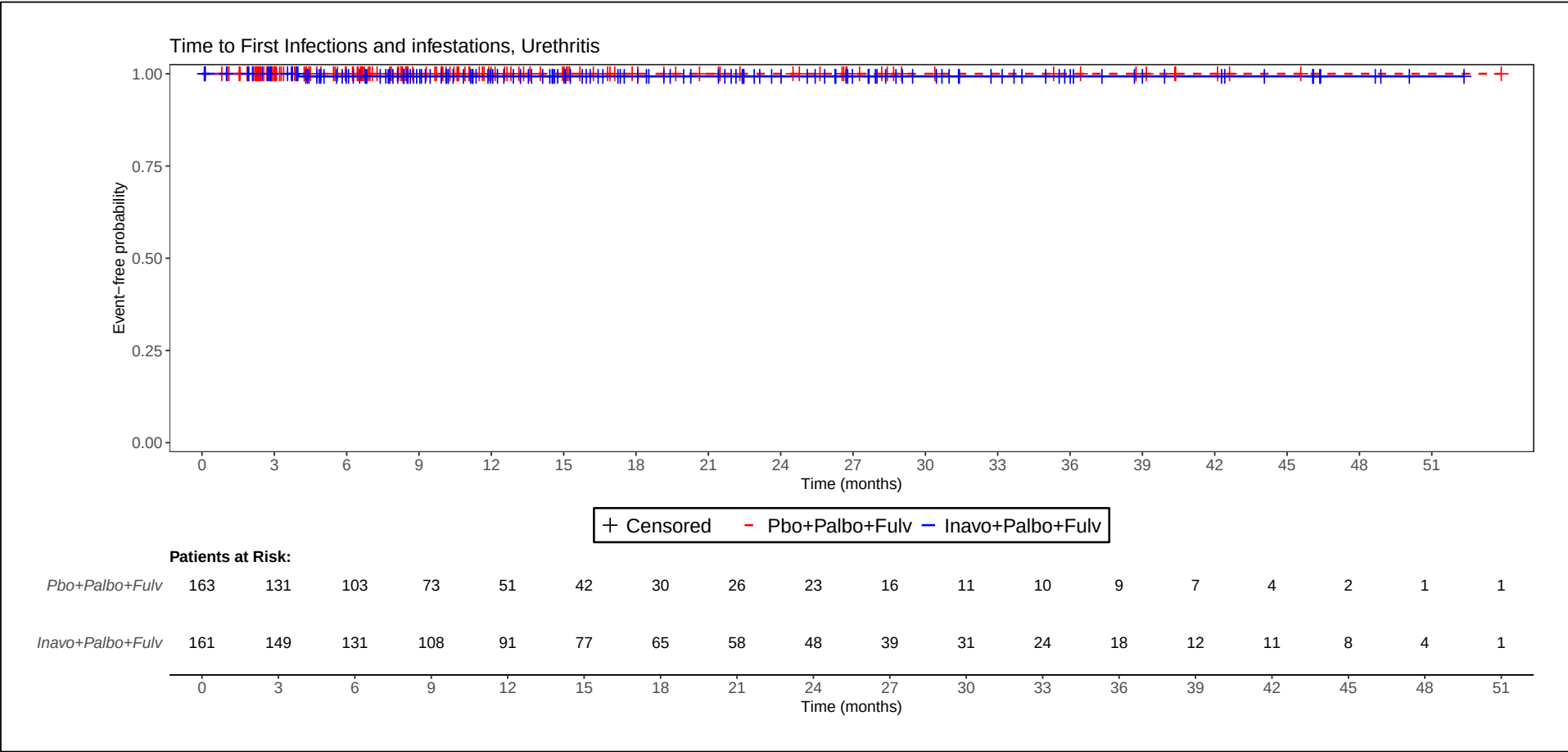
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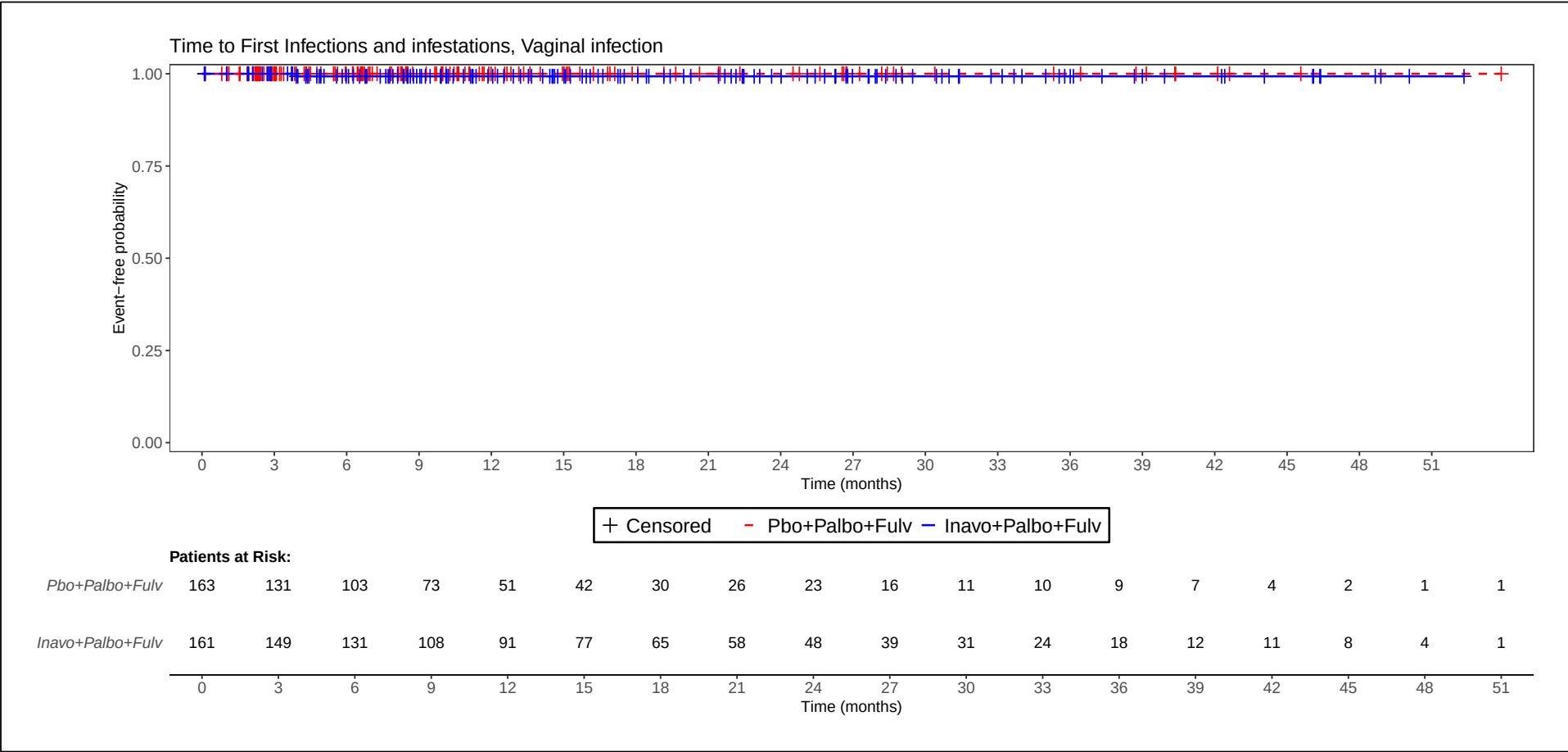
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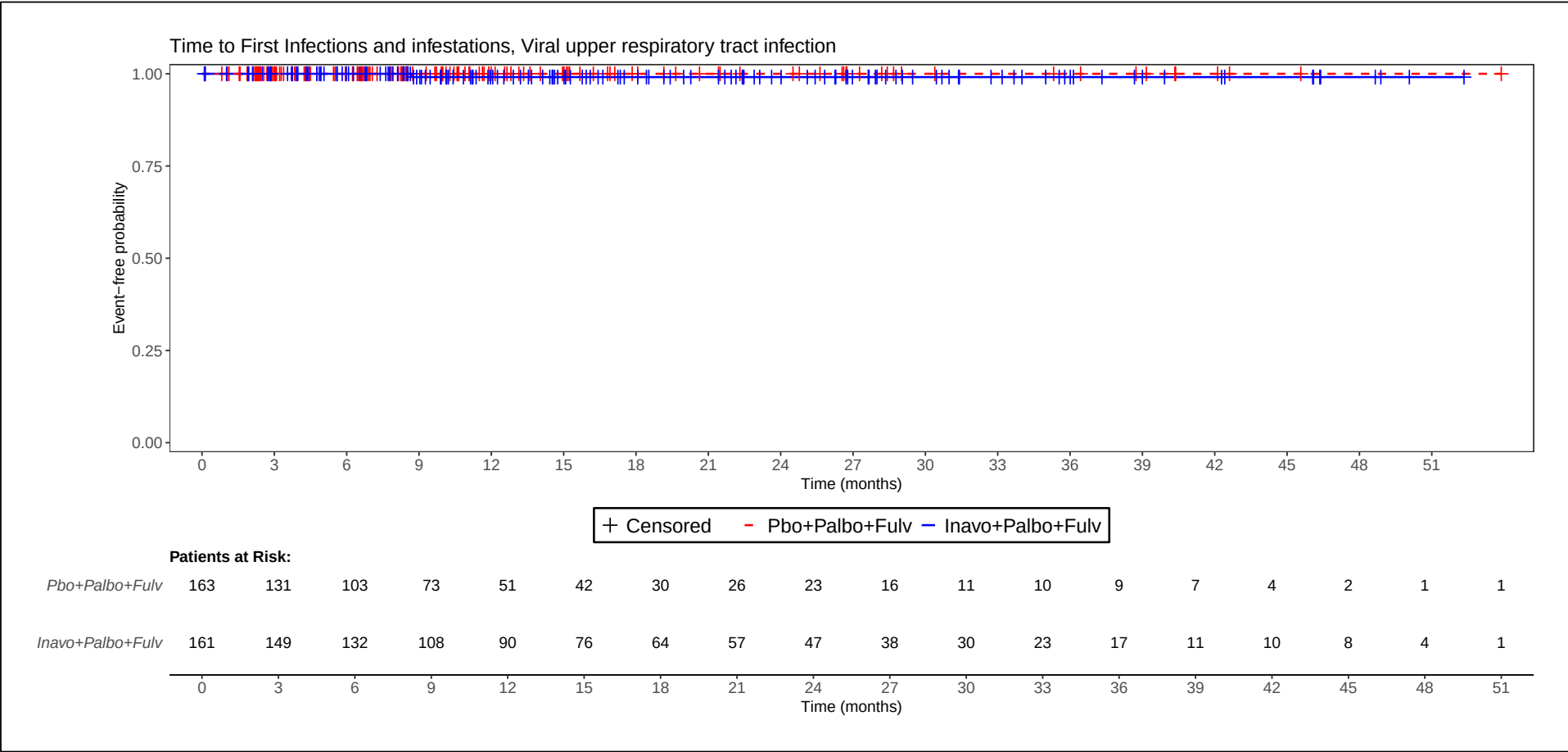
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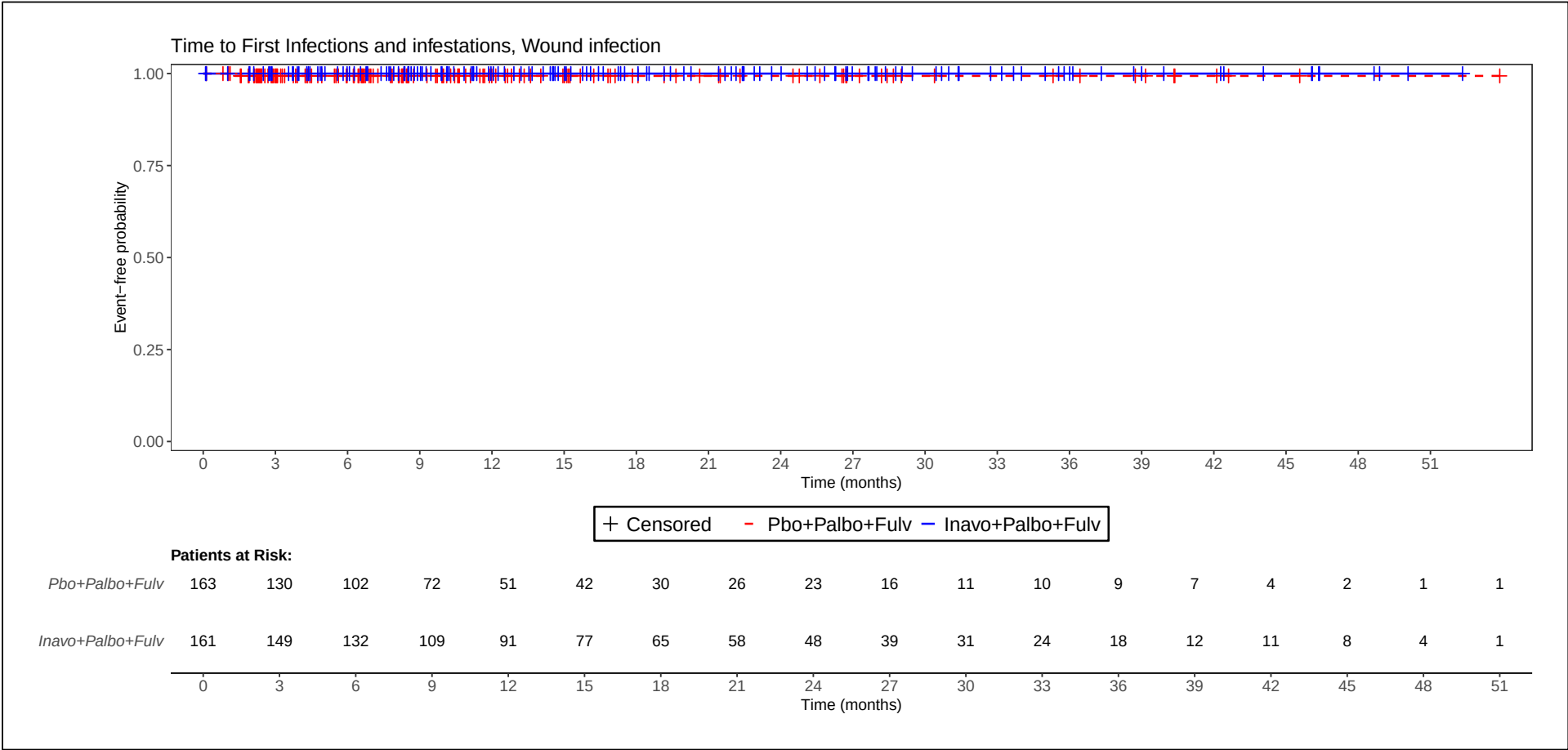
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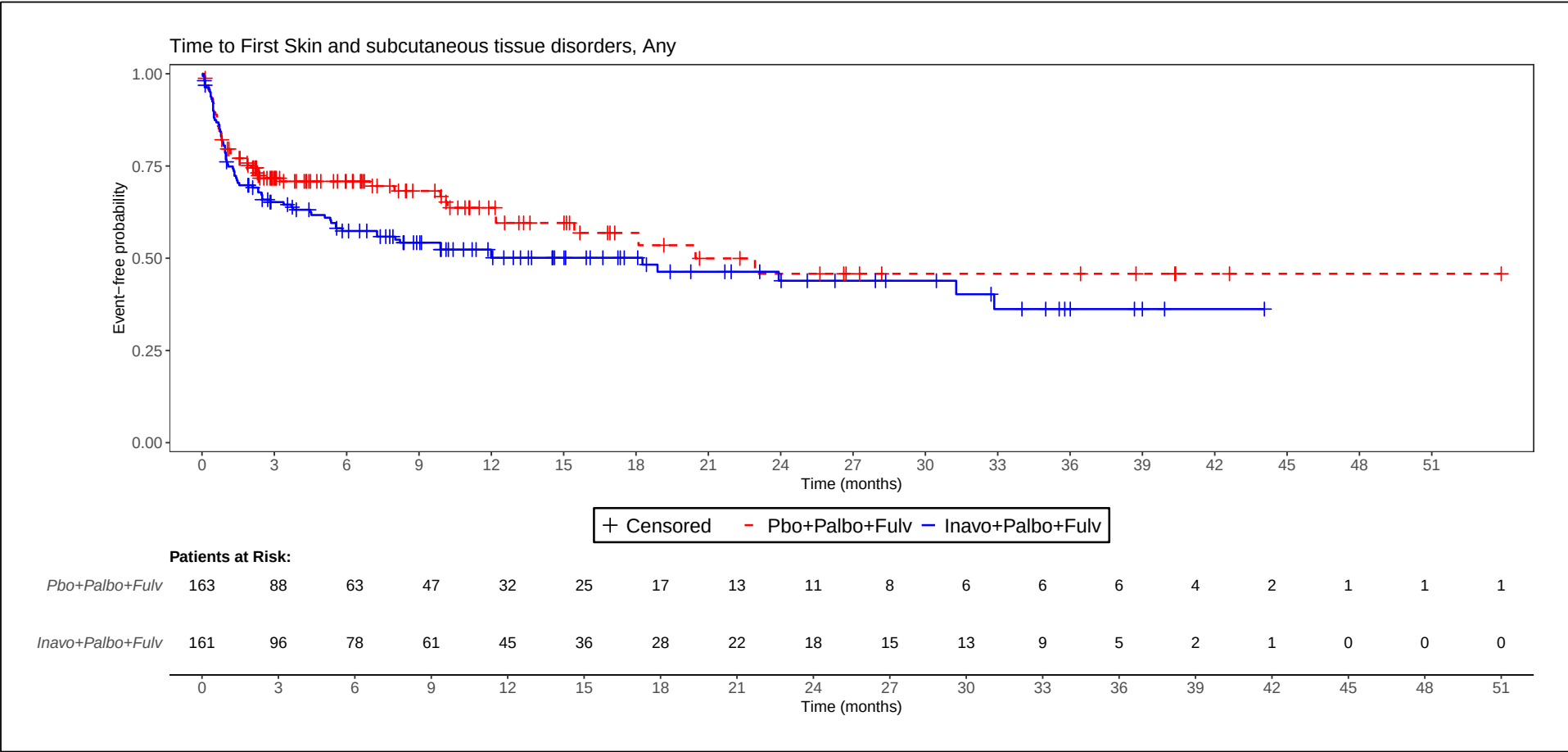
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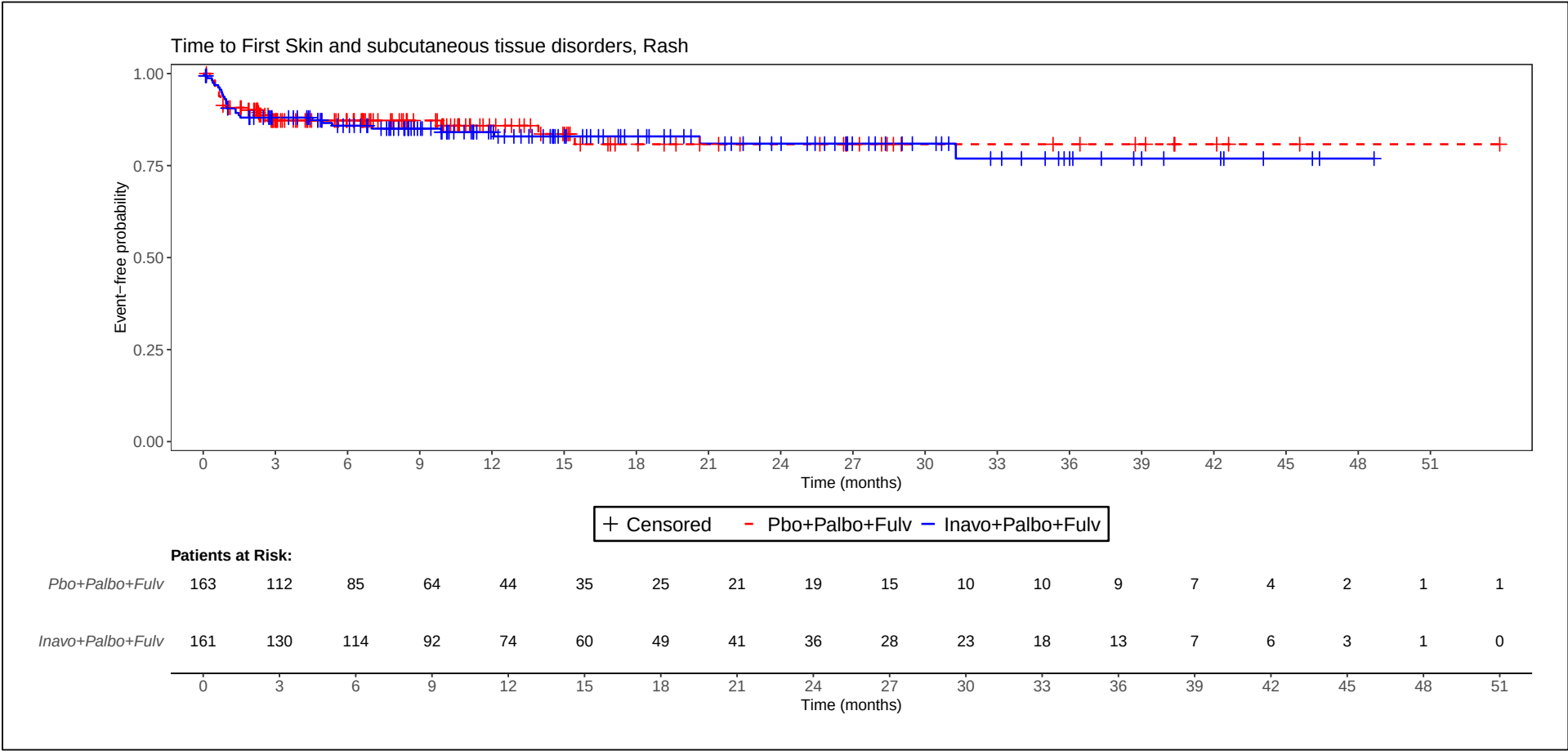
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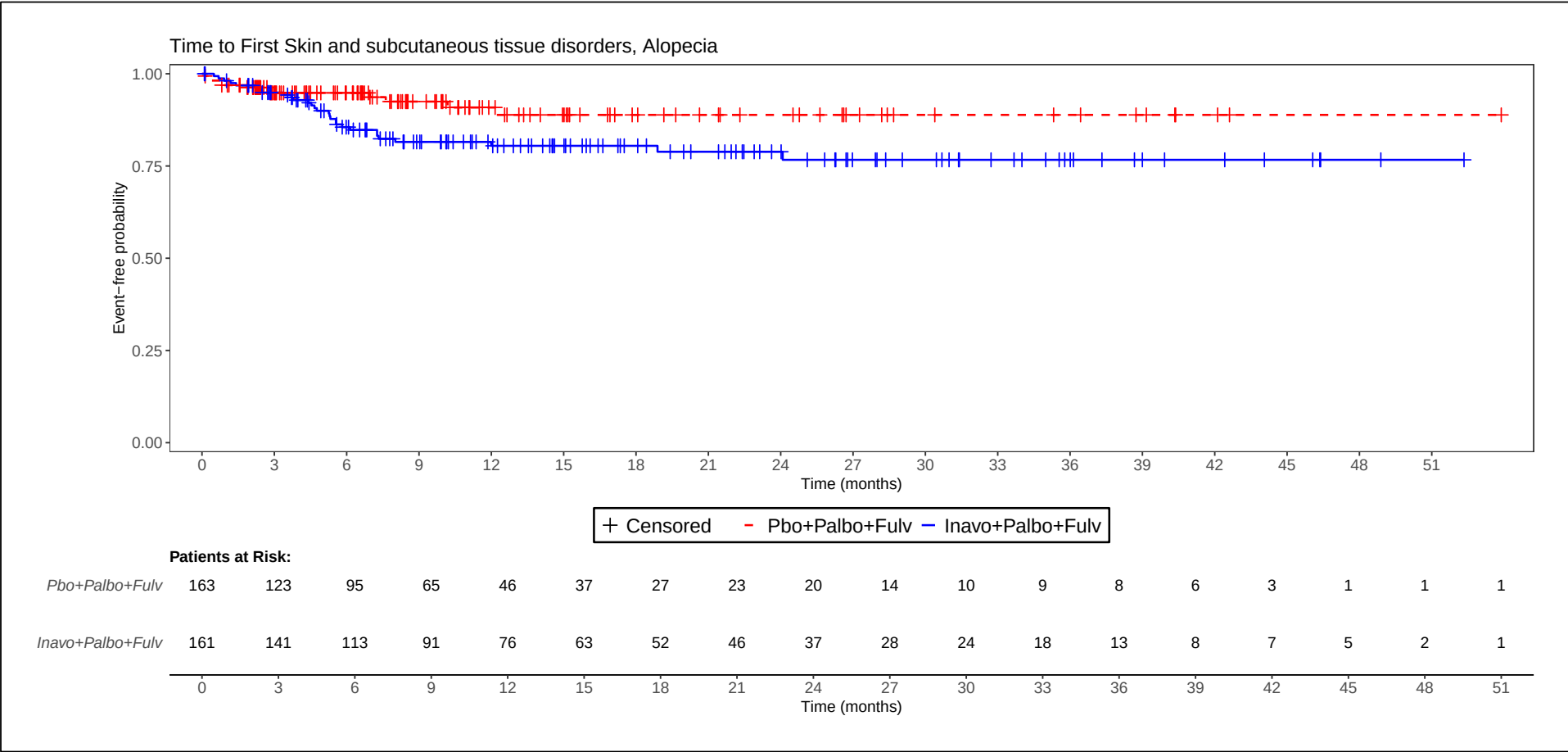
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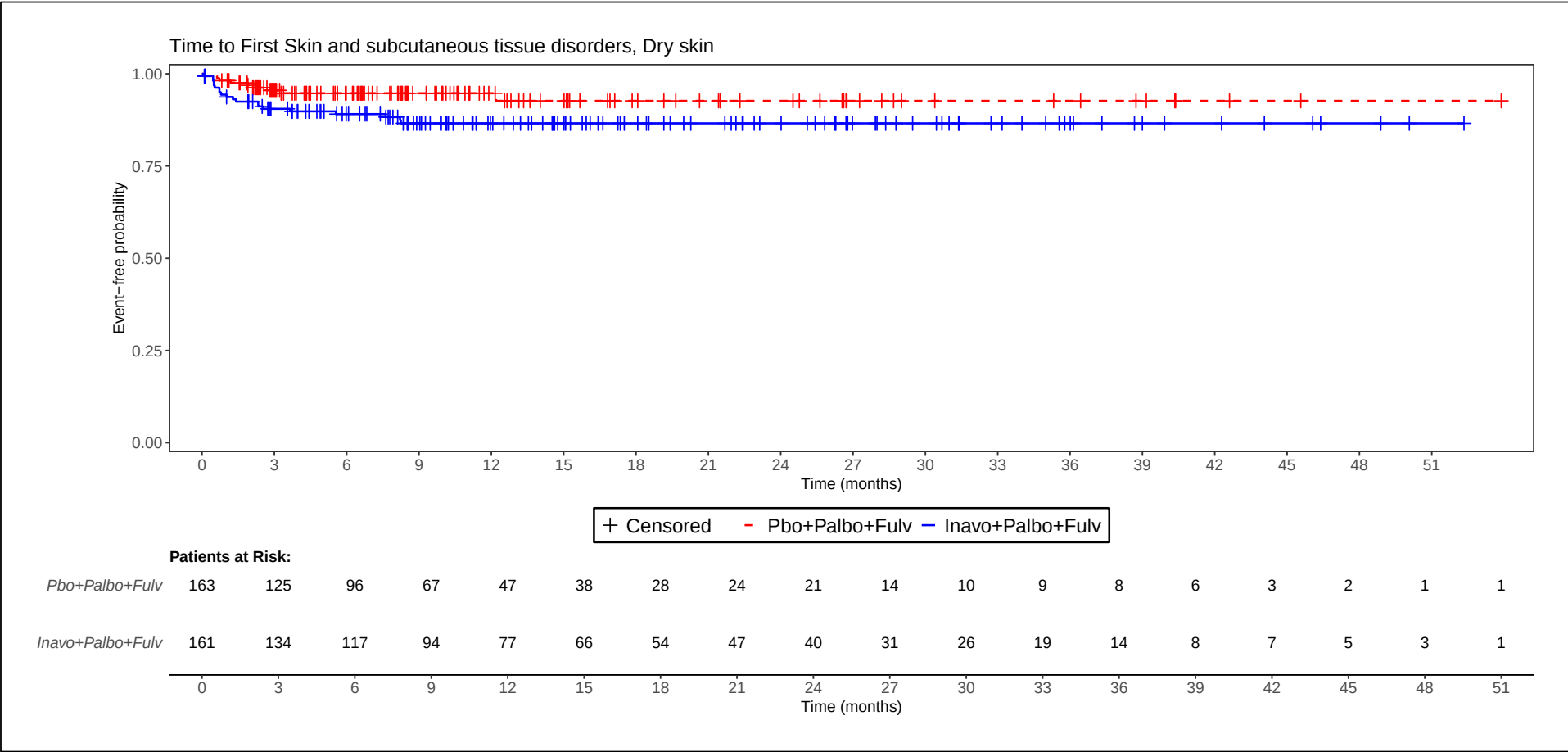
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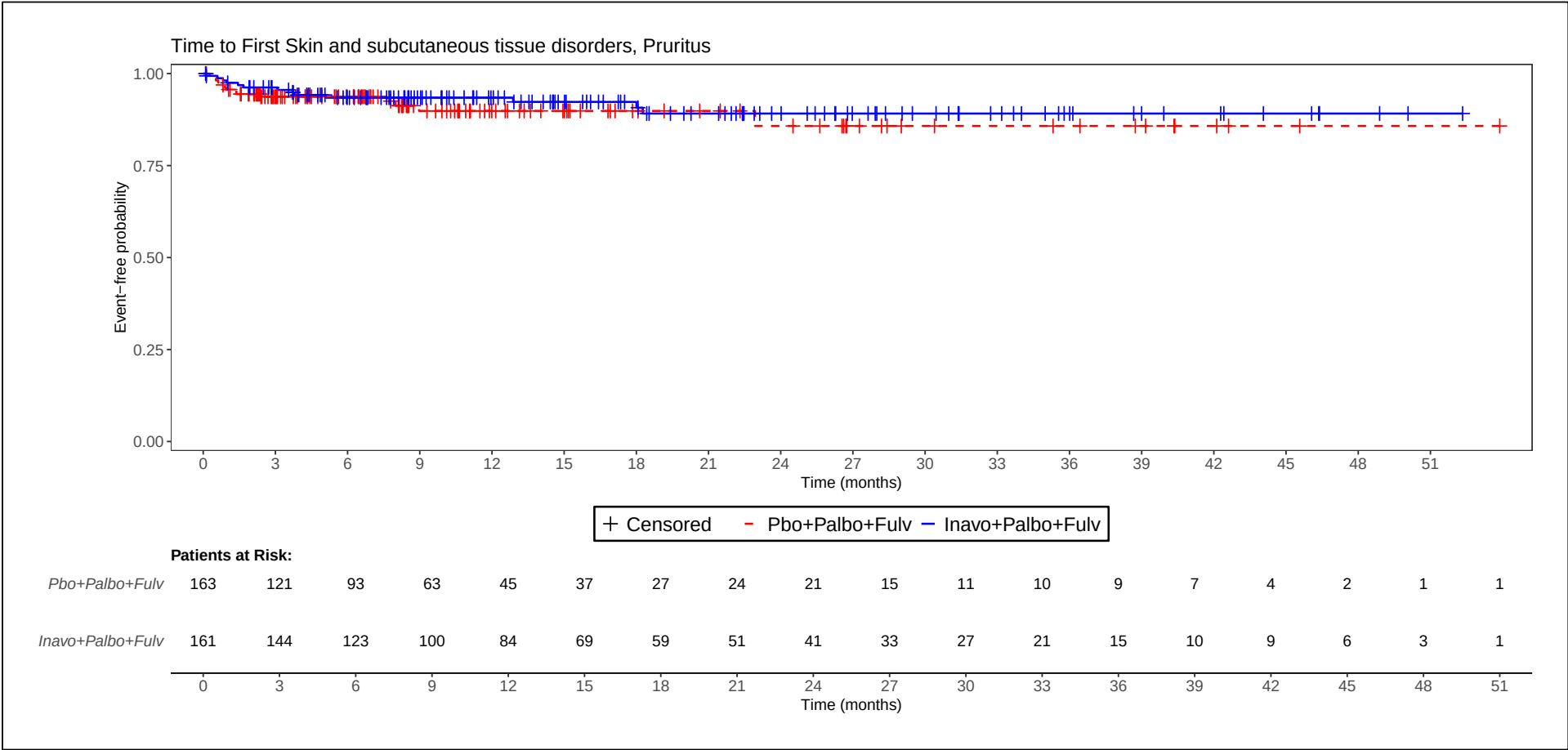
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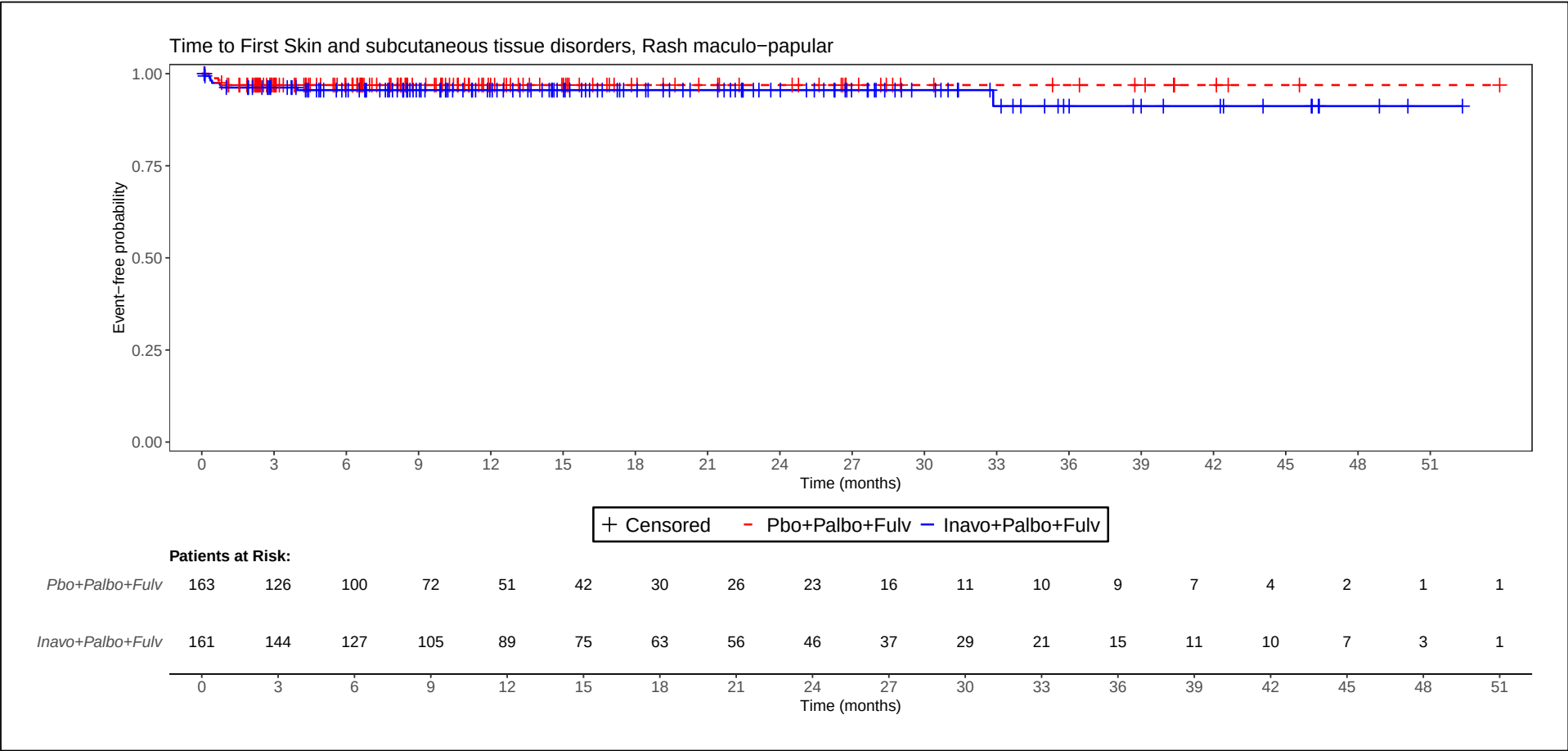
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

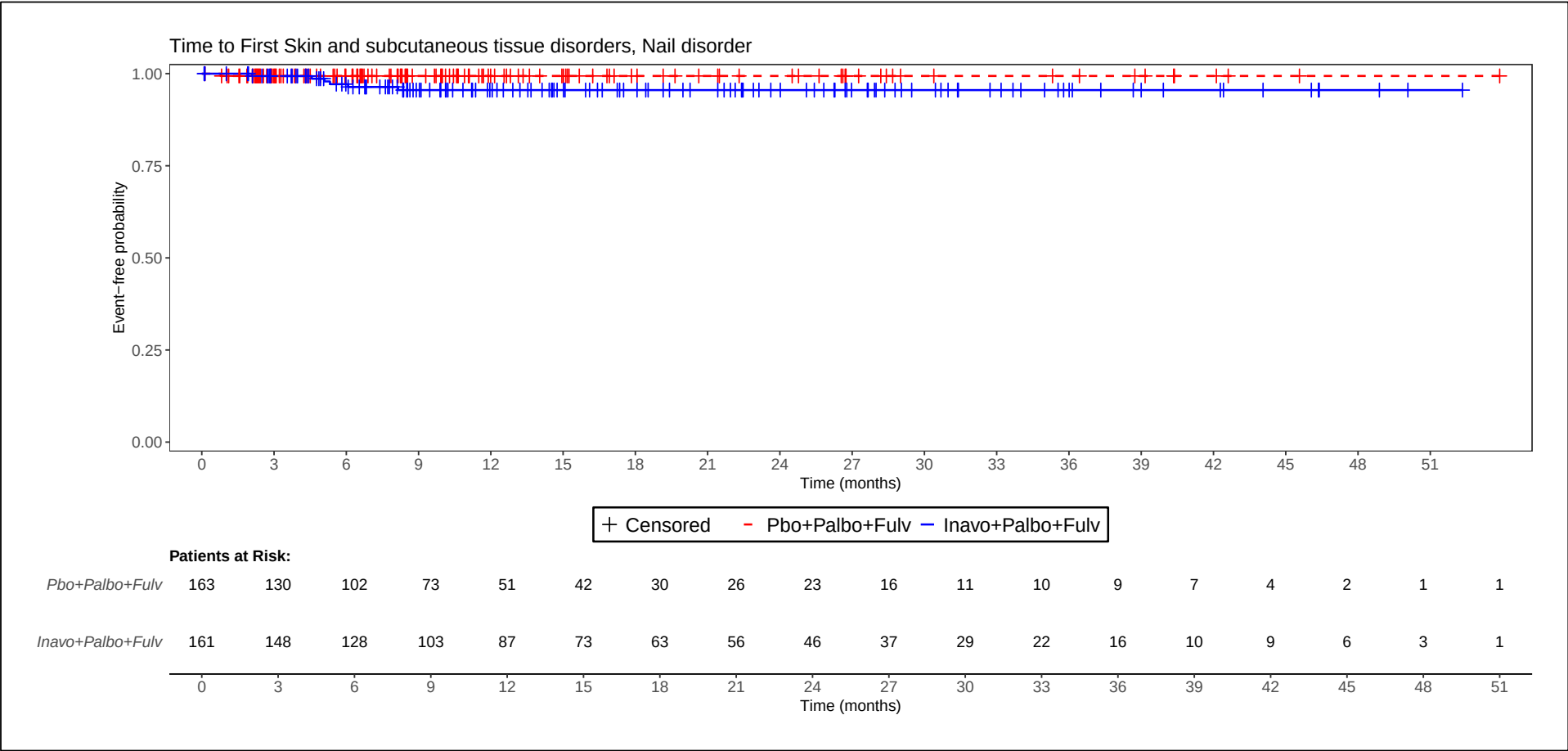
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

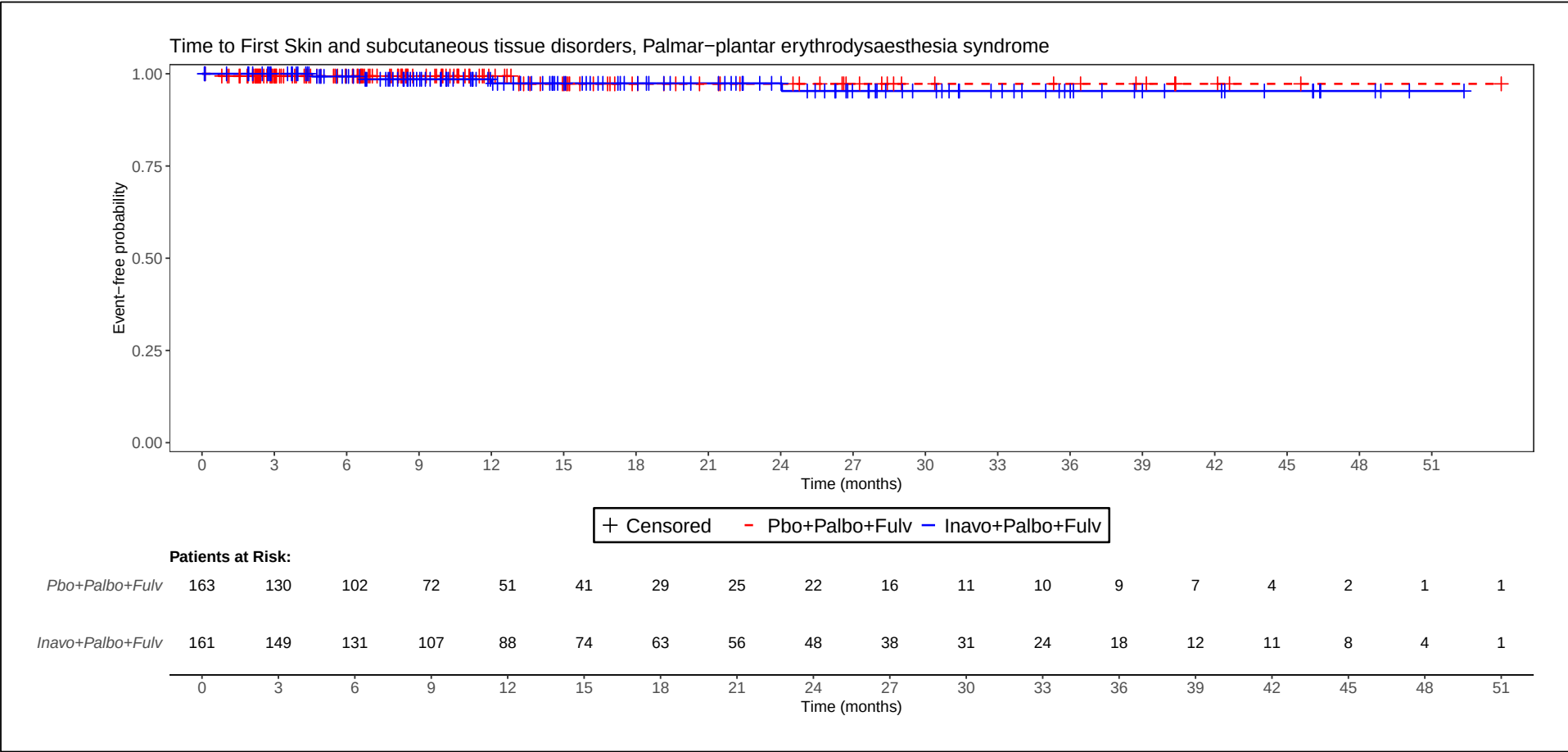
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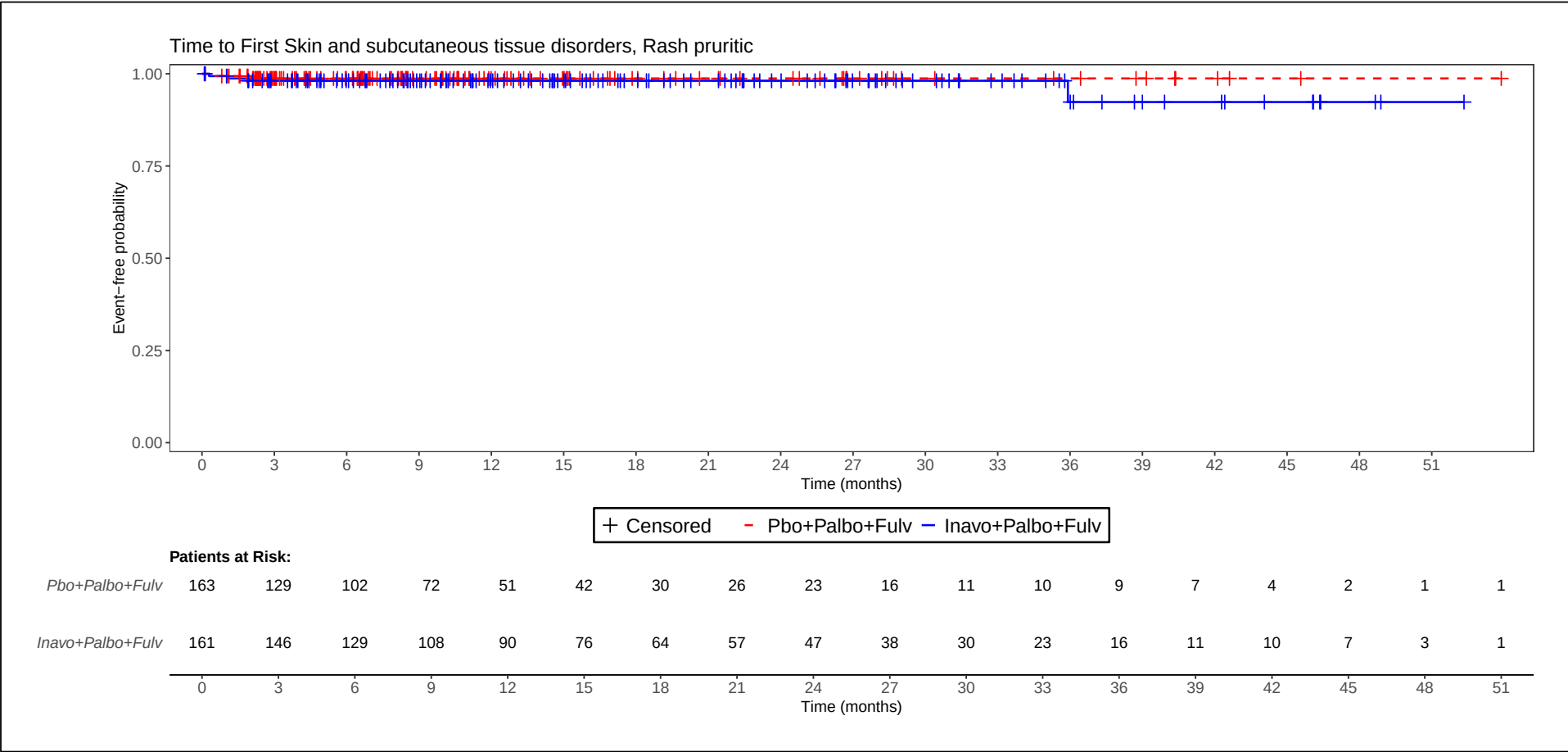
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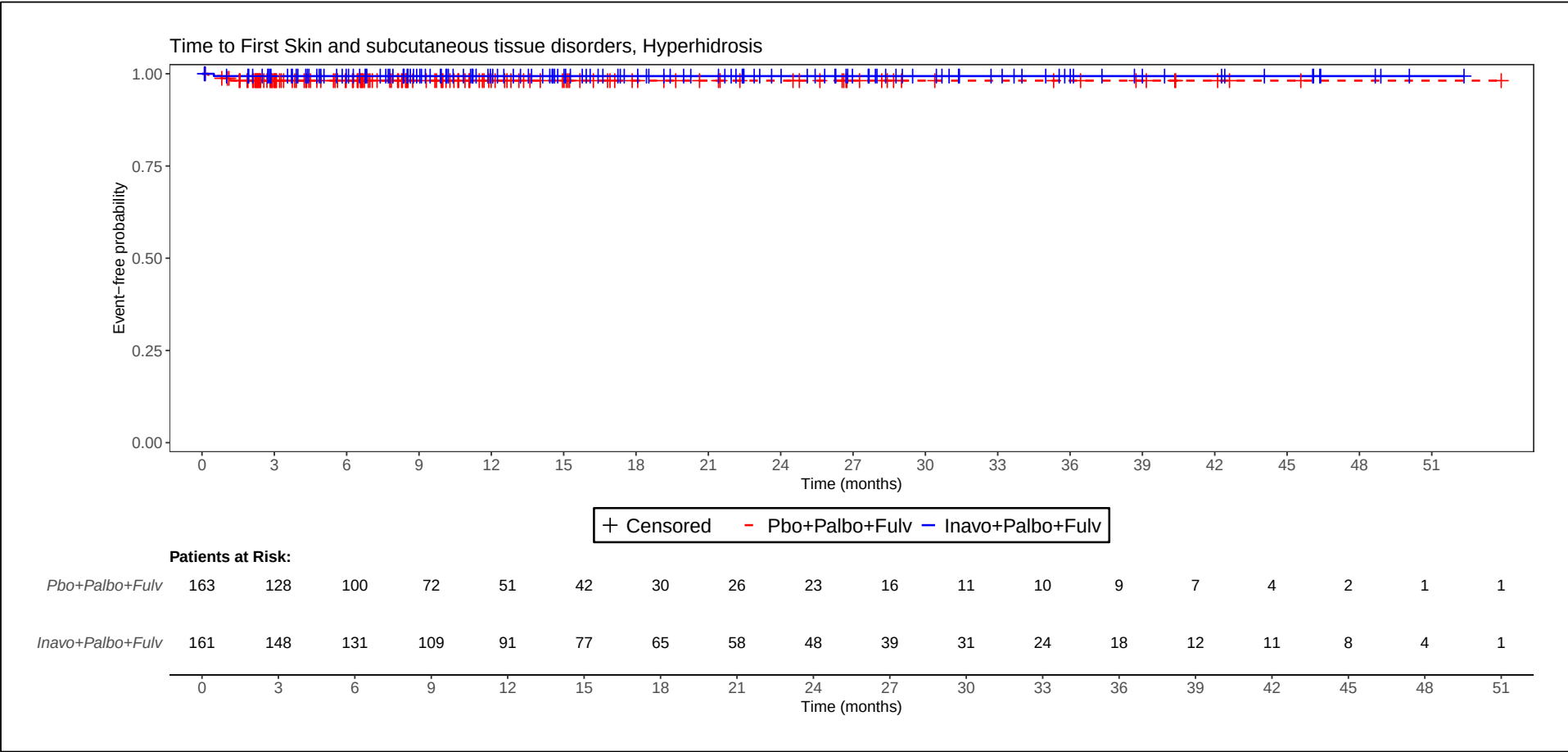
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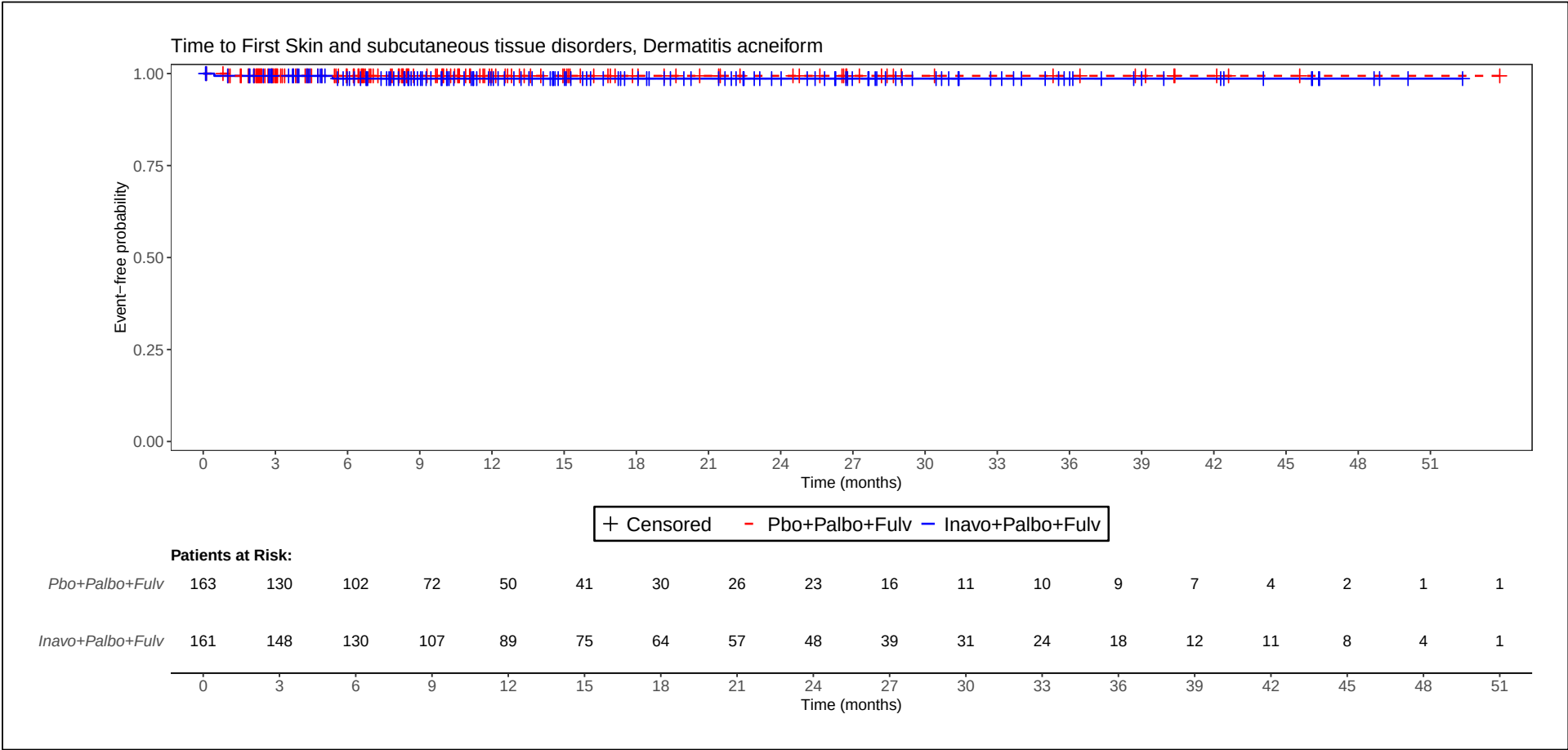
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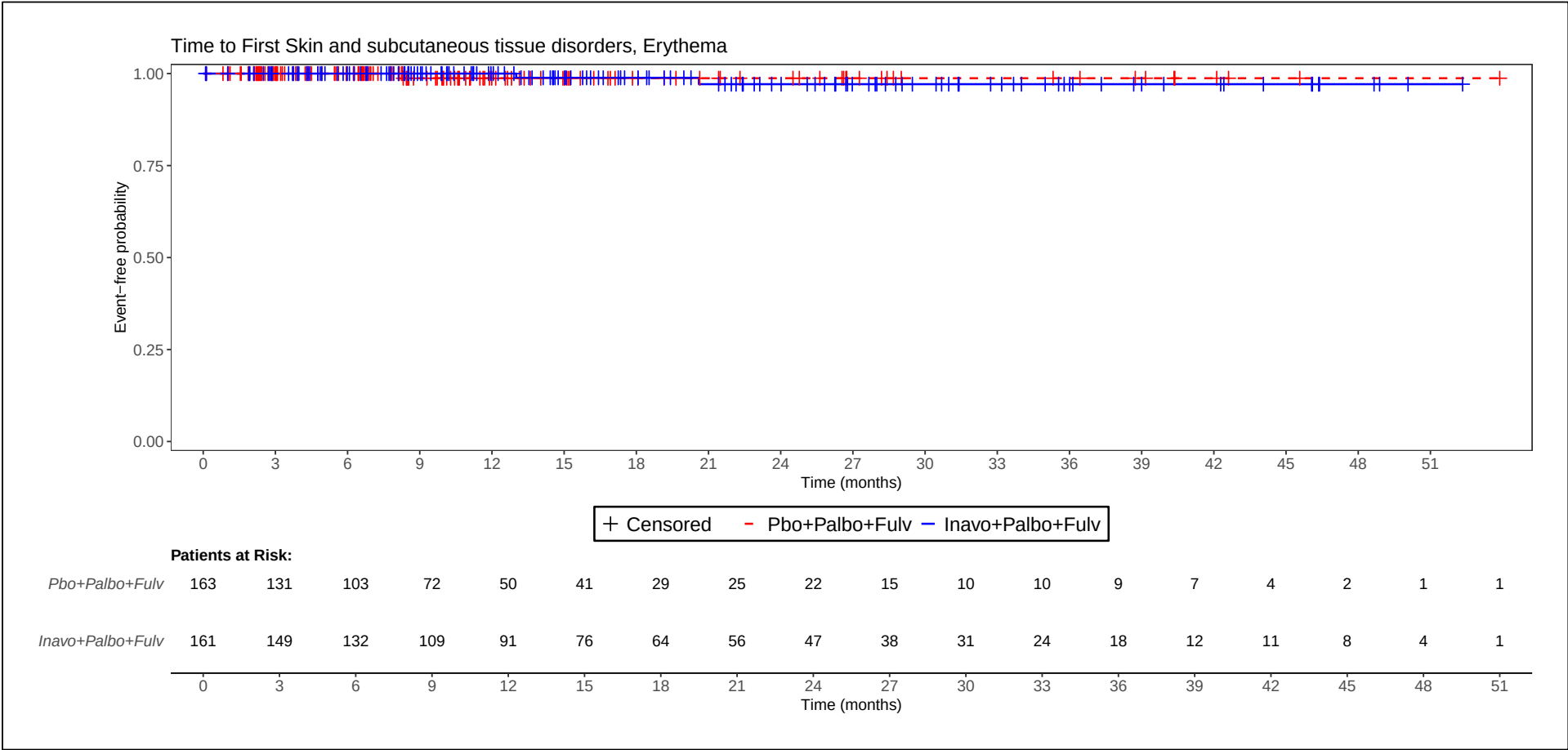
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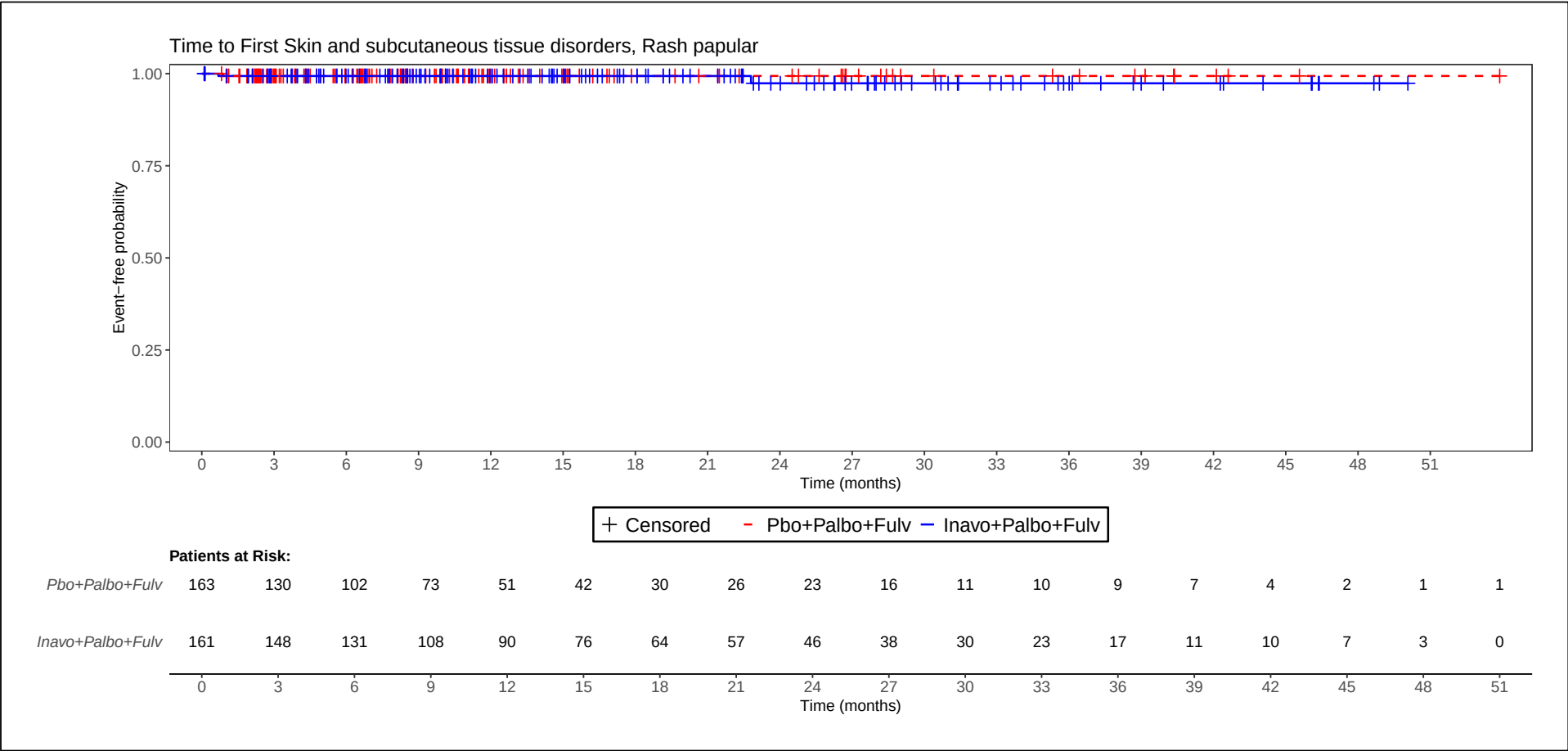
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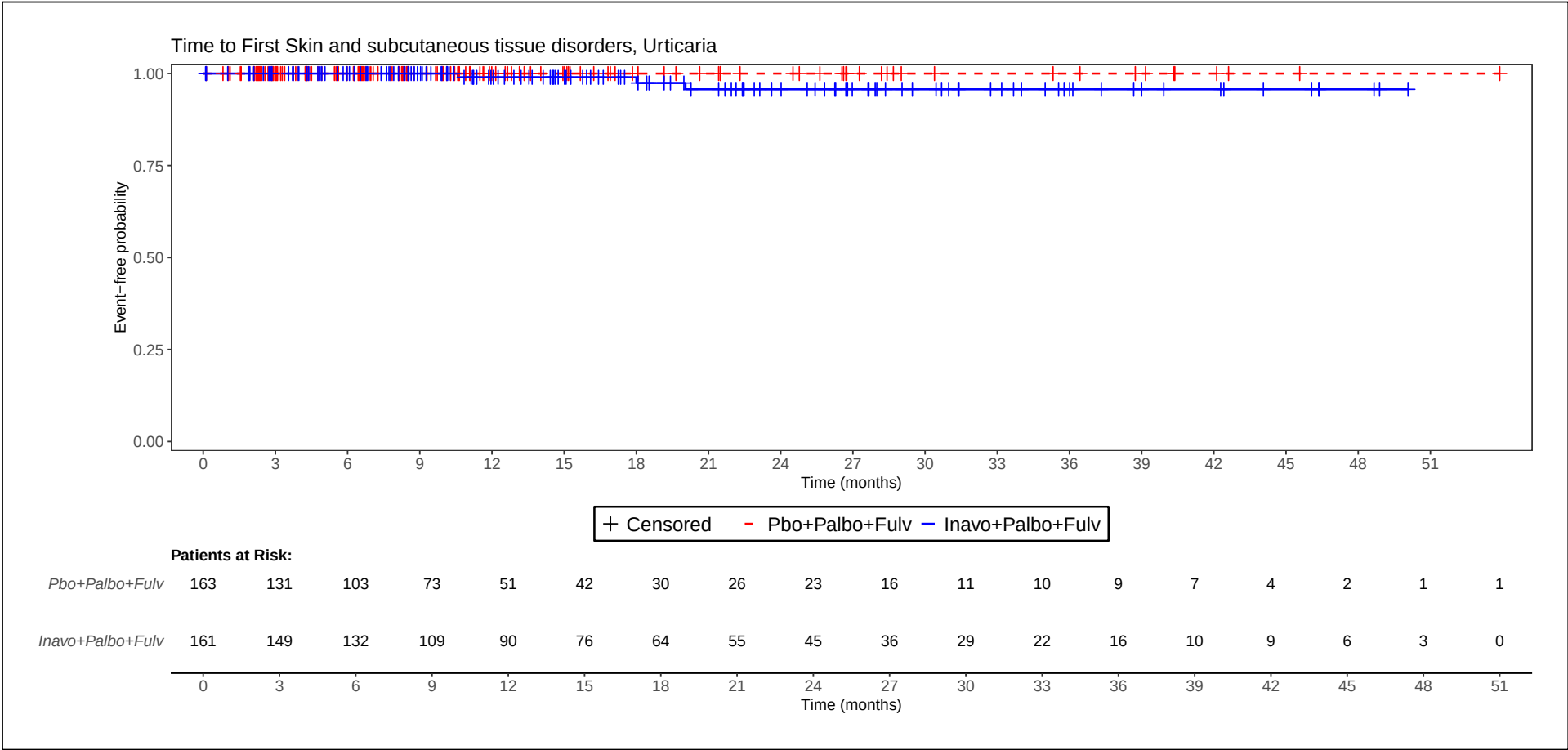
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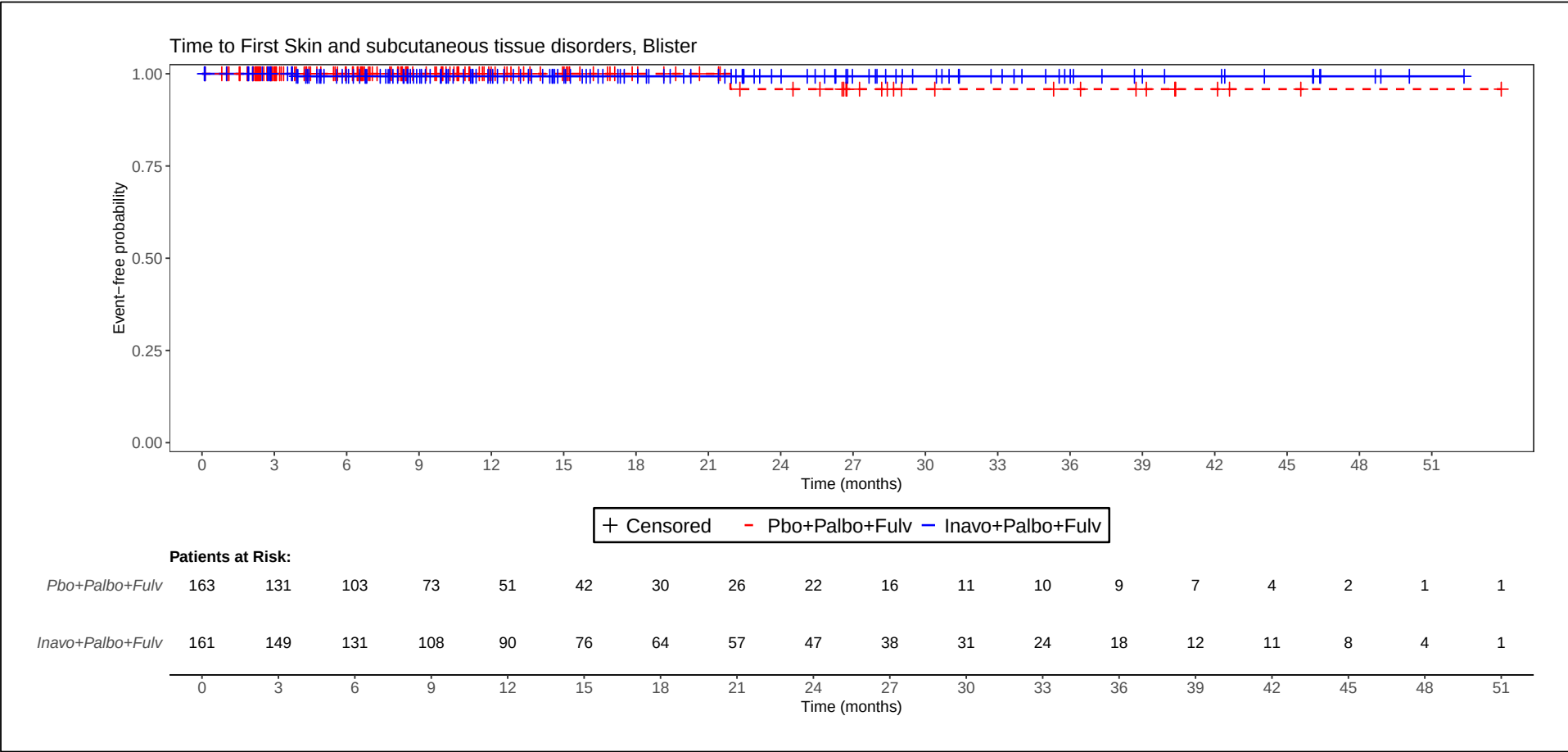
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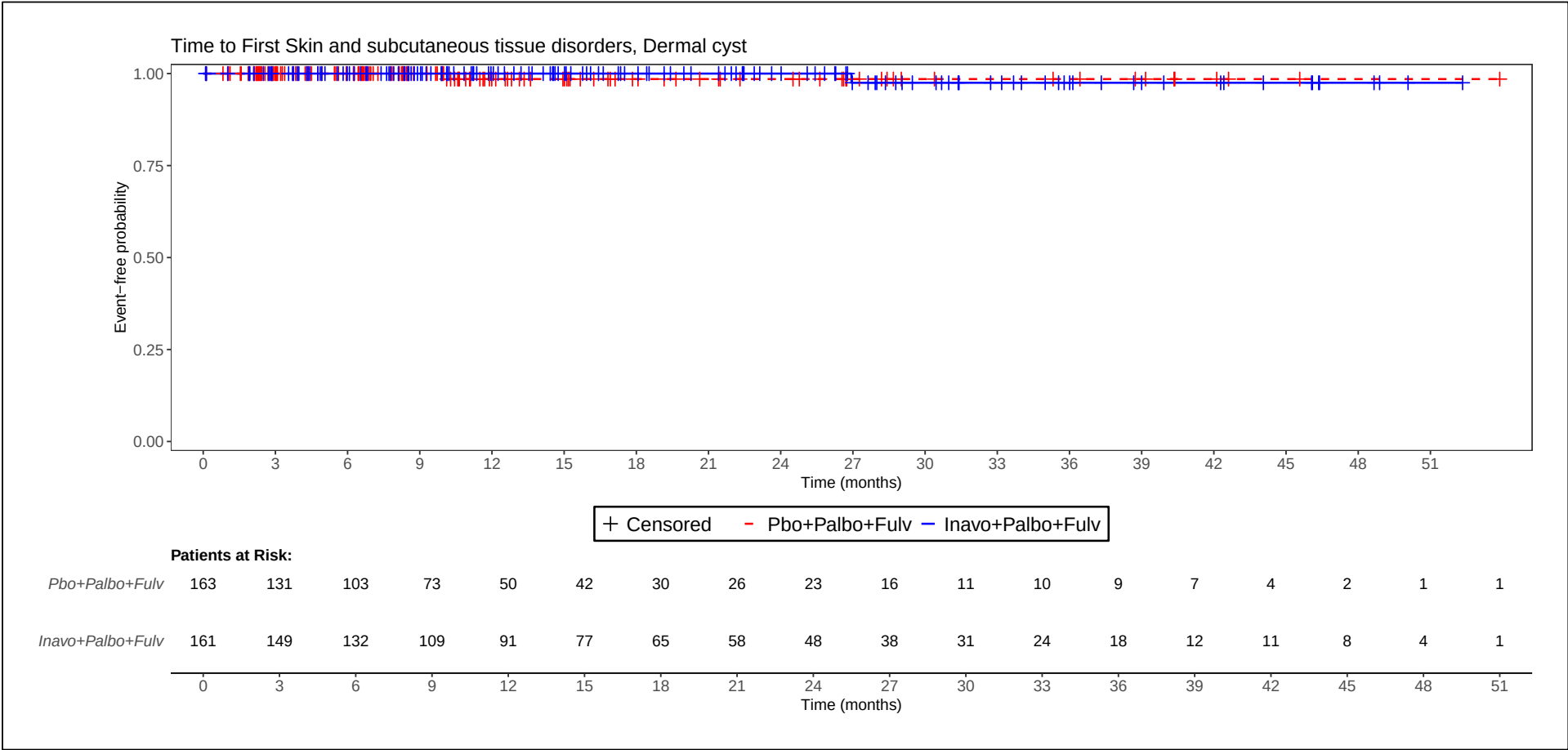
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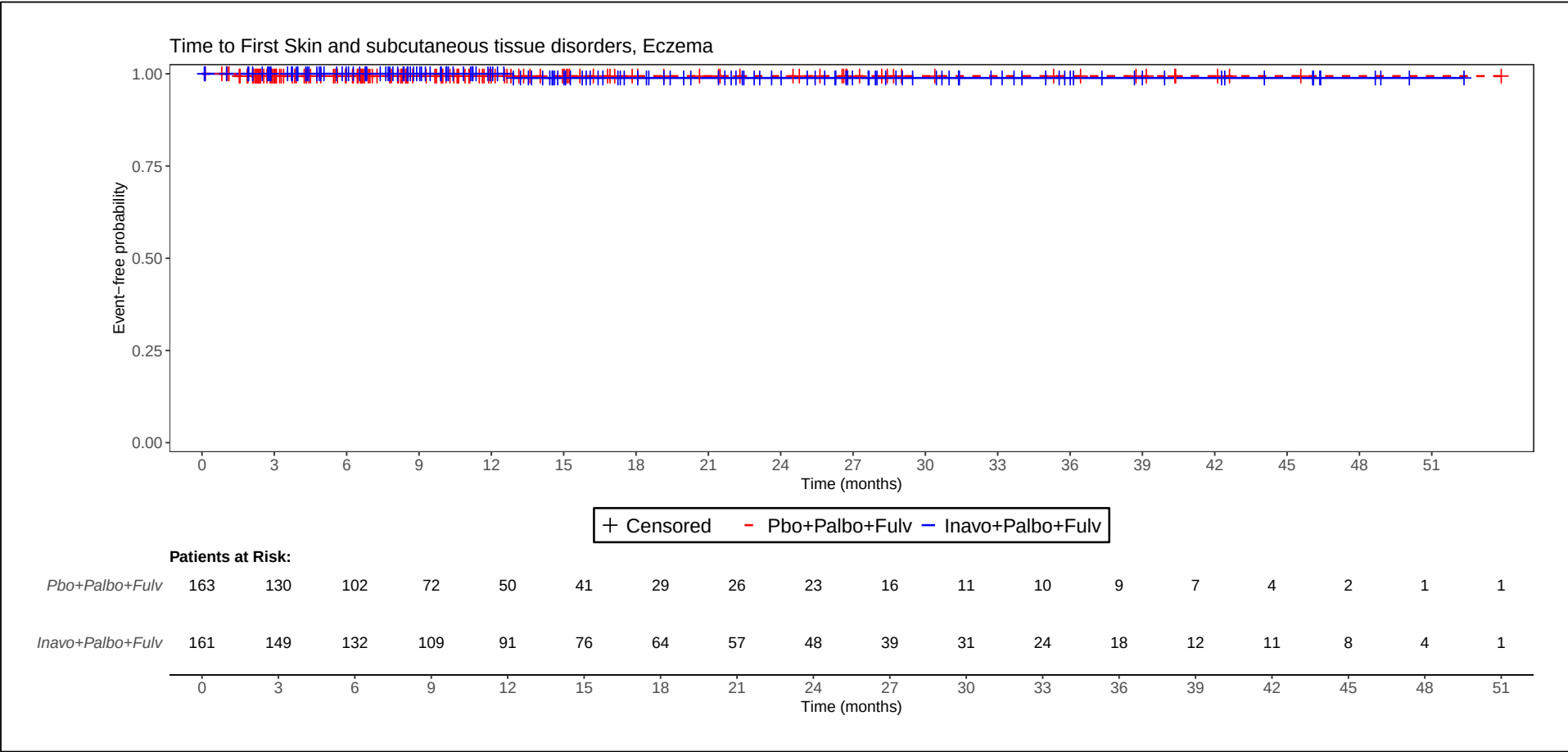
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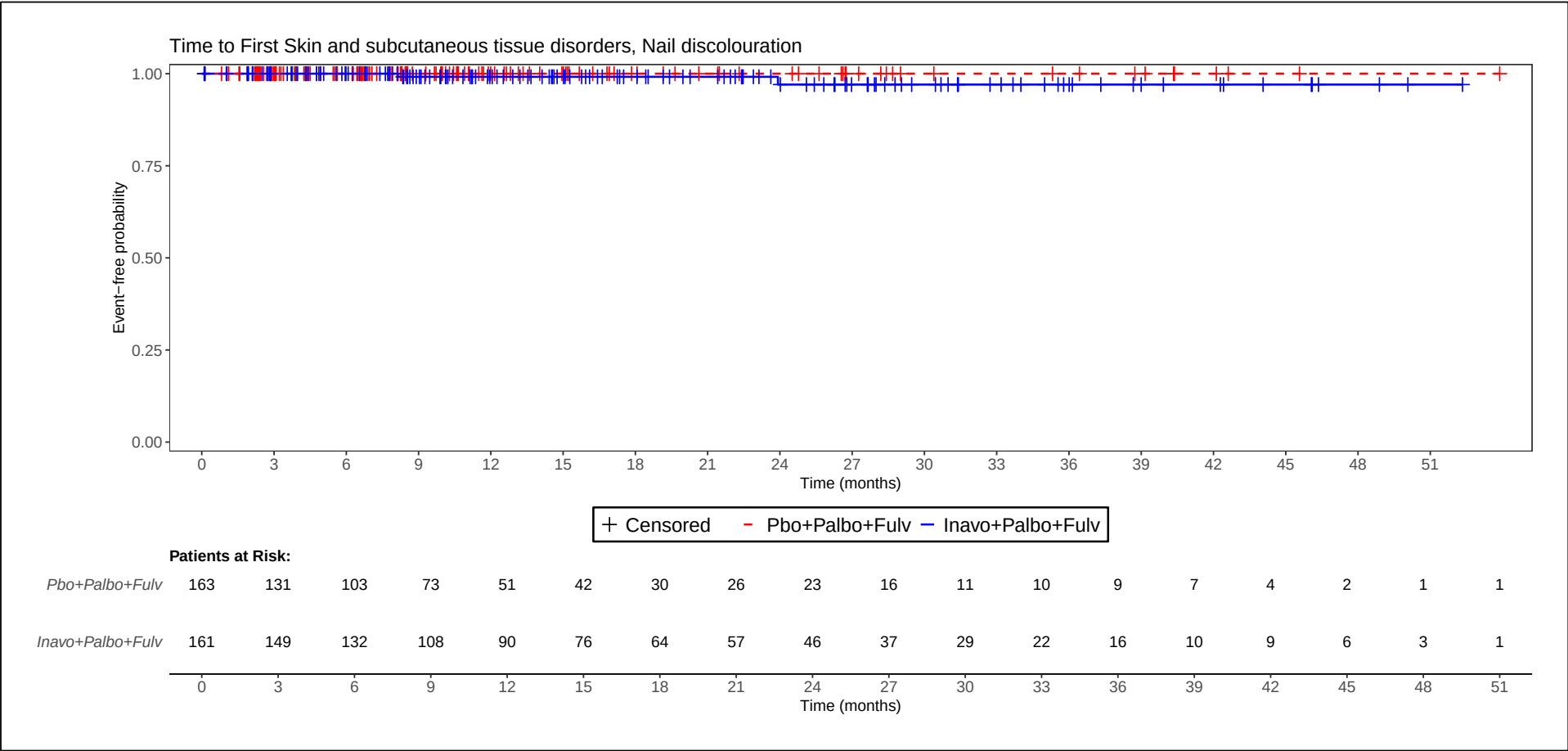
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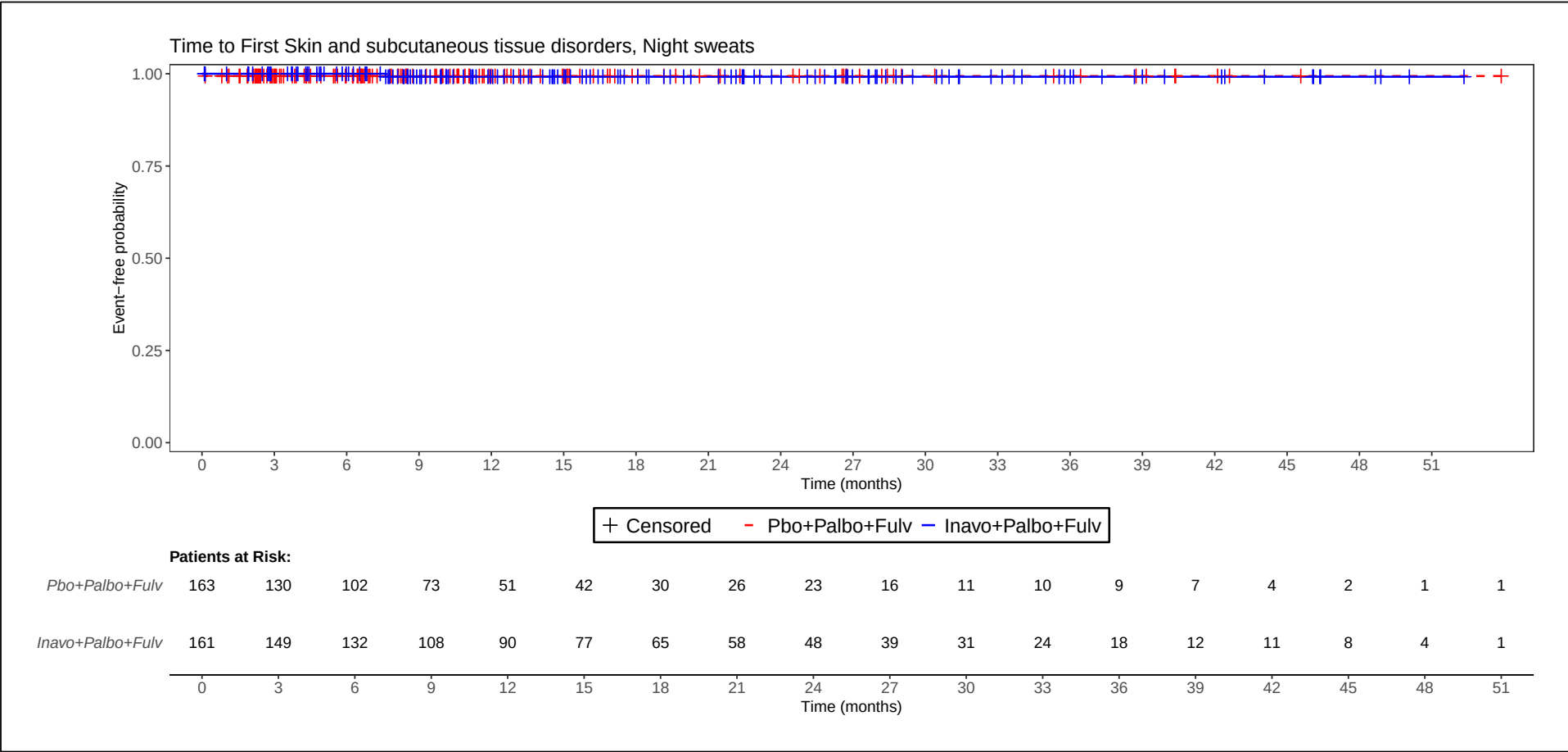
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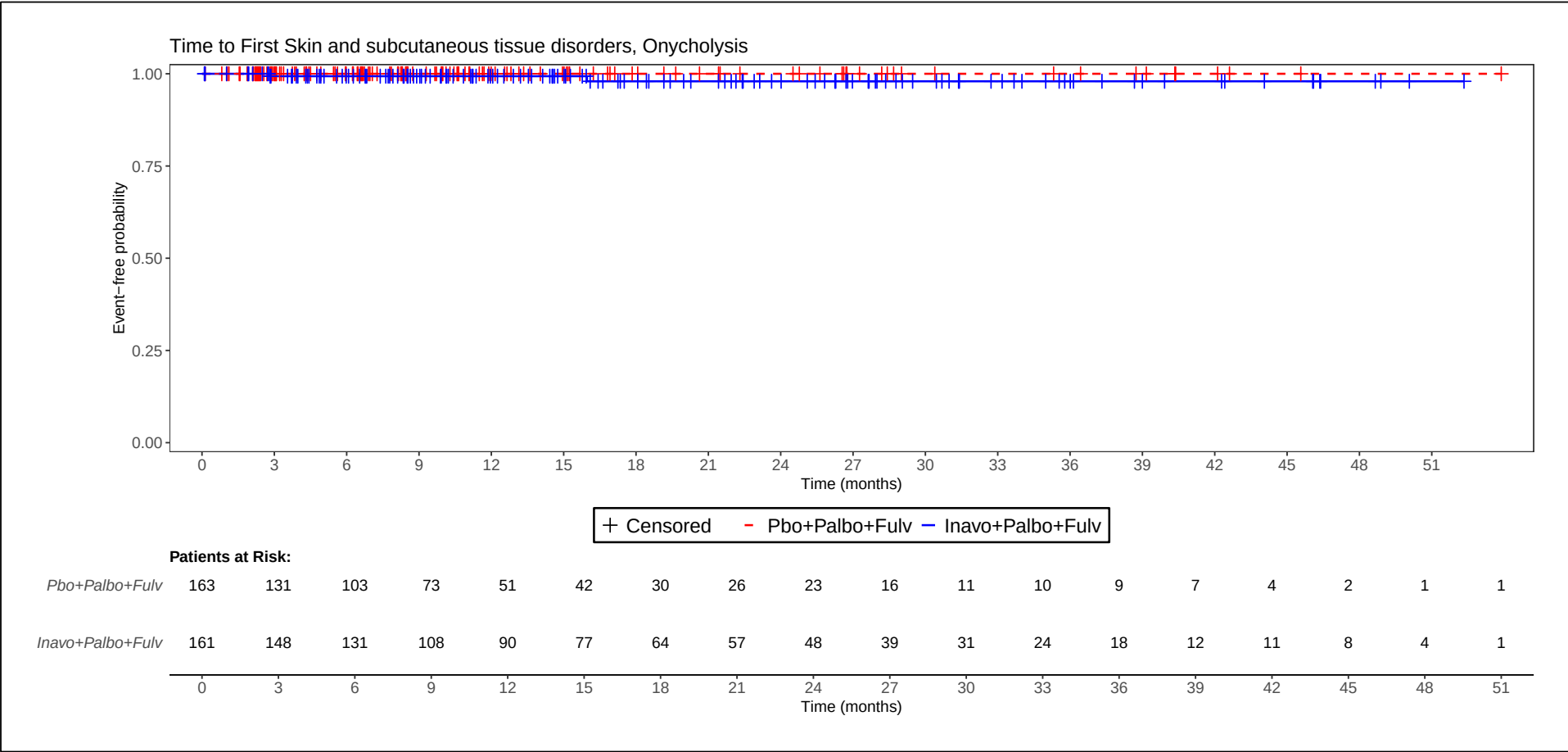
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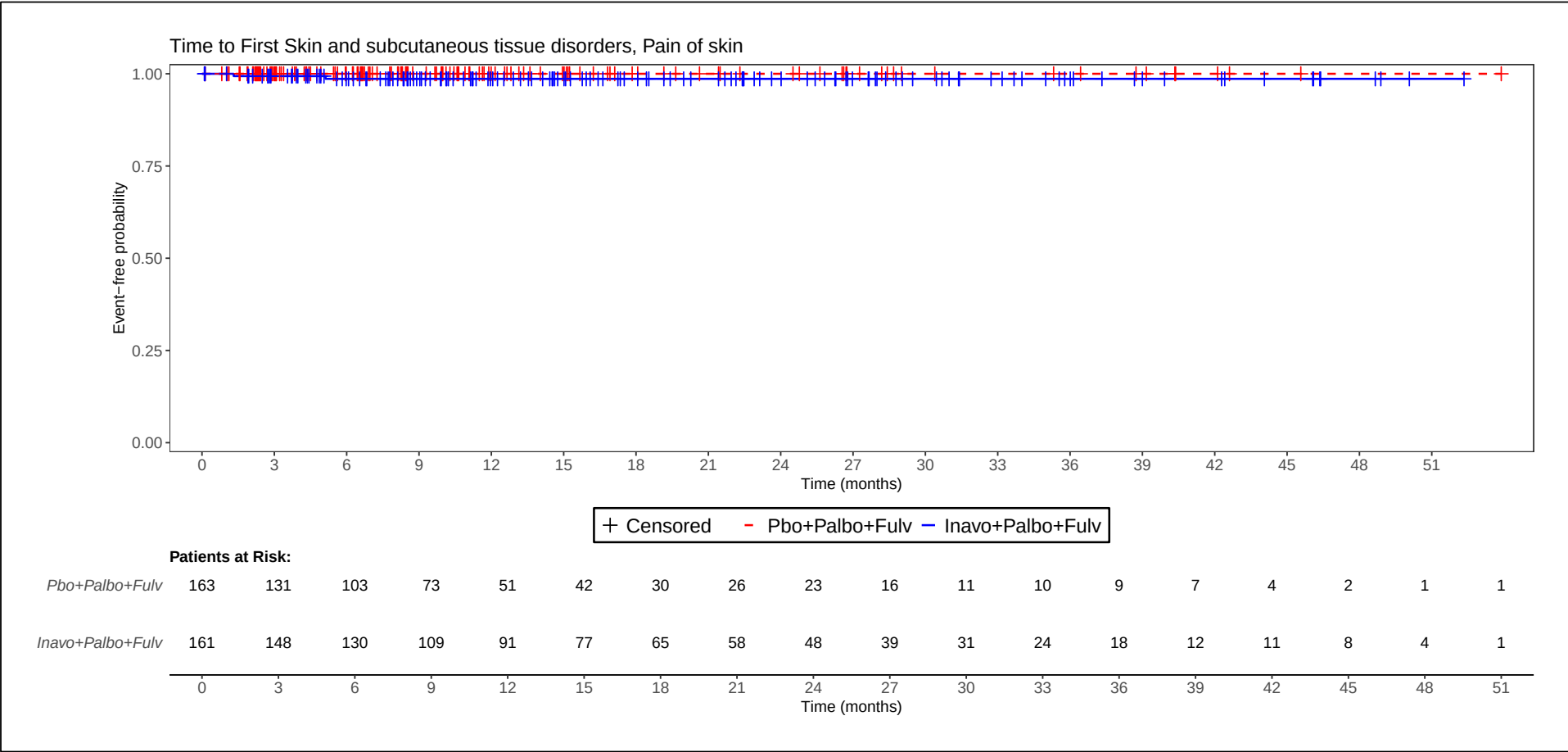
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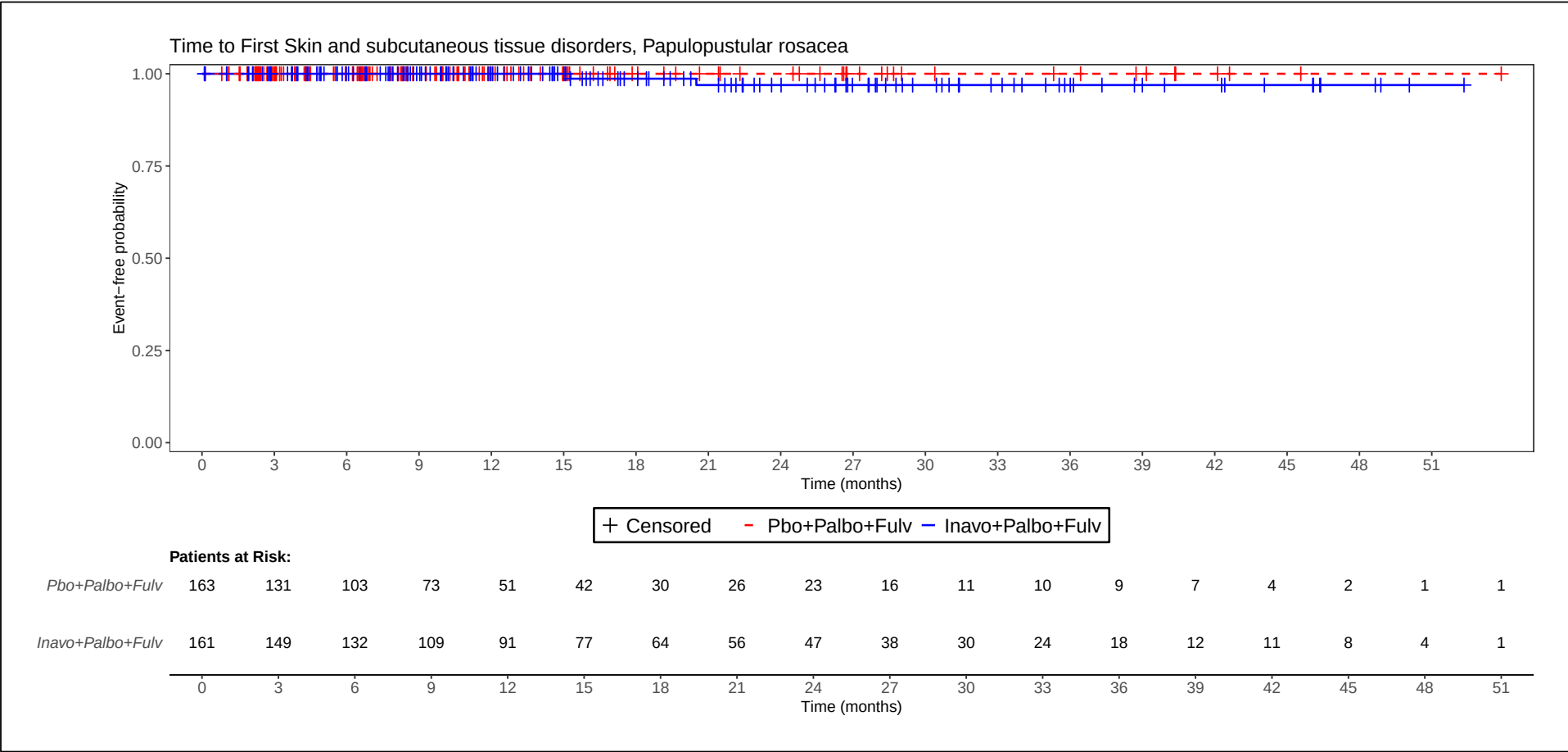
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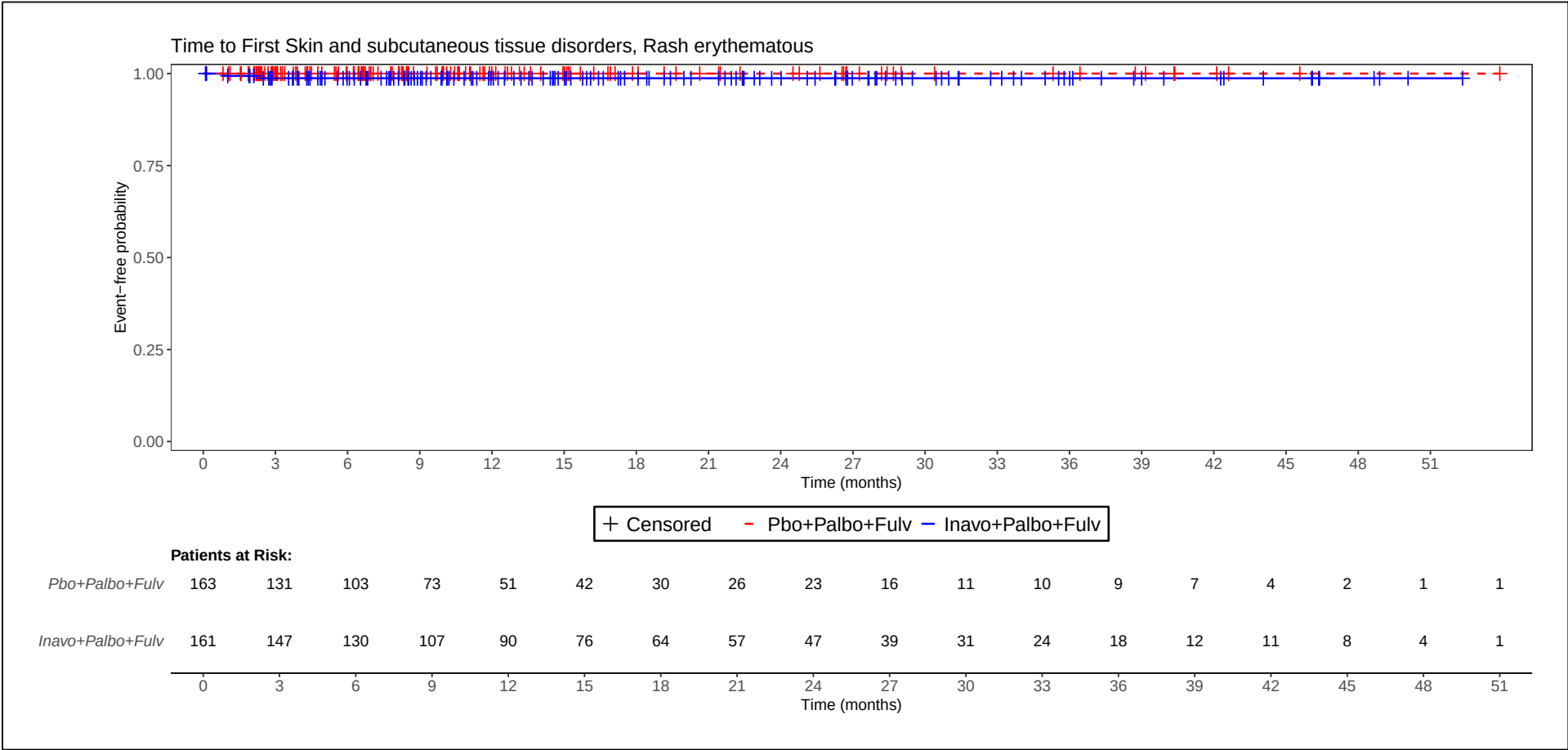
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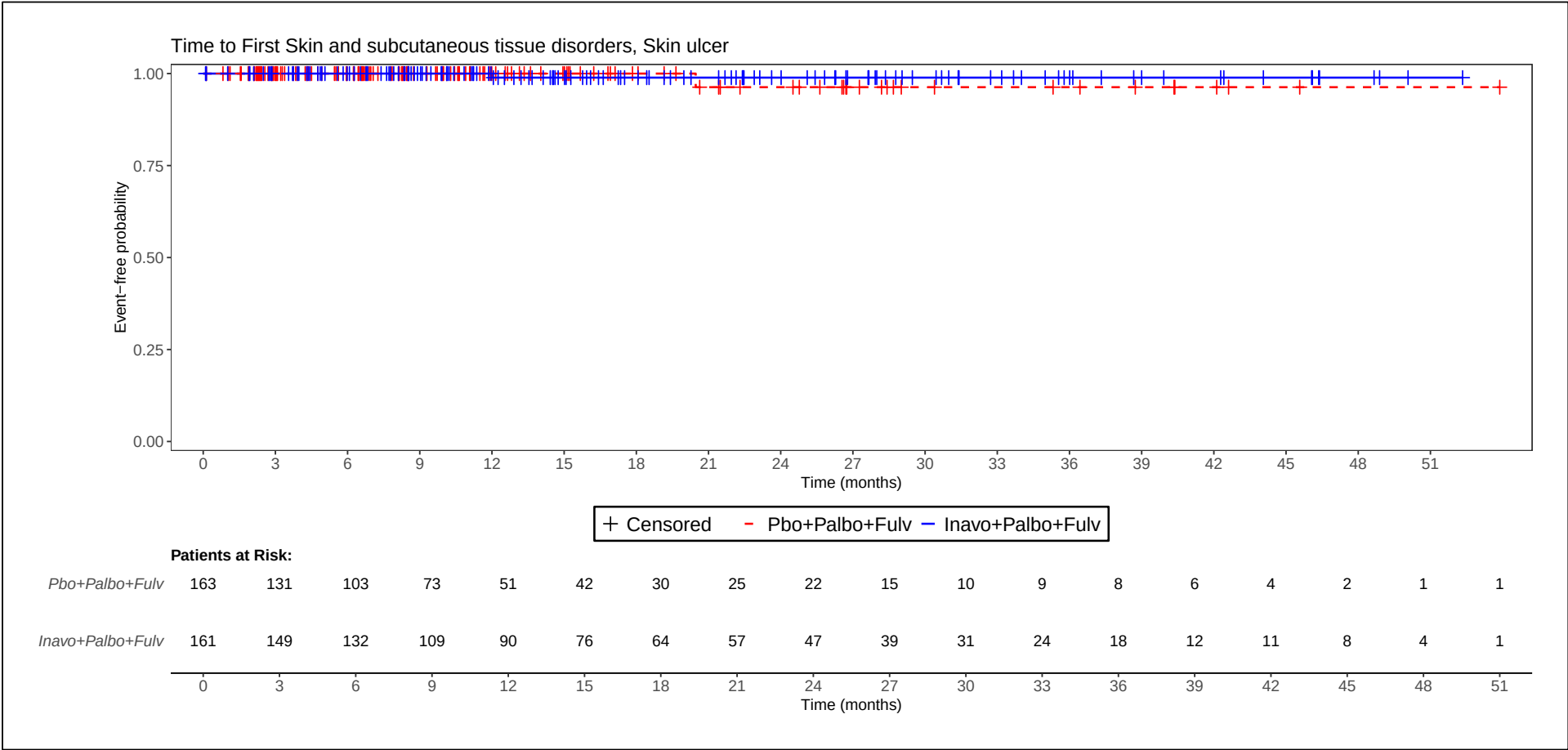
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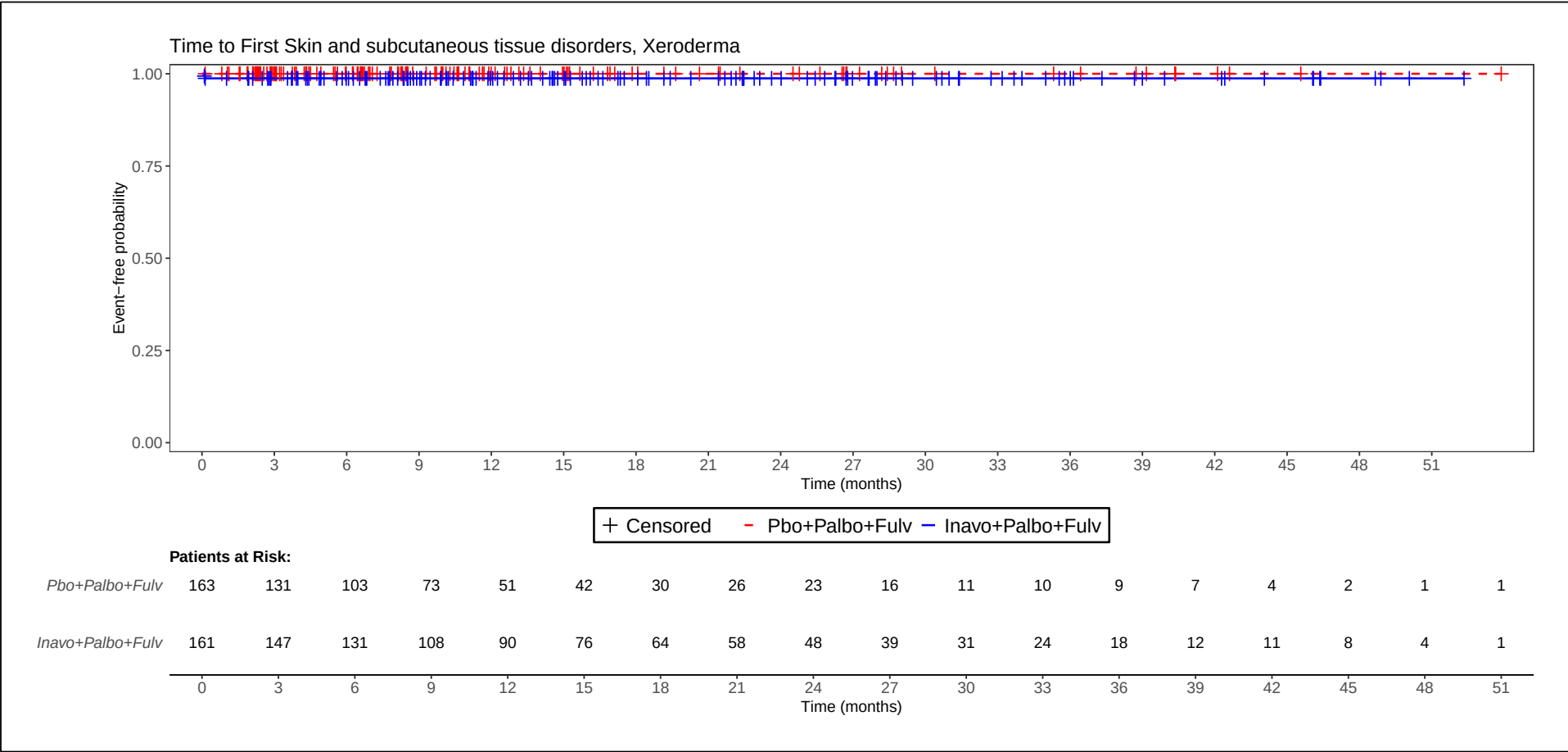
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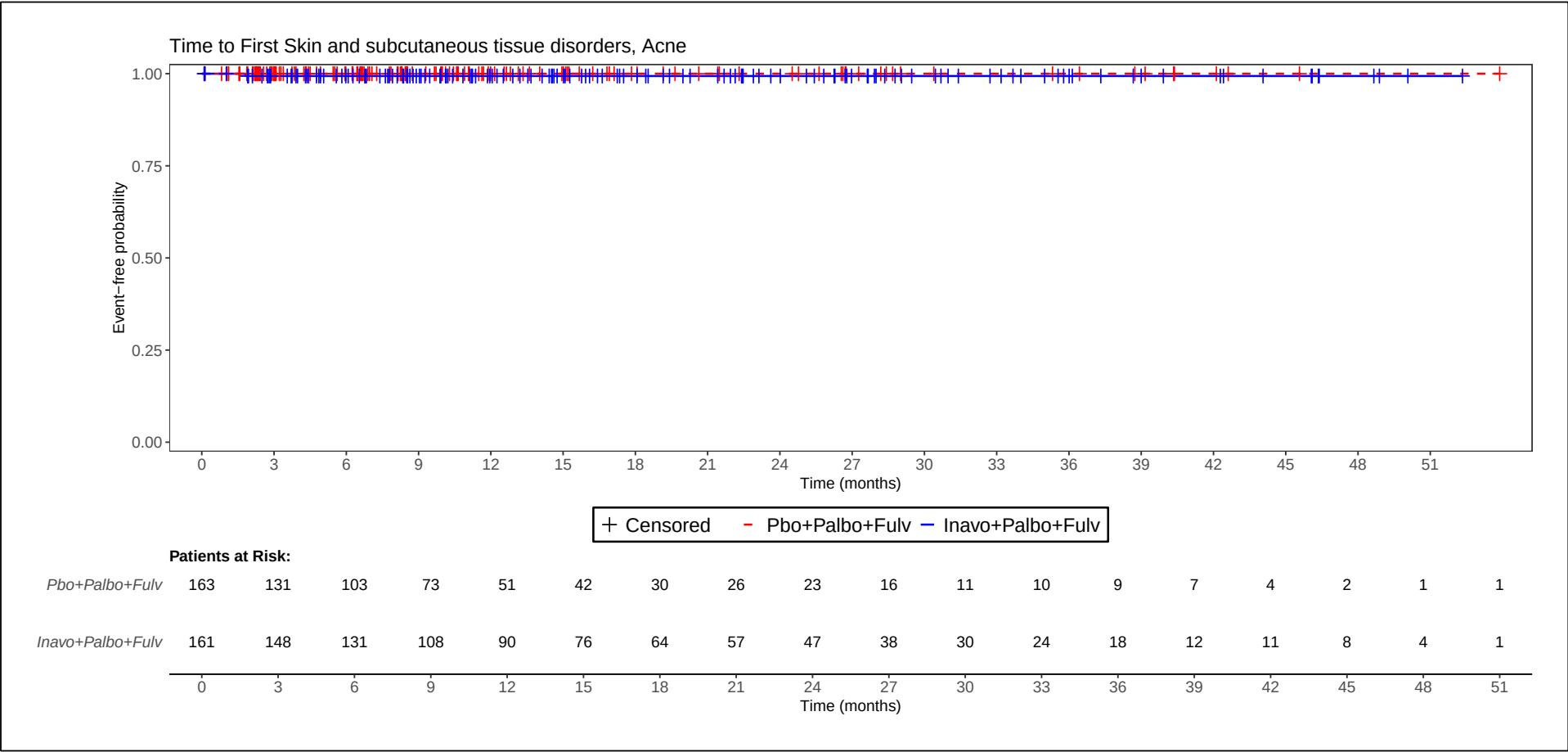
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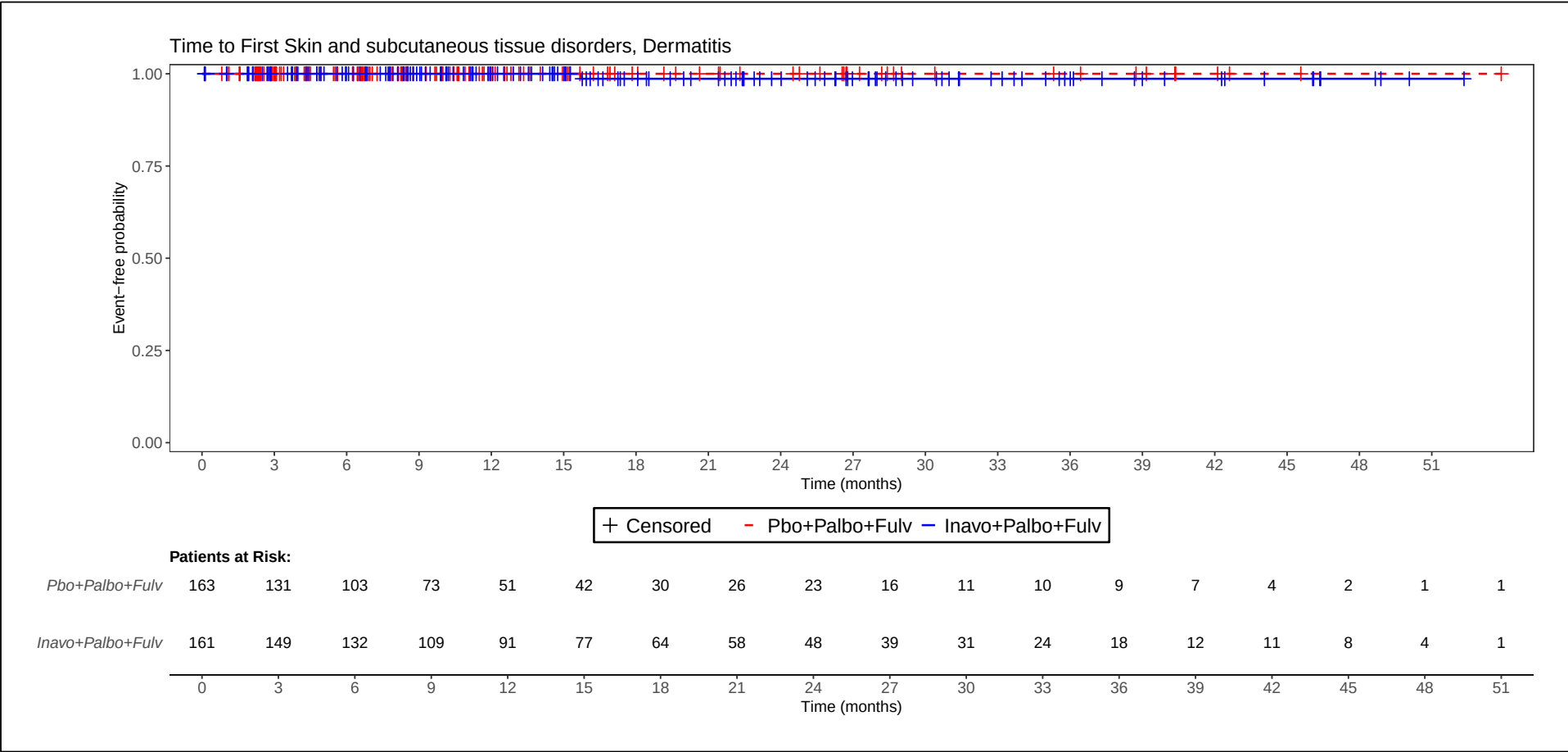
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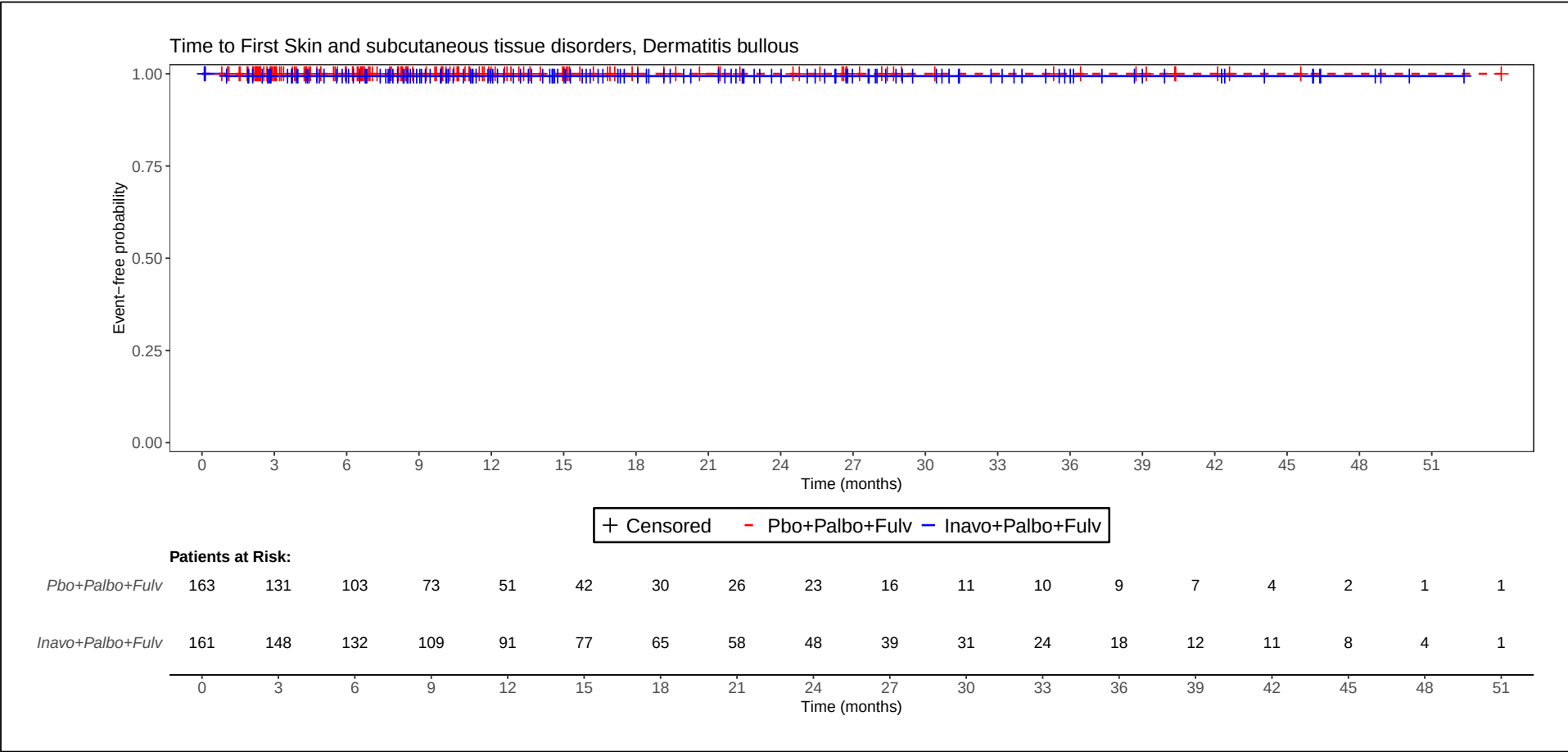
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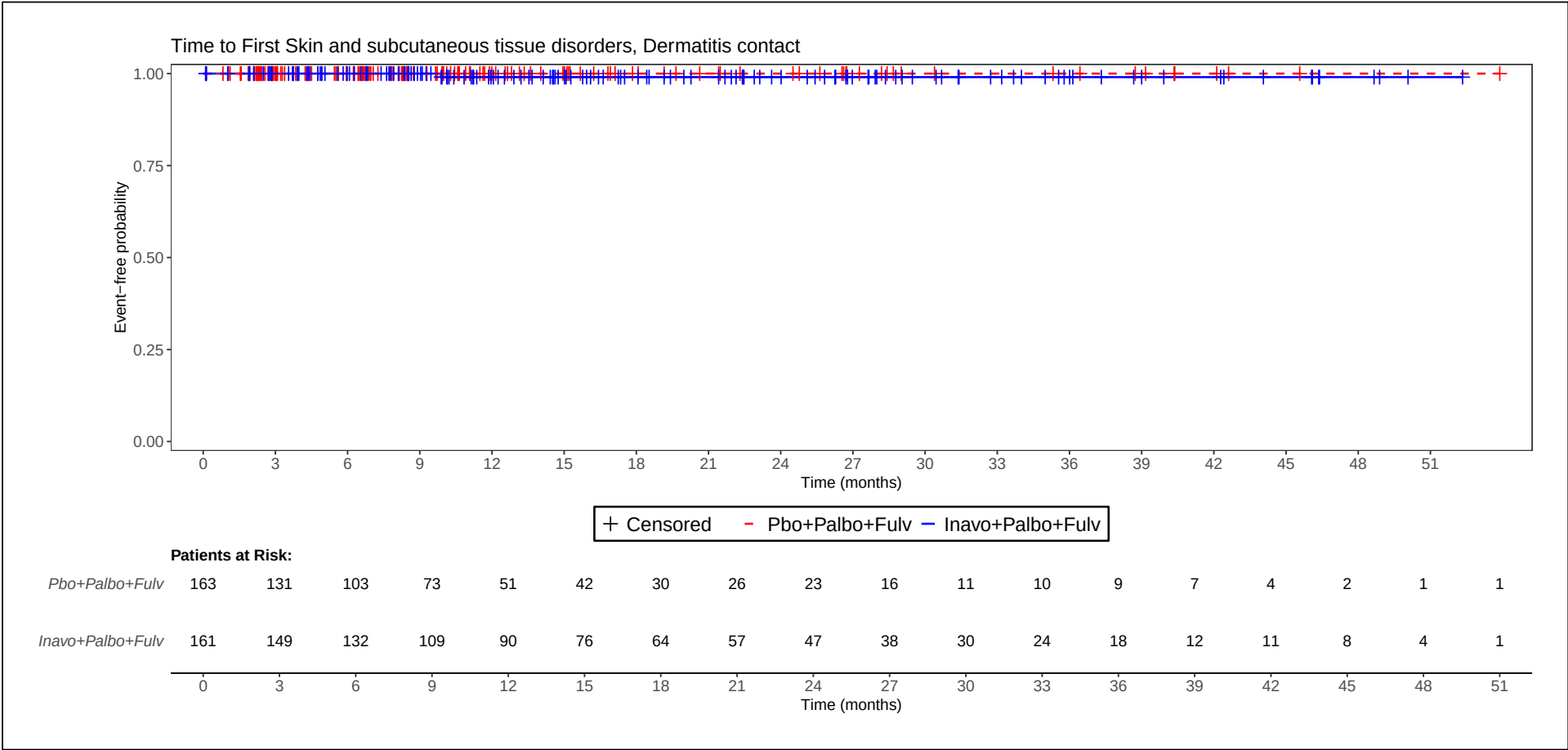
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

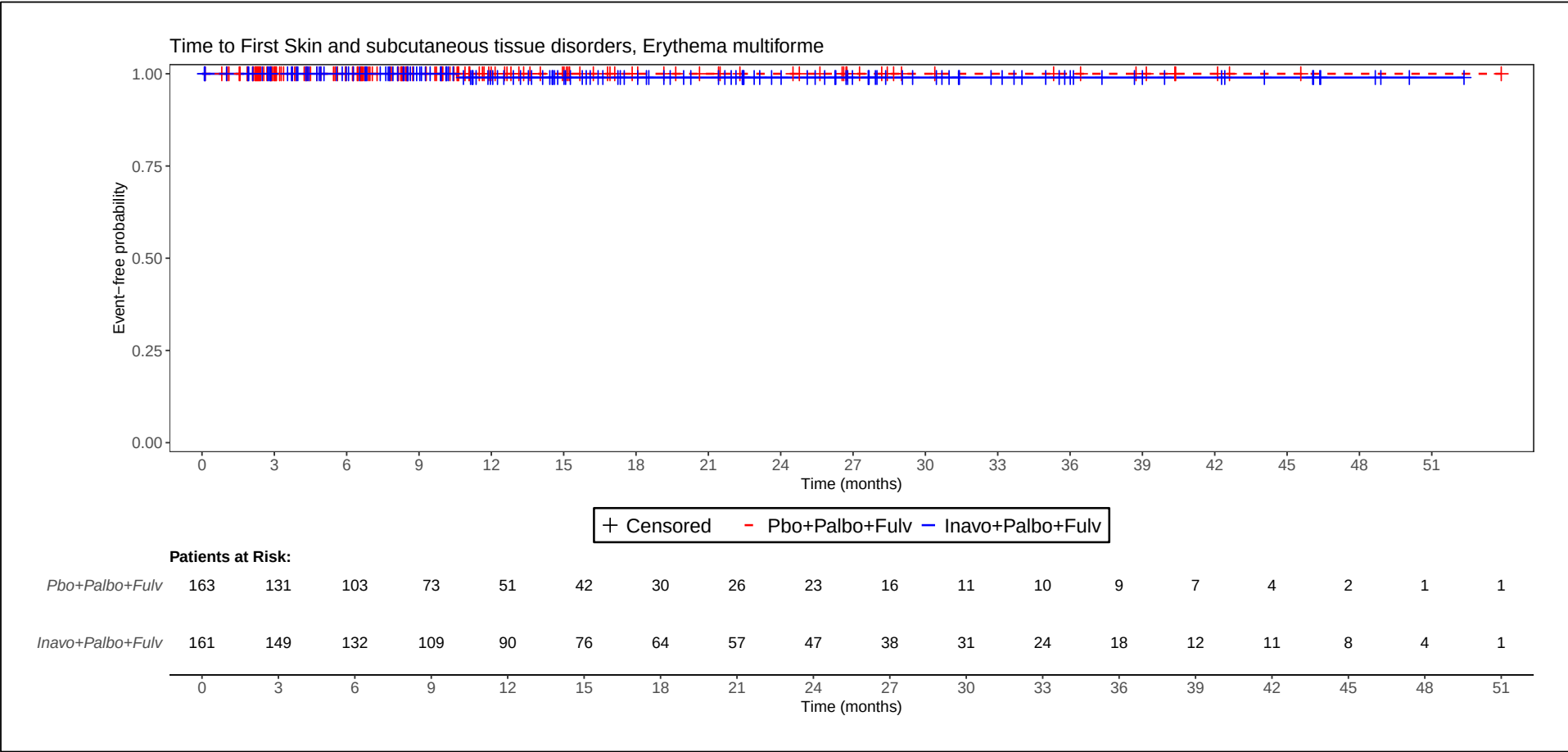
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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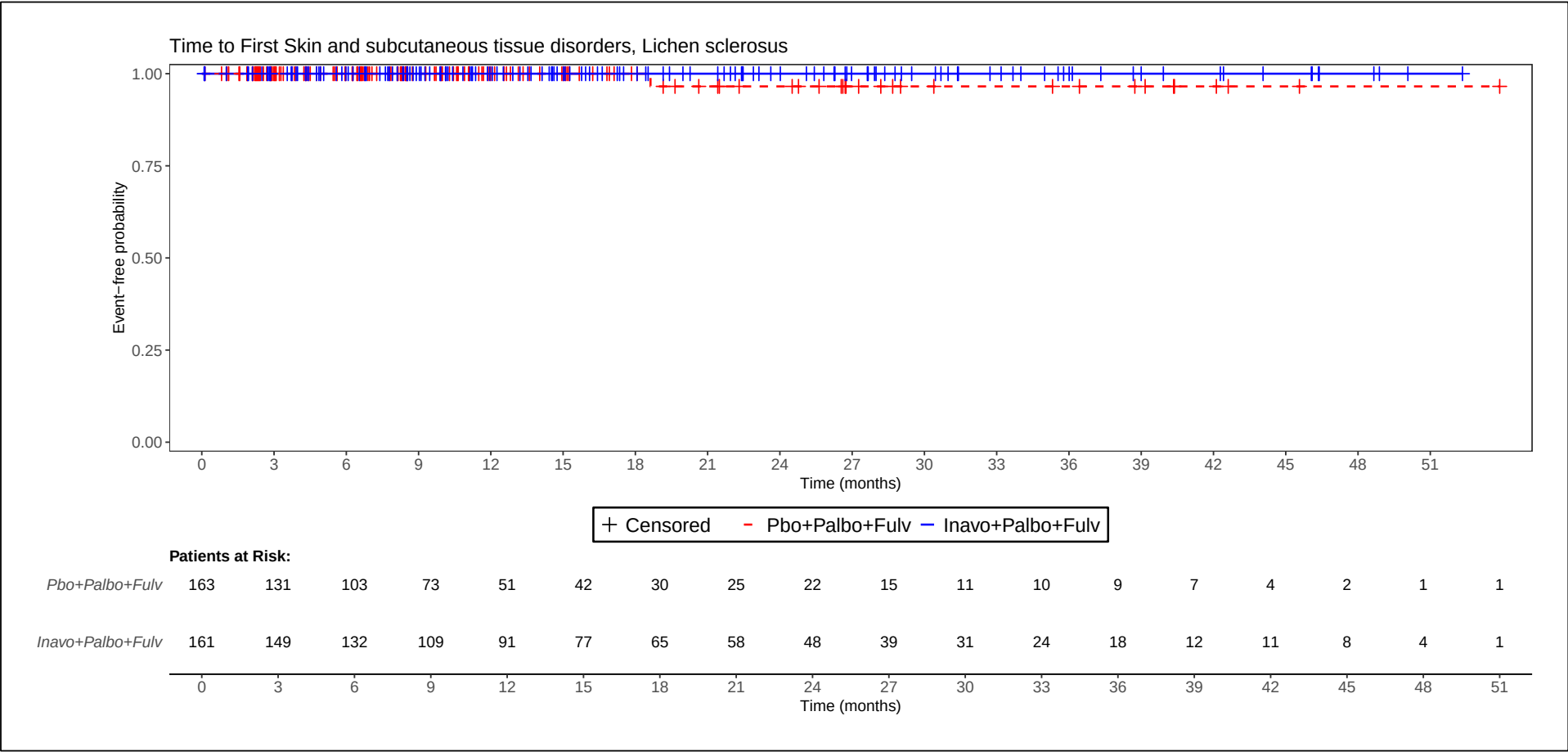
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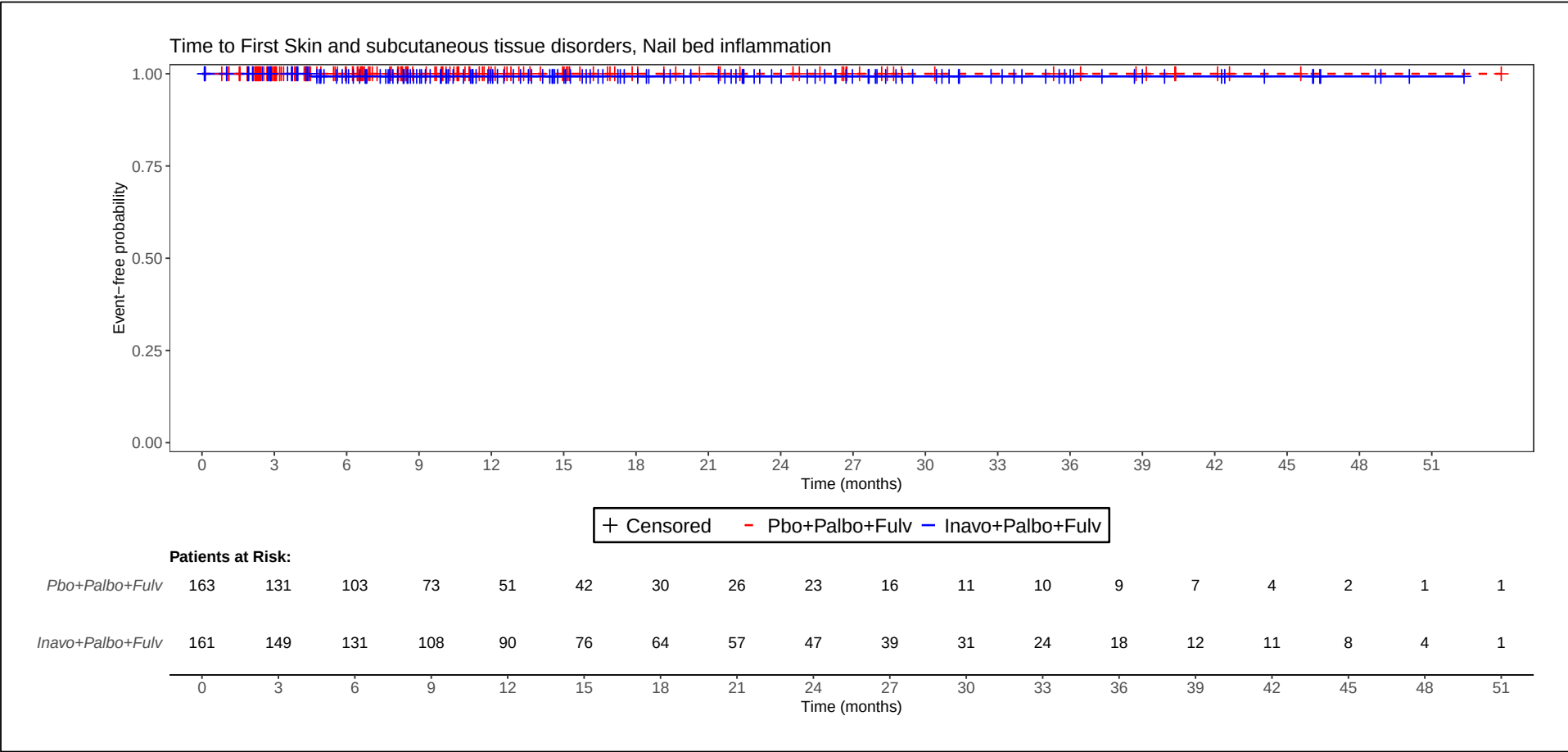
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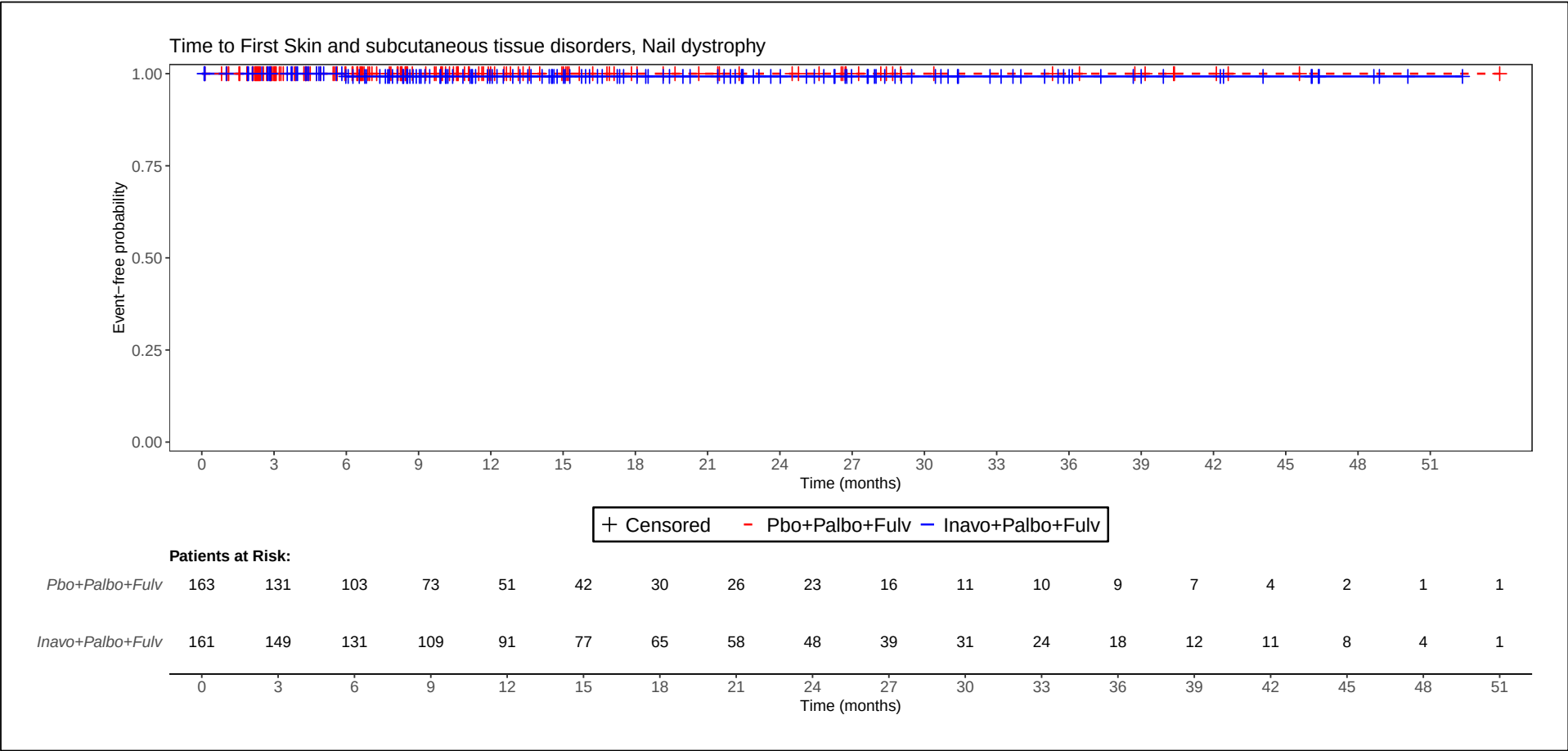
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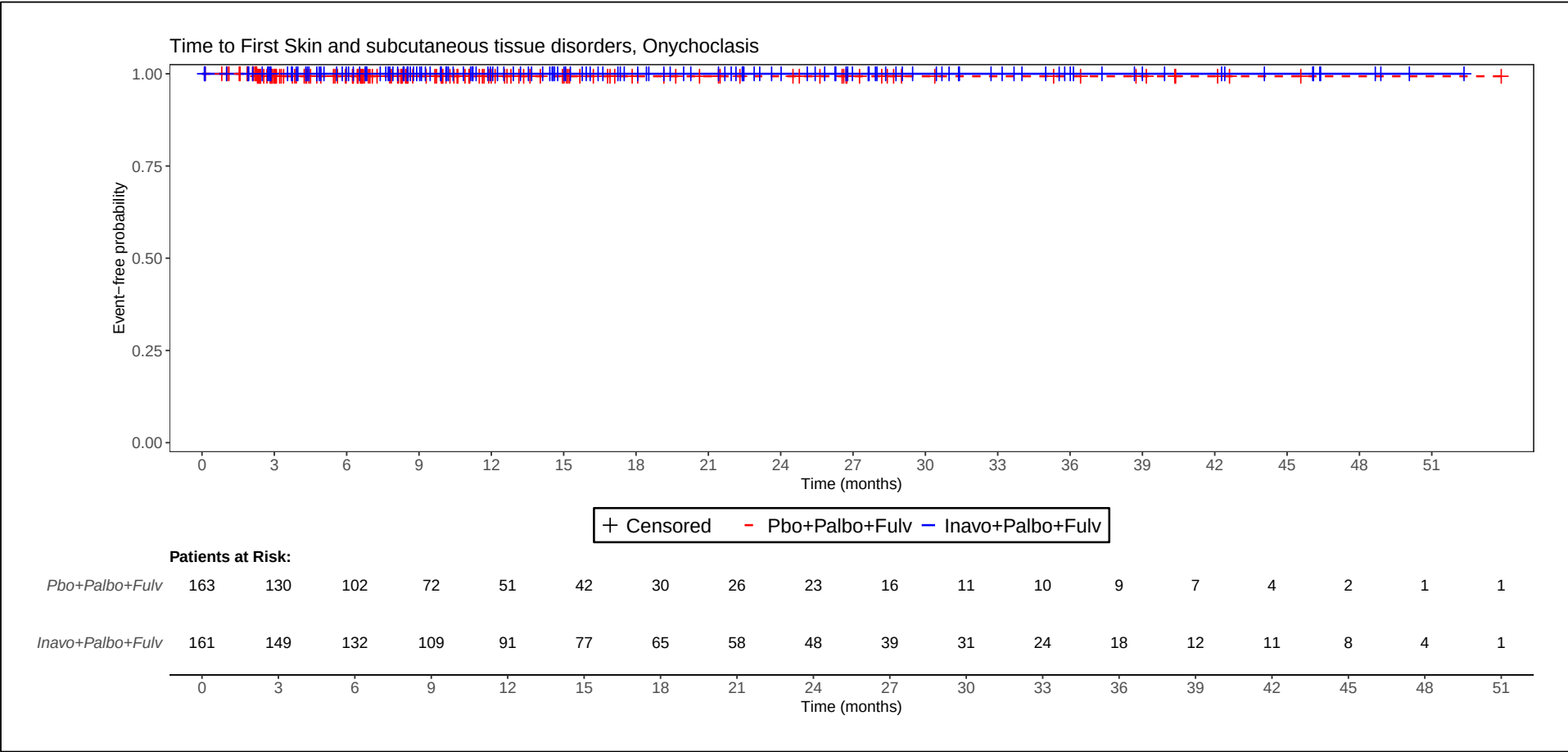
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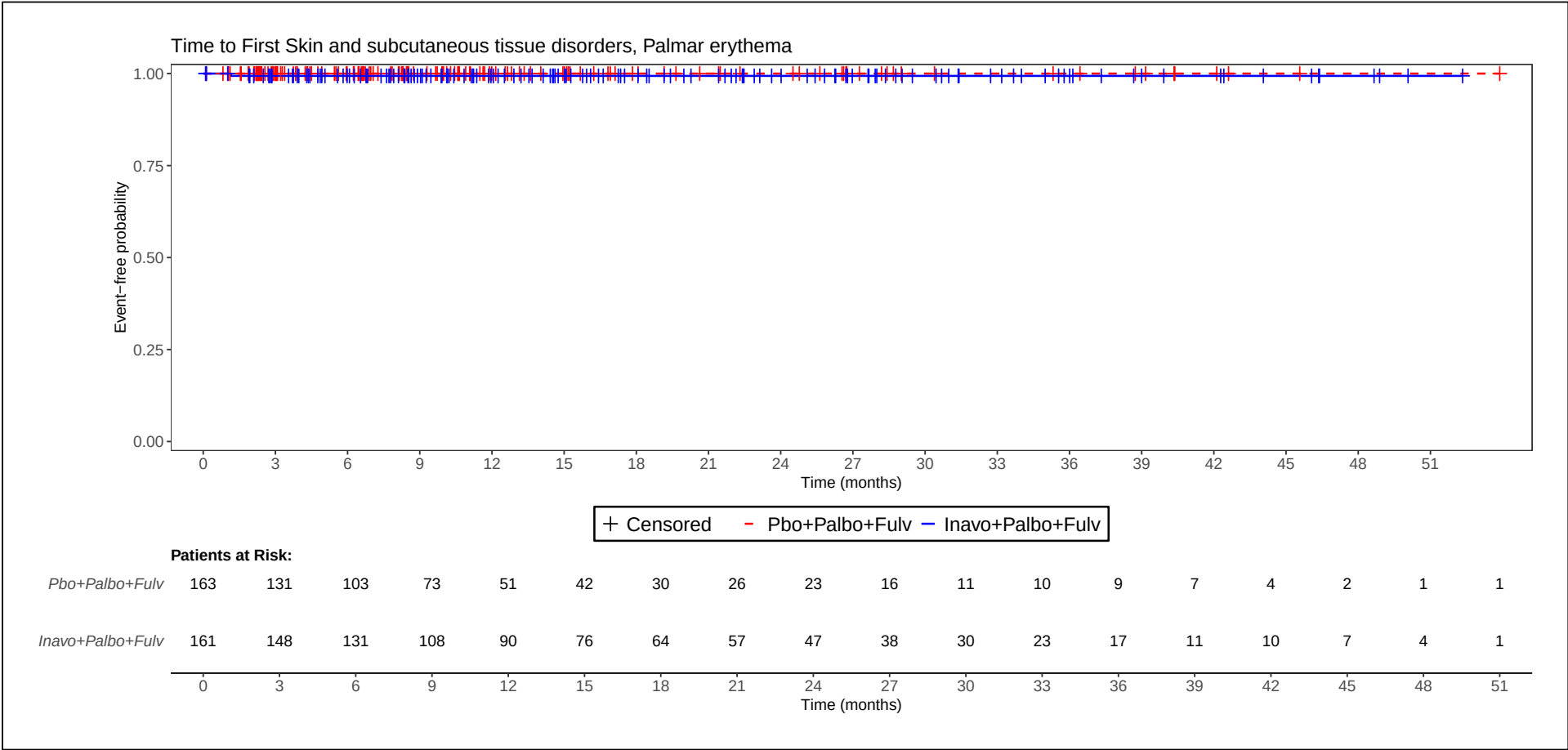
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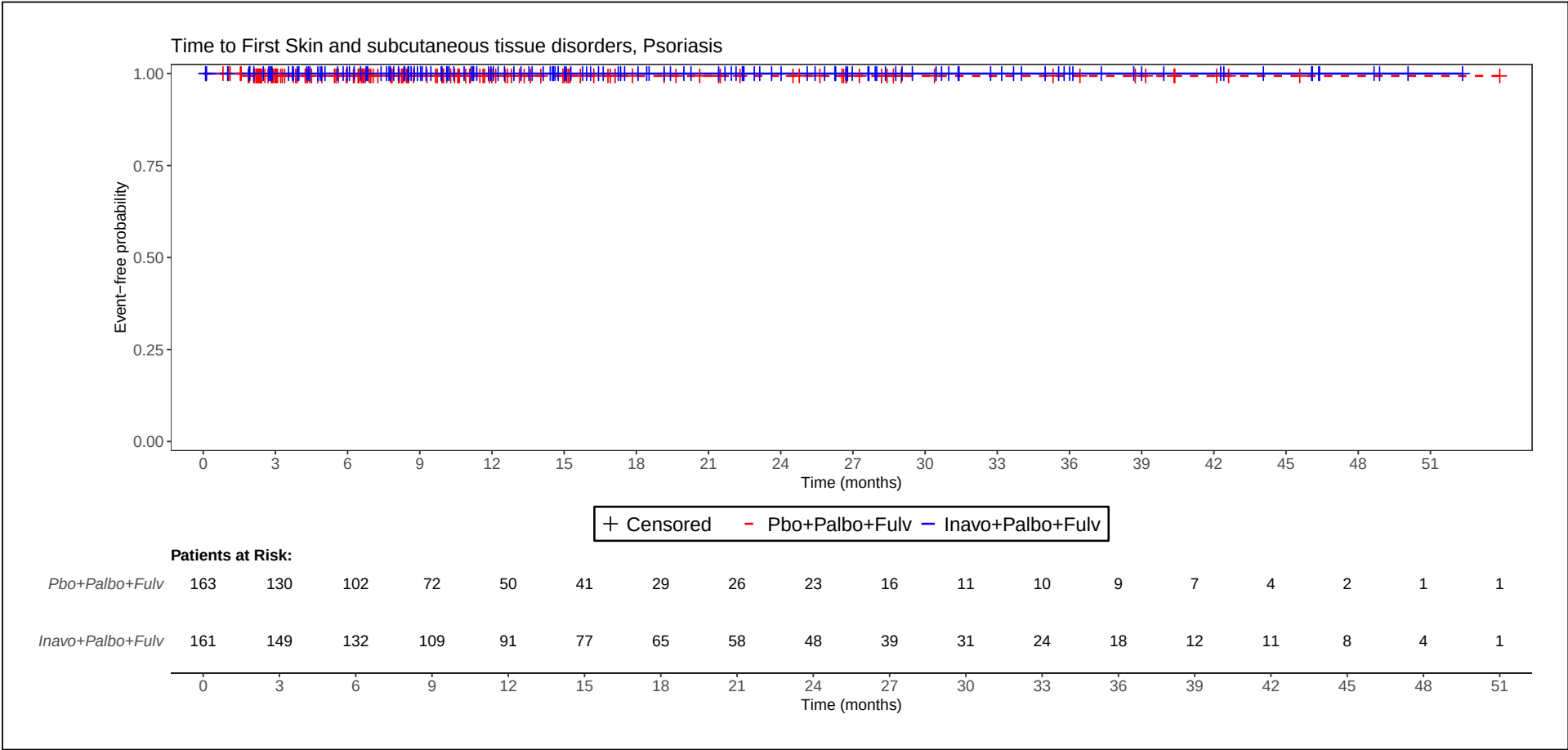
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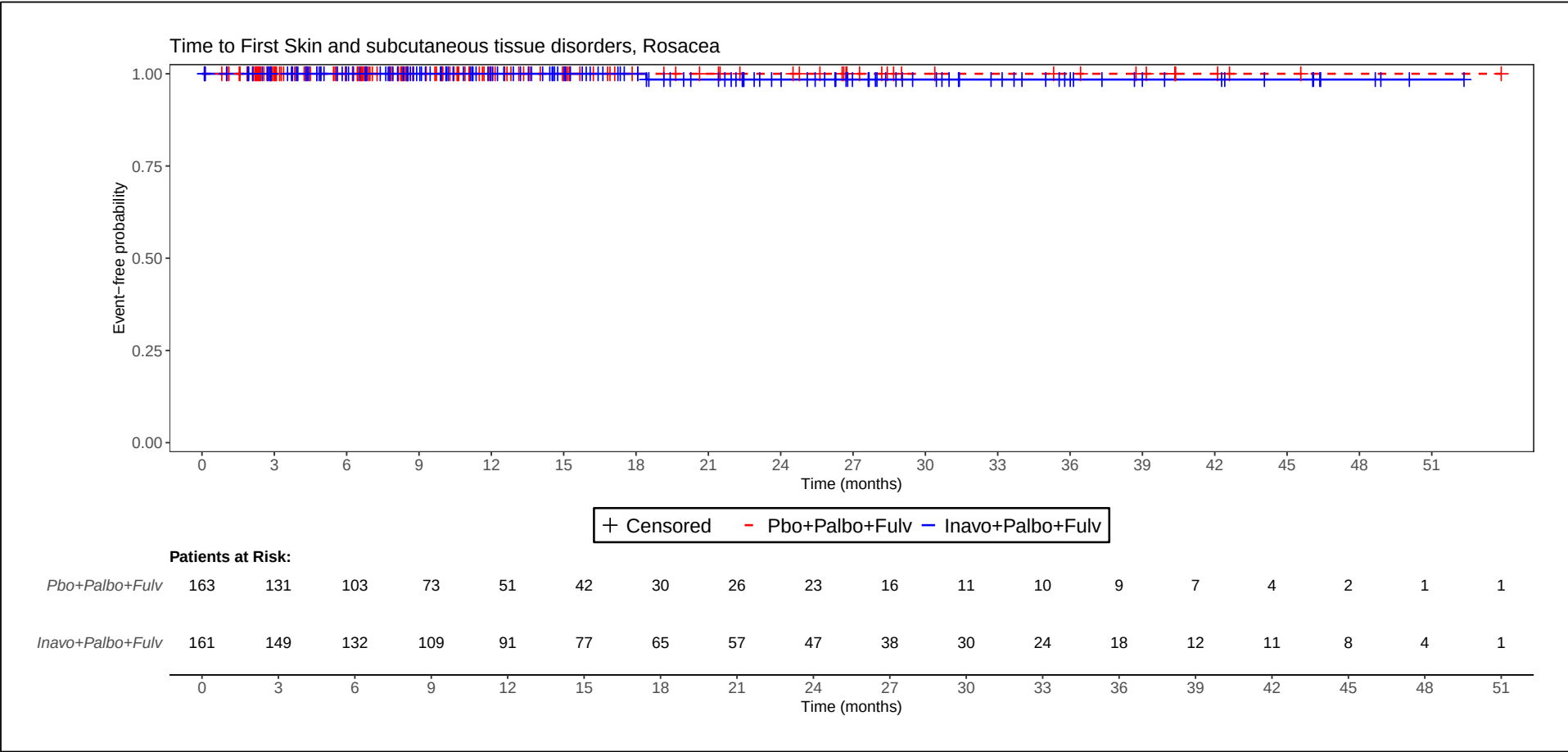
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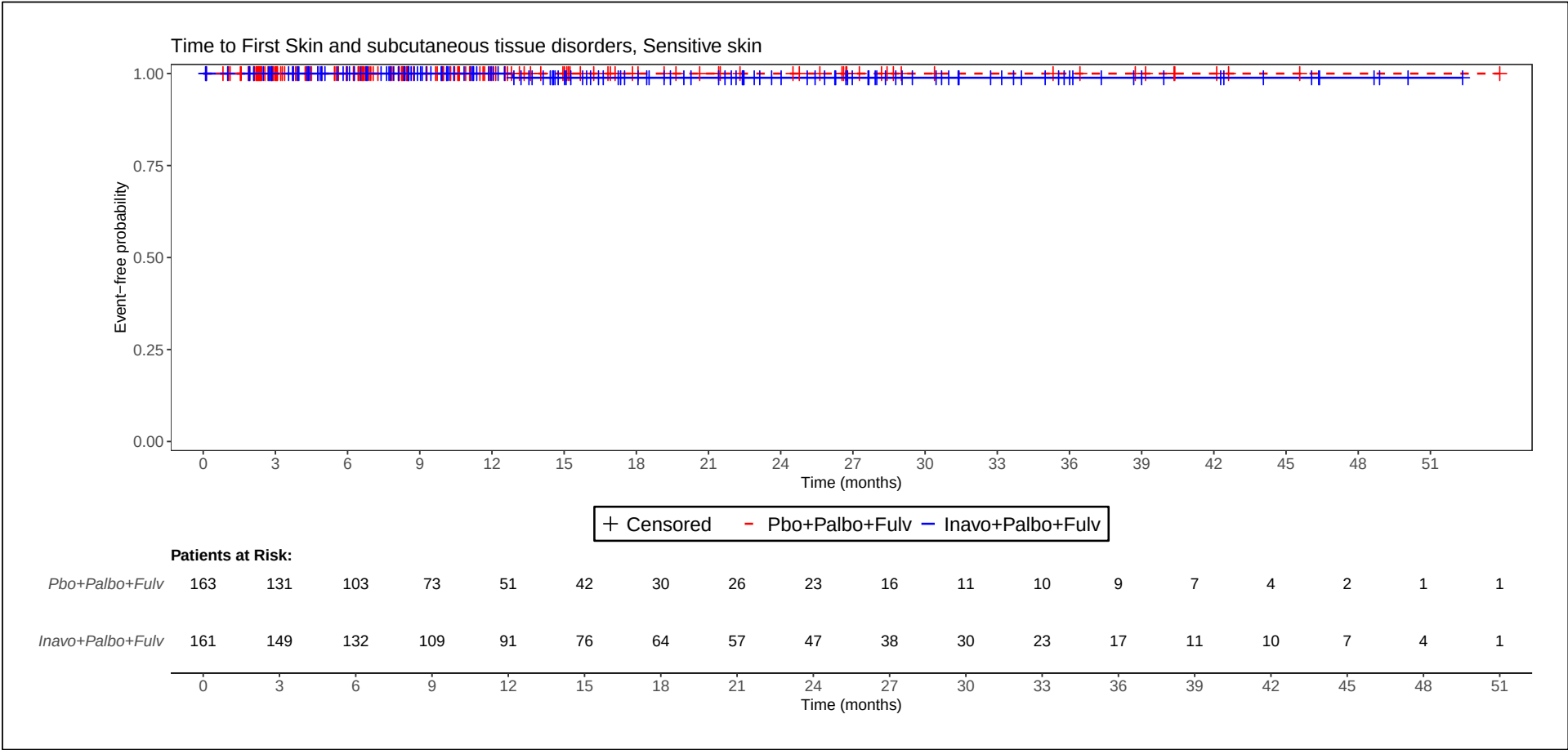
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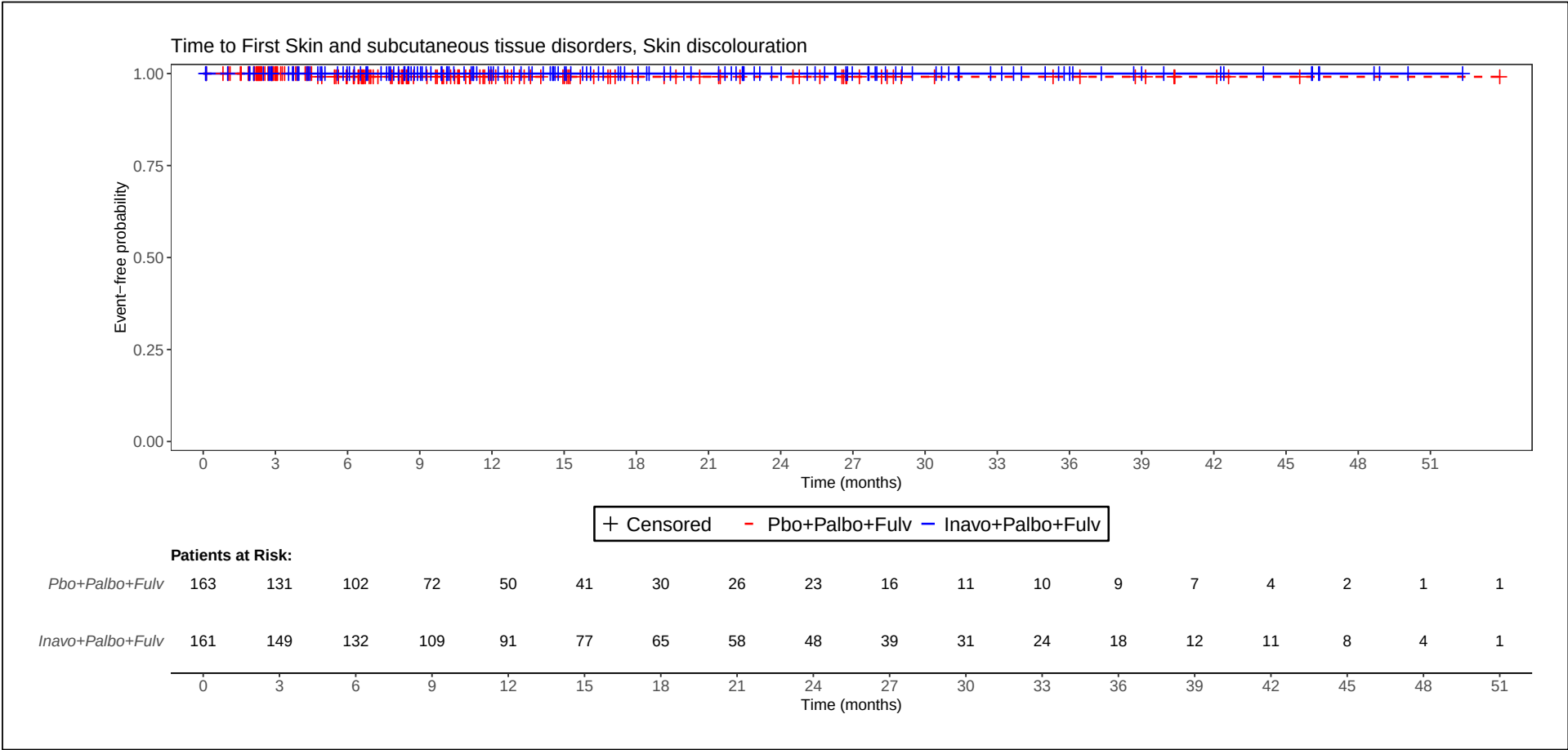
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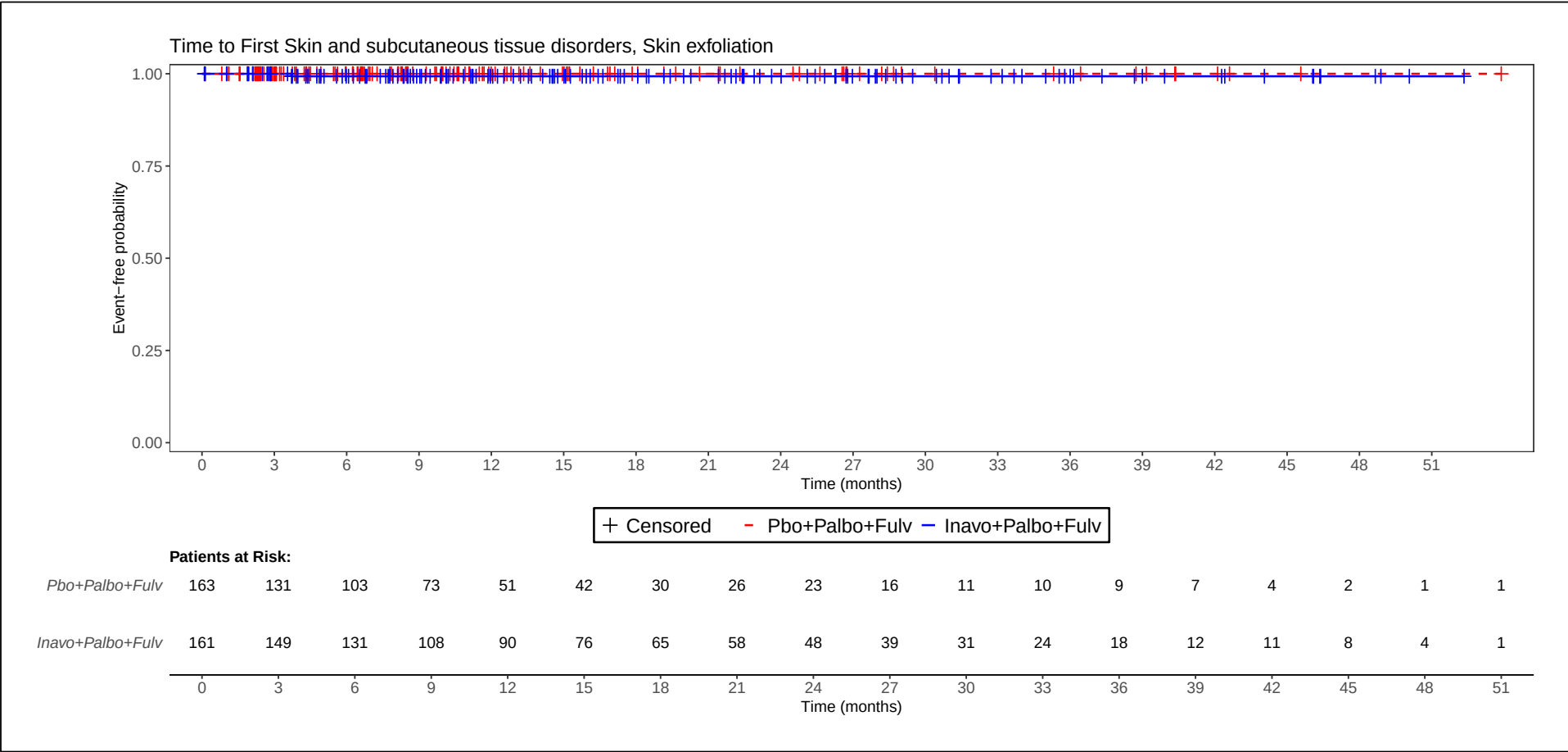
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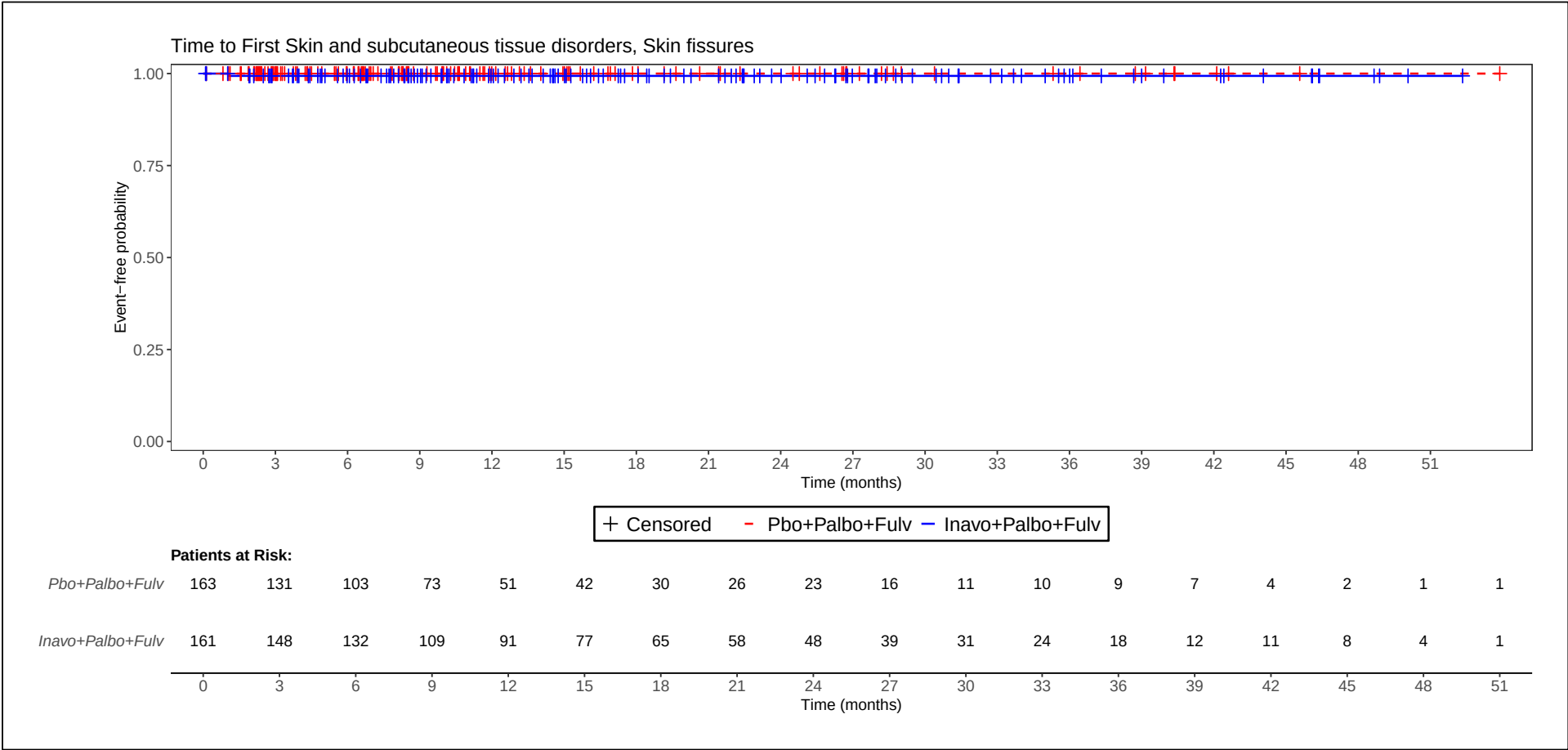
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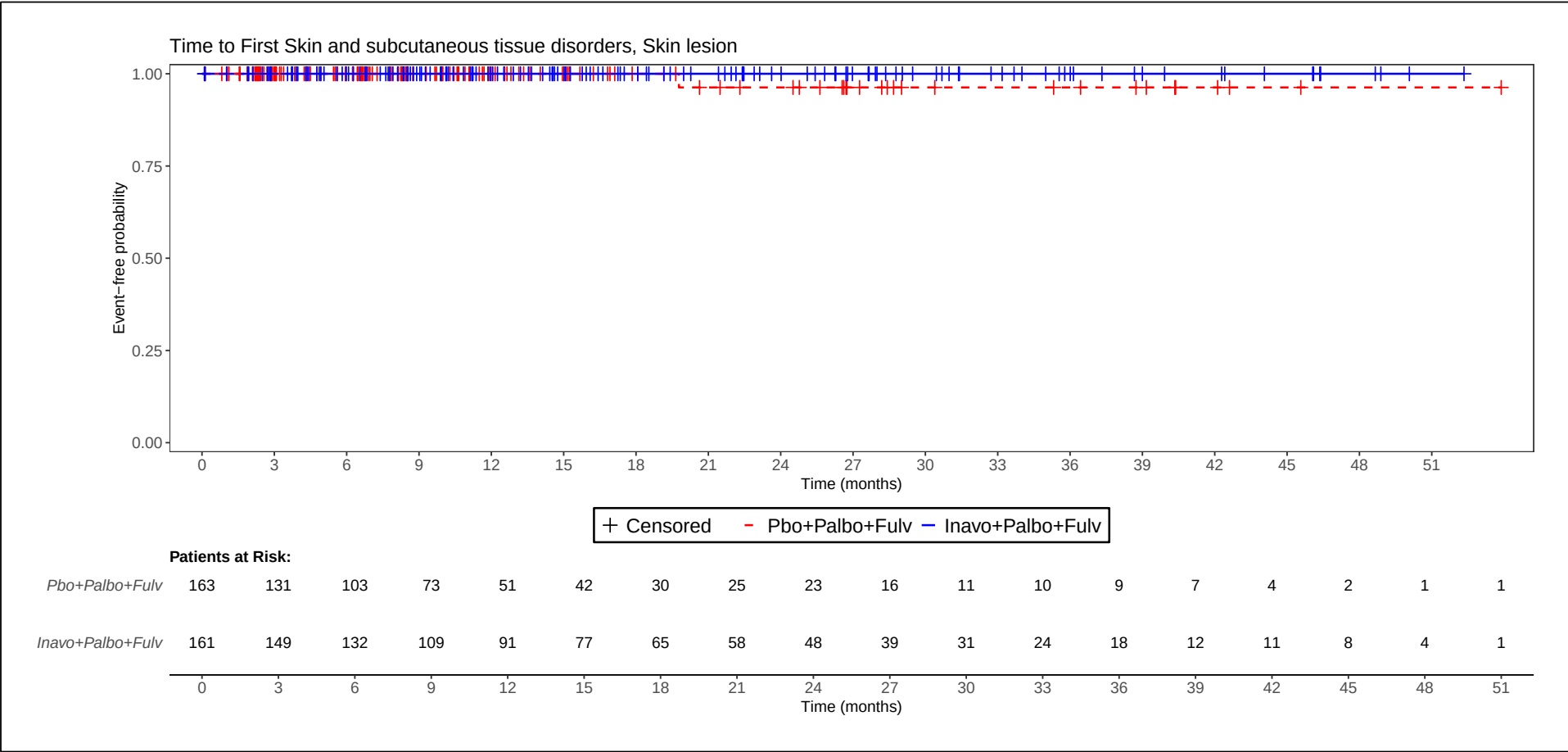
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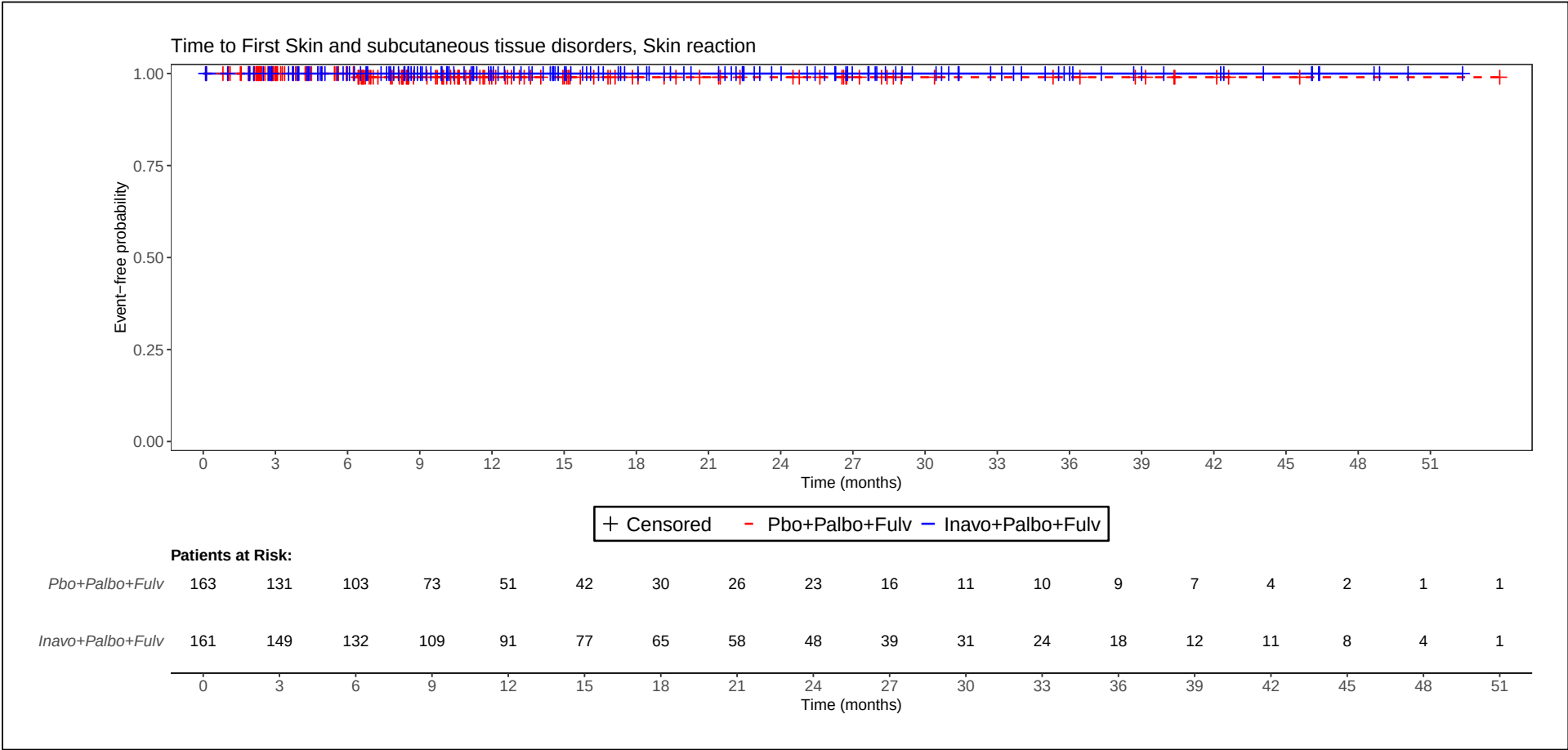
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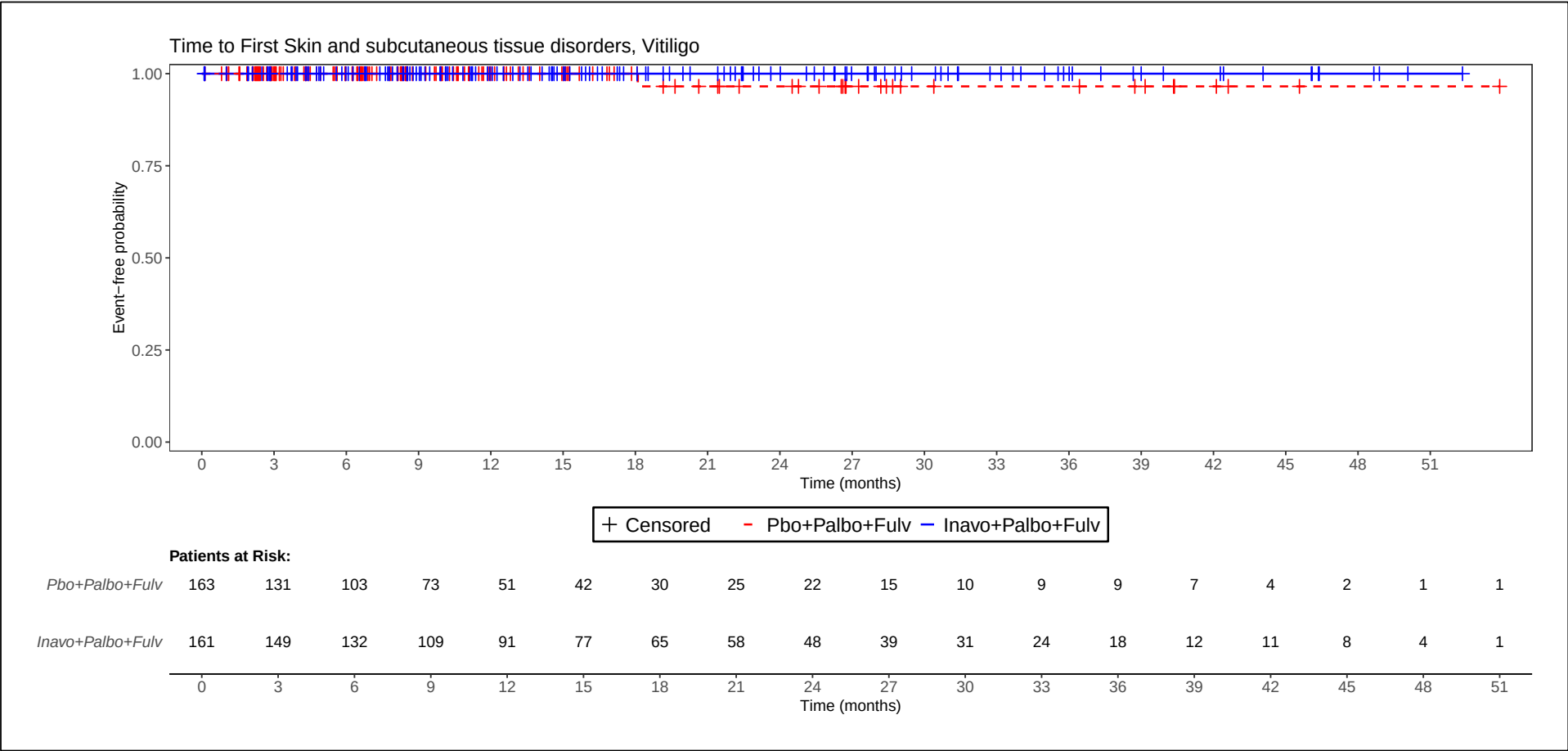
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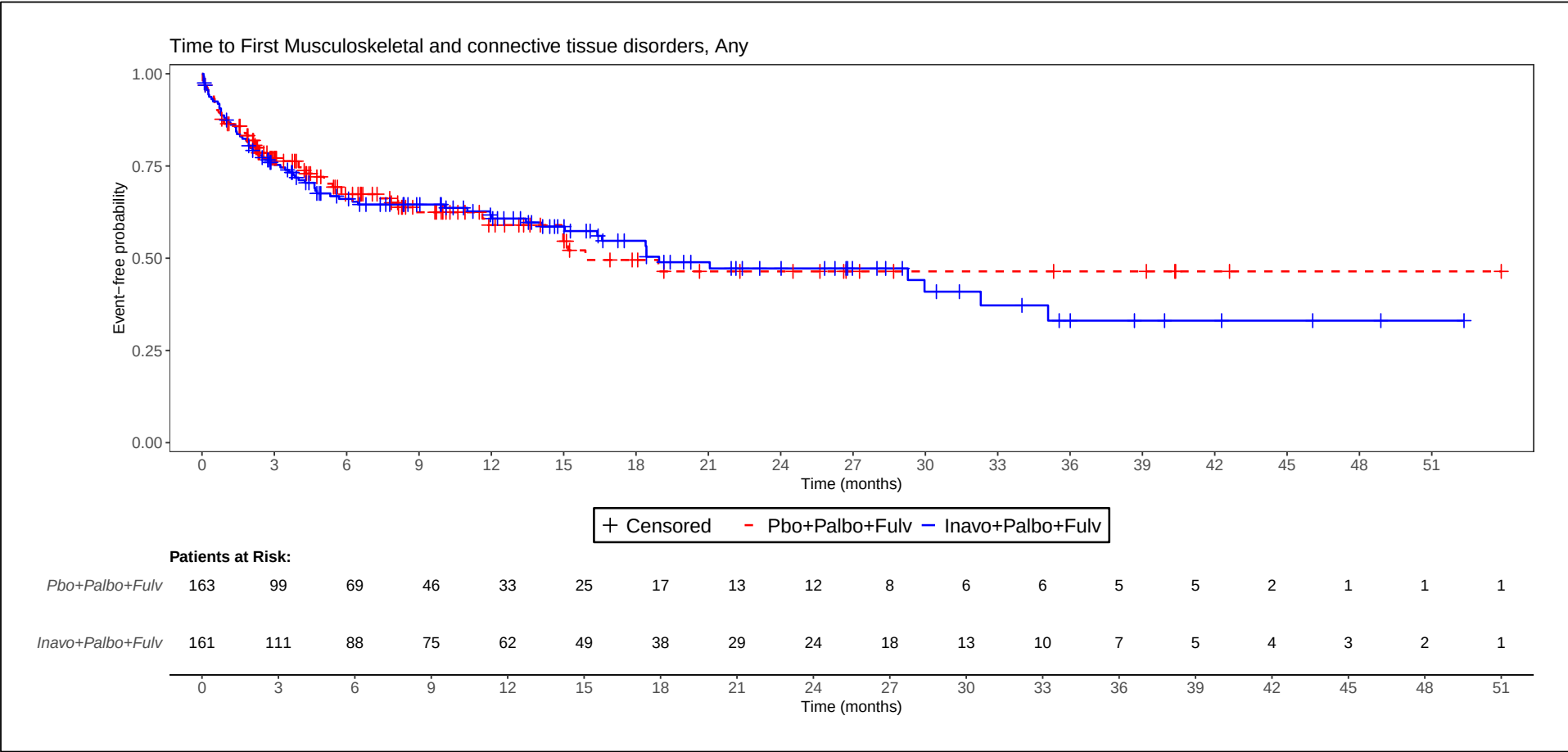
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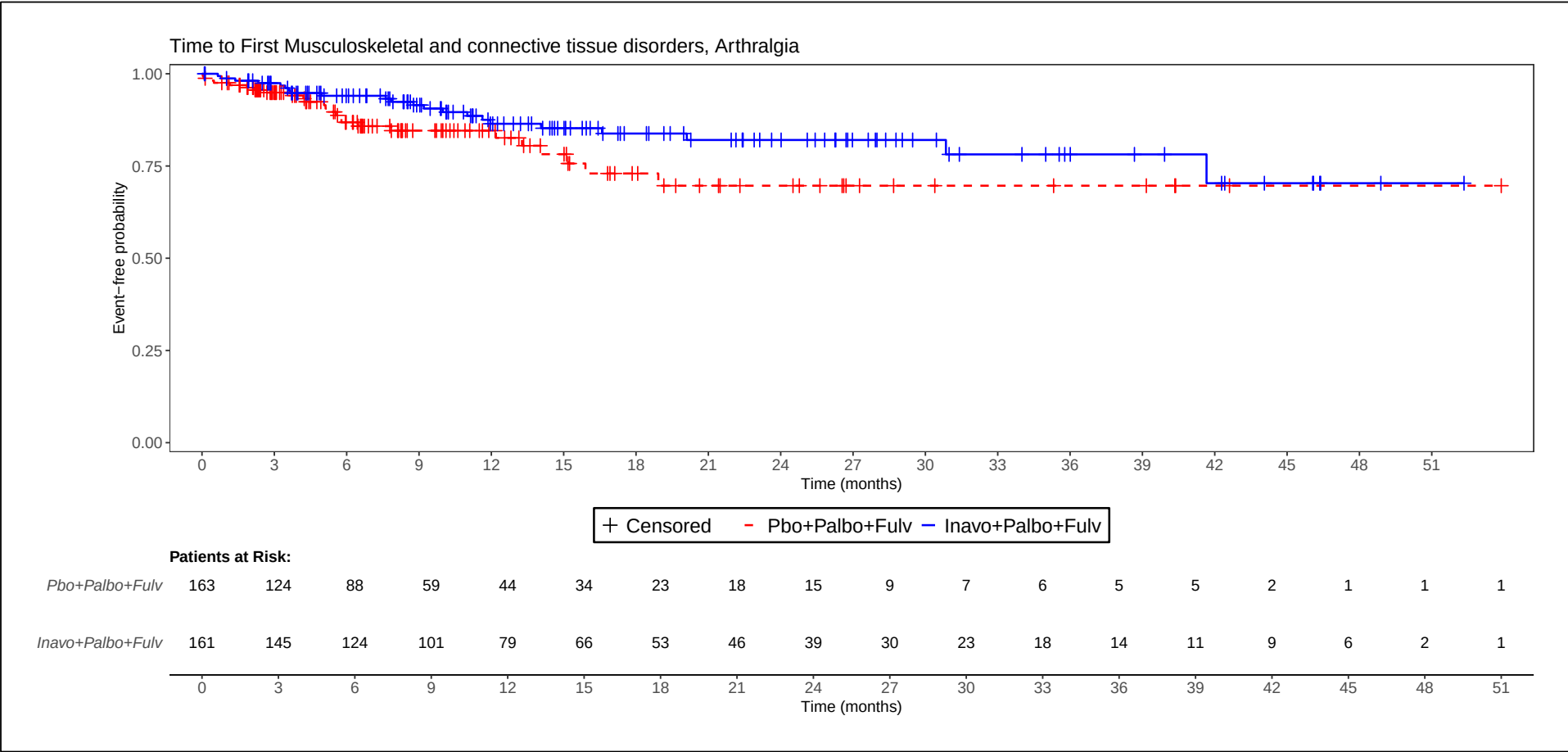
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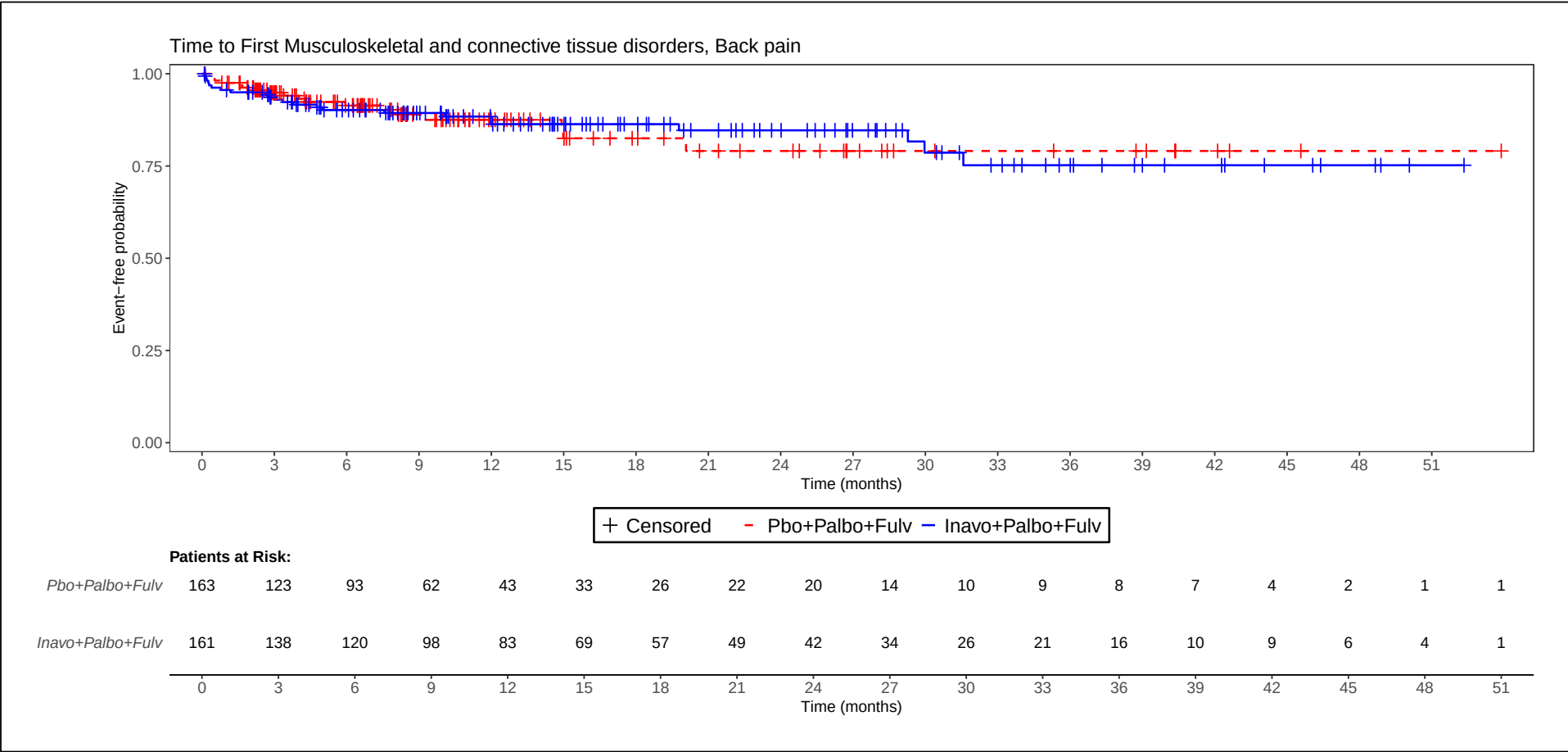
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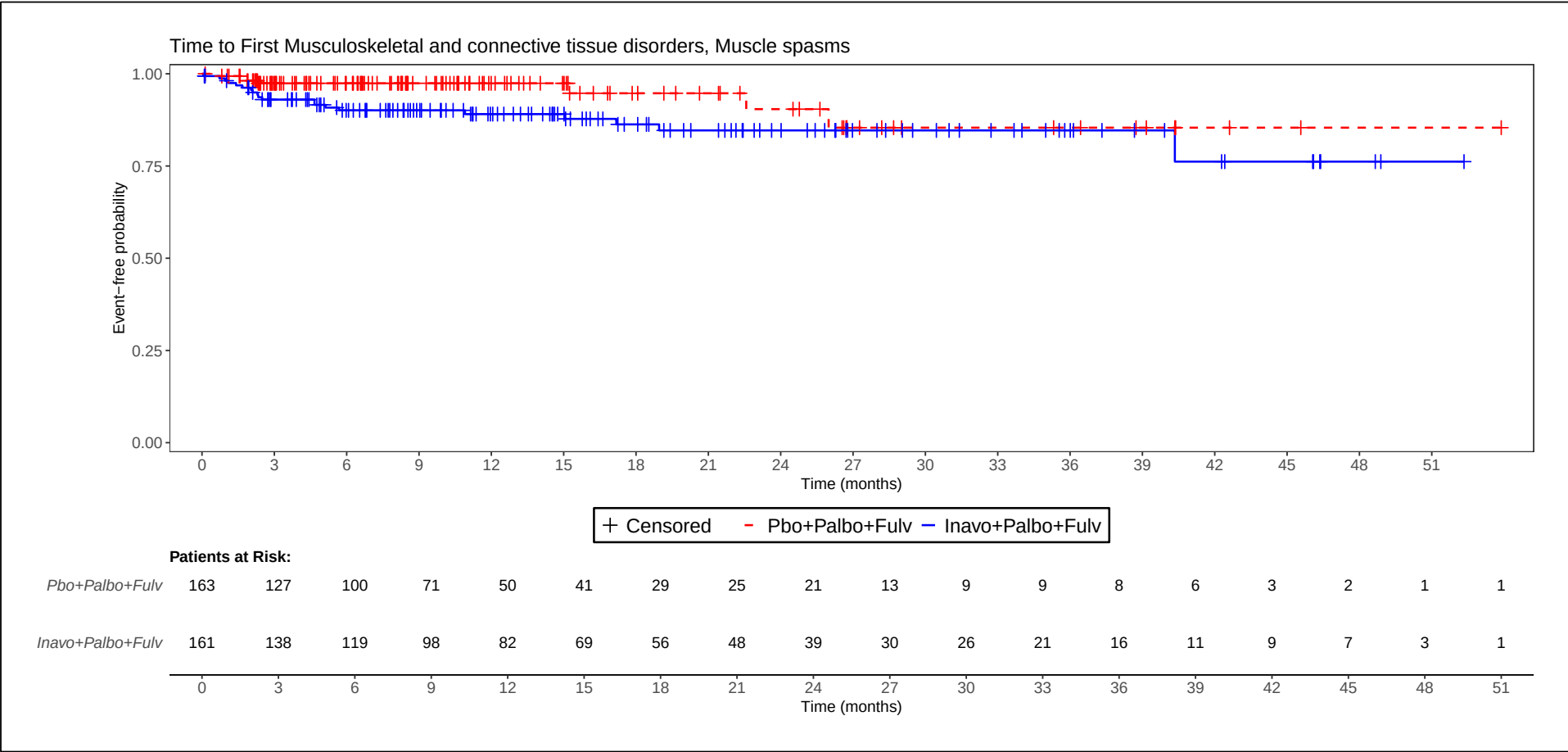
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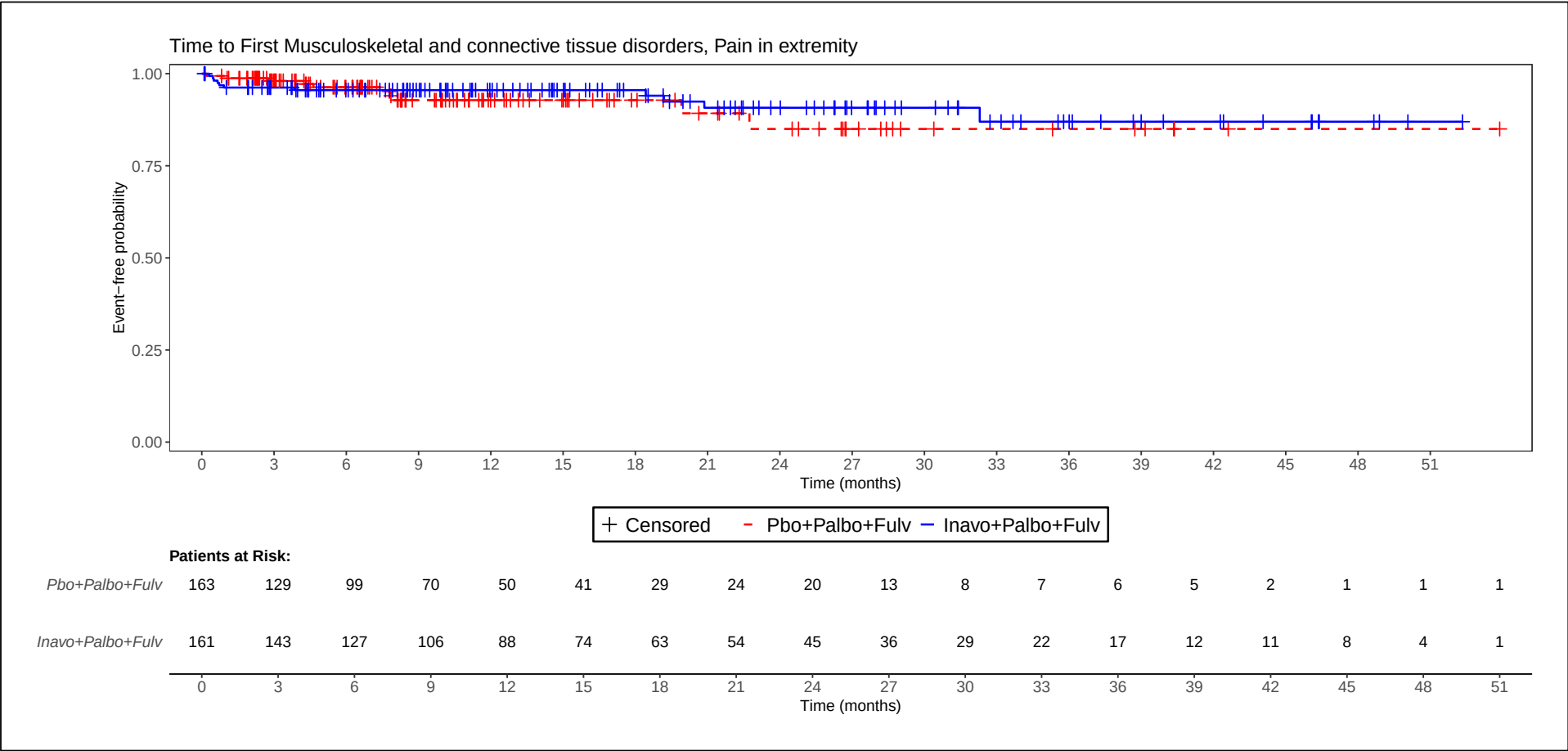
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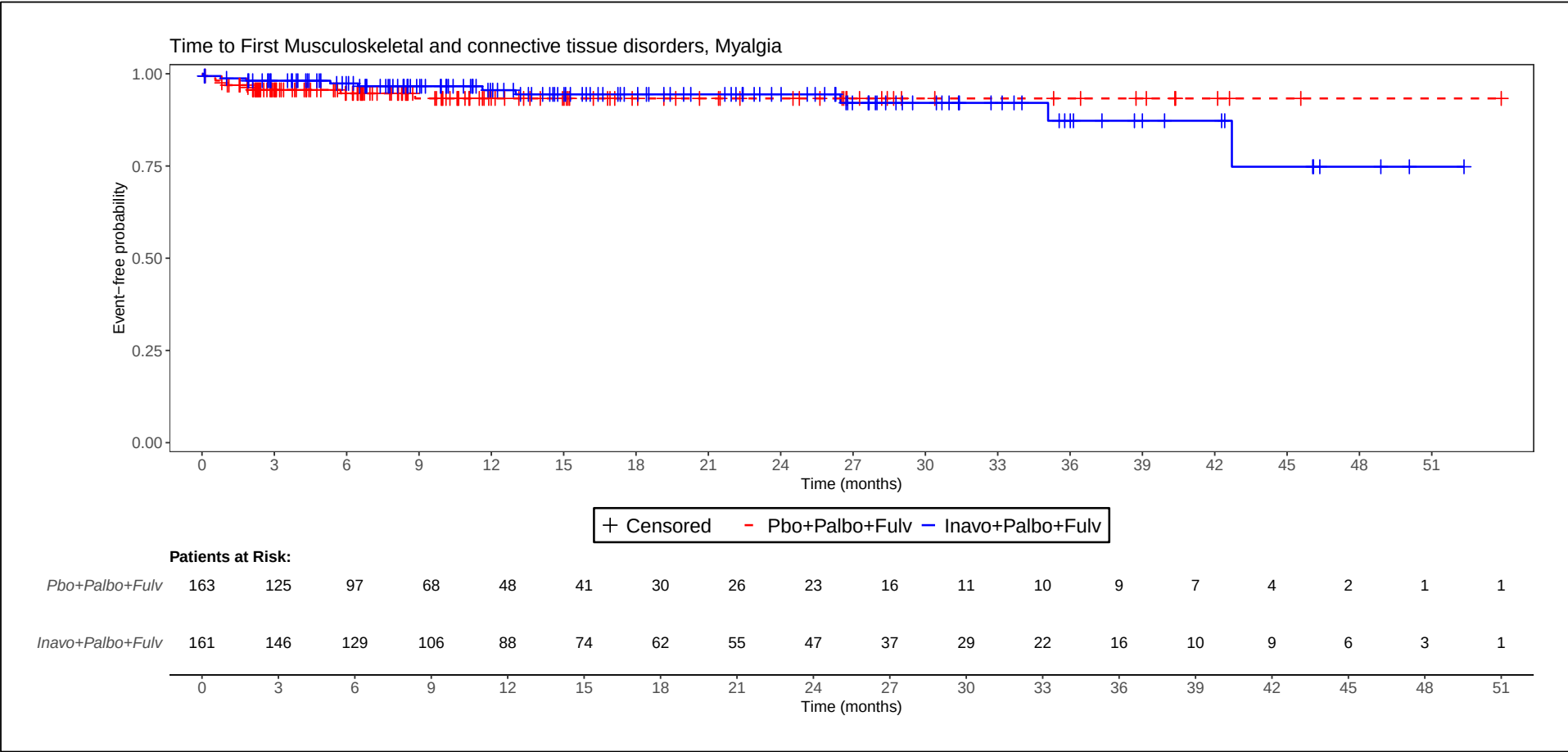
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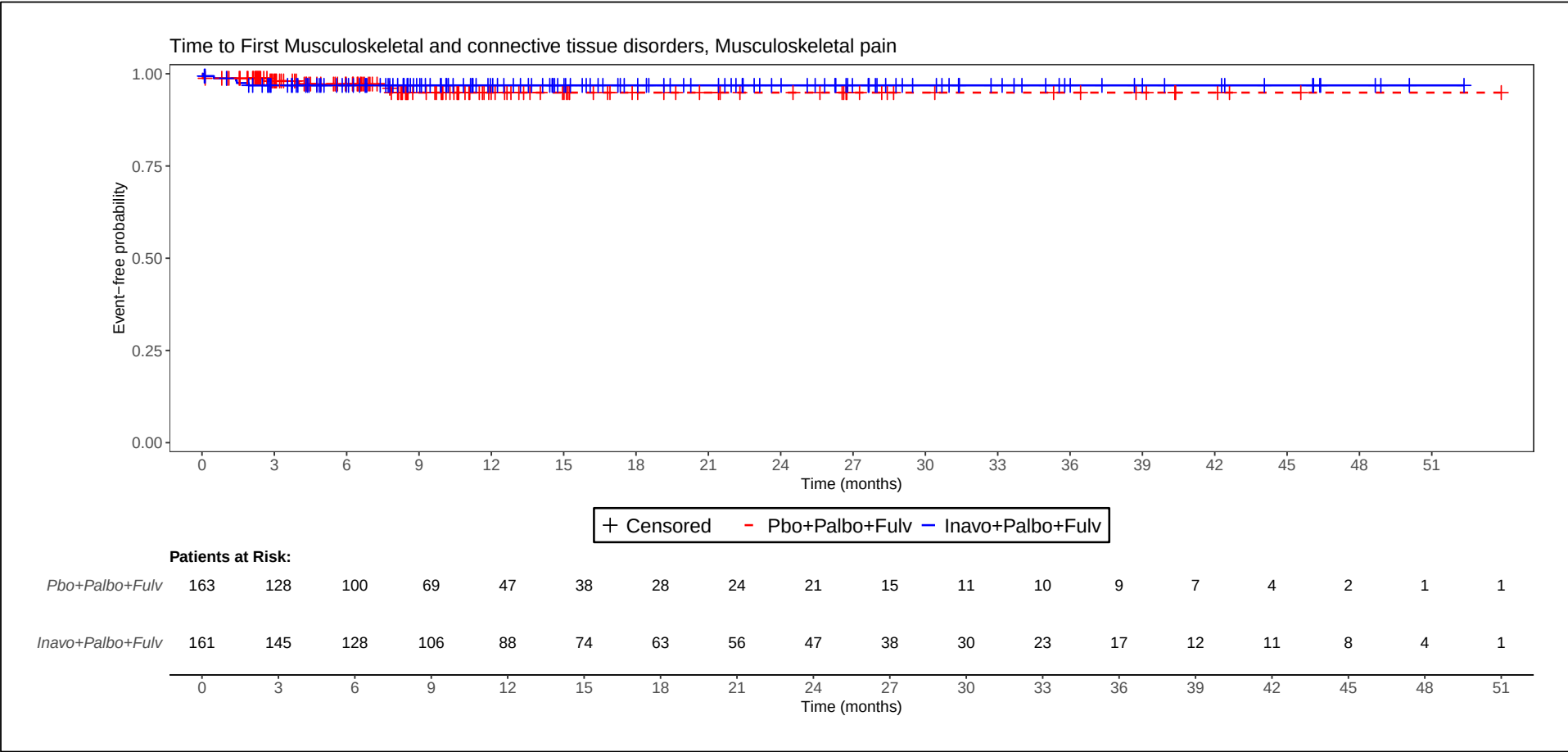
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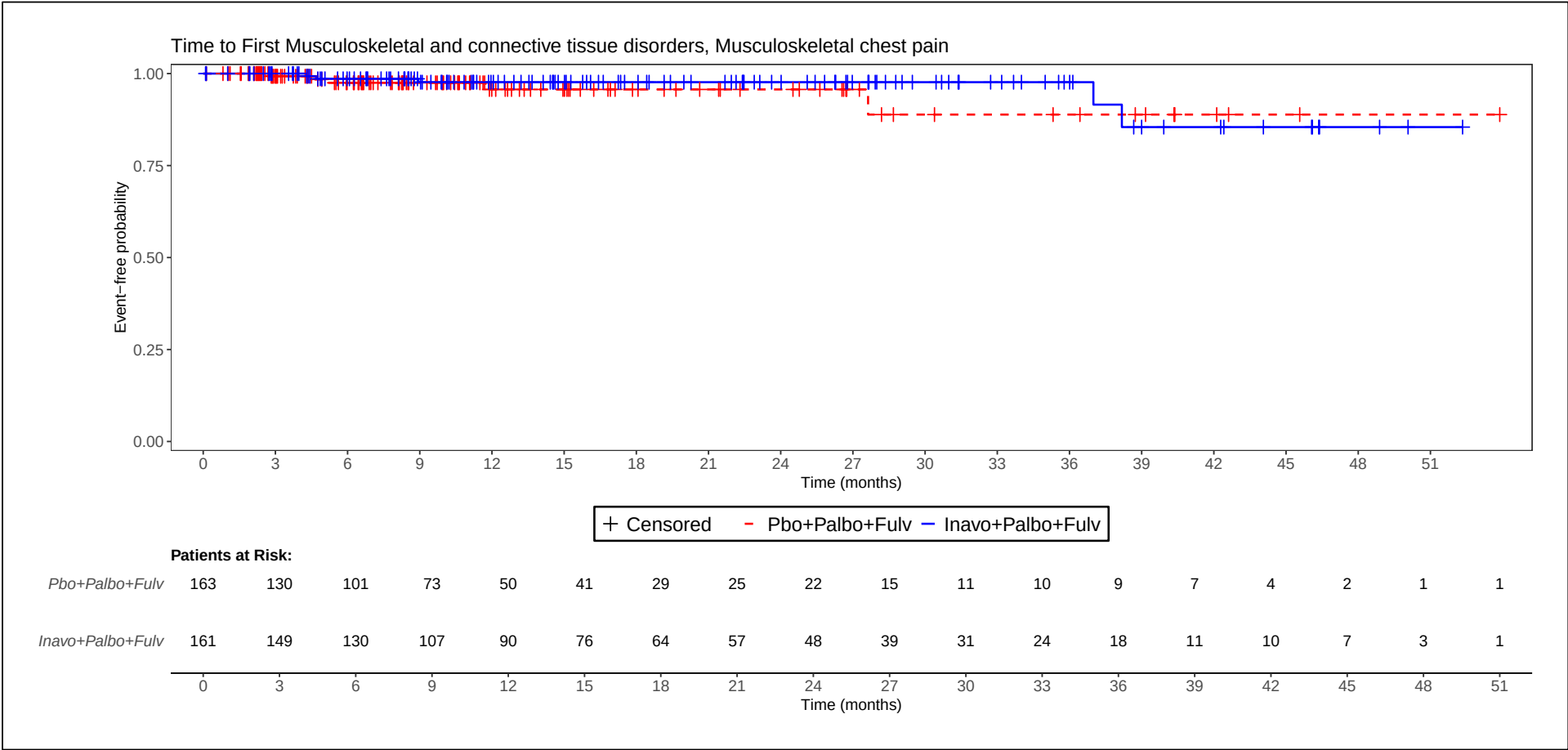
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

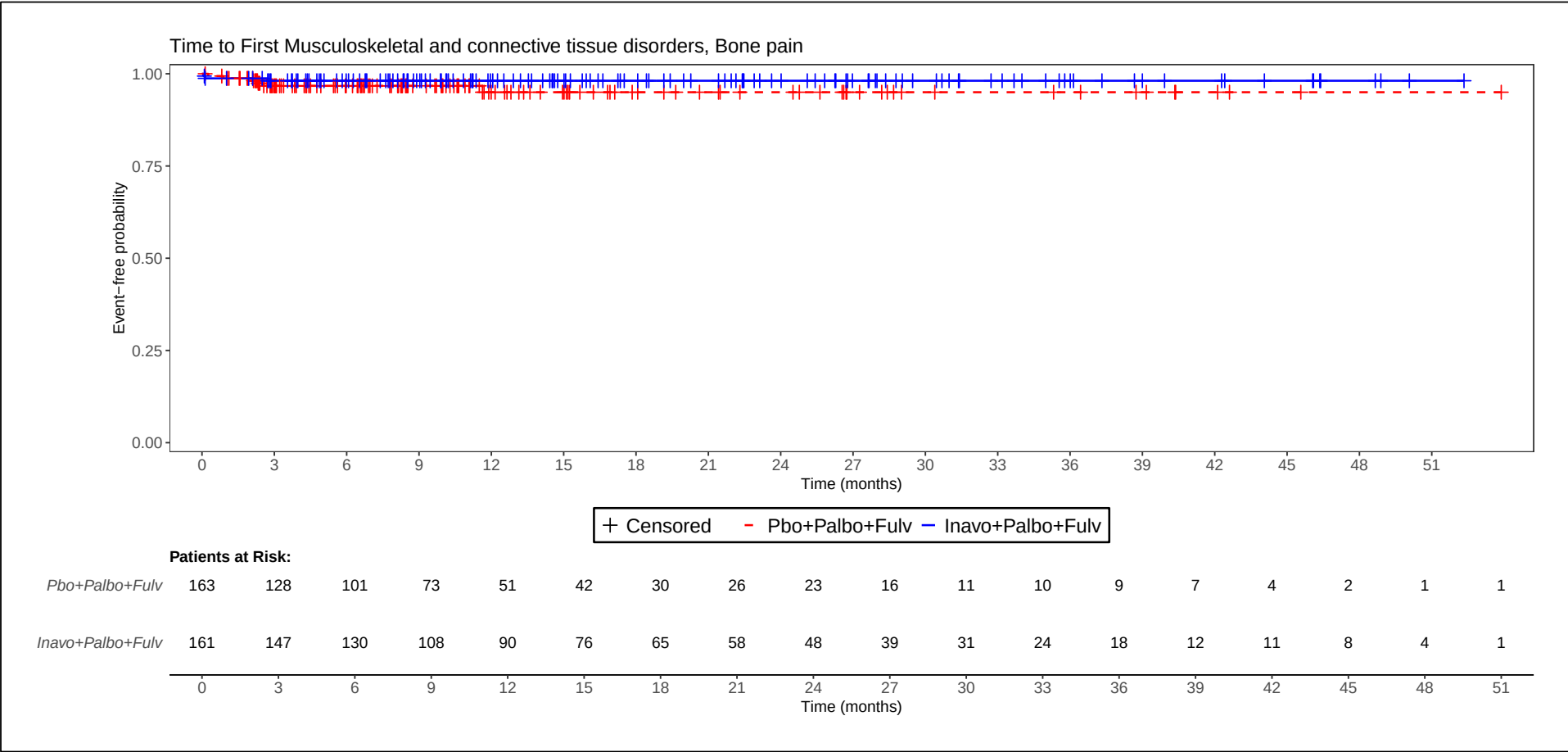
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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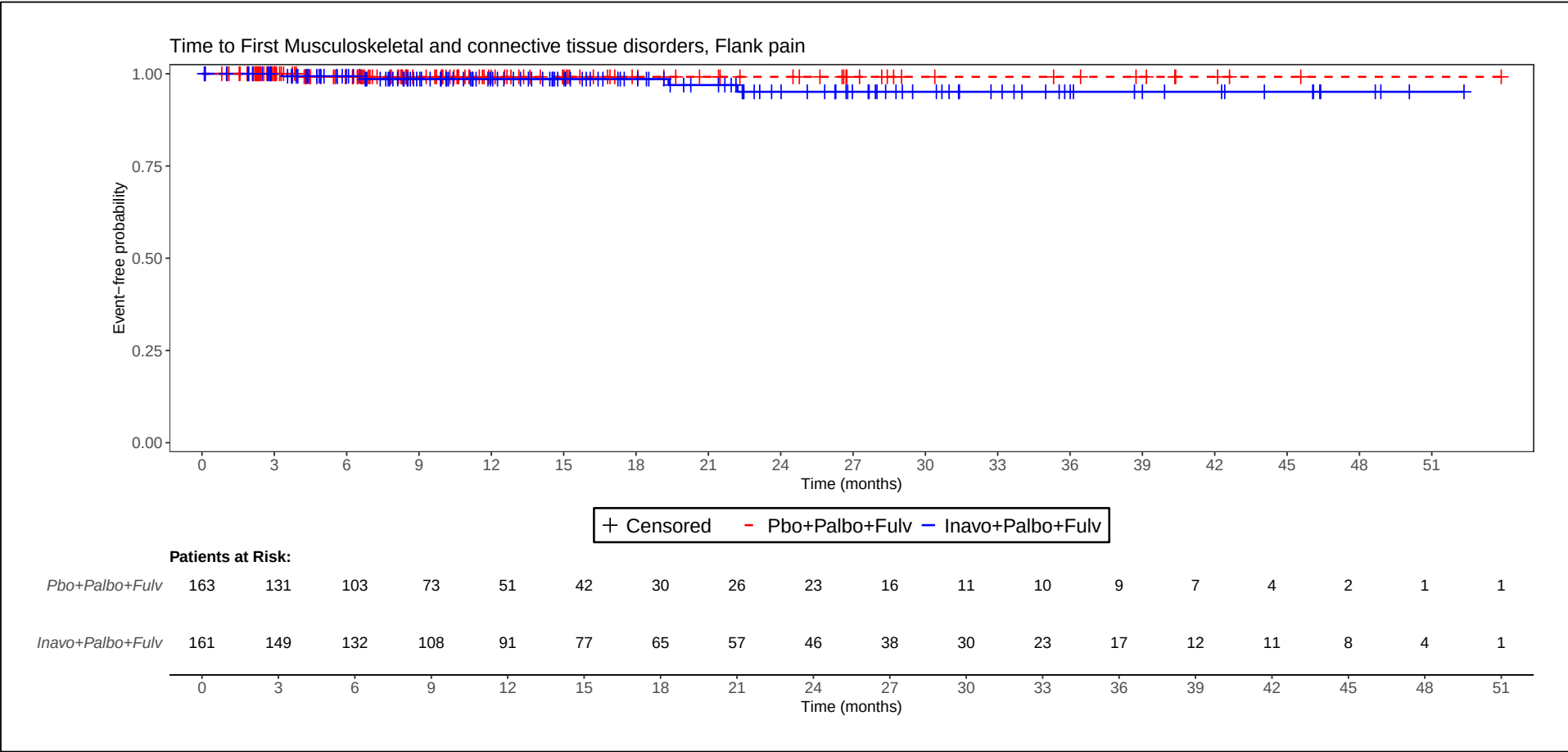
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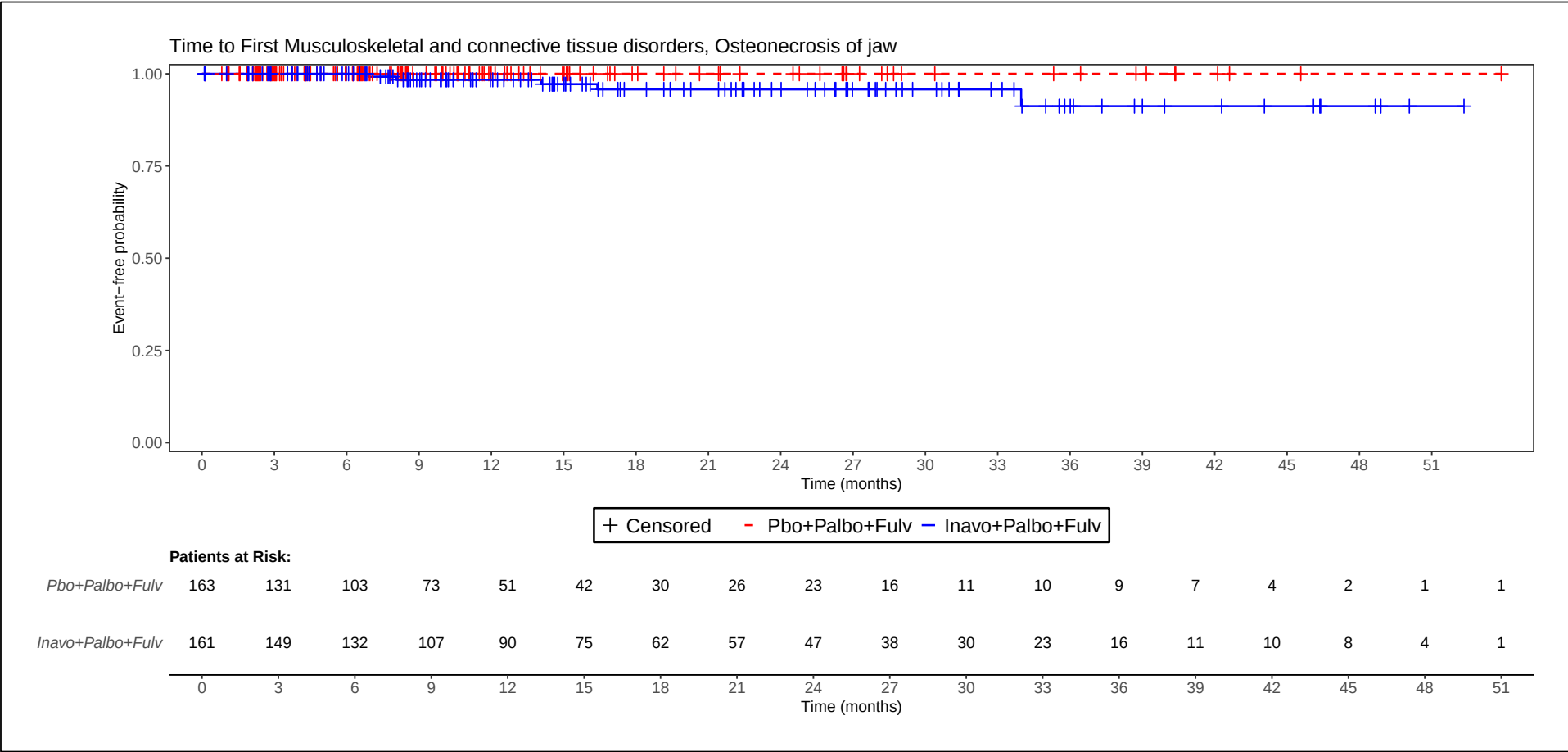
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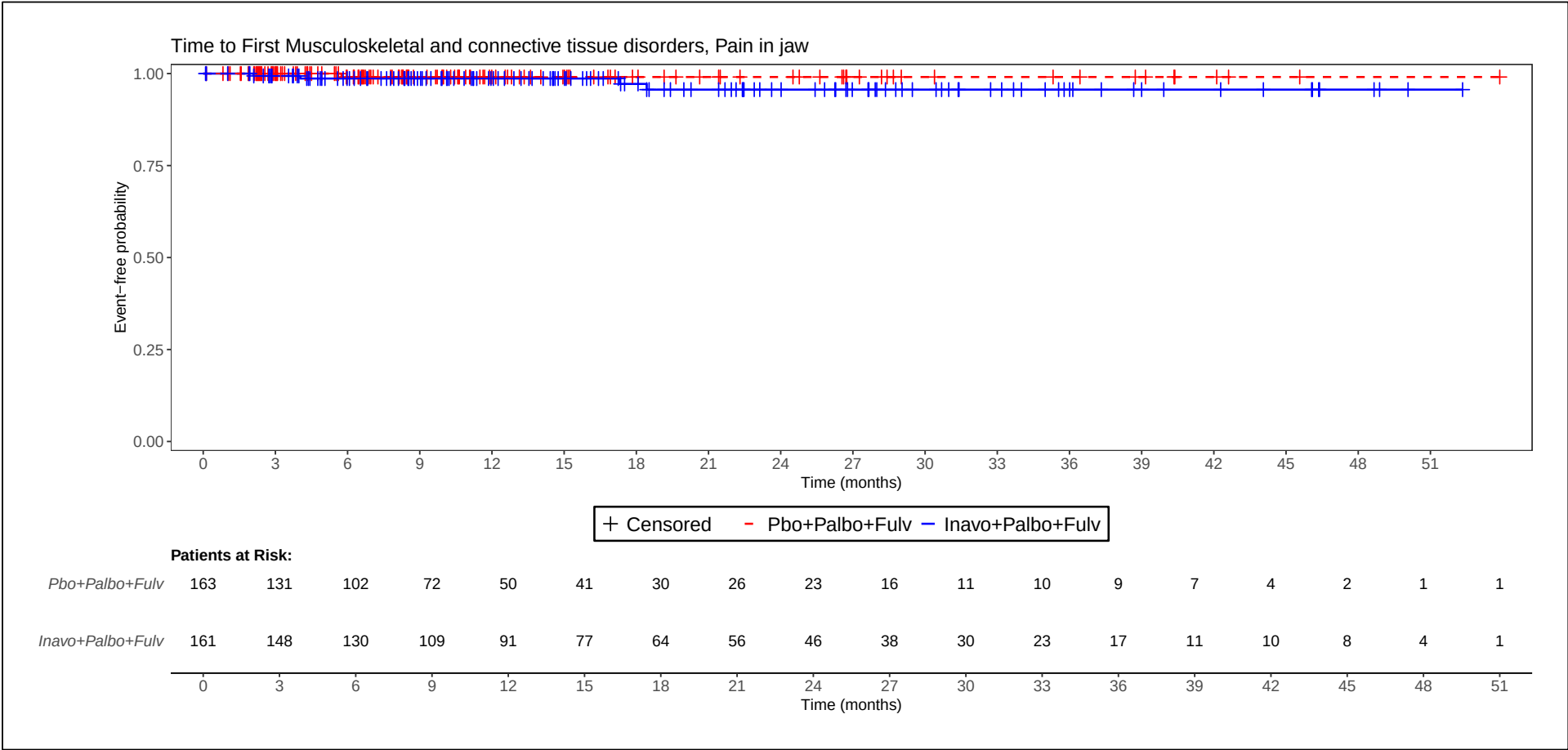
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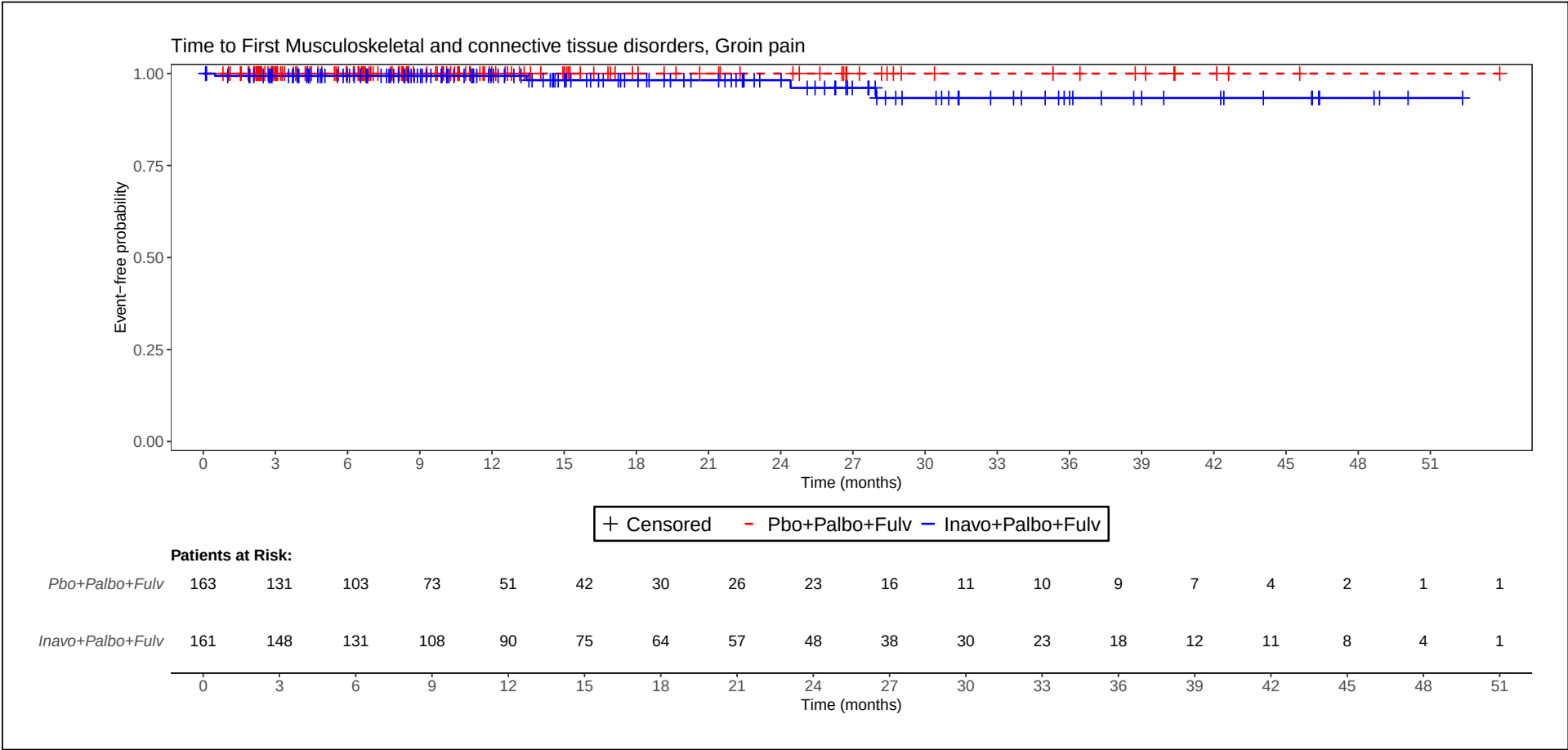
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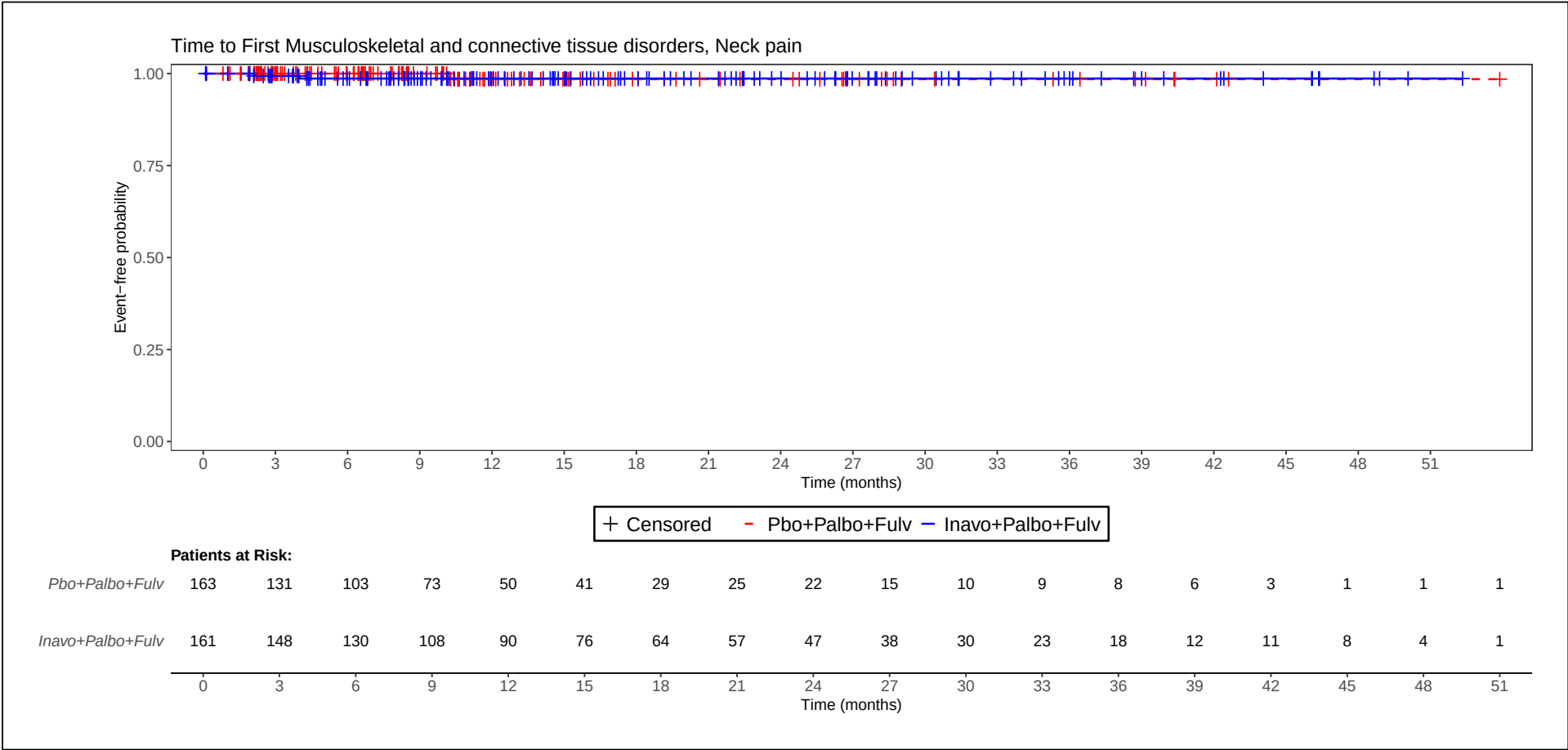
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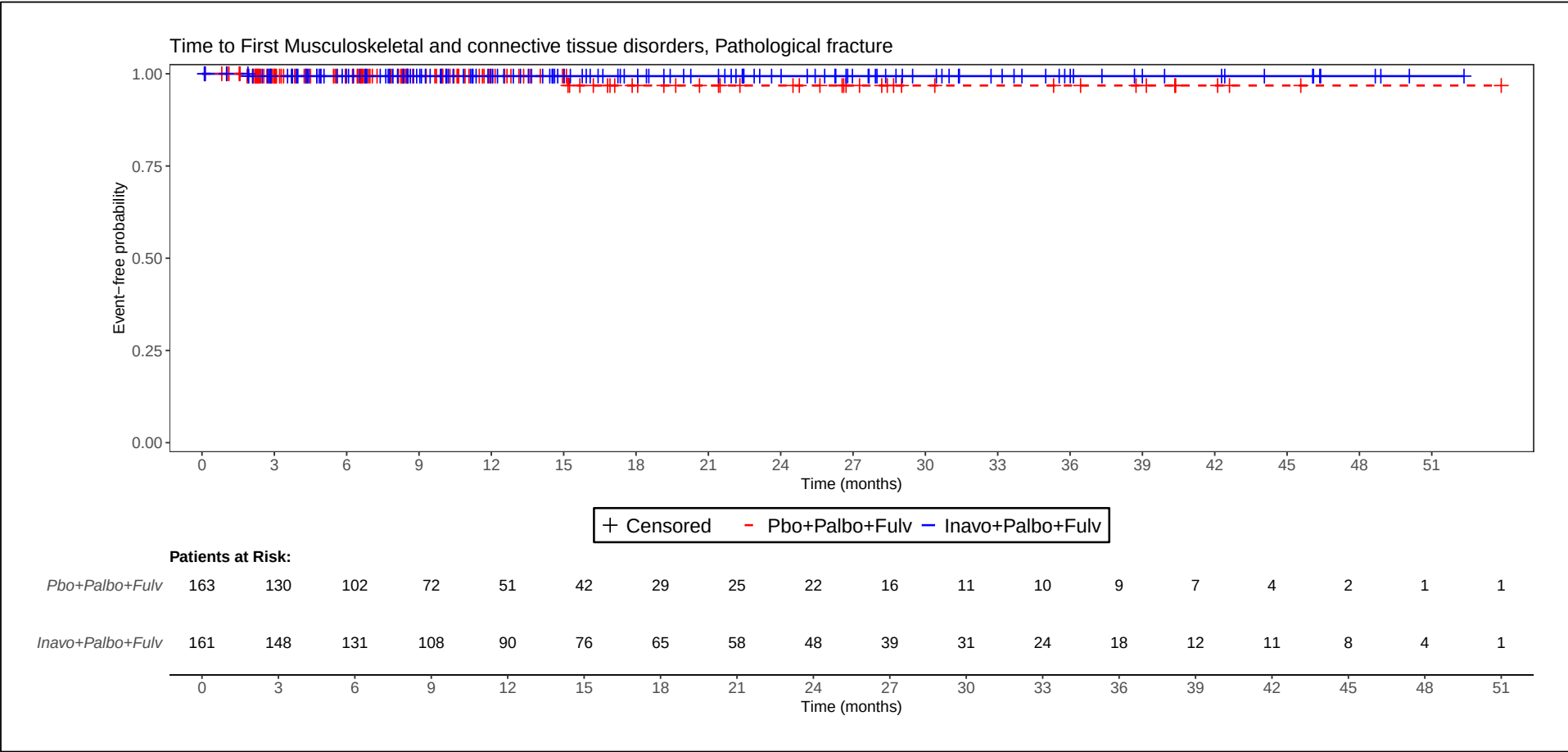
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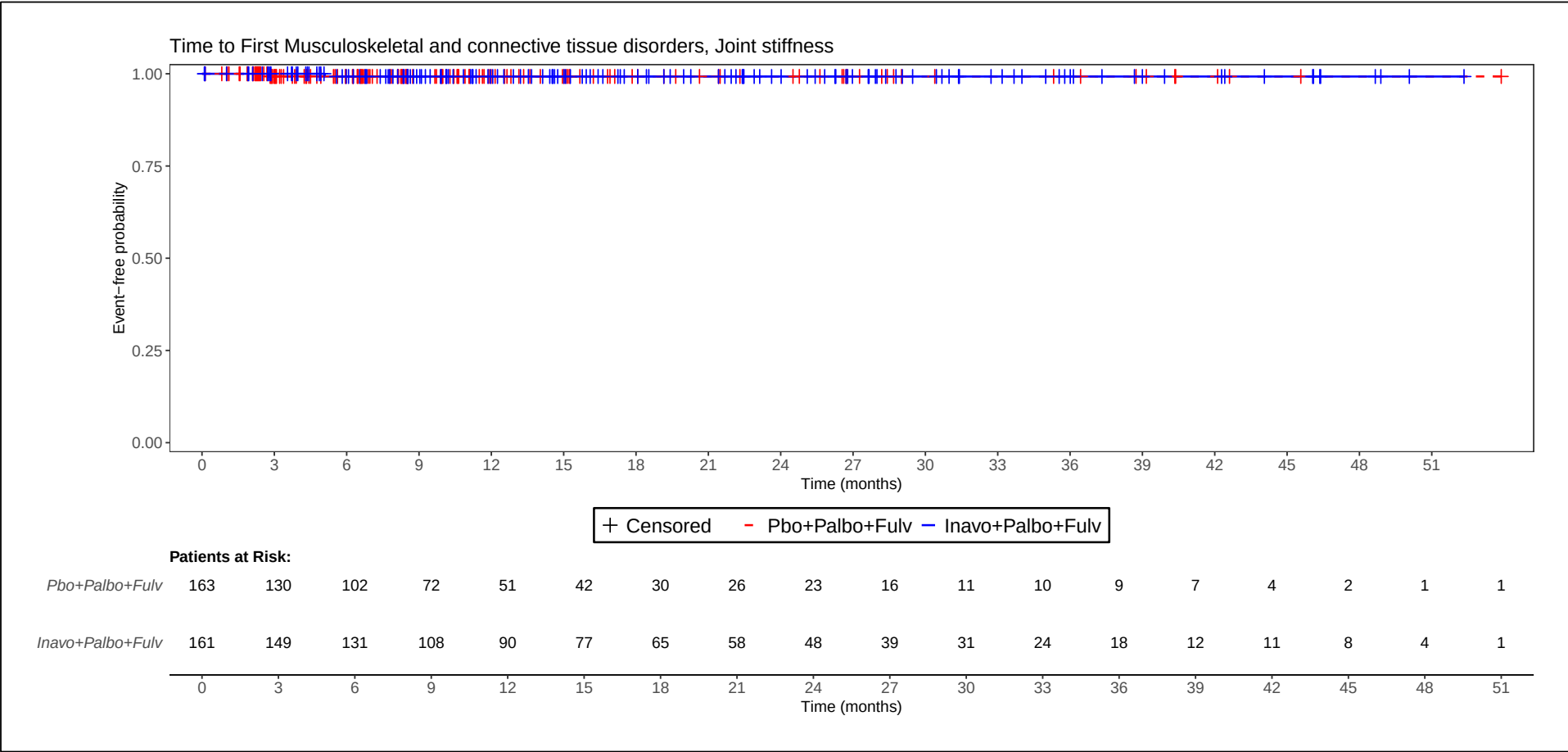
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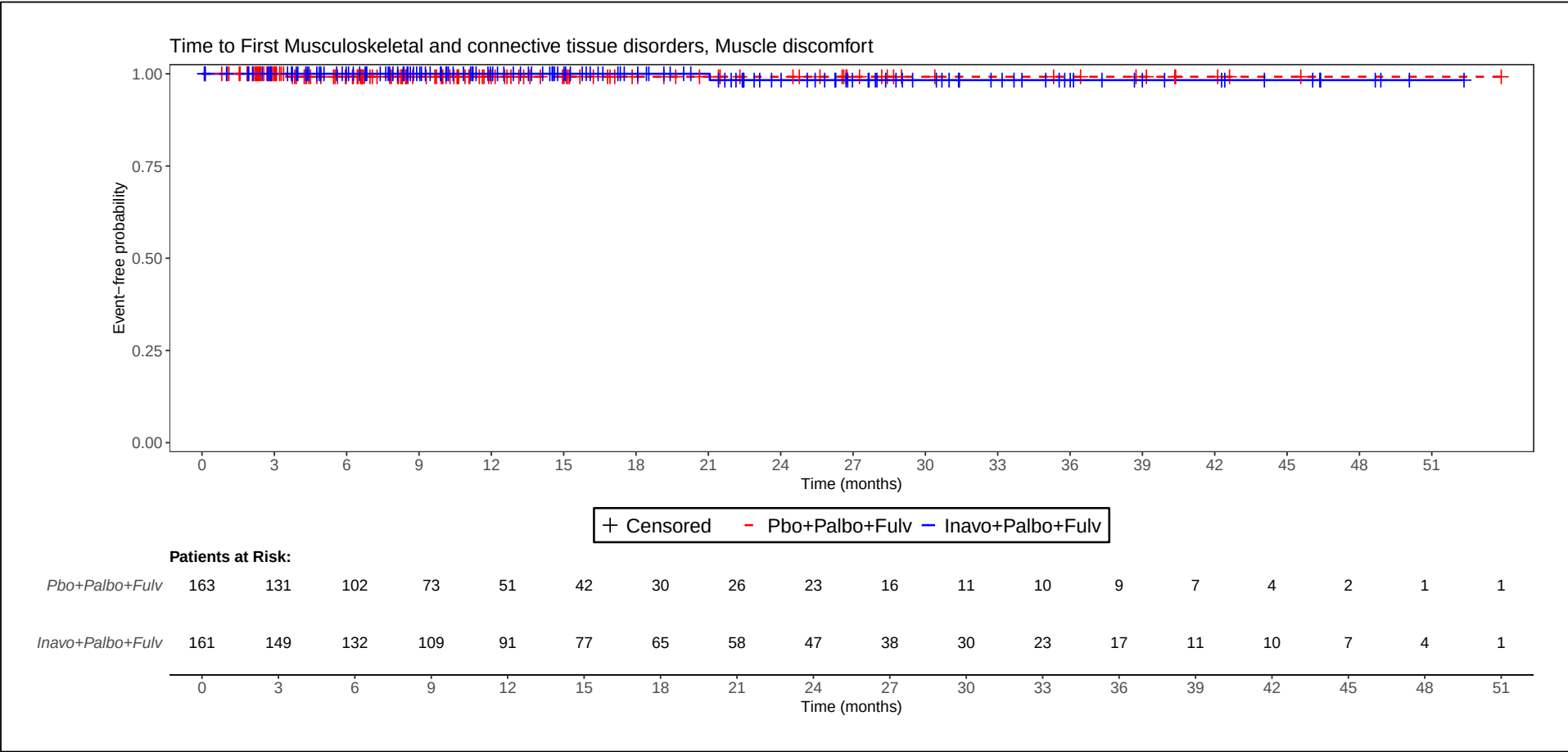
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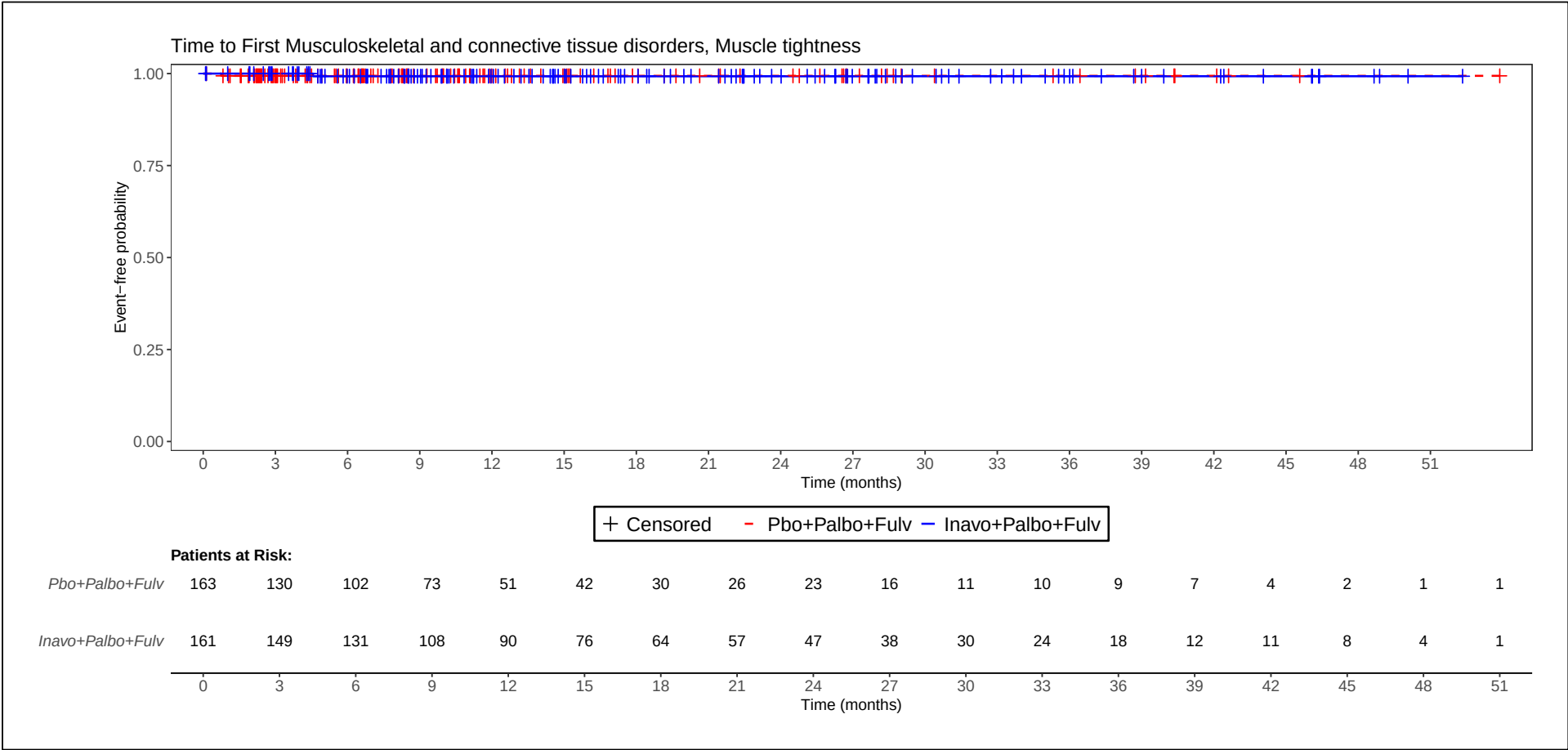
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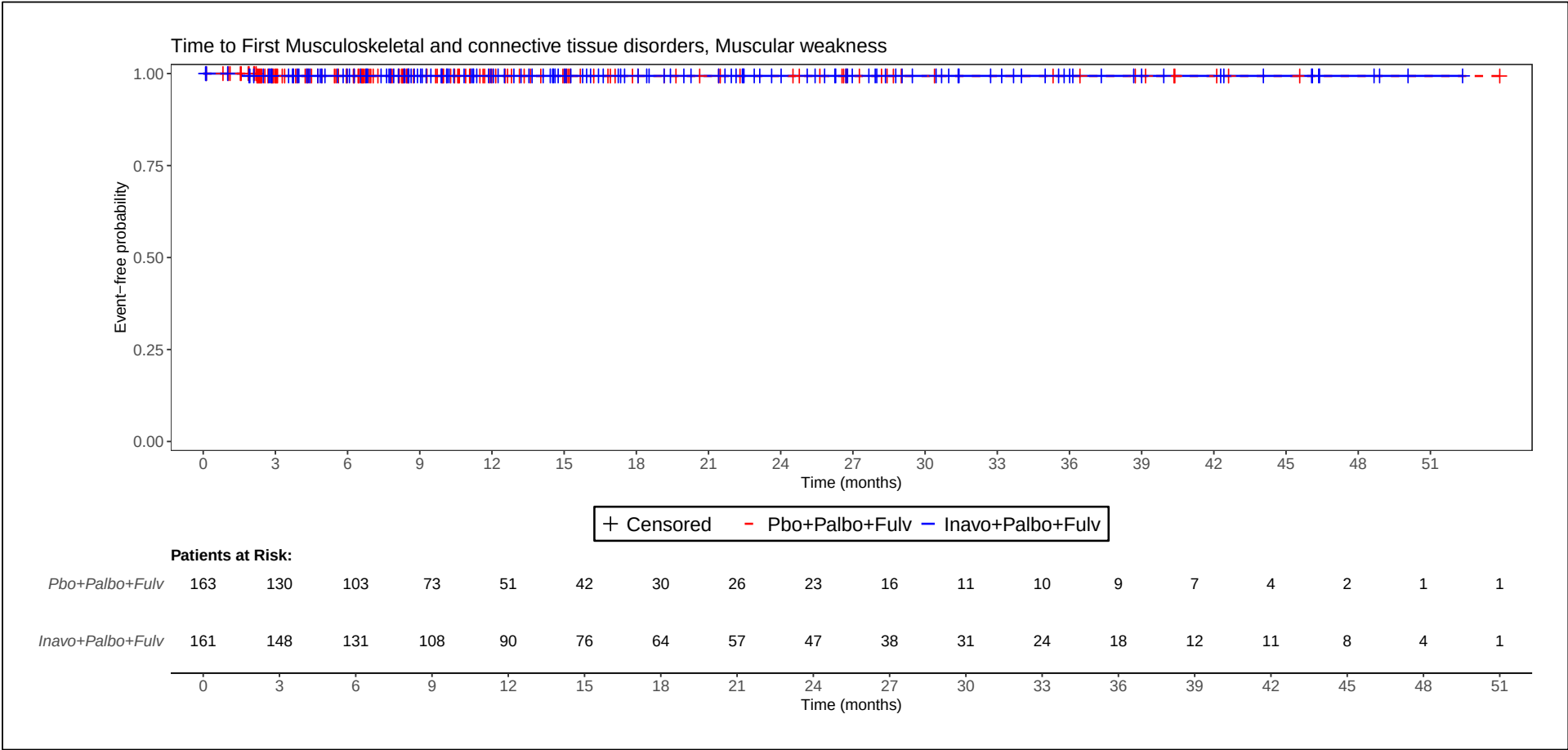
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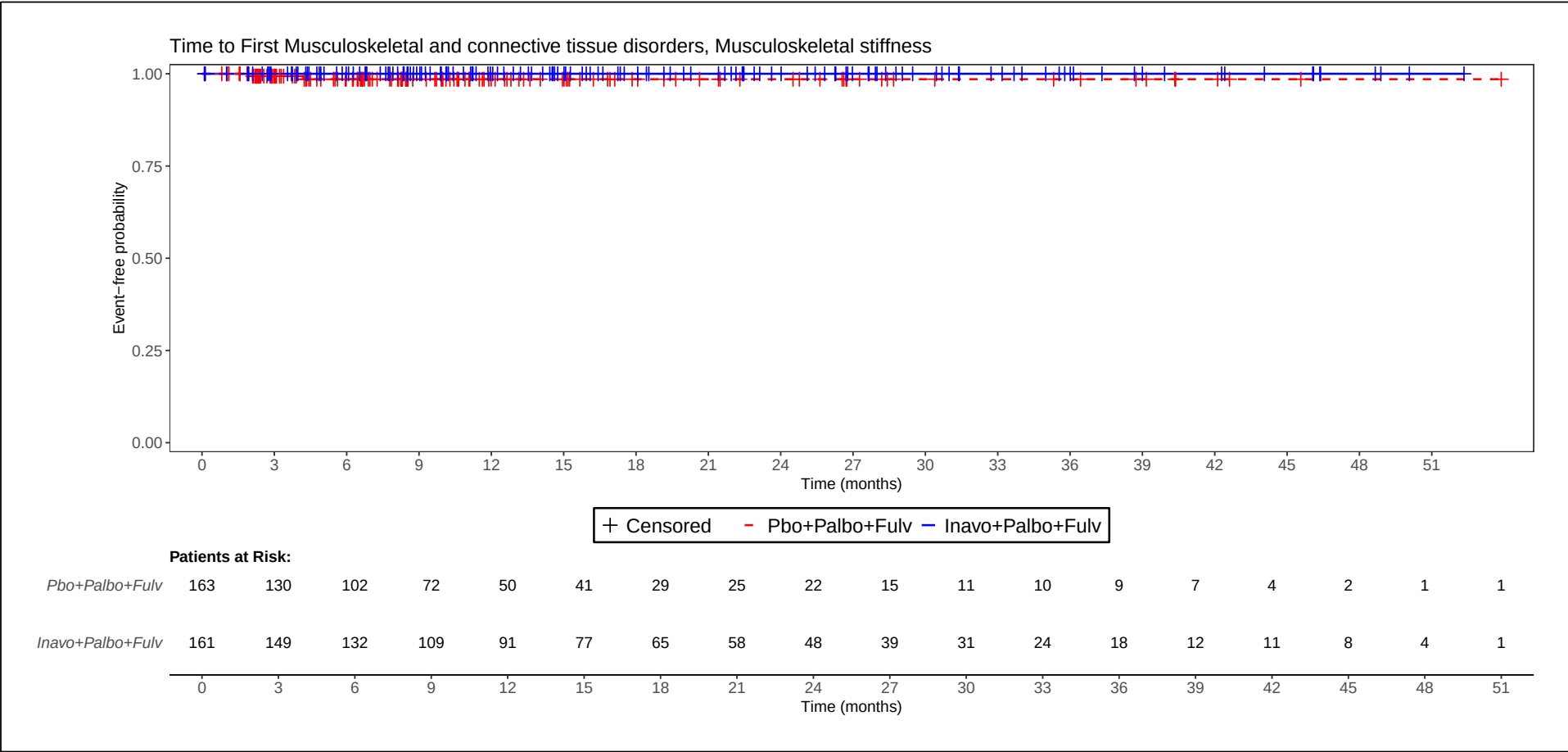
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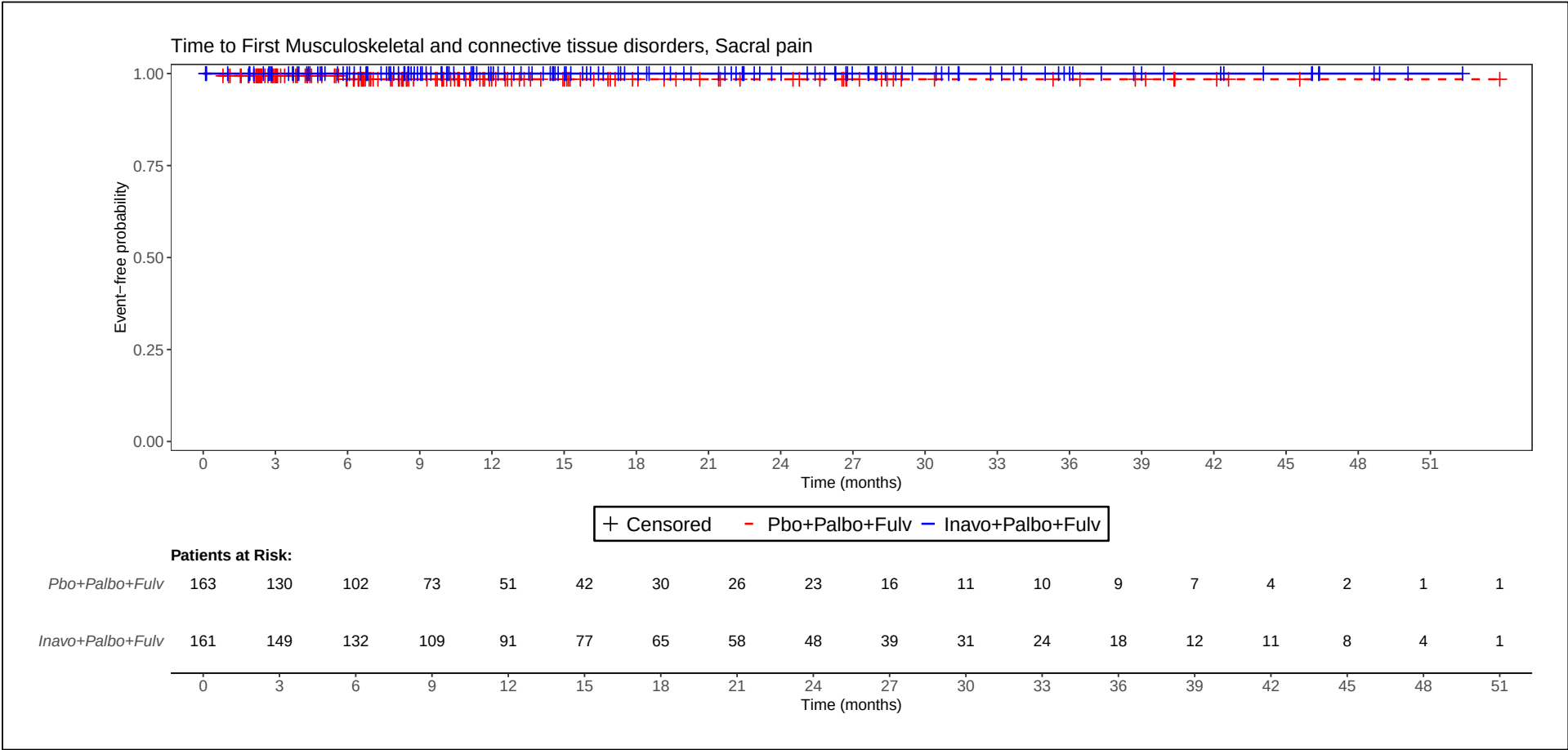
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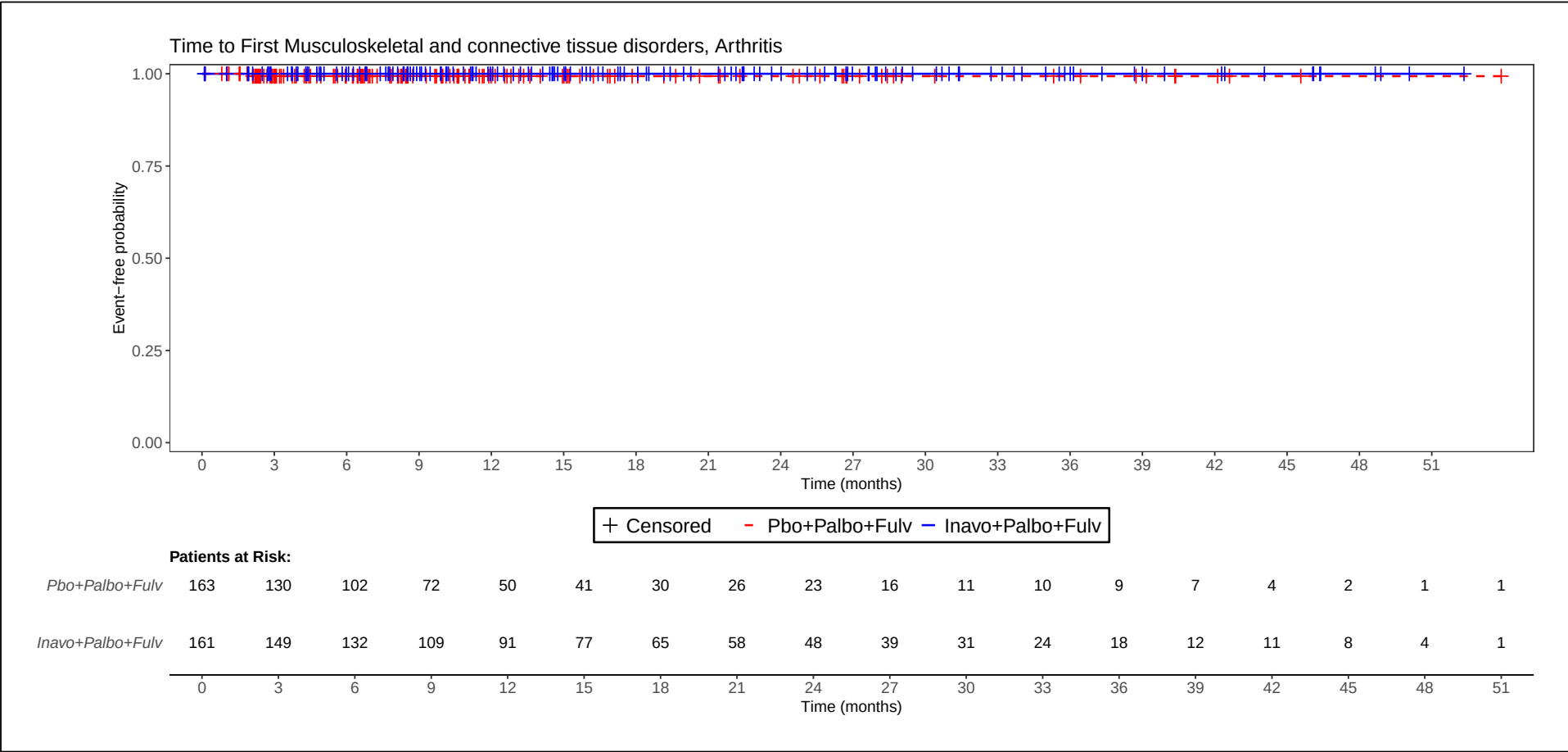
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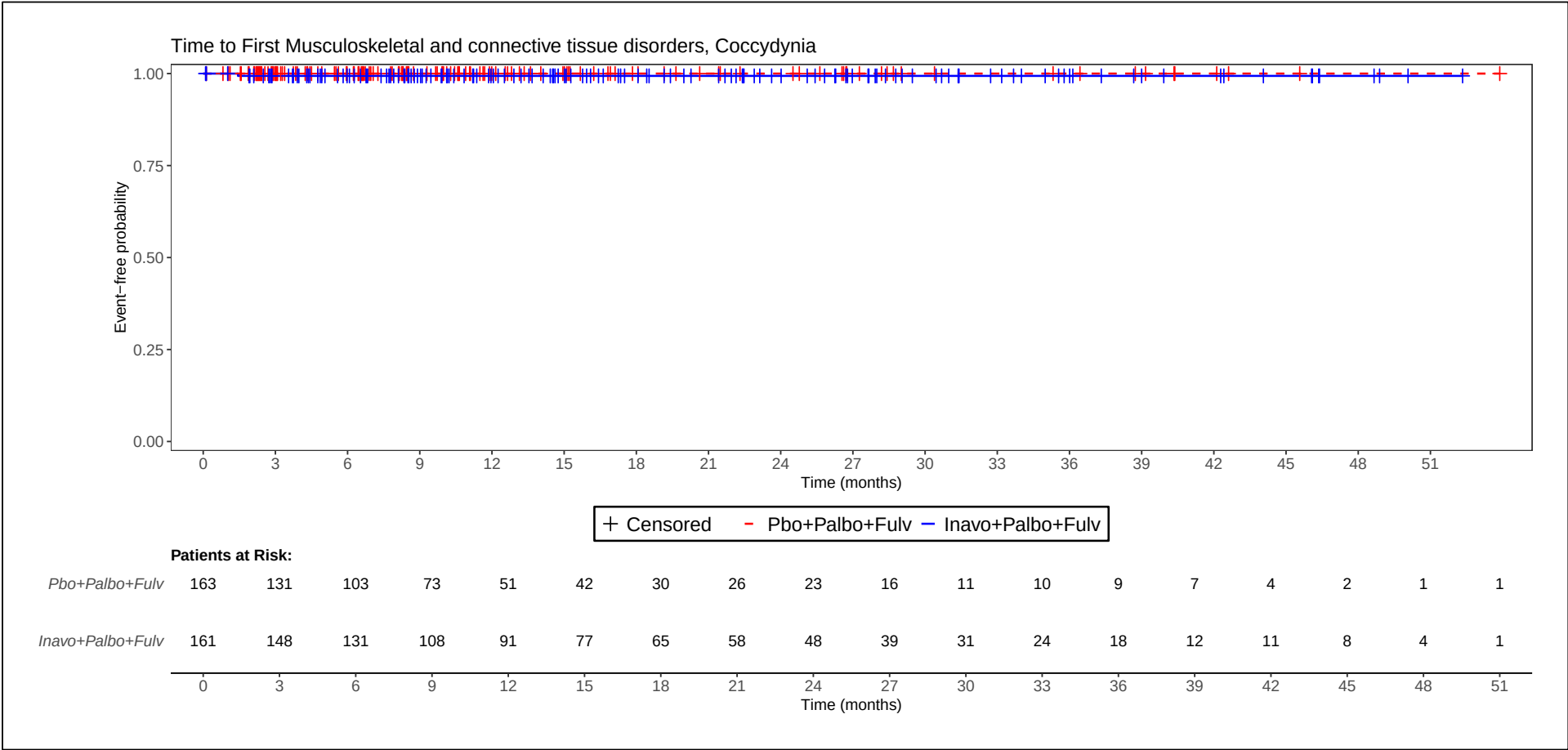
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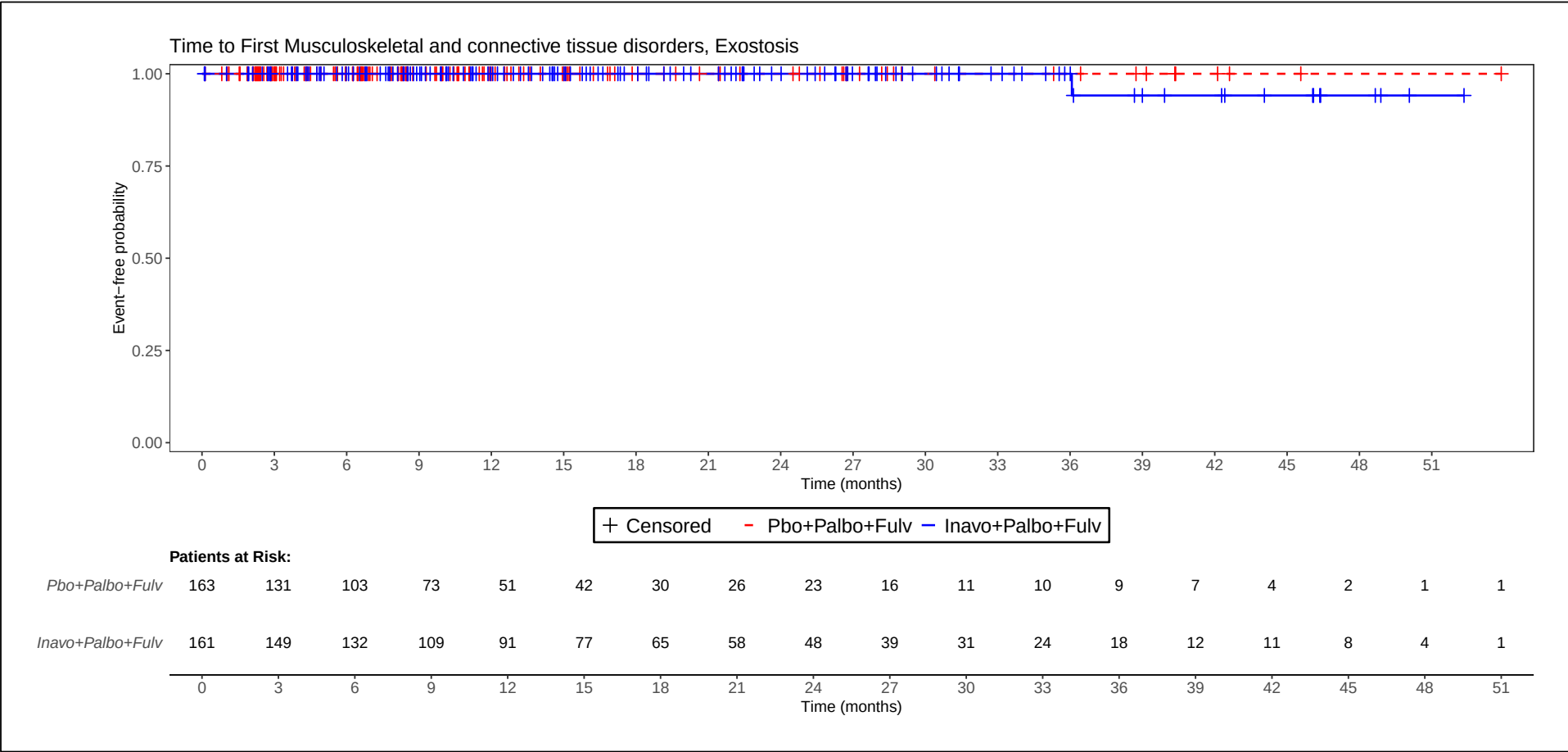
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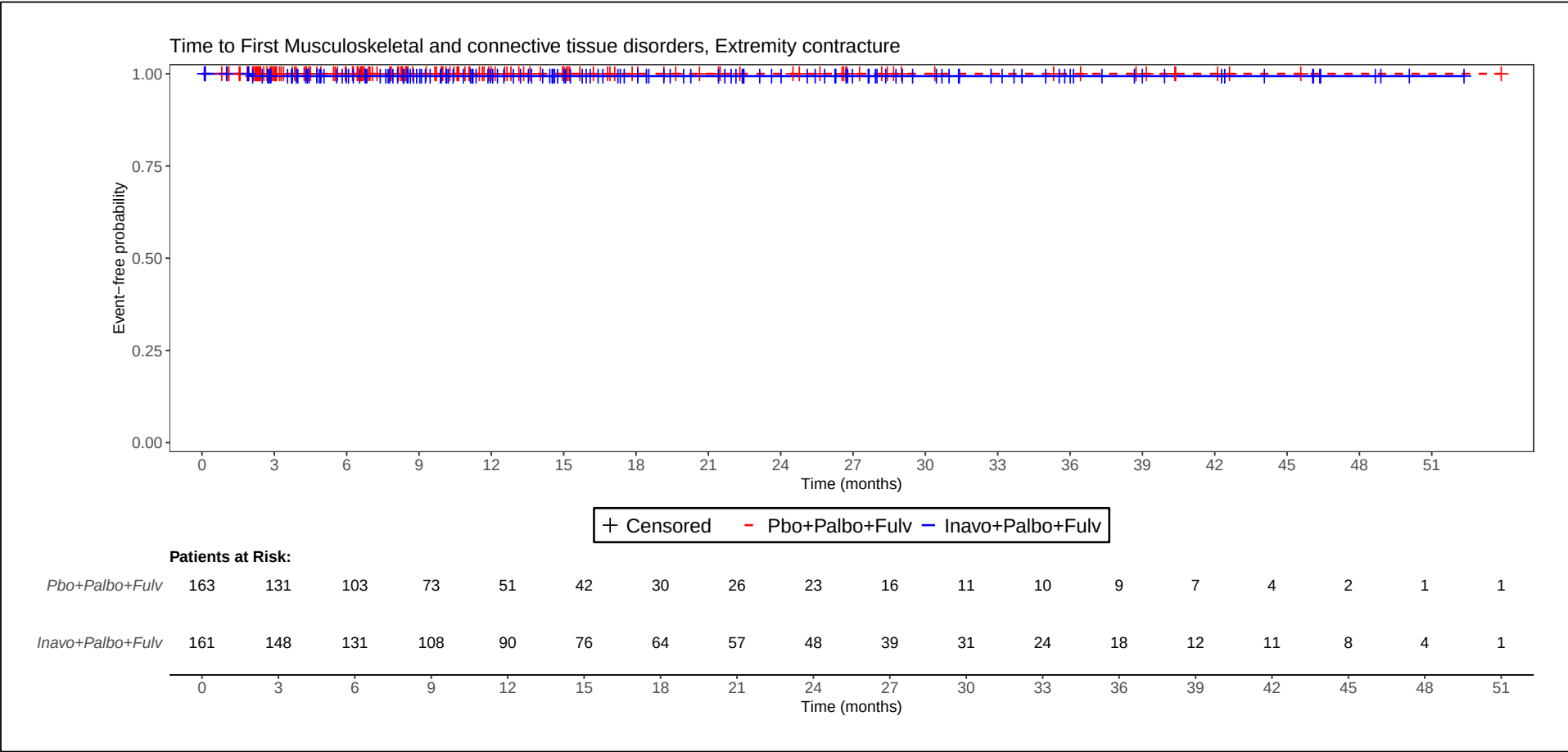
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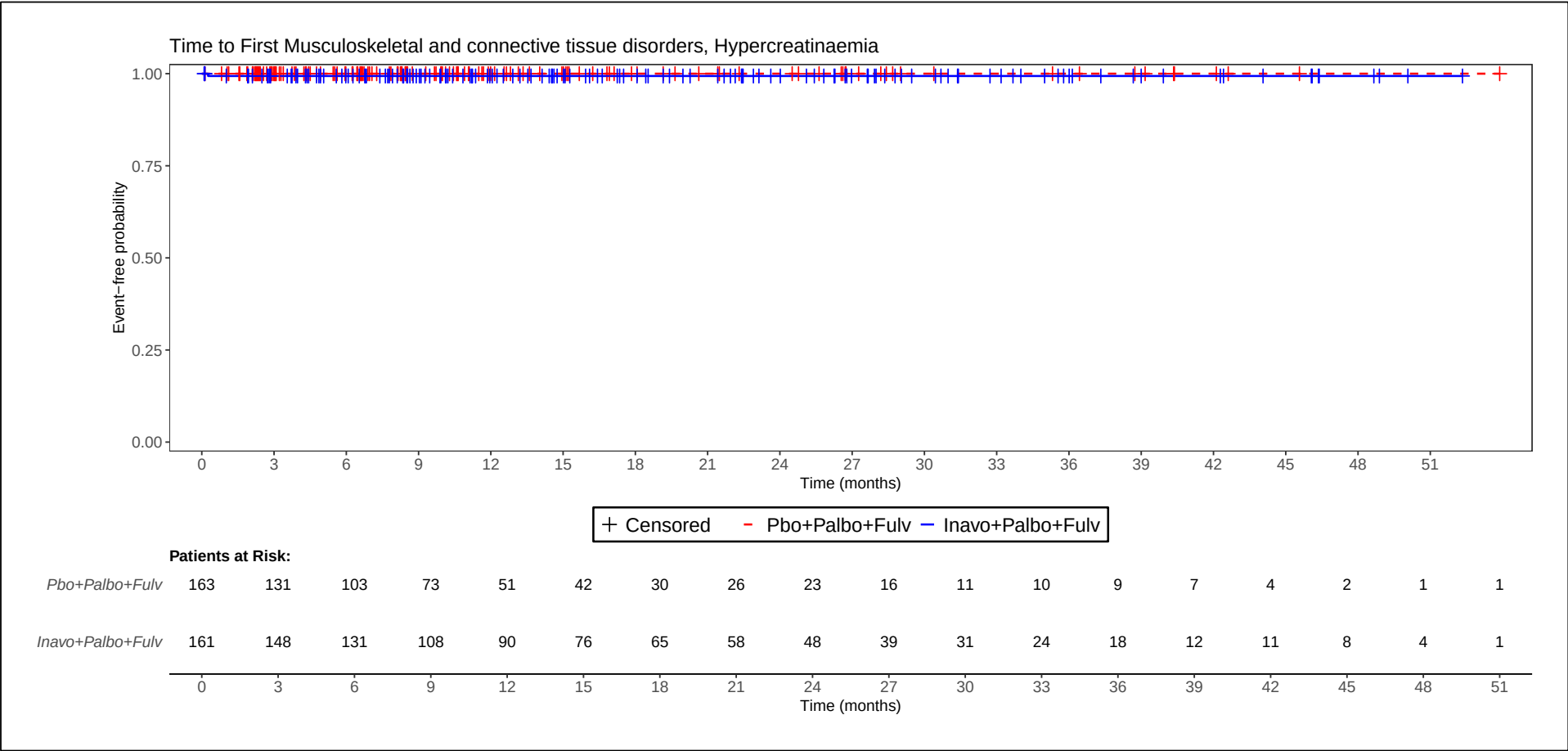
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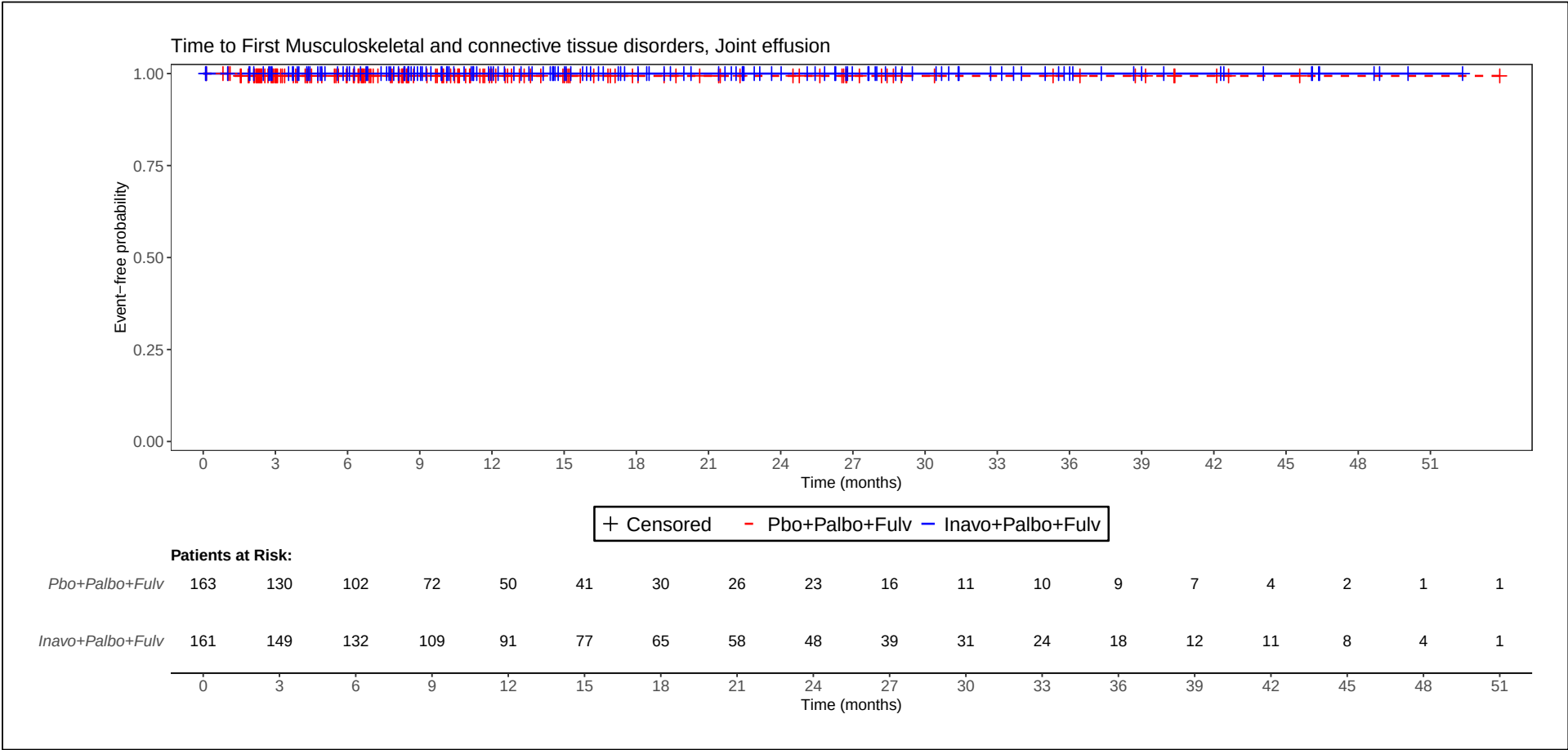
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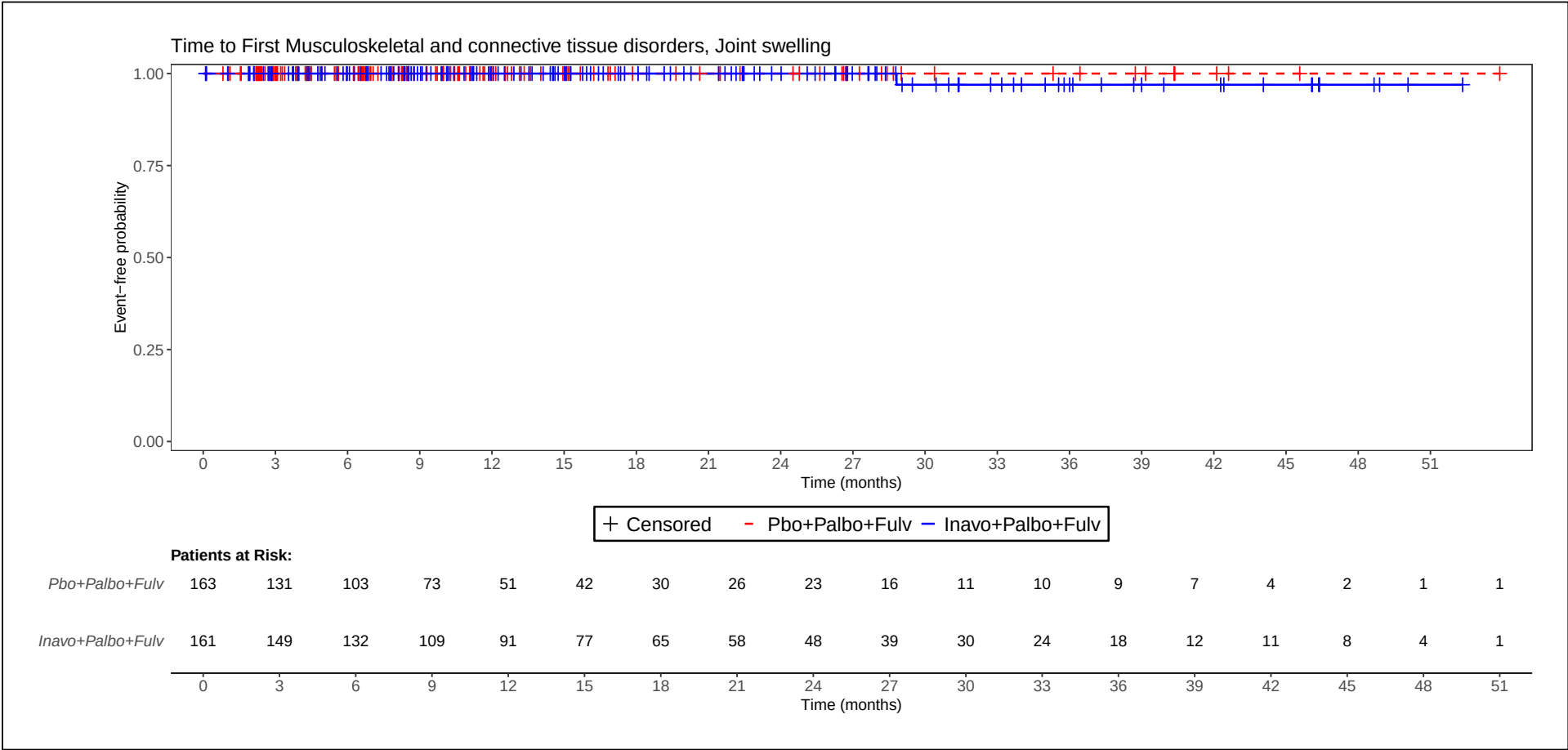
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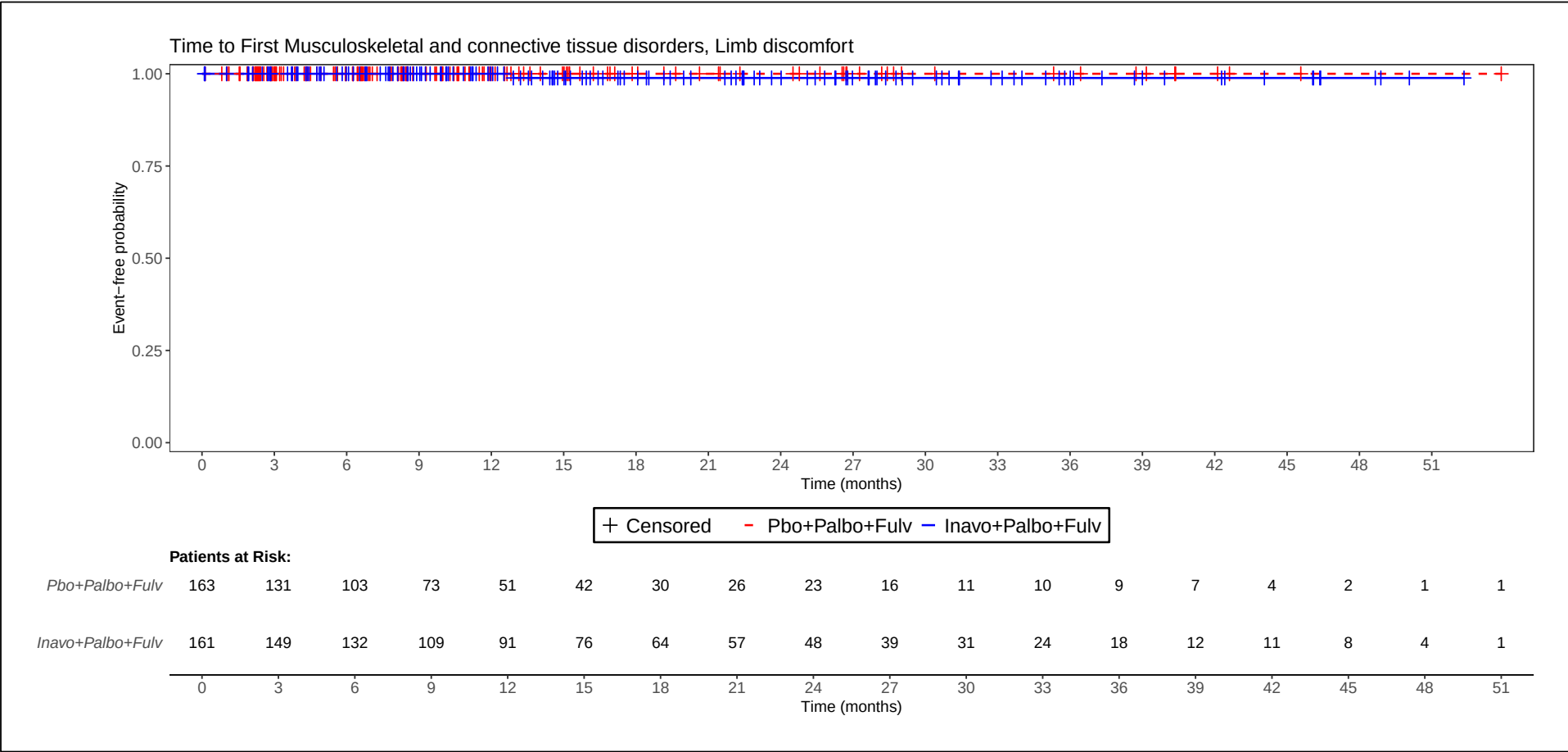
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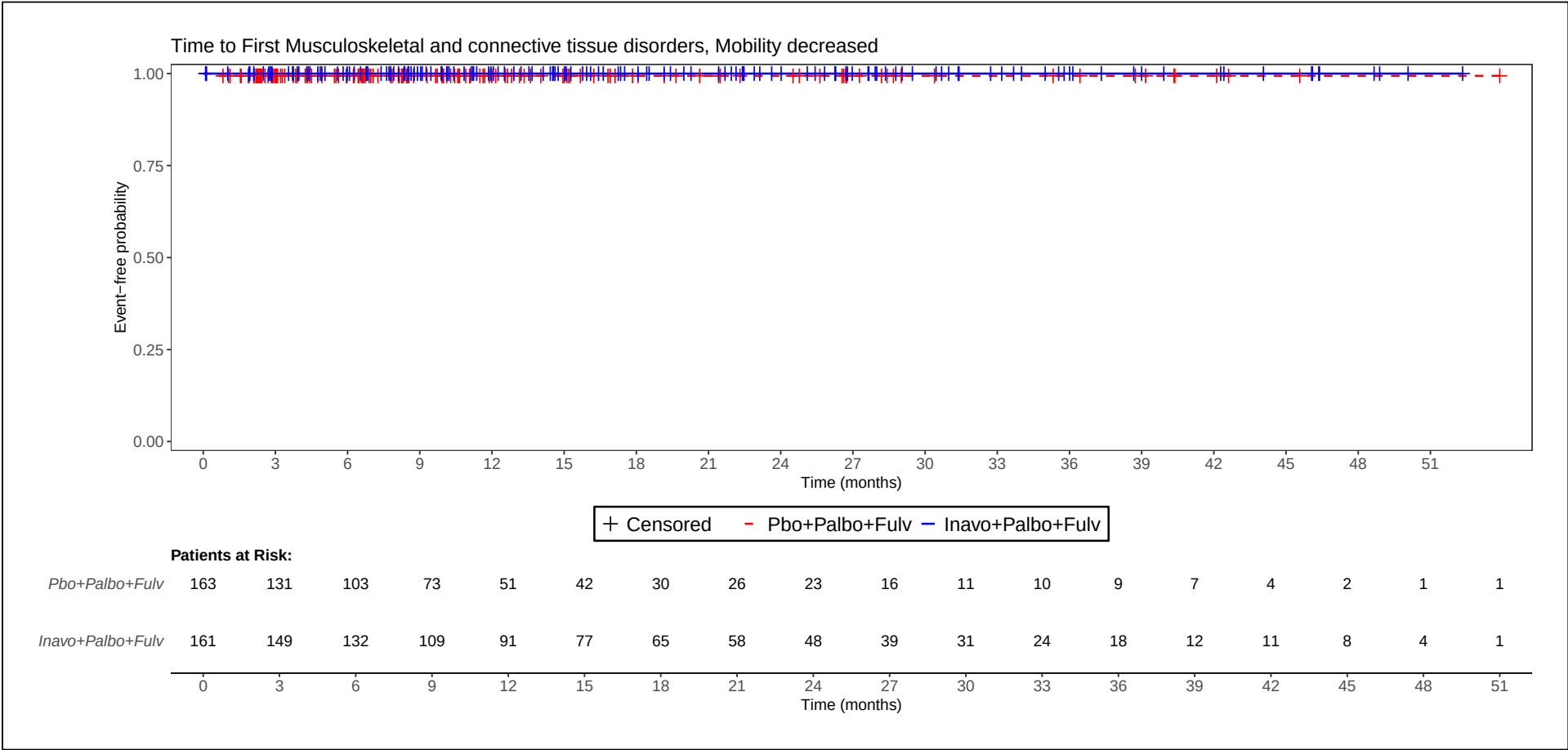
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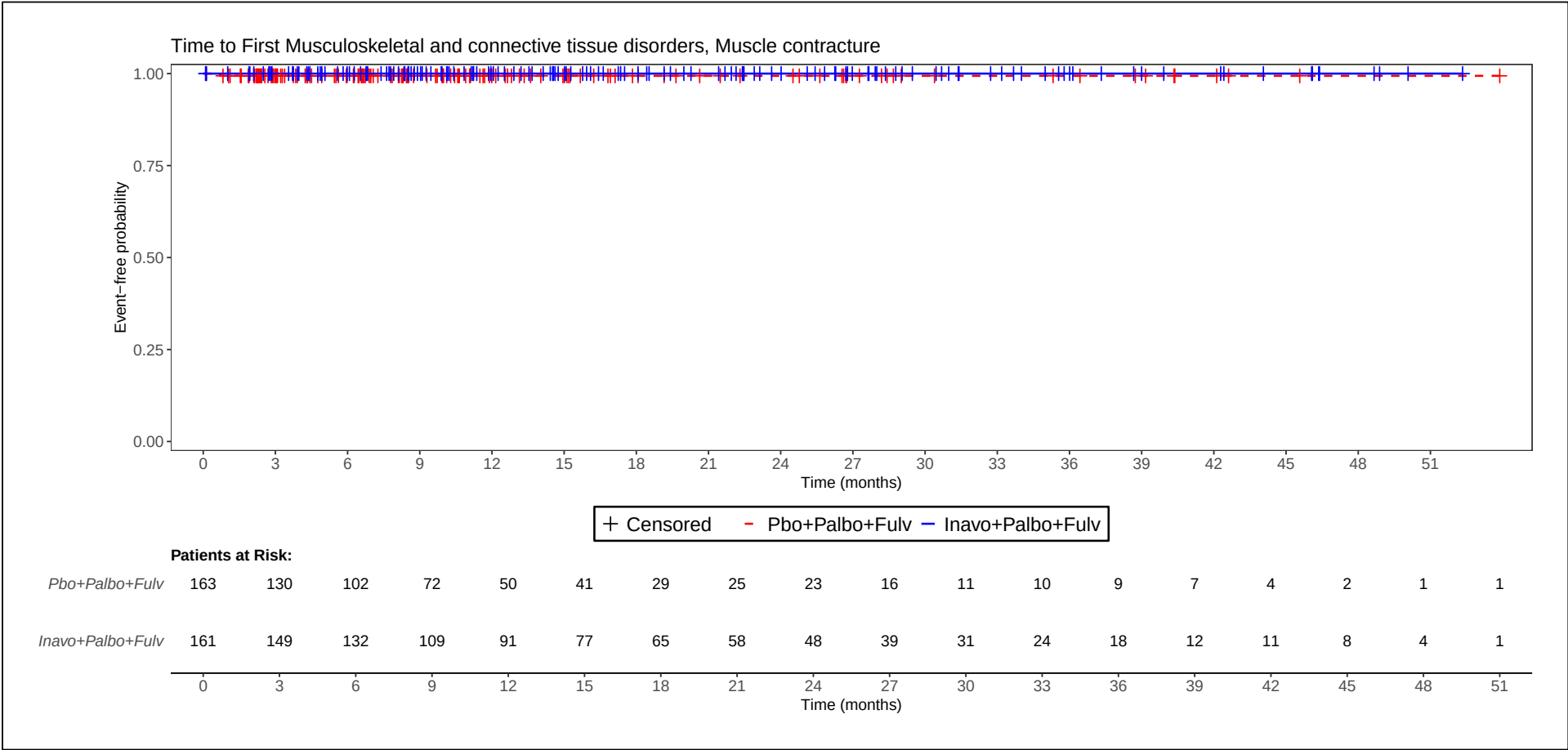
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

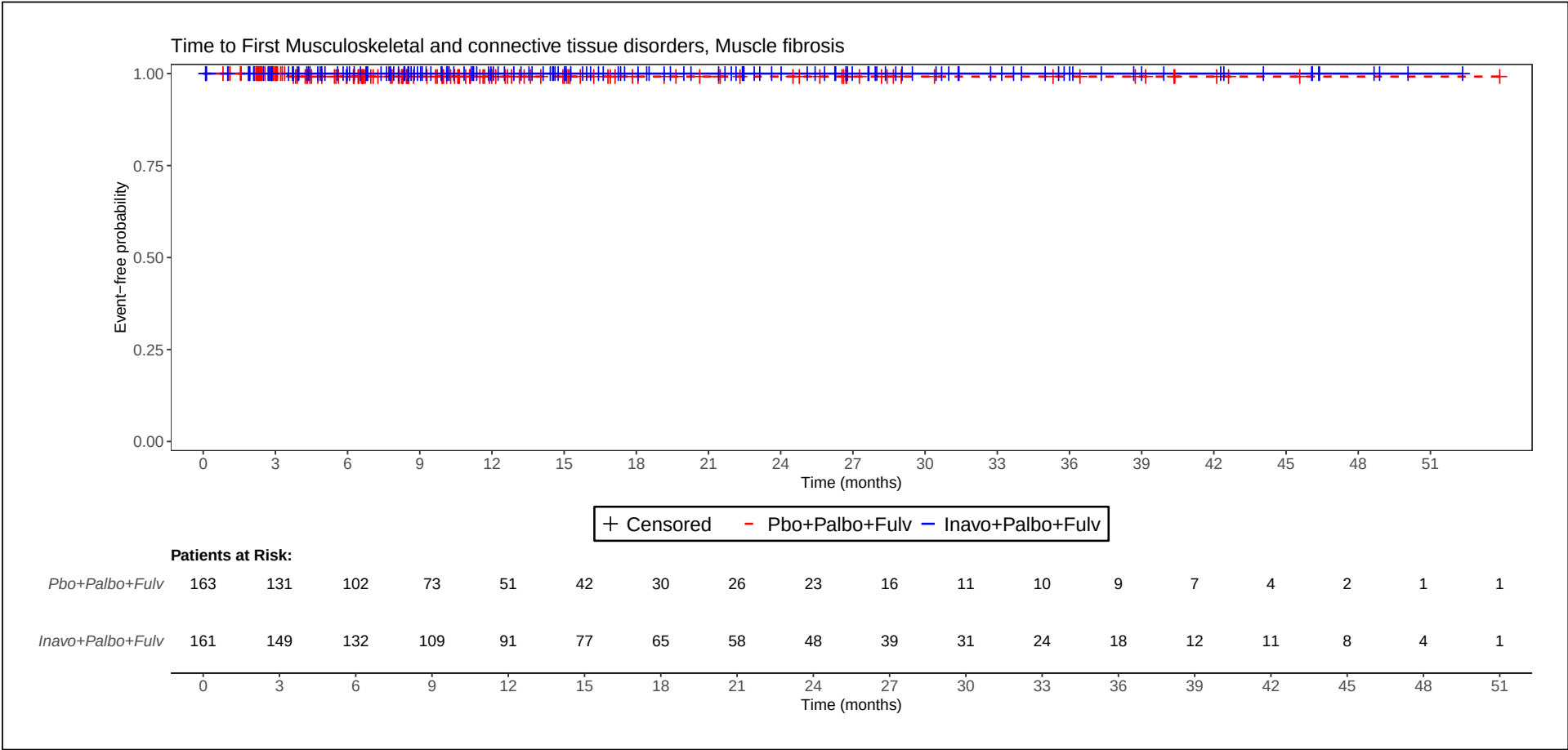
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

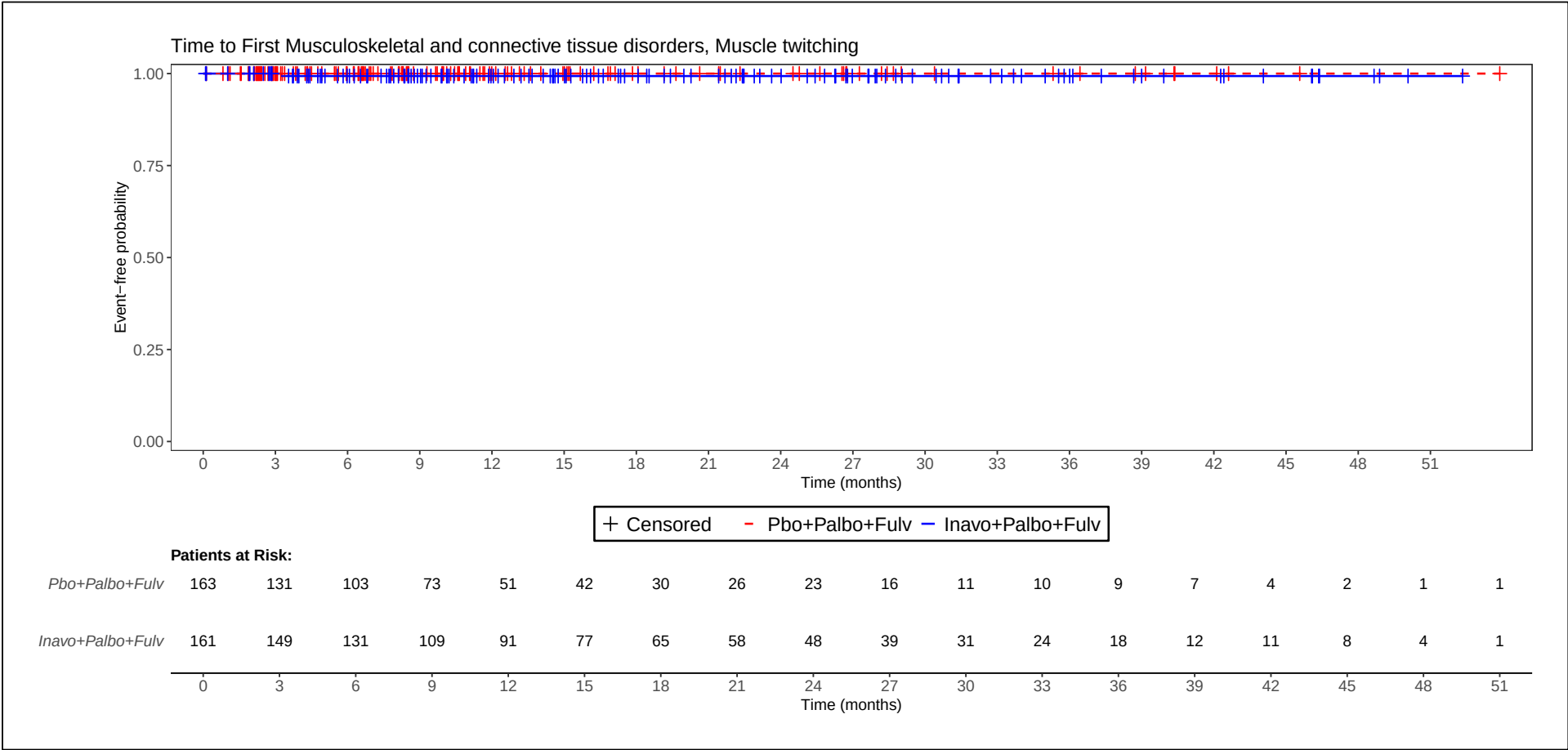
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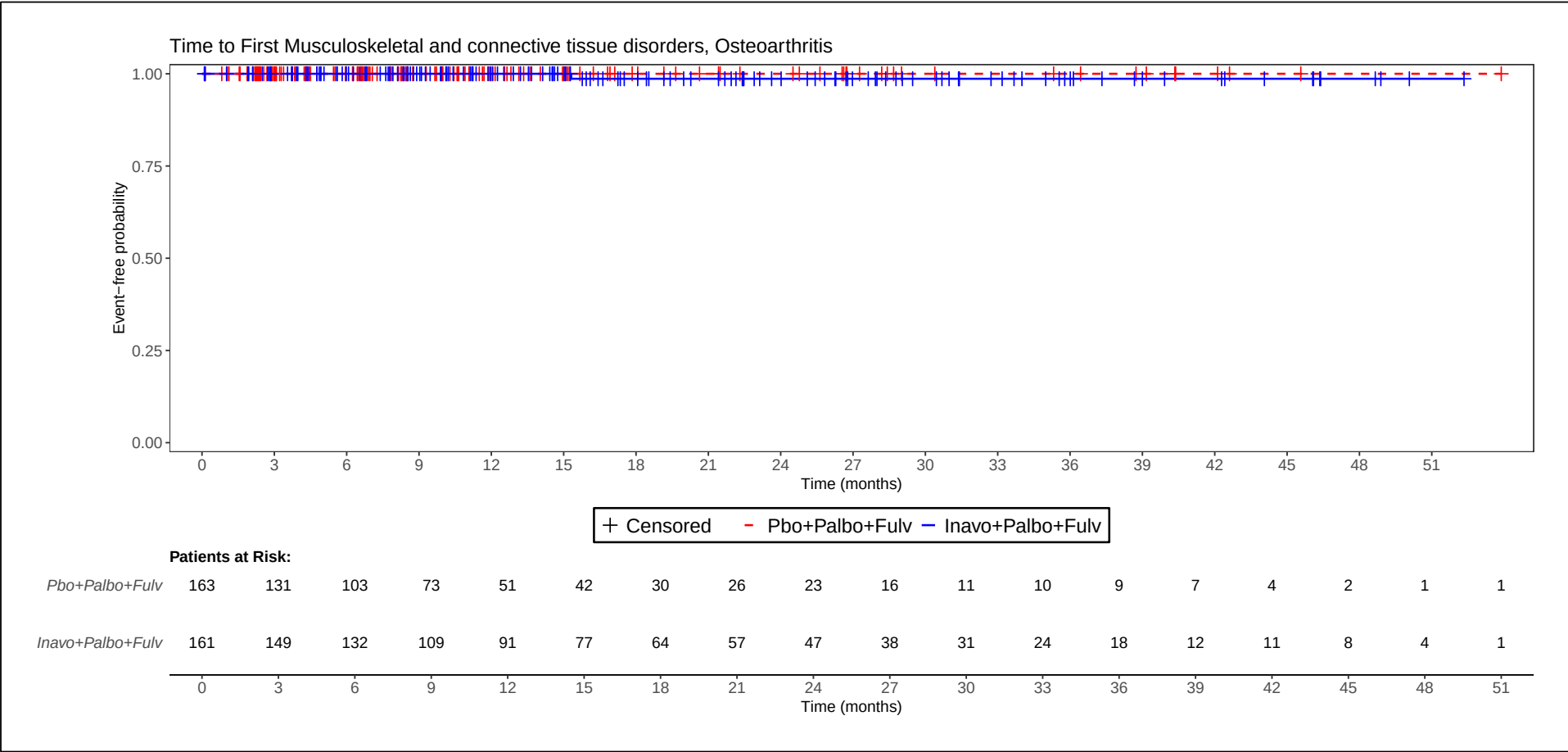
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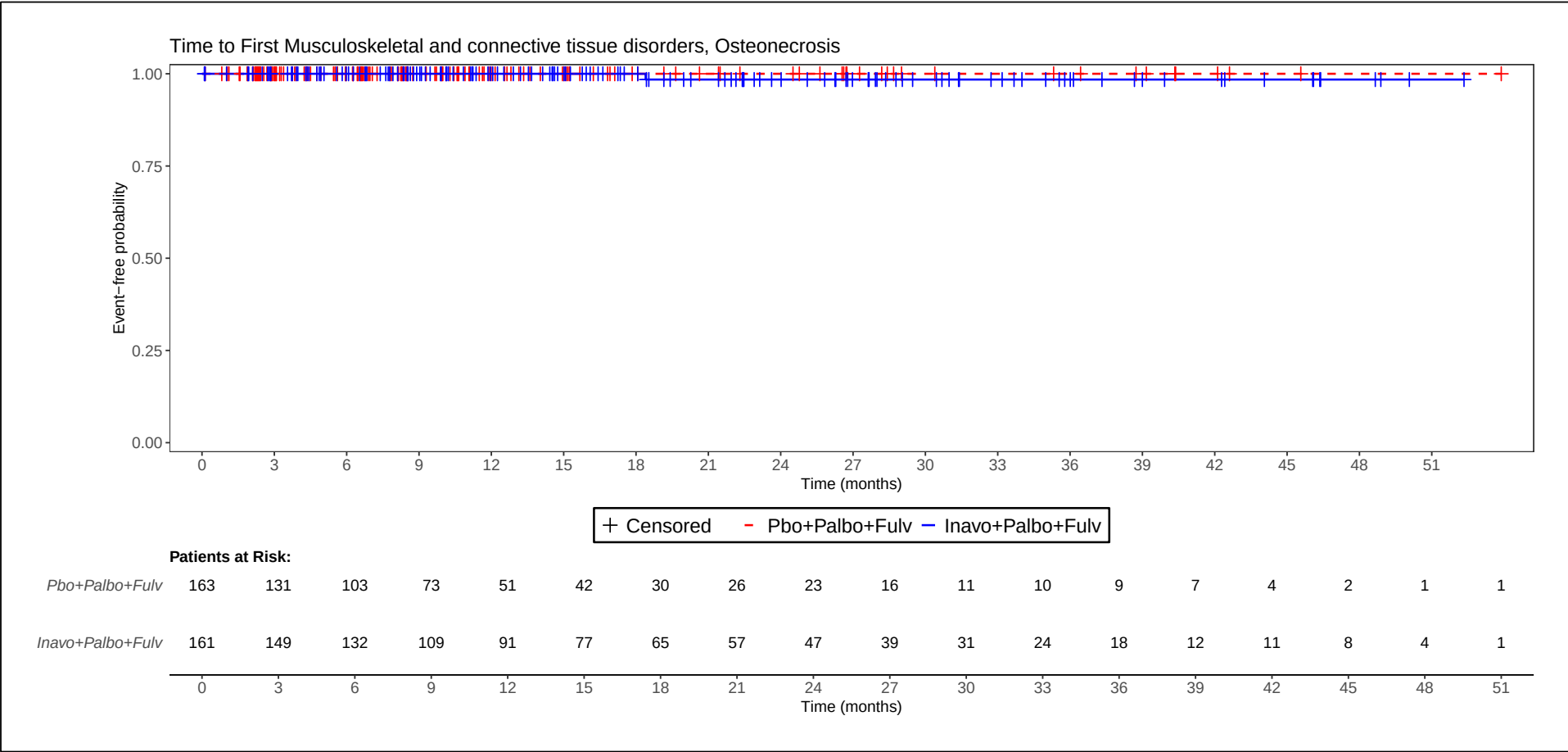
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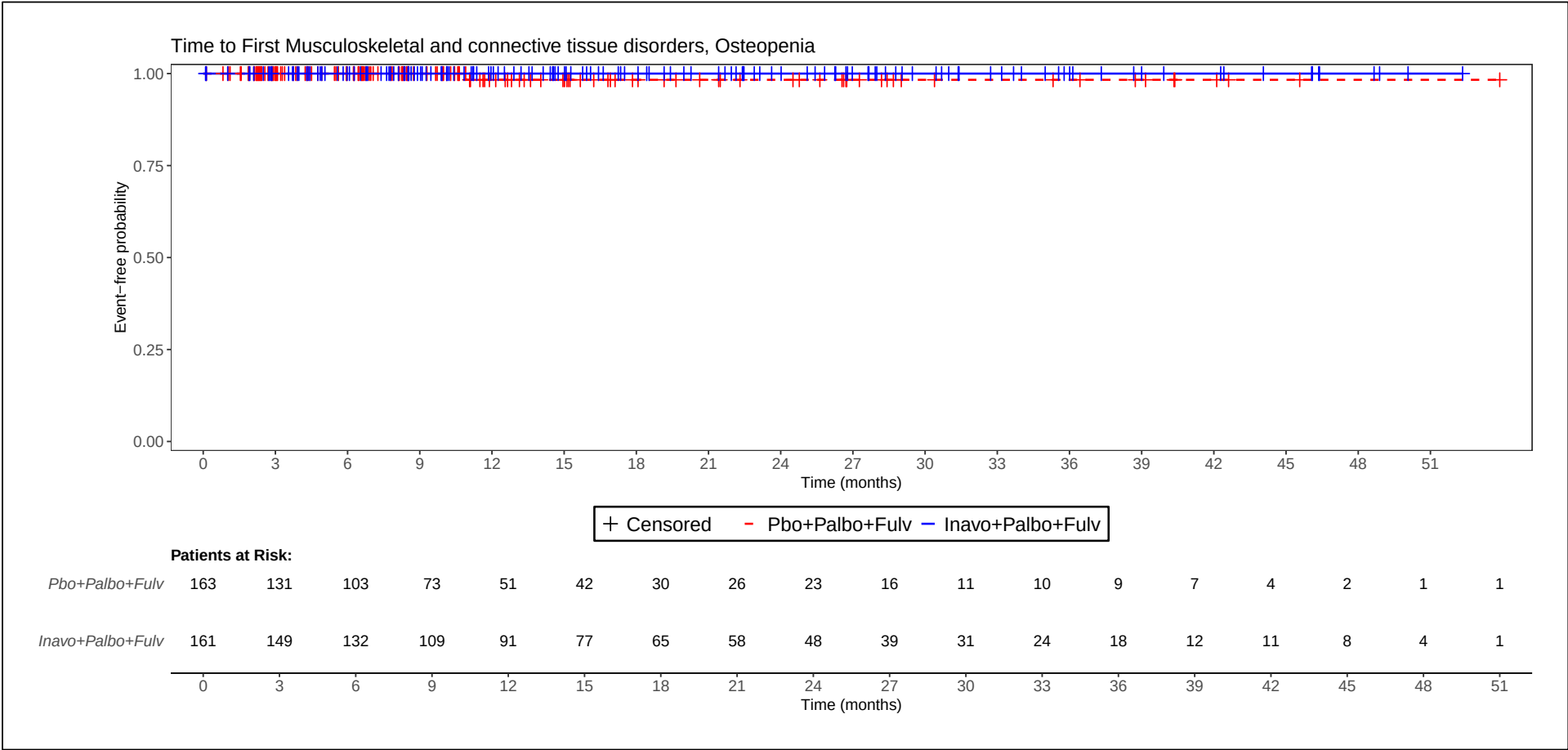
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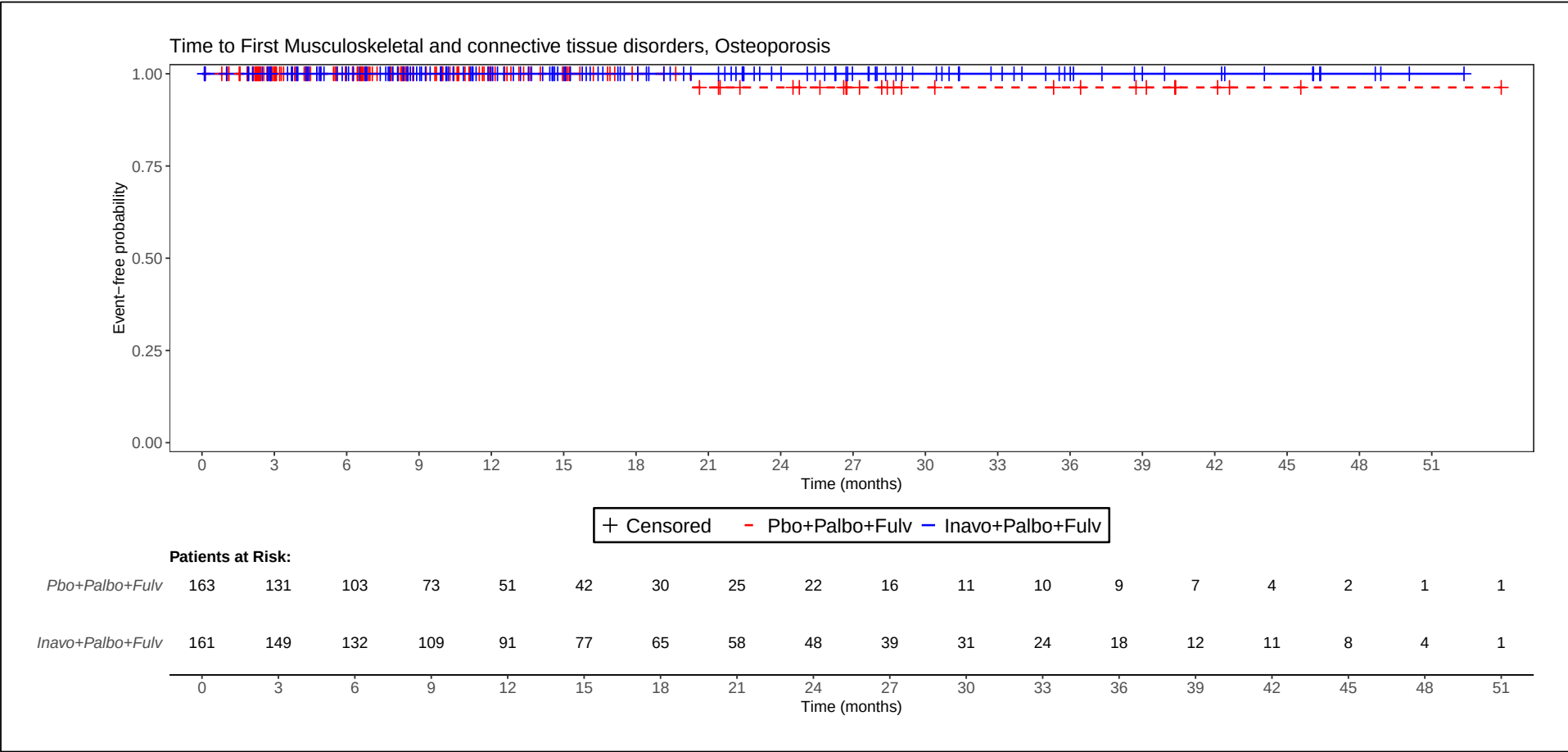
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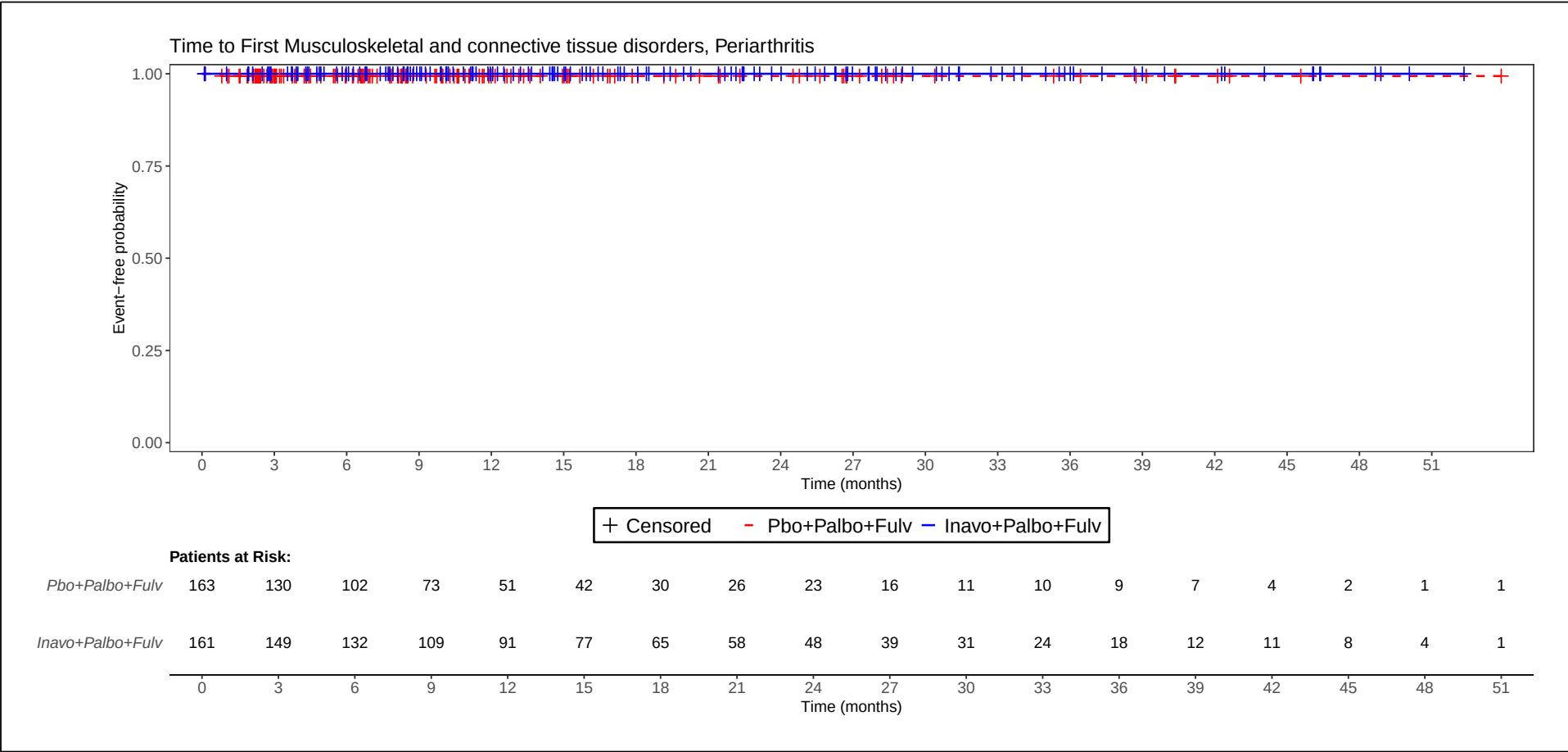
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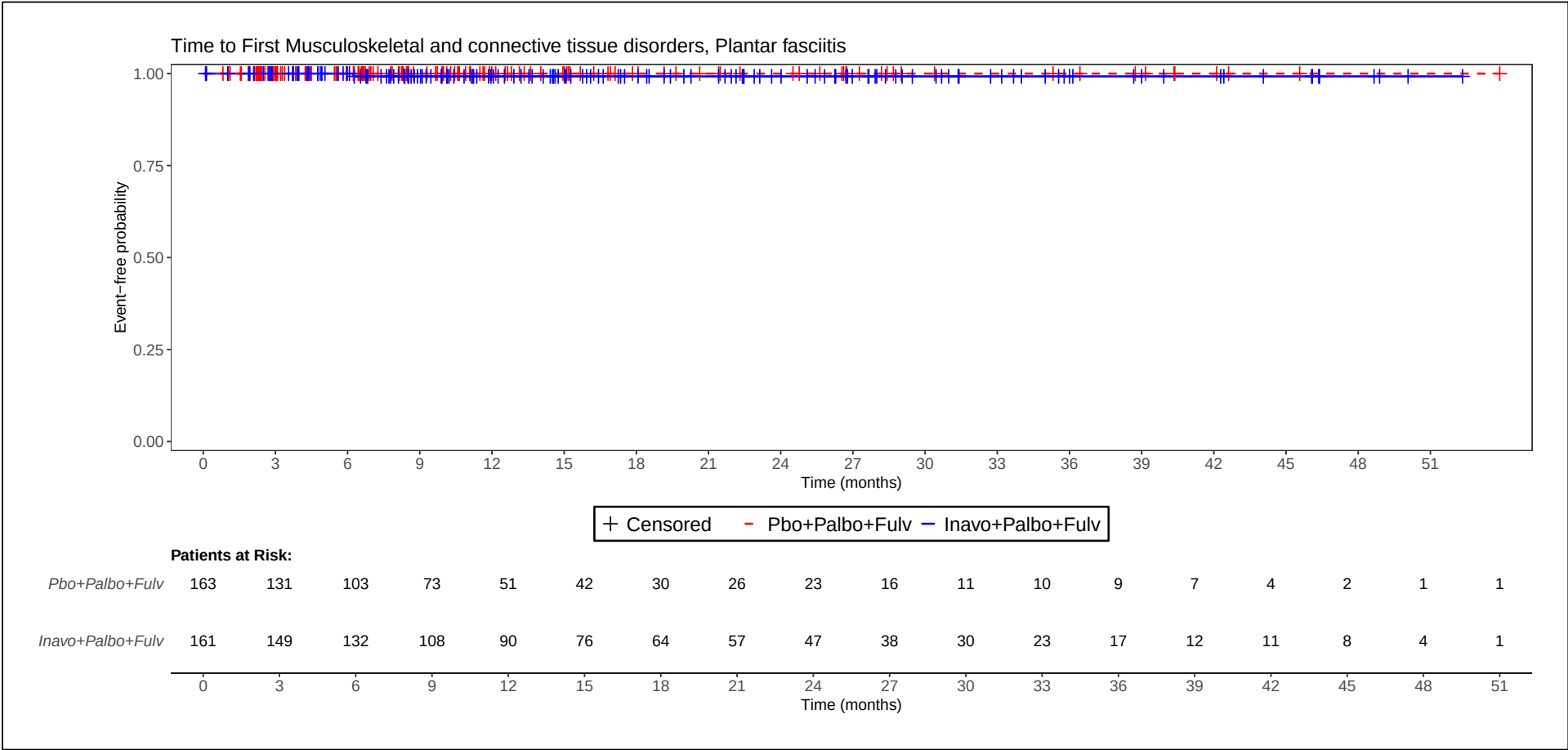
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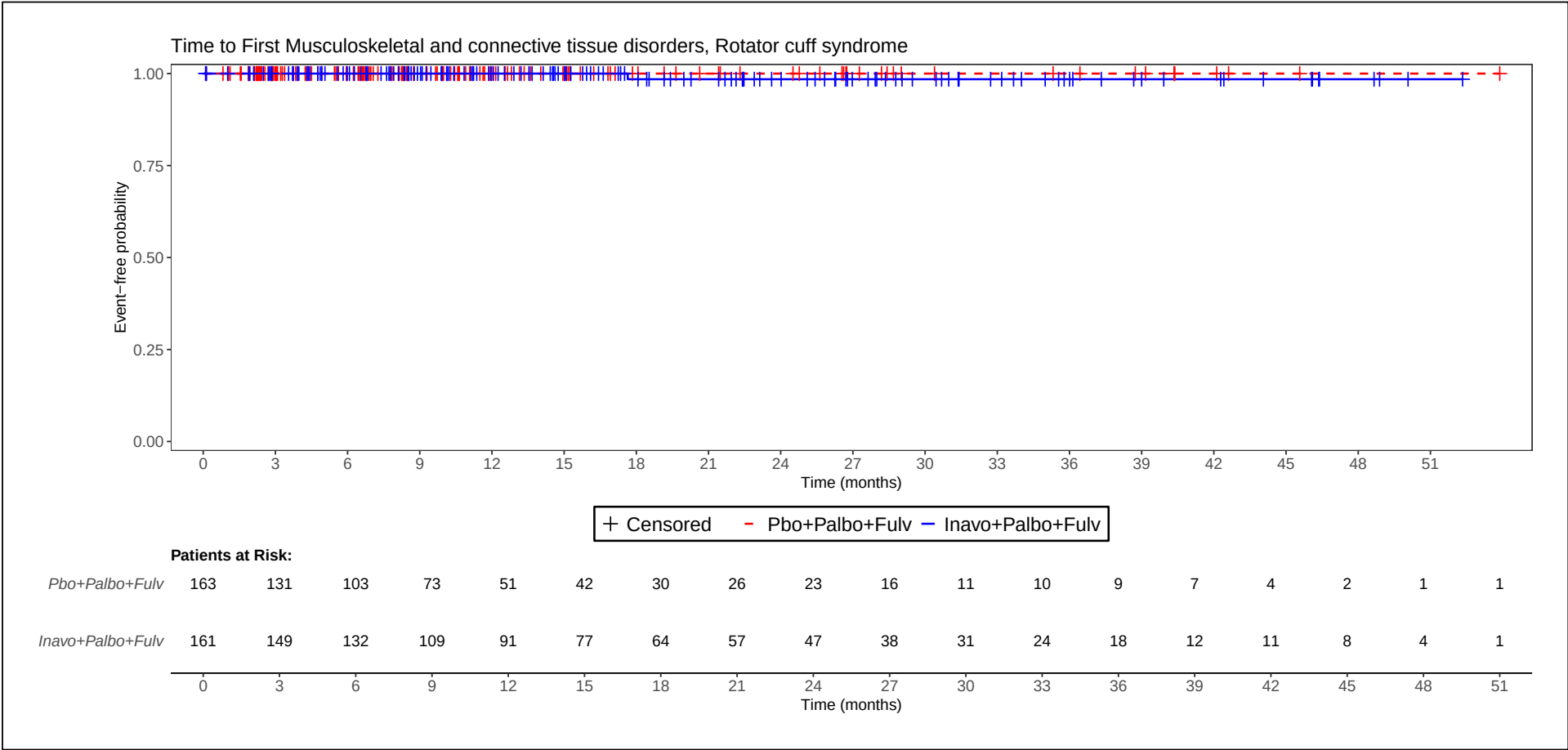
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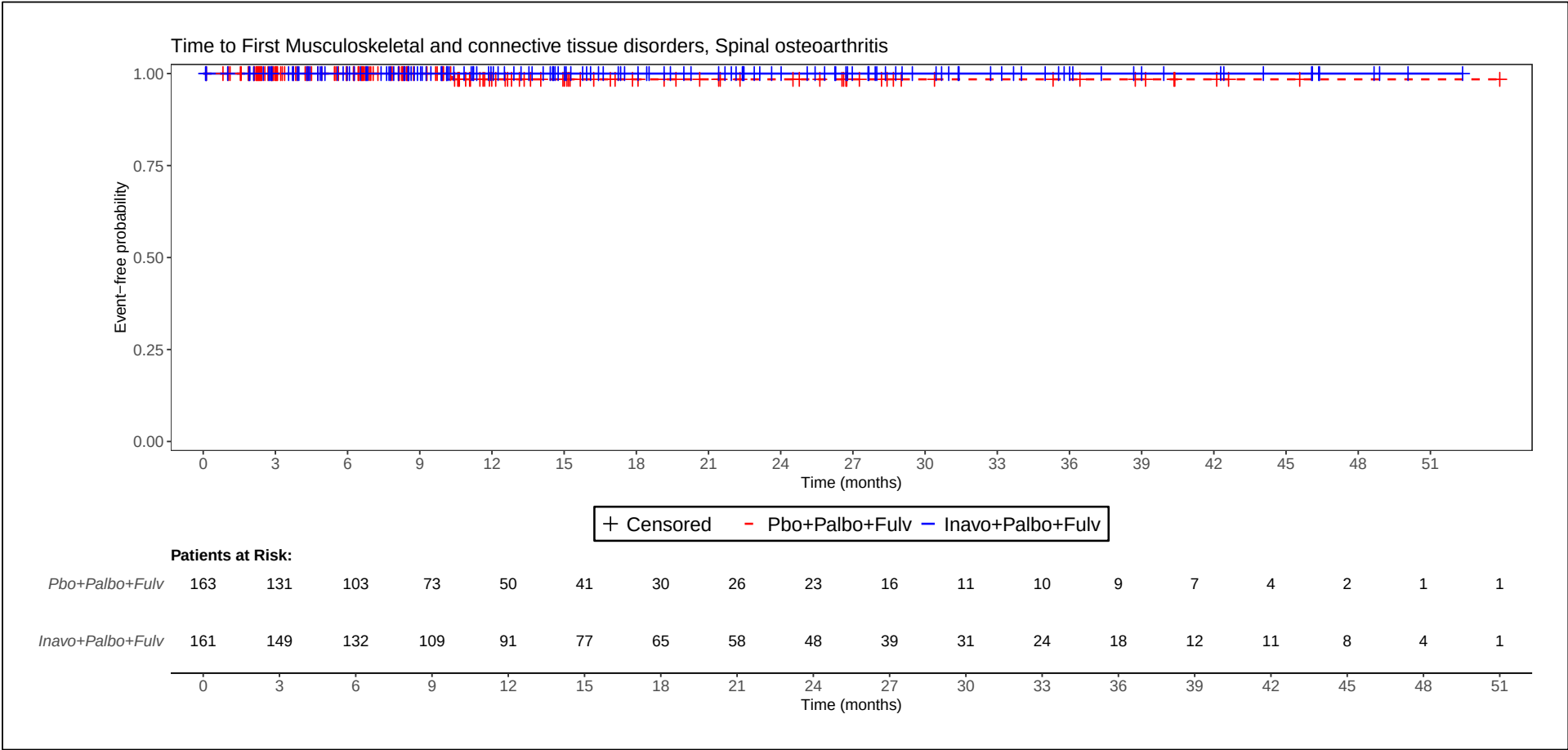
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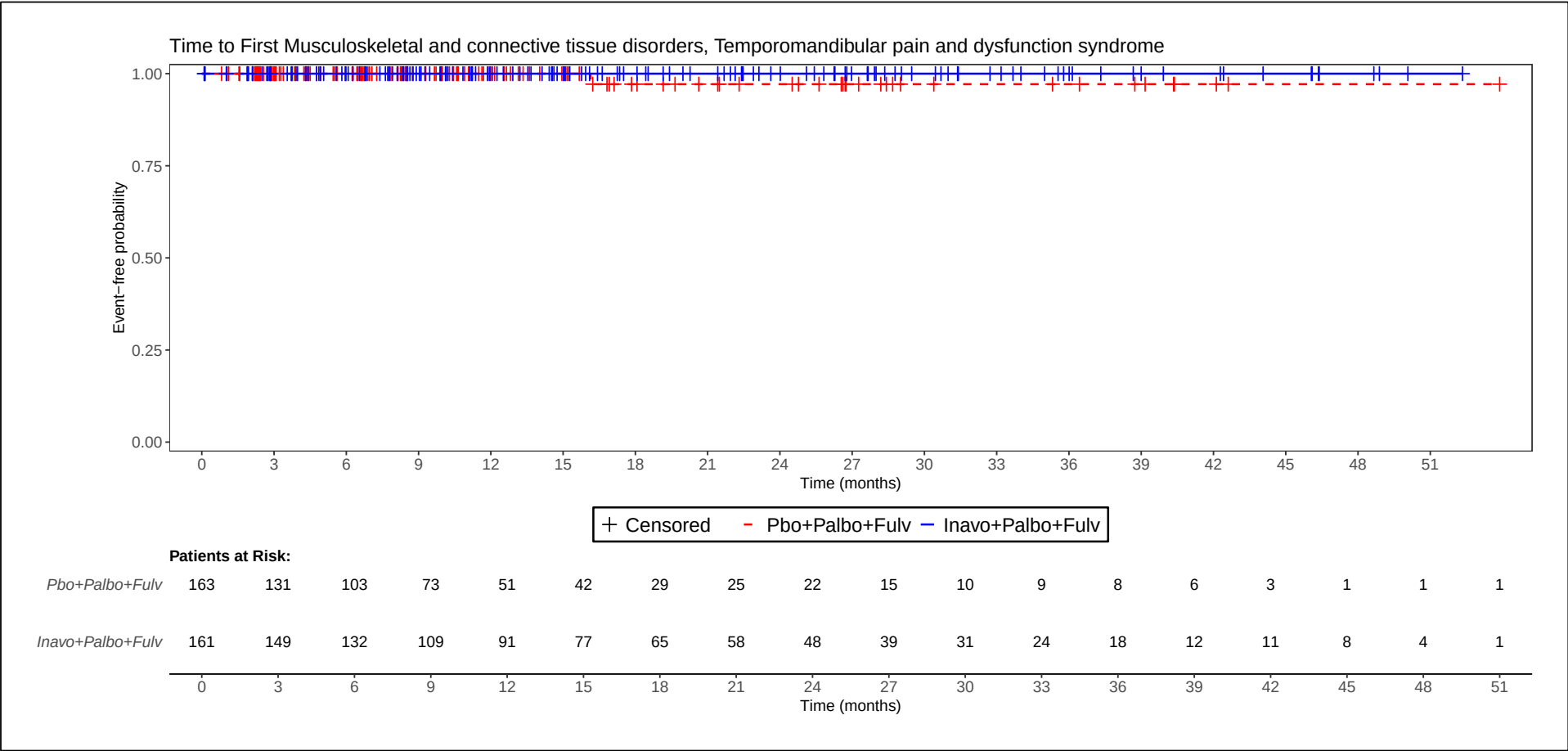
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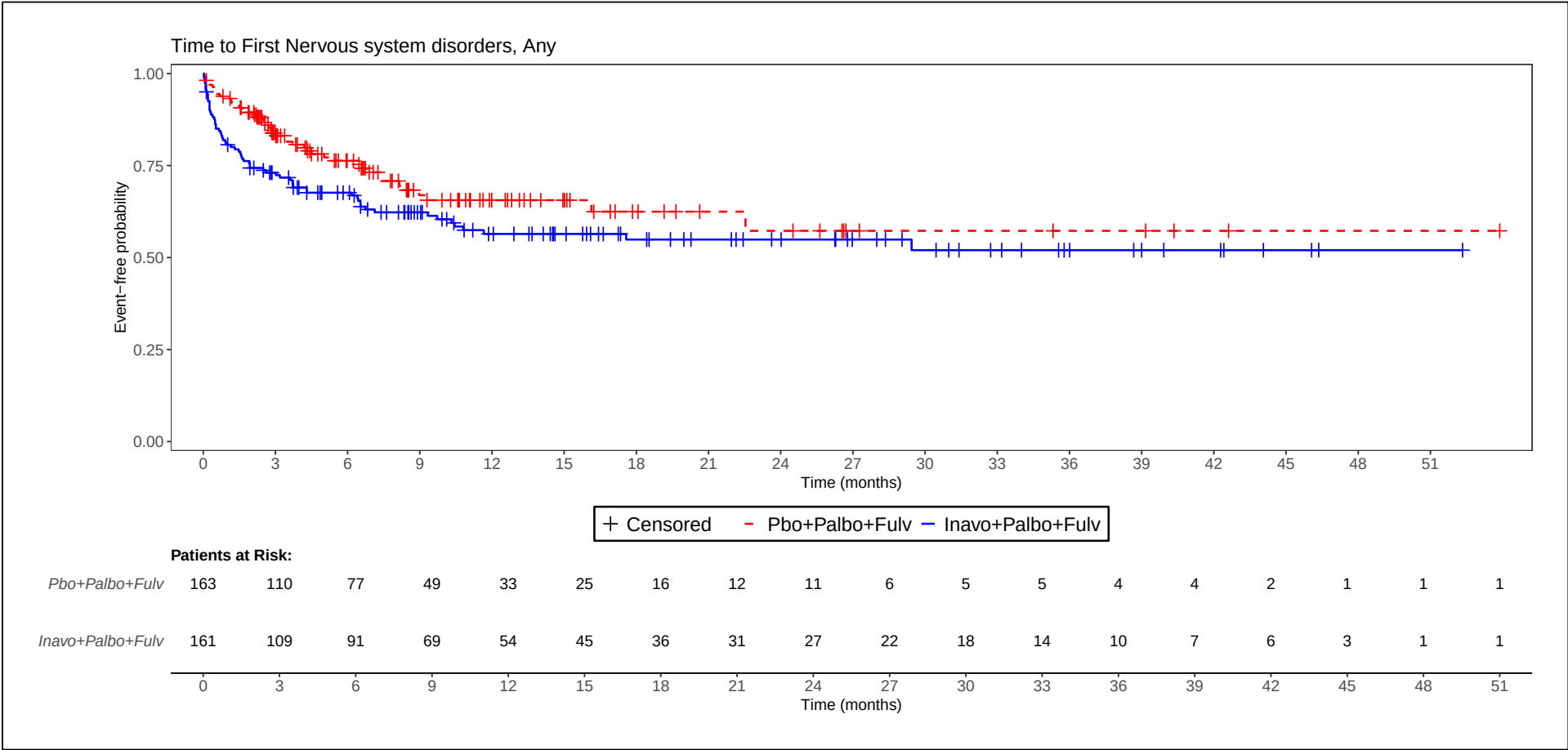
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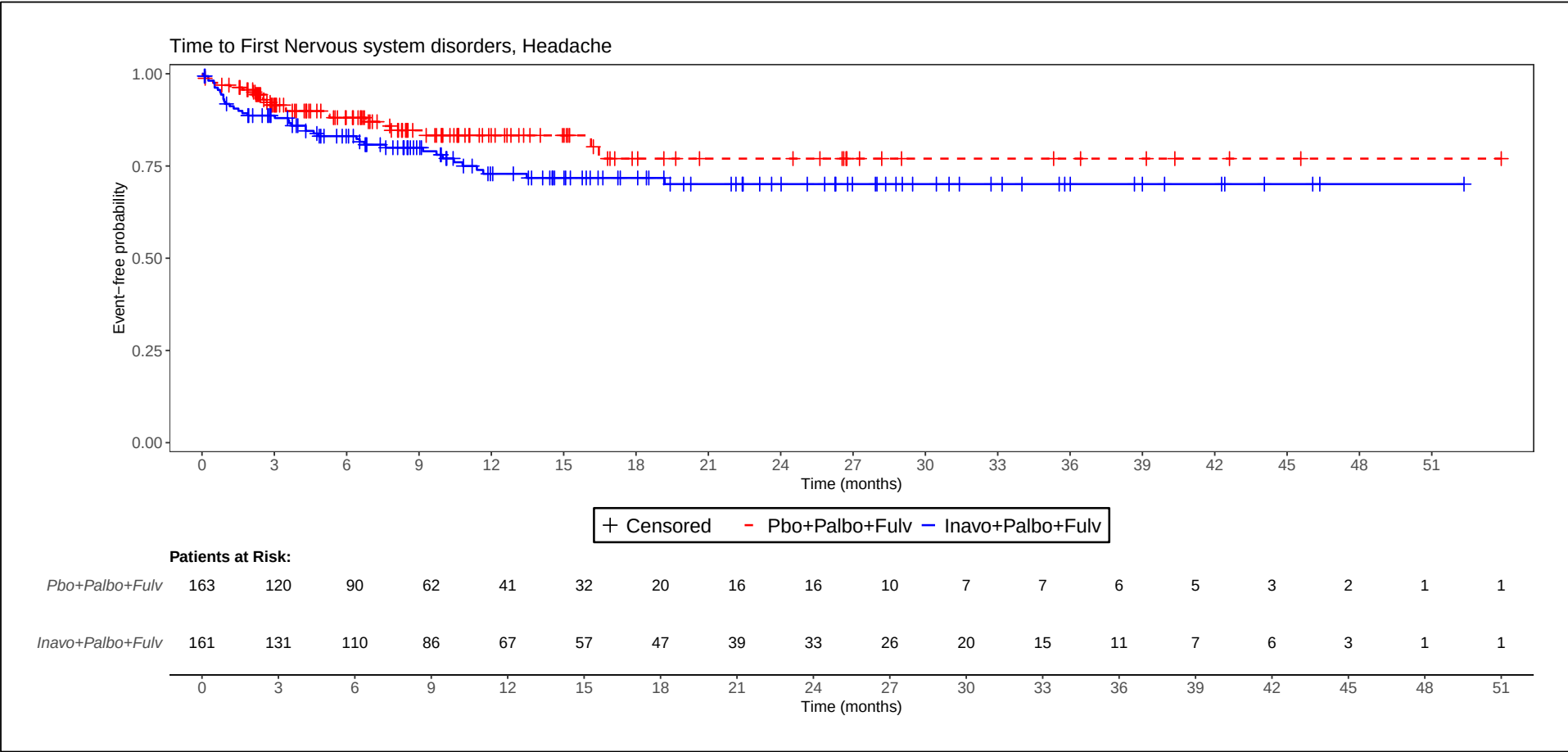
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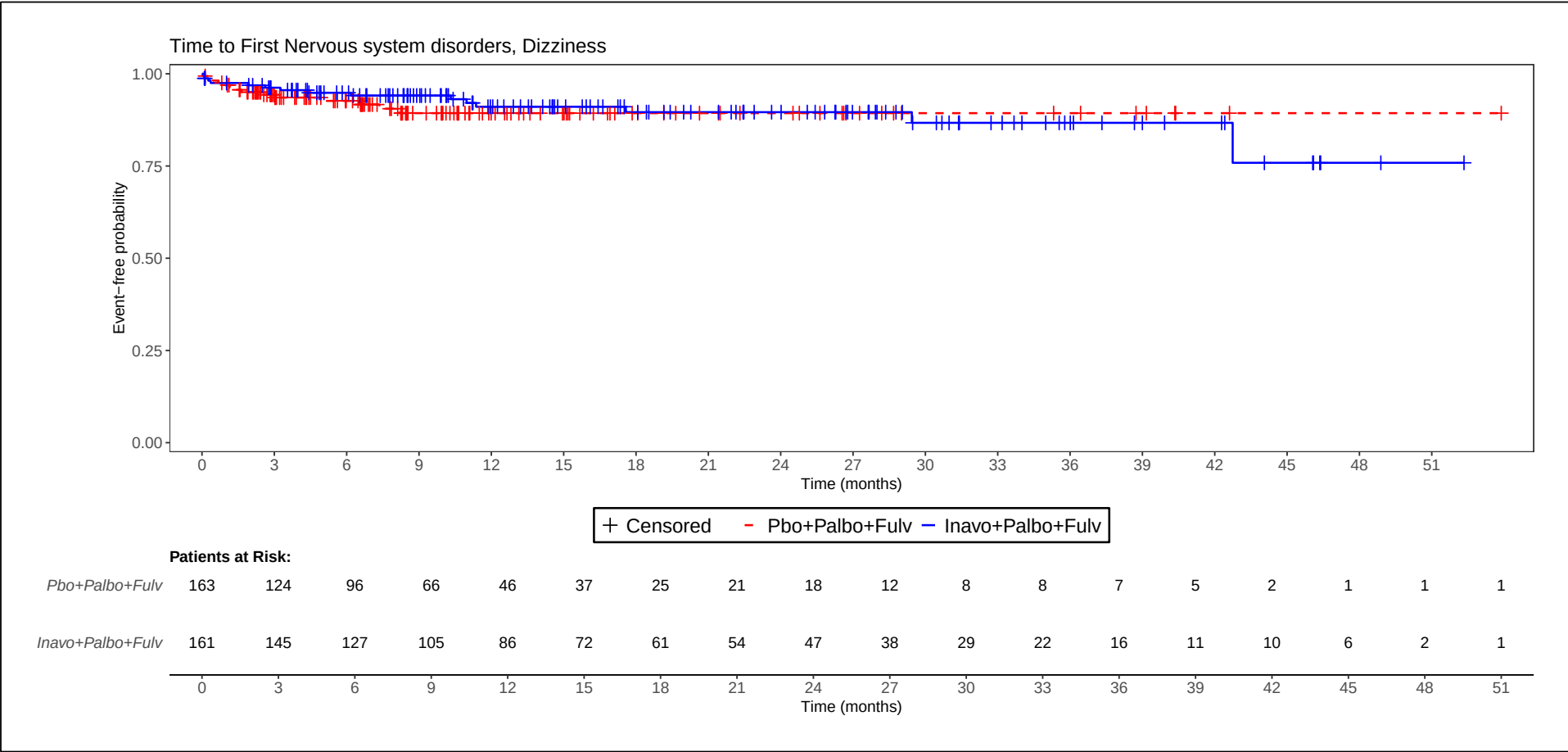
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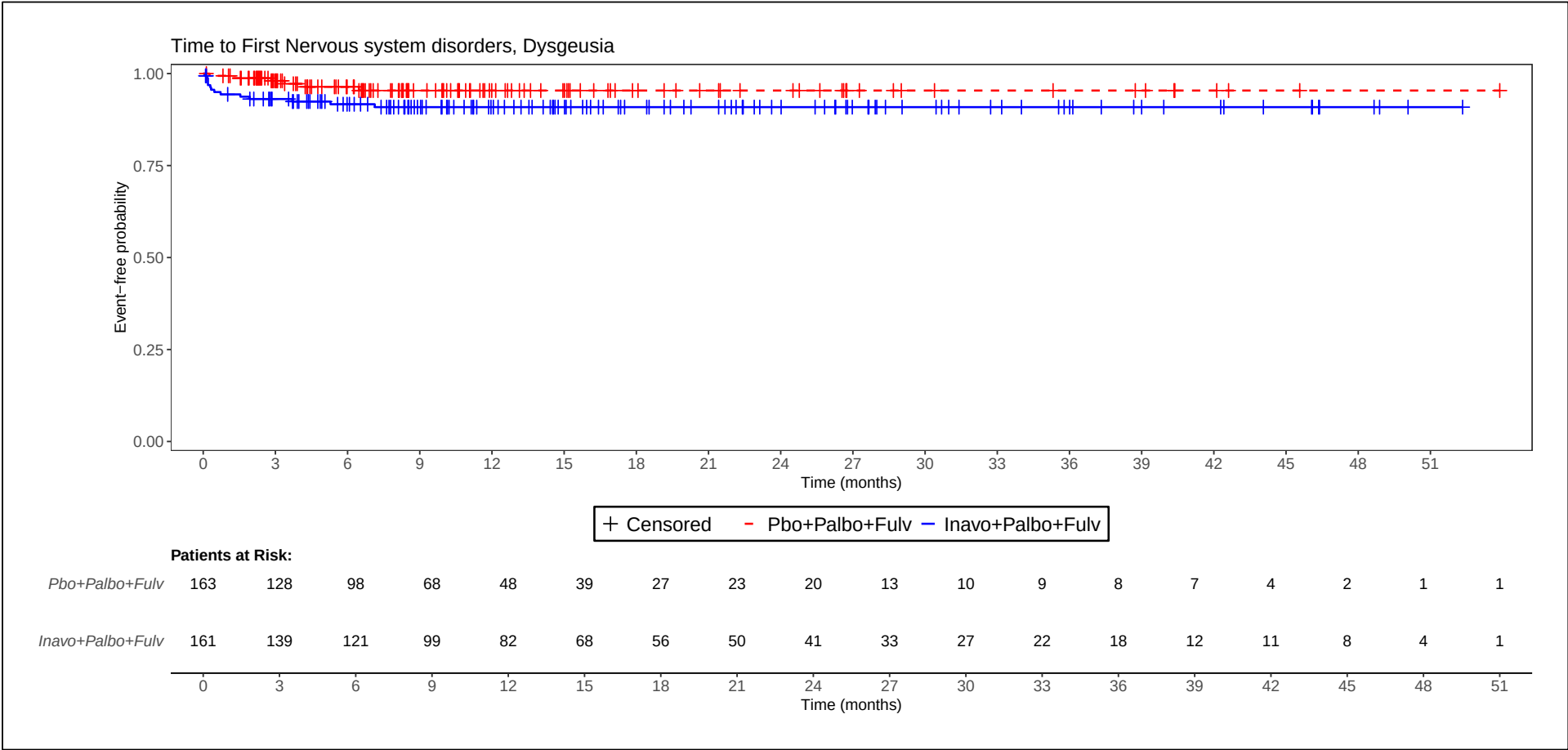
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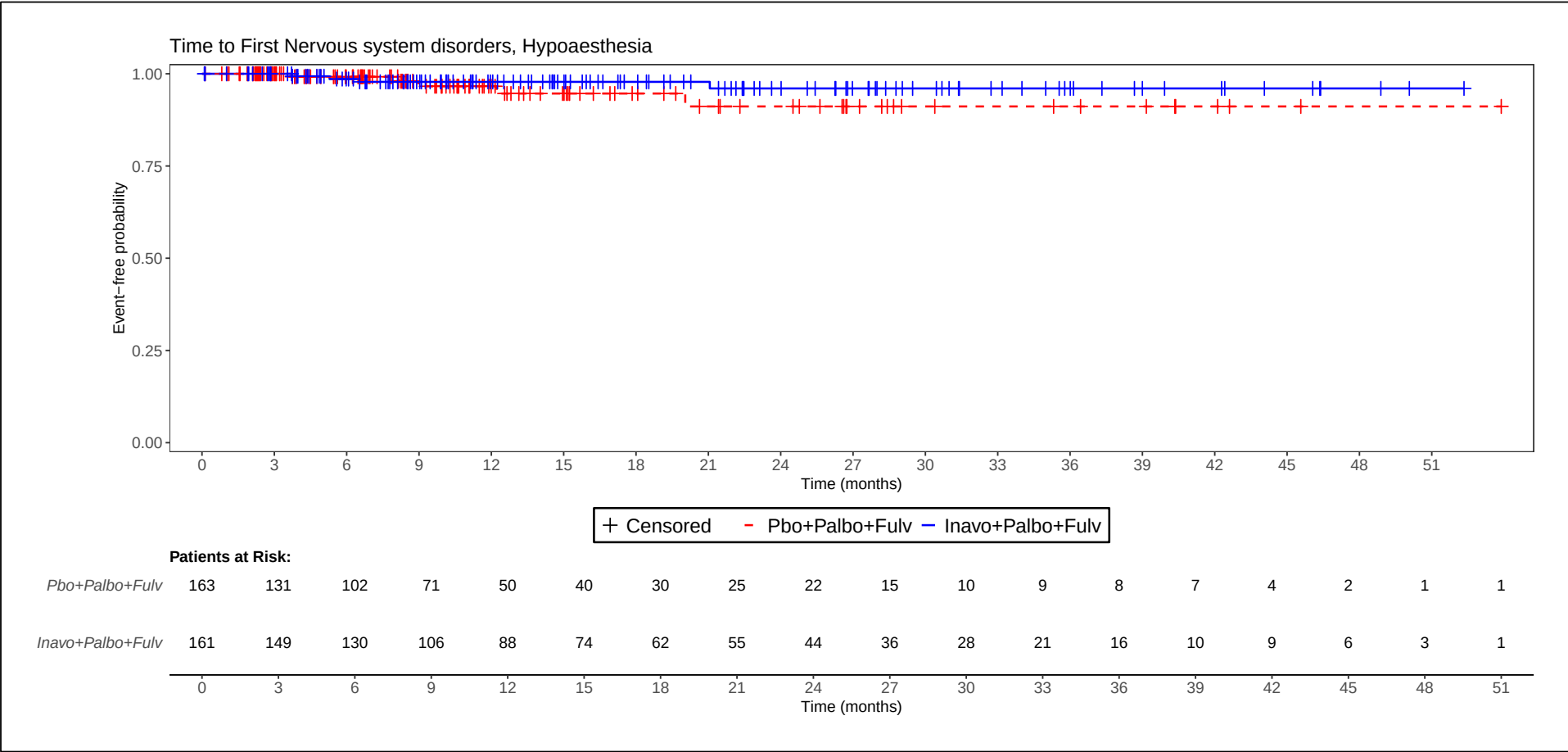
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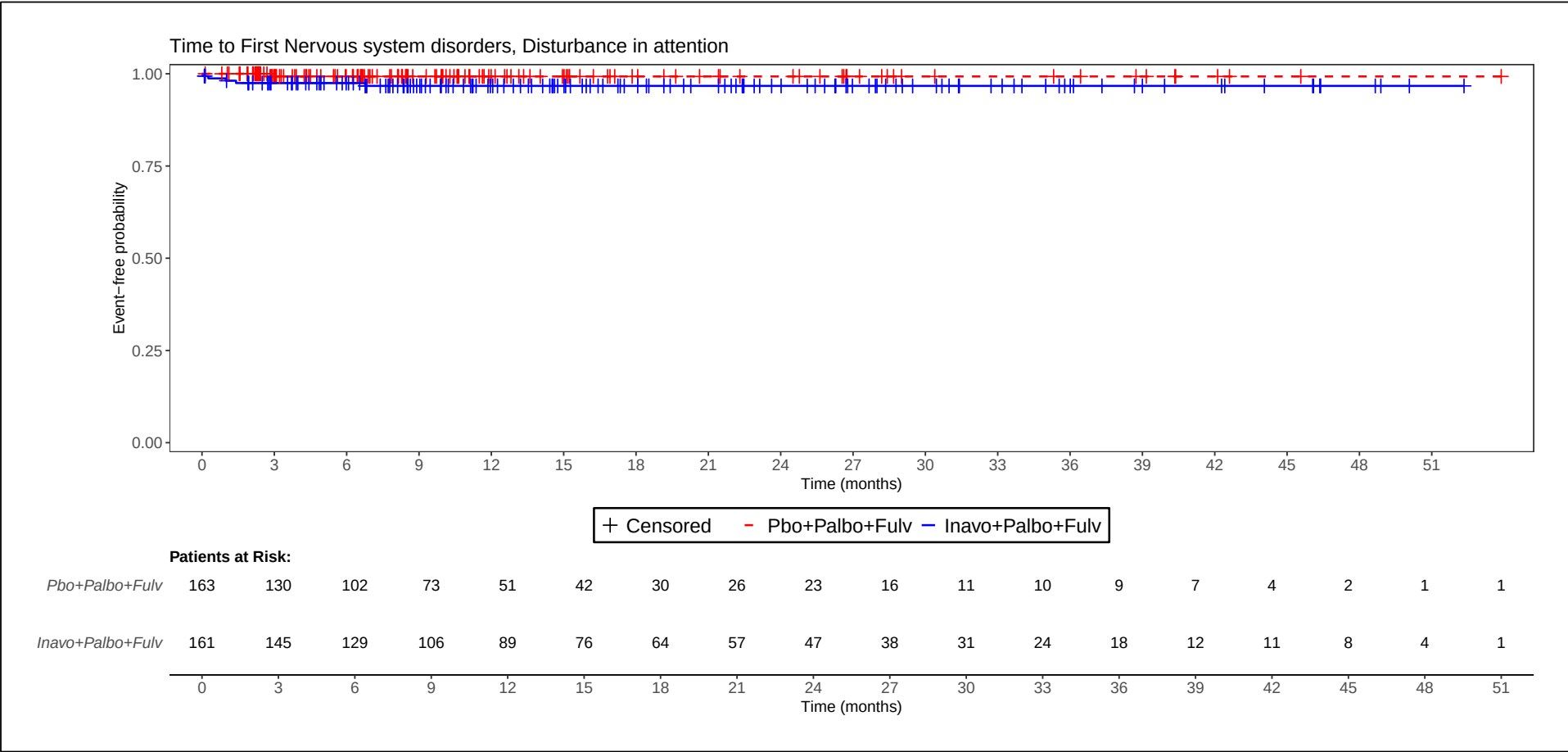
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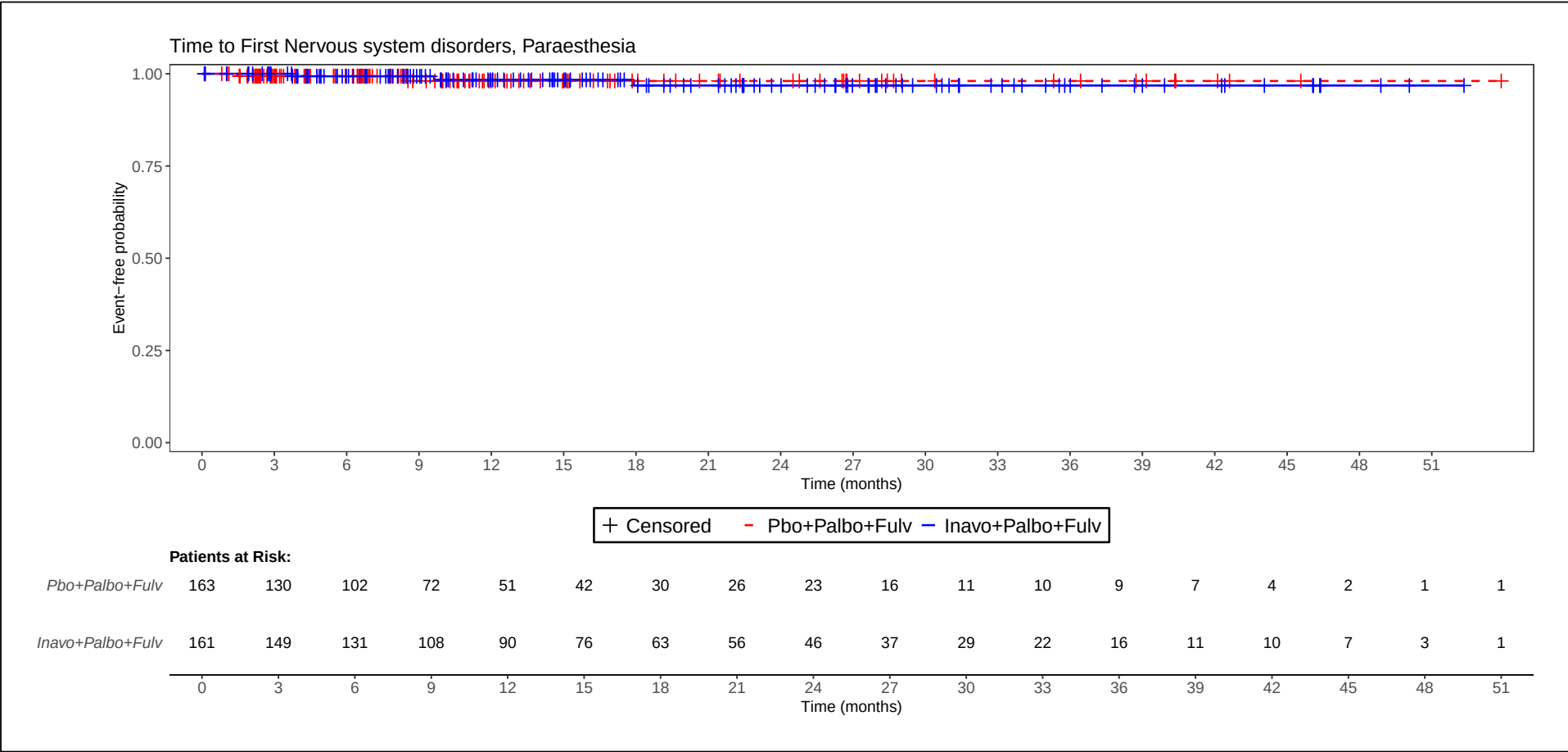
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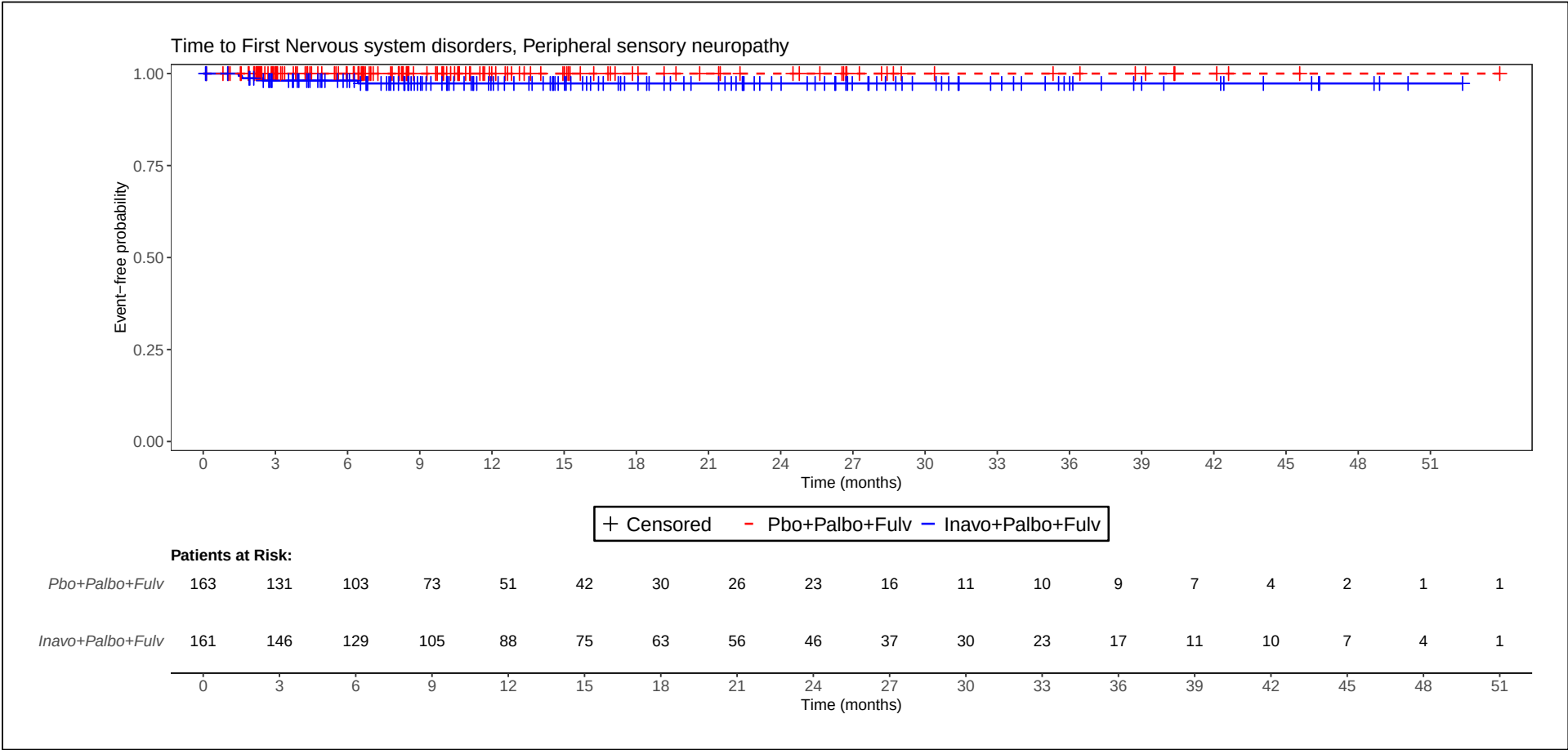
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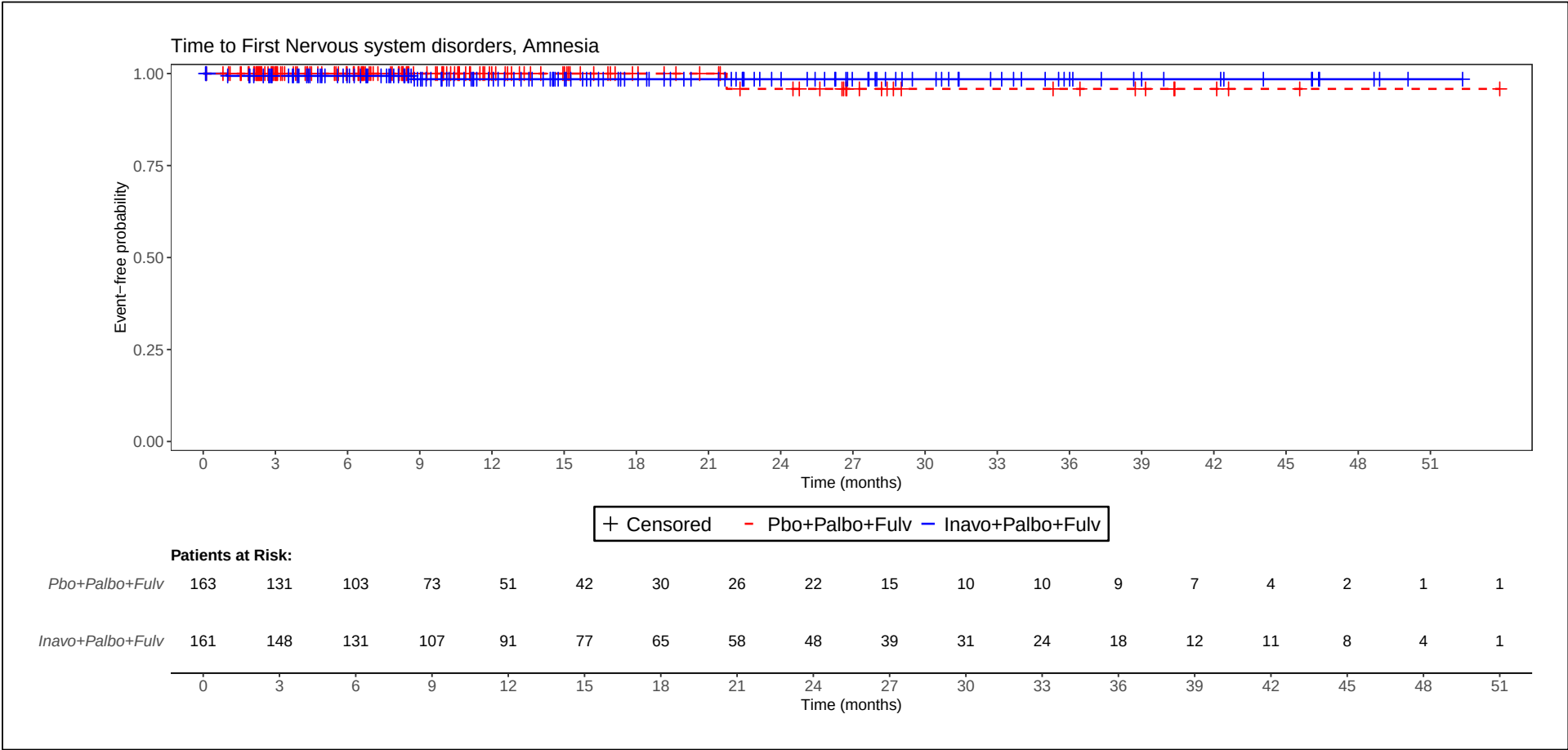
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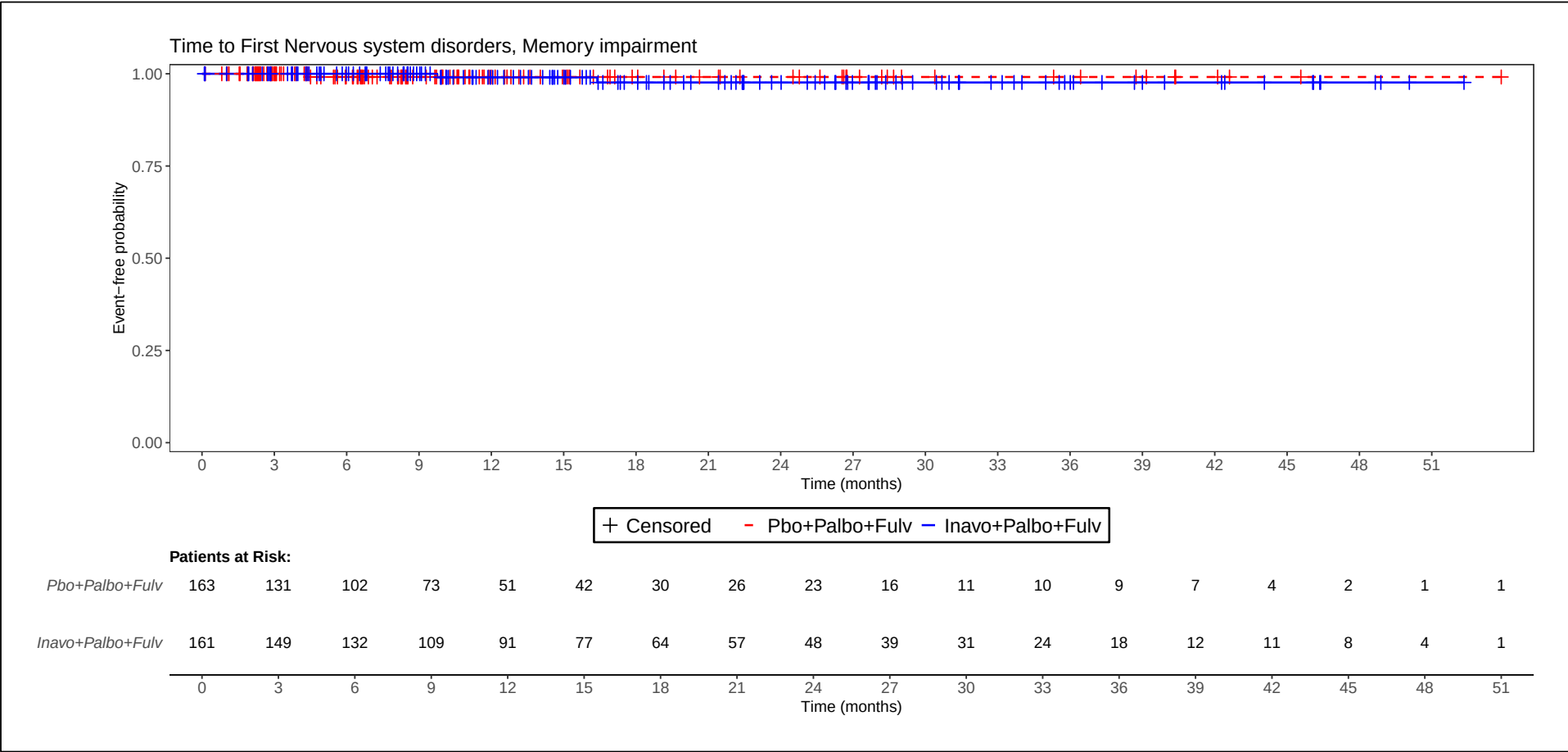
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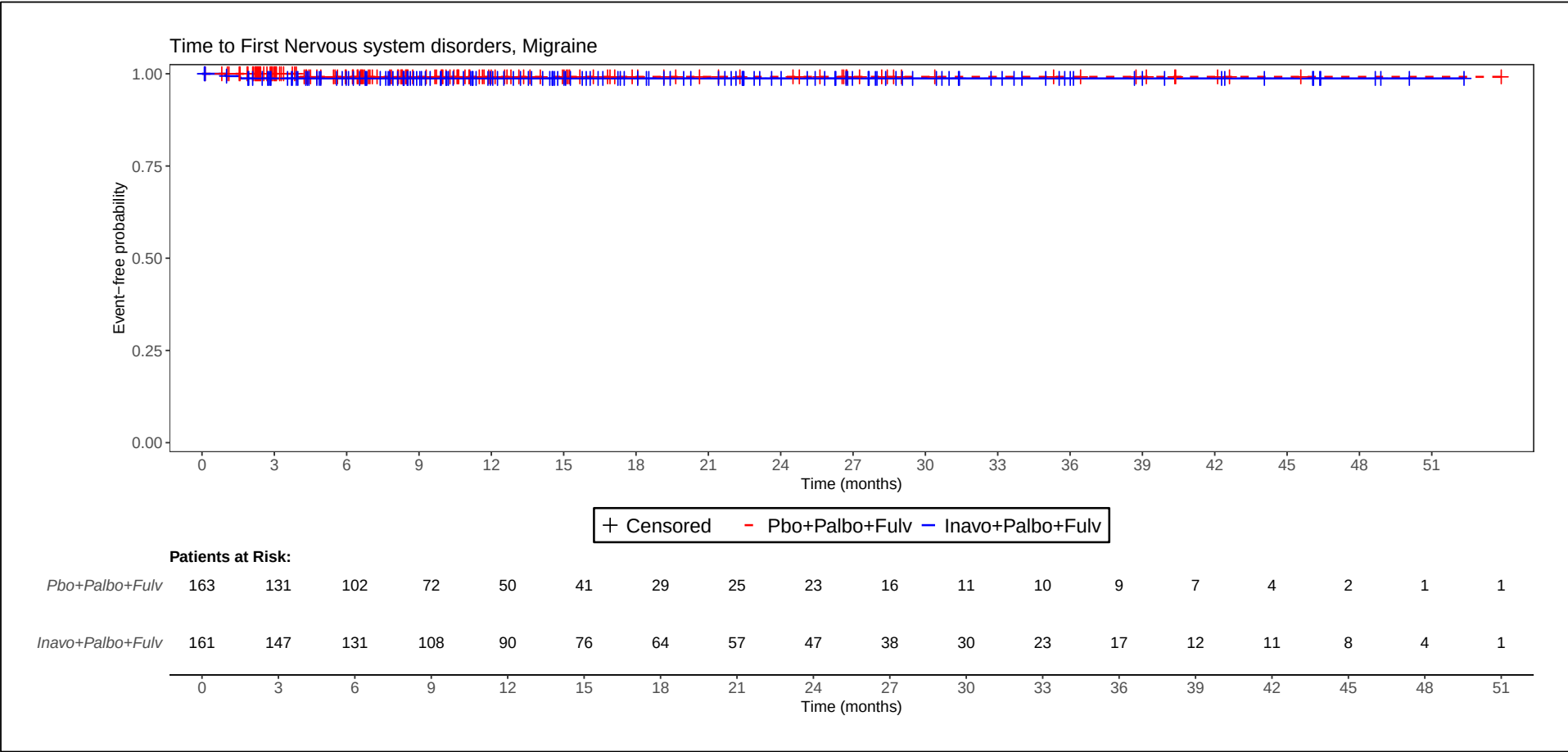
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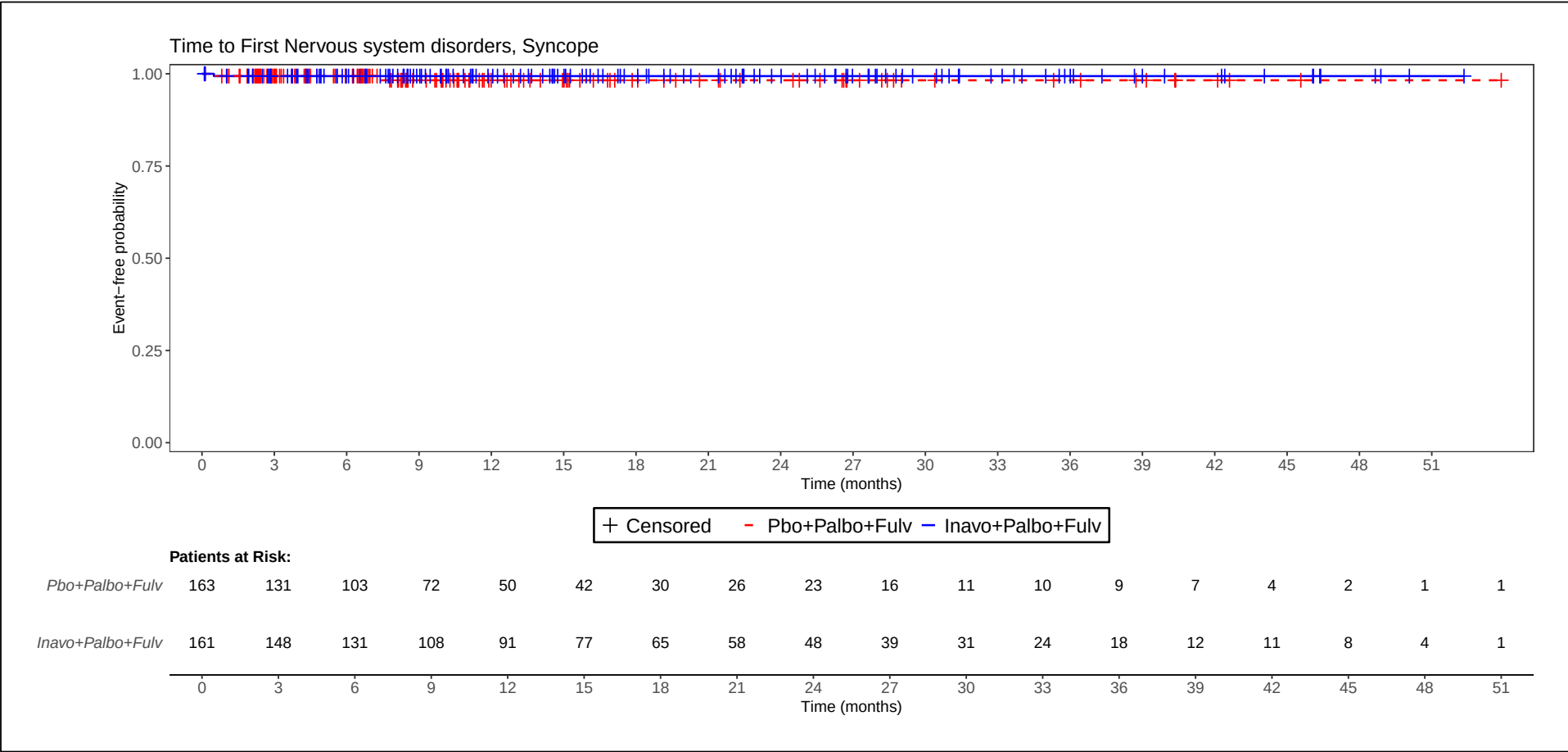
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

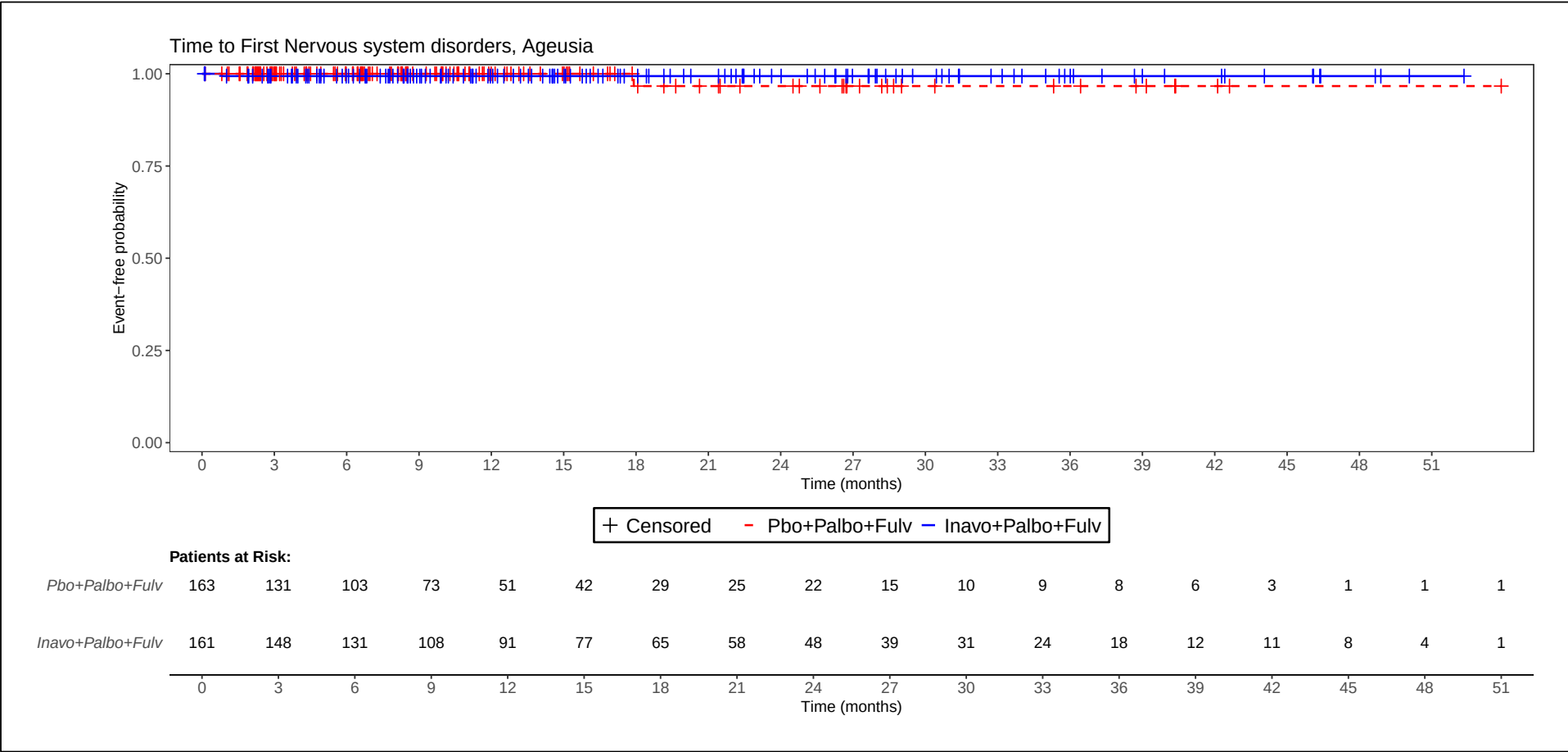
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

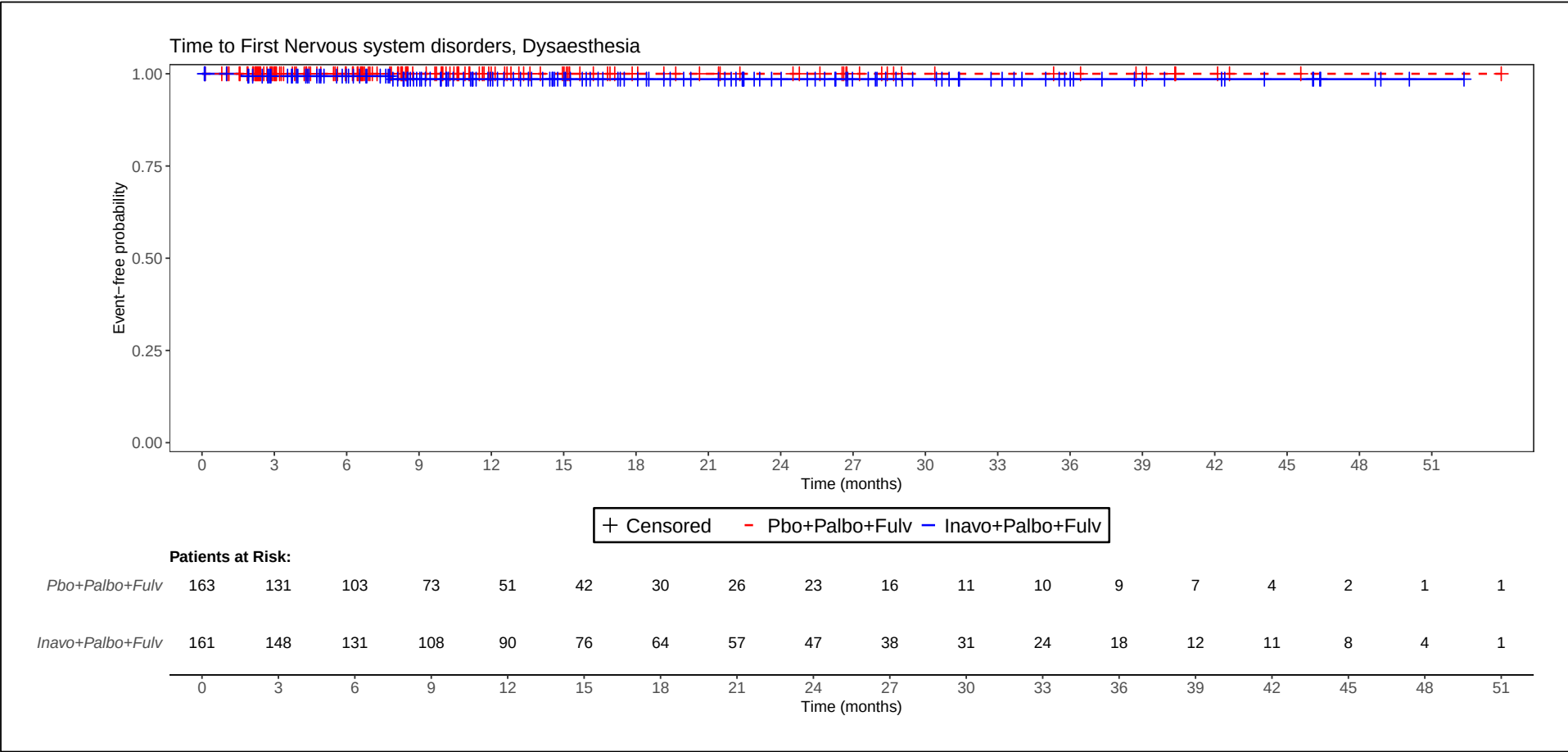
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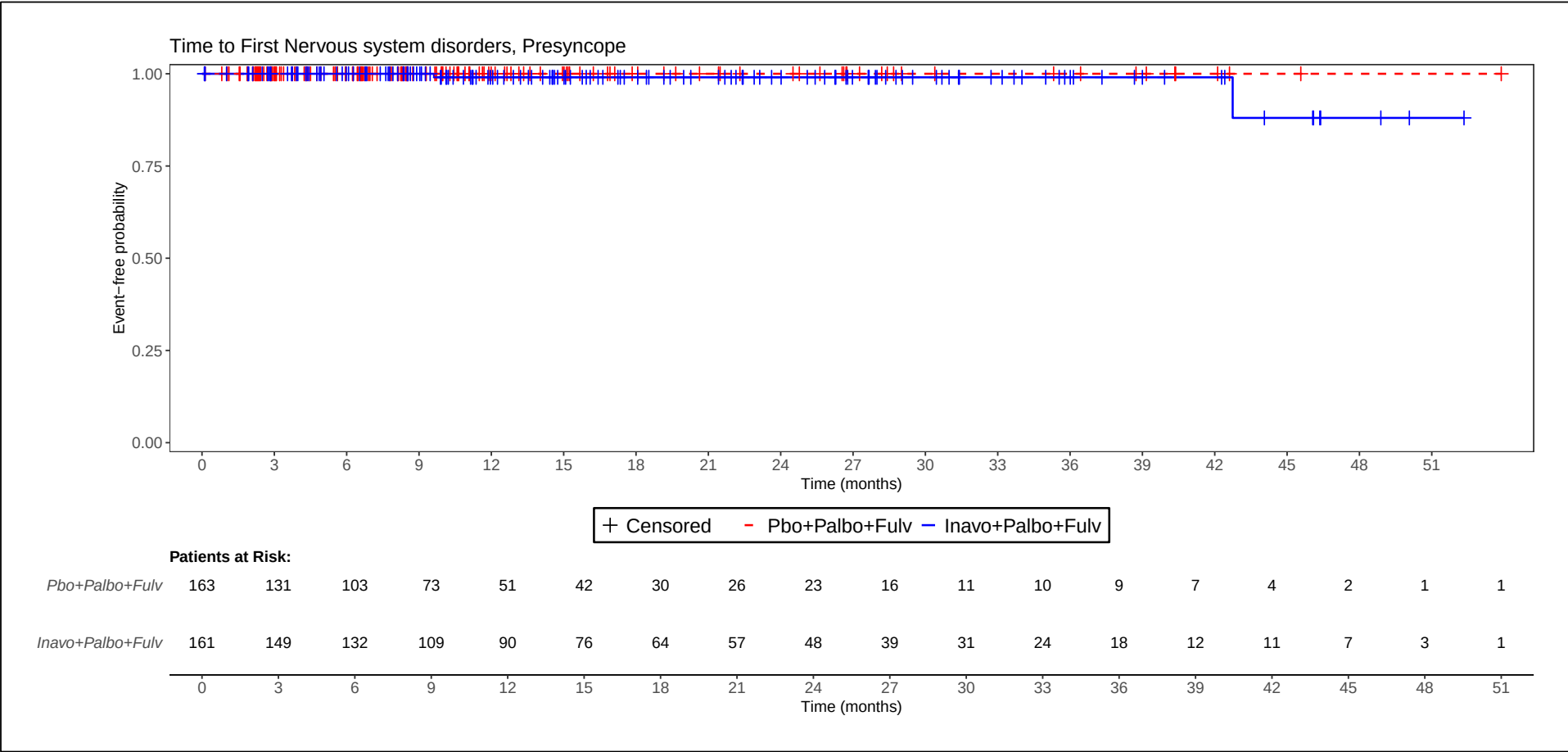
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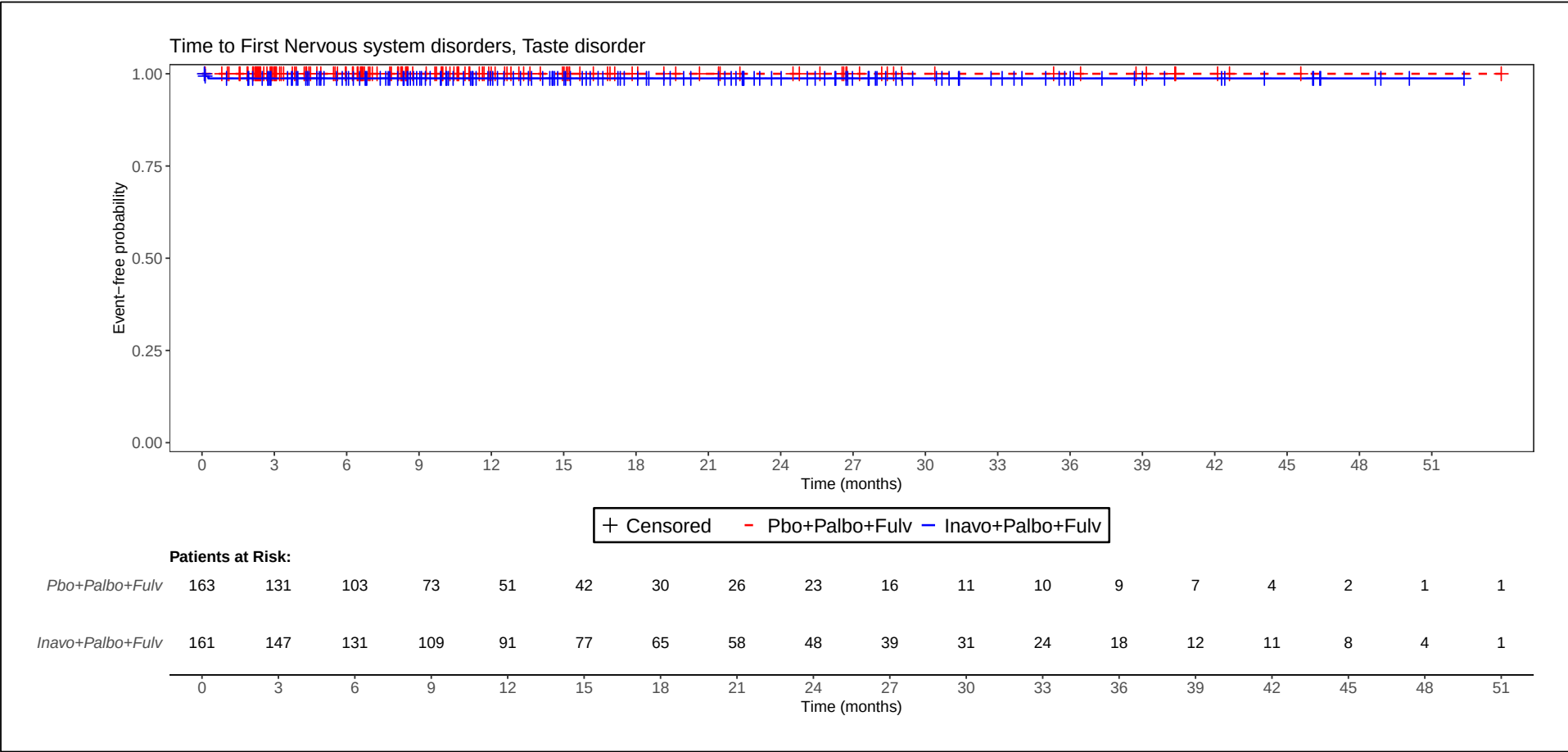
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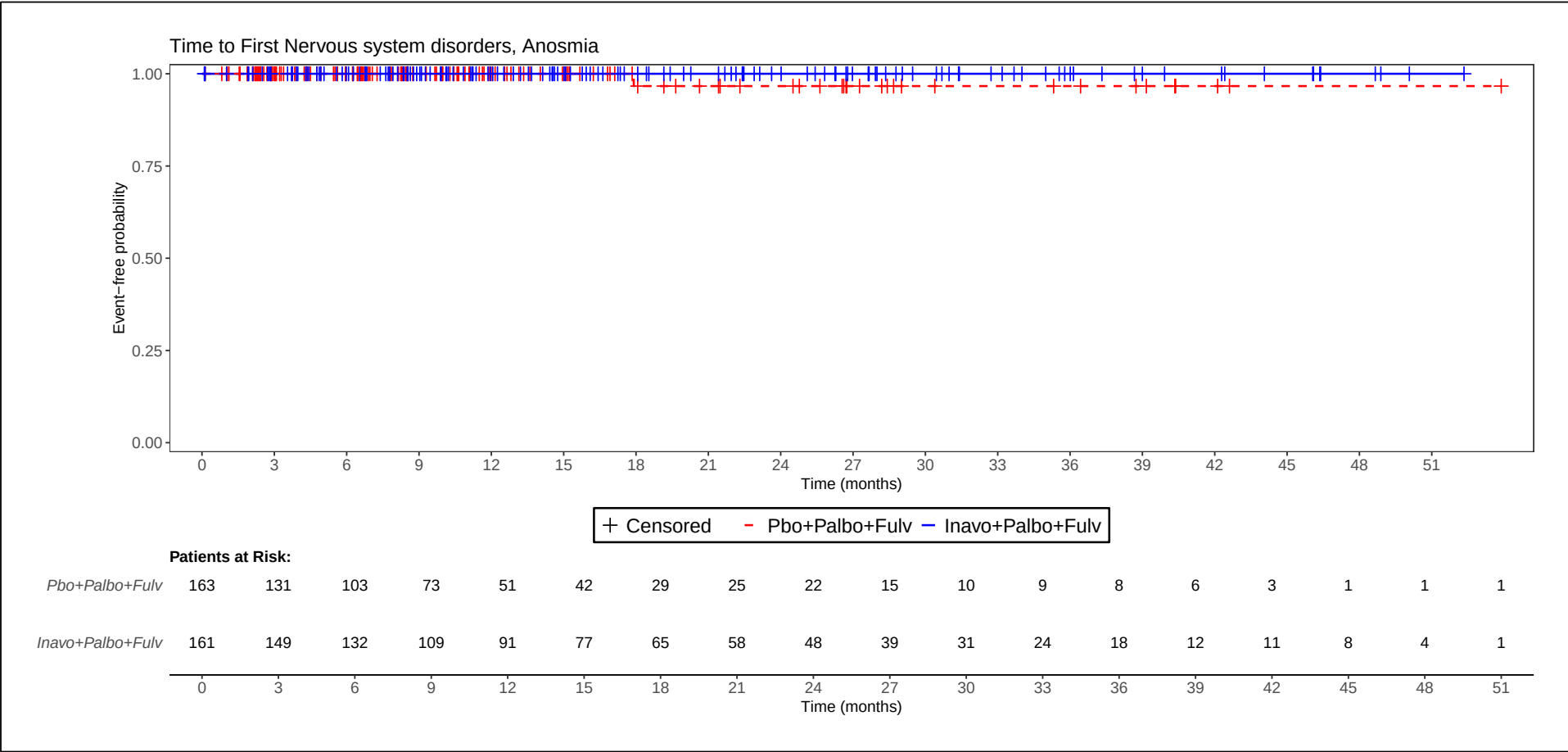
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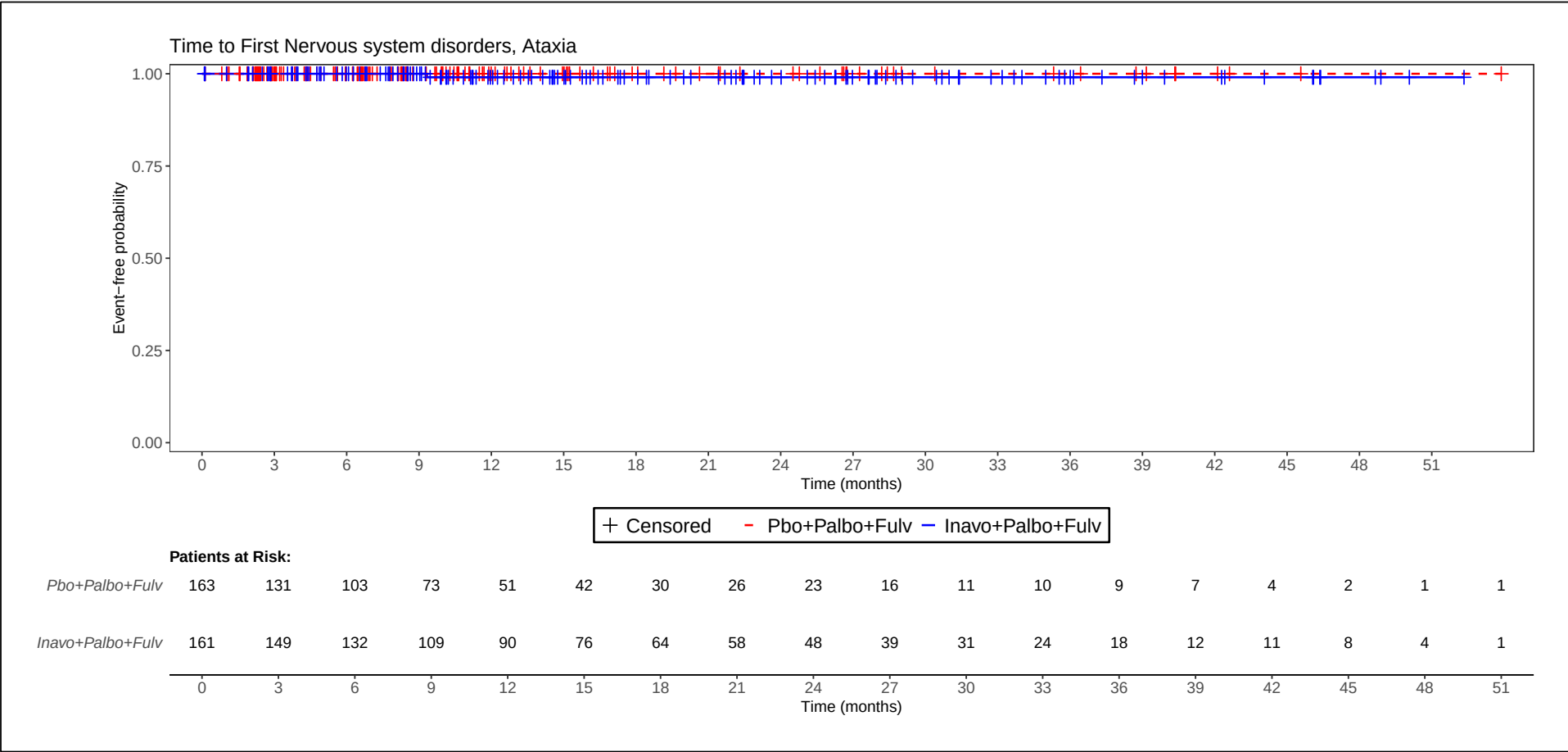
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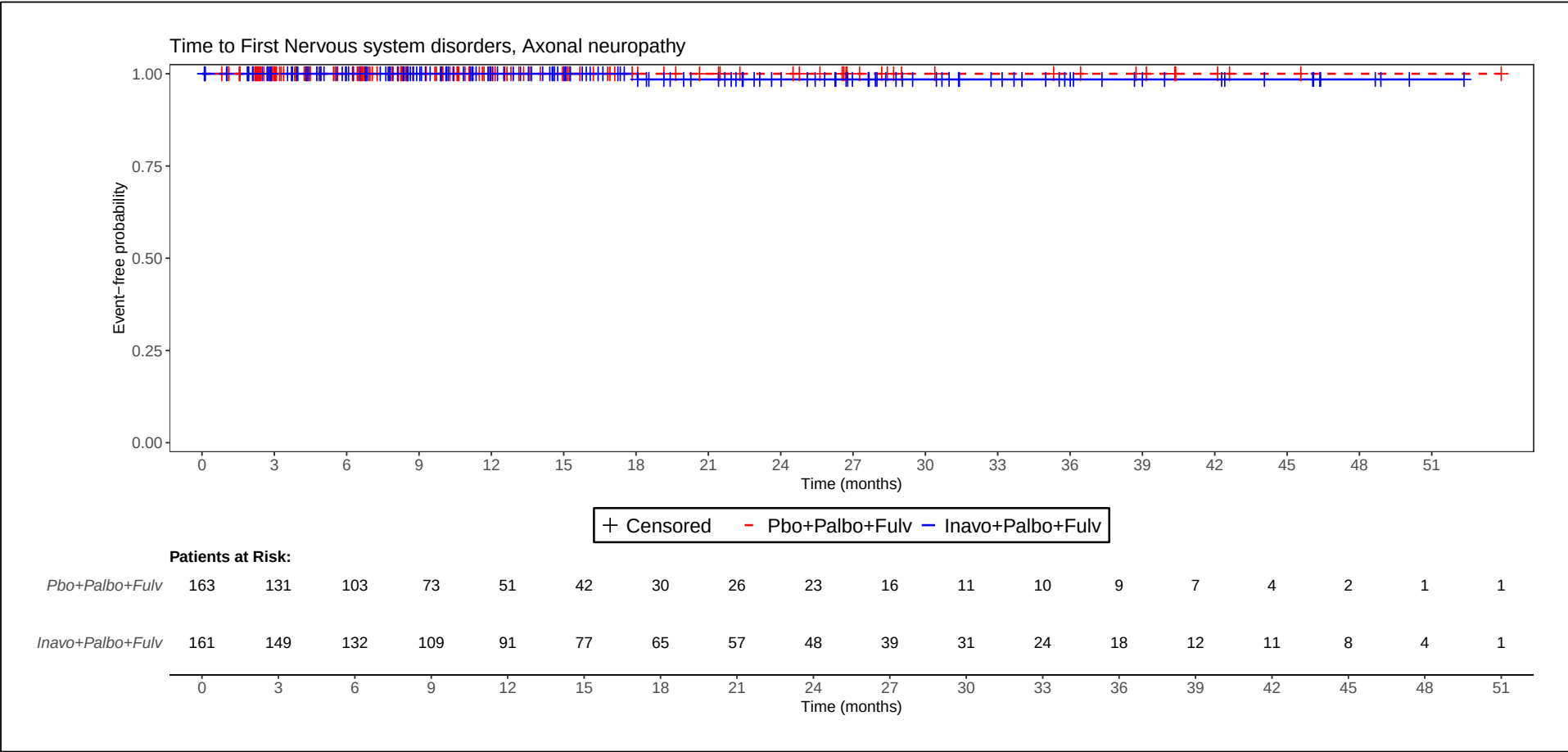
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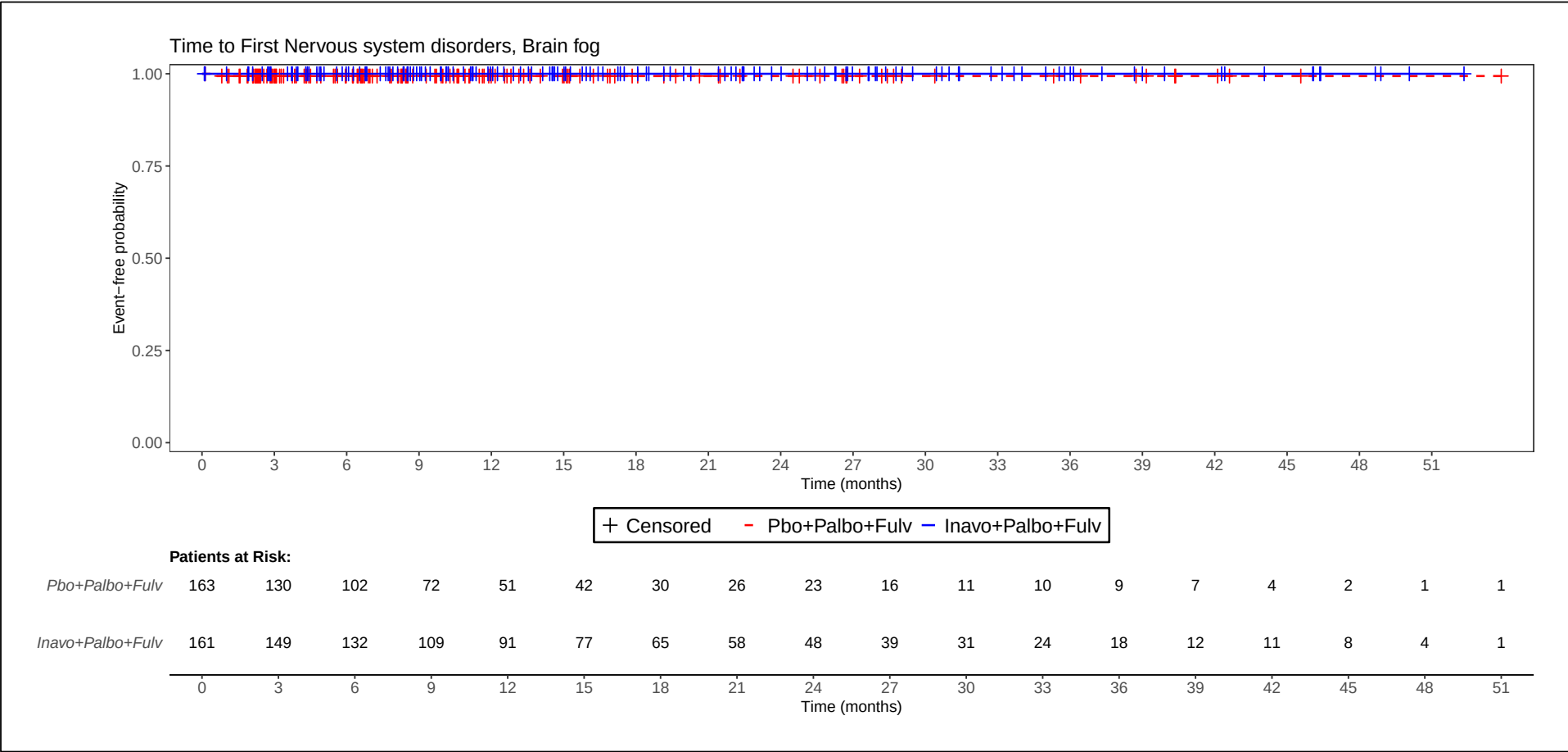
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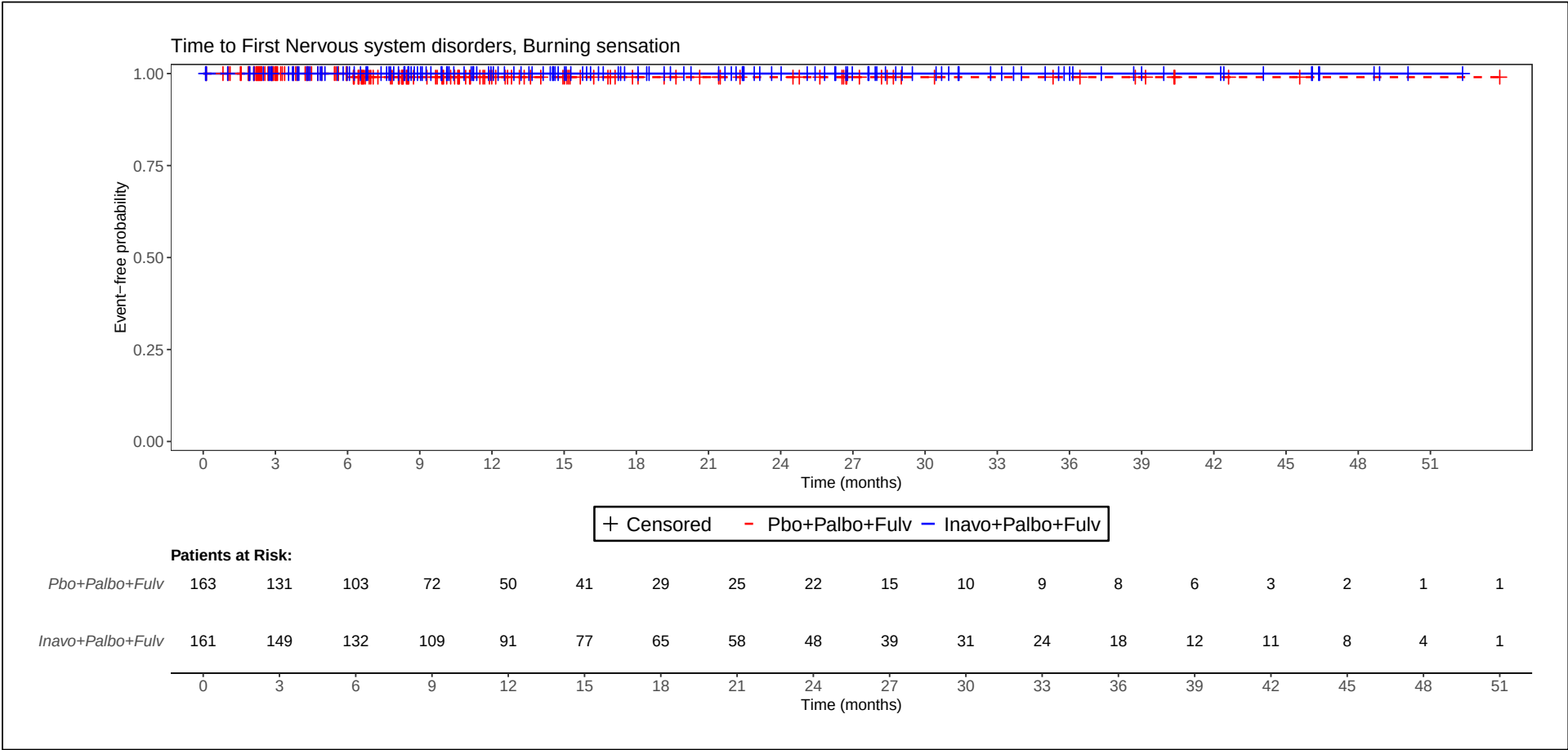
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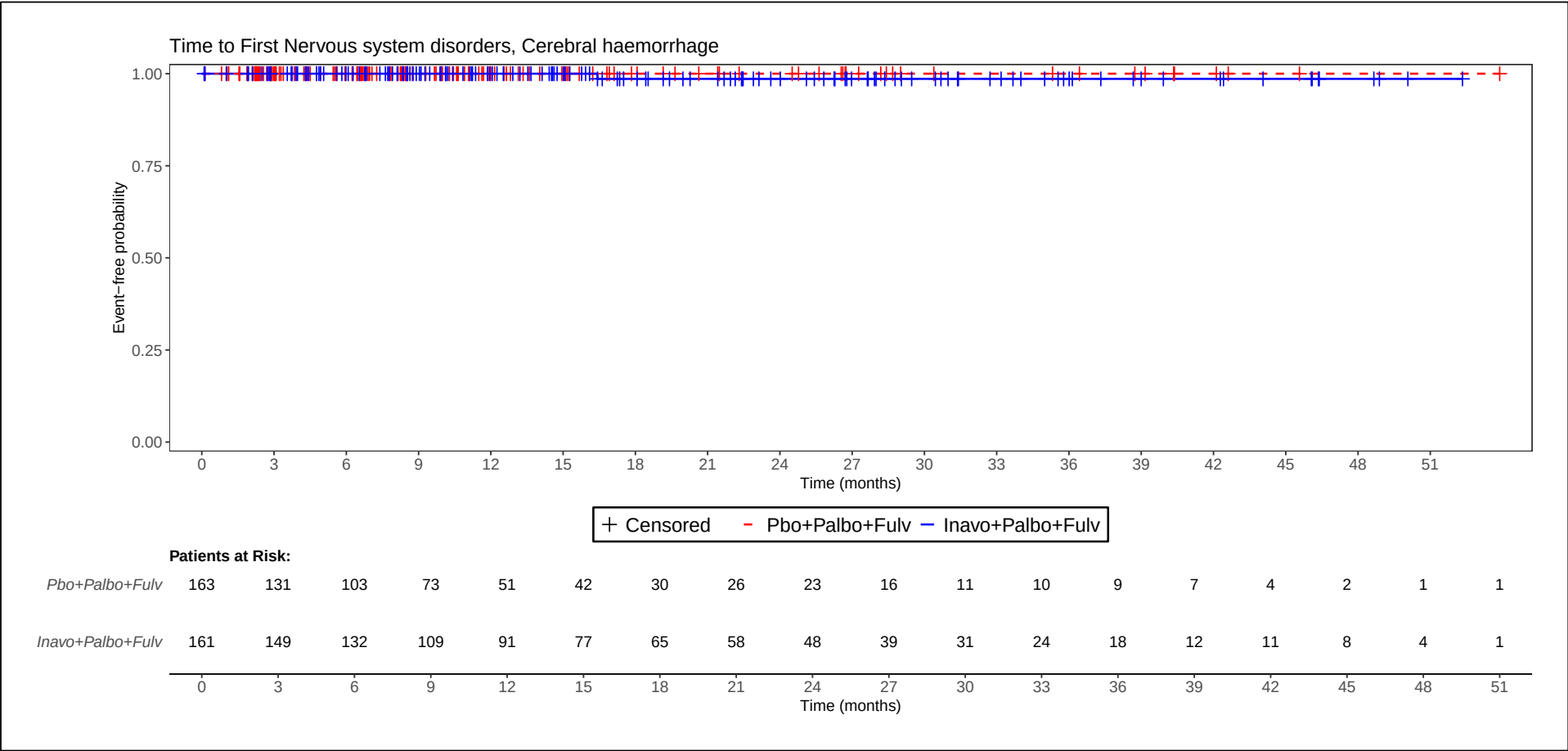
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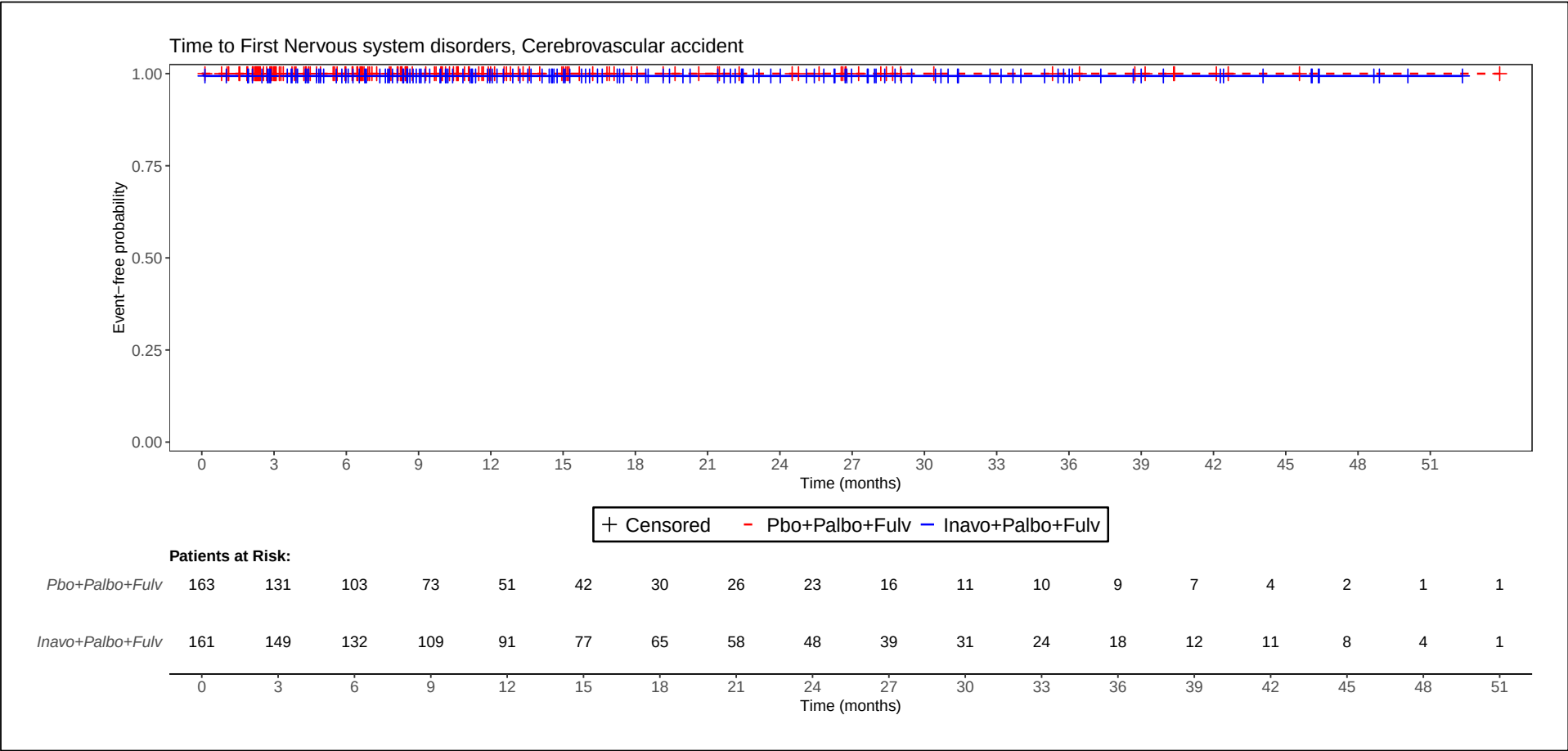
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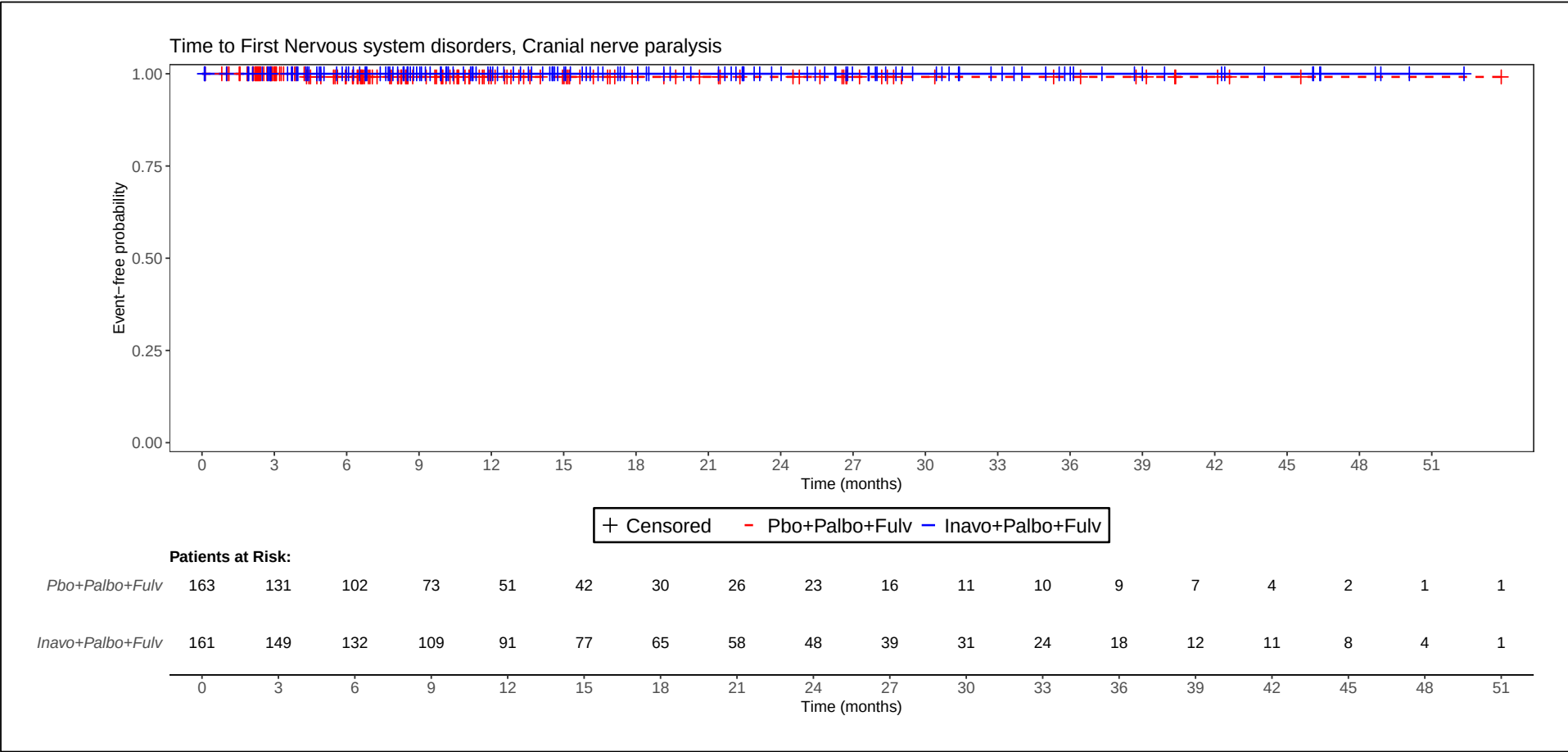
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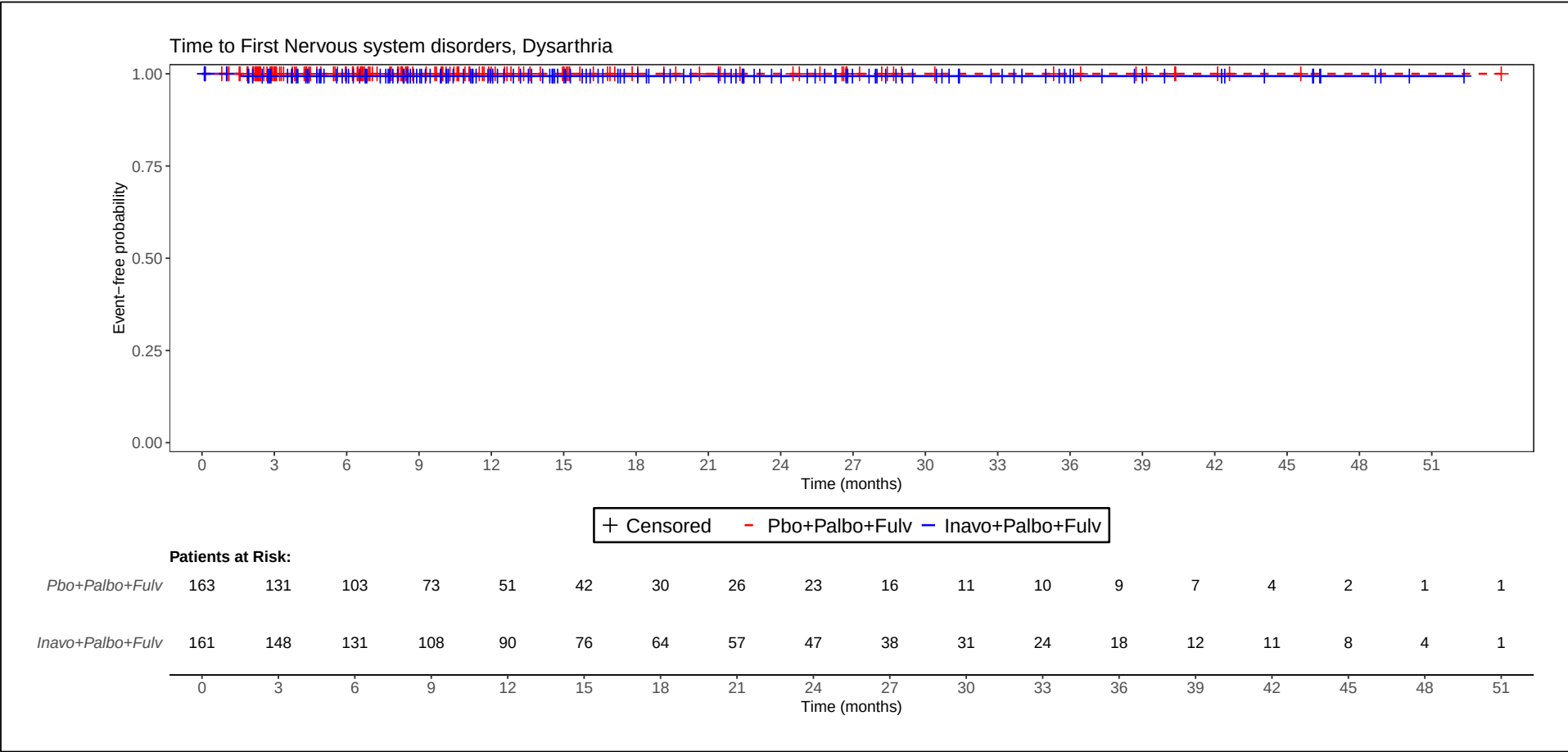
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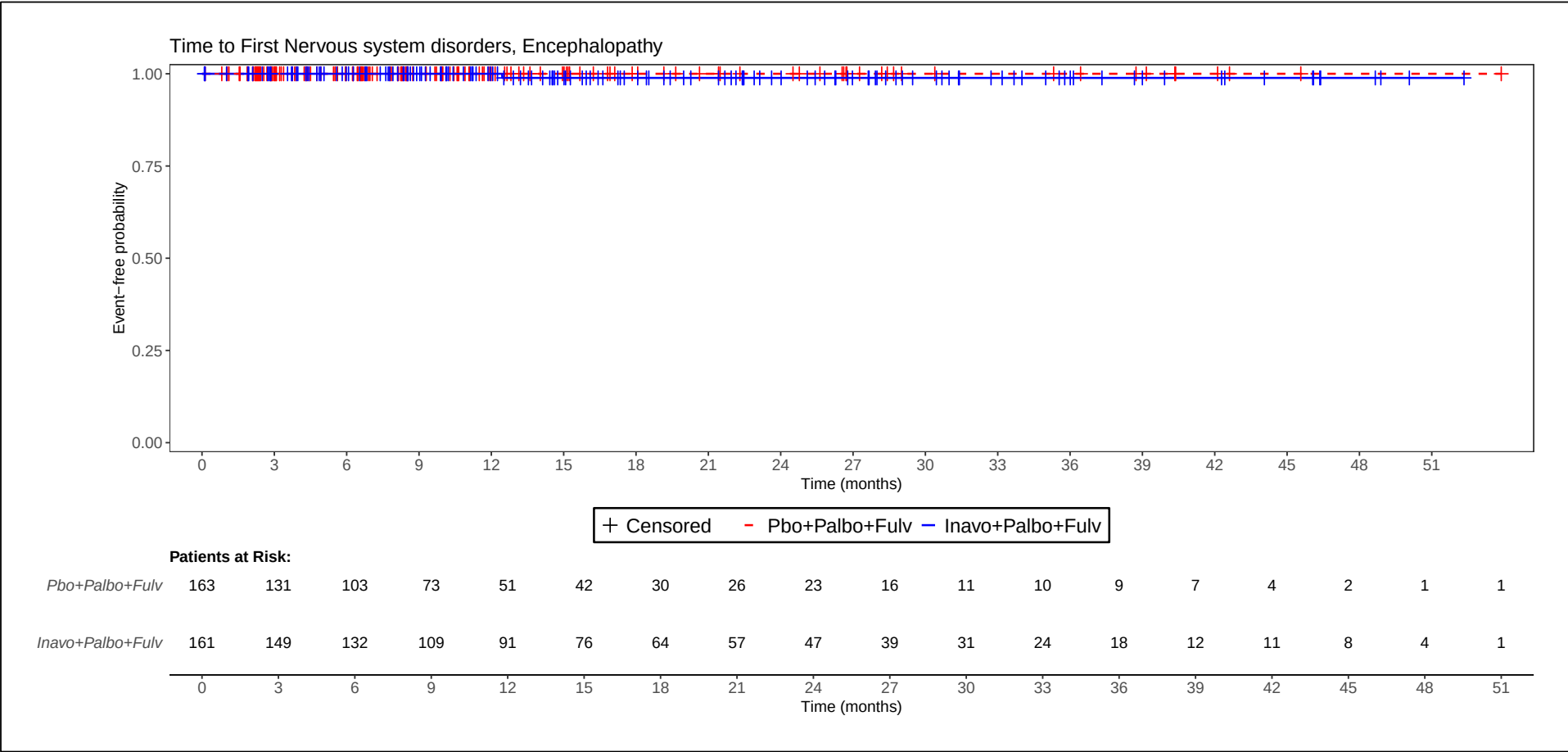
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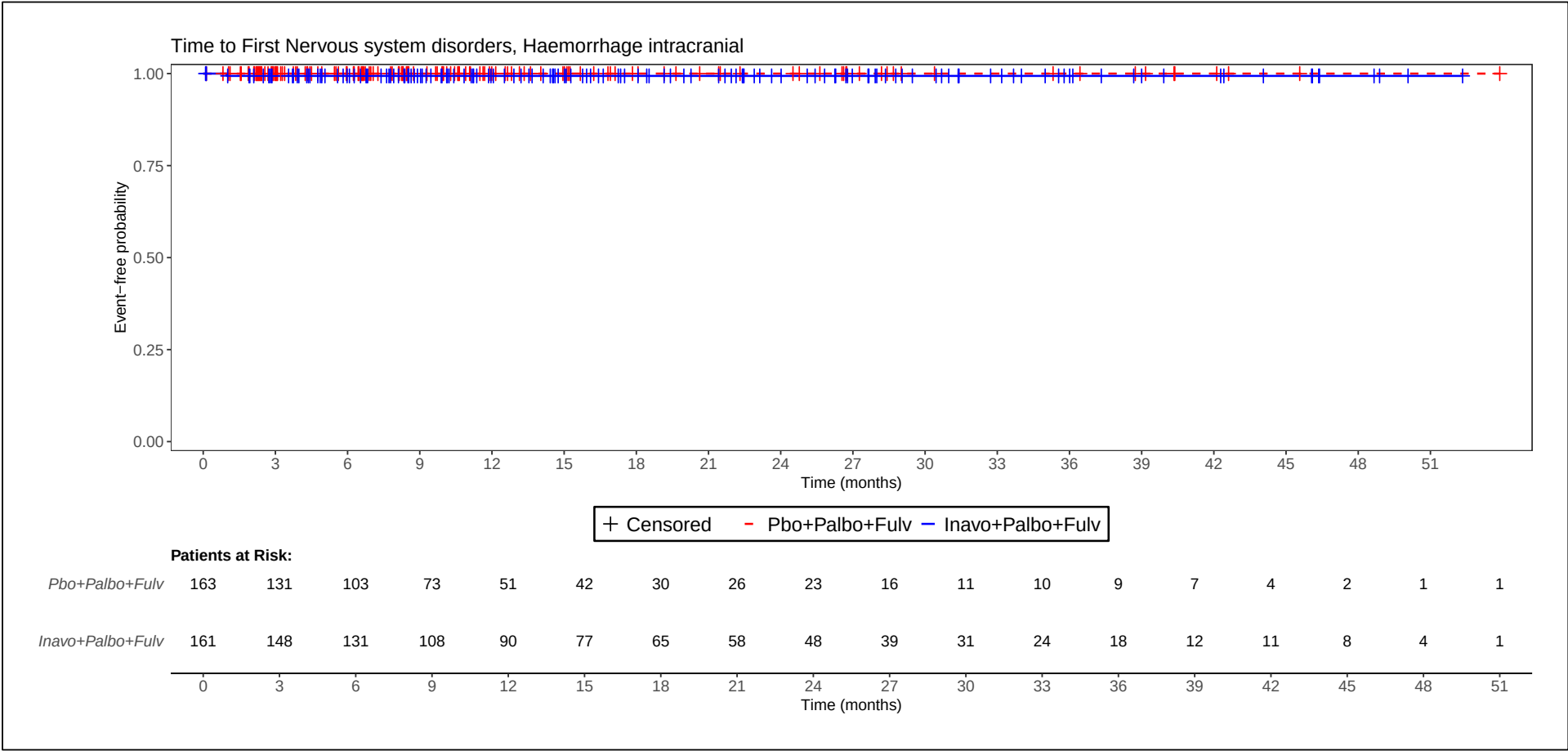
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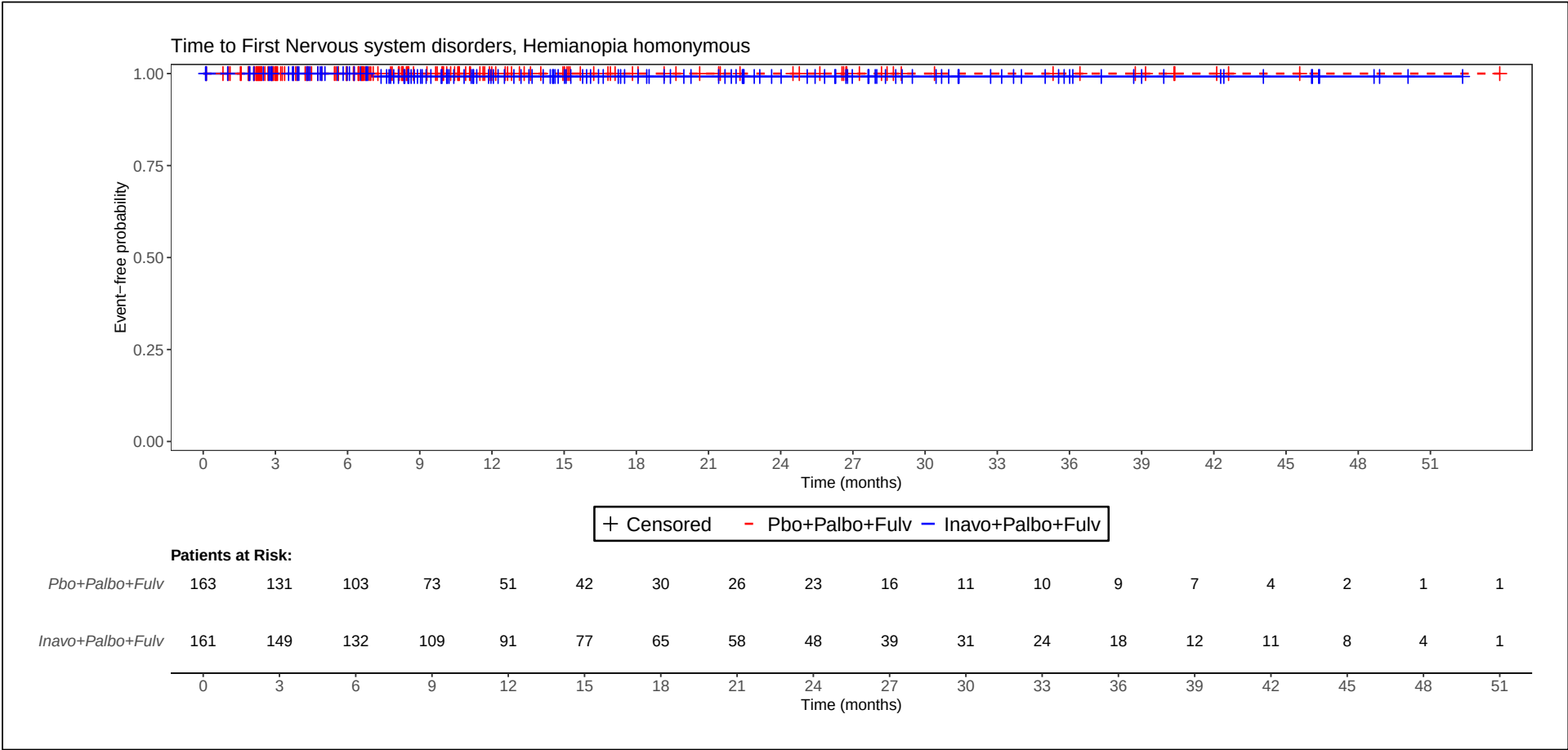
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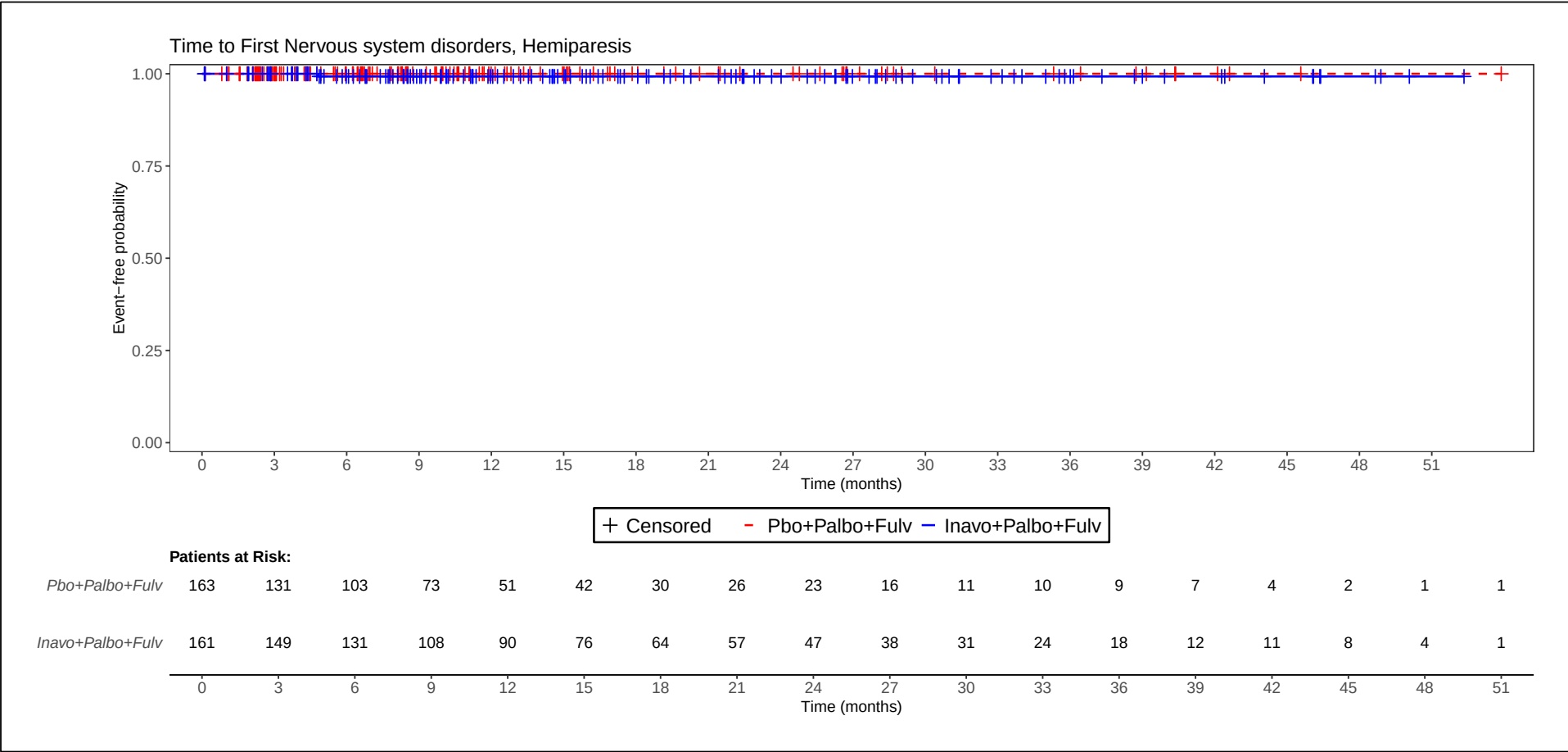
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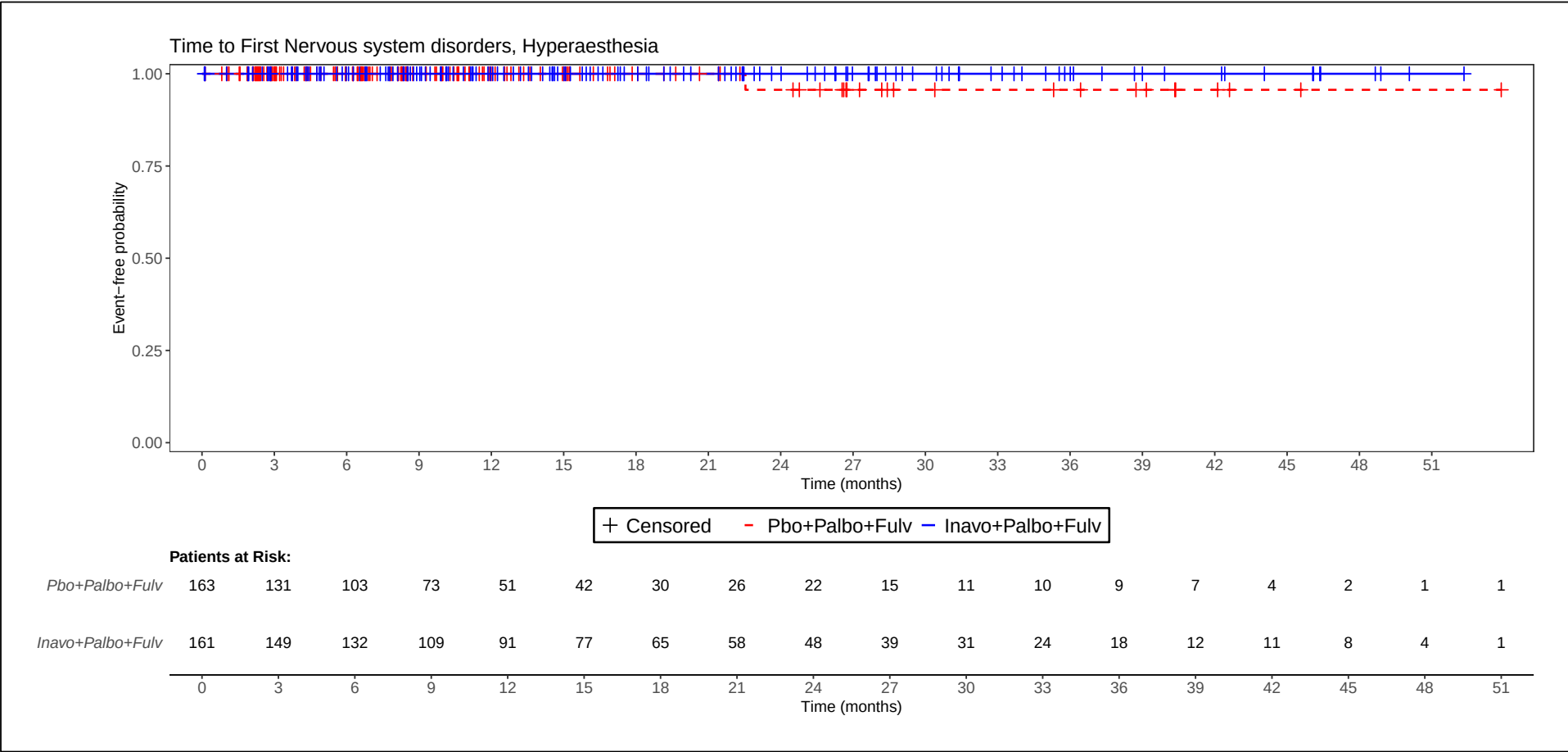
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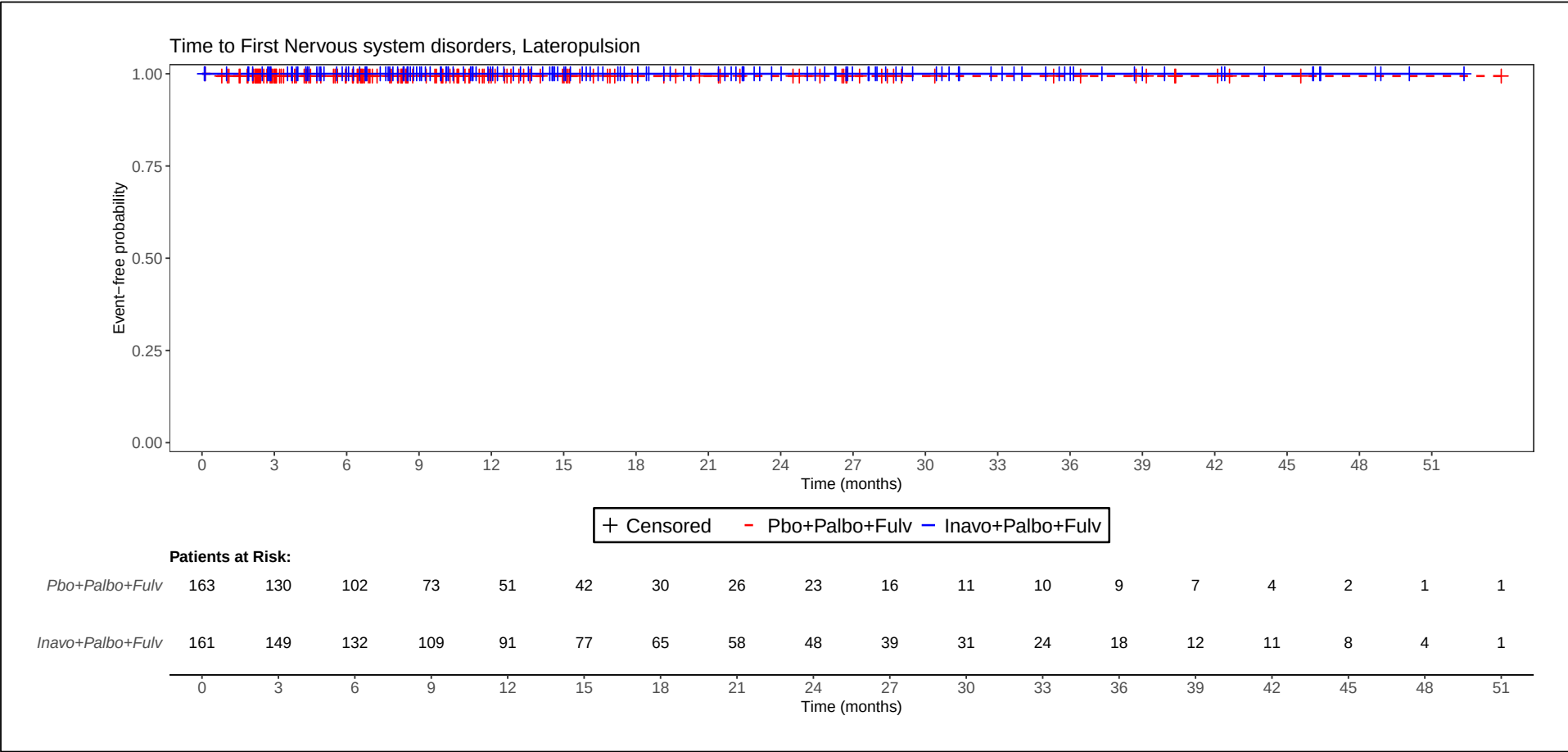
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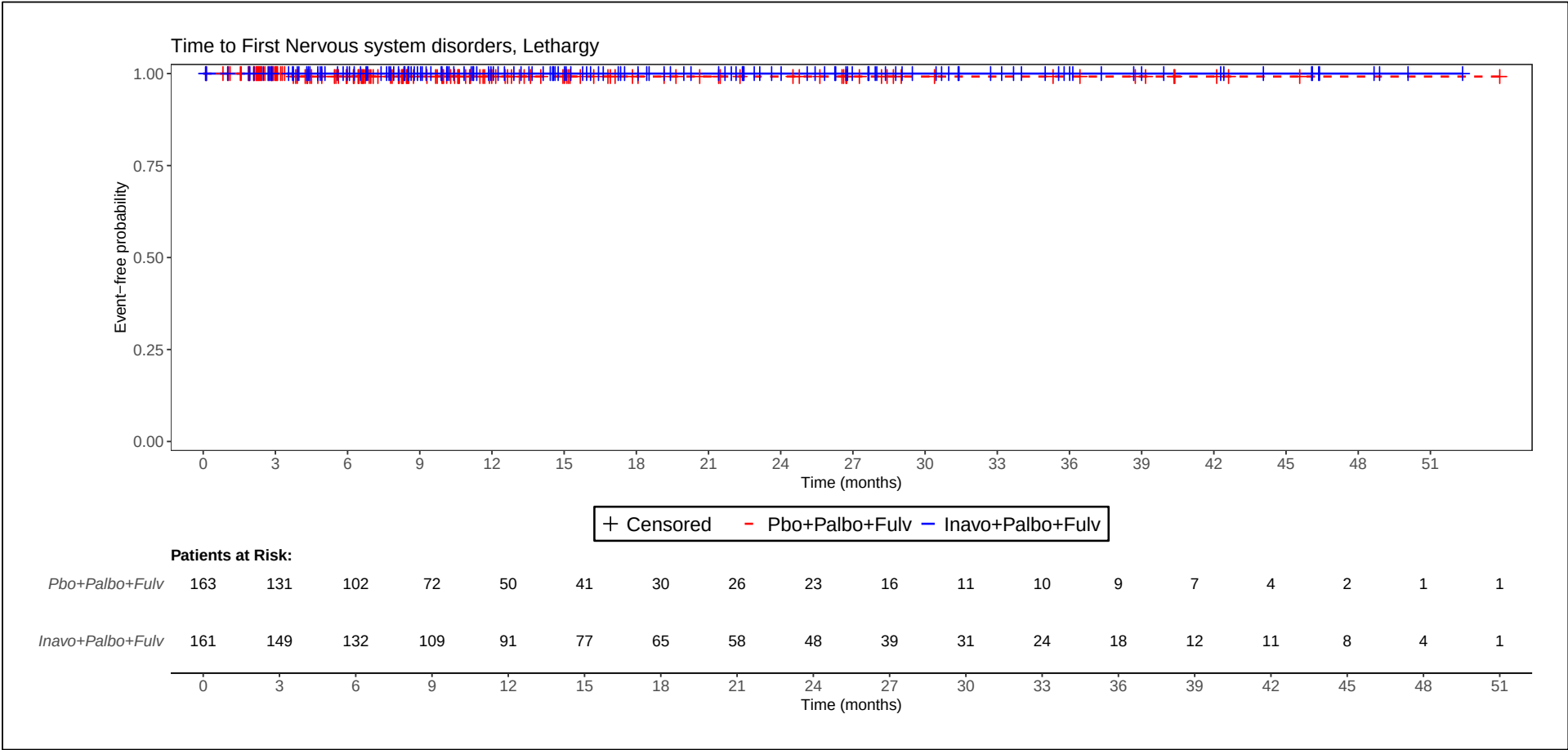
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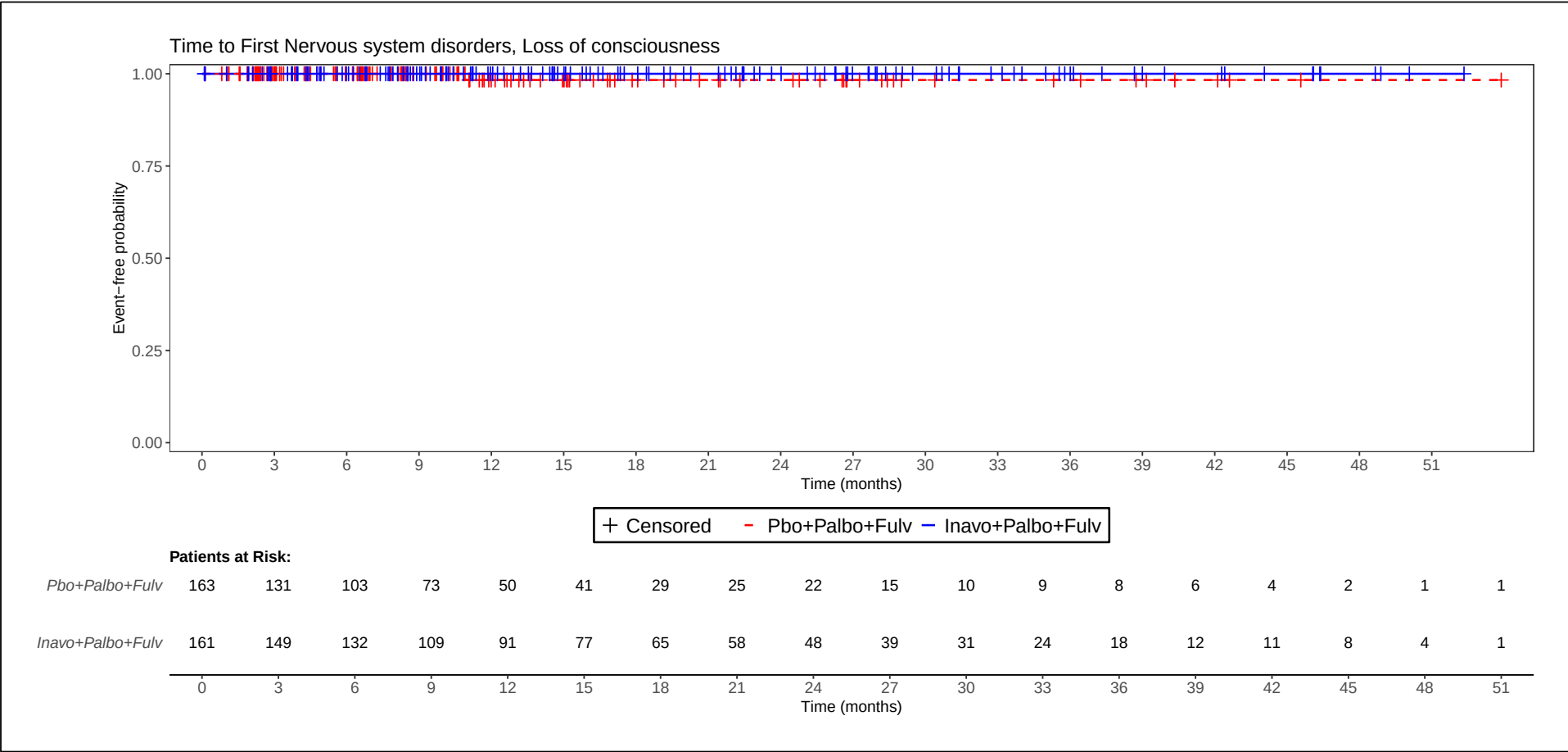
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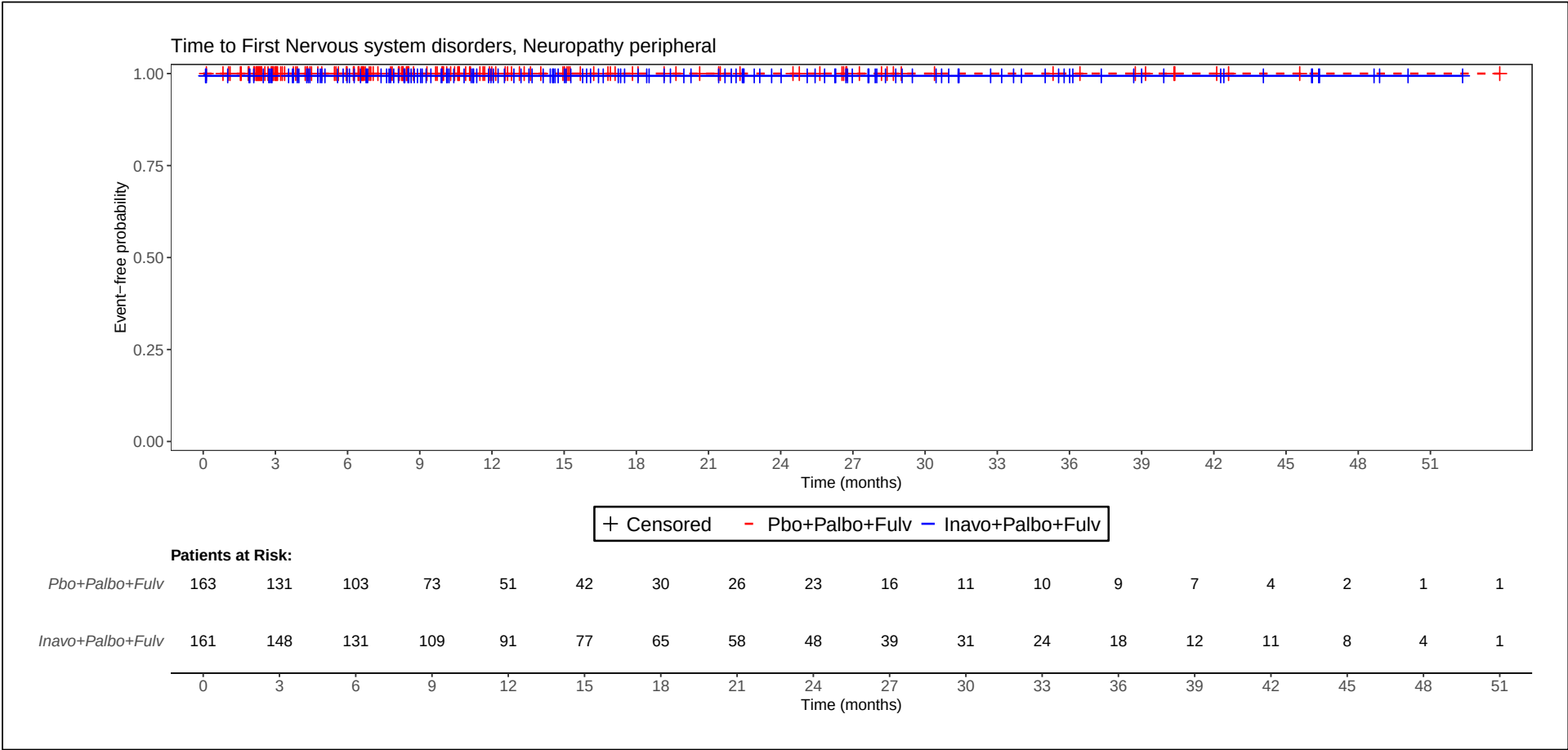
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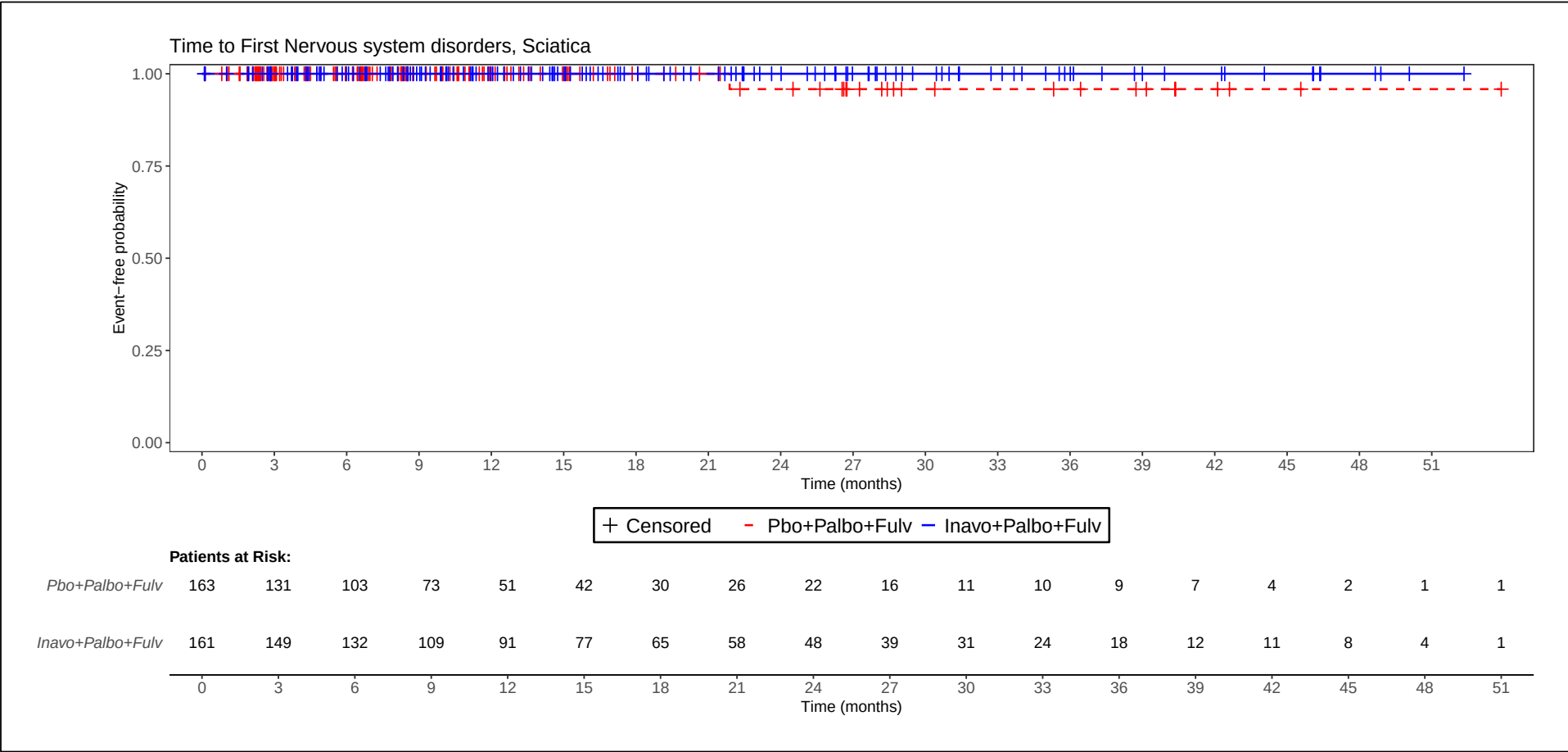
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

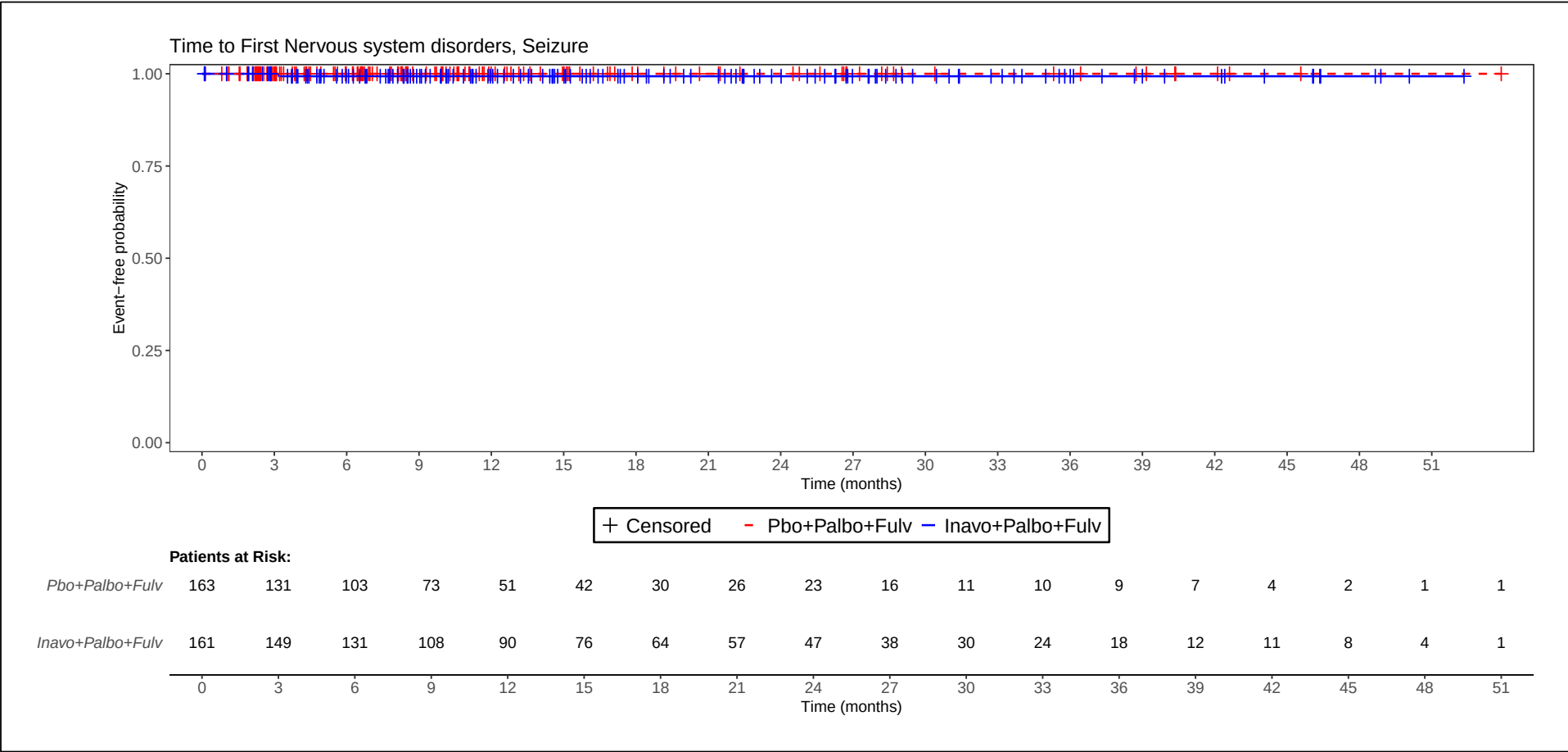
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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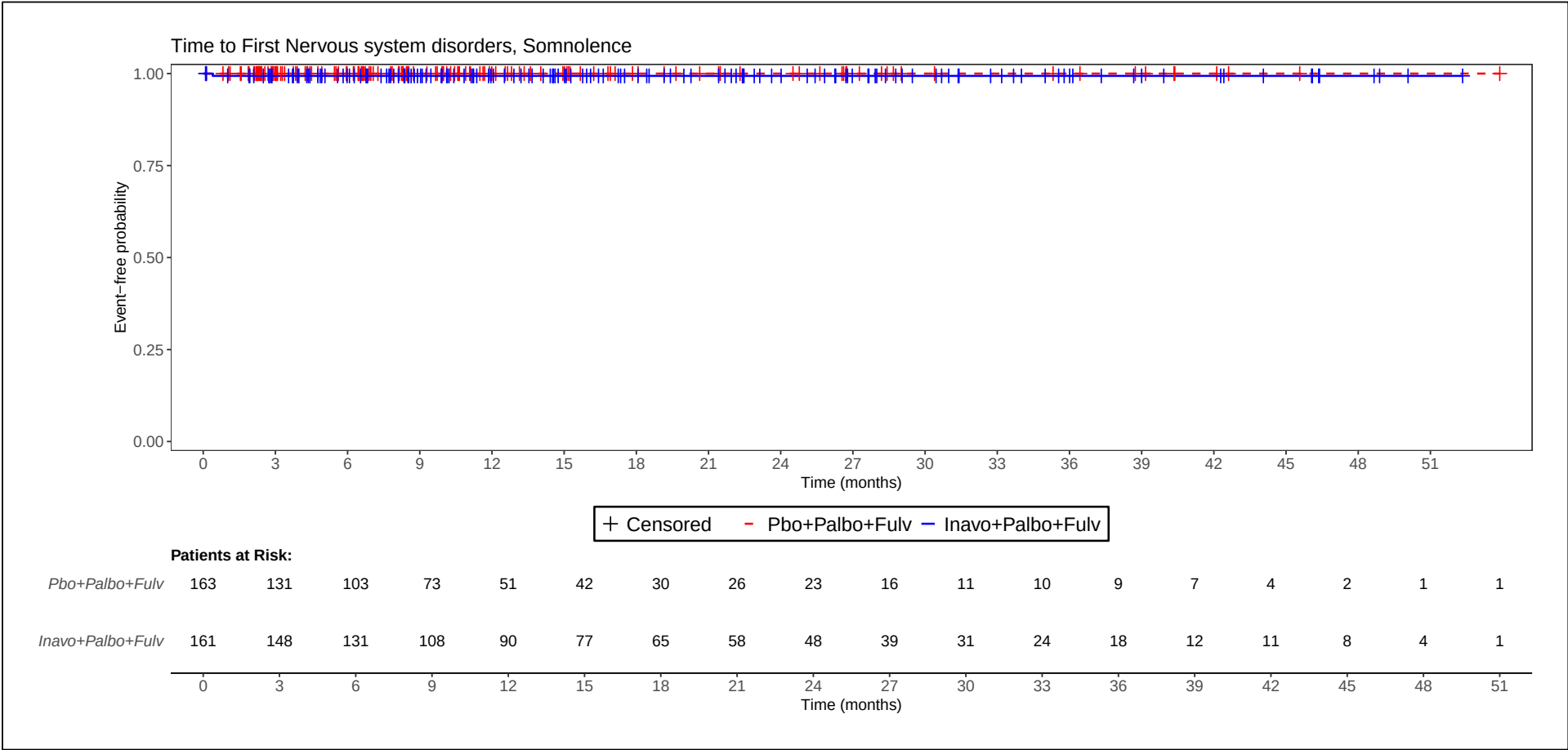
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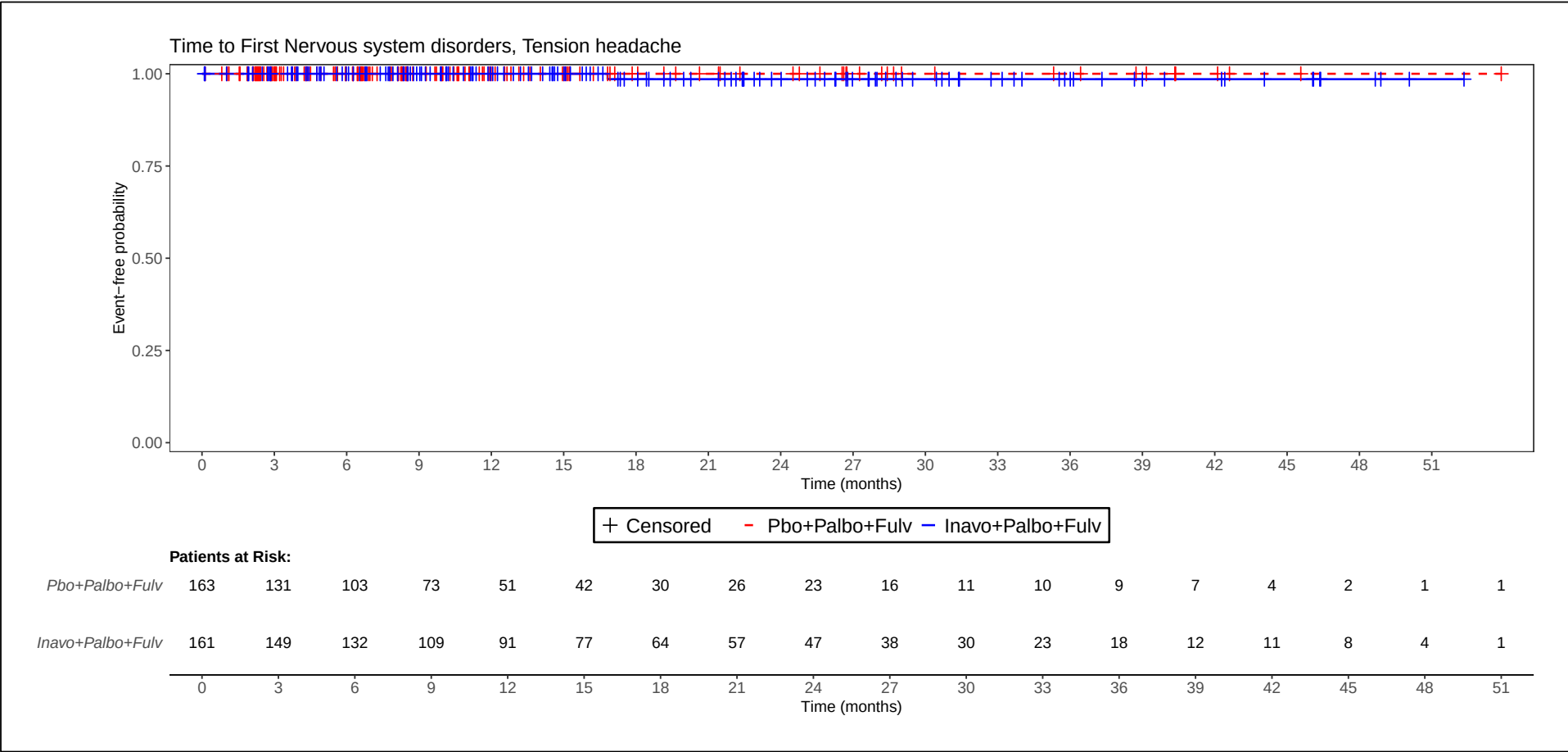
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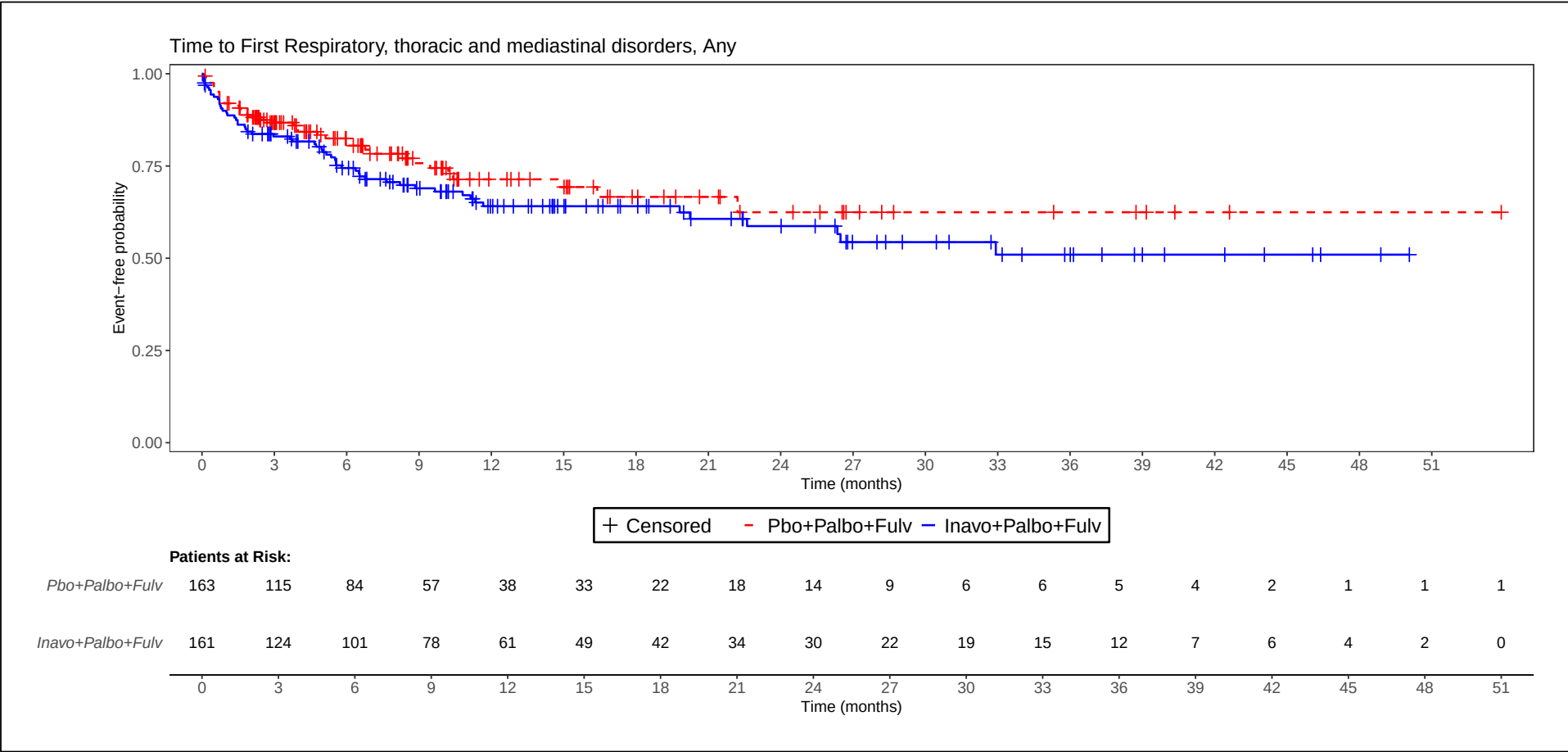
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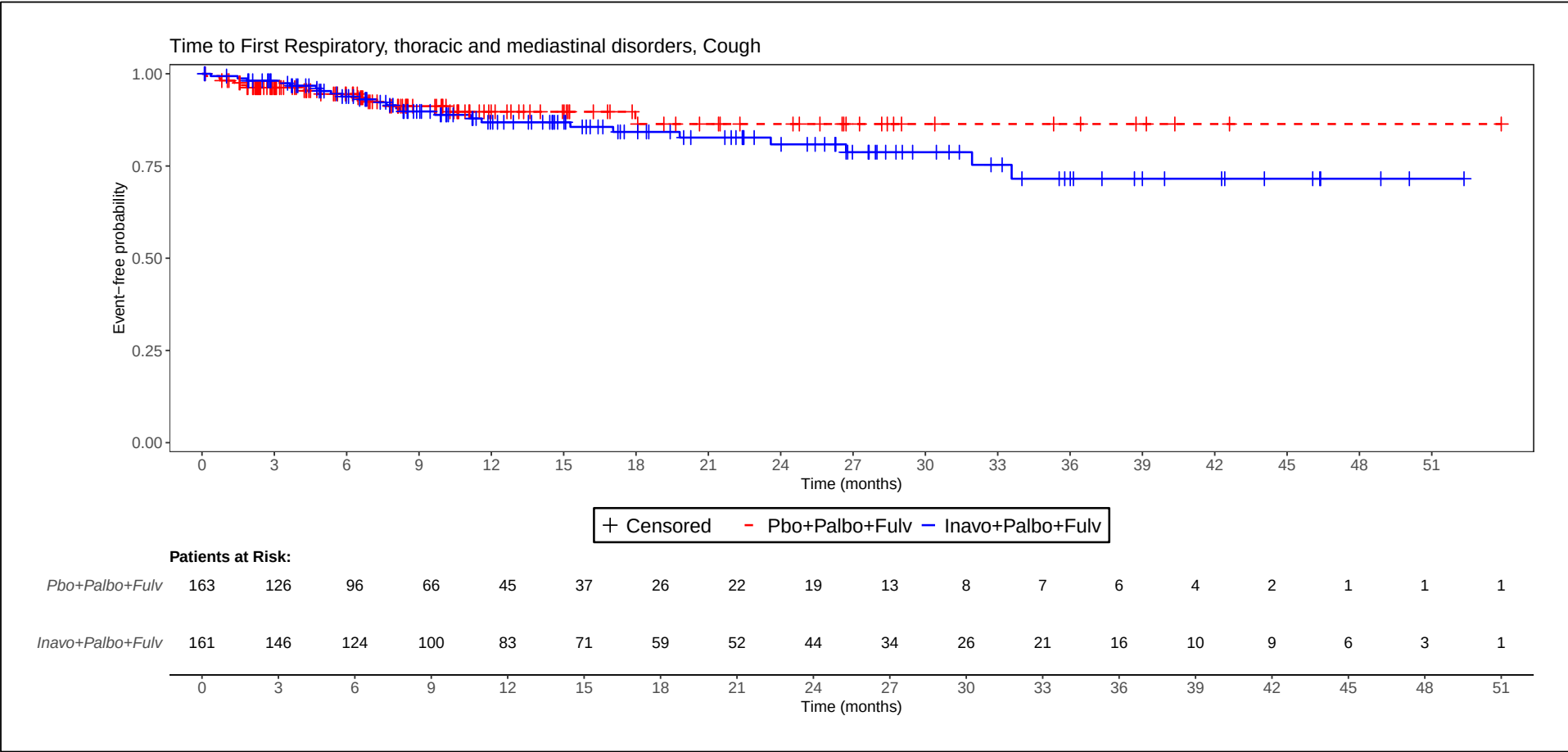
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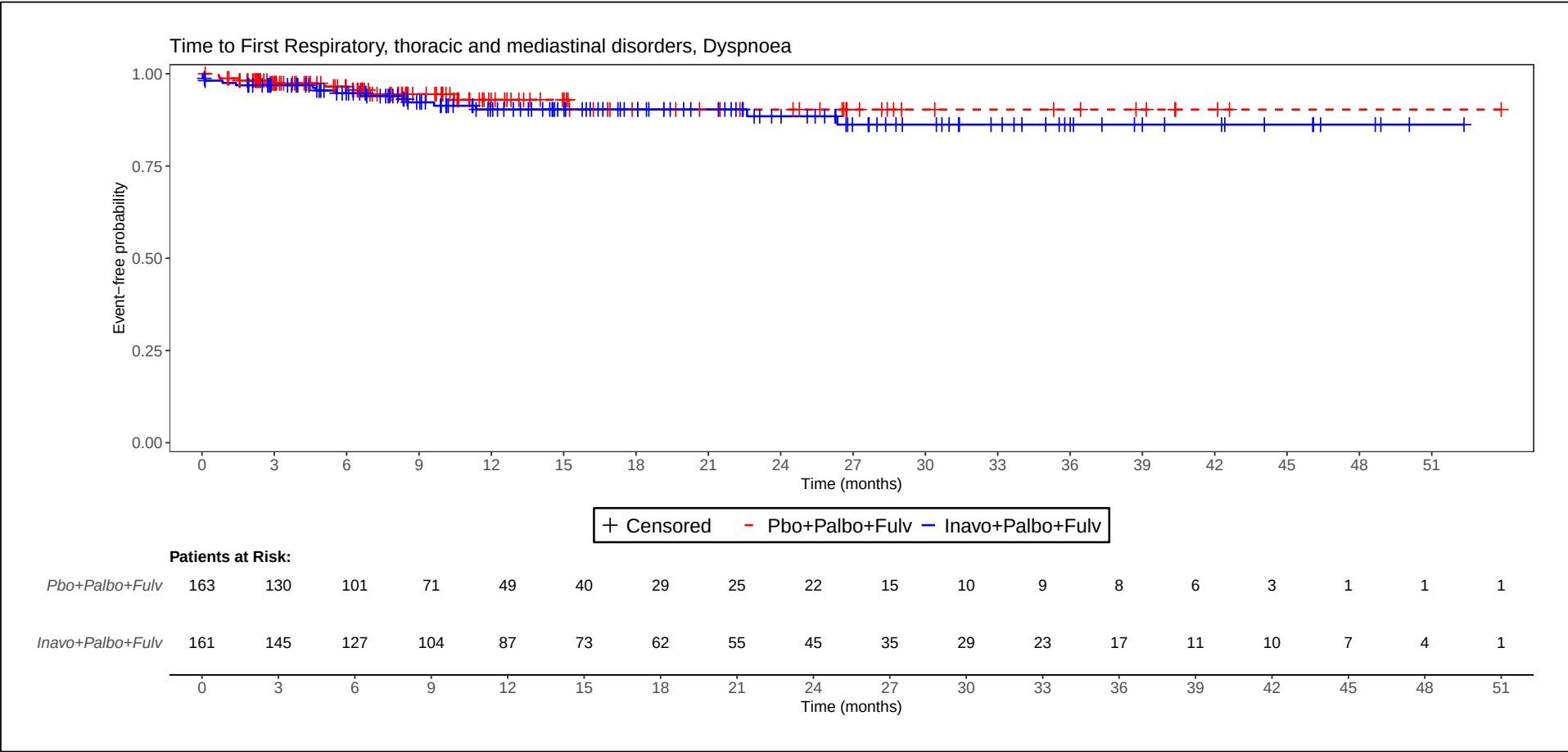
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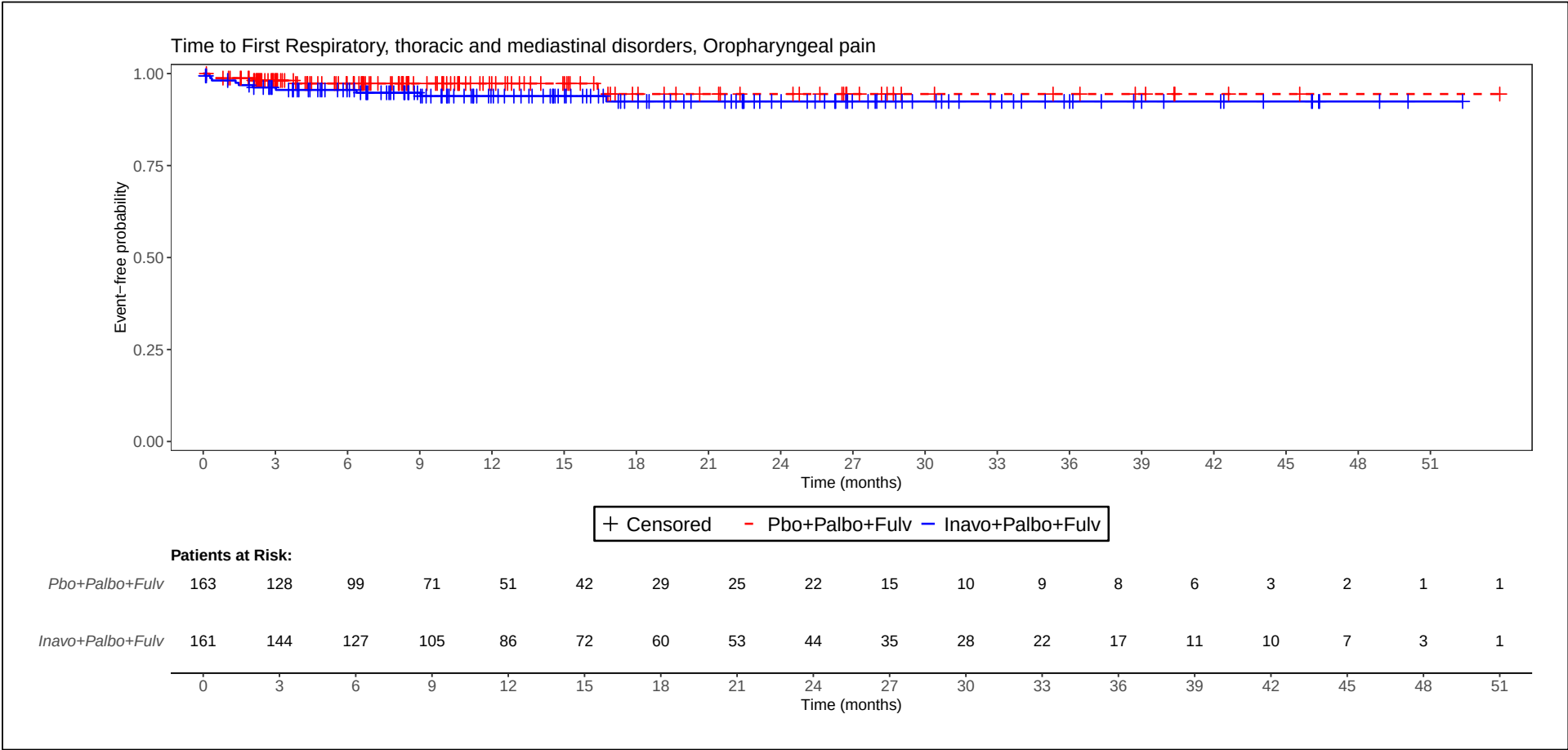
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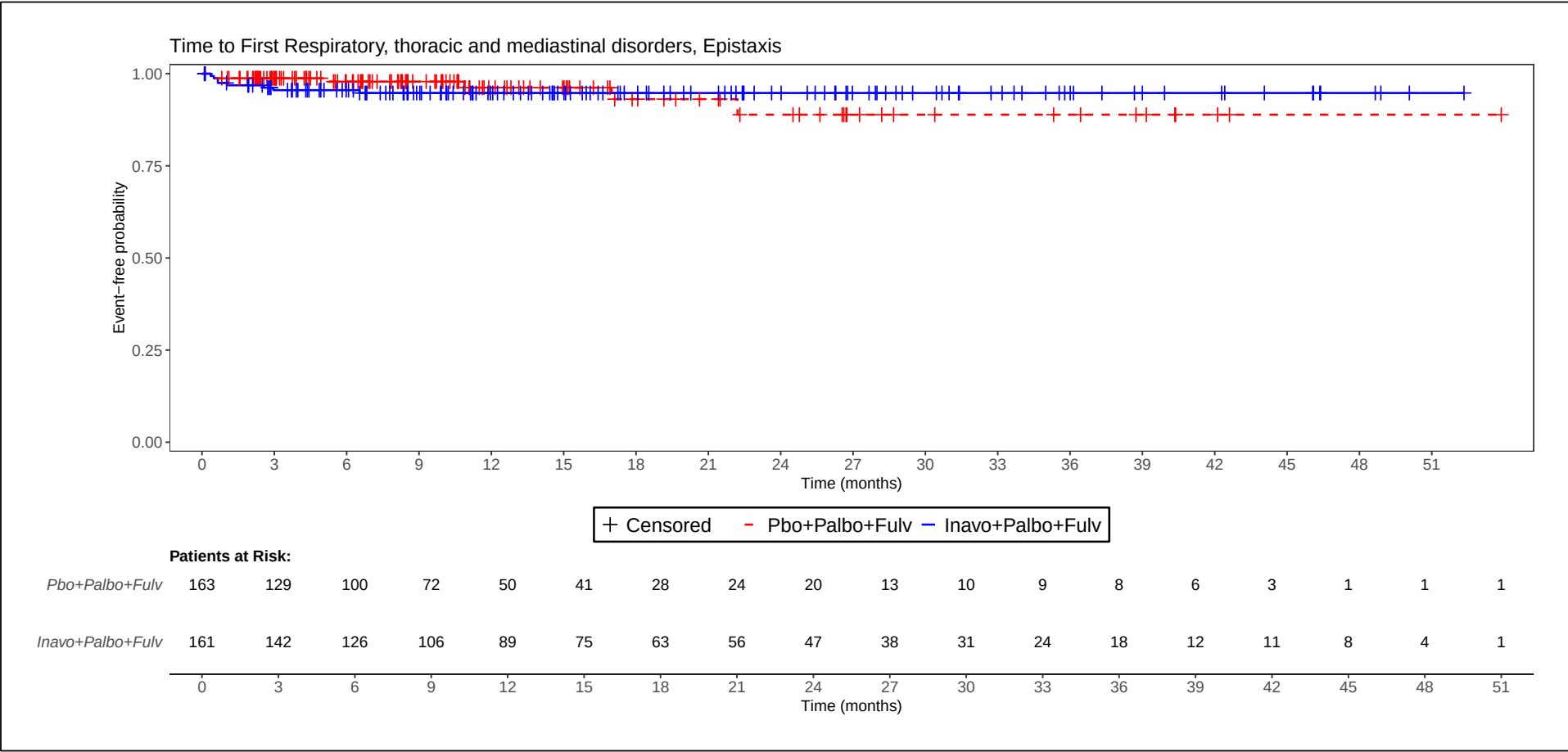
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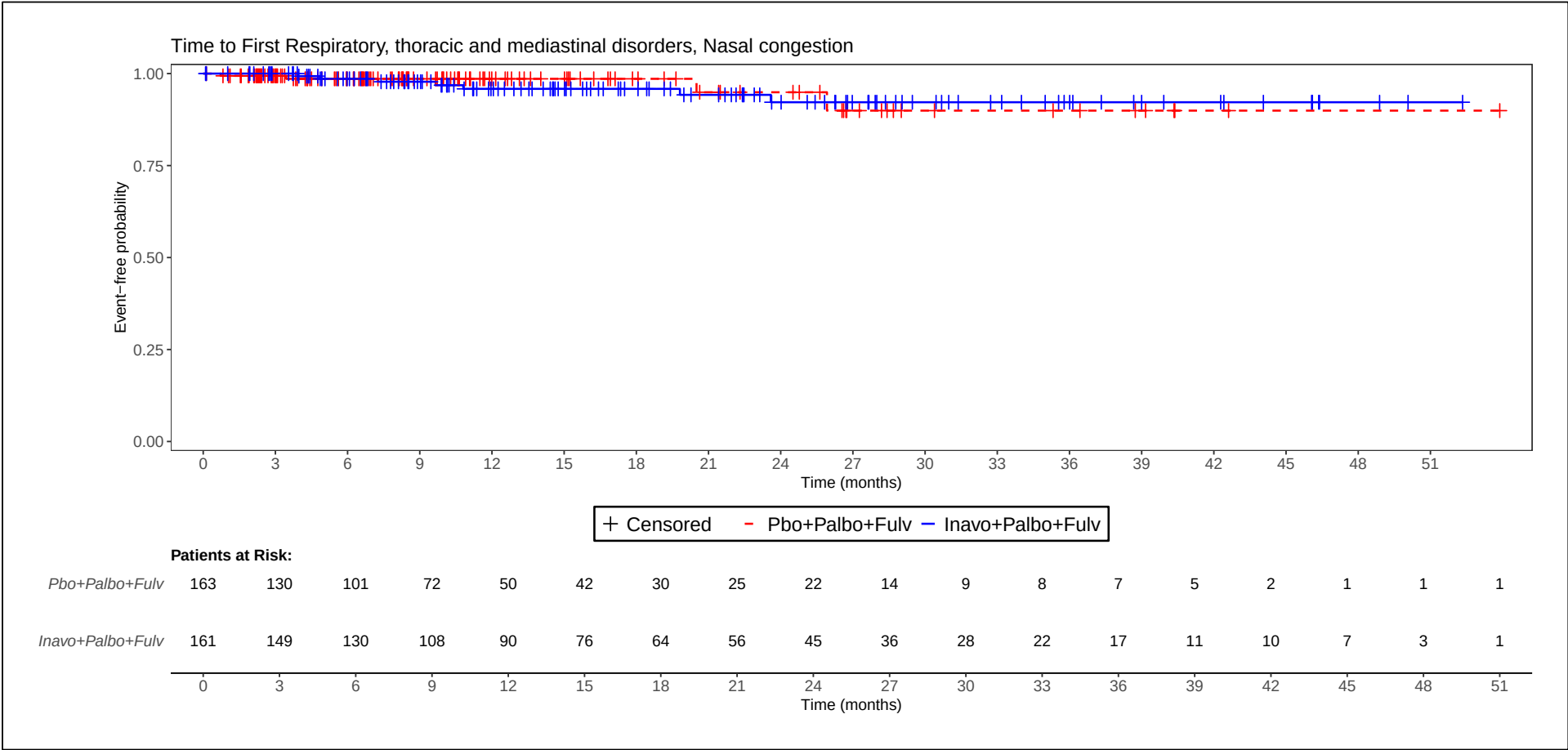
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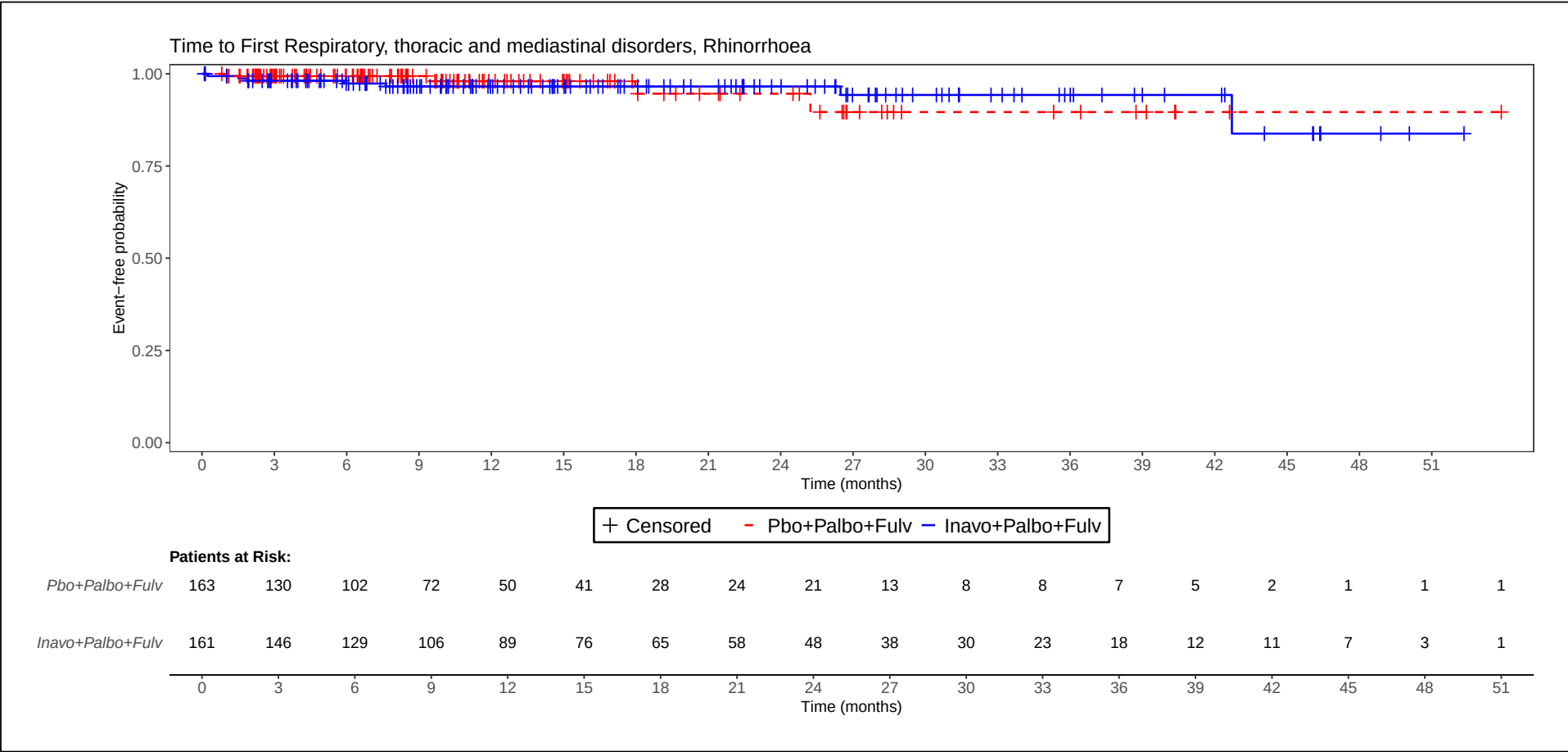
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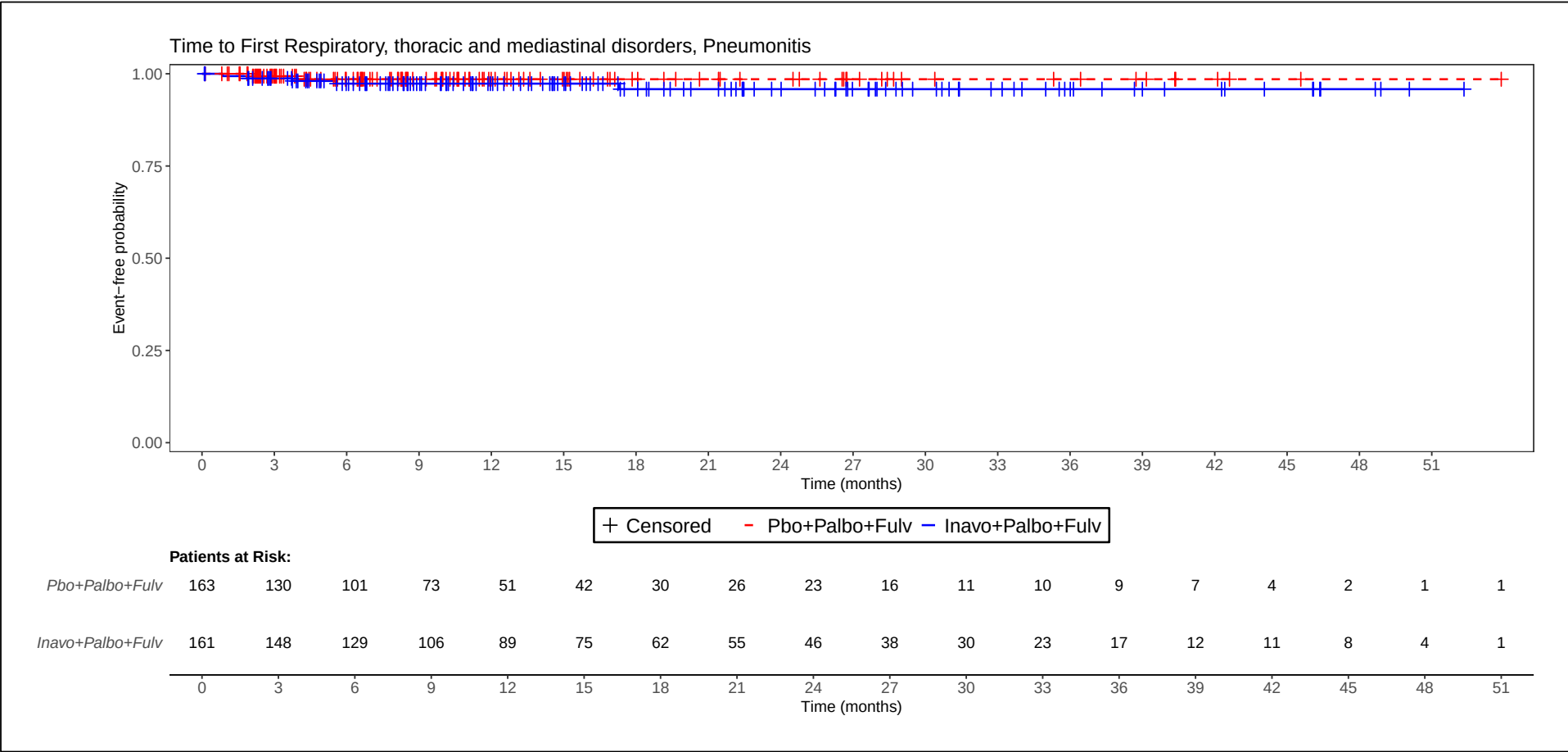
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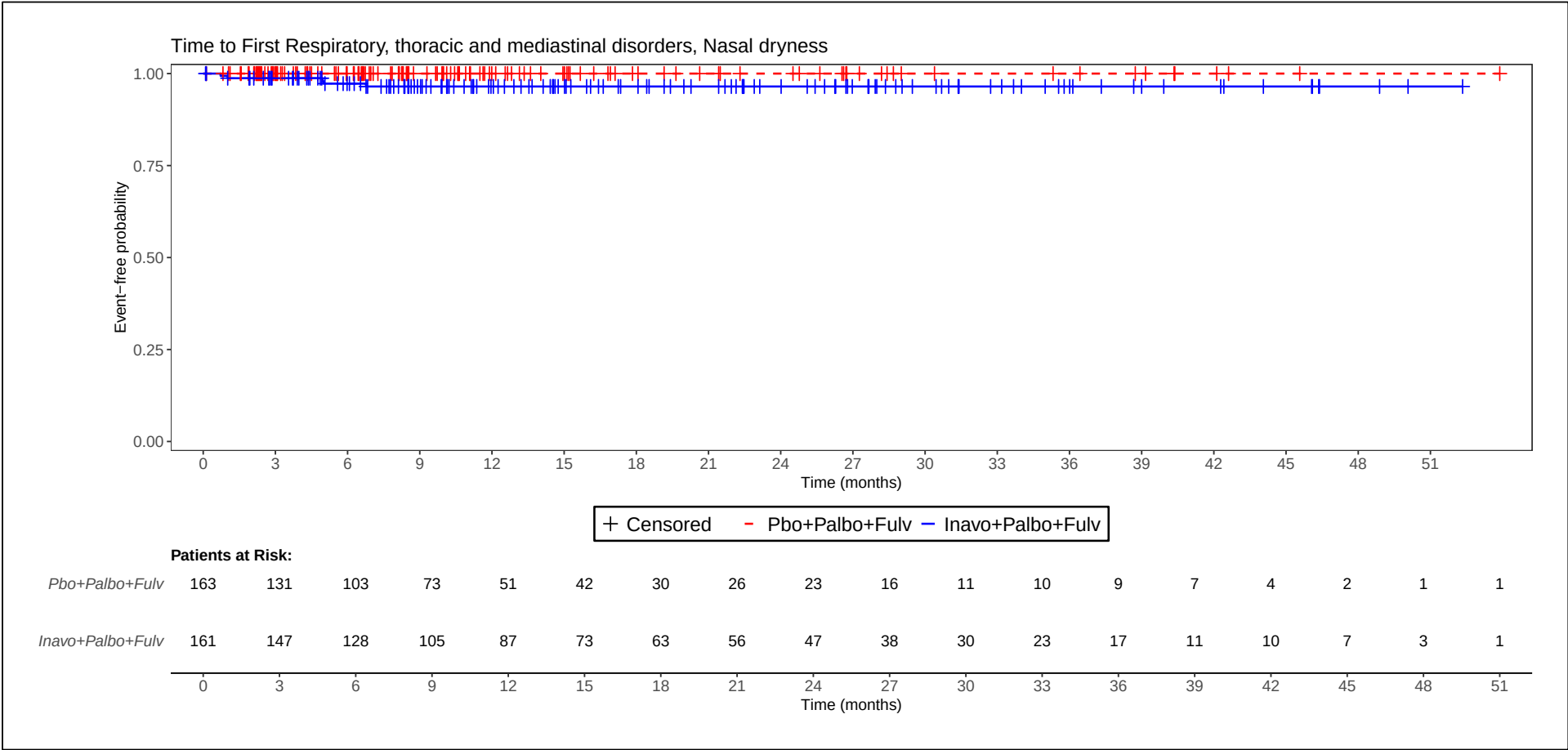
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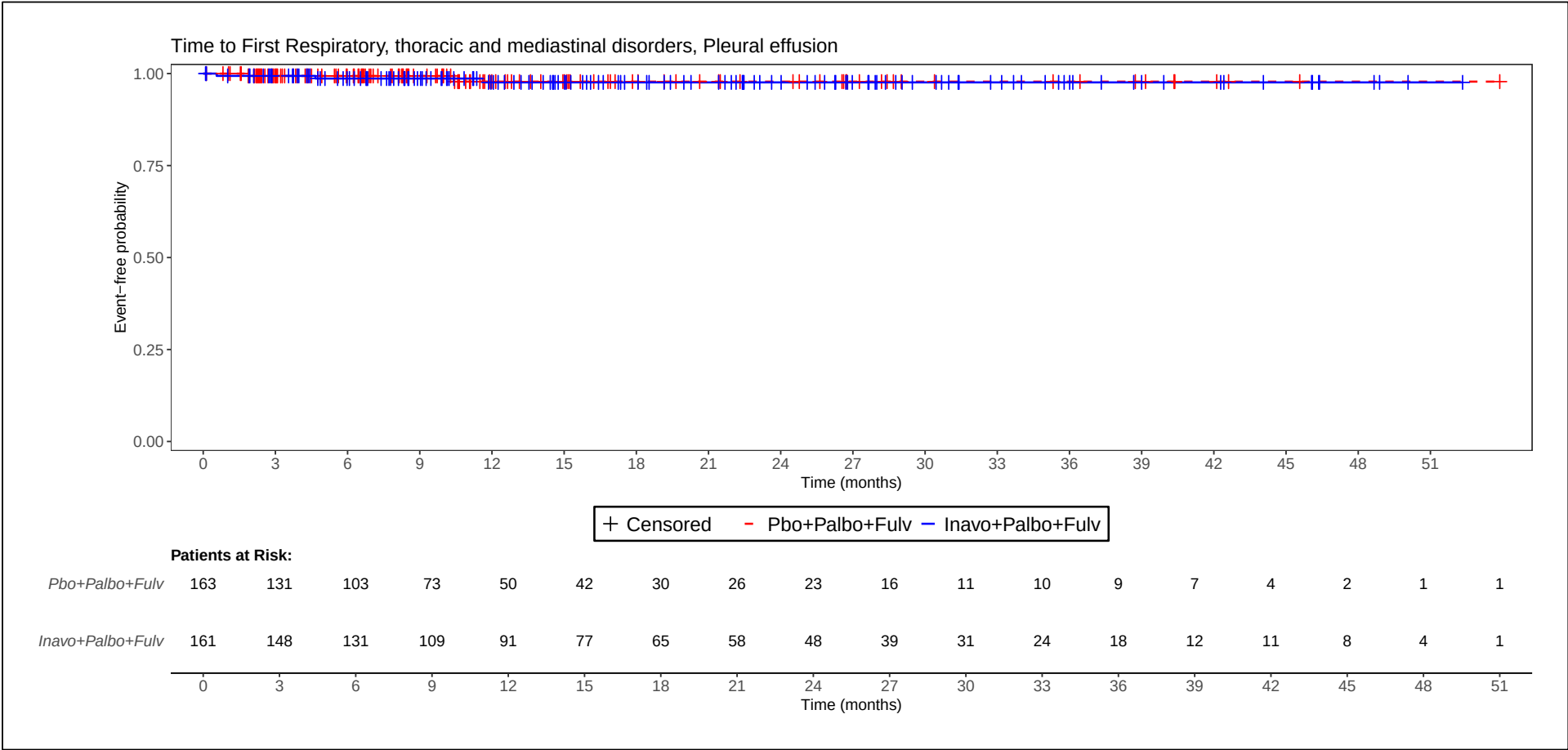
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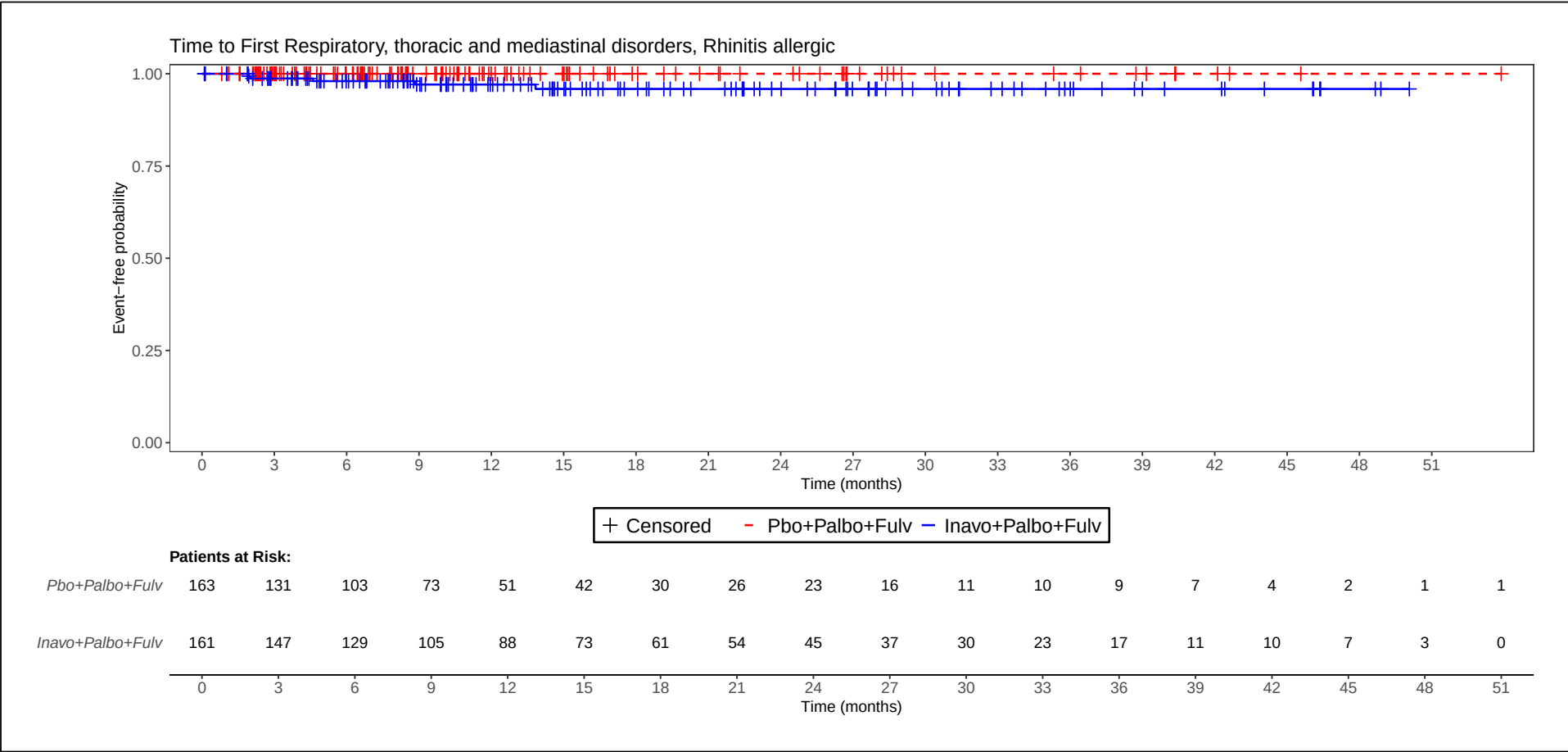
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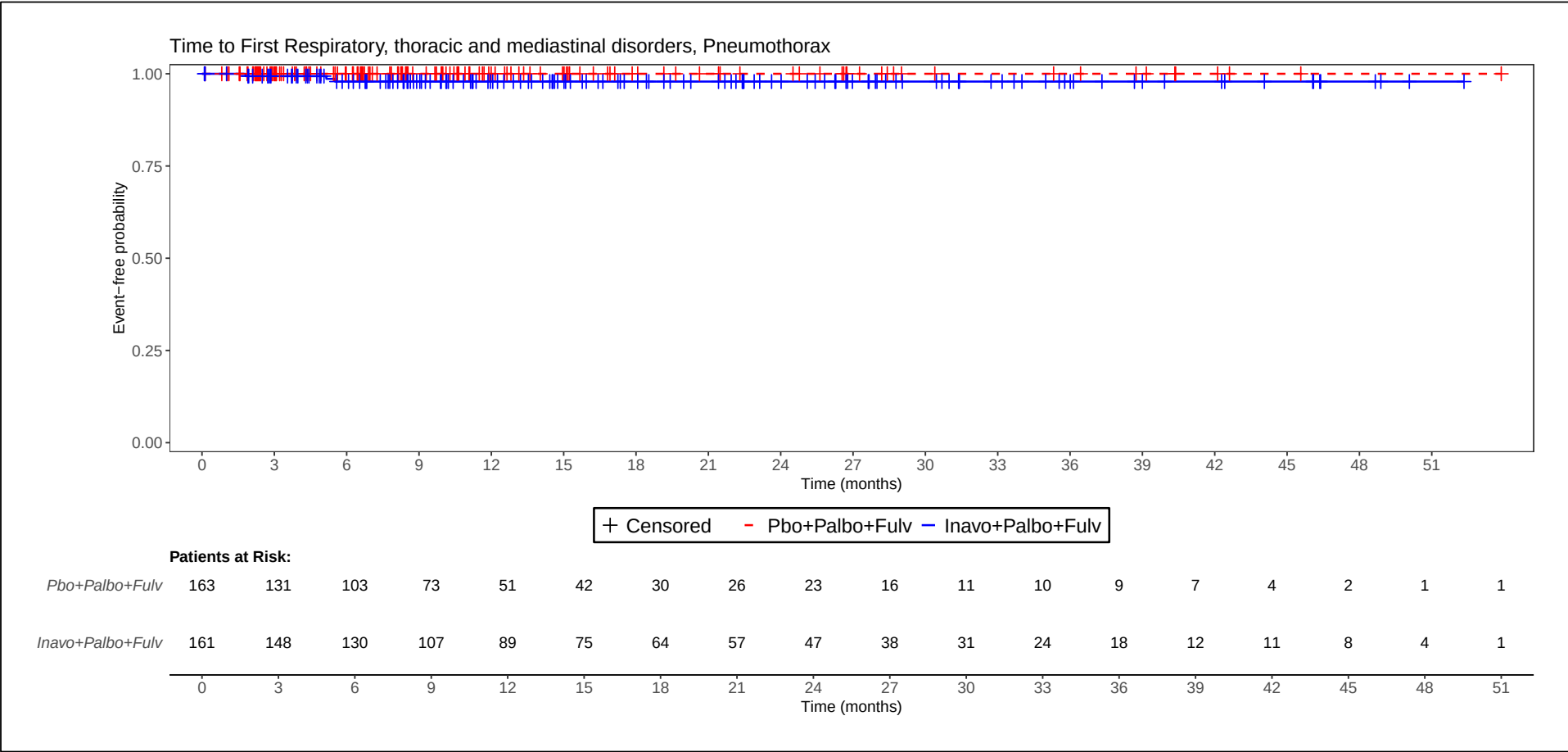
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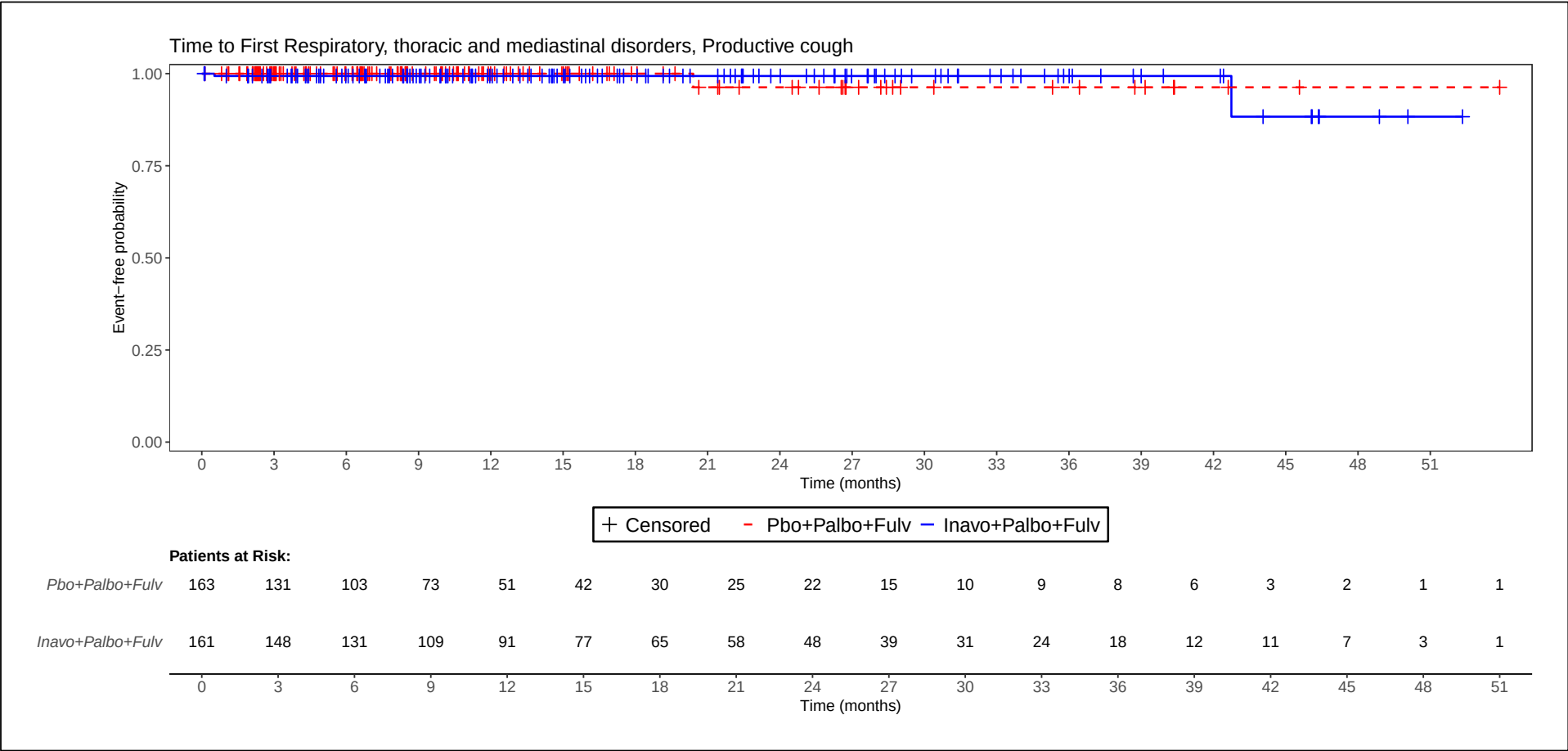
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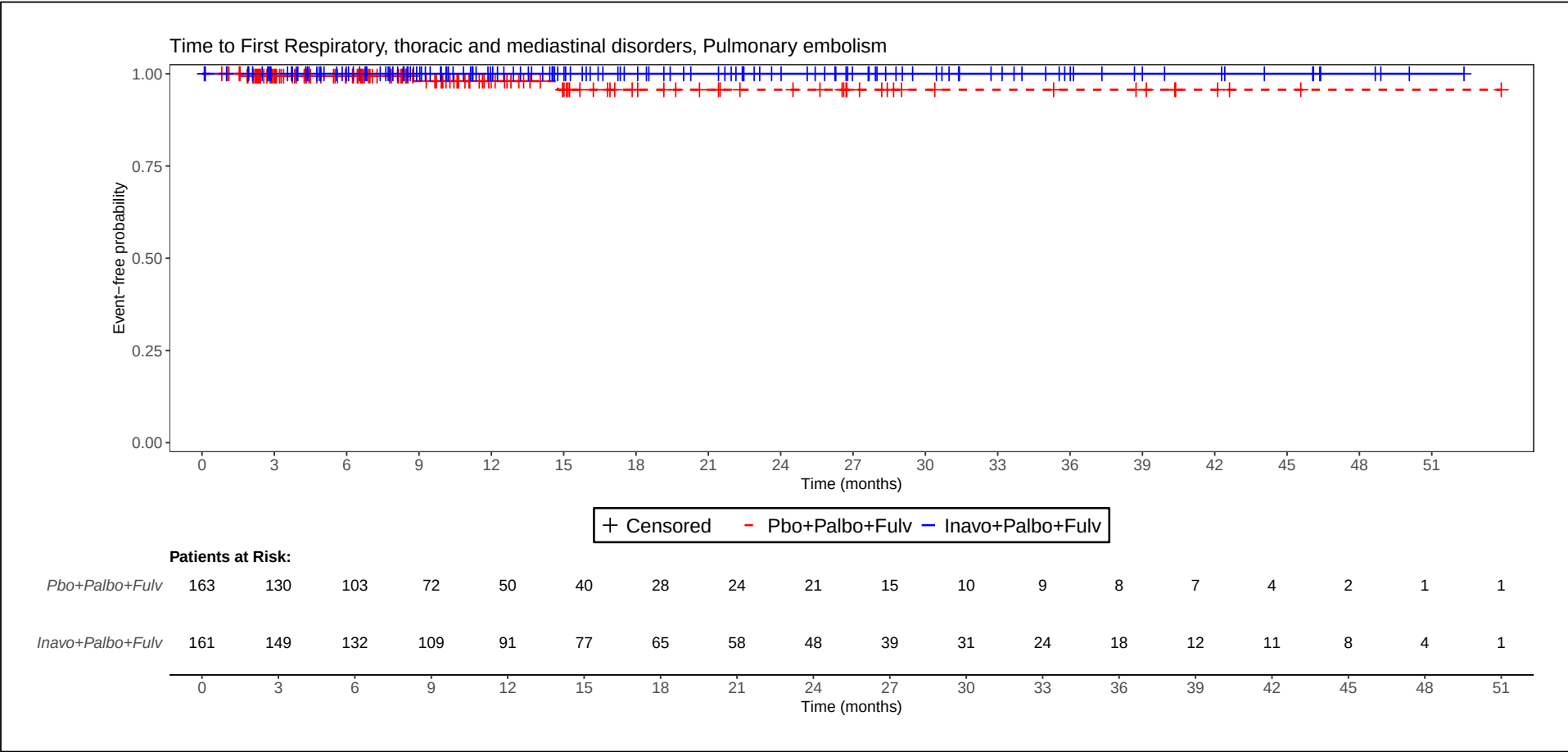
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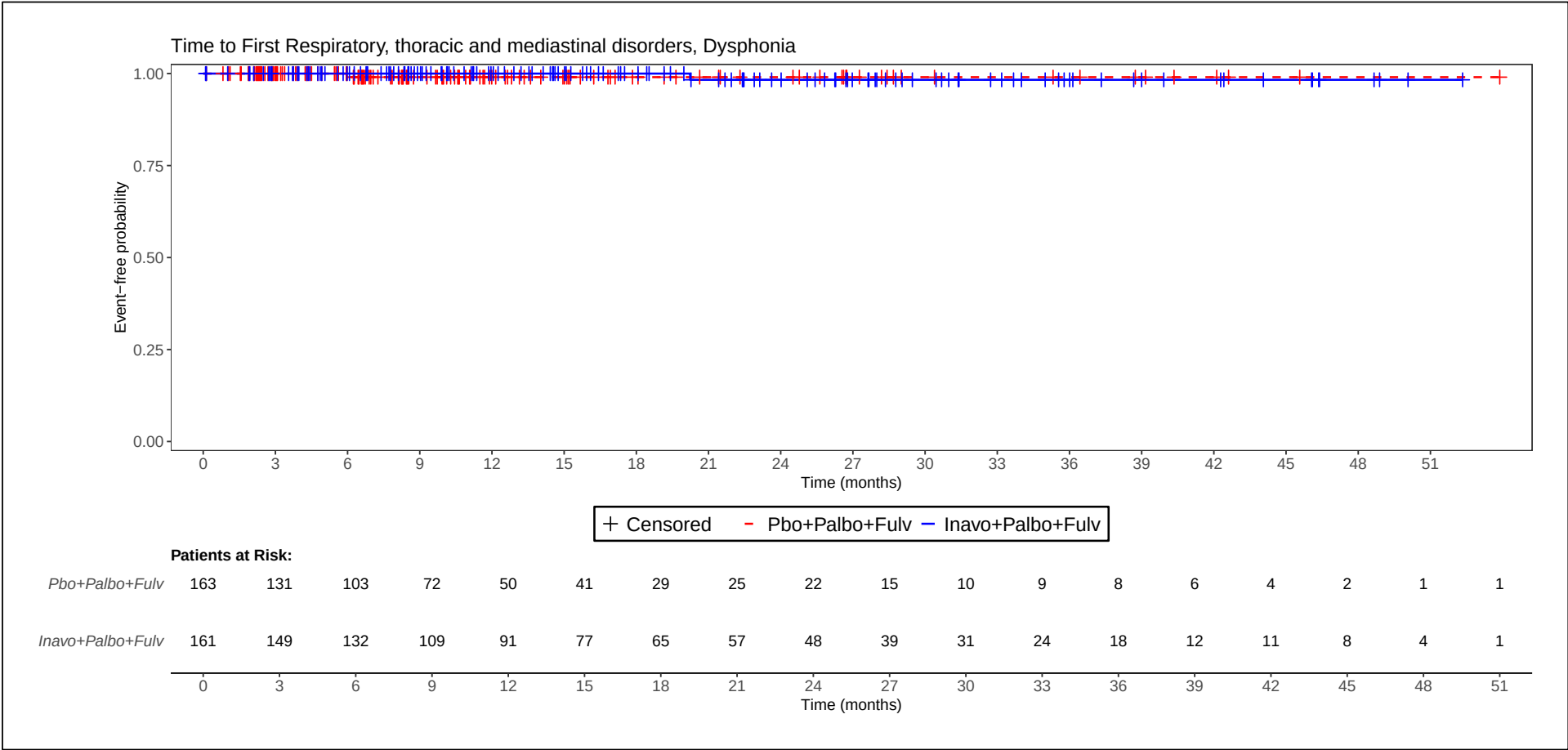
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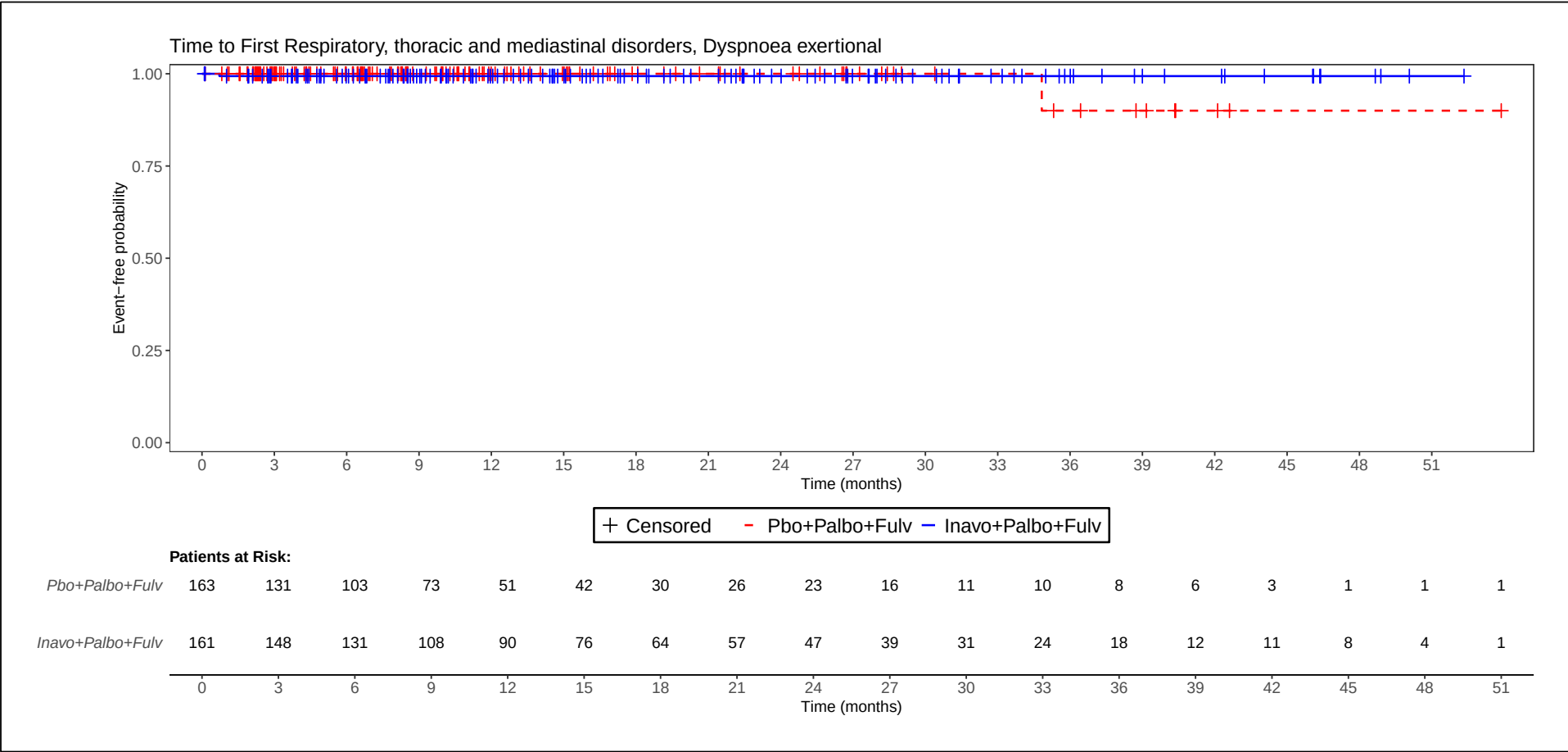
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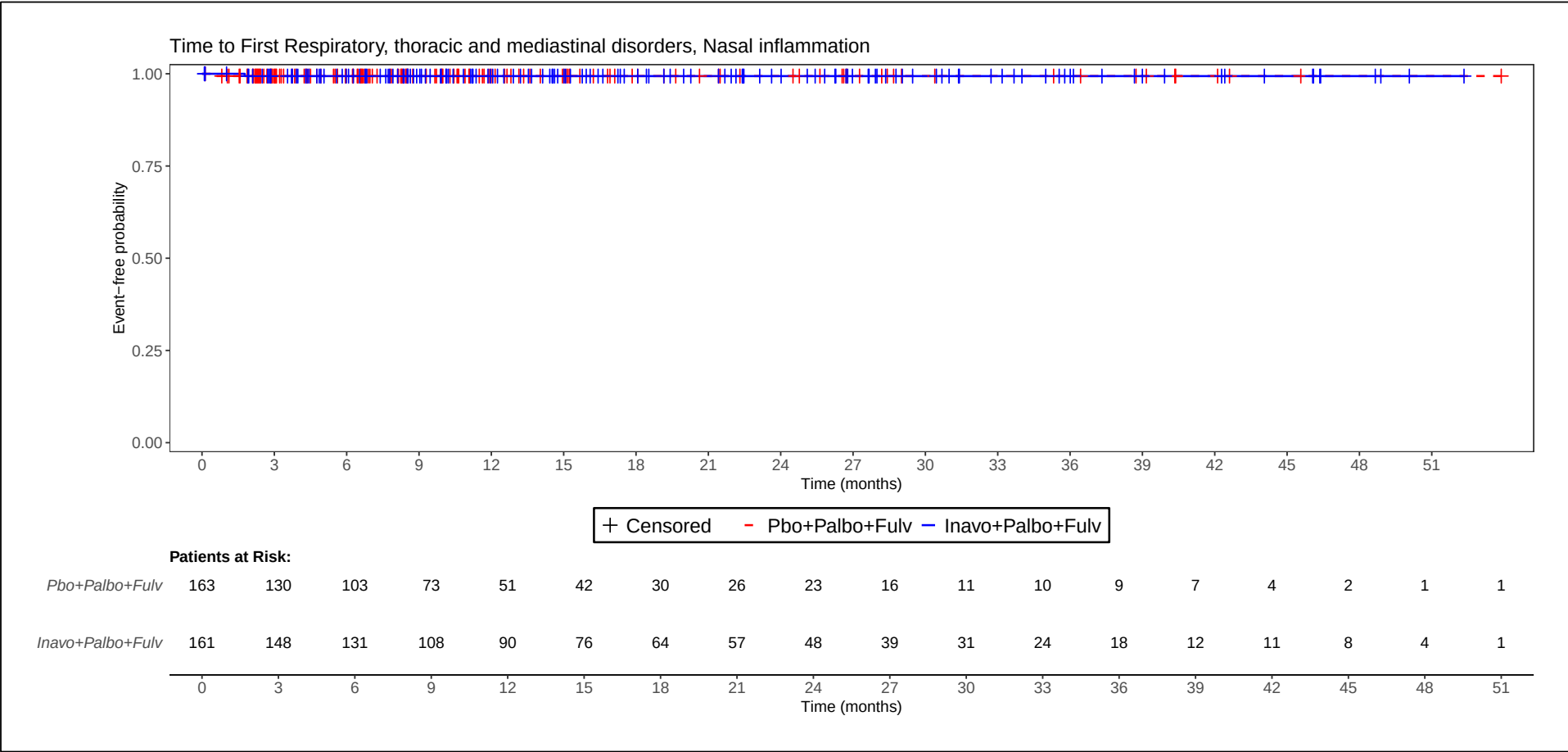
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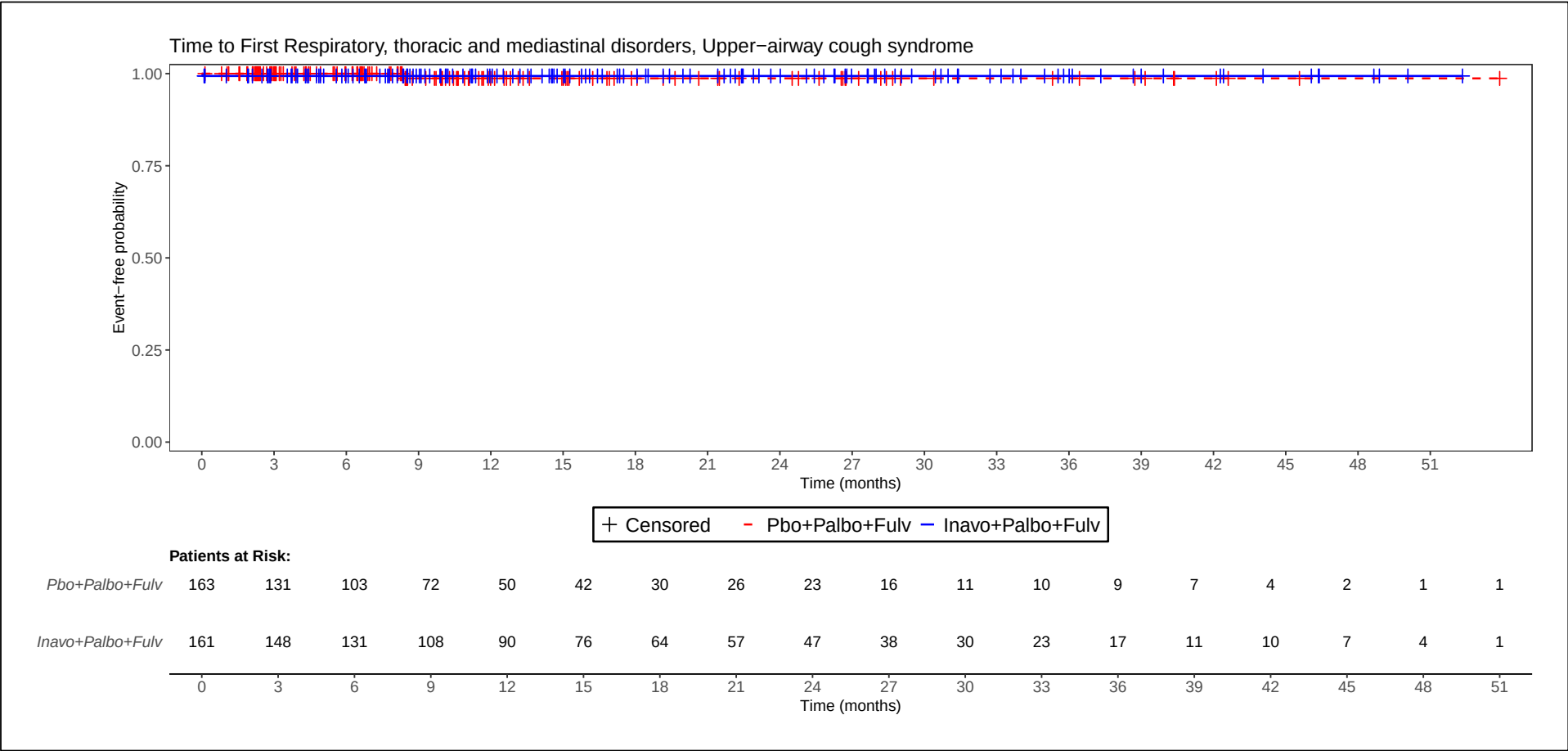
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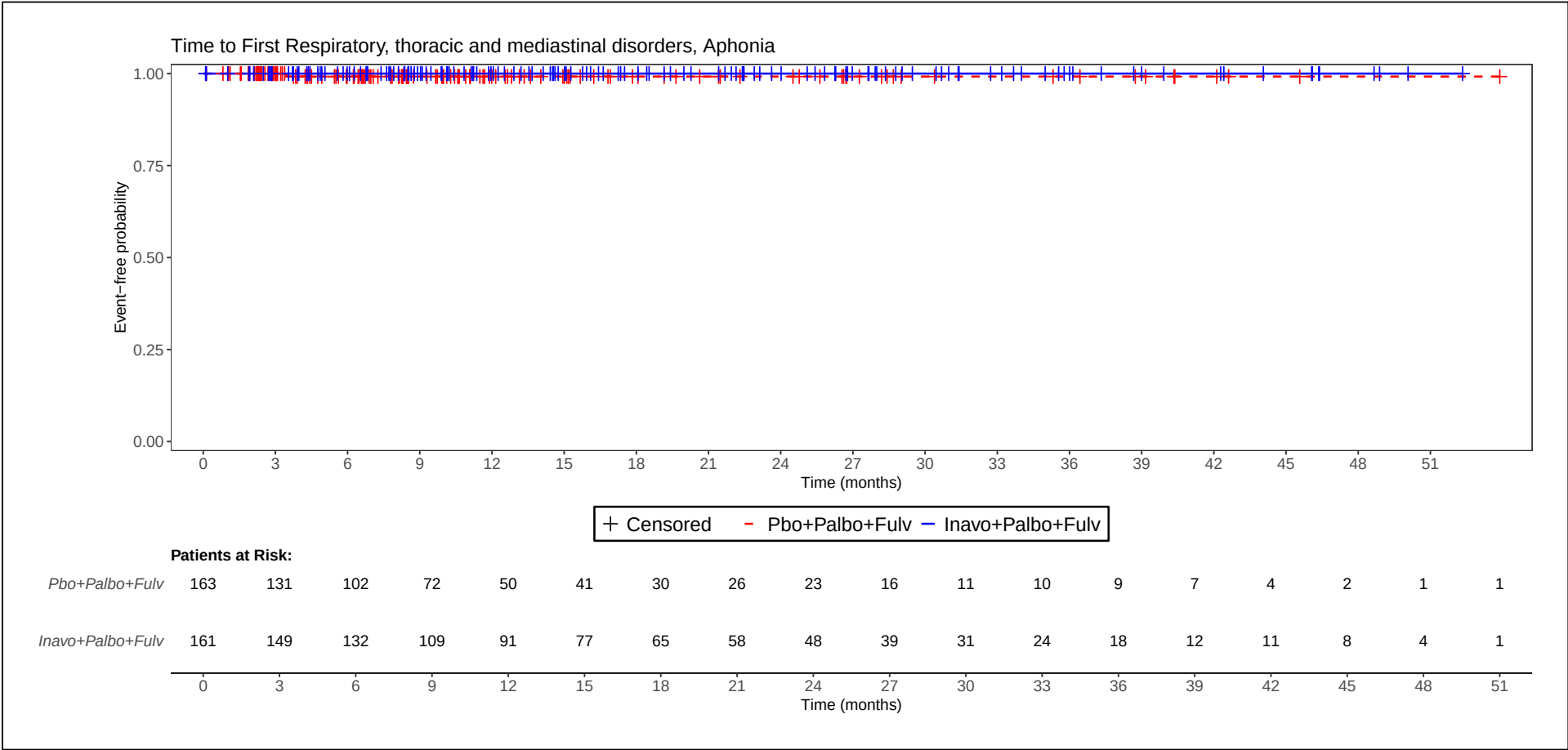
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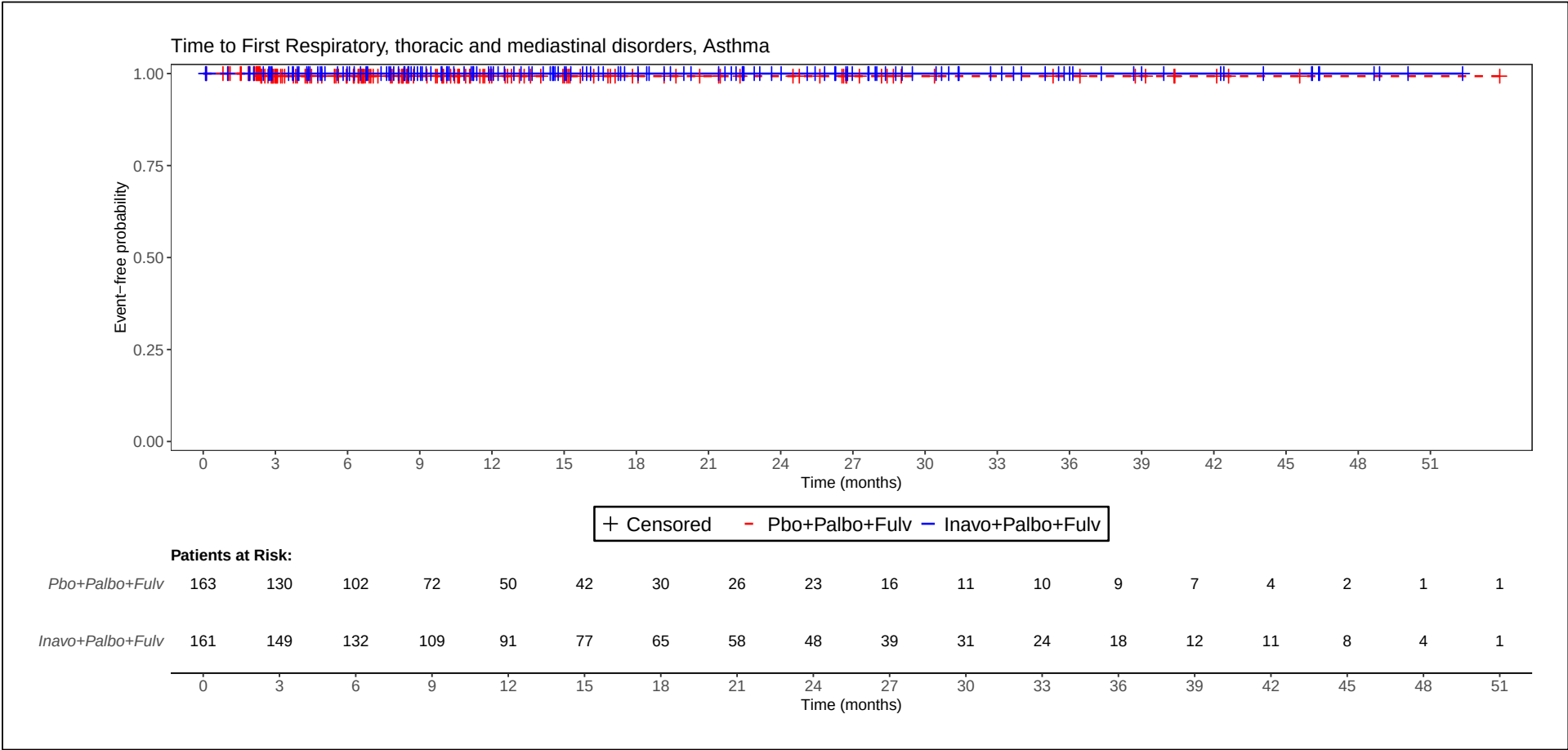
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

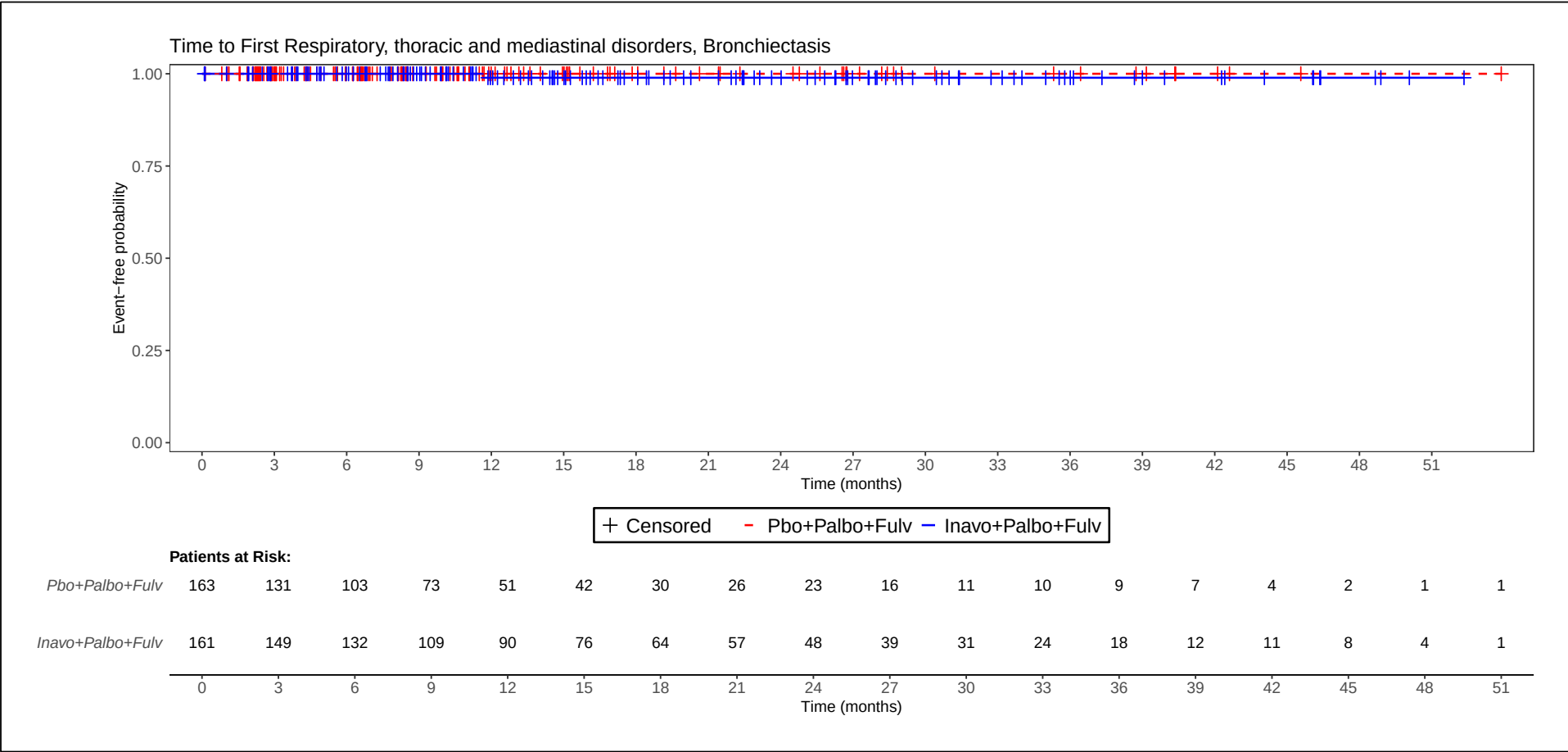
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

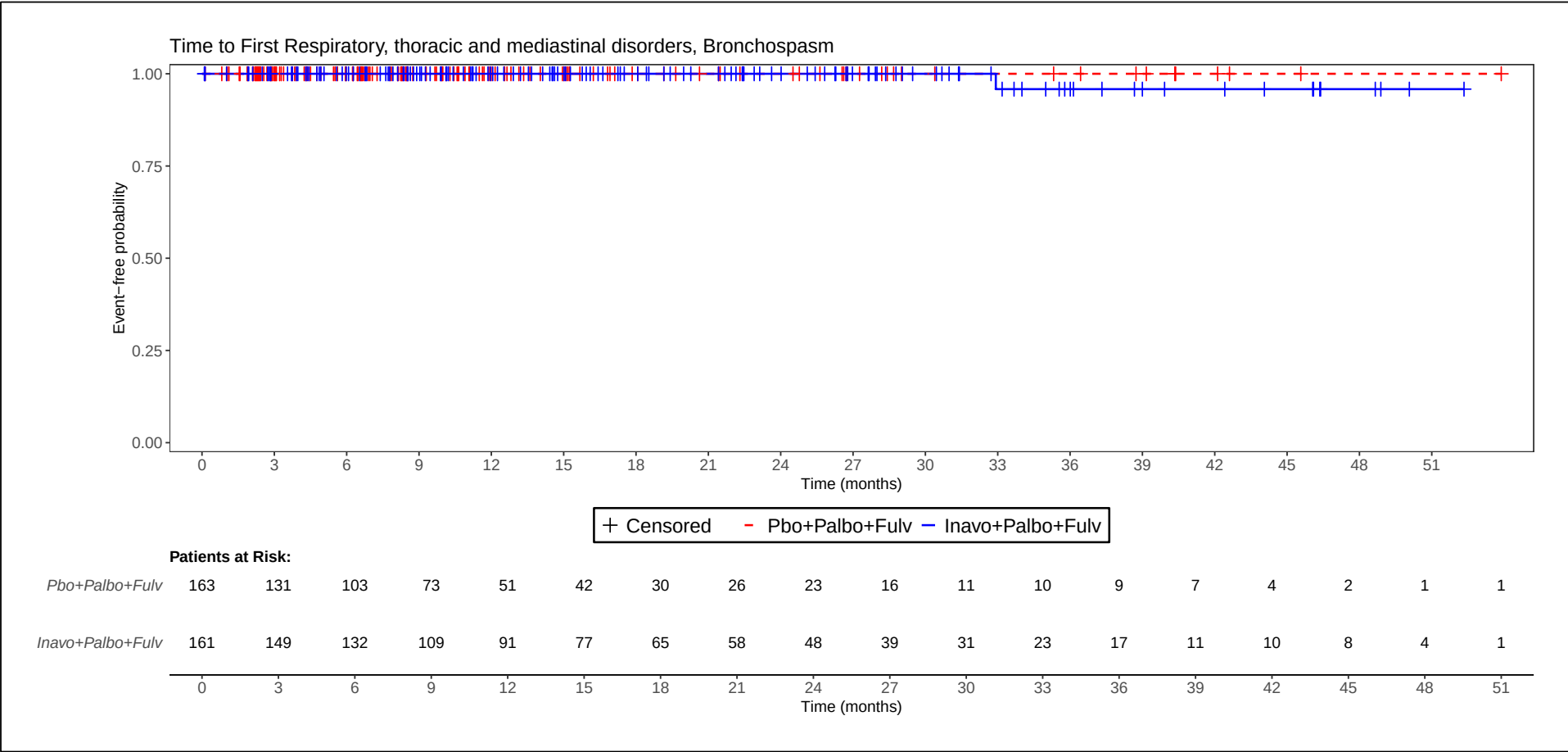
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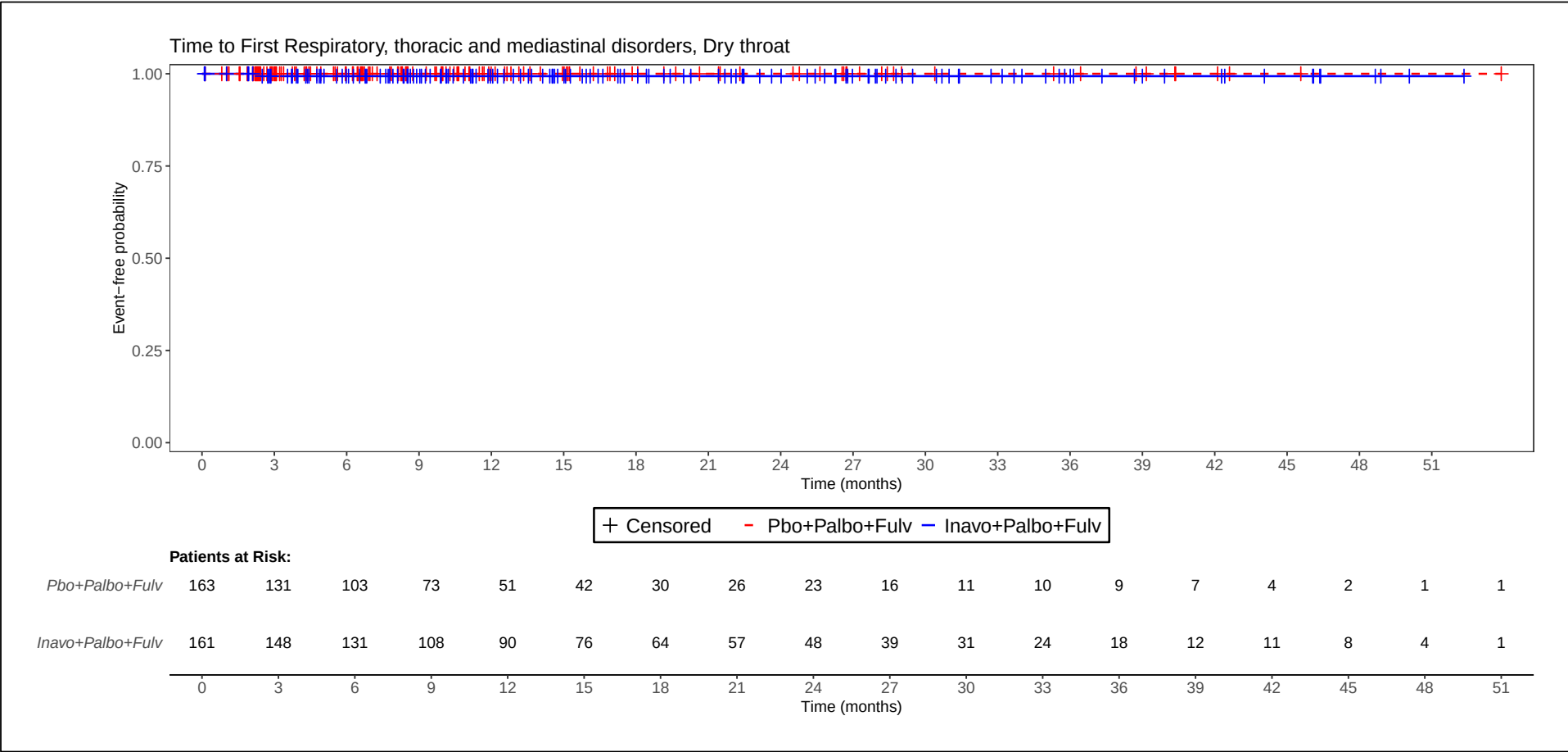
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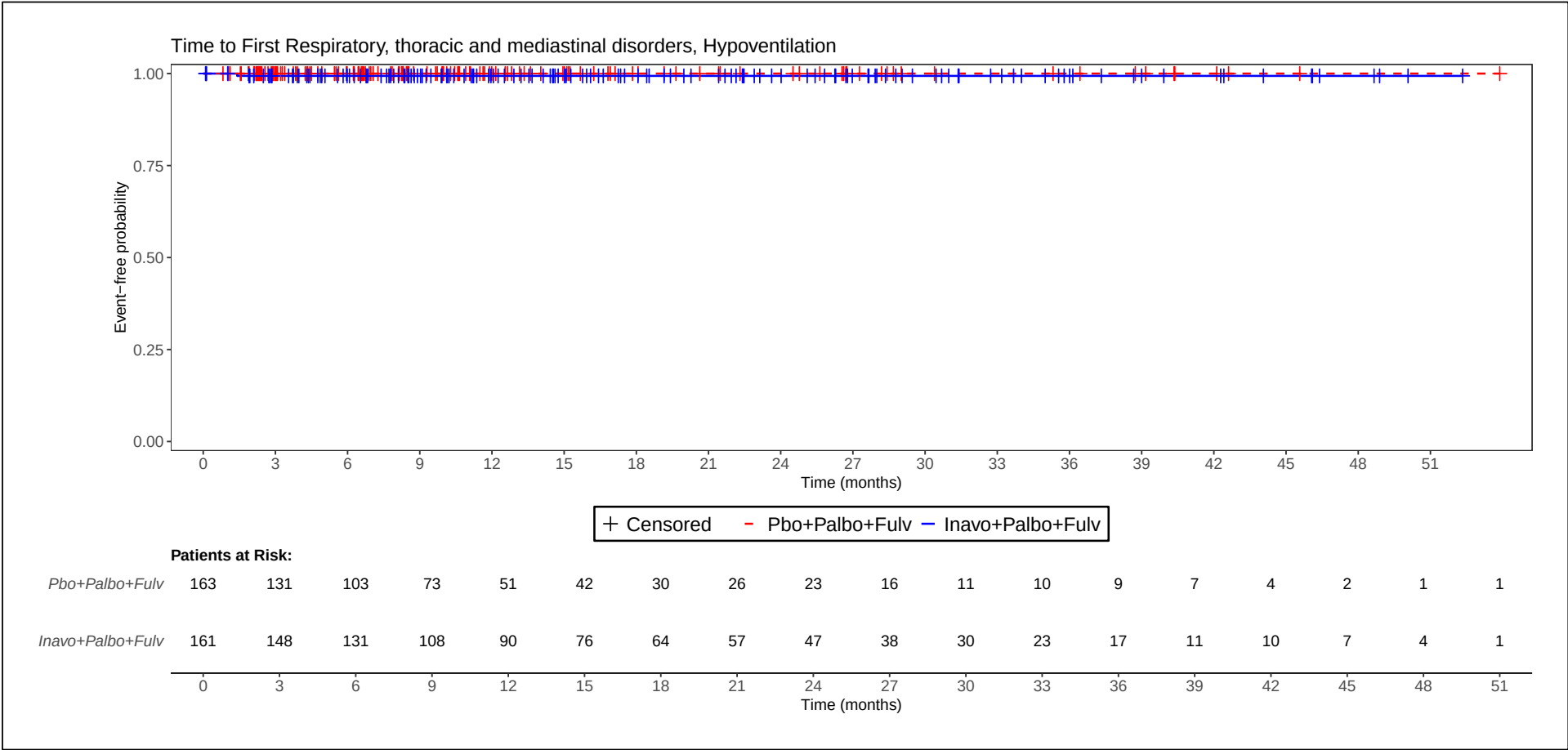
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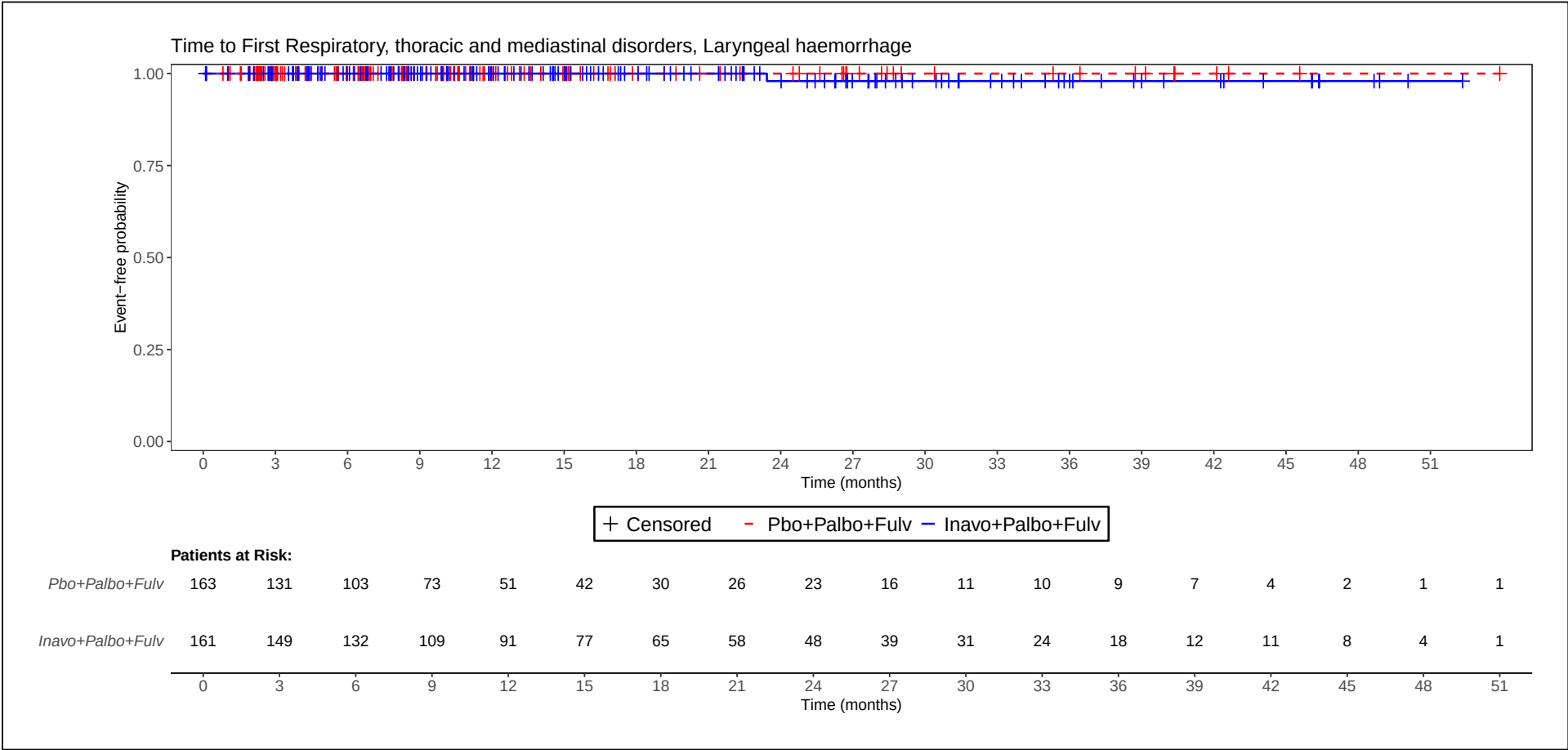
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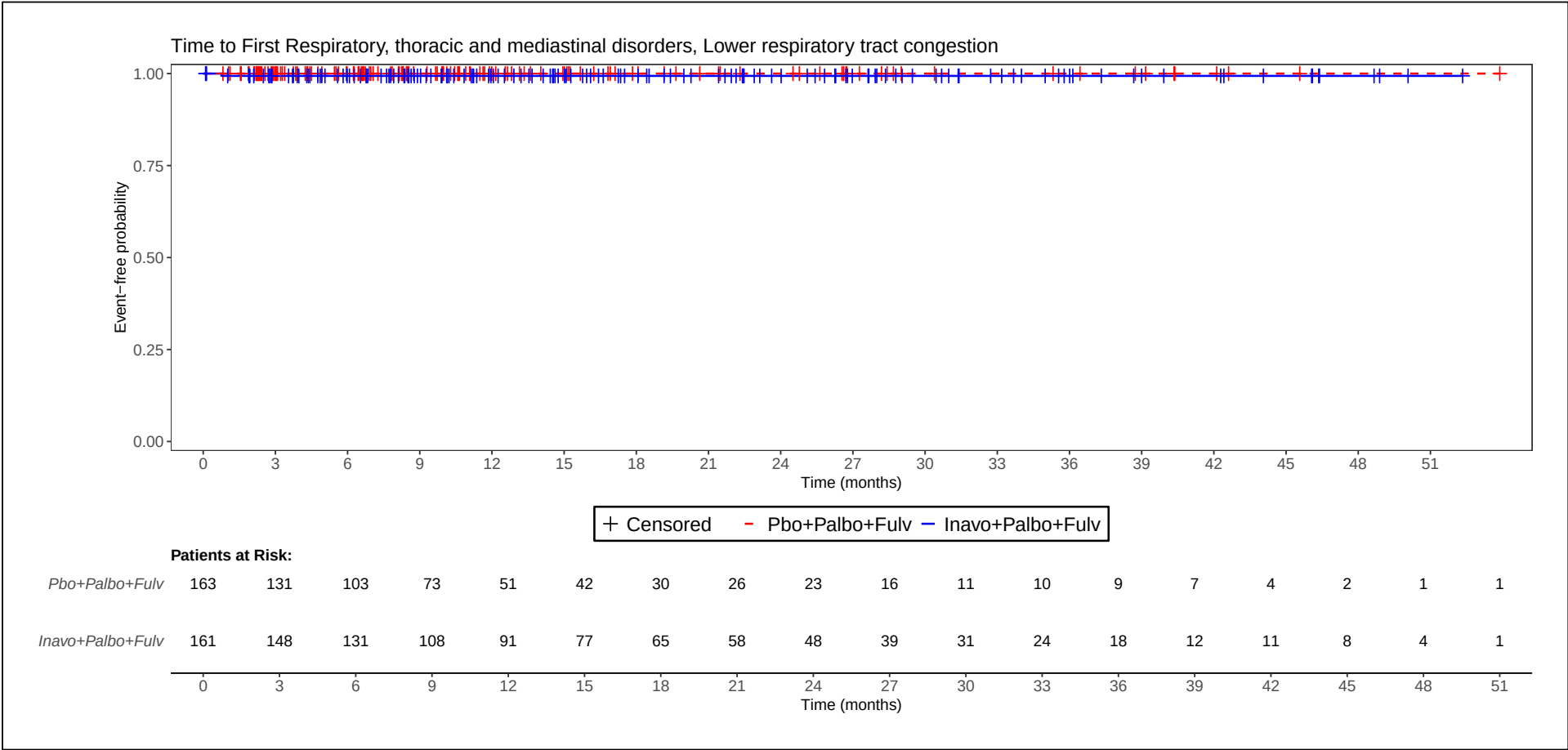
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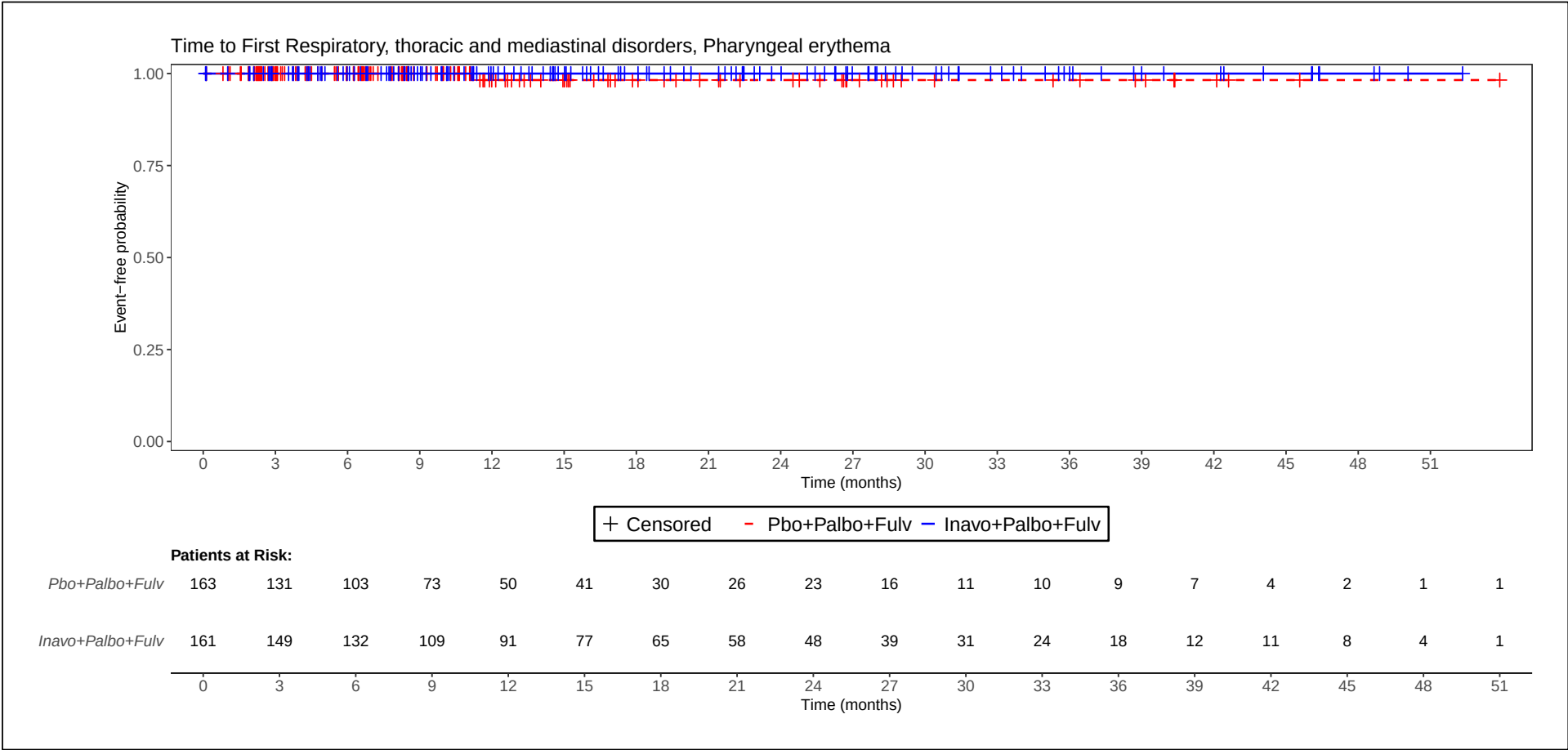
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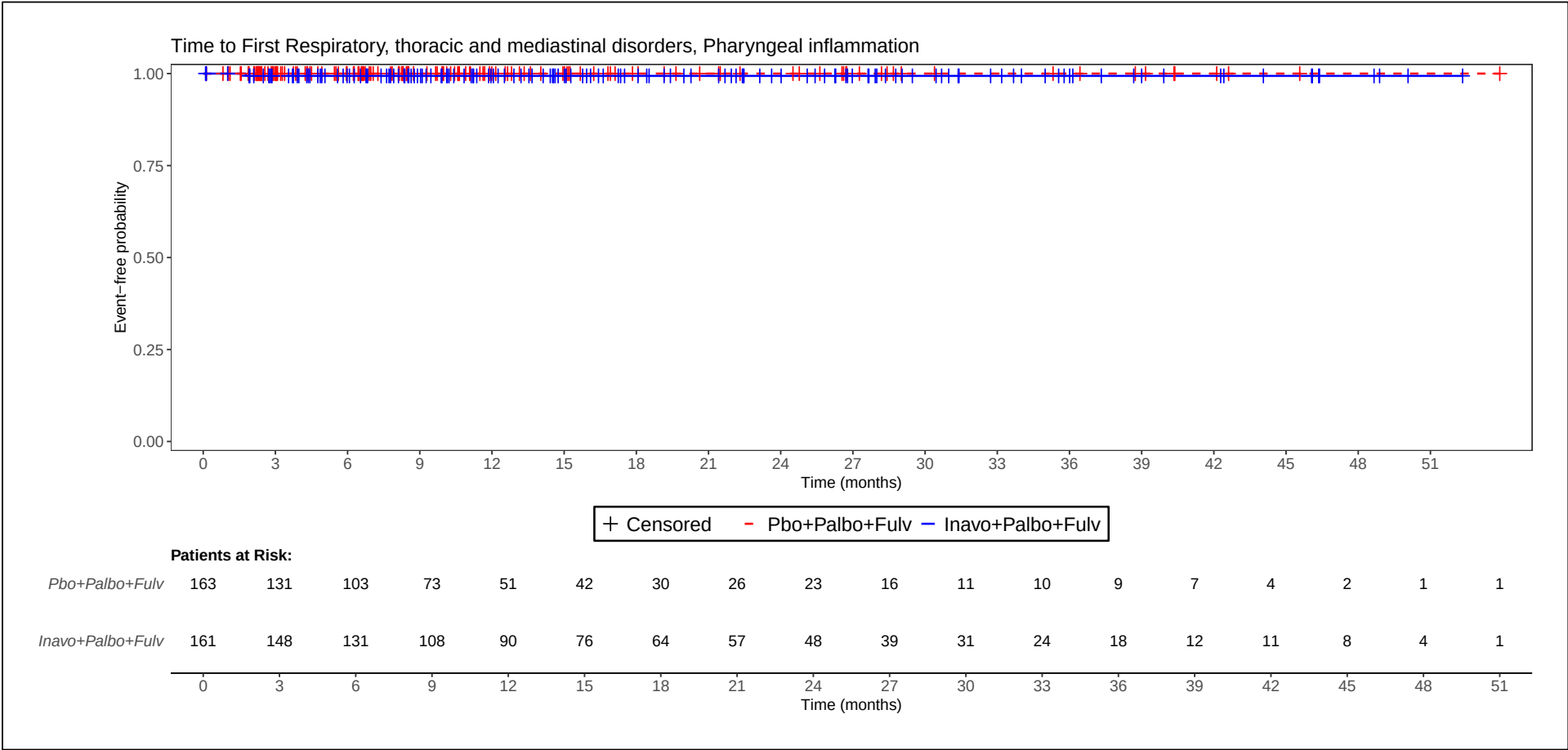
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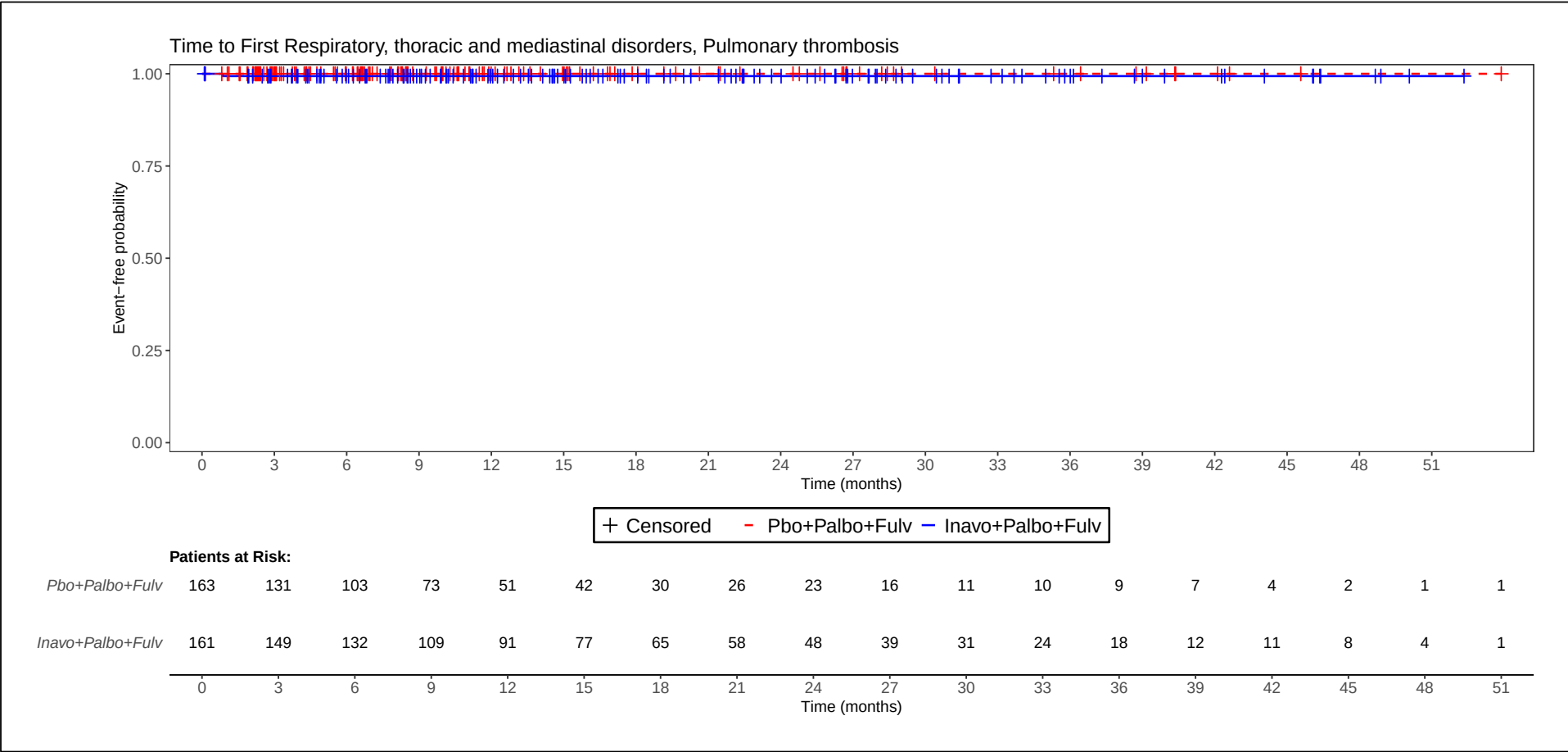
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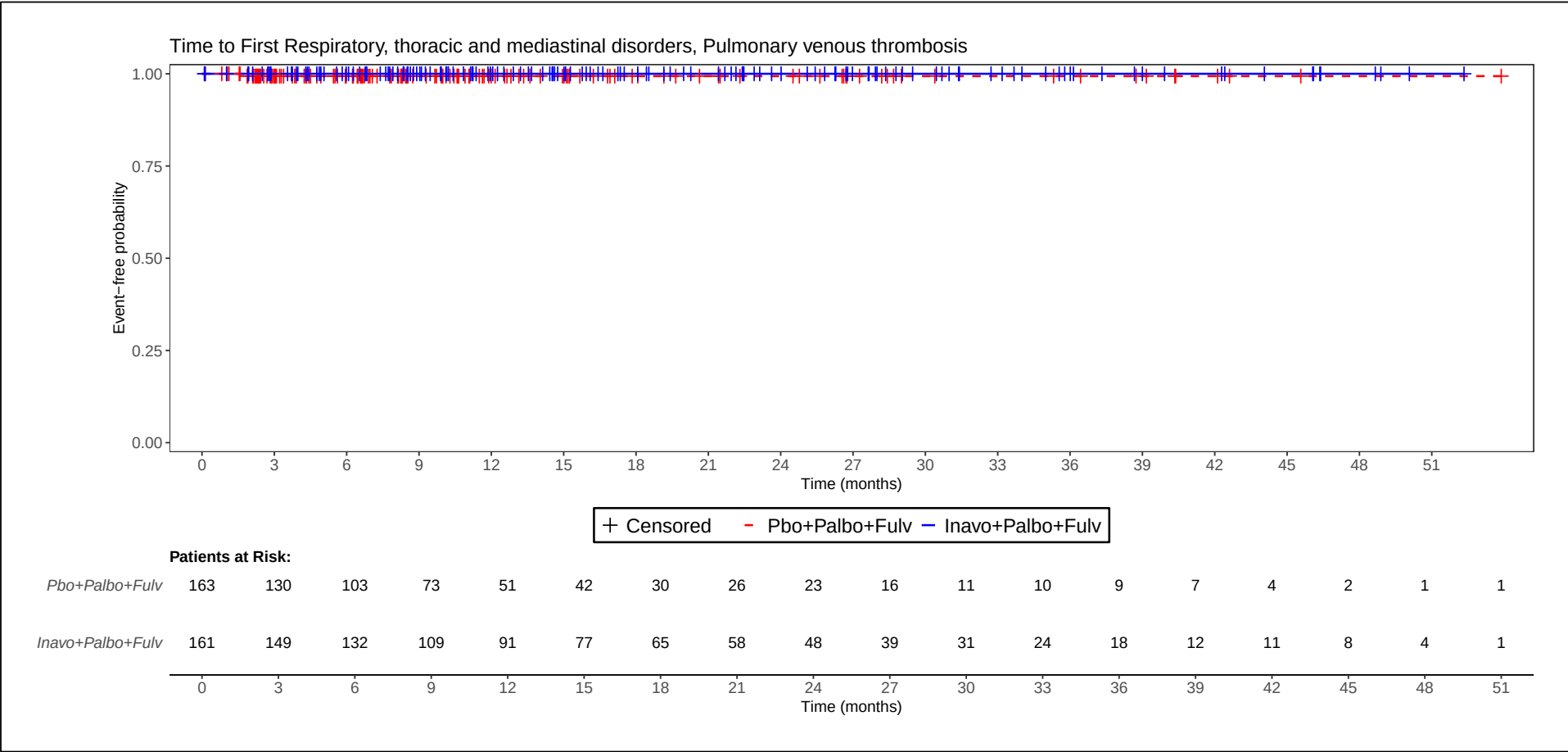
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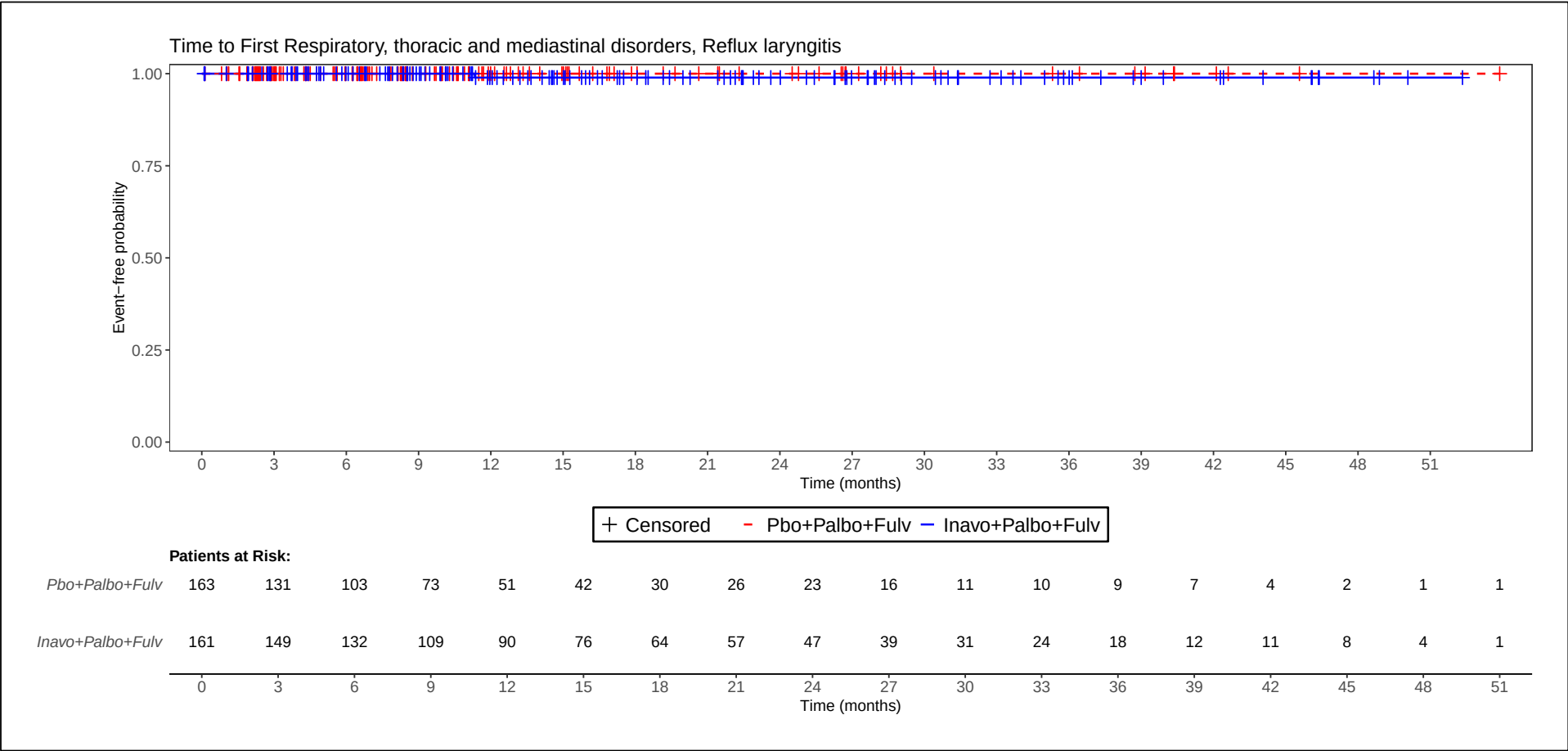
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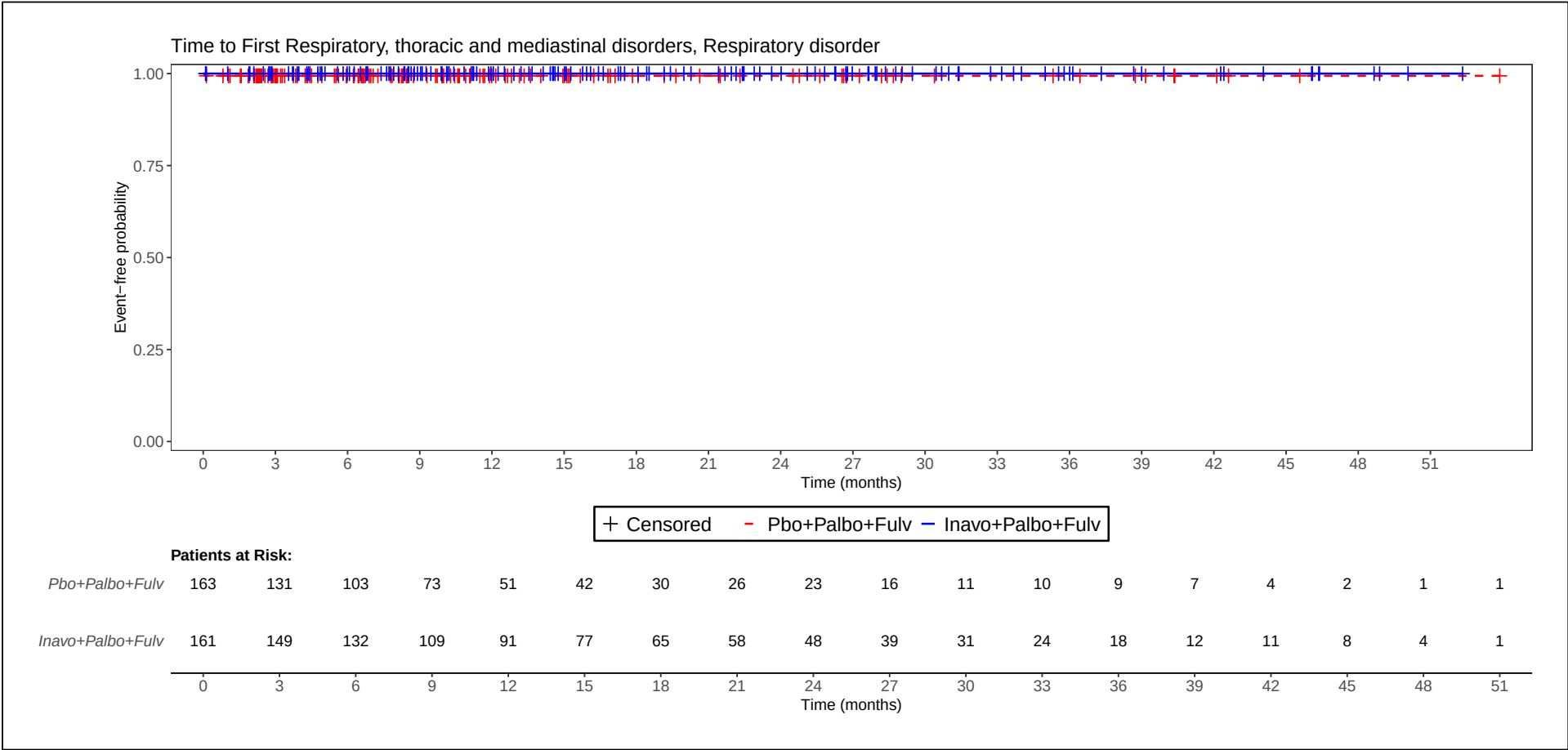
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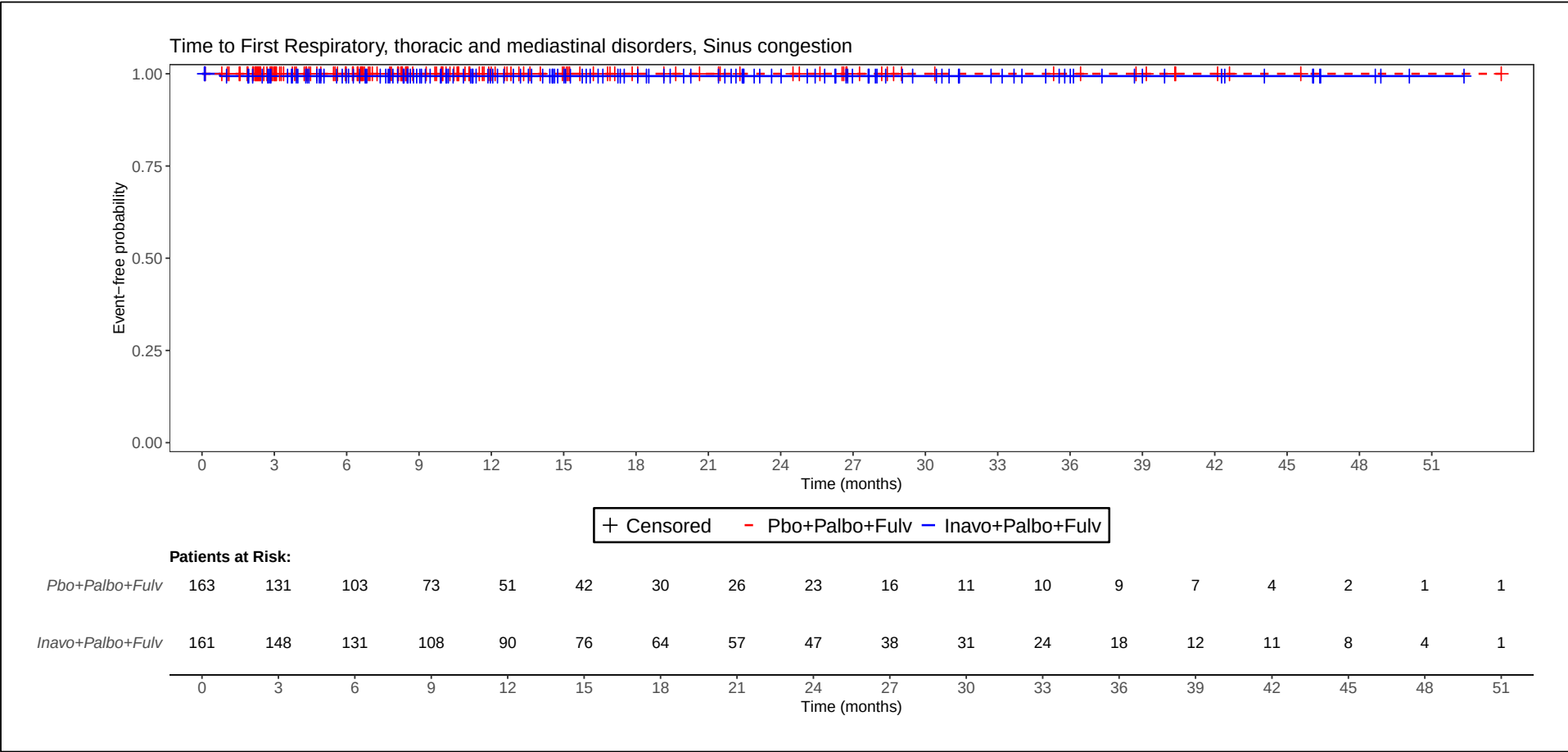
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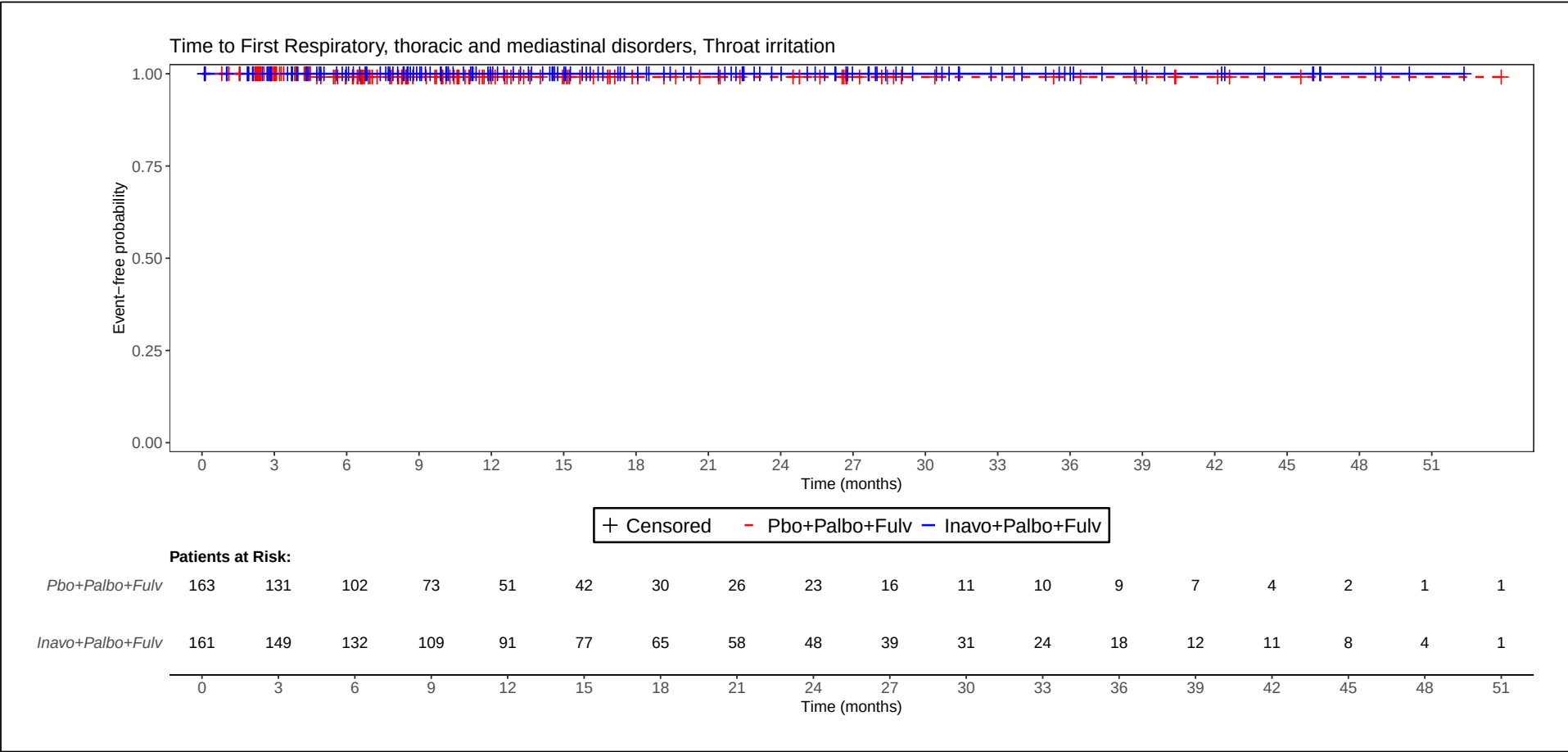
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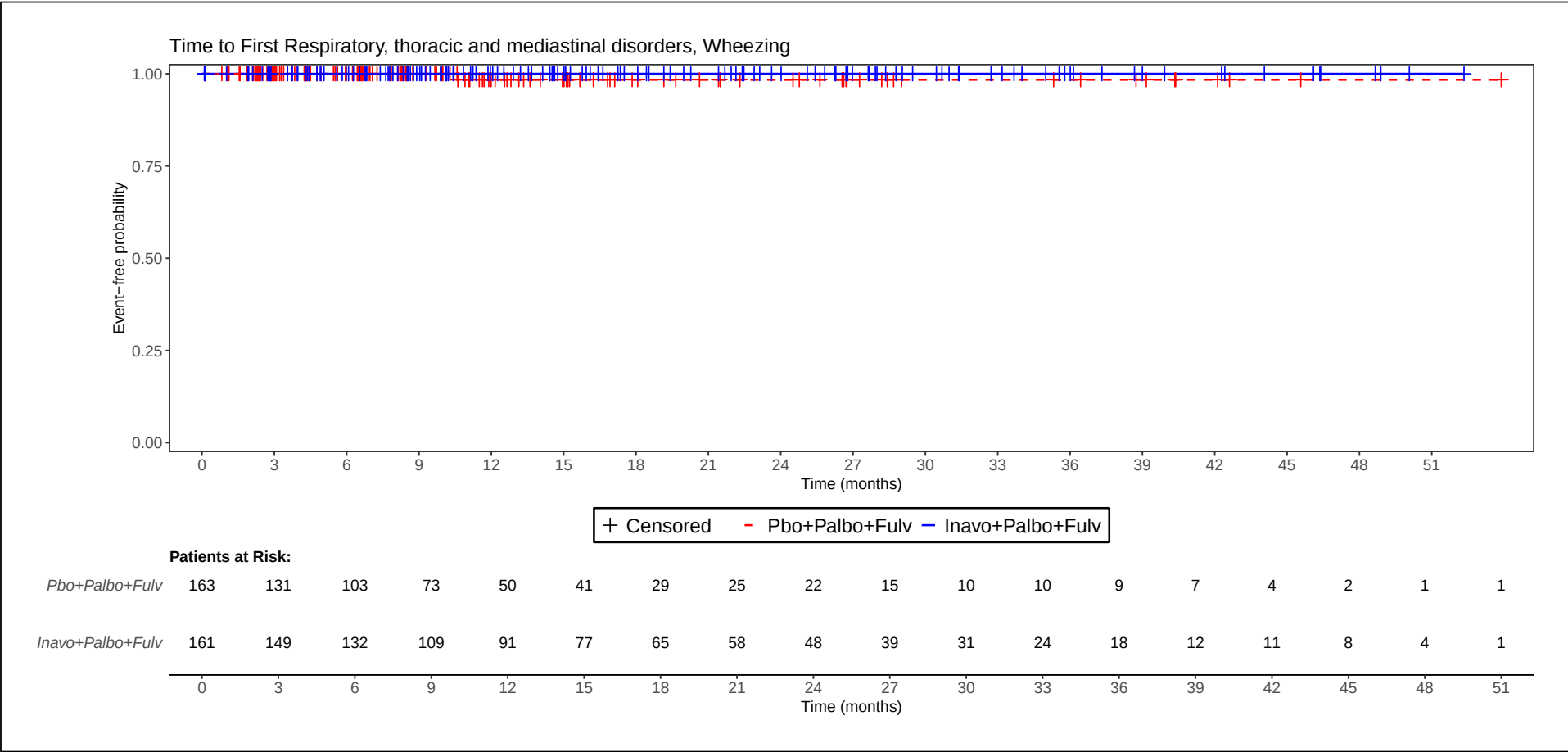
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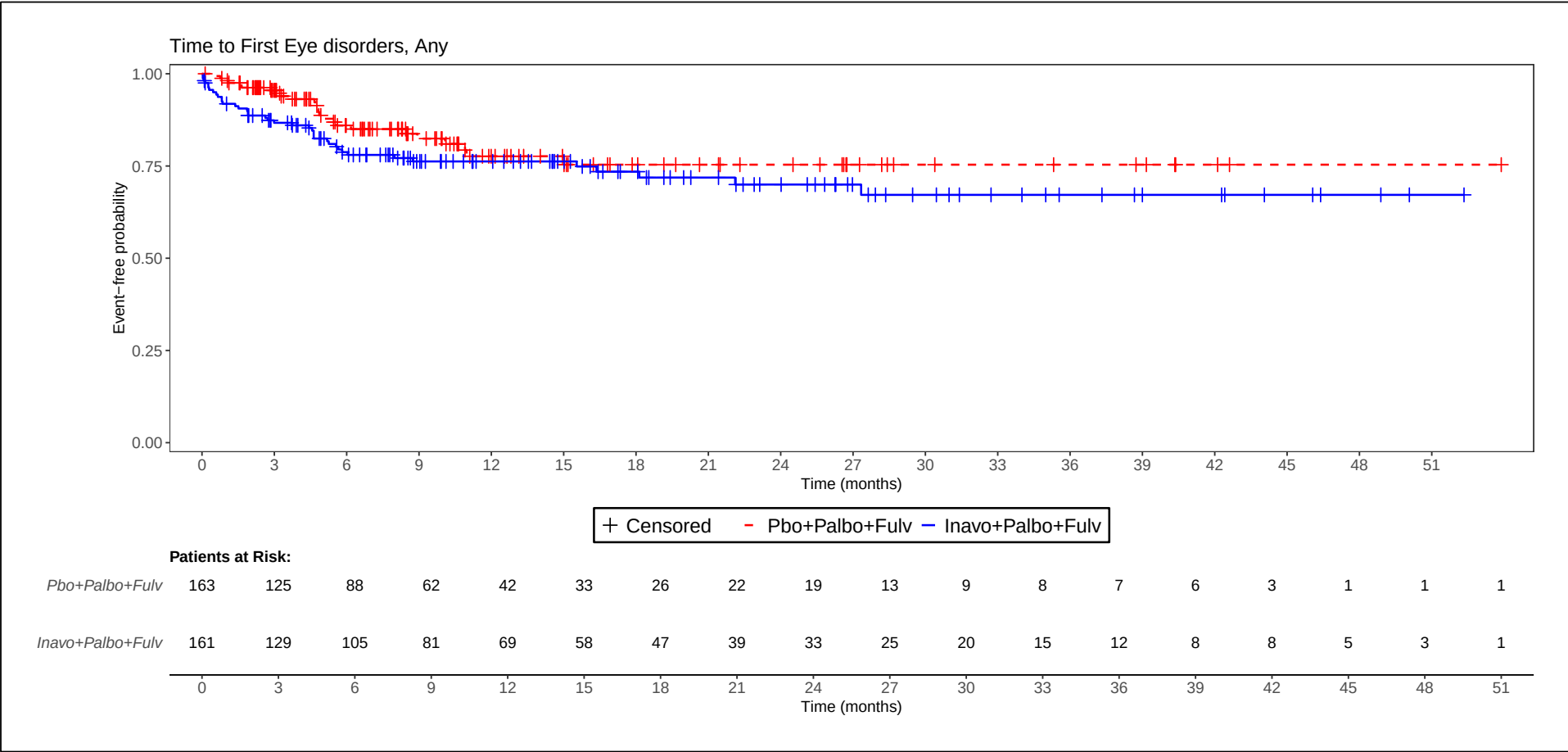
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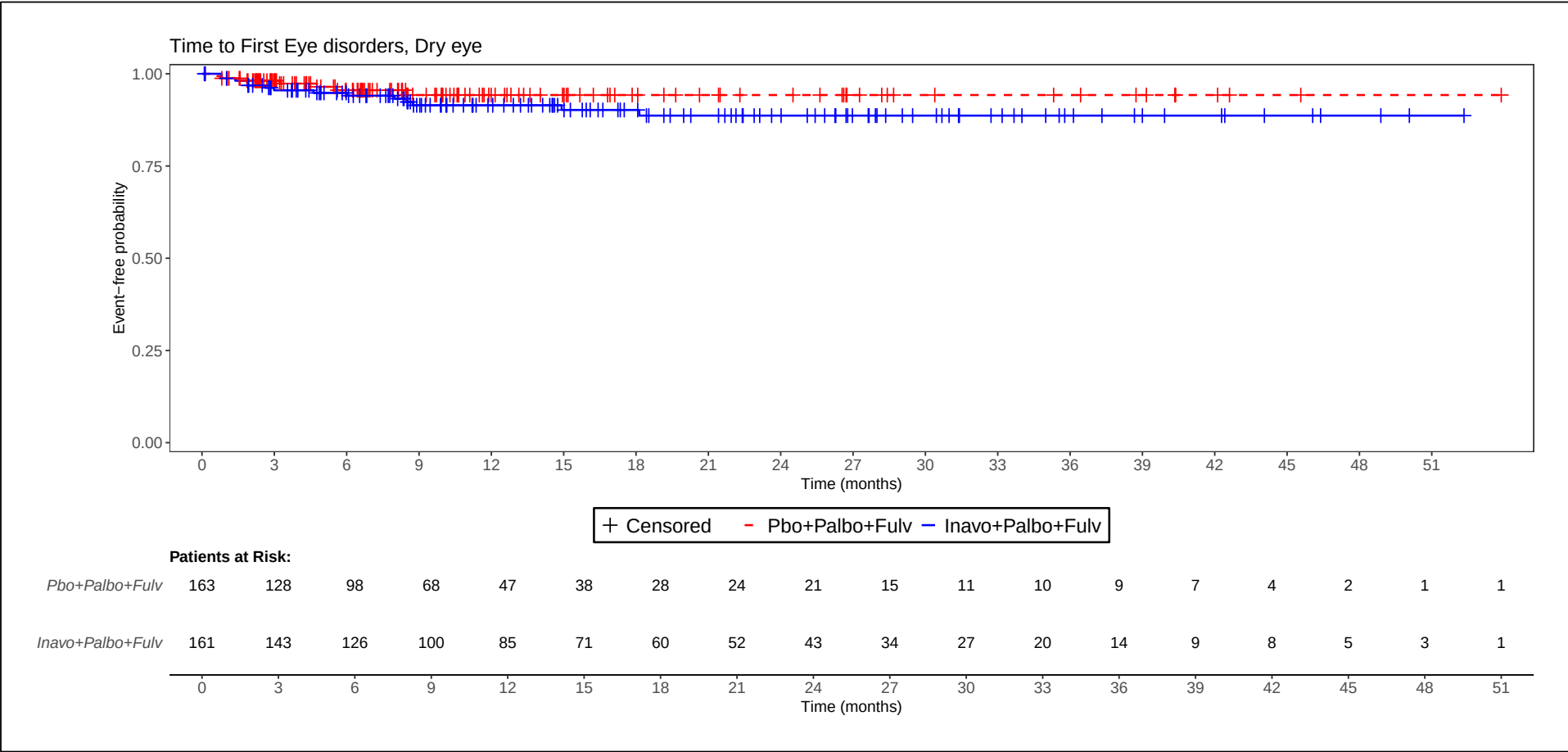
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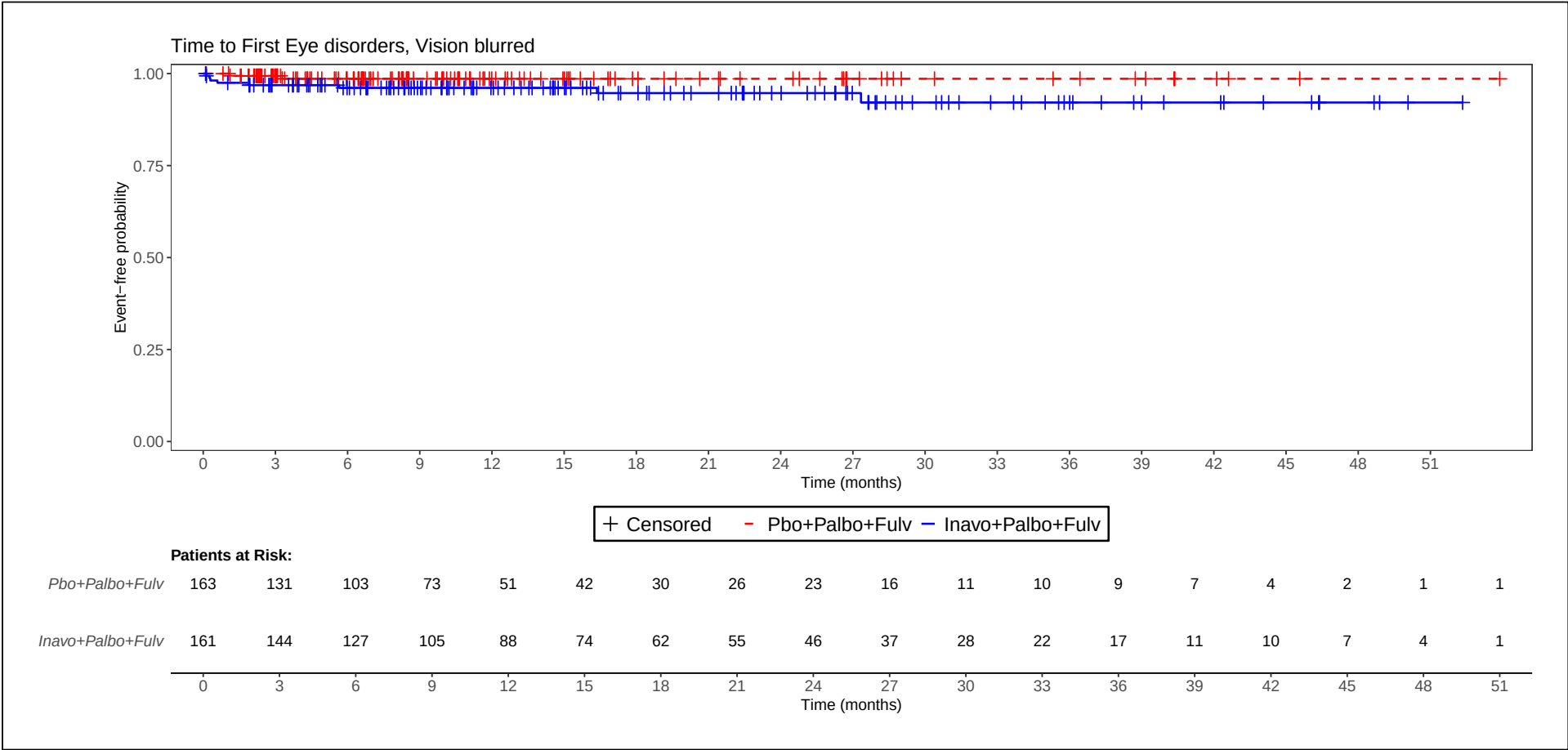
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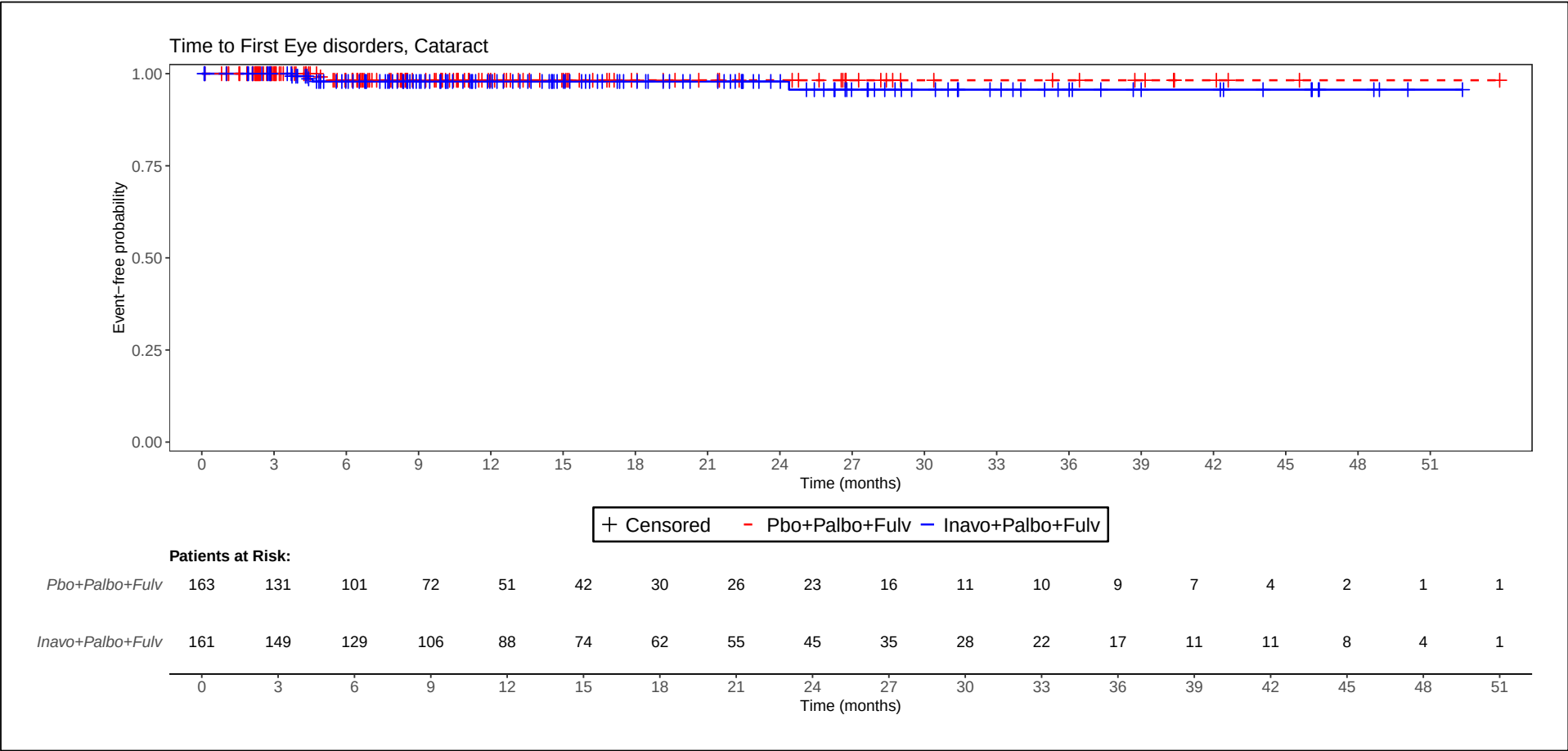
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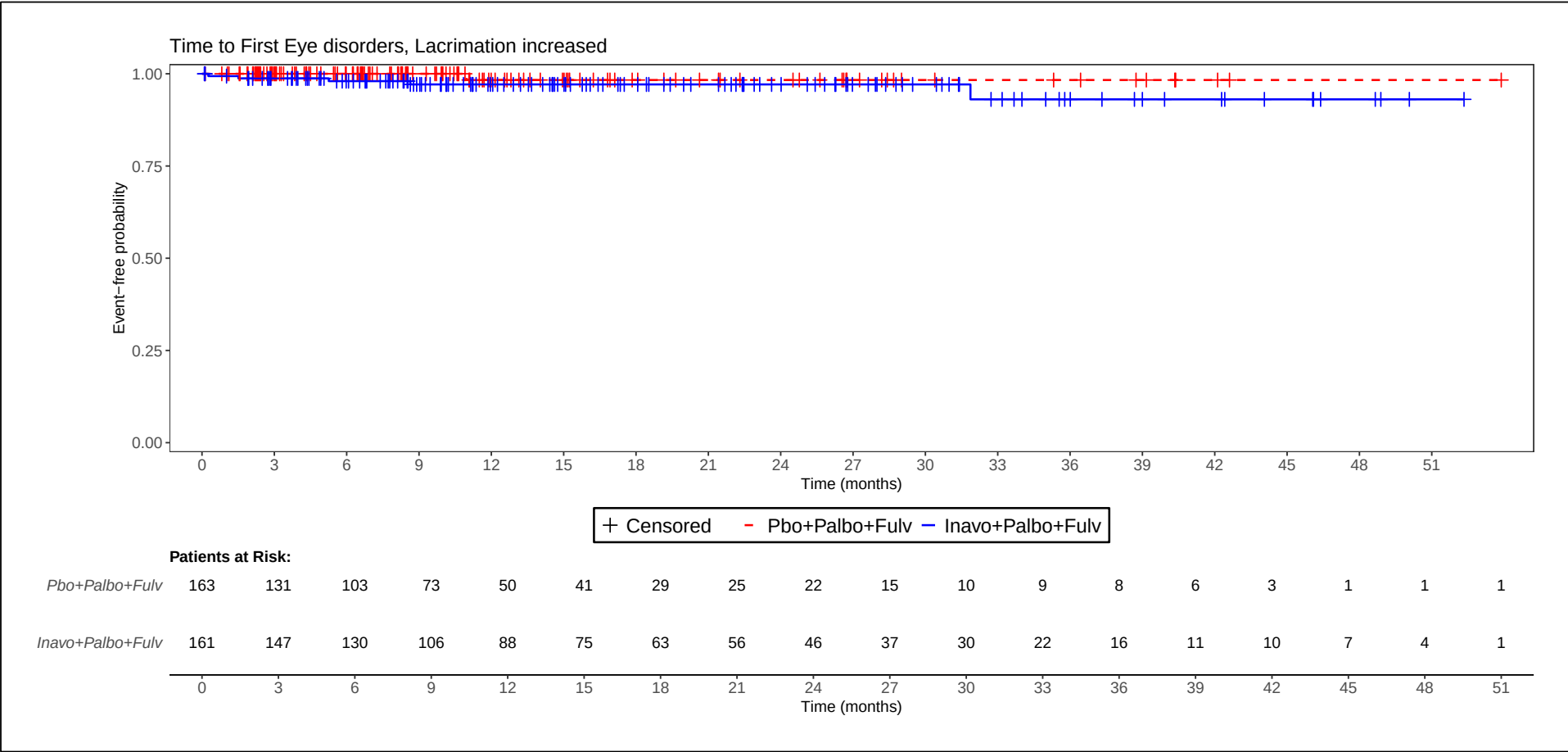
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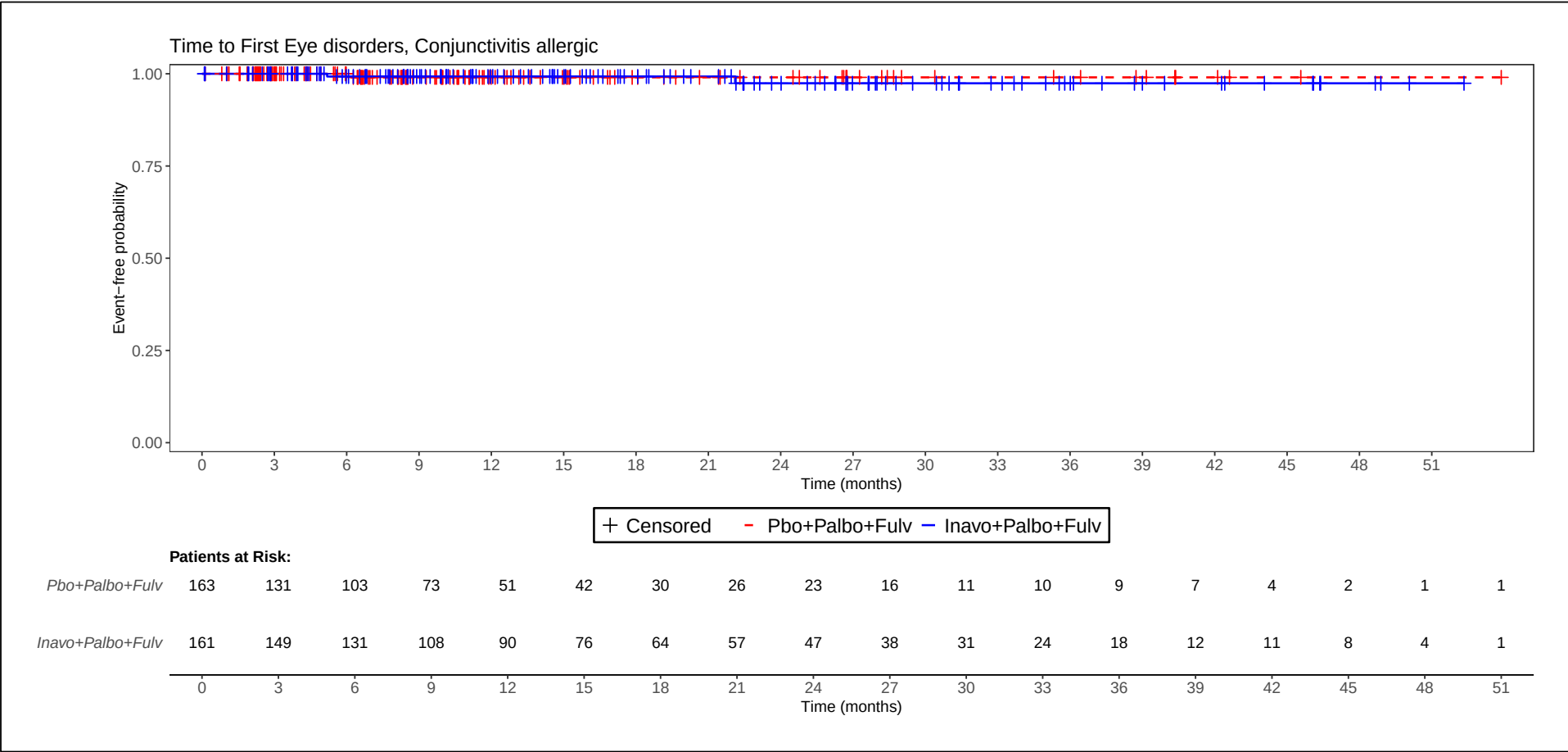
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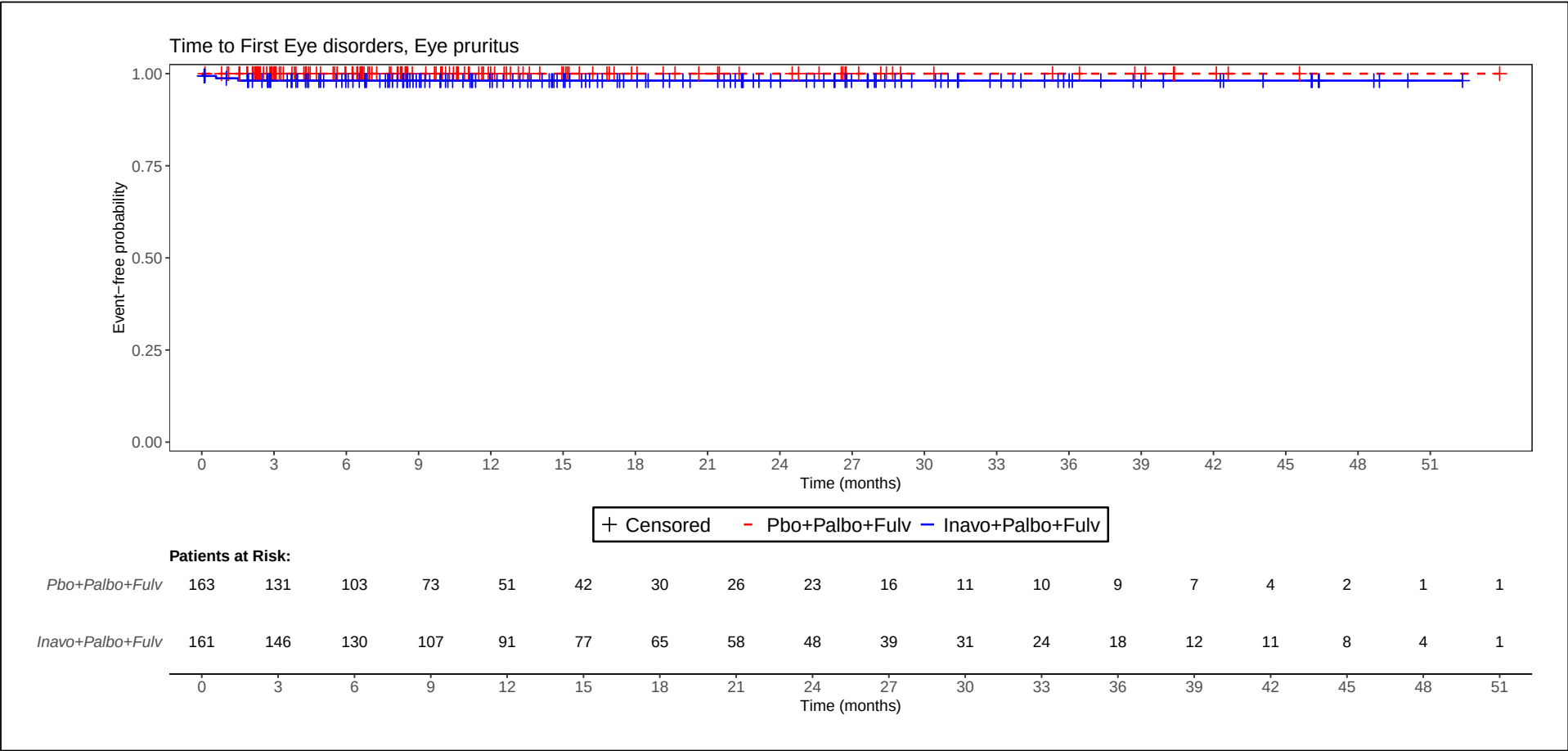
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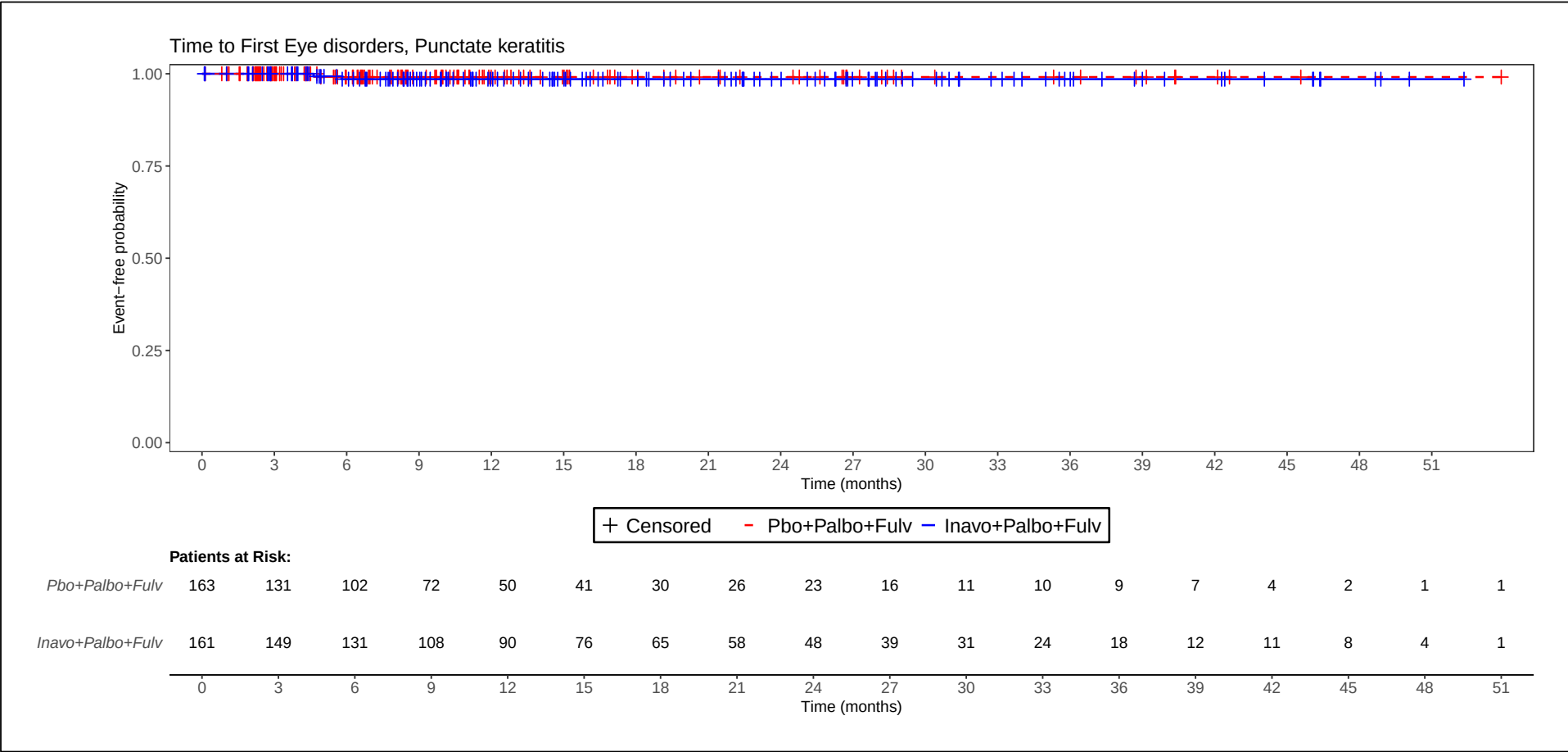
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

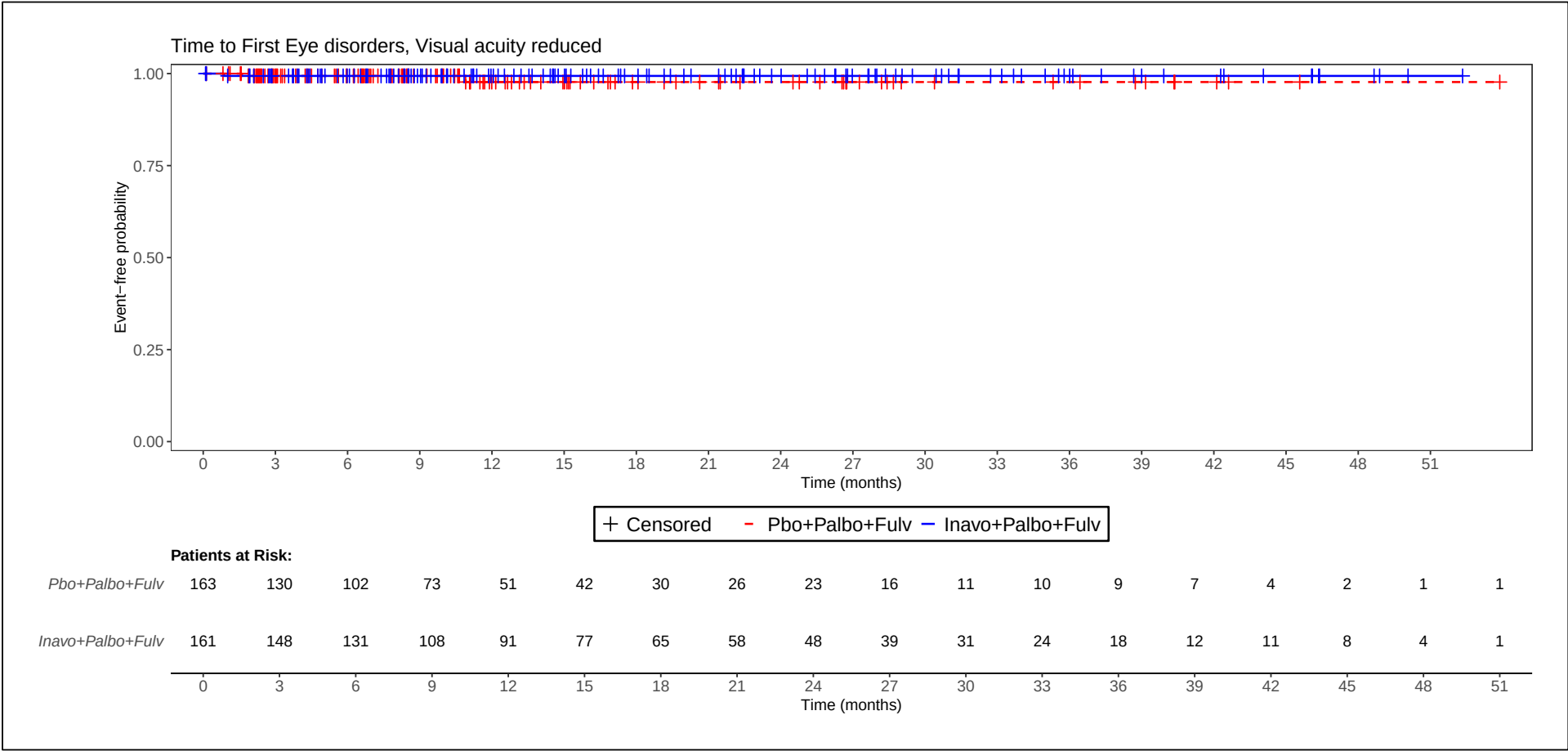
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

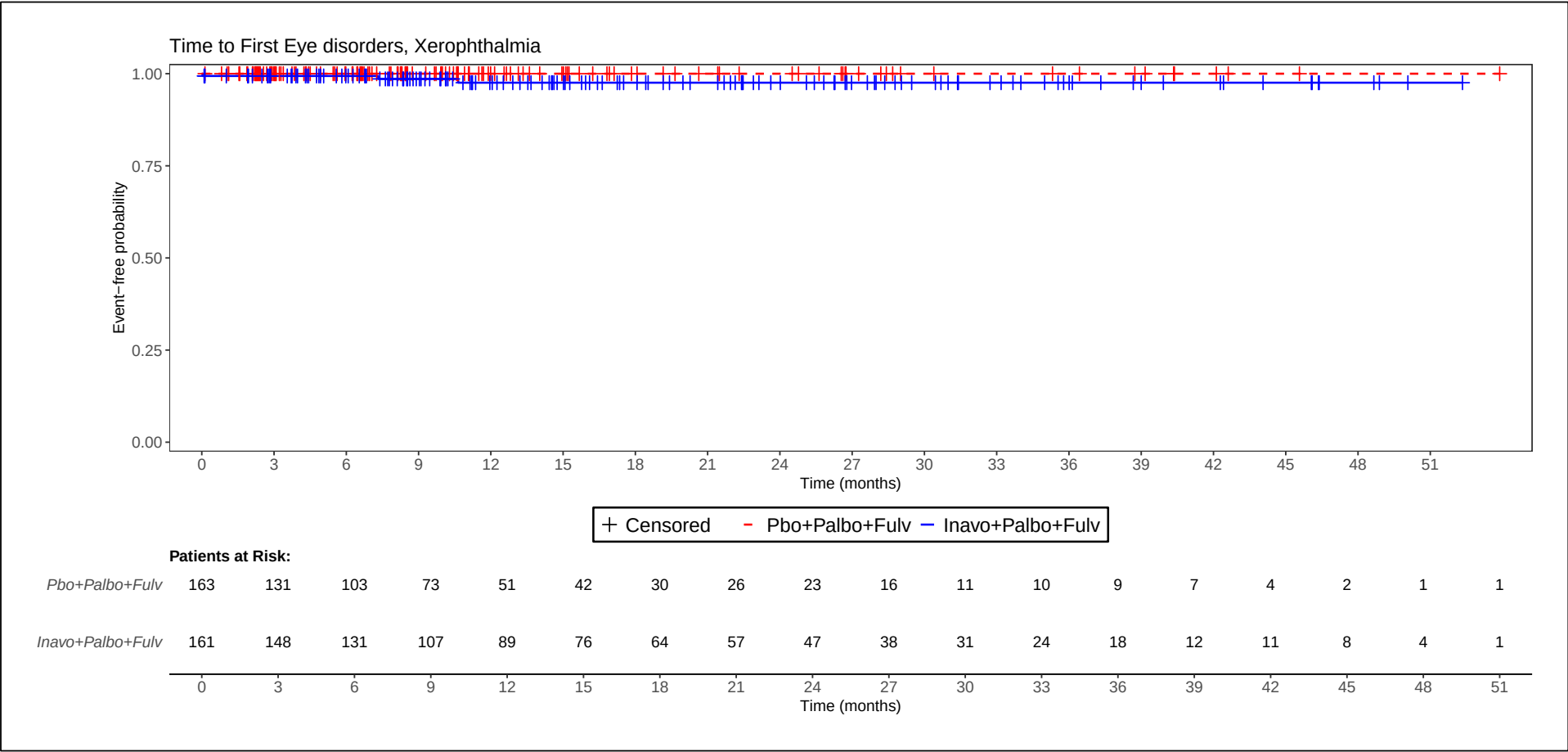
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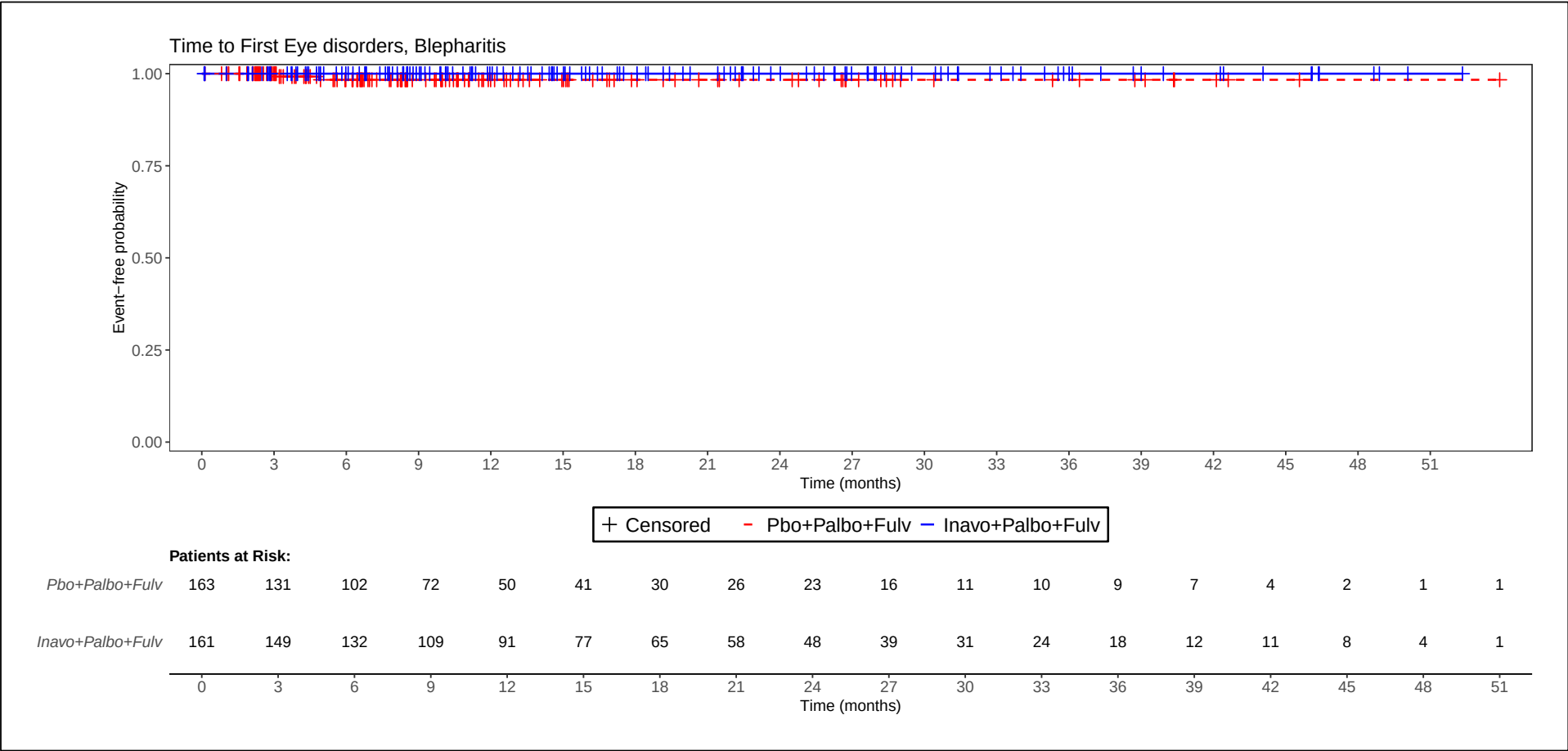
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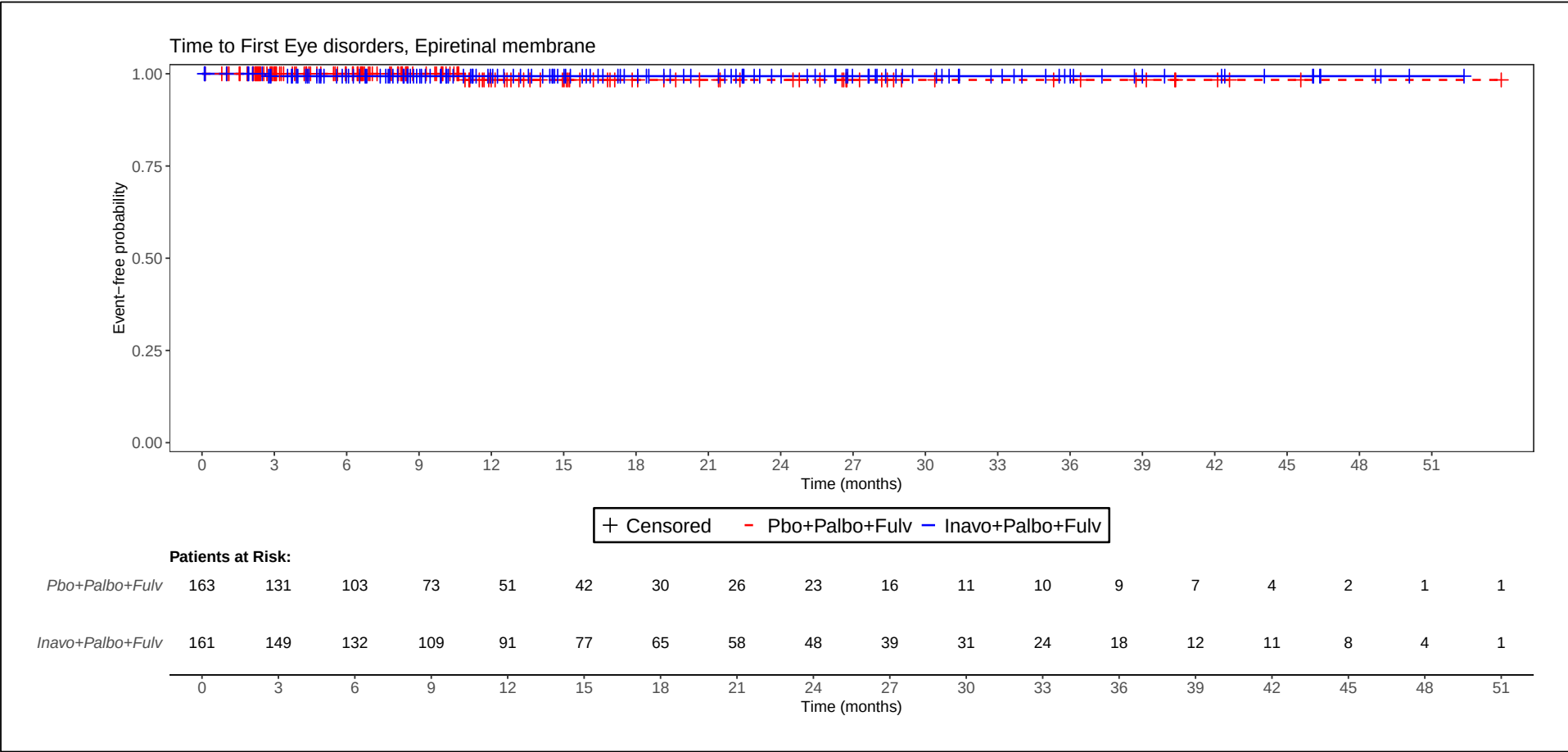
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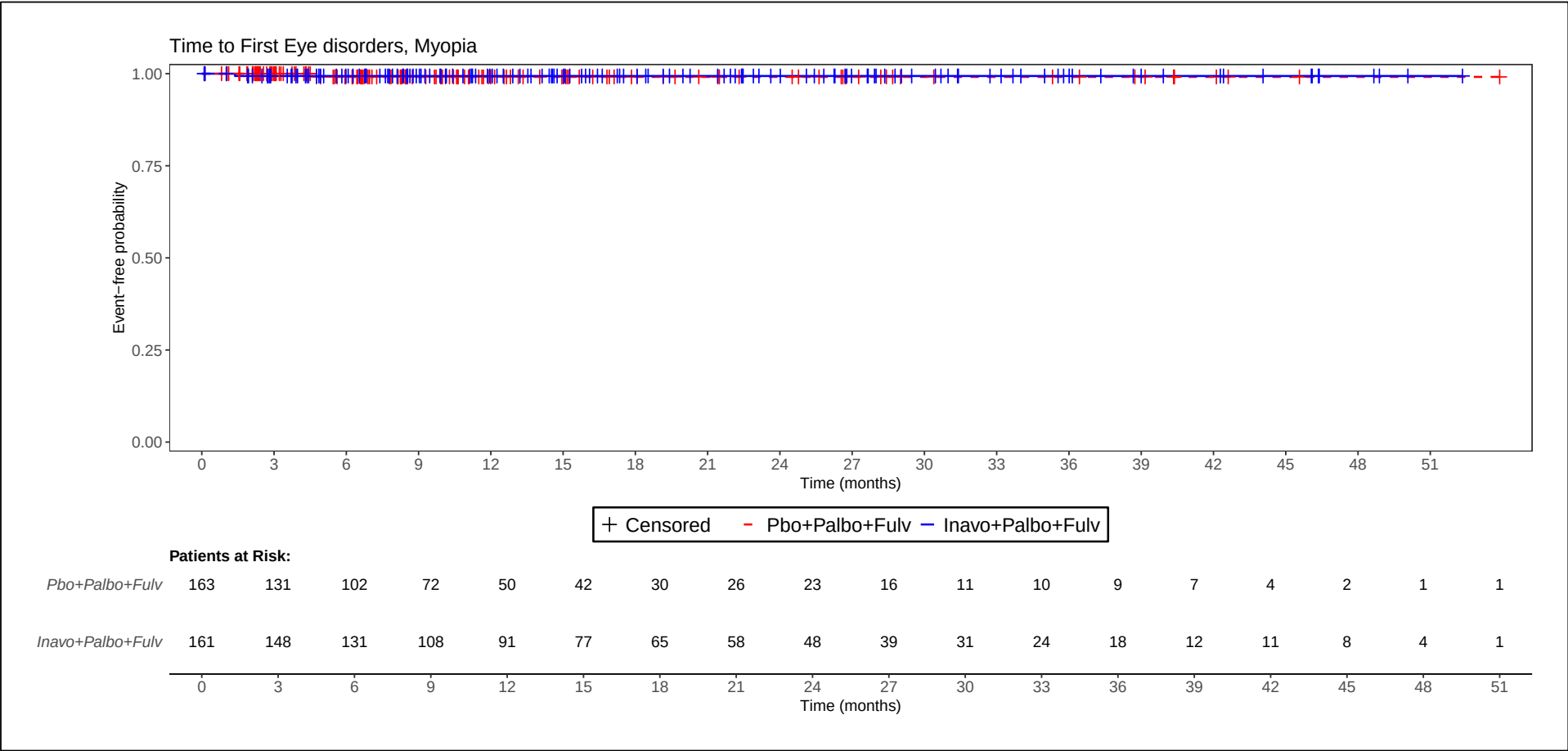
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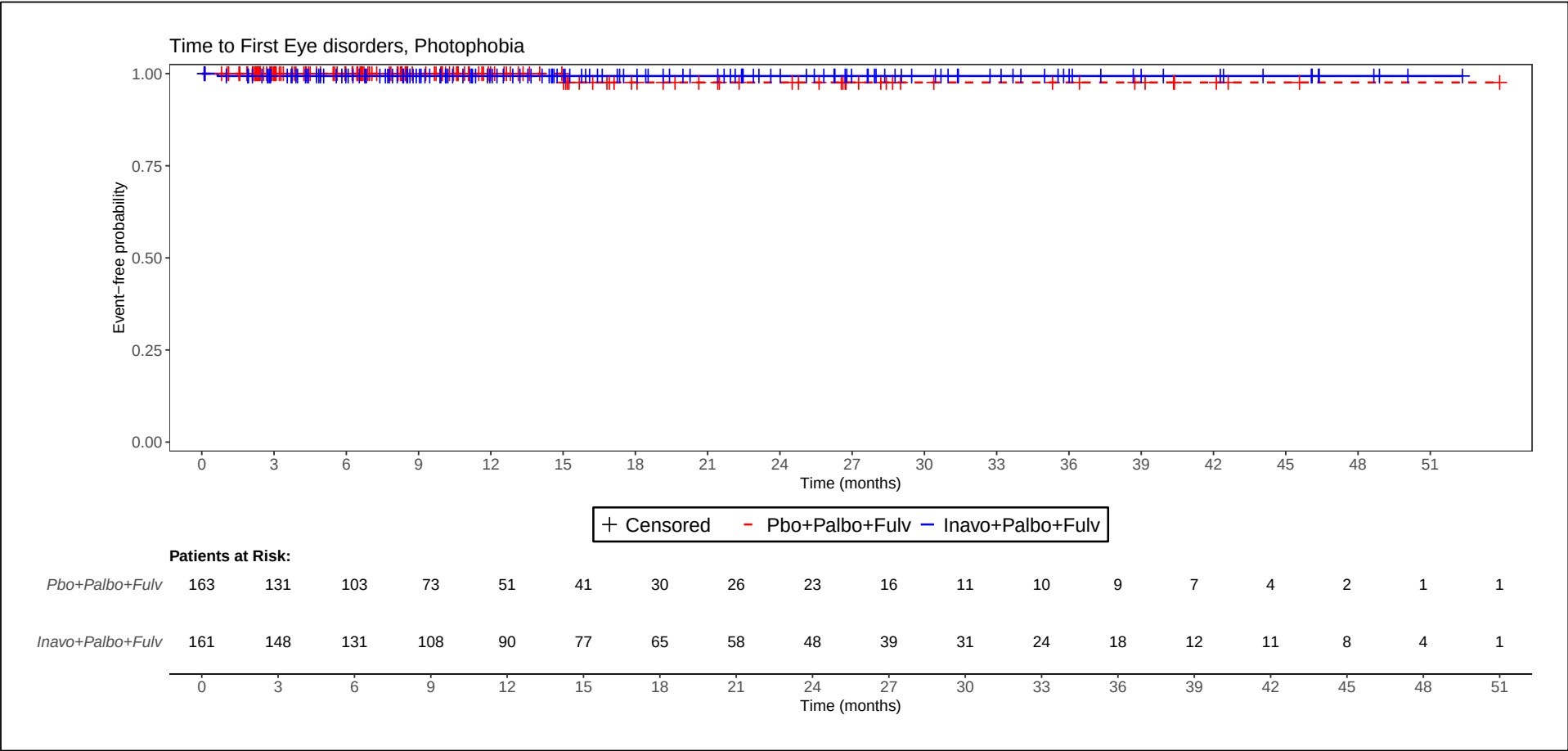
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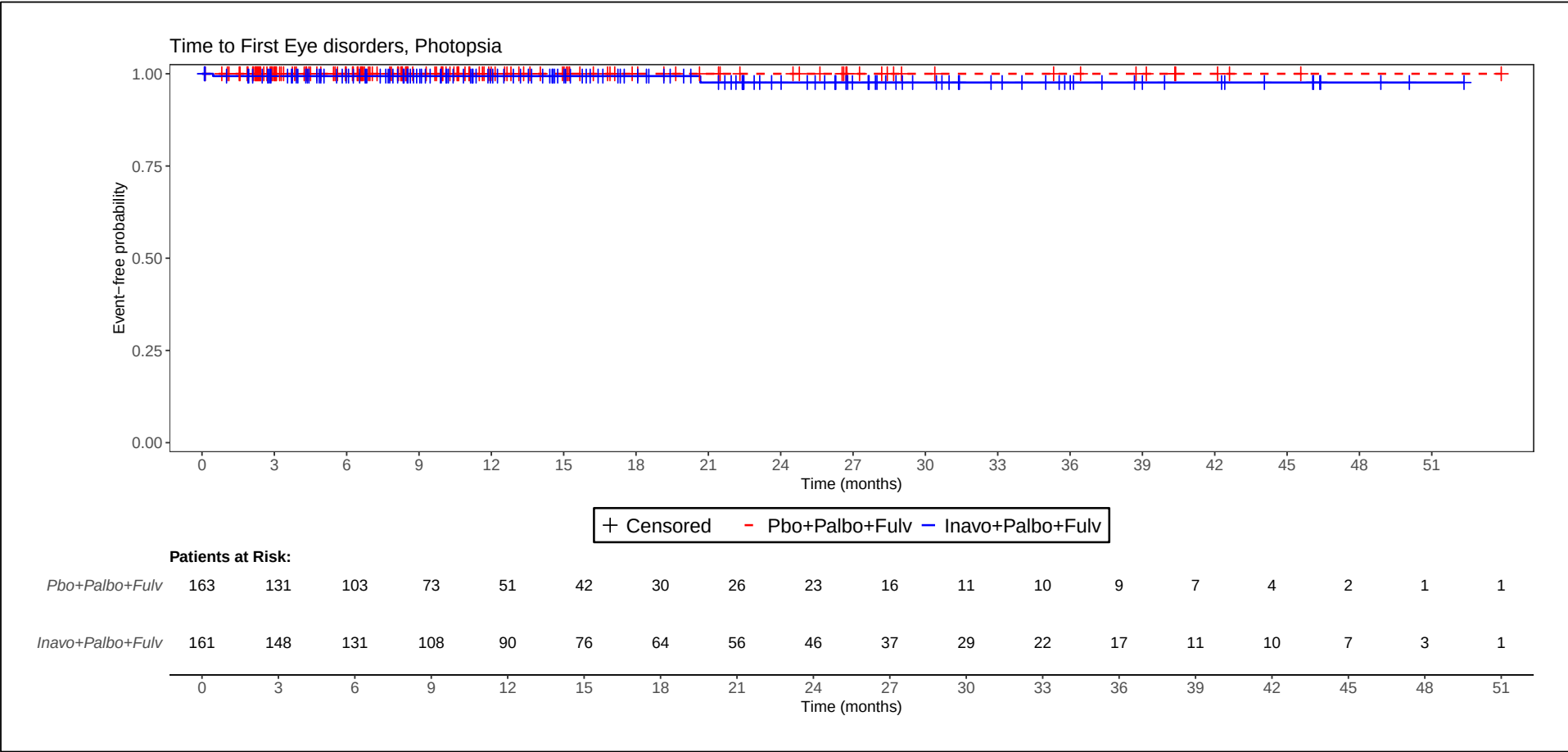
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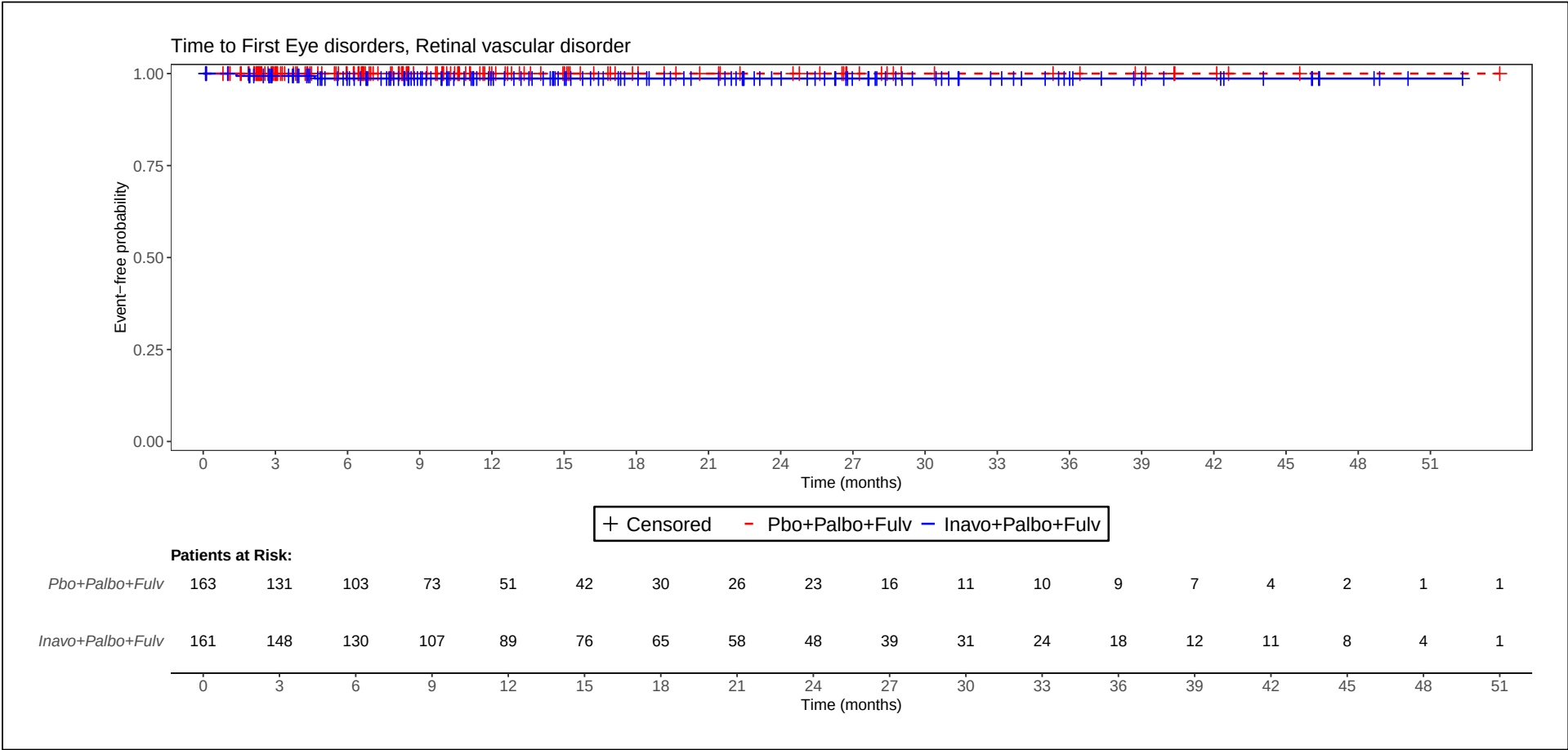
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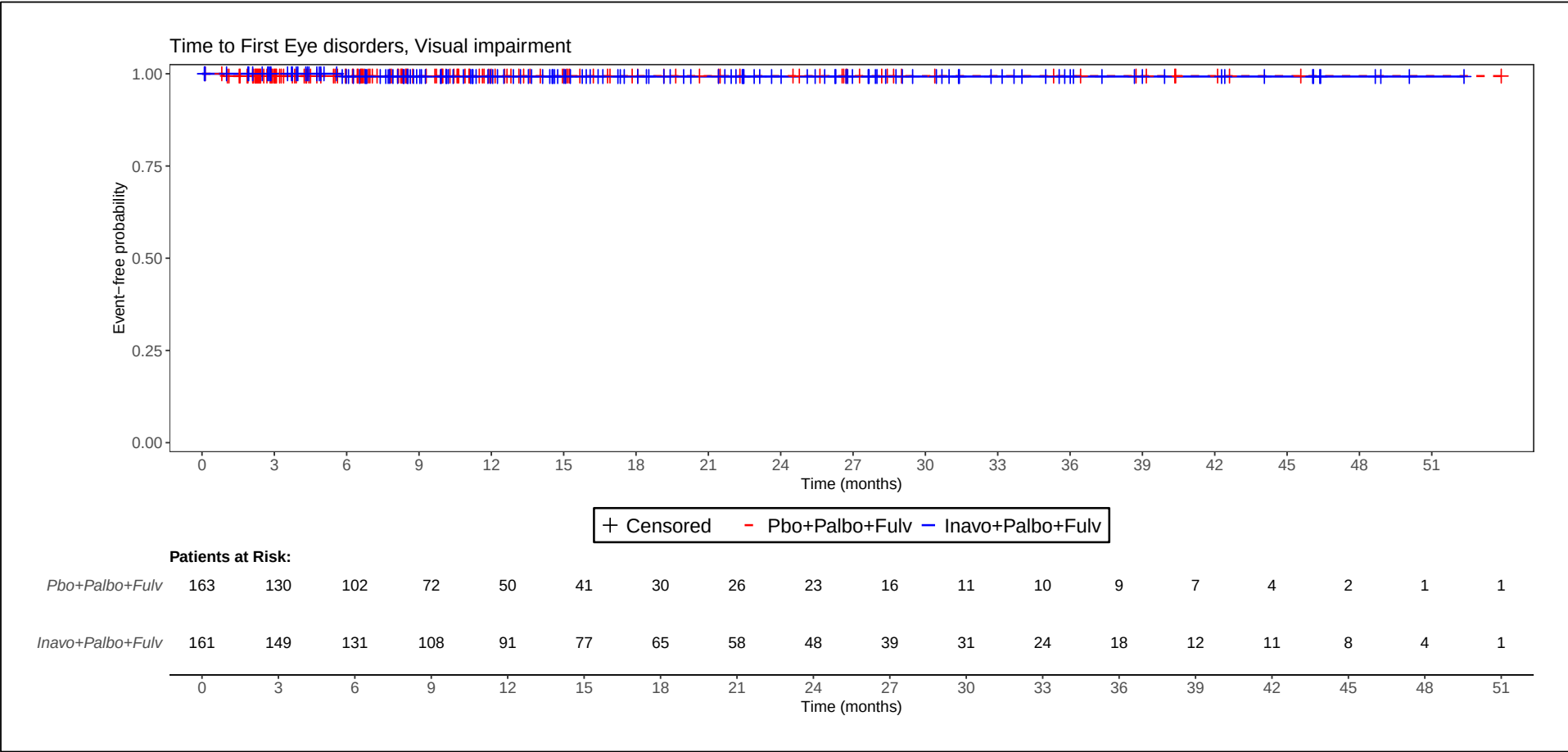
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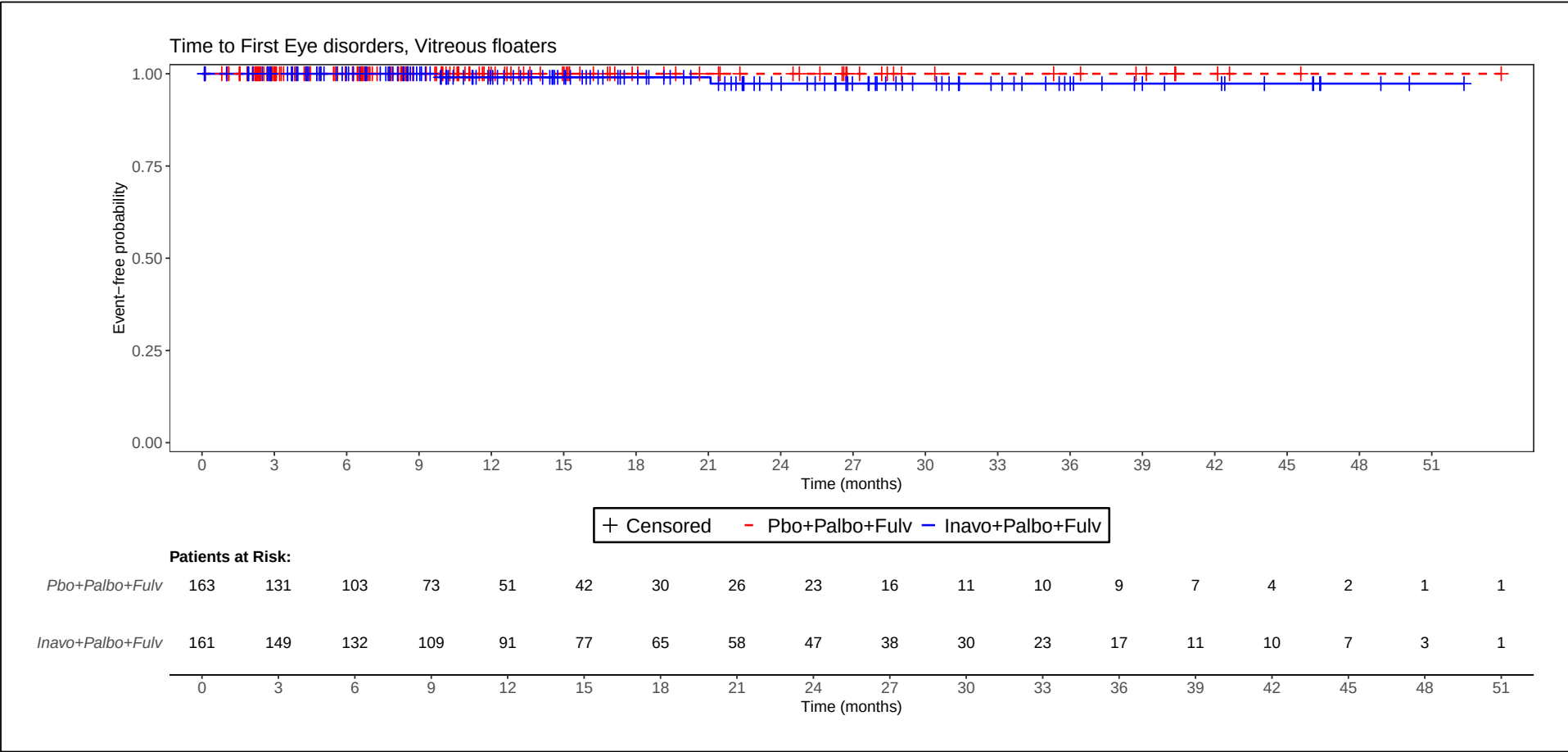
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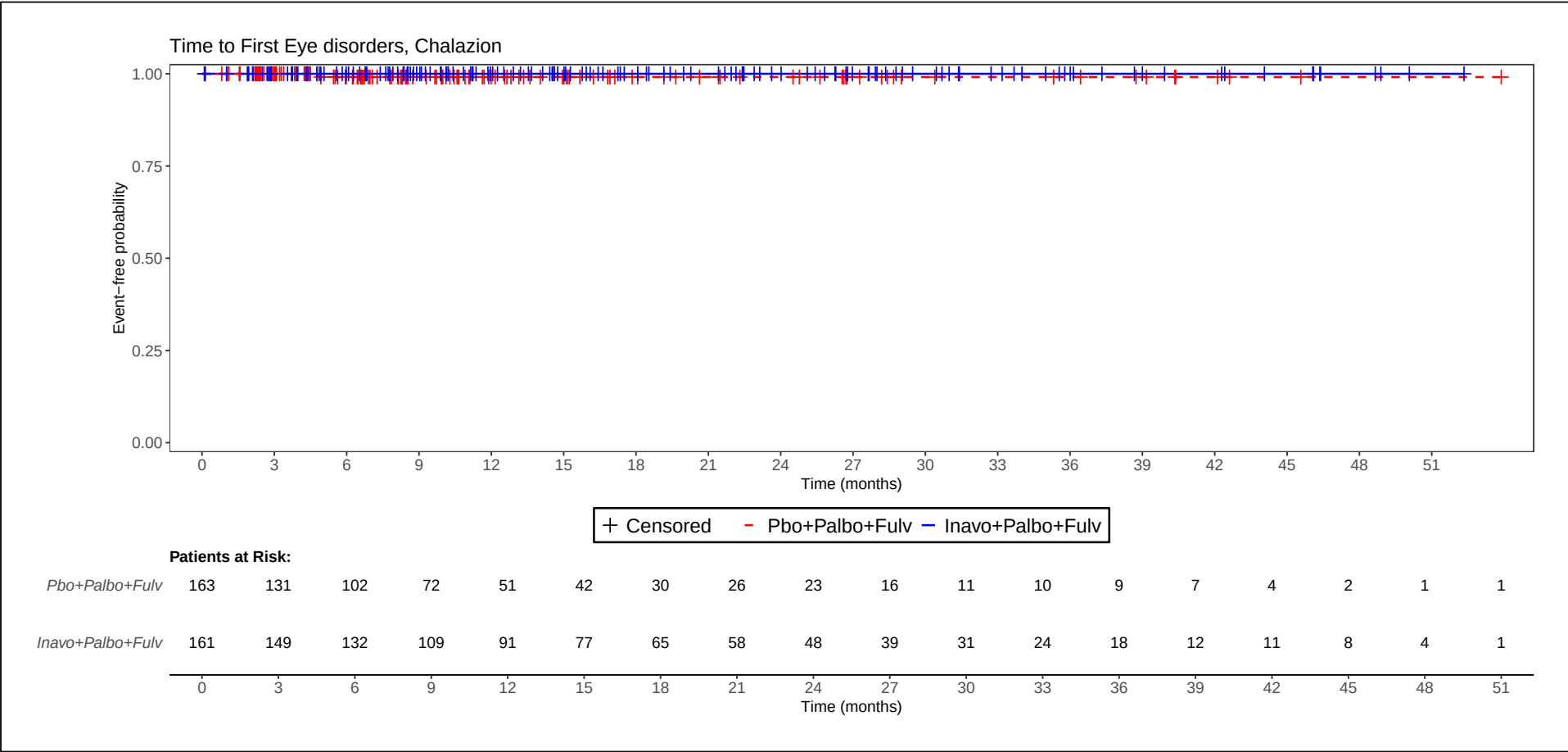
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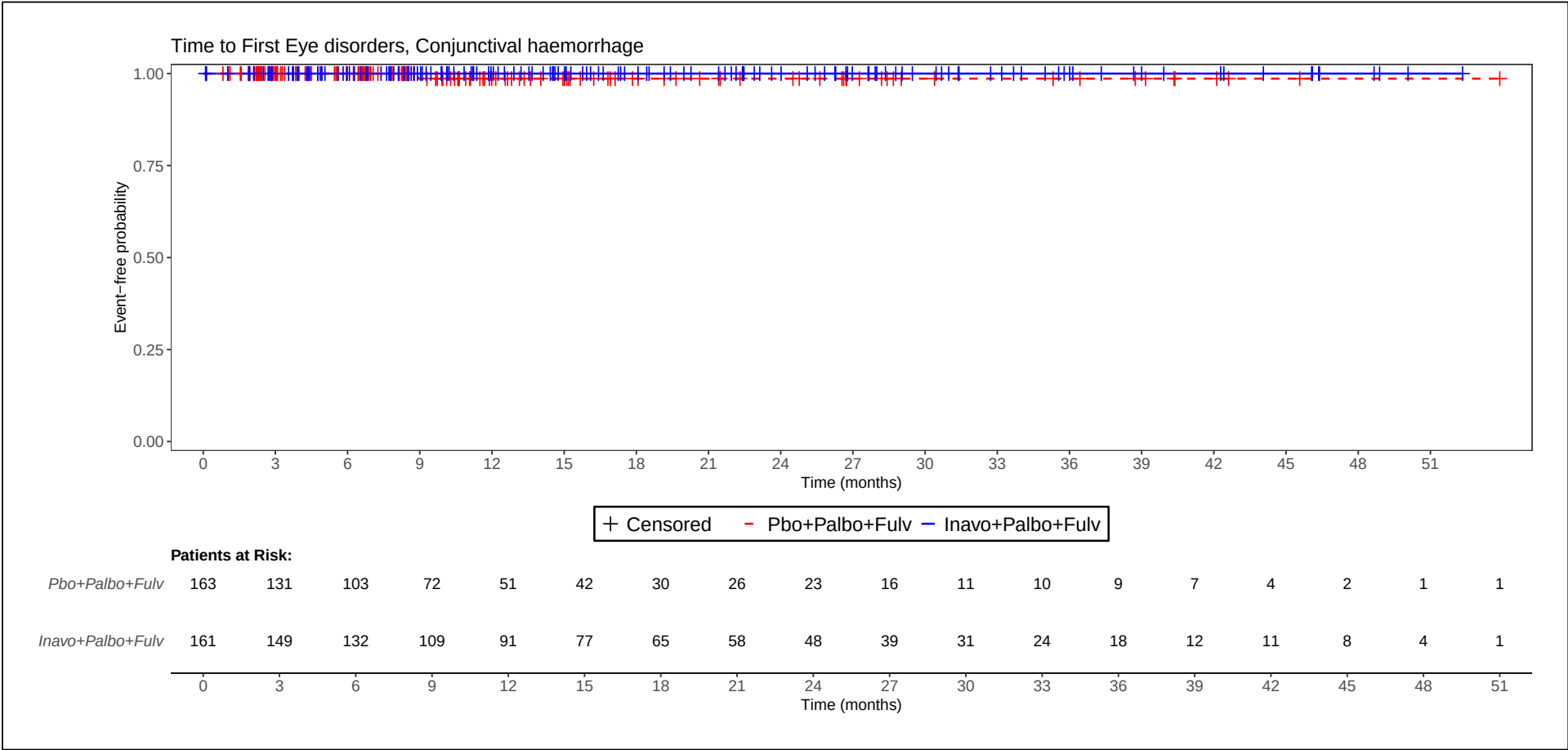
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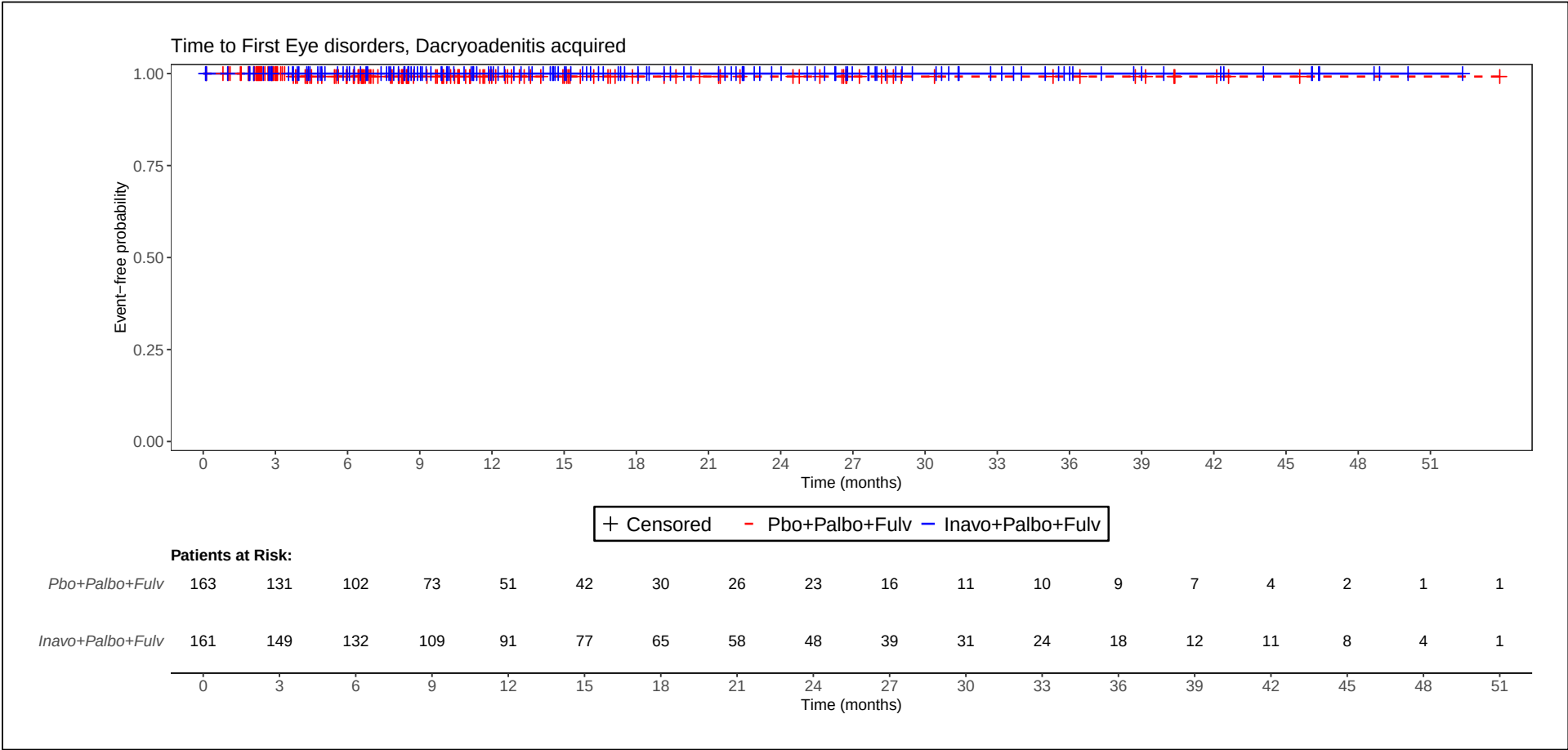
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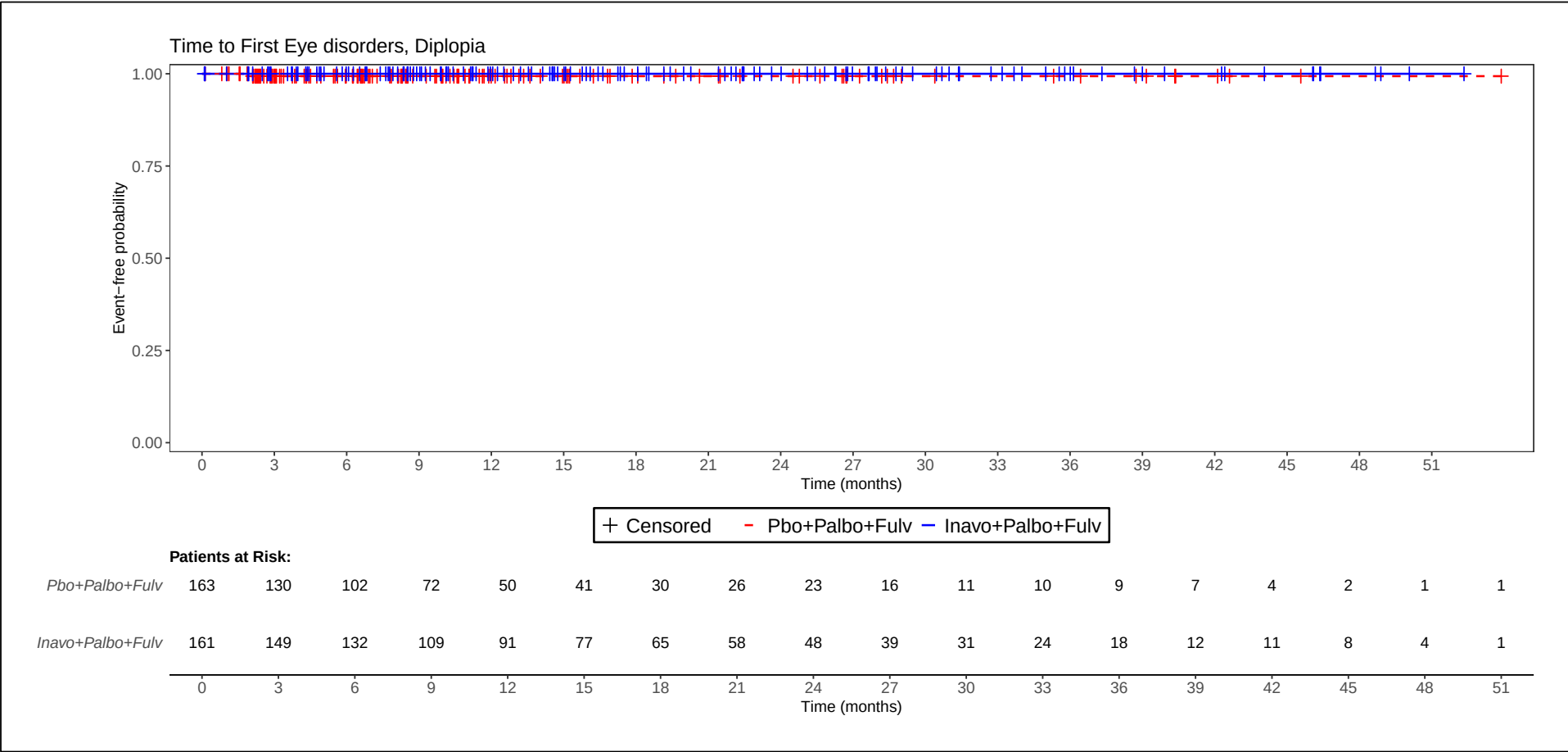
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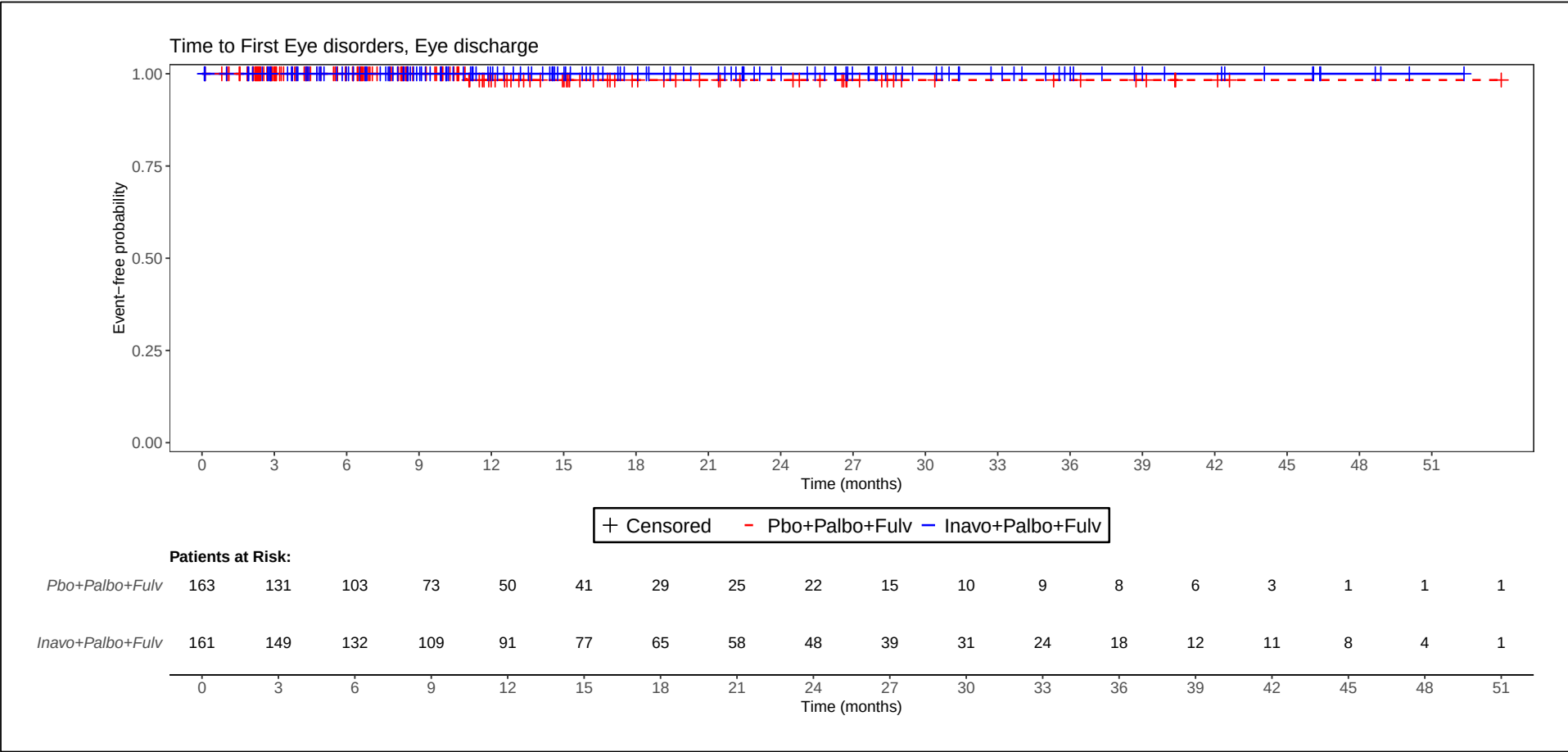
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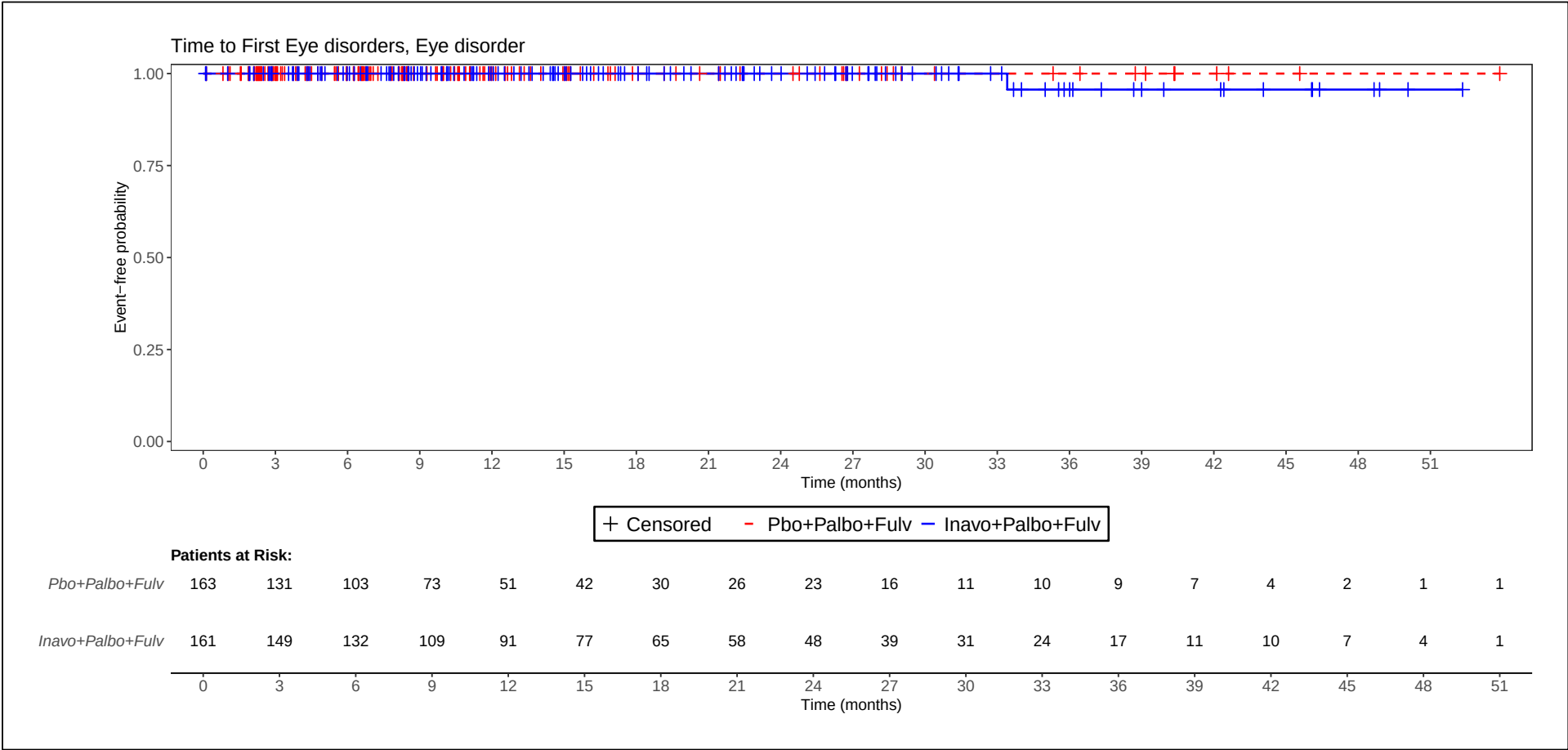
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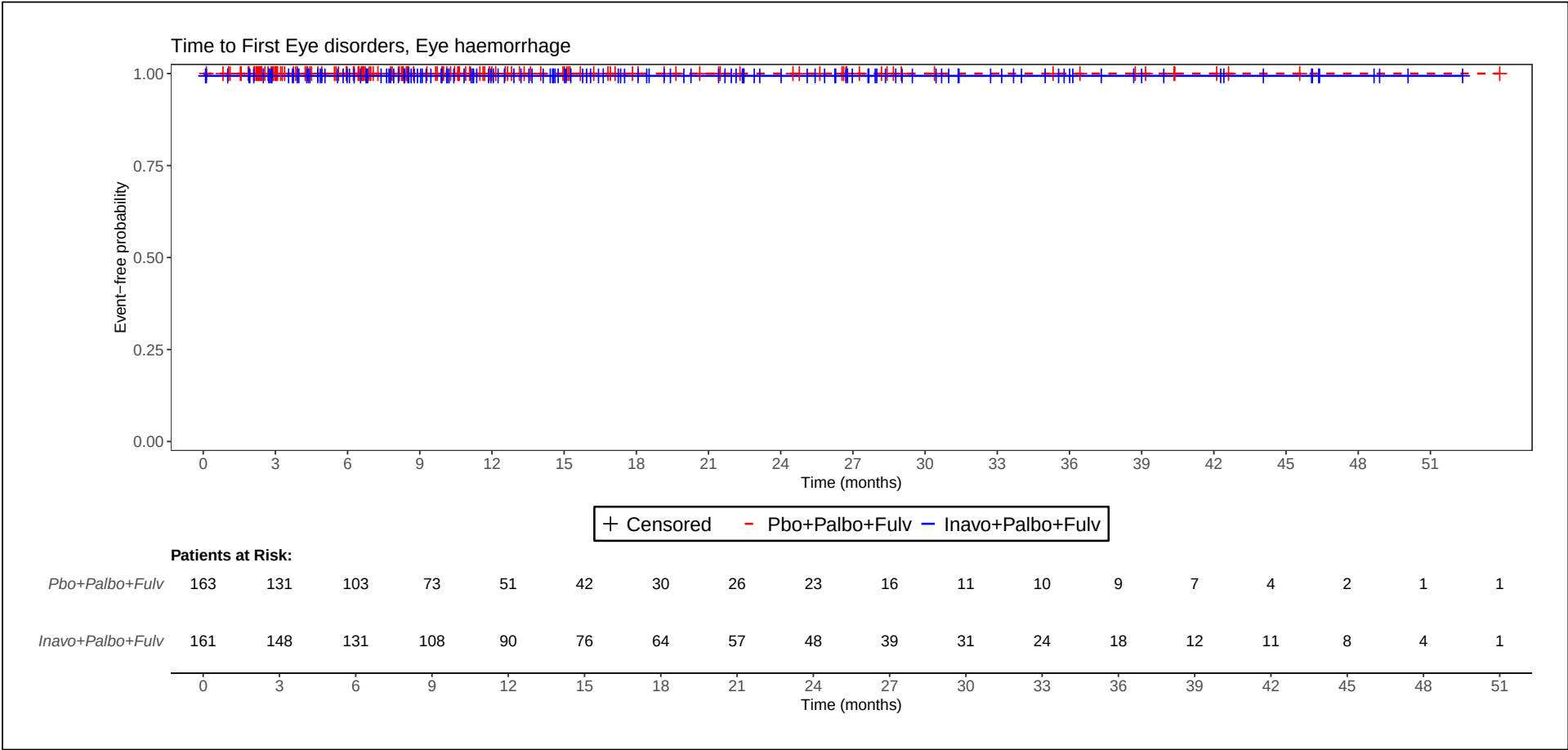
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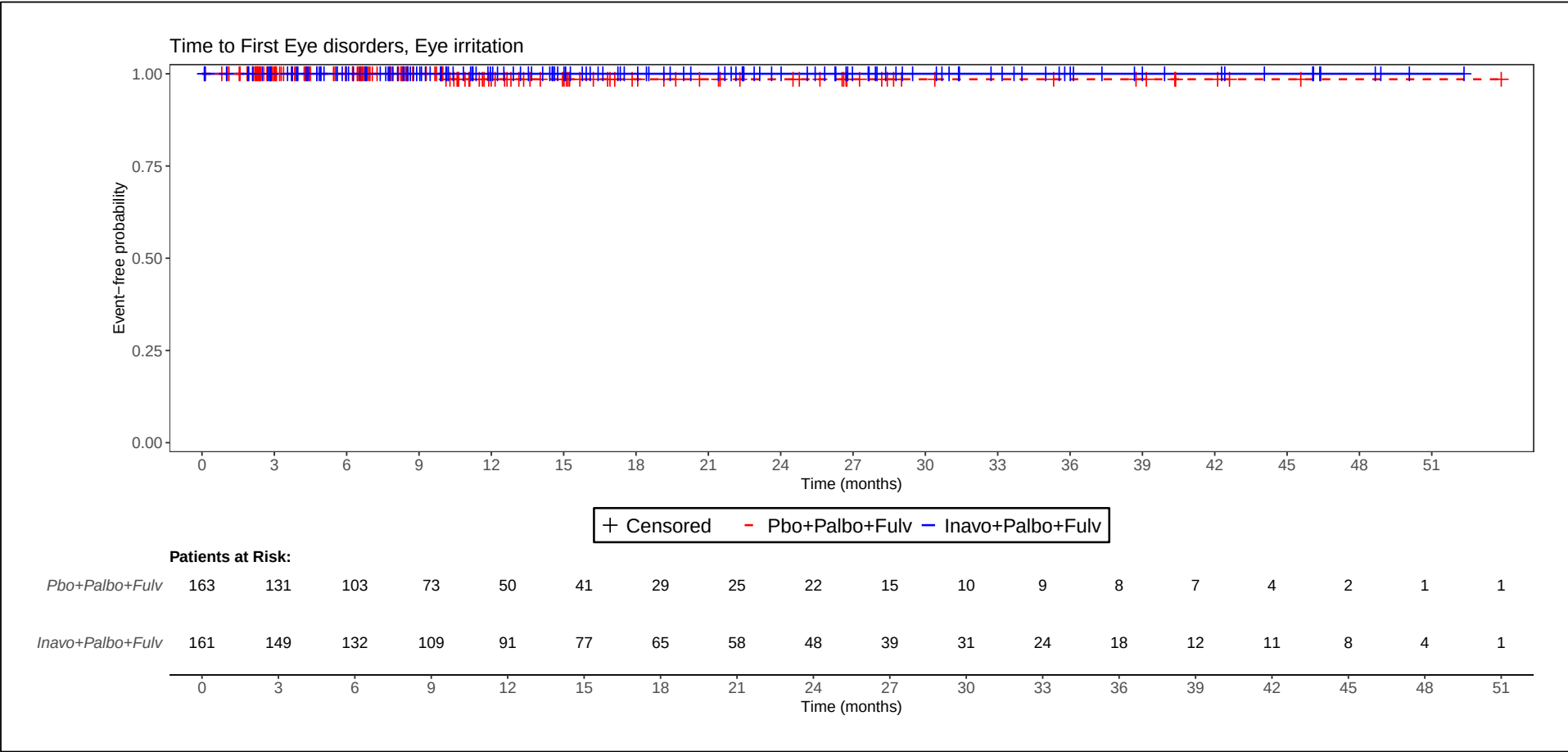
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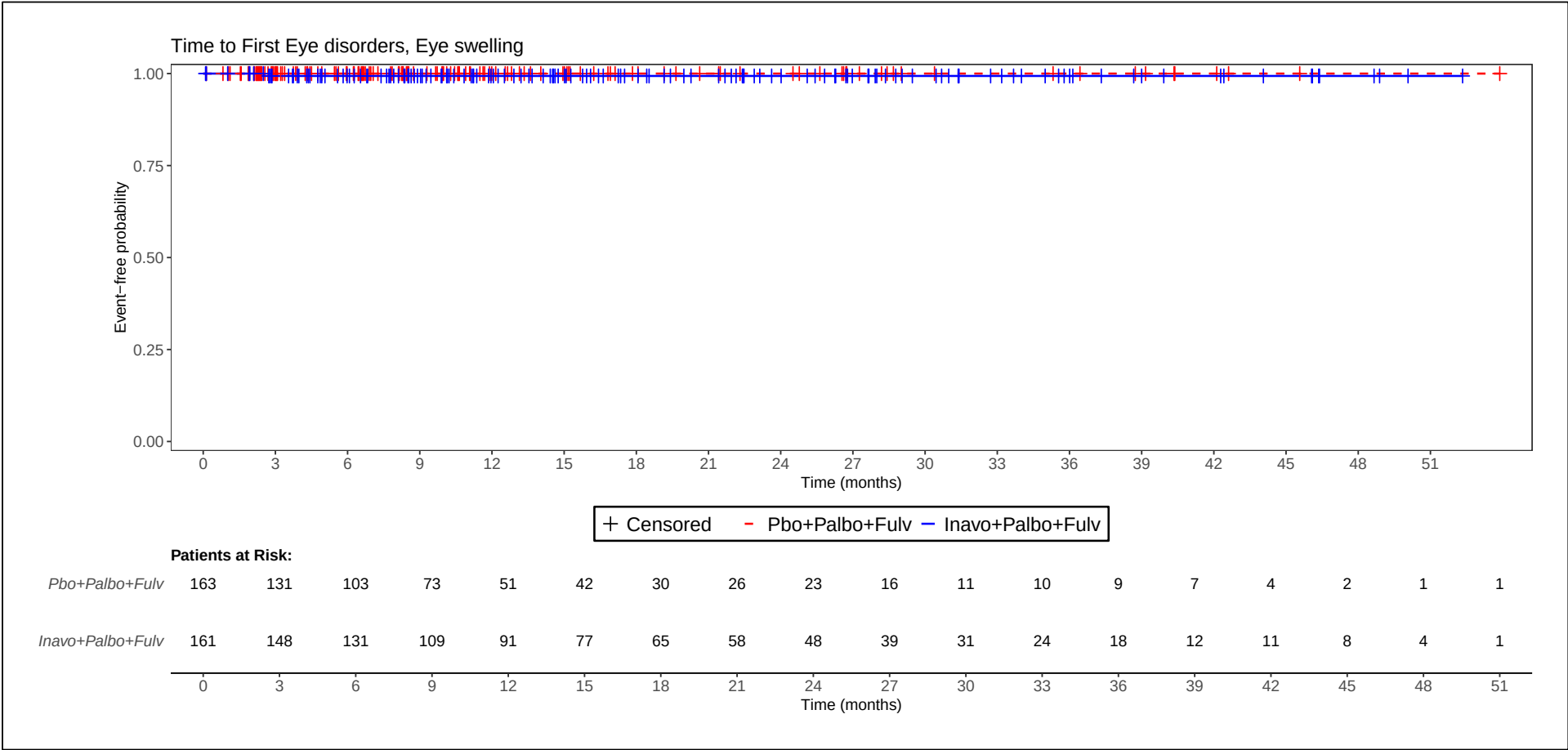
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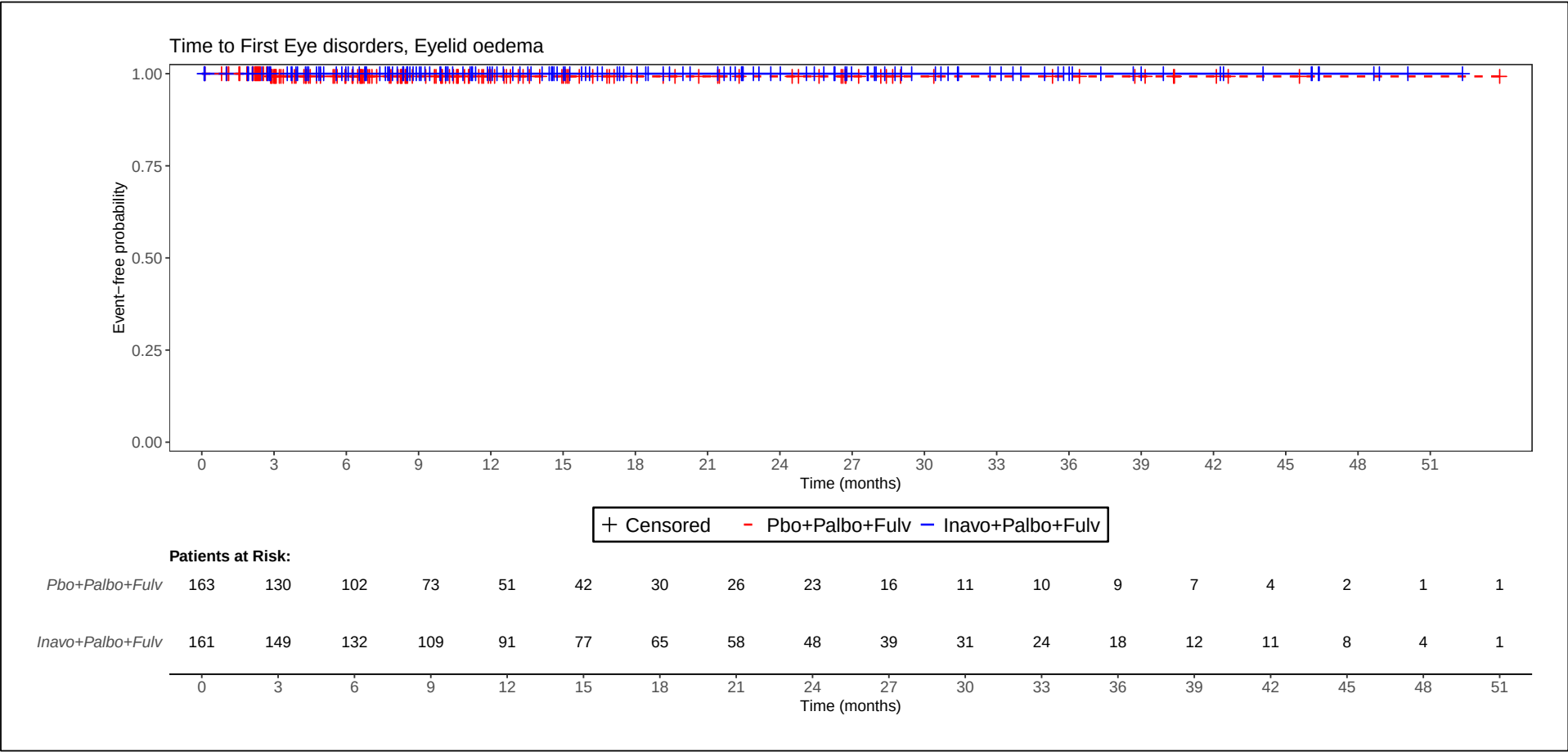
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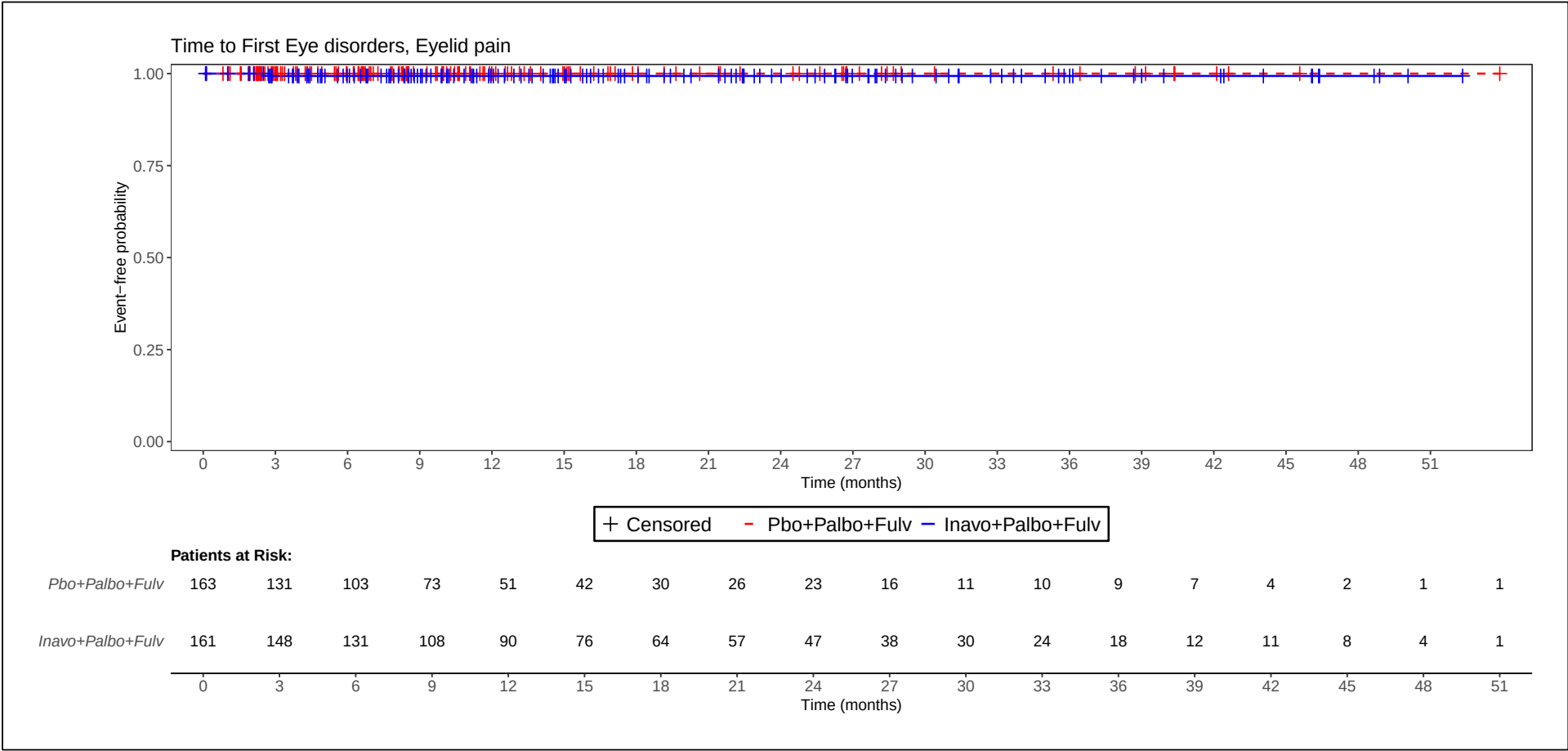
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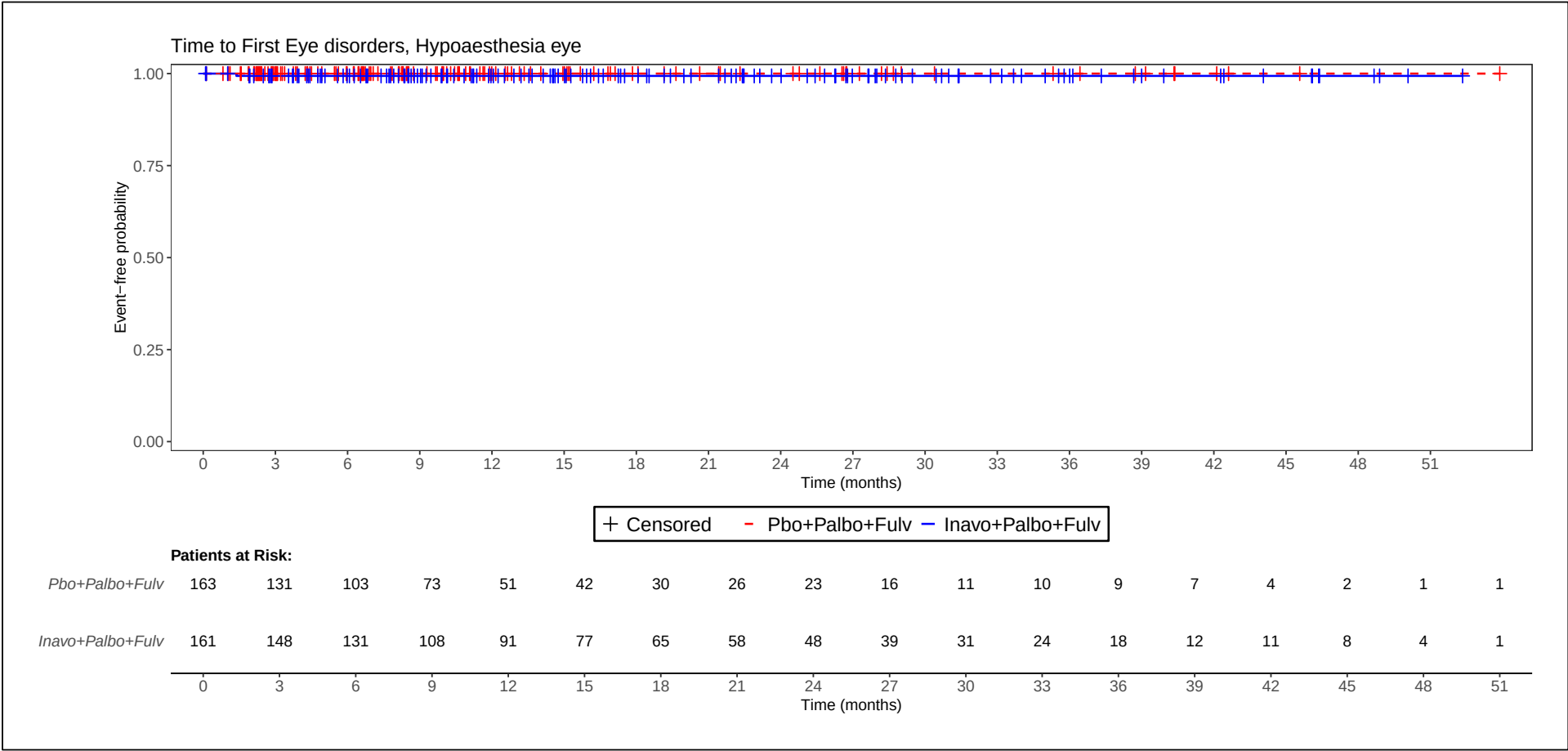
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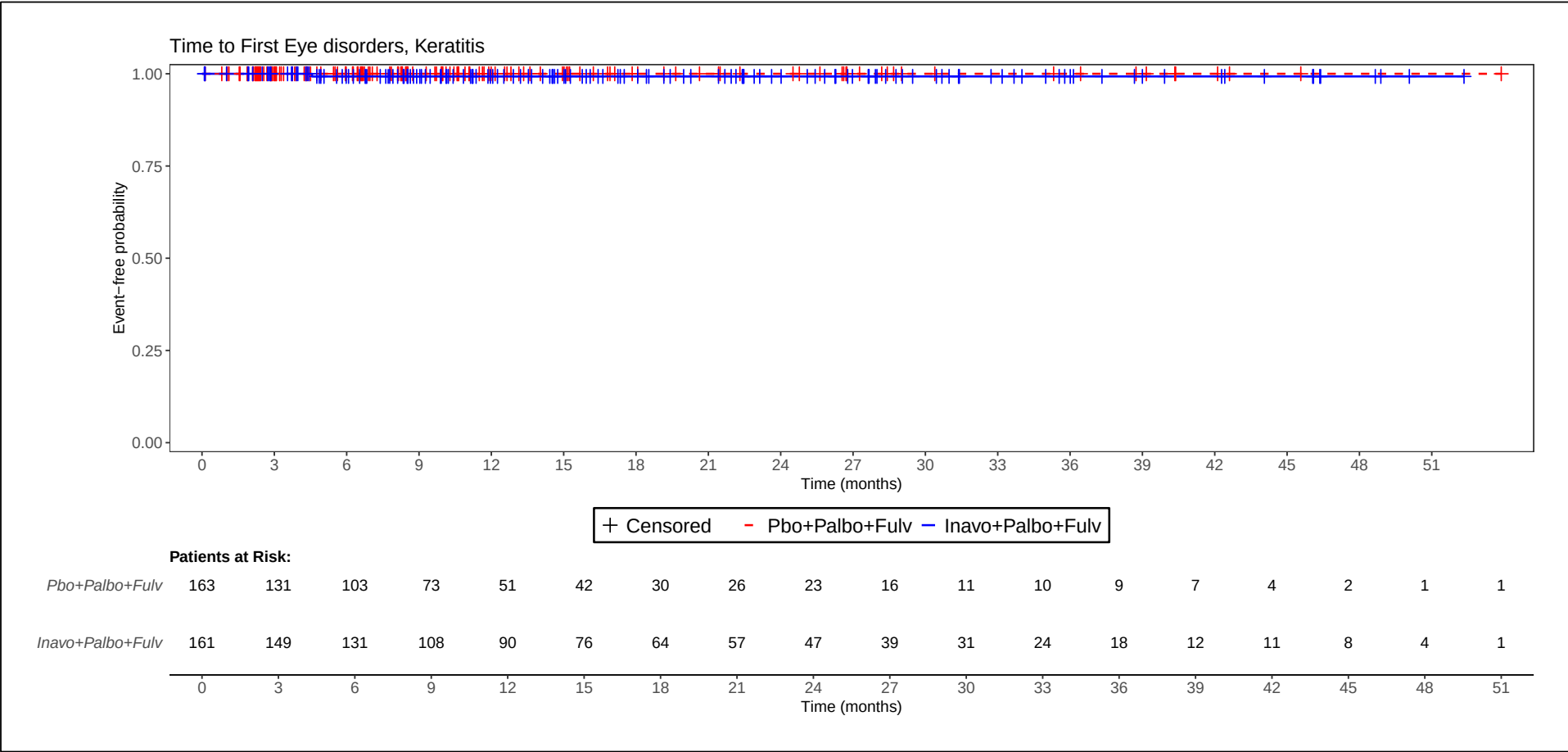
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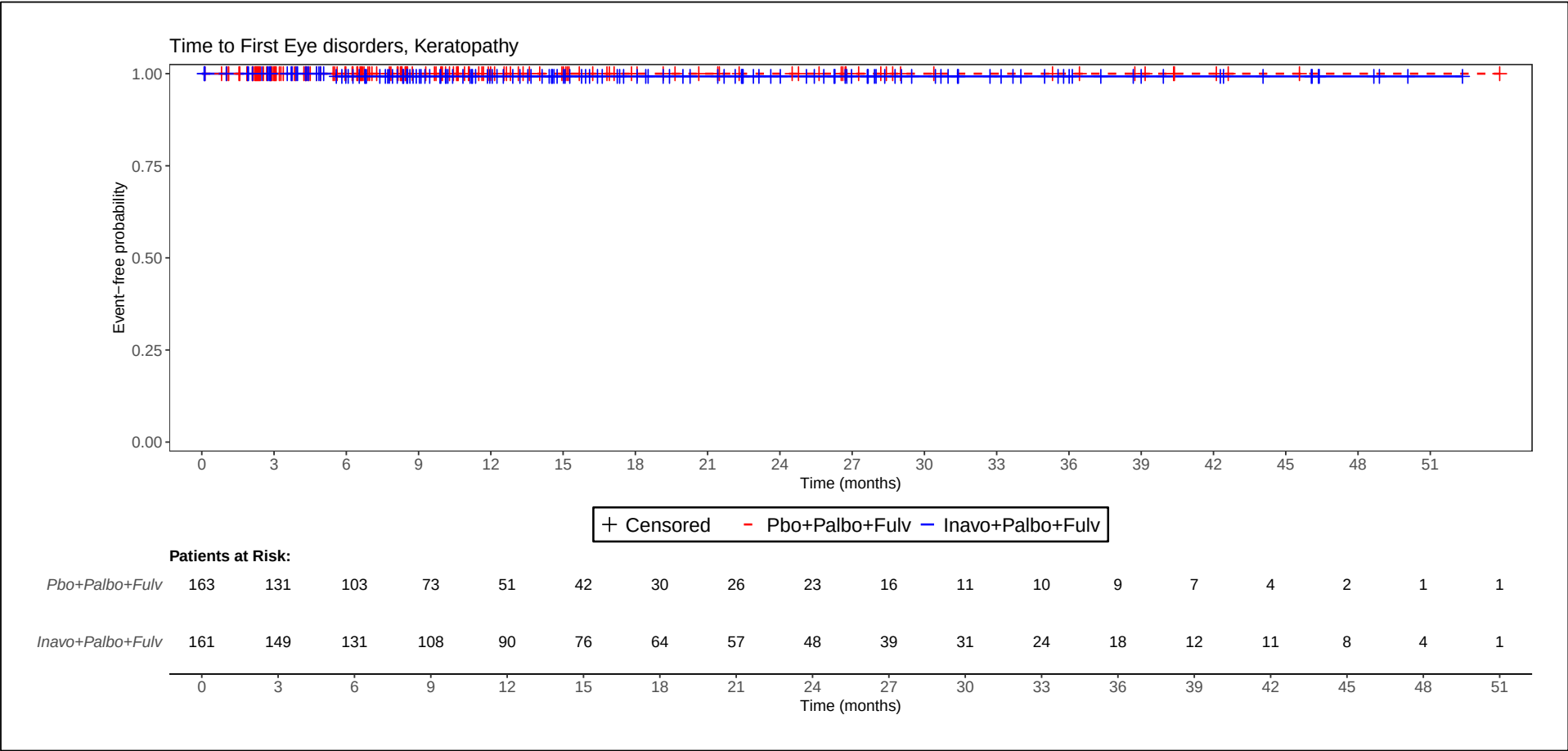
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

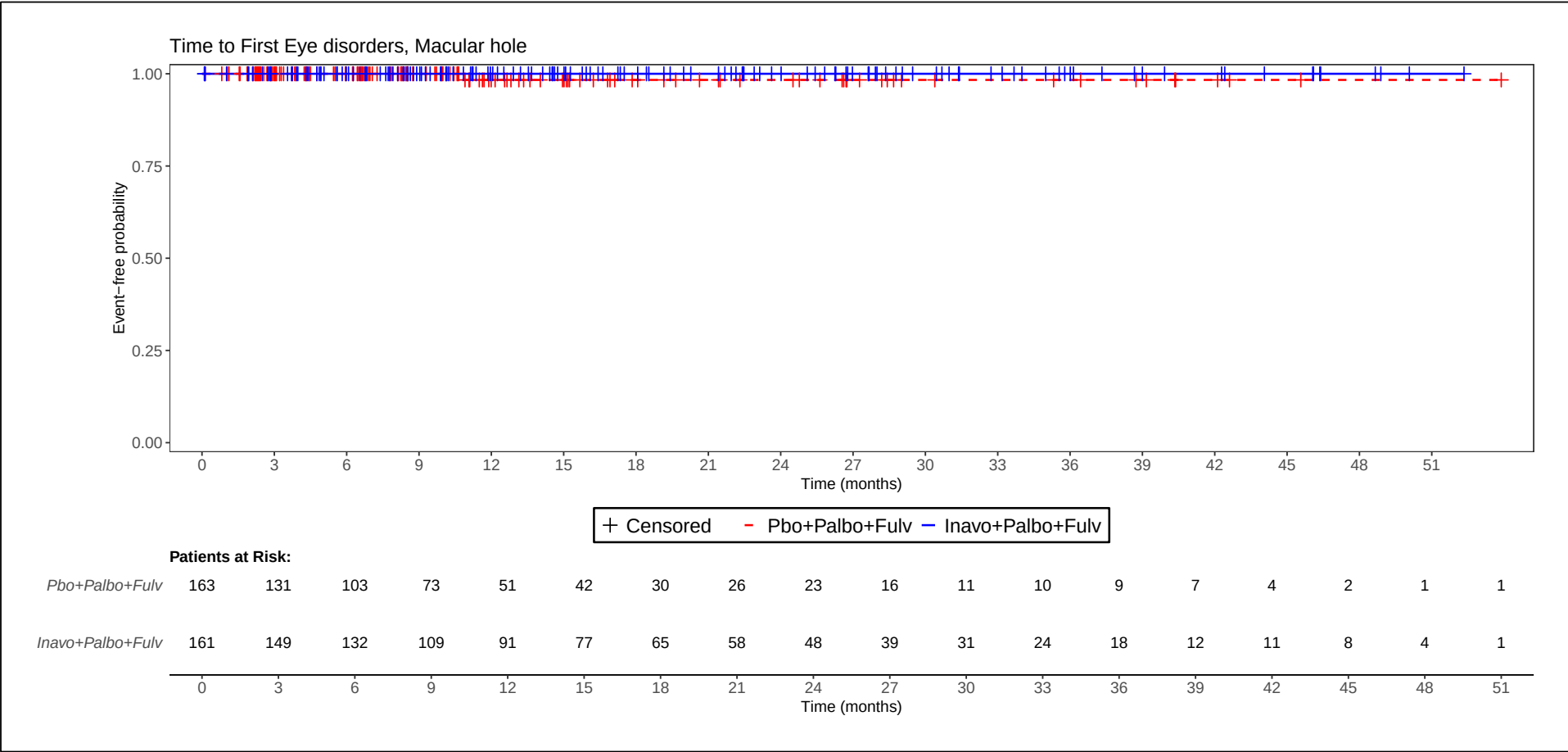
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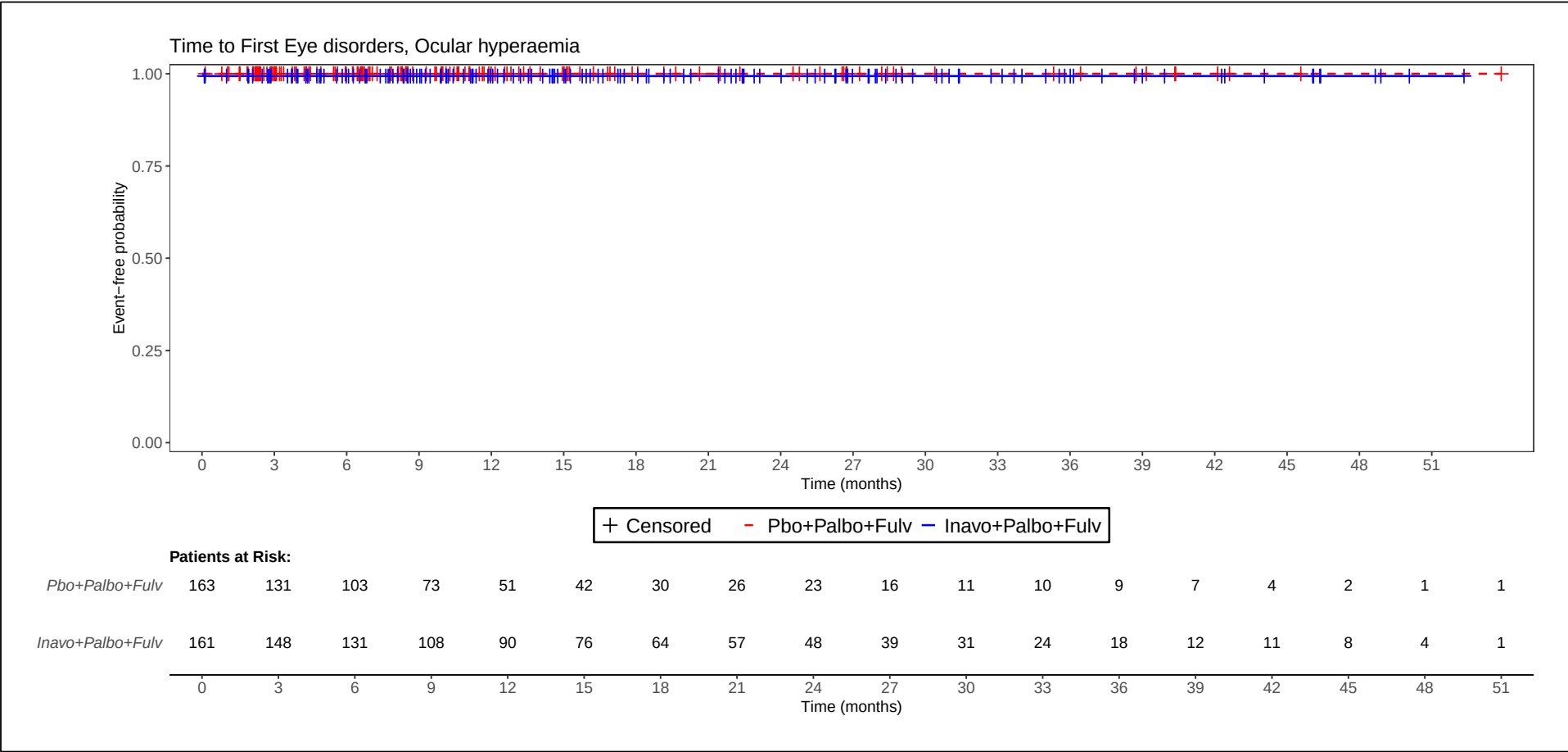
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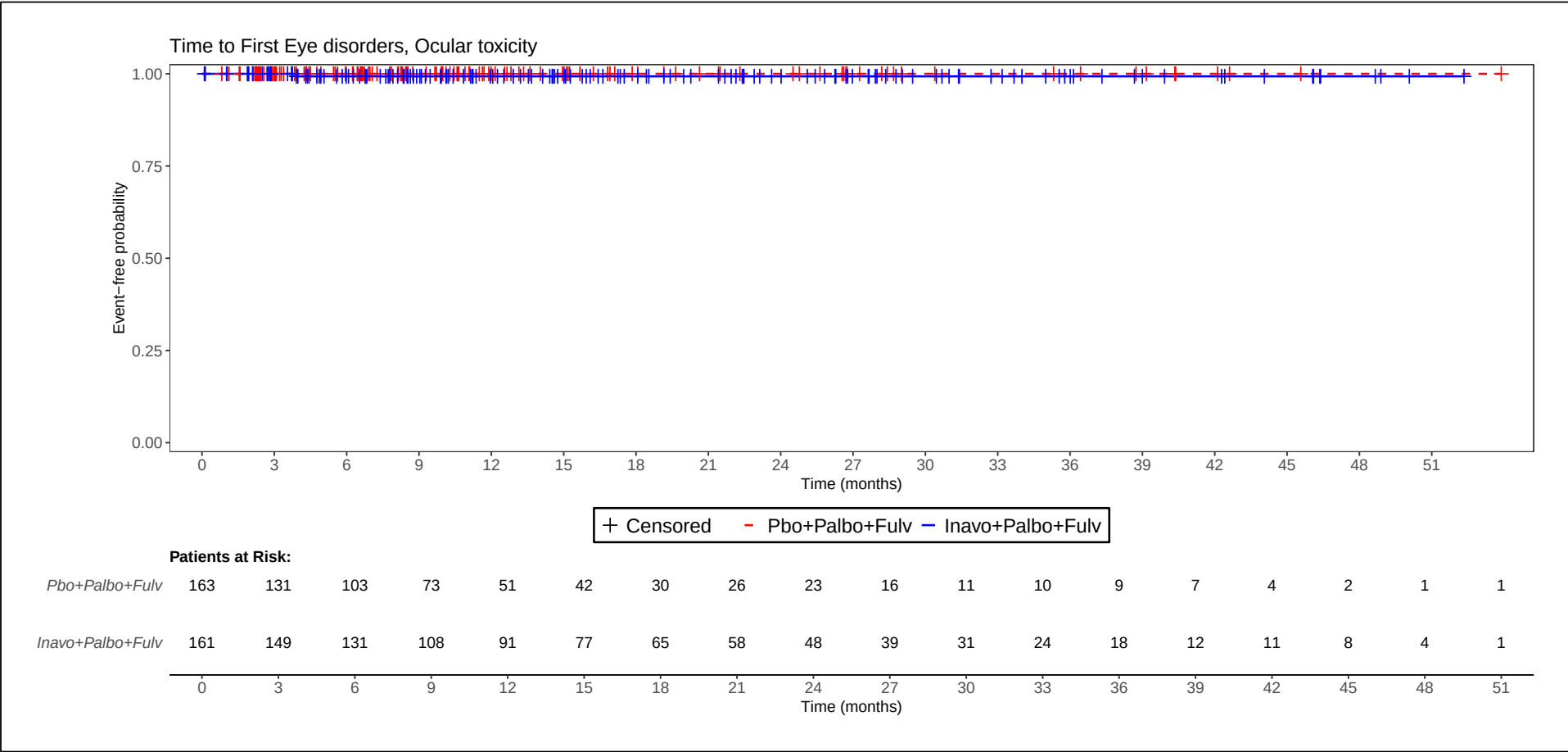
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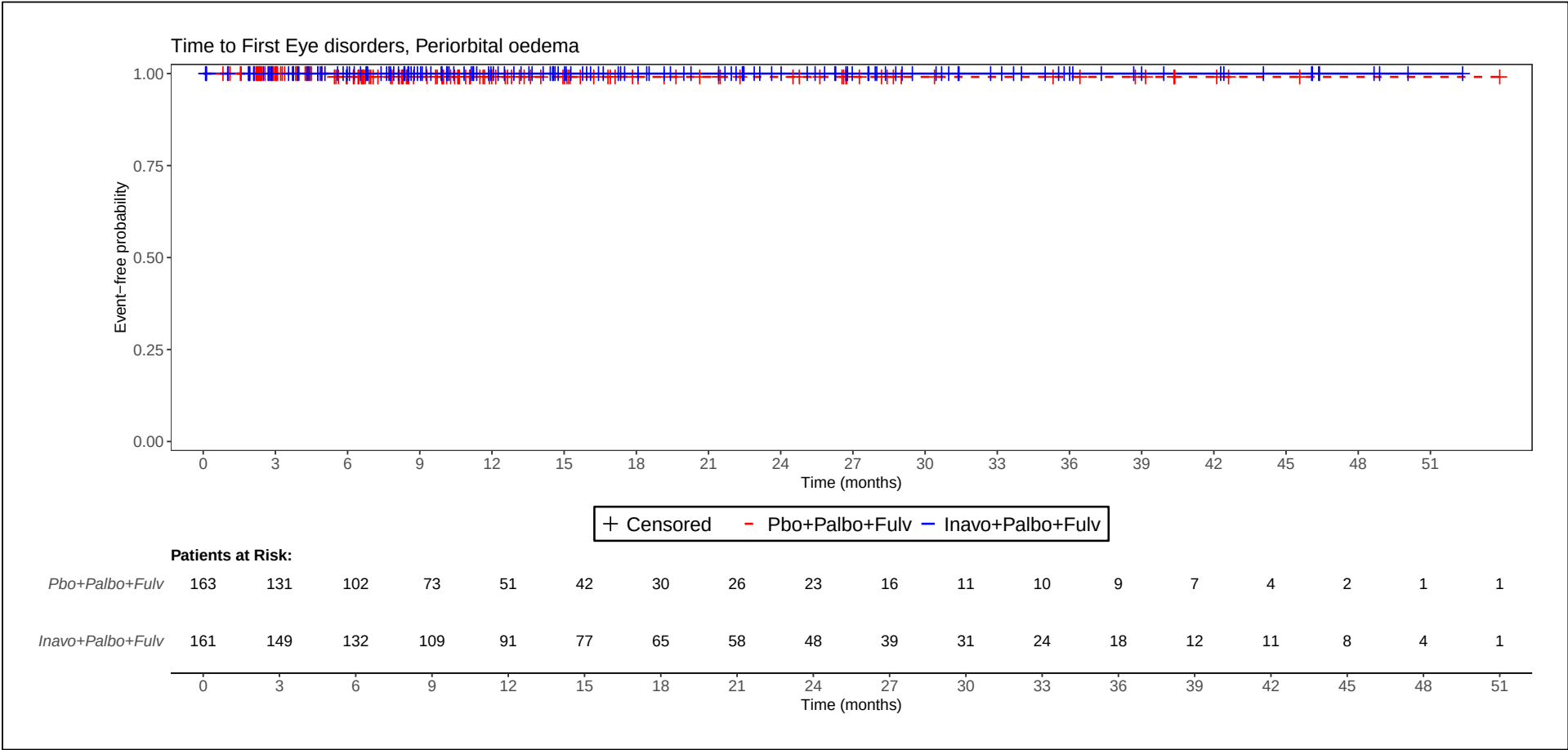
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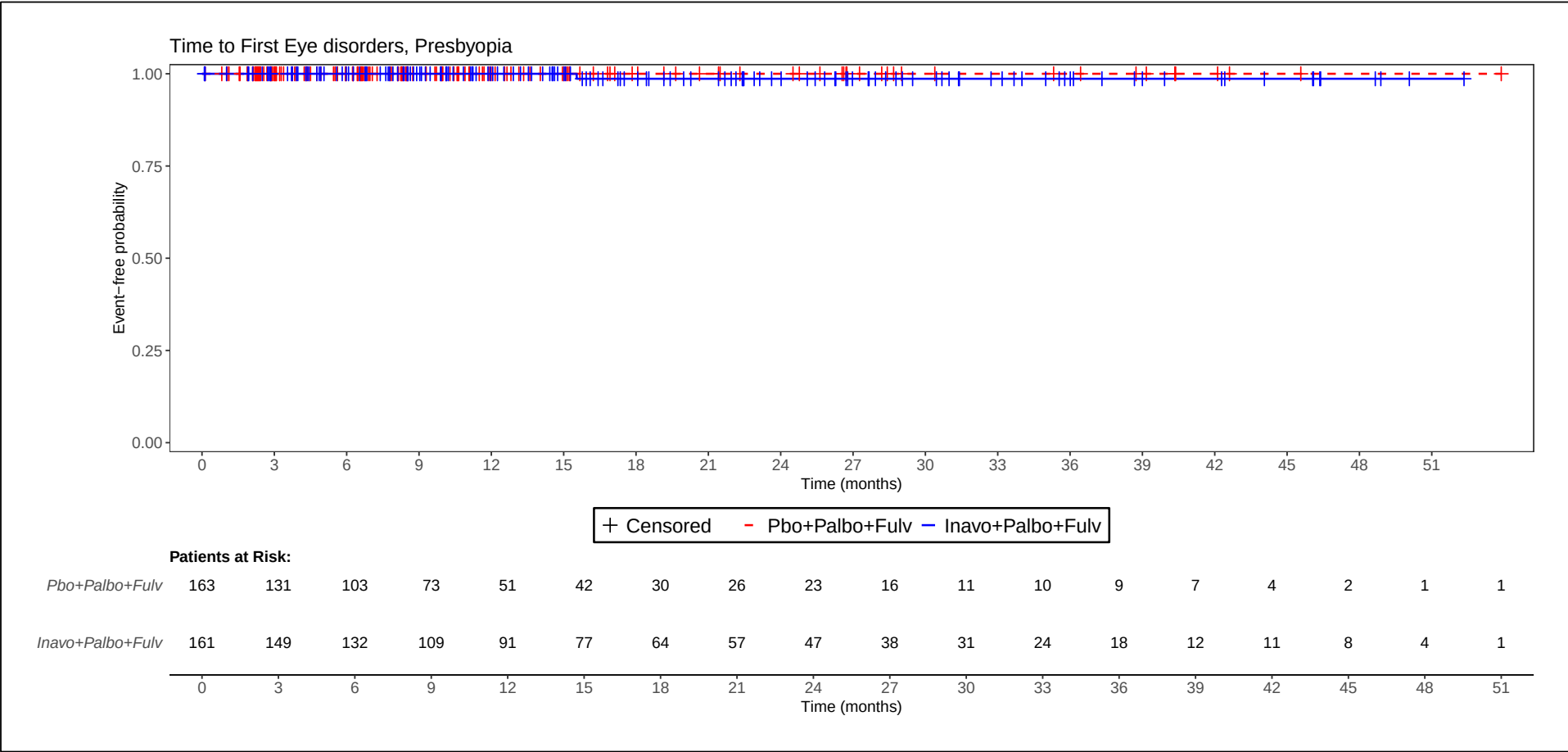
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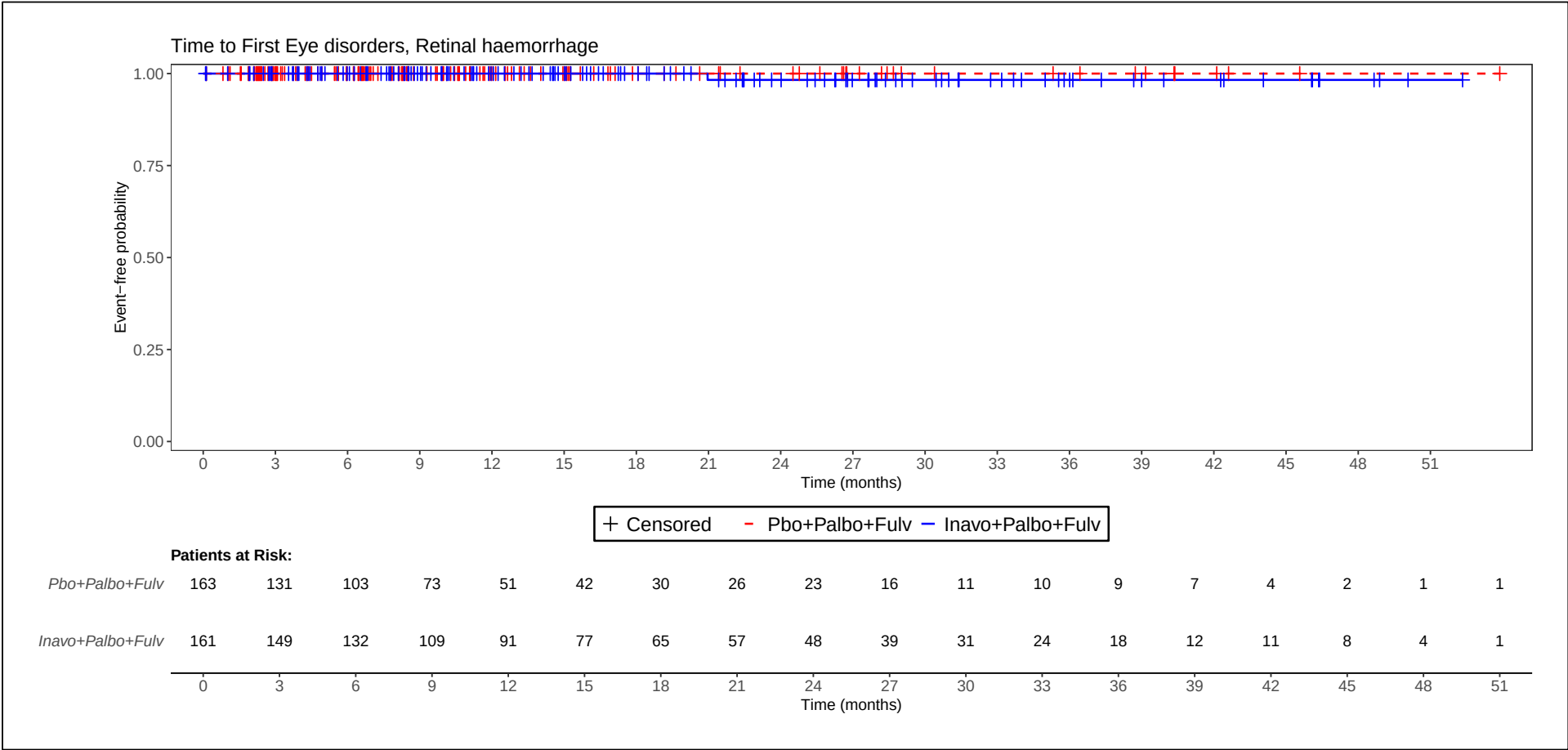
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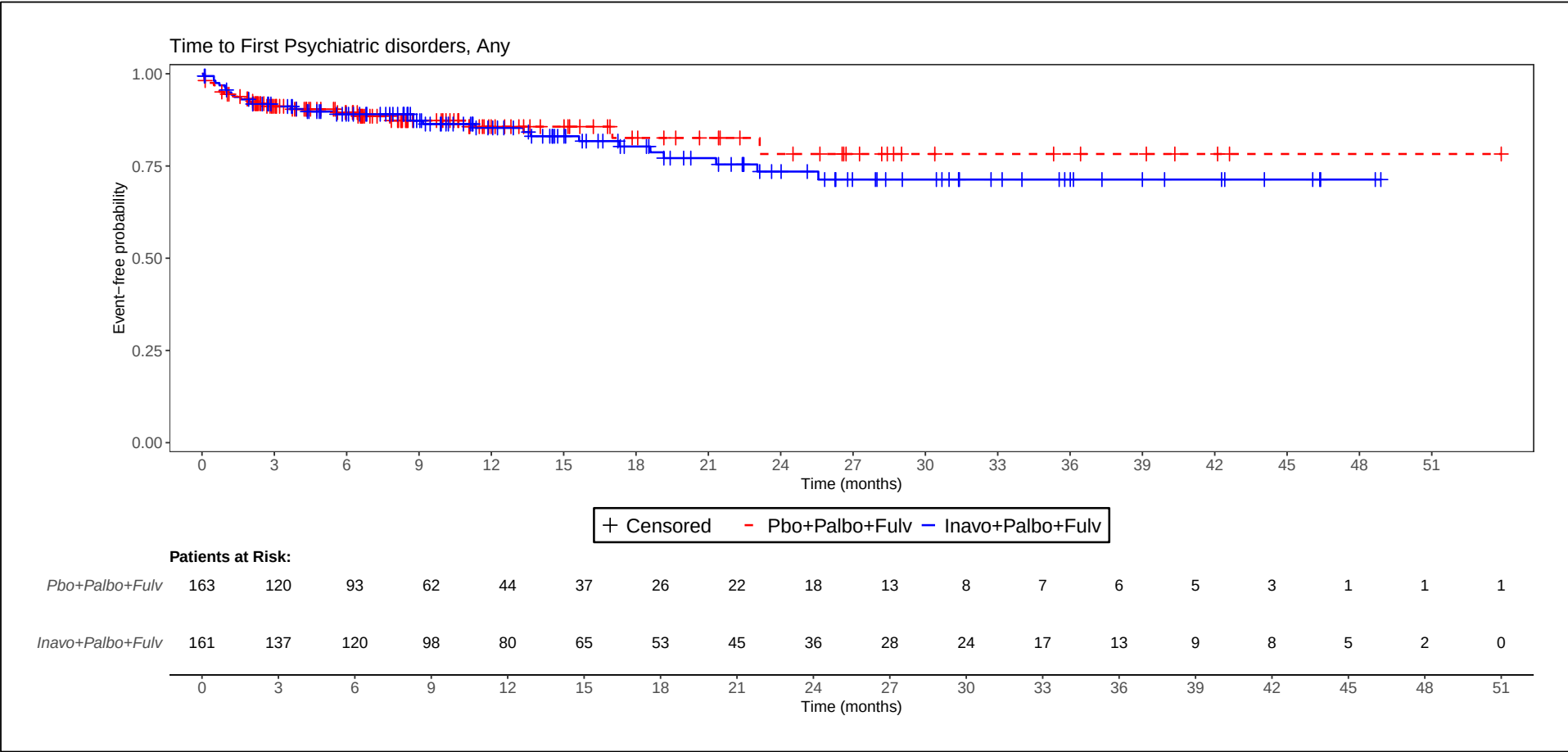
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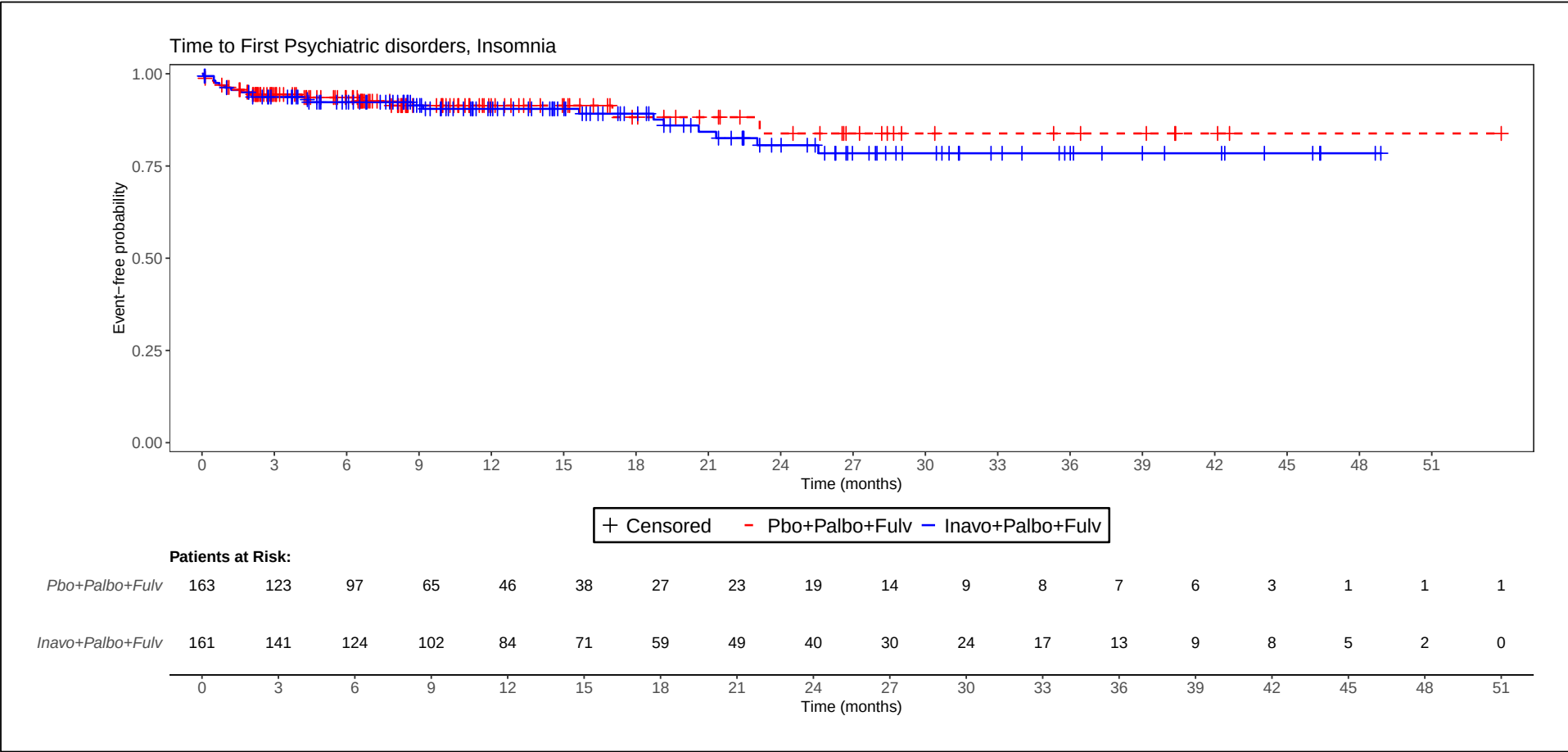
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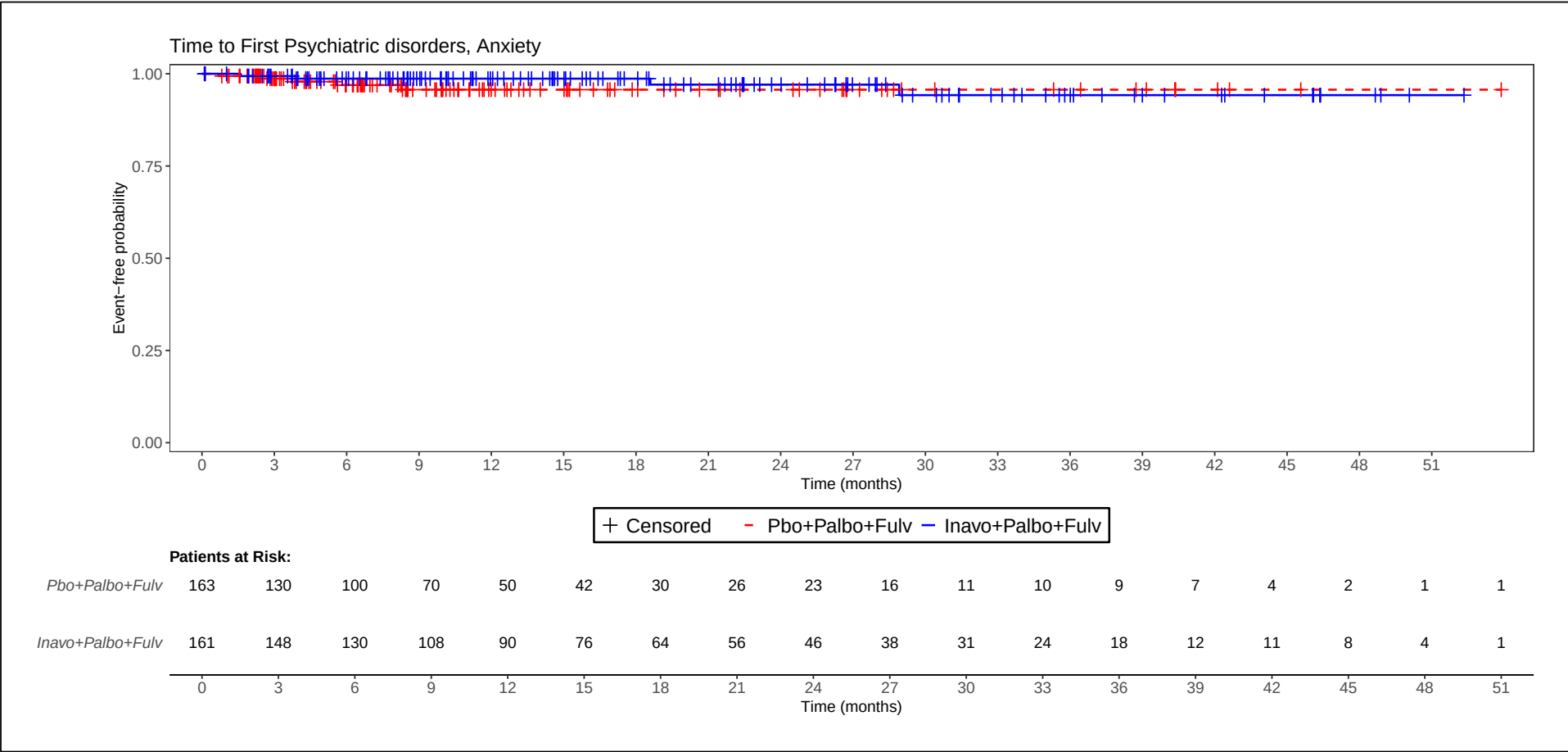
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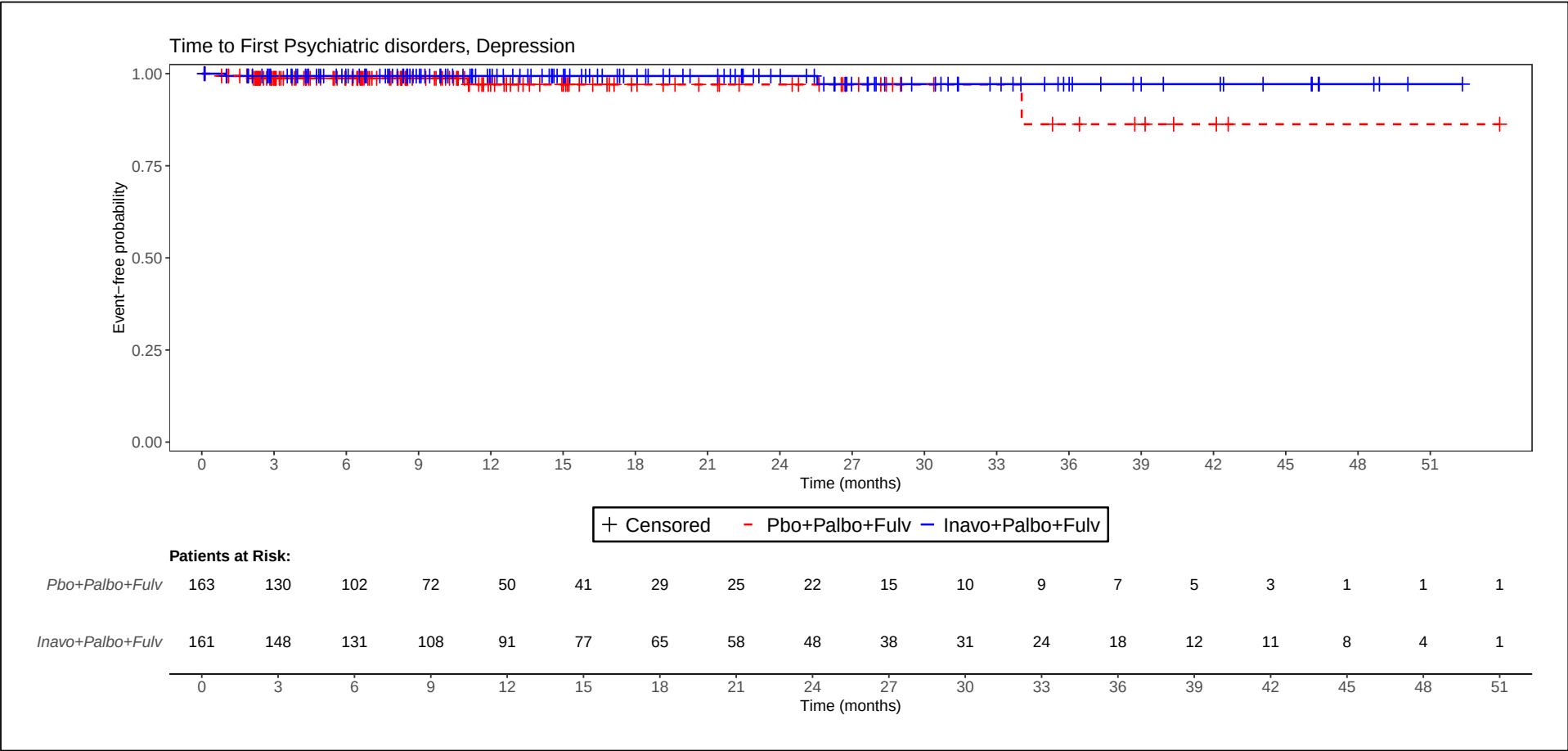
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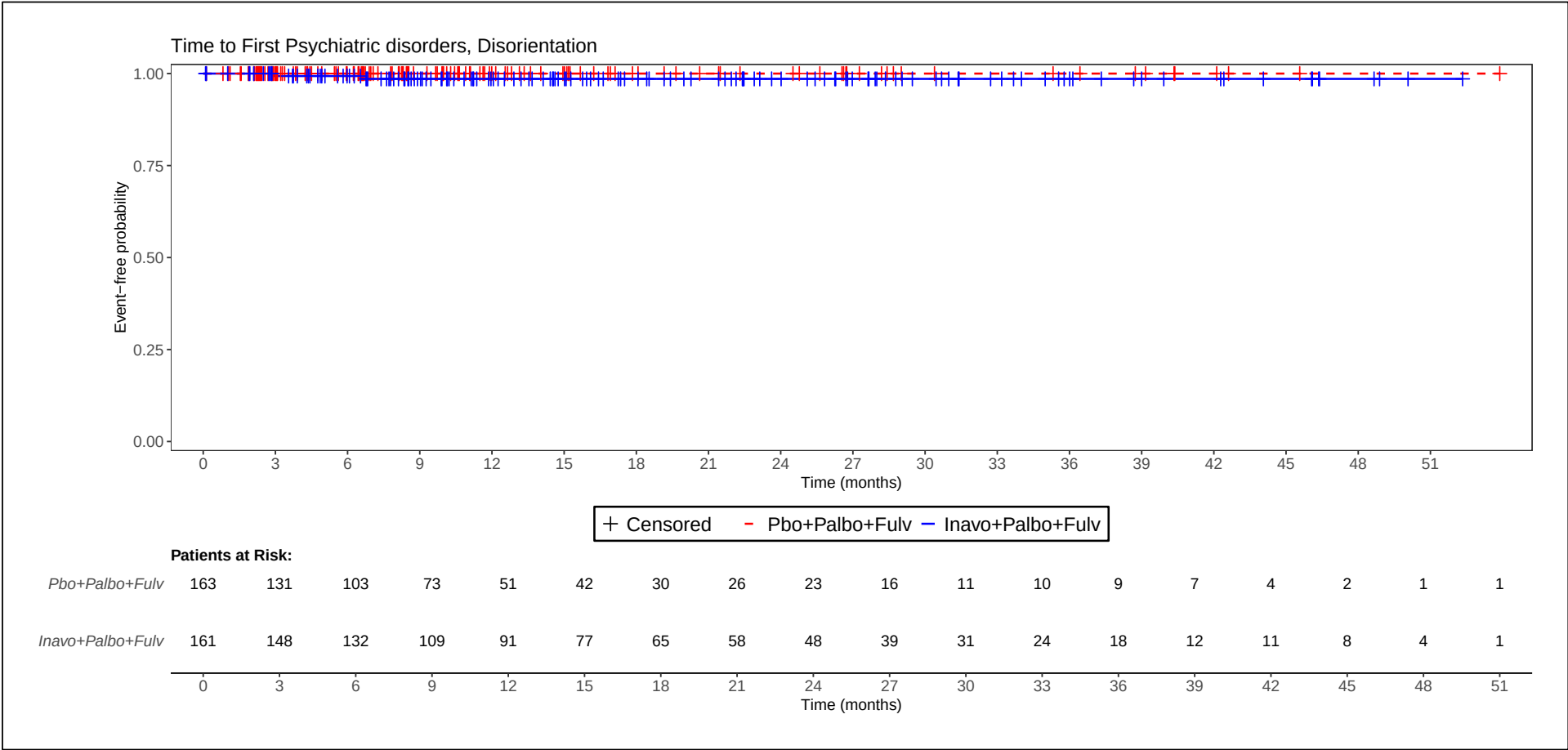
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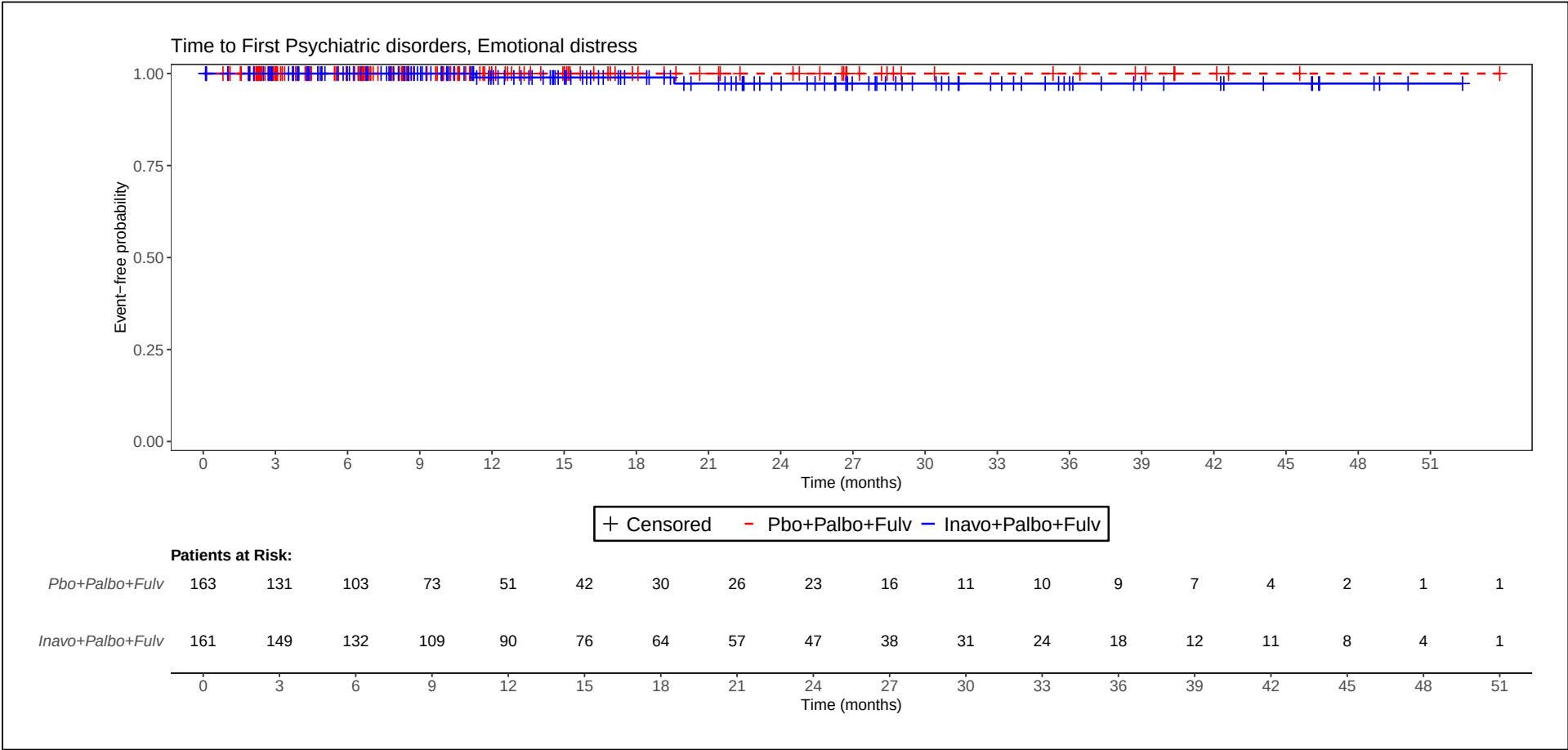
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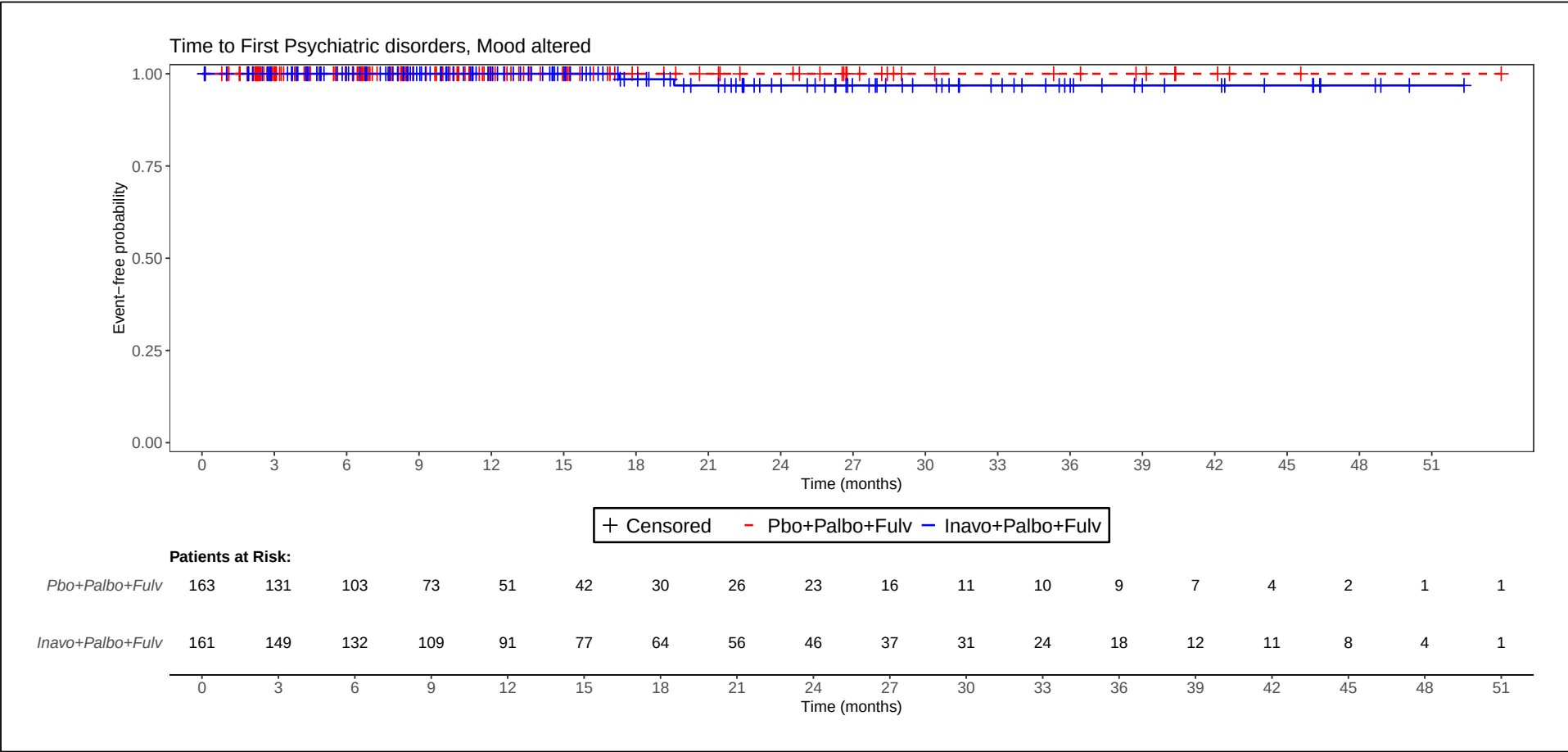
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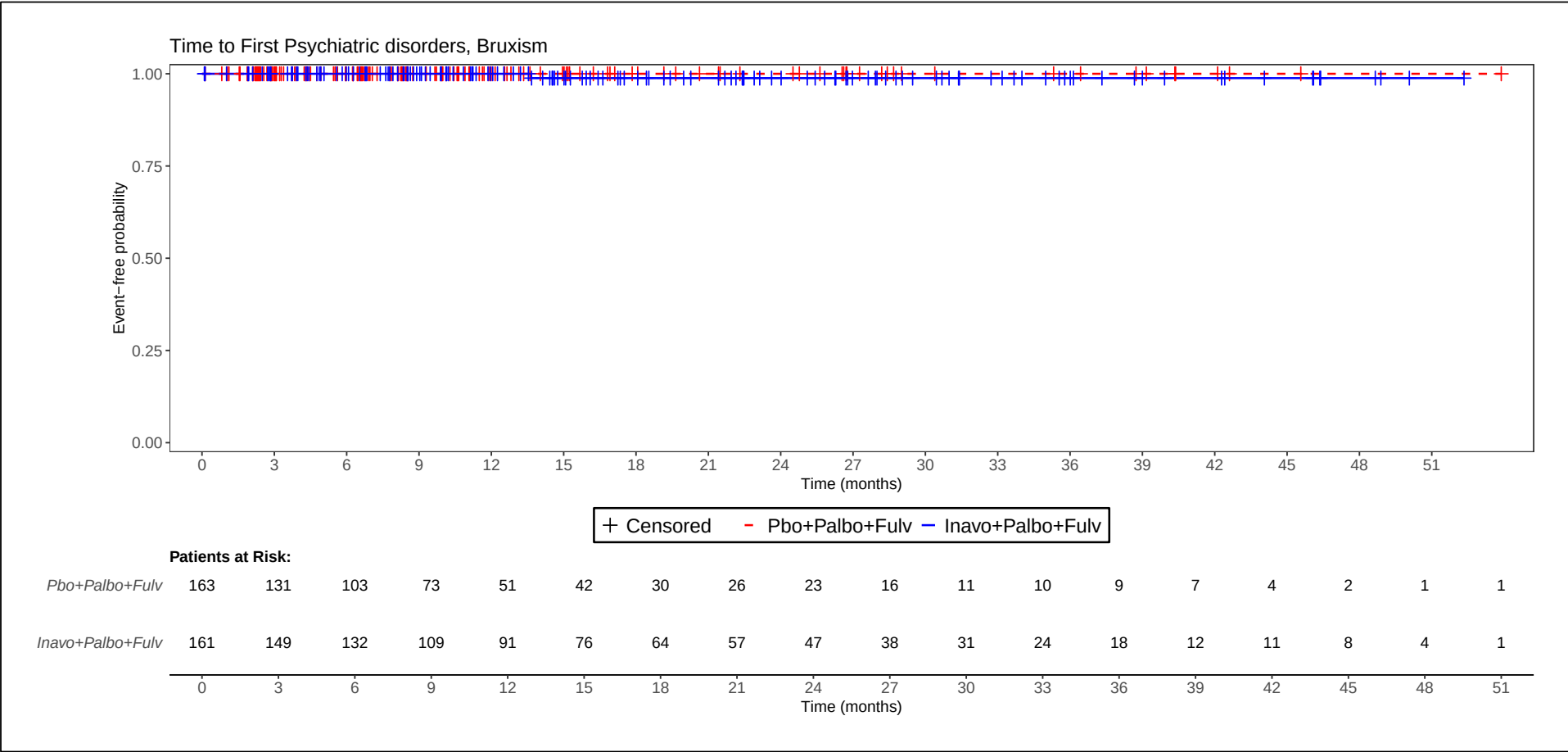
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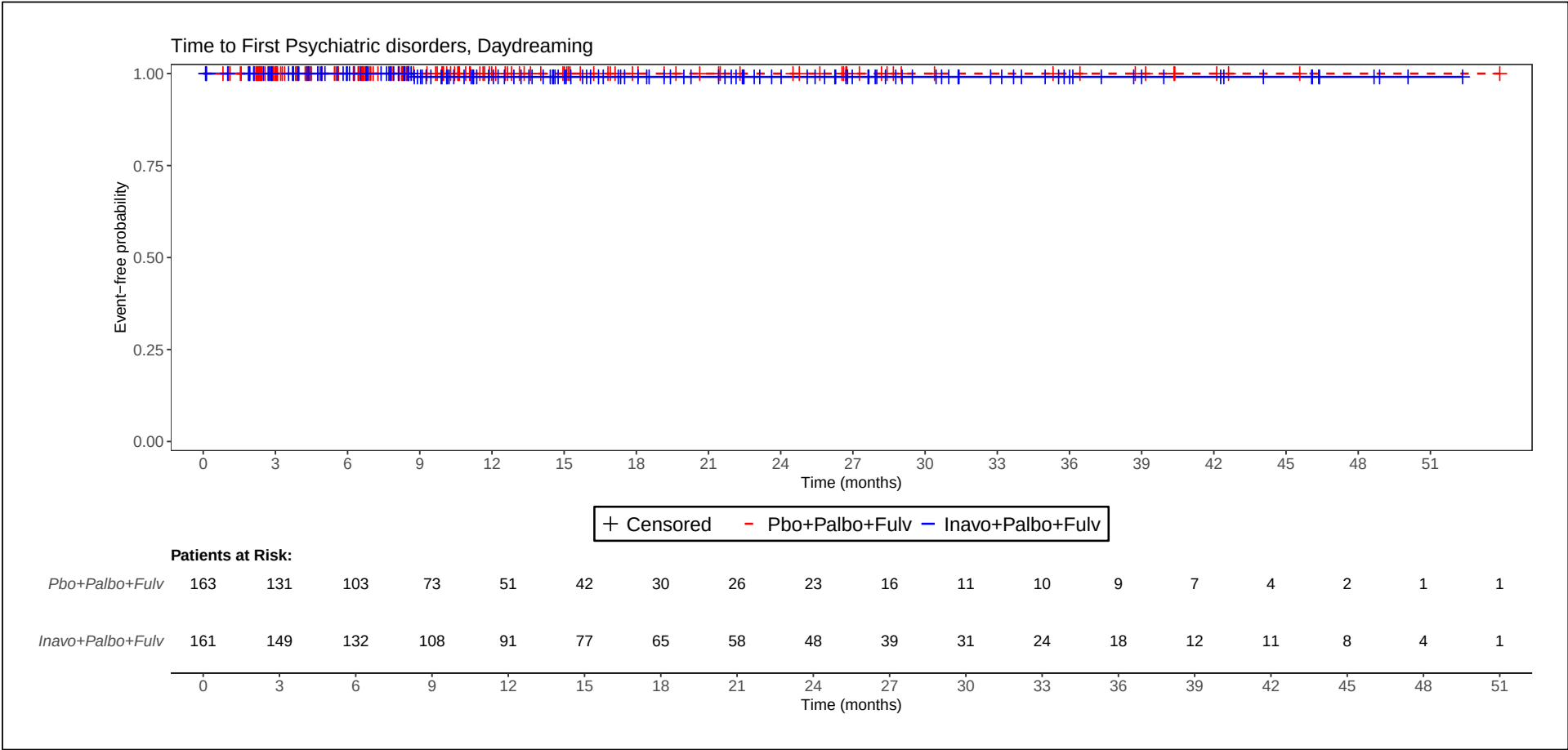
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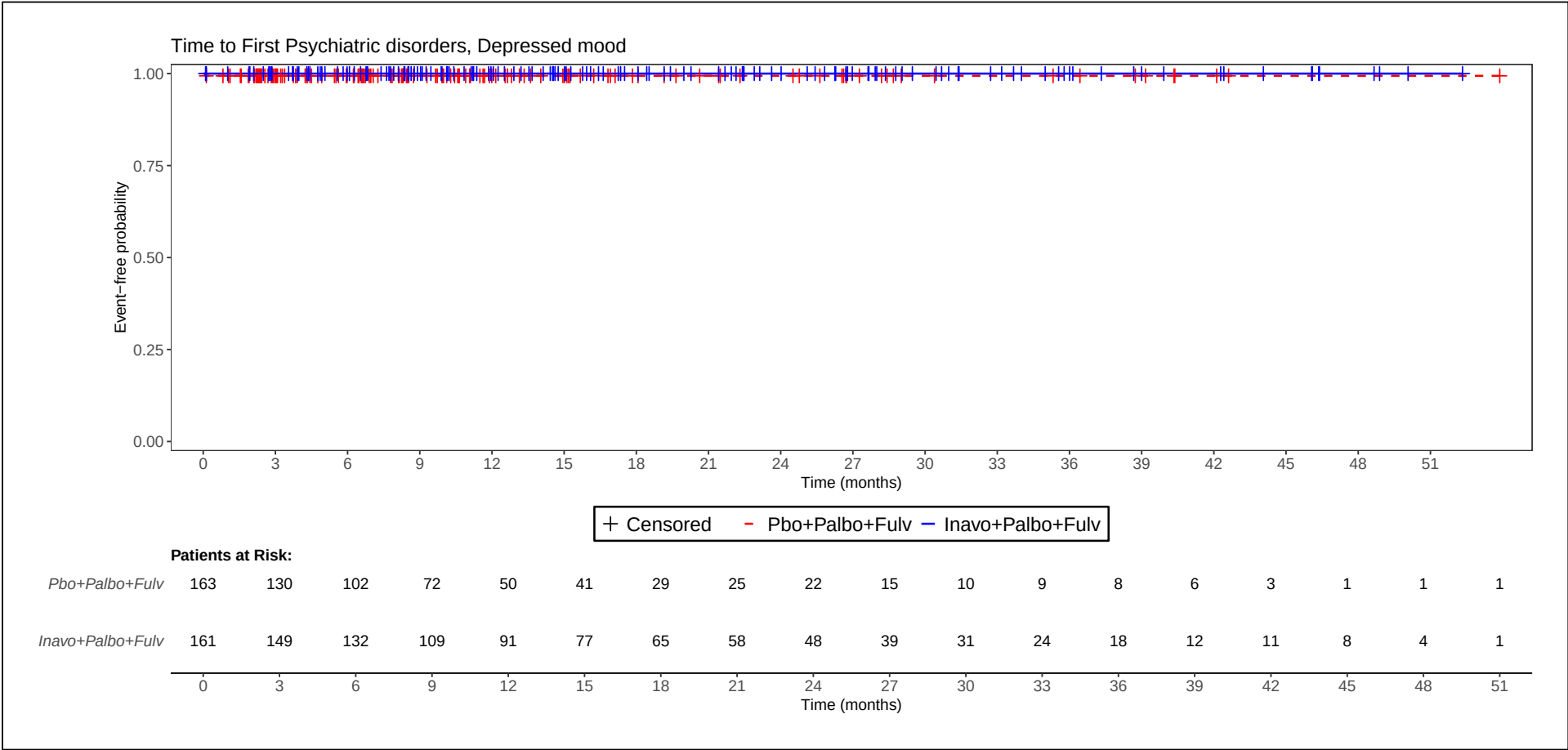
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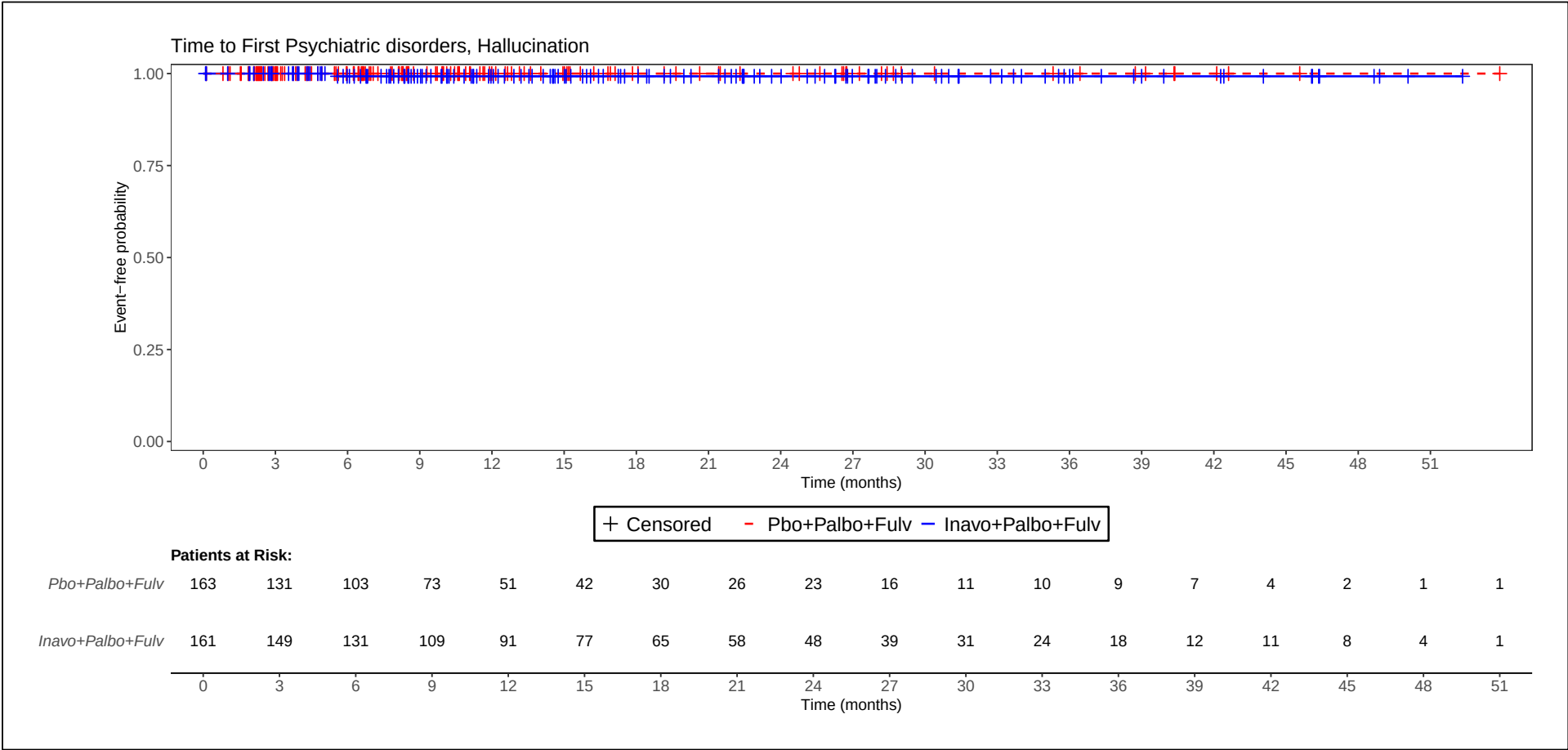
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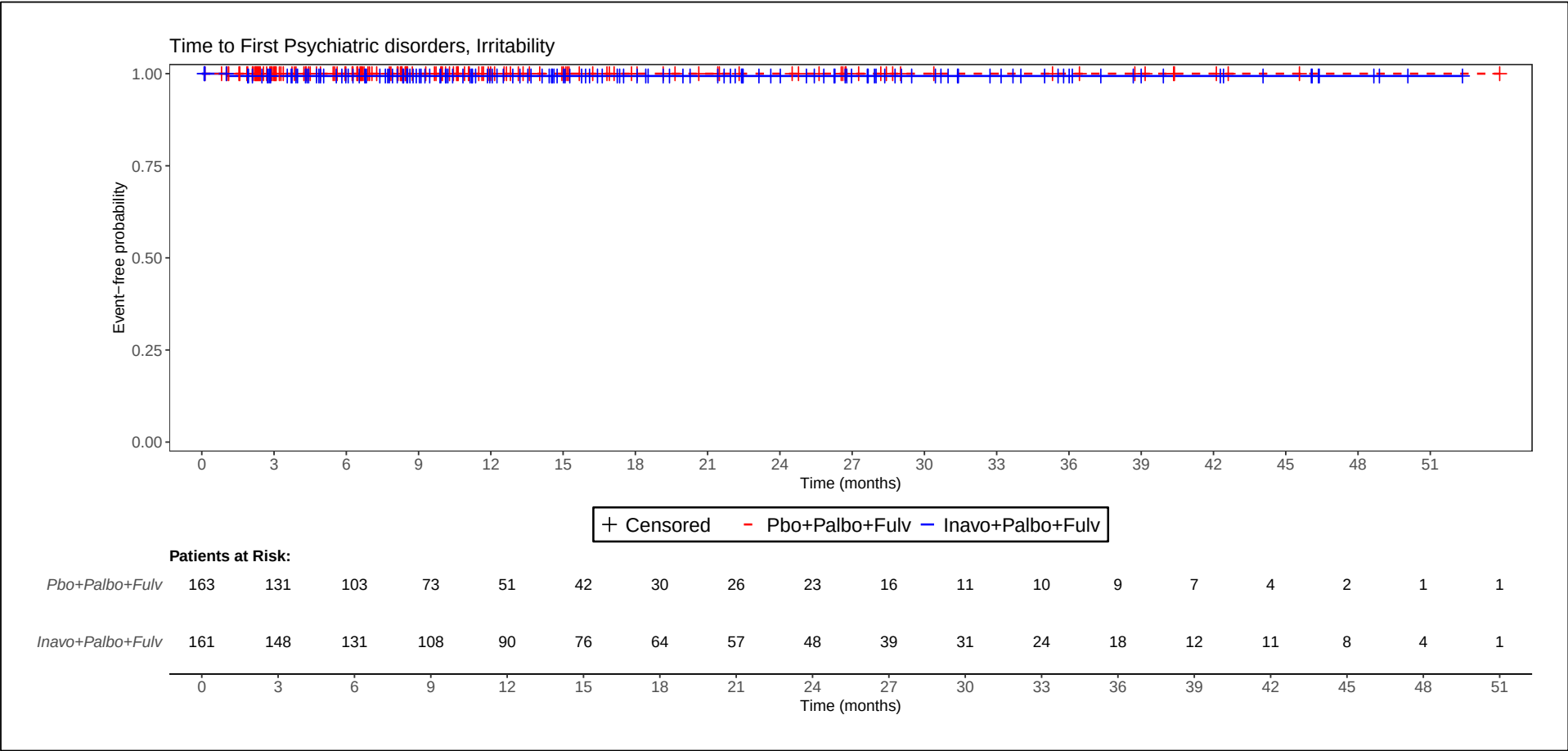
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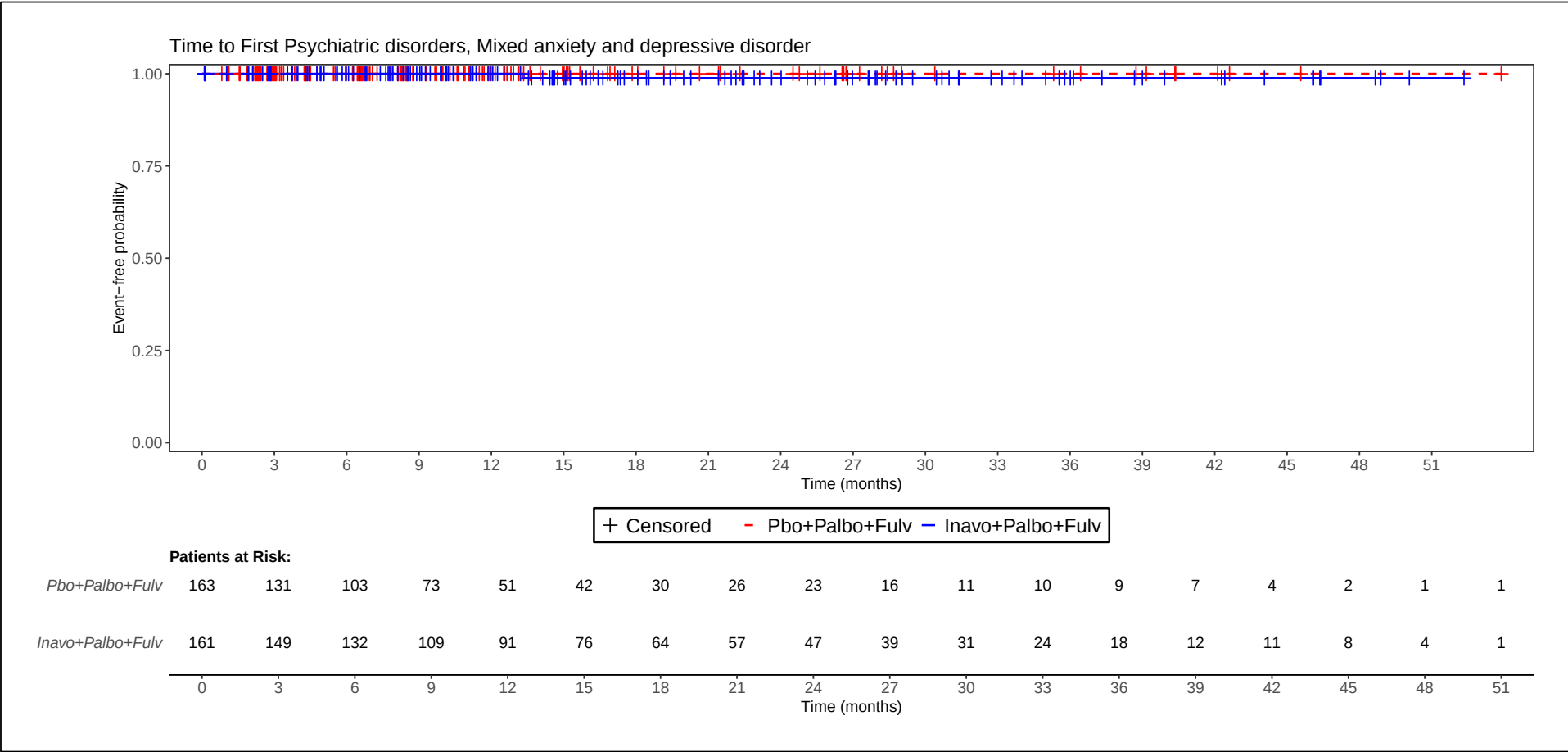
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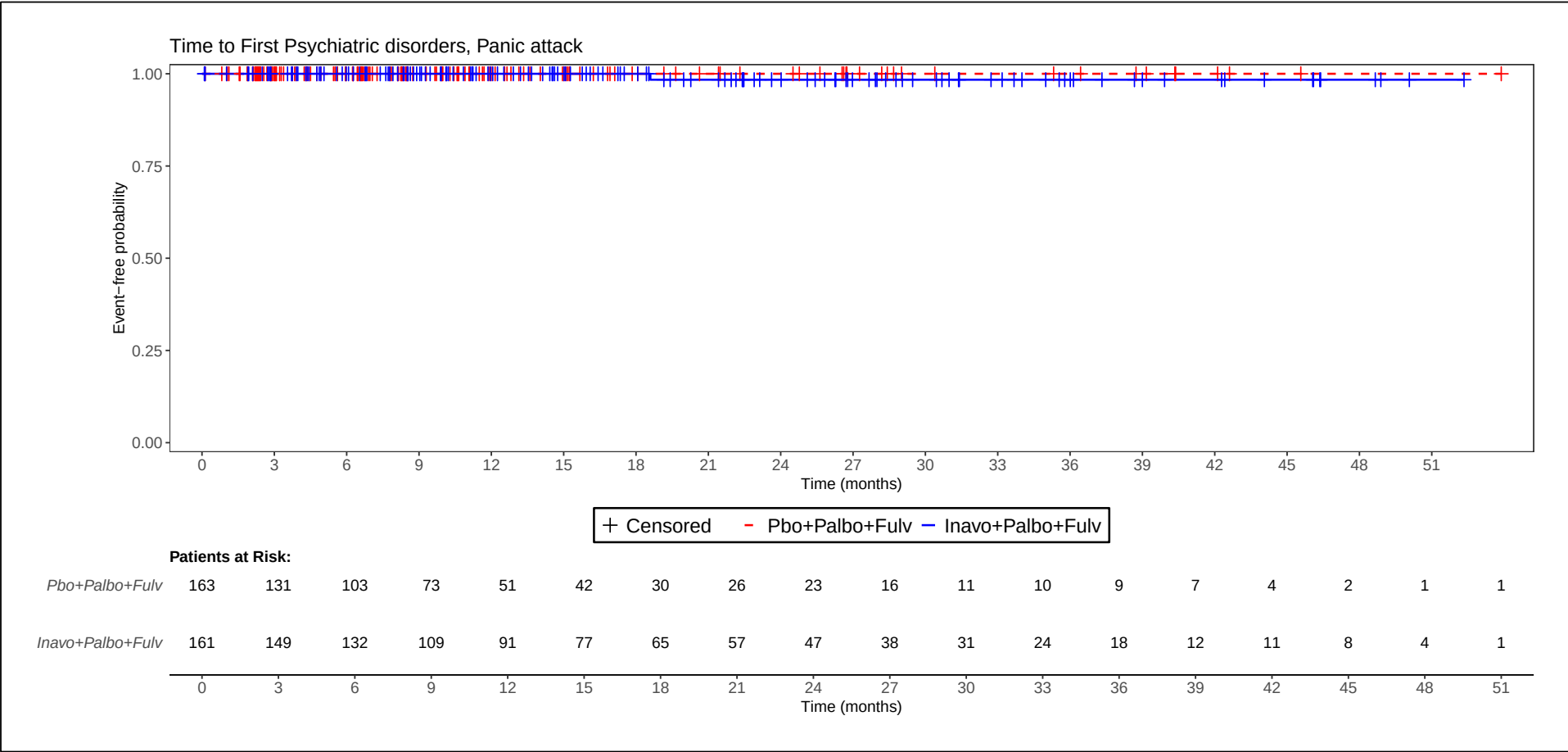
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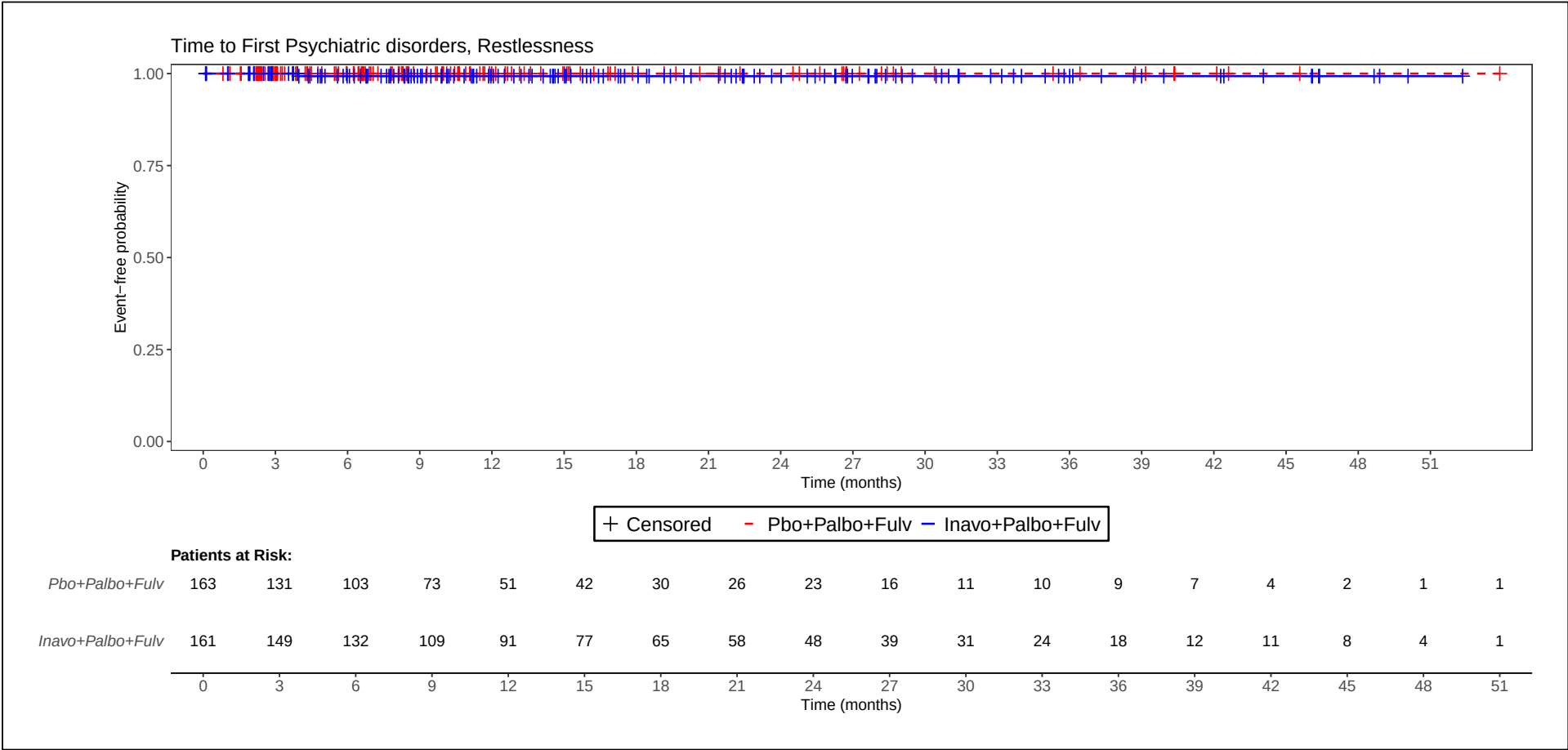
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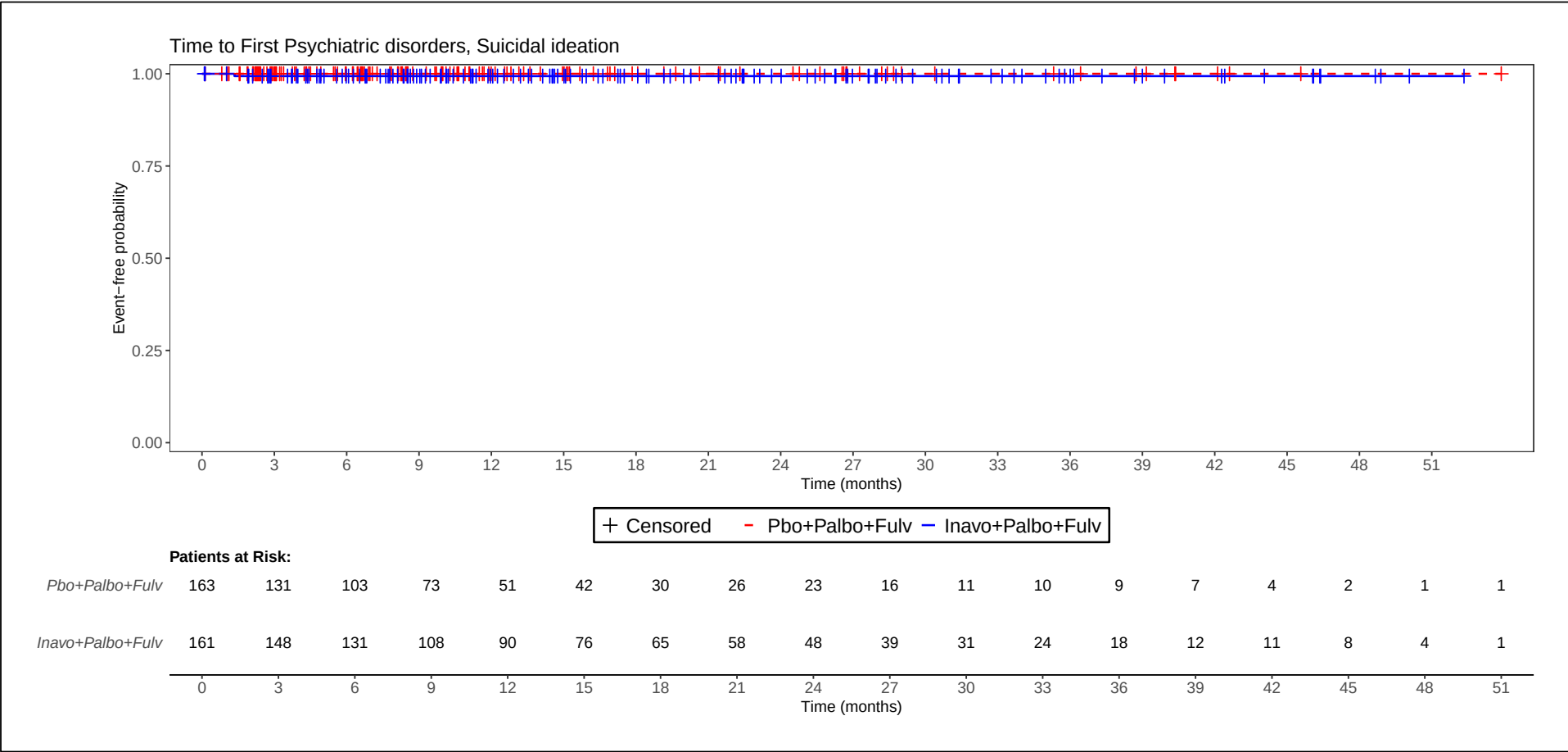
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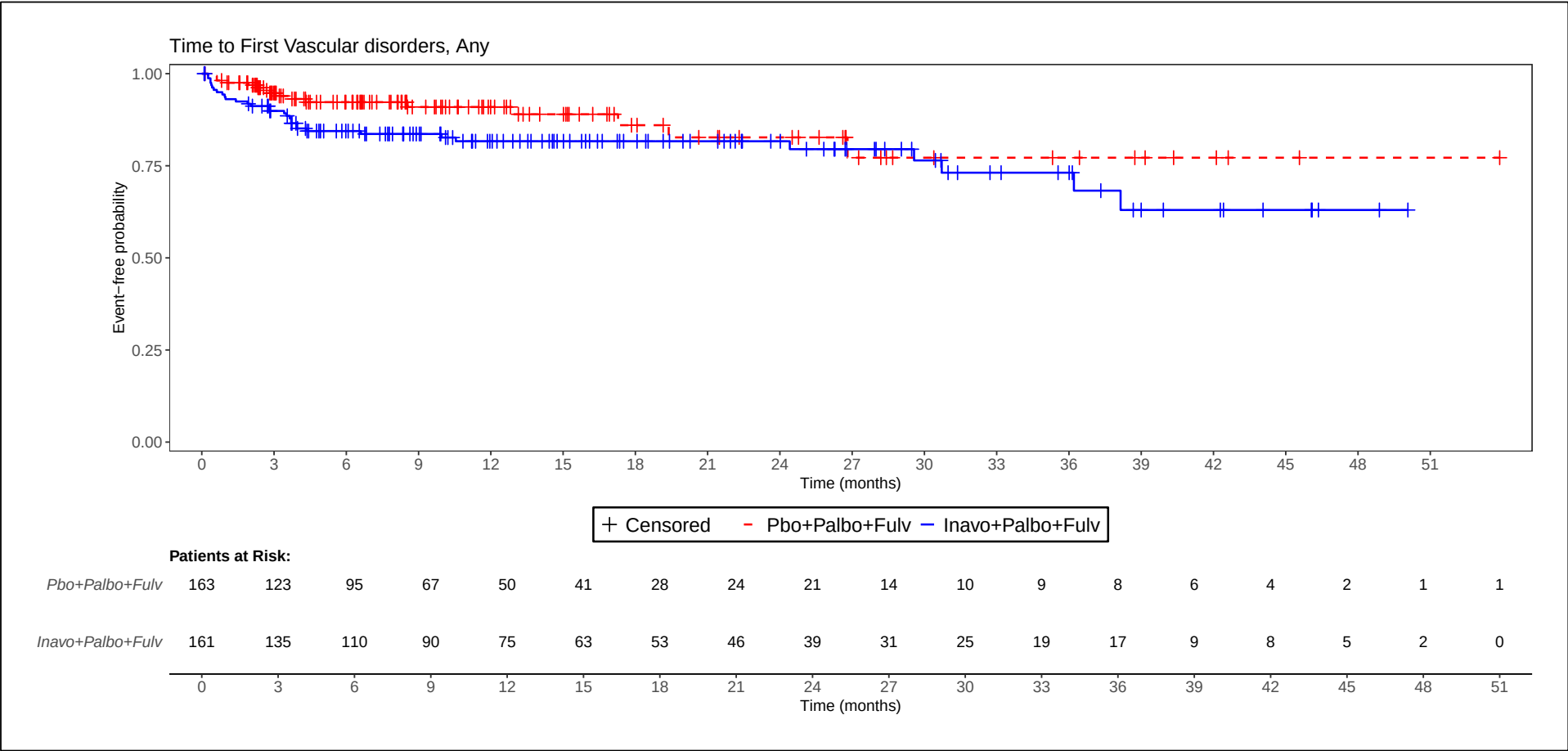
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

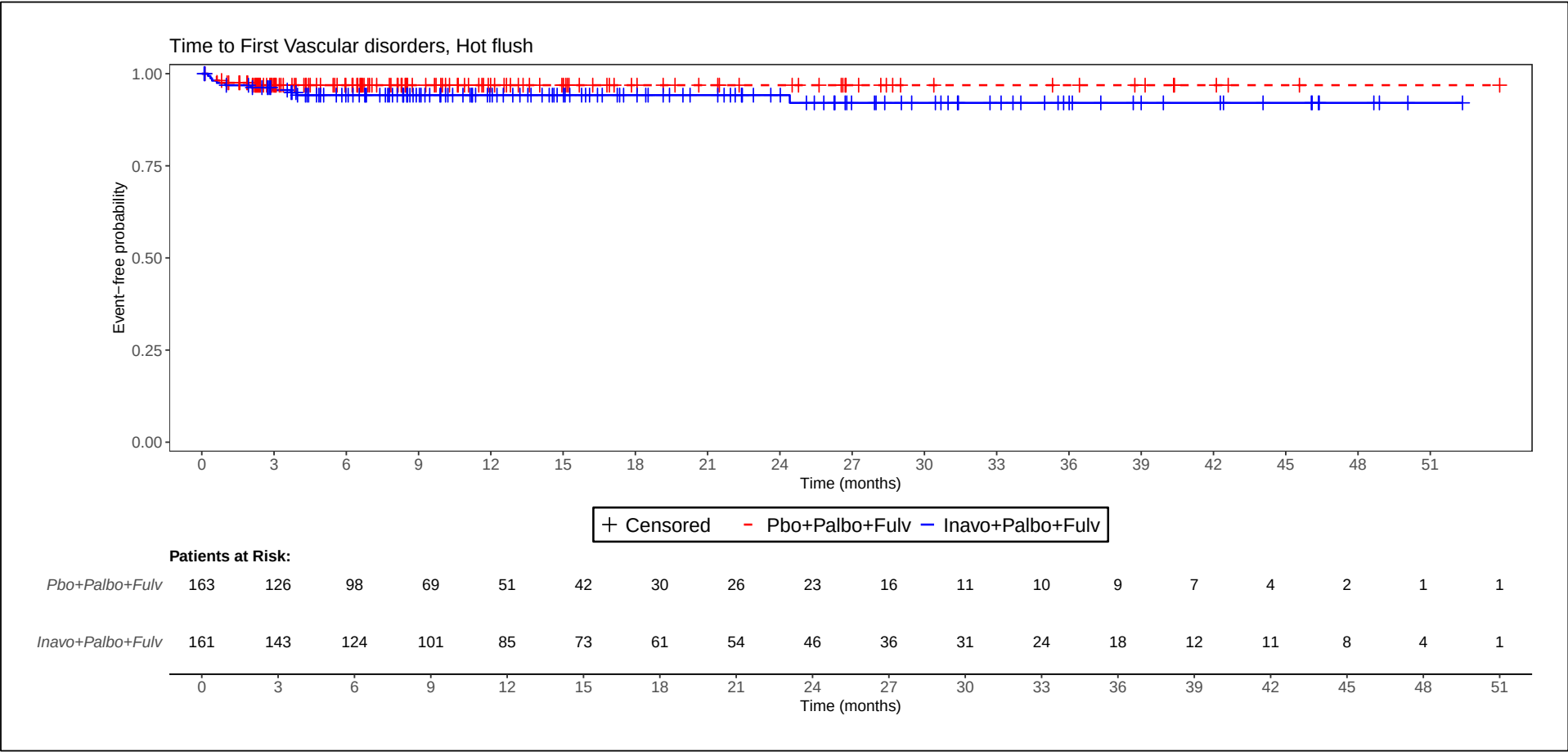
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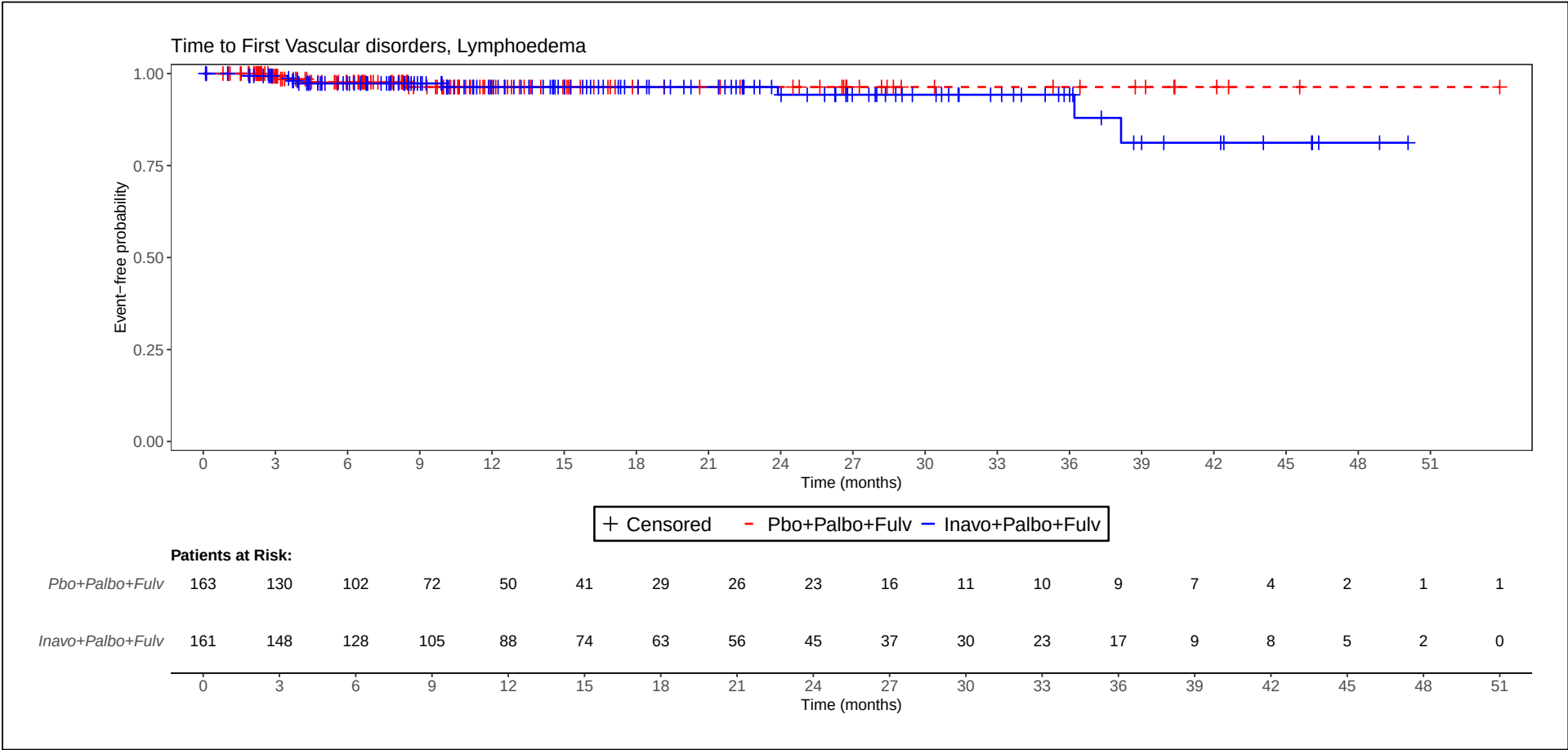
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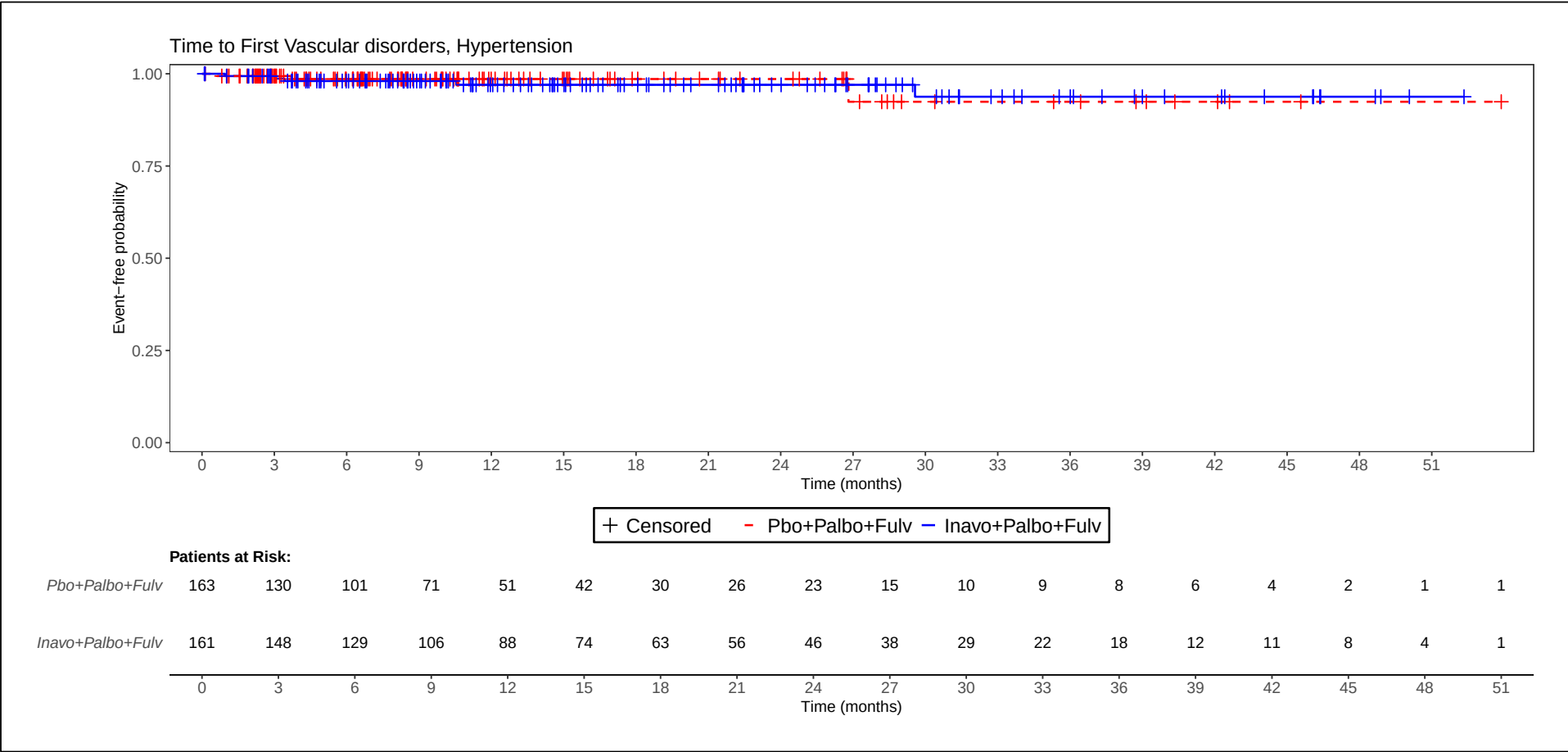
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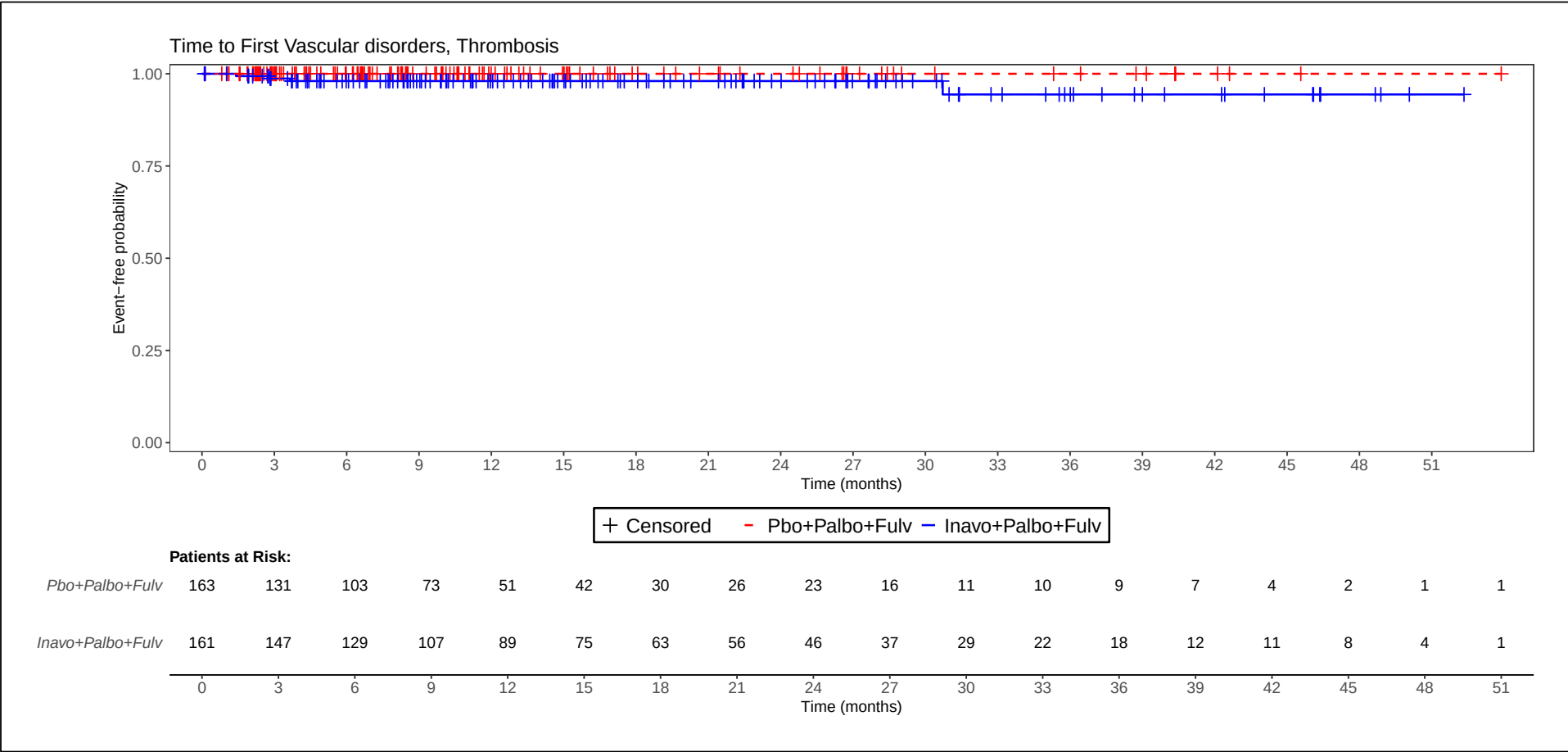
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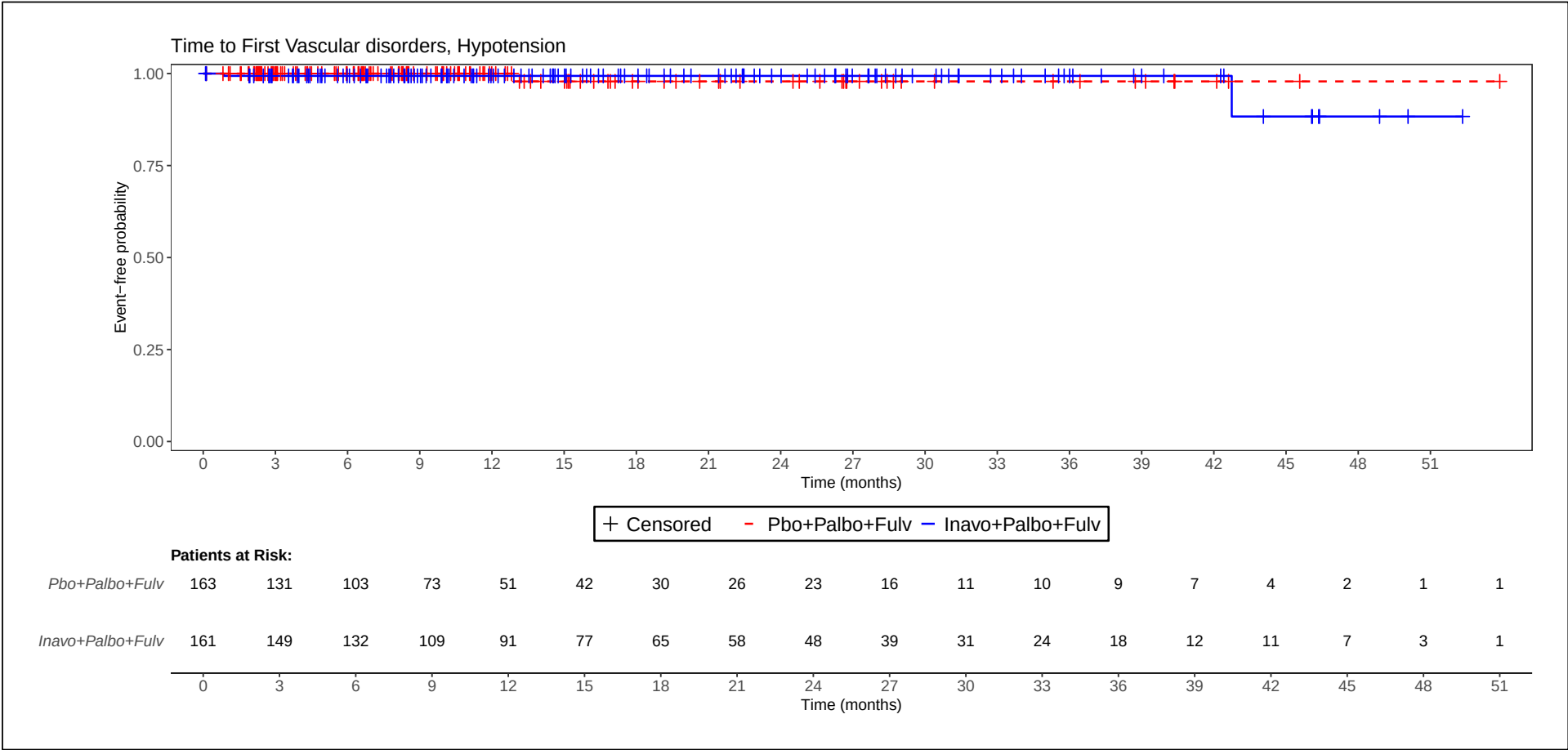
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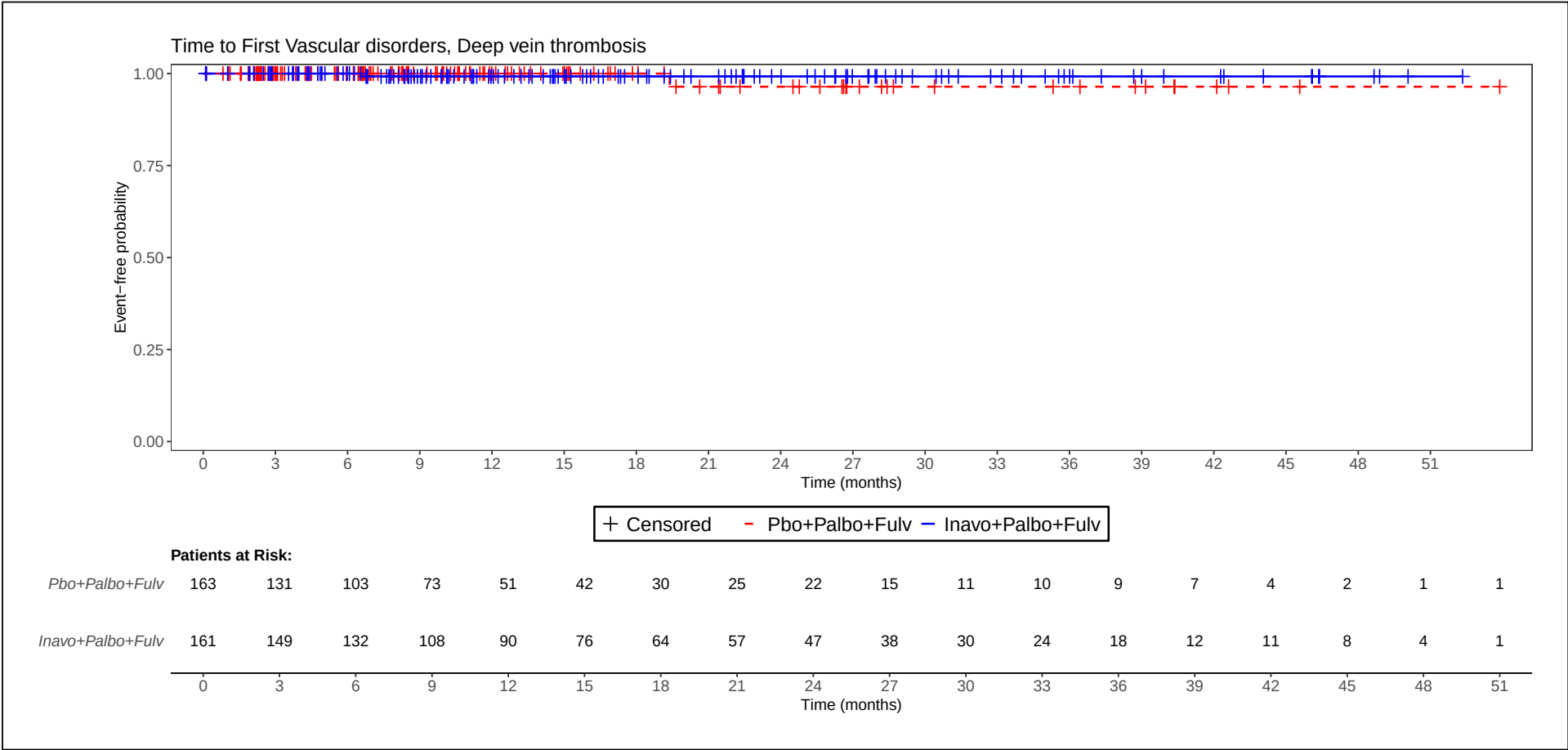
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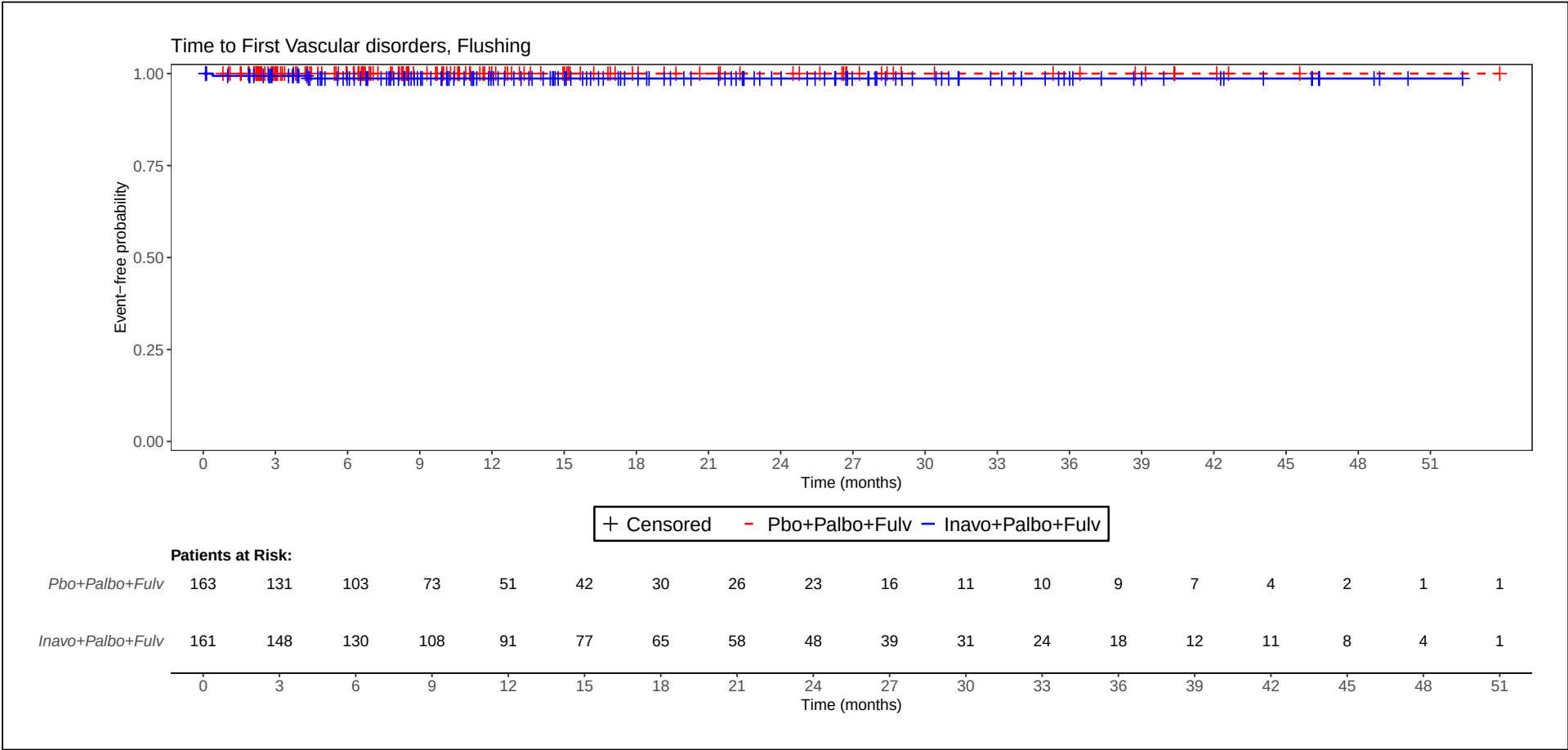
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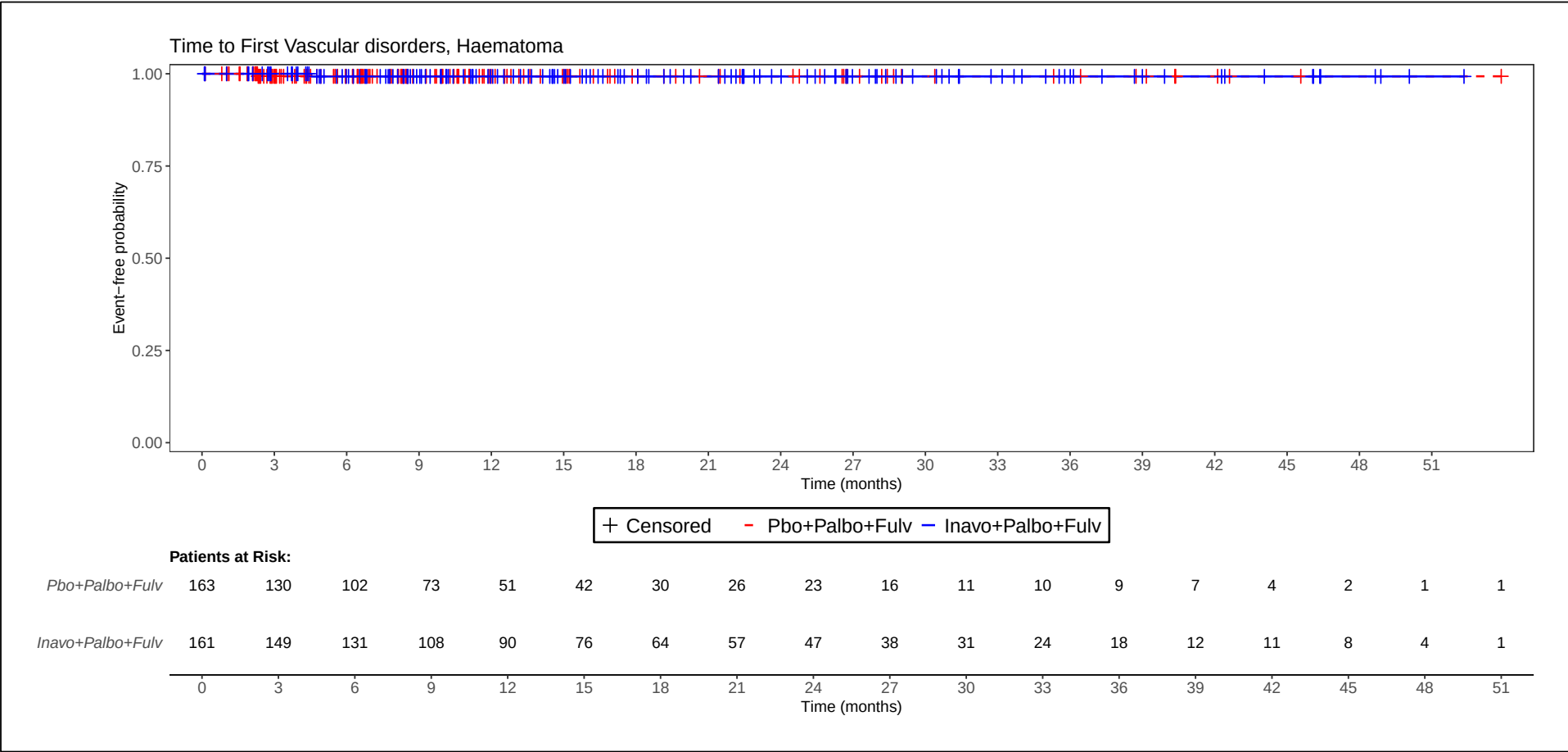
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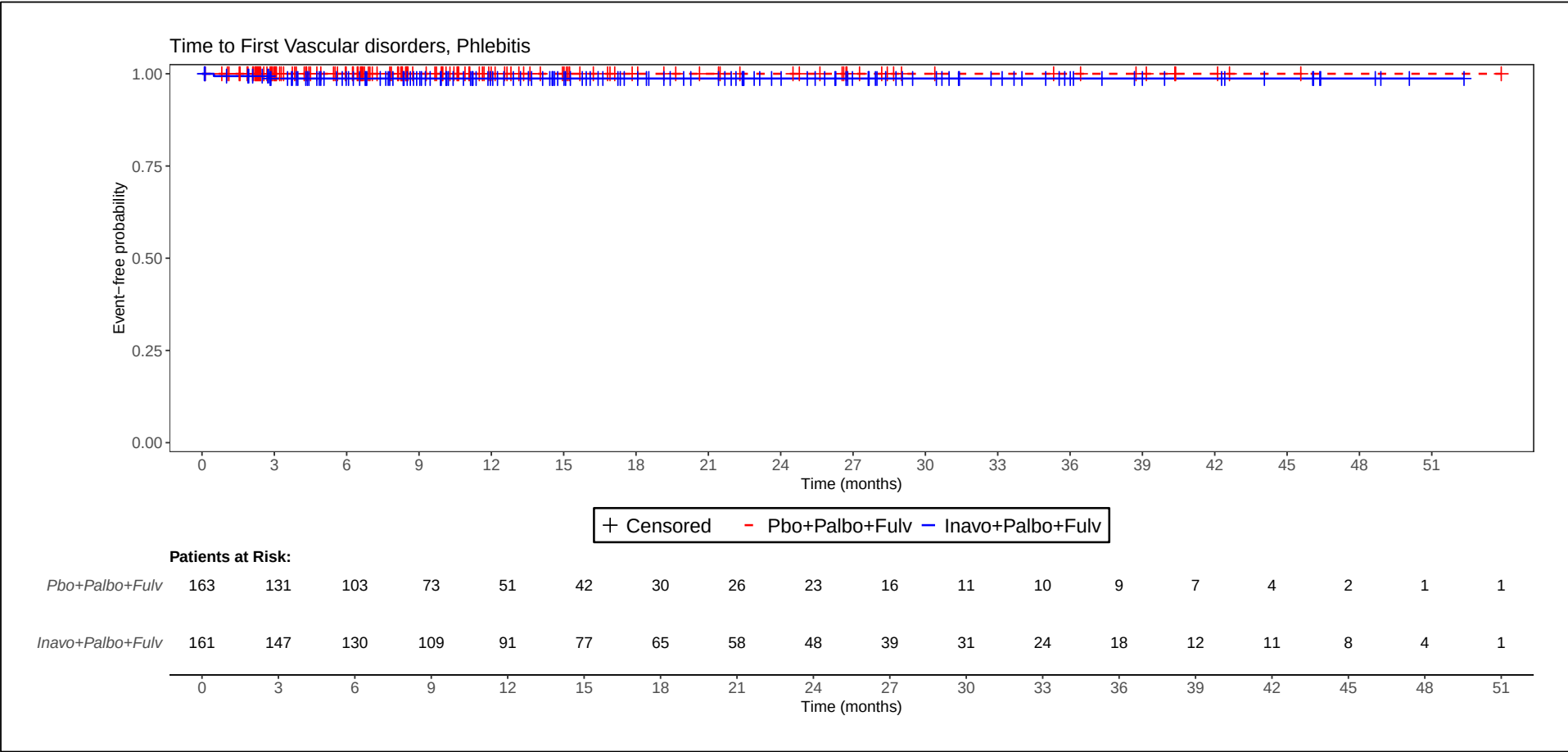
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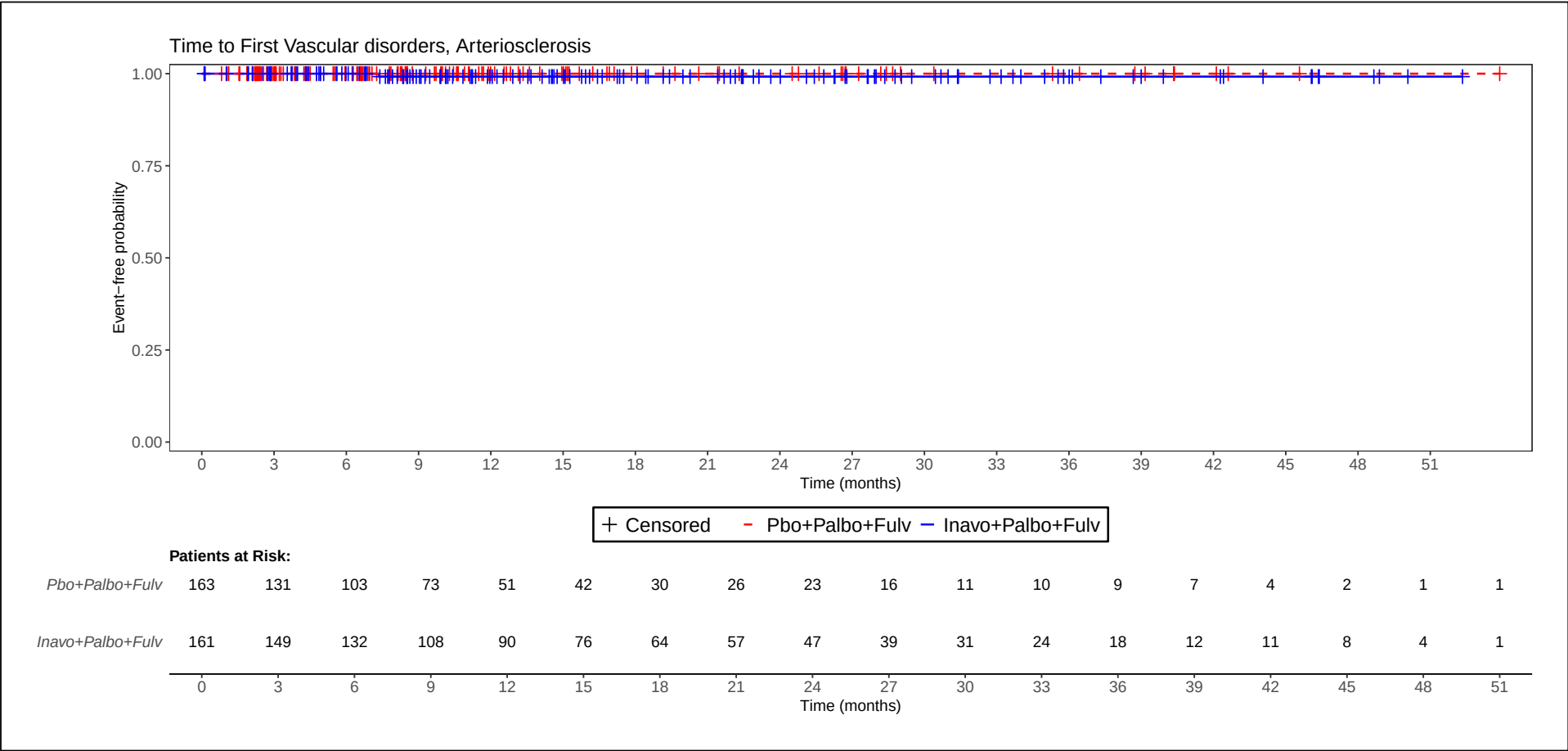
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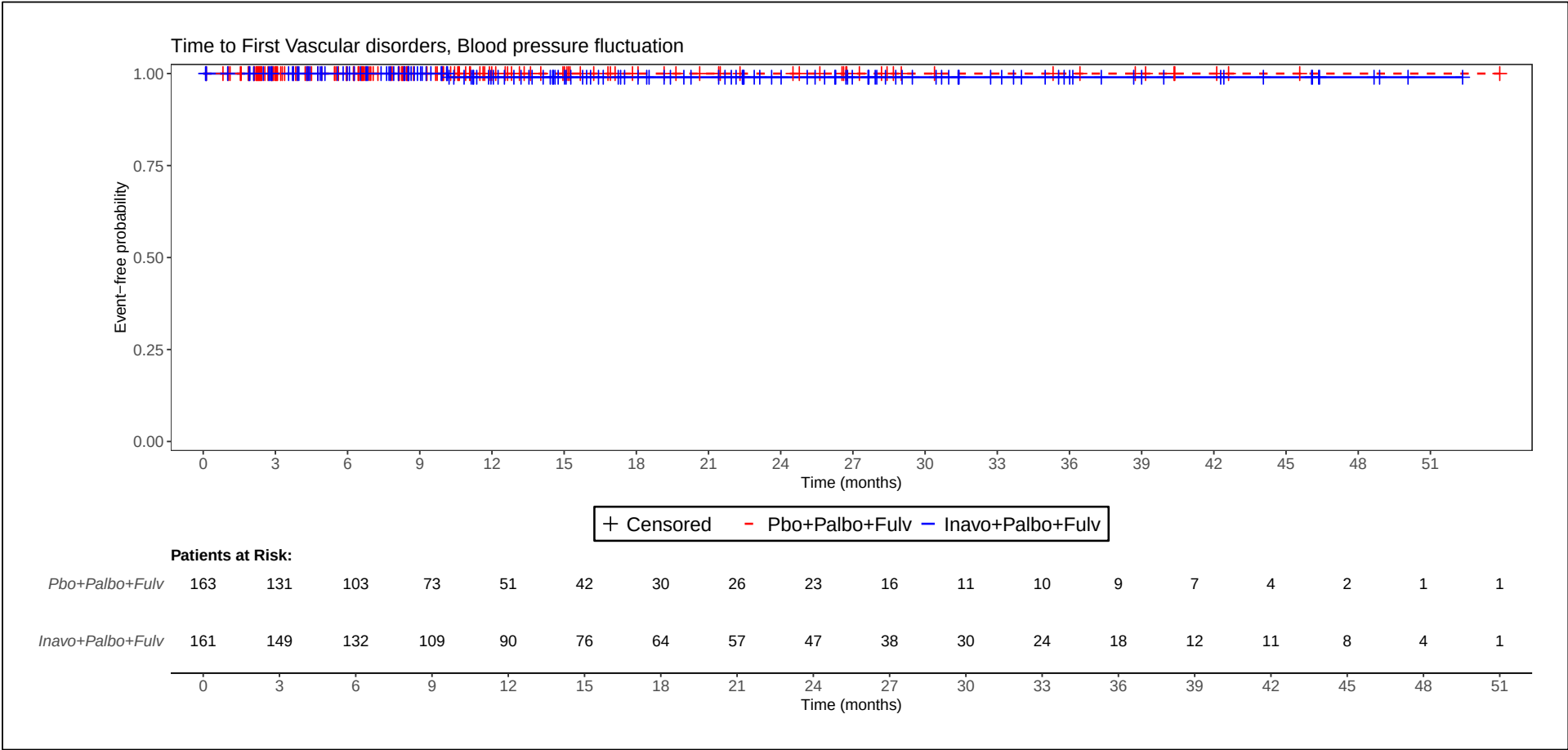
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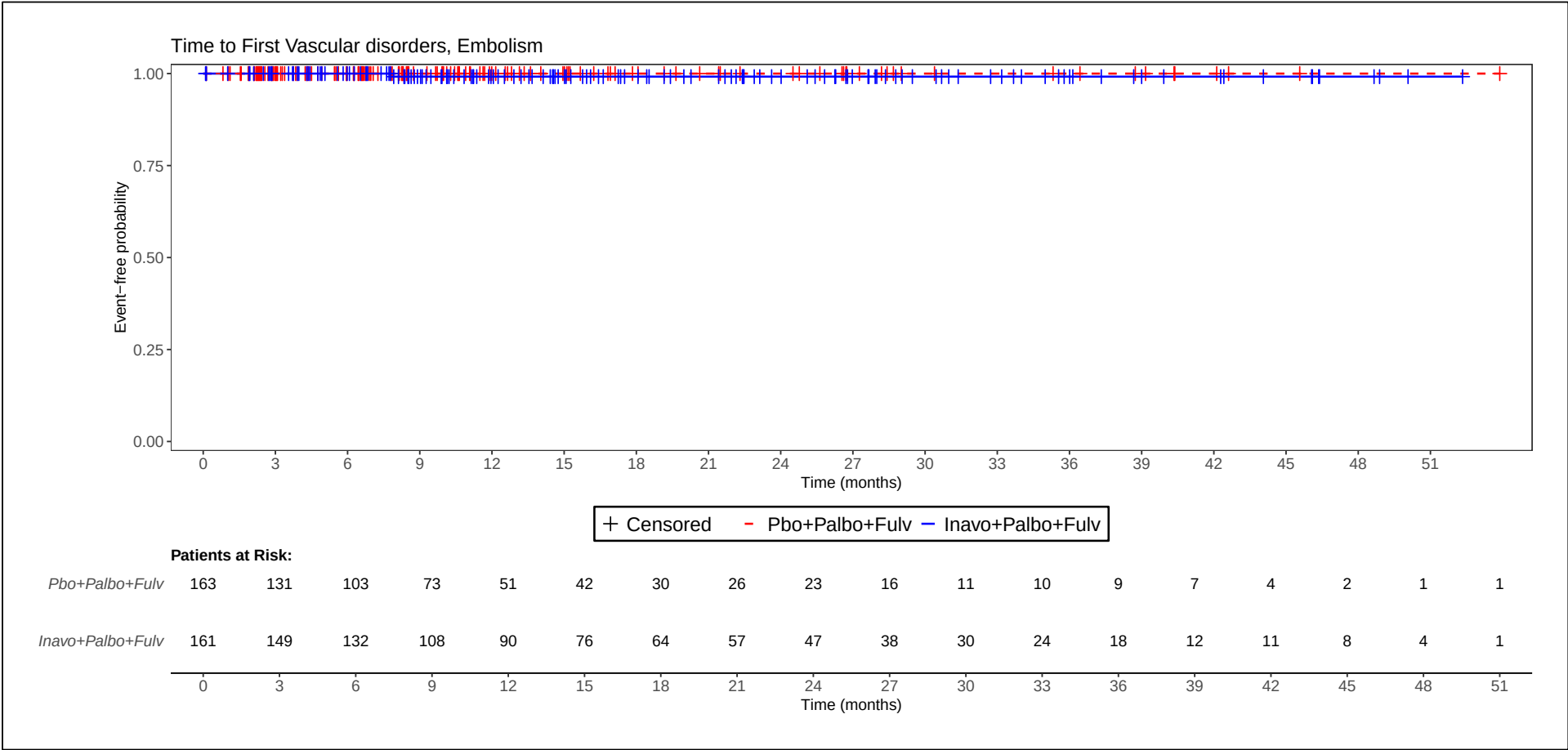
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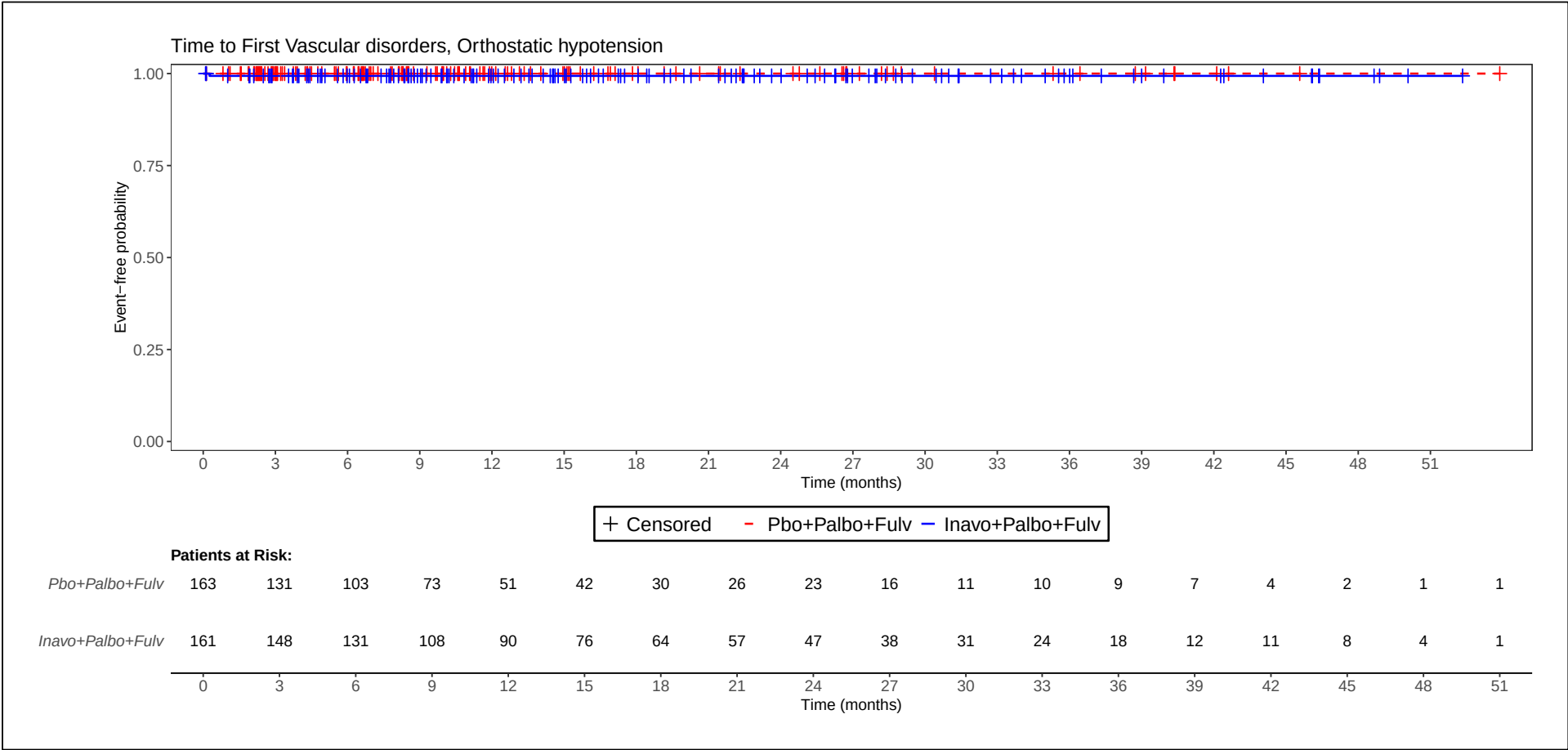
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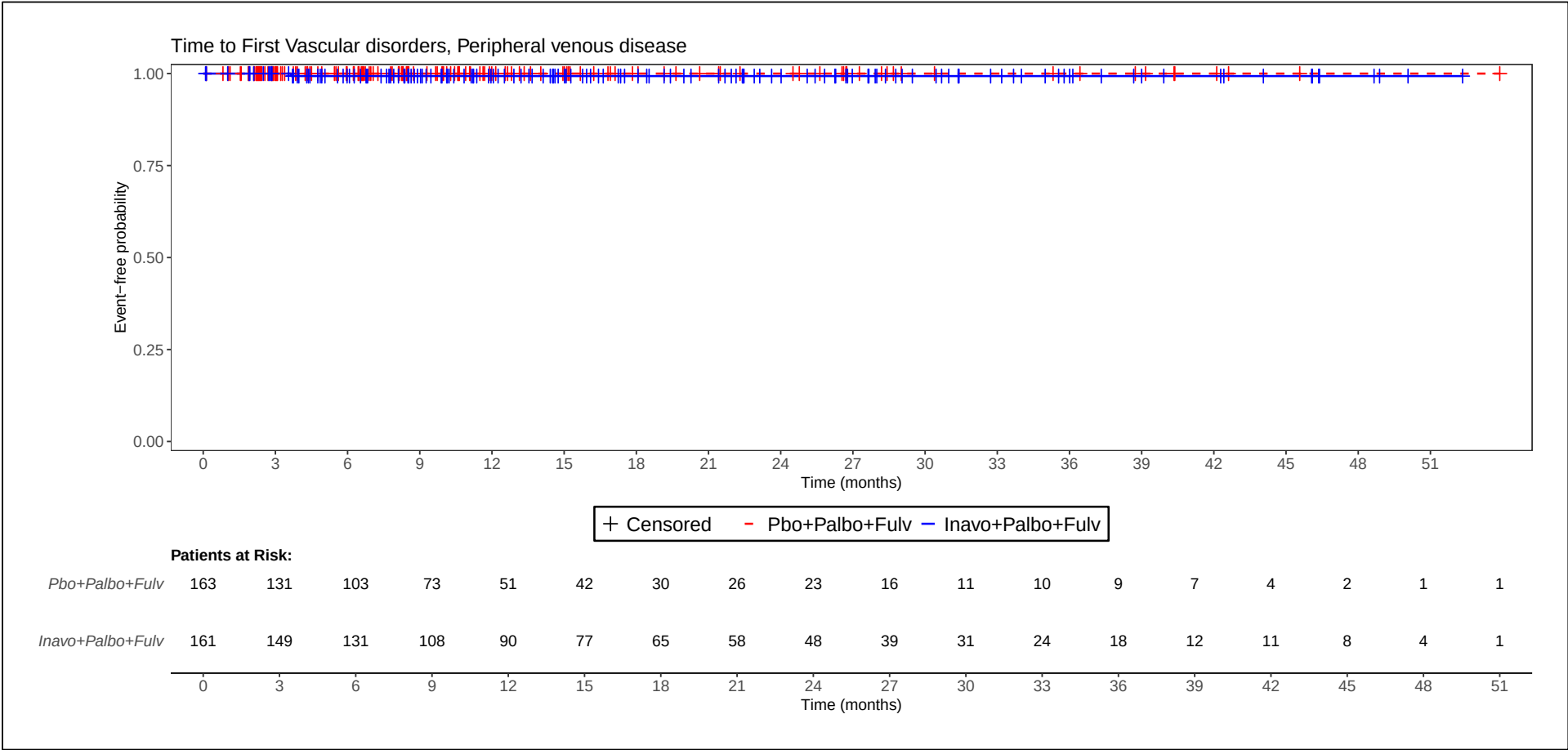
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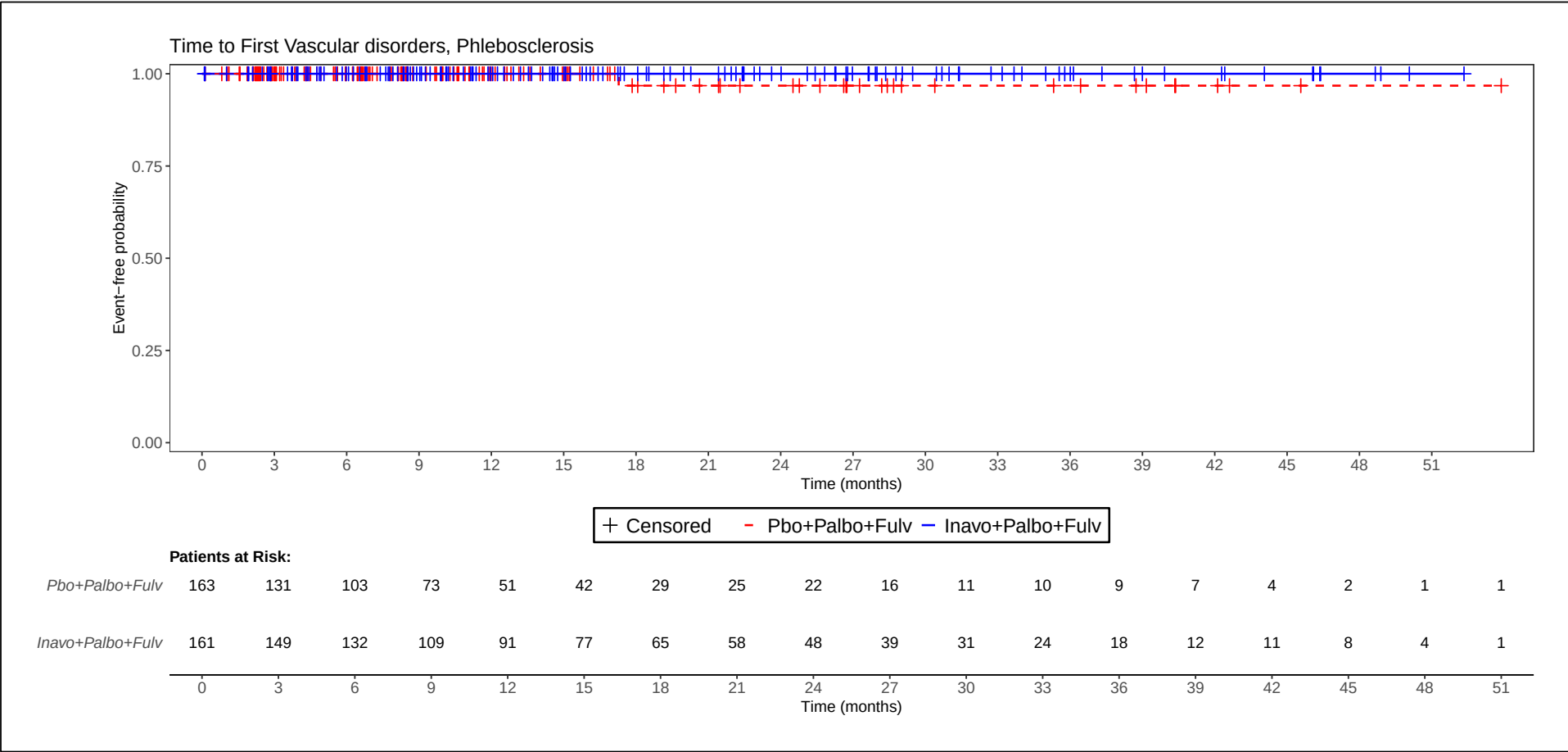
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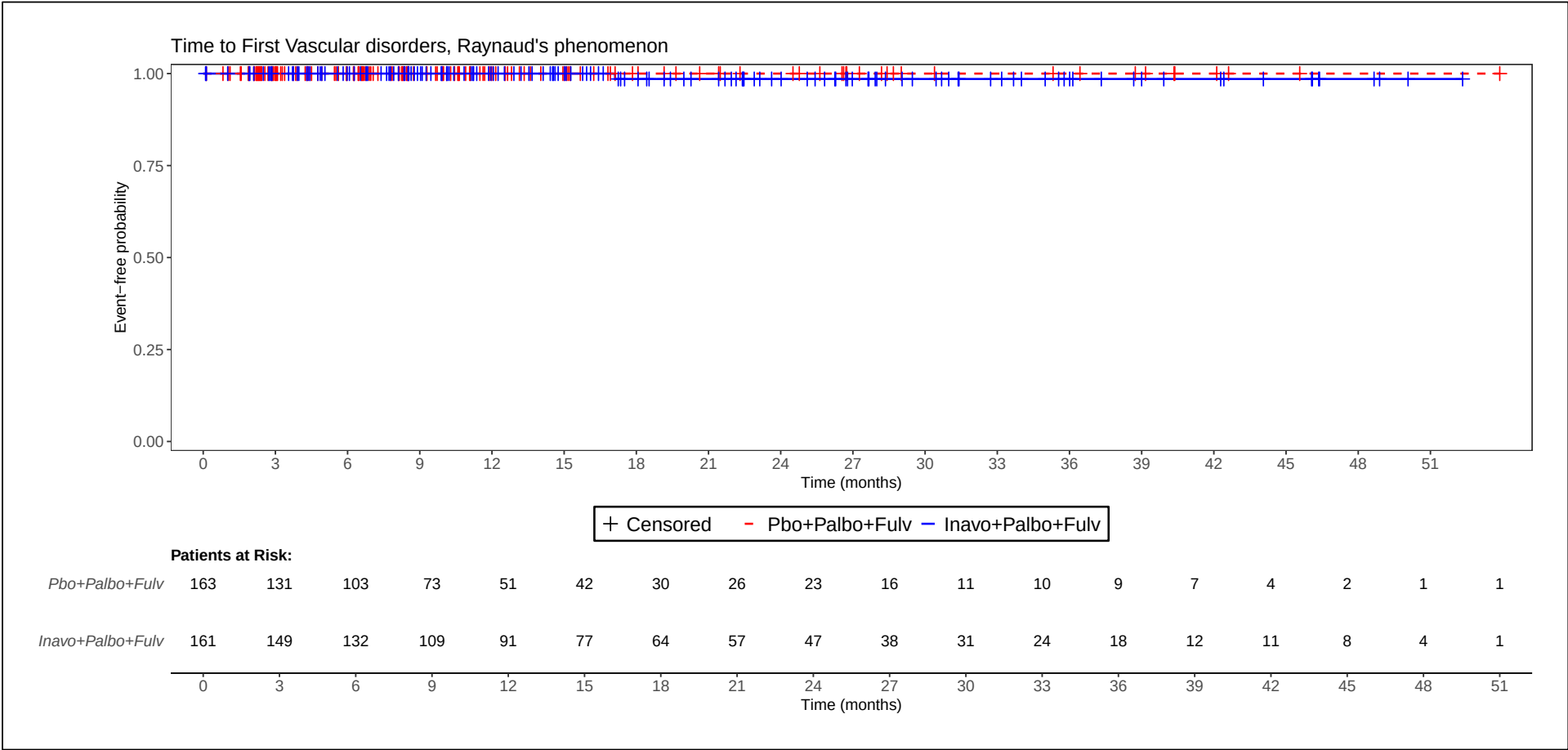
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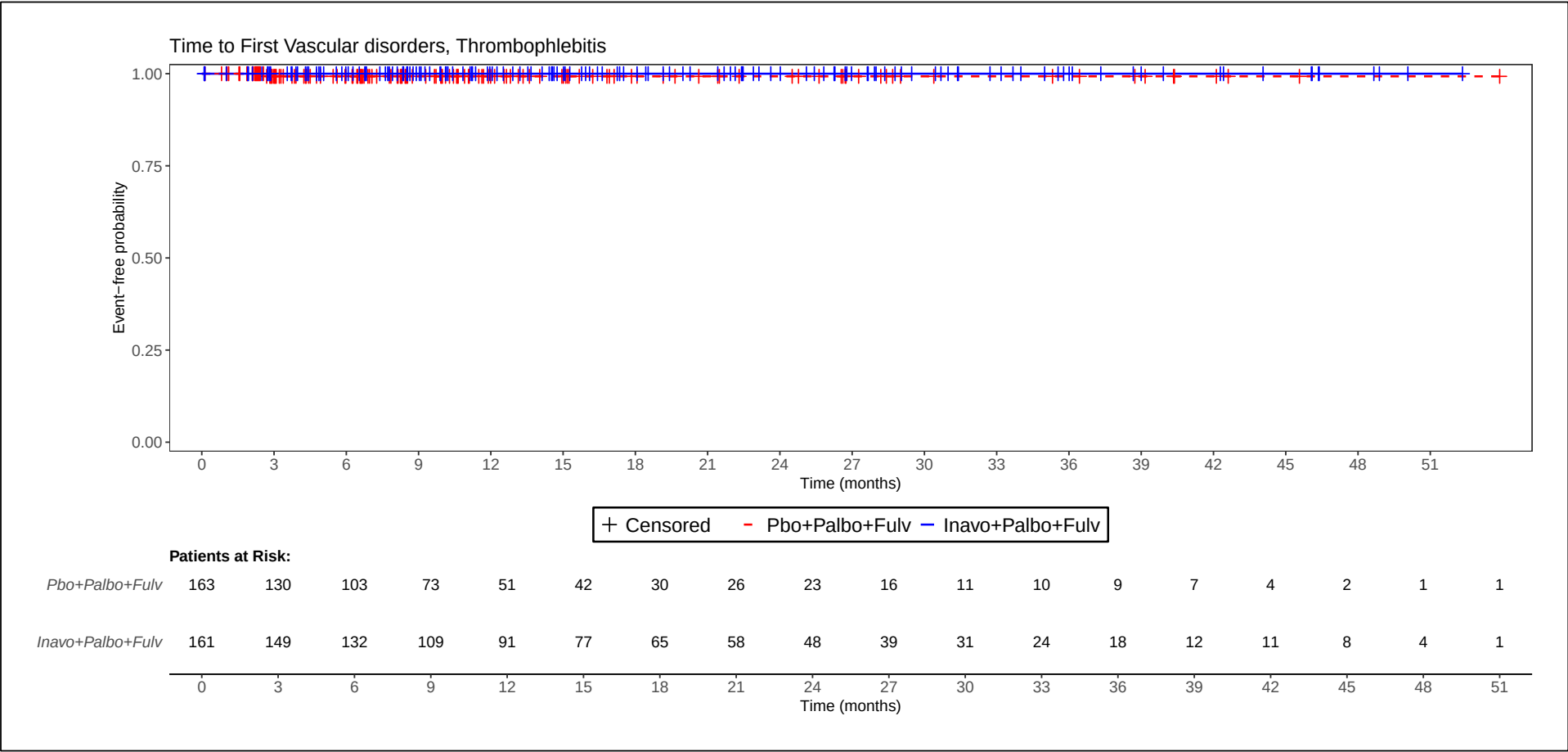
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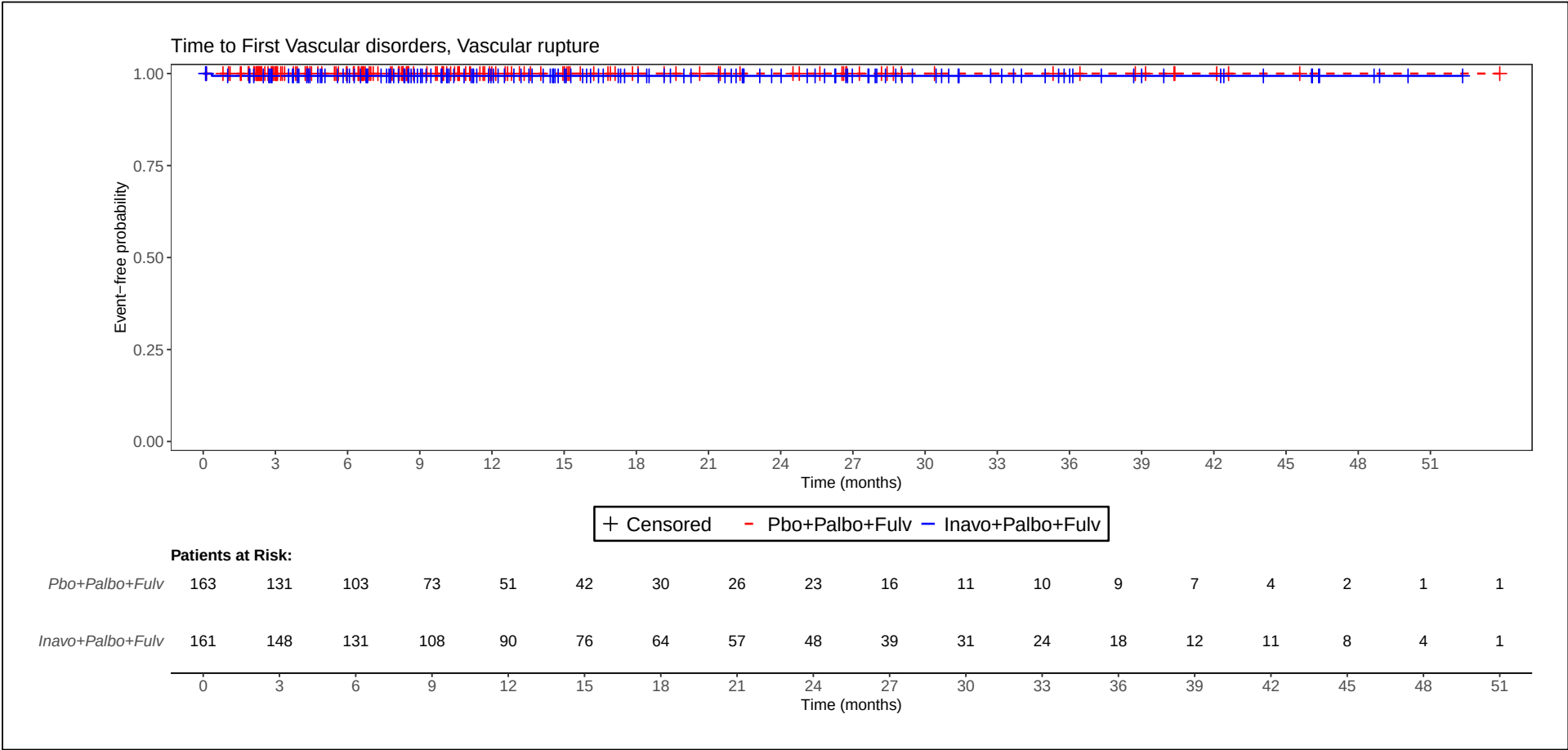
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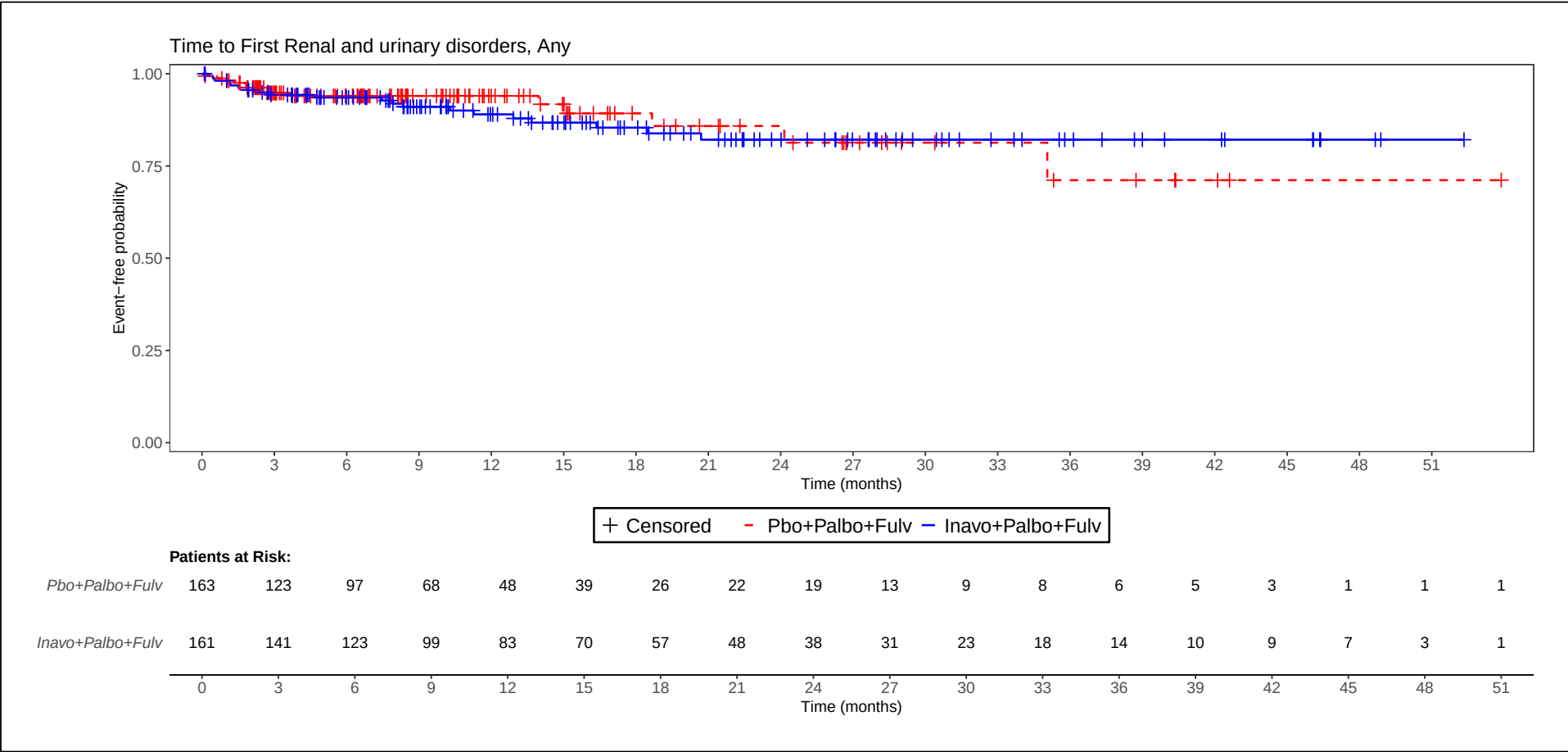
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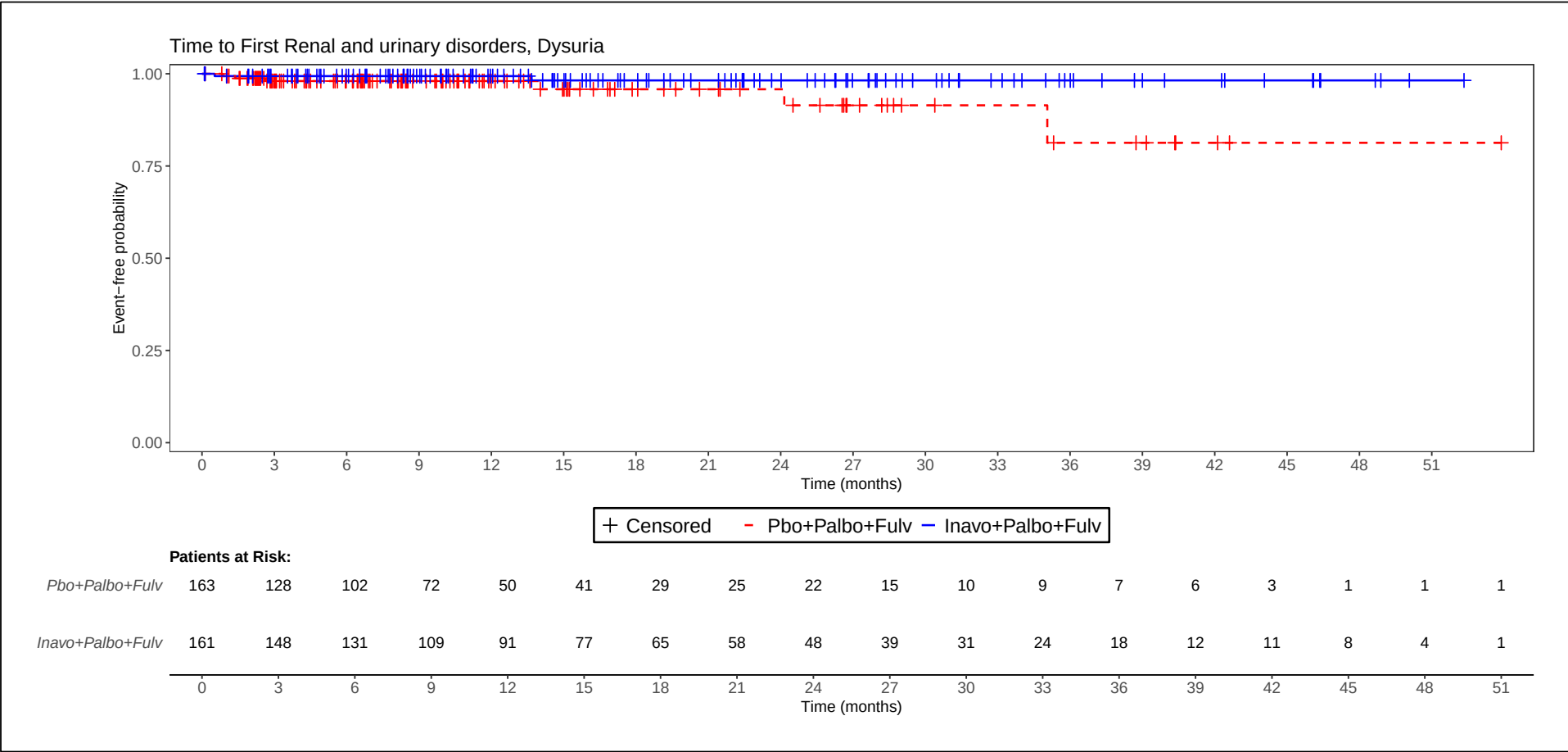
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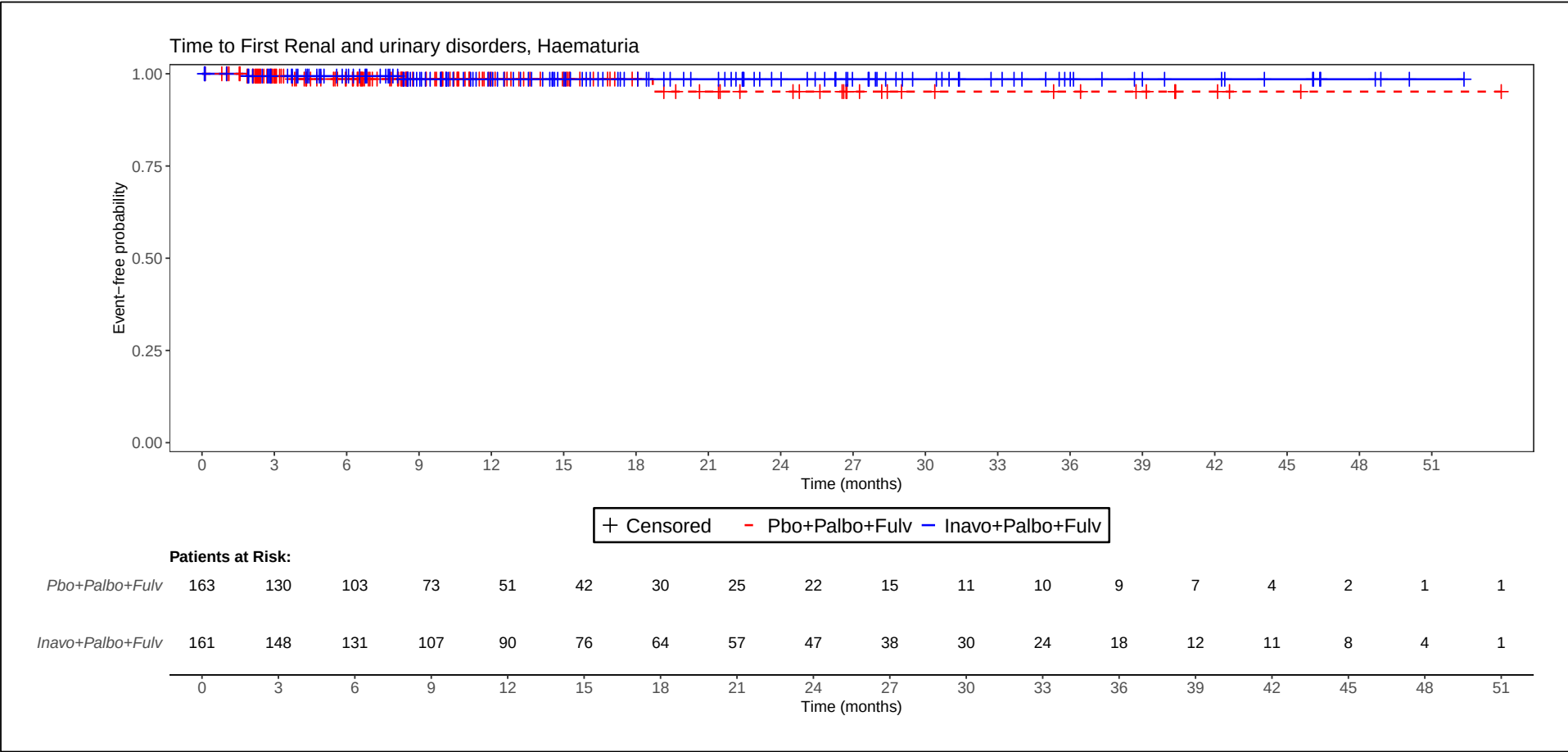
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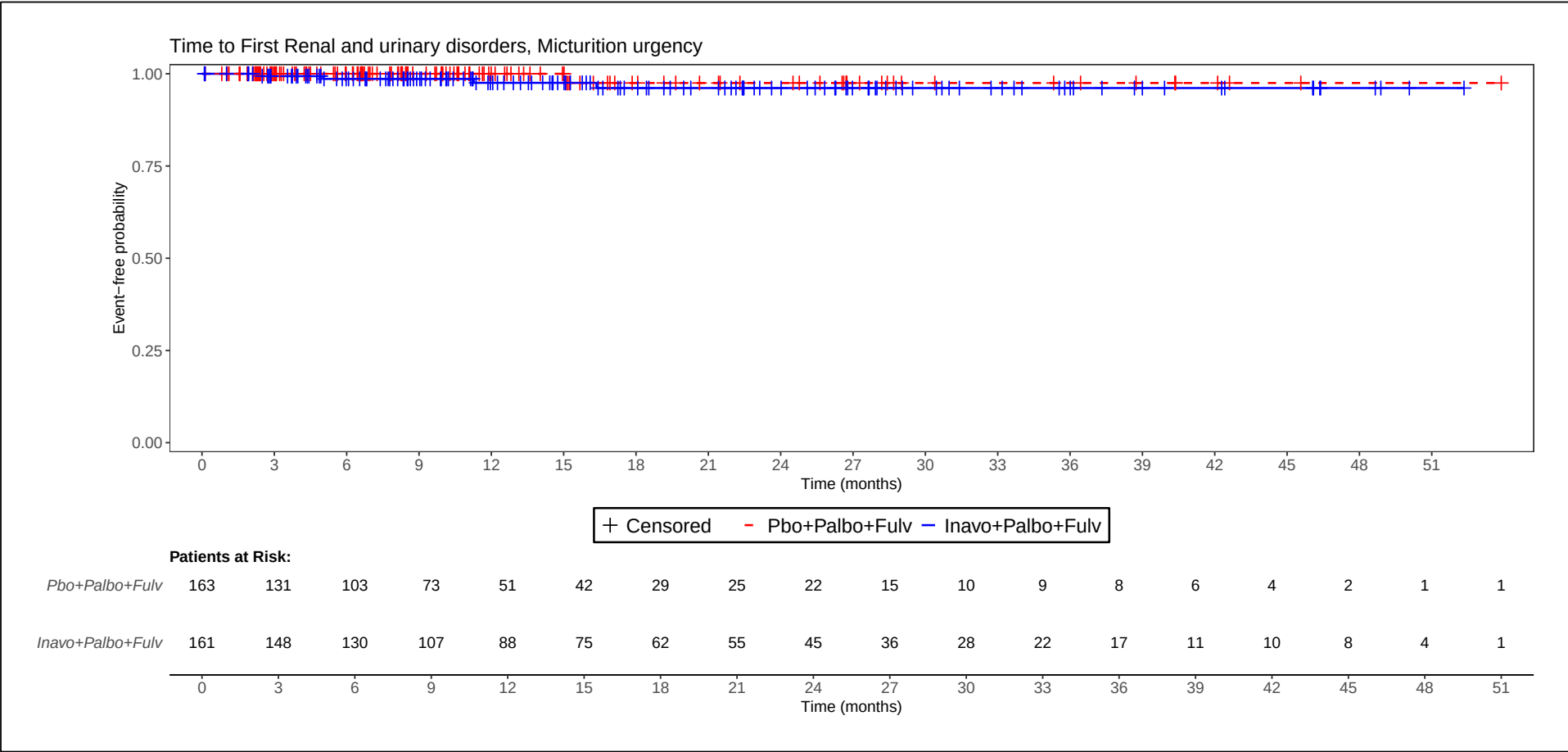
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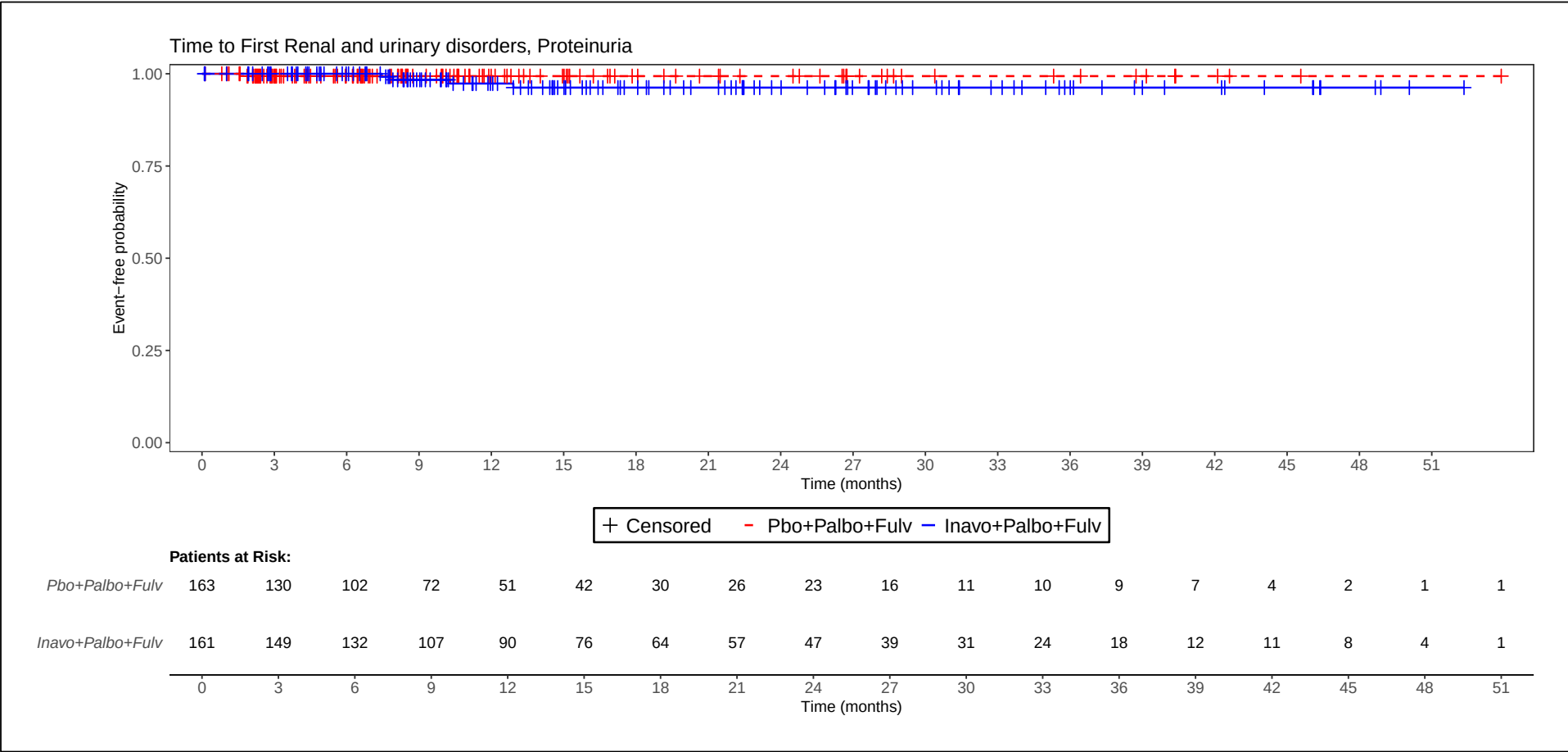
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

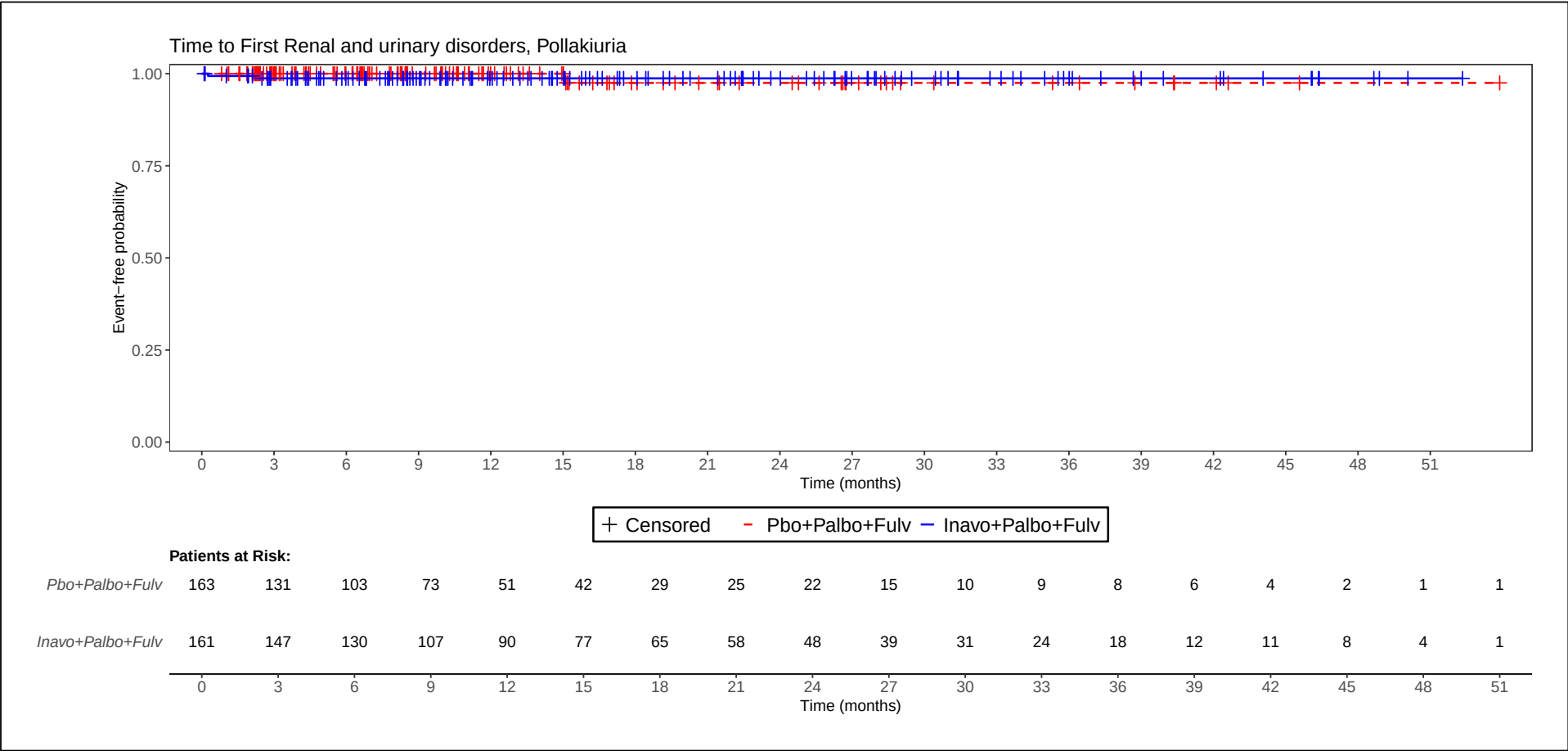
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

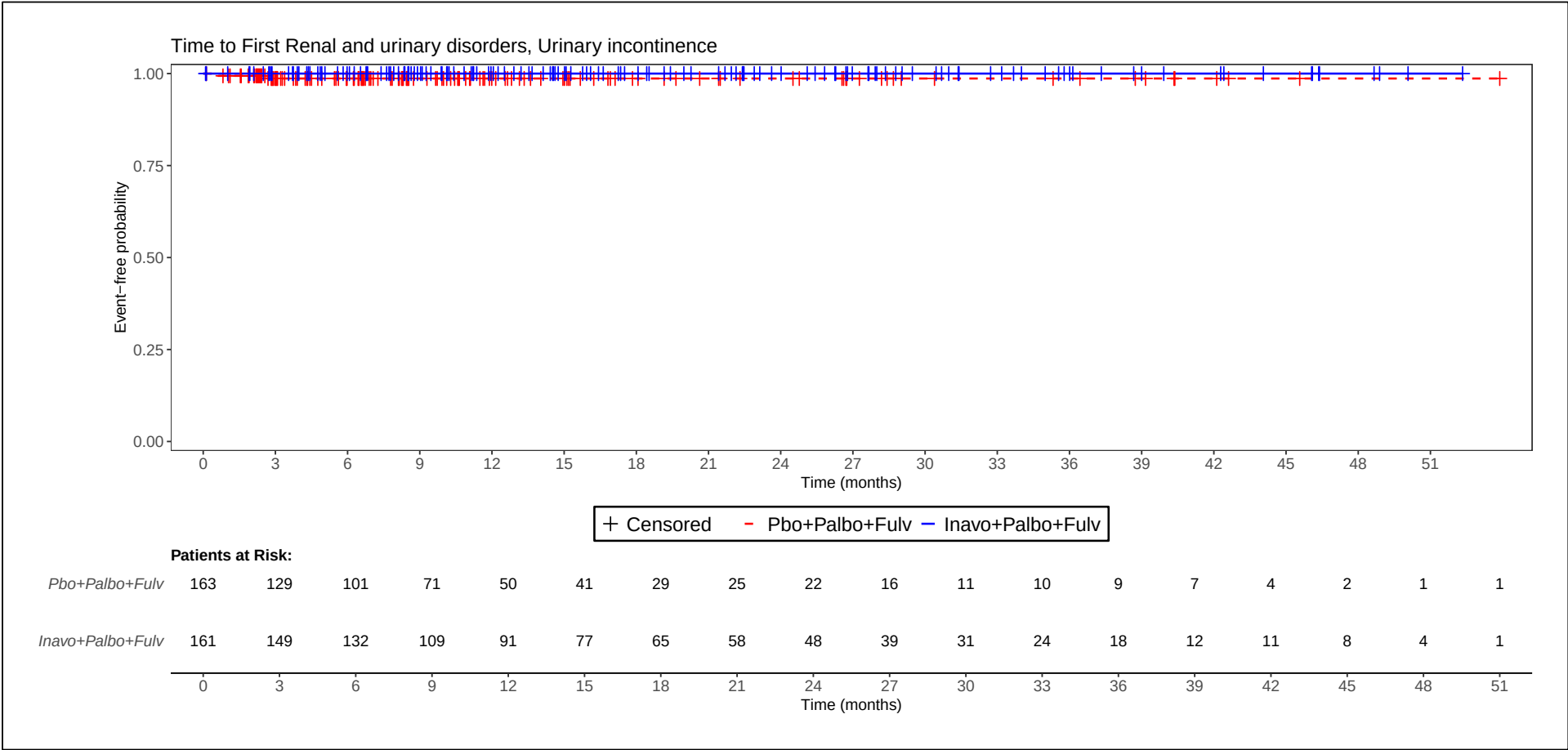
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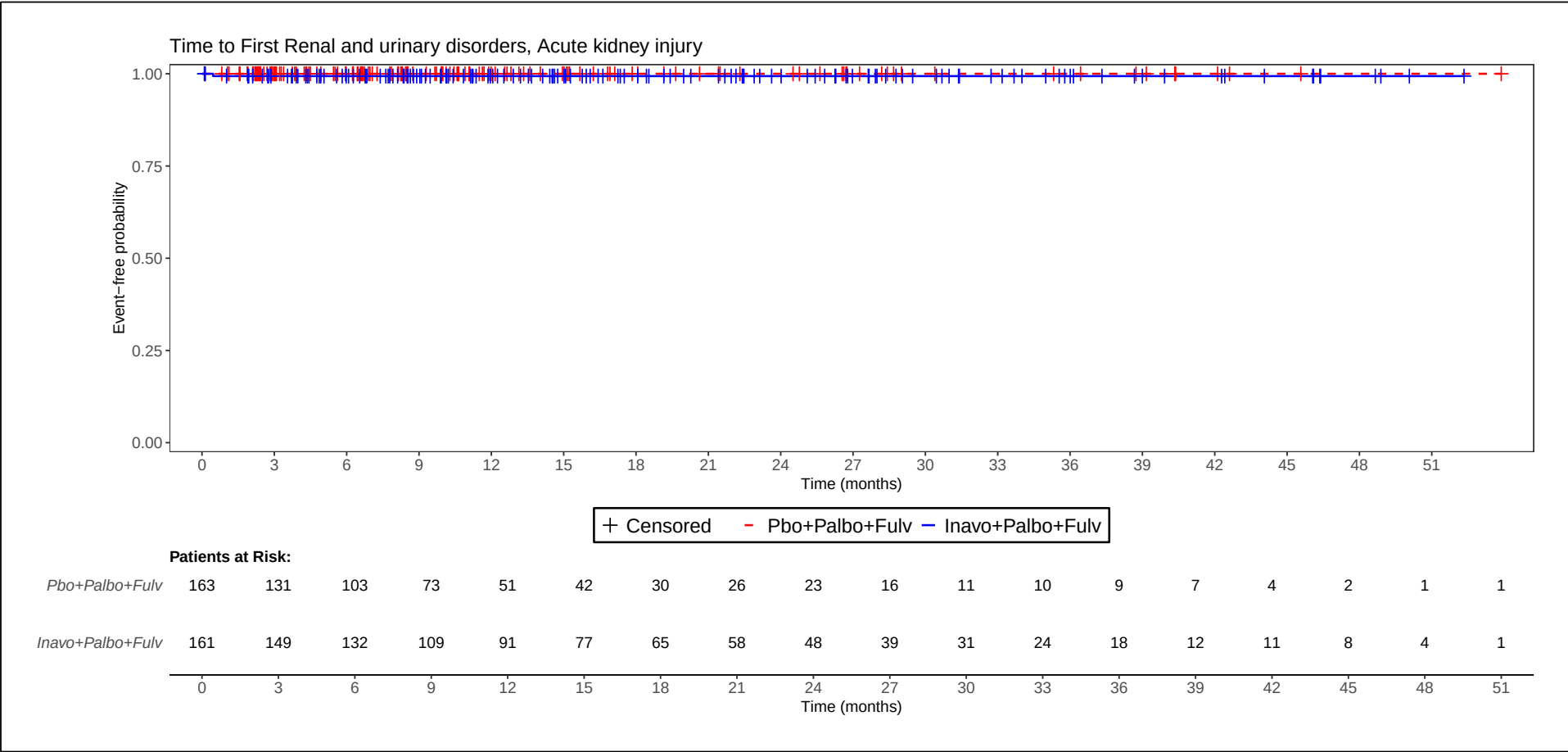
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

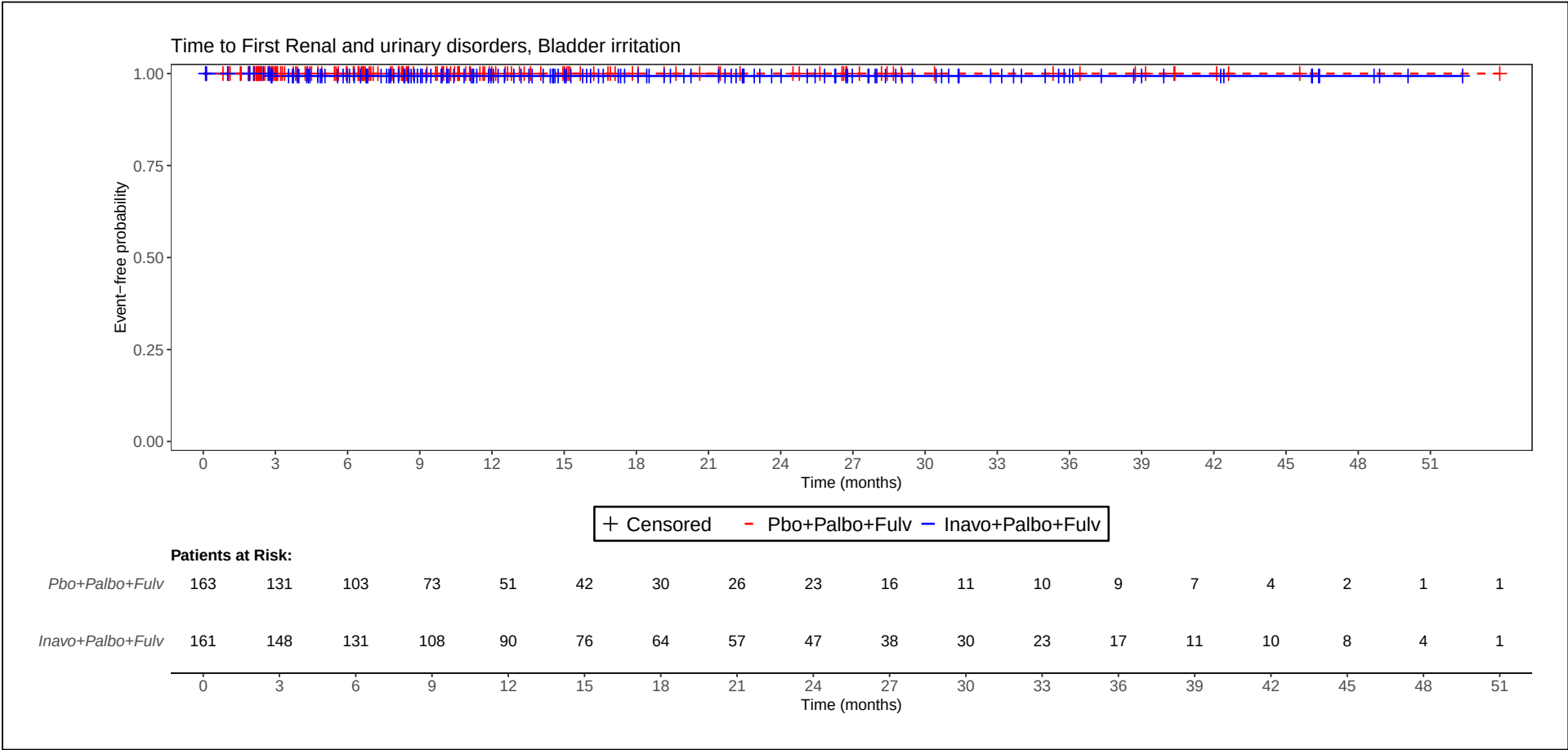
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

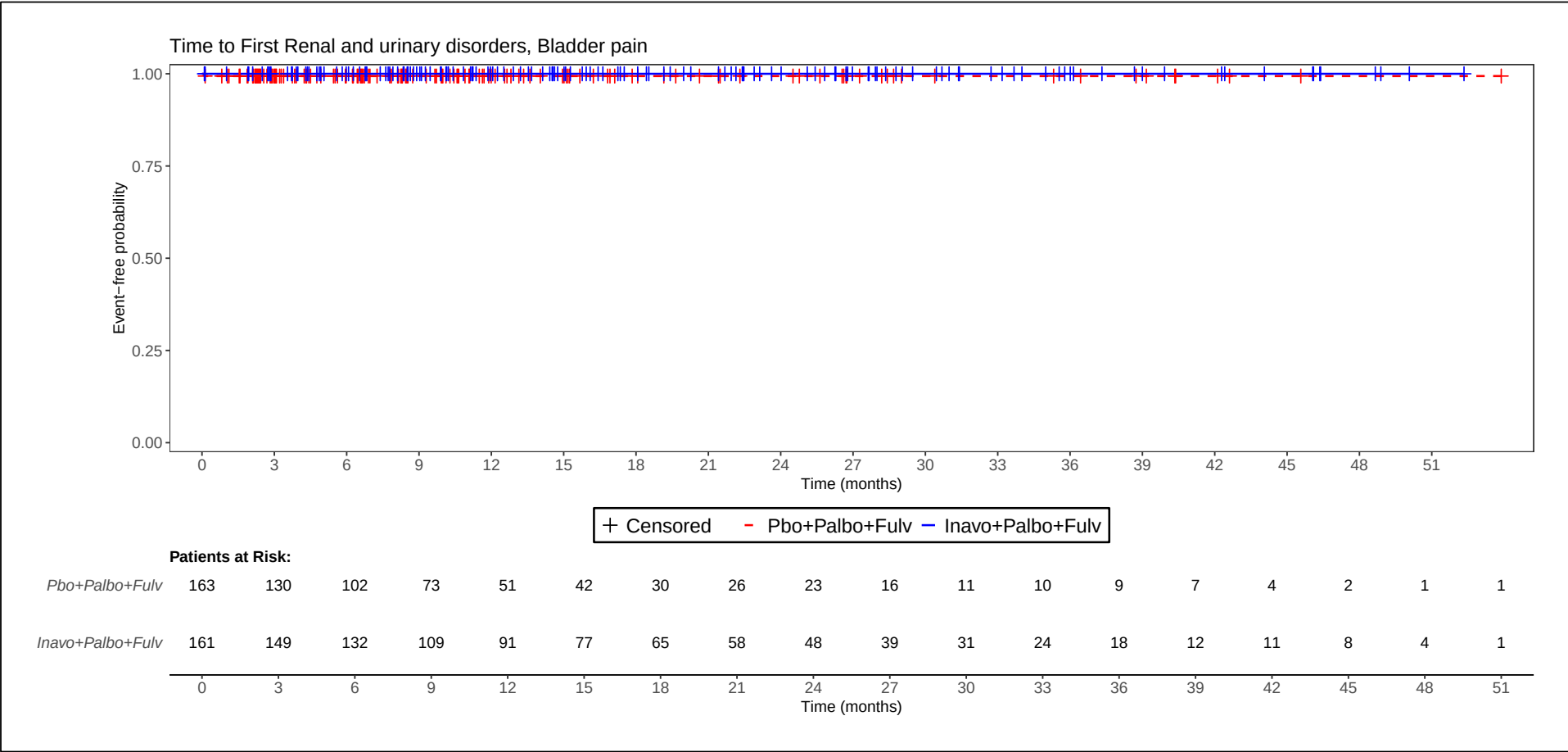
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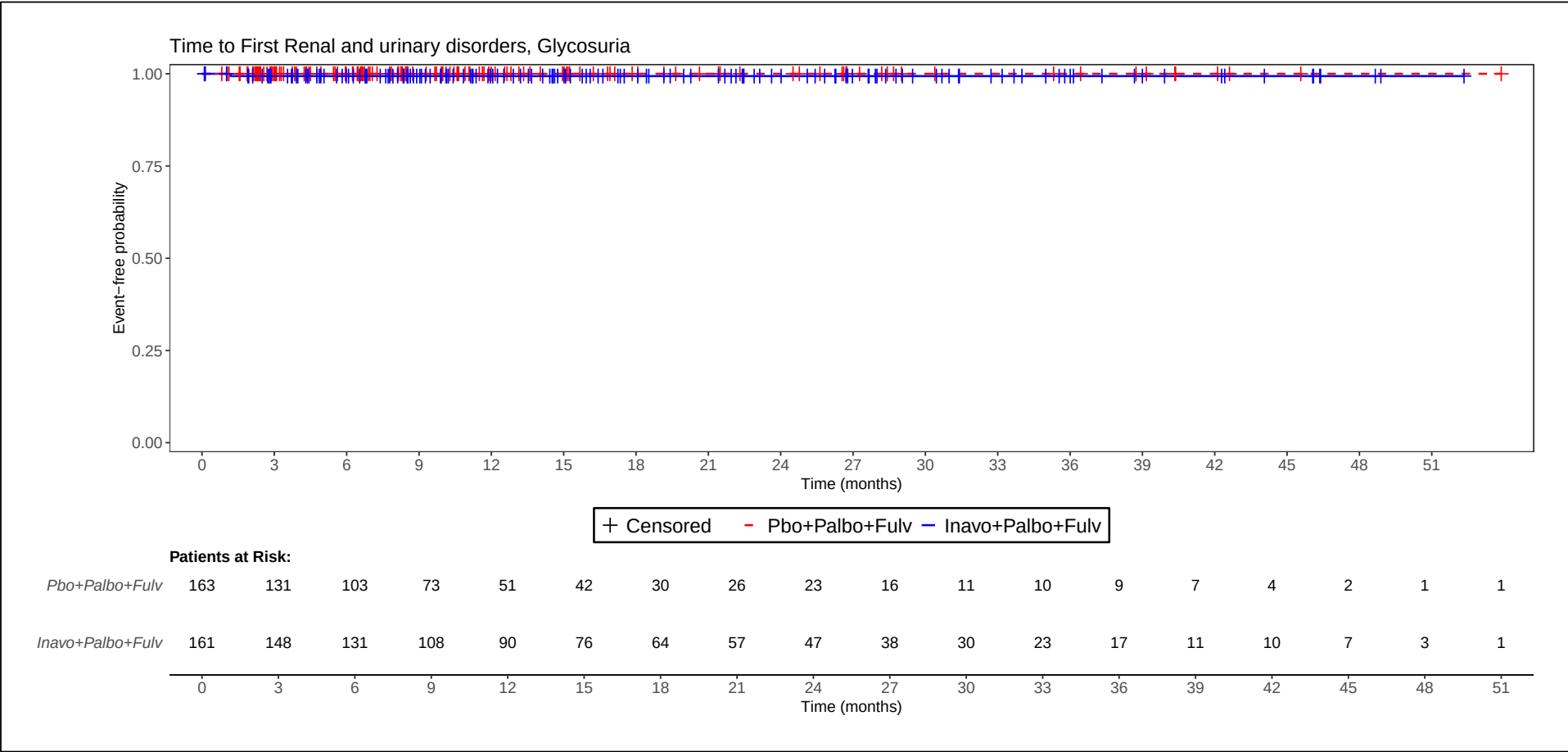
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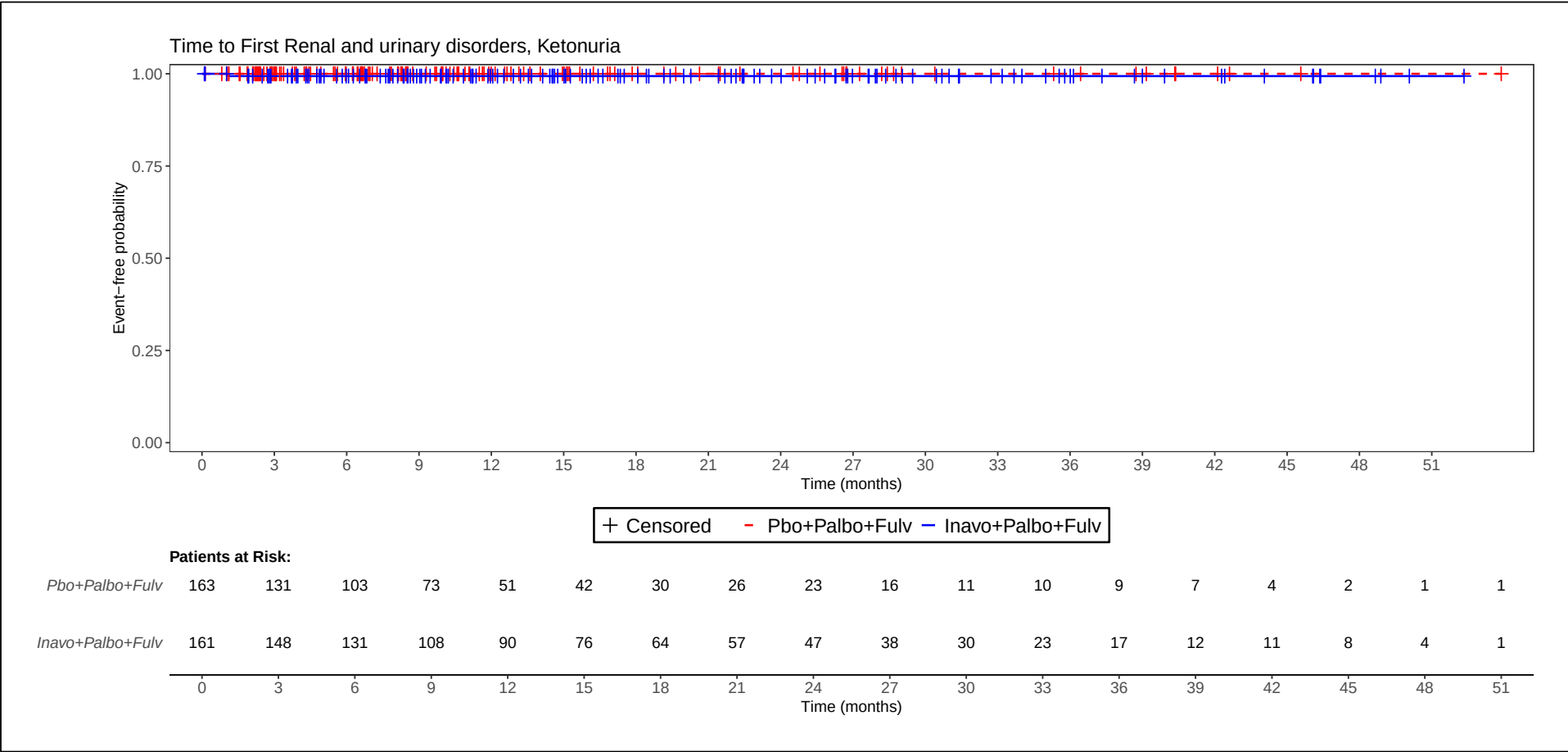
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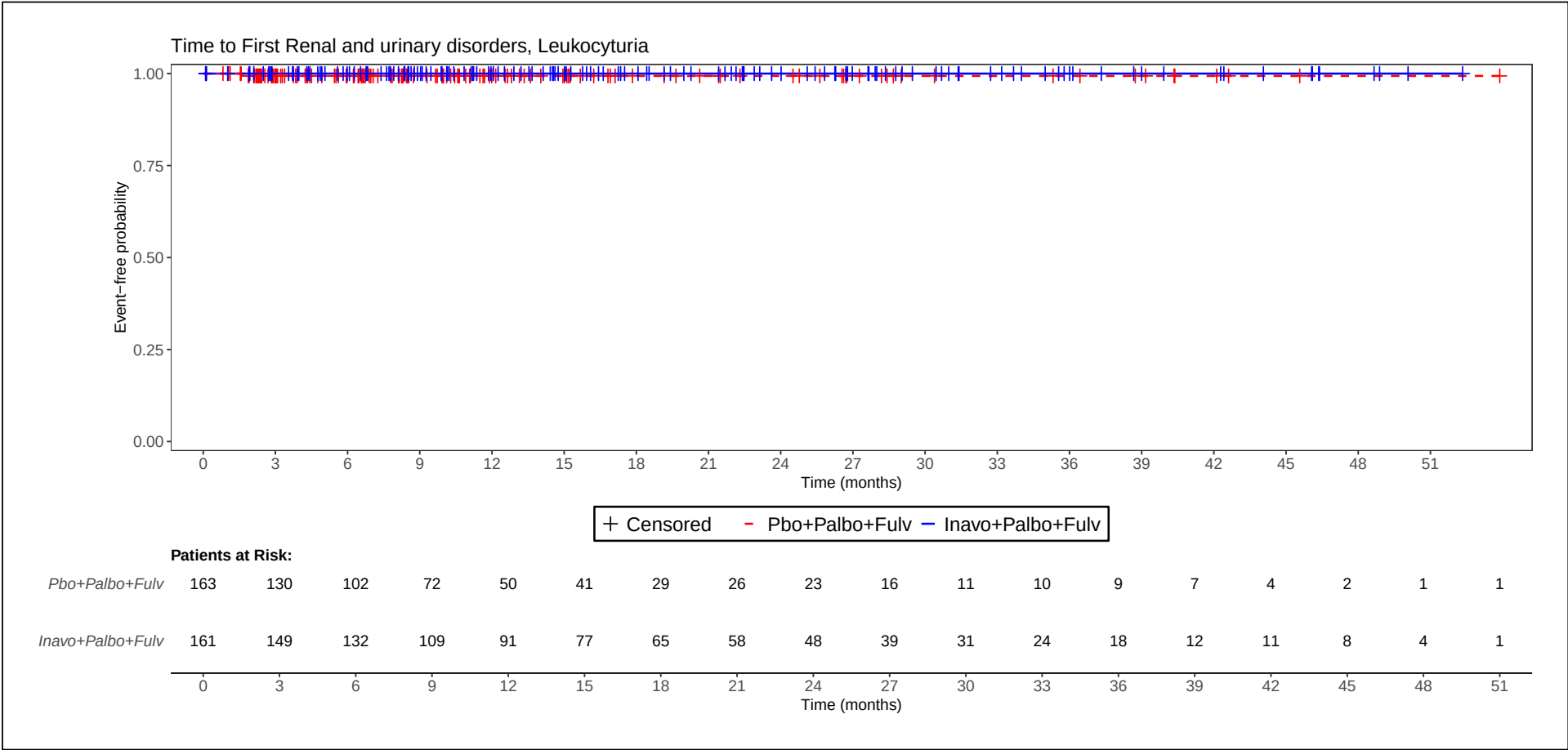
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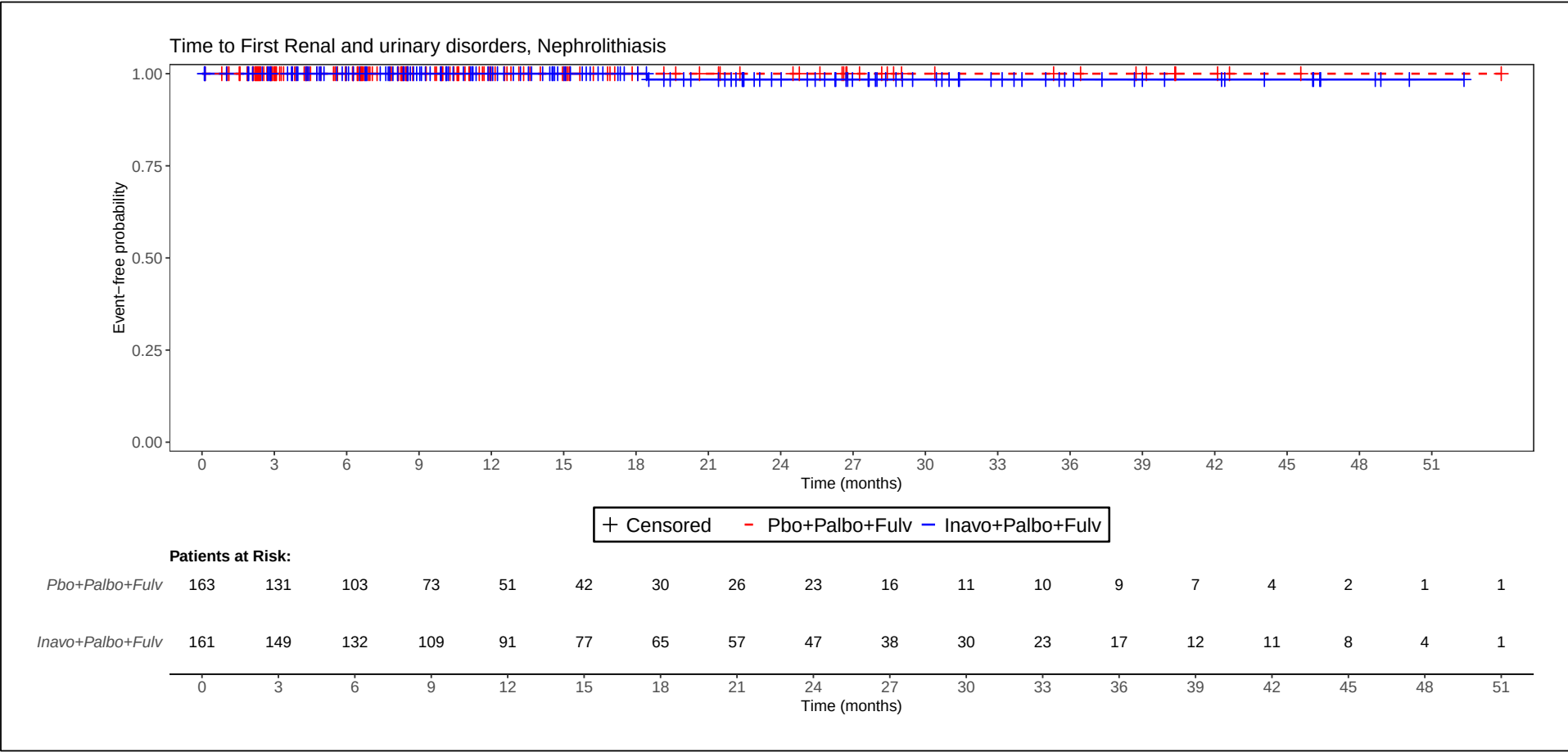
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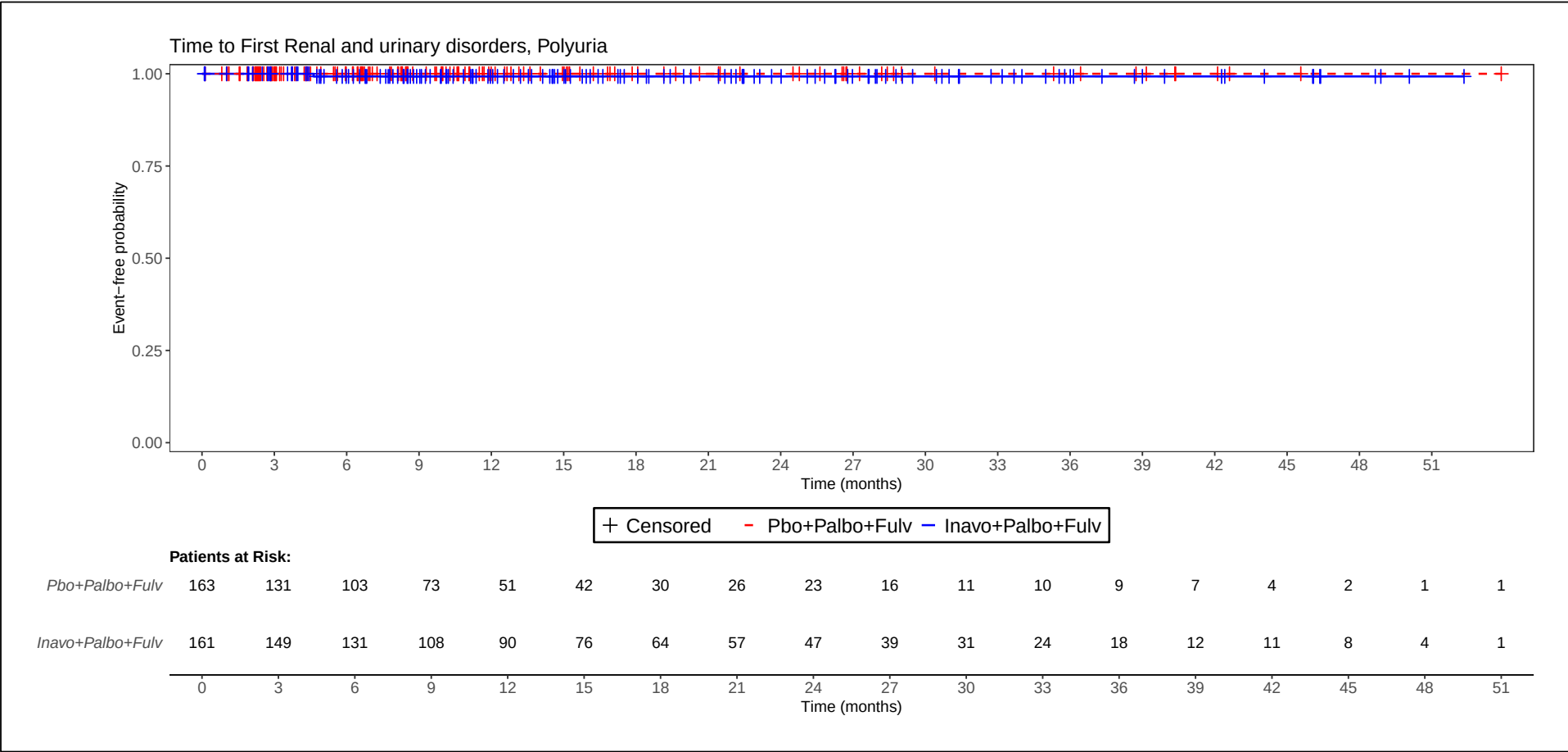
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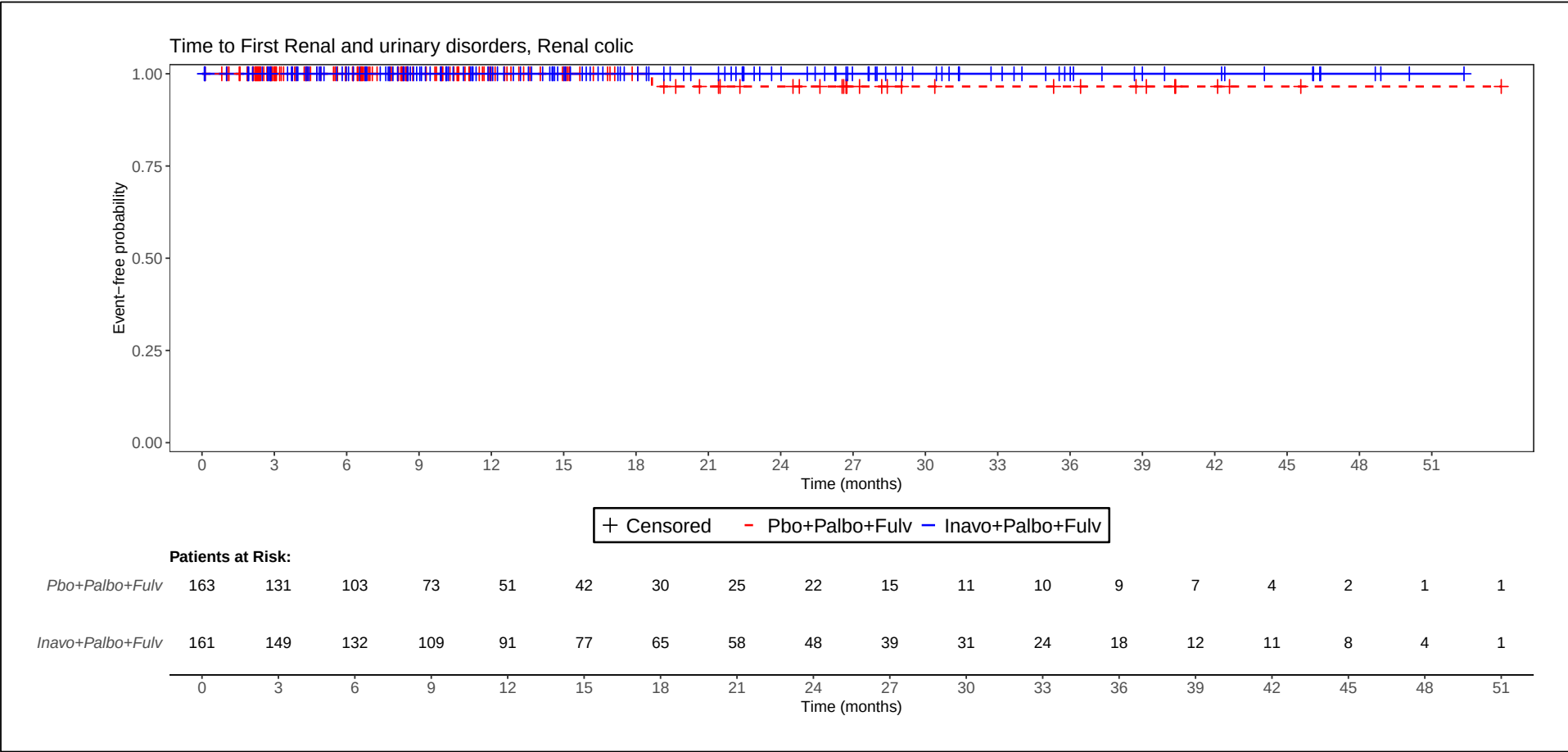
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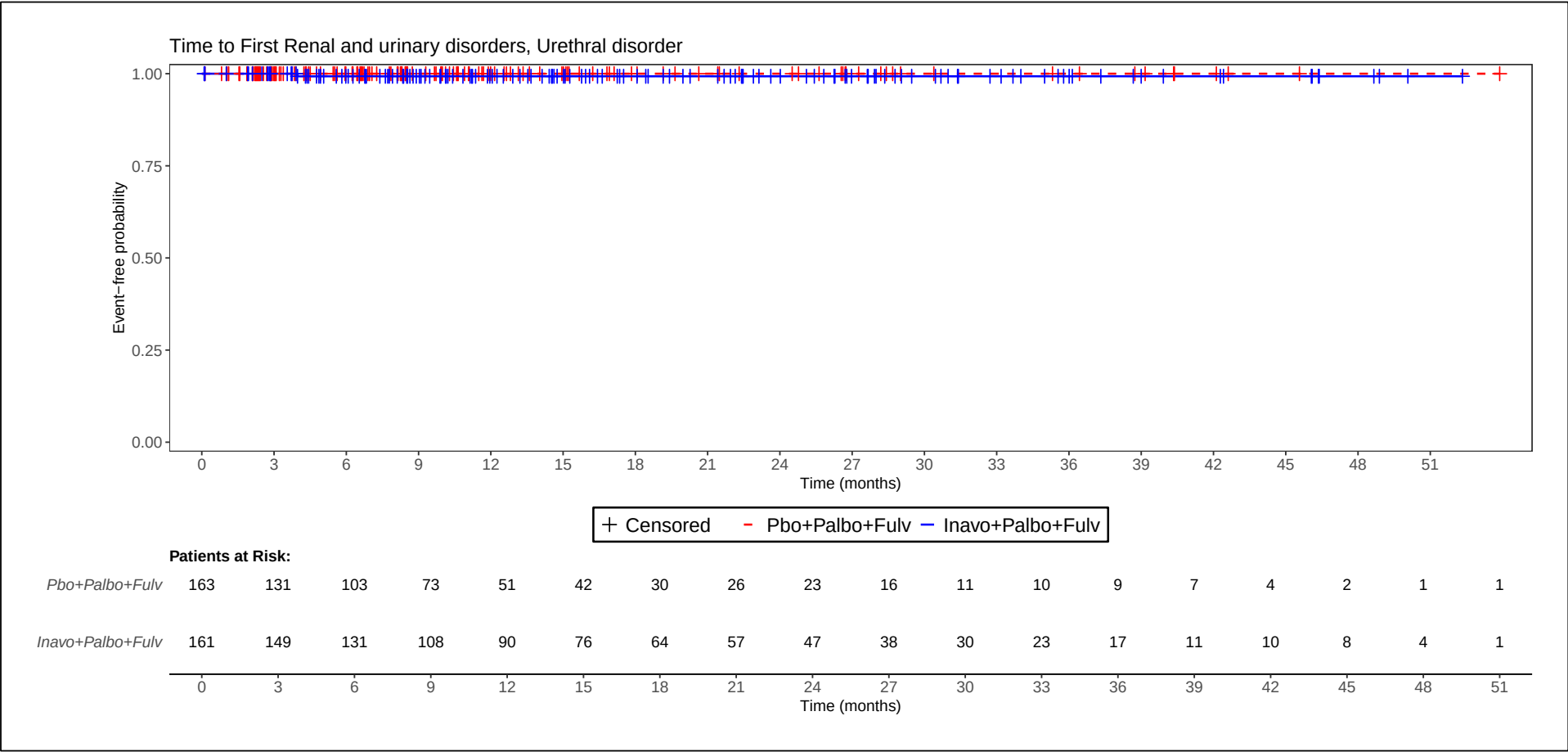
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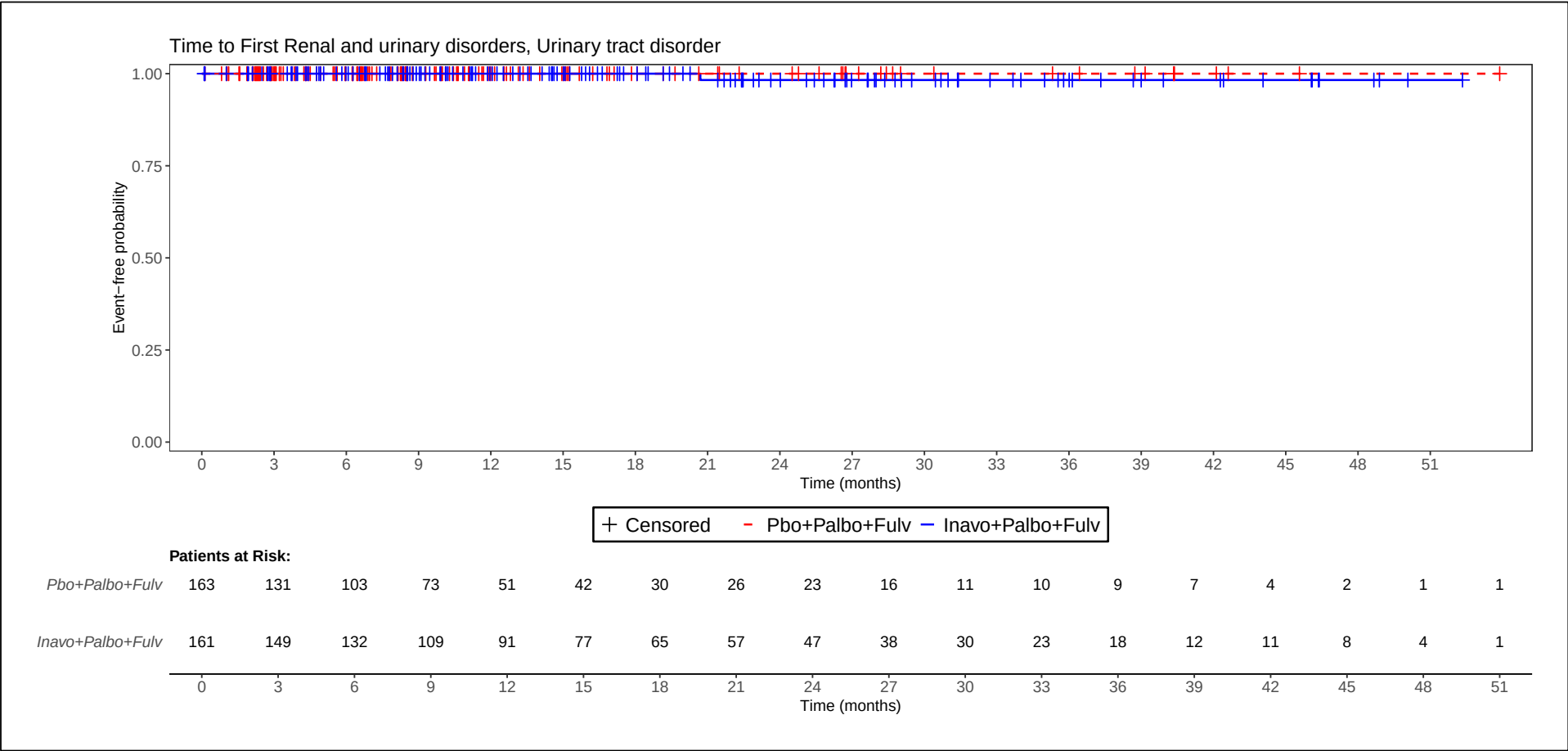
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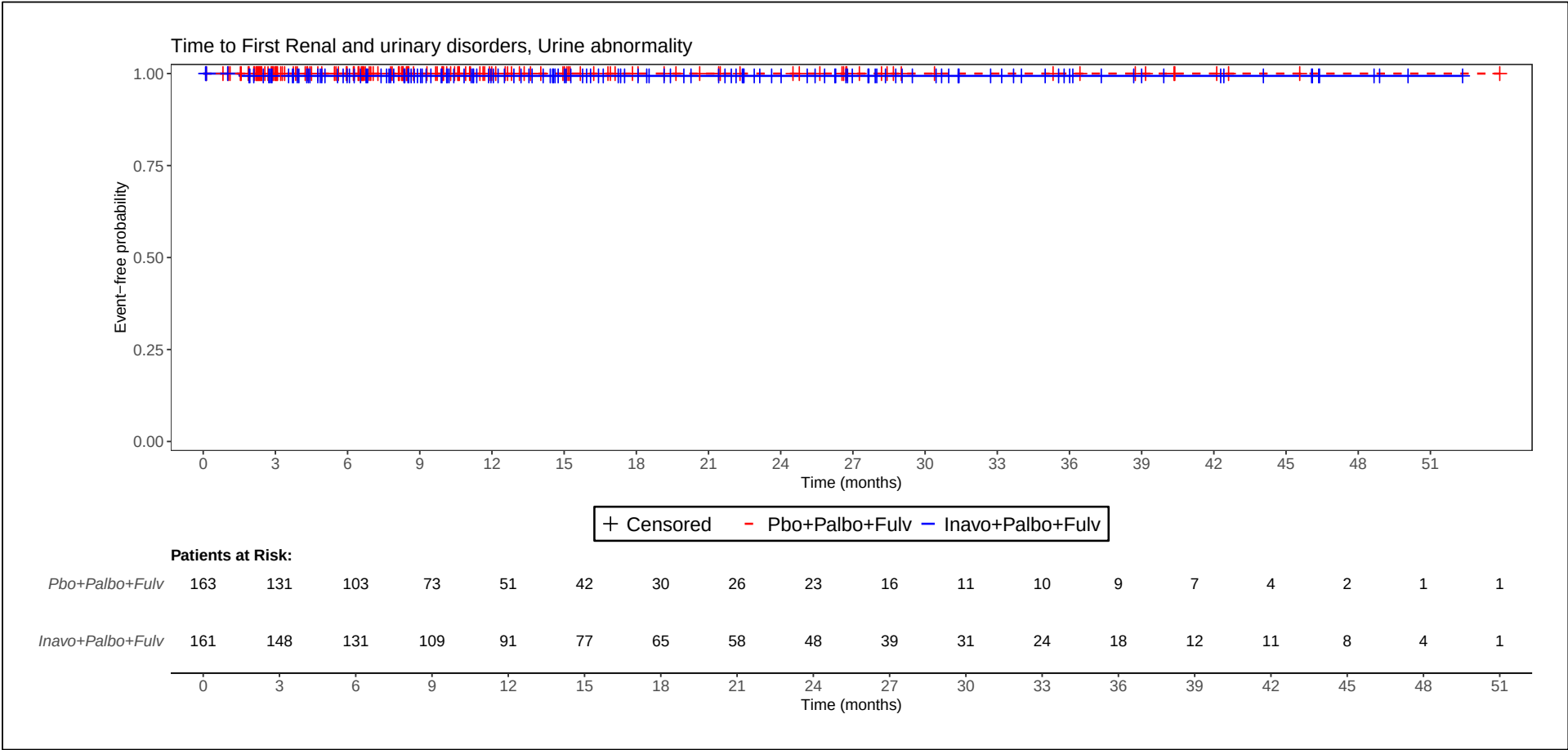
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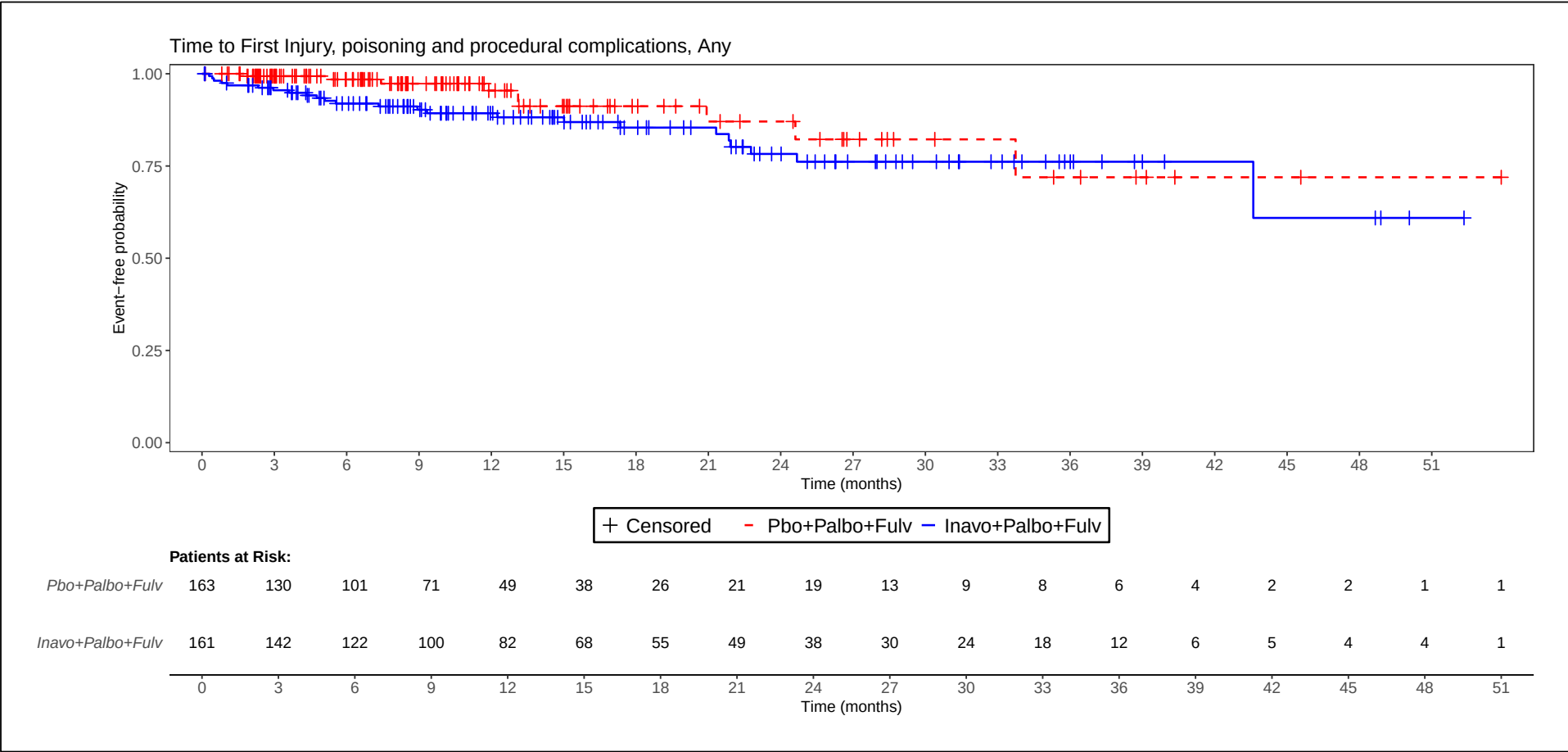
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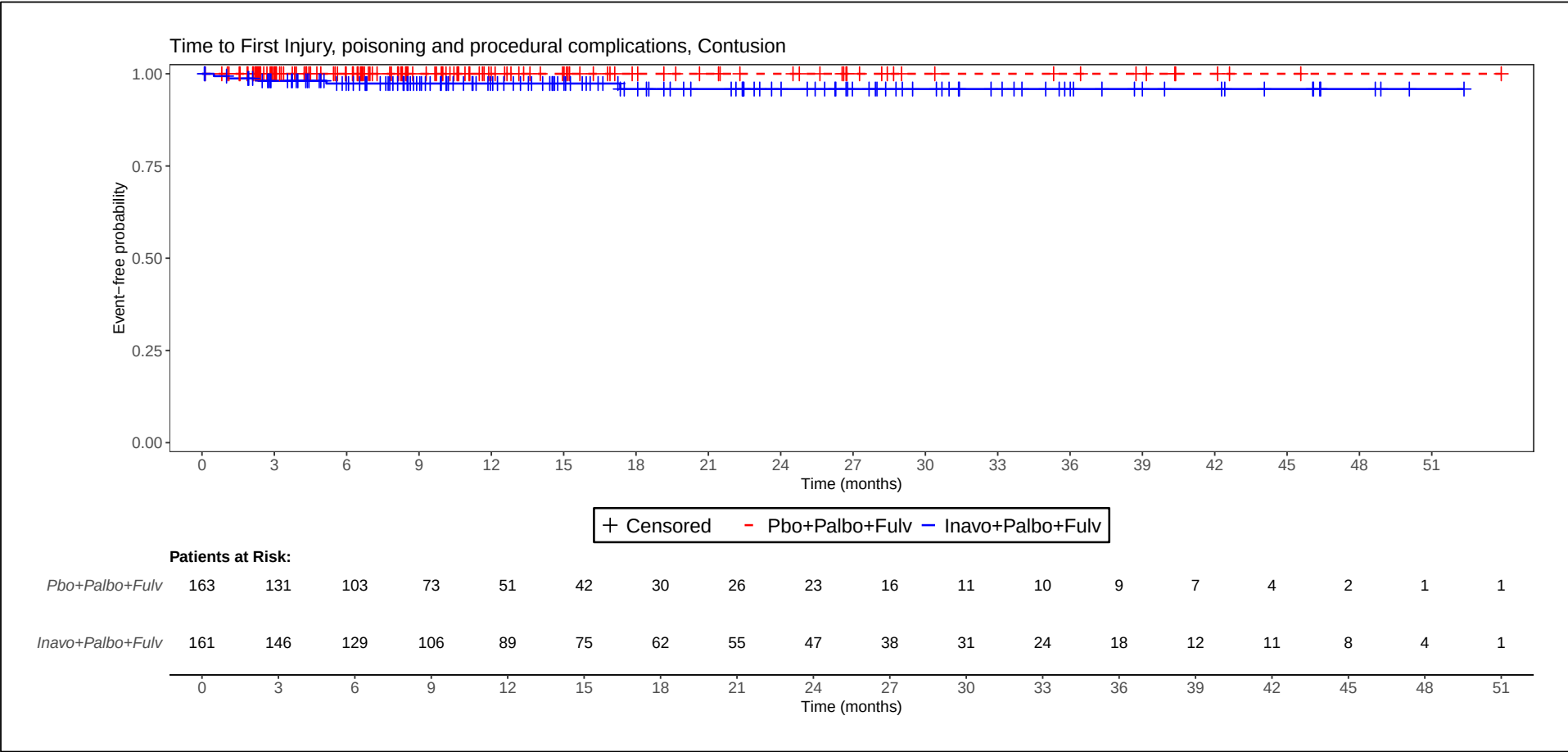
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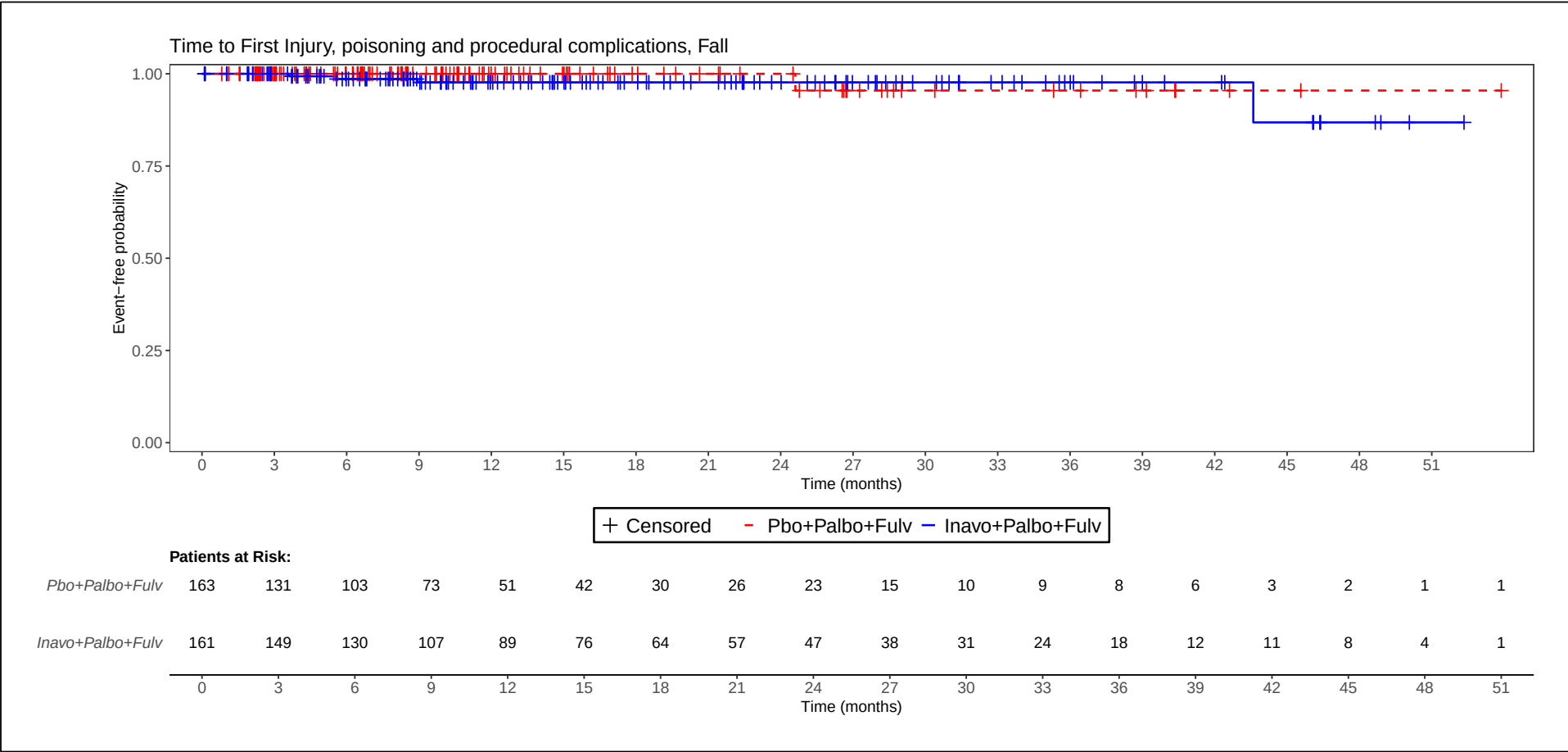
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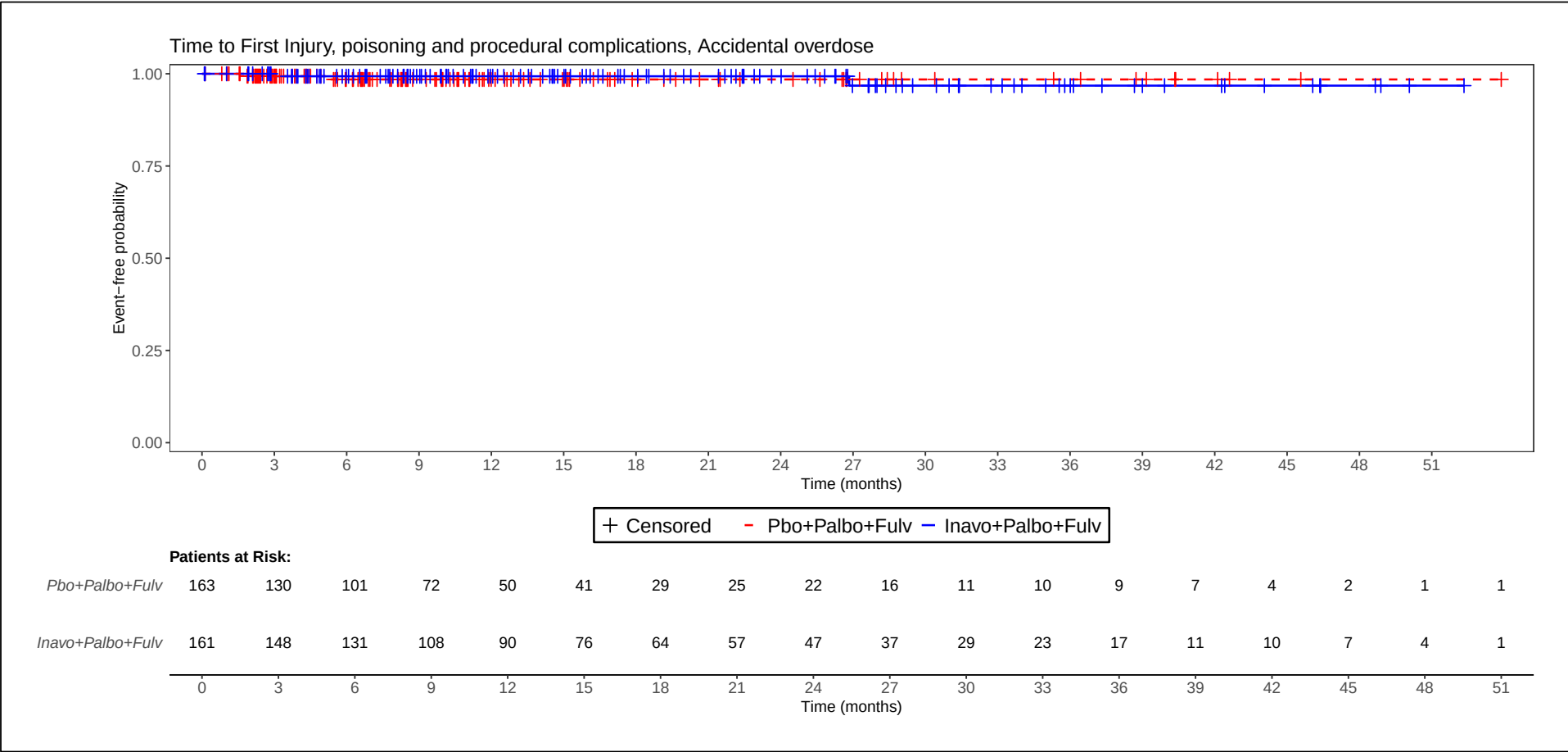
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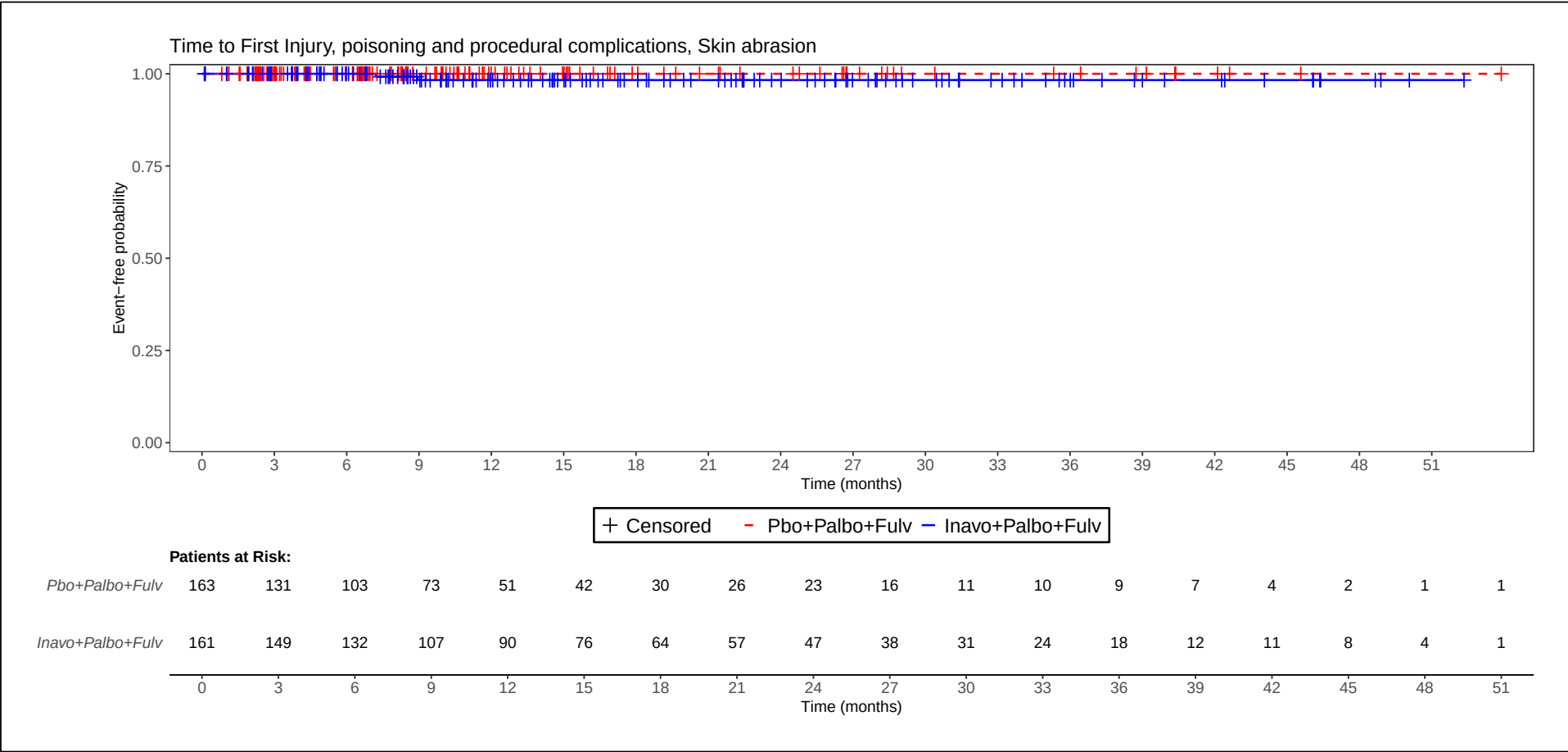
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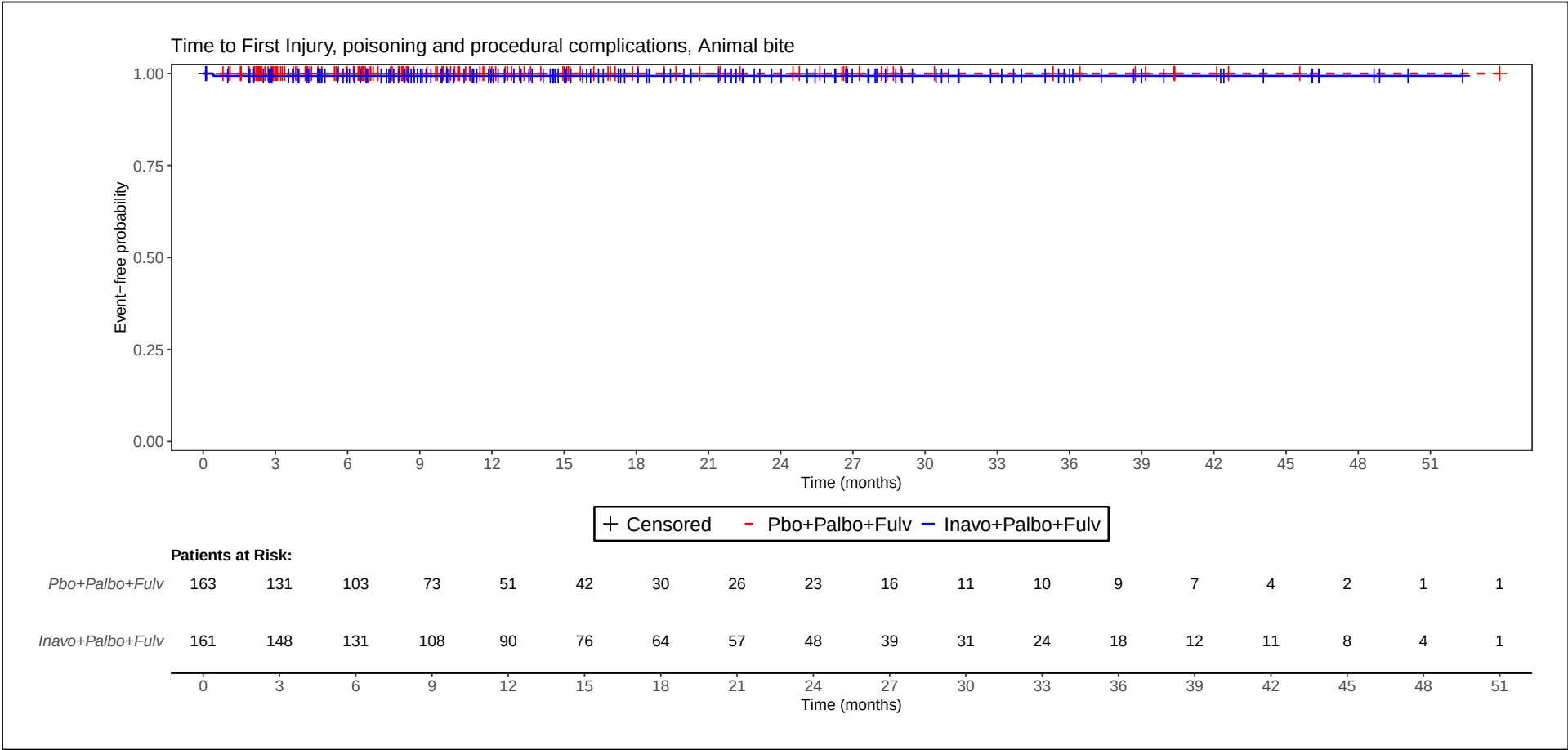
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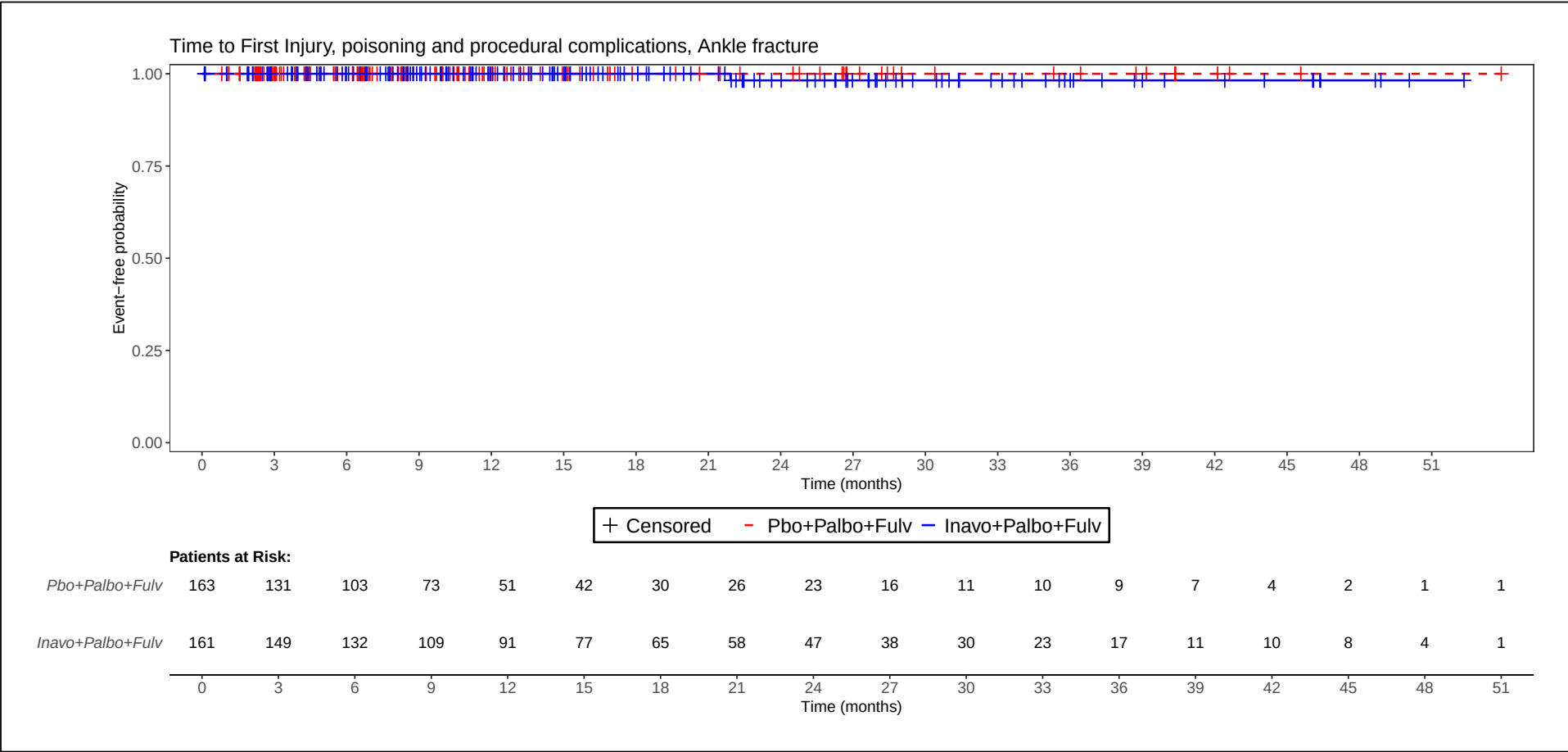
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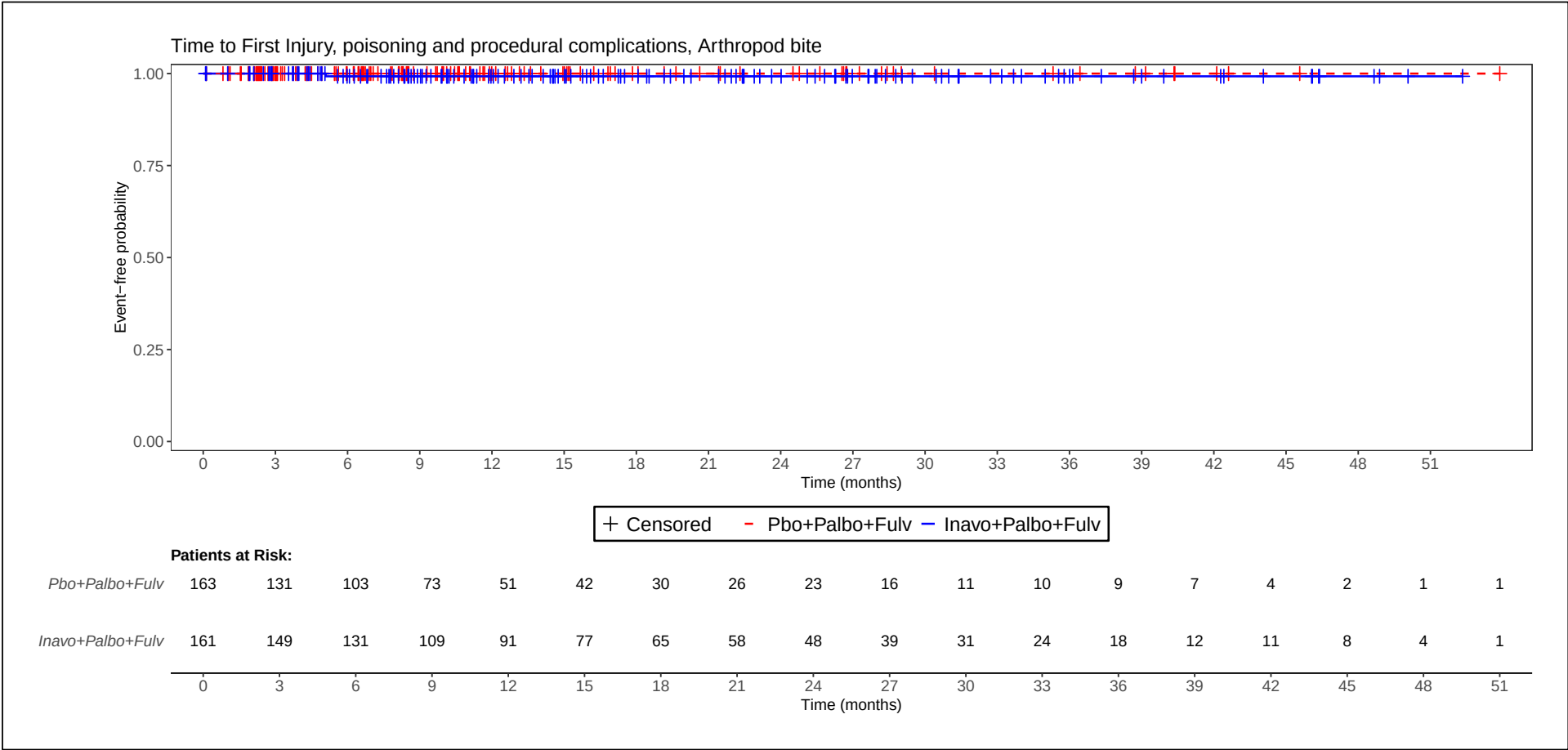
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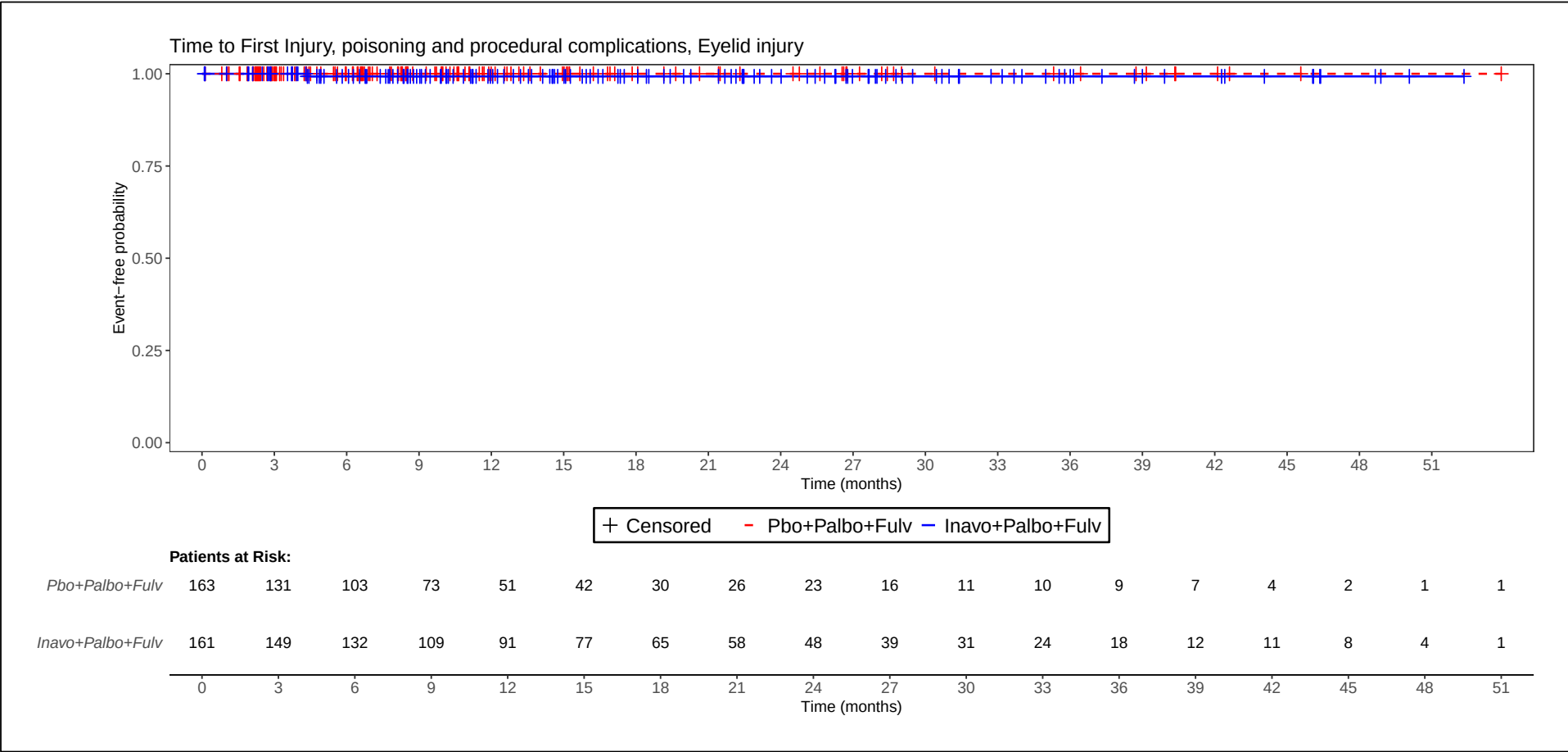
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

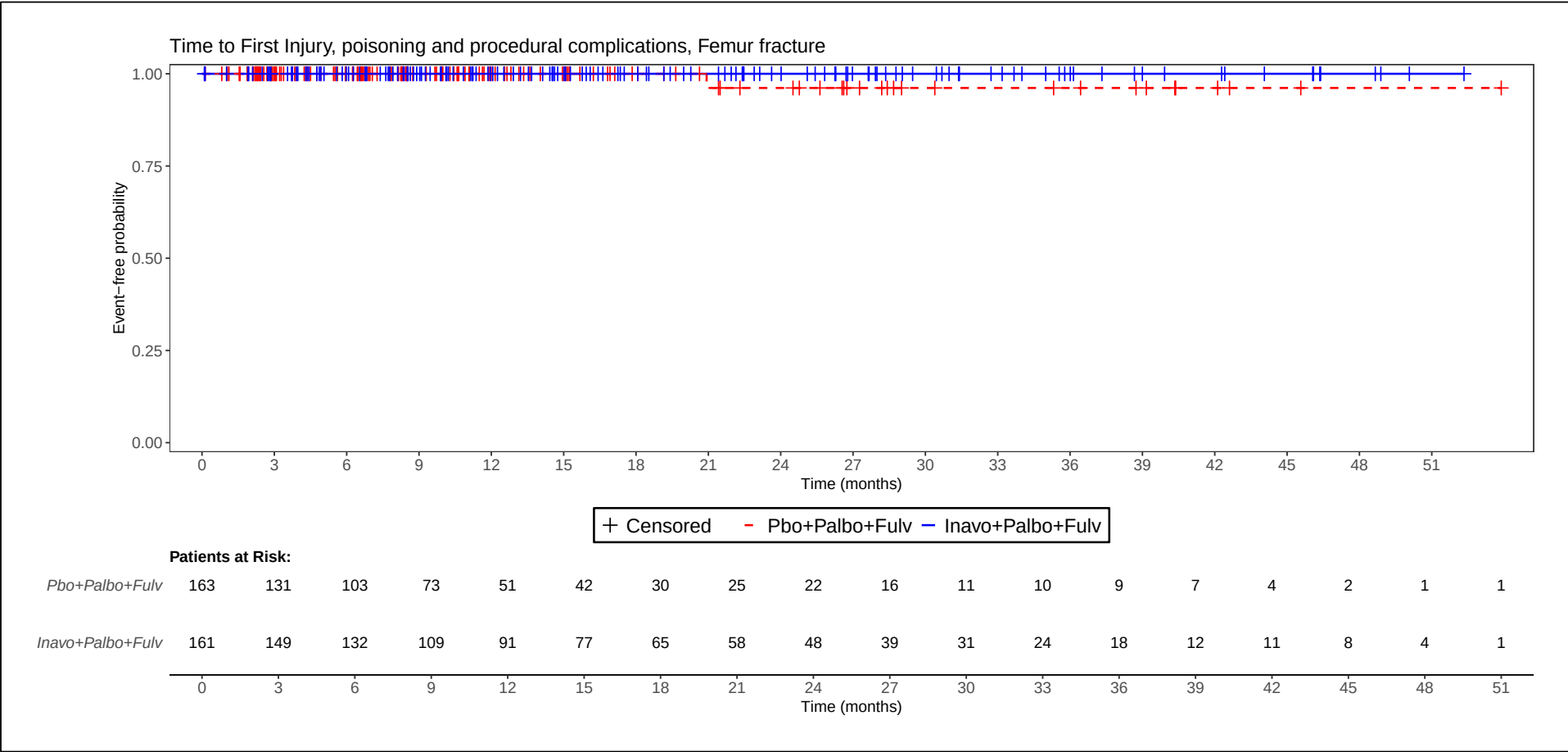
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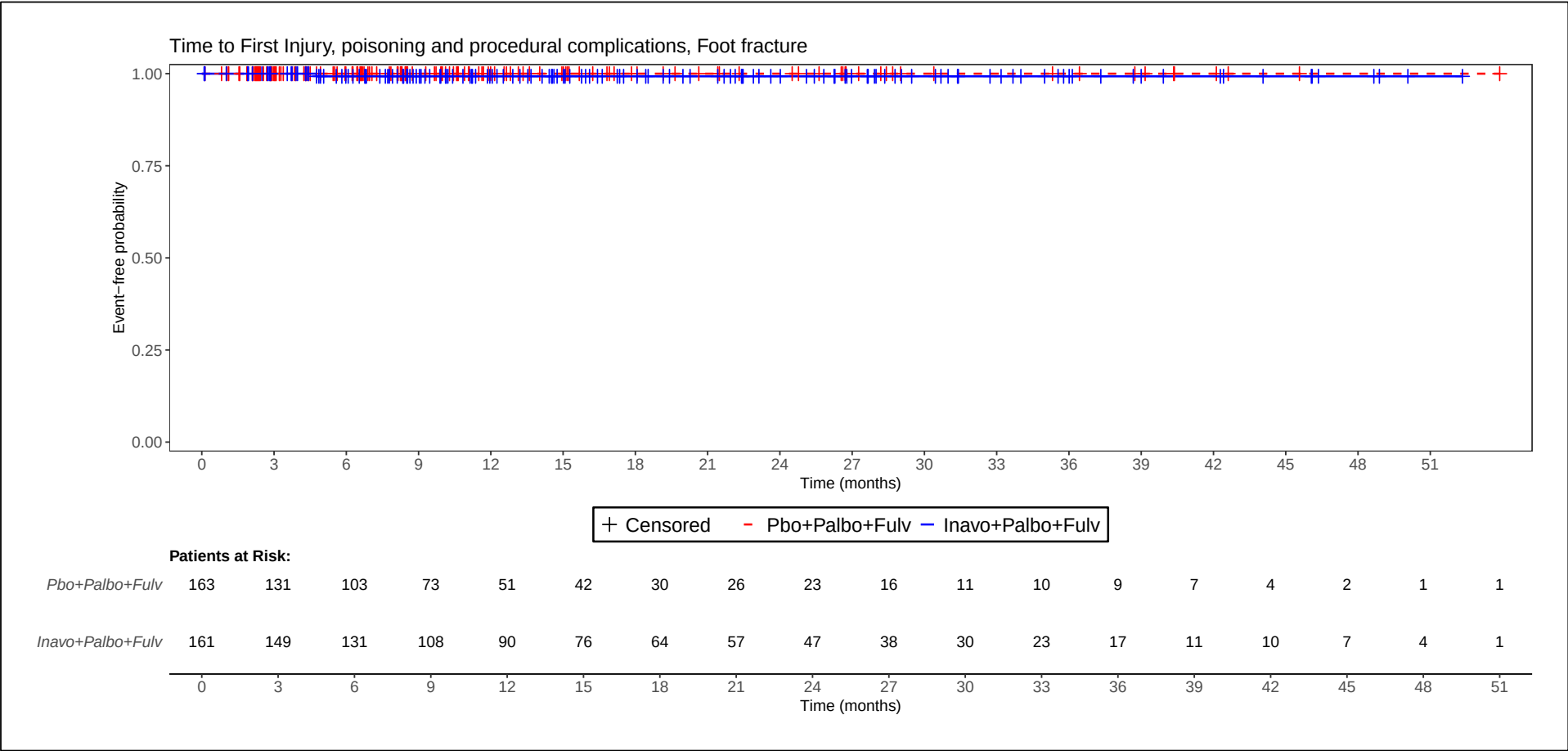
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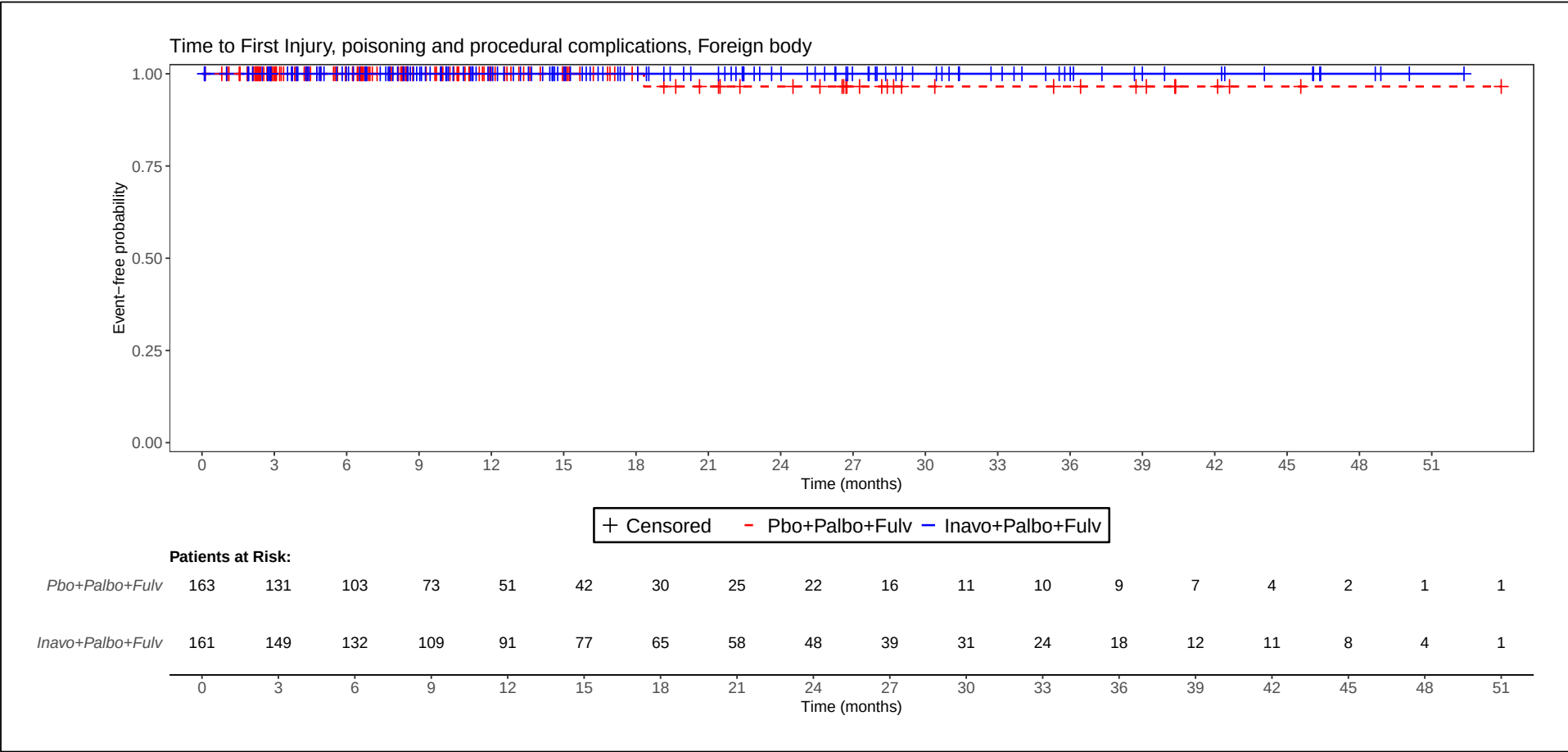
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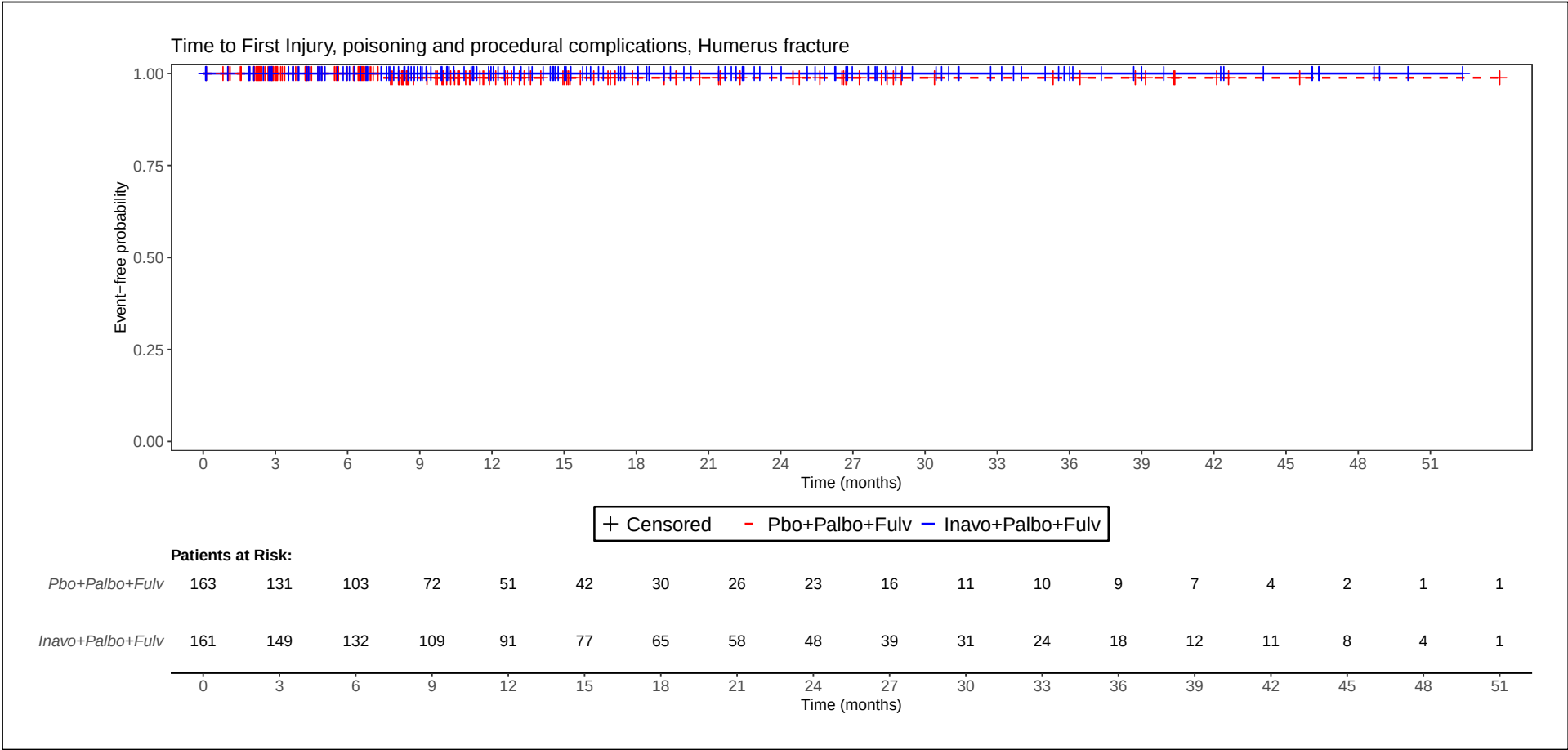
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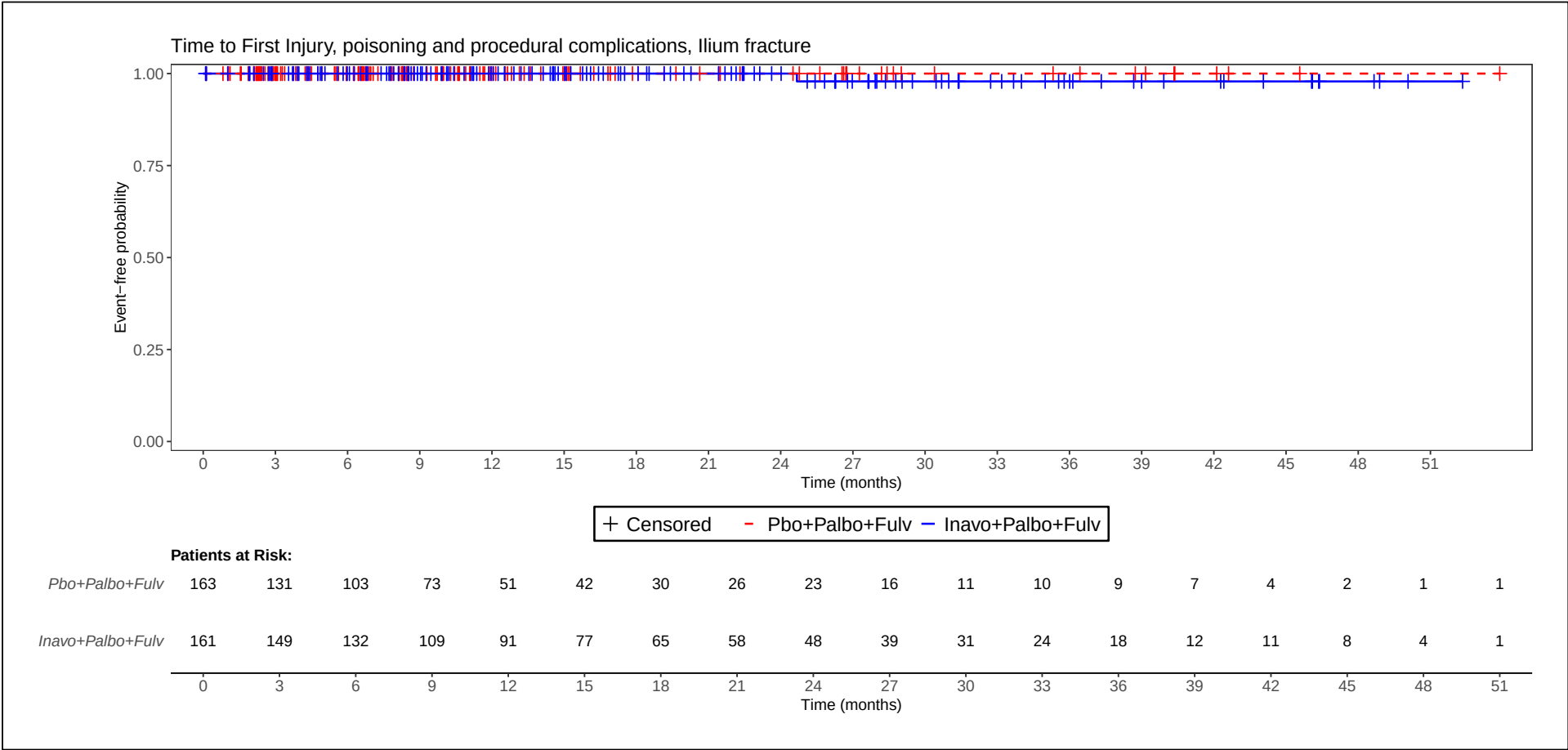
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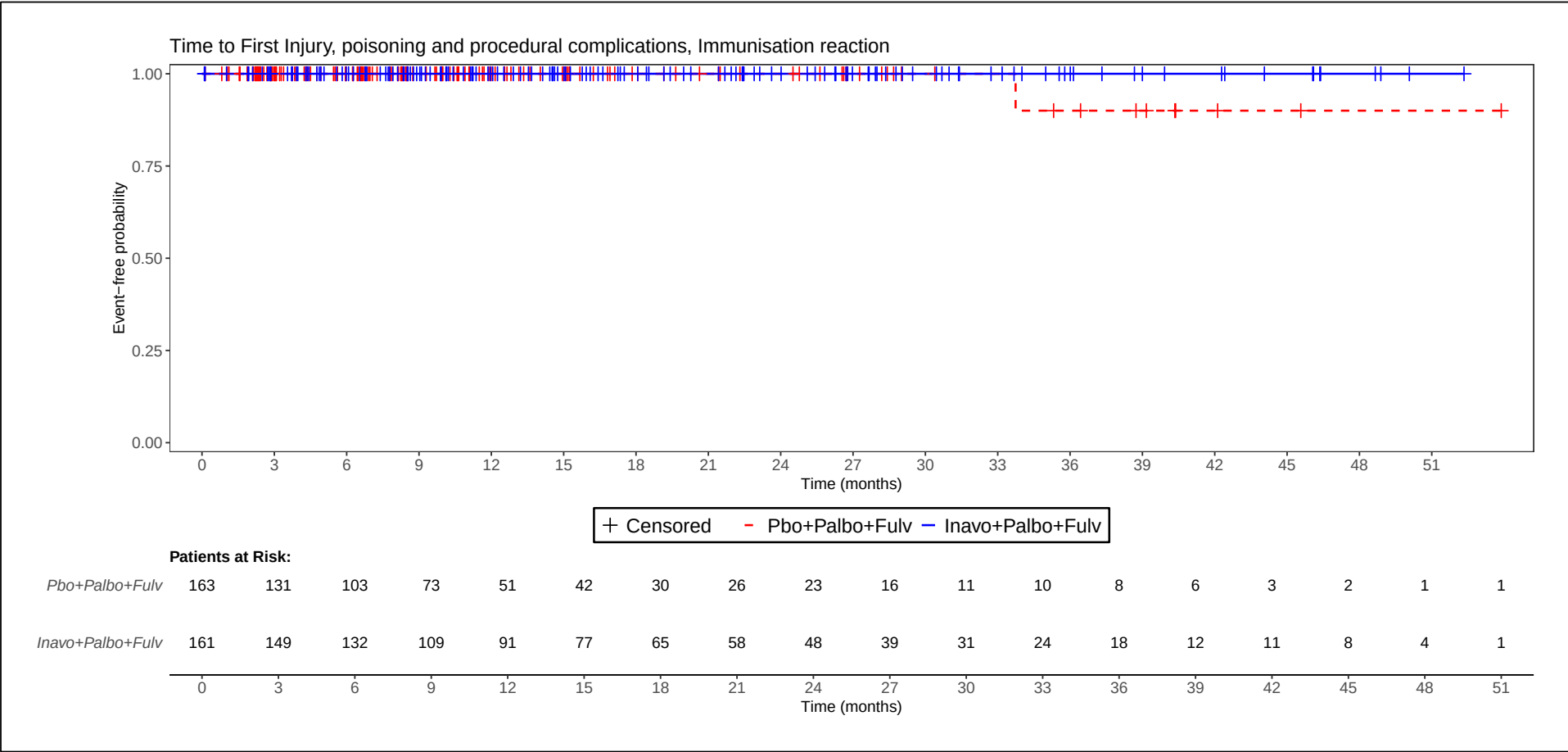
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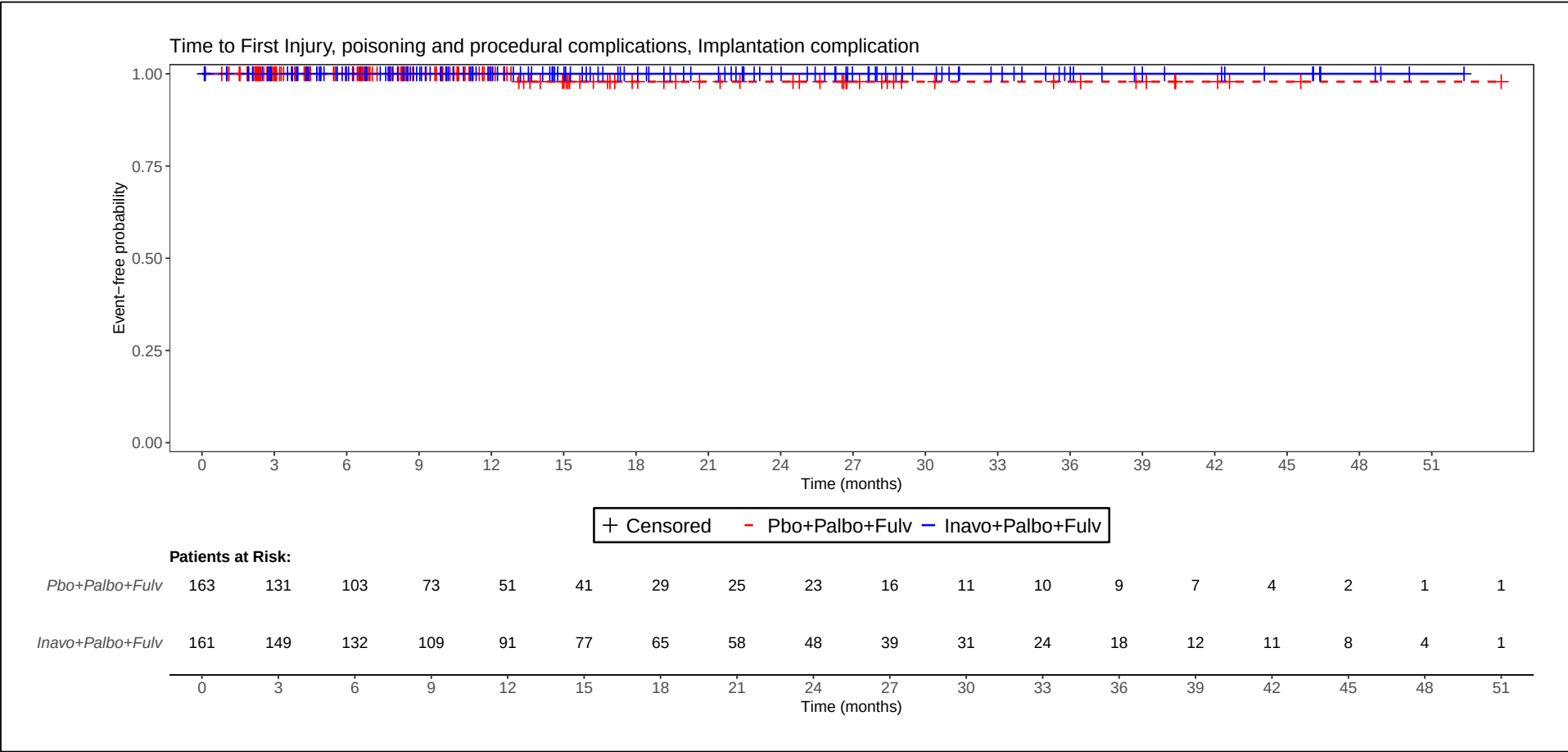
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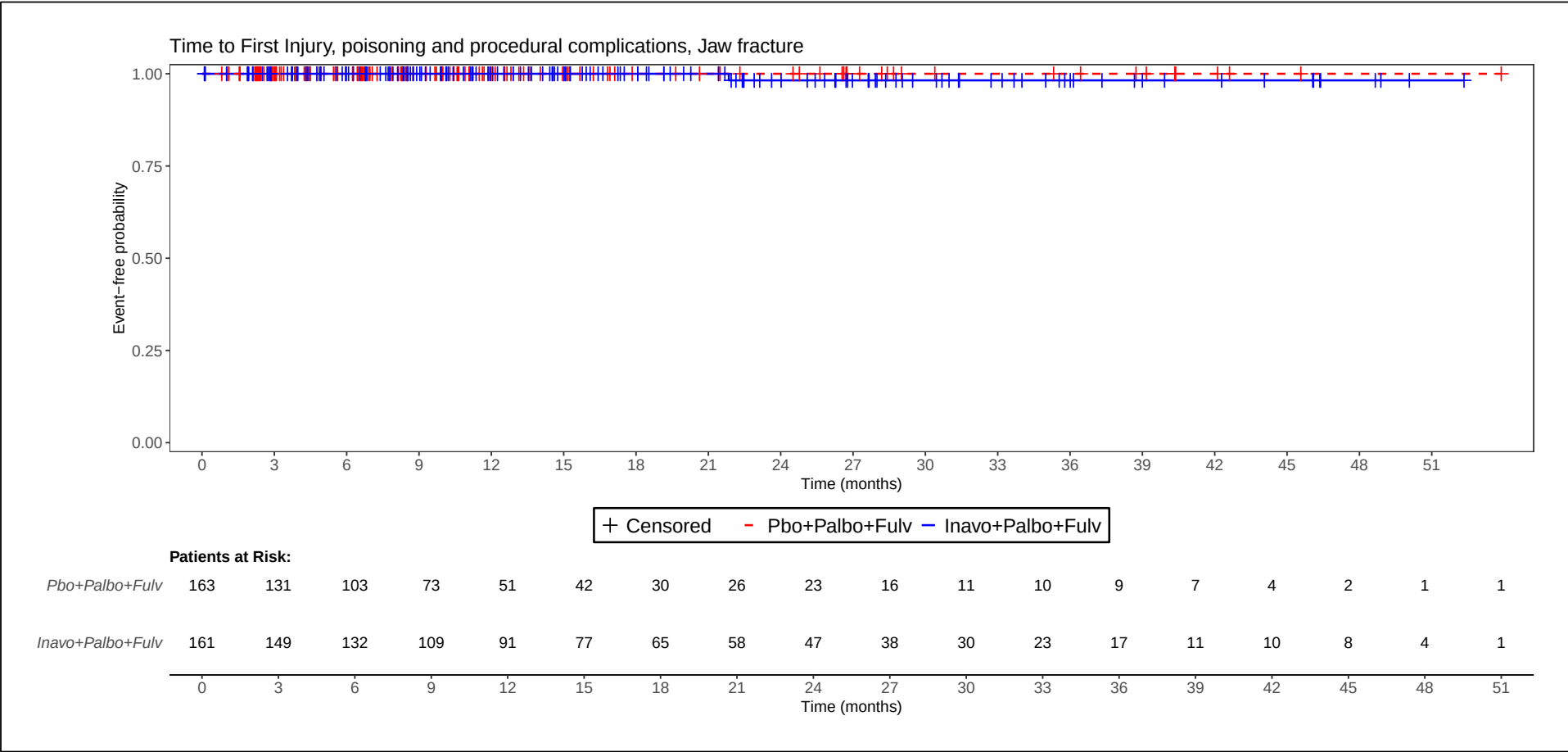
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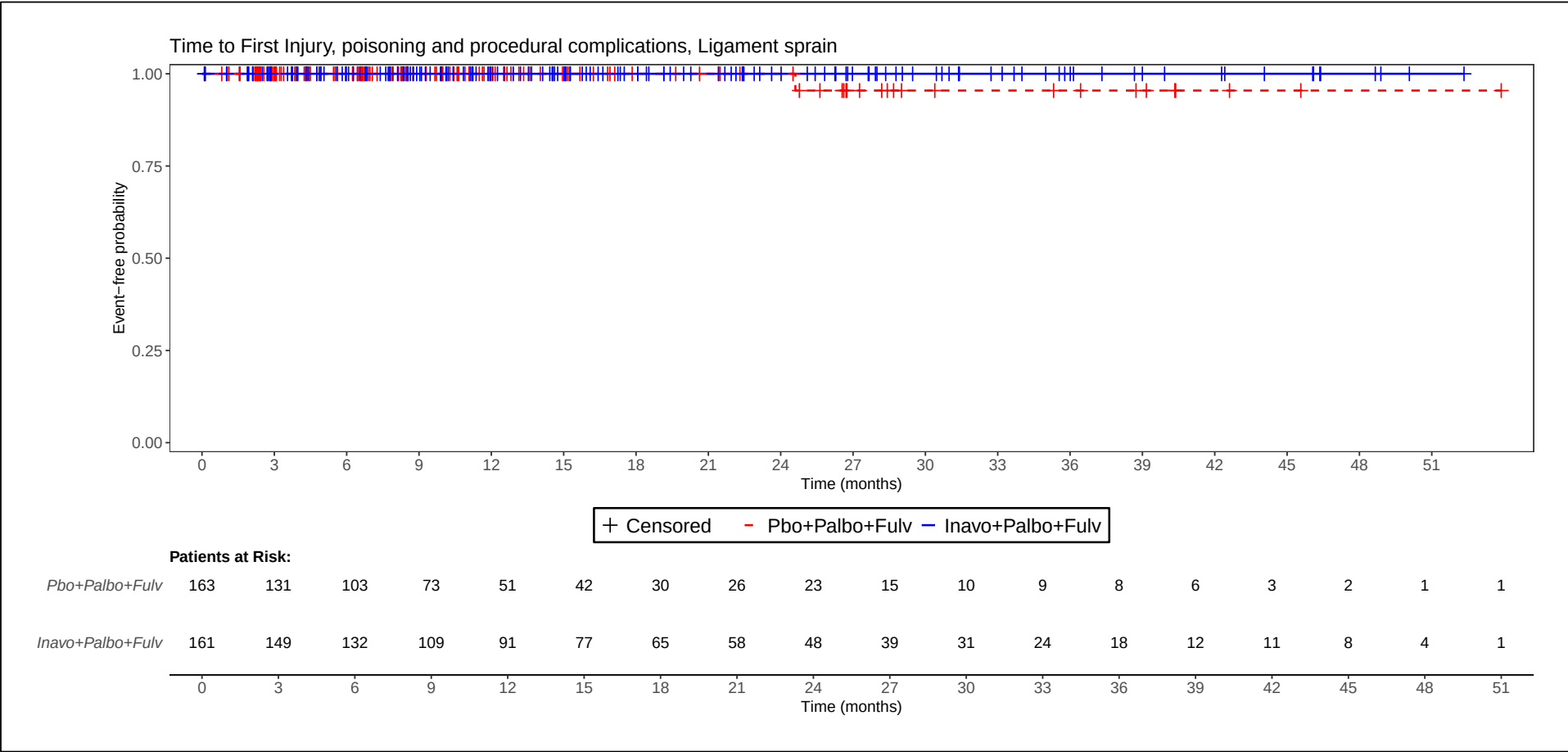
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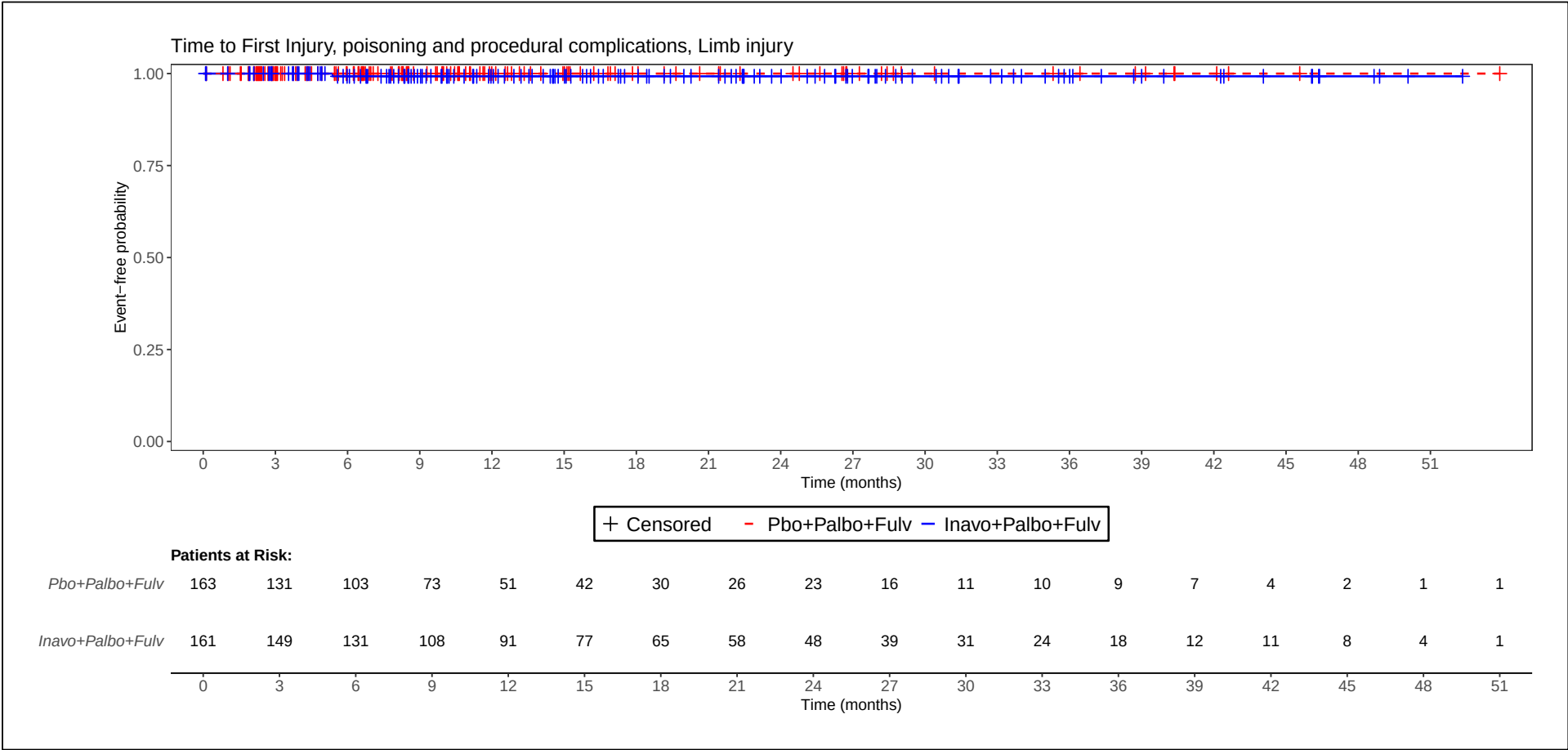
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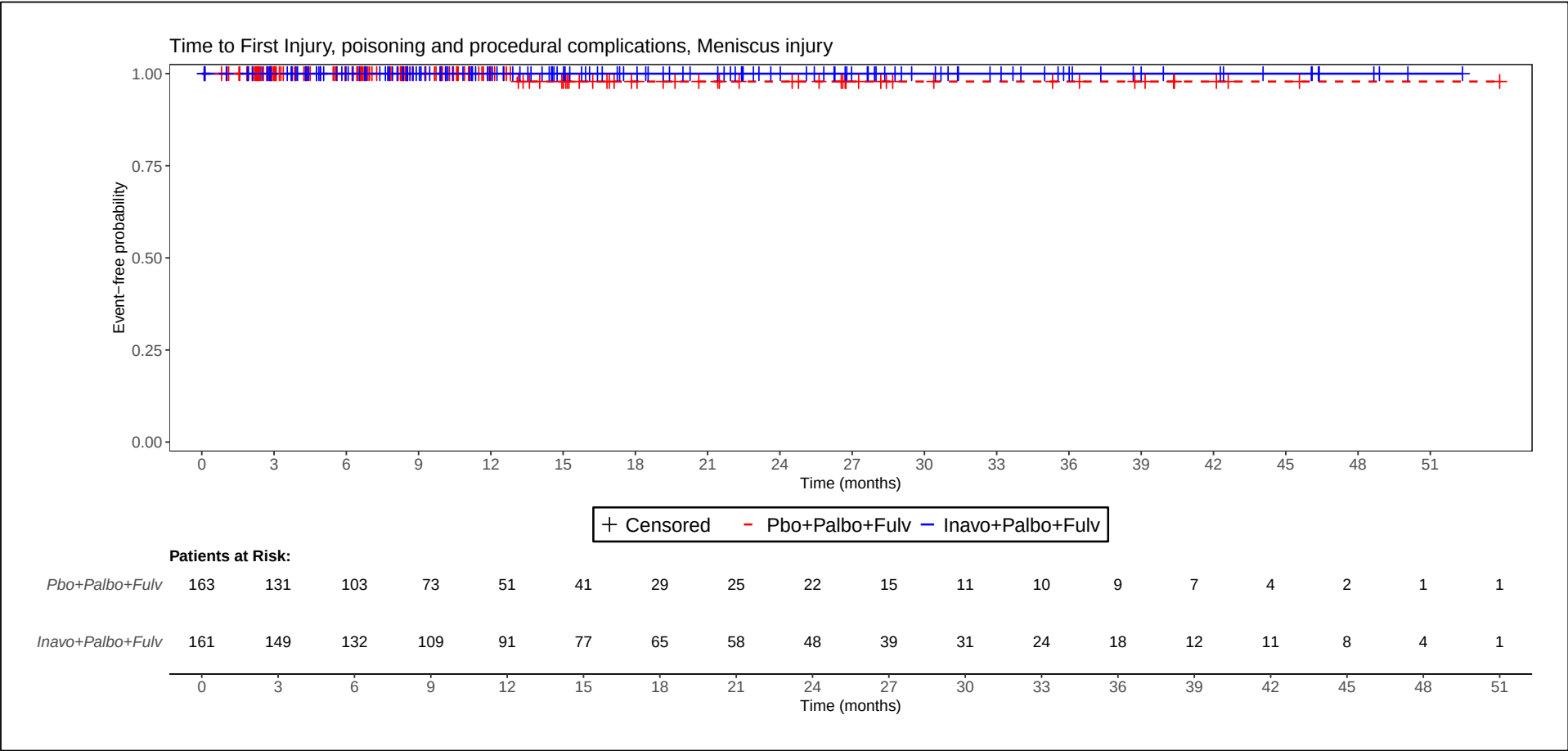
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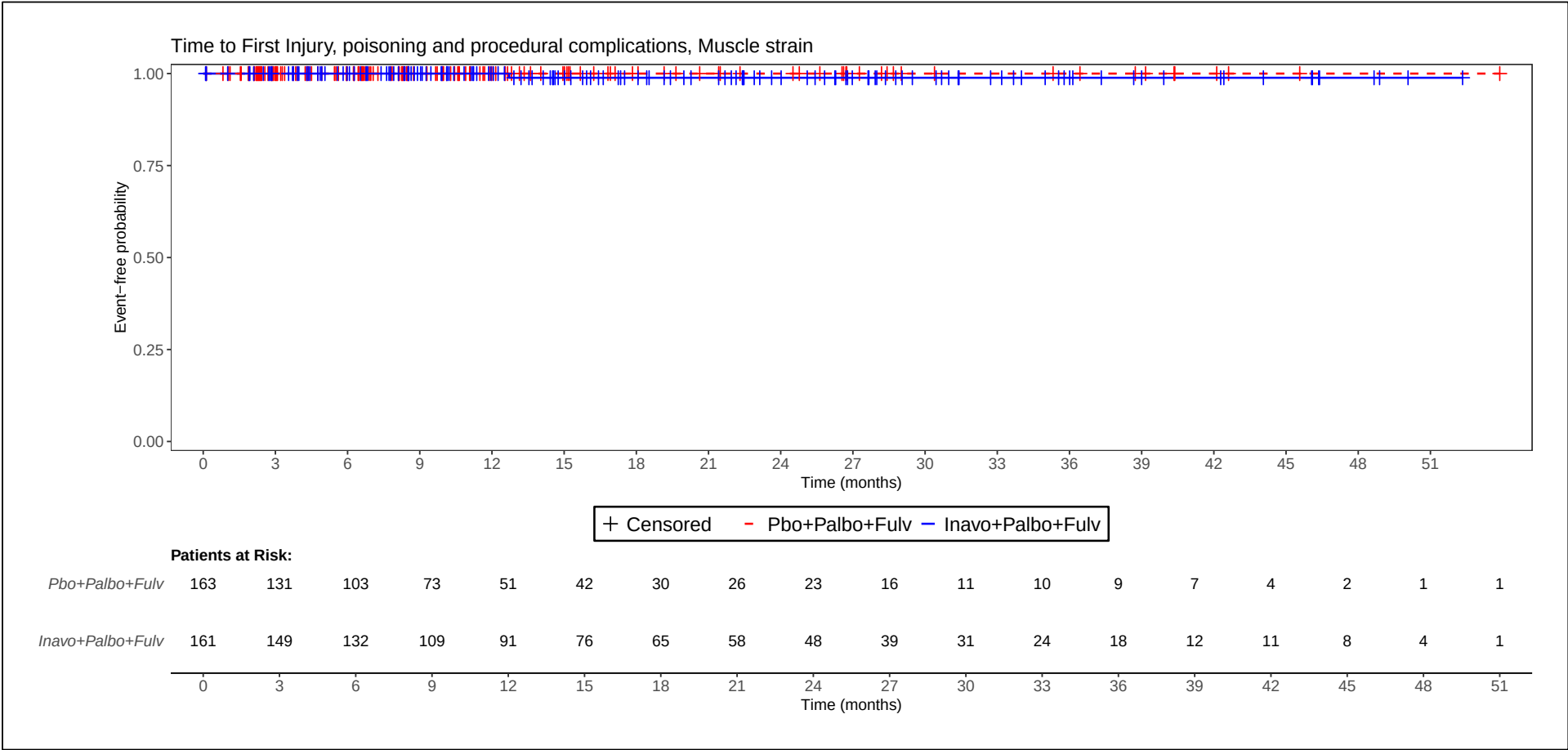
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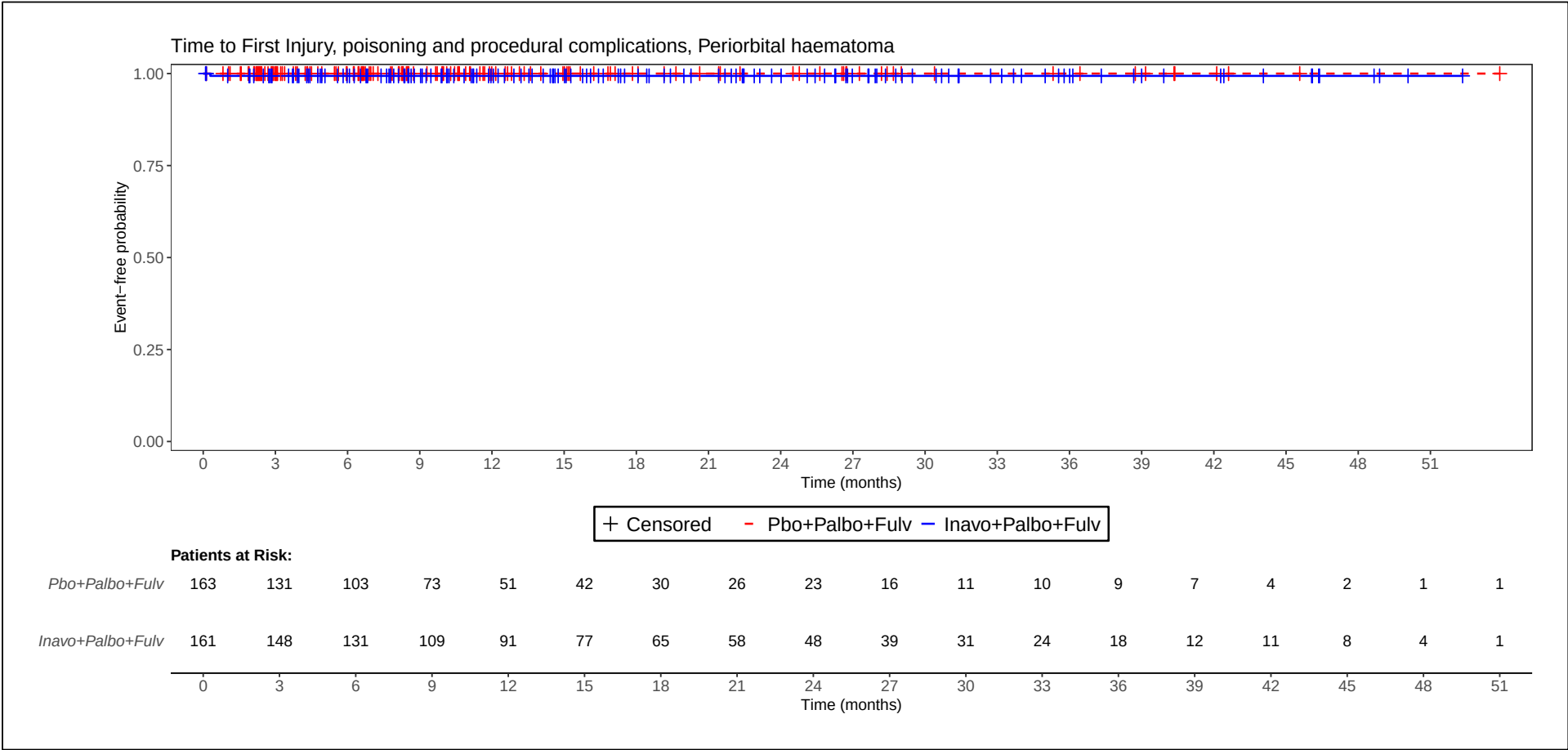
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

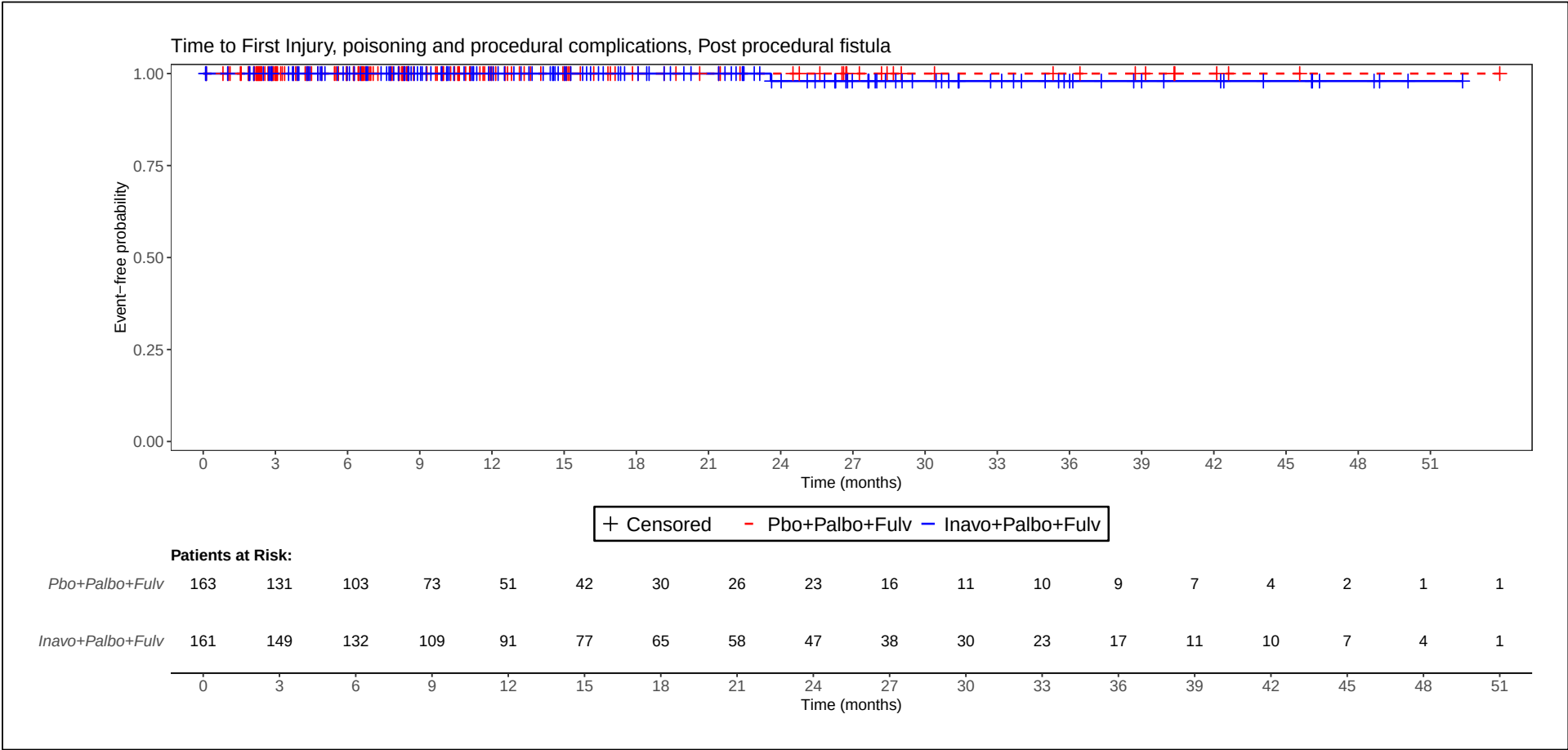
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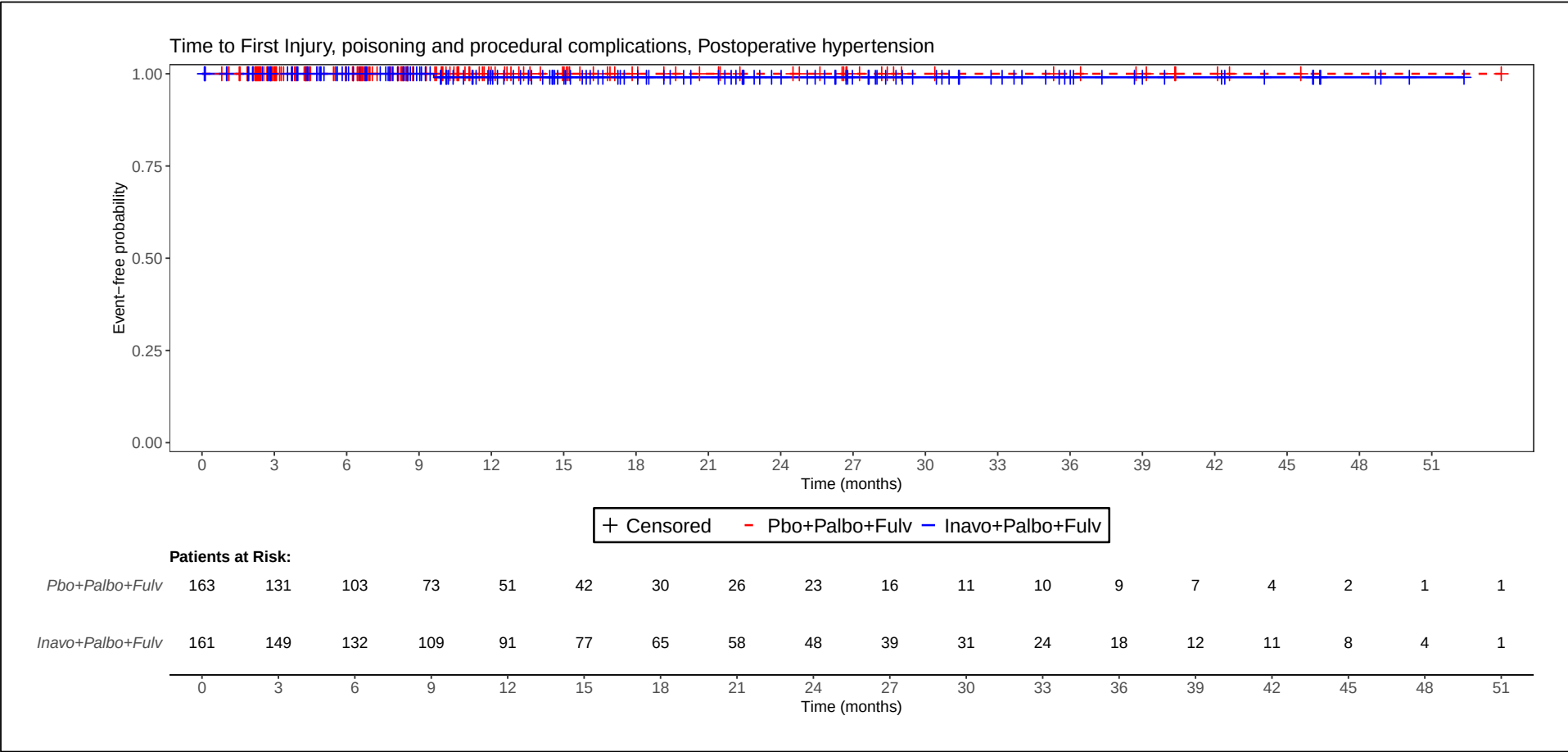
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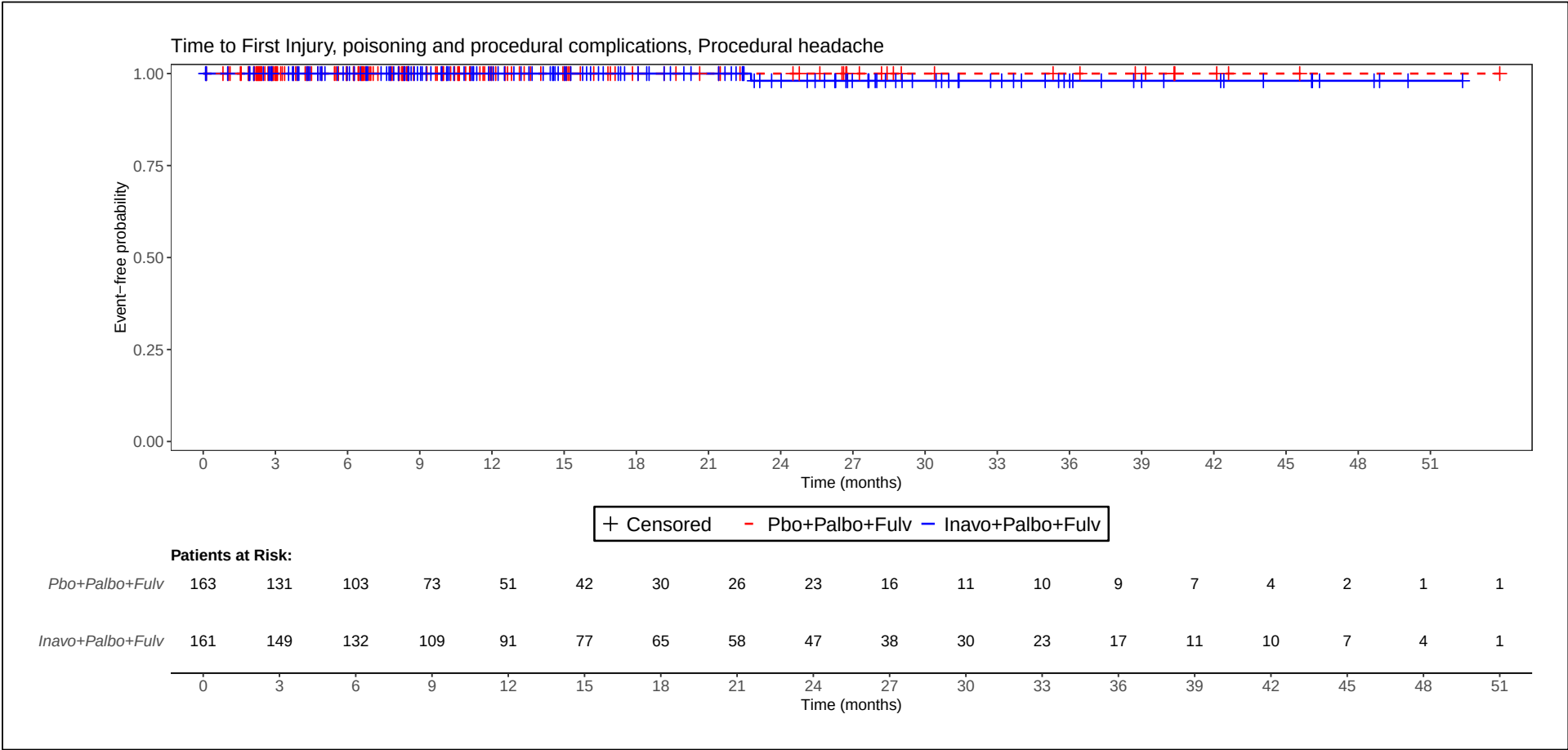
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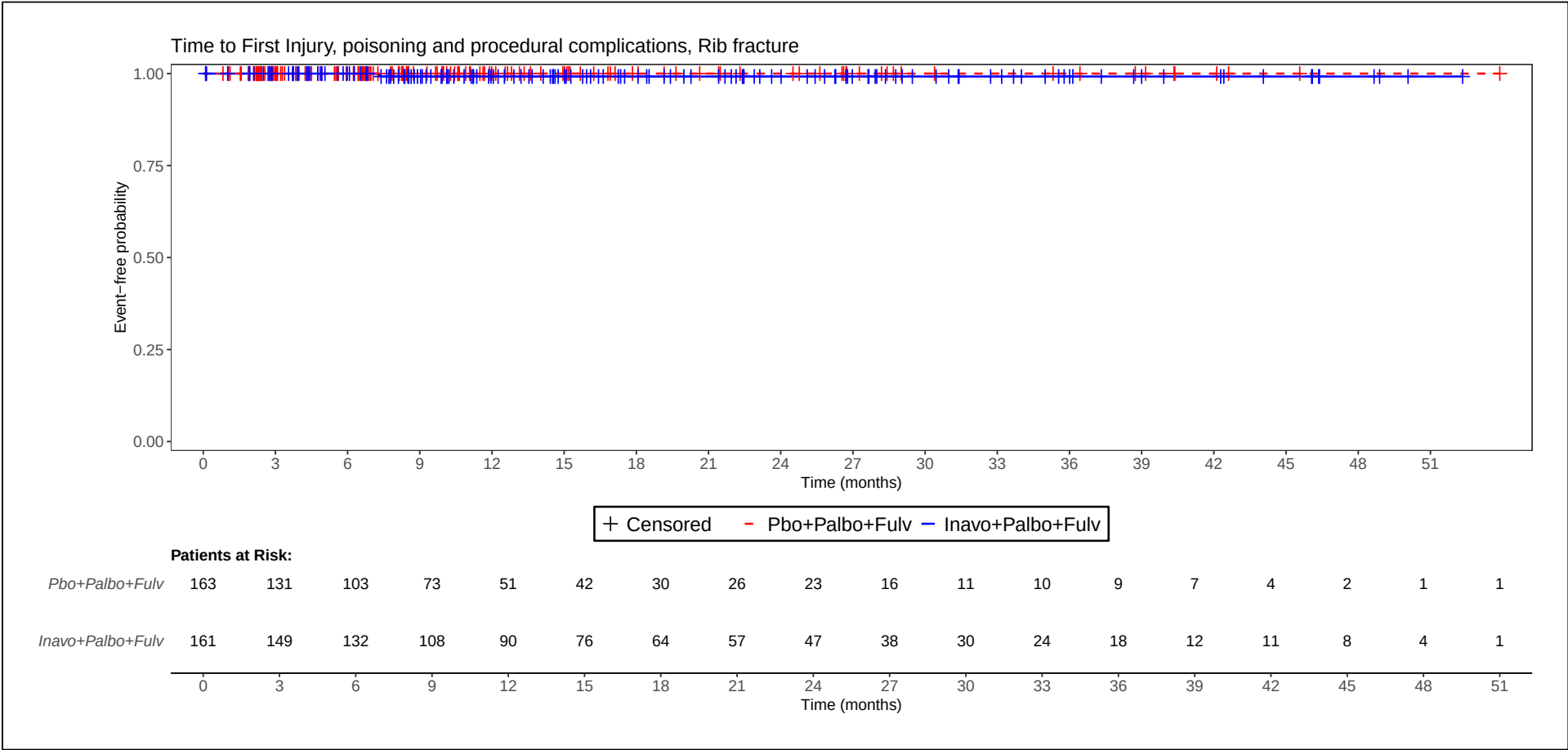
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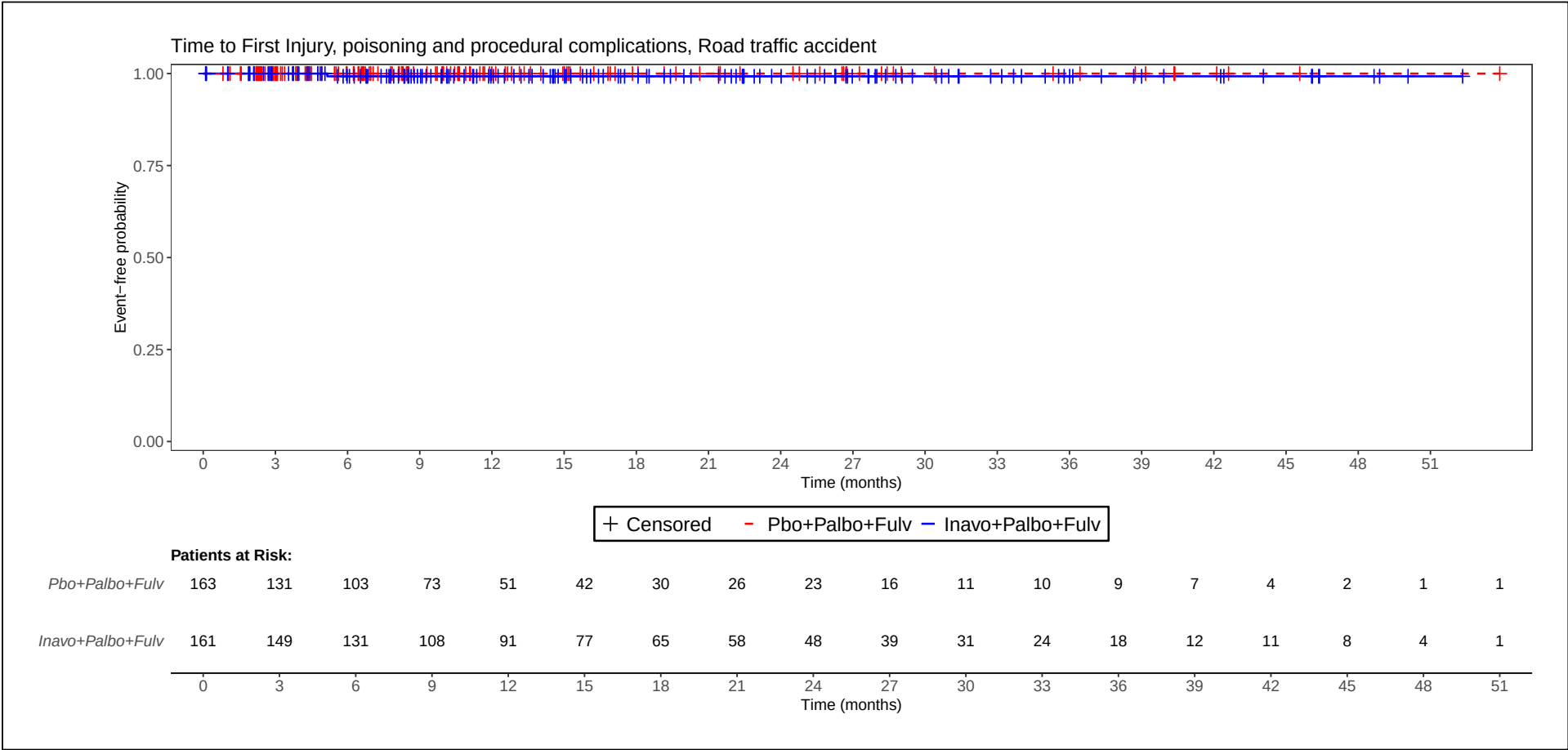
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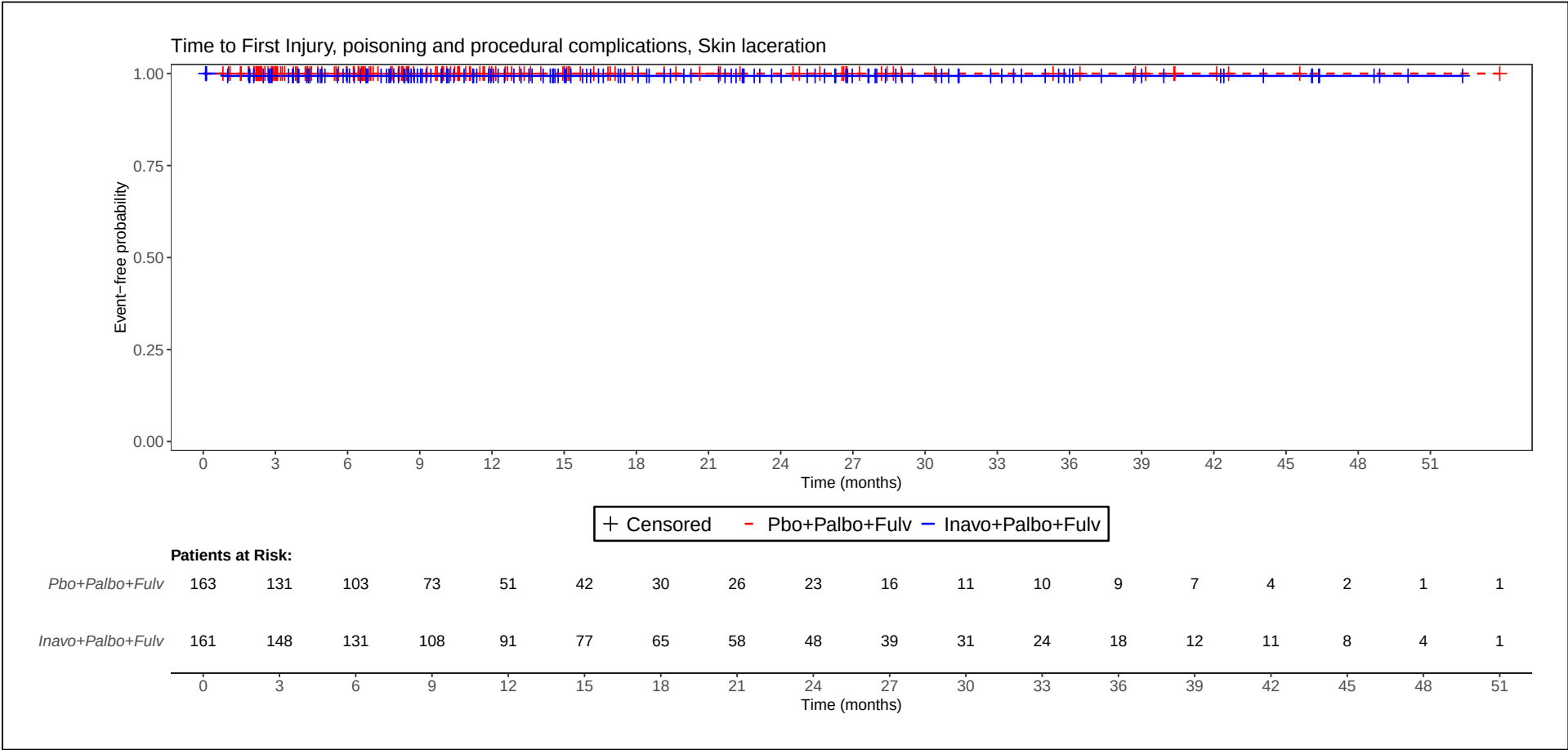
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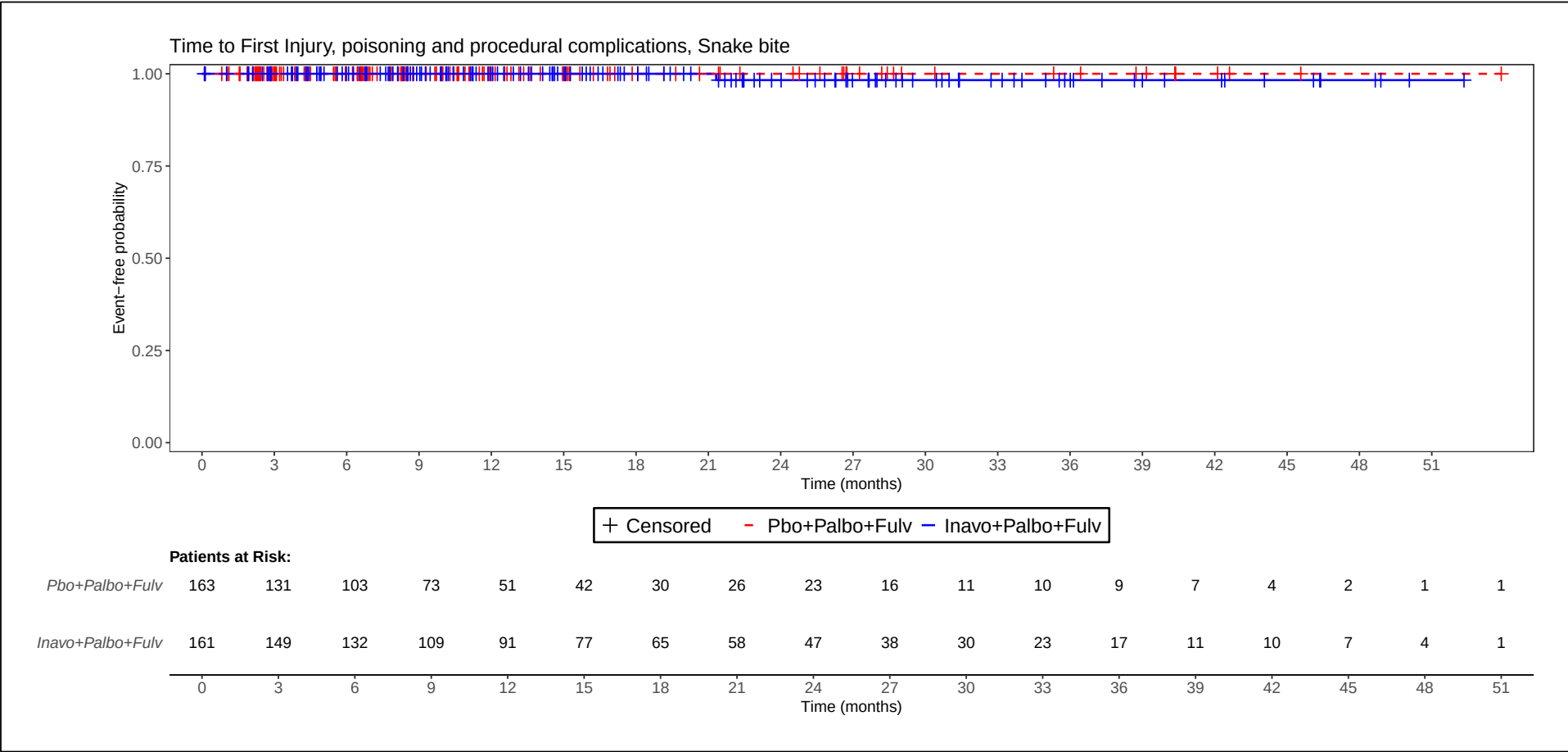
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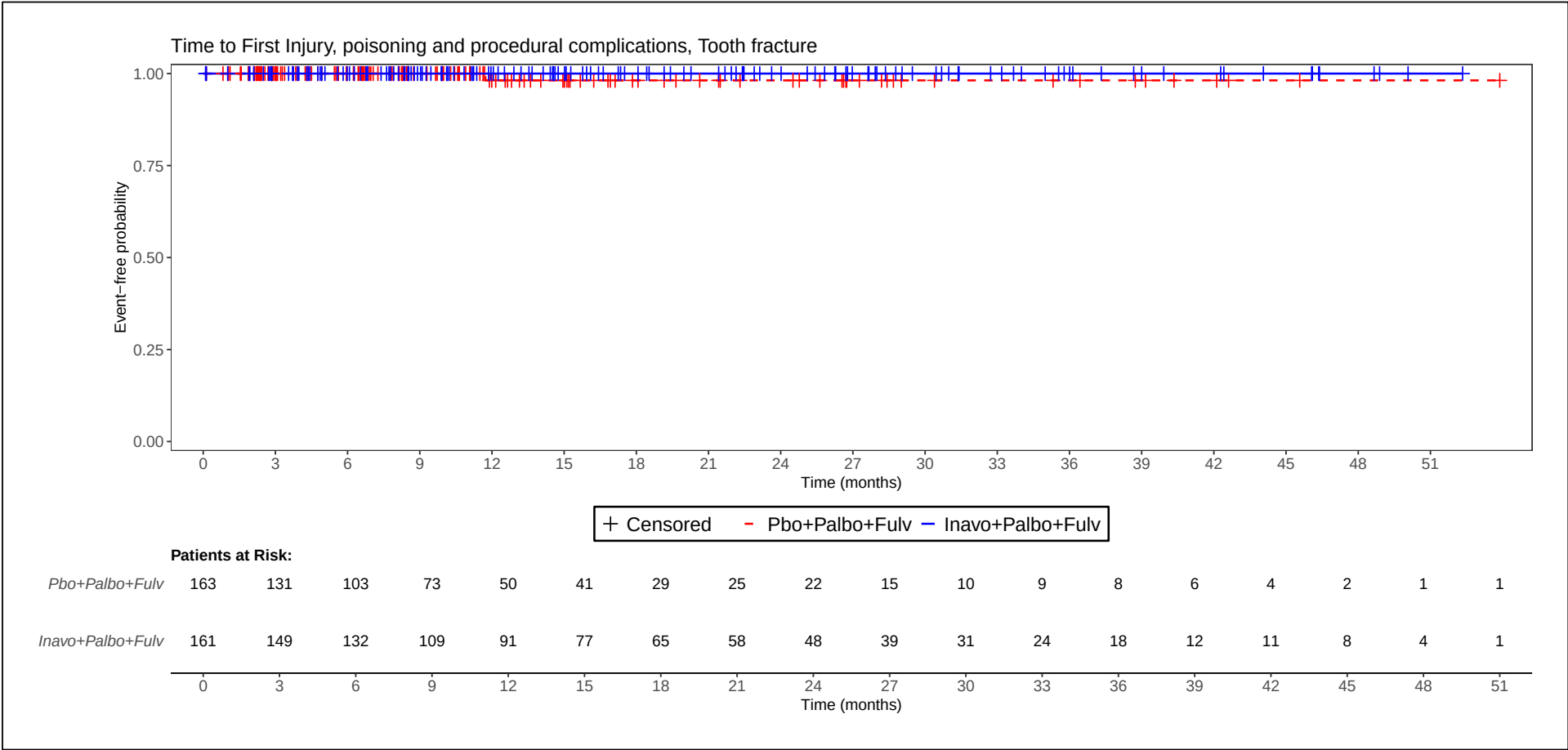
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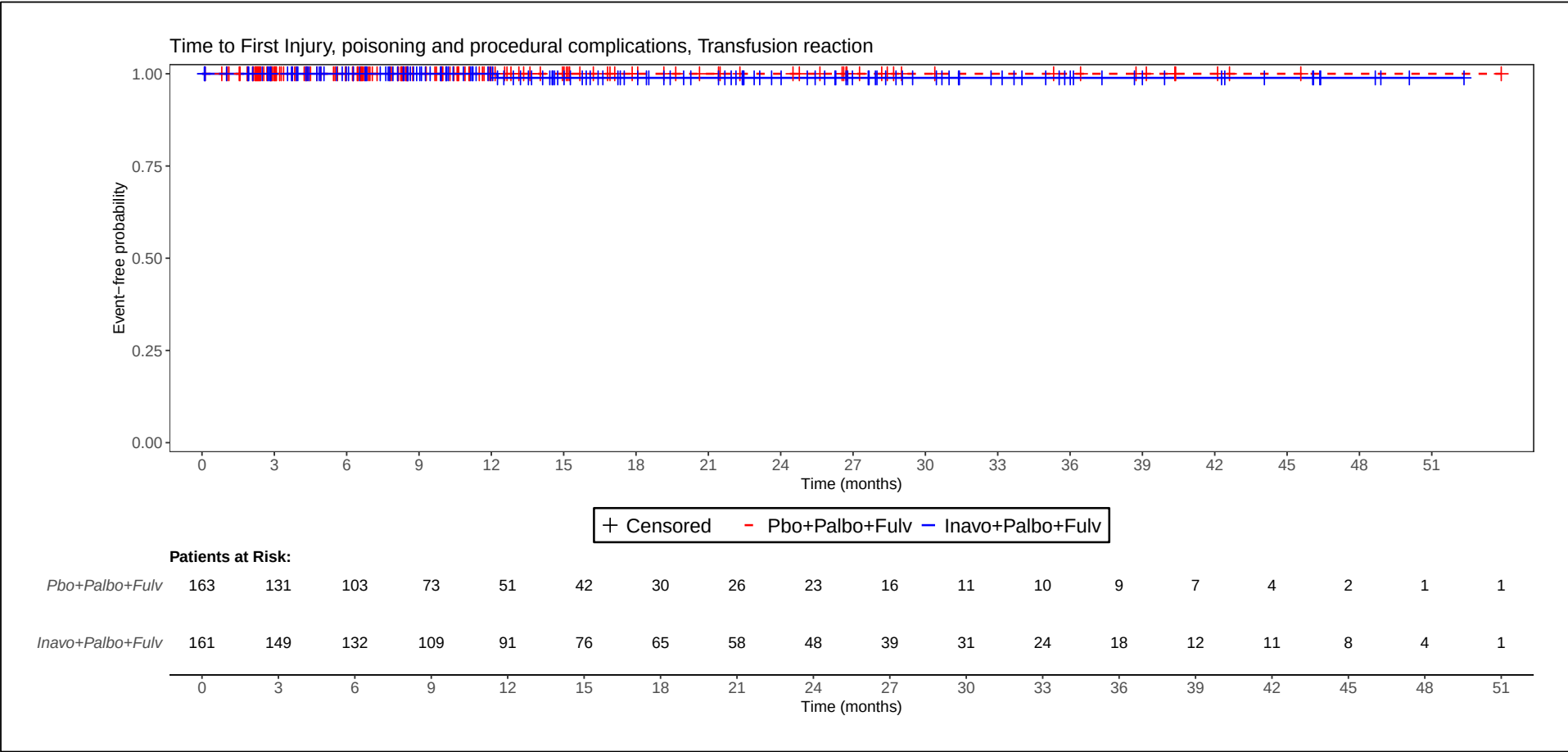
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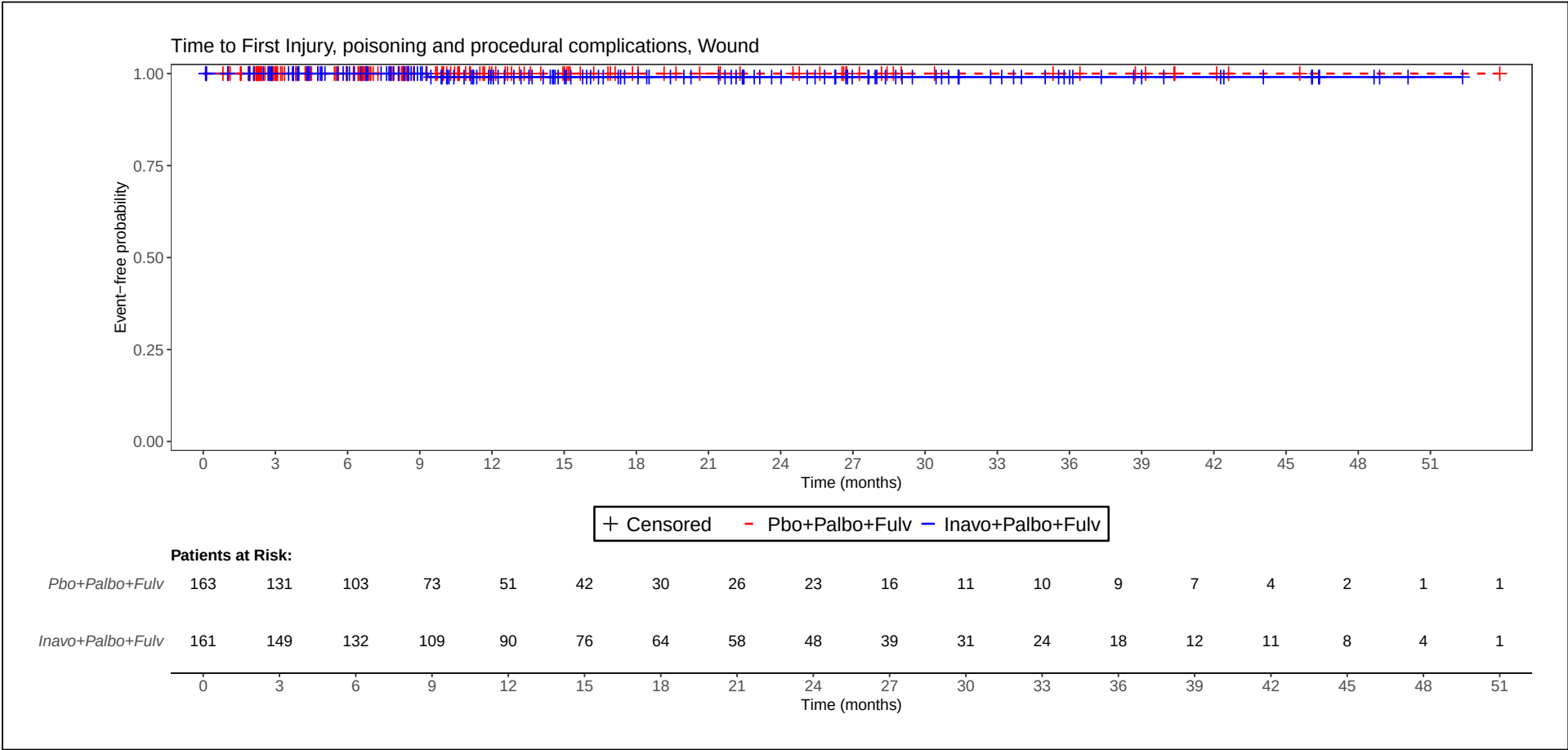
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

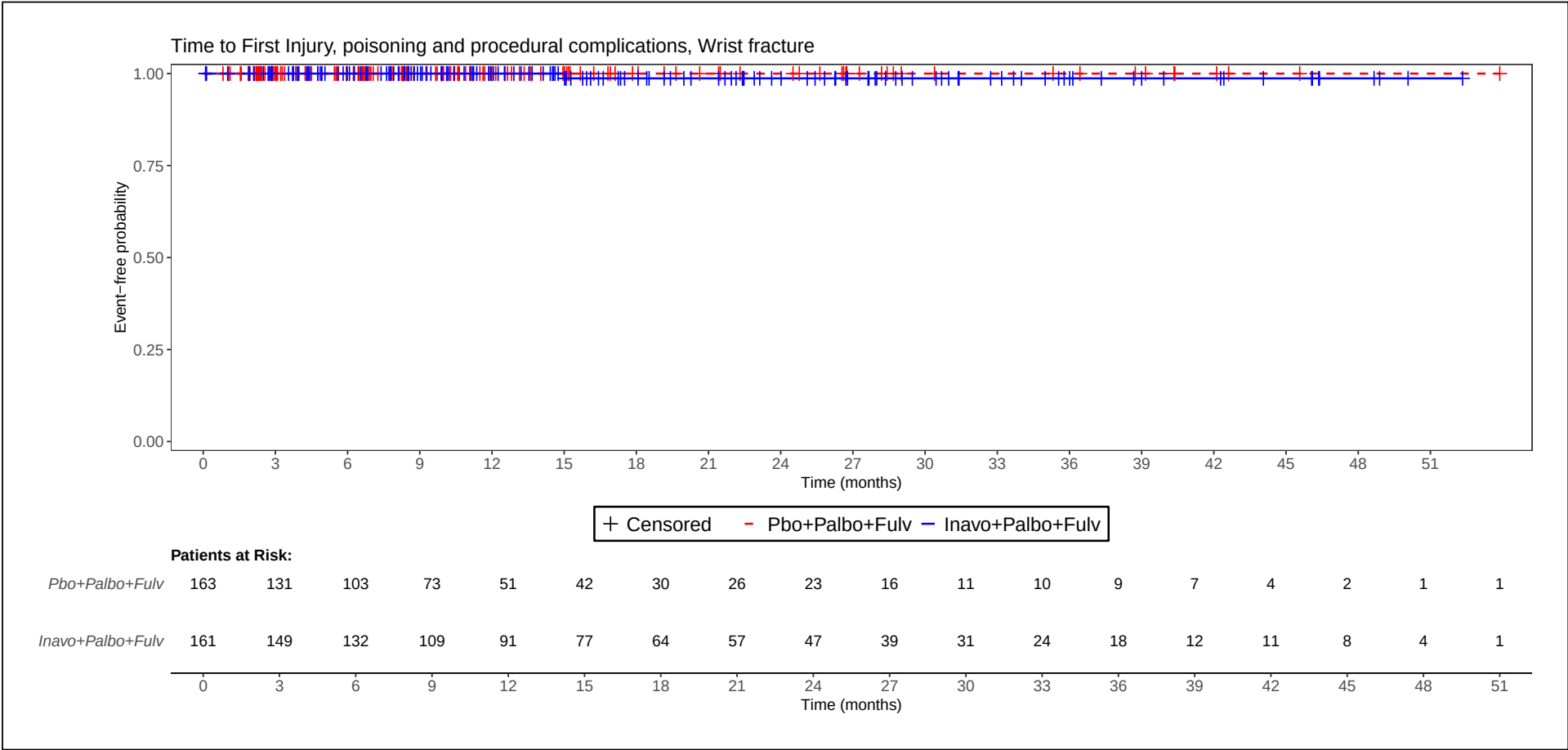
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

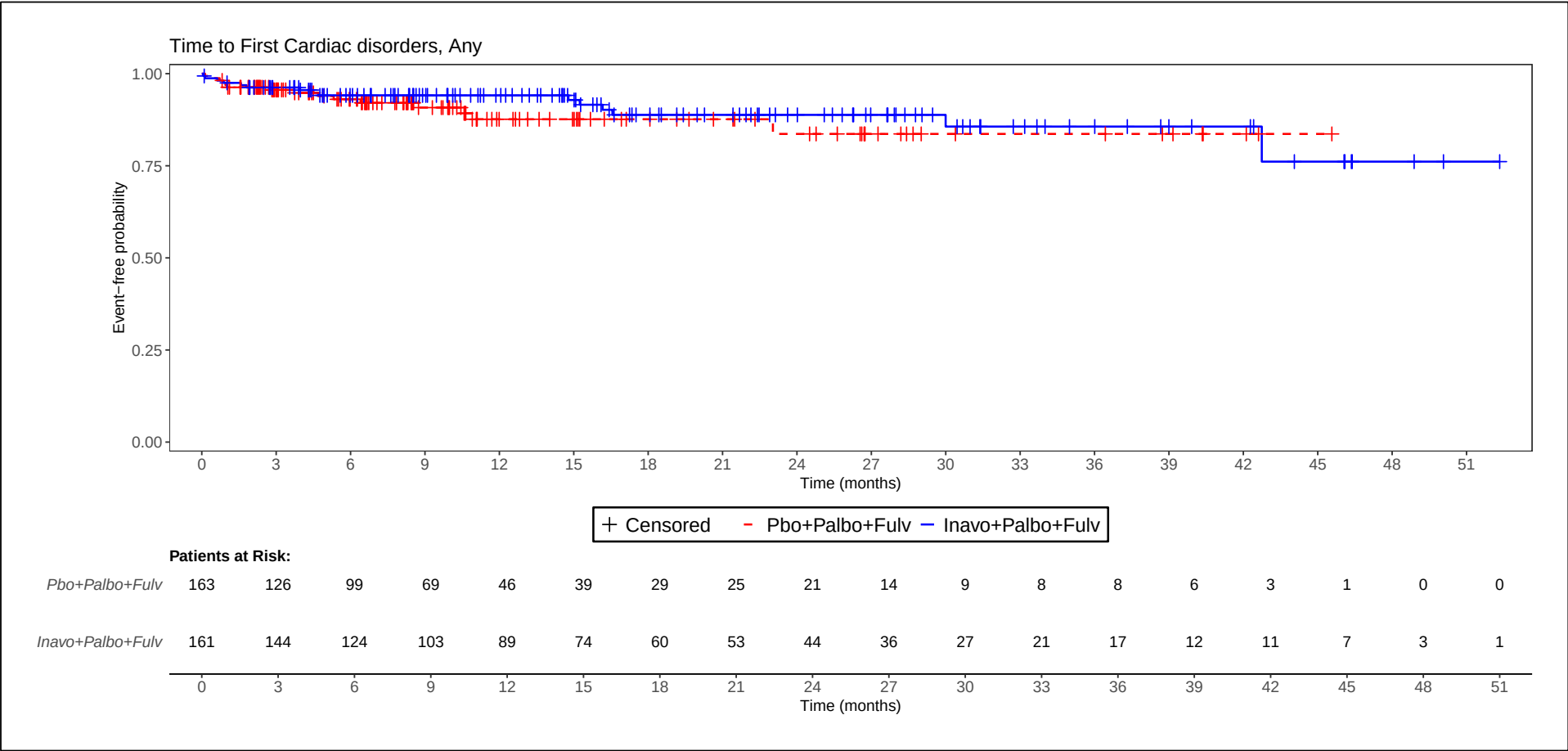
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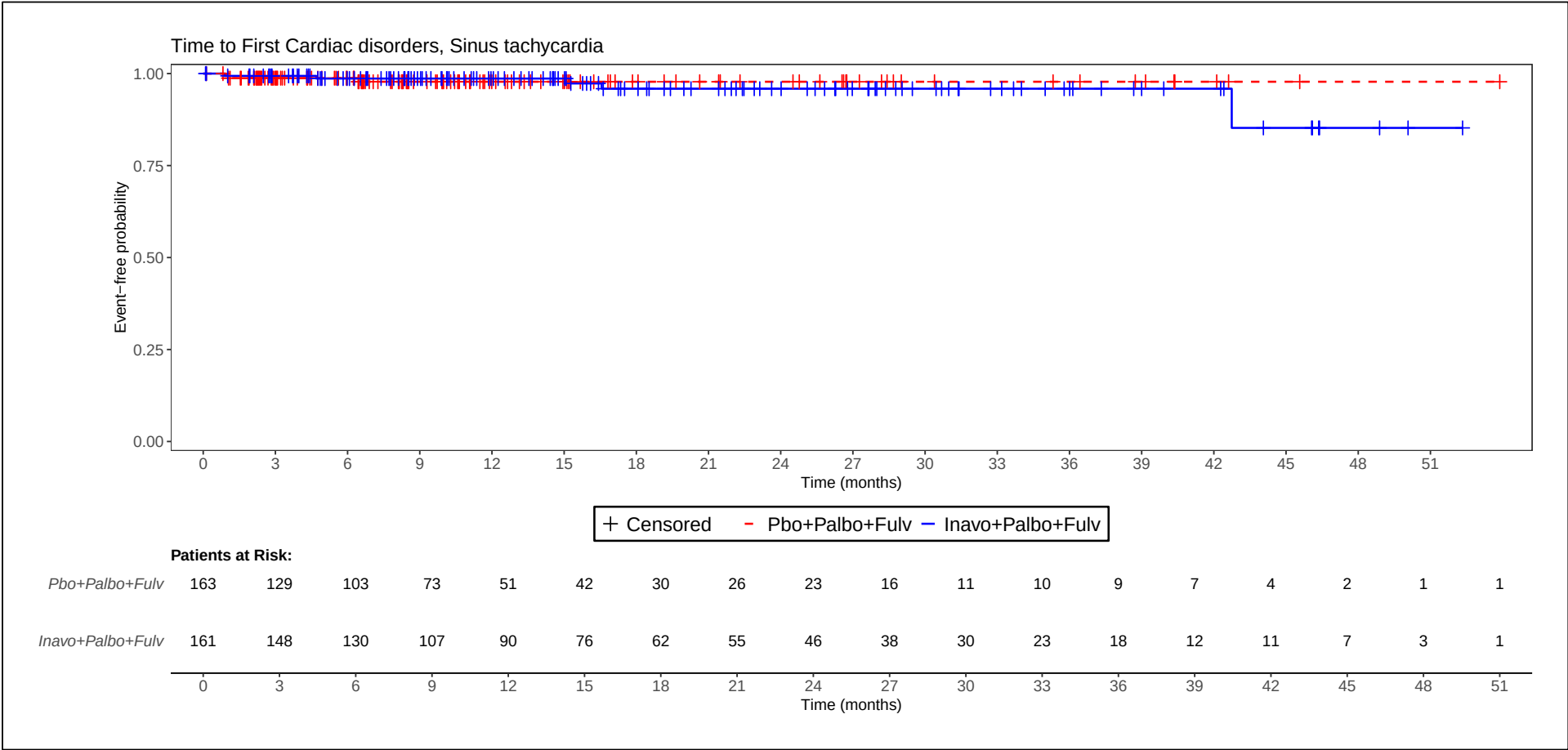
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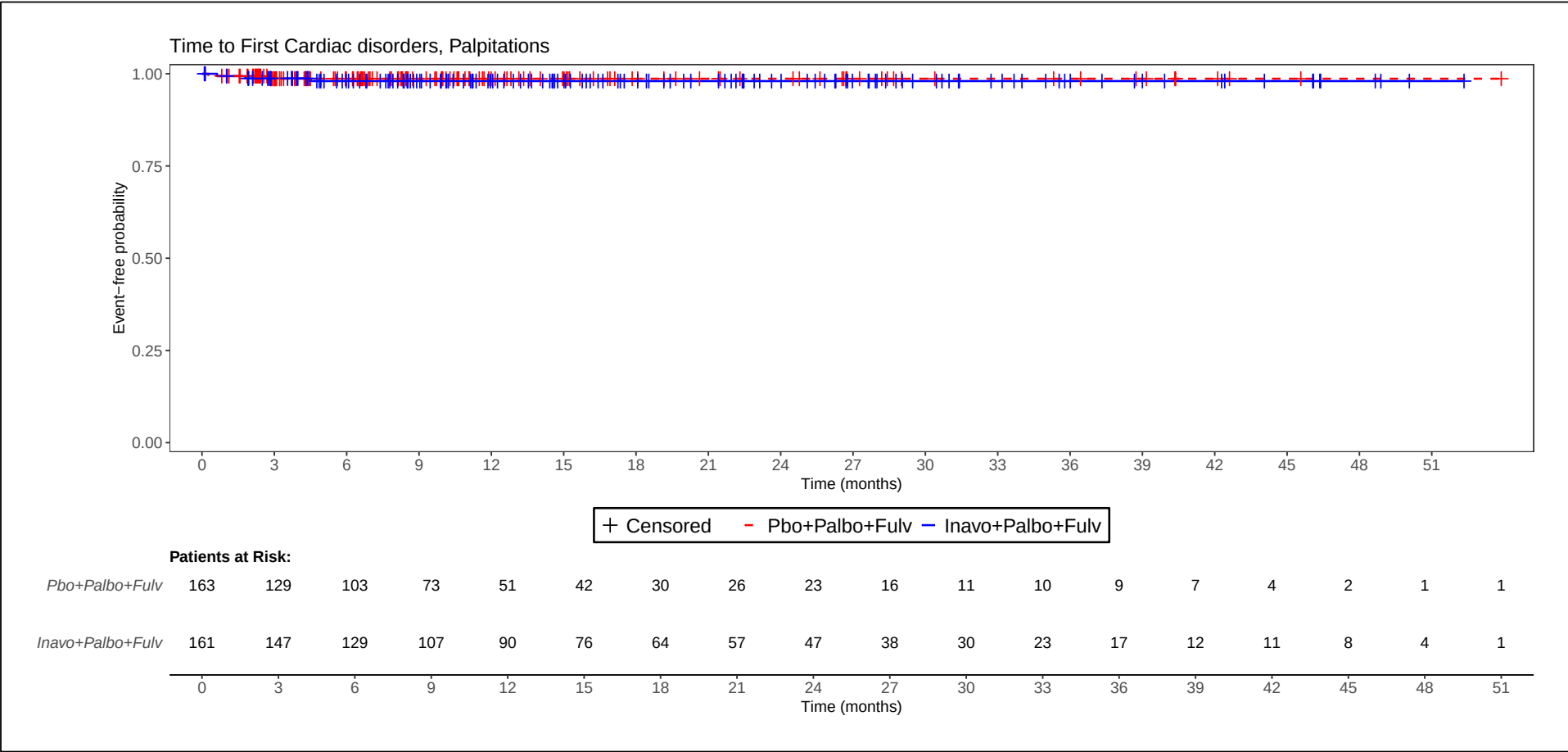
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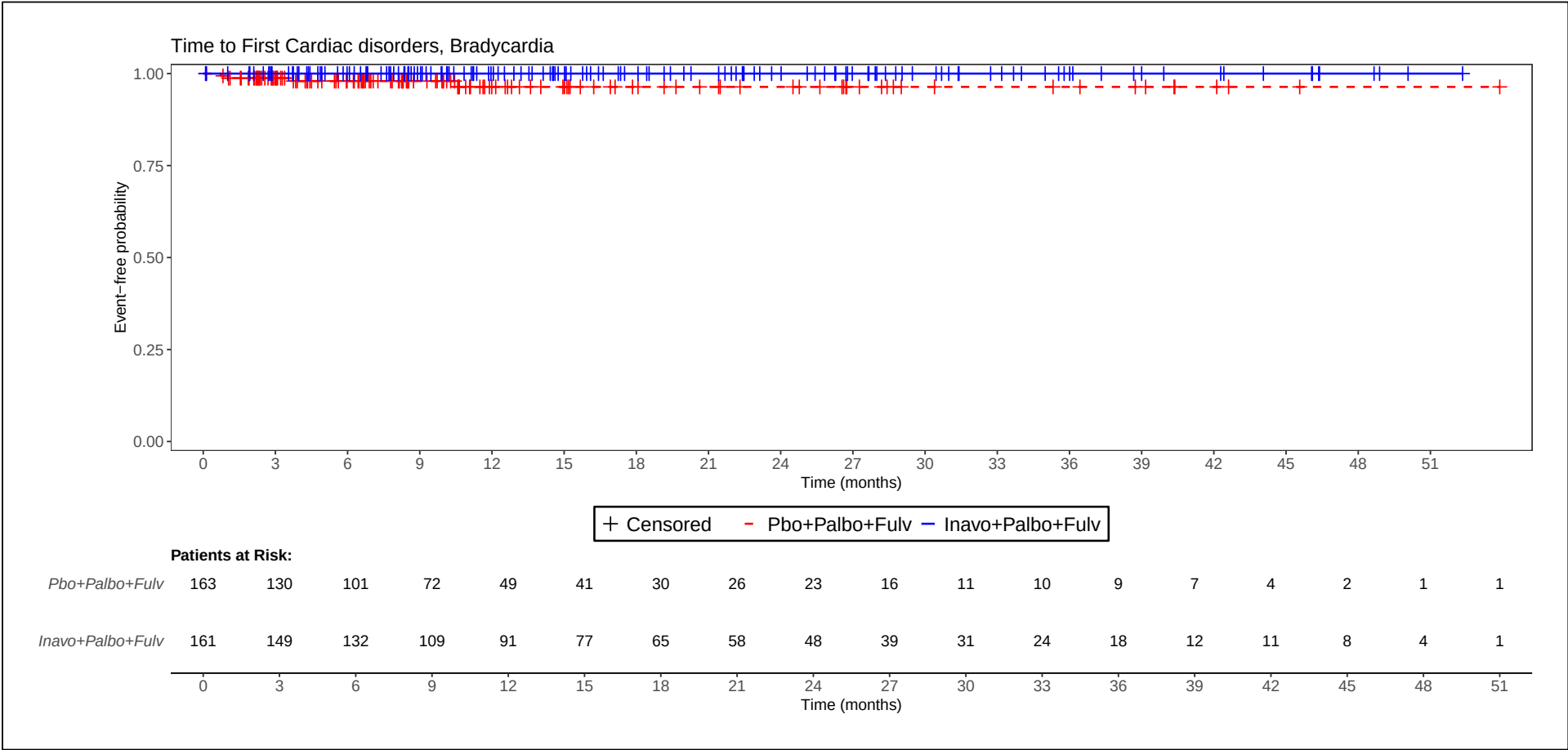
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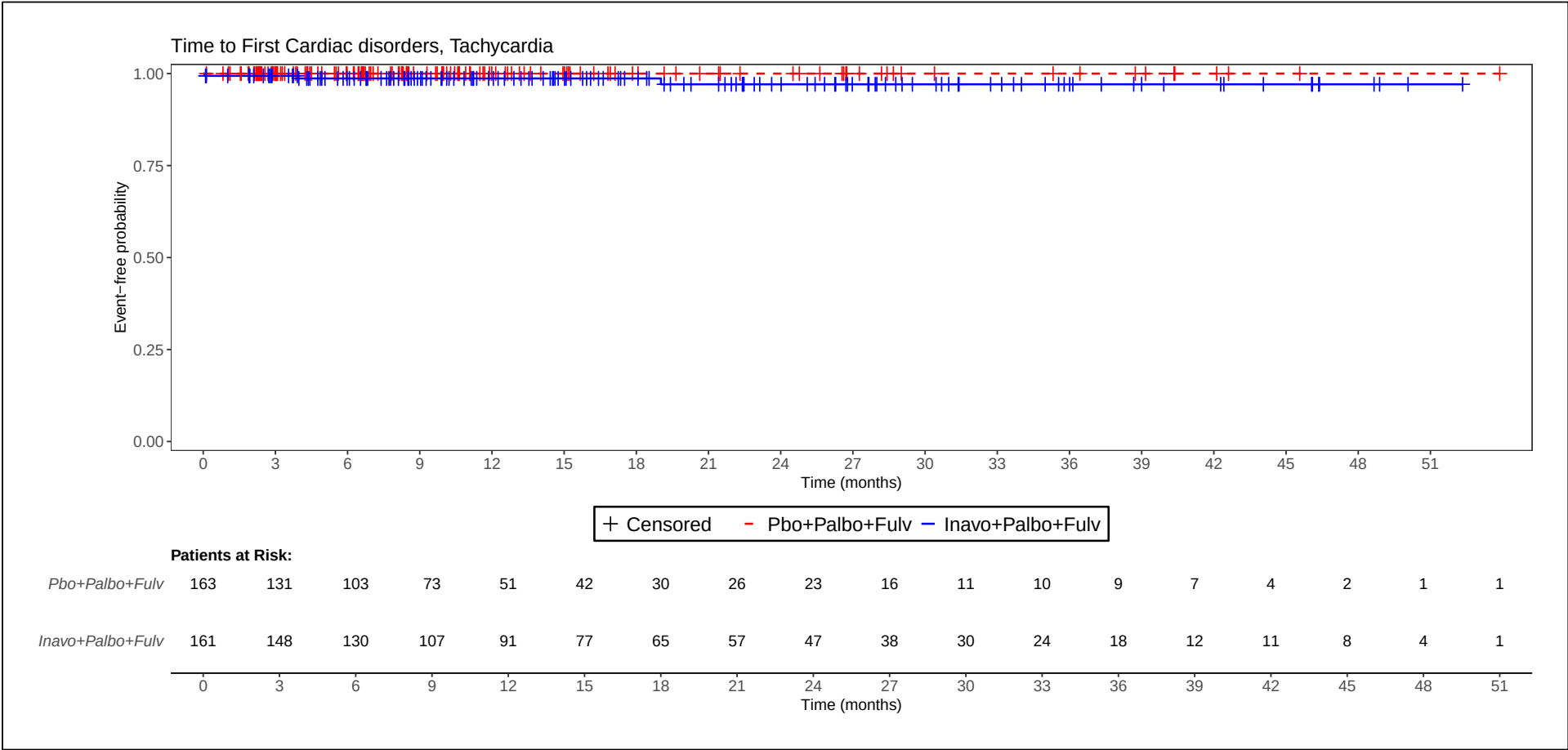
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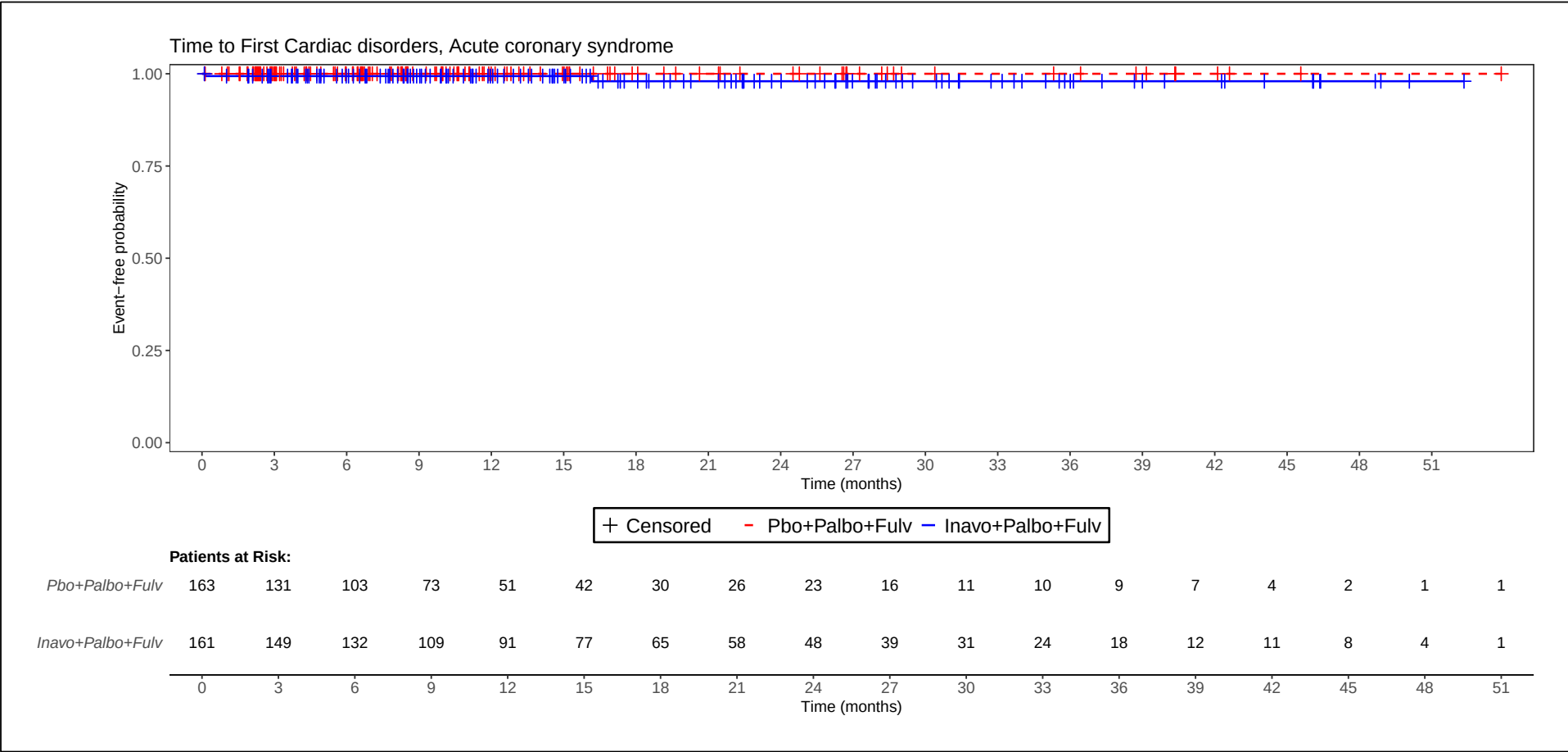
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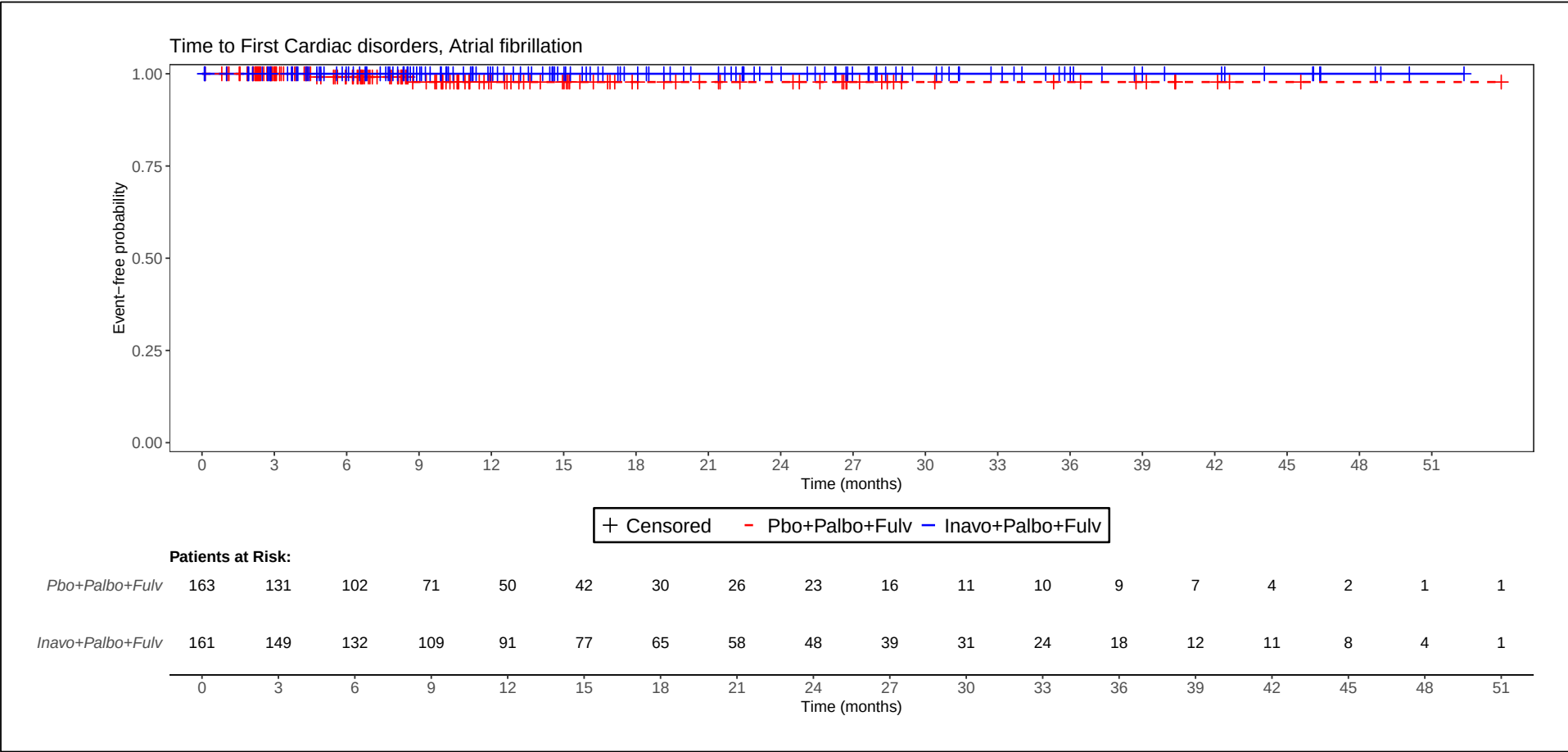
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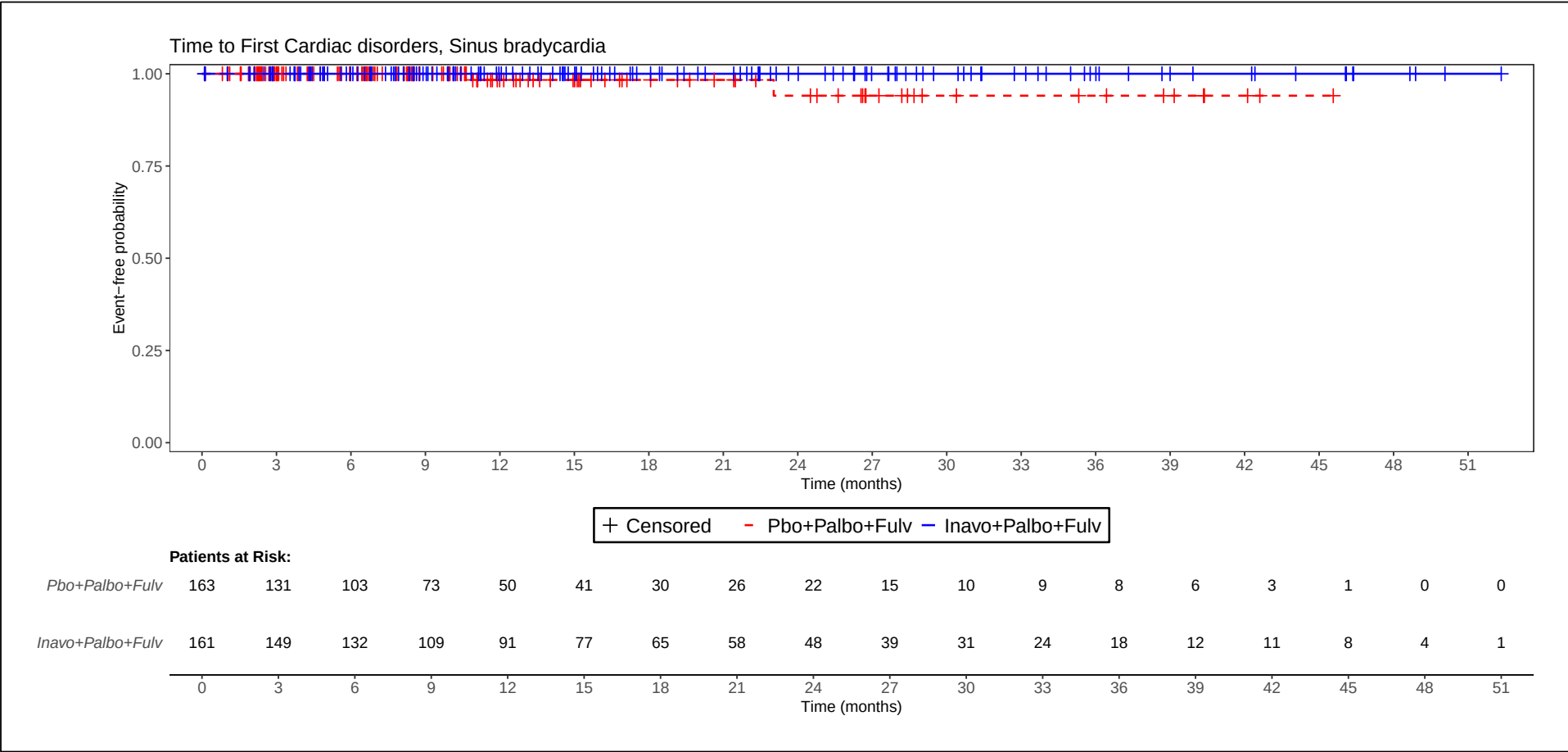
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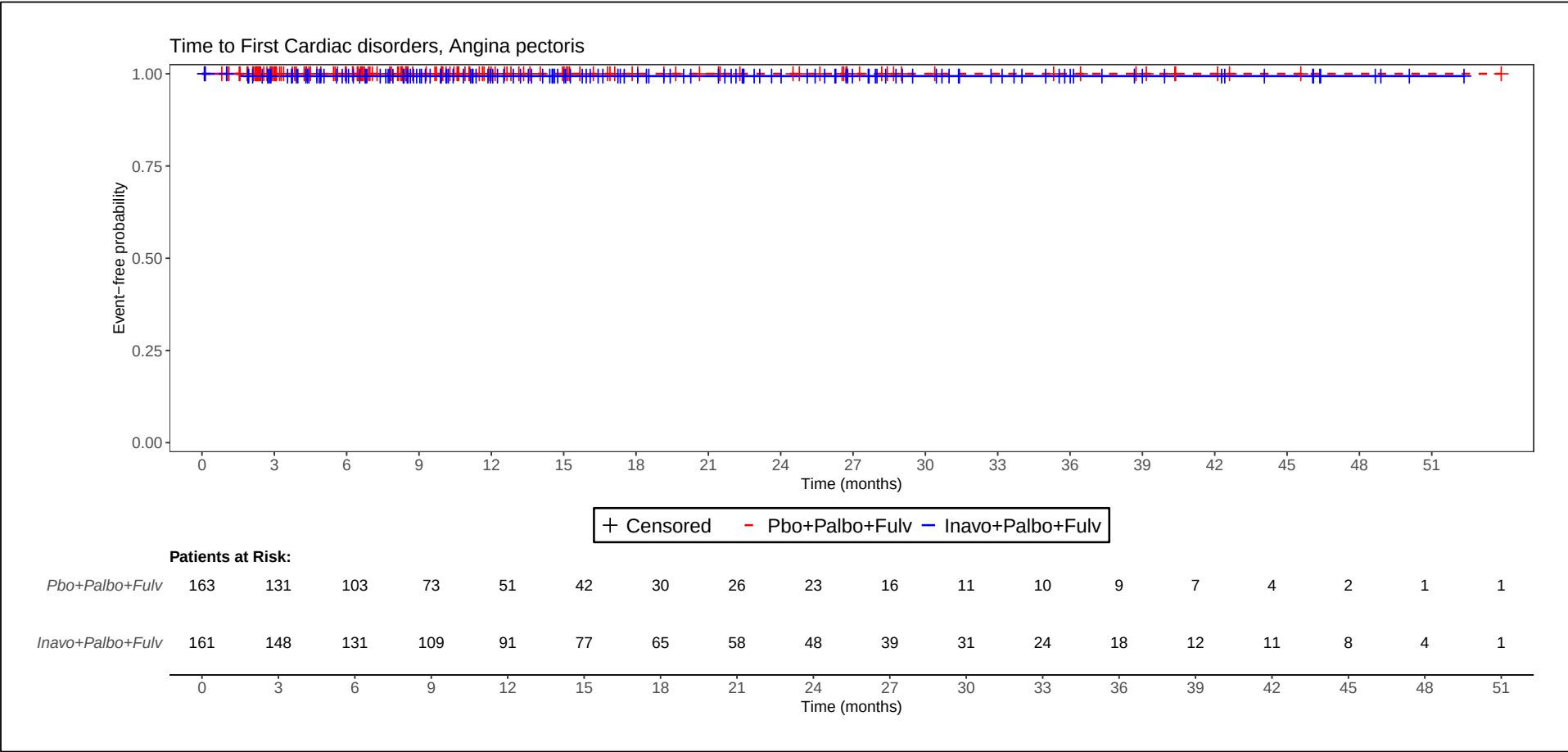
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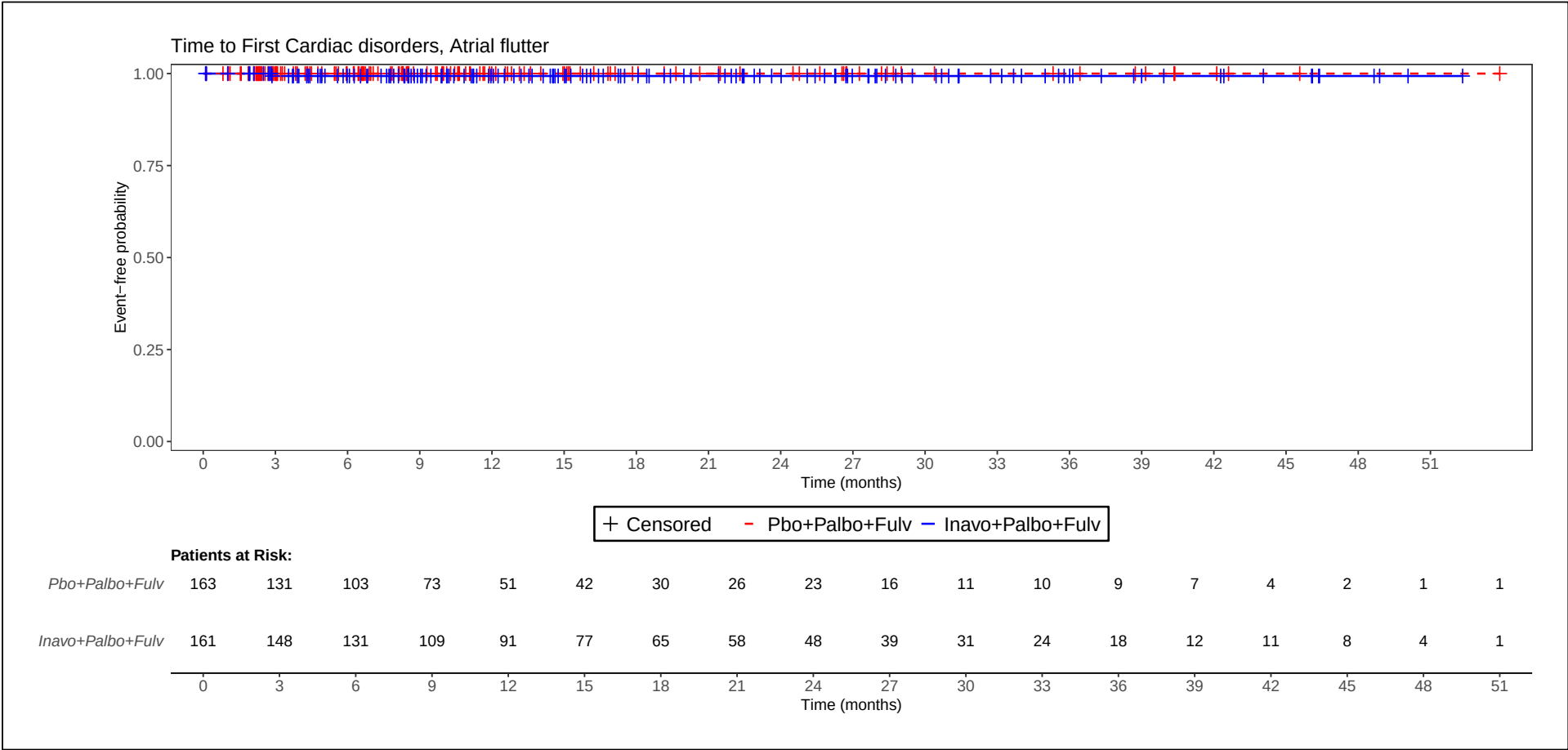
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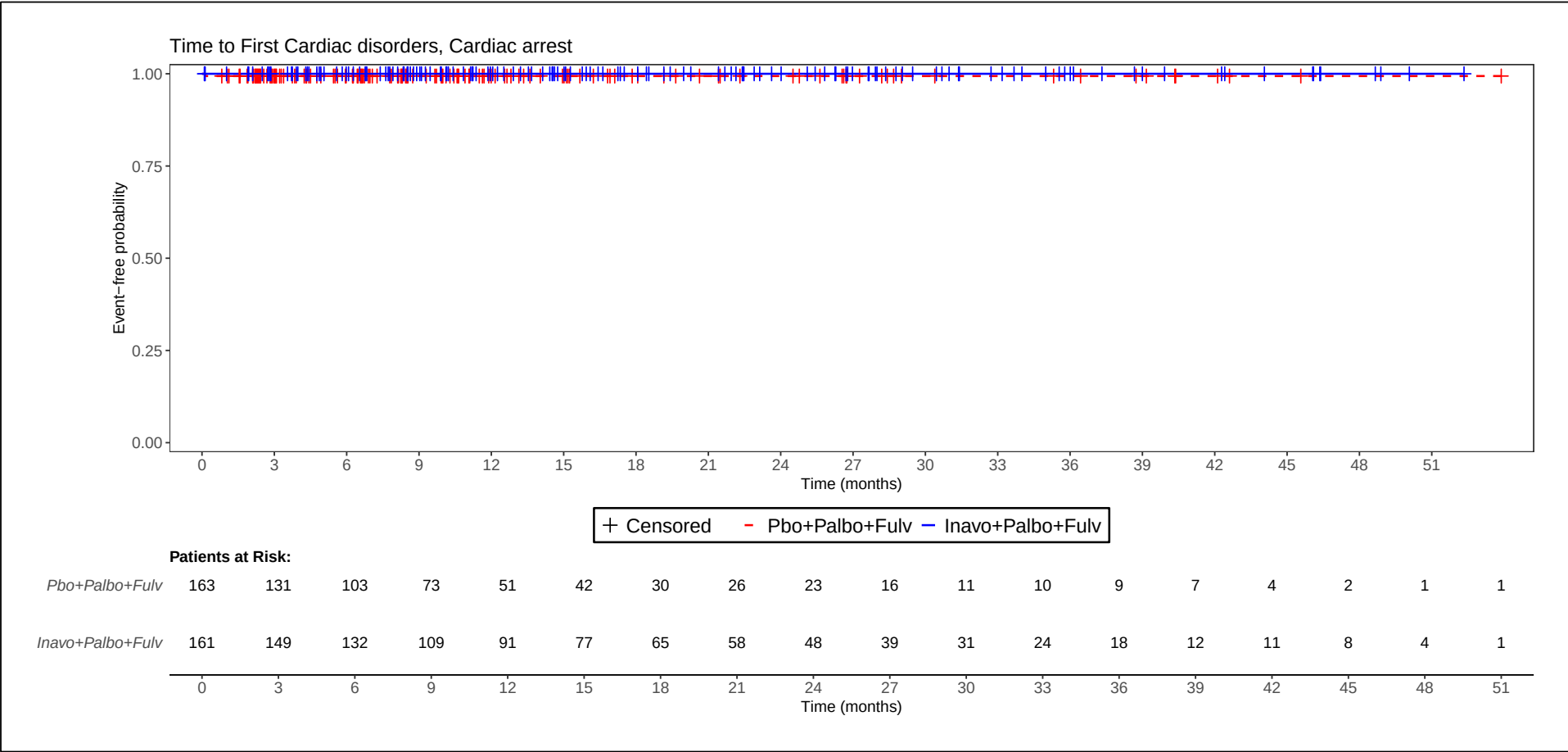
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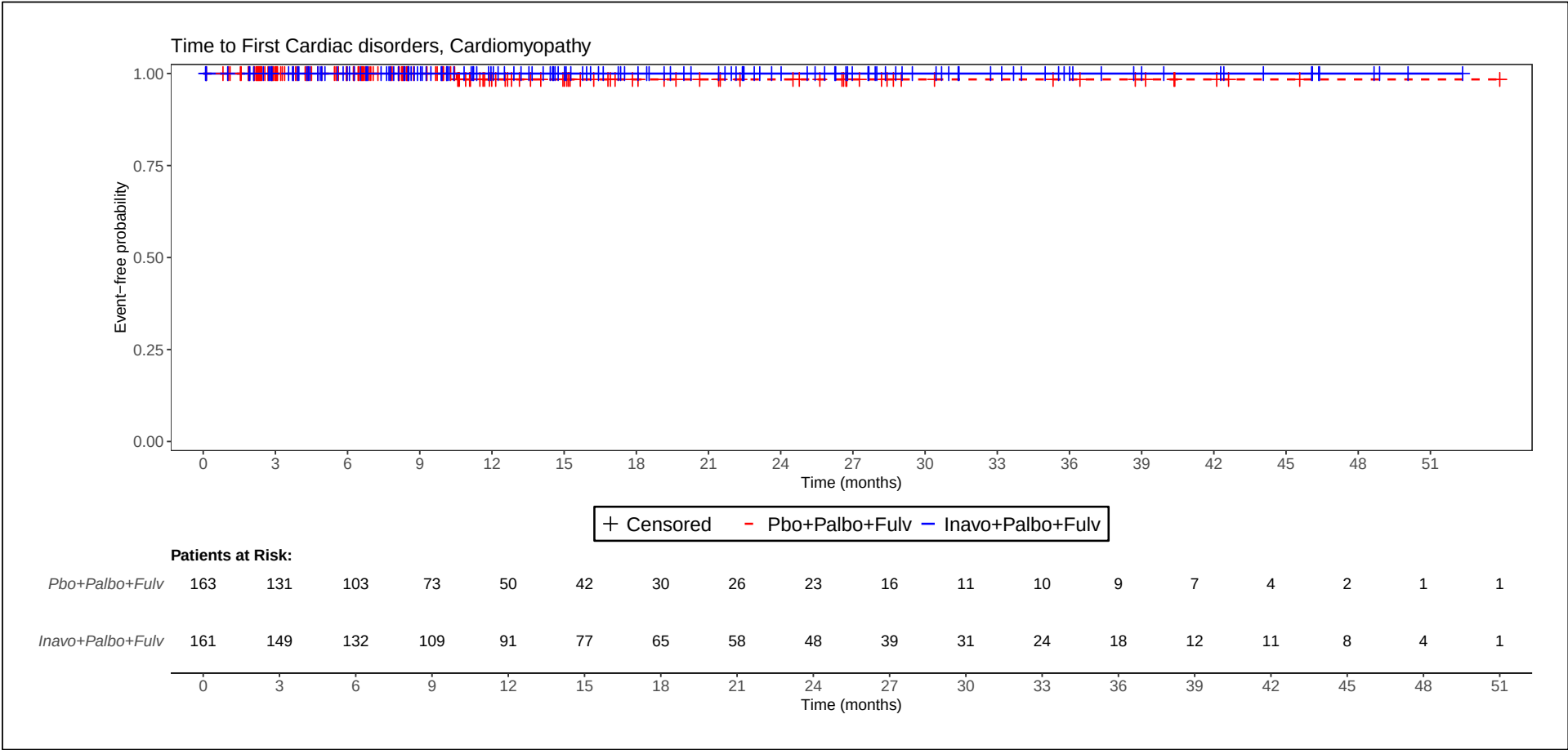
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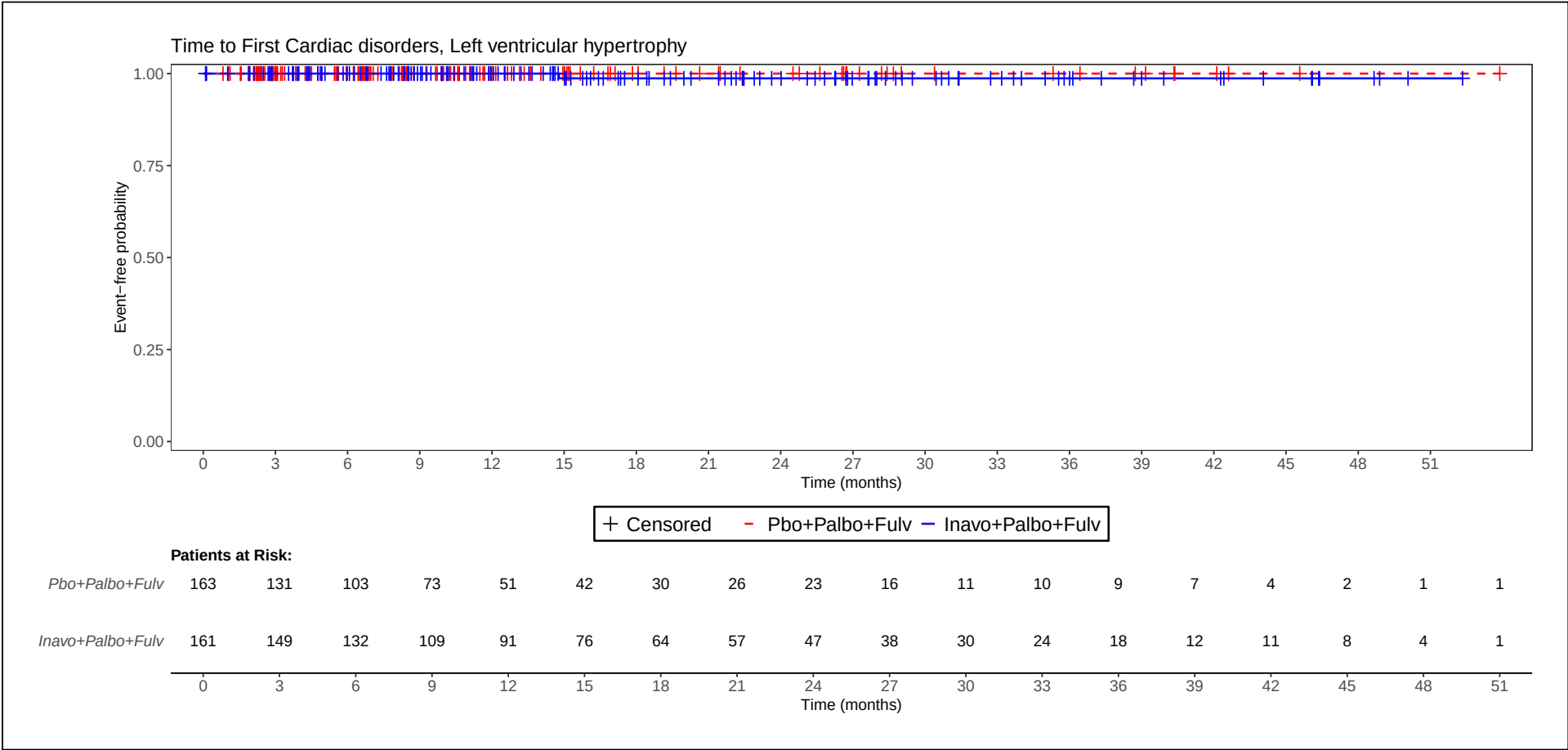
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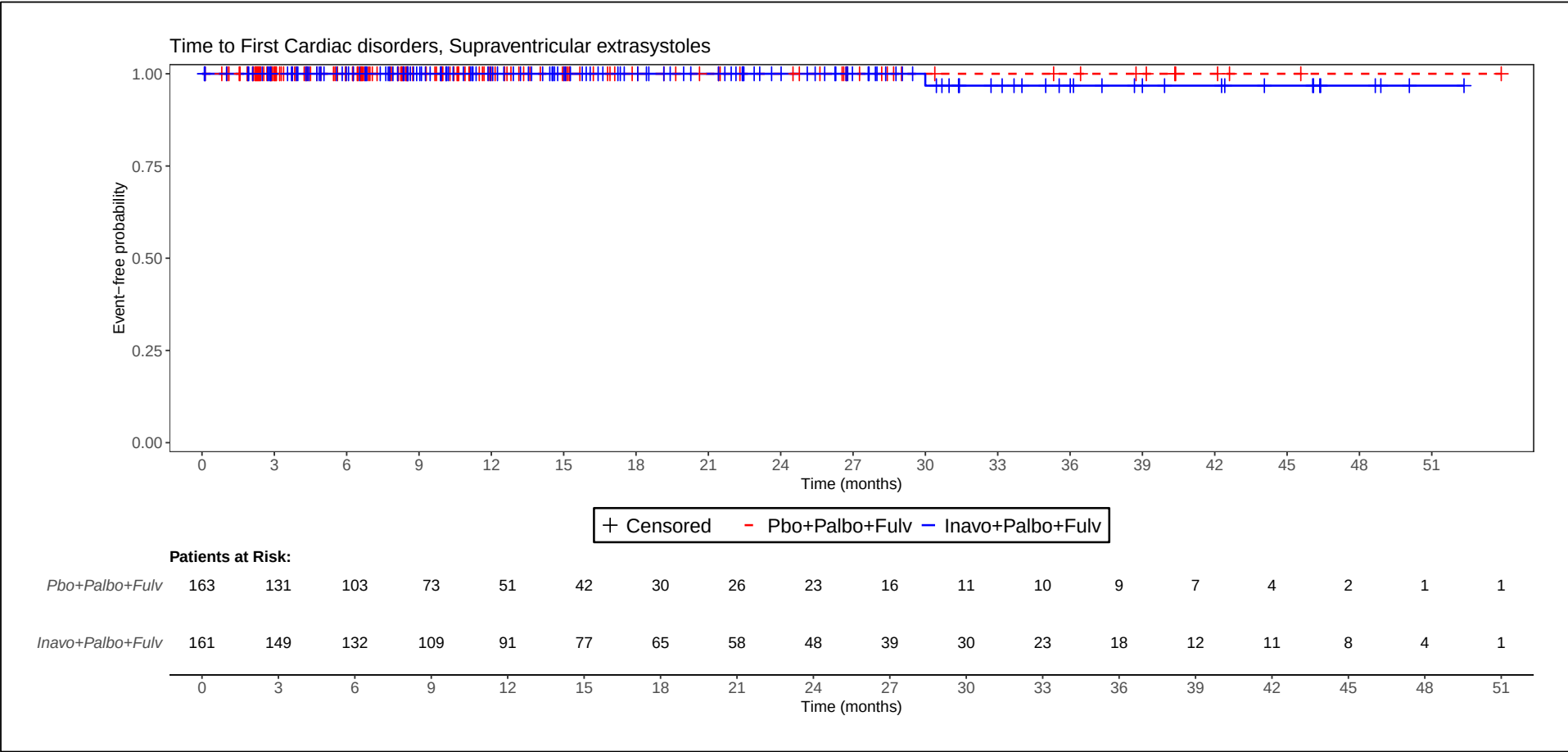
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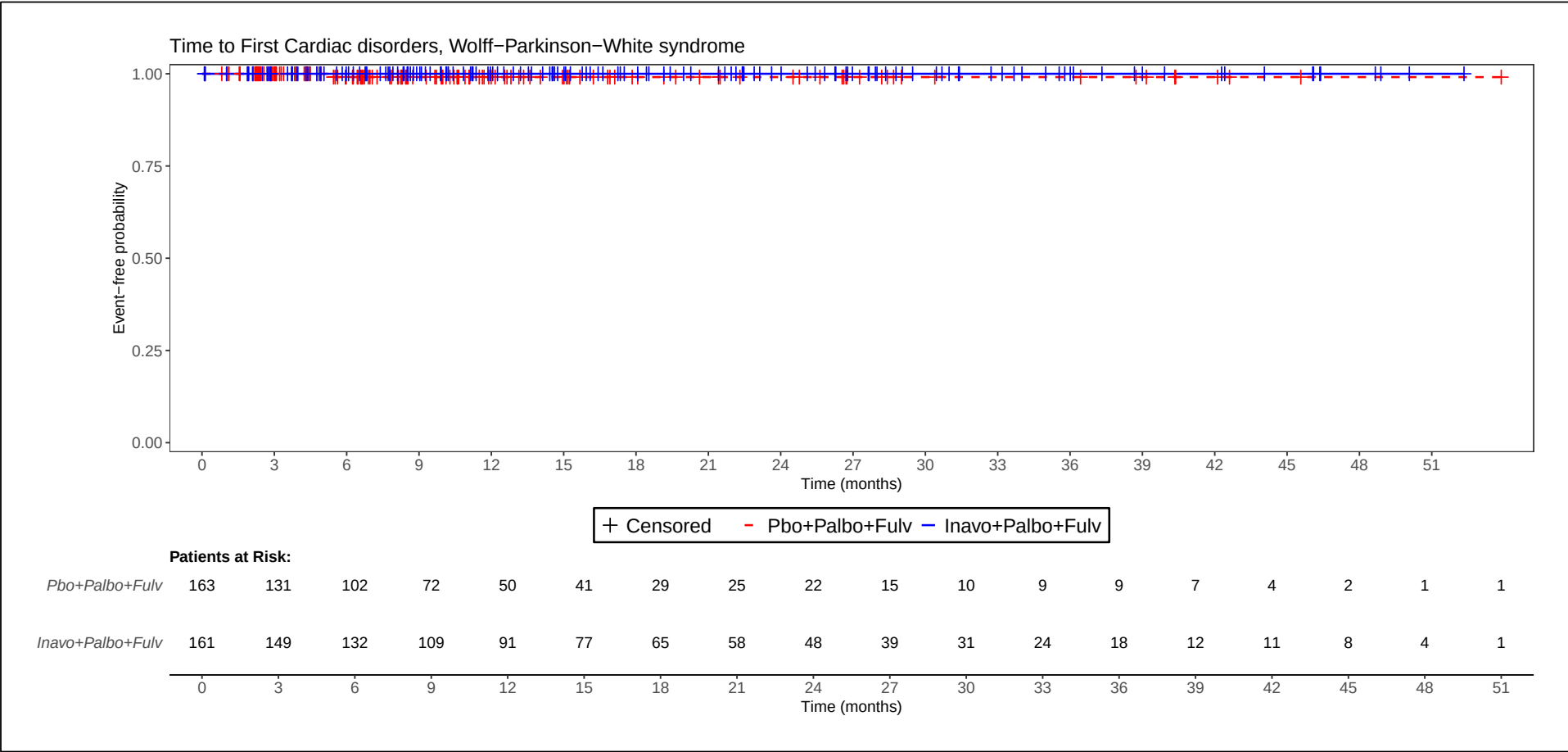
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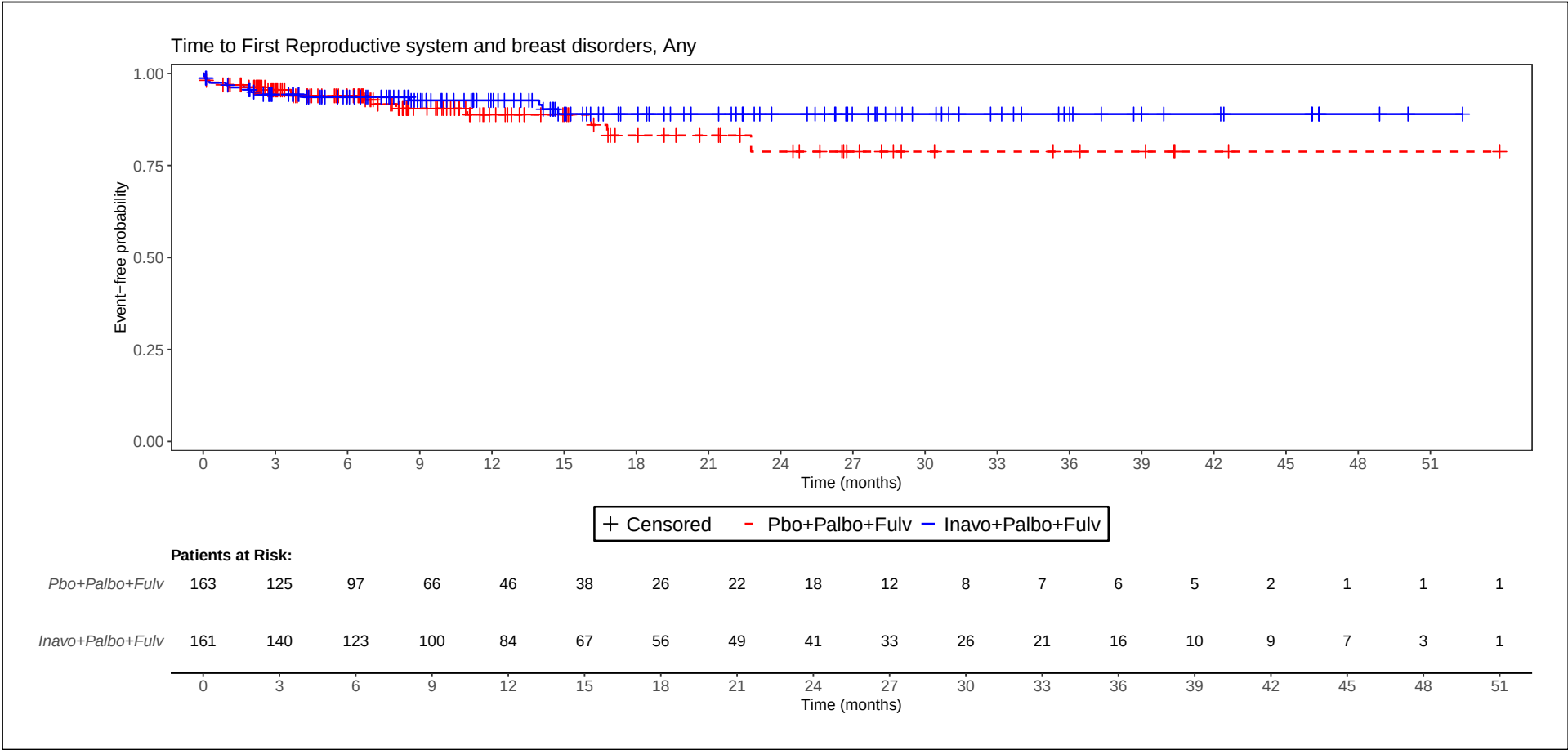
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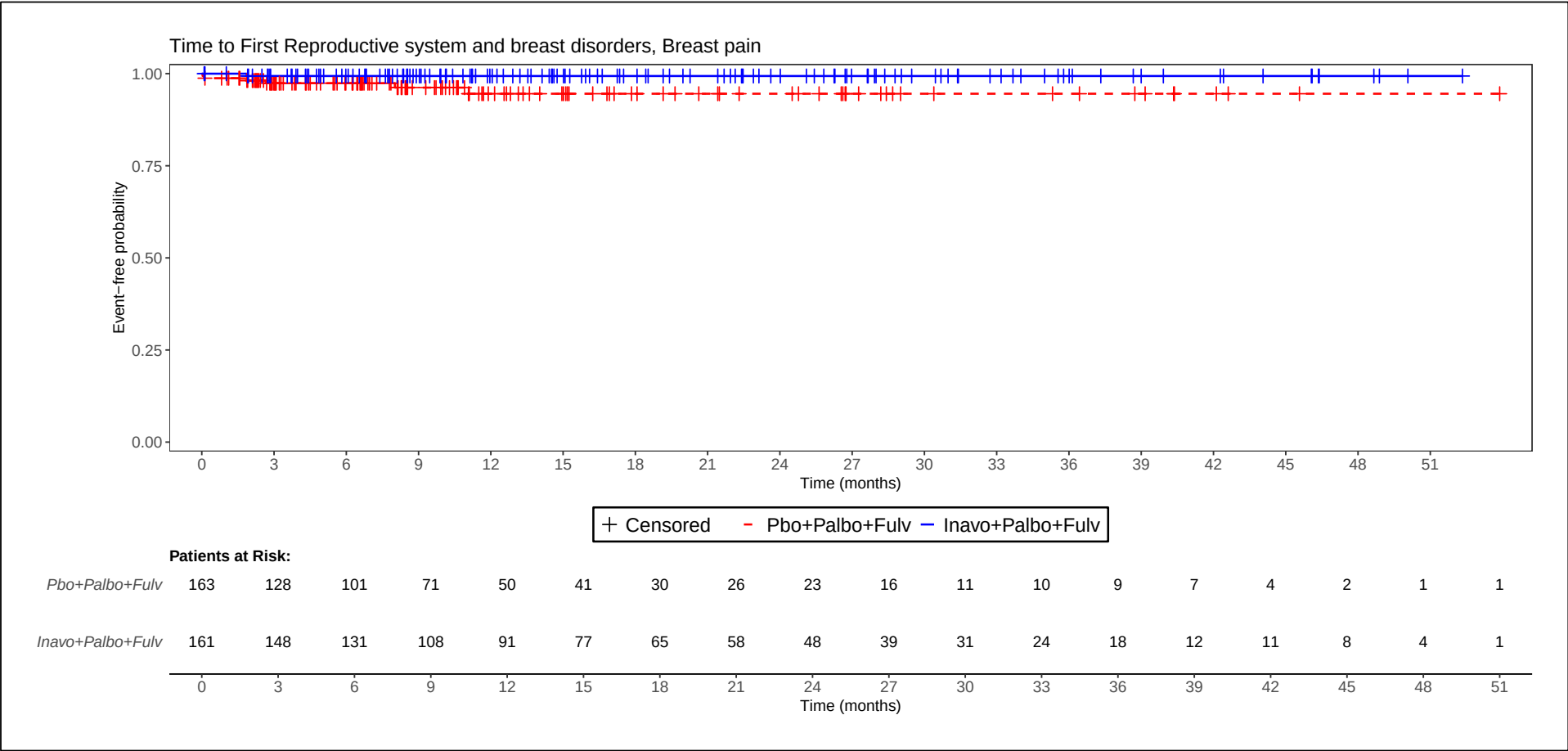
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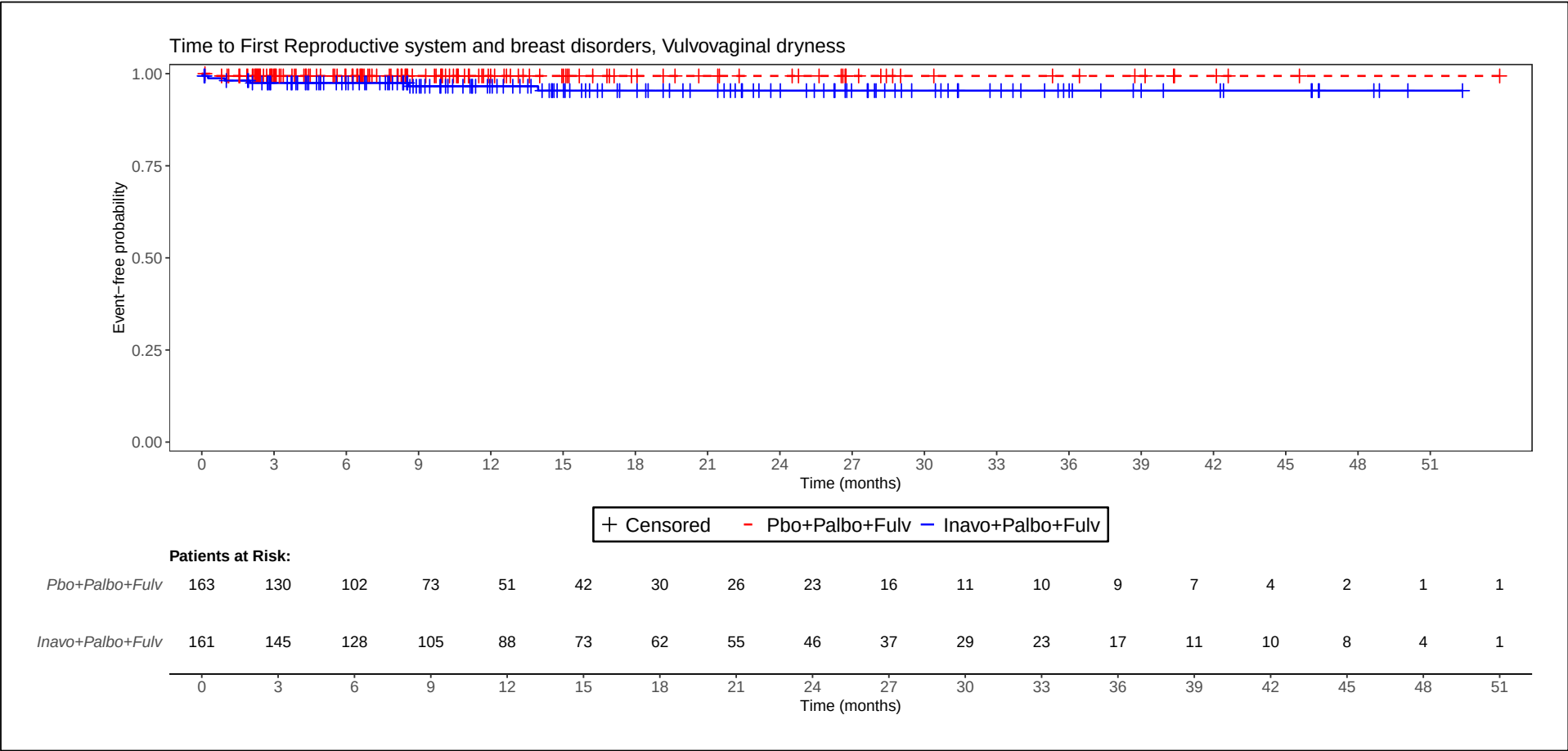
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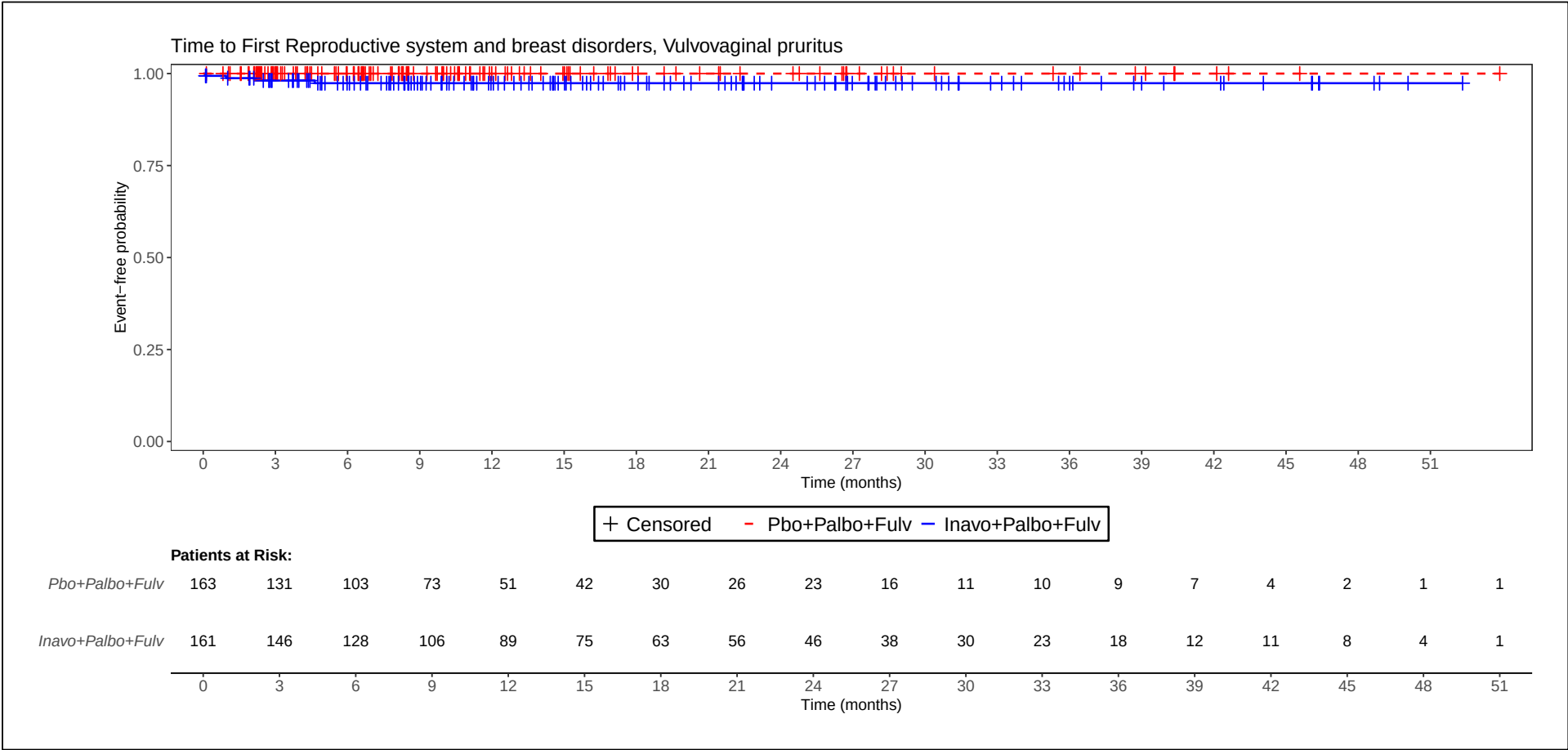
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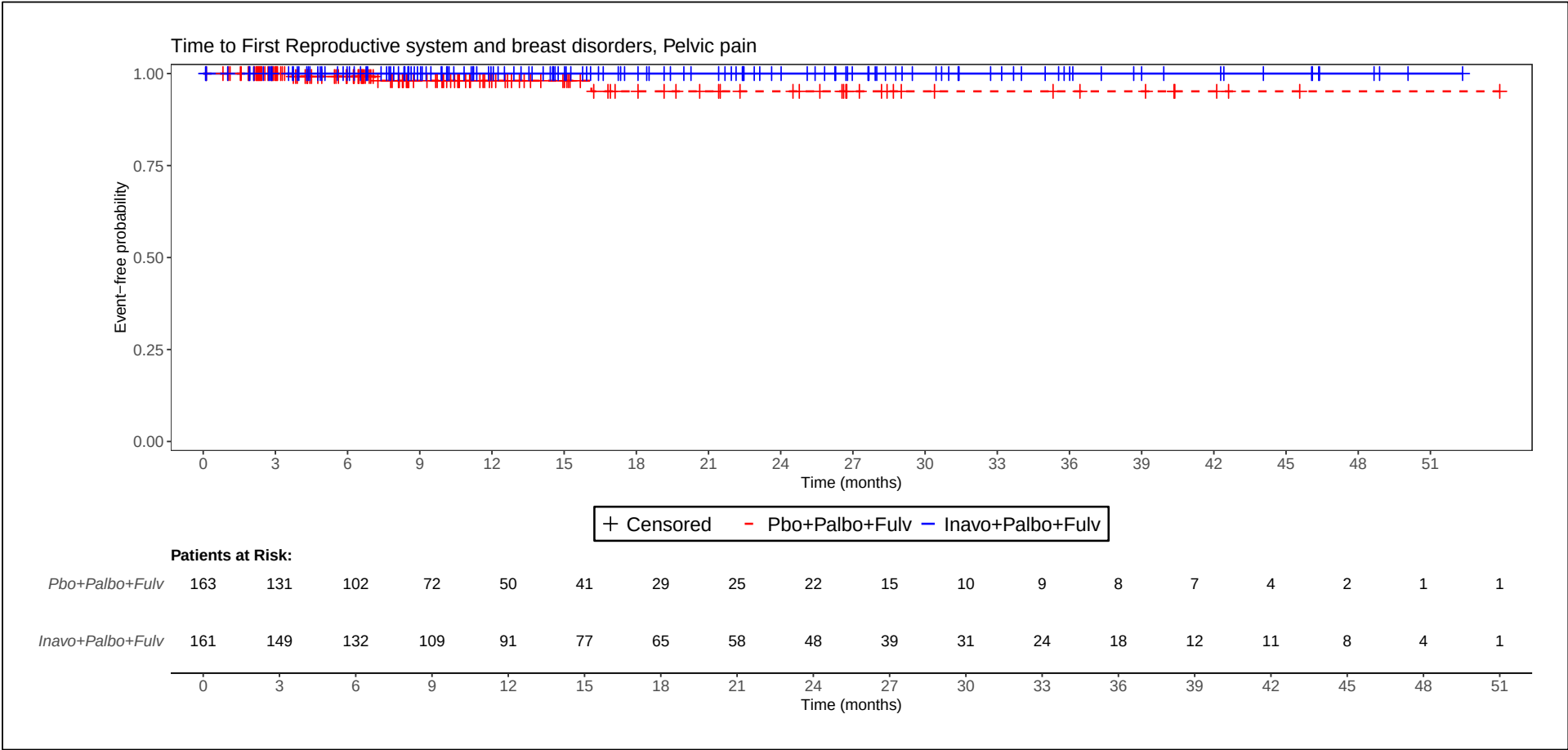
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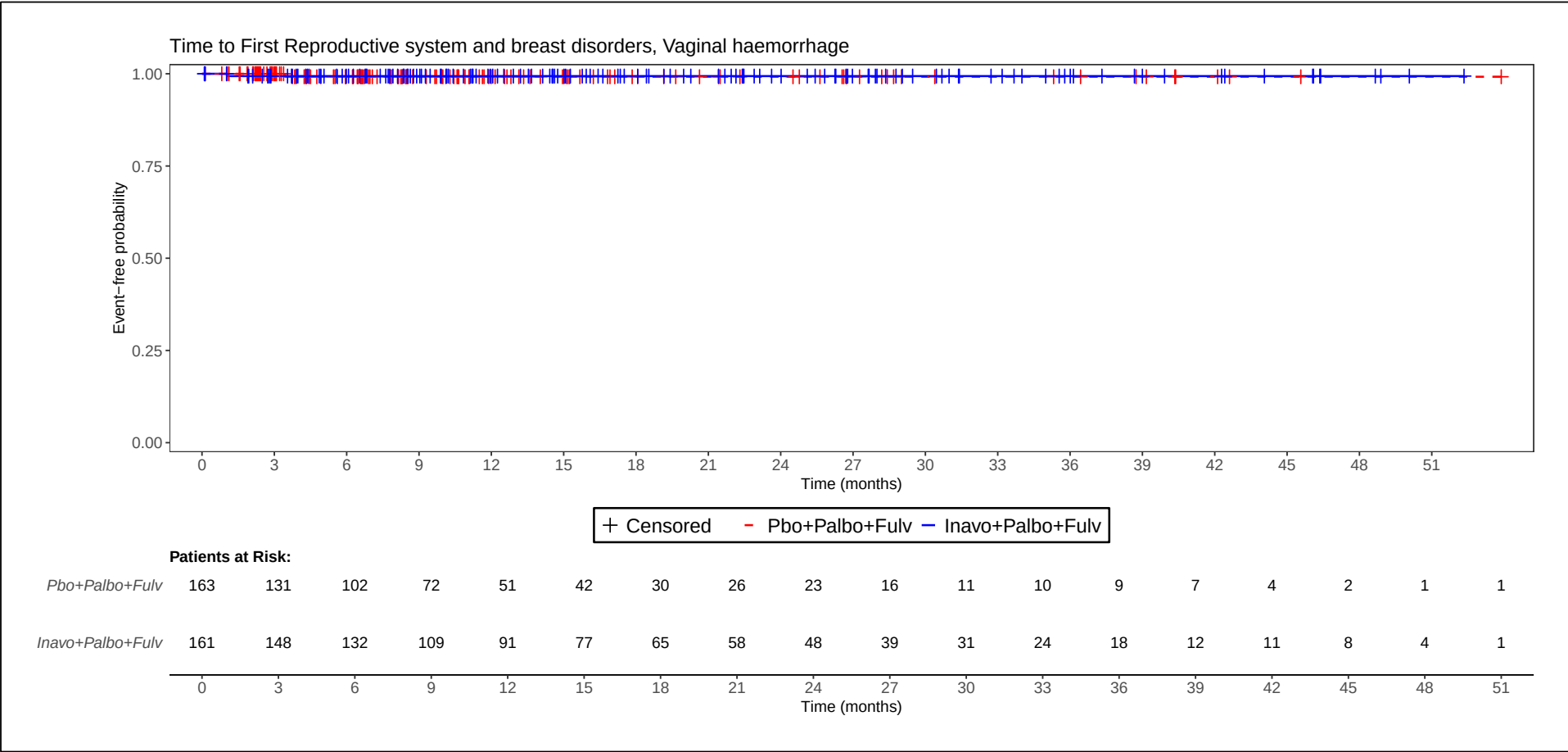
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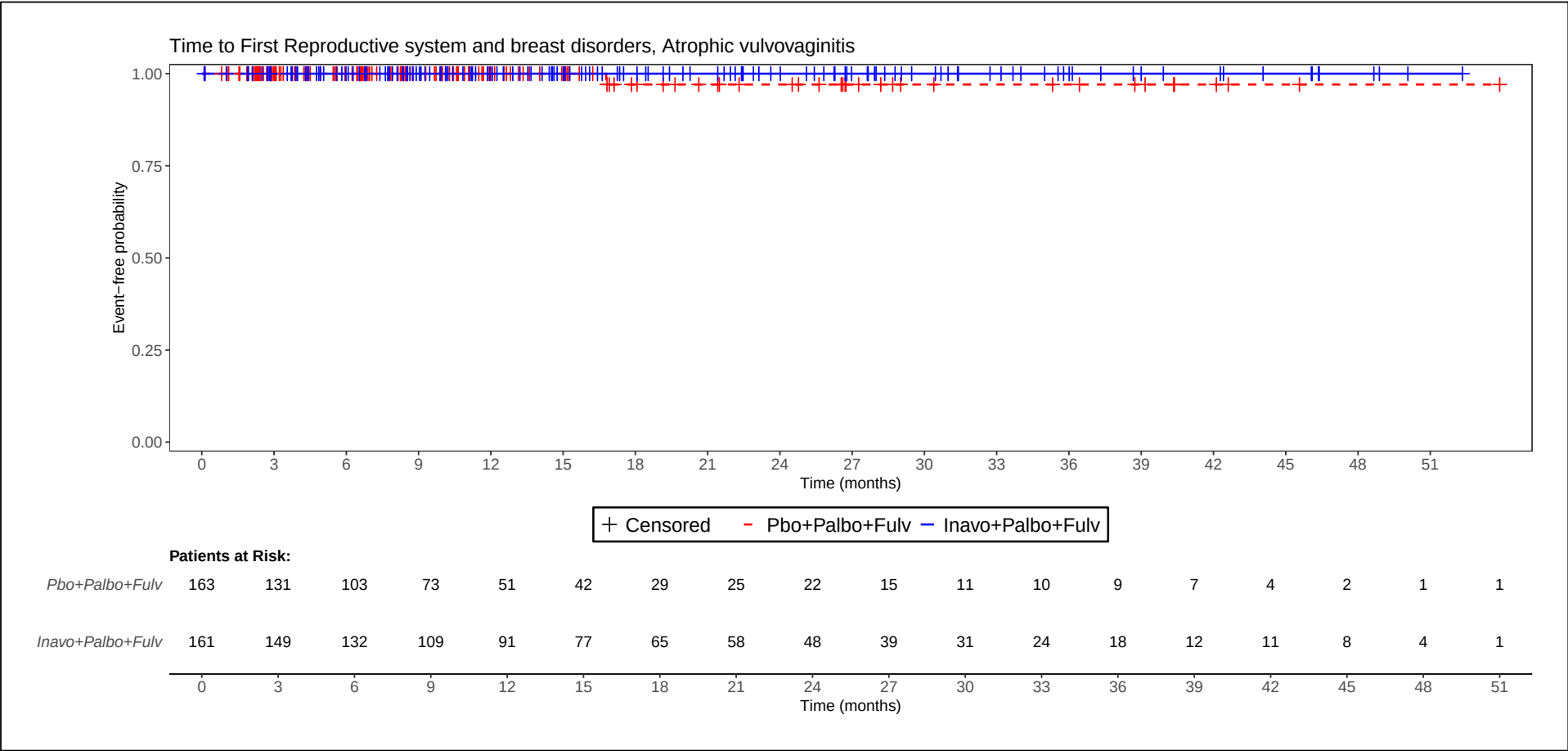
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

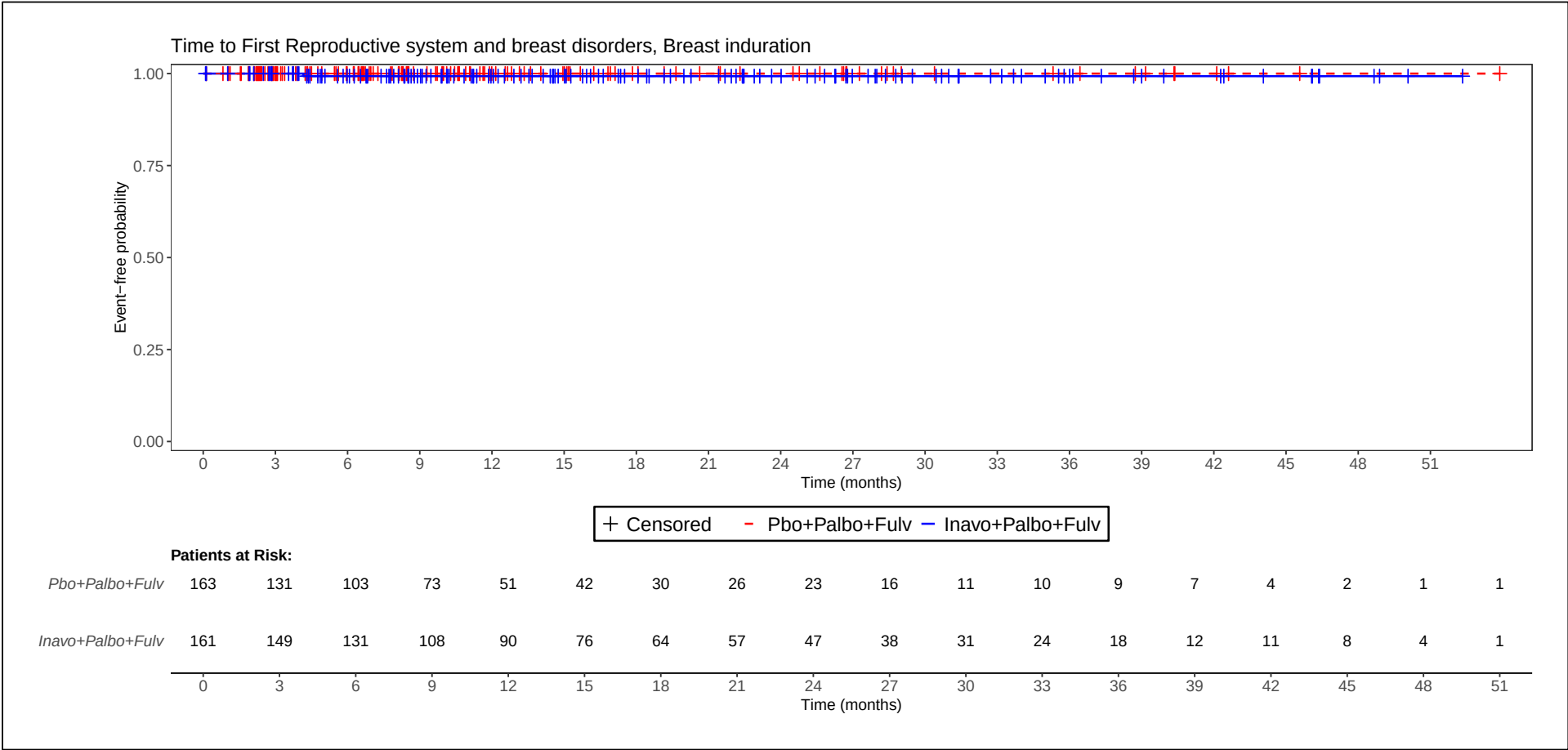
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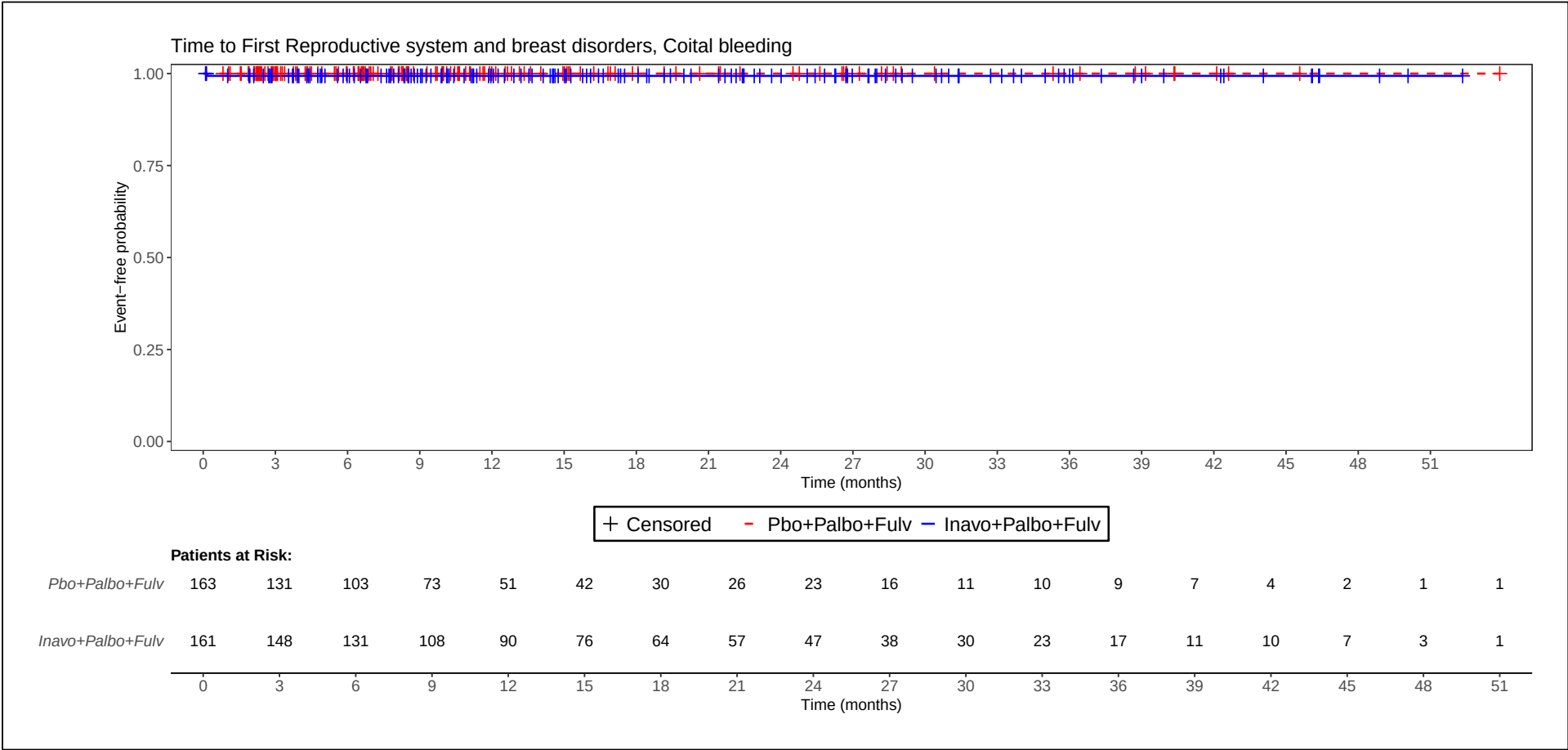
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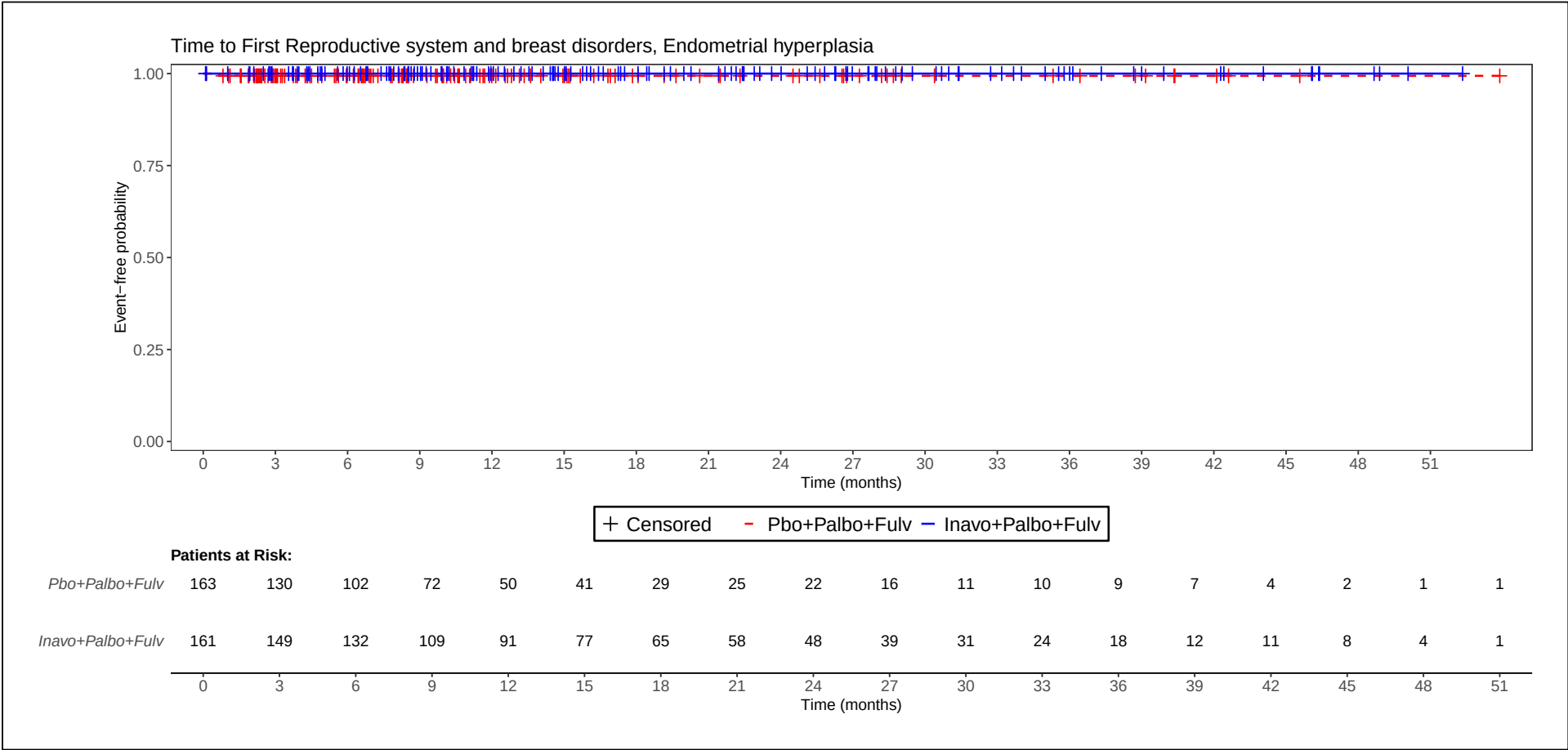
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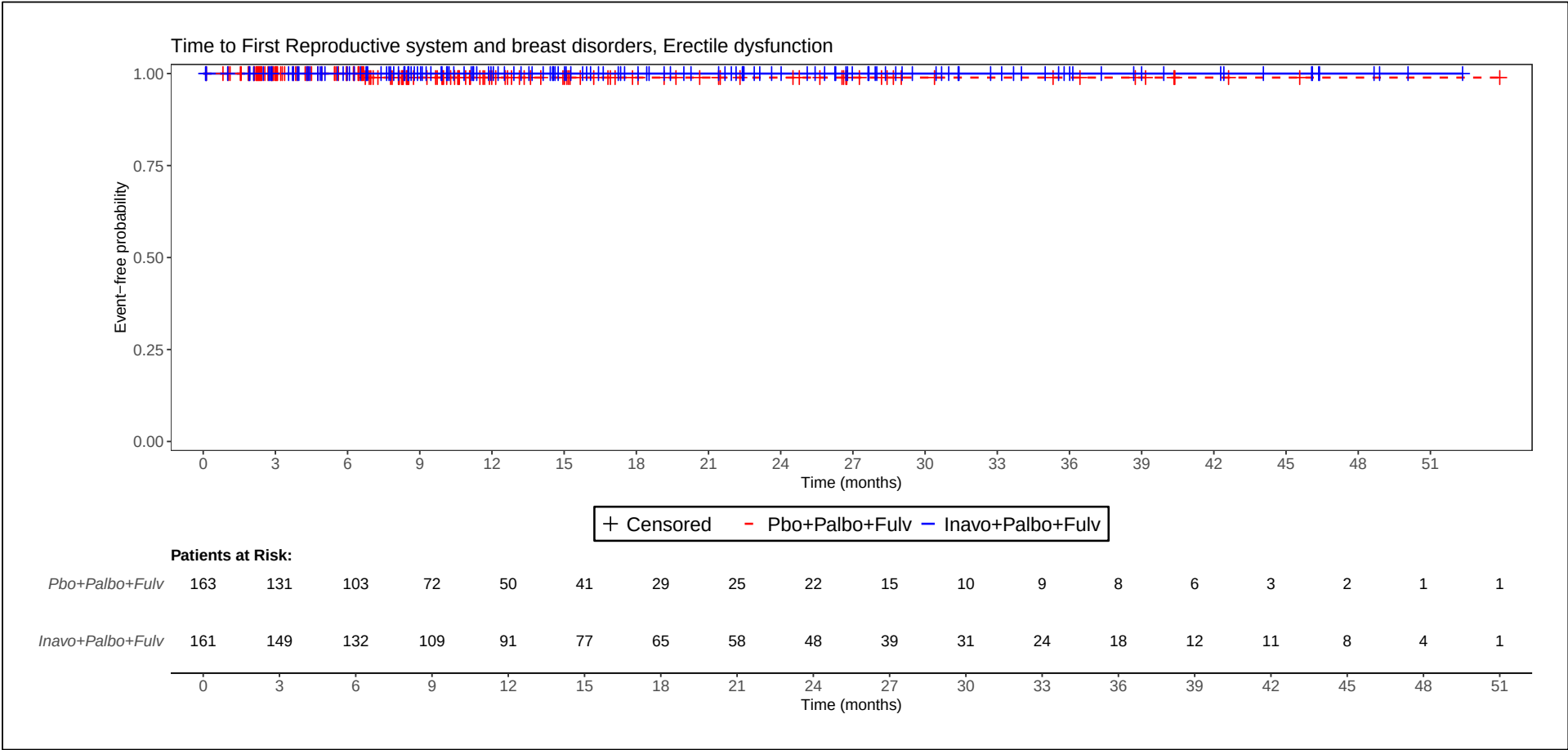
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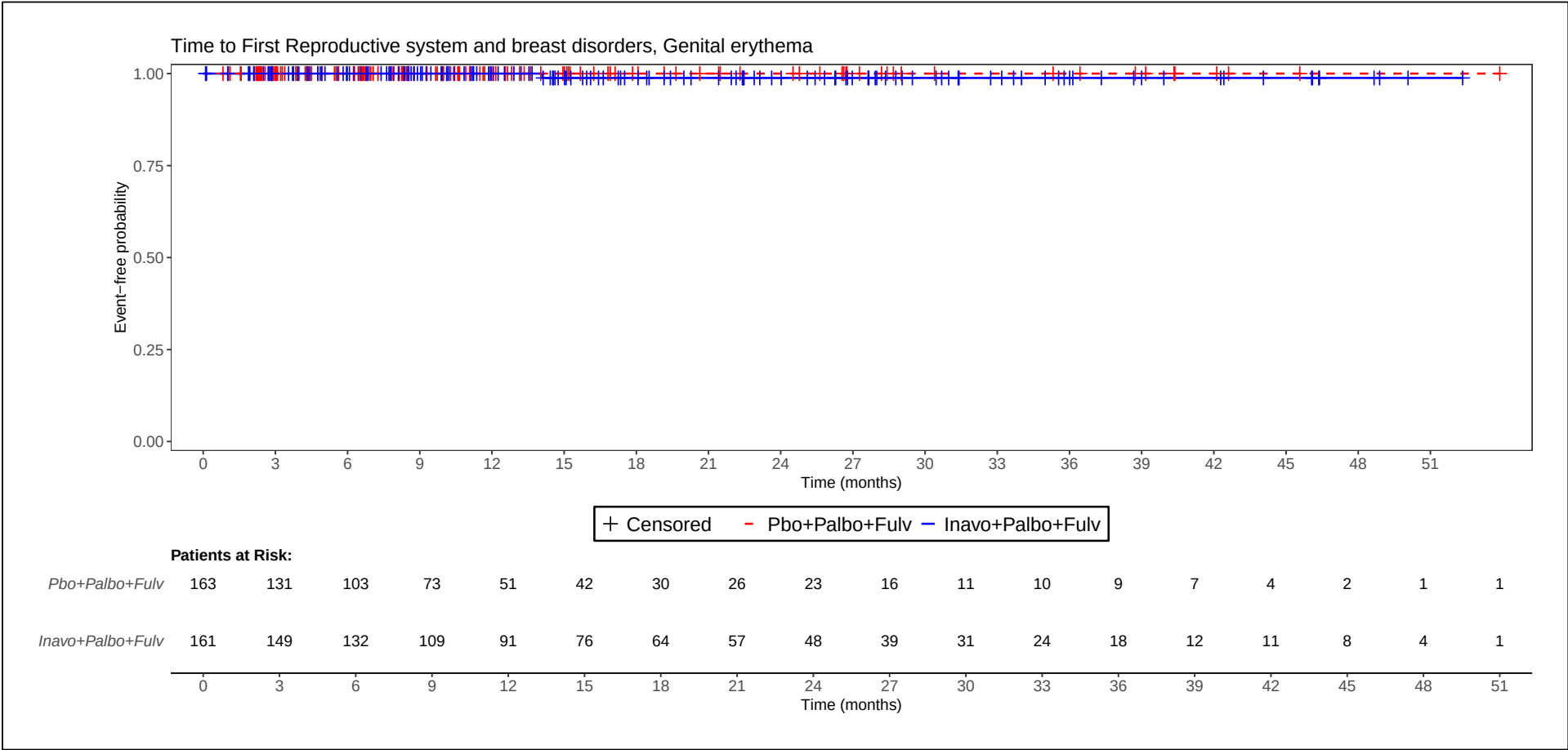
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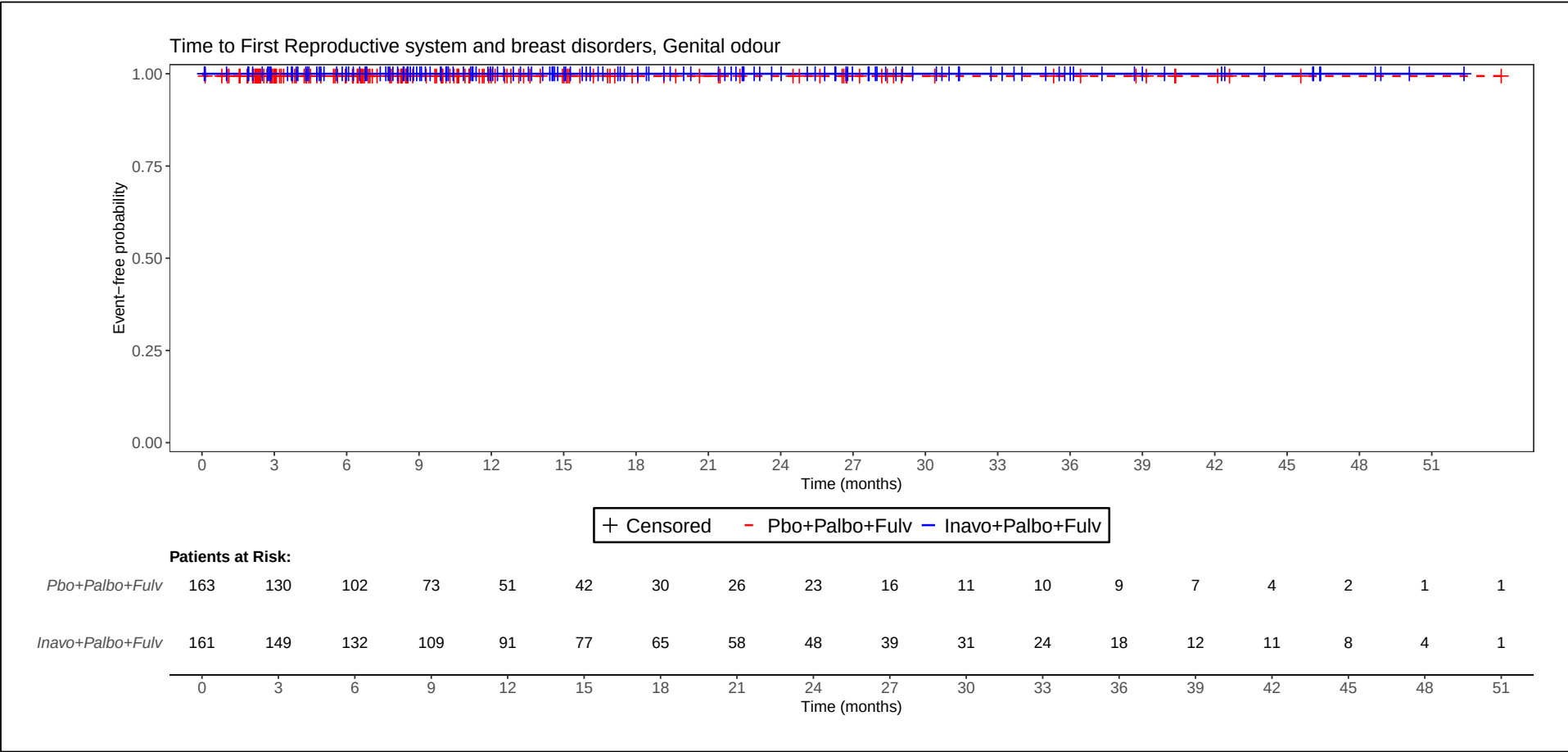
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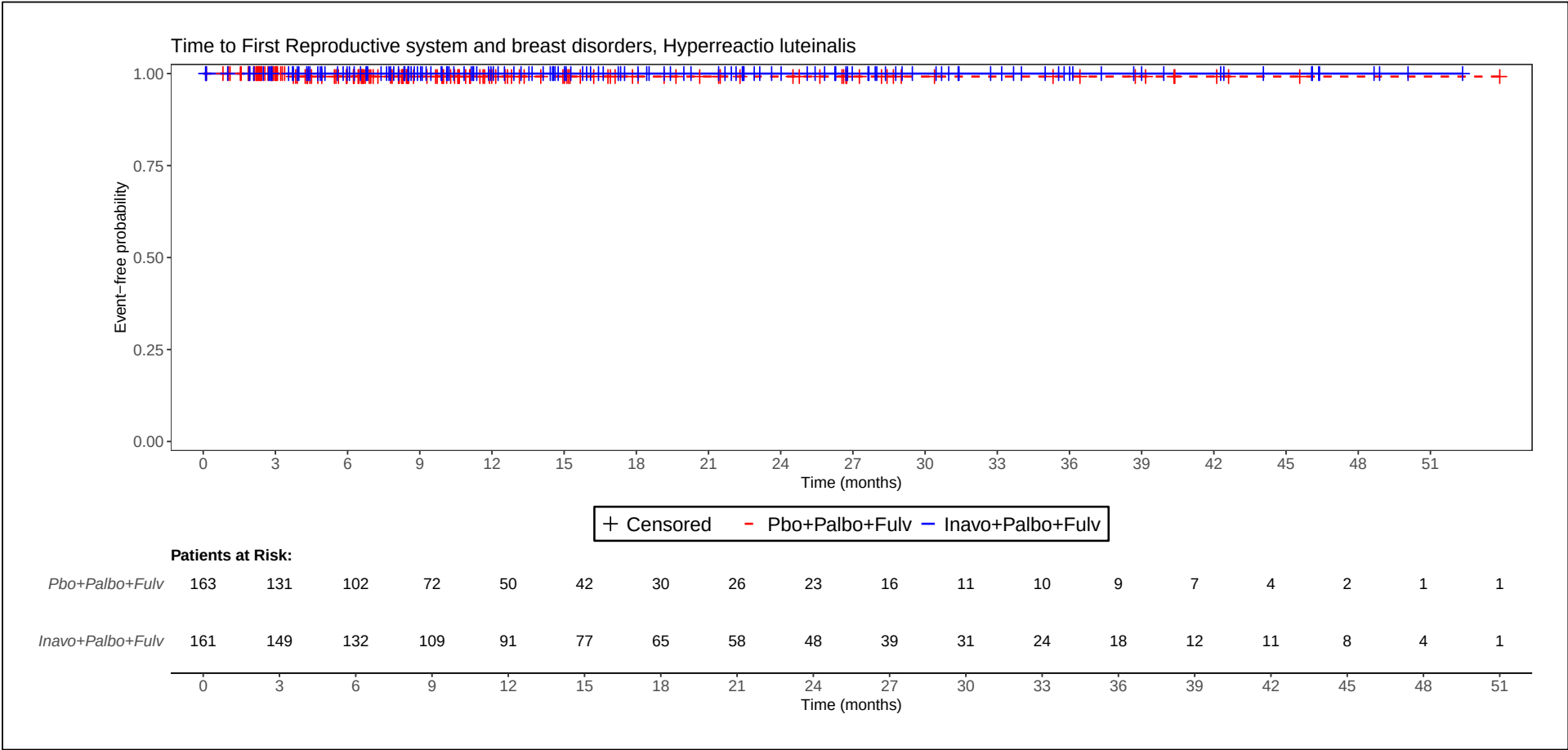
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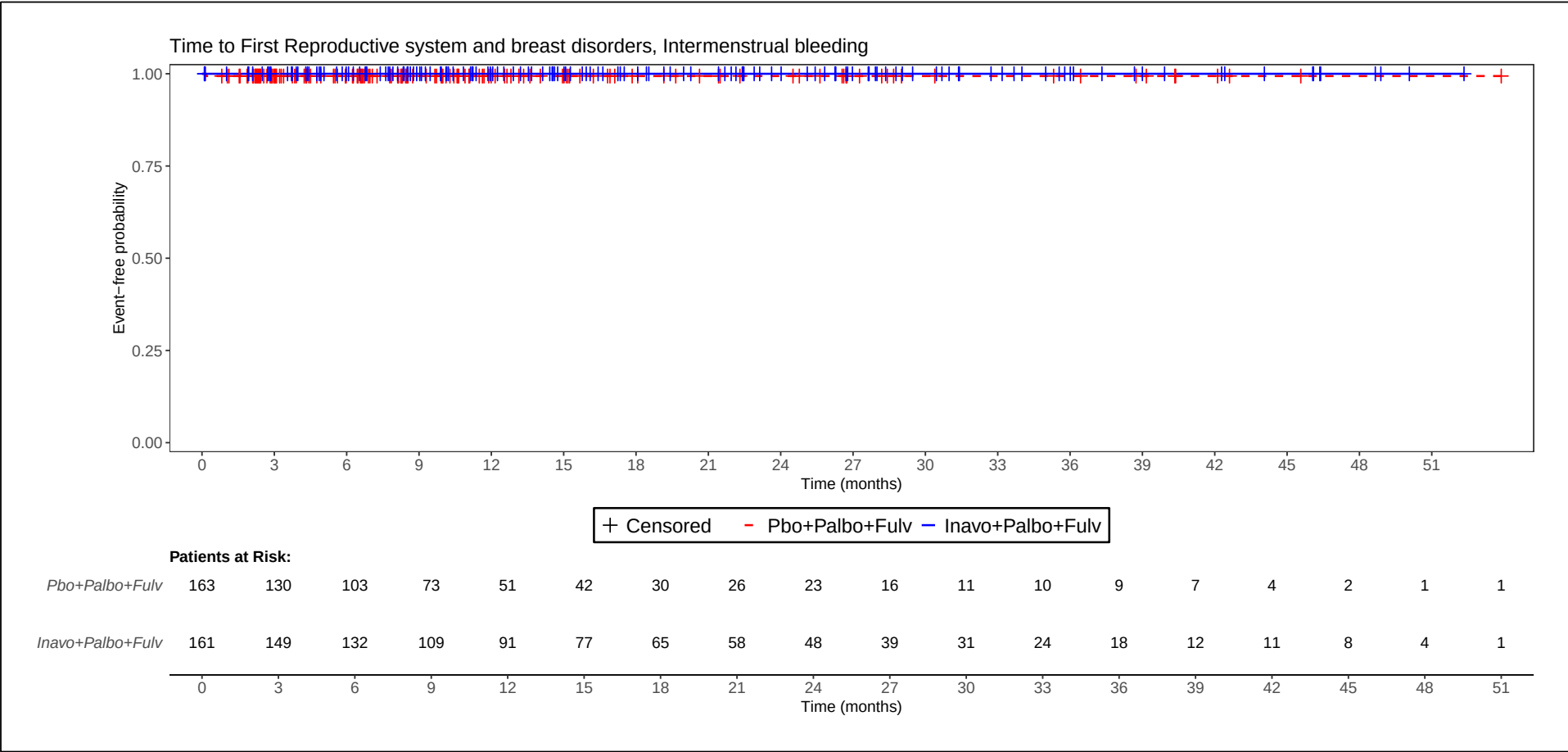
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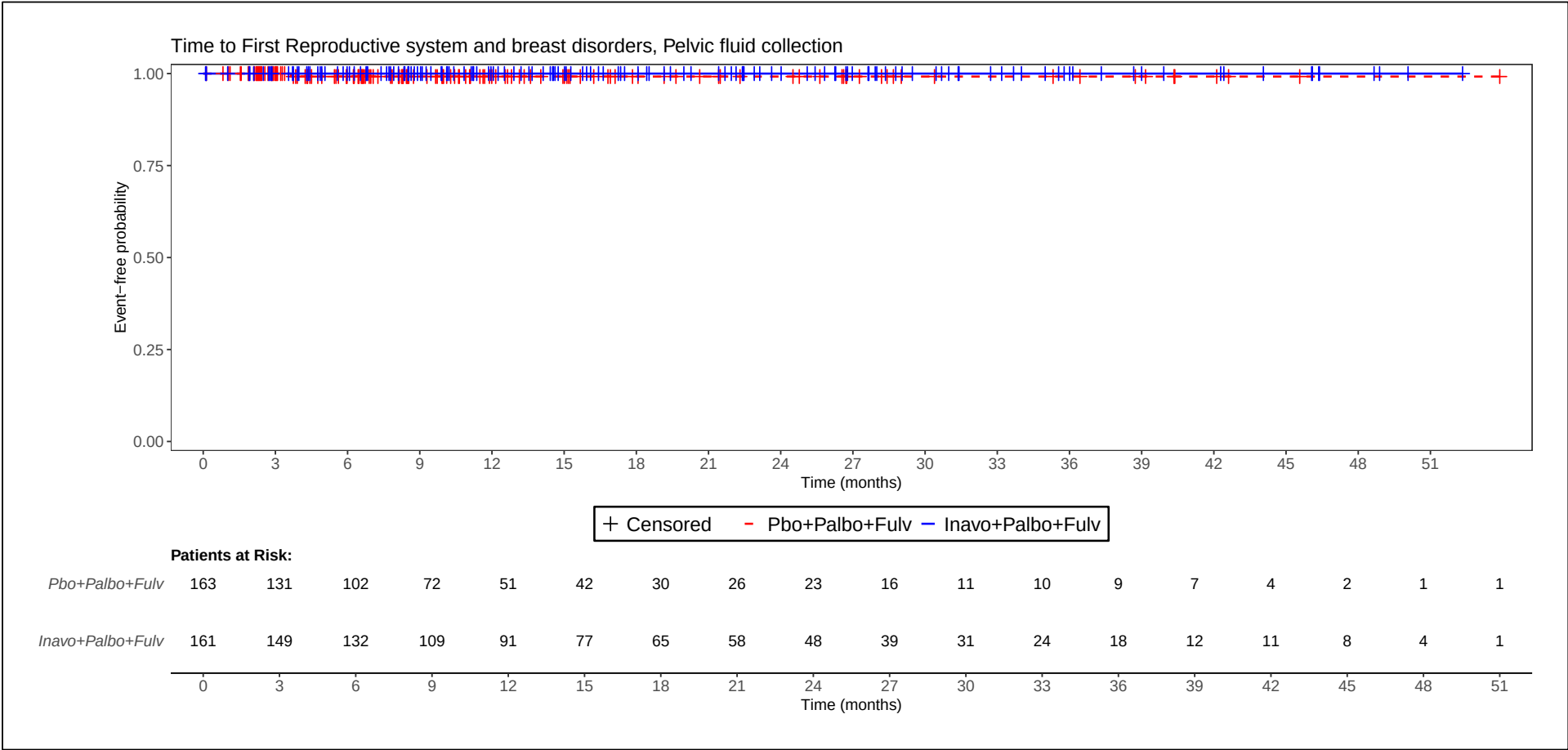
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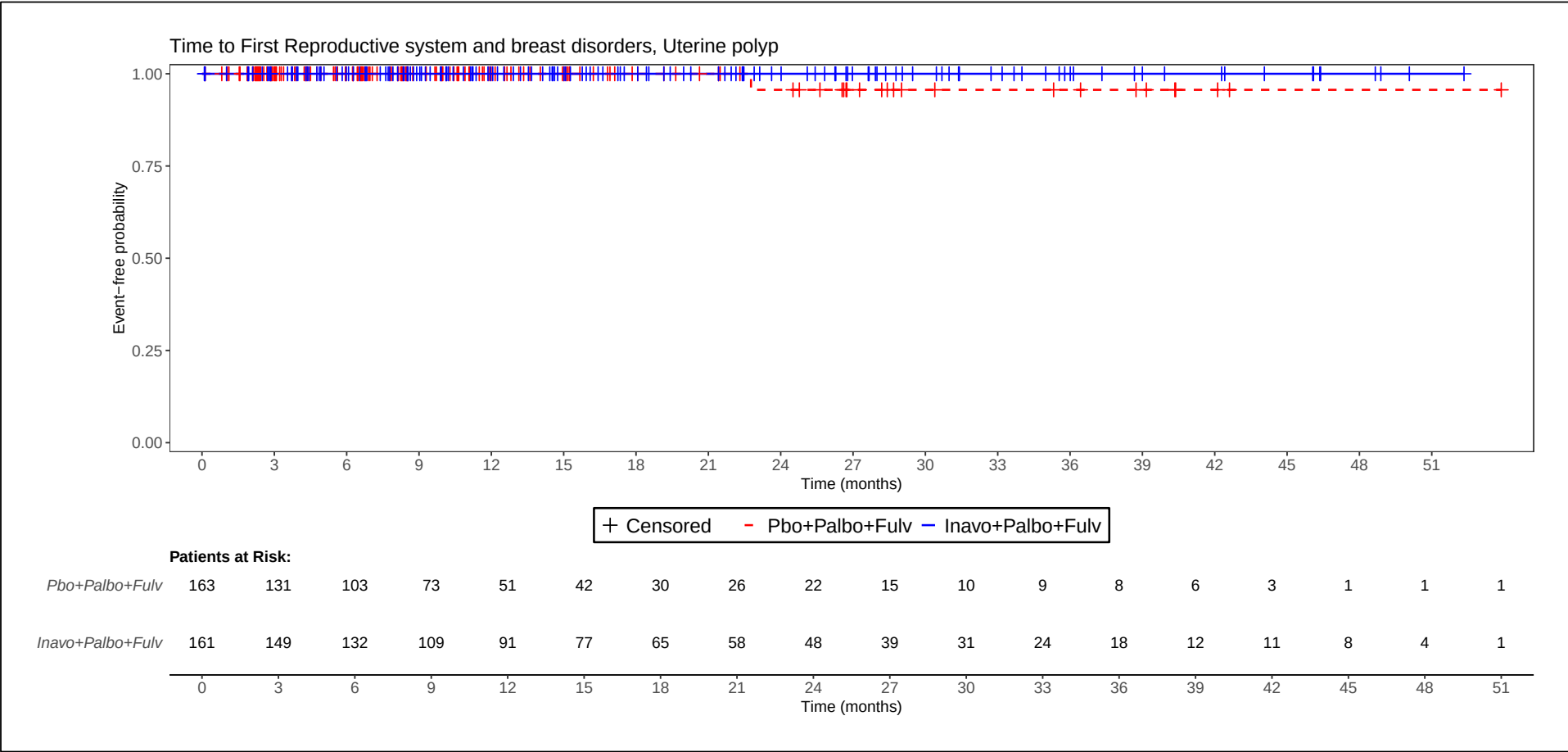
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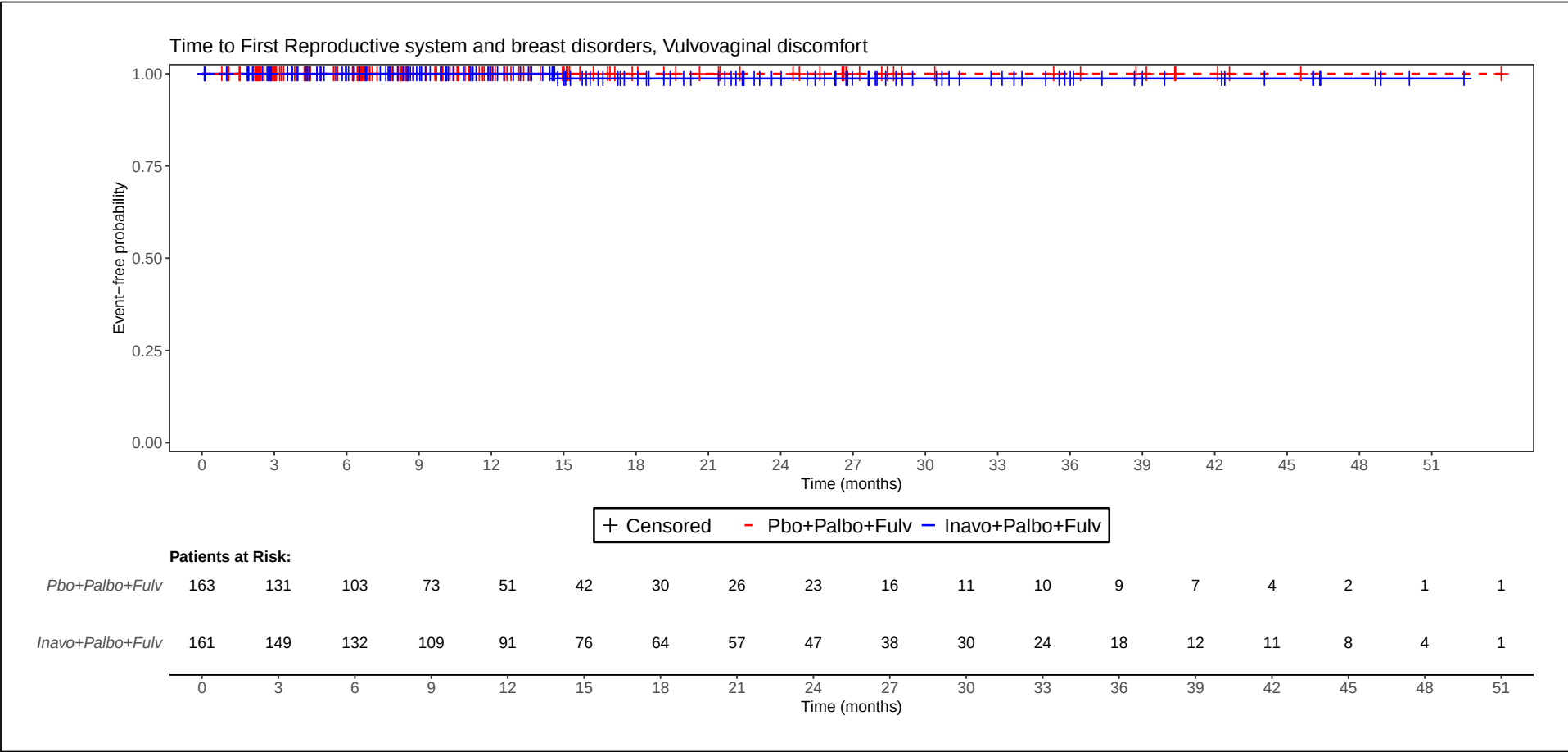
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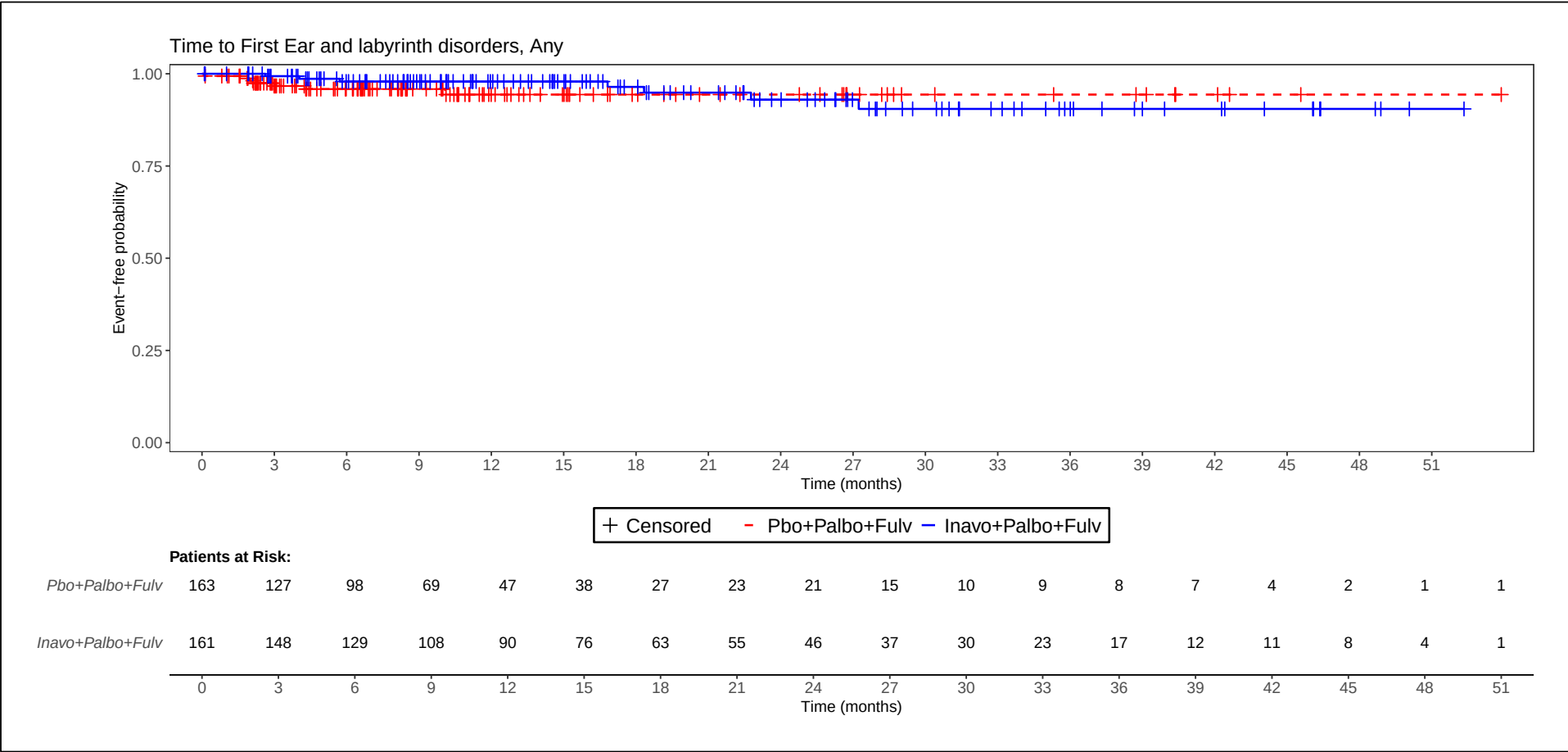
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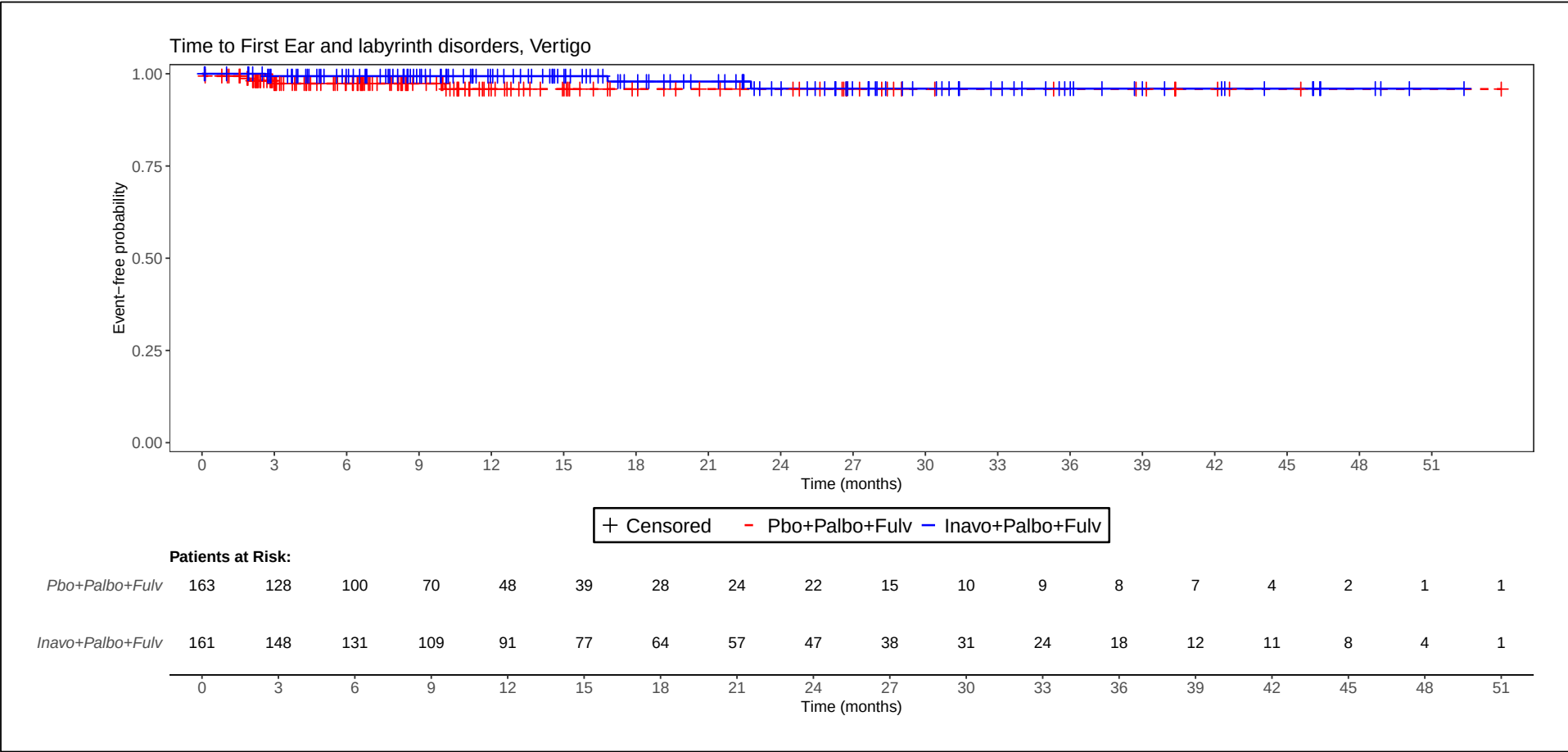
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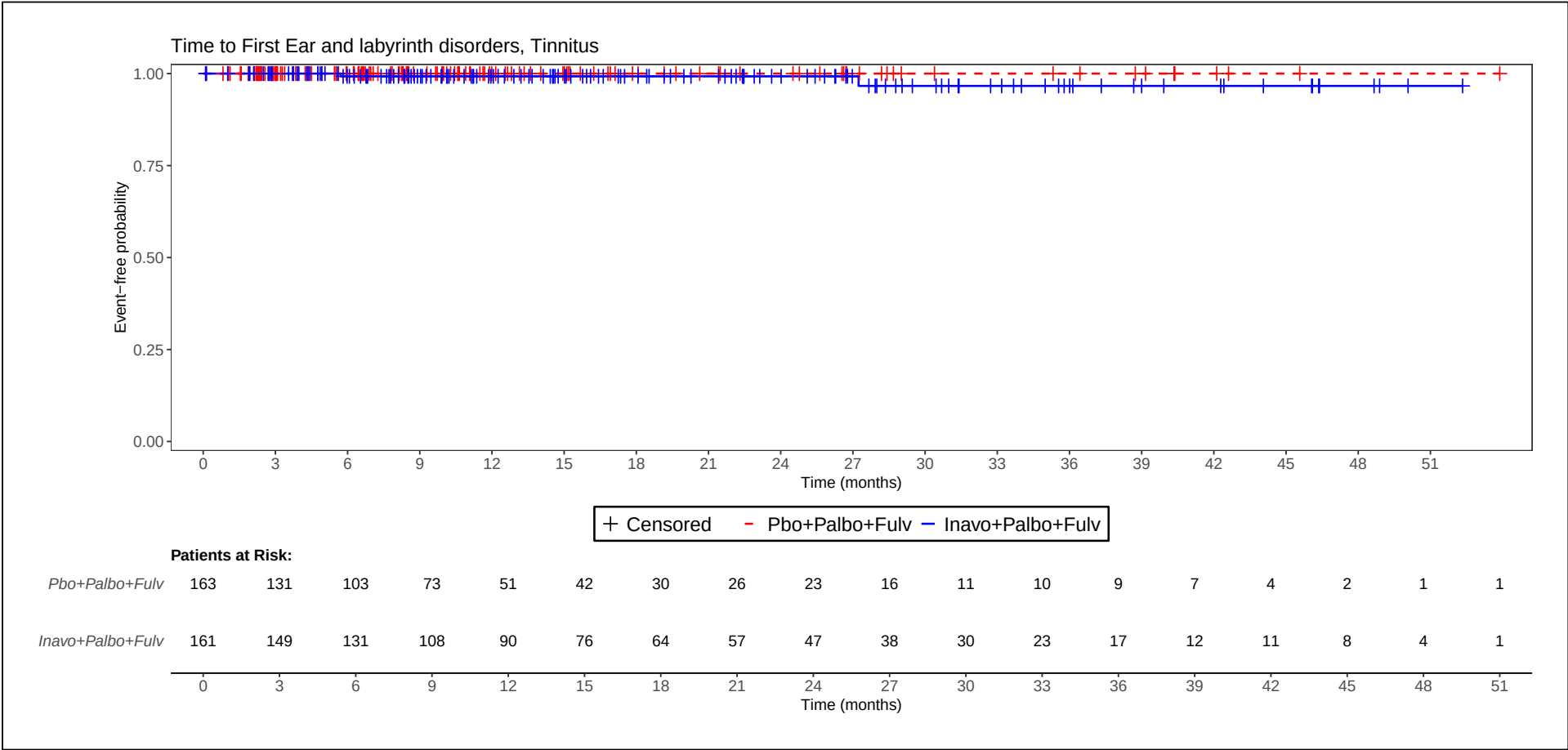
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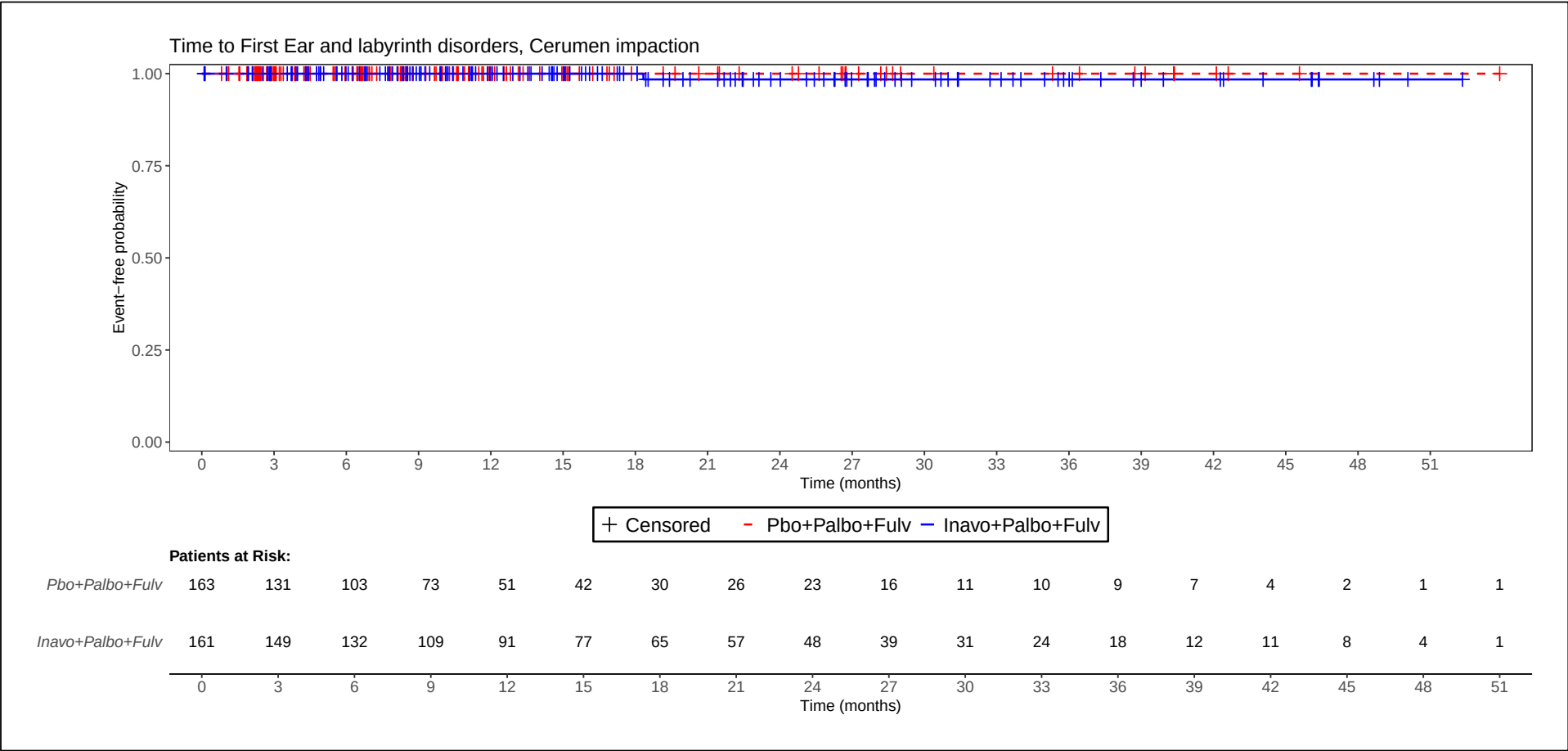
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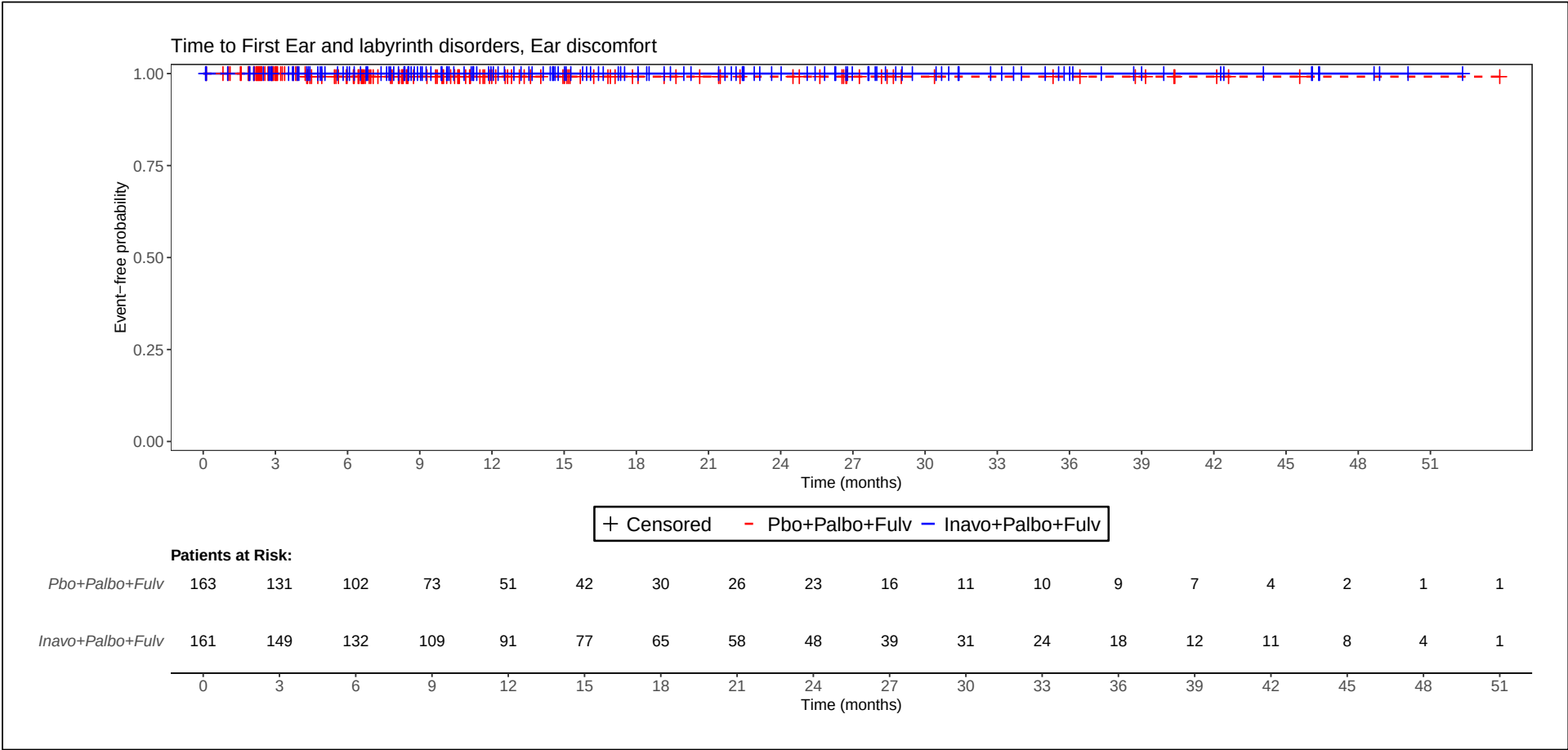
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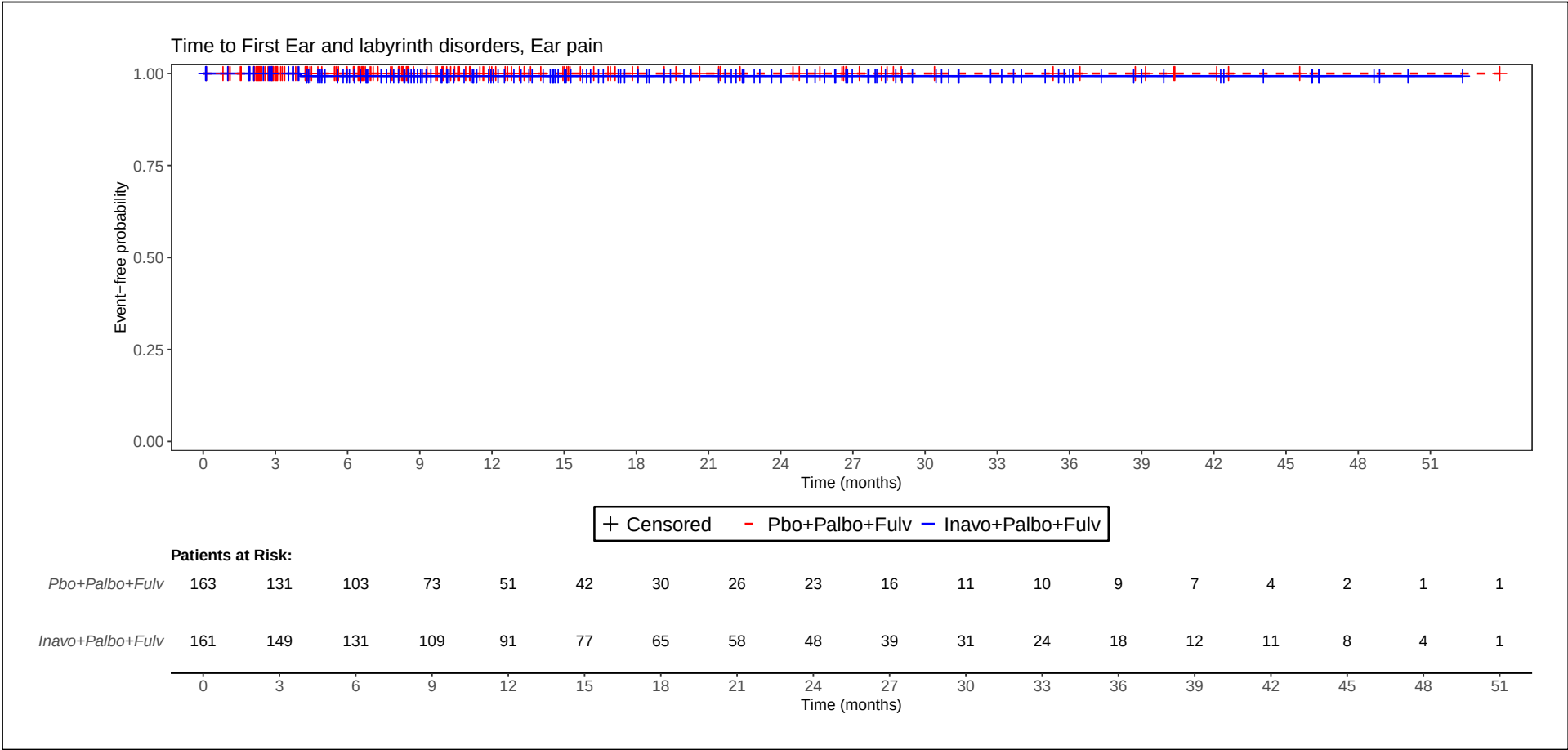
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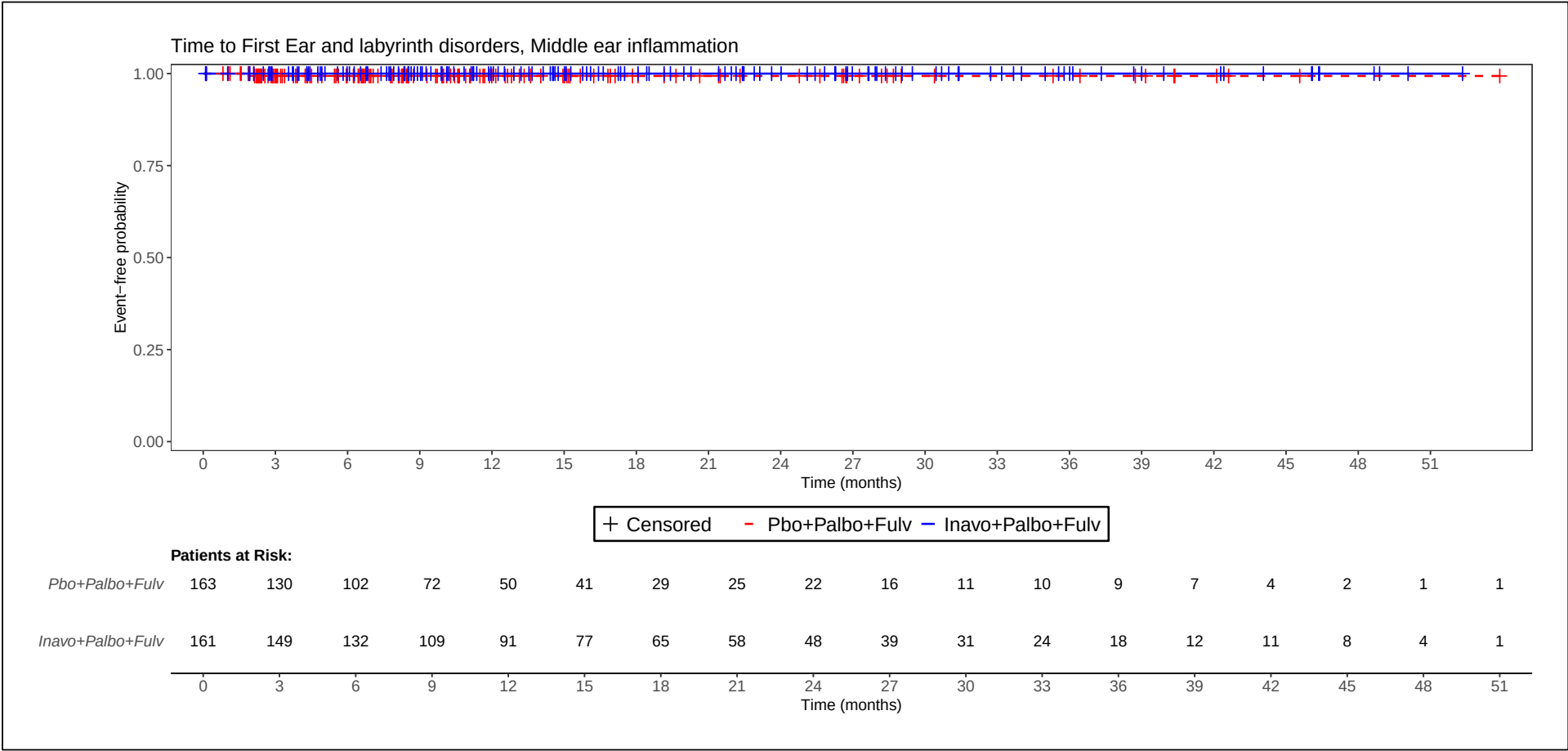
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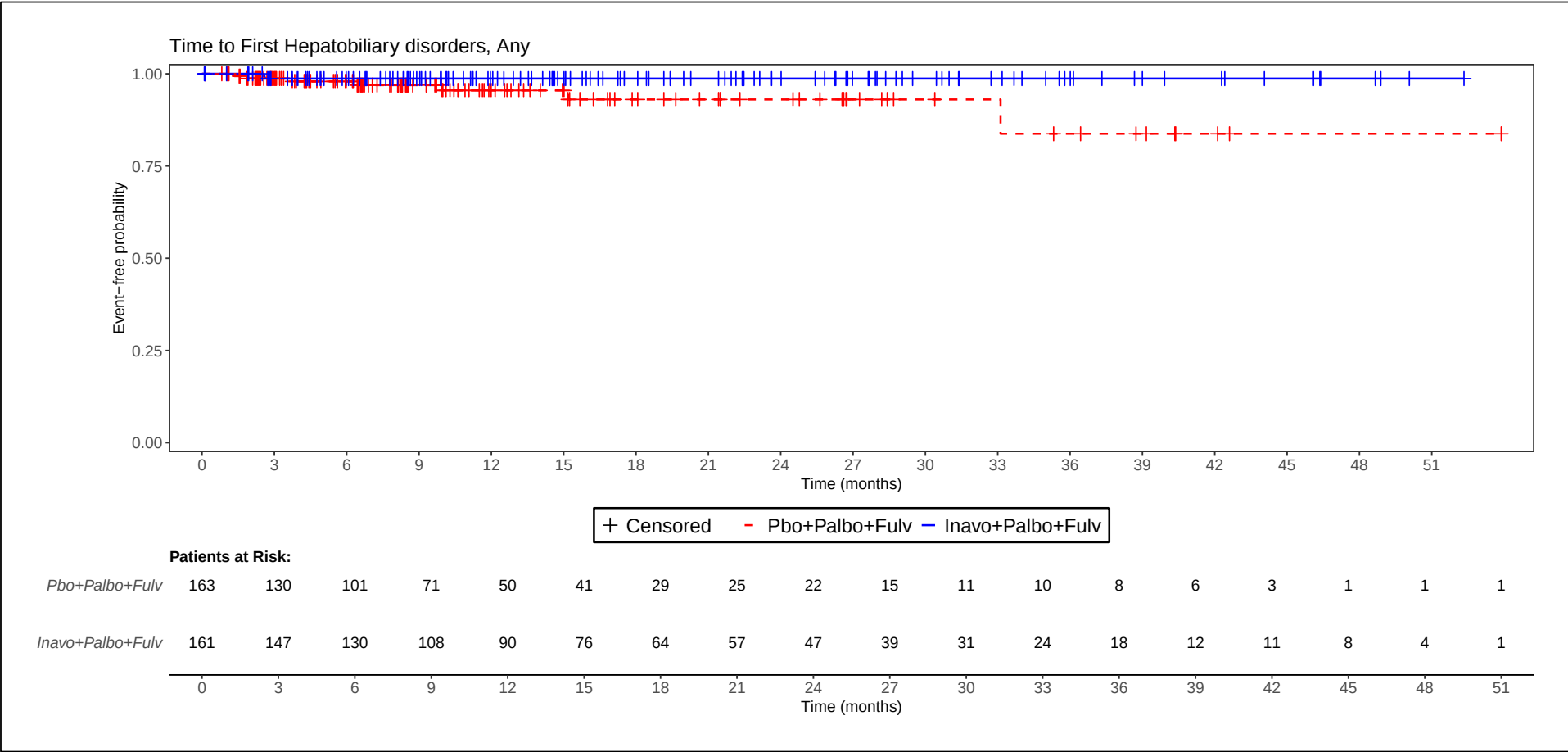
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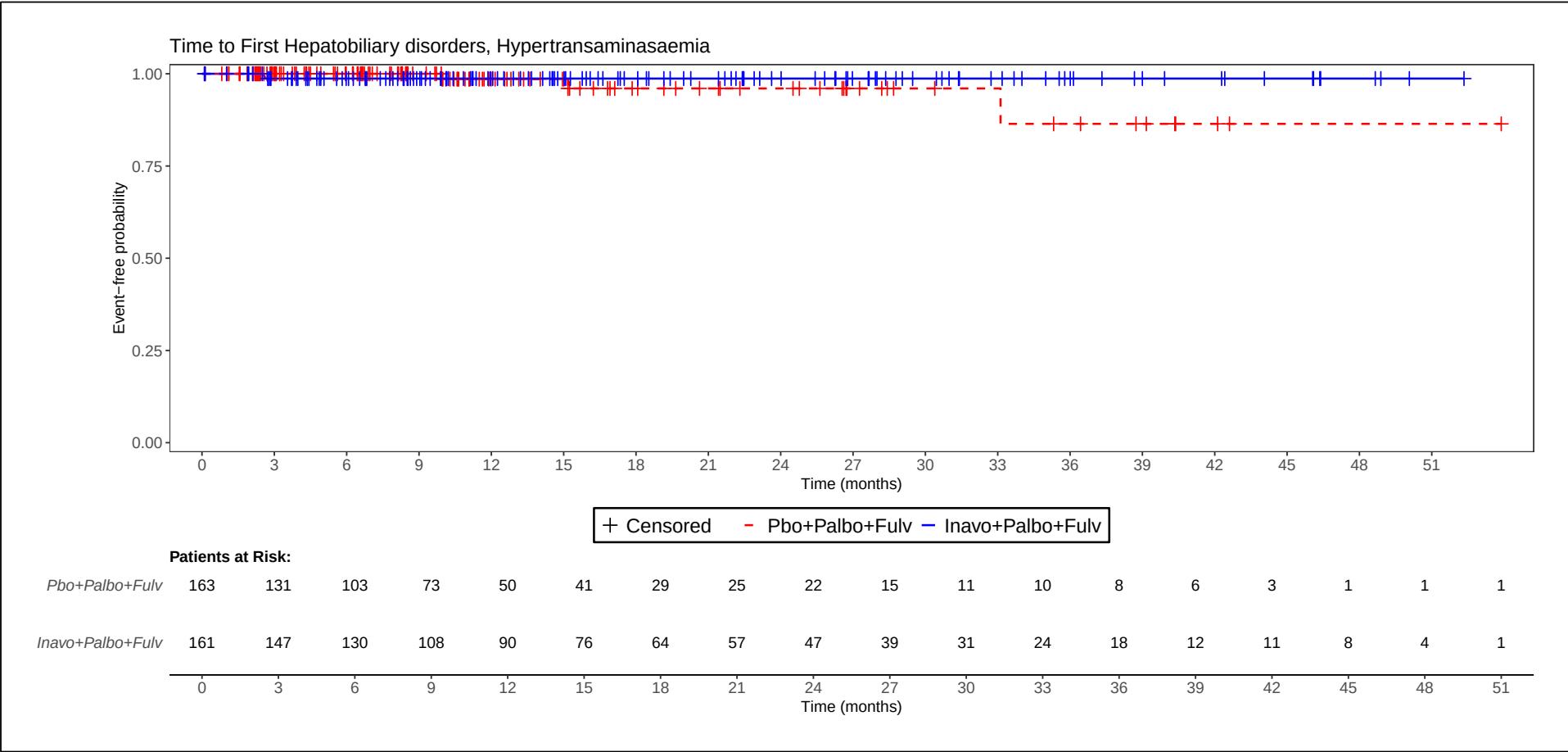
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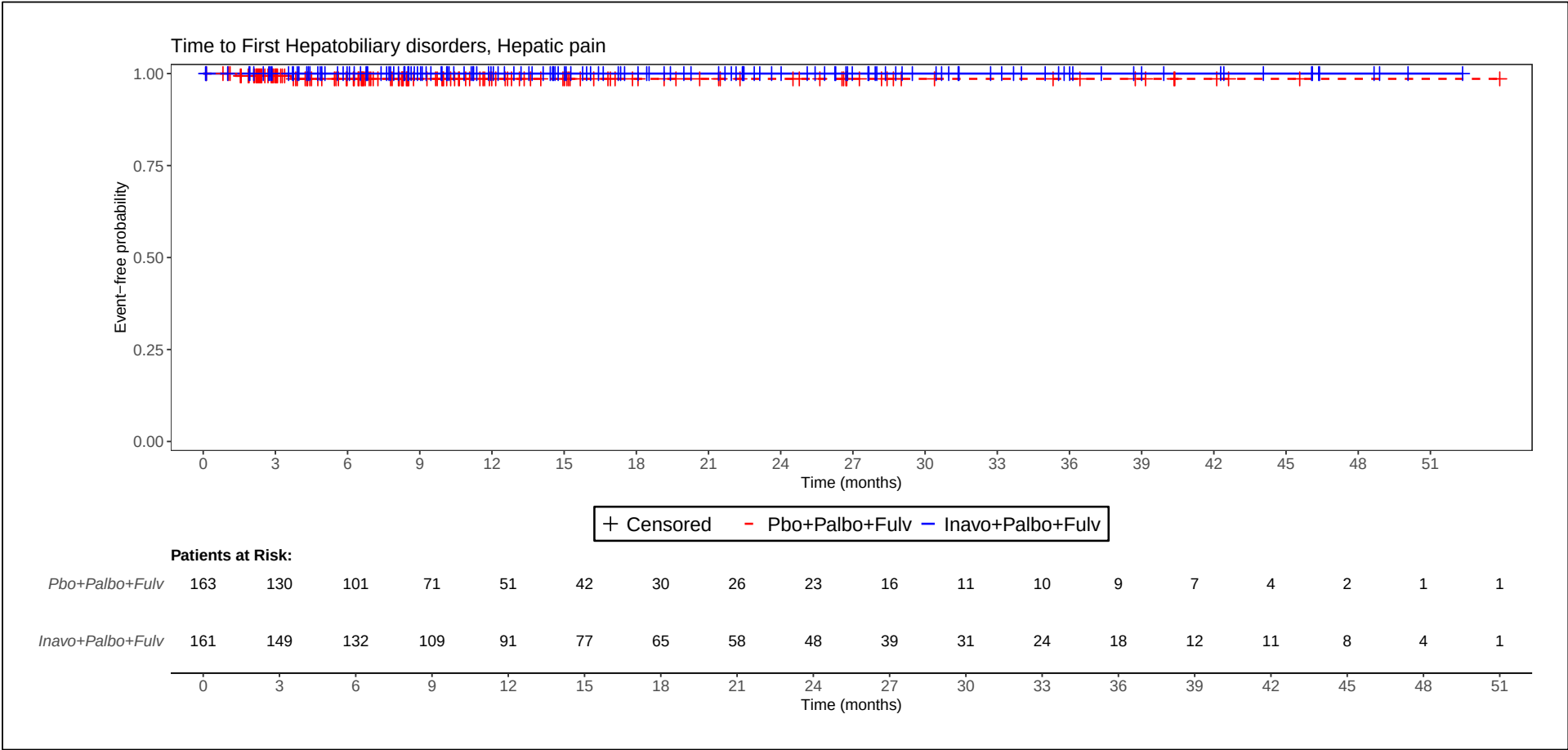
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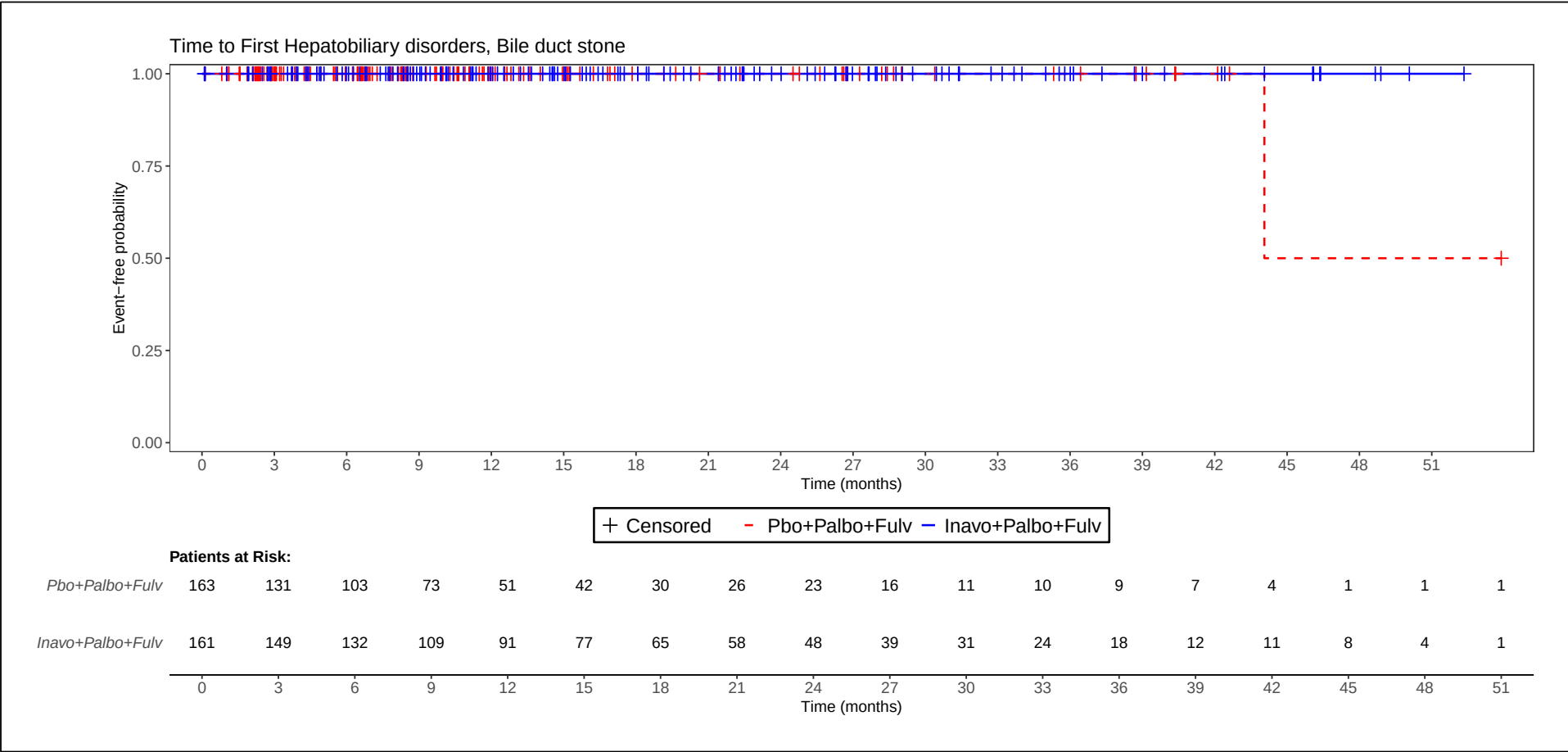
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

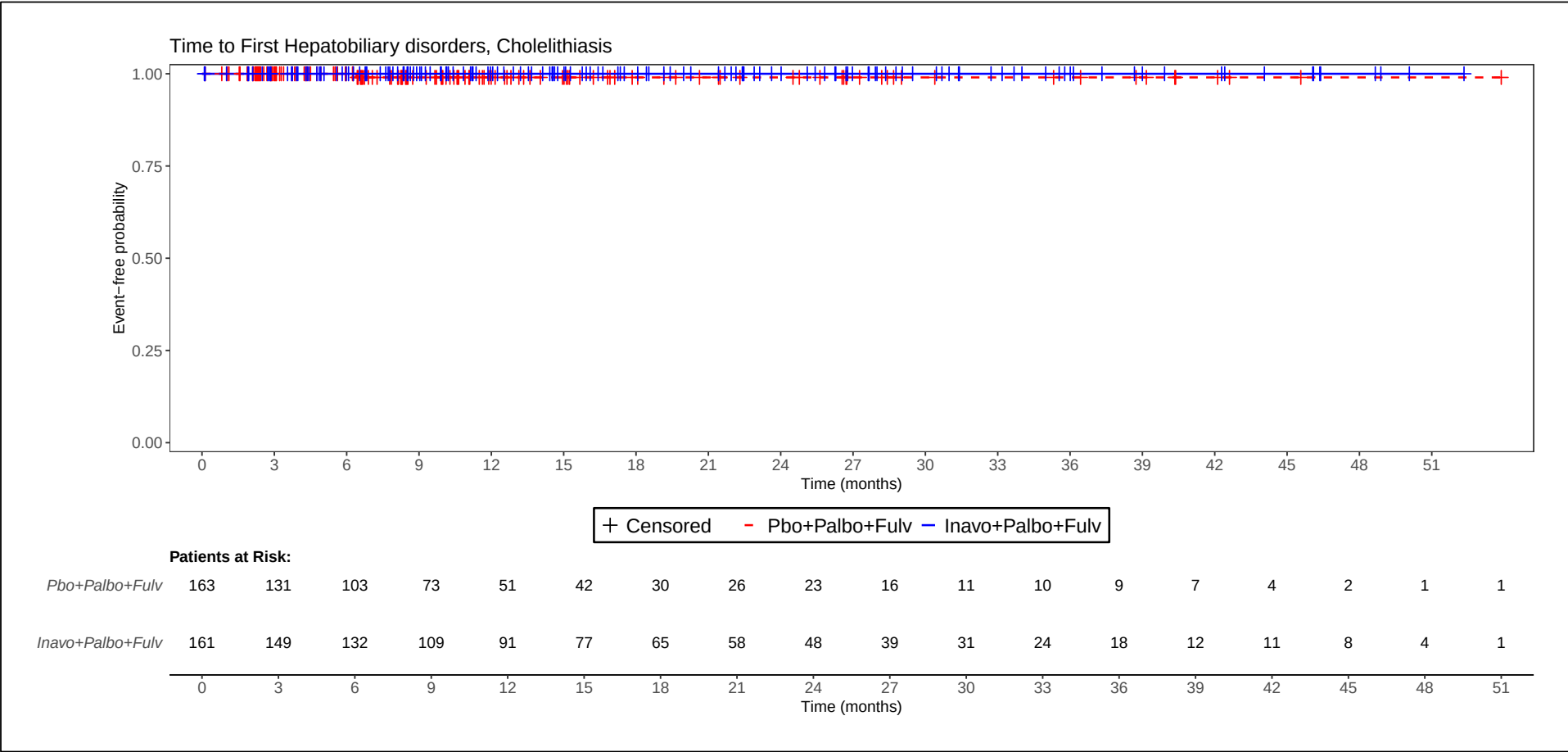
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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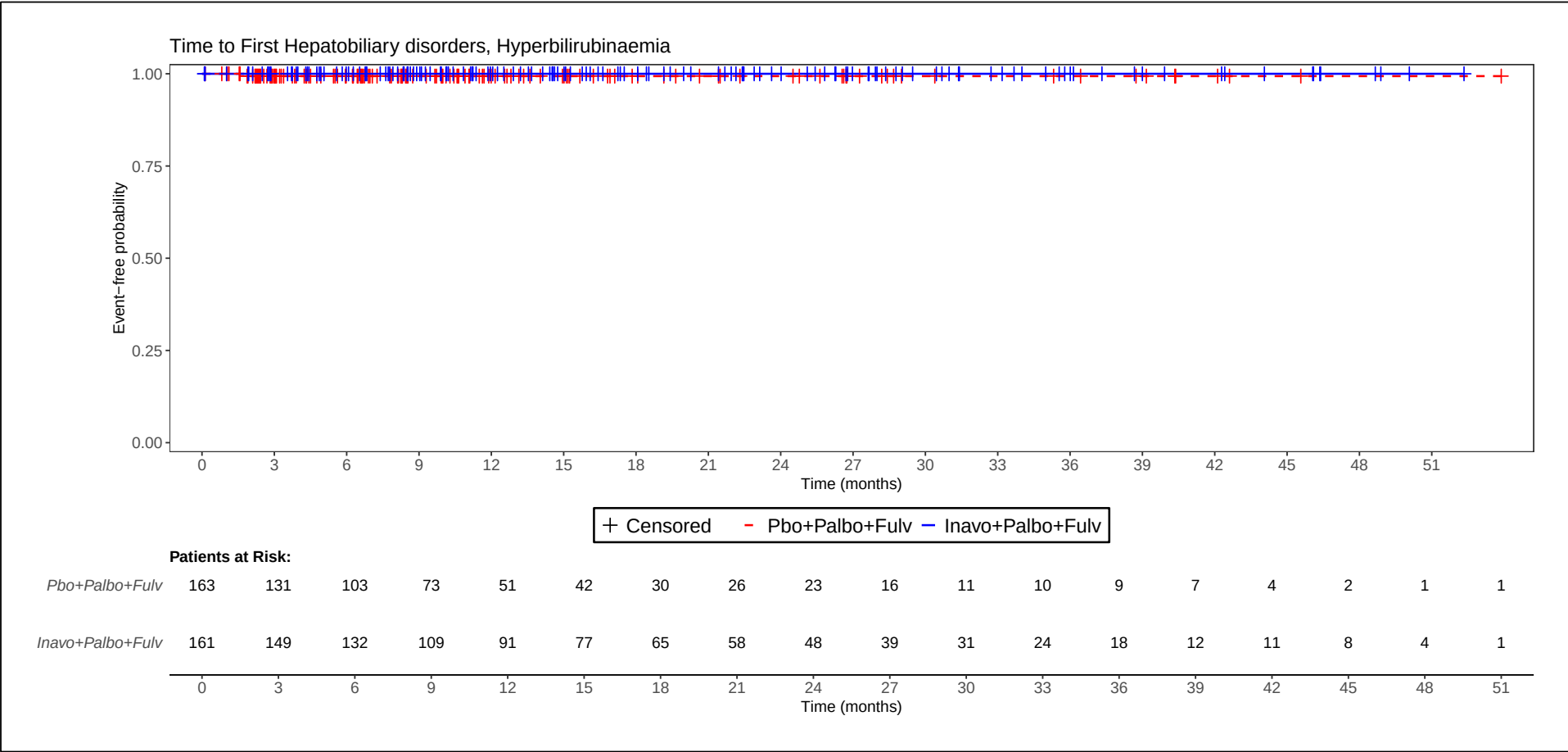
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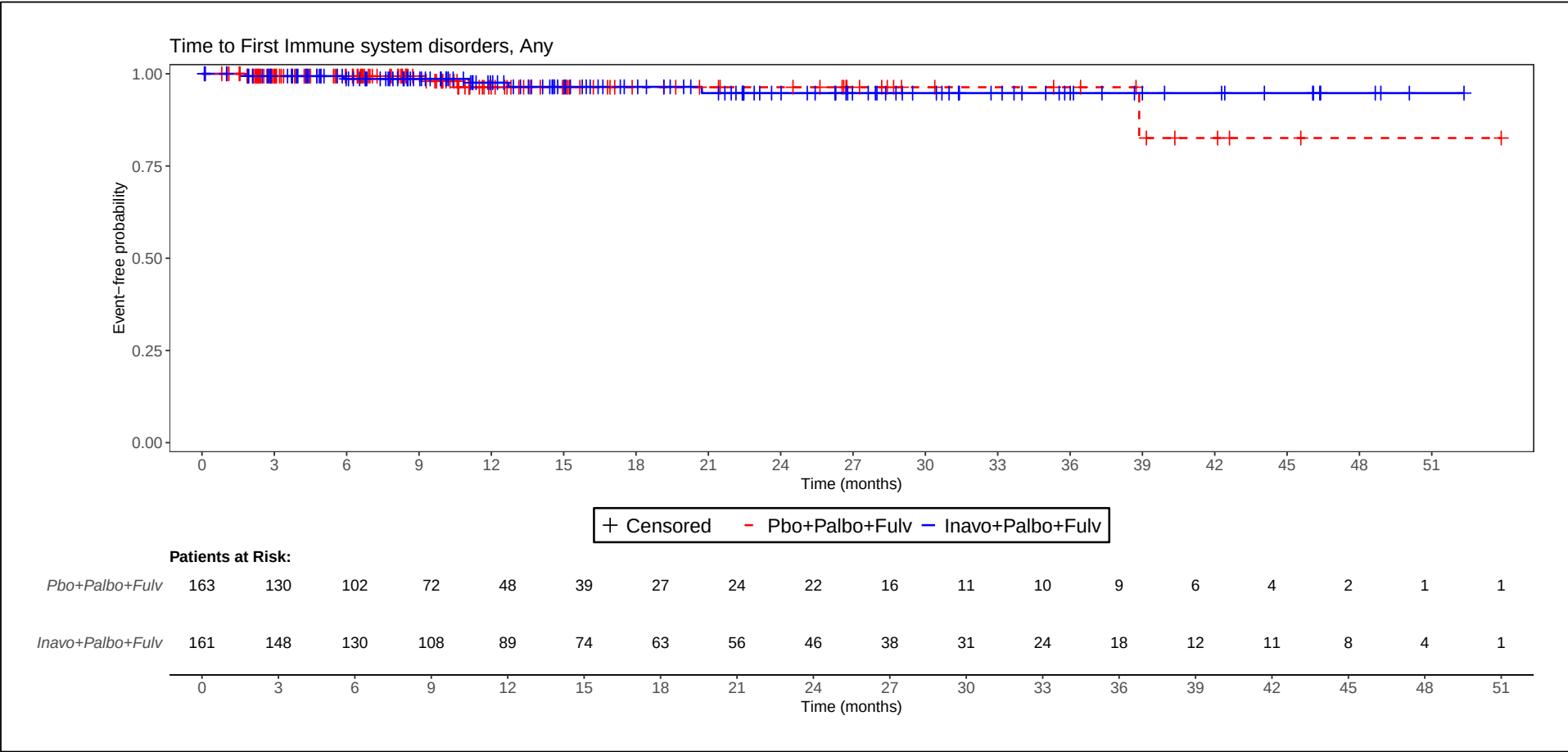
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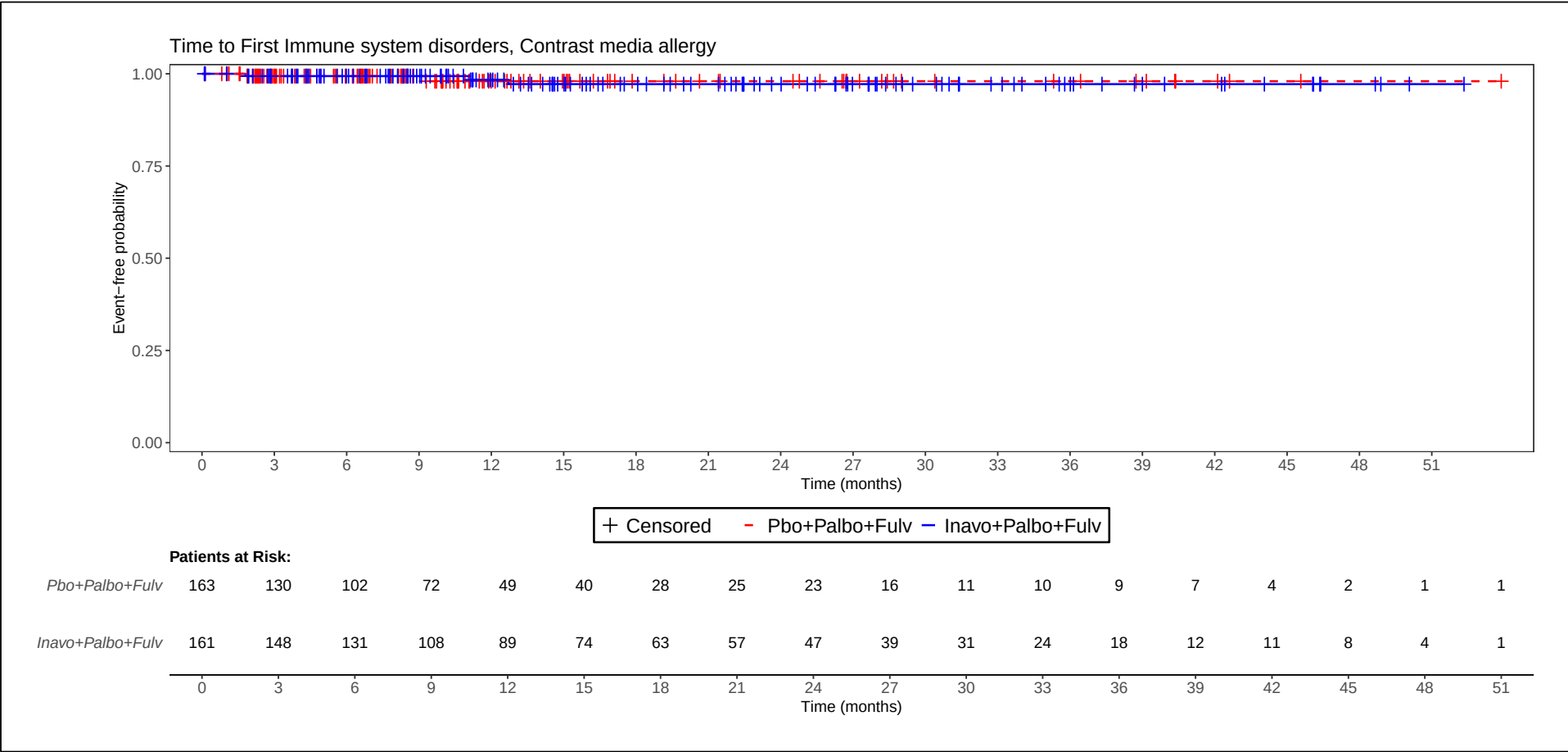
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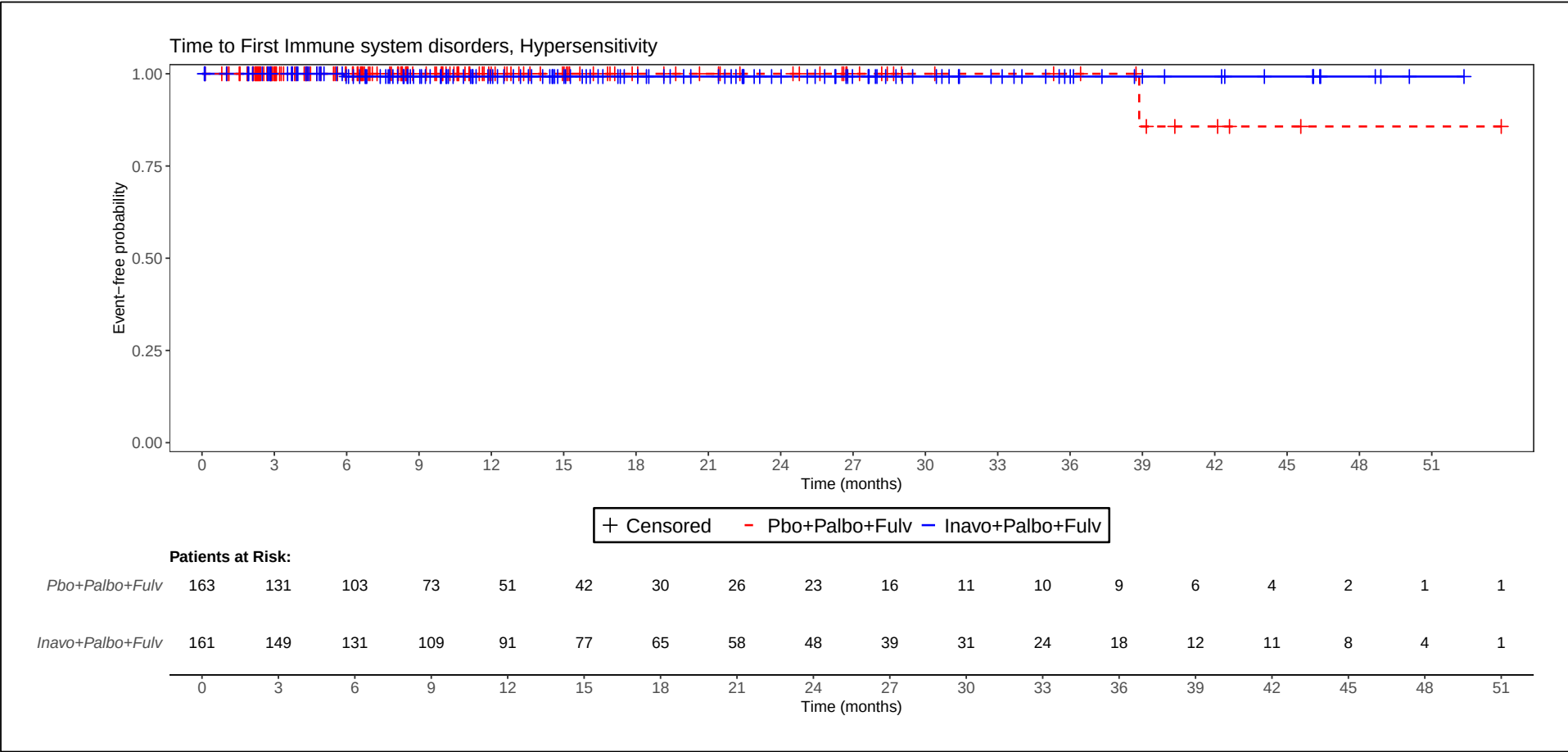
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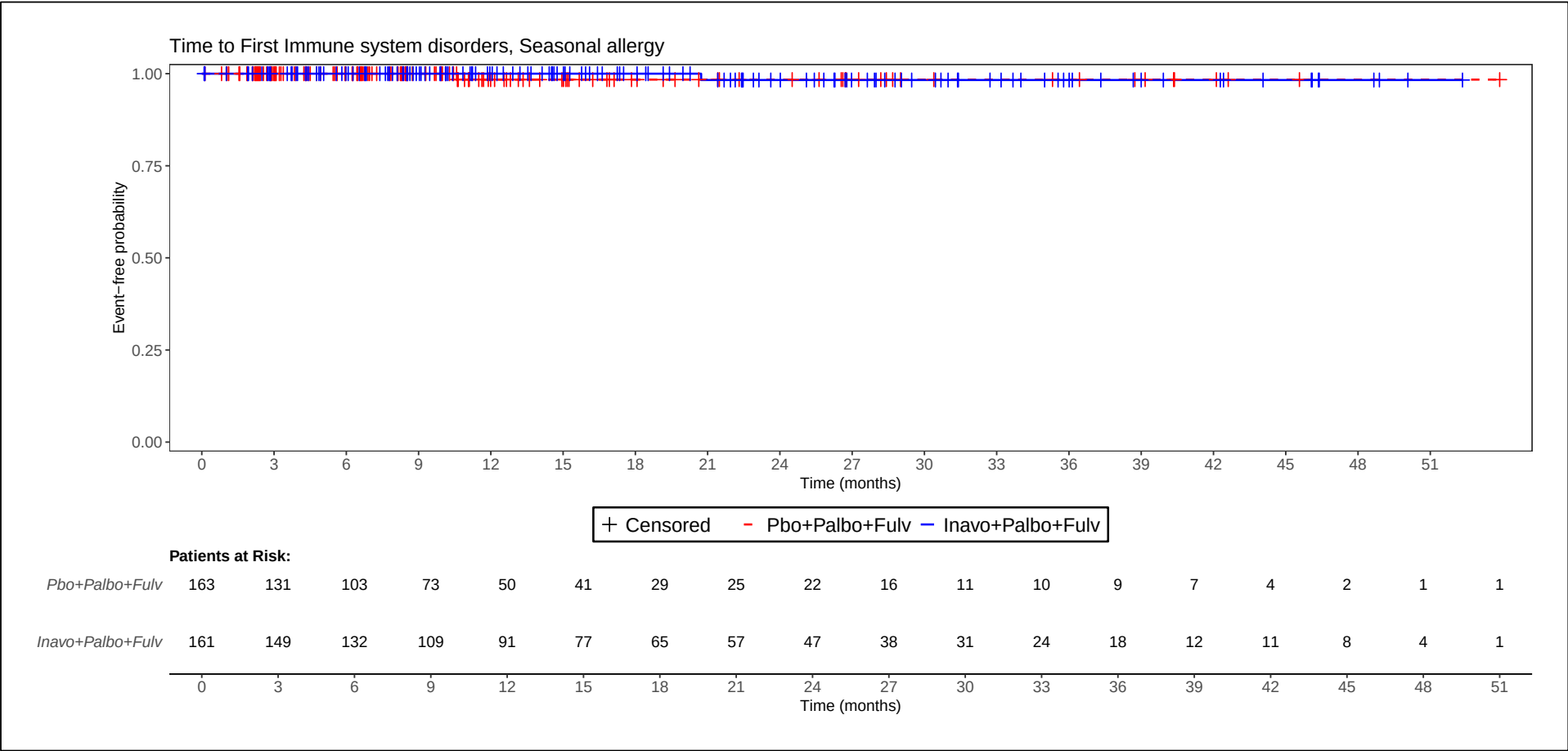
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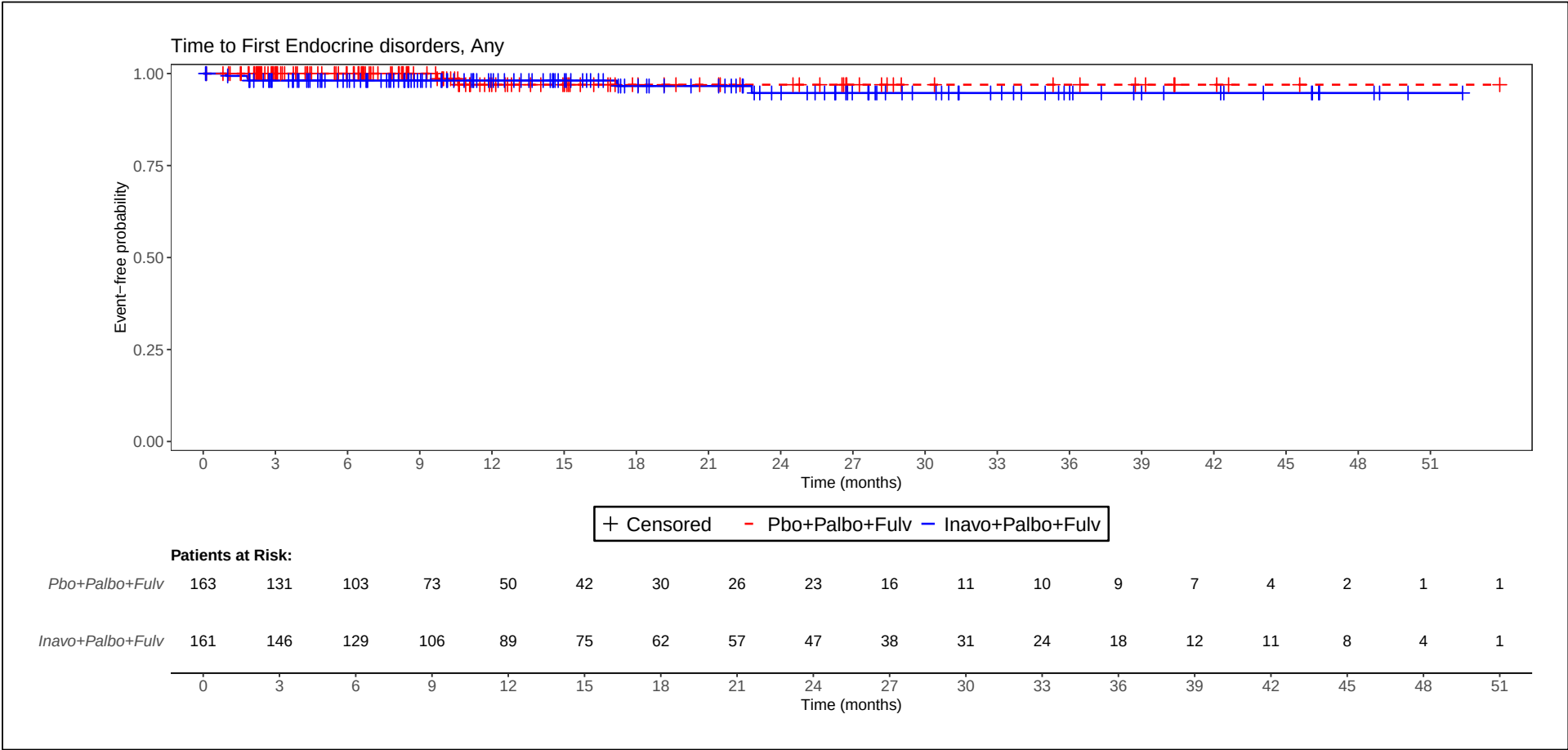
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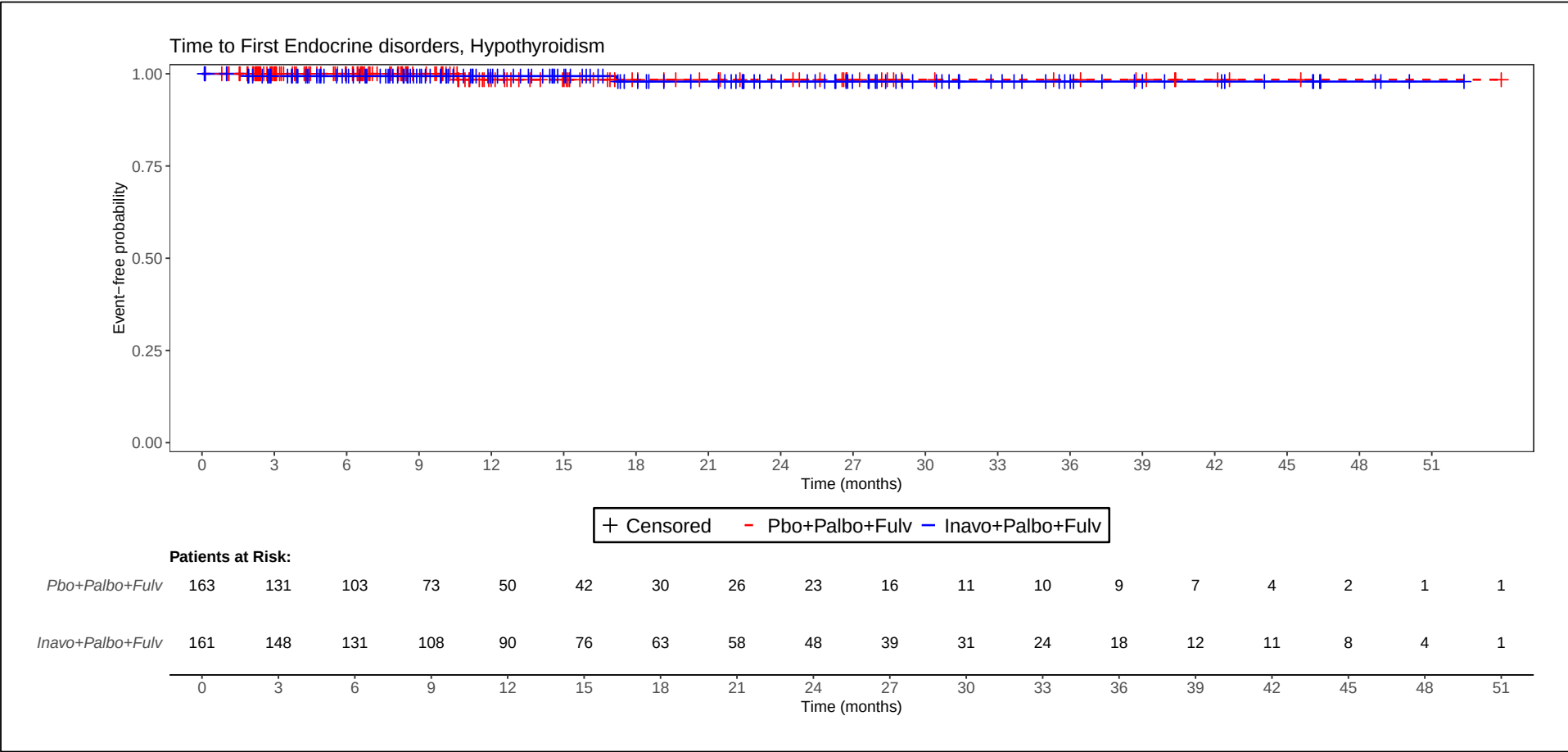
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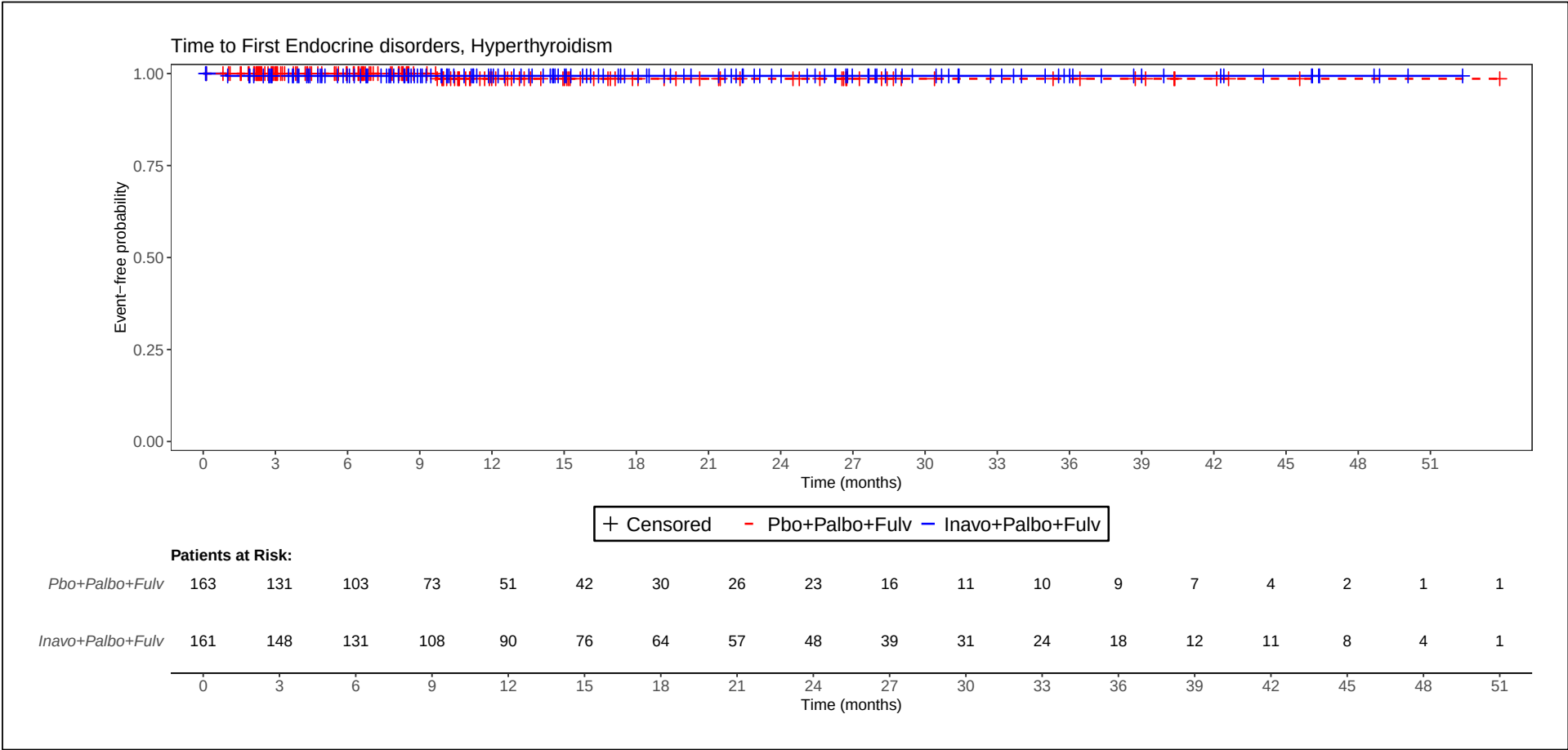
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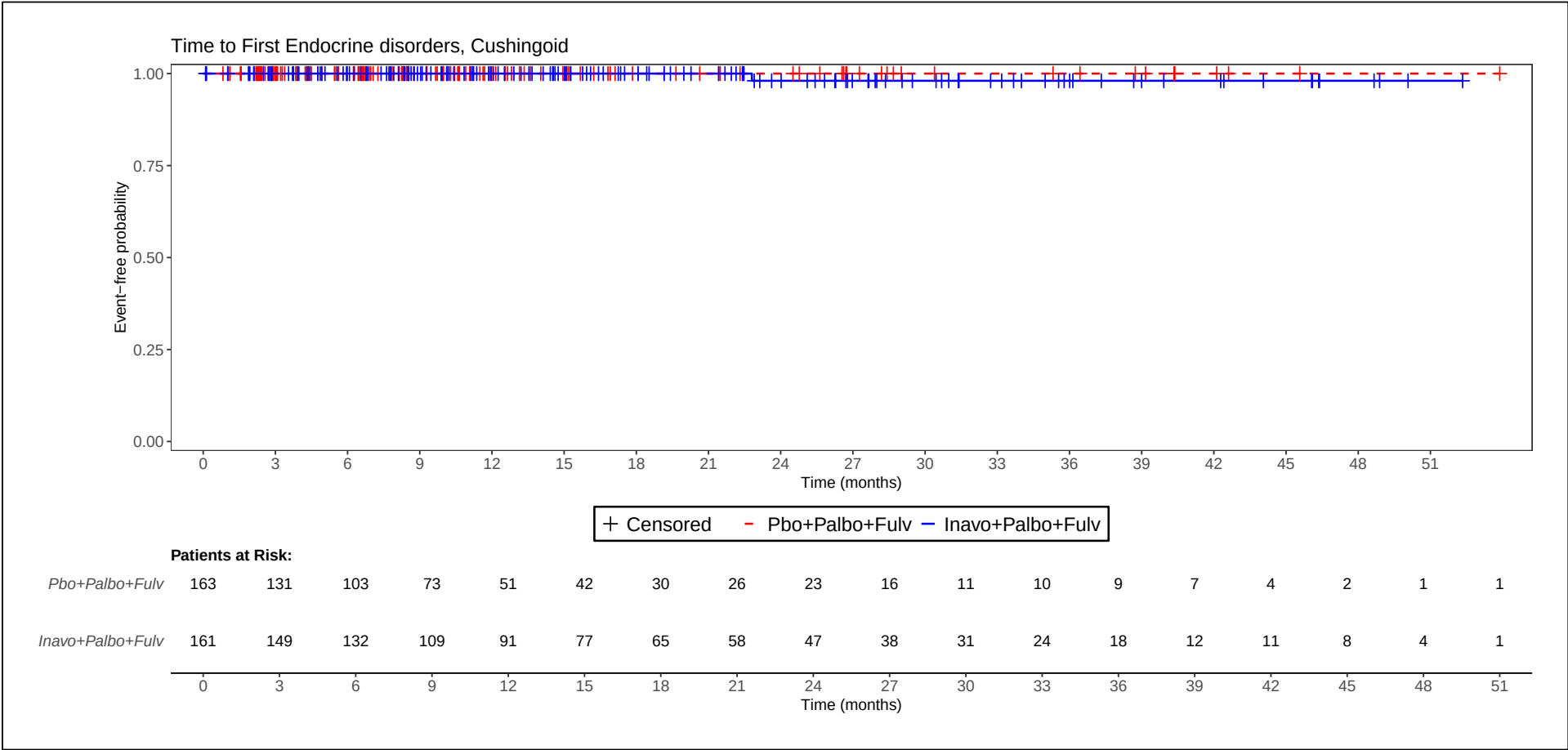
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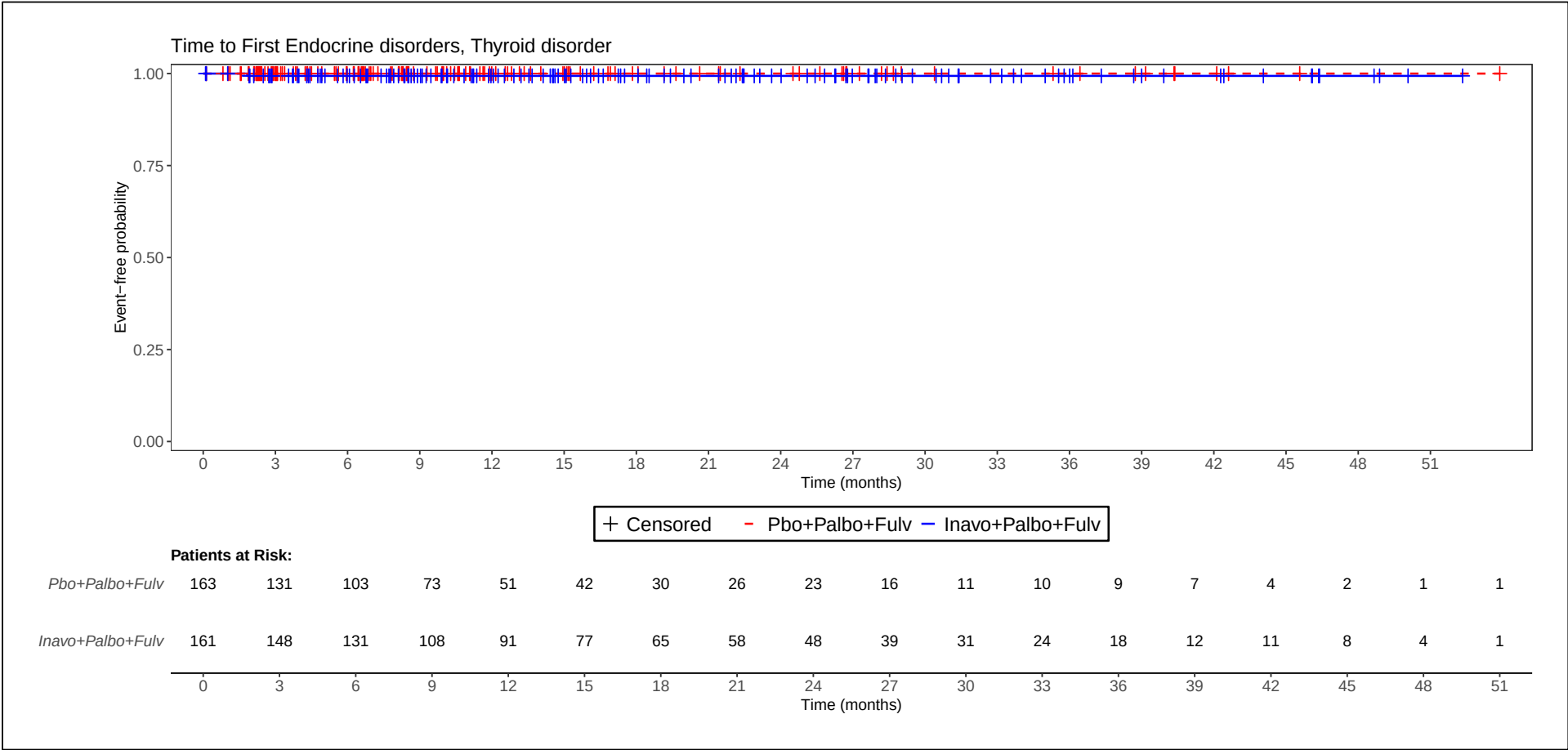
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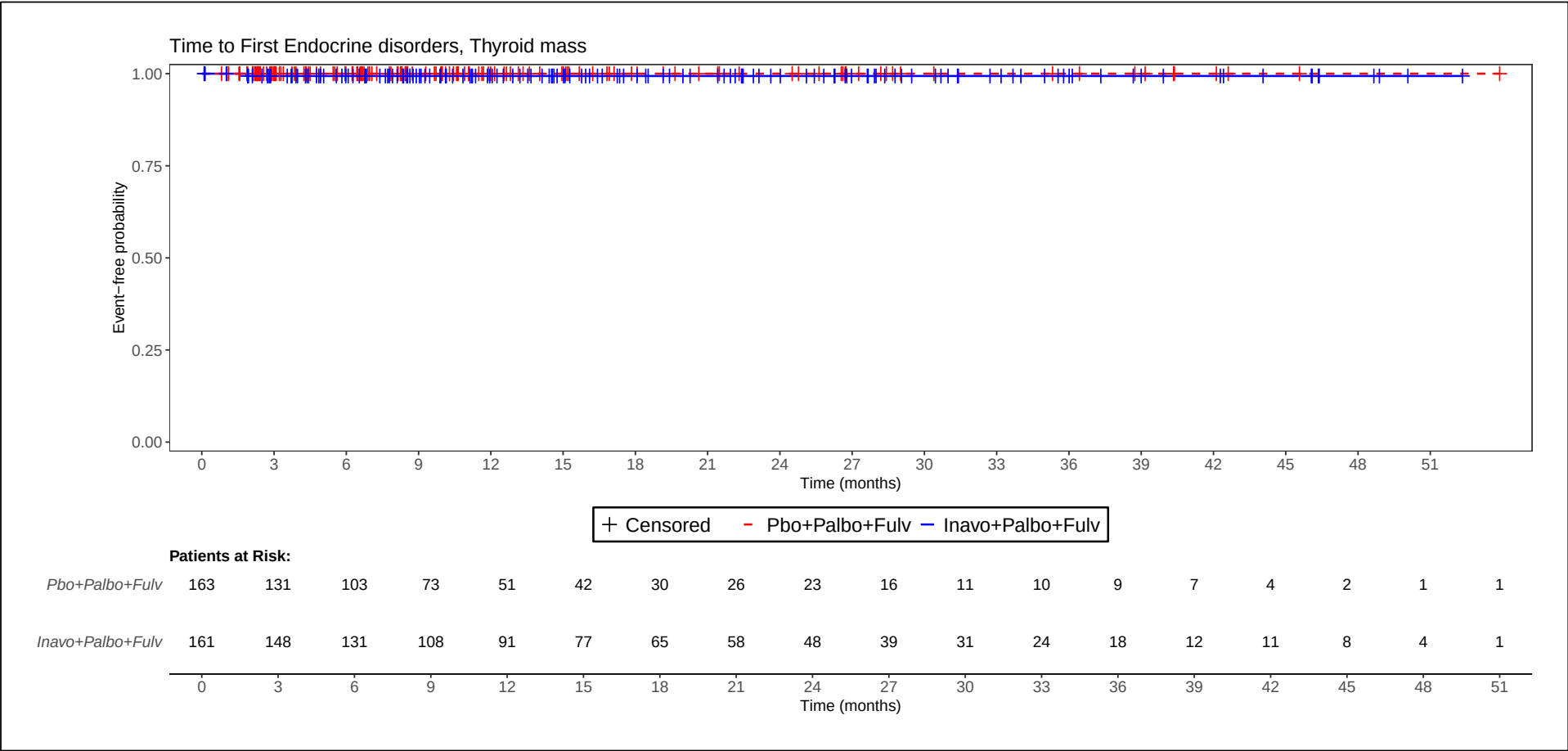
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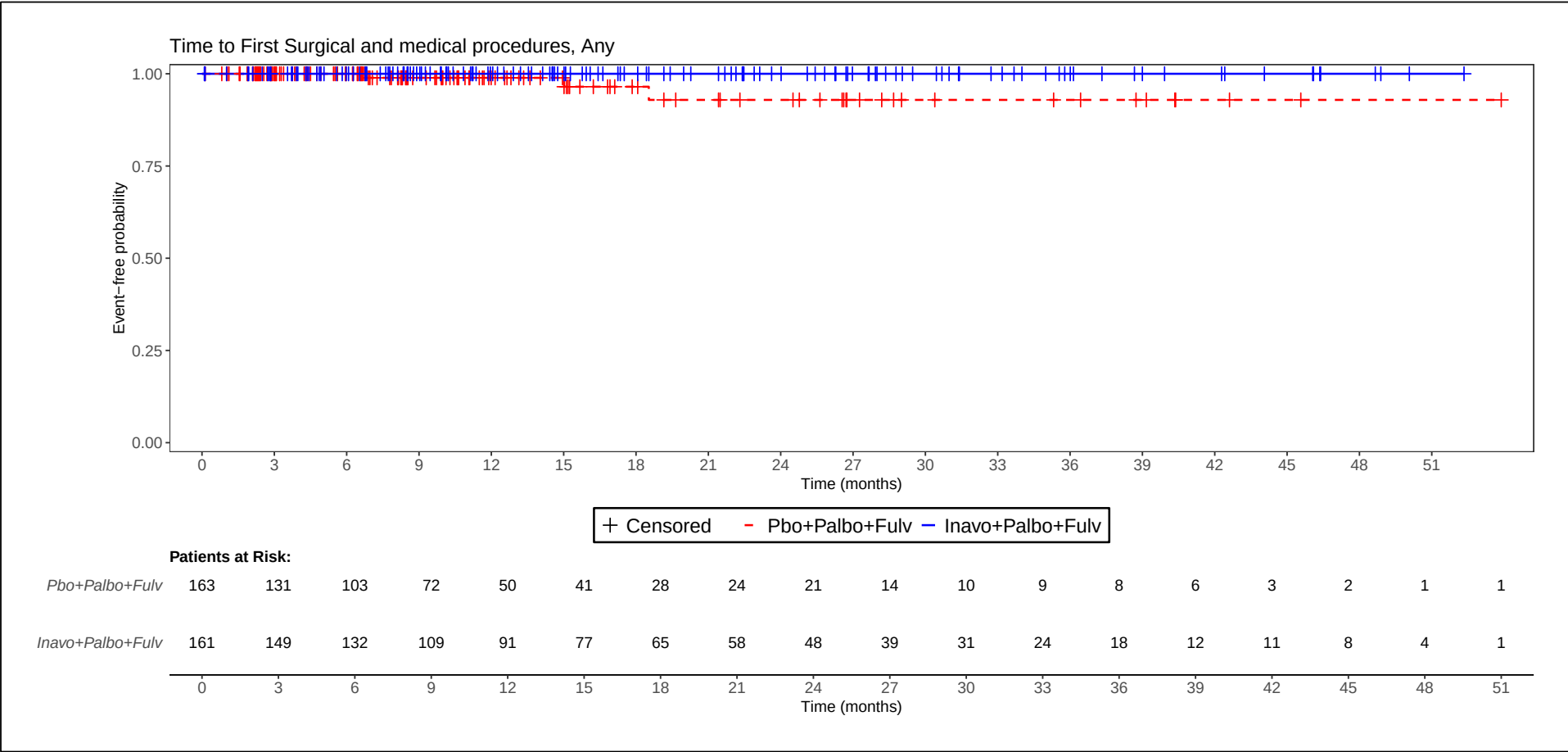
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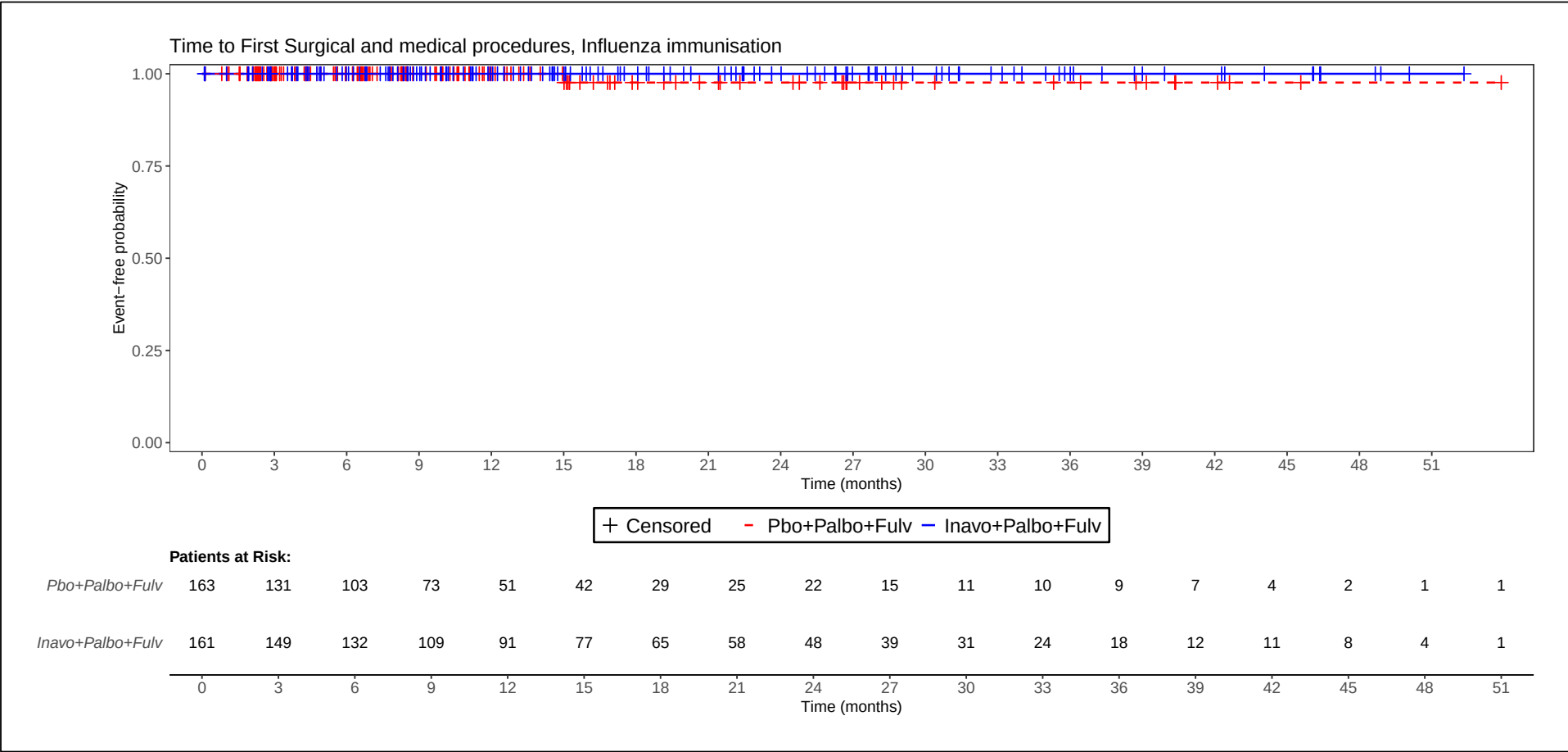
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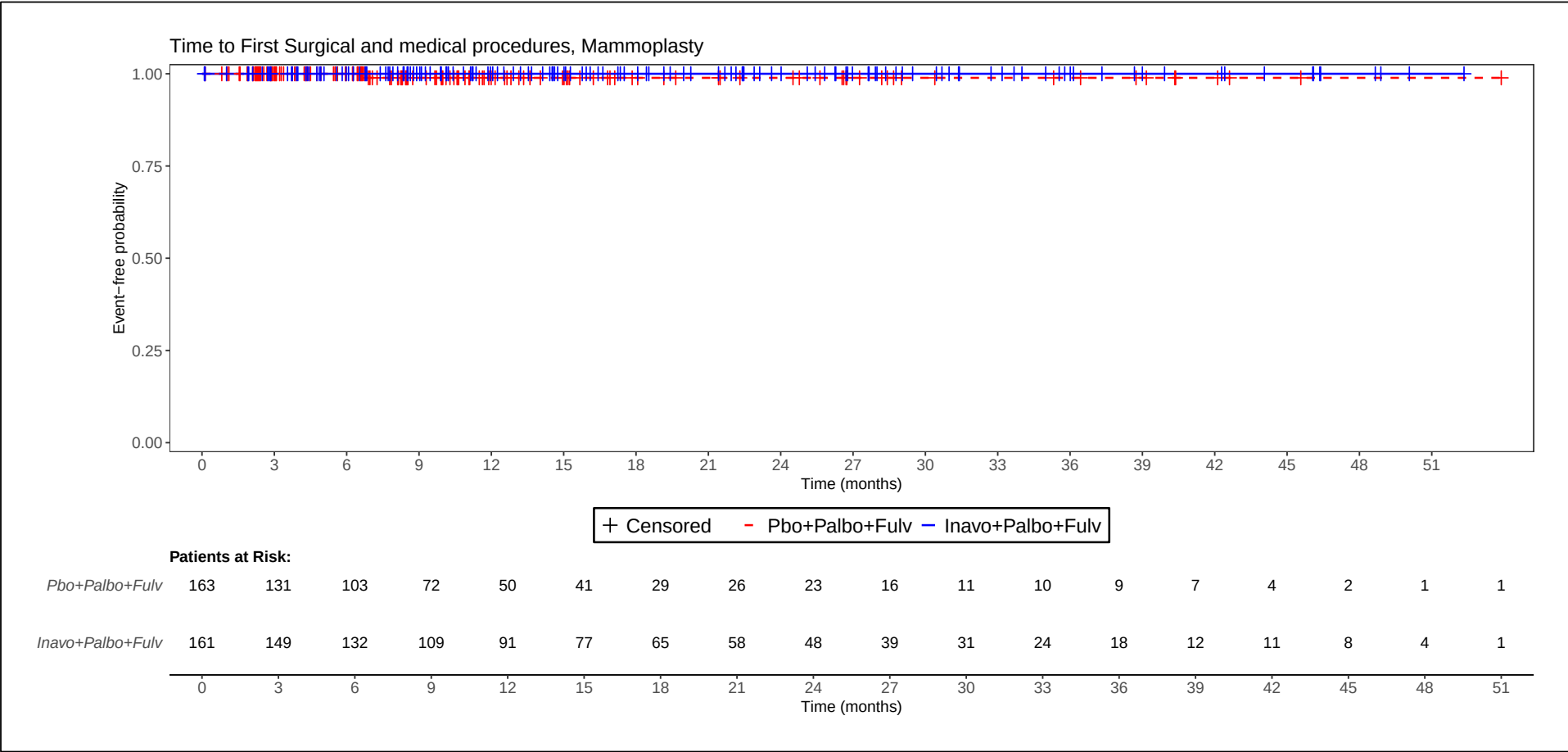
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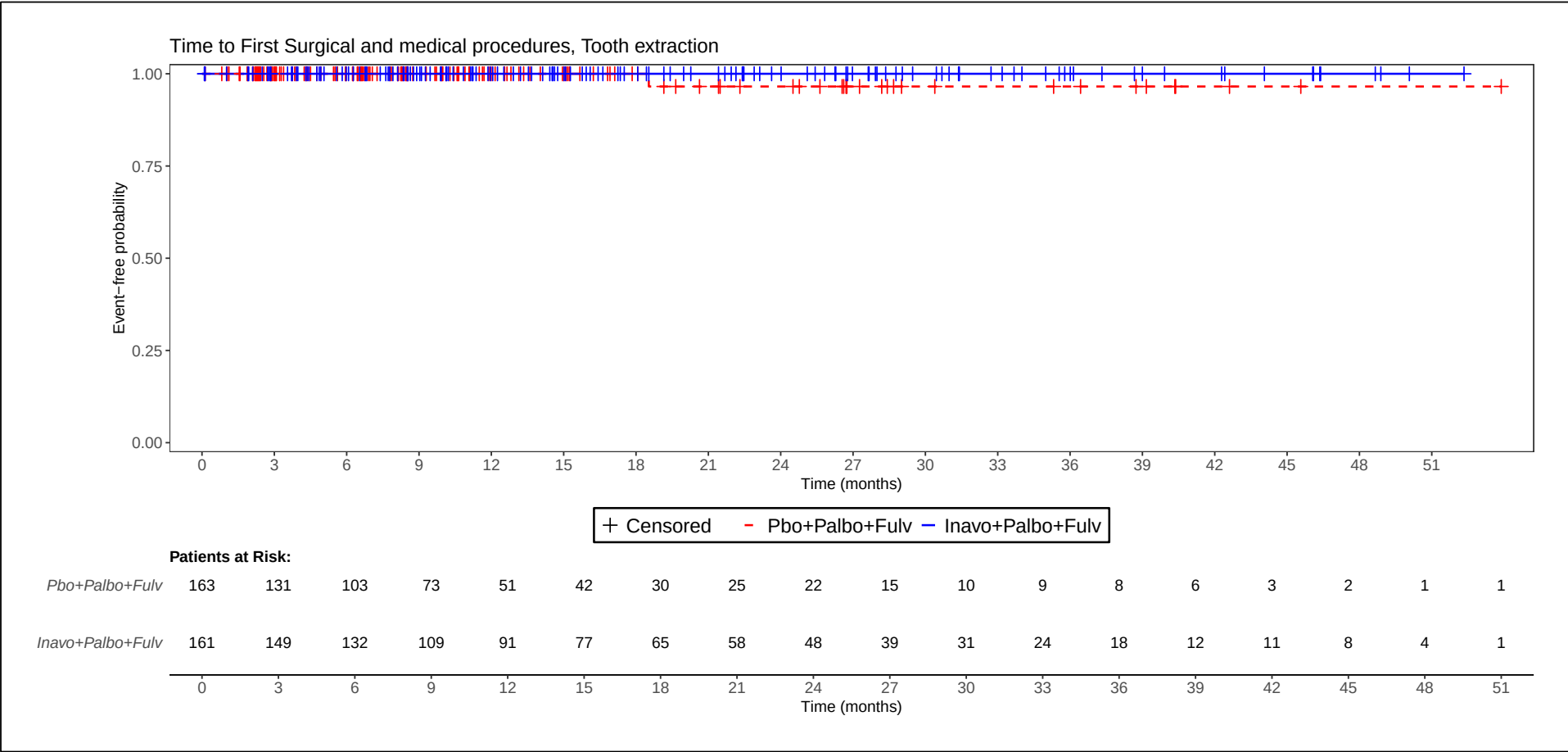
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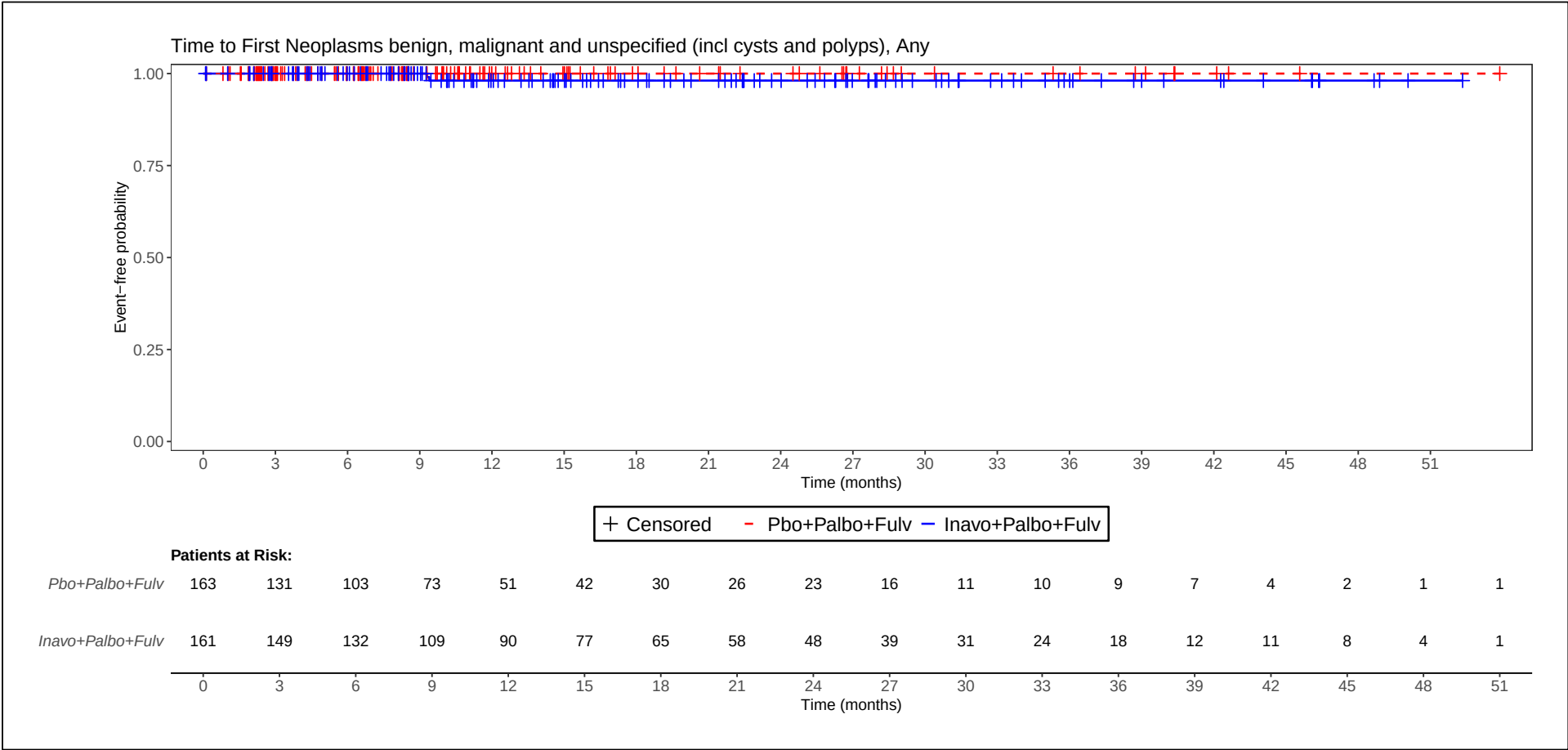
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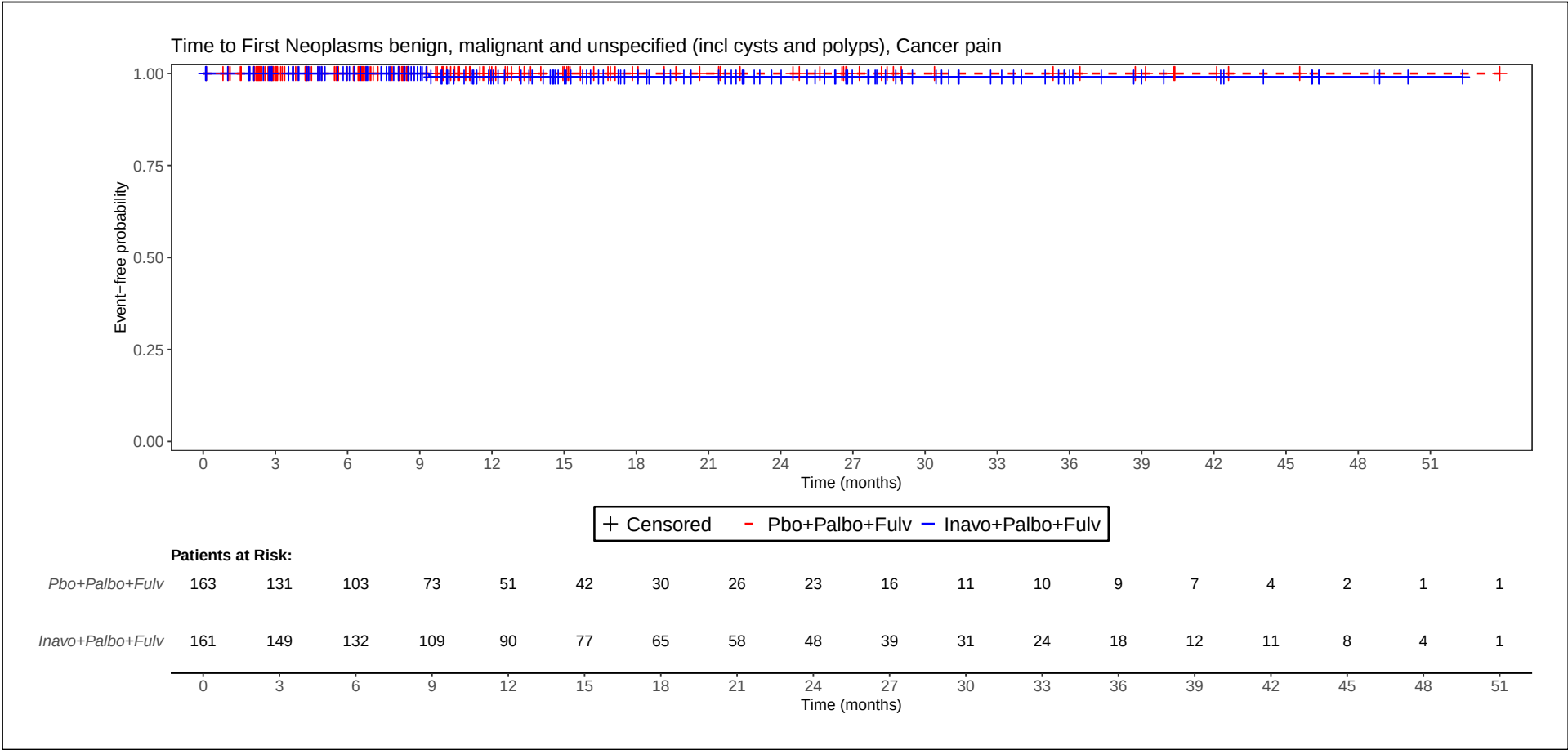
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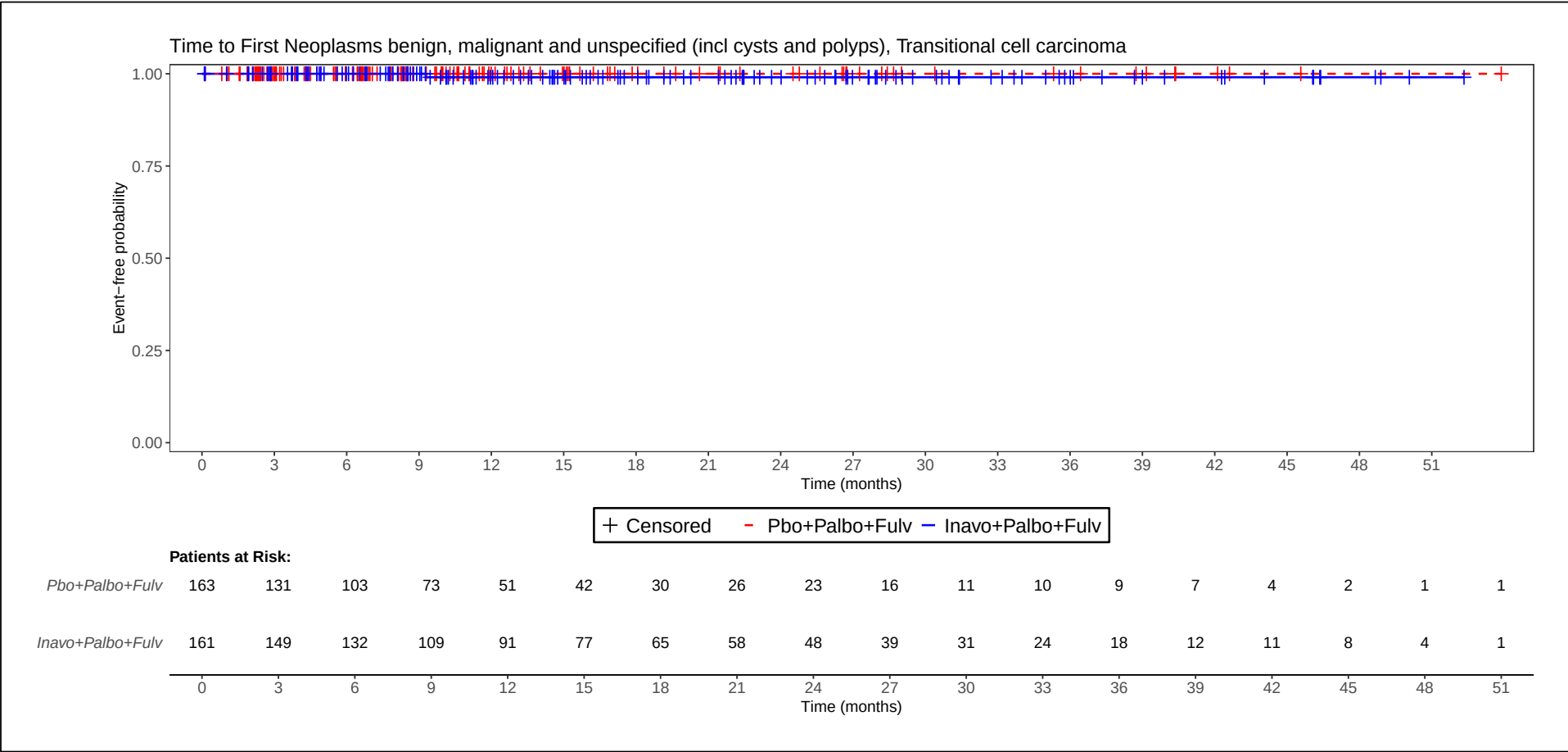
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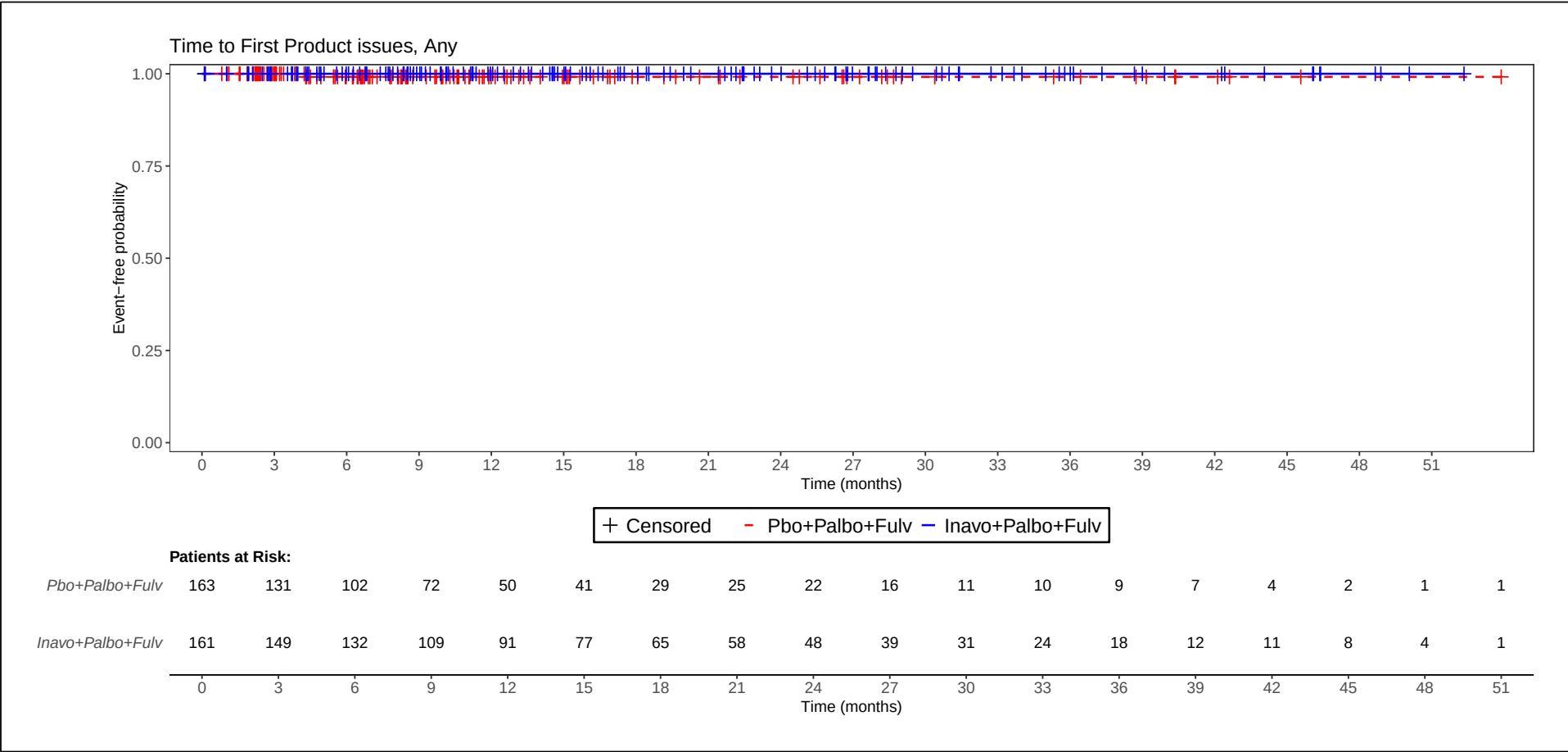
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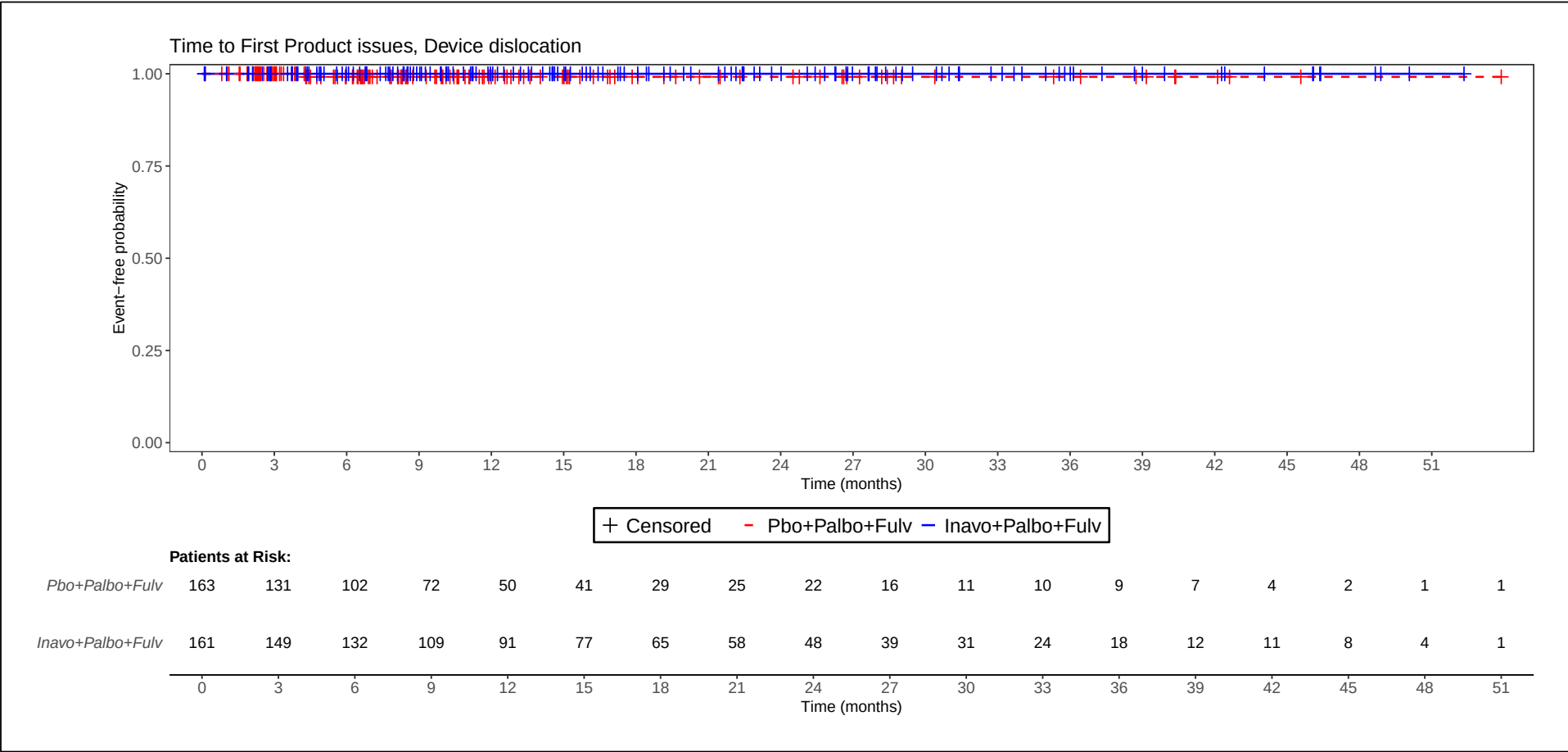
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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.1 Generelle Verträglichkeit

3.1.2 Unerwünschte Ereignisse UE nach Systemorganklassen (SOC) und Preferred Terms (PT)

3.1.2.2 Patienten mit schweren unerwünschten Ereignissen ($UE \geq \text{Grad } 3$) nach SOC/PT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis by SOC and PT Overall and with Subgroups (Safety), Adverse Events Grade >= 3 by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Grade >= 3 Blood and lymphatic system disorders, Any											
All Patients	324	163	84	51.5	161	88	54.7	0.96	(0.71, 1.30)	0.7752	NE
Age group (years)											
<65	266	129	62	48.1	137	74	54.0	1.03	(0.73, 1.45)	0.9049	0.5645
>=65	58	34	22	64.7	24	14	58.3	0.82	(0.42, 1.61)	0.6011	0.5645
Sex											
F	318	162	84	51.9	156	86	55.1	0.97	(0.72, 1.31)	0.7940	0.3320
M	6	1	0	0.0	5	2	40.0	>999.99	(0.00, >999.99)	0.5024	0.3320
Region											
ASIA	120	62	25	40.3	58	34	58.6	1.43	(0.85, 2.41)	0.1887	0.0500
NORTH AMERICA/WESTERN EUROPE	126	63	38	60.3	63	29	46.0	0.63	(0.39, 1.02)	0.0601	0.0500
OTHER	78	38	21	55.3	40	25	62.5	0.98	(0.55, 1.78)	0.9180	0.0500
Visceral disease (per eCRF)											
N	65	36	21	58.3	29	19	65.5	1.00	(0.54, 1.86)	0.9931	0.8227
Y	259	127	63	49.6	132	69	52.3	0.96	(0.68, 1.36)	0.7974	0.8227
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	20	38.5	52	33	63.5	1.55	(0.89, 2.72)	0.1105	0.0353
POST-MENOPAUSAL	214	110	64	58.2	104	53	51.0	0.79	(0.55, 1.14)	0.1768	0.0353
Time to First Grade >= 3 Blood and lymphatic system disorders, Neutropenia											
All Patients	324	163	81	49.7	161	79	49.1	0.90	(0.66, 1.23)	0.4846	NE
Age group (years)											
<65	266	129	59	45.7	137	69	50.4	1.03	(0.73, 1.47)	0.8906	0.1122
>=65	58	34	22	64.7	24	10	41.7	0.53	(0.25, 1.13)	0.0986	0.1122
Sex											
F	318	162	81	50.0	156	77	49.4	0.90	(0.66, 1.23)	0.4844	0.3157
M	6	1	0	0.0	5	2	40.0	>999.99	(0.00, >999.99)	0.5024	0.3157
Region											
ASIA	120	62	24	38.7	58	28	48.3	1.17	(0.67, 2.03)	0.6036	0.1498
NORTH AMERICA/WESTERN EUROPE	126	63	37	58.7	63	28	44.4	0.63	(0.39, 1.04)	0.0711	0.1498
OTHER	78	38	20	52.6	40	23	57.5	1.02	(0.56, 1.88)	0.9920	0.1498
Visceral disease (per eCRF)											
N	65	36	21	58.3	29	17	58.6	0.88	(0.46, 1.67)	0.6701	0.9592
Y	259	127	60	47.2	132	62	47.0	0.91	(0.64, 1.31)	0.6137	0.9592
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	19	36.5	52	30	57.7	1.49	(0.84, 2.67)	0.1598	0.0331
POST-MENOPAUSAL	214	110	62	56.4	104	47	45.2	0.73	(0.50, 1.07)	0.0853	0.0331
Time to First Grade >= 3 Blood and lymphatic system disorders, Leukopenia											
All Patients	324	163	18	11.0	161	11	6.8	0.58	(0.27, 1.23)	0.1512	NE
Age group (years)											
<65	266	129	15	11.6	137	9	6.6	0.53	(0.23, 1.21)	0.1270	0.5407

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
>=65	58	34	3	8.8	24	2	8.3	0.94	(0.16, 5.64)	0.9516	0.5407
Sex											
F	318	162	18	11.1	156	11	7.1	0.60	(0.28, 1.26)	0.1732	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	8	12.9	58	7	12.1	0.88	(0.32, 2.44)	0.8196	0.0109
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	4	6.3	1.27	(0.28, 5.68)	0.7553	0.0109
OTHER	78	38	7	18.4	40	0	0.0	<0.01	(0.00, >999.99)	0.0050	0.0109
Visceral disease (per eCRF)											
N	65	36	5	13.9	29	2	6.9	0.48	(0.09, 2.50)	0.3797	0.7784
Y	259	127	13	10.2	132	9	6.8	0.61	(0.26, 1.43)	0.2548	0.7784
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	6	11.5	52	6	11.5	0.90	(0.29, 2.81)	0.8580	0.3041
POST-MENOPAUSAL	214	110	12	10.9	104	5	4.8	0.42	(0.15, 1.20)	0.0976	0.3041
Time to First Grade >= 3 Blood and lymphatic system disorders, Anaemia											
All Patients	324	163	3	1.8	161	11	6.8	3.27	(0.91, 11.77)	0.0552	NE
Age group (years)											
<65	266	129	2	1.6	137	9	6.6	3.57	(0.77, 16.65)	0.0840	0.9342
>=65	58	34	1	2.9	24	2	8.3	3.40	(0.31, 37.59)	0.2876	0.9342
Sex											
F	318	162	3	1.9	156	11	7.1	3.37	(0.93, 12.12)	0.0489	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	1	1.6	58	8	13.8	7.21	(0.89, 58.14)	0.0309	0.1421
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	0.1421
OTHER	78	38	1	2.6	40	3	7.5	2.39	(0.25, 23.17)	0.4399	0.1421
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	5	17.2	5.38	(0.62, 46.53)	0.0872	0.5058
Y	259	127	2	1.6	132	6	4.5	2.79	(0.56, 13.84)	0.1895	0.5058
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	5	9.6	3.83	(0.44, 33.67)	0.1949	0.7946
POST-MENOPAUSAL	214	110	2	1.8	104	6	5.8	3.02	(0.61, 14.99)	0.1547	0.7946
Time to First Grade >= 3 Blood and lymphatic system disorders, Thrombocytopenia											
All Patients	324	163	3	1.8	161	8	5.0	2.59	(0.68, 9.78)	0.1469	NE
Age group (years)											
<65	266	129	1	0.8	137	5	3.6	4.53	(0.53, 38.81)	0.1306	0.6655
>=65	58	34	2	5.9	24	3	12.5	2.32	(0.39, 13.89)	0.3429	0.6655
Sex											
F	318	162	3	1.9	156	8	5.1	2.66	(0.70, 10.05)	0.1345	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	5	8.6	5.45	(0.64, 46.66)	0.0816	0.6078

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	1.02	(0.06, 16.38)	0.9864	0.6078
OTHER	78	38	1	2.6	40	2	5.0	1.25	(0.11, 14.33)	0.8582	0.6078
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	0.3575
Y	259	127	3	2.4	132	7	5.3	2.12	(0.54, 8.22)	0.2693	0.3575
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	3	5.8	>999.99	(0.00, >999.99)	0.0803	0.1402
POST-MENOPAUSAL	214	110	3	2.7	104	5	4.8	1.67	(0.40, 7.00)	0.4814	0.1402
Time to First Grade >= 3 Blood and lymphatic system disorders, Febrile neutropenia											
All Patients	324	163	1	0.6	161	5	3.1	3.86	(0.45, 33.40)	0.1878	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	1.75	(0.18, 17.39)	0.6266	0.2061
>=65	58	34	0	0.0	24	2	8.3	>999.99	(0.00, >999.99)	0.0767	0.2061
Sex											
F	318	162	1	0.6	156	5	3.2	3.97	(0.46, 34.41)	0.1768	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	4	6.9	>999.99	(0.00, >999.99)	0.0790	0.2881
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.94	(0.06, 15.01)	0.9641	0.2881
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.2881
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.82	(0.05, 13.07)	0.8862	0.1252
Y	259	127	0	0.0	132	4	3.0	>999.99	(0.00, >999.99)	0.0804	0.1252
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4547	0.5686
POST-MENOPAUSAL	214	110	1	0.9	104	4	3.8	3.50	(0.39, 31.61)	0.2353	0.5686
Time to First Grade >= 3 Blood and lymphatic system disorders, Lymphopenia											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.1605	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1660	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	2	5.3	40	0	0.0	<0.01	(0.00, >999.99)	0.1492	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	2	1.6	132	0	0.0	<0.01	(0.00, >999.99)	0.1485	0.9999
Menopausal Status at Randomization											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1703	1.0000
Time to First Grade >= 3 Investigations, Any											
All Patients	324	163	63	38.7	161	77	47.8	1.22	(0.87, 1.71)	0.2395	NE
Age group (years)											
<65	266	129	54	41.9	137	67	48.9	1.09	(0.76, 1.57)	0.6364	0.2423
>=65	58	34	9	26.5	24	10	41.7	1.92	(0.78, 4.72)	0.1495	0.2423
Sex											
F	318	162	62	38.3	156	75	48.1	1.24	(0.89, 1.74)	0.2055	0.1749
M	6	1	1	100.0	5	2	40.0	0.22	(0.01, 3.59)	0.2467	0.1749
Region											
ASIA	120	62	35	56.5	58	40	69.0	1.20	(0.76, 1.89)	0.4649	0.8990
NORTH AMERICA/WESTERN EUROPE	126	63	18	28.6	63	25	39.7	1.39	(0.76, 2.55)	0.2852	0.8990
OTHER	78	38	10	26.3	40	12	30.0	1.14	(0.49, 2.66)	0.7407	0.8990
Visceral disease (per eCRF)											
N	65	36	12	33.3	29	14	48.3	1.41	(0.65, 3.09)	0.3640	0.5243
Y	259	127	51	40.2	132	63	47.7	1.17	(0.81, 1.70)	0.4077	0.5243
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	26	50.0	52	28	53.8	0.93	(0.54, 1.60)	0.7887	0.2476
POST-MENOPAUSAL	214	110	36	32.7	104	47	45.2	1.44	(0.93, 2.22)	0.0997	0.2476
Time to First Grade >= 3 Investigations, Neutrophil count decreased											
All Patients	324	163	54	33.1	161	58	36.0	1.08	(0.75, 1.57)	0.6726	NE
Age group (years)											
<65	266	129	45	34.9	137	52	38.0	1.05	(0.70, 1.56)	0.8154	0.9600
>=65	58	34	9	26.5	24	6	25.0	1.09	(0.39, 3.07)	0.8646	0.9600
Sex											
F	318	162	53	32.7	156	56	35.9	1.09	(0.75, 1.59)	0.6445	0.2356
M	6	1	1	100.0	5	2	40.0	0.22	(0.01, 3.59)	0.2467	0.2356
Region											
ASIA	120	62	31	50.0	58	30	51.7	0.96	(0.58, 1.59)	0.8640	0.7892
NORTH AMERICA/WESTERN EUROPE	126	63	16	25.4	63	20	31.7	1.31	(0.68, 2.53)	0.4229	0.7892
OTHER	78	38	7	18.4	40	8	20.0	1.14	(0.41, 3.13)	0.7994	0.7892
Visceral disease (per eCRF)											
N	65	36	12	33.3	29	8	27.6	0.87	(0.35, 2.13)	0.7602	0.6095
Y	259	127	42	33.1	132	50	37.9	1.12	(0.74, 1.69)	0.5827	0.6095
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	24	46.2	52	18	34.6	0.71	(0.38, 1.31)	0.2611	0.0542
POST-MENOPAUSAL	214	110	29	26.4	104	38	36.5	1.44	(0.89, 2.33)	0.1399	0.0542
Time to First Grade >= 3 Investigations, White blood cell count decreased											
All Patients	324	163	18	11.0	161	22	13.7	1.15	(0.62, 2.16)	0.6662	NE
Age group (years)											
<65	266	129	18	14.0	137	21	15.3	0.98	(0.52, 1.85)	0.9478	0.1744
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.1744

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	18	11.1	156	22	14.1	1.18	(0.63, 2.22)	0.6061	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	11	17.7	58	16	27.6	1.38	(0.64, 3.00)	0.4225	0.2223
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	3	4.8	3.00	(0.31, 28.83)	0.3176	0.2223
OTHER	78	38	6	15.8	40	3	7.5	0.44	(0.11, 1.79)	0.2397	0.2223
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.80	(0.05, 13.85)	0.8790	0.9632
Y	259	127	17	13.4	132	21	15.9	1.12	(0.59, 2.12)	0.7422	0.9632
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	7	13.5	52	8	15.4	0.95	(0.34, 2.66)	0.9298	0.7006
POST-MENOPAUSAL	214	110	11	10.0	104	14	13.5	1.33	(0.60, 2.94)	0.4845	0.7006
Time to First Grade >= 3 Investigations, Platelet count decreased											
All Patients	324	163	5	3.1	161	14	8.7	2.95	(1.06, 8.20)	0.0291	NE
Age group (years)											
<65	266	129	5	3.9	137	11	8.0	2.12	(0.73, 6.09)	0.1554	0.0834
>=65	58	34	0	0.0	24	3	12.5	>999.99	(0.00, >999.99)	0.0278	0.0834
Sex											
F	318	162	5	3.1	156	14	9.0	3.03	(1.09, 8.43)	0.0250	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	4	6.5	58	13	22.4	3.73	(1.22, 11.45)	0.0132	0.6898
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.6898
OTHER	78	38	1	2.6	40	1	2.5	0.99	(0.06, 15.78)	0.9927	0.6898
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	3	10.3	>999.99	(0.00, >999.99)	0.0454	0.1078
Y	259	127	5	3.9	132	11	8.3	2.18	(0.76, 6.27)	0.1390	0.1078
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	5	9.6	2.57	(0.50, 13.23)	0.2422	0.8082
POST-MENOPAUSAL	214	110	3	2.7	104	9	8.7	3.33	(0.90, 12.30)	0.0556	0.8082
Time to First Grade >= 3 Investigations, Alanine aminotransferase increased											
All Patients	324	163	3	1.8	161	7	4.3	1.82	(0.46, 7.13)	0.3843	NE
Age group (years)											
<65	266	129	3	2.3	137	5	3.6	1.16	(0.27, 4.95)	0.8389	0.0968
>=65	58	34	0	0.0	24	2	8.3	>999.99	(0.00, >999.99)	0.1132	0.0968
Sex											
F	318	162	3	1.9	156	7	4.5	1.87	(0.48, 7.32)	0.3641	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	3	5.2	1.37	(0.23, 8.29)	0.7295	0.0528
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	4	6.3	>999.99	(0.00, >999.99)	0.0972	0.0528

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3110	0.0528
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.1206	0.1527
Y	259	127	3	2.4	132	5	3.8	1.17	(0.27, 5.00)	0.8319	0.1527
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	3	5.8	0.77	(0.15, 3.86)	0.7449	0.0404
POST-MENOPAUSAL	214	110	0	0.0	104	4	3.8	>999.99	(0.00, >999.99)	0.0890	0.0404
Time to First Grade >= 3 Investigations, Weight decreased											
All Patients	324	163	0	0.0	161	7	4.3	>999.99	(0.00, >999.99)	0.0205	NE
Age group (years)											
<65	266	129	0	0.0	137	5	3.6	>999.99	(0.00, >999.99)	0.0773	1.0000
>=65	58	34	0	0.0	24	2	8.3	>999.99	(0.00, >999.99)	0.0775	1.0000
Sex											
F	318	162	0	0.0	156	7	4.5	>999.99	(0.00, >999.99)	0.0190	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	3	5.2	>999.99	(0.00, >999.99)	0.1405	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3468	1.0000
OTHER	78	38	0	0.0	40	3	7.5	>999.99	(0.00, >999.99)	0.1561	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.3012	1.0000
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0411	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	3	5.8	>999.99	(0.00, >999.99)	0.1432	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	4	3.8	>999.99	(0.00, >999.99)	0.0794	1.0000
Time to First Grade >= 3 Investigations, Aspartate aminotransferase increased											
All Patients	324	163	2	1.2	161	3	1.9	1.05	(0.17, 6.50)	0.9575	NE
Age group (years)											
<65	266	129	2	1.6	137	1	0.7	0.29	(0.02, 3.35)	0.2922	0.0345
>=65	58	34	0	0.0	24	2	8.3	>999.99	(0.00, >999.99)	0.1132	0.0345
Sex											
F	318	162	2	1.2	156	3	1.9	1.07	(0.17, 6.65)	0.9390	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	0.2073
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2	1.22	(0.11, 13.73)	0.8745	0.2073
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3110	0.2073
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	3	2.3	0.98	(0.16, 6.04)	0.9806	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	0.1231

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	3	2.9	2.12	(0.21, 21.06)	0.5105	0.1231
Time to First Grade >= 3 Investigations, Amylase increased											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.0944	NE
Age group (years)											
<65	266	129	2	1.6	137	0	0.0	<0.01	(0.00, >999.99)	0.0724	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.0996	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3214	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.0956	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	0	0.0	<0.01	(0.00, >999.99)	0.0812	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1104	1.0000
Time to First Grade >= 3 Investigations, Electrocardiogram QT prolonged											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2488	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2822	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2631	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5403	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Investigations, Lymphocyte count decreased											
All Patients	324	163	1	0.6	161	1	0.6	0.84	(0.05, 13.60)	0.9030	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.76	(0.05, 12.33)	0.8475	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	1	0.6	156	1	0.6	0.87	(0.05, 13.99)	0.9190	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3091	0.2205
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.2205
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1380	0.2205
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3066	0.1190
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3326	0.1190
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.92	(0.06, 14.83)	0.9544	1.0000
Time to First Grade >= 3 Investigations, Blood alkaline phosphatase increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Grade >= 3 Investigations, Blood creatinine increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3082	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3012	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3037	1.0000
Time to First Grade >= 3 Investigations, Gamma-glutamyltransferase increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4855	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5403	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4763	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4183	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4292	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Investigations, International normalised ratio increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3407	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3706	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3344	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3513	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3617	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3384	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Investigations, Lipase increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5032	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2888	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4962	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4701	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5271	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4386	1.0000
Time to First Grade >= 3 Investigations, Lymphocyte count increased											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2990	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3266	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3046	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3060	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3311	1.0000
Time to First Grade >= 3 Investigations, Prothrombin time prolonged											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3407	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3706	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3344	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3513	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3617	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3384	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Metabolism and nutrition disorders, Any											
All Patients	324	163	5	3.1	161	20	12.4	3.64	(1.36, 9.75)	0.0059	NE
Age group (years)											
<65	266	129	4	3.1	137	13	9.5	2.80	(0.91, 8.63)	0.0610	0.1746
>=65	58	34	1	2.9	24	7	29.2	12.31	(1.51, 100.59)	0.0028	0.1746
Sex											
F	318	162	5	3.1	156	20	12.8	3.75	(1.40, 10.03)	0.0048	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	2	3.2	58	8	13.8	3.15	(0.66, 15.07)	0.1302	0.4255
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	3	4.8	1.33	(0.22, 8.02)	0.7569	0.4255
OTHER	78	38	1	2.6	40	9	22.5	9.30	(1.18, 73.53)	0.0099	0.4255
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	3	10.3	0.71	(0.15, 3.28)	0.6580	0.0095
Y	259	127	1	0.8	132	17	12.9	15.14	(2.01, 113.98)	0.0004	0.0095
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	8	15.4	>999.99	(0.00, >999.99)	0.0089	0.0418
POST-MENOPAUSAL	214	110	5	4.5	104	12	11.5	2.32	(0.82, 6.63)	0.1044	0.0418
Time to First Grade >= 3 Metabolism and nutrition disorders, Hyperglycaemia											
All Patients	324	163	0	0.0	161	9	5.6	>999.99	(0.00, >999.99)	0.0031	NE
Age group (years)											
<65	266	129	0	0.0	137	5	3.6	>999.99	(0.00, >999.99)	0.0291	1.0000
>=65	58	34	0	0.0	24	4	16.7	>999.99	(0.00, >999.99)	0.0102	1.0000
Sex											
F	318	162	0	0.0	156	9	5.8	>999.99	(0.00, >999.99)	0.0027	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3012	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.1057	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	0	0.0	40	5	12.5	>999.99	(0.00, >999.99)	0.0241	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	9	6.8	>999.99	(0.00, >999.99)	0.0039	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	4	7.7	>999.99	(0.00, >999.99)	0.0424	0.9999
POST-MENOPAUSAL	214	110	0	0.0	104	5	4.8	>999.99	(0.00, >999.99)	0.0274	0.9999
Time to First Grade >= 3 Metabolism and nutrition disorders, Hypokalaemia											
All Patients	324	163	0	0.0	161	5	3.1	>999.99	(0.00, >999.99)	0.0505	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.1408	0.9999
>=65	58	34	0	0.0	24	2	8.3	>999.99	(0.00, >999.99)	0.1021	0.9999
Sex											
F	318	162	0	0.0	156	5	3.2	>999.99	(0.00, >999.99)	0.0473	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	5	8.6	>999.99	(0.00, >999.99)	0.0476	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0626	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	3	5.8	>999.99	(0.00, >999.99)	0.1286	0.9999
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.2168	0.9999
Time to First Grade >= 3 Metabolism and nutrition disorders, Hypocalcaemia											
All Patients	324	163	1	0.6	161	2	1.2	1.86	(0.17, 20.57)	0.6069	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.65	(0.15, 18.33)	0.6784	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	2	1.3	1.91	(0.17, 21.13)	0.5910	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.1592
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3134	0.1592
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2067	0.1592
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	1.36	(0.08, 21.73)	0.8277	0.3740
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3967	0.3740
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	2.00	(0.18, 22.02)	0.5652	1.0000
Time to First Grade >= 3 Metabolism and nutrition disorders, Type 2 diabetes mellitus											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1528	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.1700	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1475	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.1626	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.1646	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1428	1.0000
Time to First Grade >= 3 Metabolism and nutrition disorders, Decreased appetite											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4993	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2367	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5002	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4669	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5186	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4516	1.0000
Time to First Grade >= 3 Metabolism and nutrition disorders, Hypercalcaemia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2990	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3266	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3295	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3060	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3311	1.0000
Time to First Grade >= 3 Metabolism and nutrition disorders, Hyperkalaemia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3110	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Grade >= 3 Metabolism and nutrition disorders, Hypermagnesaemia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2701	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4561	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2770	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2924	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3613	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3023	1.0000
Time to First Grade >= 3 Metabolism and nutrition disorders, Hypertriglyceridaemia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3295	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Grade >= 3 Metabolism and nutrition disorders, Hypoalbuminaemia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4889	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5305	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4795	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5097	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4533	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6095	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Metabolism and nutrition disorders, Hyponatraemia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4623	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2770	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4539	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4867	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3819	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4317	1.0000
Time to First Grade >= 3 Metabolism and nutrition disorders, Tetany											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3416	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3126	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3103	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Any											
All Patients	324	163	4	2.5	161	18	11.2	4.12	(1.39, 12.21)	0.0057	NE
Age group (years)											
<65	266	129	3	2.3	137	13	9.5	3.38	(0.96, 11.93)	0.0451	0.4594

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
>=65	58	34	1	2.9	24	5	20.8	8.34	(0.97, 71.49)	0.0208	0.4594
Sex											
F	318	162	4	2.5	156	17	10.9	3.99	(1.34, 11.92)	0.0073	0.7308
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.7308
Region											
ASIA	120	62	2	3.2	58	5	8.6	2.31	(0.44, 12.02)	0.3068	0.4027
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	9	14.3	4.58	(0.99, 21.20)	0.0326	0.4027
OTHER	78	38	0	0.0	40	4	10.0	>999.99	(0.00, >999.99)	0.1130	0.4027
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	2	6.9	2.66	(0.24, 29.34)	0.4061	0.6379
Y	259	127	3	2.4	132	16	12.1	4.47	(1.30, 15.40)	0.0095	0.6379
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	4	7.7	2.80	(0.30, 25.91)	0.3460	0.8375
POST-MENOPAUSAL	214	110	3	2.7	104	13	12.5	4.41	(1.25, 15.51)	0.0115	0.8375
Time to First Grade >= 3 Gastrointestinal disorders, Diarrhoea											
All Patients	324	163	0	0.0	161	6	3.7	>999.99	(0.00, >999.99)	0.0162	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.0555	0.9999
>=65	58	34	0	0.0	24	2	8.3	>999.99	(0.00, >999.99)	0.0898	0.9999
Sex											
F	318	162	0	0.0	156	6	3.8	>999.99	(0.00, >999.99)	0.0148	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	4	6.3	>999.99	(0.00, >999.99)	0.0457	1.0000
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.1785	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0356	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	6	5.8	>999.99	(0.00, >999.99)	0.0133	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Stomatitis											
All Patients	324	163	0	0.0	161	5	3.1	>999.99	(0.00, >999.99)	0.0310	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.0706	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	5	3.2	>999.99	(0.00, >999.99)	0.0287	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.1452	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.1523	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5708	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0361	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.2312	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	3	2.9	>999.99	(0.00, >999.99)	0.0720	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Vomiting											
All Patients	324	163	2	1.2	161	2	1.2	0.95	(0.13, 6.72)	0.9550	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2544	0.1188
>=65	58	34	1	2.9	24	2	8.3	3.26	(0.30, 35.92)	0.3075	0.1188
Sex											
F	318	162	2	1.2	156	2	1.3	0.97	(0.14, 6.90)	0.9761	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	1	1.7	0.49	(0.04, 5.43)	0.5547	0.4342
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	0.4342
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.4342
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	2	1.5	0.87	(0.12, 6.18)	0.8877	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	1.00	(0.14, 7.13)	0.9975	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Anal fistula											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2666	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3068	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5298	0.9999
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.9999
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3469	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5351	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2847	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5050	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Grade >= 3 Gastrointestinal disorders, Abdominal pain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3689	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4084	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3621	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4241	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2733	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3355	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Aphthous ulcer											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3466	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3762	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3402	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3519	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2528	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3554	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Diverticulum intestinal											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2969	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3251	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3865	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Food poisoning											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2767	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2482	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2833	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2987	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3674	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.2482	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Gastric ulcer											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4264	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4623	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4180	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3627	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4425	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3813	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Gastrointestinal haemorrhage											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4857	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5338	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4762	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5186	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5040	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Intestinal perforation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4264	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4623	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4180	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3627	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4425	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3813	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Odynophagia											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Oesophageal stenosis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2925	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2645	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2988	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2879	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2714	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2998	1.0000
Time to First Grade >= 3 Gastrointestinal disorders, Proctitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5271	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5804	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5298	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5351	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5338	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5050	1.0000
Time to First Grade >= 3 Infections and infestations, Any											
All Patients	324	163	6	3.7	161	13	8.1	1.81	(0.69, 4.80)	0.2227	NE
Age group (years)											
<65	266	129	5	3.9	137	11	8.0	1.64	(0.57, 4.75)	0.3569	0.6210
>=65	58	34	1	2.9	24	2	8.3	2.72	(0.25, 30.08)	0.3964	0.6210
Sex											
F	318	162	6	3.7	156	13	8.3	1.85	(0.70, 4.90)	0.2072	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	5	8.6	4.18	(0.49, 36.00)	0.1568	0.0558
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.0808	0.0558
OTHER	78	38	5	13.2	40	5	12.5	0.59	(0.17, 2.10)	0.4130	0.0558
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	2	6.9	1.87	(0.17, 21.09)	0.6078	0.8679
Y	259	127	5	3.9	132	11	8.3	1.75	(0.61, 5.05)	0.2957	0.8679
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	6	11.5	>999.99	(0.00, >999.99)	0.0149	0.0190
POST-MENOPAUSAL	214	110	6	5.5	104	7	6.7	0.95	(0.32, 2.86)	0.9334	0.0190
Time to First Grade >= 3 Infections and infestations, COVID-19											
All Patients	324	163	1	0.6	161	4	2.5	2.91	(0.32, 26.15)	0.3181	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	1.90	(0.20, 18.41)	0.5734	0.3358
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2871	0.3358
Sex											
F	318	162	1	0.6	156	4	2.6	3.00	(0.33, 26.96)	0.3030	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4227	0.7265
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.7265
OTHER	78	38	1	2.6	40	3	7.5	1.67	(0.17, 16.35)	0.6569	0.7265
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4008	0.4025
Y	259	127	1	0.8	132	3	2.3	2.11	(0.22, 20.29)	0.5091	0.4025

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4250	0.5231
POST-MENOPAUSAL	214	110	1	0.9	104	3	2.9	2.42	(0.25, 23.39)	0.4308	0.5231
Time to First Grade >= 3 Infections and infestations, Pneumonia											
All Patients	324	163	2	1.2	161	2	1.2	0.81	(0.11, 5.87)	0.8346	NE
Age group (years)											
<65	266	129	2	1.6	137	2	1.5	0.73	(0.10, 5.28)	0.7515	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	2	1.2	156	2	1.3	0.81	(0.11, 5.92)	0.8379	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3091	0.3692
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.3692
OTHER	78	38	2	5.3	40	1	2.5	0.32	(0.03, 3.64)	0.3350	0.3692
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	0.1691
Y	259	127	2	1.6	132	1	0.8	0.36	(0.03, 4.03)	0.3883	0.1691
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.1642
POST-MENOPAUSAL	214	110	2	1.8	104	1	1.0	0.35	(0.03, 4.08)	0.3826	0.1642
Time to First Grade >= 3 Infections and infestations, Upper respiratory tract infection											
All Patients	324	163	1	0.6	161	1	0.6	0.64	(0.04, 10.66)	0.7530	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.53	(0.03, 8.97)	0.6519	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.66	(0.04, 10.97)	0.7687	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	1	2.5	0.55	(0.03, 9.32)	0.6771	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4328	0.0759
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2741	0.0759
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.73	(0.04, 11.83)	0.8209	1.0000
Time to First Grade >= 3 Infections and infestations, Urinary tract infection											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1799	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2048	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1740	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.1718	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.1974	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3487	1.0000
Time to First Grade >= 3 Infections and infestations, Anal abscess											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4214	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4555	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4130	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3545	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4357	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5002	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Infections and infestations, COVID-19 pneumonia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3220	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3042	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2981	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3243	1.0000
Time to First Grade >= 3 Infections and infestations, Candida infection											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Infections and infestations, Cellulitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4054	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4419	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3971	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4206	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4171	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3711	1.0000
Time to First Grade >= 3 Infections and infestations, Clostridium difficile colitis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2217	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4008	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2294	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1367	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2819	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2494	1.0000
Time to First Grade >= 3 Infections and infestations, Gastroenteritis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Infections and infestations, Gastroenteritis norovirus											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4795	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5186	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5186	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4386	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4561	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4795	1.0000
Time to First Grade >= 3 Infections and infestations, Infection											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2348	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2072	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2420	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2180	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2110	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2675	1.0000
Time to First Grade >= 3 Infections and infestations, Lung abscess											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3638	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4011	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3570	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4241	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3922	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3350	1.0000
Time to First Grade >= 3 Infections and infestations, Tooth abscess											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3205	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3442	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3141	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3254	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3390	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3076	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 General disorders and administration site conditions, Any											
All Patients	324	163	5	3.1	161	9	5.6	1.37	(0.46, 4.14)	0.5702	NE
Age group (years)											
<65	266	129	3	2.3	137	7	5.1	1.59	(0.41, 6.22)	0.5009	0.8840
>=65	58	34	2	5.9	24	2	8.3	1.38	(0.19, 9.84)	0.7479	0.8840
Sex											
F	318	162	5	3.1	156	8	5.1	1.22	(0.39, 3.76)	0.7329	0.5290
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.5290
Region											
ASIA	120	62	1	1.6	58	3	5.2	2.15	(0.22, 20.92)	0.5001	0.7176
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	3	4.8	0.95	(0.19, 4.69)	0.9453	0.7176
OTHER	78	38	1	2.6	40	3	7.5	1.29	(0.13, 12.38)	0.8277	0.7176
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	4	13.8	2.26	(0.41, 12.51)	0.3362	0.6361
Y	259	127	3	2.4	132	5	3.8	1.09	(0.26, 4.63)	0.9071	0.6361
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	4	7.7	>999.99	(0.00, >999.99)	0.0832	0.0287
POST-MENOPAUSAL	214	110	5	4.5	104	4	3.8	0.59	(0.15, 2.24)	0.4314	0.0287

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Grade >= 3 General disorders and administration site conditions, Asthenia											
All Patients	324	163	1	0.6	161	4	2.5	3.03	(0.33, 27.57)	0.3006	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2998	0.4022
>=65	58	34	1	2.9	24	2	8.3	2.84	(0.26, 31.56)	0.3738	0.4022
Sex											
F	318	162	1	0.6	156	4	2.6	3.10	(0.34, 28.19)	0.2910	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	0.3517
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.90	(0.06, 14.33)	0.9382	0.3517
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.3286	0.3517
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	1.23	(0.08, 19.59)	0.8856	0.1669
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.1642	0.1669
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.1869	0.2551
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.26	(0.11, 14.75)	0.8520	0.2551
Time to First Grade >= 3 General disorders and administration site conditions, Mucosal inflammation											
All Patients	324	163	0	0.0	161	3	1.9	>999.99	(0.00, >999.99)	0.0916	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.1076	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1693	0.9999
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.9999
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.0900	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.0992	0.9999
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3897	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3467	1.0000
Time to First Grade >= 3 General disorders and administration site conditions, Fatigue											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.1065	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3918	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1119	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1044	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	0	0.0	<0.01	(0.00, >999.99)	0.0955	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1275	1.0000
Time to First Grade >= 3 General disorders and administration site conditions, Pain											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2609	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2985	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2528	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4363	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4936	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.2094	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5002	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3876	1.0000
Time to First Grade >= 3 General disorders and administration site conditions, Axillary pain											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2288	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2014	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2356	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2079	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2032	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2590	1.0000
Time to First Grade >= 3 General disorders and administration site conditions, Chest pain											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2756	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2495	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2821	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2857	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3674	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2953	1.0000
Time to First Grade >= 3 General disorders and administration site conditions, Death											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4088	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4008	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5016	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4254	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3819	1.0000
Time to First Grade >= 3 General disorders and administration site conditions, Pyrexia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4022	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4296	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3953	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4221	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4297	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4442	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Nervous system disorders, Any											
All Patients	324	163	3	1.8	161	4	2.5	1.03	(0.23, 4.72)	0.9671	NE
Age group (years)											
<65	266	129	2	1.6	137	3	2.2	0.98	(0.16, 6.15)	0.9859	0.8942
>=65	58	34	1	2.9	24	1	4.2	1.34	(0.08, 21.44)	0.8357	0.8942
Sex											
F	318	162	3	1.9	156	4	2.6	1.06	(0.23, 4.85)	0.9370	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.0986
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	1	1.6	0.26	(0.03, 2.57)	0.2175	0.0986
OTHER	78	38	0	0.0	40	3	7.5	>999.99	(0.00, >999.99)	0.1341	0.0986
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2652	0.2283
Y	259	127	3	2.4	132	3	2.3	0.69	(0.14, 3.50)	0.6521	0.2283
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.3028
POST-MENOPAUSAL	214	110	3	2.7	104	3	2.9	0.83	(0.16, 4.16)	0.8187	0.3028
Time to First Grade >= 3 Nervous system disorders, Syncope											
All Patients	324	163	2	1.2	161	1	0.6	0.45	(0.04, 4.98)	0.5017	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.94	(0.06, 14.99)	0.9637	0.3996
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3743	0.3996

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	2	1.2	156	1	0.6	0.46	(0.04, 5.11)	0.5169	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.1633
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	0	0.0	<0.01	(0.00, >999.99)	0.1421	0.1633
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	0.1633
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	1	0.8	0.41	(0.04, 4.63)	0.4605	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.0561
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1384	0.0561
Time to First Grade >= 3 Nervous system disorders, Cerebral haemorrhage											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4889	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5305	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4795	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5541	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5002	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4281	1.0000
Time to First Grade >= 3 Nervous system disorders, Cerebrovascular accident											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3082	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2652	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3037	1.0000
Time to First Grade >= 3 Nervous system disorders, Haemorrhage intracranial											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First Grade >= 3 Nervous system disorders, Sciatica											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1266	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0833	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1327	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.1482	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1222	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1747	1.0000
Time to First Grade >= 3 Injury, poisoning and procedural complications, Any											
All Patients	324	163	1	0.6	161	4	2.5	1.95	(0.22, 17.57)	0.5442	NE
Age group (years)											
<65	266	129	1	0.8	137	4	2.9	1.54	(0.17, 13.89)	0.7005	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	4	2.6	2.01	(0.22, 18.11)	0.5256	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5439	0.2659
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.2370	0.2659
OTHER	78	38	1	2.6	40	1	2.5	0.37	(0.02, 5.97)	0.4655	0.2659
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.58	(0.04, 9.22)	0.6926	0.1582
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.2163	0.1582
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6464	0.5961
POST-MENOPAUSAL	214	110	1	0.9	104	3	2.9	1.85	(0.19, 17.86)	0.5905	0.5961
Time to First Grade >= 3 Injury, poisoning and procedural complications, Ankle fracture											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5127	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5637	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5060	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5403	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5176	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4613	1.0000
Time to First Grade >= 3 Injury, poisoning and procedural complications, Femur fracture											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1353	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0863	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1416	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1306	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2024	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1967	1.0000
Time to First Grade >= 3 Injury, poisoning and procedural complications, Post procedural fistula											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4933	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5371	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4892	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4795	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5036	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4461	1.0000
Time to First Grade >= 3 Injury, poisoning and procedural complications, Postoperative hypertension											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4054	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4419	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3971	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3378	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4171	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3711	1.0000
Time to First Grade >= 3 Injury, poisoning and procedural complications, Snake bite											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5032	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5598	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4962	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5439	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4328	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6464	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Musculoskeletal and connective tissue disorders, Any											
All Patients	324	163	1	0.6	161	4	2.5	2.85	(0.31, 25.91)	0.3328	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.1331	0.0486
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.0486
Sex											
F	318	162	1	0.6	156	4	2.6	2.93	(0.32, 26.69)	0.3178	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3258	0.0840
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2	>999.99	(0.00, >999.99)	0.1685	0.0840
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.3848	0.0840
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.2505	0.2286
Y	259	127	1	0.8	132	2	1.5	1.64	(0.15, 18.21)	0.6861	0.2286
Menopausal Status at Randomization											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	4	3.8	3.15	(0.35, 28.50)	0.2809	1.0000
Time to First Grade >= 3 Musculoskeletal and connective tissue disorders, Back pain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4153	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4497	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4076	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3435	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4308	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3887	1.0000
Time to First Grade >= 3 Musculoskeletal and connective tissue disorders, Bone pain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3319	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3082	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3037	1.0000
Time to First Grade >= 3 Musculoskeletal and connective tissue disorders, Flank pain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4981	NE
Age group (years)											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5493	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4913	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5083	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4497	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4406	1.0000
Time to First Grade >= 3 Musculoskeletal and connective tissue disorders, Muscular weakness											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3110	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3173	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3258	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2914	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3125	1.0000
Time to First Grade >= 3 Musculoskeletal and connective tissue disorders, Osteonecrosis of jaw											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4743	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5146	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4659	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5892	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4008	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4400	1.0000
Time to First Grade >= 3 Respiratory, thoracic and mediastinal disorders, Any											
All Patients	324	163	3	1.8	161	2	1.2	0.54	(0.09, 3.25)	0.4939	NE
Age group (years)											
<65	266	129	2	1.6	137	2	1.5	0.76	(0.11, 5.45)	0.7848	0.4032
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3819	0.4032
Sex											
F	318	162	3	1.9	156	2	1.3	0.56	(0.09, 3.35)	0.5154	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4206	0.2304
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3134	0.2304
OTHER	78	38	2	5.3	40	1	2.5	0.31	(0.03, 3.50)	0.3175	0.2304
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.56	(0.05, 6.23)	0.6303	0.8335
Y	259	127	1	0.8	132	1	0.8	0.68	(0.04, 10.87)	0.7833	0.8335
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.1549
POST-MENOPAUSAL	214	110	3	2.7	104	1	1.0	0.28	(0.03, 2.72)	0.2424	0.1549
Time to First Grade >= 3 Respiratory, thoracic and mediastinal disorders, Dyspnoea											
All Patients	324	163	1	0.6	161	1	0.6	0.73	(0.05, 11.77)	0.8271	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.63	(0.04, 10.12)	0.7435	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.76	(0.05, 12.15)	0.8449	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4206	0.2124
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.2124
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1967	0.2124
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	1	0.8	132	1	0.8	0.68	(0.04, 10.87)	0.7833	0.9999

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.84	(0.05, 13.41)	0.9005	1.0000
Time to First Grade >= 3 Respiratory, thoracic and mediastinal disorders, Pulmonary embolism											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.1142	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3819	1.0000
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1195	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1306	1.0000
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.1643	0.9999
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1279	1.0000
Time to First Grade >= 3 Respiratory, thoracic and mediastinal disorders, Pneumonitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Cardiac disorders, Any											
All Patients	324	163	2	1.2	161	2	1.2	0.76	(0.11, 5.56)	0.7903	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.61	(0.04, 10.40)	0.7294	0.7392
>=65	58	34	1	2.9	24	1	4.2	1.39	(0.09, 22.26)	0.8150	0.7392
Sex											
F	318	162	2	1.2	156	2	1.3	0.79	(0.11, 5.73)	0.8147	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3334	0.0804
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2850	0.0804
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2615	0.0804
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	2	1.5	0.72	(0.10, 5.21)	0.7409	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.86	(0.12, 6.20)	0.8833	1.0000
Time to First Grade >= 3 Cardiac disorders, Acute coronary syndrome											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2239	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5305	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2240	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2165	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2615	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2389	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1926	1.0000
Time to First Grade >= 3 Cardiac disorders, Atrial fibrillation											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2207	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3819	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2282	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2850	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2059	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2471	1.0000
Time to First Grade >= 3 Cardiac disorders, Cardiac arrest											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3280	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3080	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3332	1.0000
Time to First Grade >= 3 Hepatobiliary disorders, Any											
All Patients	324	163	3	1.8	161	1	0.6	0.16	(0.02, 1.66)	0.0870	NE
Age group (years)											
<65	266	129	2	1.6	137	1	0.7	0.19	(0.02, 2.25)	0.1491	0.6110
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4193	0.6110
Sex											
F	318	162	3	1.9	156	1	0.6	0.16	(0.02, 1.70)	0.0919	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	3	4.8	63	1	1.6	0.20	(0.02, 2.00)	0.1324	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.0575	0.2627
Y	259	127	1	0.8	132	1	0.8	0.77	(0.05, 12.33)	0.8524	0.2627

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	0.9999
POST-MENOPAUSAL	214	110	3	2.7	104	1	1.0	0.19	(0.02, 1.97)	0.1275	0.9999
Time to First Grade >= 3 Hepatobiliary disorders, Hypertransaminasaemia											
All Patients	324	163	1	0.6	161	1	0.6	0.65	(0.04, 10.79)	0.7602	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.54	(0.03, 9.14)	0.6630	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	0.67	(0.04, 11.10)	0.7760	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.71	(0.04, 11.51)	0.8069	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2024	0.1185
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3587	0.1185
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.75	(0.05, 12.14)	0.8370	1.0000
Time to First Grade >= 3 Hepatobiliary disorders, Bile duct stone											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.0339	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0339	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.0339	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.0833	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.0614	1.0000
Time to First Grade >= 3 Hepatobiliary disorders, Cholelithiasis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2566	NE
Age group (years)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4193	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2636	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2918	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2304	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2855	1.0000
Time to First Grade >= 3 Vascular disorders, Any											
All Patients	324	163	1	0.6	161	3	1.9	2.28	(0.23, 22.59)	0.4687	NE
Age group (years)											
<65	266	129	1	0.8	137	2	1.5	1.36	(0.12, 15.91)	0.8045	0.2853
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2259	0.2853
Sex											
F	318	162	1	0.6	156	3	1.9	2.32	(0.23, 23.05)	0.4592	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	3	7.5	2.14	(0.22, 21.05)	0.5031	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	0.3769
Y	259	127	1	0.8	132	2	1.5	1.27	(0.11, 14.55)	0.8484	0.3769
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.3950
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.36	(0.11, 16.04)	0.8076	0.3950
Time to First Grade >= 3 Vascular disorders, Deep vein thrombosis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3859	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2259	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3789	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4363	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4120	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3595	1.0000
Time to First Grade >= 3 Vascular disorders, Embolism											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2604	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3927	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4862	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4240	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3671	1.0000
Time to First Grade >= 3 Vascular disorders, Hypertension											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3110	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Grade >= 3 Vascular disorders, Hypotension											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Vascular disorders, Thrombosis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5501	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5716	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5563	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5186	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5541	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5930	1.0000
Time to First Grade >= 3 Skin and subcutaneous tissue disorders, Any											
All Patients	324	163	2	1.2	161	1	0.6	0.32	(0.03, 3.61)	0.3317	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0956	0.1824
>=65	58	34	1	2.9	24	1	4.2	1.40	(0.09, 22.50)	0.8103	0.1824

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	2	1.2	156	1	0.6	0.33	(0.03, 3.73)	0.3471	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.0995	0.5487
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.89	(0.06, 14.33)	0.9351	0.5487
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.5487
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	0.3515
Y	259	127	1	0.8	132	1	0.8	0.48	(0.03, 7.66)	0.5933	0.3515
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.0513	0.2516
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.83	(0.05, 13.53)	0.8952	0.2516
Time to First Grade >= 3 Skin and subcutaneous tissue disorders, Skin ulcer											
All Patients	324	163	1	0.6	161	1	0.6	0.52	(0.03, 8.34)	0.6385	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0956	0.0440
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2593	0.0440
Sex											
F	318	162	1	0.6	156	1	0.6	0.54	(0.03, 8.65)	0.6578	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.0995	0.2047
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3768	0.2047
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.2047
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.48	(0.03, 7.66)	0.5933	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.0513	0.0660
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4204	0.0660
Time to First Grade >= 3 Skin and subcutaneous tissue disorders, Rash maculo-papular											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3266	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3311	1.0000
Time to First Grade >= 3 Ear and labyrinth disorders, Any											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2173	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4070	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2254	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1432	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2801	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2579	1.0000
Time to First Grade >= 3 Ear and labyrinth disorders, Vertigo											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2173	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4070	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2254	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1432	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2801	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2579	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Grade >= 3 Eye disorders, Any											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4842	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5371	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4795	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5271	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4920	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5930	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Eye disorders, Cataract											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4842	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5371	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4795	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5271	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4920	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.5930	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Immune system disorders, Any											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1730	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1410	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1410	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1967	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1380	1.0000
Time to First Grade >= 3 Immune system disorders, Hypersensitivity											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1730	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1410	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1410	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1967	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1380	1.0000
Time to First Grade >= 3 Product issues, Any											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2747	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2457	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2813	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2207	1.0000
Visceral disease (per eCRF)											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3674	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3004	1.0000
Time to First Grade >= 3 Product issues, Device dislocation											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2747	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2457	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2813	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2207	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3674	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3004	1.0000
Time to First Grade >= 3 Renal and urinary disorders, Any											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Grade >= 3 Renal and urinary disorders, Acute kidney injury											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE

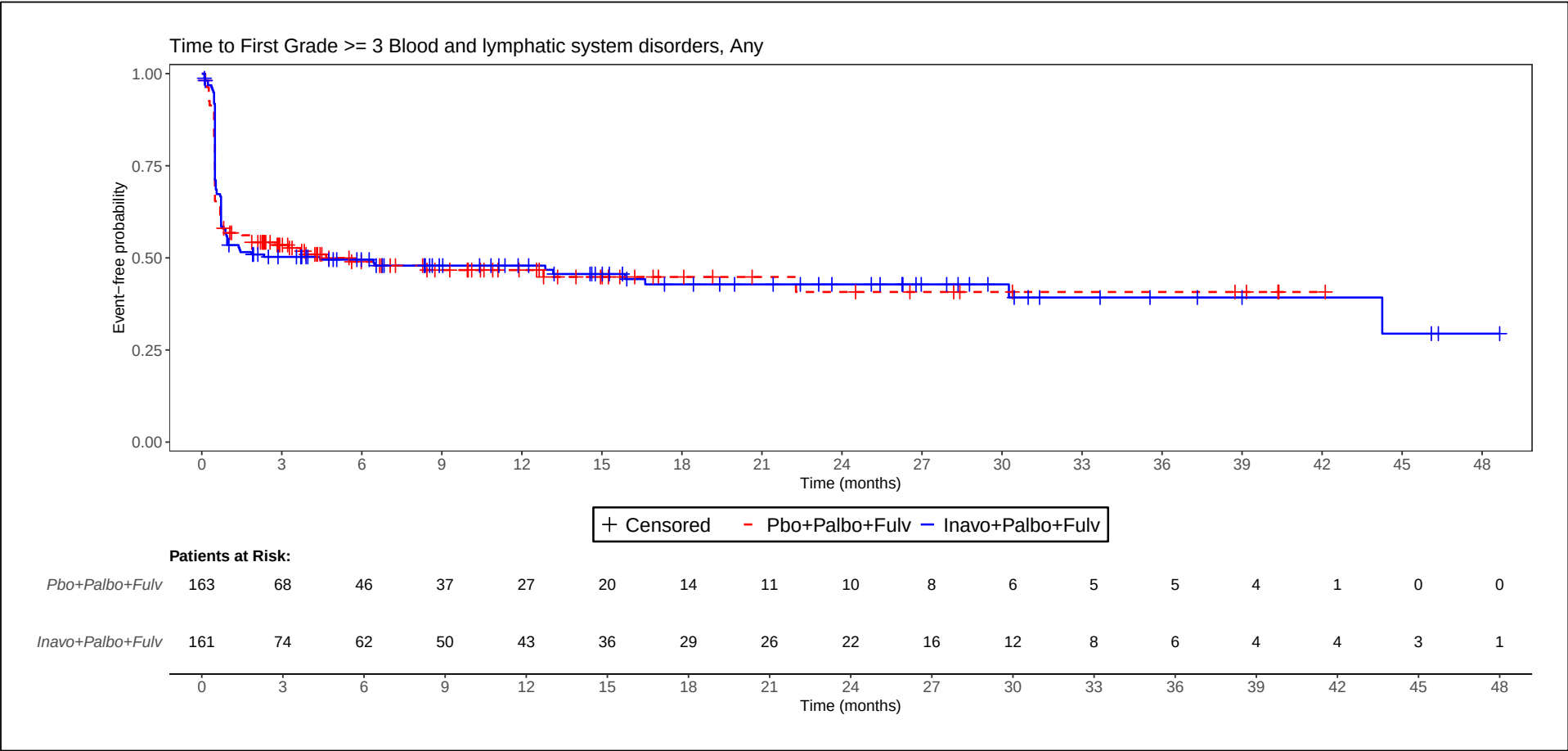
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000

Men are excluded from the subgroups of "Menopausal Status at Randomization"
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08 APR 2025 18:02 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

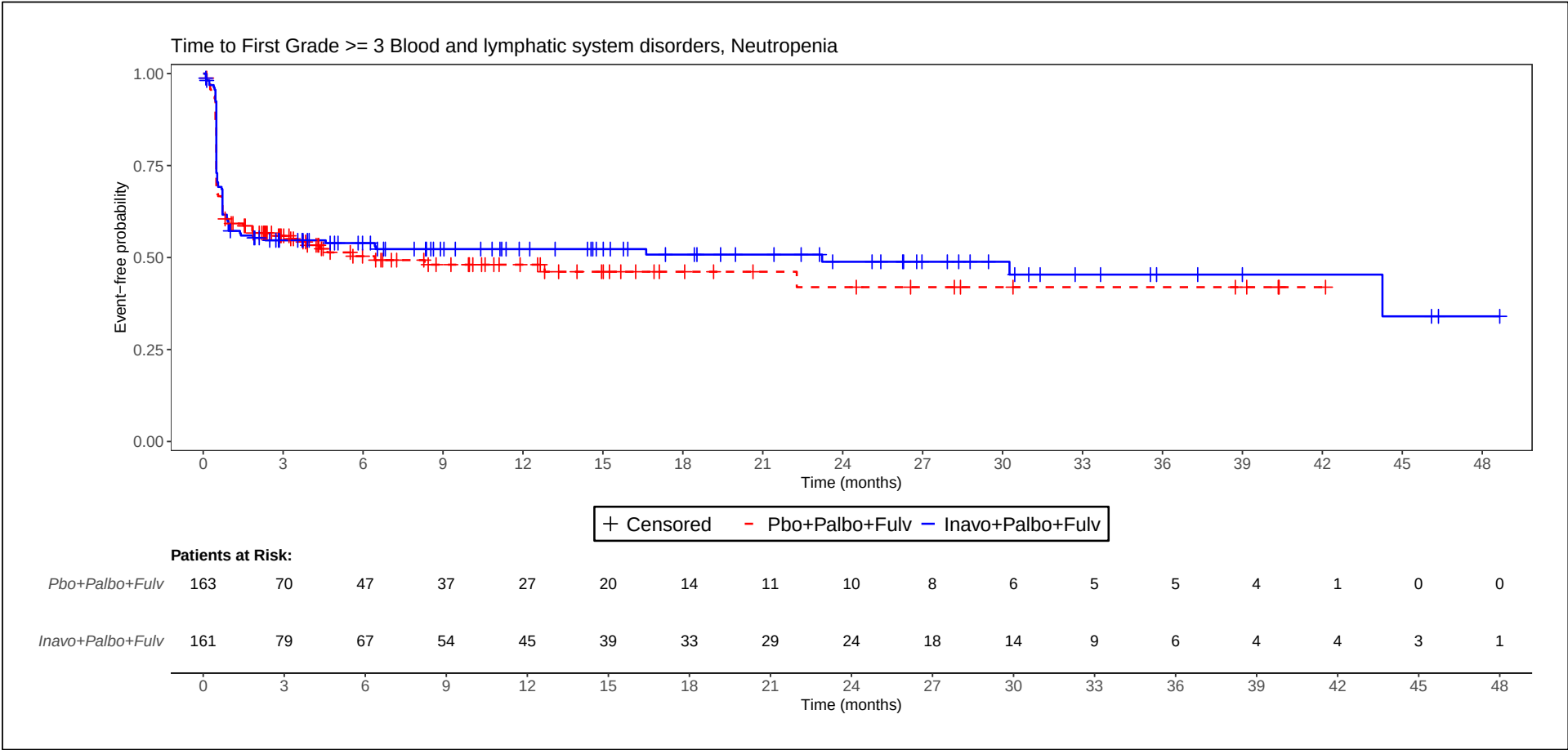
Kaplan Meier Plot for Safety, Adverse Events Grade >= 3 by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

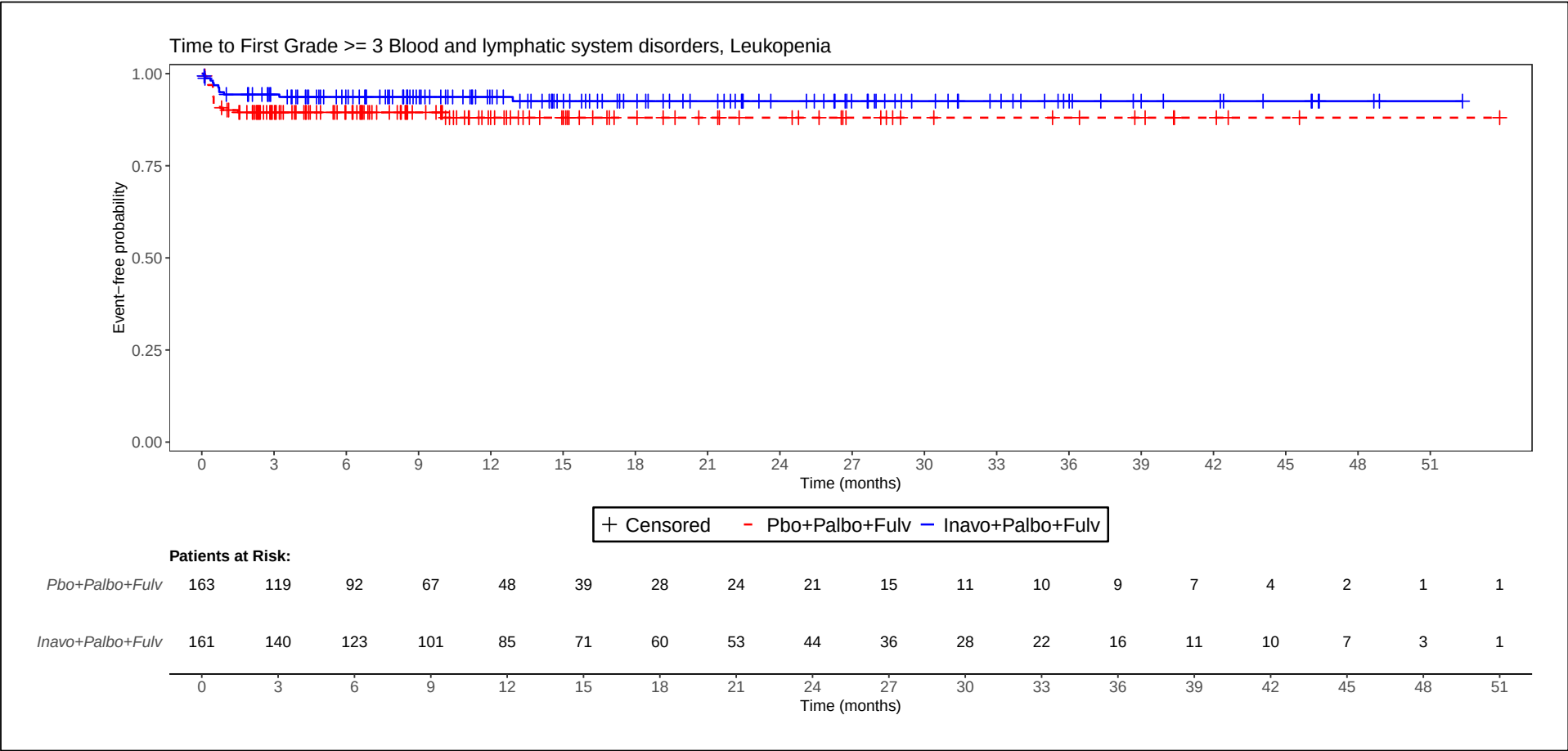
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

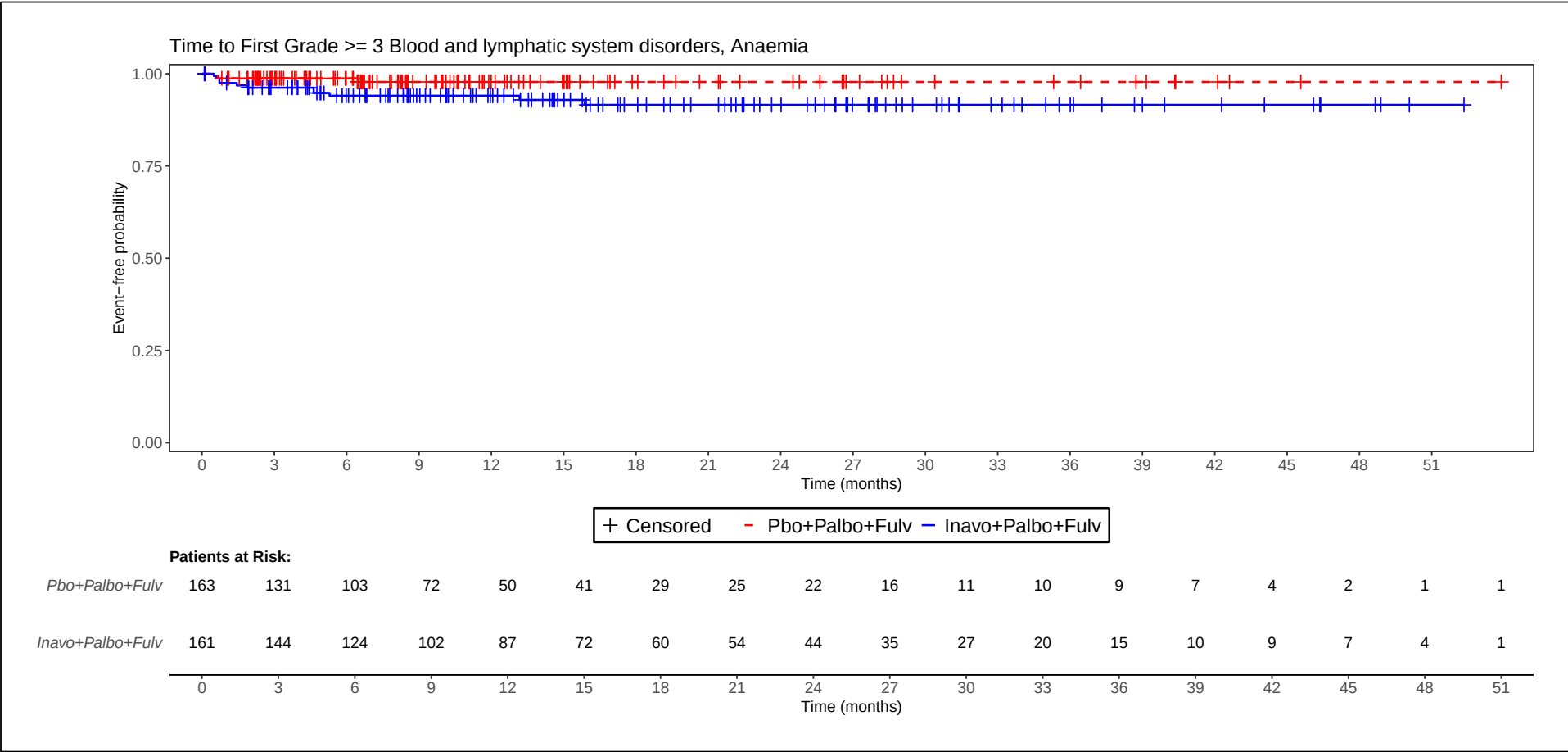
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

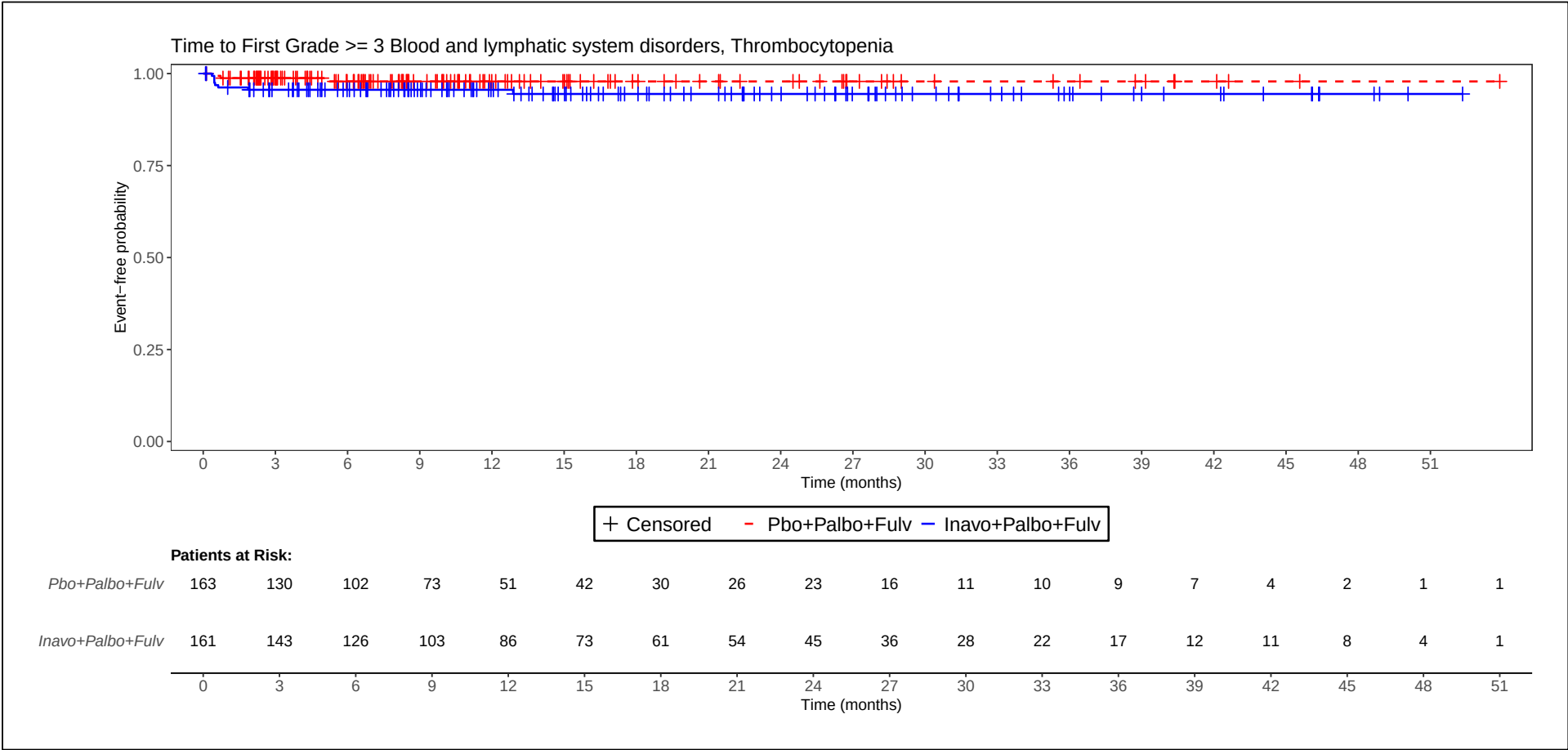
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

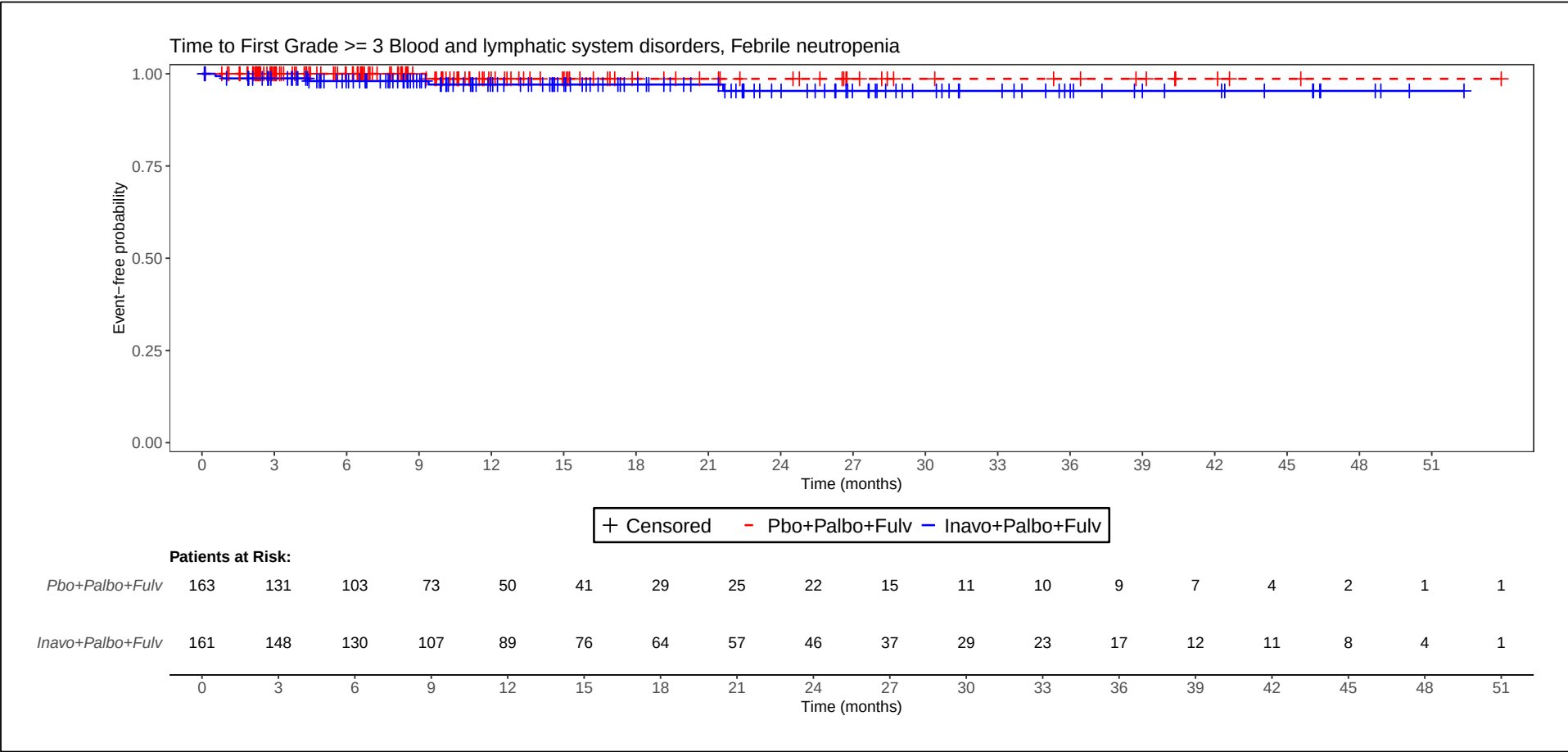
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

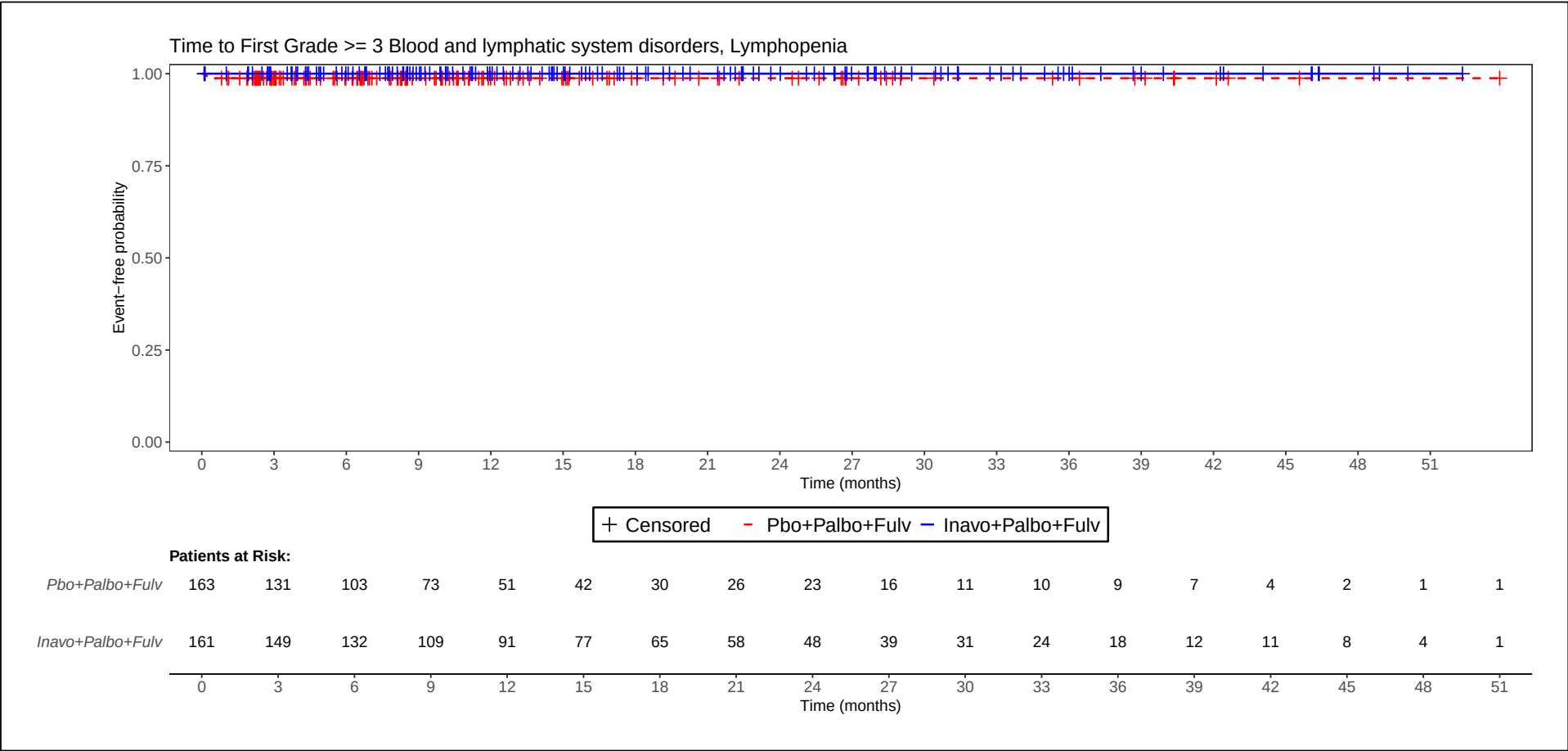
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

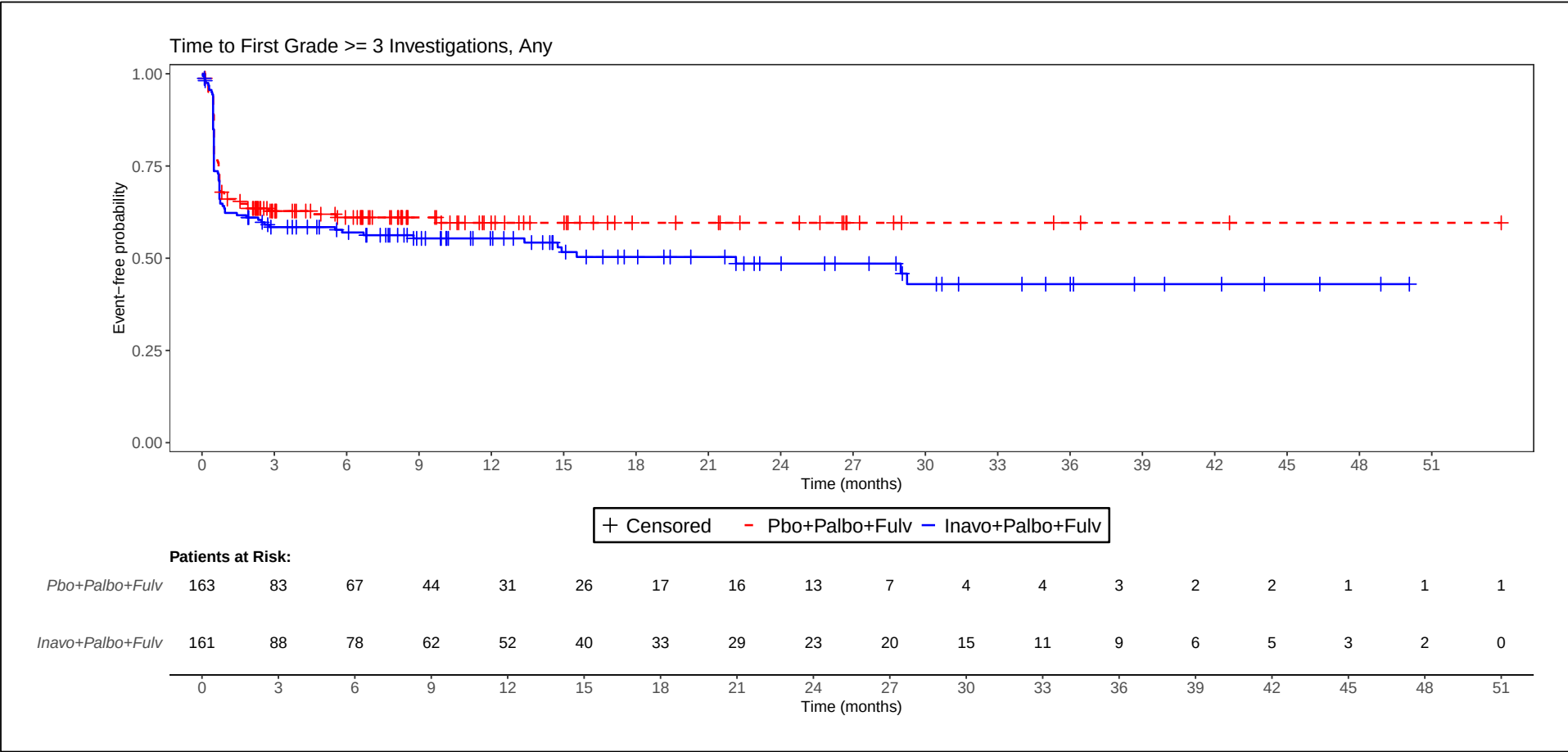
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

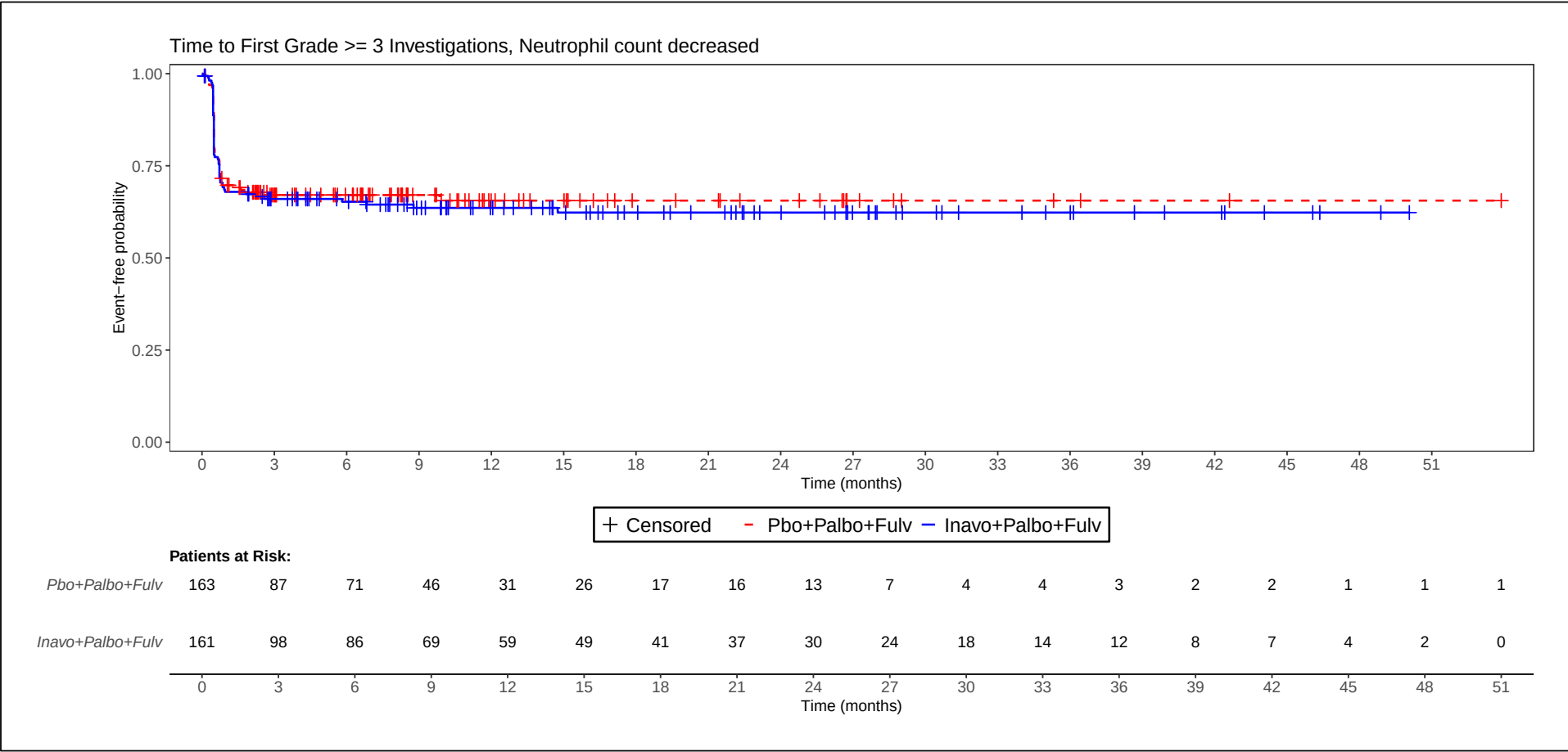
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

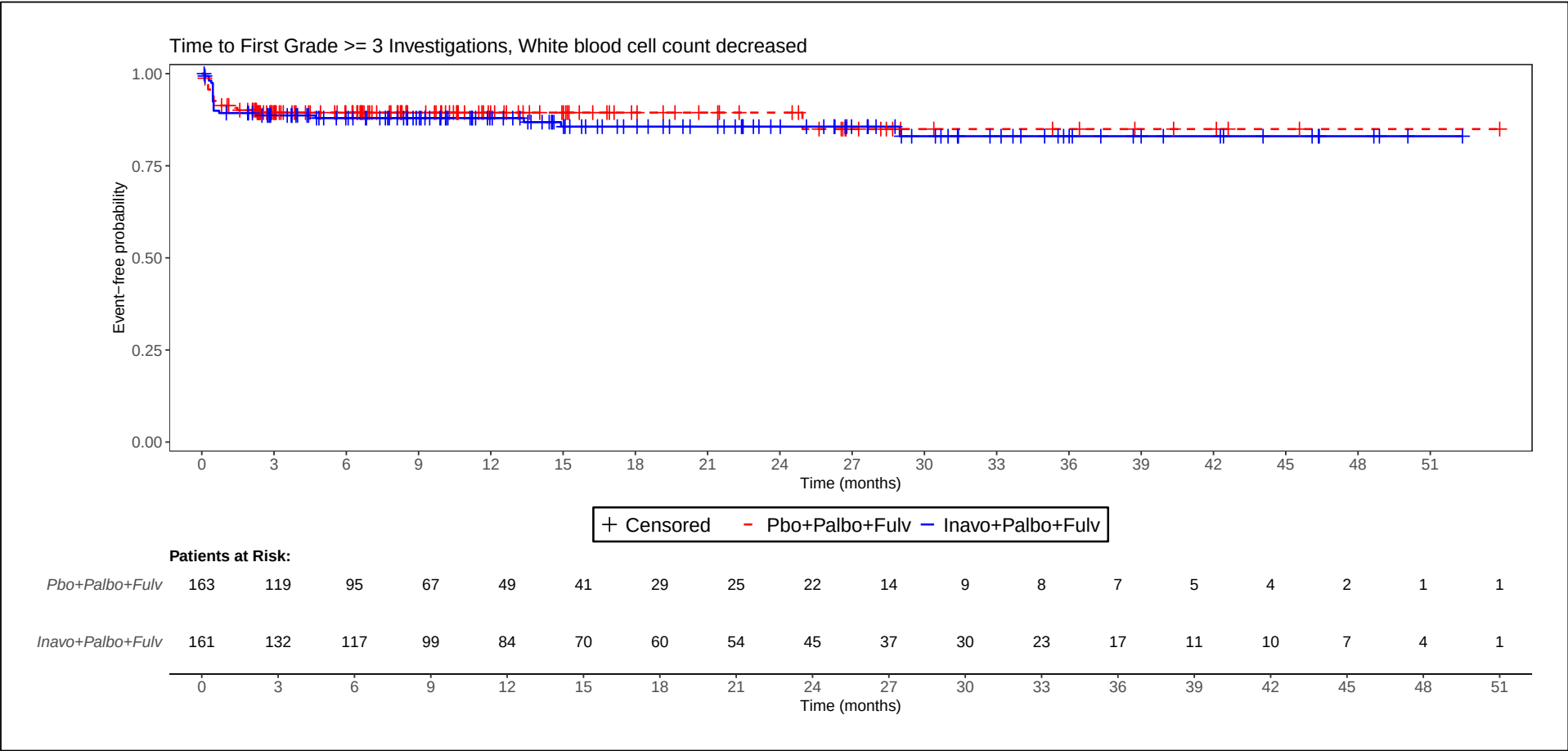
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

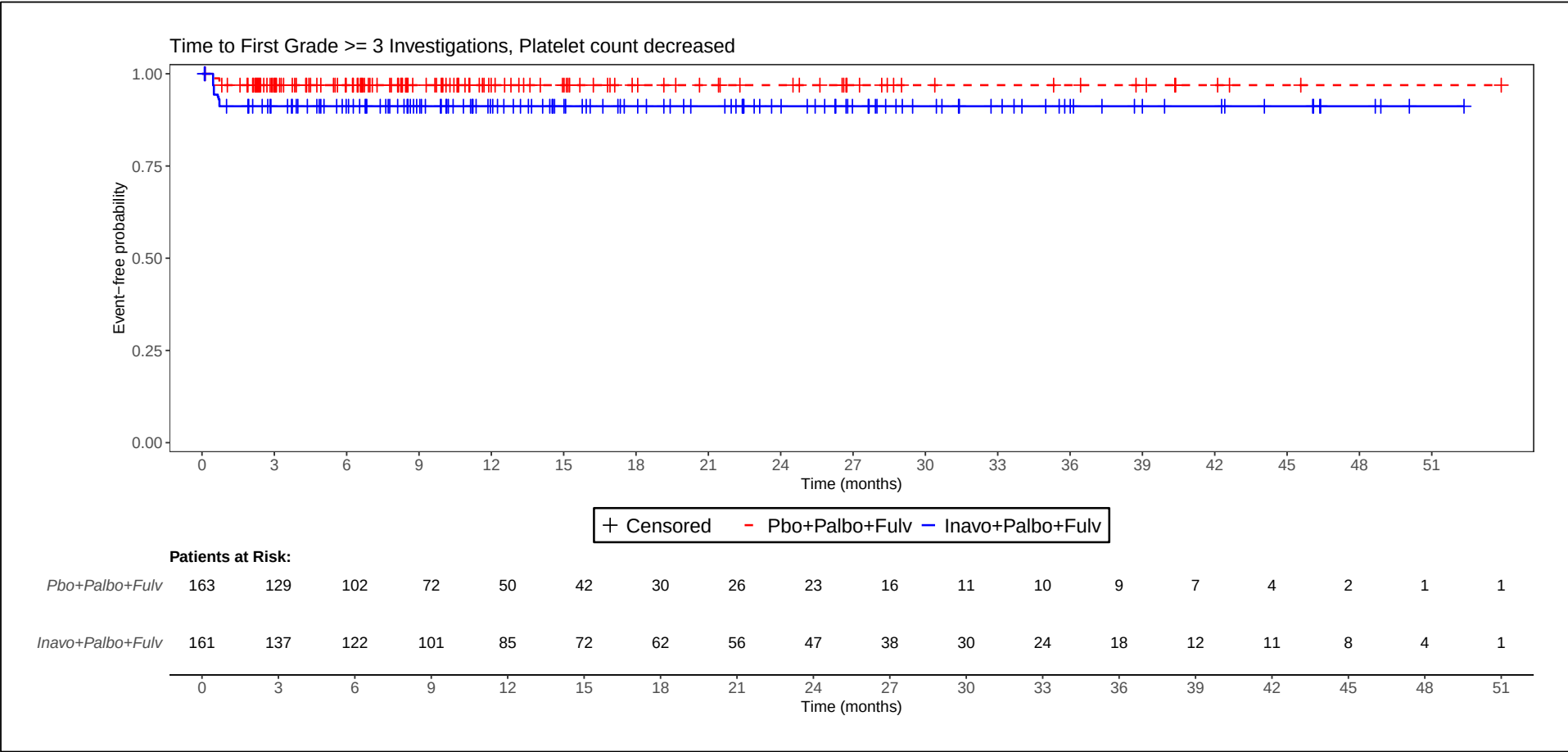
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

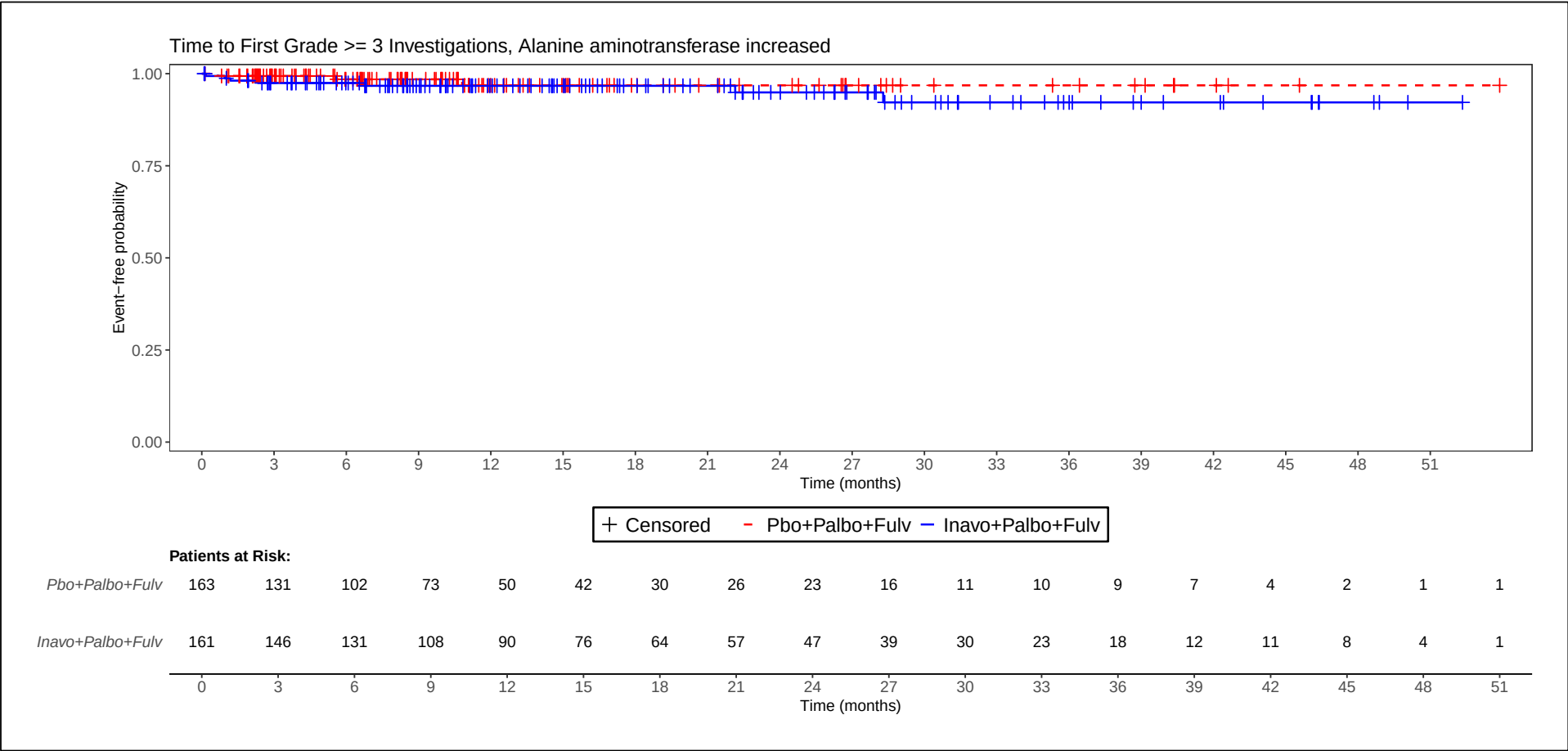
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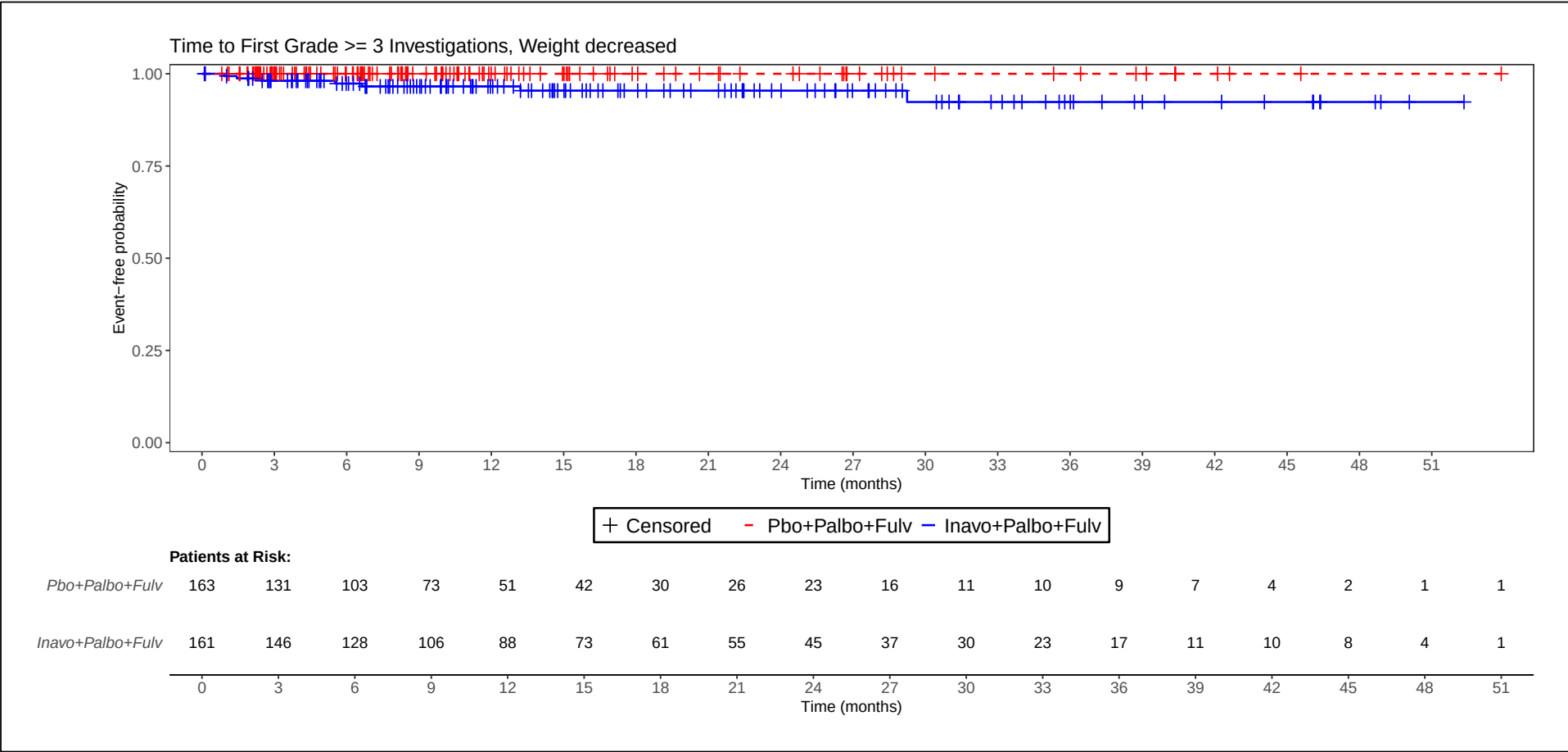
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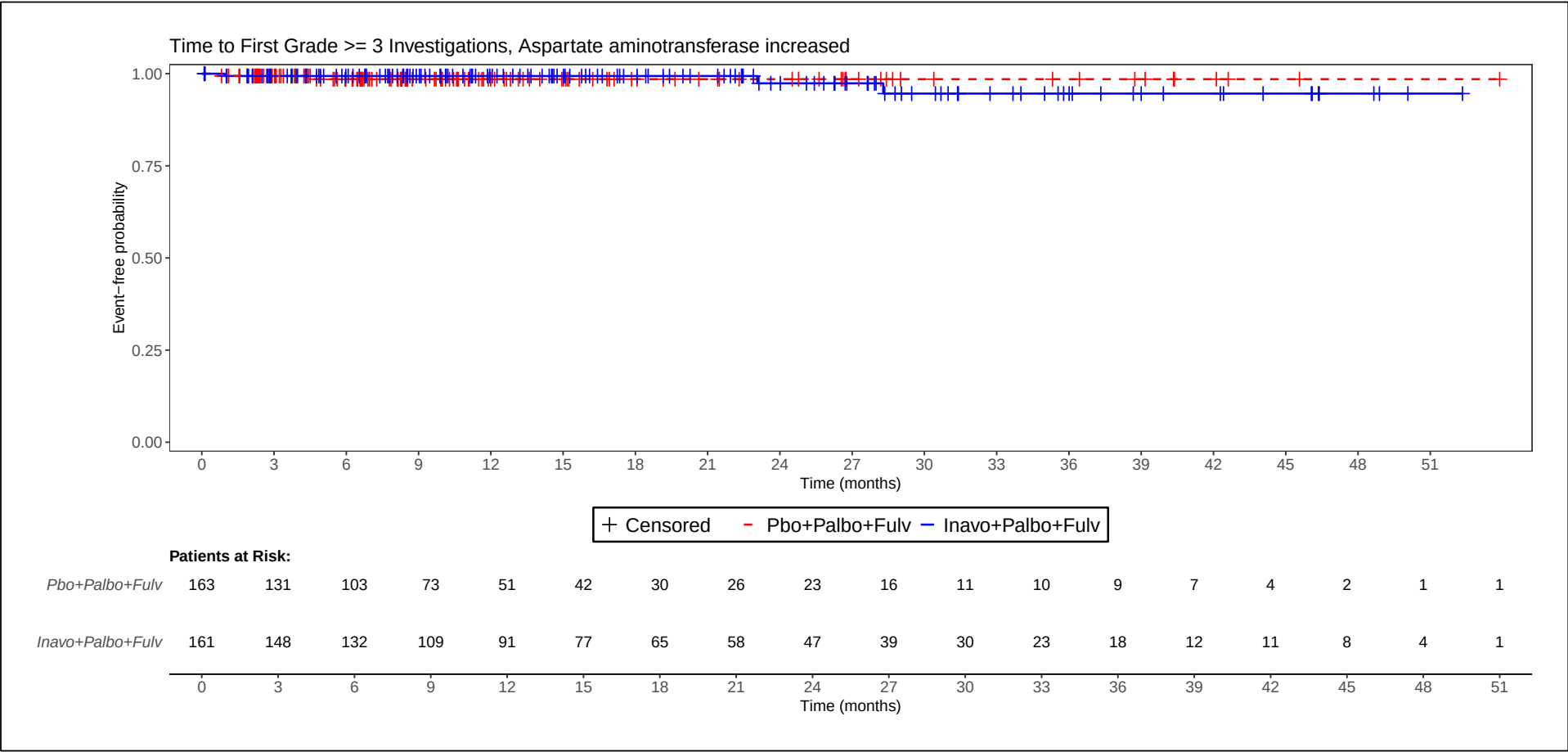
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

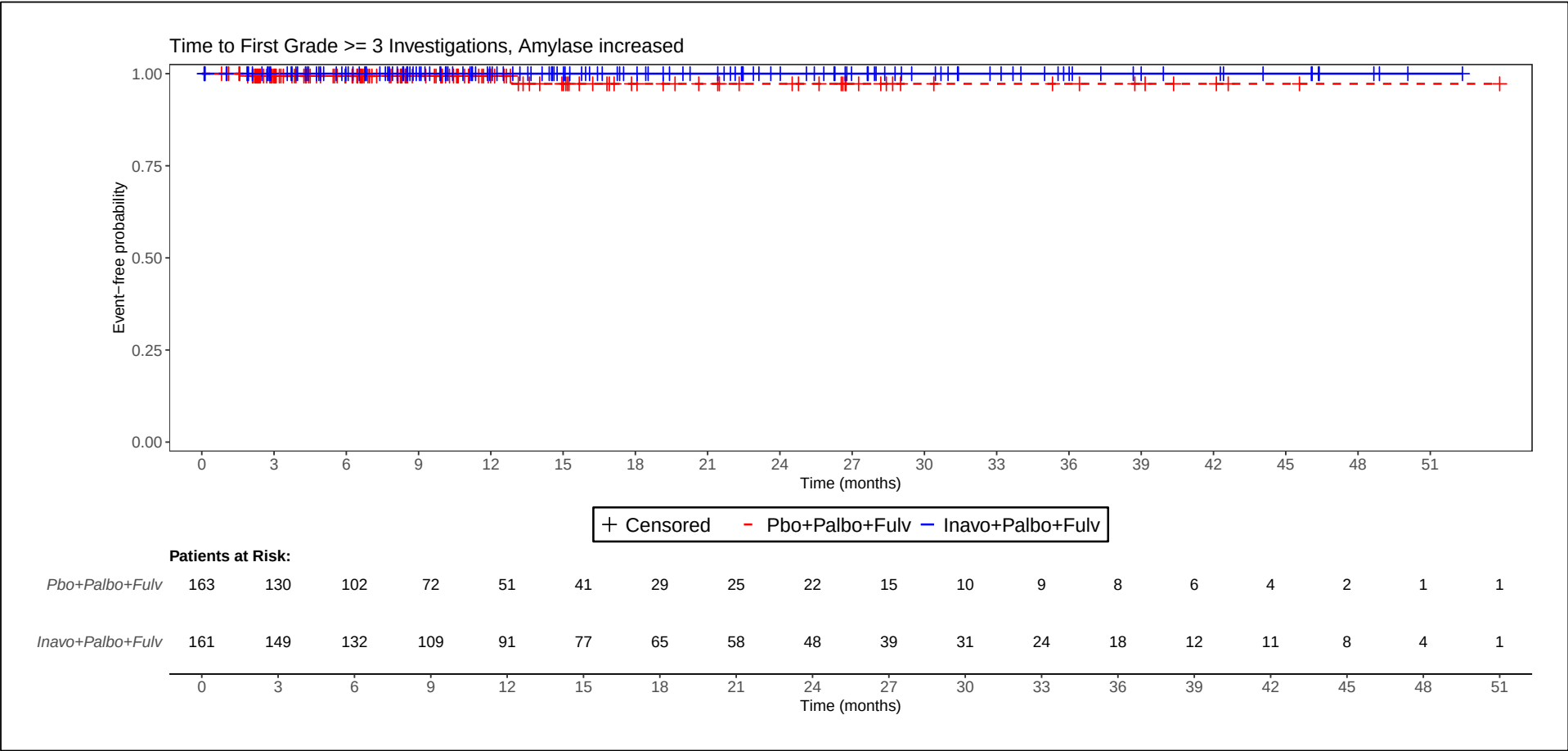
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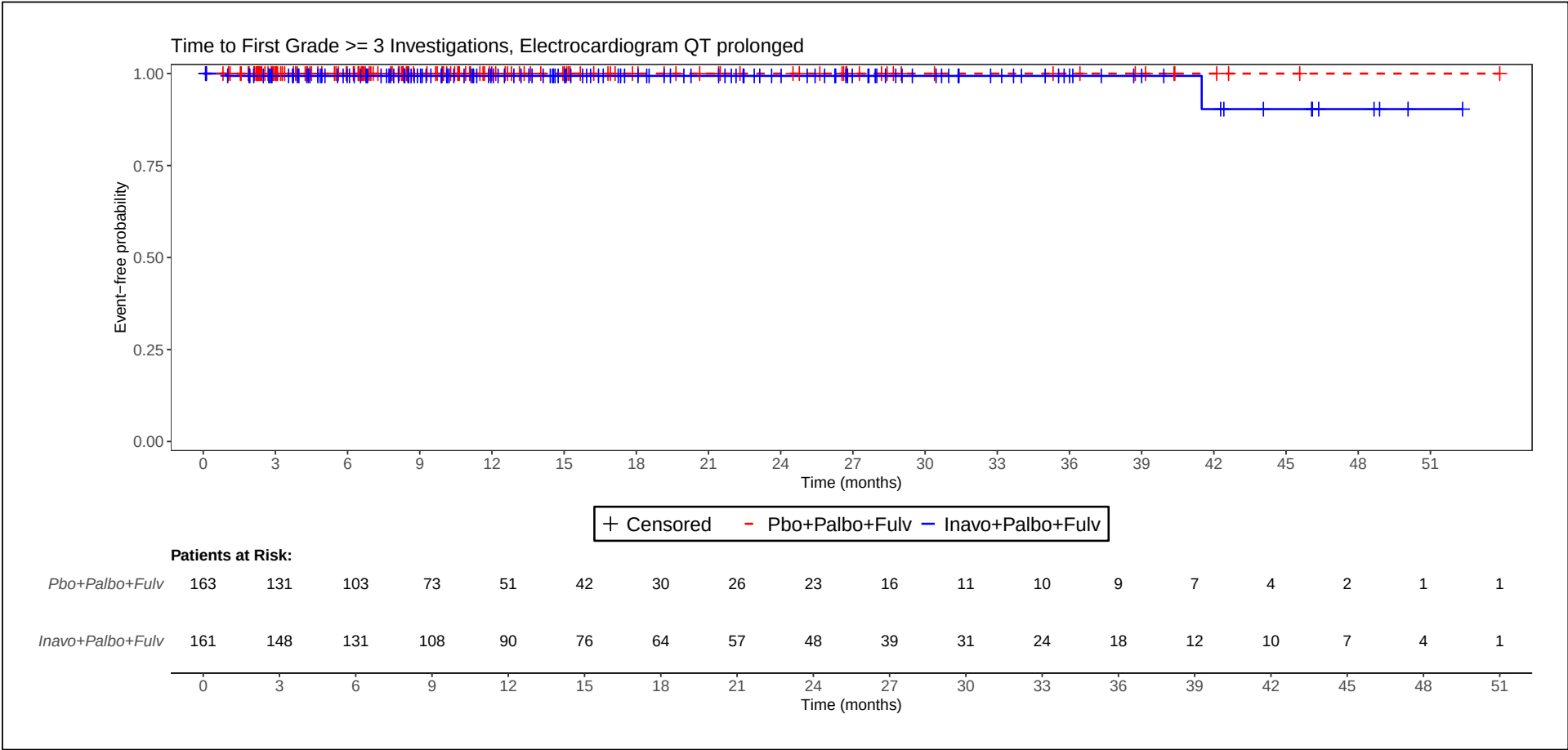
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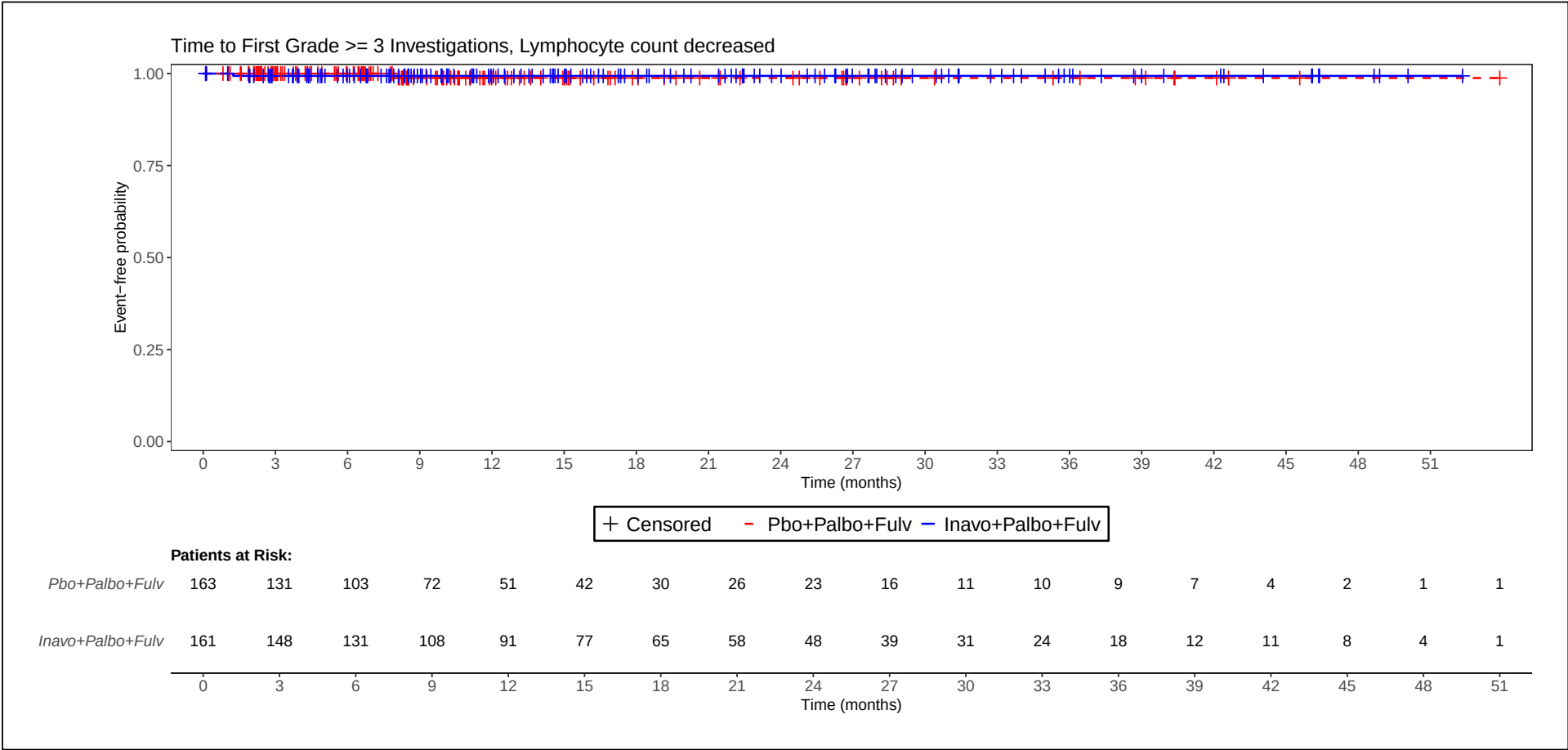
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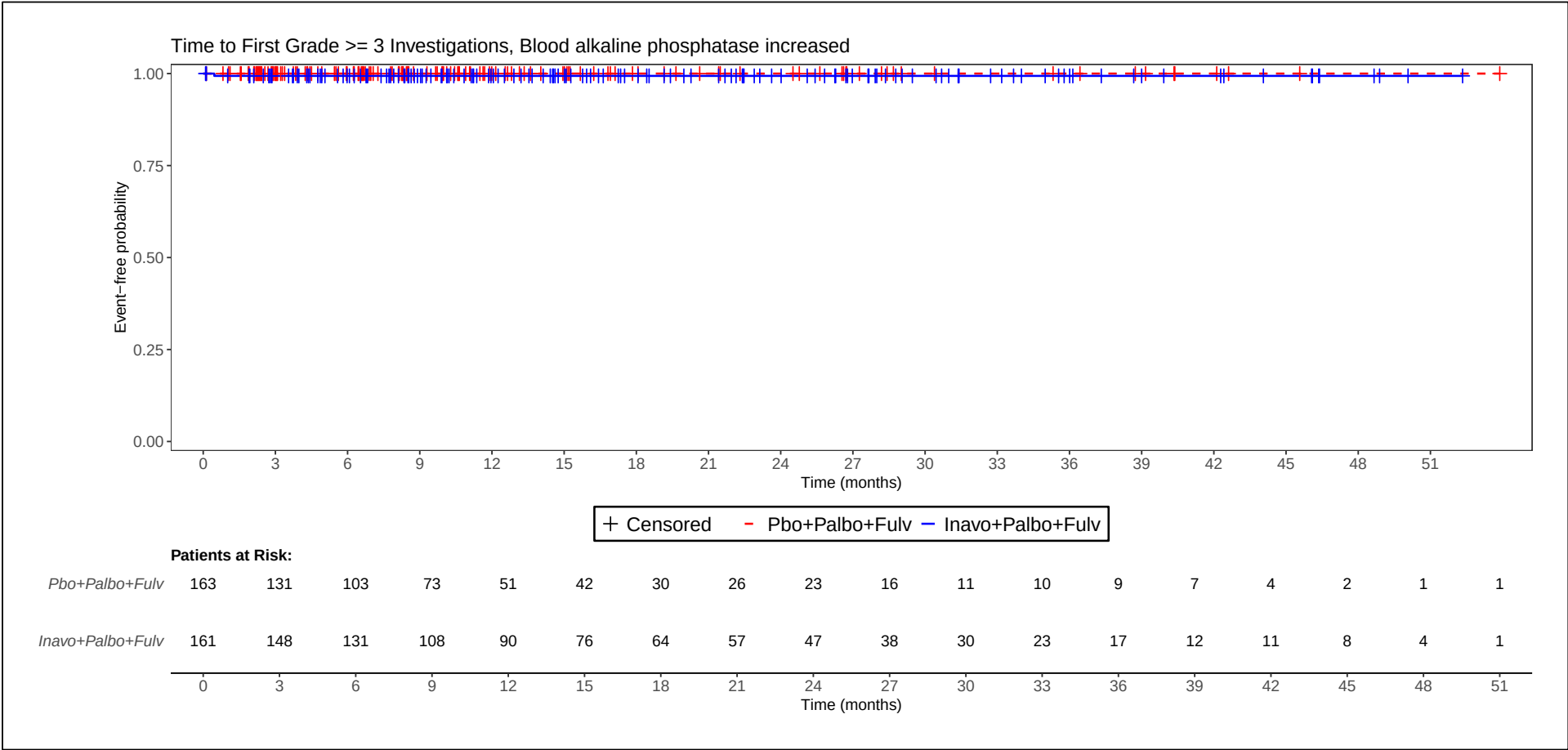
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

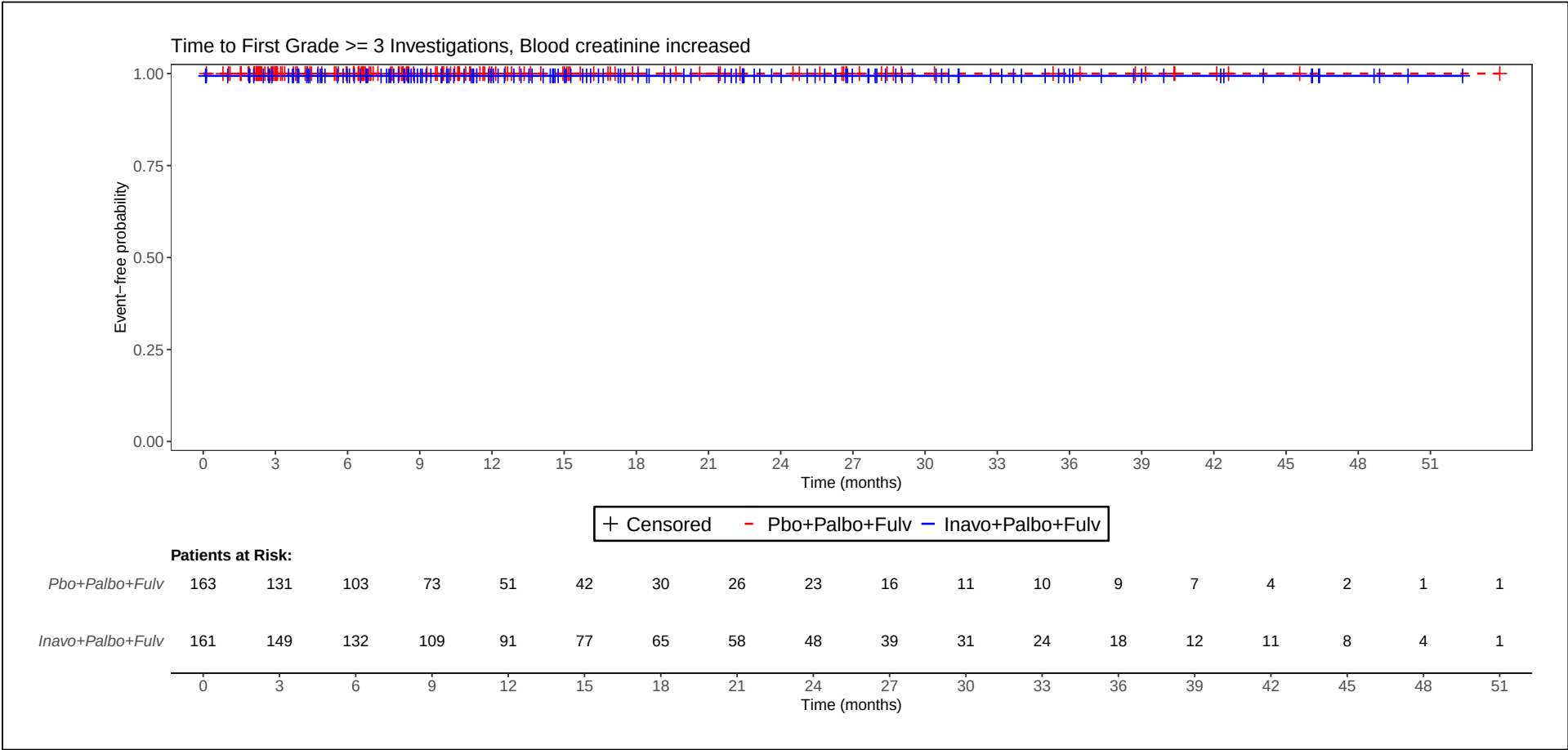
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

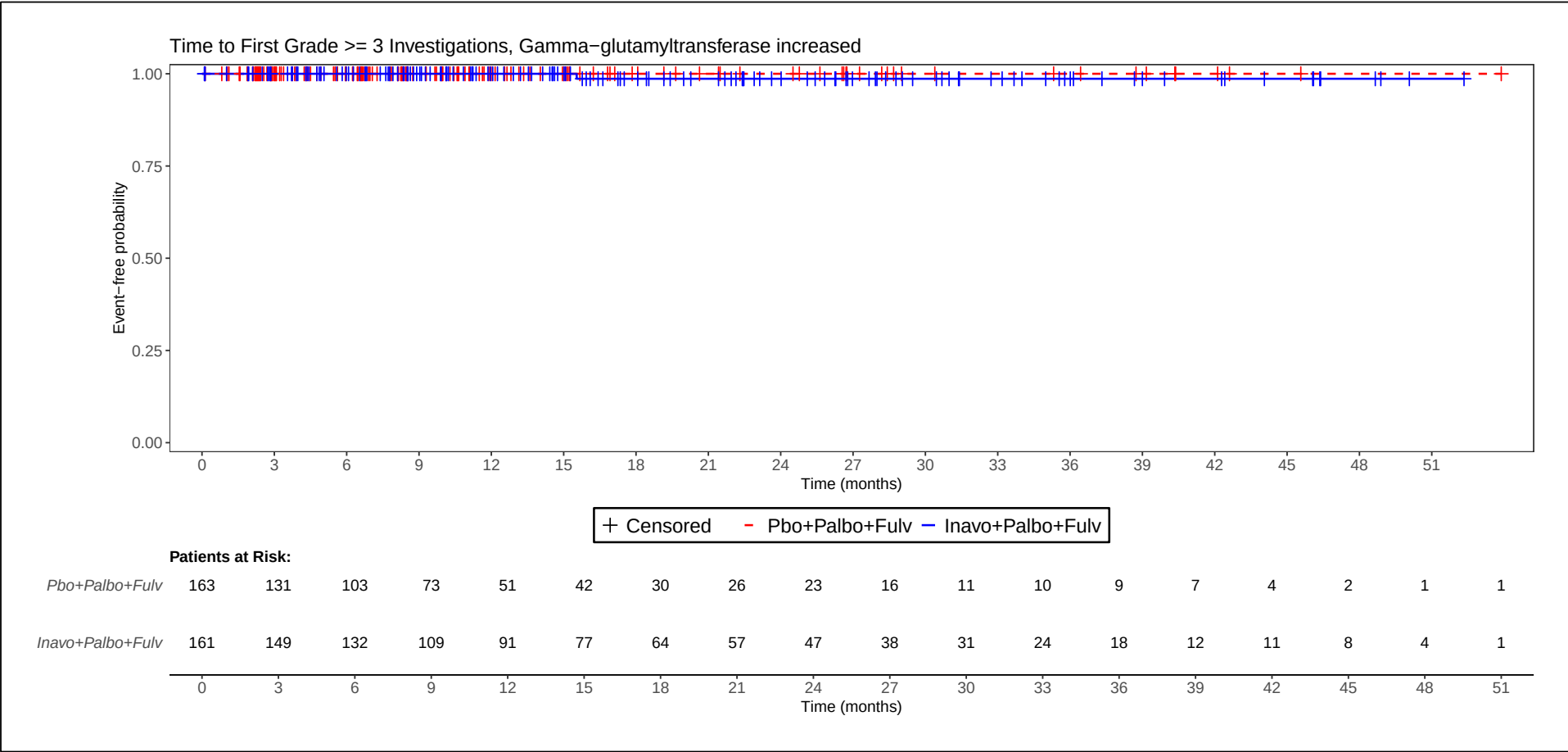
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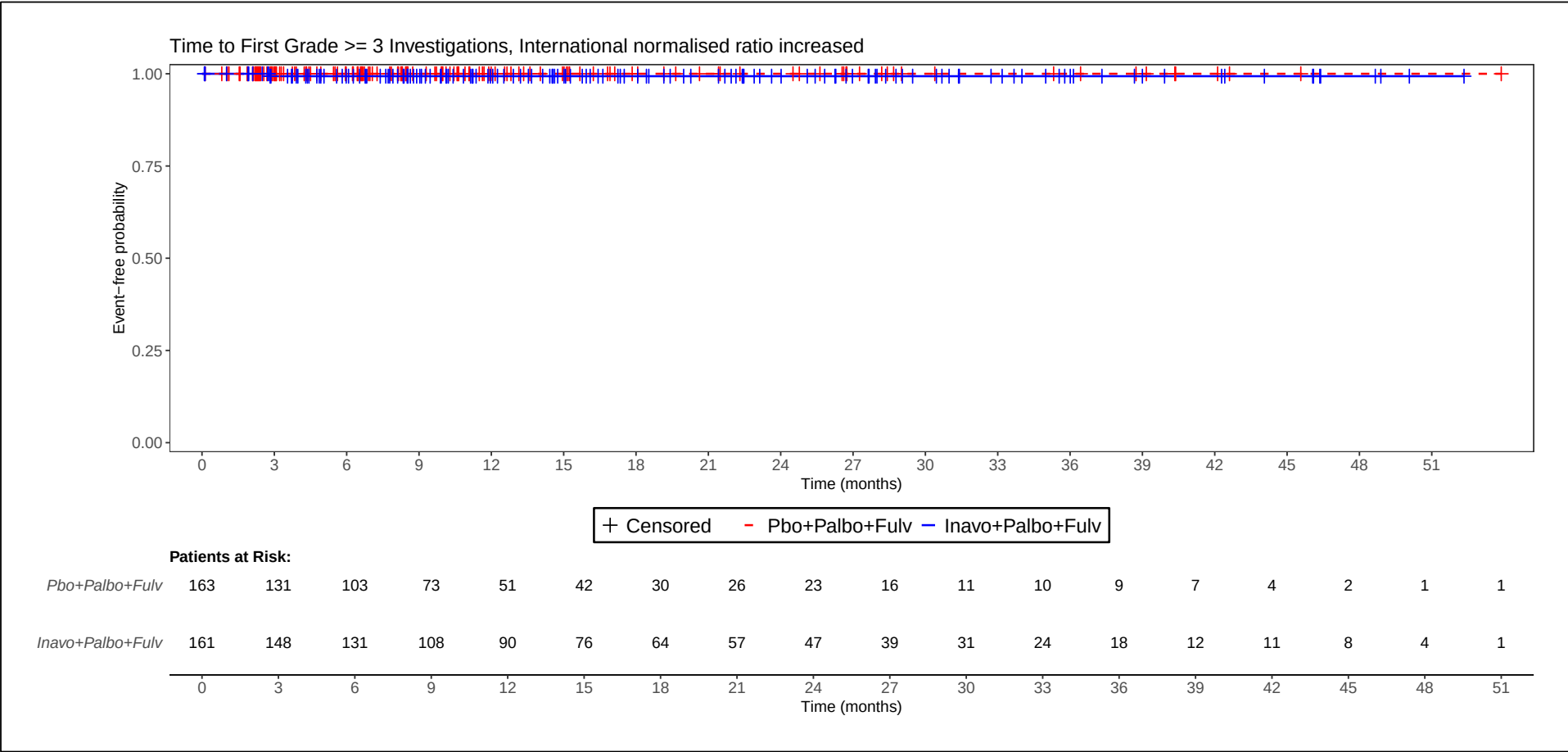
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

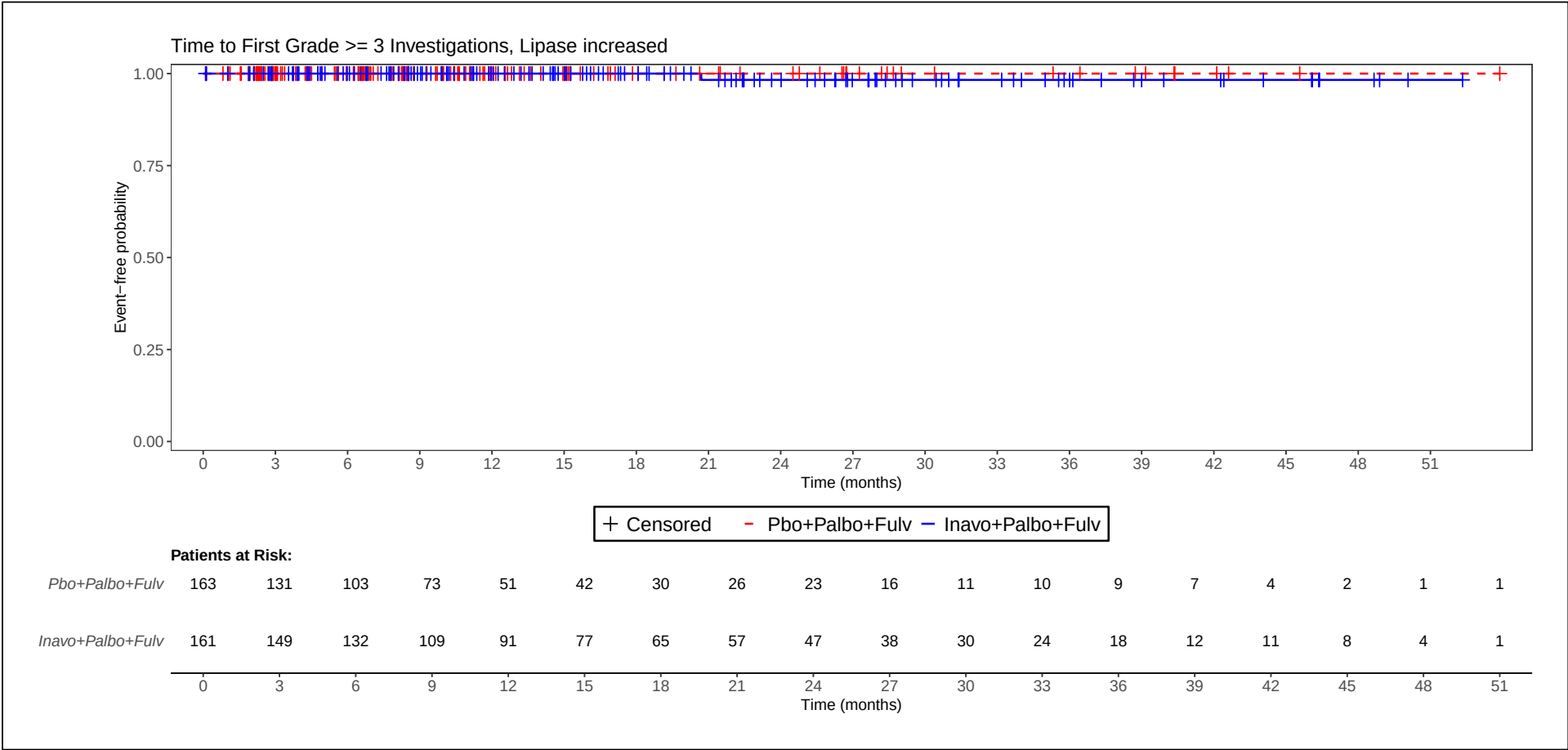
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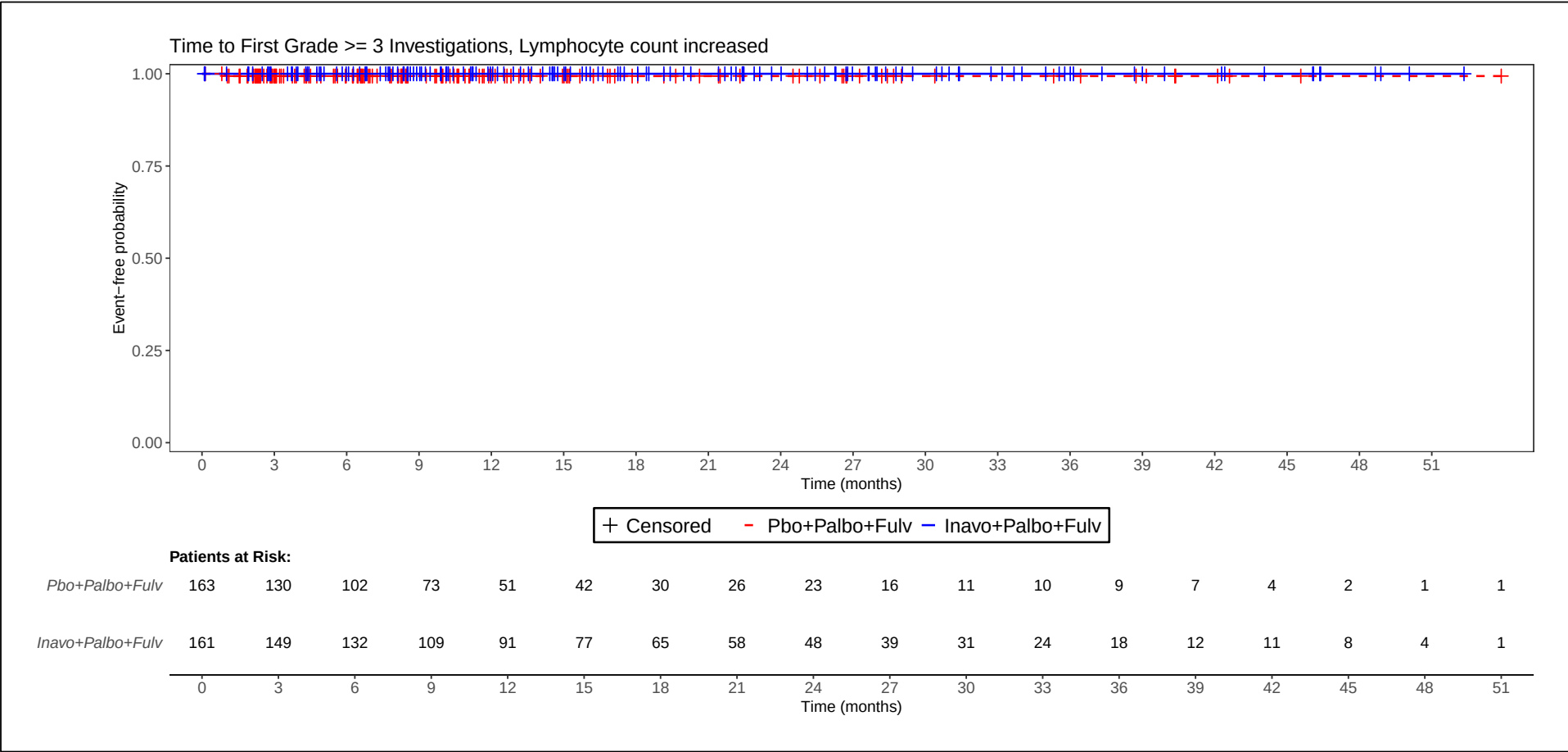
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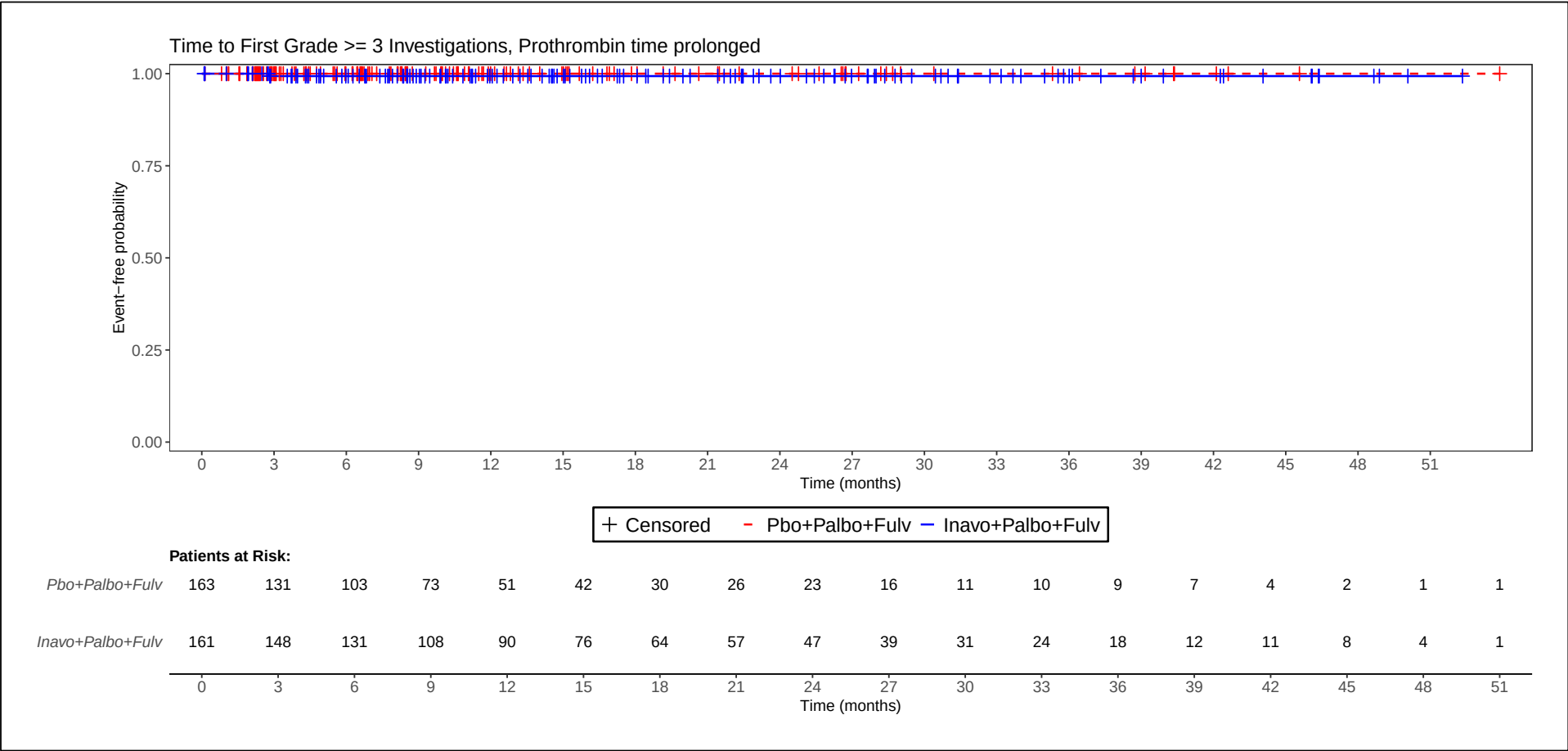
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

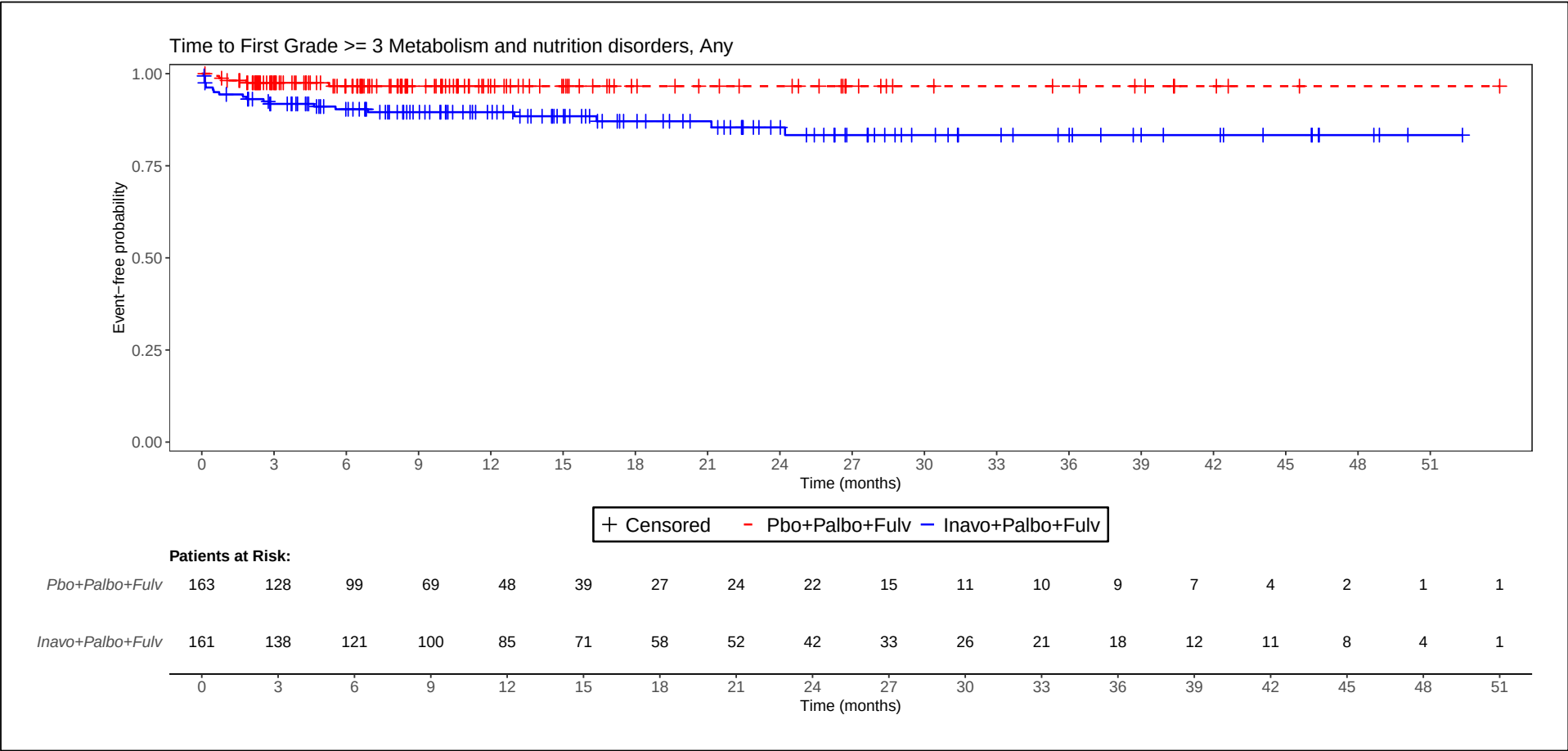
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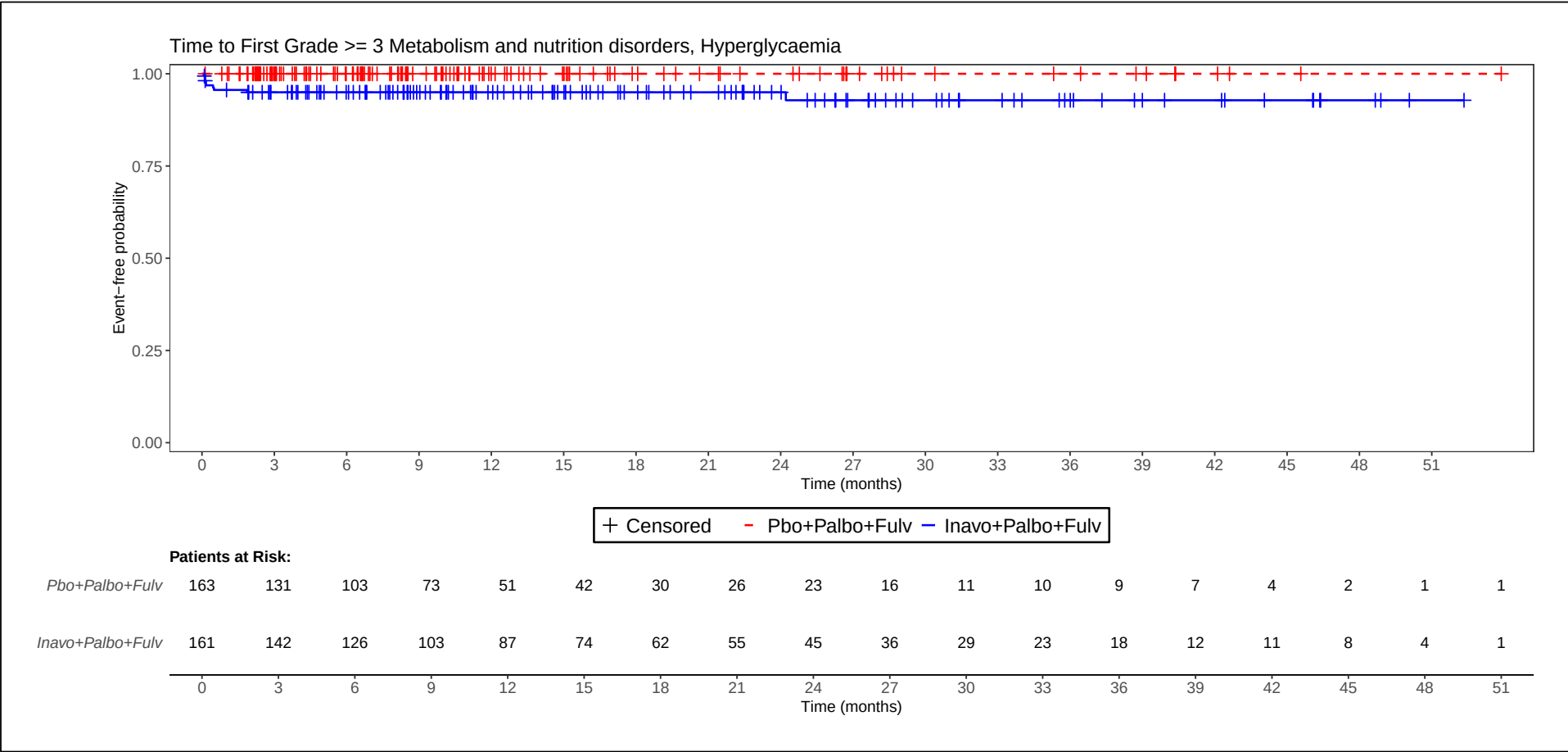
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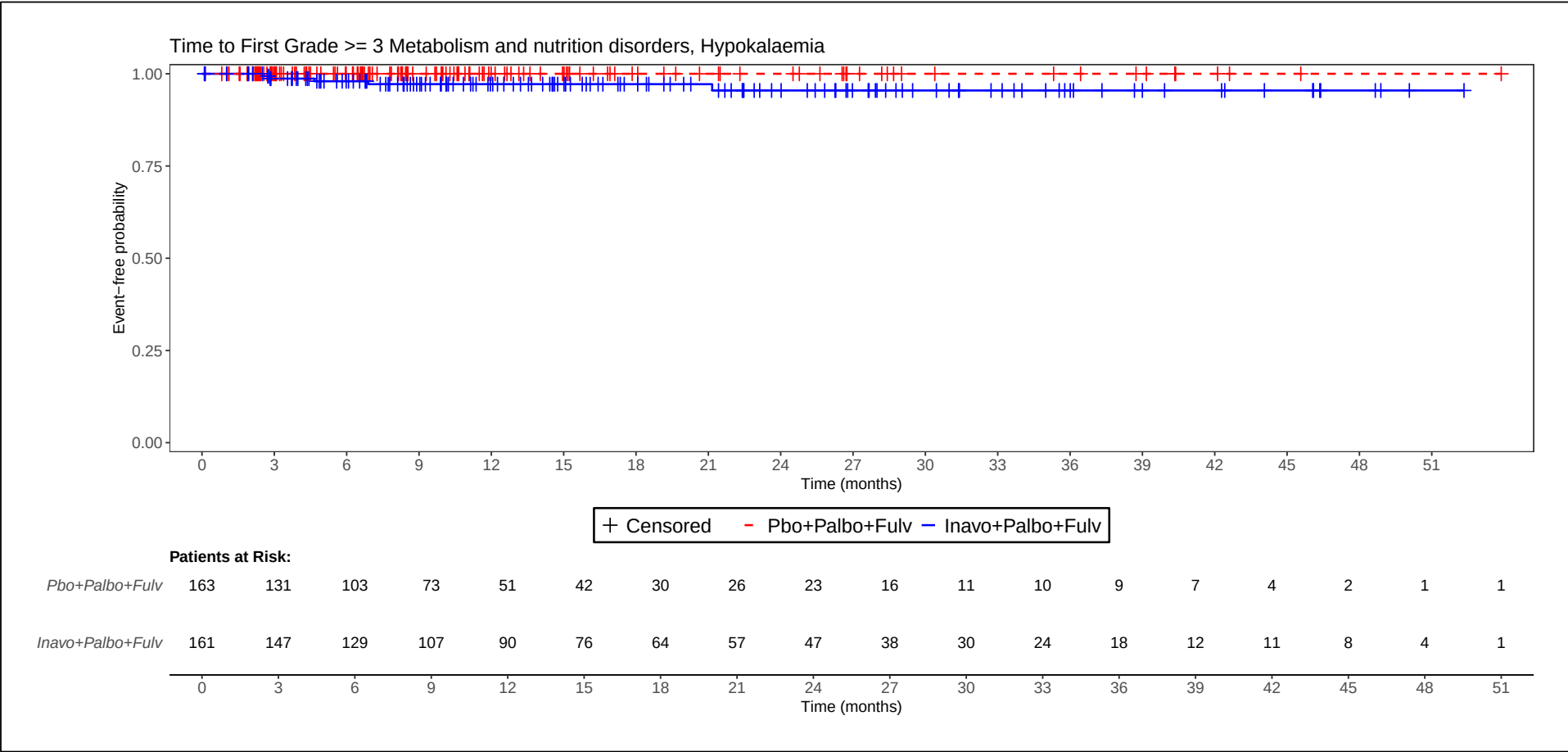
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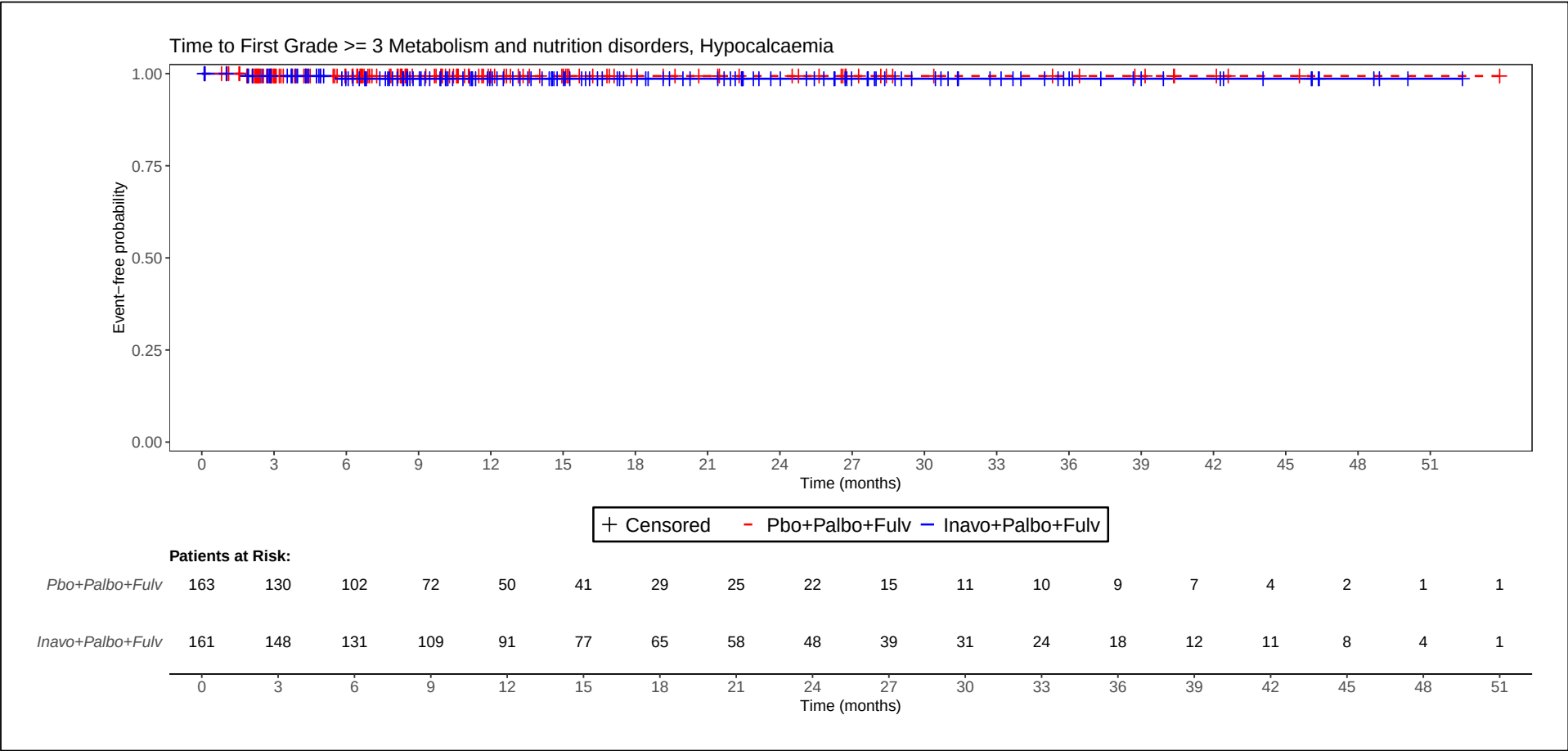
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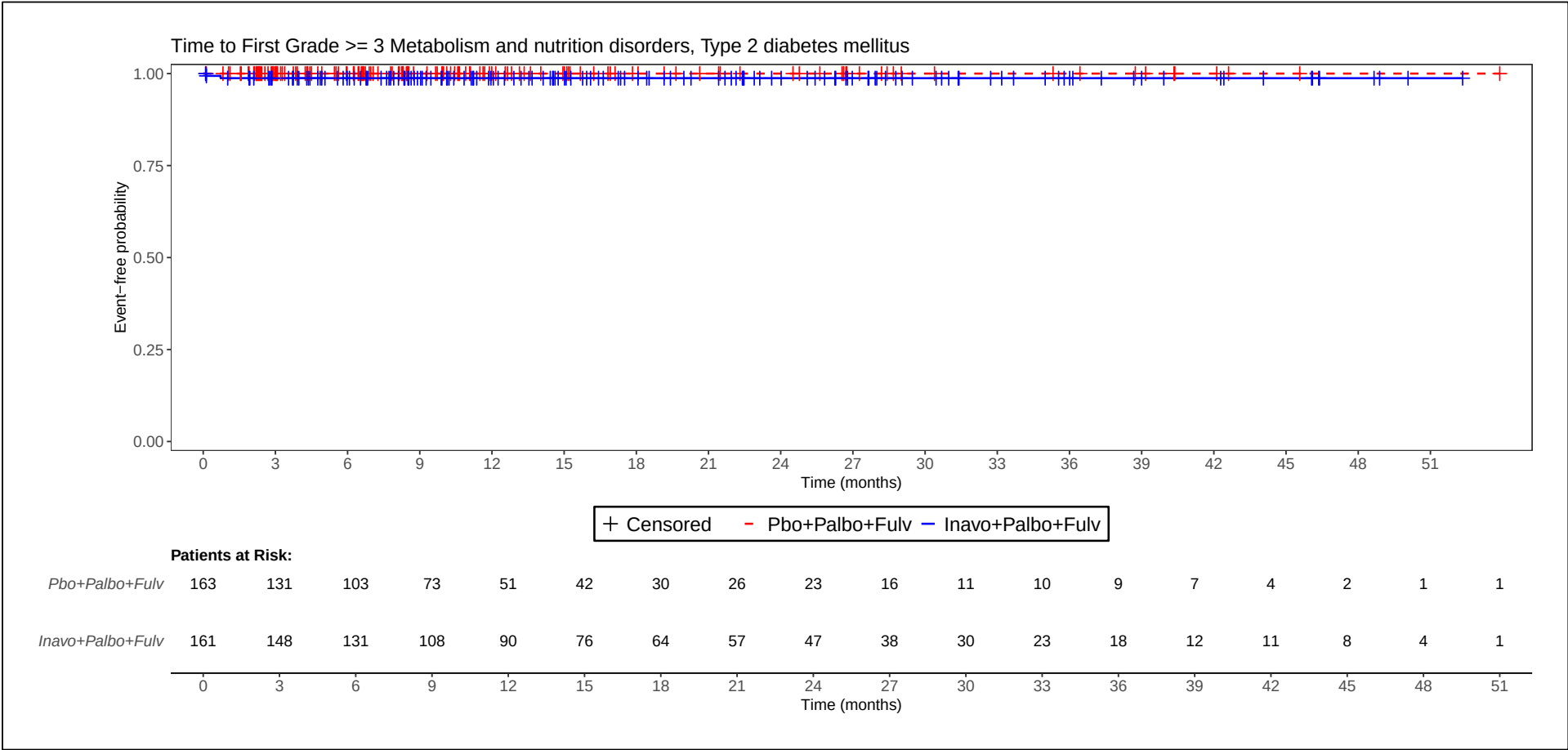
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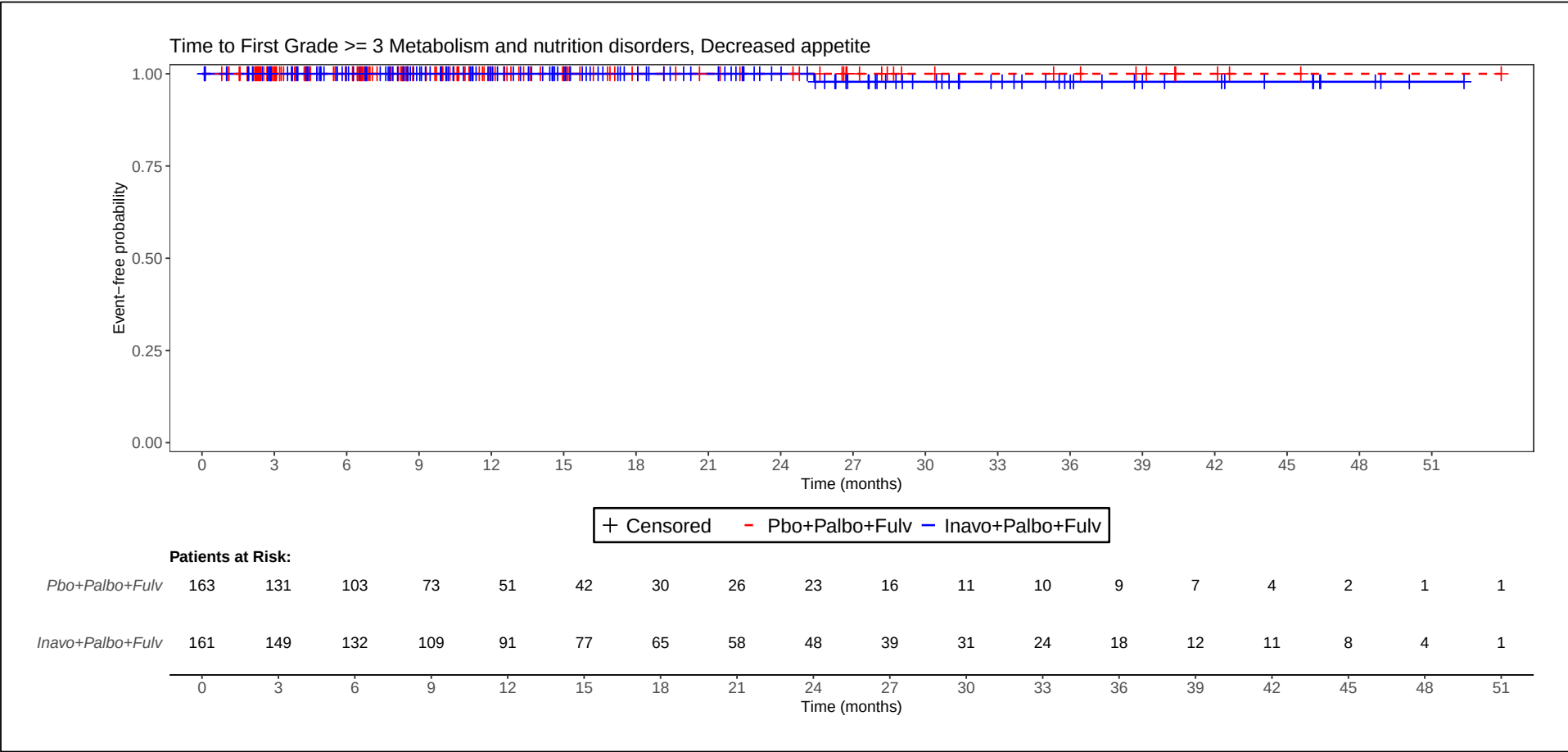
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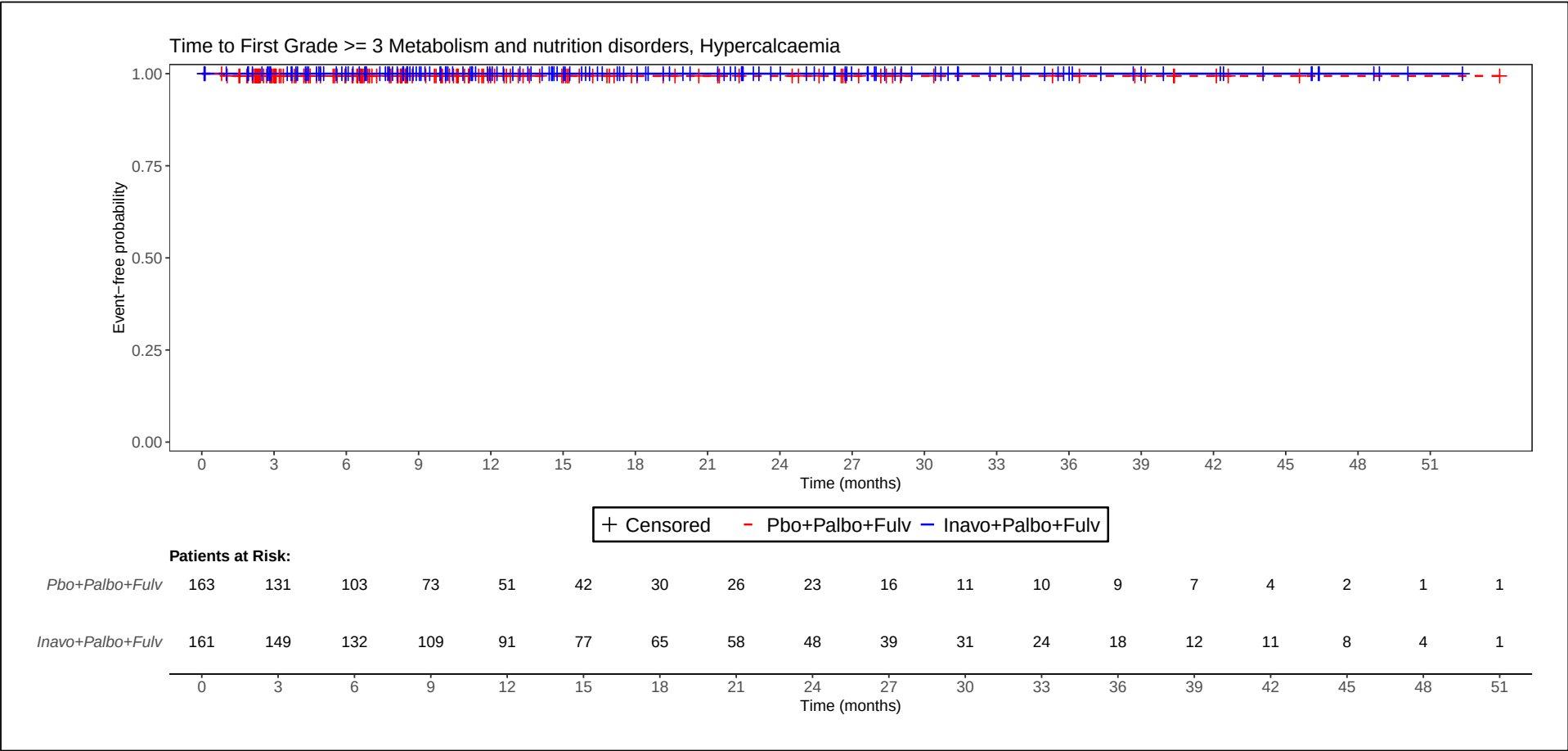
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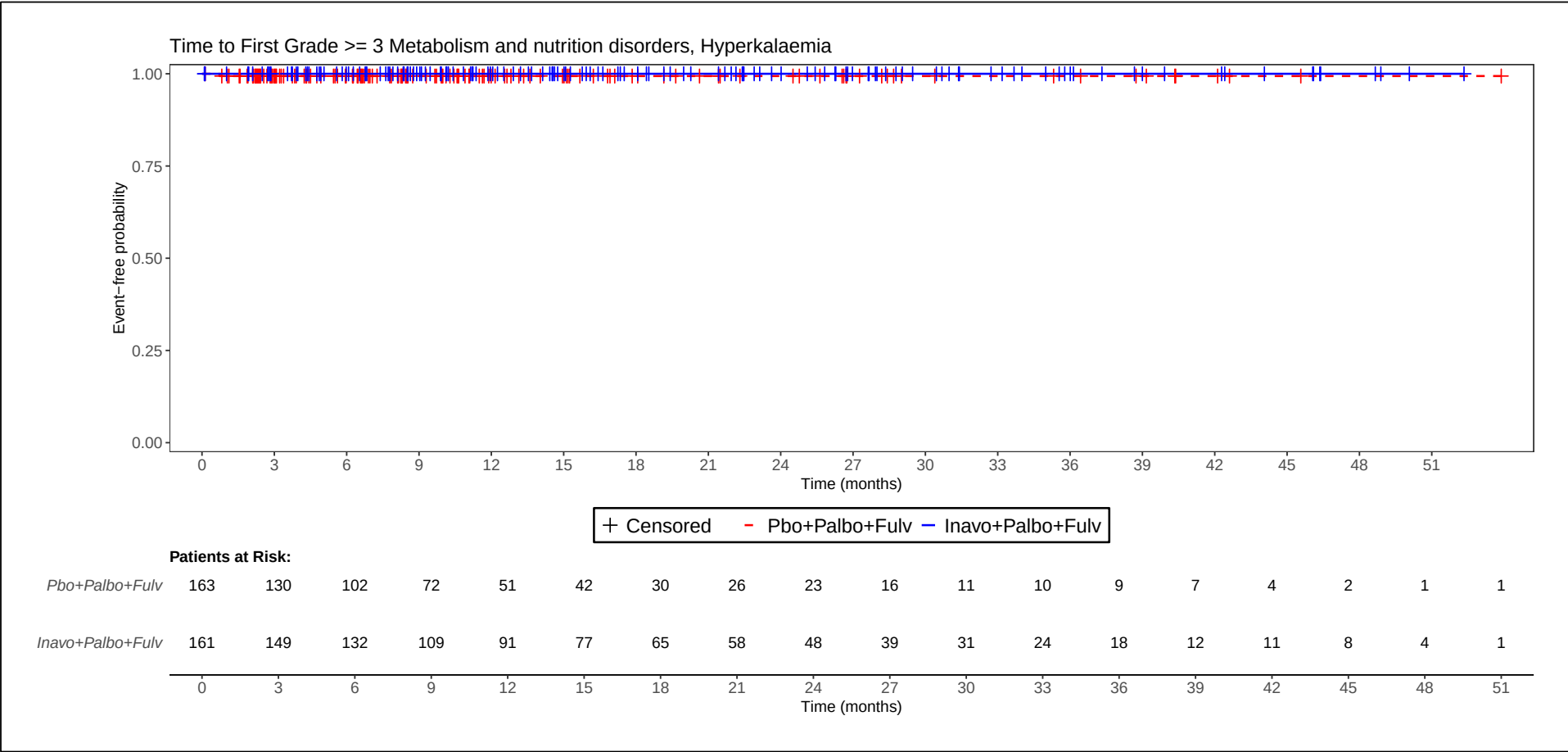
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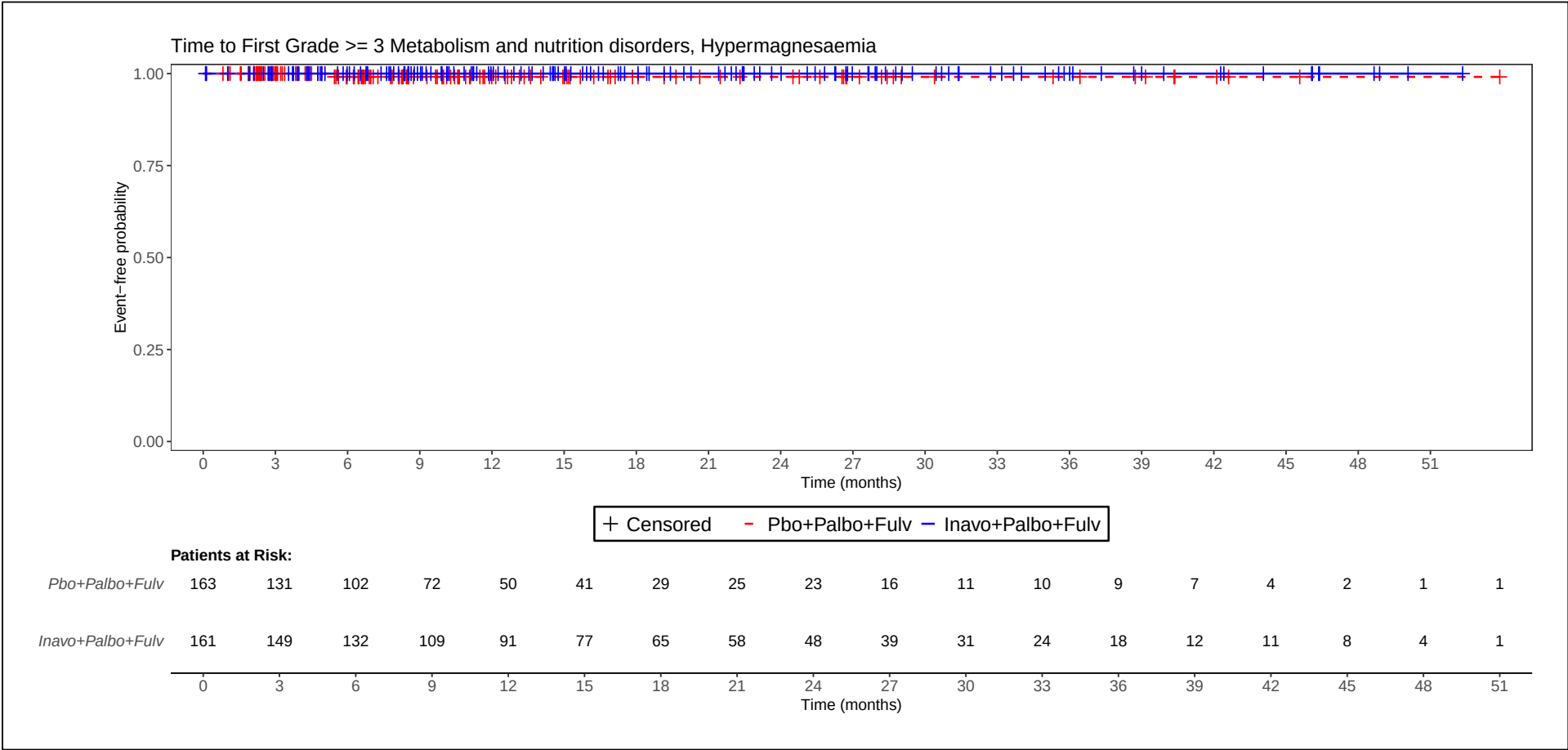
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

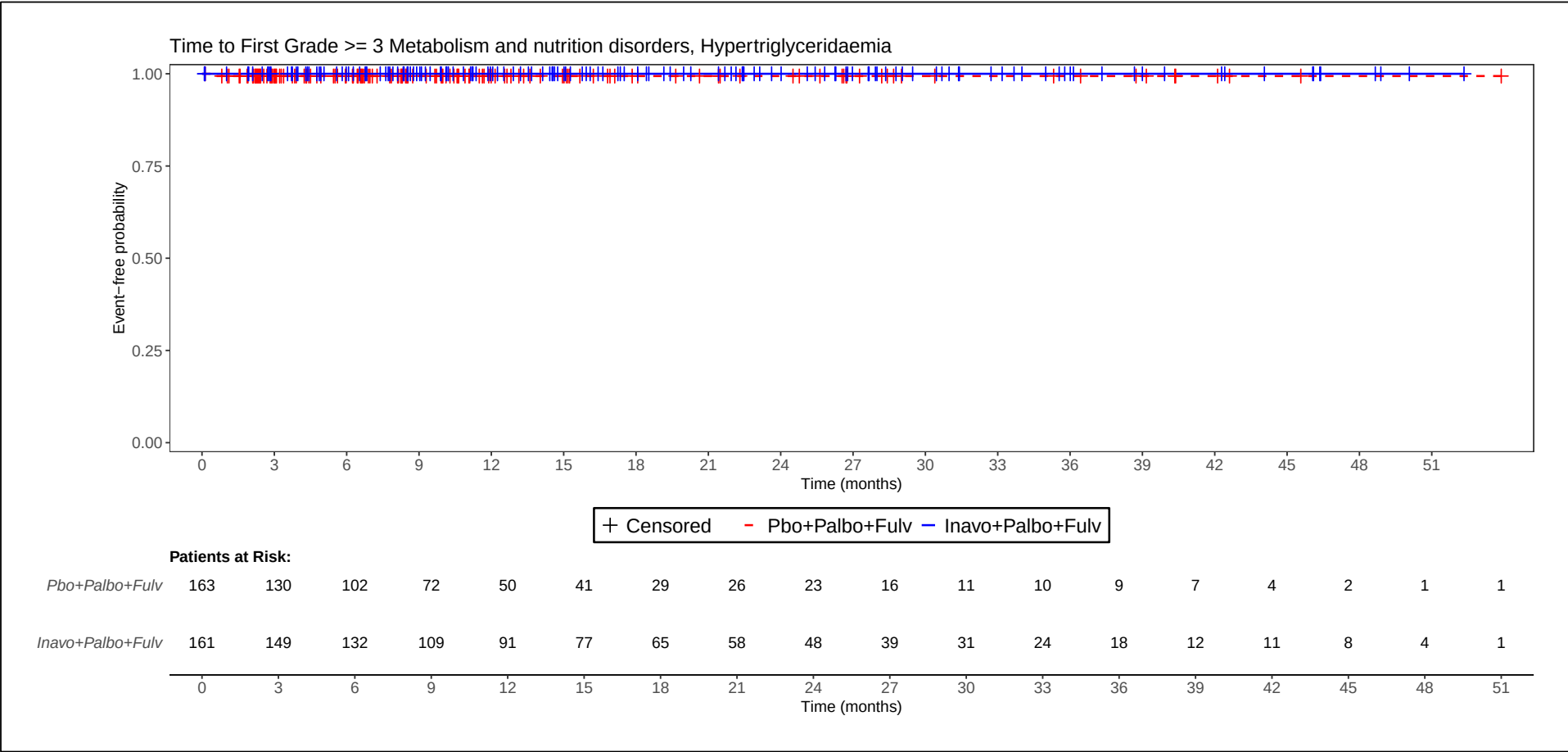
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

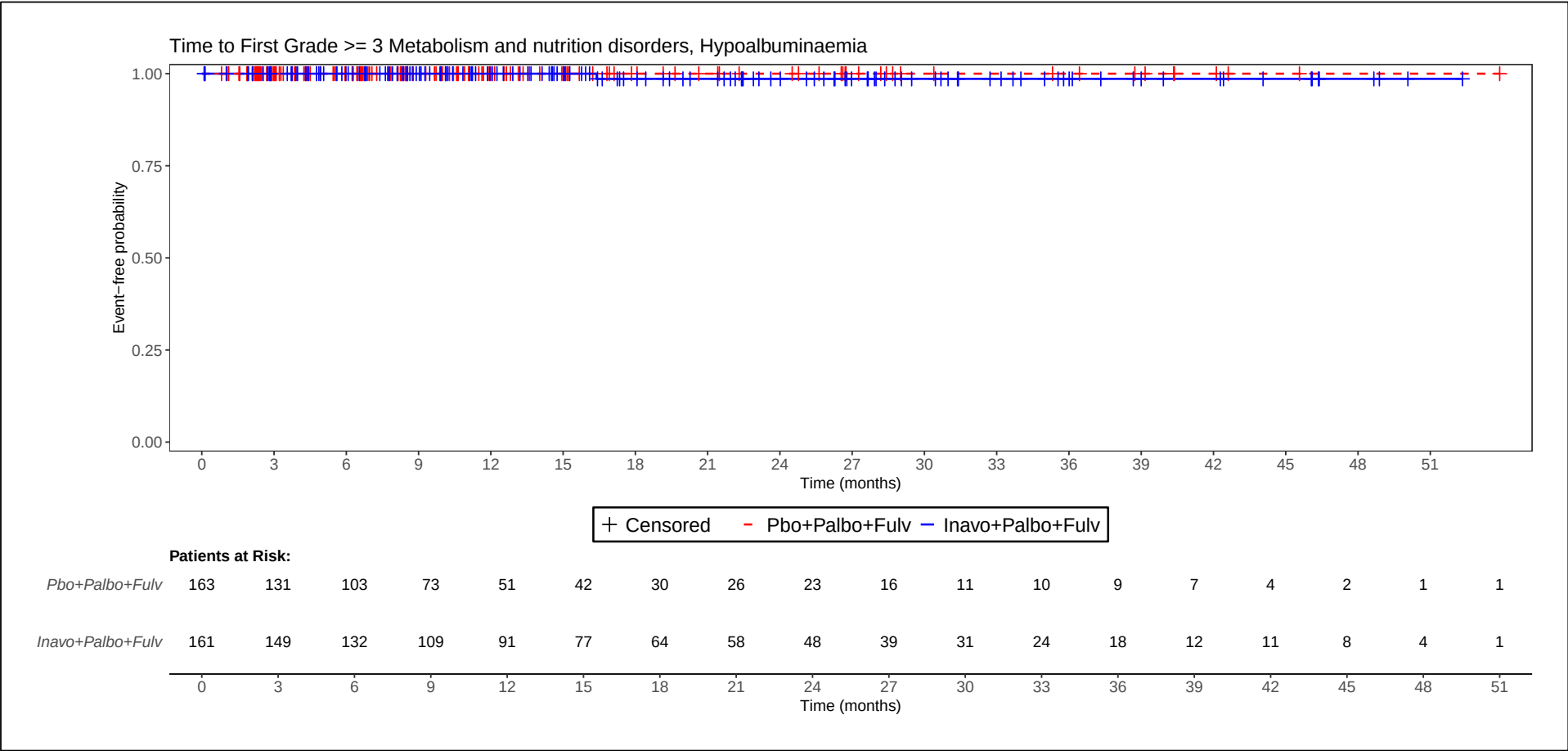
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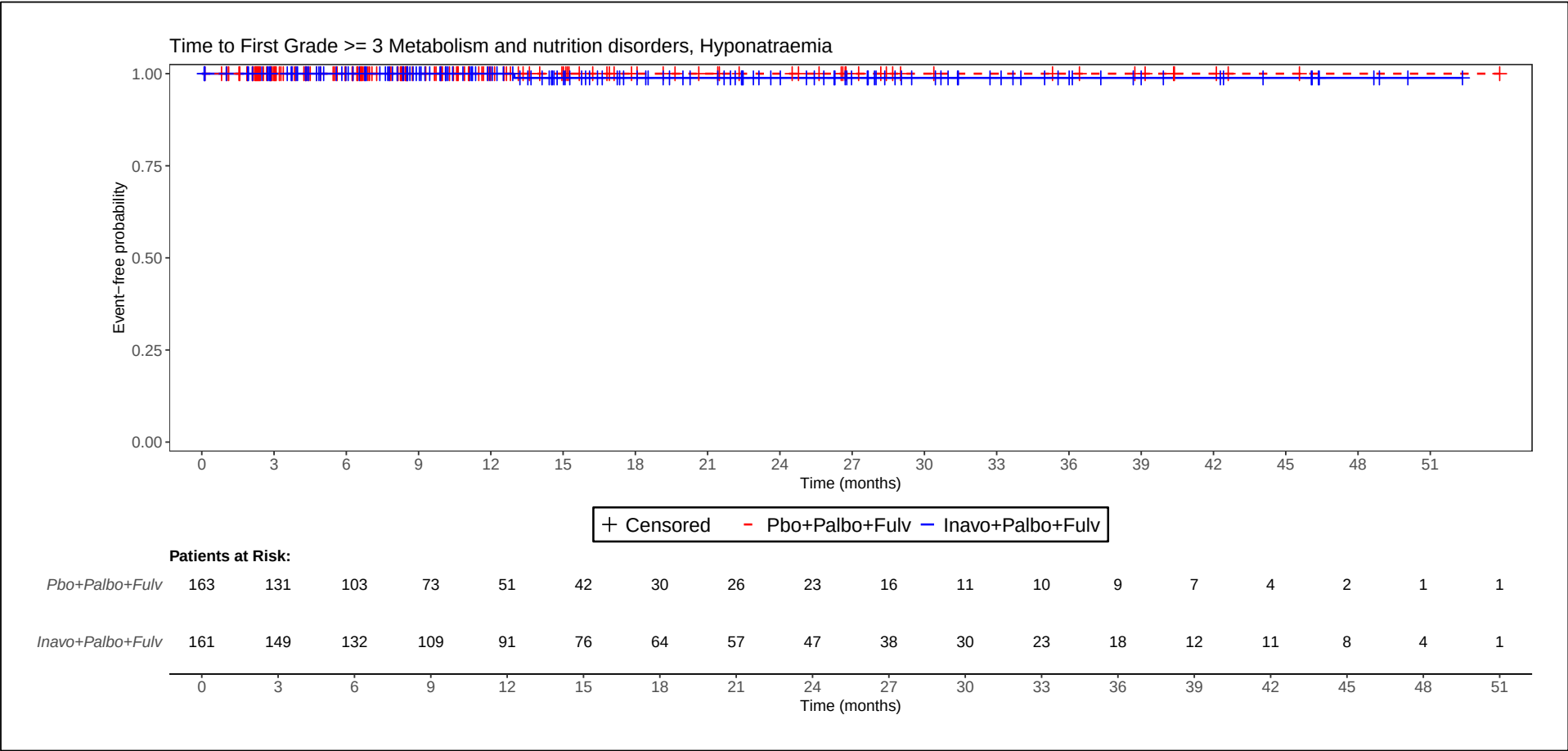
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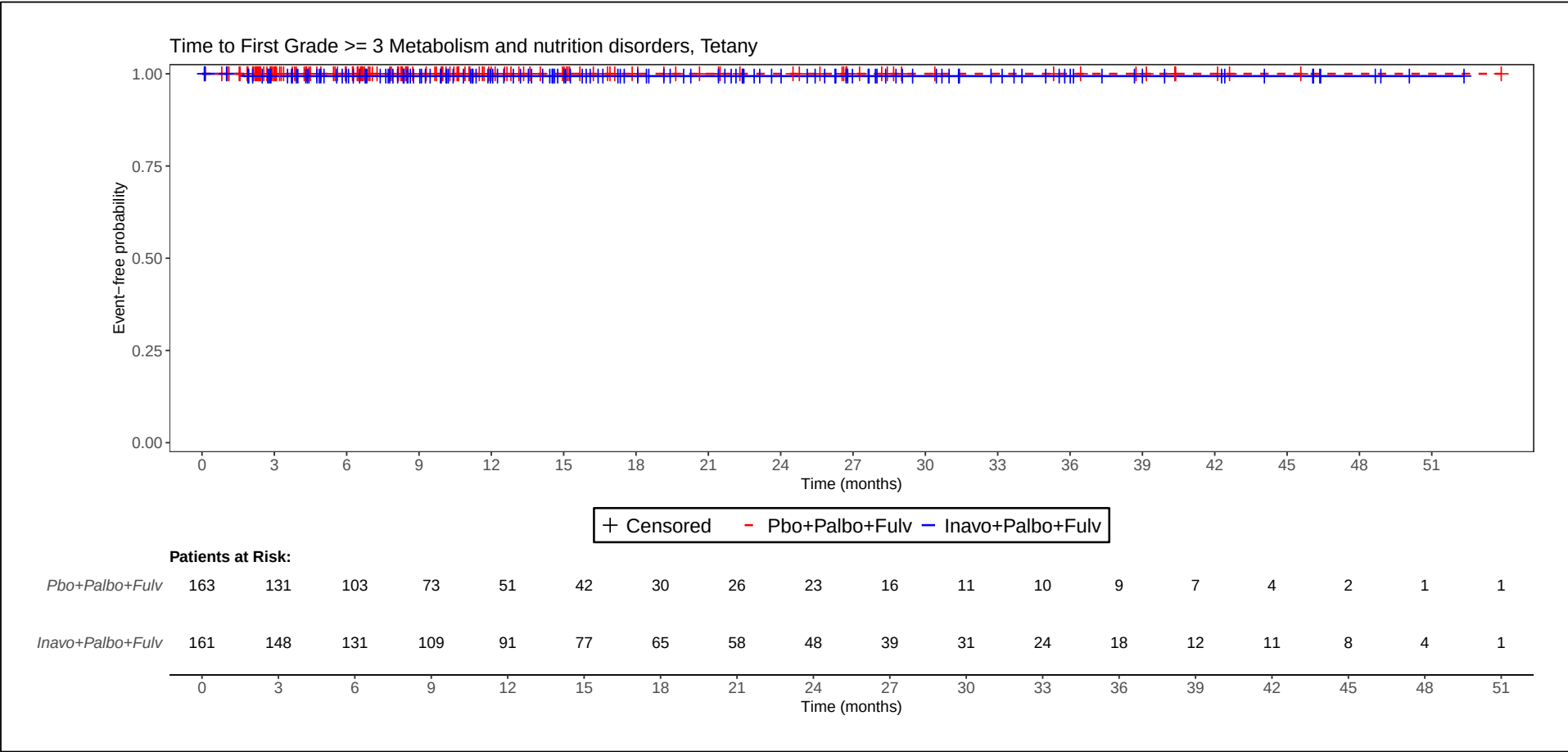
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

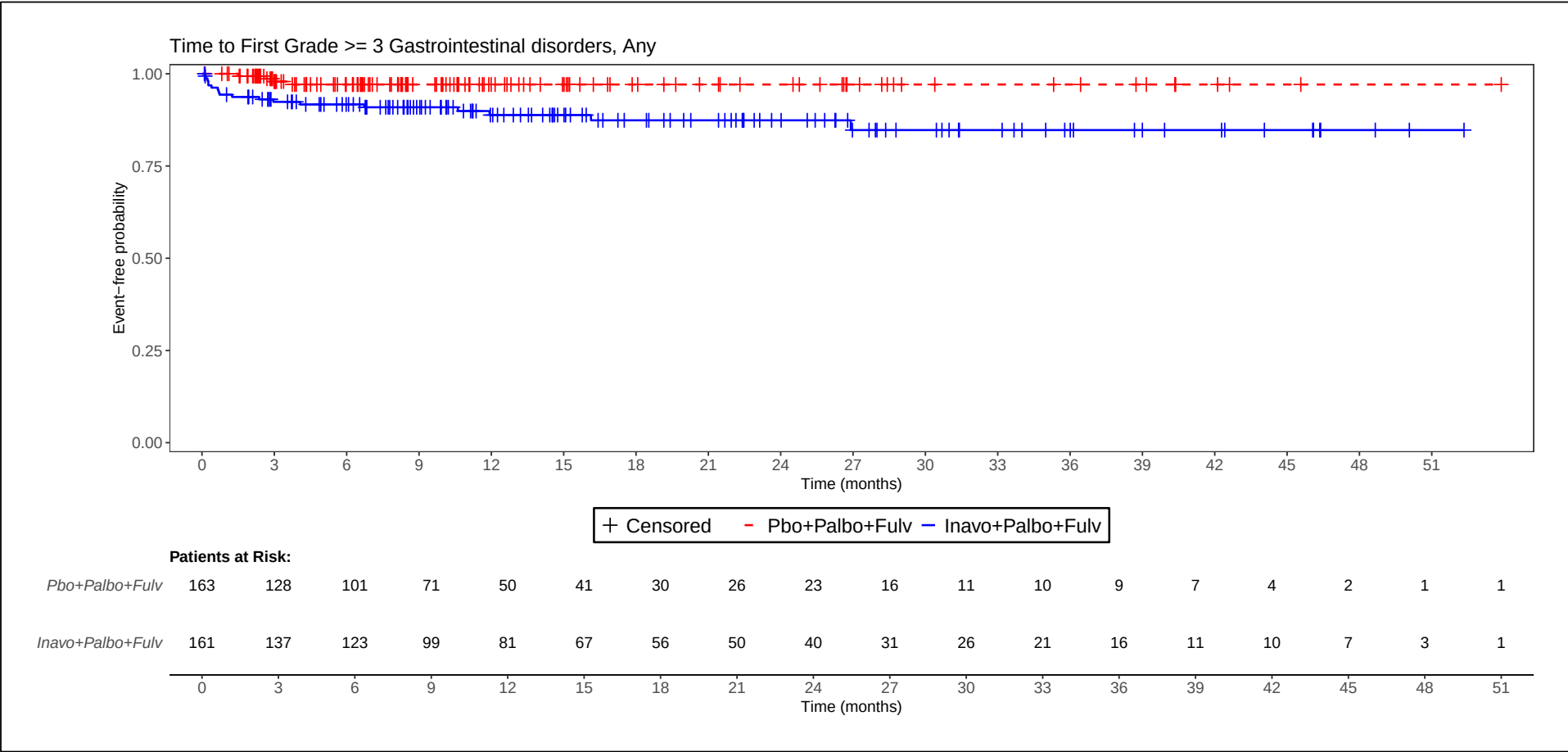
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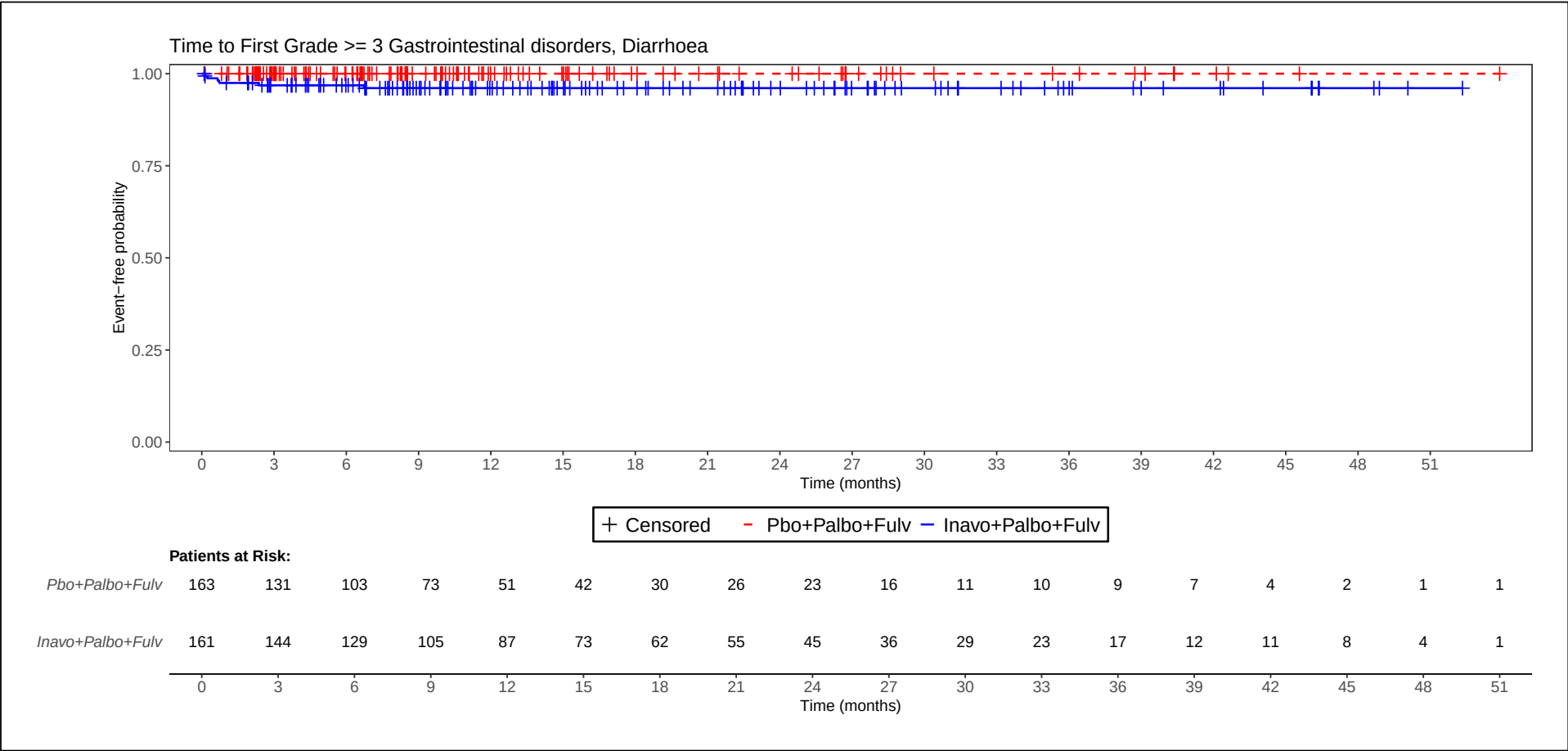
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

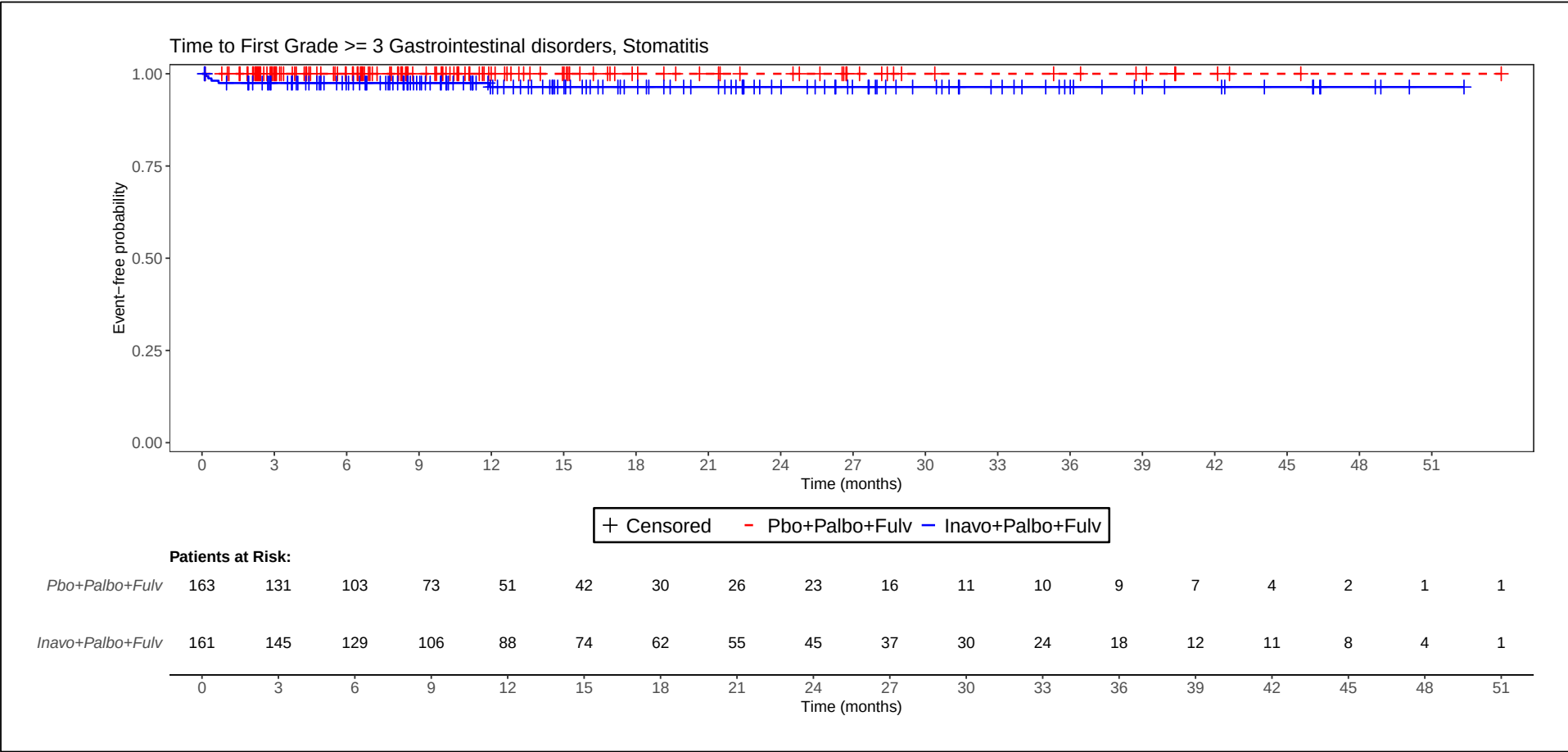
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

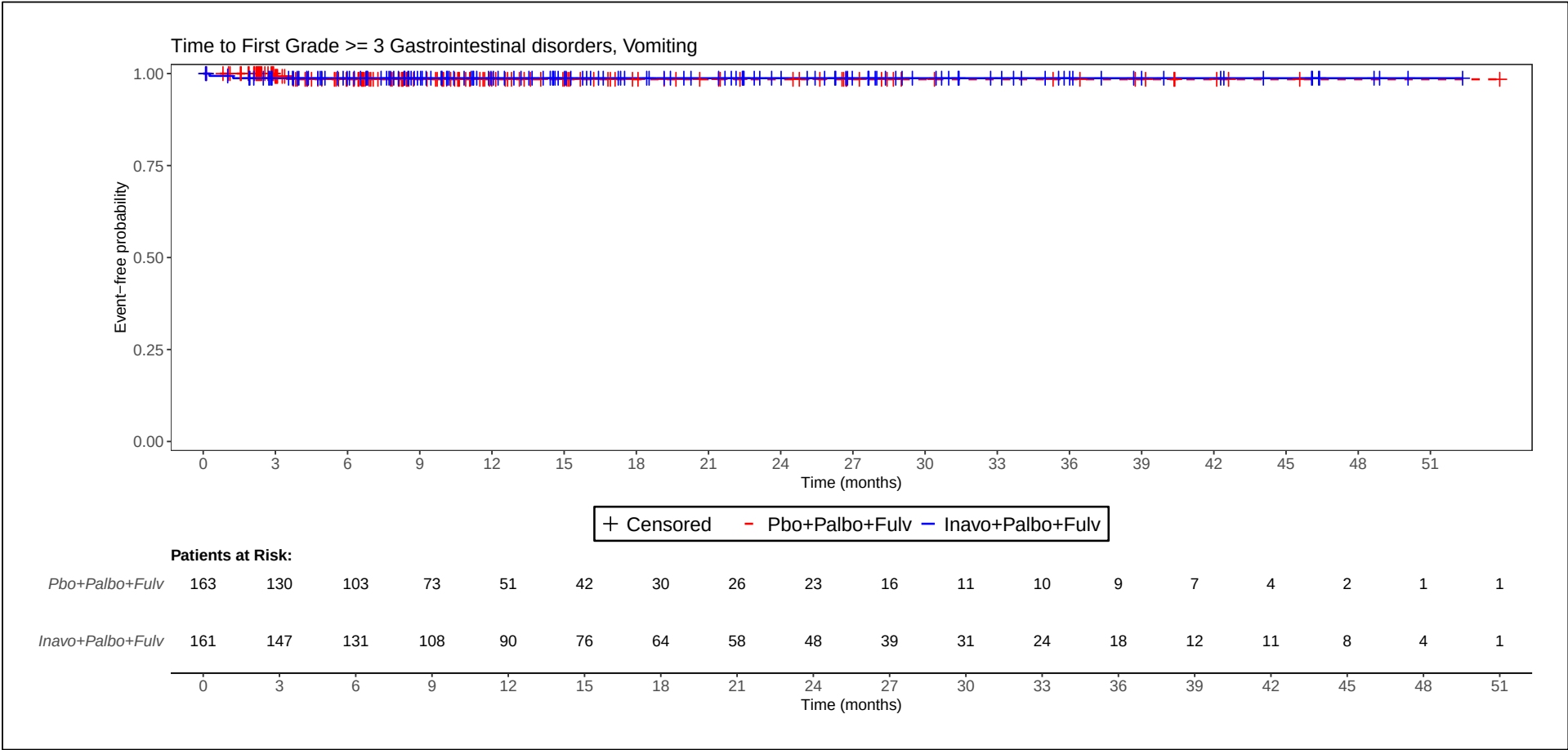
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

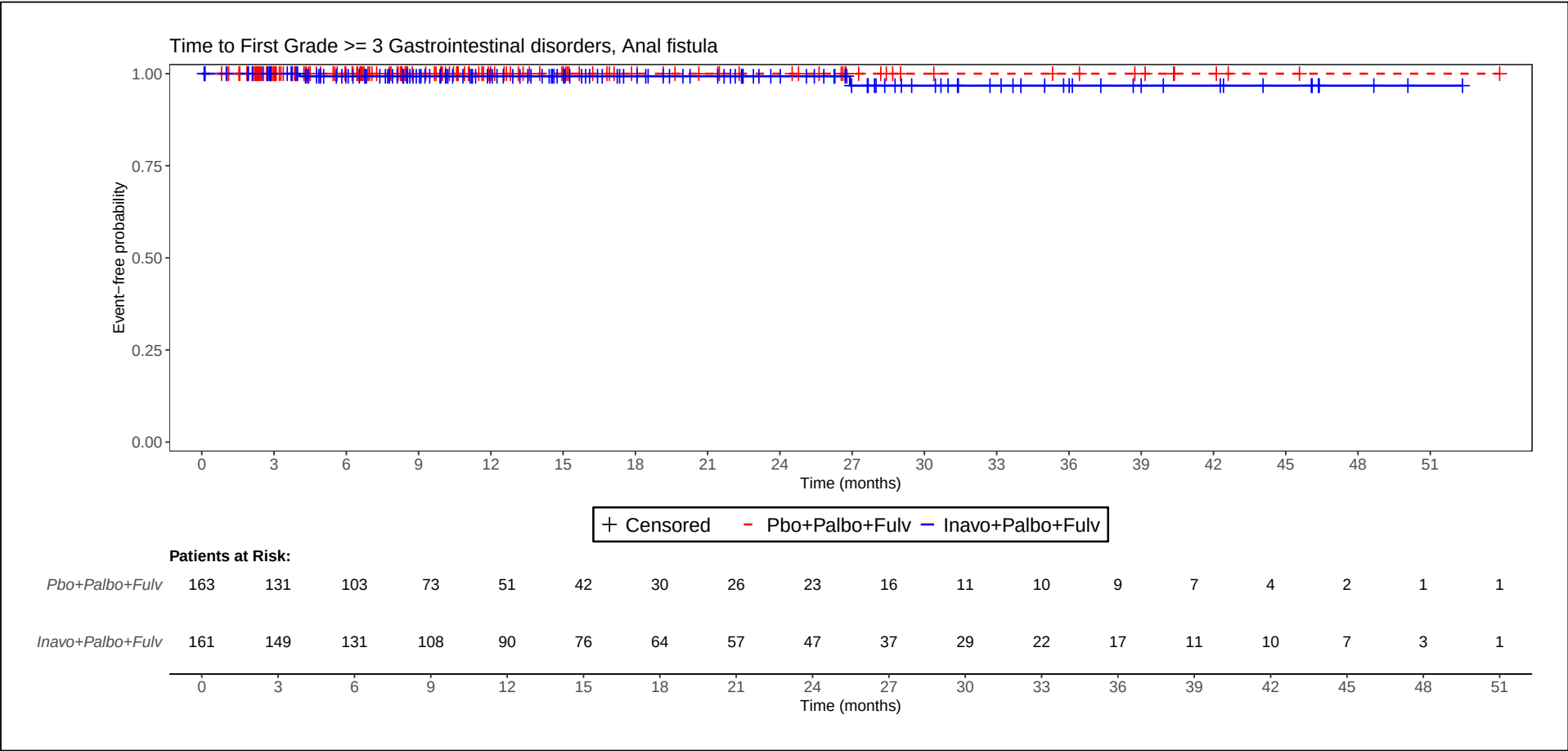
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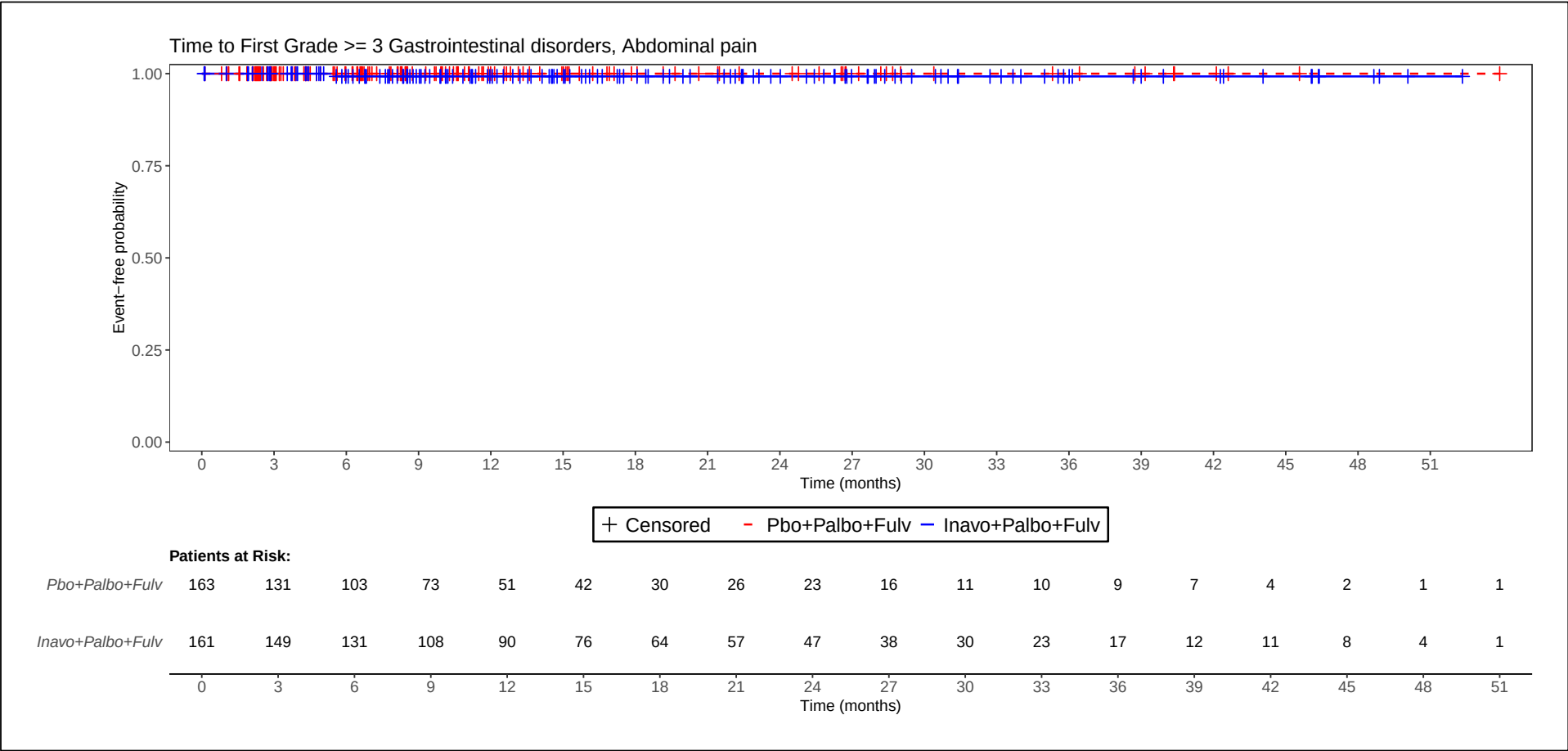
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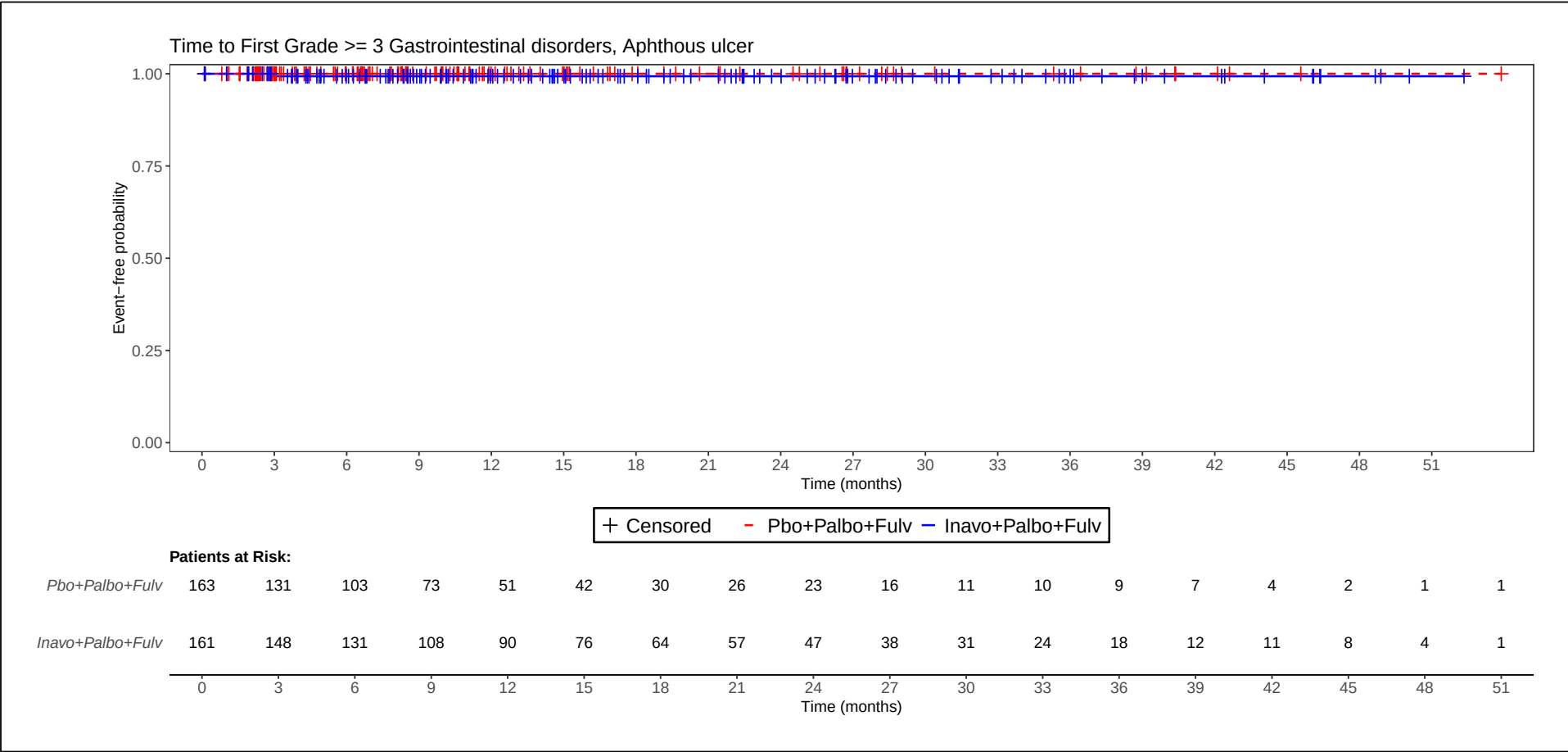
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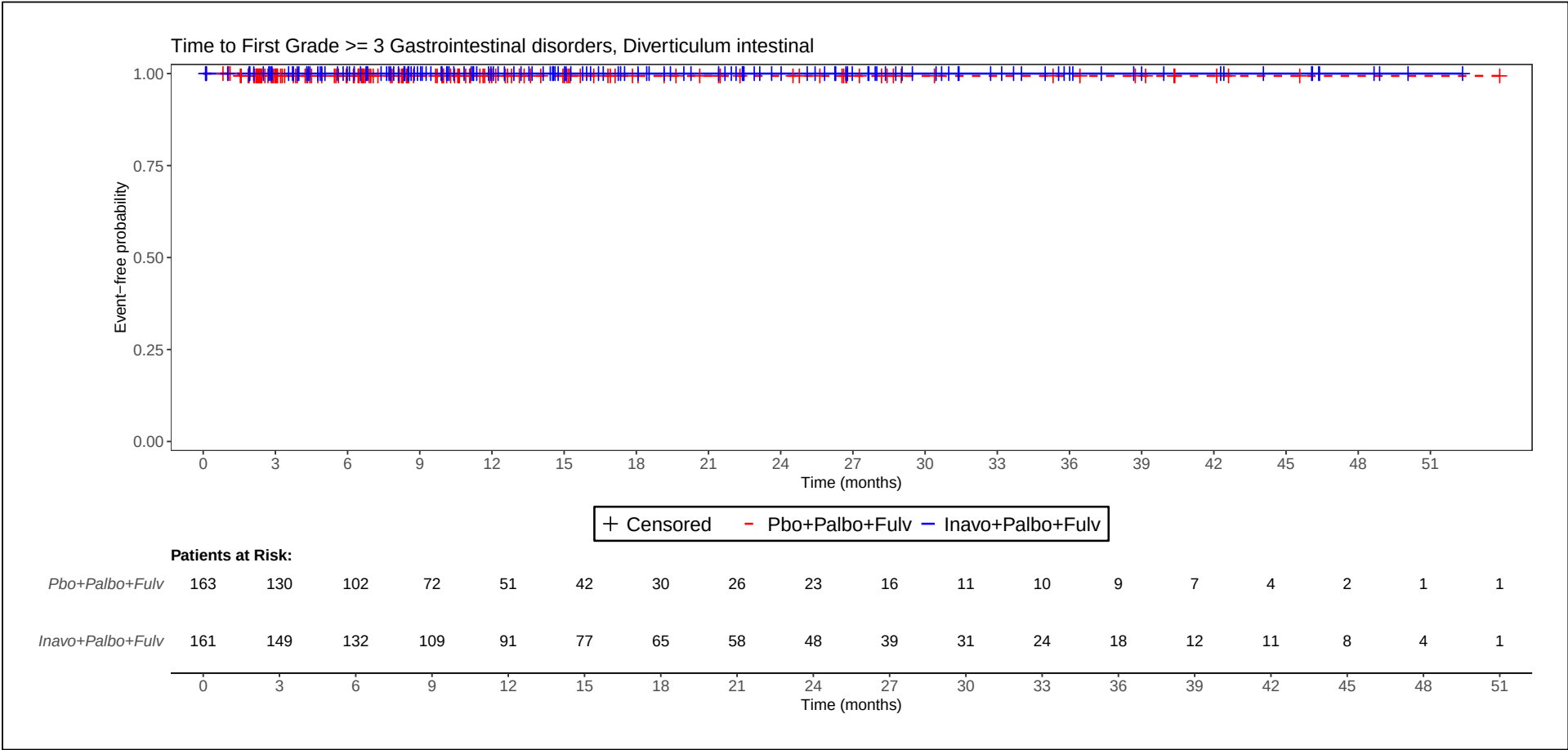
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

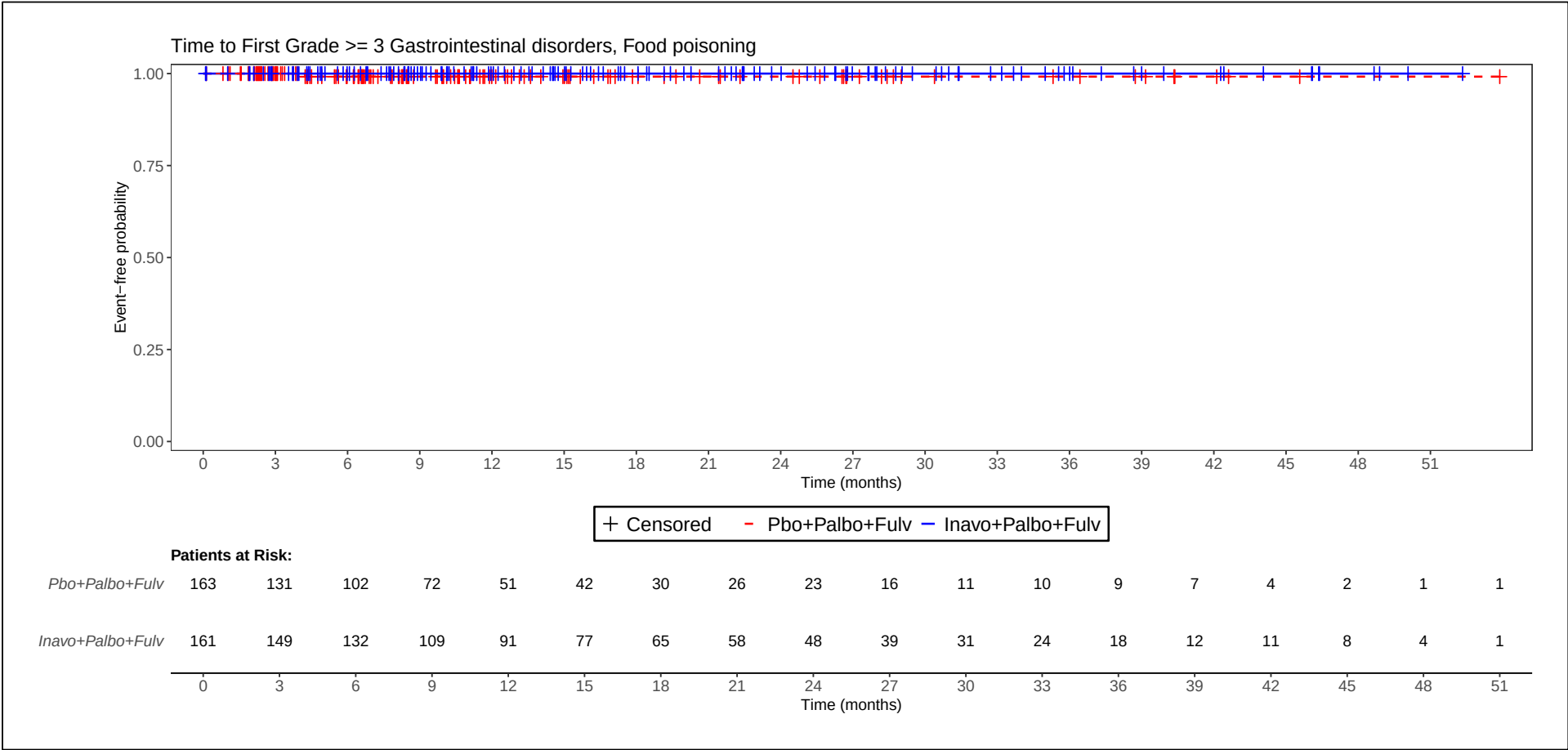
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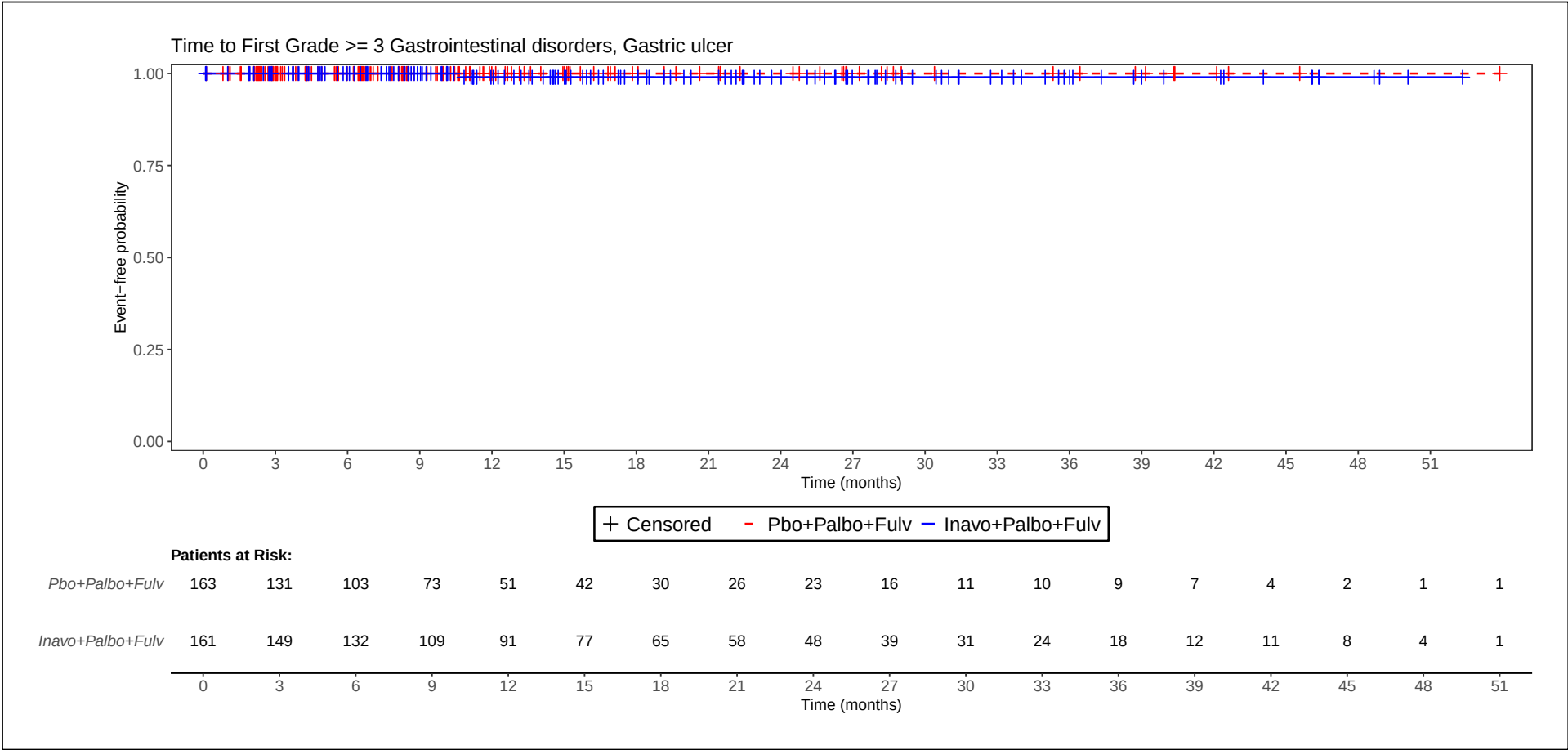
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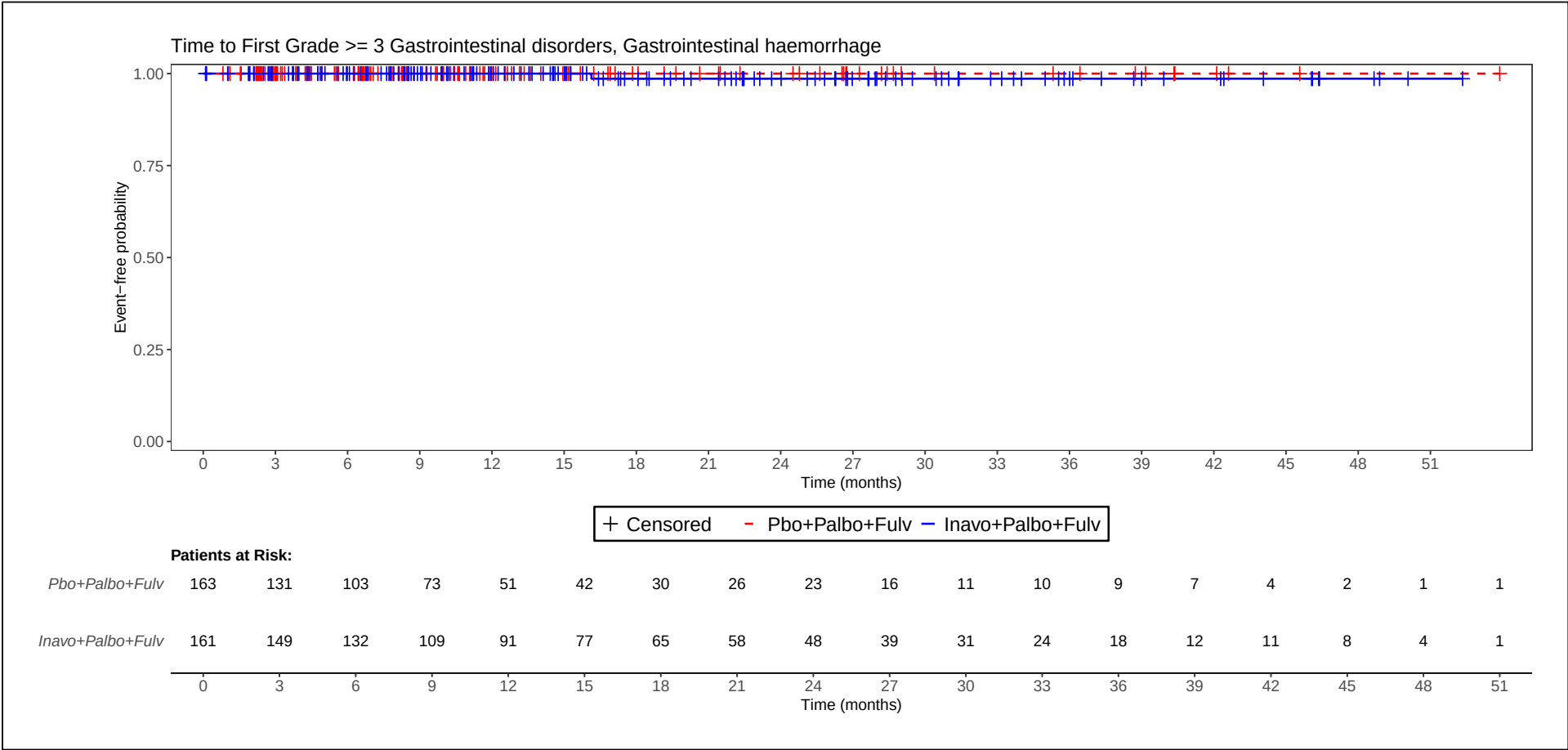
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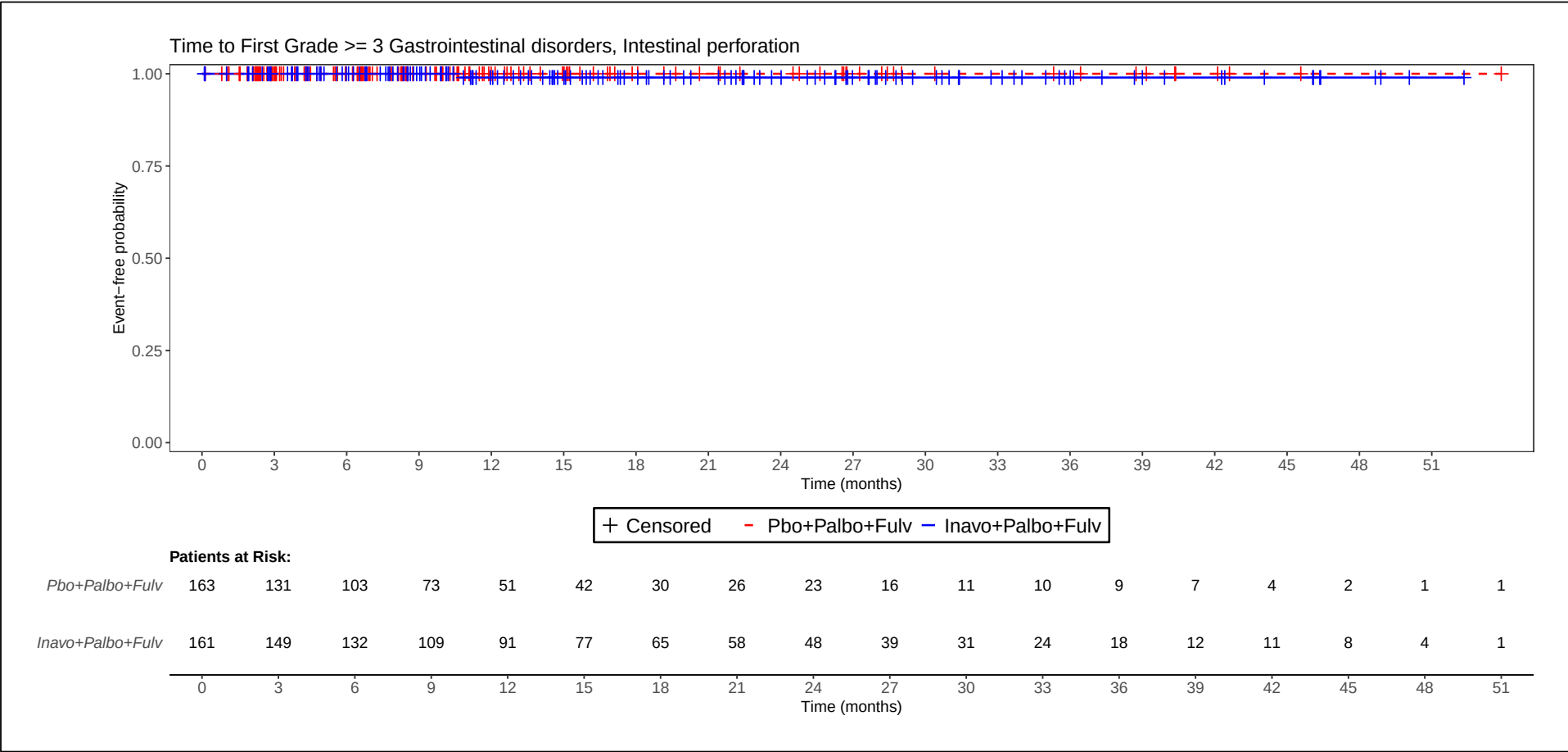
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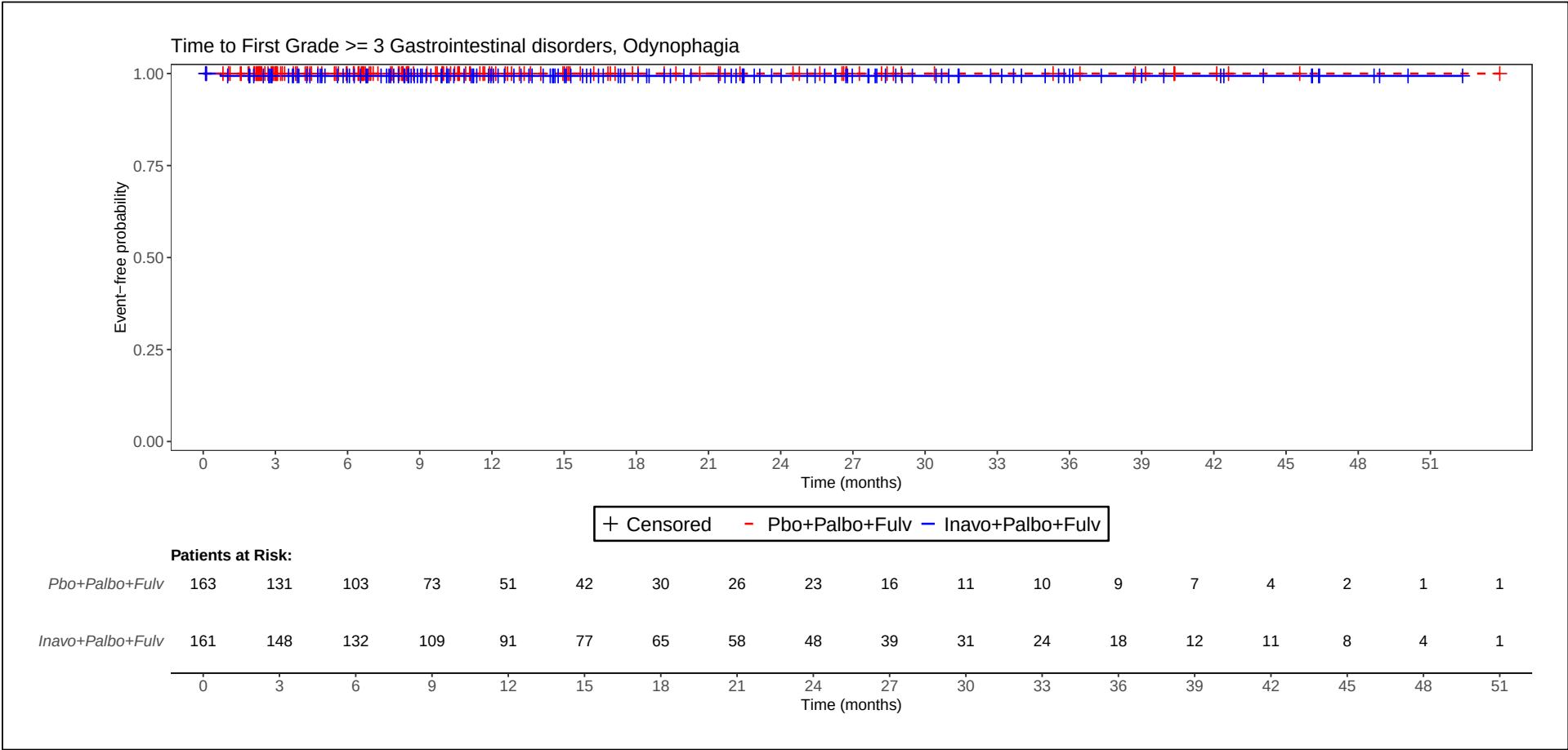
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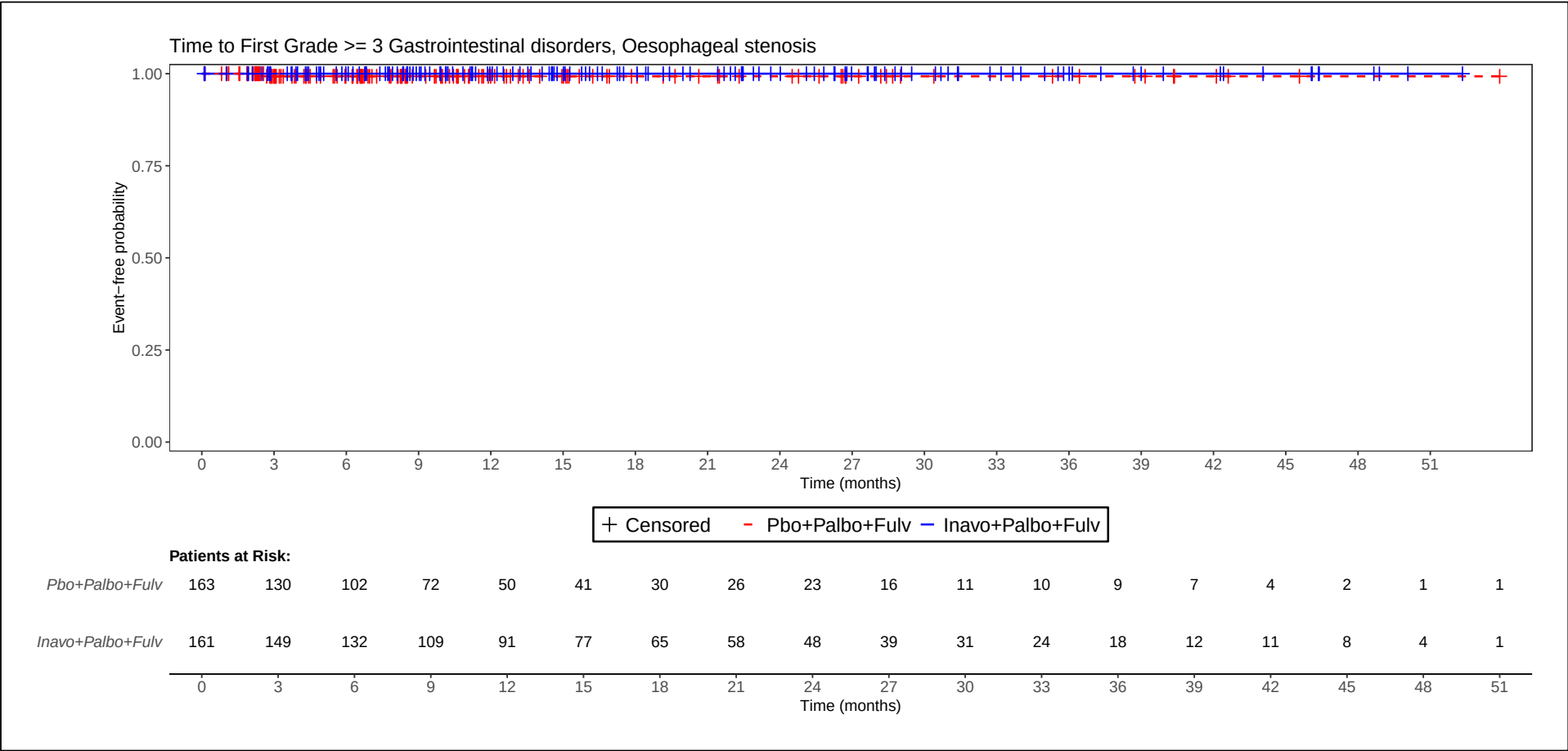
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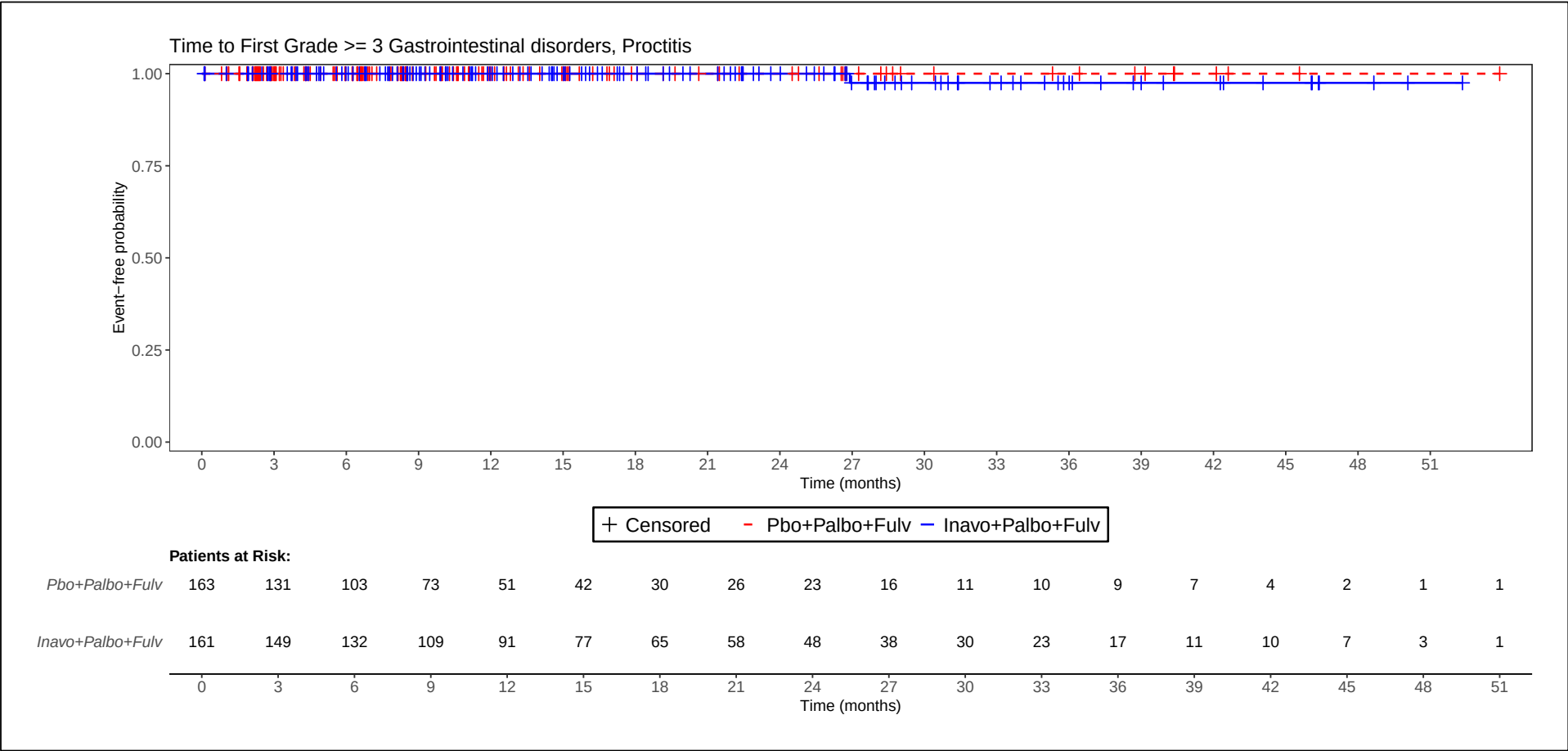
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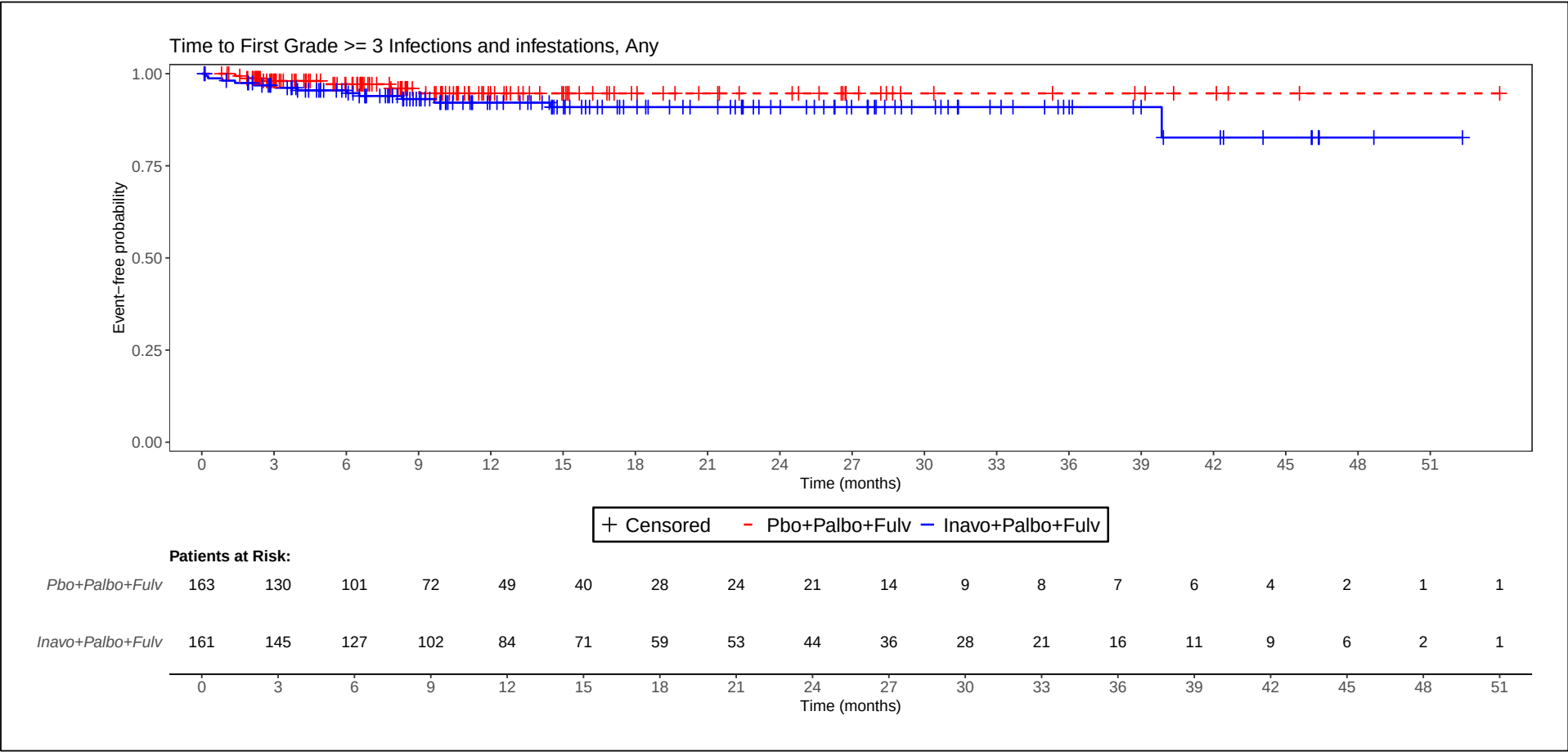
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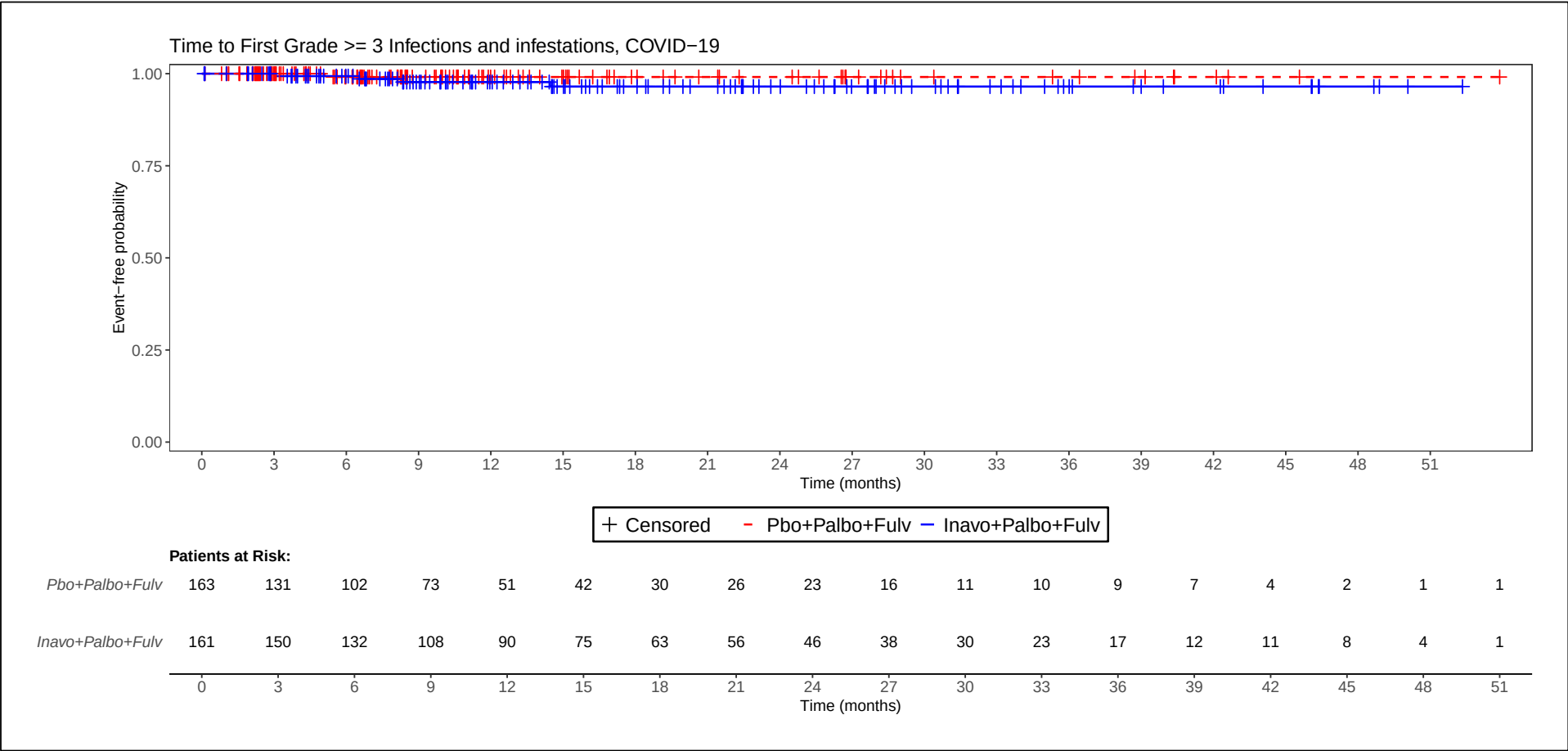
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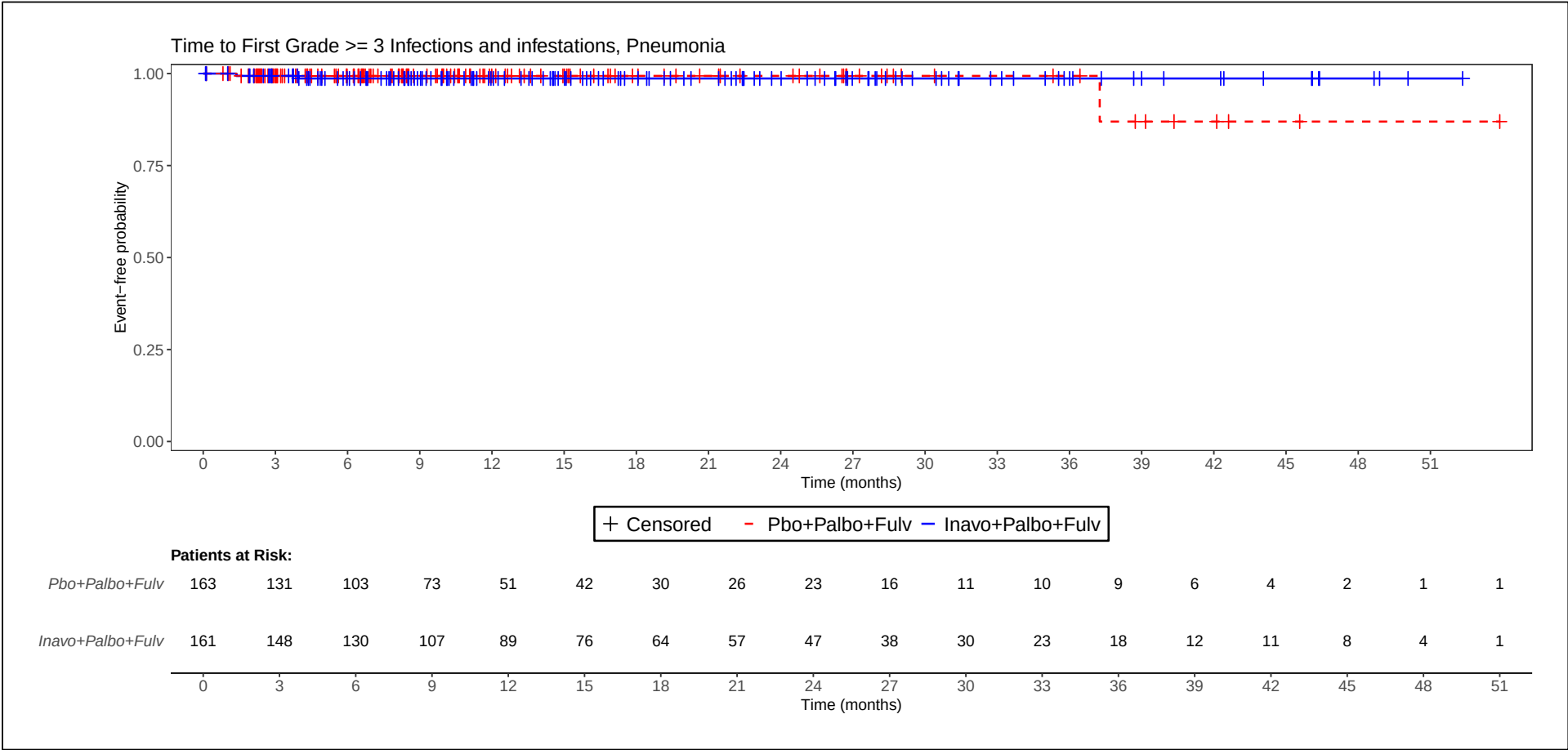
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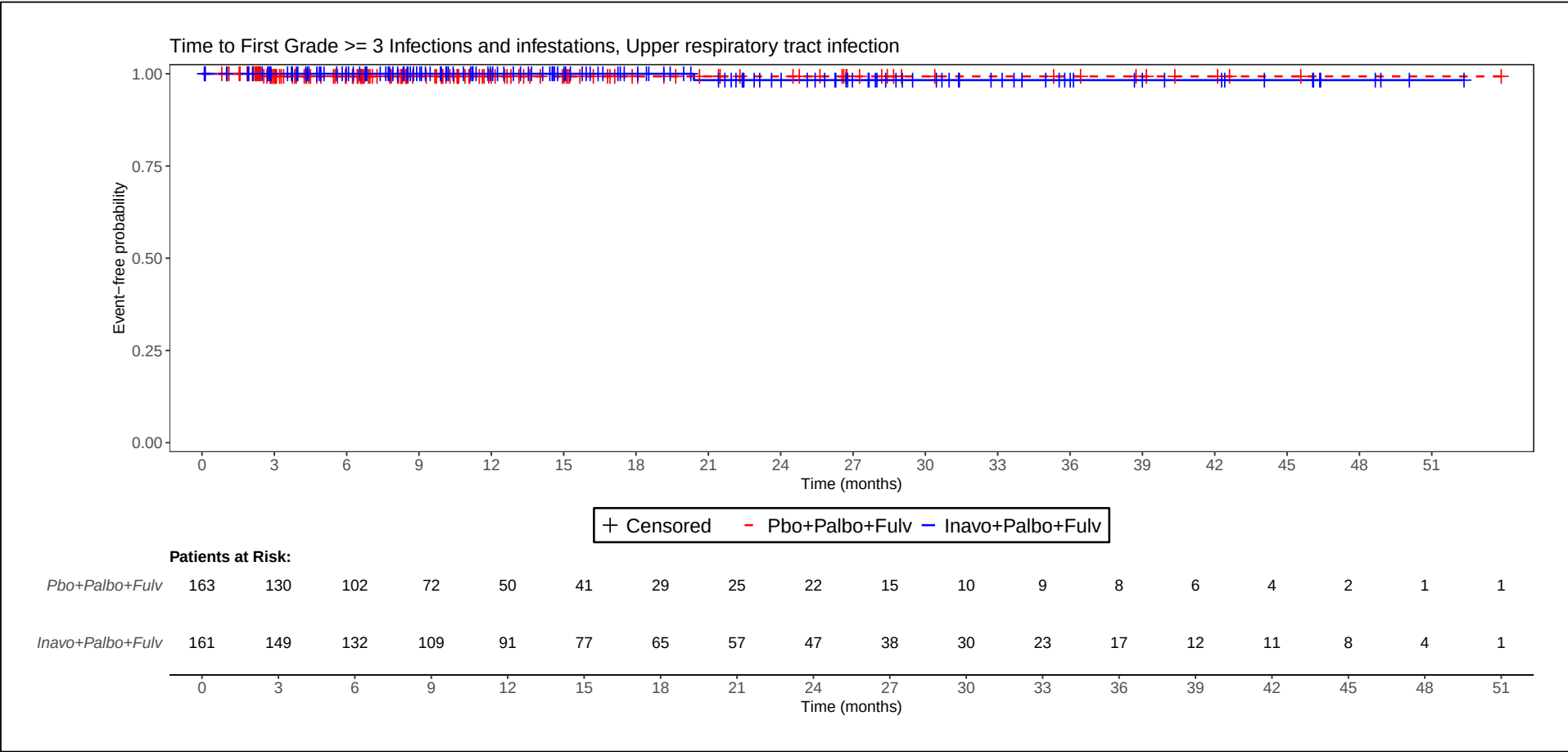
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

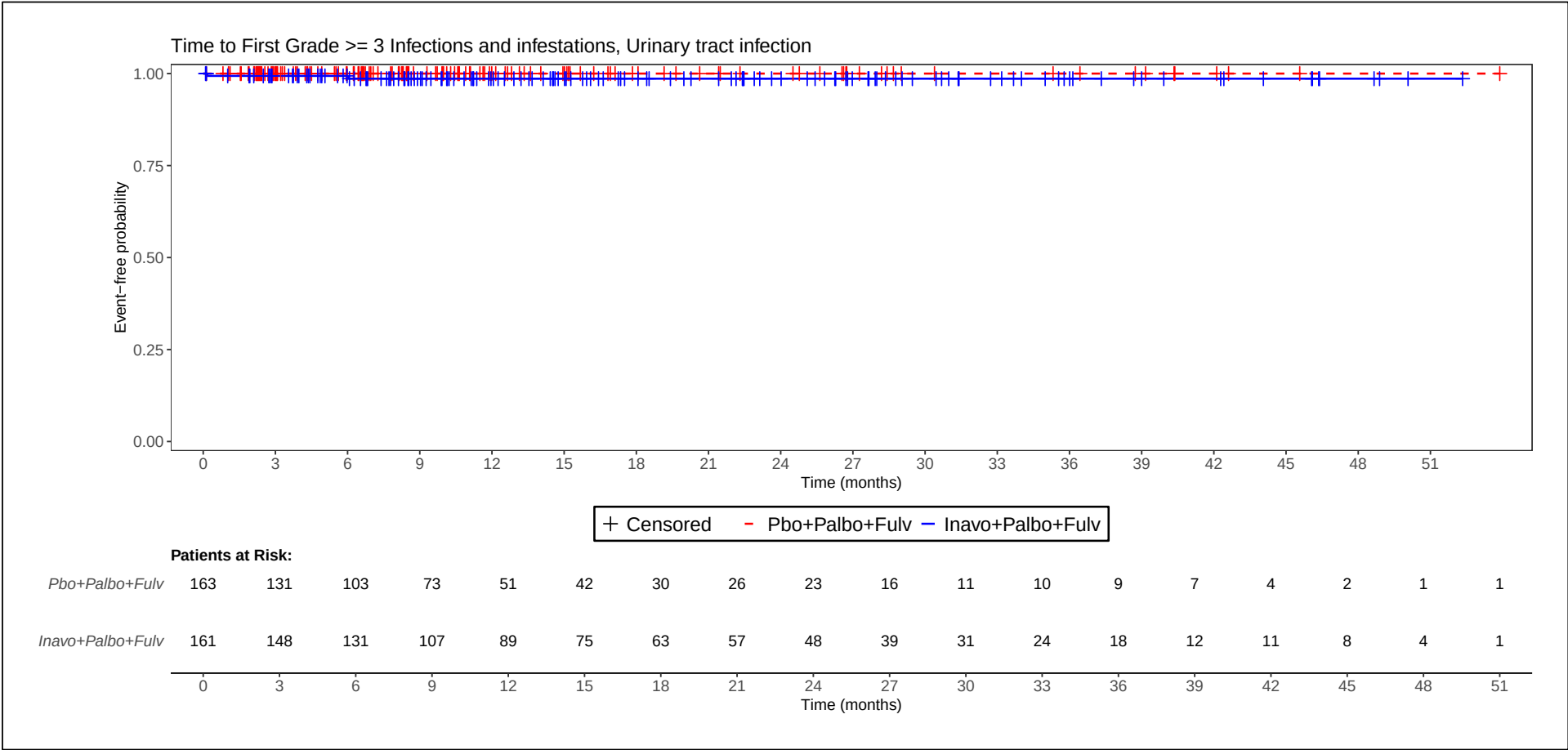
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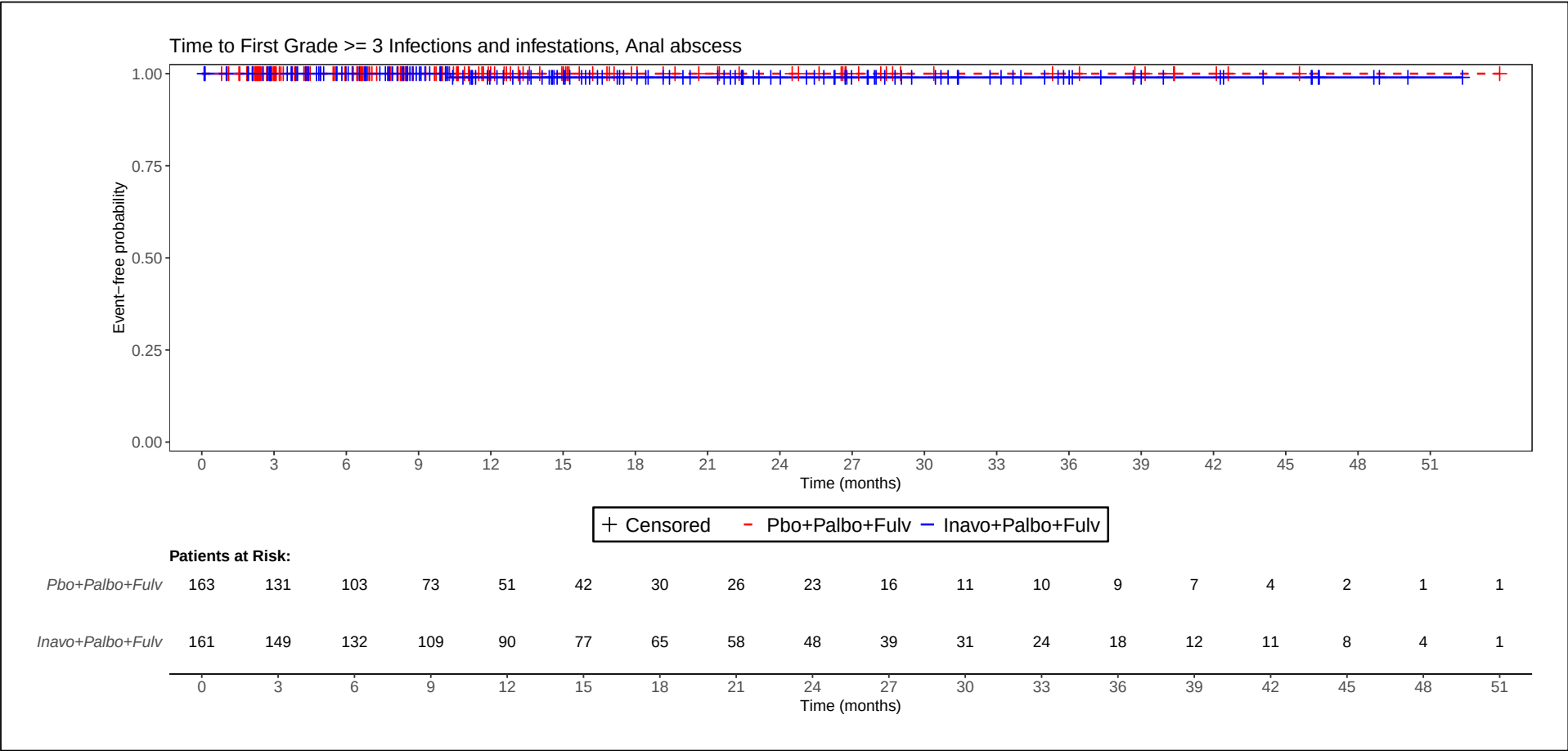
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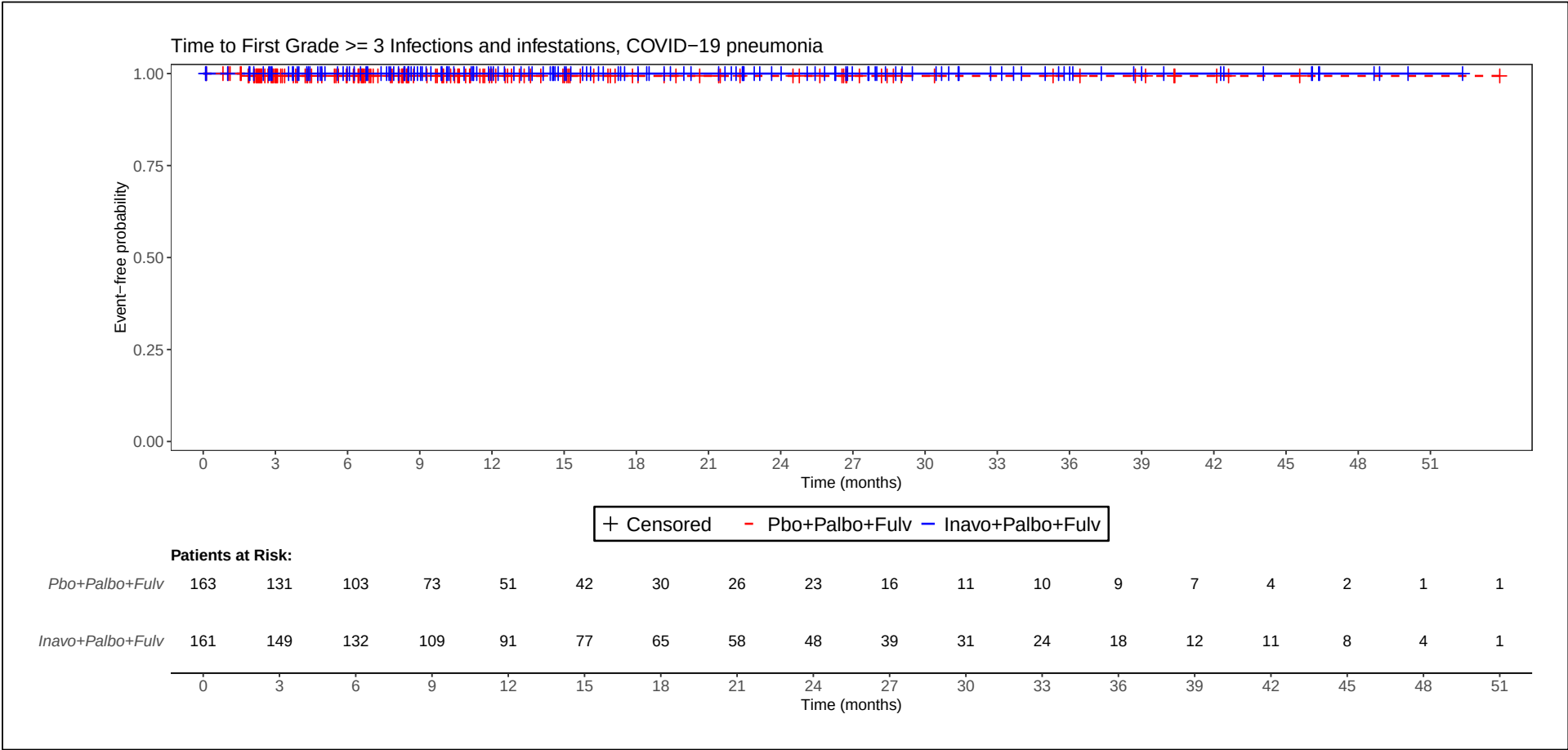
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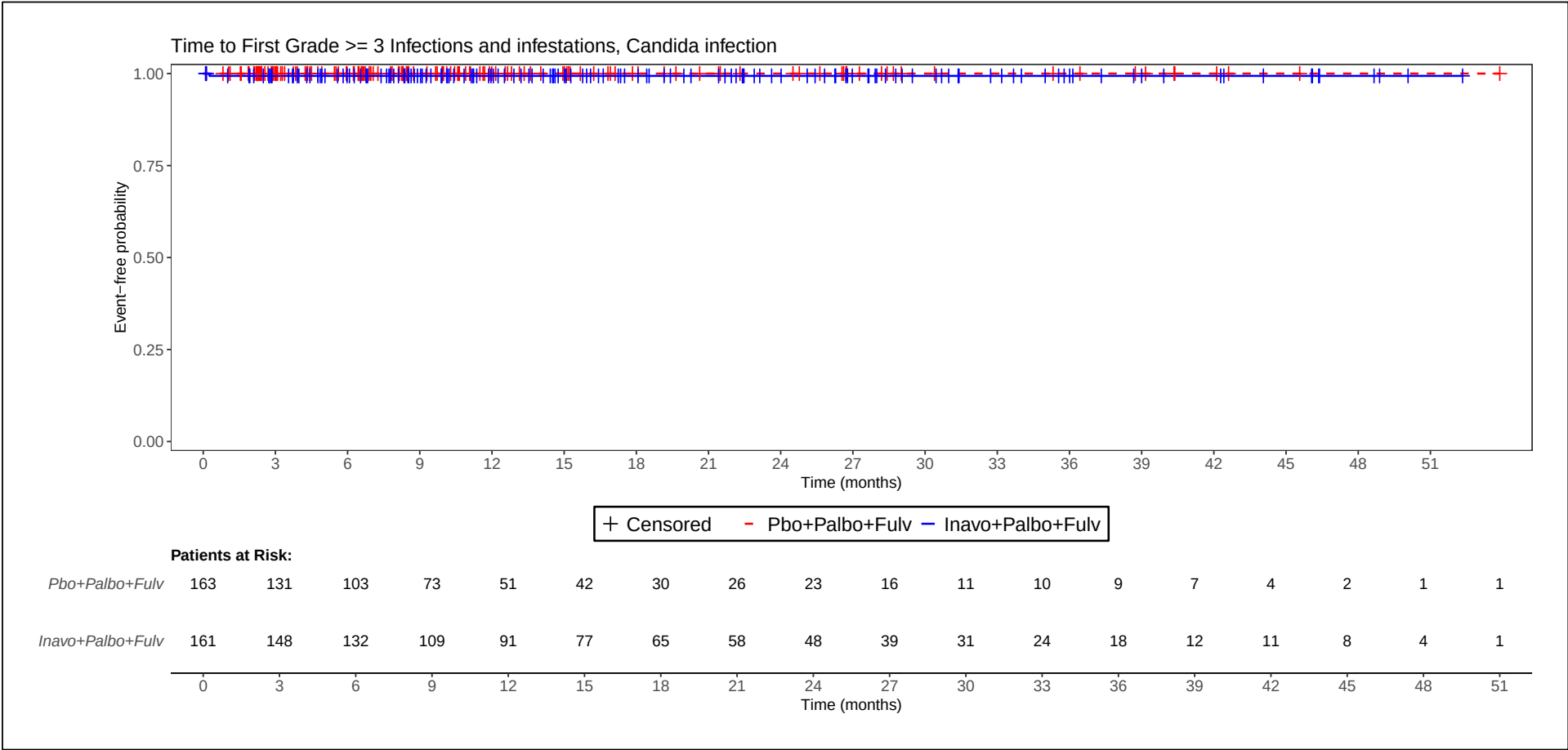
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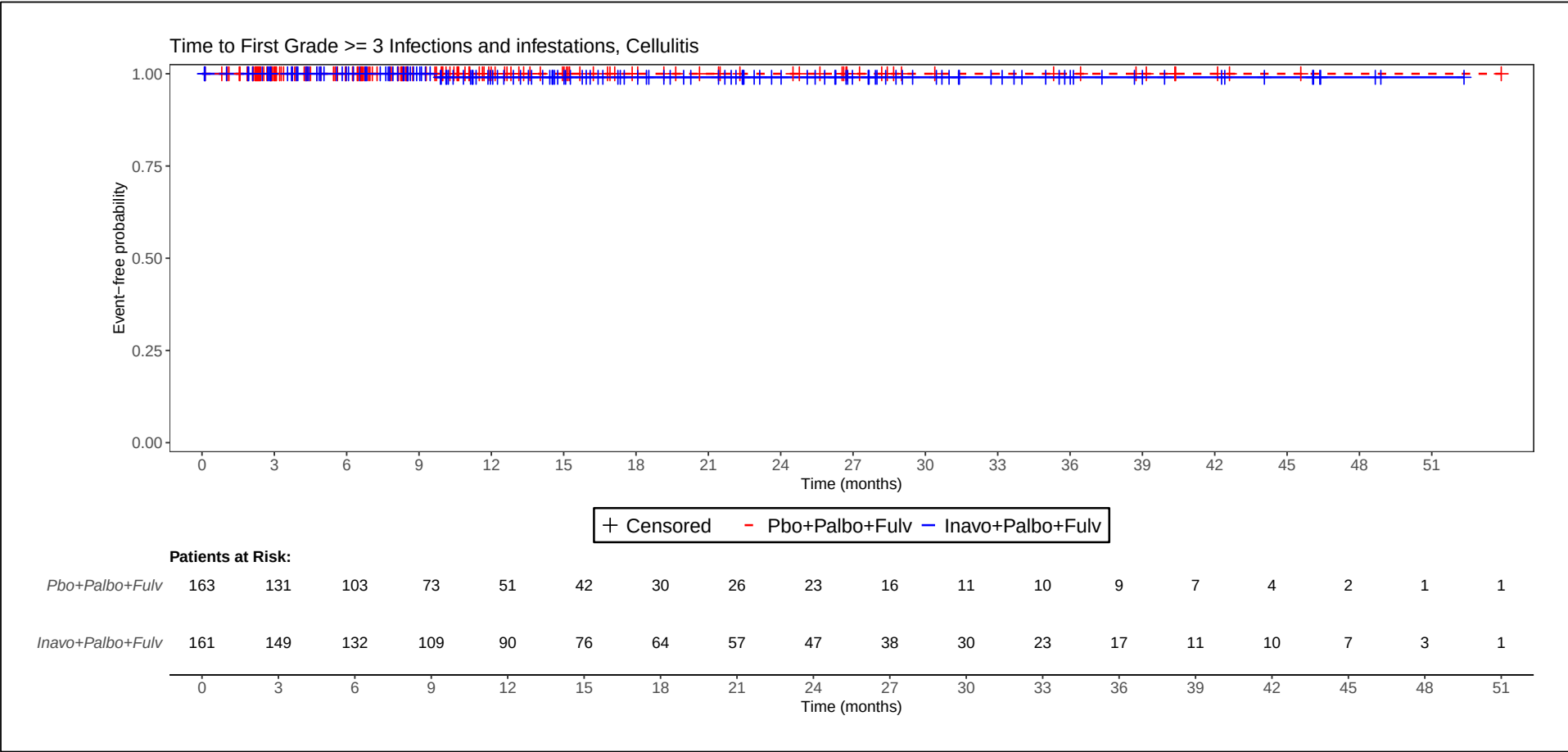
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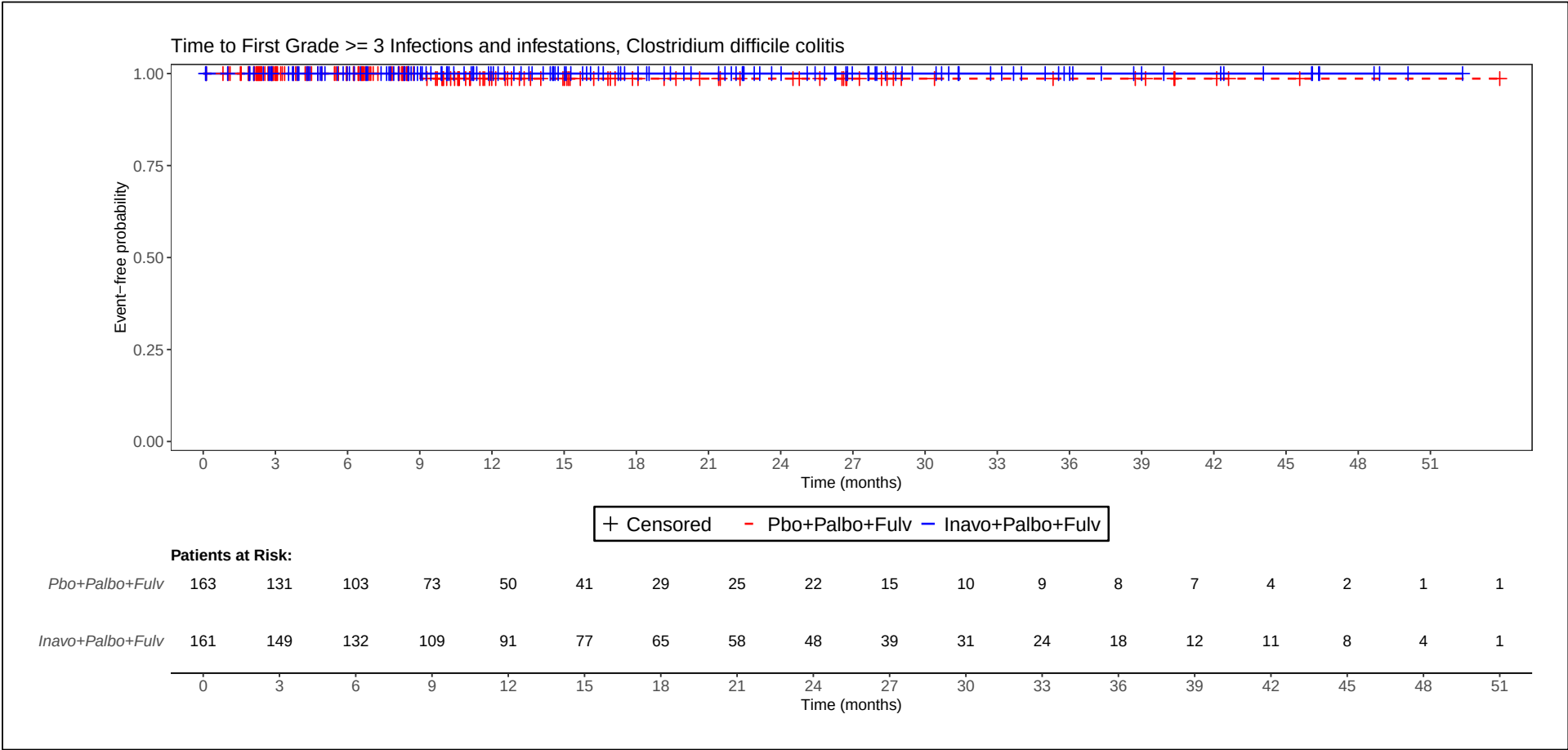
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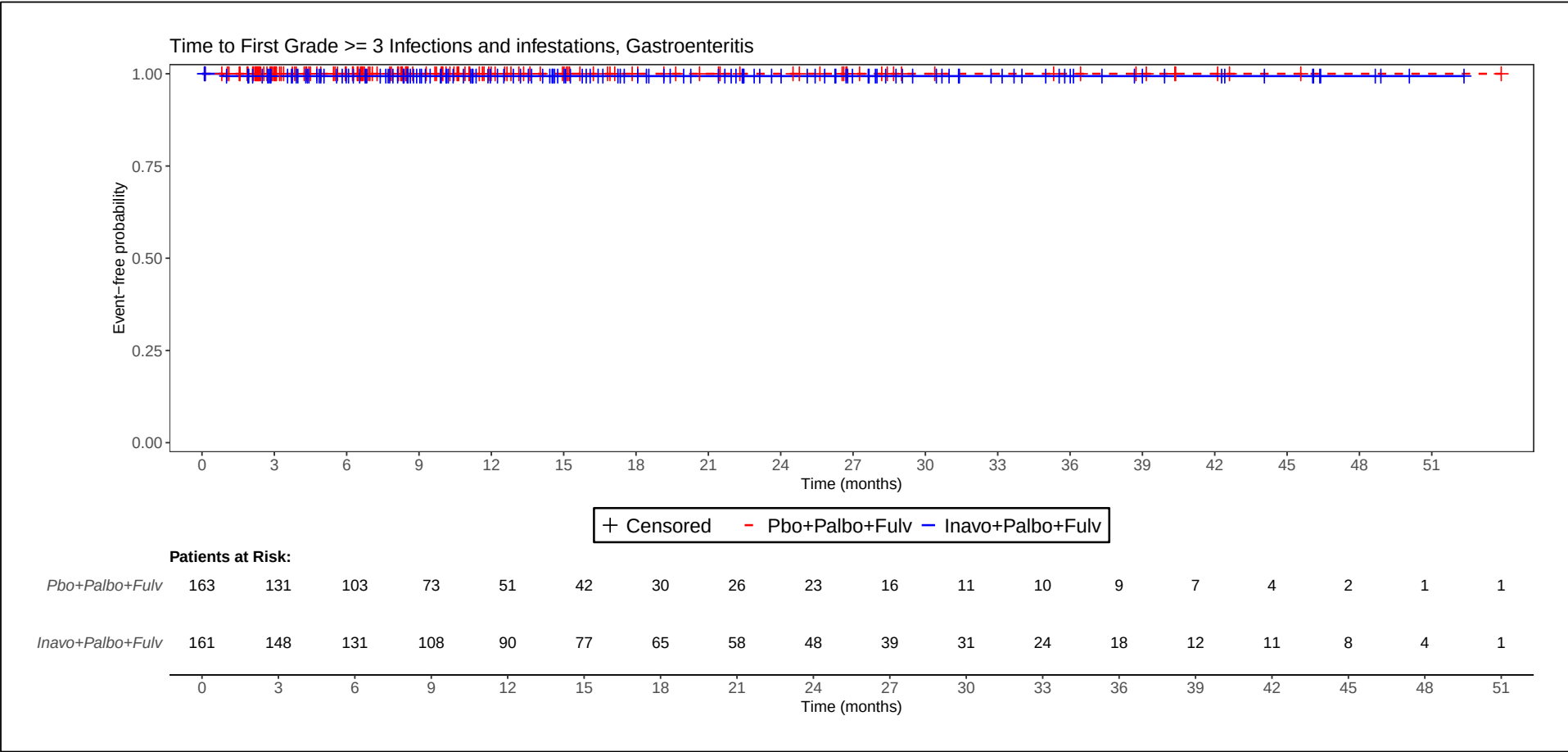
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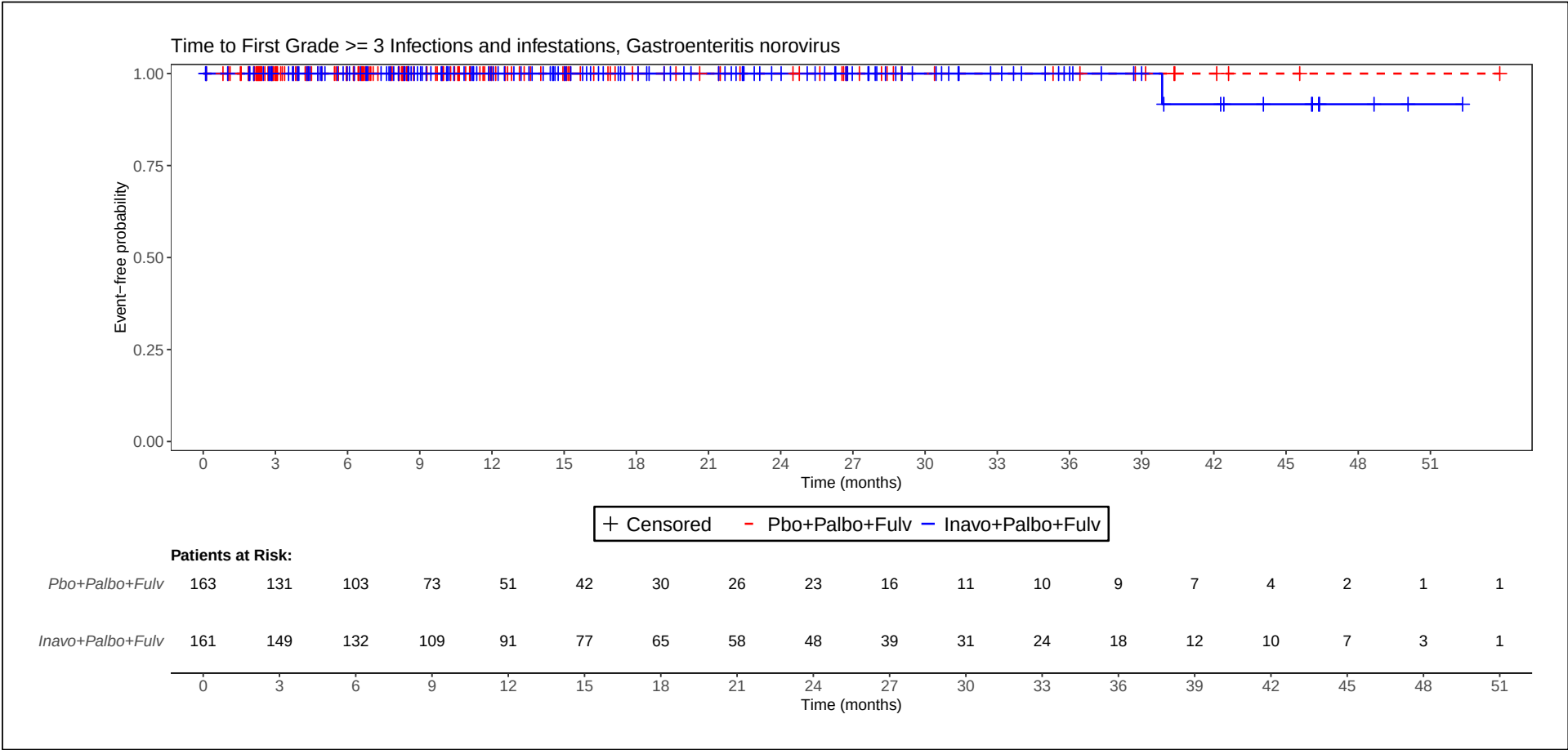
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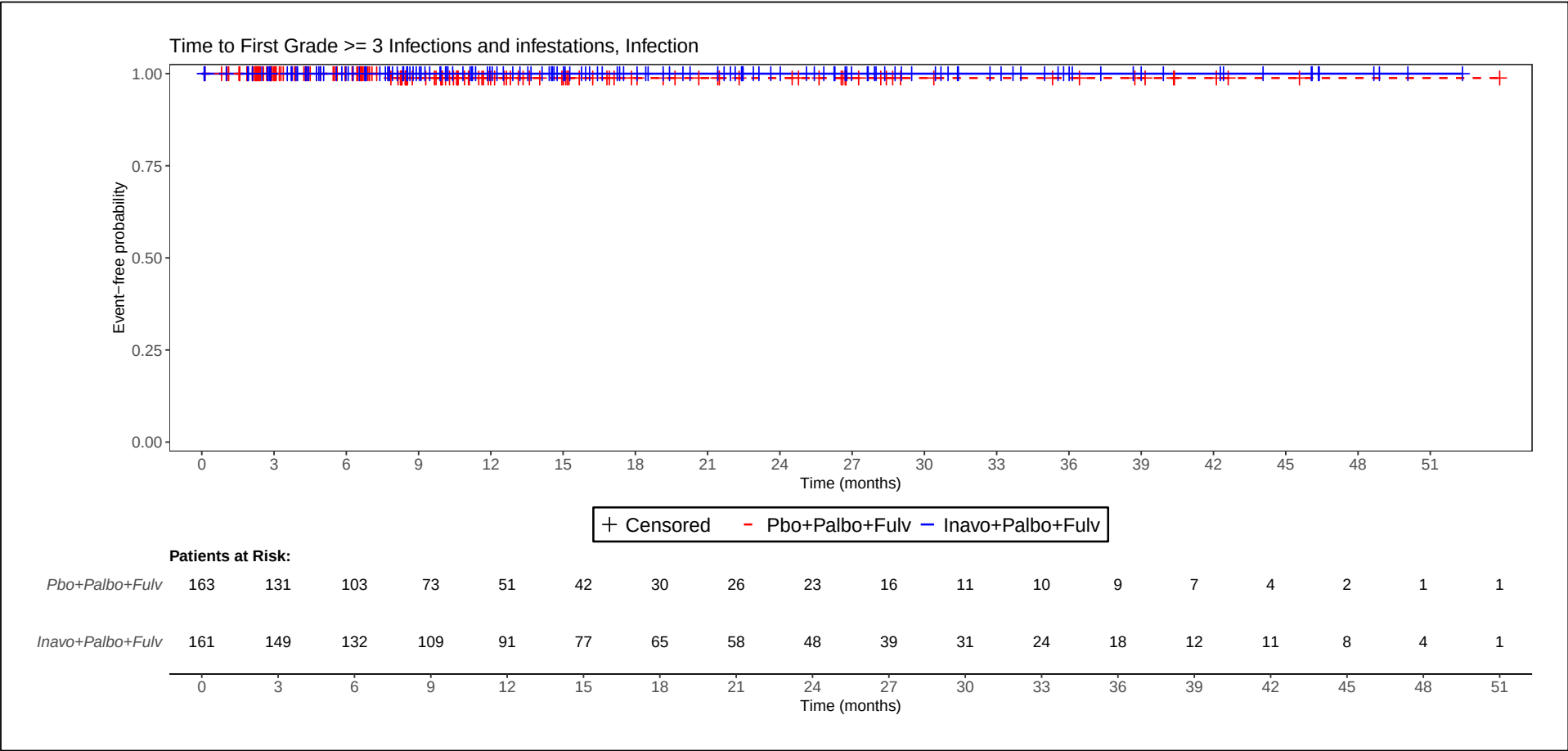
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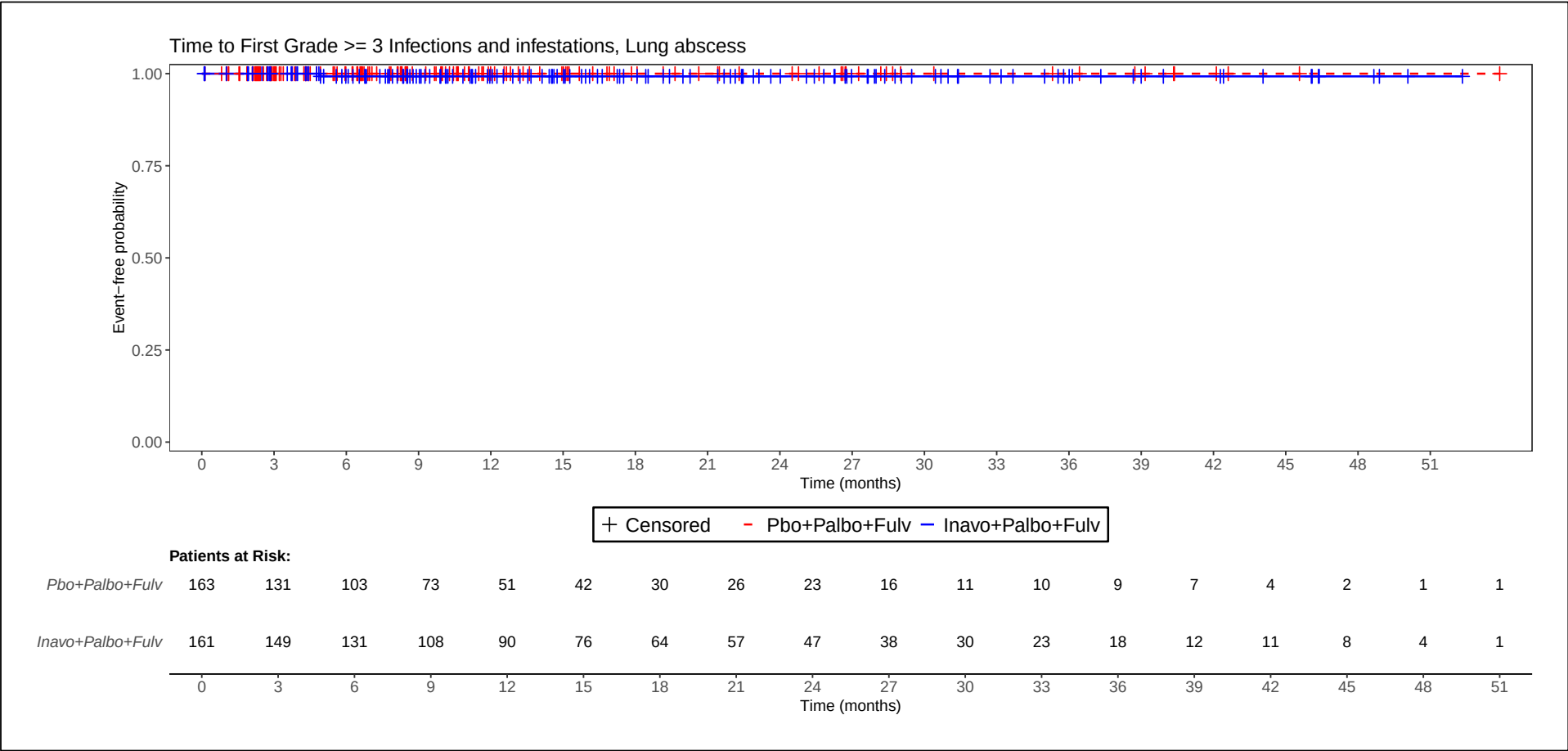
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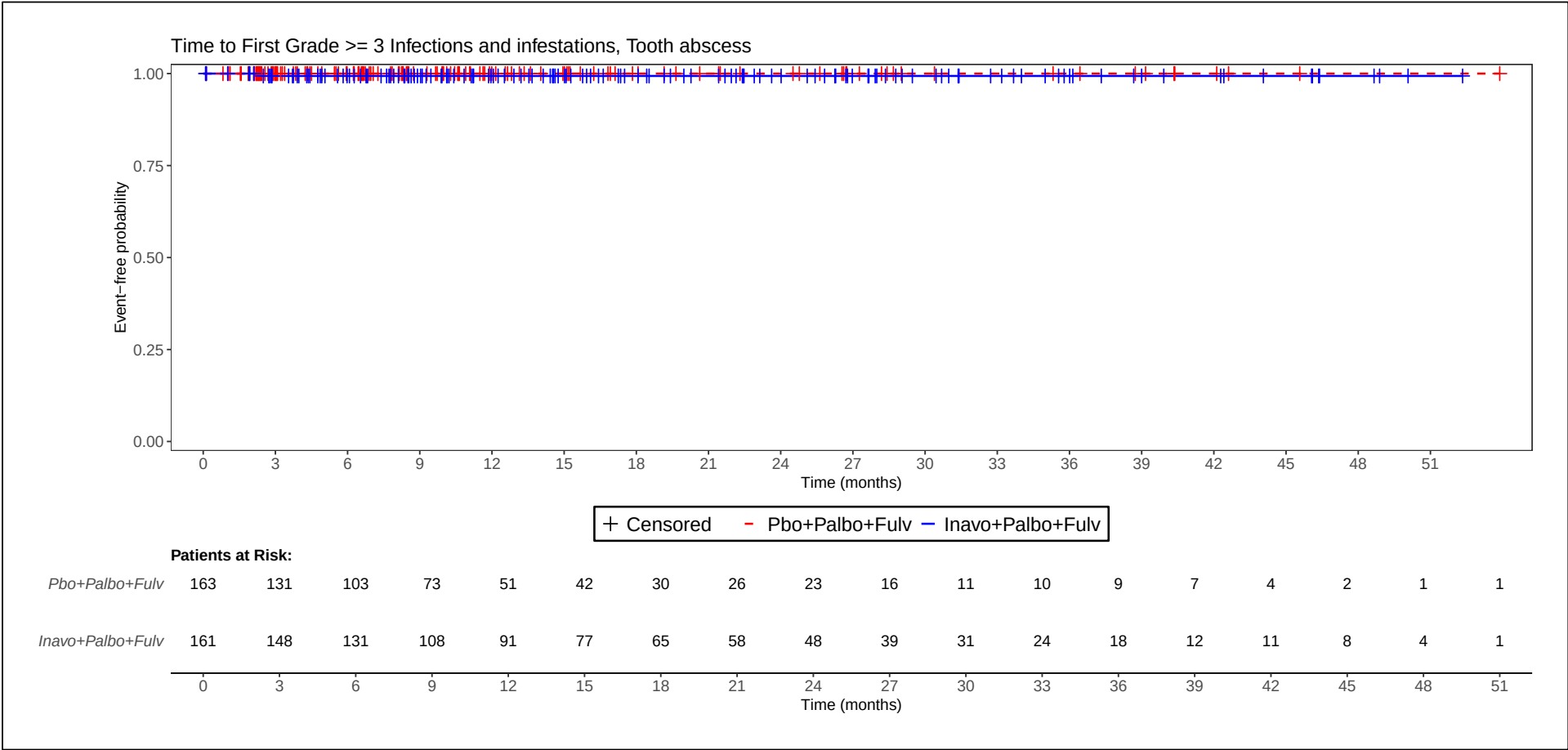
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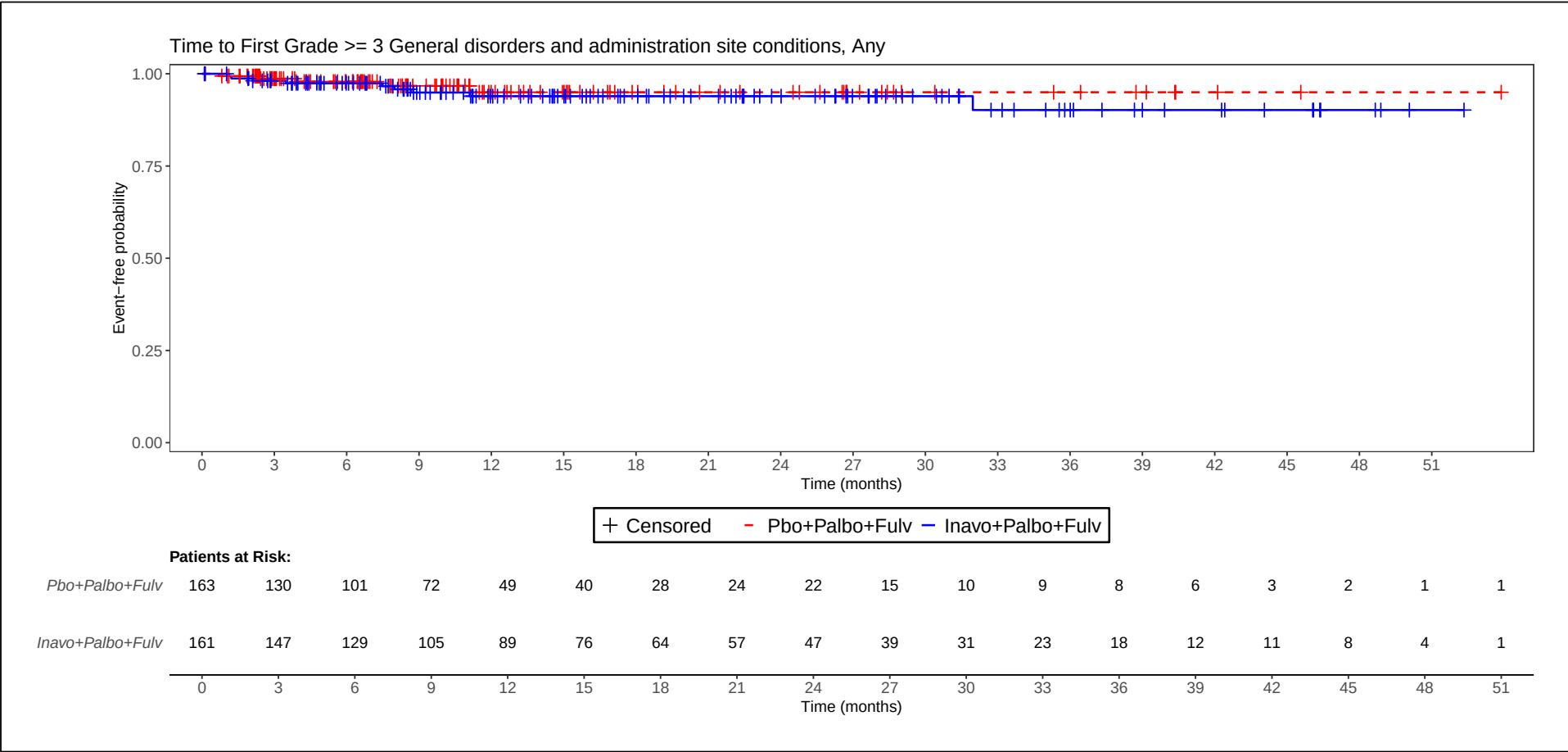
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

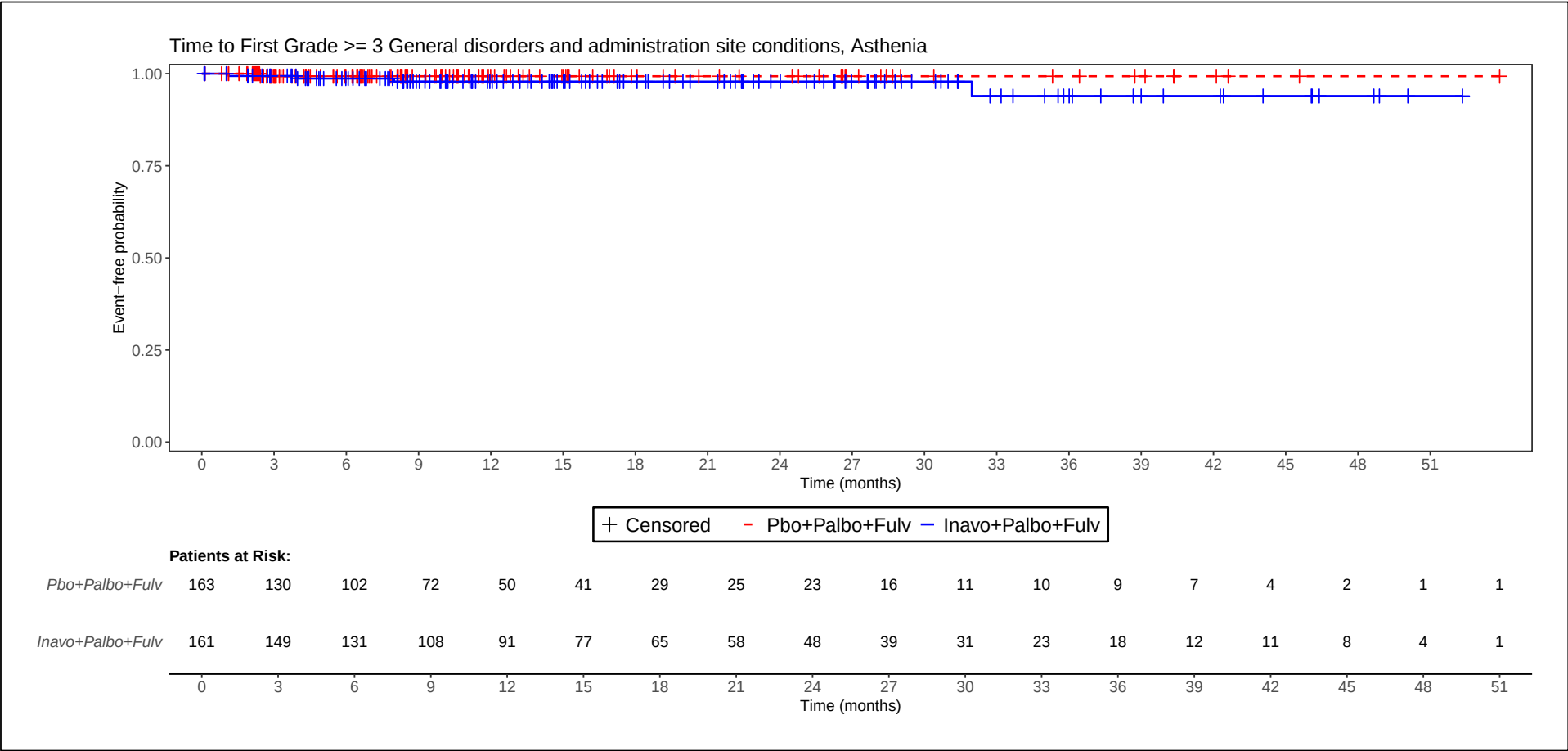
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

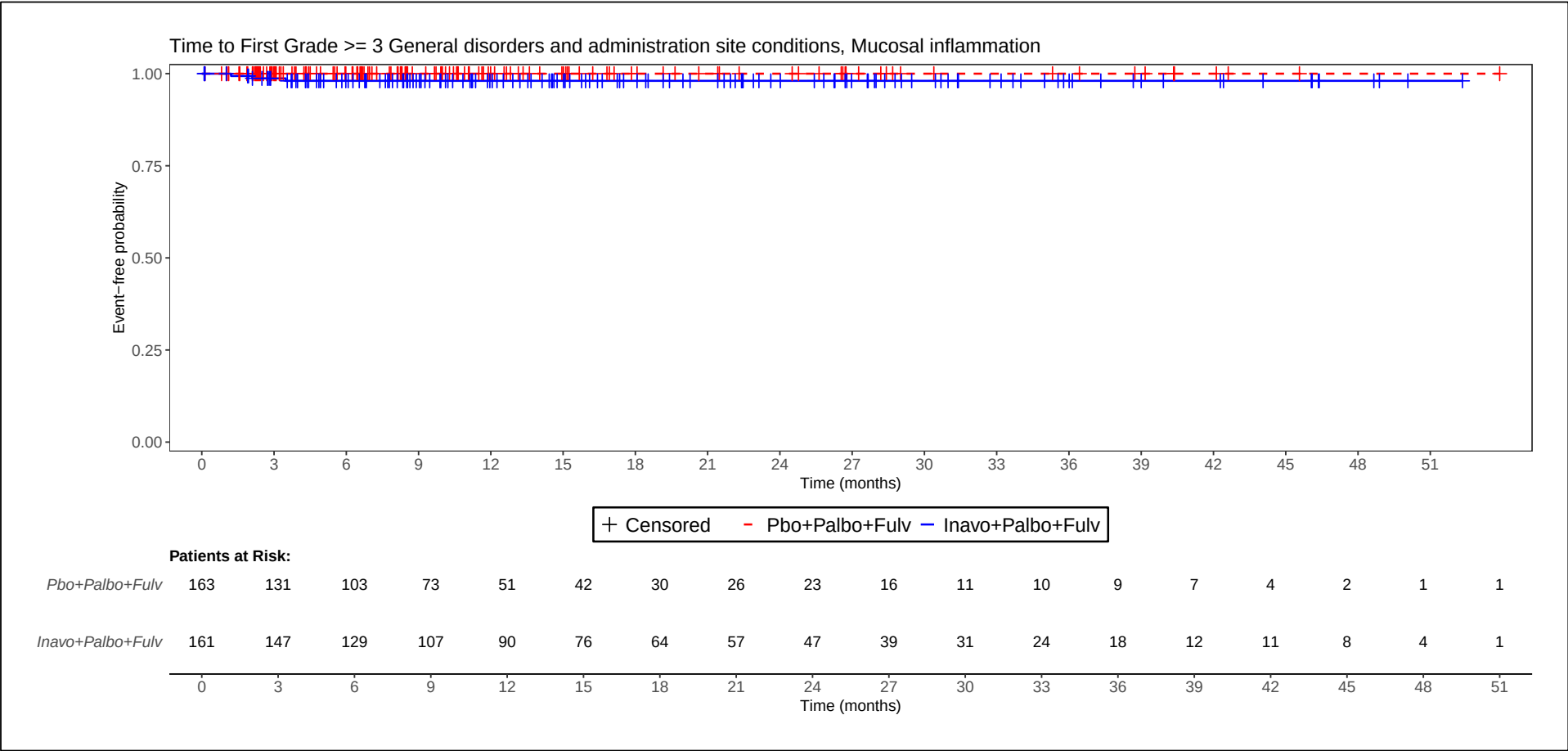
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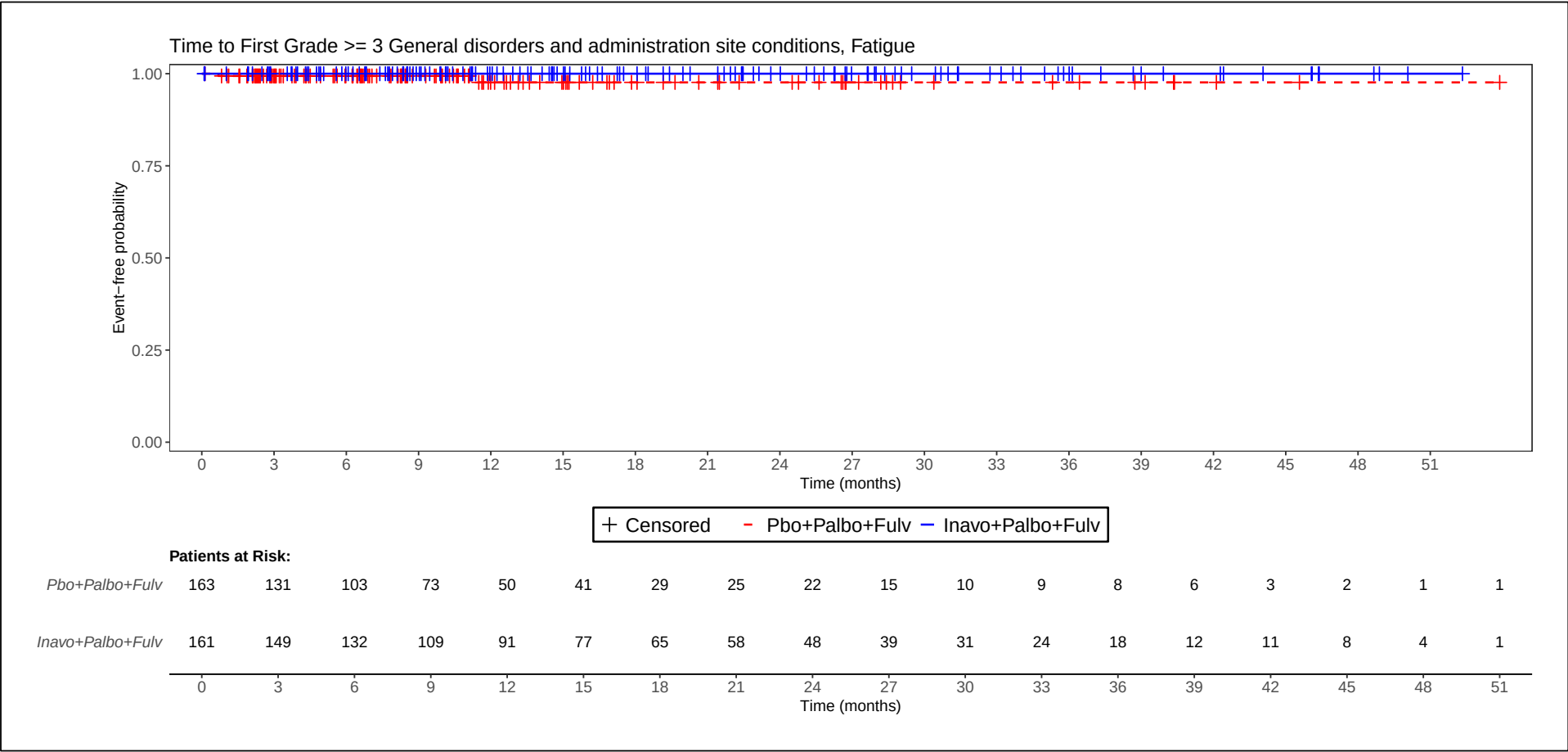
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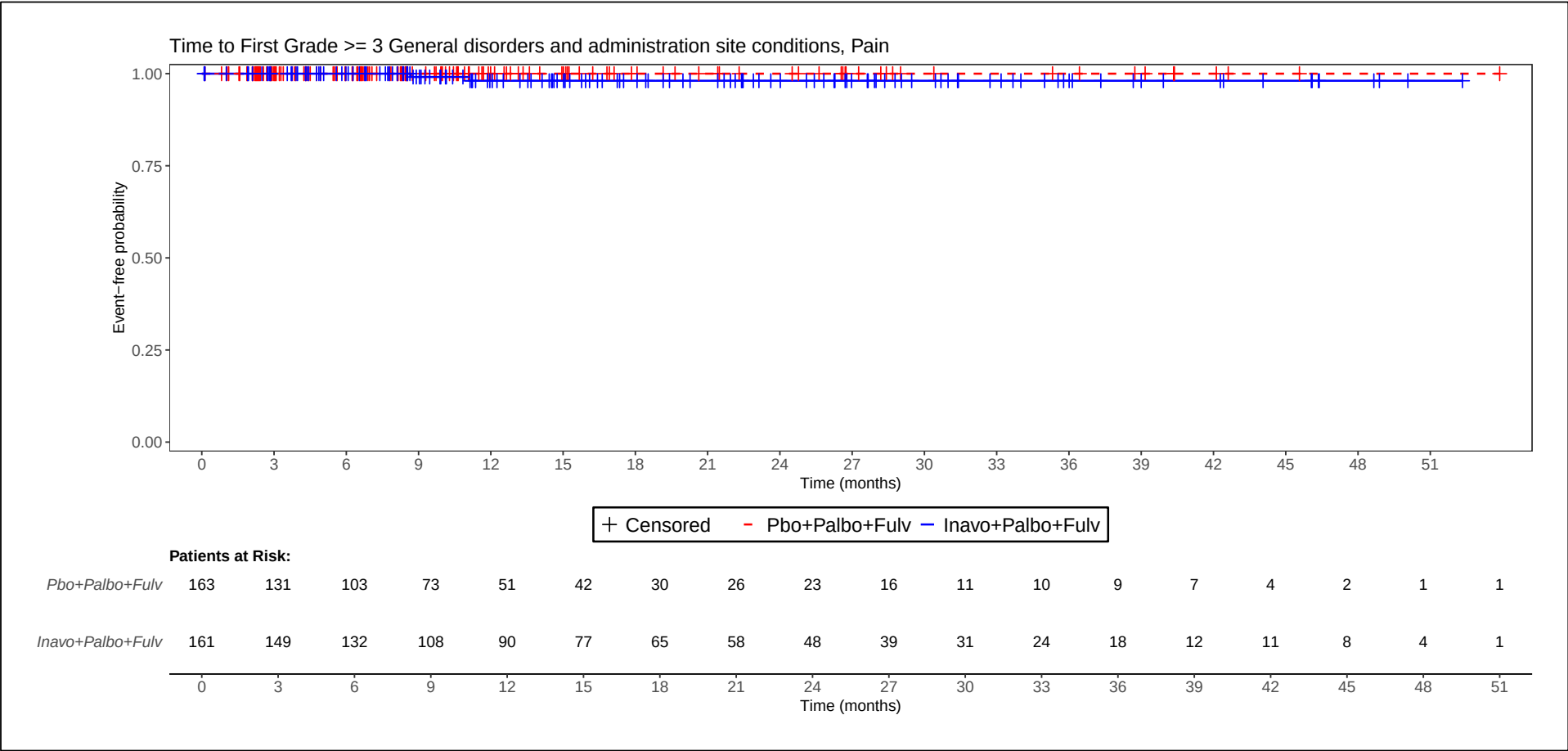
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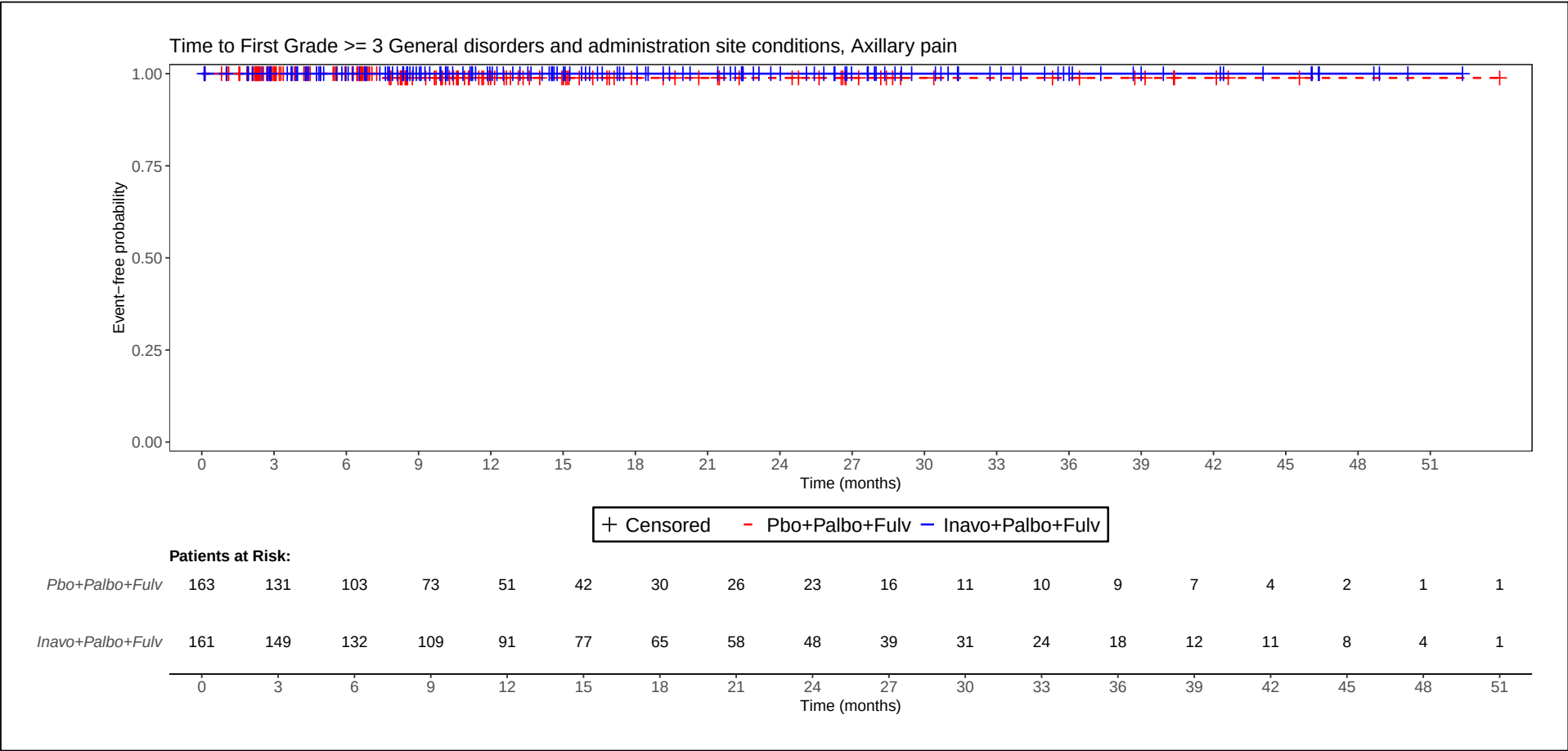
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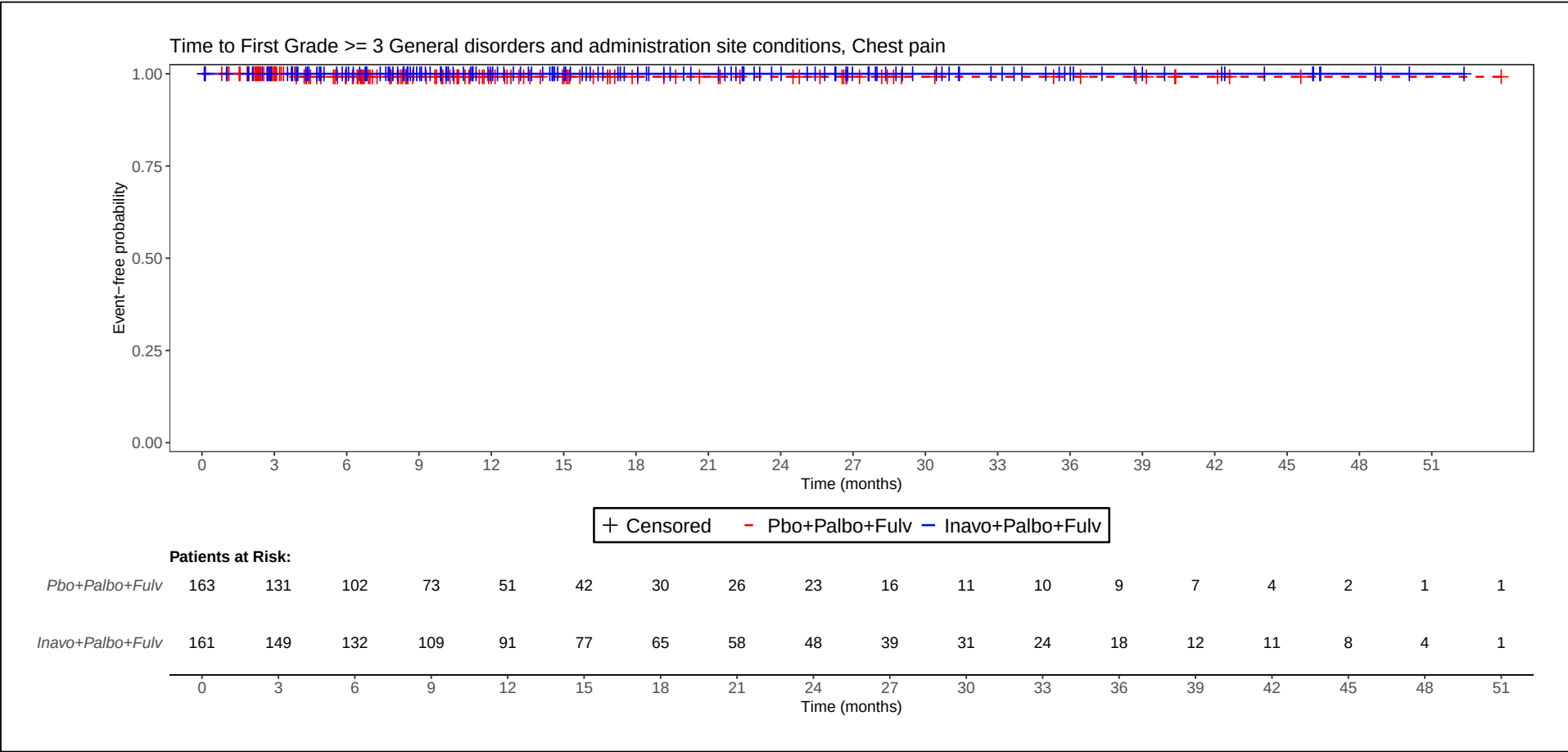
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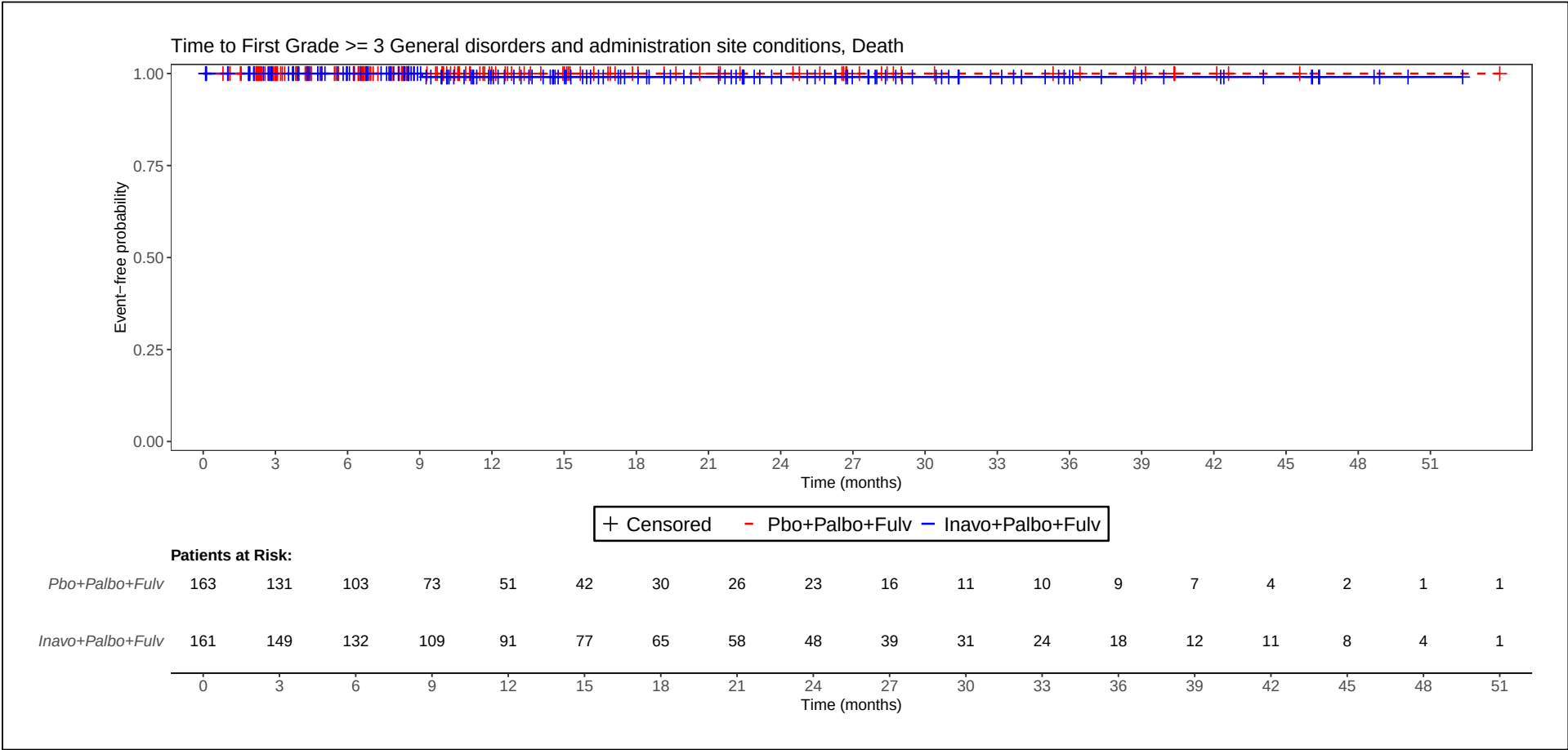
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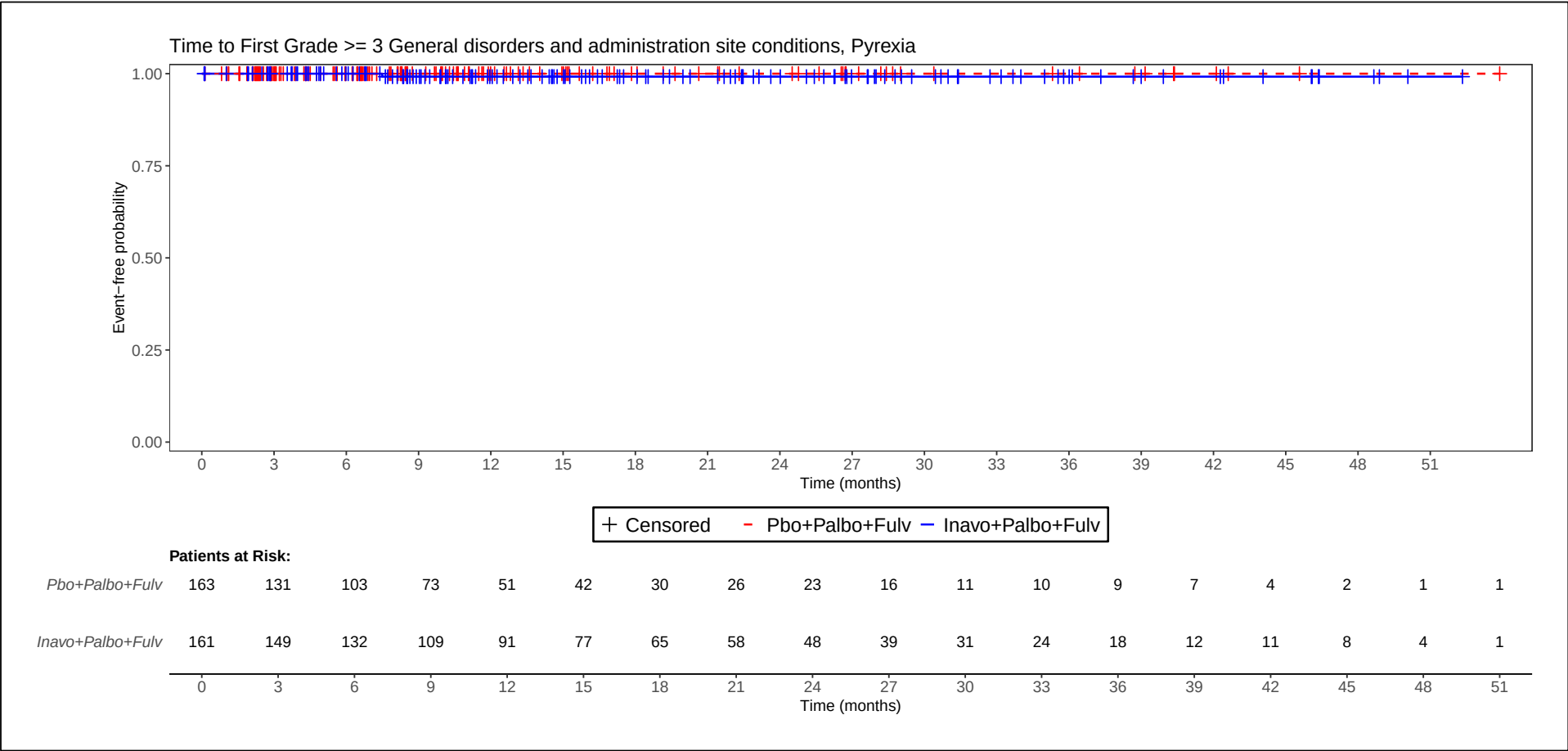
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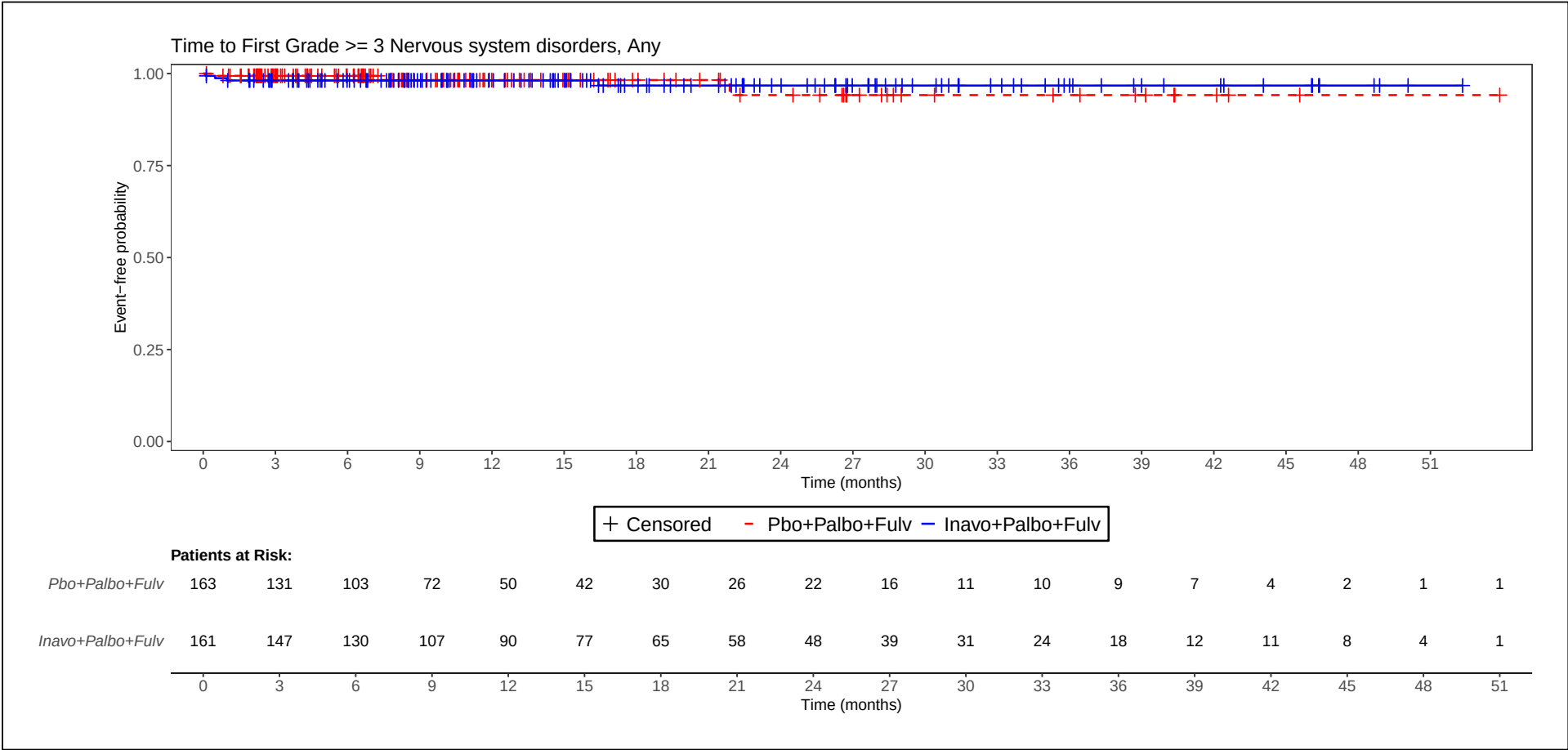
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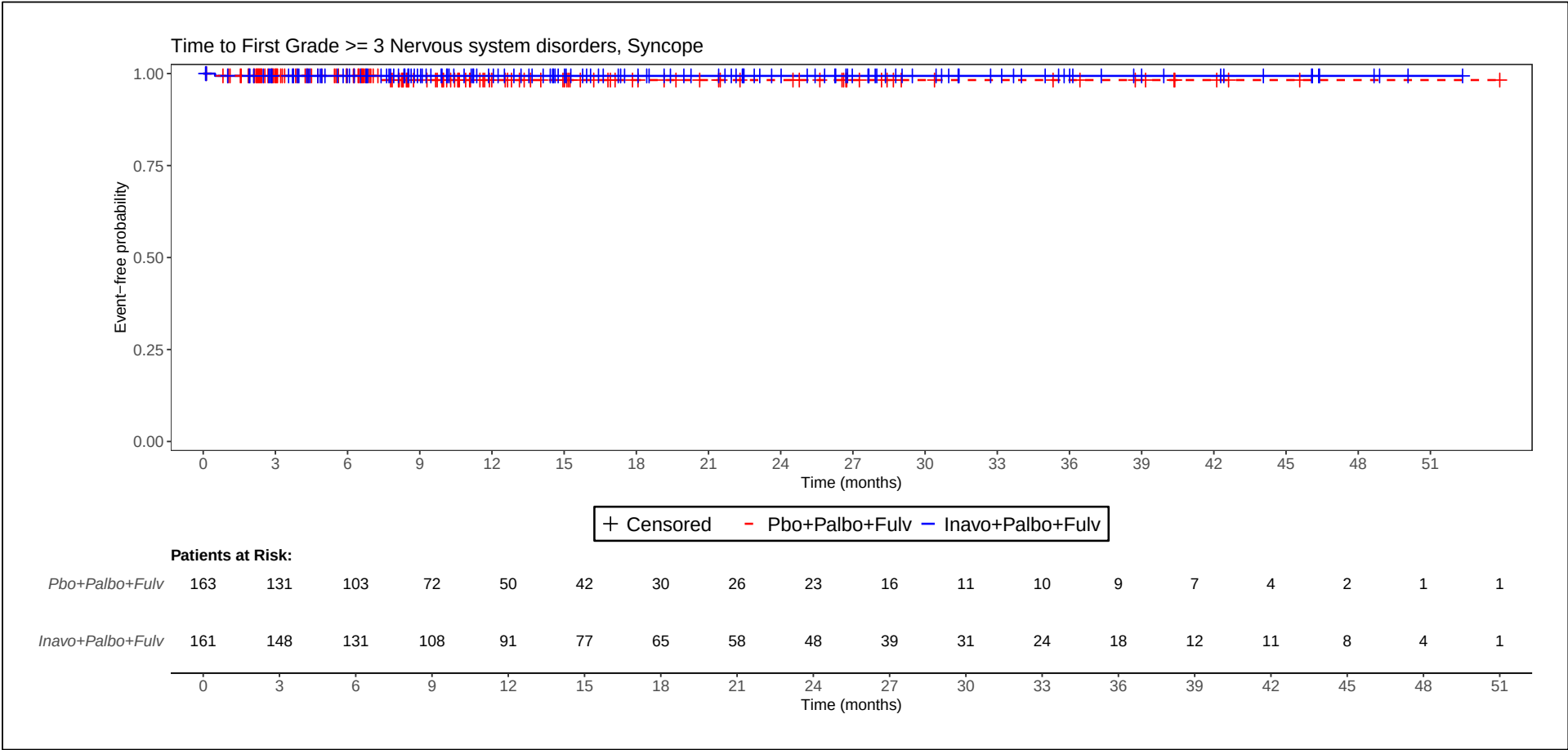
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

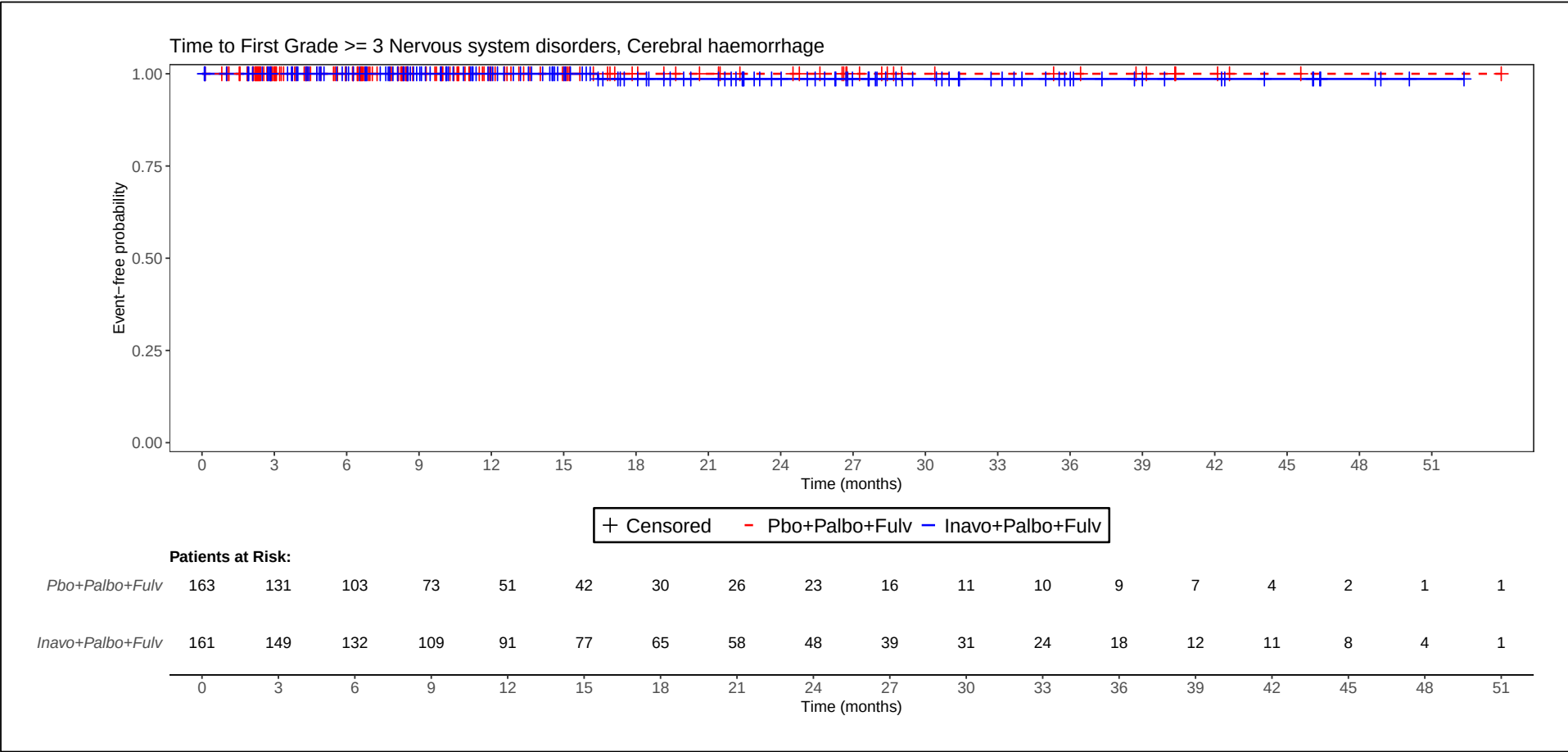
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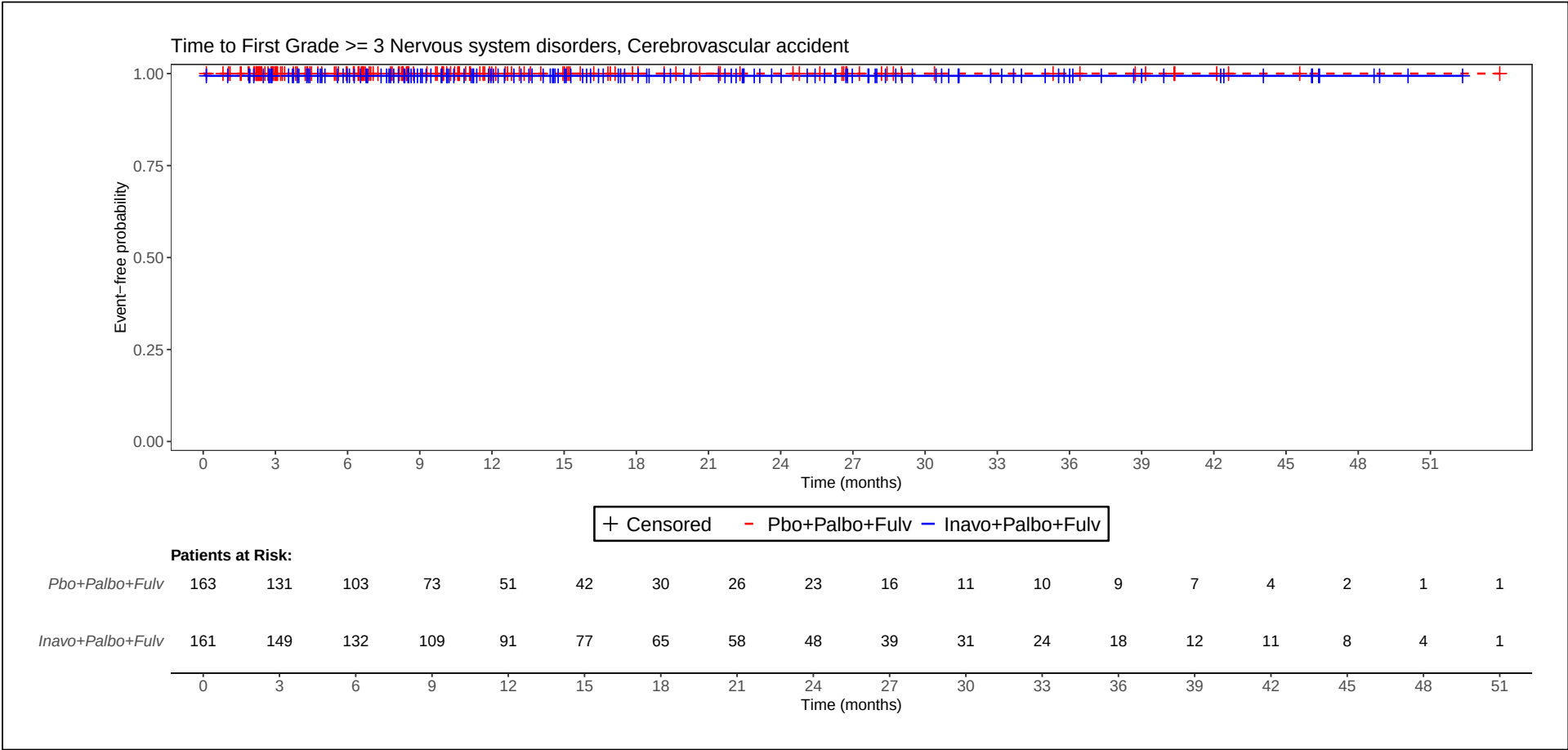
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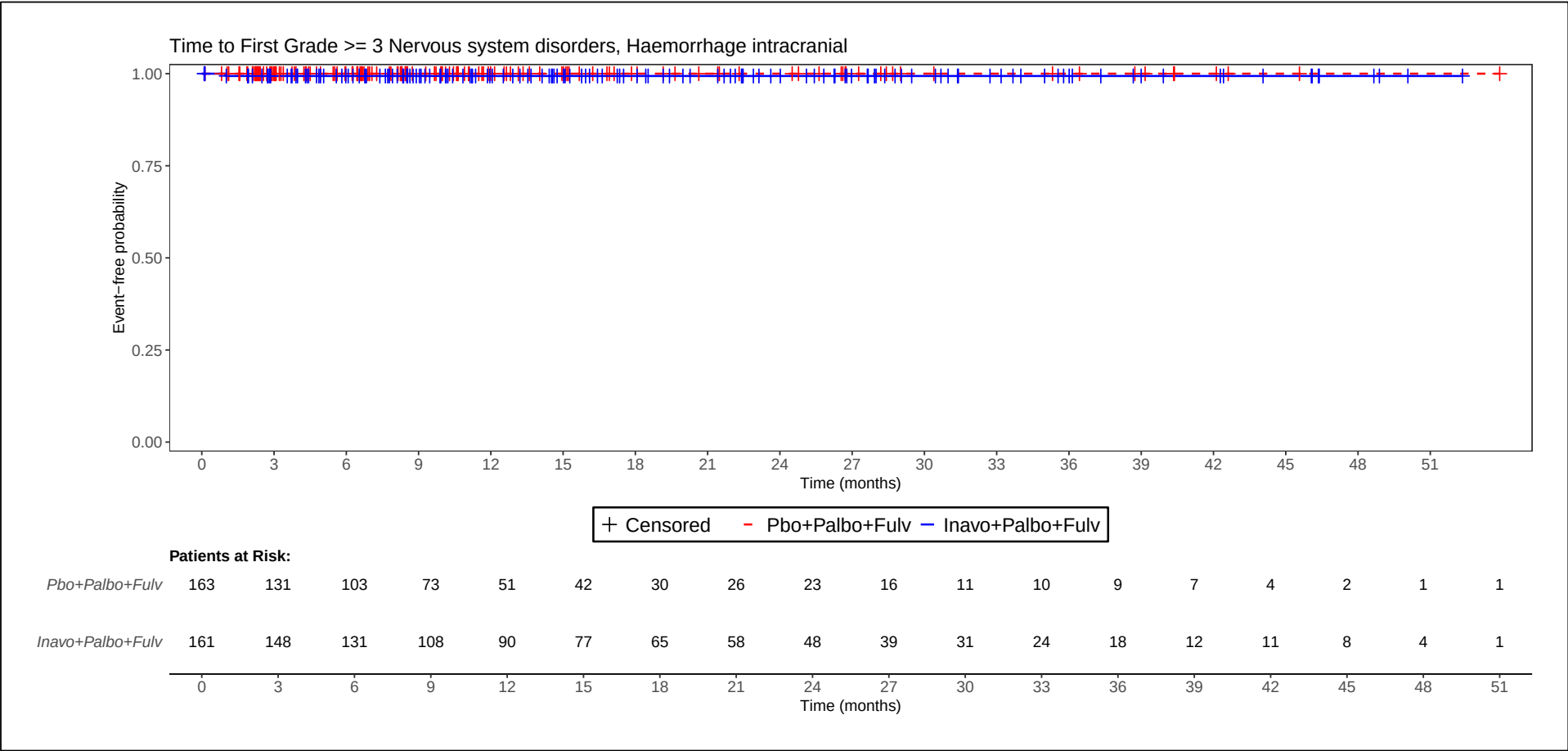
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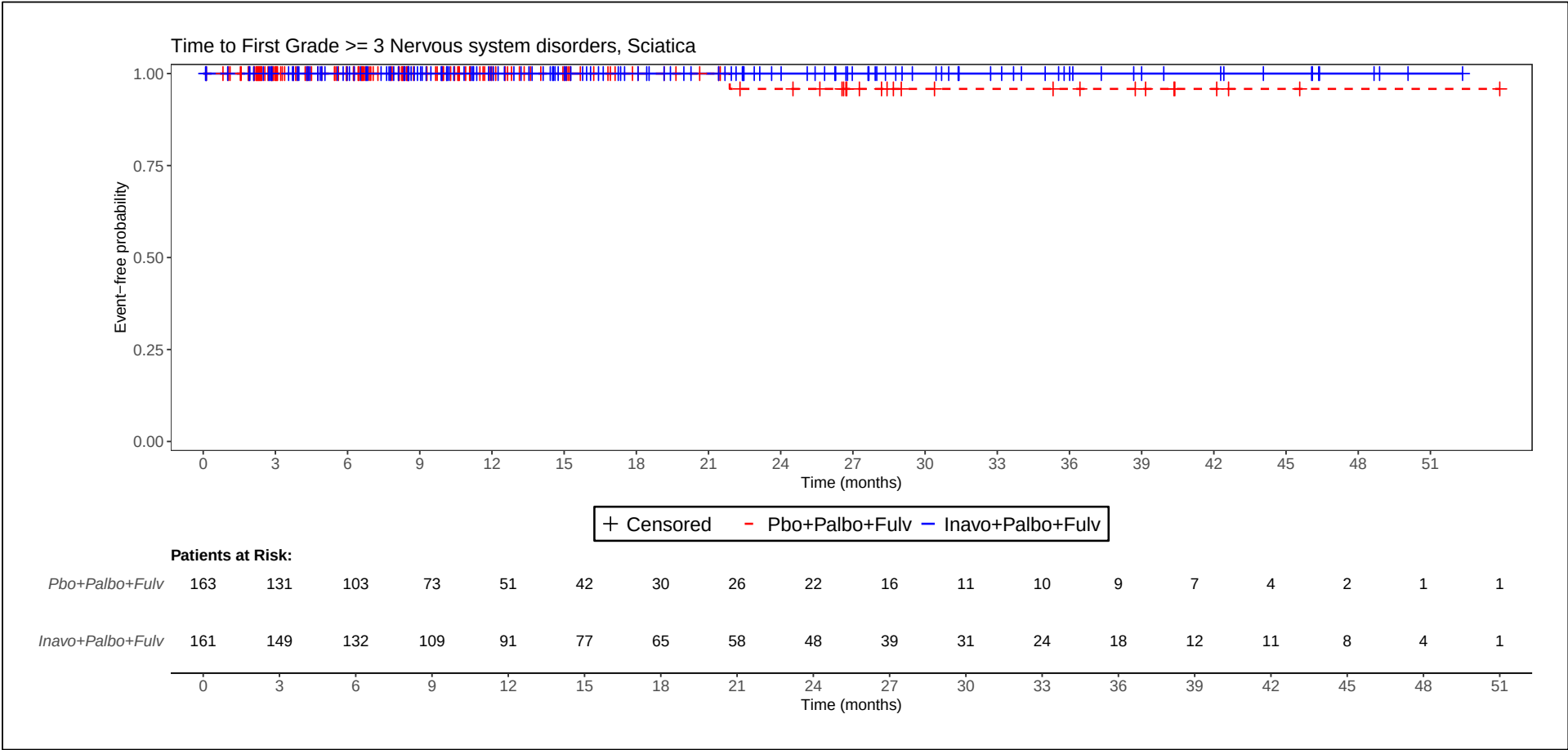
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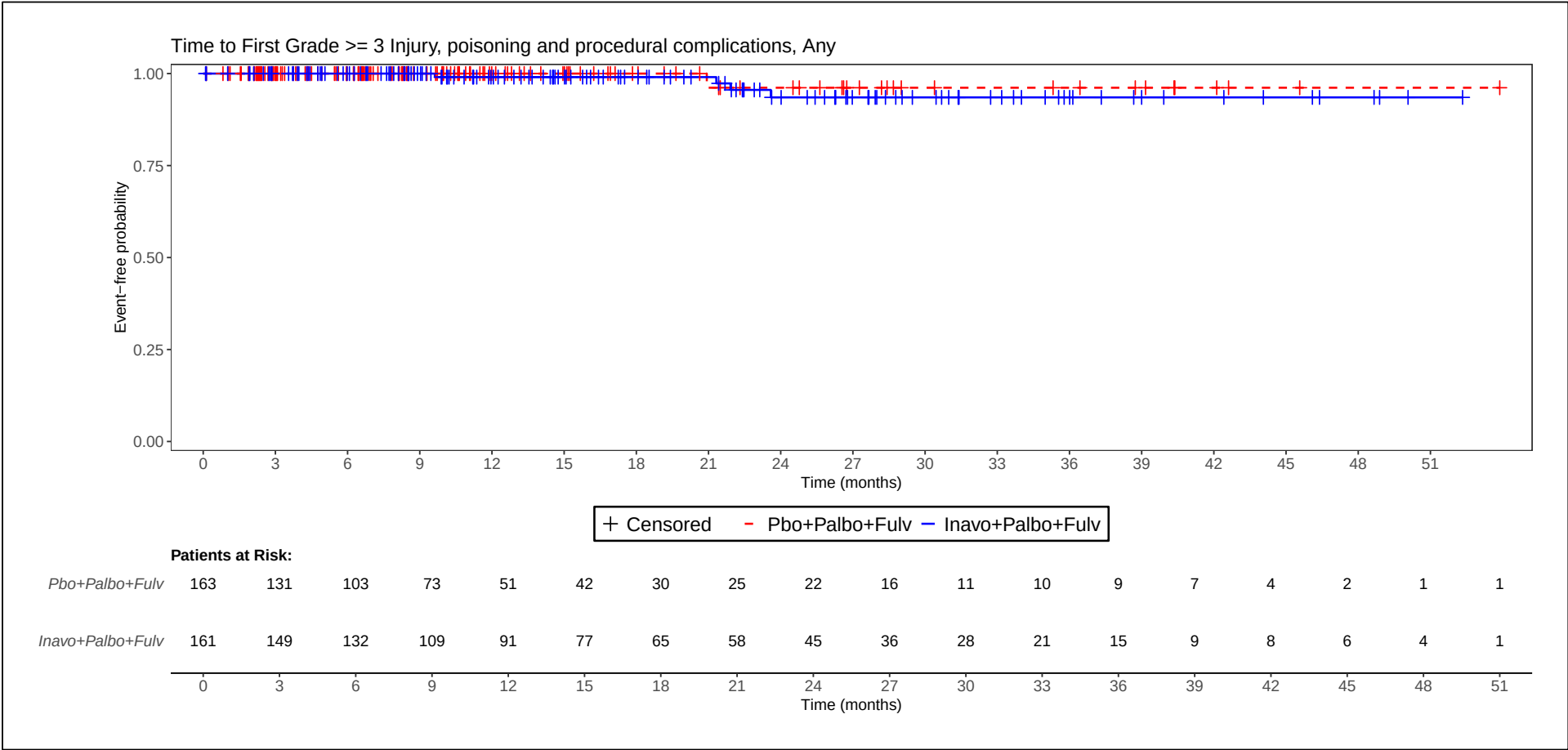
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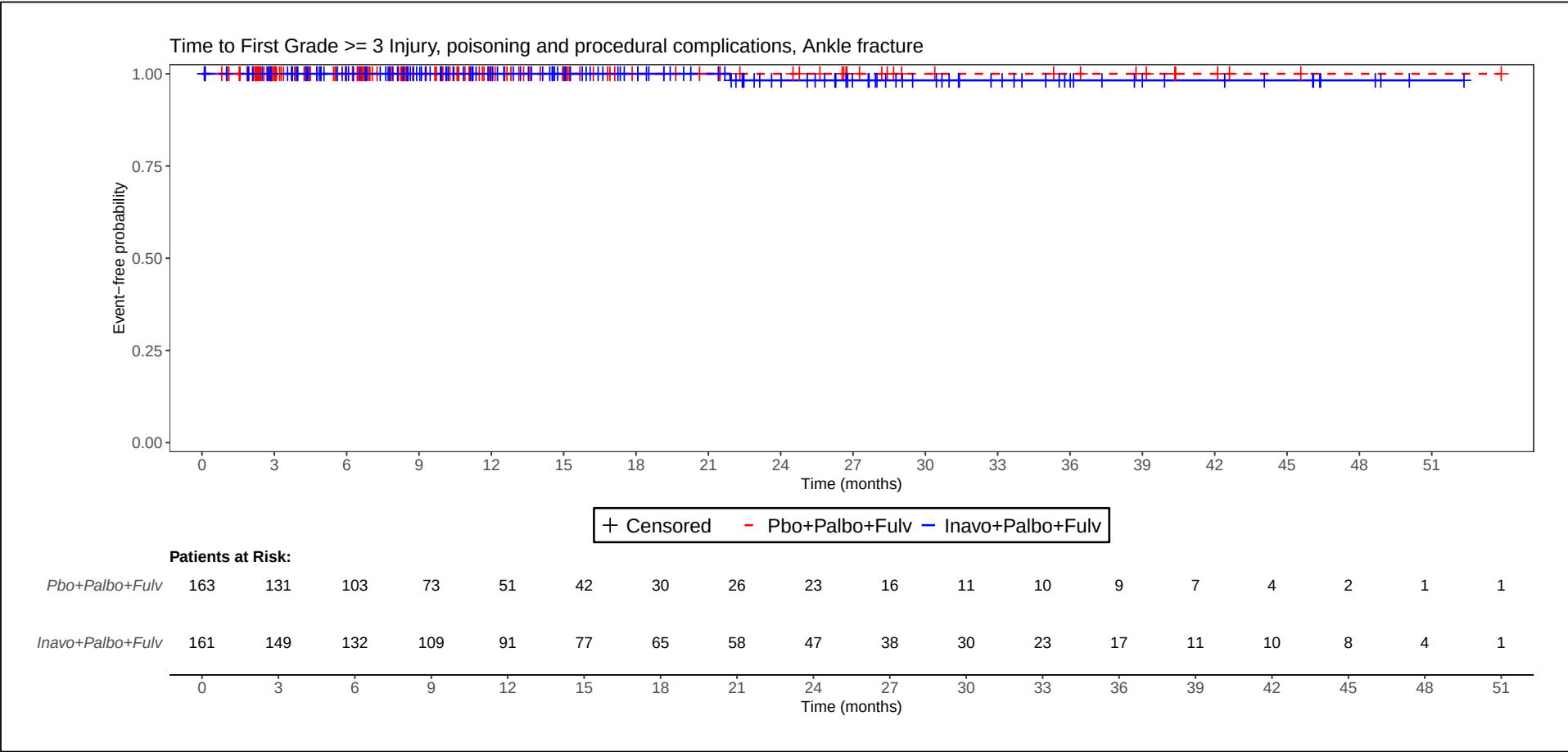
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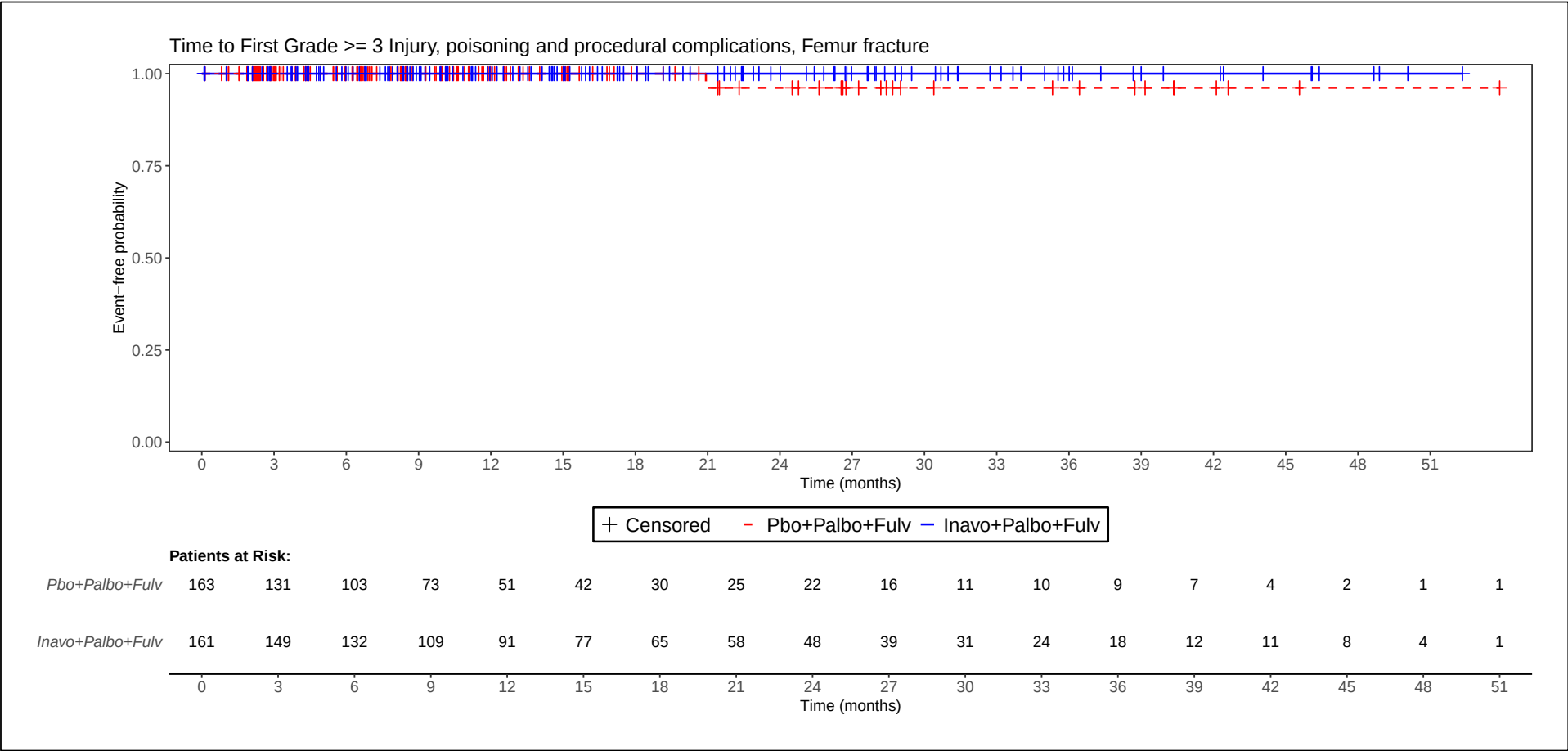
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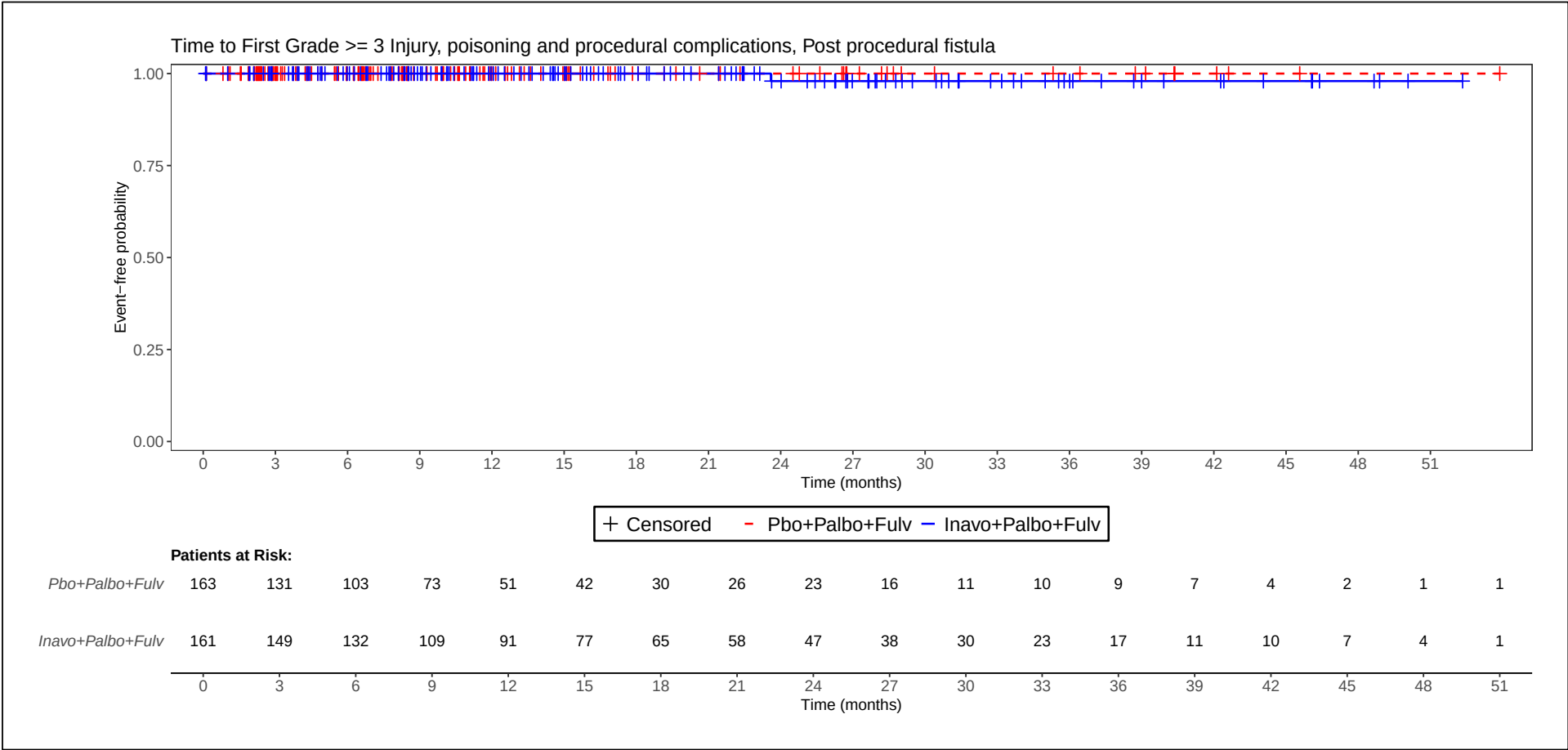
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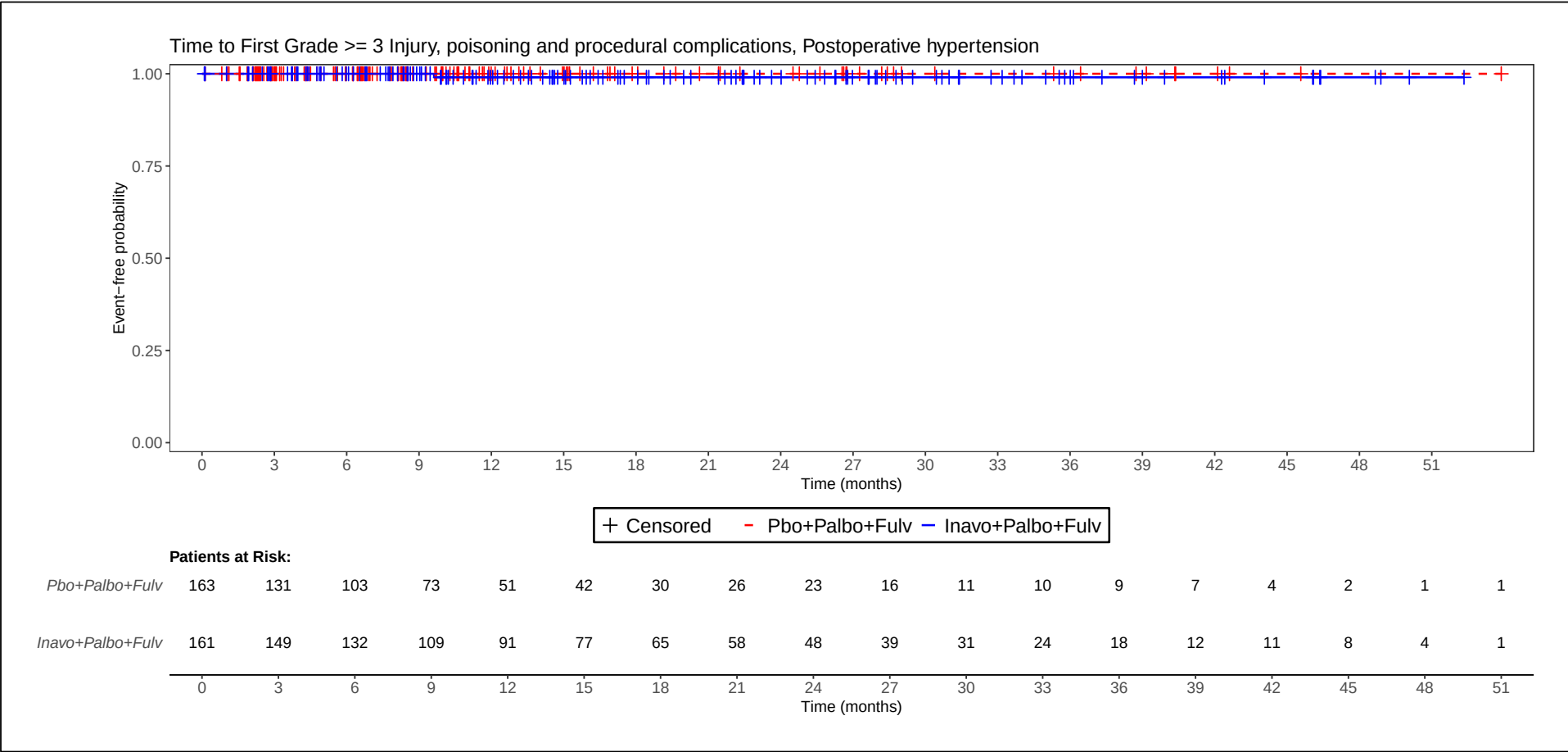
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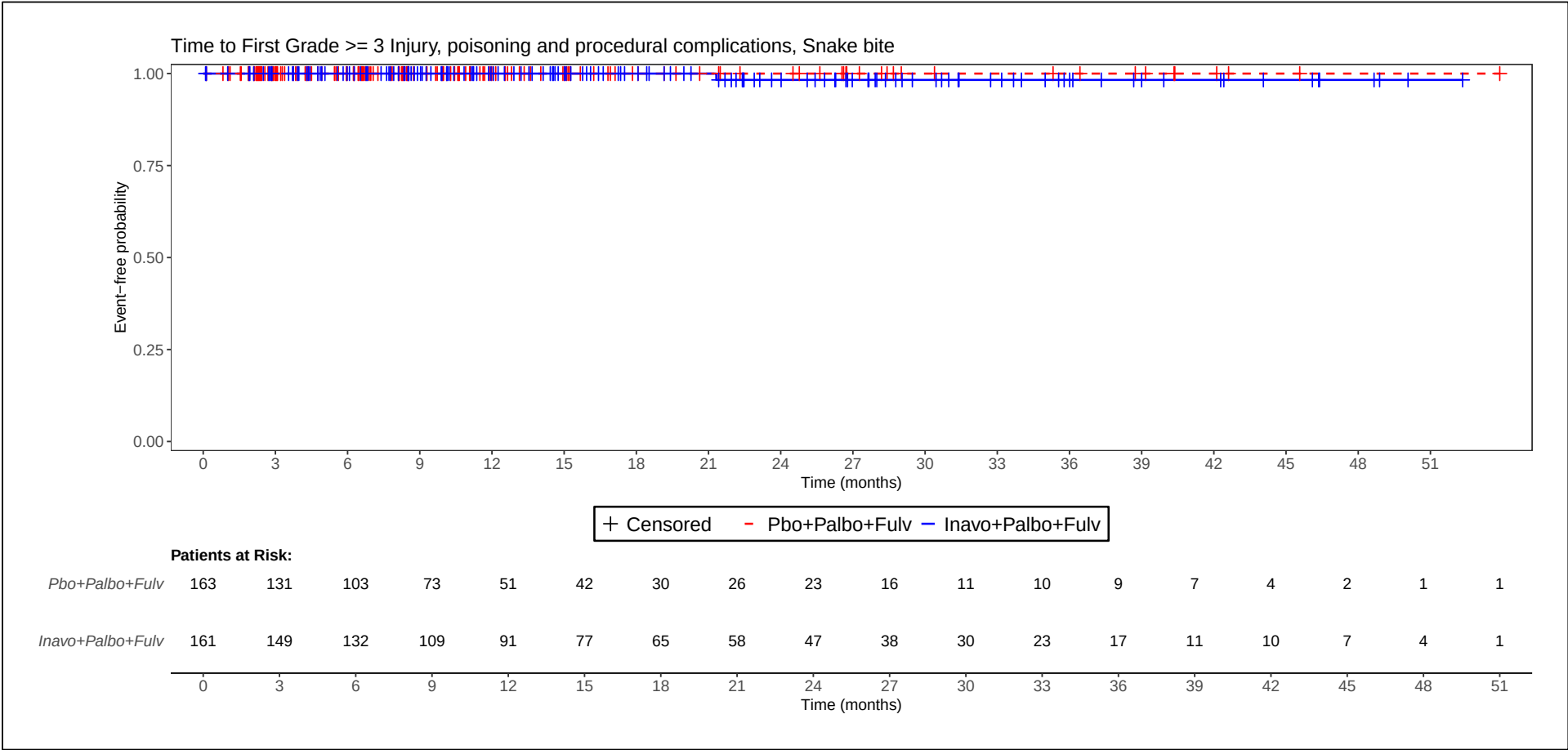
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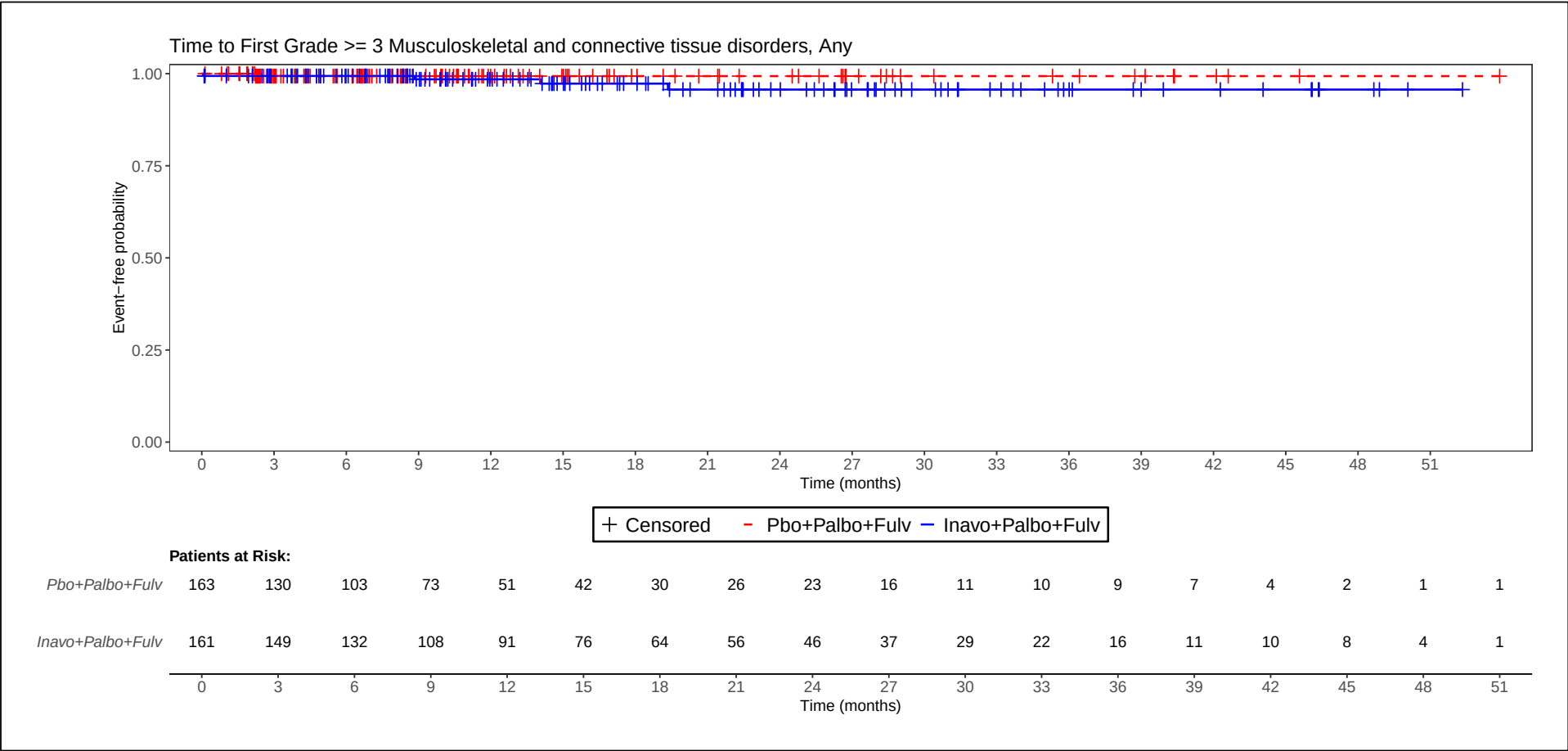
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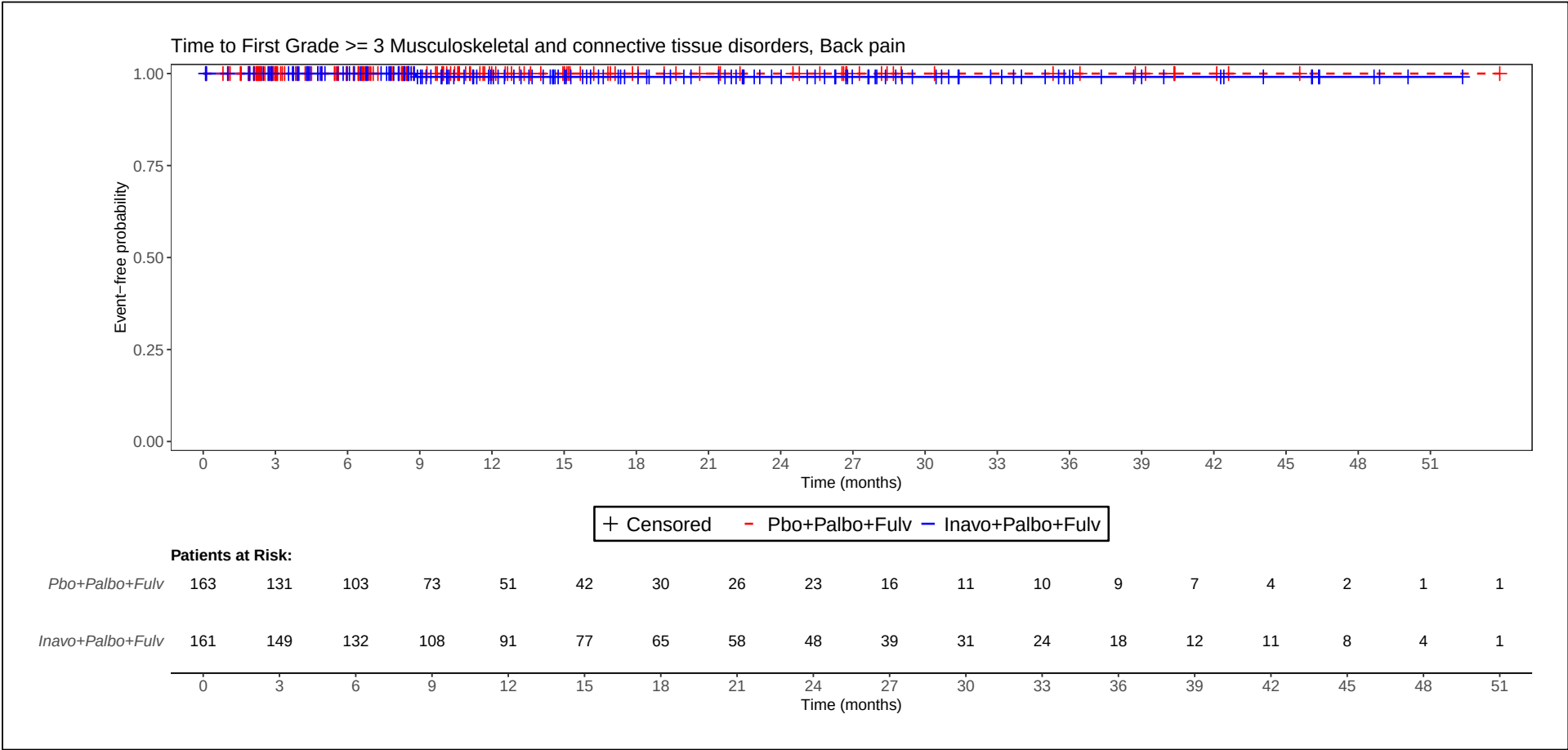
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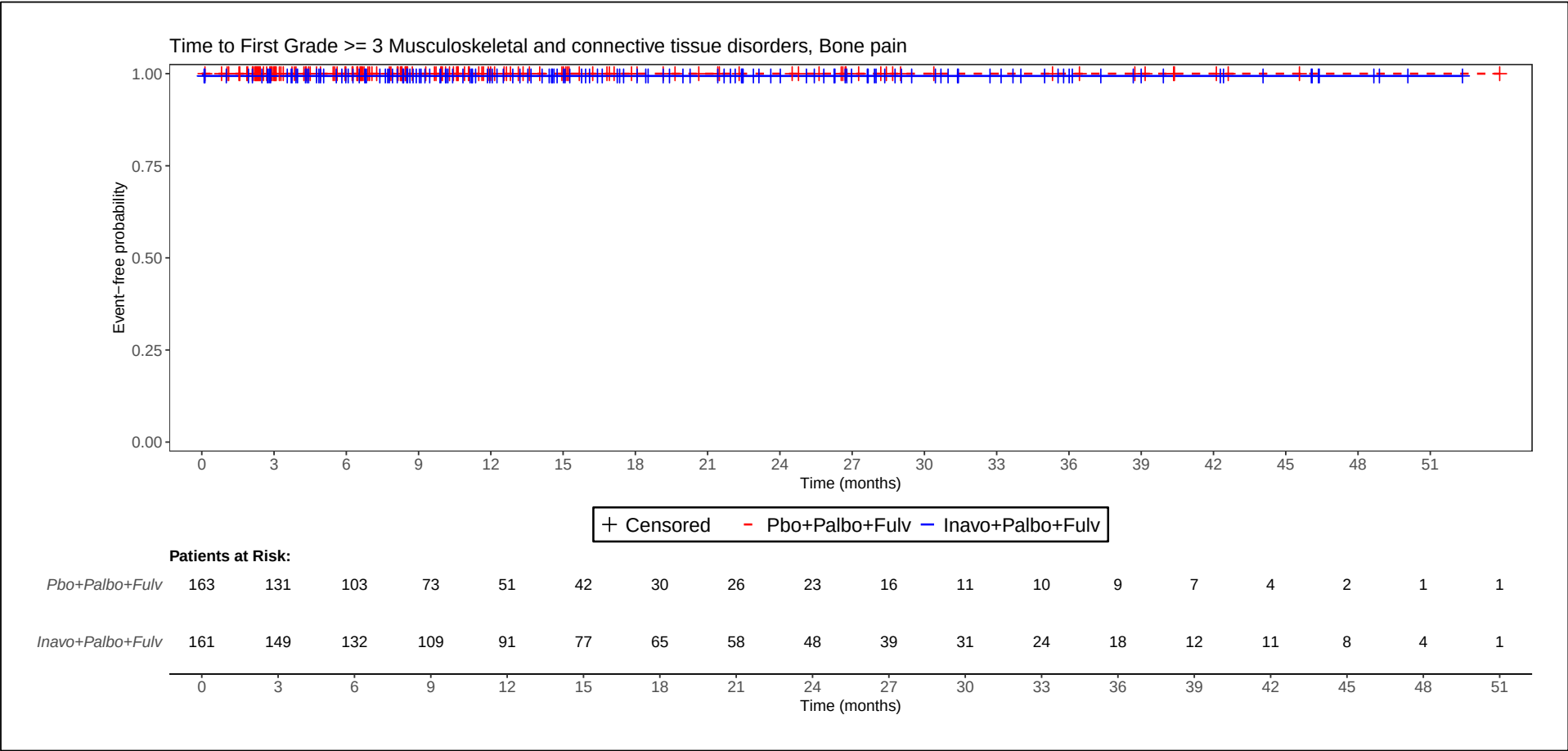
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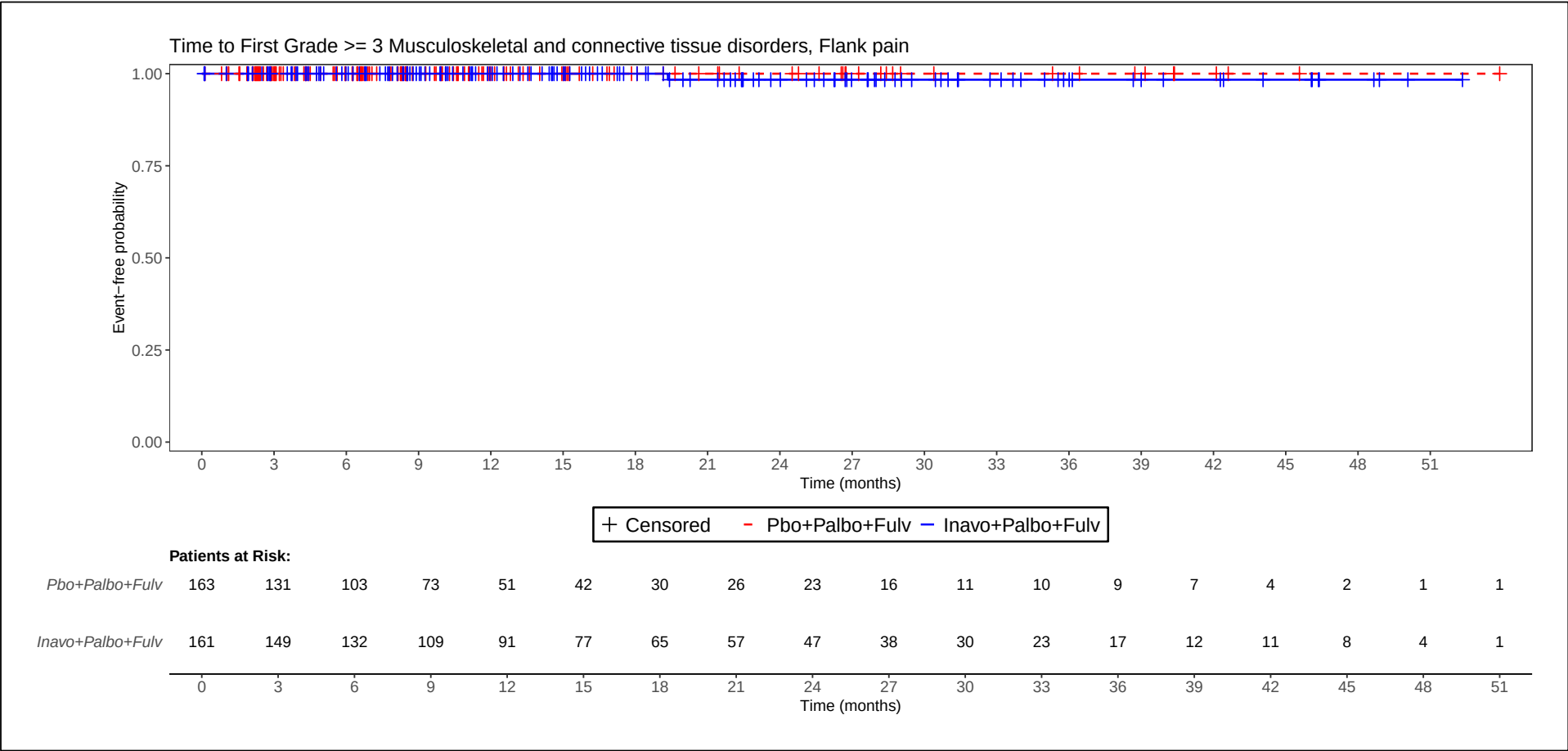
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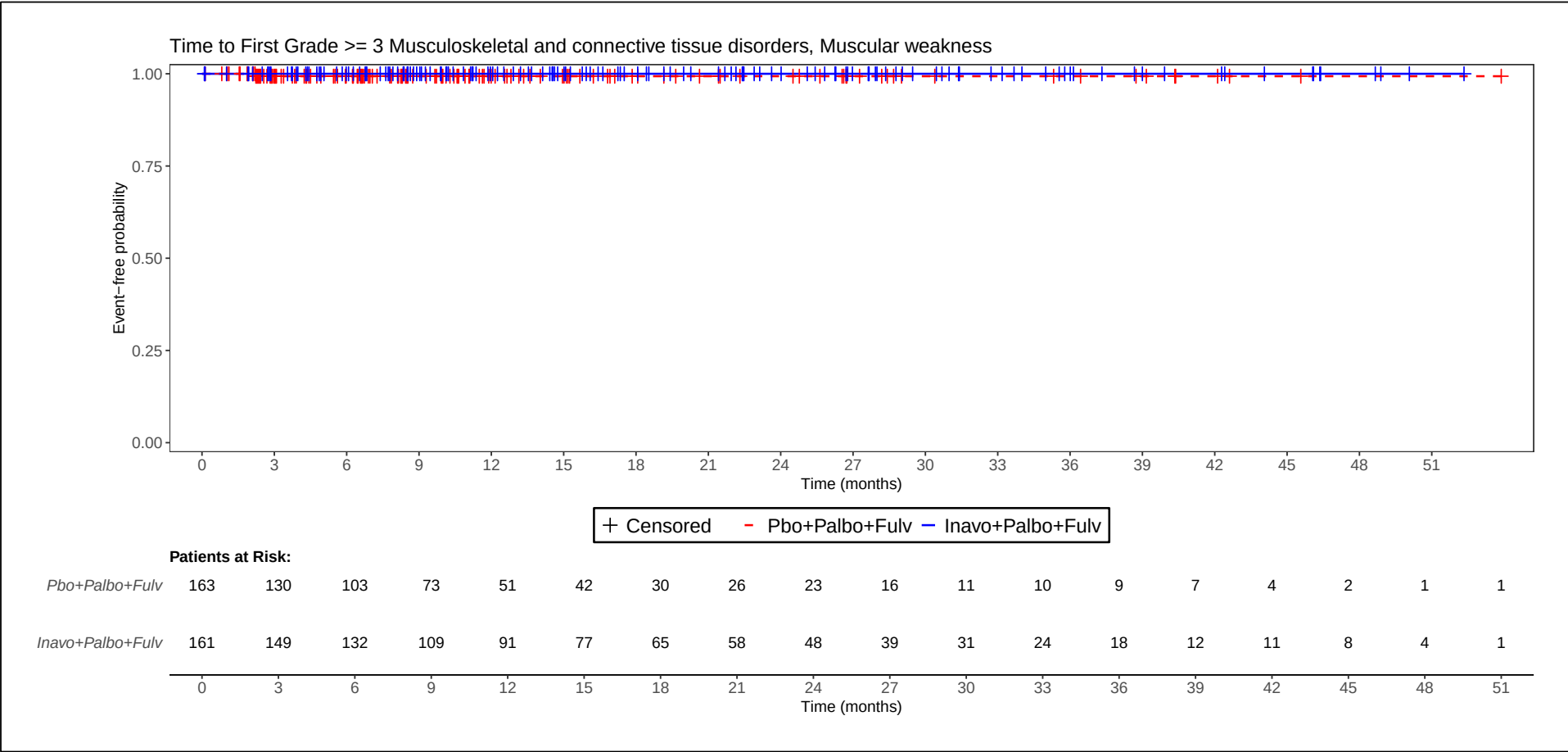
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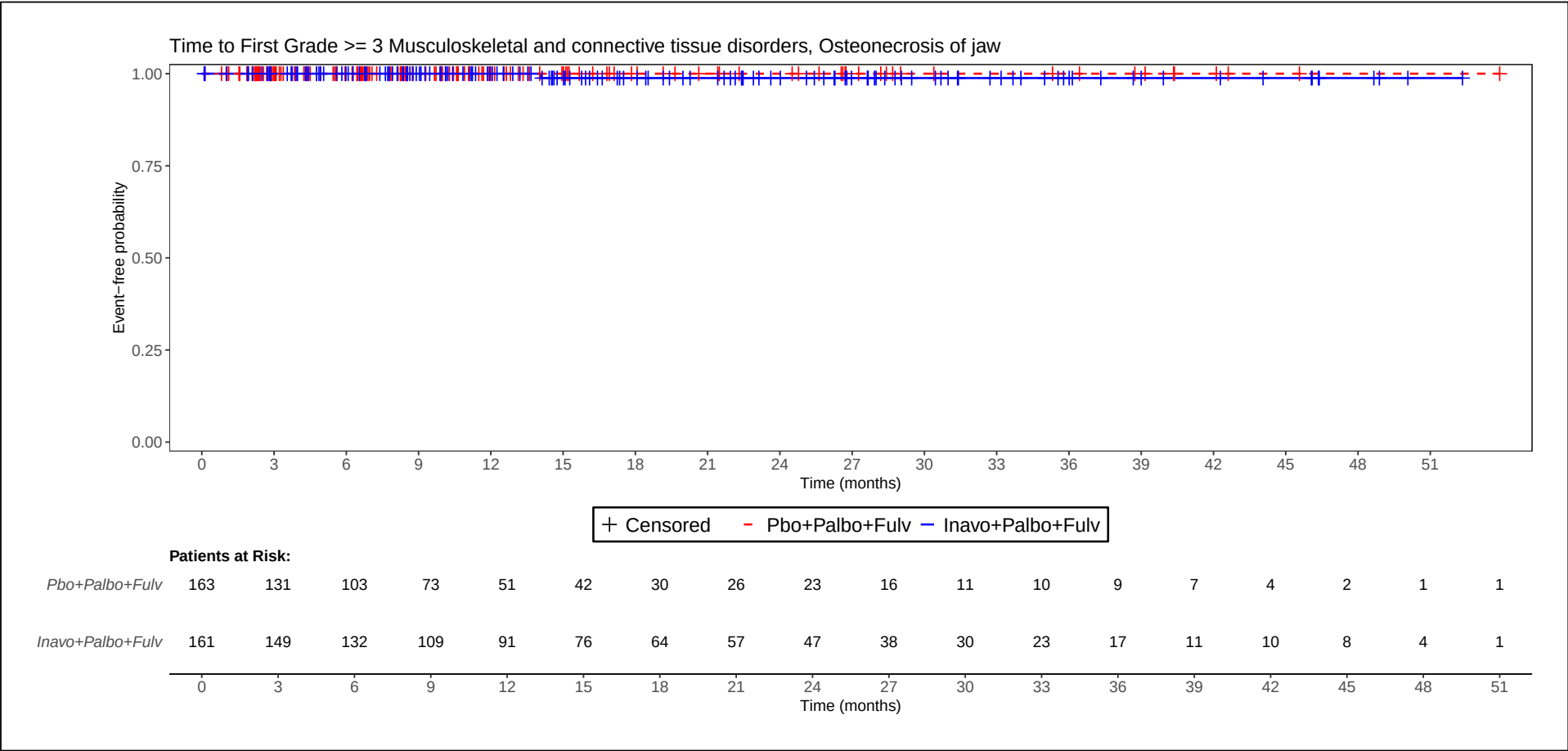
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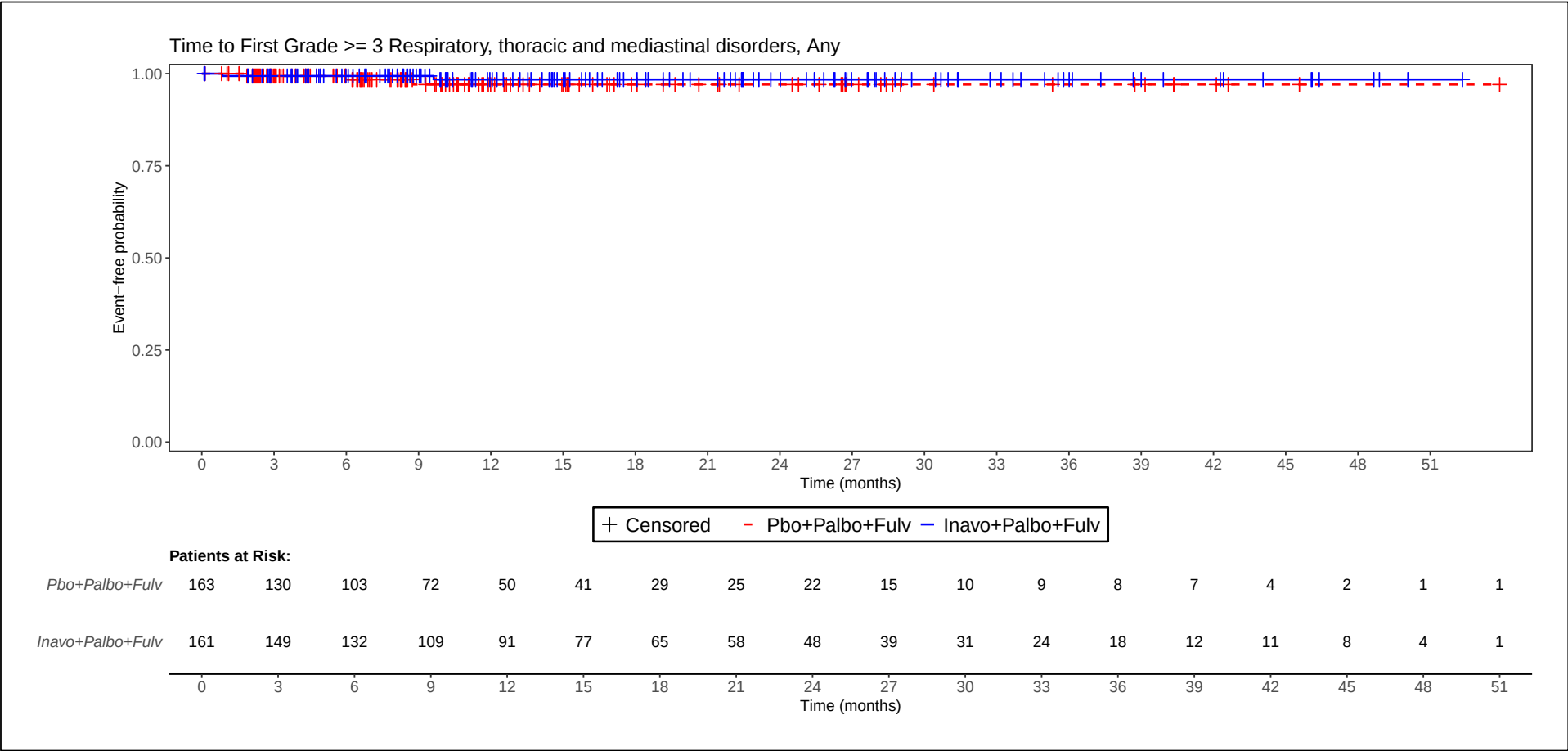
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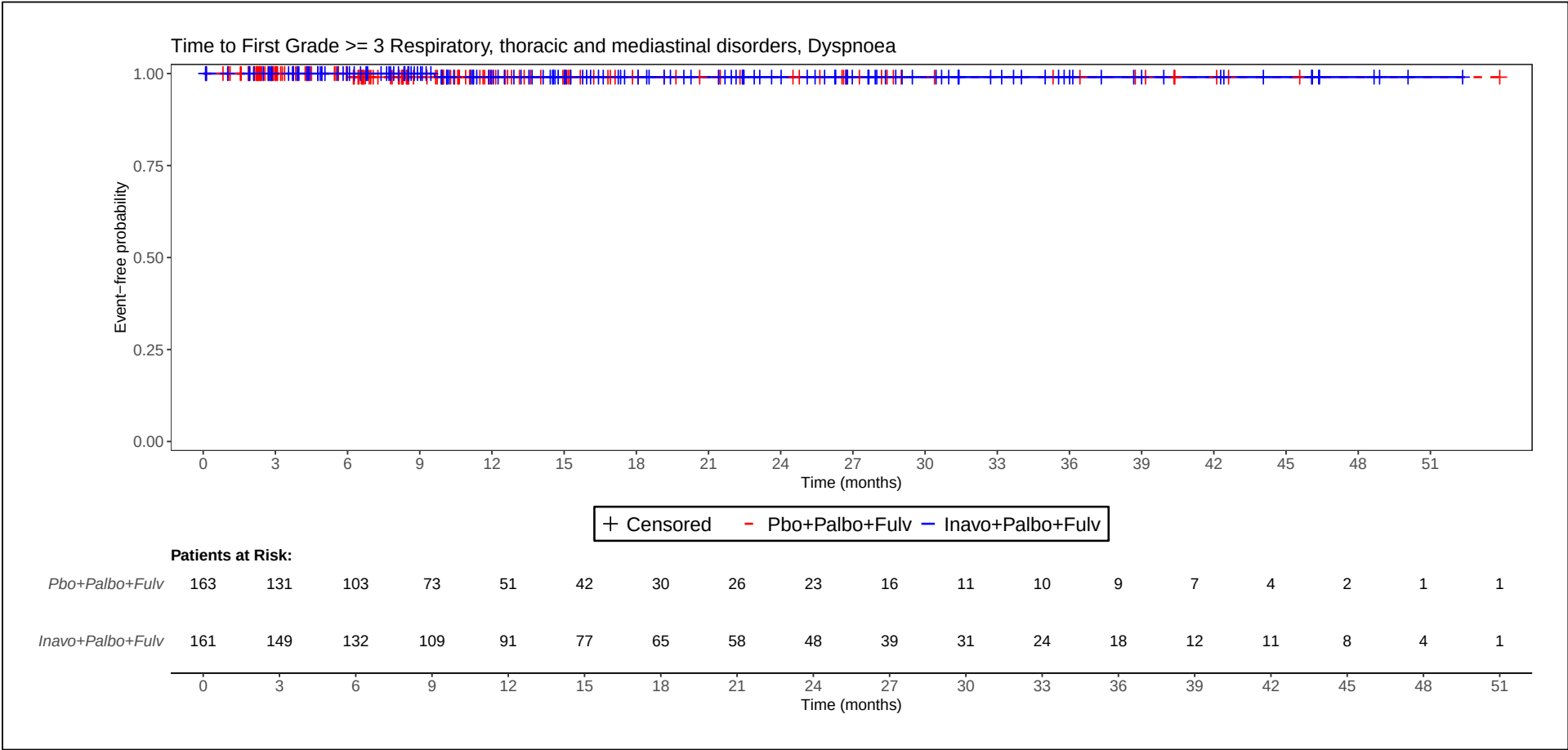
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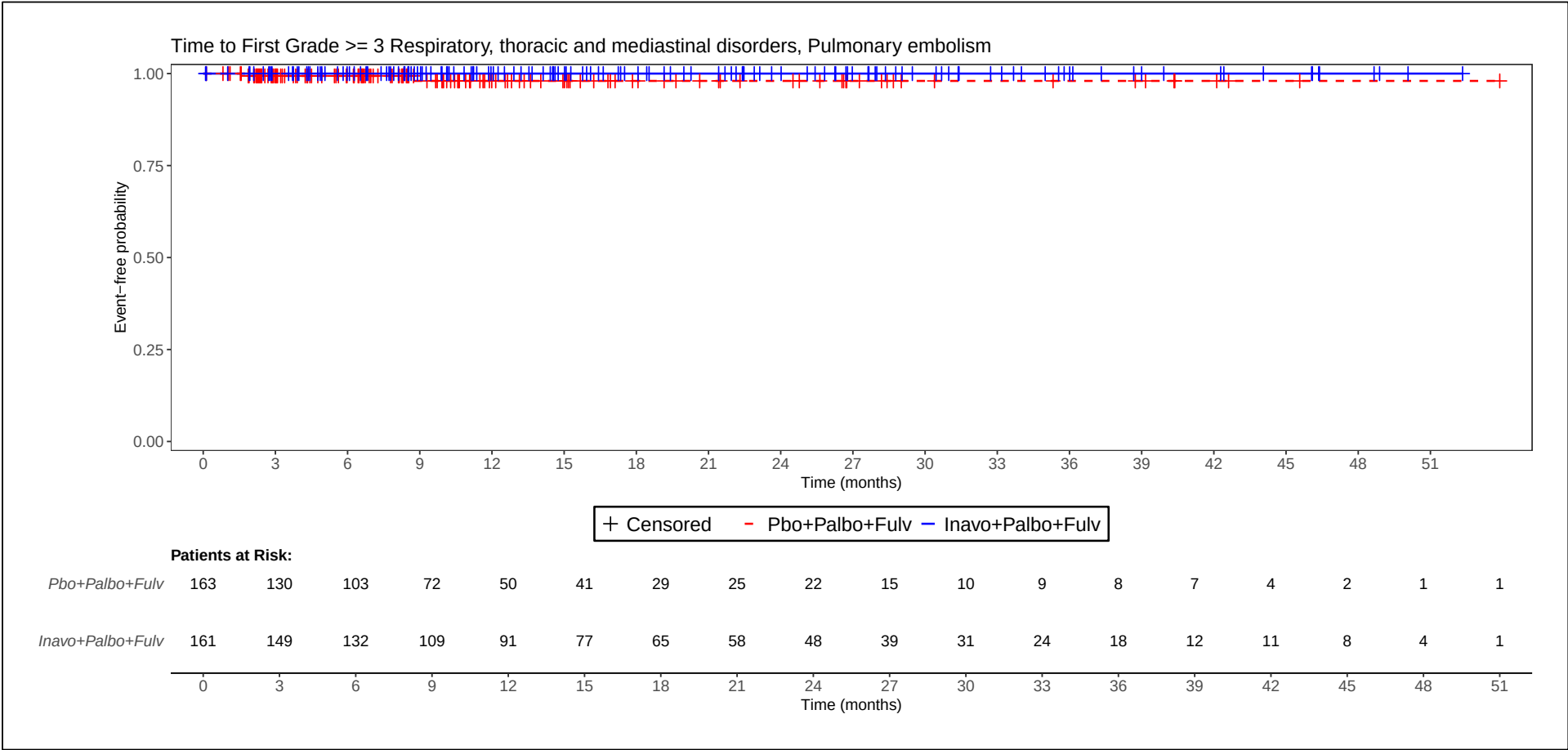
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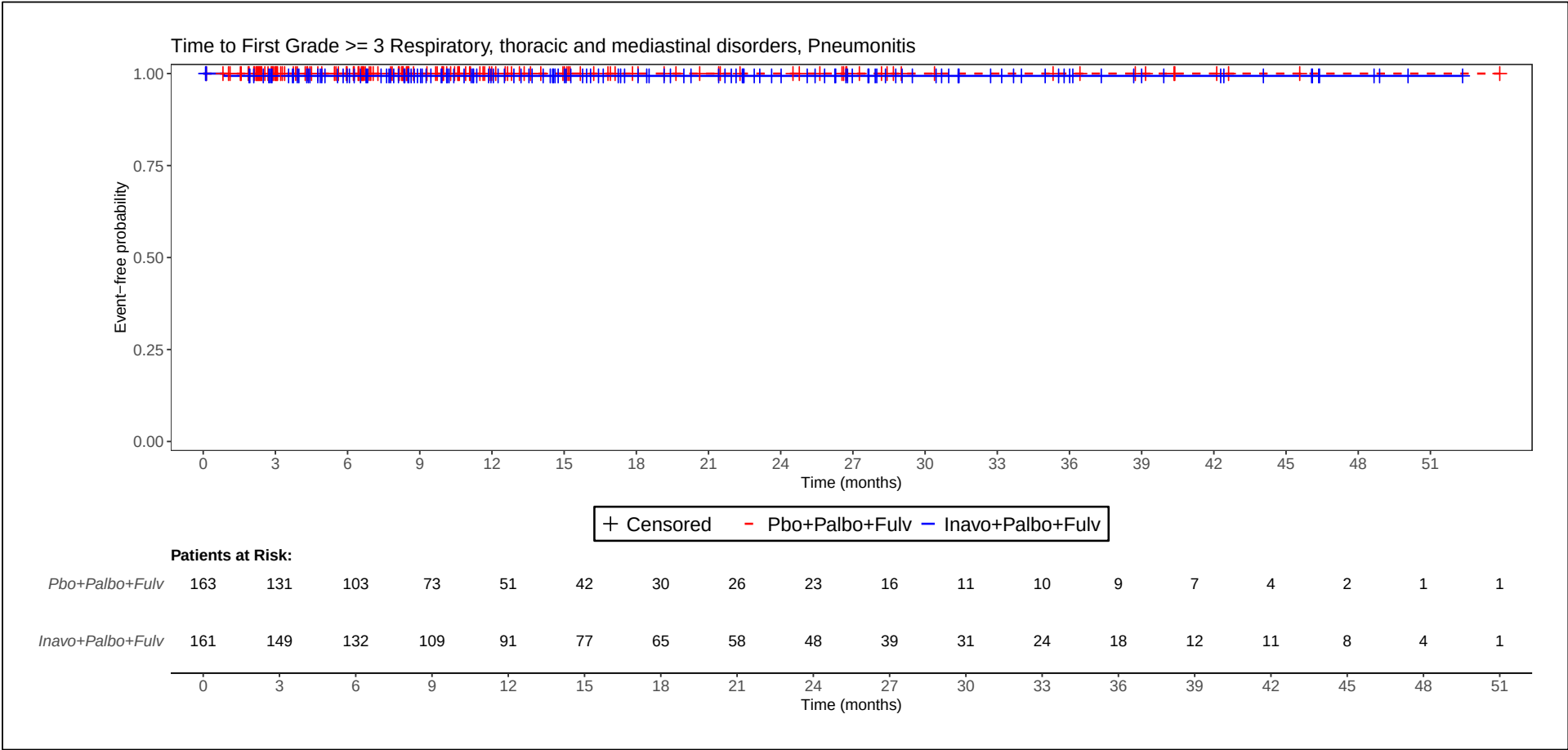
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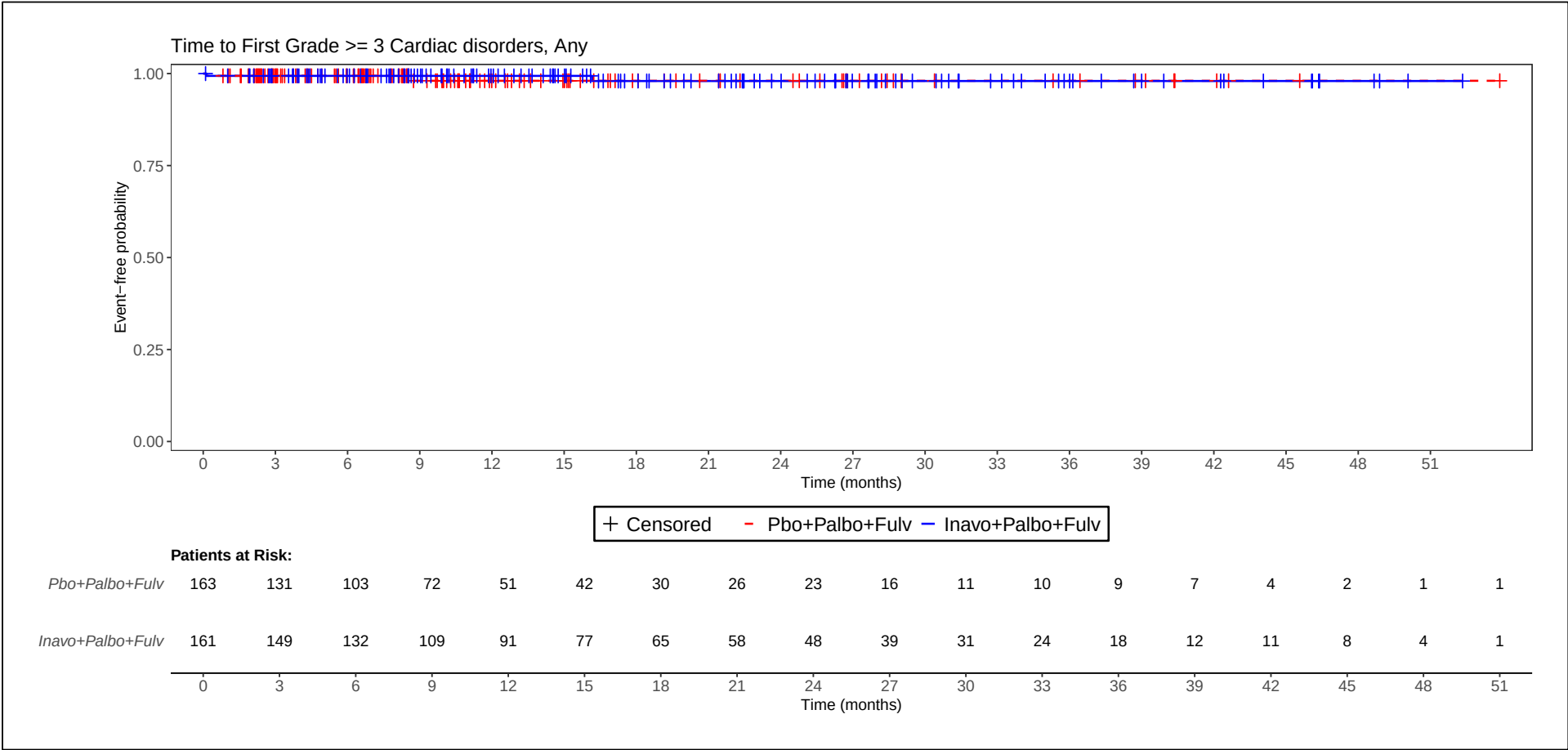
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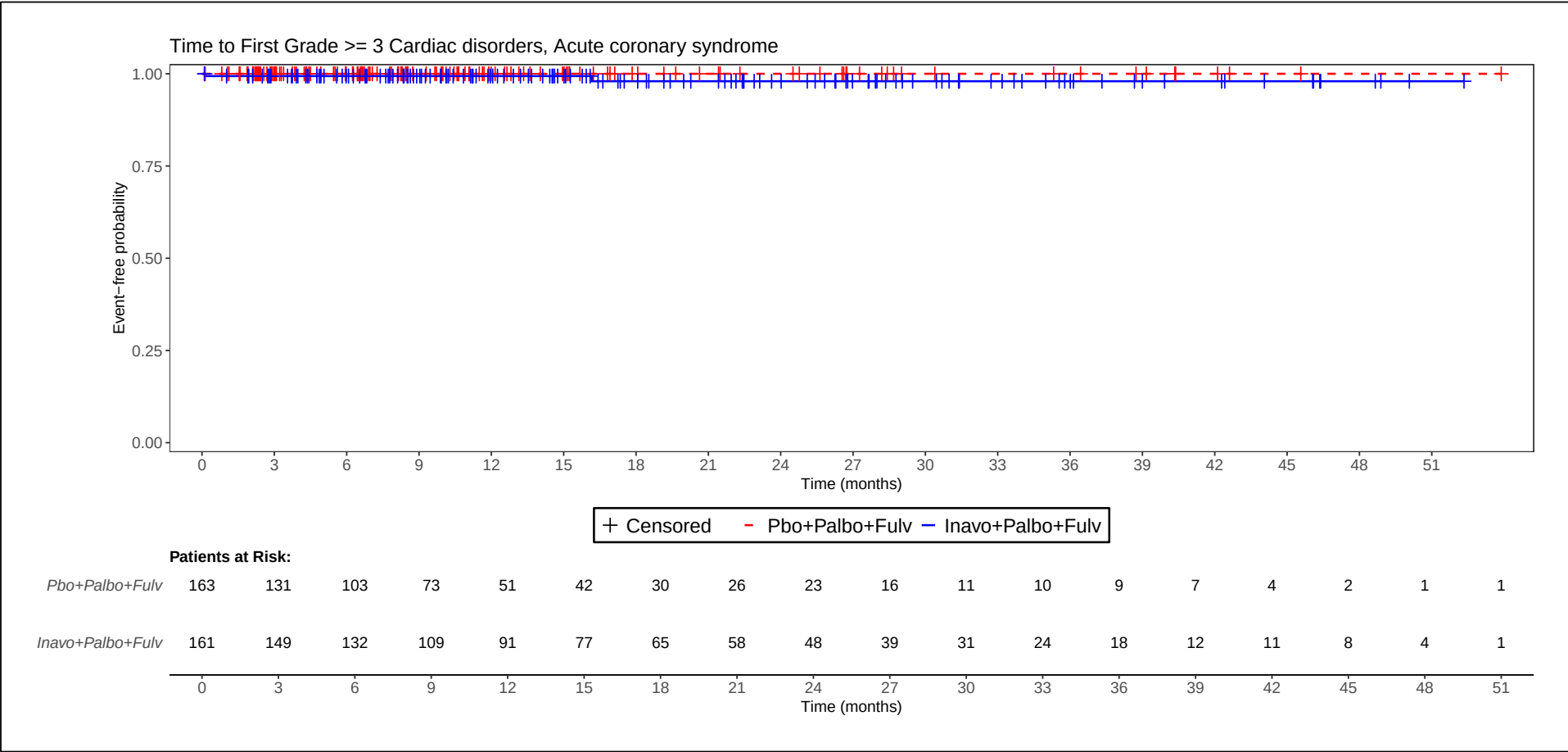
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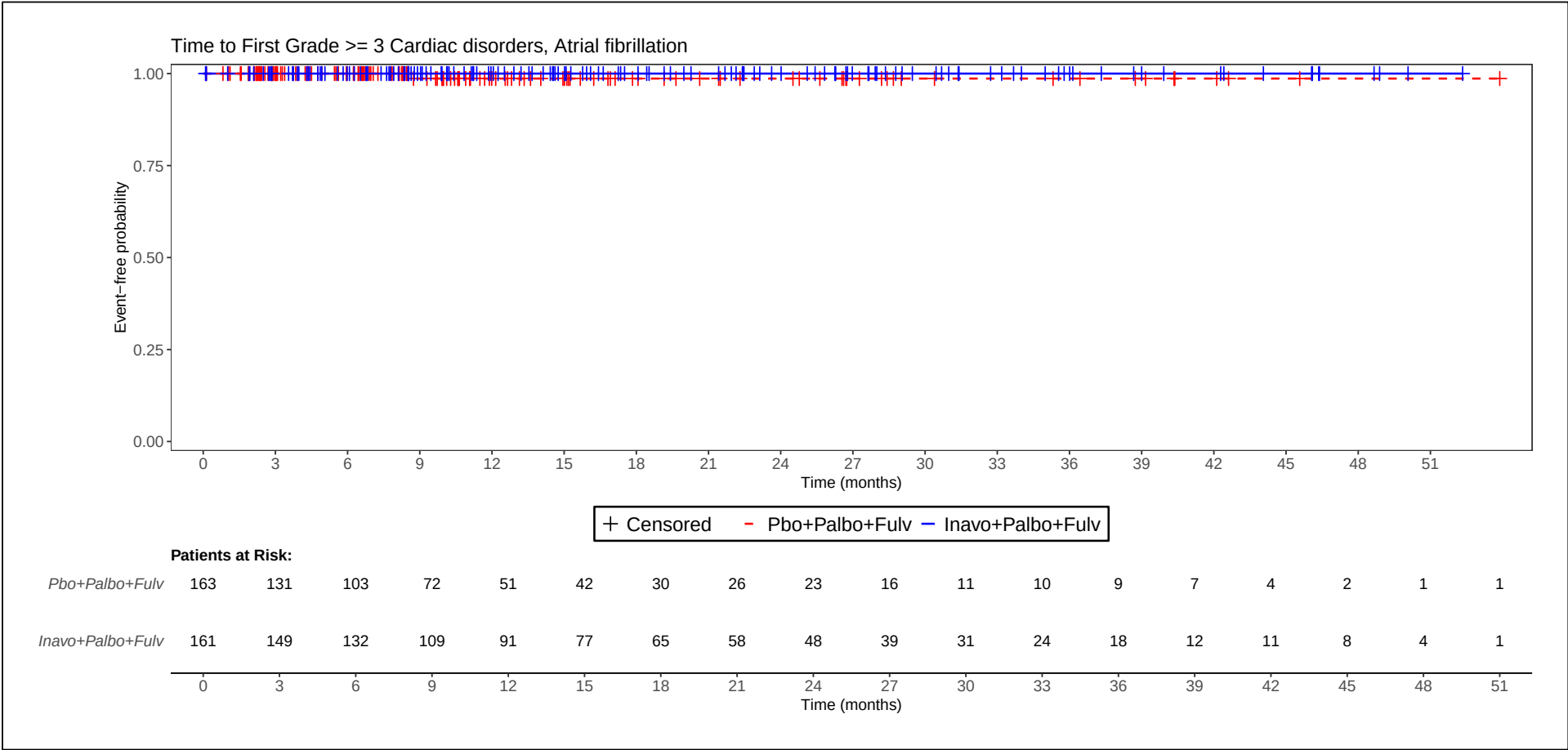
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

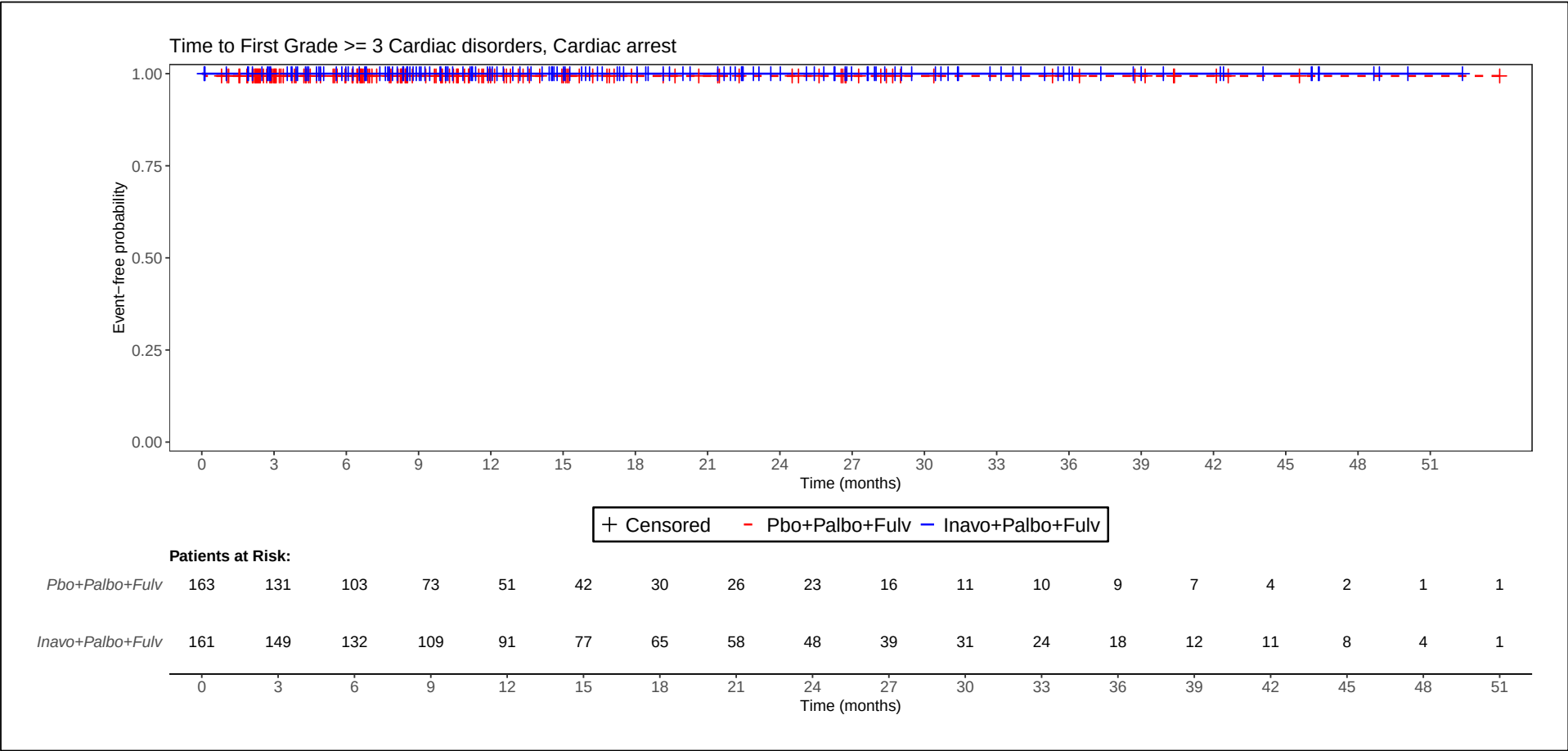
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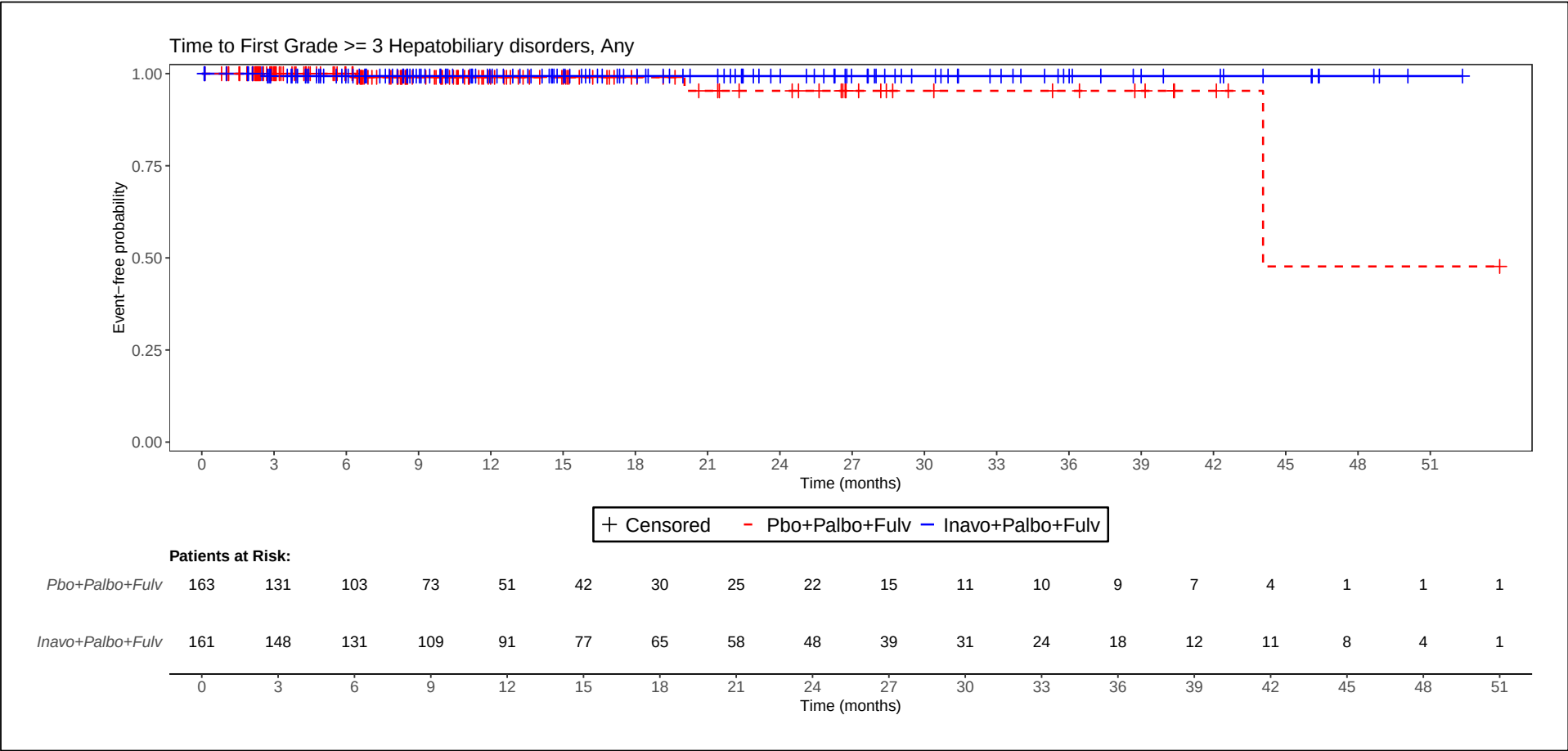
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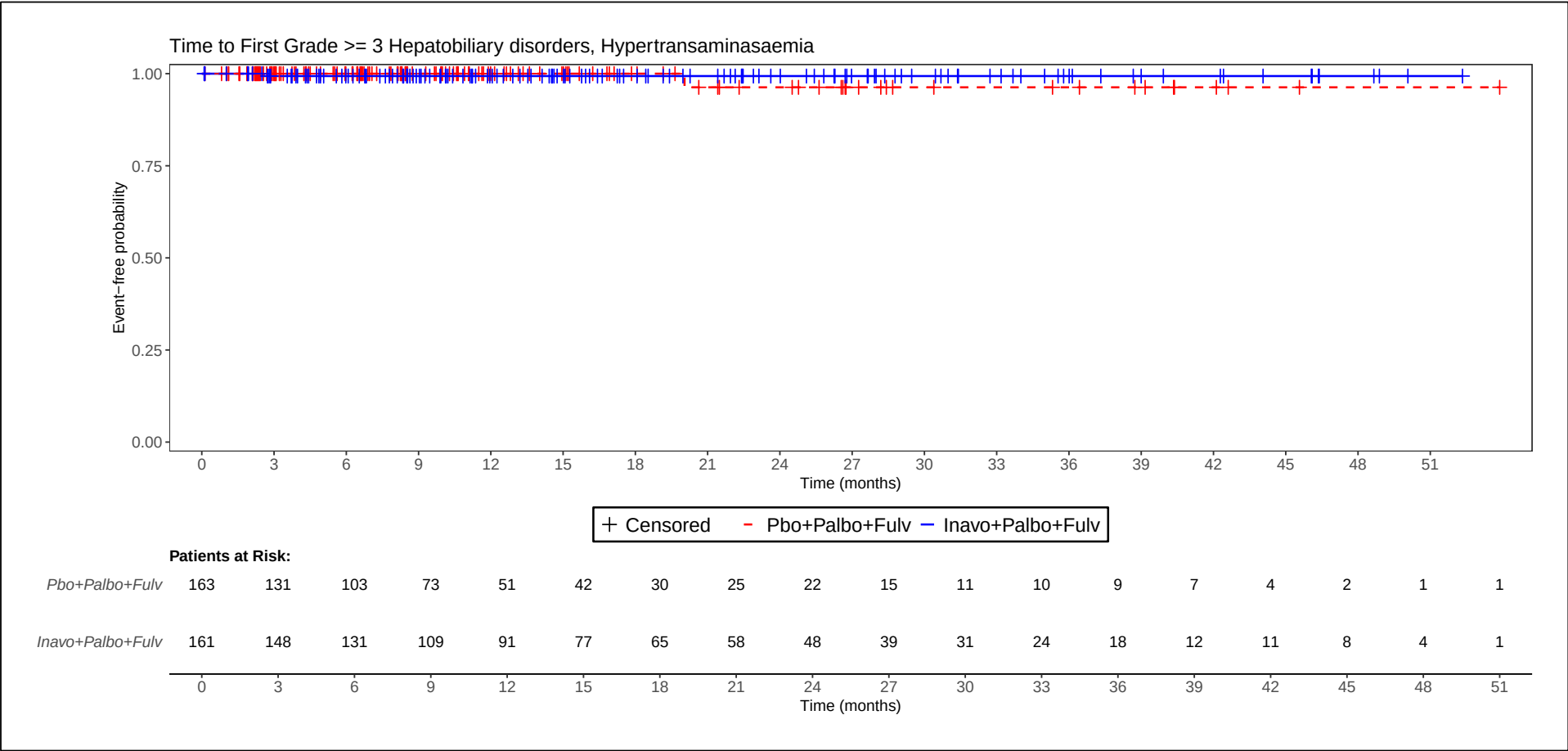
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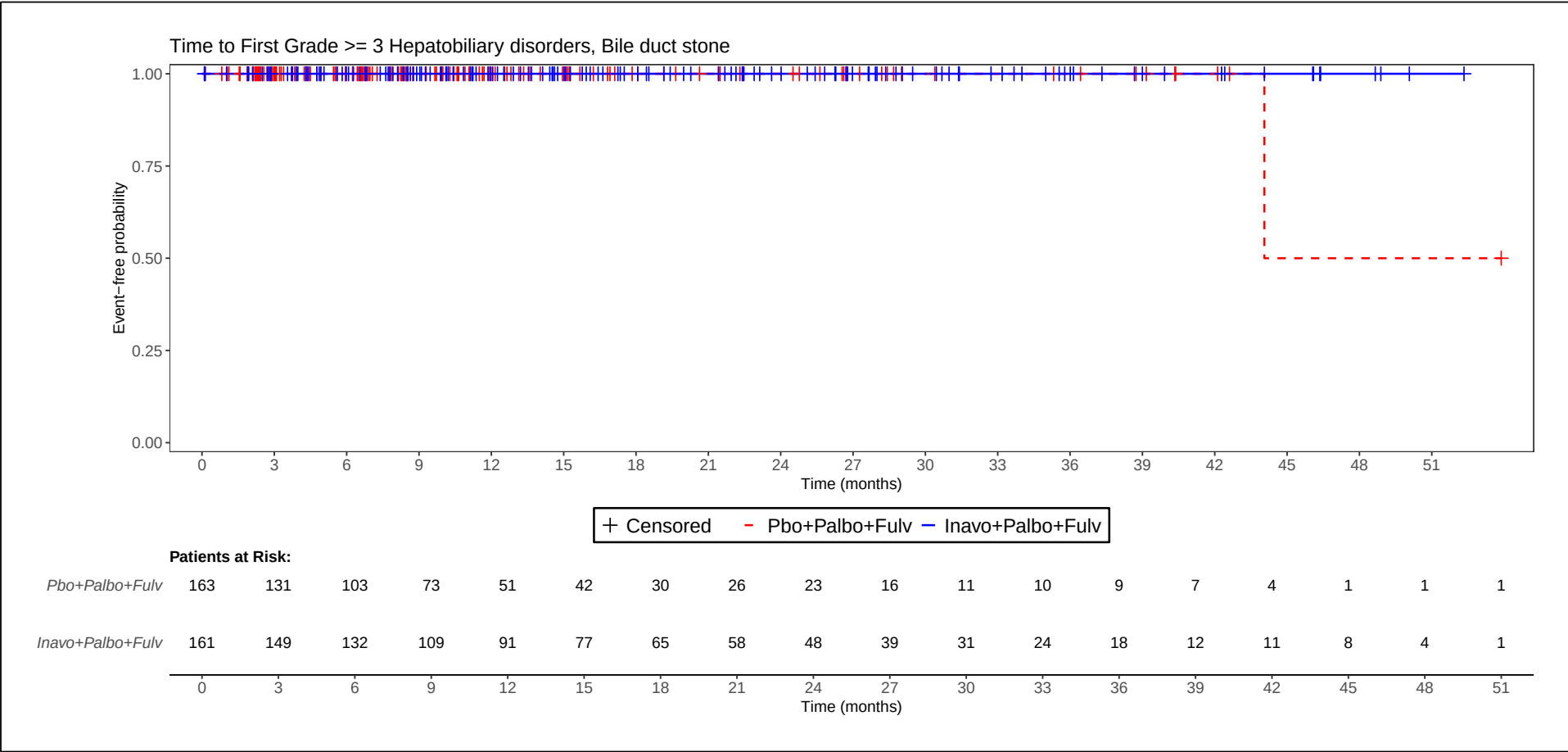
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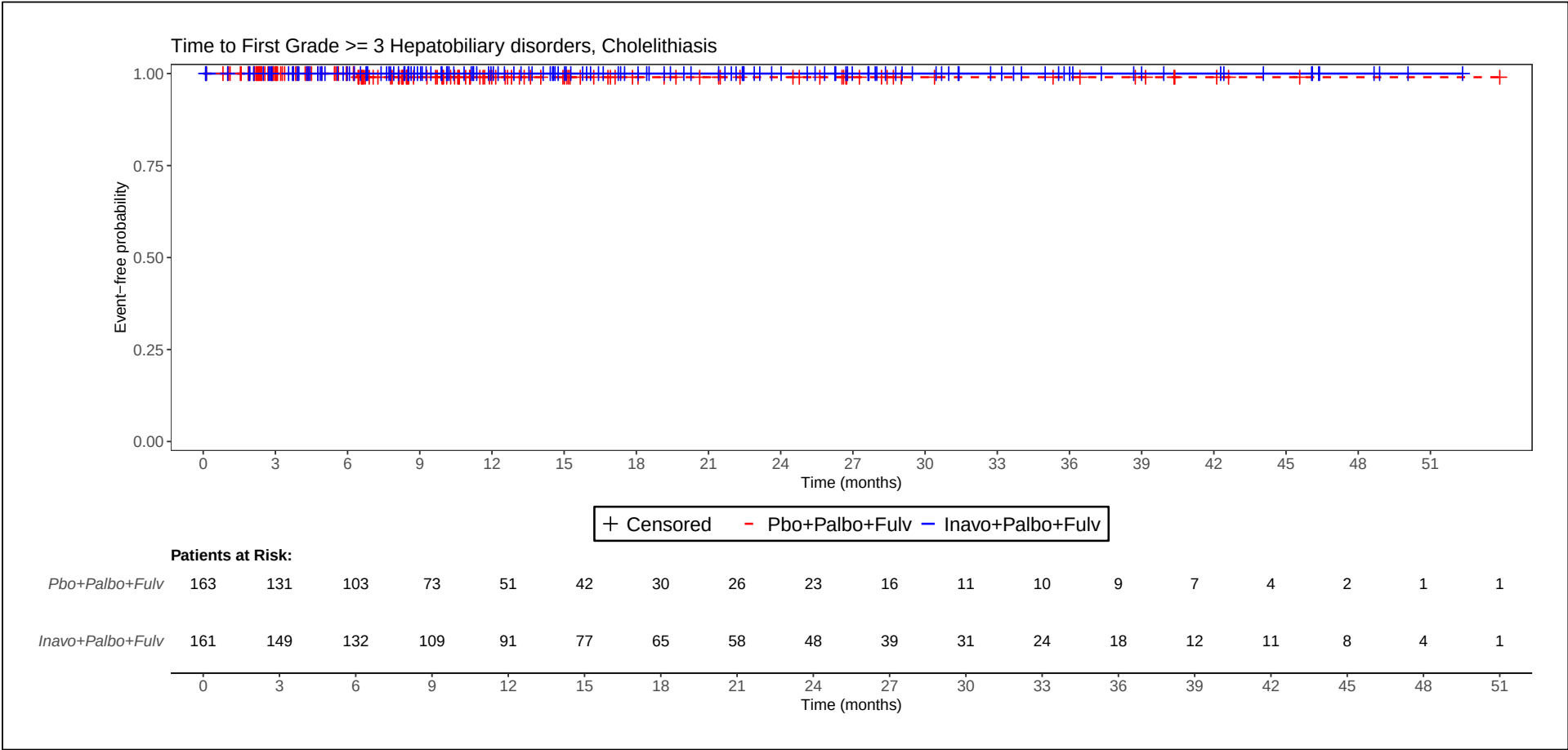
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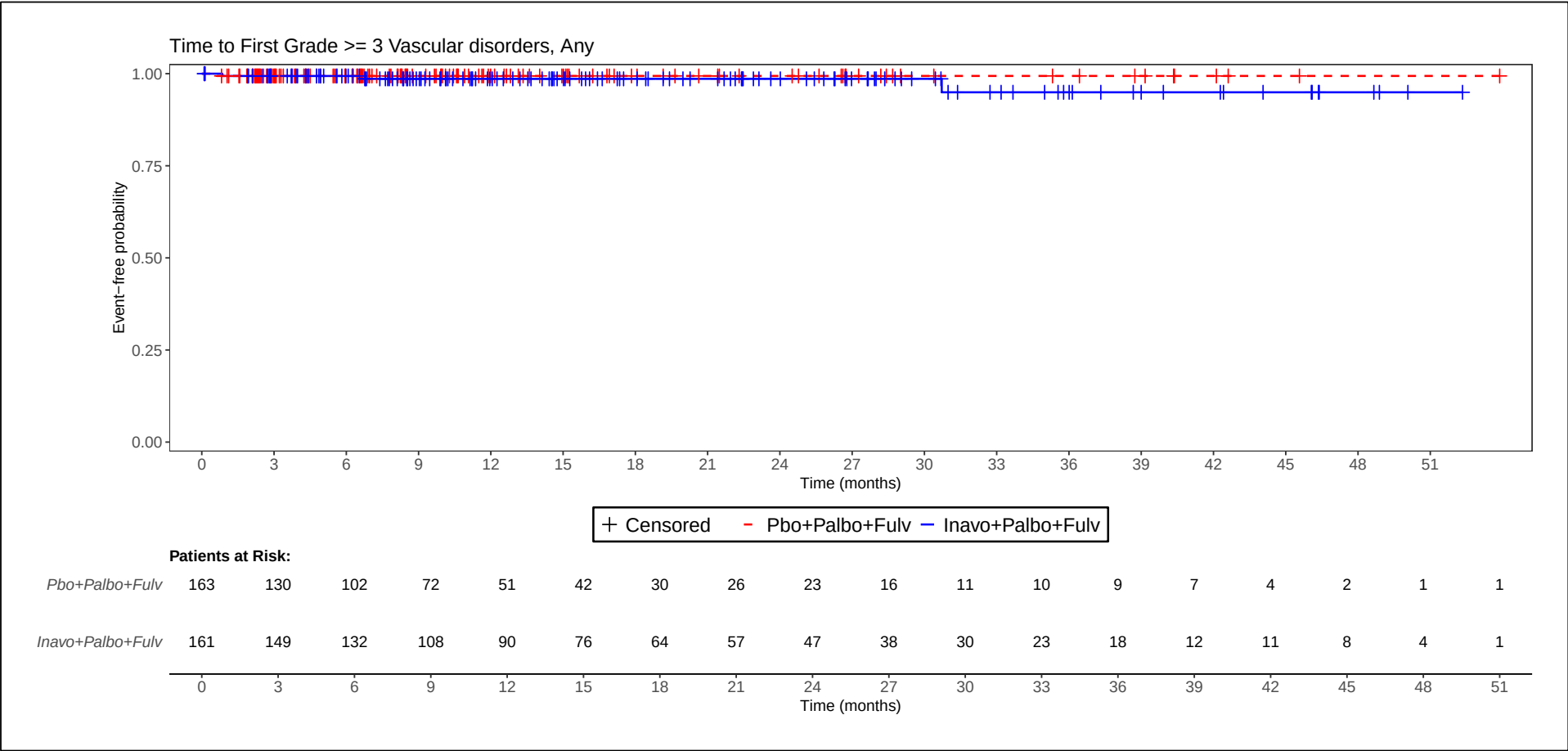
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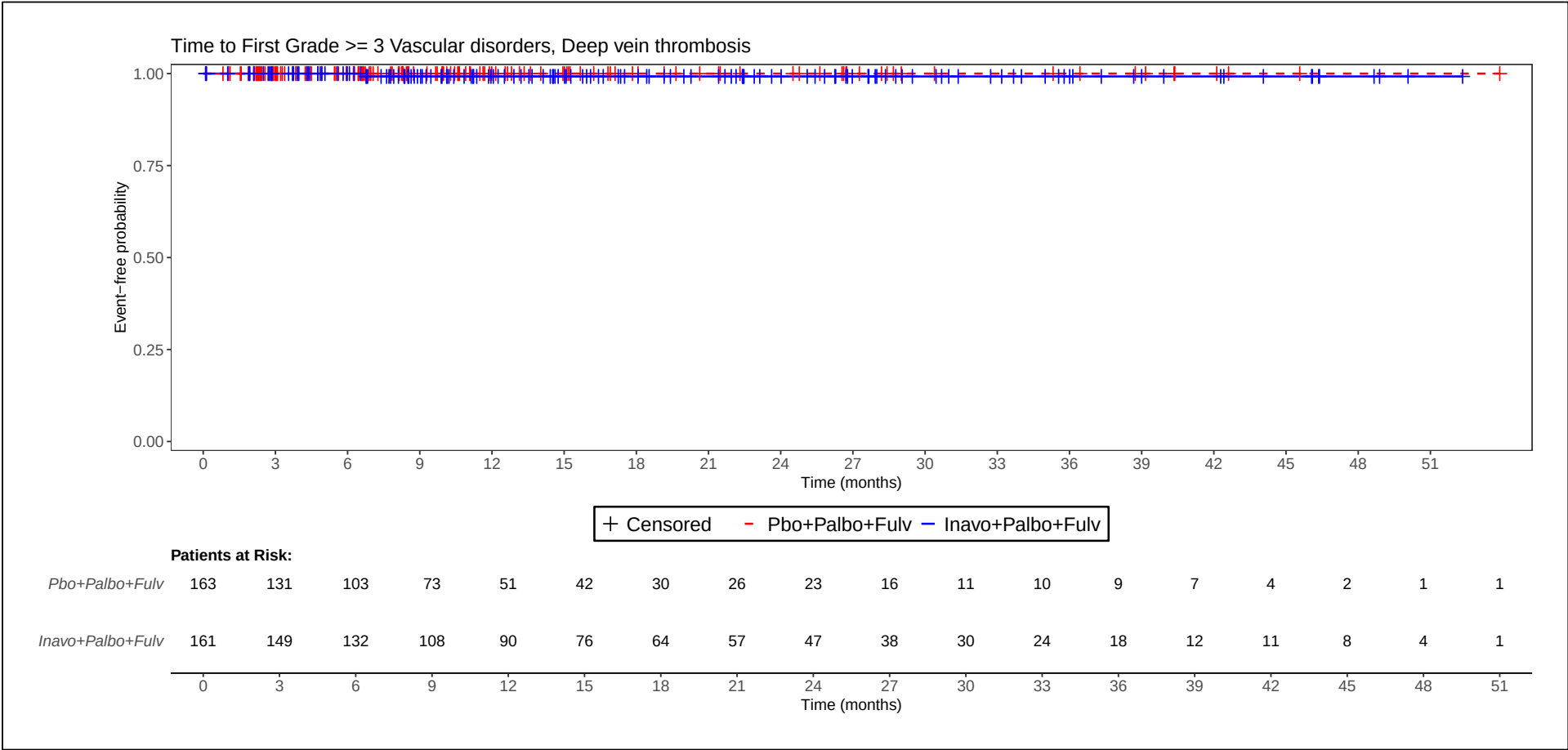
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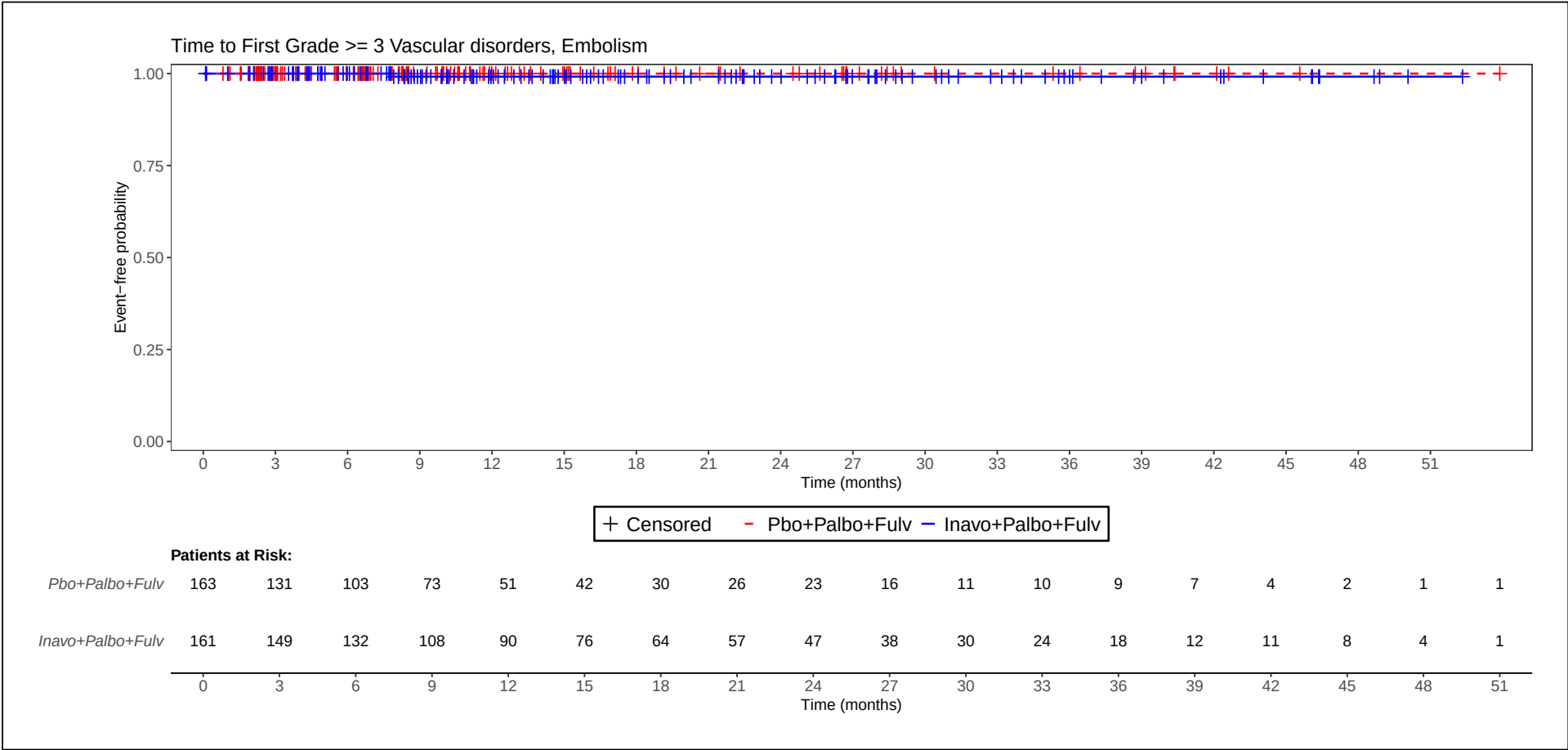
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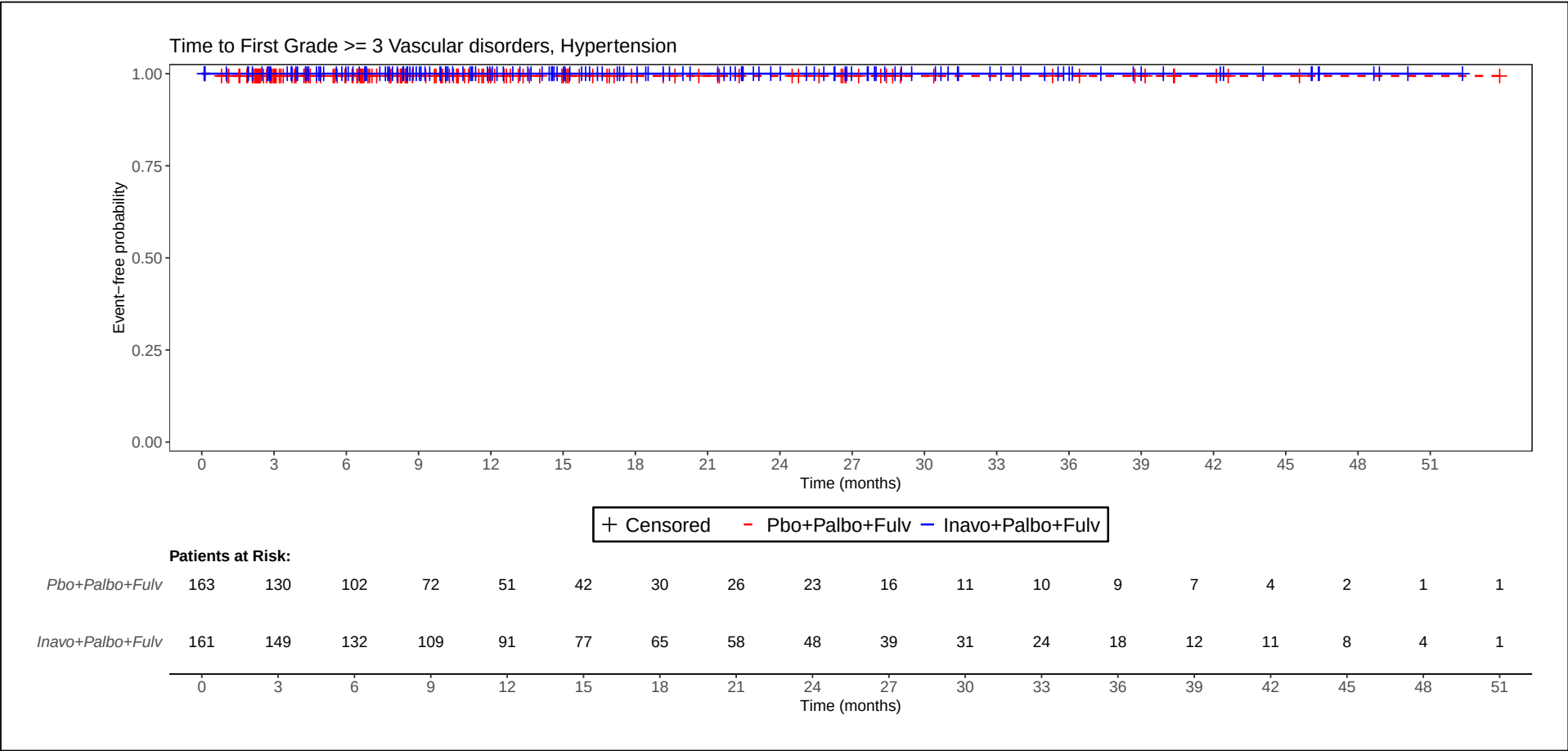
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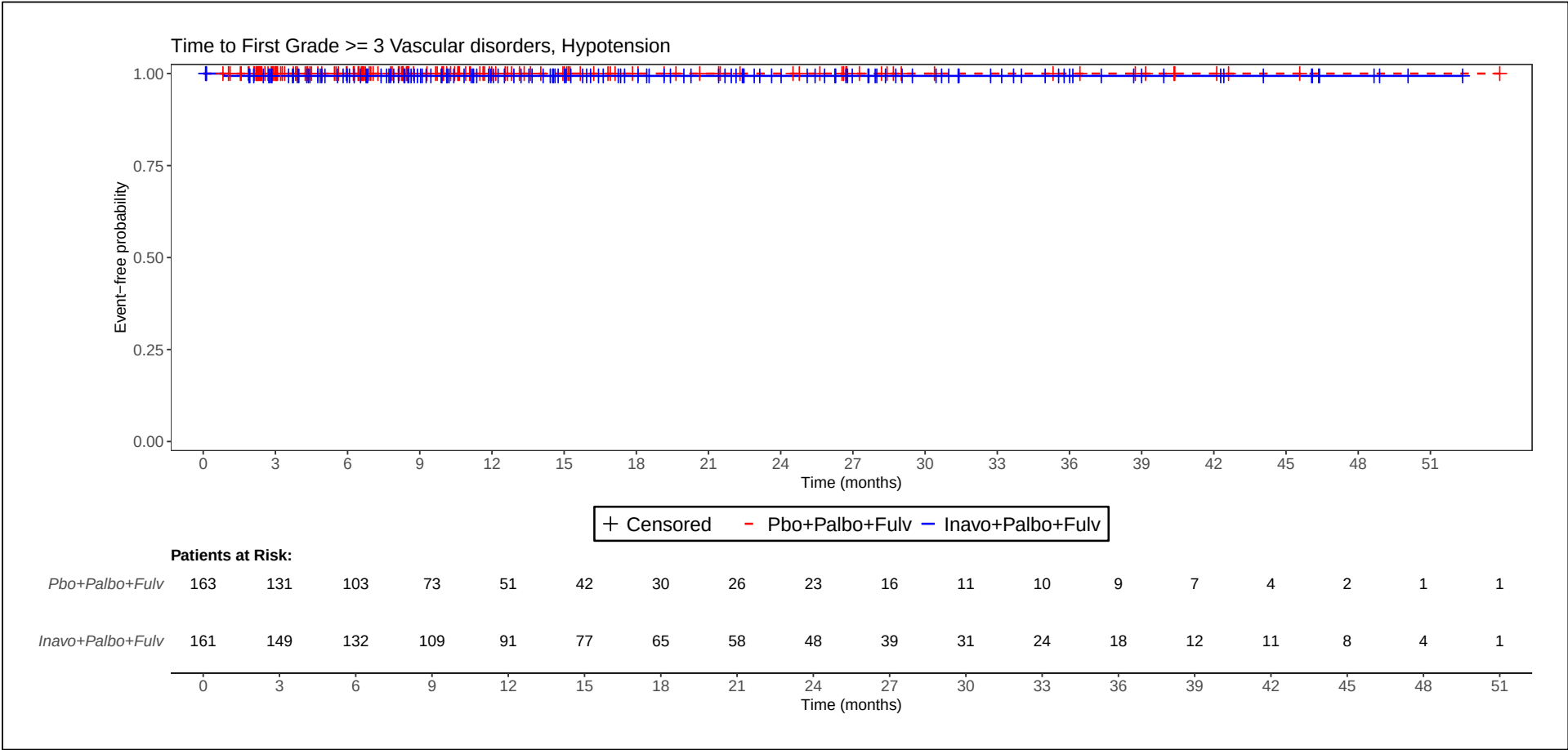
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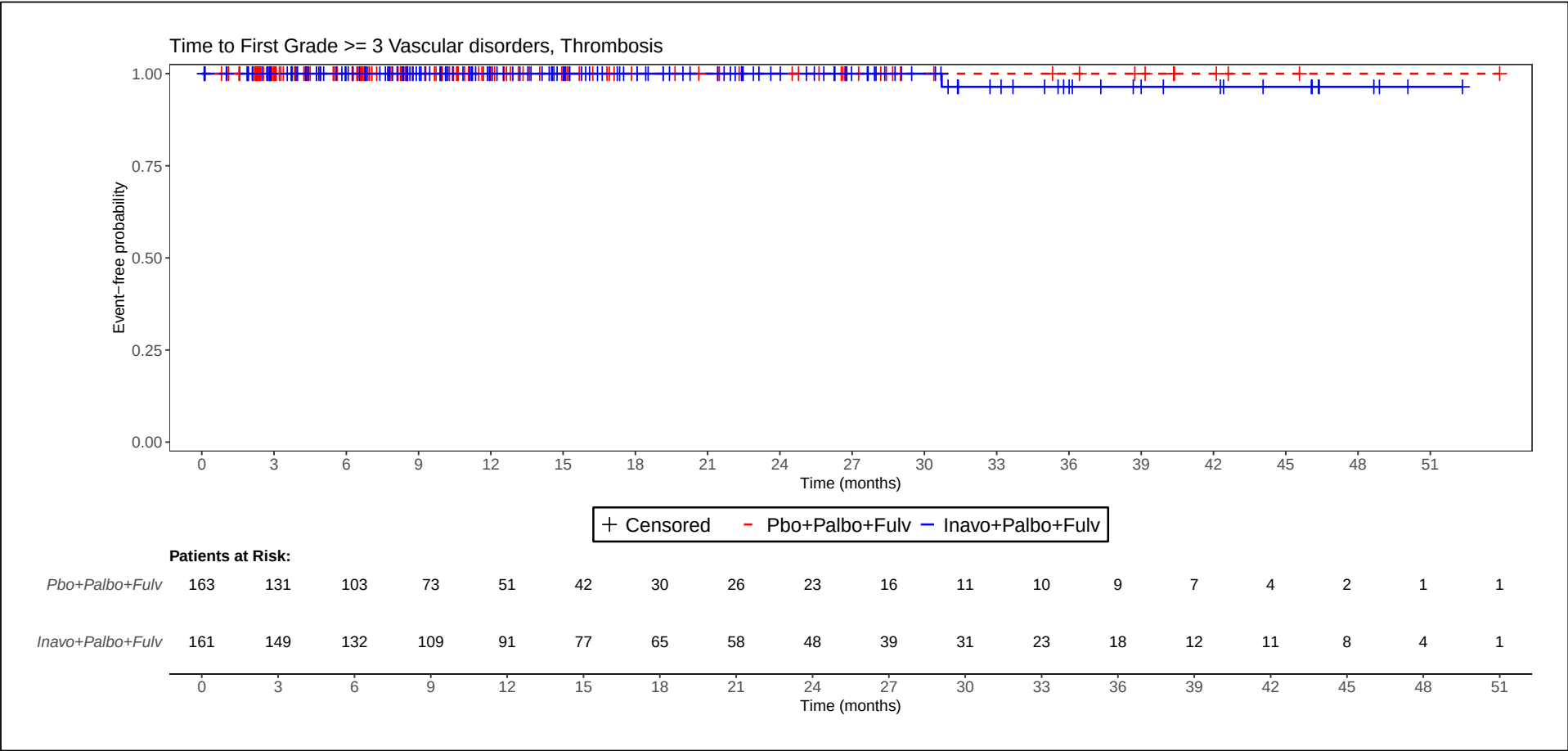
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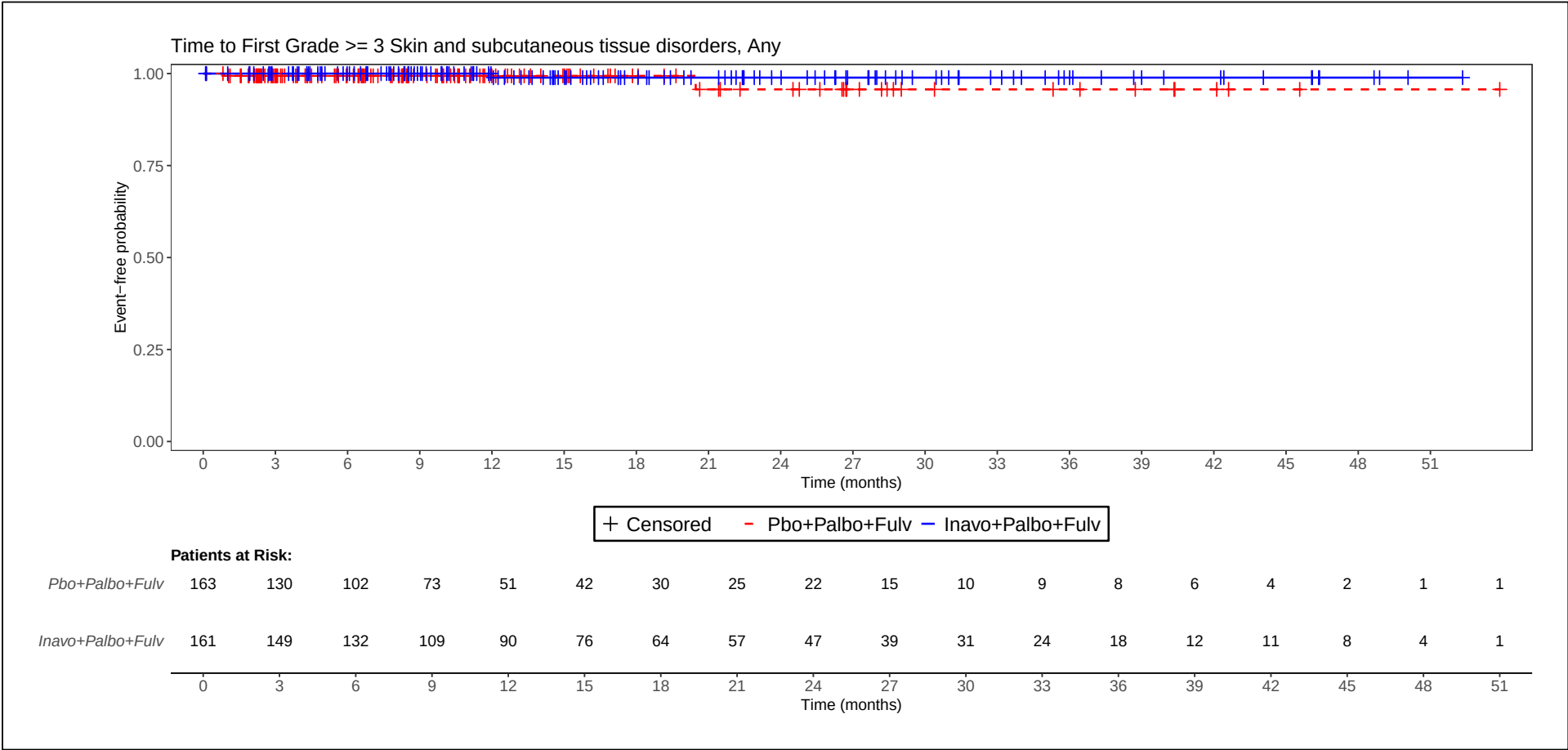
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

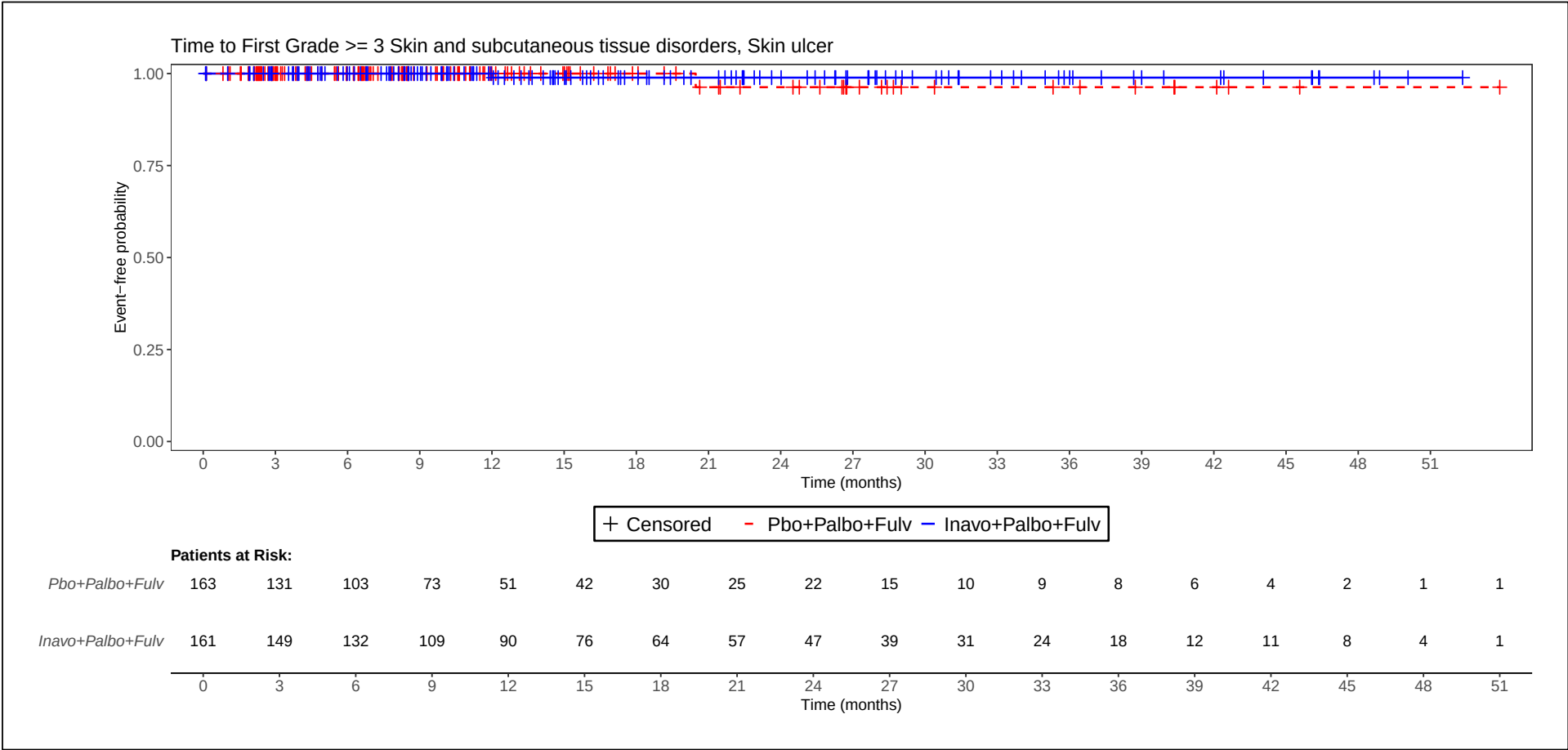
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

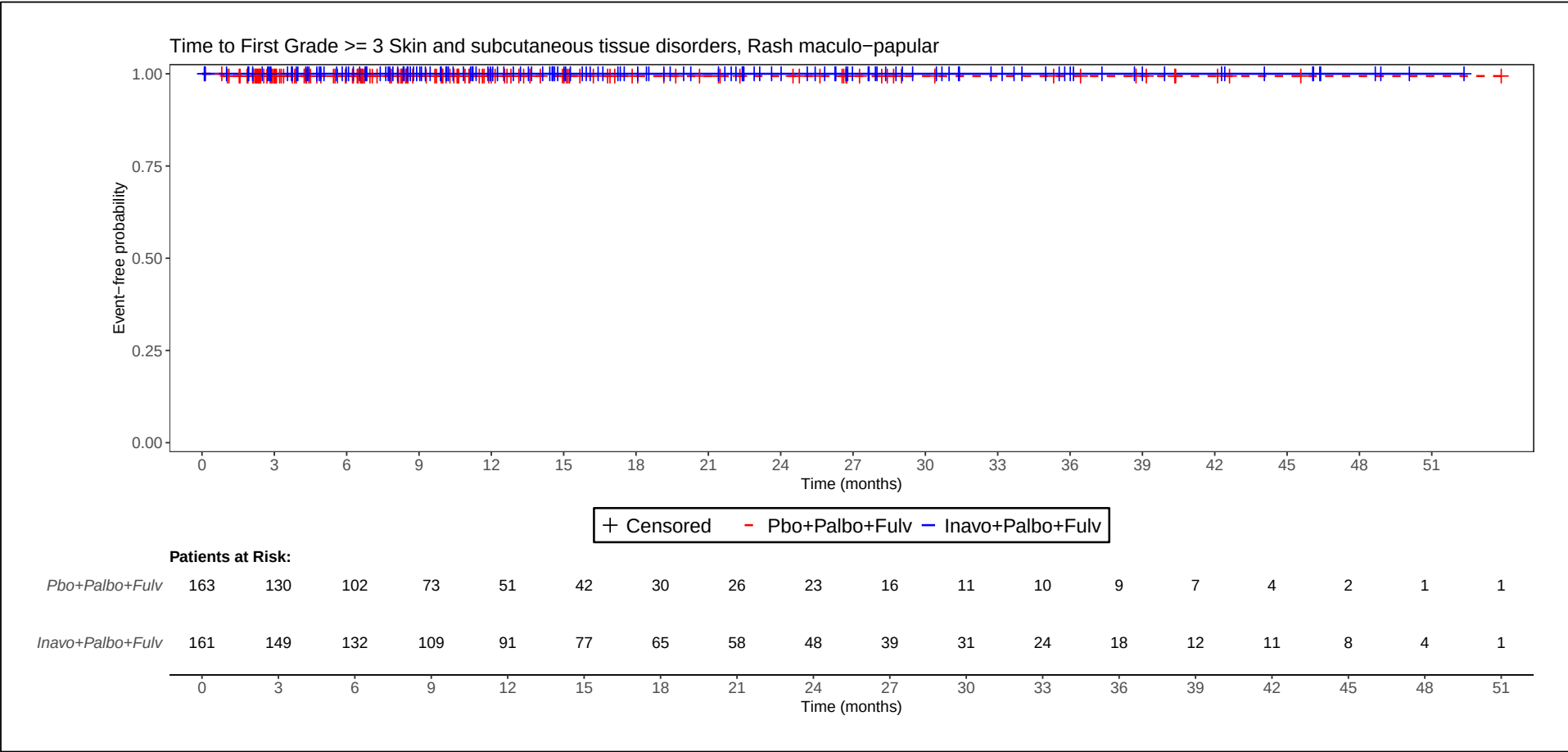
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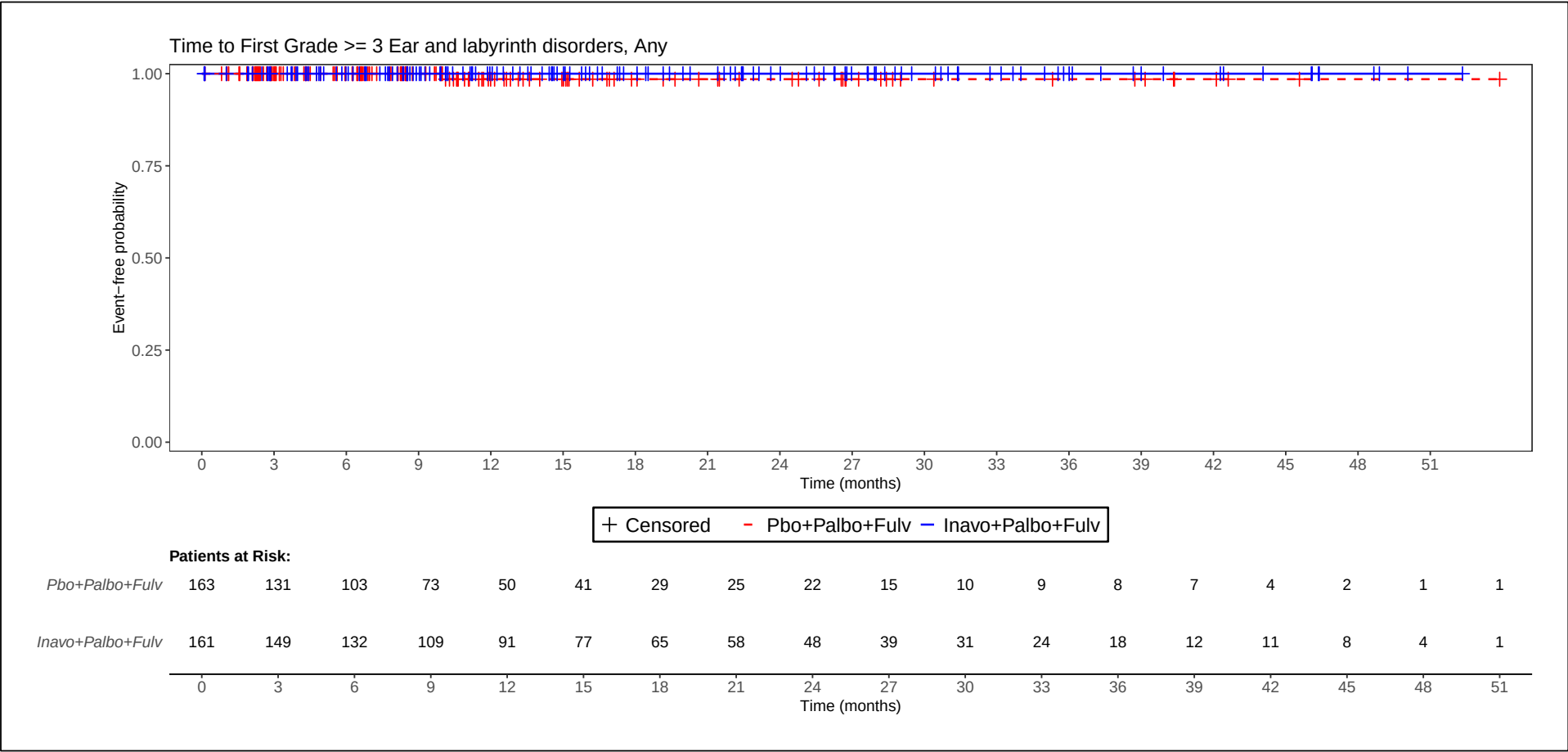
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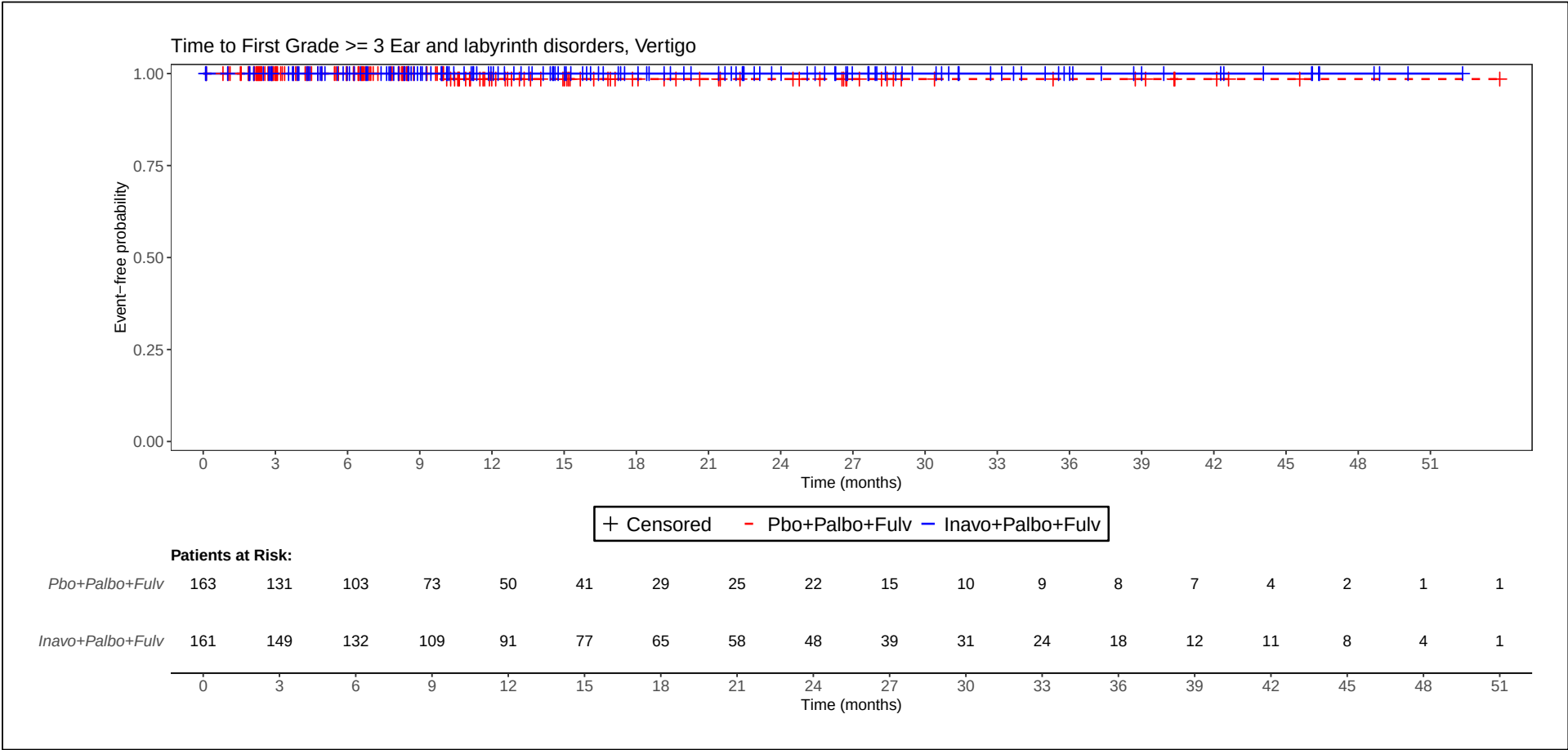
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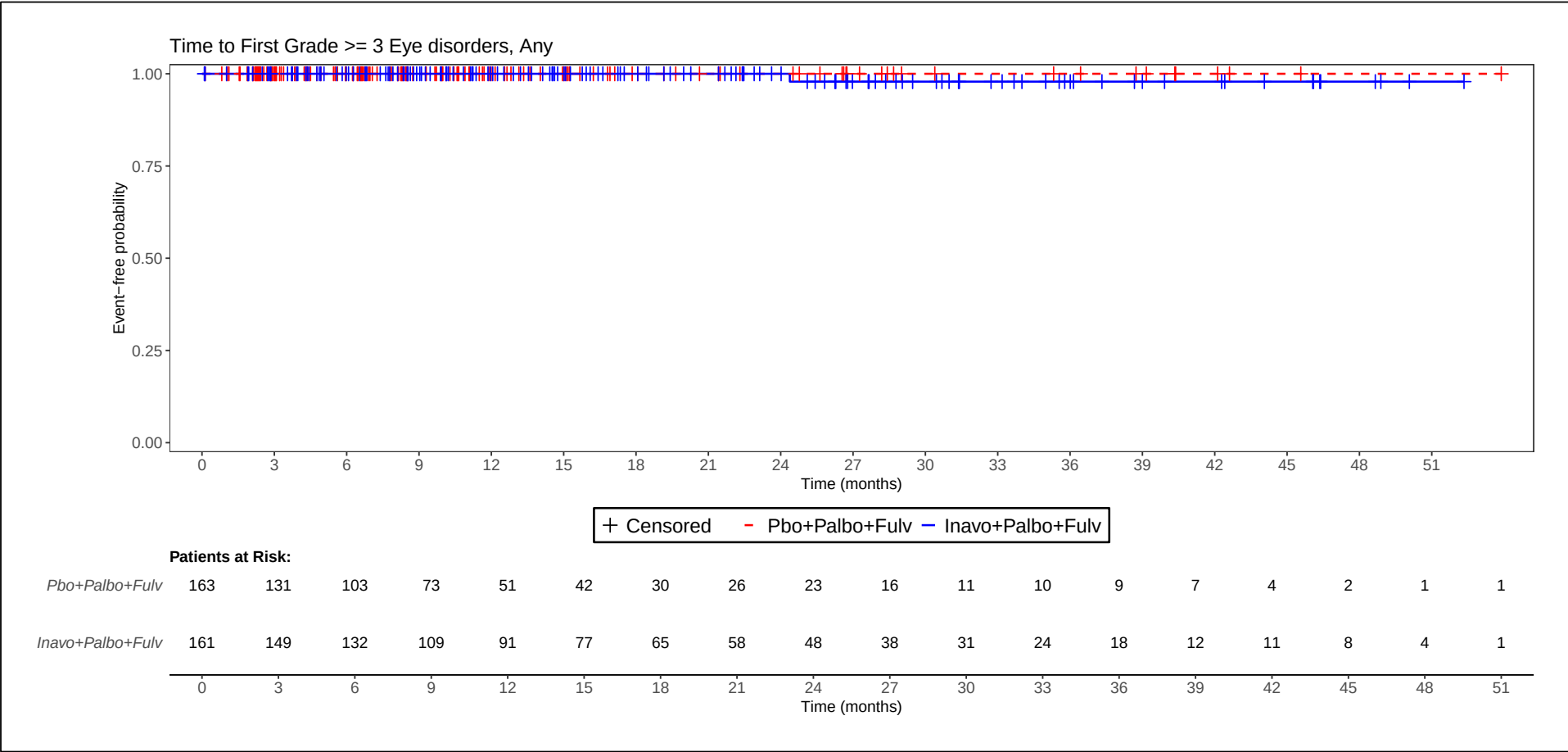
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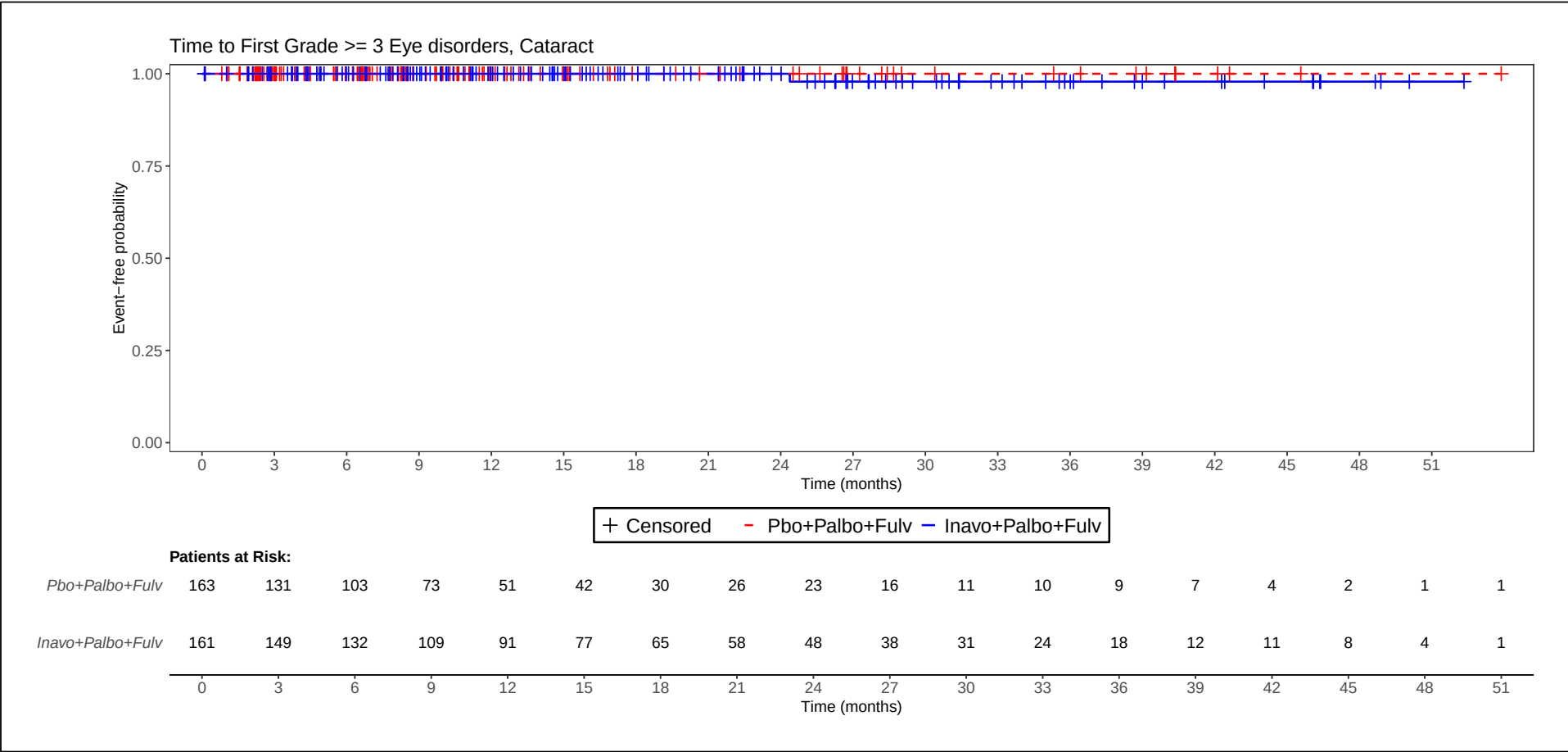
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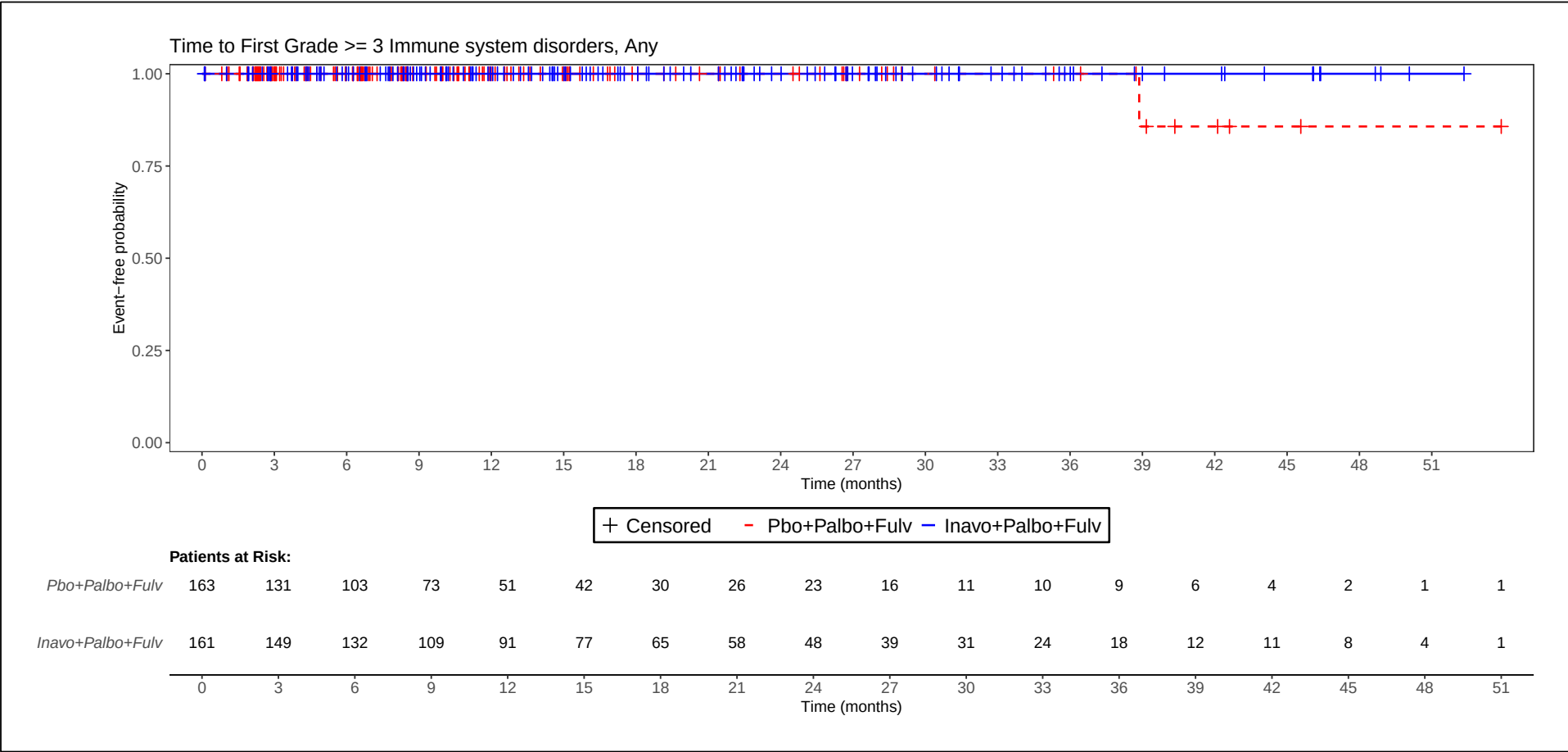
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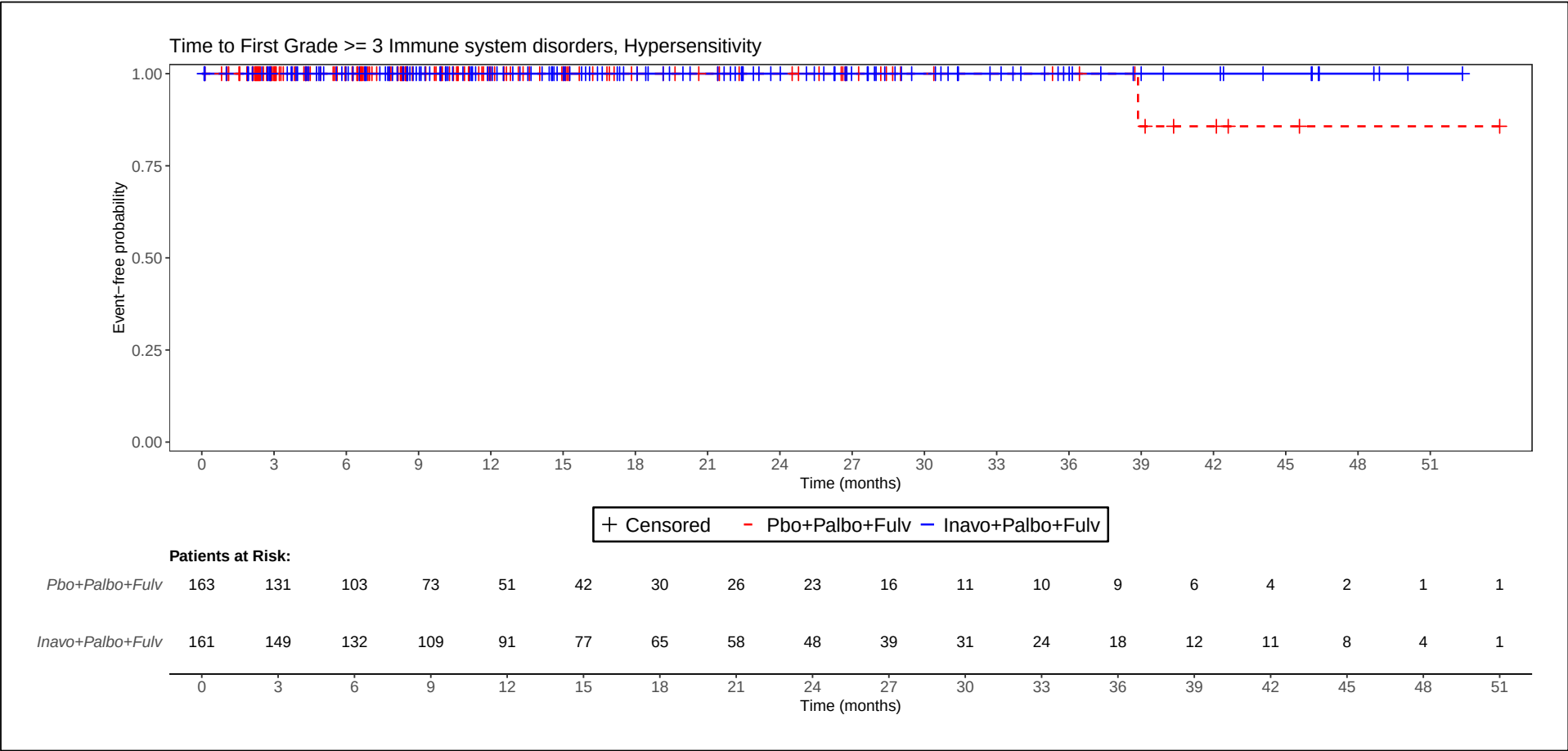
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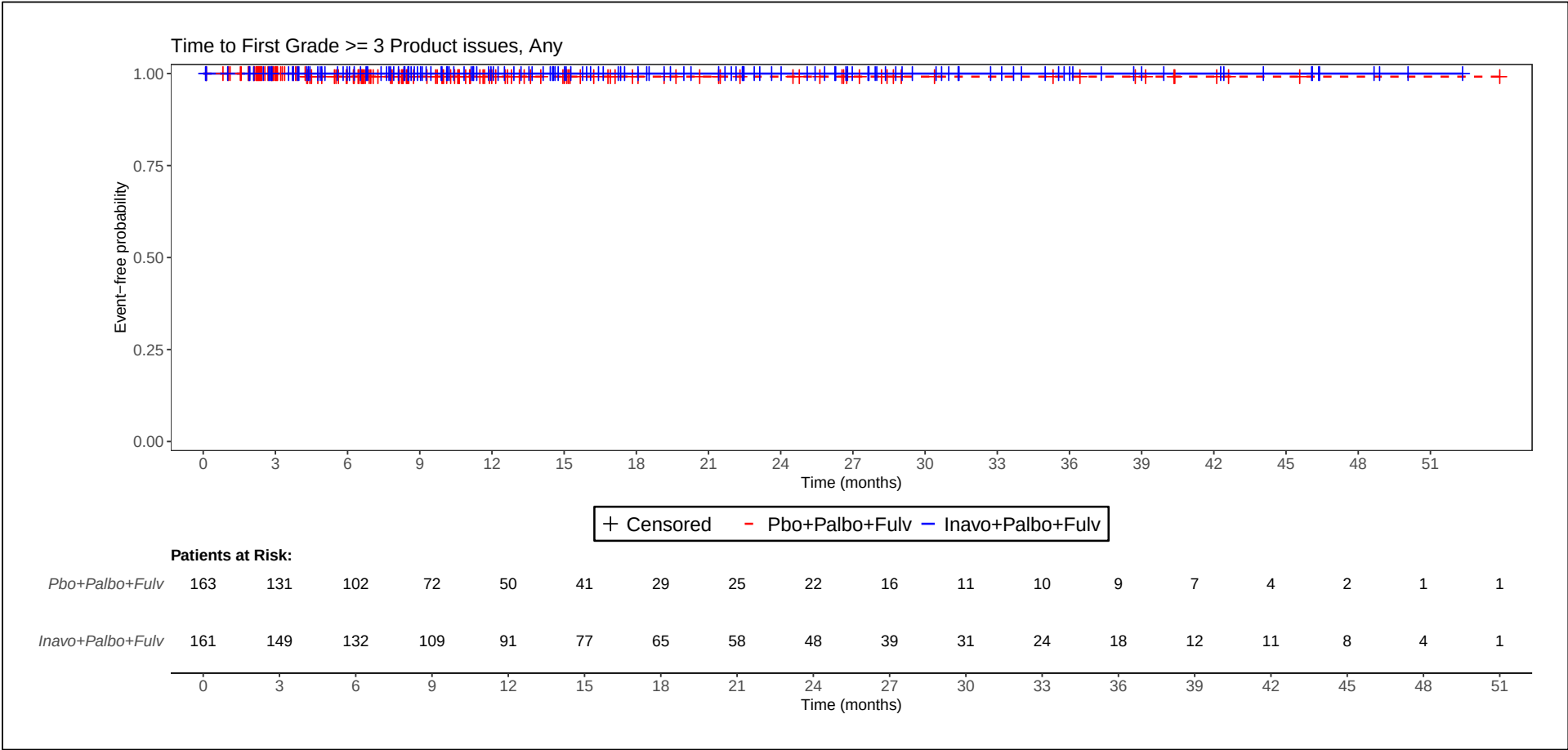
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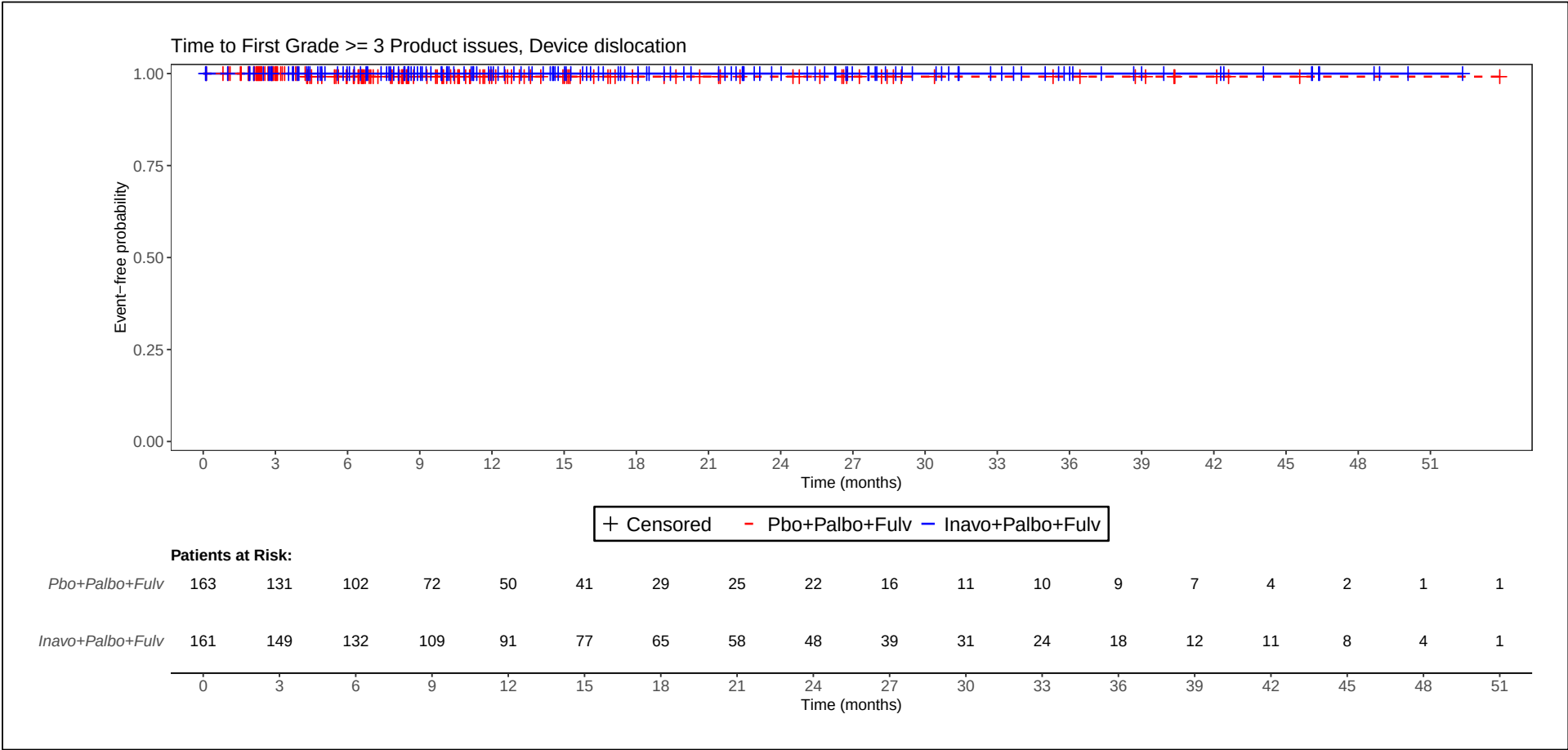
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Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:16 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

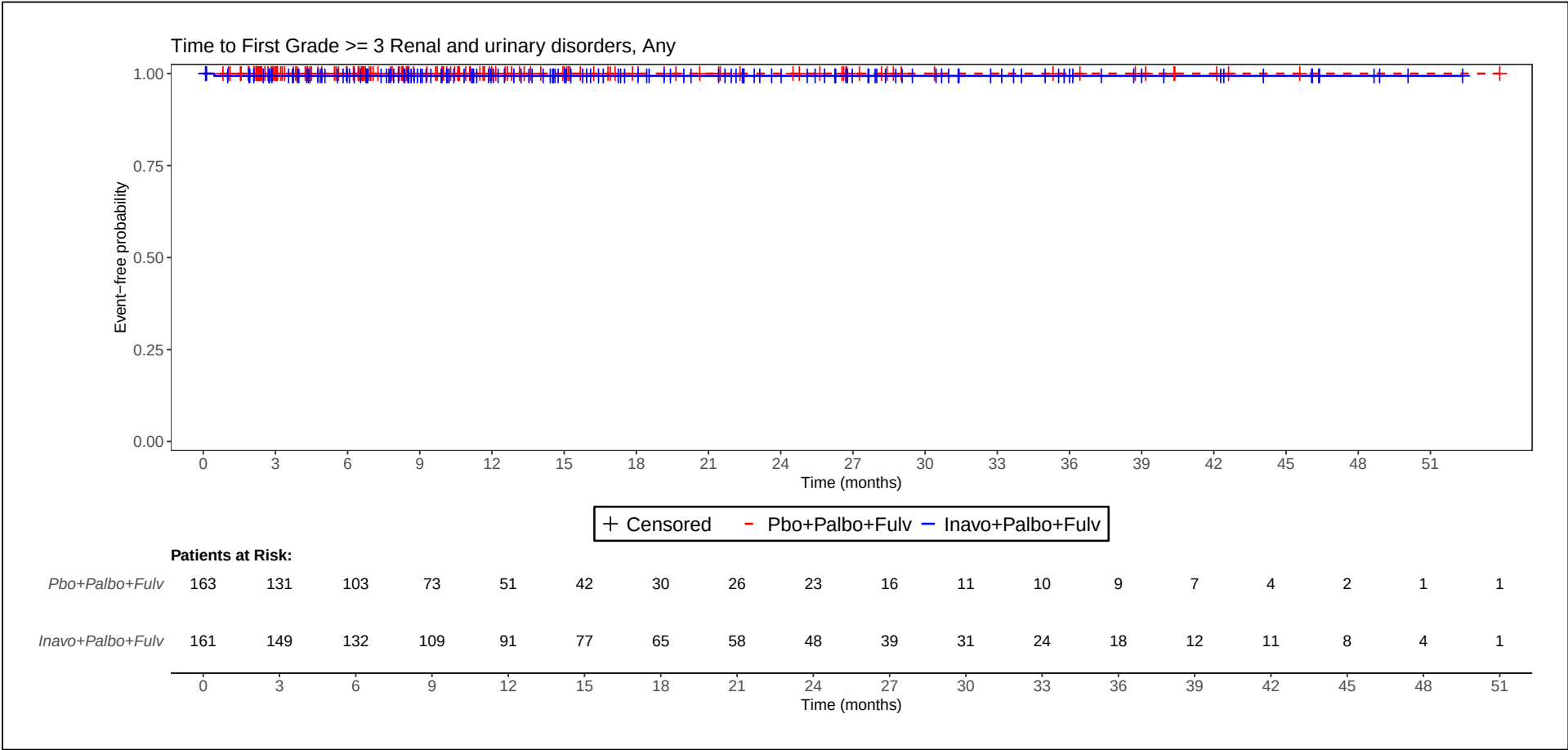
Kaplan Meier Plot for Safety, Adverse Events Grade >= 3 by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
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Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:16 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

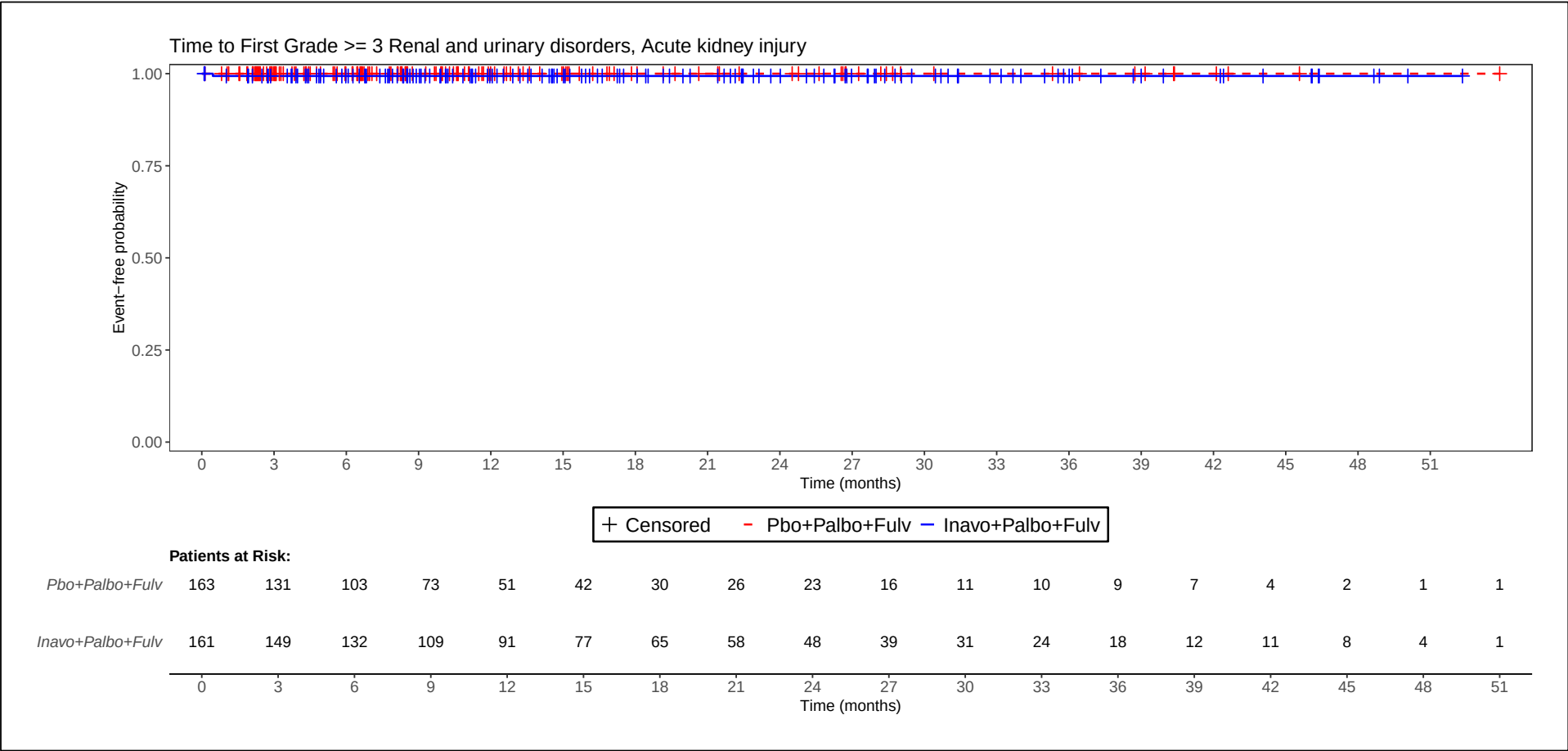
Kaplan Meier Plot for Safety, Adverse Events Grade >= 3 by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
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Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:16 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Safety, Adverse Events Grade >= 3 by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
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Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:16 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.1 Generelle Verträglichkeit

3.1.2 Unerwünschte Ereignisse UE nach Systemorganklassen (SOC) und Preferred Terms (PT)

3.1.2.3 Patienten mit schwerwiegenden unerwünschten Ereignissen (SUE) nach SOC/PT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis by SOC and PT Overall and with Subgroups (Safety), Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Serious Infections and infestations, Any											
All Patients	324	163	6	3.7	161	12	7.5	1.59	(0.60, 4.26)	0.3484	NE
Age group (years)											
<65	266	129	5	3.9	137	11	8.0	1.58	(0.55, 4.57)	0.3942	0.9973
>=65	58	34	1	2.9	24	1	4.2	1.22	(0.08, 19.50)	0.8893	0.9973
Sex											
F	318	162	6	3.7	156	12	7.7	1.62	(0.60, 4.34)	0.3325	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	5	8.6	4.18	(0.49, 35.98)	0.1569	0.2017
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3534	0.2017
OTHER	78	38	5	13.2	40	6	15.0	0.78	(0.24, 2.59)	0.6839	0.2017
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	2	6.9	2.17	(0.20, 24.07)	0.5188	0.7972
Y	259	127	5	3.9	132	10	7.6	1.47	(0.50, 4.31)	0.4835	0.7972
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	5	9.6	>999.99	(0.00, >999.99)	0.0442	0.0291
POST-MENOPAUSAL	214	110	6	5.5	104	7	6.7	0.93	(0.31, 2.78)	0.8907	0.0291
Time to First Serious Infections and infestations, COVID-19											
All Patients	324	163	1	0.6	161	4	2.5	2.94	(0.33, 26.39)	0.3136	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	1.94	(0.20, 18.78)	0.5610	0.3387
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2871	0.3387
Sex											
F	318	162	1	0.6	156	4	2.6	3.03	(0.34, 27.19)	0.2989	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4142	0.7256
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.7256
OTHER	78	38	1	2.6	40	3	7.5	1.71	(0.17, 16.82)	0.6437	0.7256
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4268	0.4124
Y	259	127	1	0.8	132	3	2.3	2.13	(0.22, 20.54)	0.5019	0.4124
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4221	0.5159
POST-MENOPAUSAL	214	110	1	0.9	104	3	2.9	2.40	(0.25, 23.24)	0.4342	0.5159
Time to First Serious Infections and infestations, Pneumonia											
All Patients	324	163	2	1.2	161	3	1.9	1.19	(0.20, 7.24)	0.8471	NE
Age group (years)											
<65	266	129	2	1.6	137	3	2.2	1.07	(0.18, 6.50)	0.9415	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	2	1.2	156	3	1.9	1.21	(0.20, 7.34)	0.8387	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3091	0.5041
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.5041
OTHER	78	38	2	5.3	40	2	5.0	0.64	(0.09, 4.62)	0.6527	0.5041
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.1241	0.0632
Y	259	127	2	1.6	132	1	0.8	0.35	(0.03, 3.95)	0.3770	0.0632
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.2618
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.74	(0.10, 5.44)	0.7664	0.2618
Time to First Serious Infections and infestations, Urinary tract infection											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1795	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2040	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1736	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.1761	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.1970	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3451	1.0000
Time to First Serious Infections and infestations, Anal abscess											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4224	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4561	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4142	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3534	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4386	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4862	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Infections and infestations, COVID-19 pneumonia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3220	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3042	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2981	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3243	1.0000
Time to First Serious Infections and infestations, Cellulitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4012	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4362	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3929	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4206	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4156	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3702	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Serious Infections and infestations, Clostridium difficile colitis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2186	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3819	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2260	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1441	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2712	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2438	1.0000
Time to First Serious Infections and infestations, Device related infection											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3551	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3852	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3486	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3954	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3793	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3736	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Infections and infestations, Gastroenteritis norovirus											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4450	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4795	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4795	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4386	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4561	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4795	1.0000
Time to First Serious Infections and infestations, Infection											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2317	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2042	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2387	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.2207	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2100	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2643	1.0000
Time to First Serious Infections and infestations, Influenza											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4902	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5271	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4913	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4561	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4795	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5403	1.0000
Time to First Serious Infections and infestations, Lung abscess											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3648	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4041	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3581	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4241	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3907	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3404	1.0000
Time to First Serious Infections and infestations, Upper respiratory tract infection											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4872	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5376	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4795	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5083	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4328	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4279	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Serious Gastrointestinal disorders, Any											
All Patients	324	163	4	2.5	161	7	4.3	1.49	(0.43, 5.12)	0.5238	NE
Age group (years)											
<65	266	129	3	2.3	137	4	2.9	0.94	(0.21, 4.28)	0.9392	0.2375
>=65	58	34	1	2.9	24	3	12.5	4.76	(0.49, 45.77)	0.1357	0.2375
Sex											
F	318	162	4	2.5	156	6	3.8	1.31	(0.37, 4.67)	0.6787	0.5849
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.5849
Region											
ASIA	120	62	2	3.2	58	3	5.2	1.23	(0.20, 7.53)	0.8212	0.6559
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	3	4.8	1.42	(0.24, 8.53)	0.6969	0.6559
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	0.6559
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	0.2604
Y	259	127	4	3.1	132	6	4.5	1.15	(0.32, 4.09)	0.8345	0.2604
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	0.3291
POST-MENOPAUSAL	214	110	4	3.6	104	5	4.8	1.20	(0.32, 4.49)	0.7828	0.3291
Time to First Serious Gastrointestinal disorders, Vomiting											
All Patients	324	163	2	1.2	161	2	1.2	0.95	(0.13, 6.76)	0.9596	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2560	0.1186
>=65	58	34	1	2.9	24	2	8.3	3.23	(0.29, 35.65)	0.3109	0.1186
Sex											
F	318	162	2	1.2	156	2	1.3	0.98	(0.14, 6.93)	0.9804	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	1	1.7	0.49	(0.04, 5.40)	0.5517	0.4349
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	0.4349
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.4349
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	2	1.5	0.88	(0.12, 6.25)	0.8968	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	1.00	(0.14, 7.11)	0.9990	1.0000
Time to First Serious Gastrointestinal disorders, Diarrhoea											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1880	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2367	1.0000
Sex											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1821	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3428	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4198	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1709	1.0000
Time to First Serious Gastrointestinal disorders, Abdominal pain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3642	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4020	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3573	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4241	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2749	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3322	1.0000
Time to First Serious Gastrointestinal disorders, Anal fistula											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3551	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3852	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3463	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3793	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Gastrointestinal disorders, Dysphagia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2336	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1991	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2418	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2974	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2193	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2645	1.0000
Time to First Serious Gastrointestinal disorders, Gastrointestinal haemorrhage											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4887	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5371	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4795	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5271	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5078	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Gastrointestinal disorders, Intestinal obstruction											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Serious Gastrointestinal disorders, Intestinal perforation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4237	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4581	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4154	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3466	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4405	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3839	1.0000
Time to First Serious Gastrointestinal disorders, Oesophageal stenosis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2910	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2627	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2971	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2879	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2695	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2998	1.0000
Time to First Serious Blood and lymphatic system disorders, Any											
All Patients	324	163	1	0.6	161	8	5.0	6.45	(0.80, 52.00)	0.0446	NE
Age group (years)											
<65	266	129	0	0.0	137	6	4.4	>999.99	(0.00, >999.99)	0.0517	0.2112
>=65	58	34	1	2.9	24	2	8.3	3.21	(0.29, 35.37)	0.3144	0.2112
Sex											
F	318	162	1	0.6	156	8	5.1	6.64	(0.82, 53.53)	0.0405	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	0	0.0	58	5	8.6	>999.99	(0.00, >999.99)	0.0715	0.2586
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3452	0.2586
OTHER	78	38	1	2.6	40	2	5.0	1.93	(0.17, 21.27)	0.5852	0.2586
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	4	13.8	>999.99	(0.00, >999.99)	0.0465	0.2089
Y	259	127	1	0.8	132	4	3.0	3.16	(0.35, 28.71)	0.2807	0.2089
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	2	3.8	>999.99	(0.00, >999.99)	0.3597	0.5074
POST-MENOPAUSAL	214	110	1	0.9	104	6	5.8	5.67	(0.68, 47.33)	0.0705	0.5074
Time to First Serious Blood and lymphatic system disorders, Febrile neutropenia											
All Patients	324	163	0	0.0	161	4	2.5	>999.99	(0.00, >999.99)	0.0861	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3396	0.9999
>=65	58	34	0	0.0	24	2	8.3	>999.99	(0.00, >999.99)	0.0715	0.9999
Sex											
F	318	162	0	0.0	156	4	2.6	>999.99	(0.00, >999.99)	0.0816	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	3	5.2	>999.99	(0.00, >999.99)	0.1575	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3452	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3527	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.1470	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4431	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	3	2.9	>999.99	(0.00, >999.99)	0.1126	1.0000
Time to First Serious Blood and lymphatic system disorders, Anaemia											
All Patients	324	163	0	0.0	161	3	1.9	>999.99	(0.00, >999.99)	0.1328	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.1600	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	3	1.9	>999.99	(0.00, >999.99)	0.1270	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.2667	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3238	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.1957	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3326	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6095	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1586	1.0000
Time to First Serious Blood and lymphatic system disorders, Neutropenia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3220	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3042	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2981	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3243	1.0000
Time to First Serious Blood and lymphatic system disorders, Thrombocytopenia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3188	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3416	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3126	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3103	1.0000
Time to First Serious General disorders and administration site conditions, Any											
All Patients	324	163	1	0.6	161	6	3.7	4.14	(0.49, 34.88)	0.1575	NE
Age group (years)											
<65	266	129	1	0.8	137	5	3.6	3.06	(0.35, 26.70)	0.2876	0.4098
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2528	0.4098
Sex											
F	318	162	1	0.6	156	6	3.8	4.25	(0.50, 35.88)	0.1483	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	4	6.9	>999.99	(0.00, >999.99)	0.0744	0.2678
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.54	(0.03, 9.29)	0.6646	0.2678
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4936	0.2678
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.99	(0.06, 16.12)	0.9957	0.1196
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0818	0.1196
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	4	7.7	>999.99	(0.00, >999.99)	0.0885	0.1843
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.21	(0.10, 14.16)	0.8786	0.1843
Time to First Serious General disorders and administration site conditions, Pyrexia											
All Patients	324	163	0	0.0	161	4	2.5	>999.99	(0.00, >999.99)	0.1242	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.1483	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	4	2.6	>999.99	(0.00, >999.99)	0.1192	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	3	5.2	>999.99	(0.00, >999.99)	0.1444	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5637	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3711	1.0000
Y	259	127	0	0.0	132	3	2.3	>999.99	(0.00, >999.99)	0.2204	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	3	5.8	>999.99	(0.00, >999.99)	0.1725	0.9999
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5930	0.9999
Time to First Serious General disorders and administration site conditions, Chest pain											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2768	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2488	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2831	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2821	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3674	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2932	1.0000
Time to First Serious General disorders and administration site conditions, Death											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4121	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2528	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4044	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4936	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4266	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3876	1.0000
Time to First Serious General disorders and administration site conditions, Malaise											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3252	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3501	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3189	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3131	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3451	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3125	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious General disorders and administration site conditions, Pain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4264	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4623	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4180	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4431	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.3711	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.4862	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Nervous system disorders, Any											
All Patients	324	163	1	0.6	161	4	2.5	3.34	(0.37, 30.25)	0.2567	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.1369	0.2059
>=65	58	34	1	2.9	24	1	4.2	1.34	(0.08, 21.44)	0.8357	0.2059
Sex											
F	318	162	1	0.6	156	4	2.6	3.43	(0.38, 31.11)	0.2442	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.3651
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.92	(0.06, 14.81)	0.9556	0.3651
OTHER	78	38	0	0.0	40	3	7.5	>999.99	(0.00, >999.99)	0.1341	0.3651
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2652	0.4295
Y	259	127	1	0.8	132	3	2.3	2.20	(0.22, 21.63)	0.4867	0.4295
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.5092
POST-MENOPAUSAL	214	110	1	0.9	104	3	2.9	2.61	(0.27, 25.40)	0.3898	0.5092
Time to First Serious Nervous system disorders, Syncope											
All Patients	324	163	1	0.6	161	1	0.6	0.85	(0.05, 13.69)	0.9064	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	0.1370
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3743	0.1370
Sex											
F	318	162	1	0.6	156	1	0.6	0.87	(0.05, 14.07)	0.9217	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.2794
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2793	0.2794
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	0.2794
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.78	(0.05, 12.65)	0.8603	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.1058
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2598	0.1058
Time to First Serious Nervous system disorders, Cerebral haemorrhage											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4920	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5338	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4828	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5541	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5040	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4334	1.0000
Time to First Serious Nervous system disorders, Cerebrovascular accident											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3082	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2652	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3037	1.0000
Time to First Serious Nervous system disorders, Haemorrhage intracranial											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First Serious Respiratory, thoracic and mediastinal disorders, Any											
All Patients	324	163	2	1.2	161	3	1.9	1.10	(0.18, 6.70)	0.9188	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	2.06	(0.21, 20.26)	0.5288	0.2172
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3642	0.2172
Sex											
F	318	162	2	1.2	156	2	1.3	0.85	(0.12, 6.06)	0.8672	0.5010
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6171	0.5010
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4206	0.5354
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.71	(0.04, 11.83)	0.8135	0.5354
OTHER	78	38	1	2.6	40	1	2.5	0.67	(0.04, 11.13)	0.7765	0.5354
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	1	3.4	0.55	(0.05, 6.15)	0.6214	0.1113
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.3007	0.1113
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	0.2066
POST-MENOPAUSAL	214	110	2	1.8	104	1	1.0	0.42	(0.04, 4.61)	0.4605	0.2066
Time to First Serious Respiratory, thoracic and mediastinal disorders, Pneumonitis											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2313	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2592	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	0.9997
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6171	0.9997
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4715	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5194	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Respiratory, thoracic and mediastinal disorders, Pulmonary embolism											

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.1130	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3642	1.0000
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.1181	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3134	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1441	1.0000
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	0	0.0	<0.01	(0.00, >999.99)	0.1593	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.1257	1.0000
Time to First Serious Respiratory, thoracic and mediastinal disorders, Dyspnoea											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4012	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.4362	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3929	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4206	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4156	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3702	1.0000
Time to First Serious Cardiac disorders, Any											
All Patients	324	163	2	1.2	161	2	1.2	0.76	(0.10, 5.51)	0.7826	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.60	(0.04, 10.34)	0.7253	0.7425
>=65	58	34	1	2.9	24	1	4.2	1.34	(0.08, 21.49)	0.8358	0.7425
Sex											
F	318	162	2	1.2	156	2	1.3	0.78	(0.11, 5.68)	0.8065	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3334	0.0792
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2733	0.0792
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2615	0.0792
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	2	1.5	0.71	(0.10, 5.17)	0.7334	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.85	(0.12, 6.11)	0.8707	1.0000
Time to First Serious Cardiac disorders, Acute coronary syndrome											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2251	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5338	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2240	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2178	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2615	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.2405	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1947	1.0000
Time to First Serious Cardiac disorders, Atrial fibrillation											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2145	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.3642	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2217	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2733	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2008	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2374	1.0000
Time to First Serious Cardiac disorders, Cardiac arrest											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3280	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3080	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3332	1.0000
Time to First Serious Injury, poisoning and procedural complications, Any											
All Patients	324	163	1	0.6	161	3	1.9	1.30	(0.13, 12.47)	0.8216	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	1.00	(0.10, 9.57)	0.9970	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	3	1.9	1.34	(0.14, 12.87)	0.7997	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5439	0.3806
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5002	0.3806
OTHER	78	38	1	2.6	40	1	2.5	0.37	(0.02, 5.97)	0.4655	0.3806
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	0.58	(0.04, 9.22)	0.6926	0.2163
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.3584	0.2163
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6464	0.5535
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.08	(0.10, 11.98)	0.9473	0.5535
Time to First Serious Injury, poisoning and procedural complications, Ankle fracture											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5127	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5637	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5060	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5403	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5176	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4613	1.0000
Time to First Serious Injury, poisoning and procedural complications, Femur fracture											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.1353	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0863	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1416	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1306	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2024	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1967	1.0000
Time to First Serious Injury, poisoning and procedural complications, Post procedural fistula											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5019	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5419	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4984	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4795	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5145	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4602	1.0000
Time to First Serious Injury, poisoning and procedural complications, Procedural headache											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5101	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5510	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5028	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5002	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5196	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4669	1.0000
Time to First Serious Injury, poisoning and procedural complications, Snake bite											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5032	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5598	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4962	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5439	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4328	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6464	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Investigations, Any											
All Patients	324	163	2	1.2	161	2	1.2	0.71	(0.09, 5.56)	0.7446	NE
Age group (years)											
<65	266	129	2	1.6	137	1	0.7	0.27	(0.02, 3.41)	0.2875	0.0871
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	0.0871
Sex											
F	318	162	2	1.2	156	2	1.3	0.73	(0.09, 5.70)	0.7601	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	1	1.7	1.04	(0.07, 16.68)	0.9762	0.2509
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5637	0.2509
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3109	0.2509
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	2	1.5	0.62	(0.08, 5.10)	0.6564	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	0.78	(0.10, 5.93)	0.8068	1.0000
Time to First Serious Investigations, Alanine aminotransferase increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First Serious Investigations, Aspartate aminotransferase increased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First Serious Investigations, Neutrophil count decreased											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.6374	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.6374	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.6374	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5637	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.7055	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.5930	1.0000
Time to First Serious Investigations, Platelet count decreased											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3009	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3281	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3295	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
Time to First Serious Investigations, White blood cell count decreased											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2969	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3251	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3109	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3021	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3289	1.0000
Time to First Serious Musculoskeletal and connective tissue disorders, Any											
All Patients	324	163	1	0.6	161	2	1.2	1.27	(0.11, 14.35)	0.8490	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.3656	0.0930
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.0930
Sex											
F	318	162	1	0.6	156	2	1.3	1.31	(0.12, 14.80)	0.8288	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3215	0.1711
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.1711
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.3922	0.1711
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.2641	0.0398

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2895	0.0398
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	2	1.9	1.43	(0.13, 15.98)	0.7714	1.0000
Time to First Serious Musculoskeletal and connective tissue disorders, Flank pain											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4905	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5390	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4834	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5083	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4497	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4406	1.0000
Time to First Serious Musculoskeletal and connective tissue disorders, Muscular weakness											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3094	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3157	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3215	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2895	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3125	1.0000
Time to First Serious Musculoskeletal and connective tissue disorders, Osteonecrosis of jaw											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4720	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5099	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4639	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.6038	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.4268	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4414	1.0000
Time to First Serious Skin and subcutaneous tissue disorders, Any											
All Patients	324	163	2	1.2	161	1	0.6	0.33	(0.03, 3.73)	0.3477	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1048	0.1875
>=65	58	34	1	2.9	24	1	4.2	1.40	(0.09, 22.50)	0.8103	0.1875
Sex											
F	318	162	2	1.2	156	1	0.6	0.34	(0.03, 3.86)	0.3638	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.1233	0.5498
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.94	(0.06, 15.10)	0.9669	0.5498
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.5498
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	0.3448
Y	259	127	1	0.8	132	1	0.8	0.51	(0.03, 8.22)	0.6297	0.3448
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.0513	0.2459
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.87	(0.05, 14.03)	0.9188	0.2459
Time to First Serious Skin and subcutaneous tissue disorders, Skin ulcer											
All Patients	324	163	1	0.6	161	1	0.6	0.55	(0.03, 8.78)	0.6653	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1048	0.0465
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2593	0.0465
Sex											
F	318	162	1	0.6	156	1	0.6	0.57	(0.04, 9.11)	0.6852	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.1233	0.2064
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3496	0.2064
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.2064
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.51	(0.03, 8.22)	0.6297	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0	<0.01	(0.00, >999.99)	0.0513	0.0630
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4005	0.0630
Time to First Serious Skin and subcutaneous tissue disorders, Rash maculo-papular											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3266	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3311	1.0000
Time to First Serious Hepatobiliary disorders, Any											
All Patients	324	163	2	1.2	161	0	0.0	<0.01	(0.00, >999.99)	0.0279	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0339	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4193	1.0000
Sex											
F	318	162	2	1.2	156	0	0.0	<0.01	(0.00, >999.99)	0.0288	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	2	3.2	63	0	0.0	<0.01	(0.00, >999.99)	0.0547	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2292	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	0	0.0	<0.01	(0.00, >999.99)	0.0437	1.0000
Time to First Serious Hepatobiliary disorders, Bile duct stone											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.0339	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.0339	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.0339	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.0833	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.0614	1.0000
Time to First Serious Hepatobiliary disorders, Cholelithiasis											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2558	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4193	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2626	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.2976	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2292	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2863	1.0000
Time to First Serious Metabolism and nutrition disorders, Any											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1728	NE

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.1953	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1673	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3566	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3784	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1632	1.0000
Time to First Serious Metabolism and nutrition disorders, Hypocalcaemia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3416	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3126	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3103	1.0000
Time to First Serious Metabolism and nutrition disorders, Hypokalaemia											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3535	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3805	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3472	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3566	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3784	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3409	1.0000
Time to First Serious Metabolism and nutrition disorders, Tetany											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3188	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3416	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3126	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3103	1.0000
Time to First Serious Vascular disorders, Any											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.3100	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5862	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2604	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.3083	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.3361	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	2	1.5	>999.99	(0.00, >999.99)	0.3272	1.0000

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Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.3061	1.0000
Time to First Serious Vascular disorders, Embolism											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4031	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2604	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3960	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.4927	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4250	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3703	1.0000
Time to First Serious Vascular disorders, Thrombosis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.5637	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5862	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.5708	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5186	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5727	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.6095	1.0000
Time to First Serious Eye disorders, Any											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4888	NE
Age group (years)											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5371	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4844	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5271	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4979	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6056	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Eye disorders, Cataract											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4888	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5371	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4844	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5271	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4979	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6056	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Immune system disorders, Any											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2024	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1730	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1730	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1967	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1380	1.0000
Time to First Serious Immune system disorders, Hypersensitivity											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2024	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.1730	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.1730	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.1573	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.1967	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.1380	1.0000
Time to First Serious Product issues, Any											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2776	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2470	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2841	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2393	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3674	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2982	1.0000
Time to First Serious Product issues, Device dislocation											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.2776	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2470	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.2841	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.2393	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3674	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.2982	1.0000
Time to First Serious Renal and urinary disorders, Any											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000
Time to First Serious Renal and urinary disorders, Acute kidney injury											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000

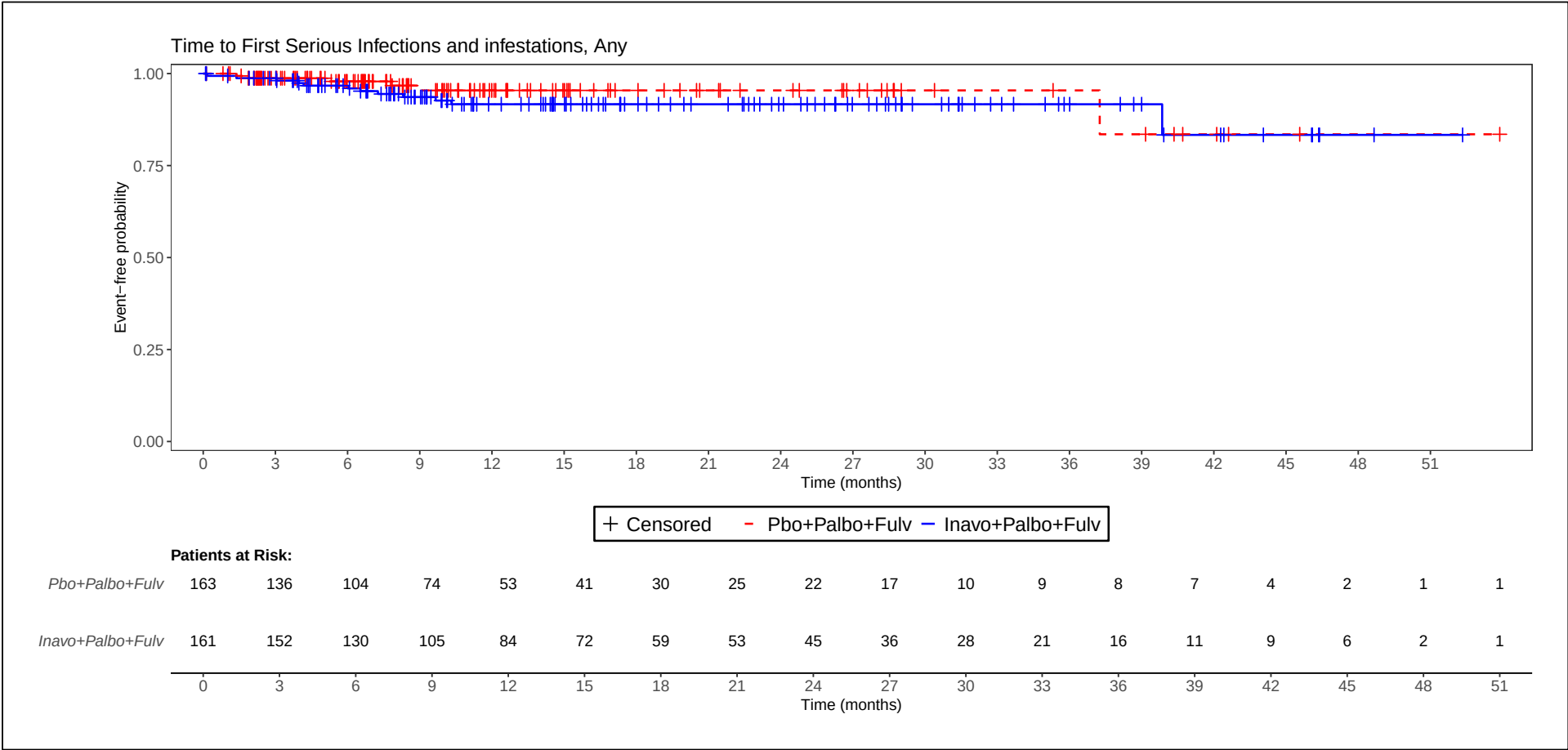
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3013	1.0000

Men are excluded from the subgroups of "Menopausal Status at Randomization"
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

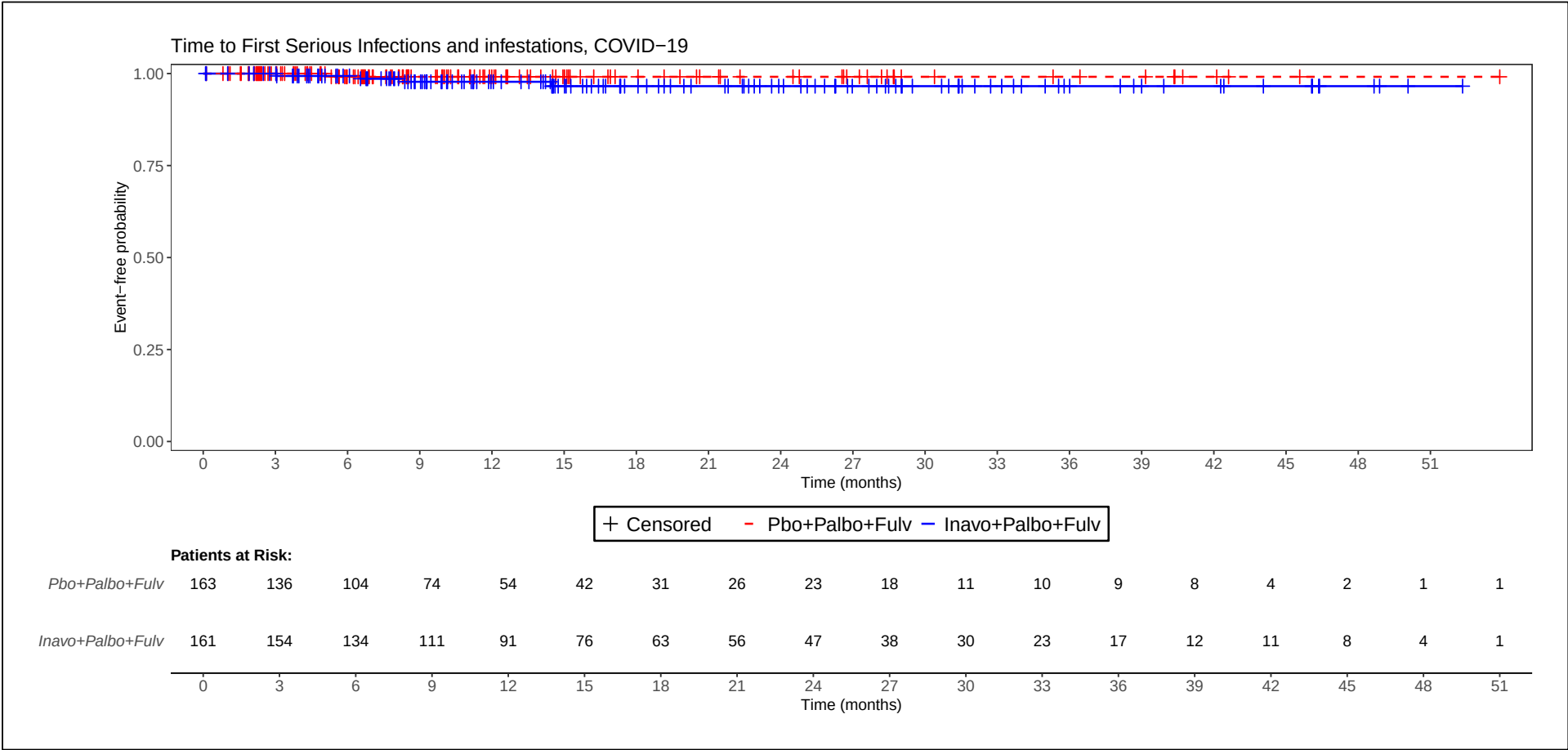
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

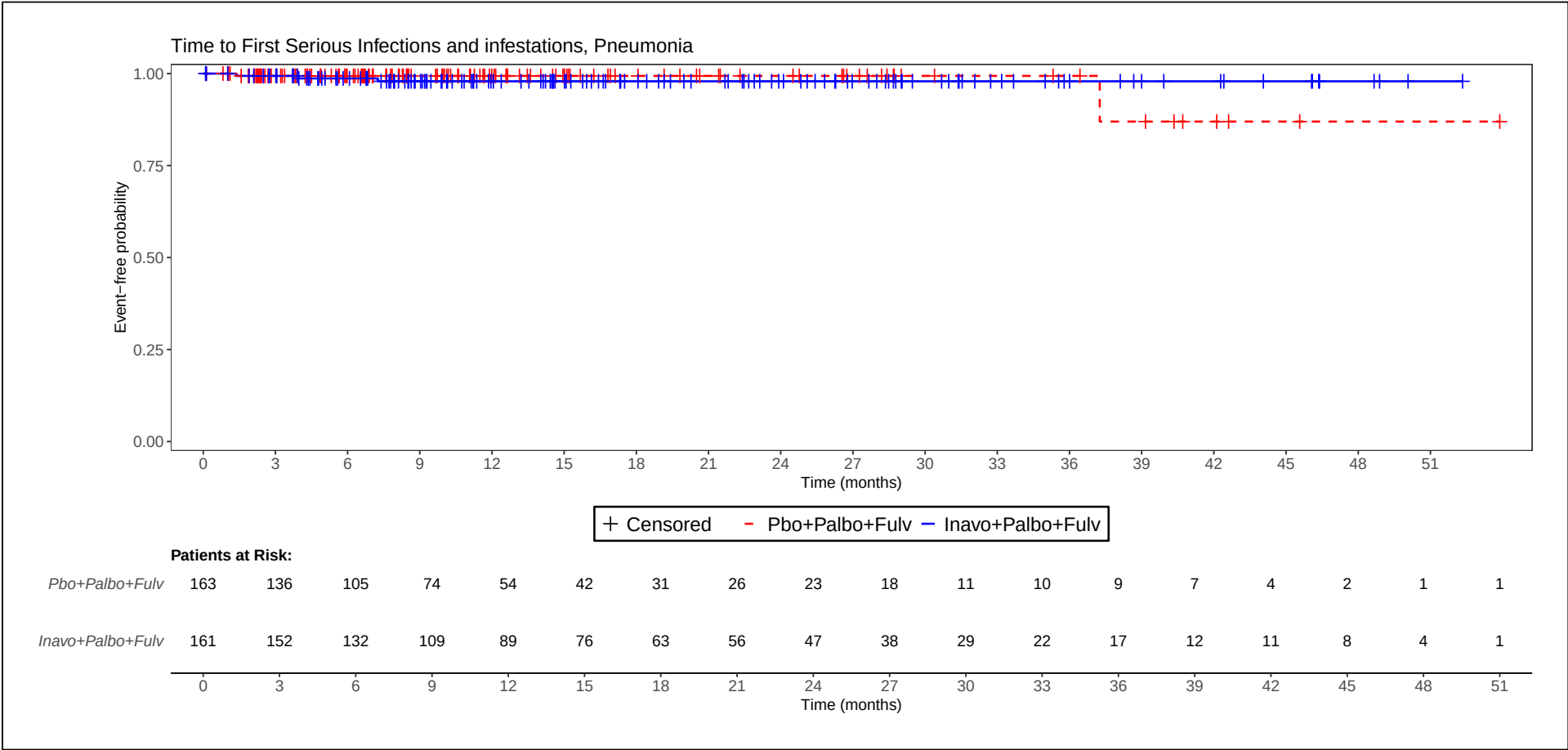
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

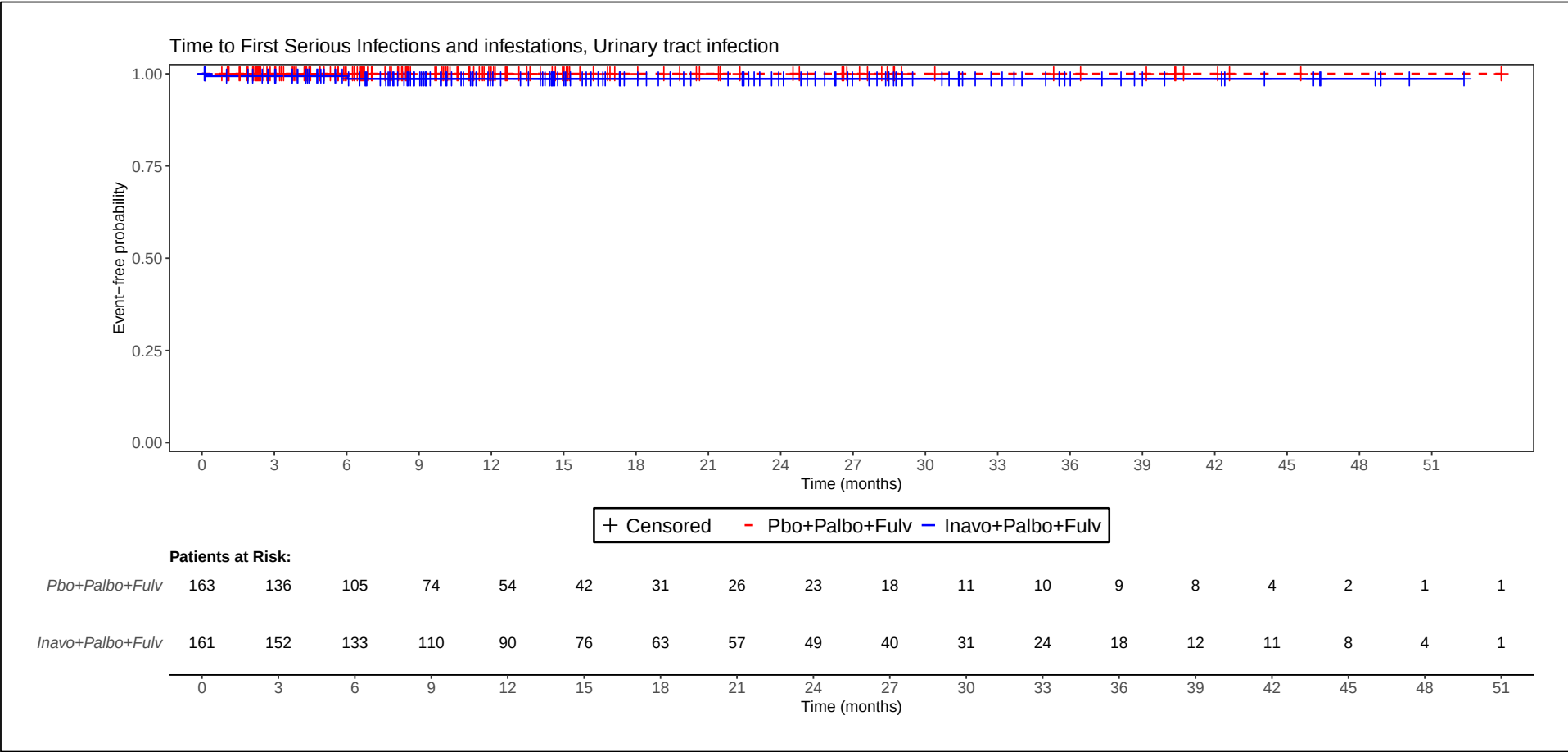
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

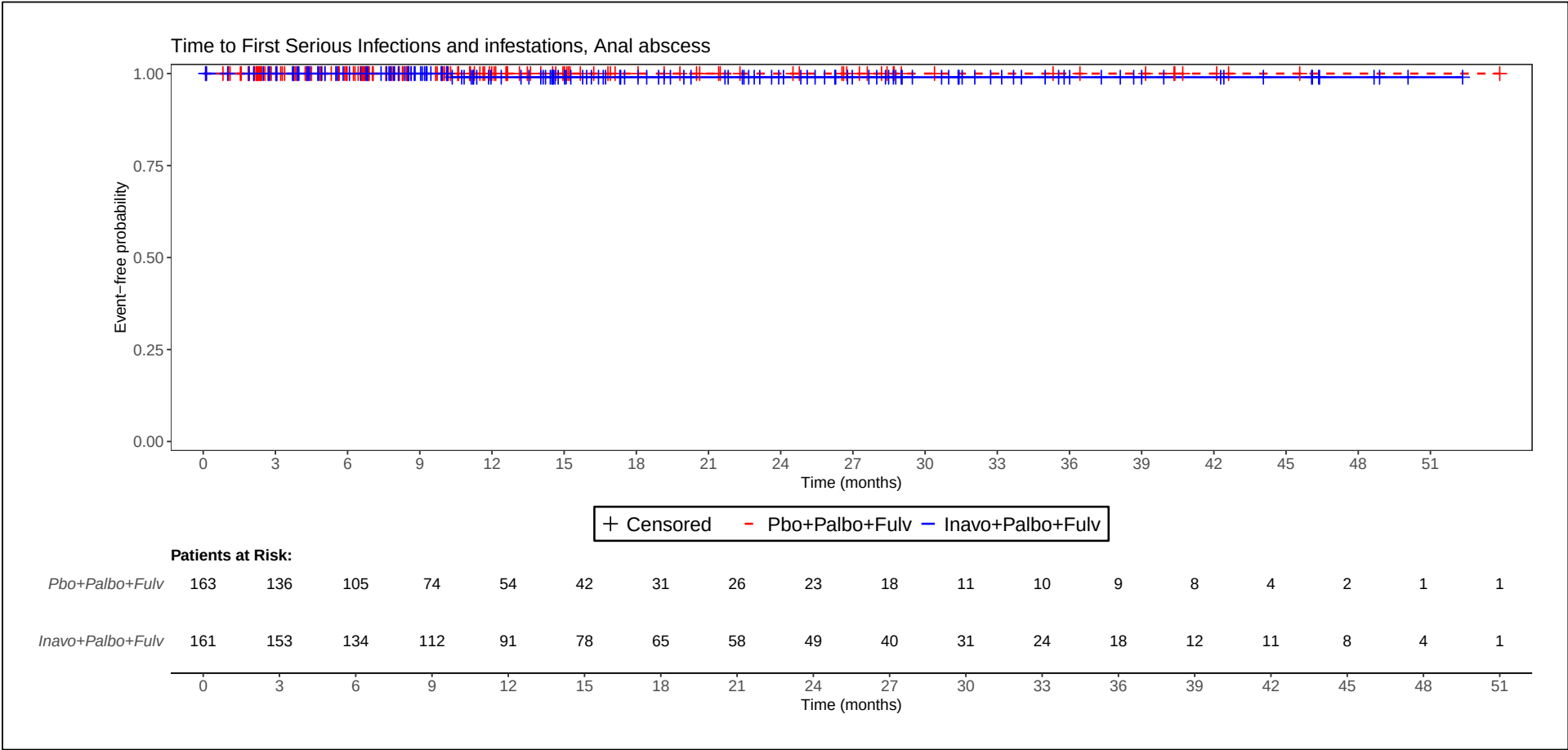
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

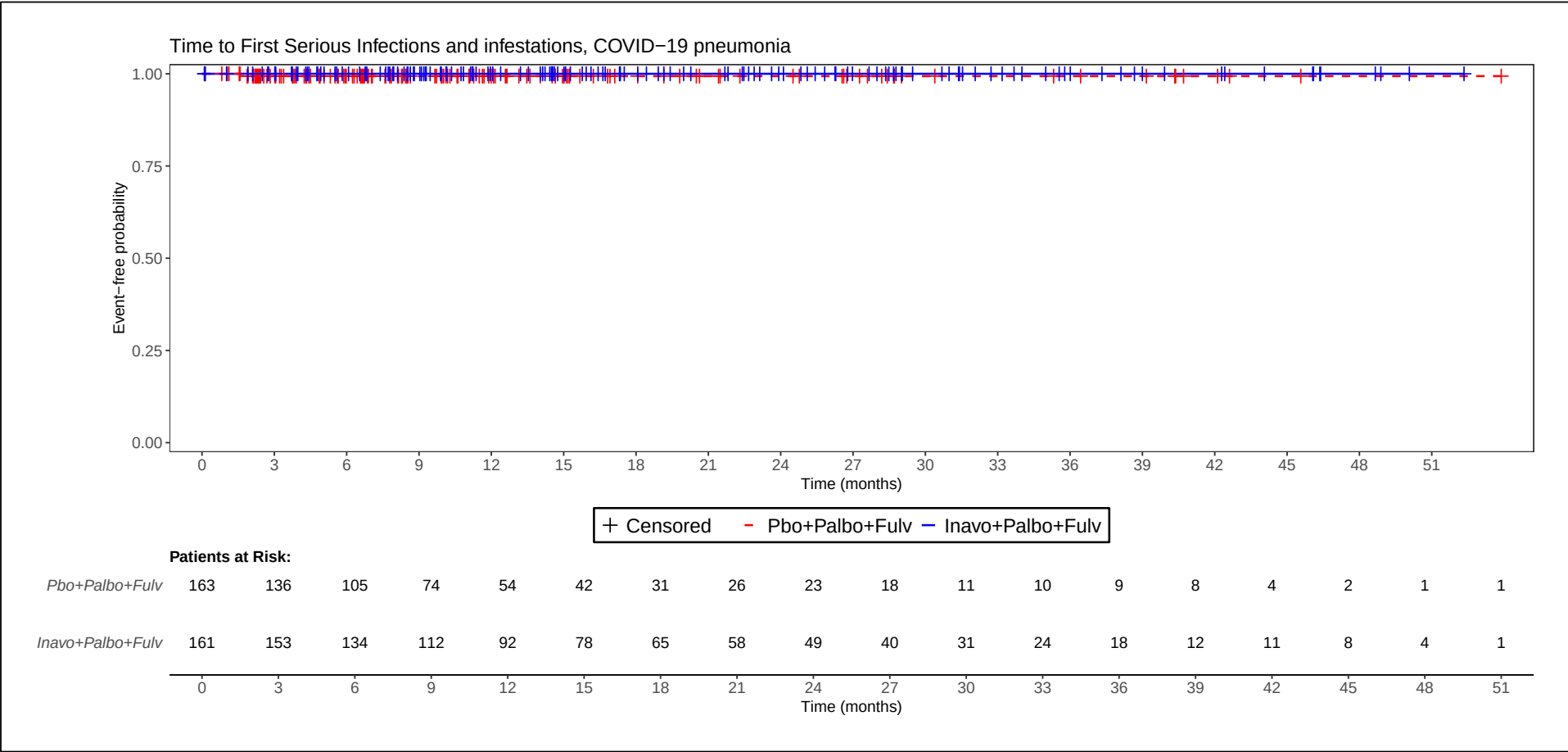
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

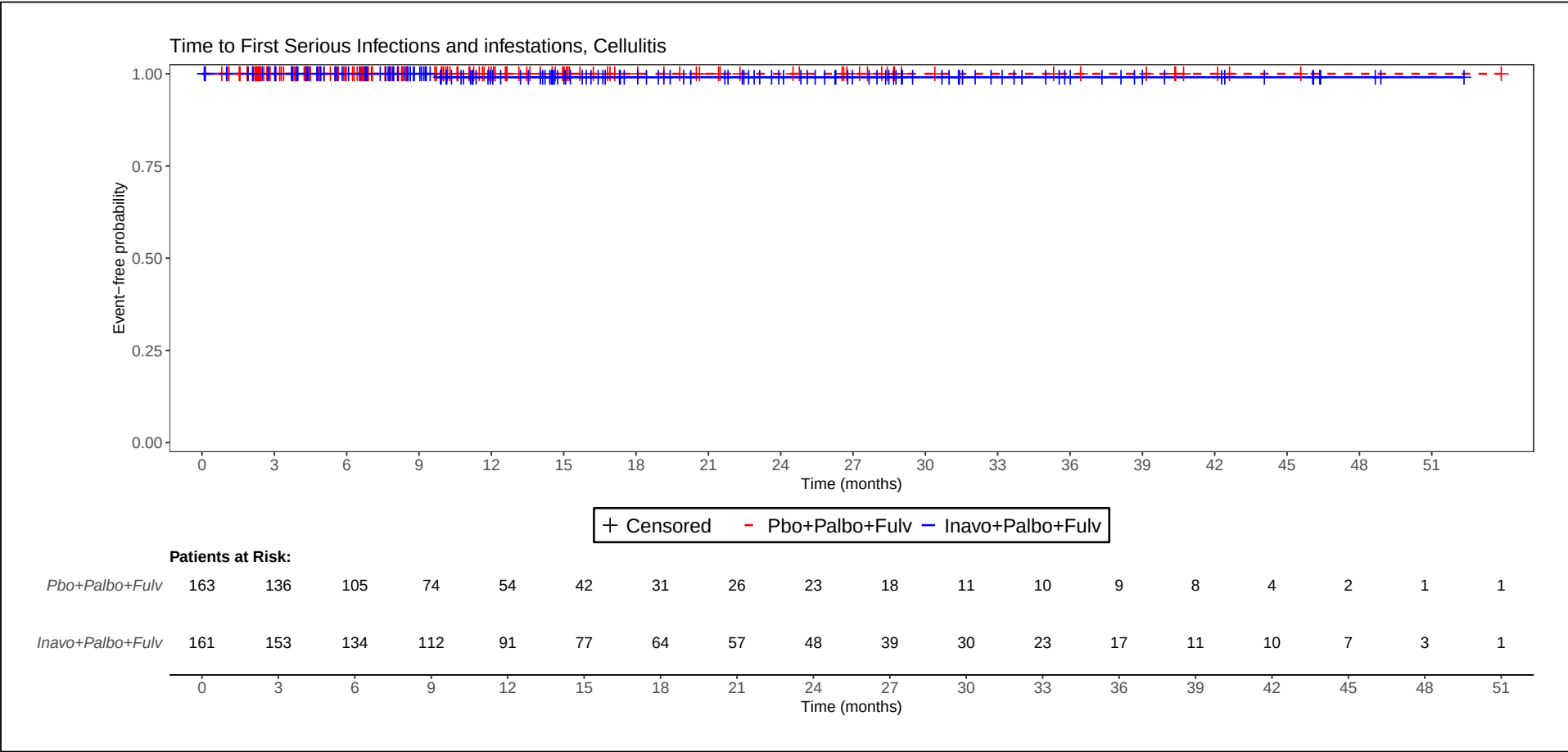
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

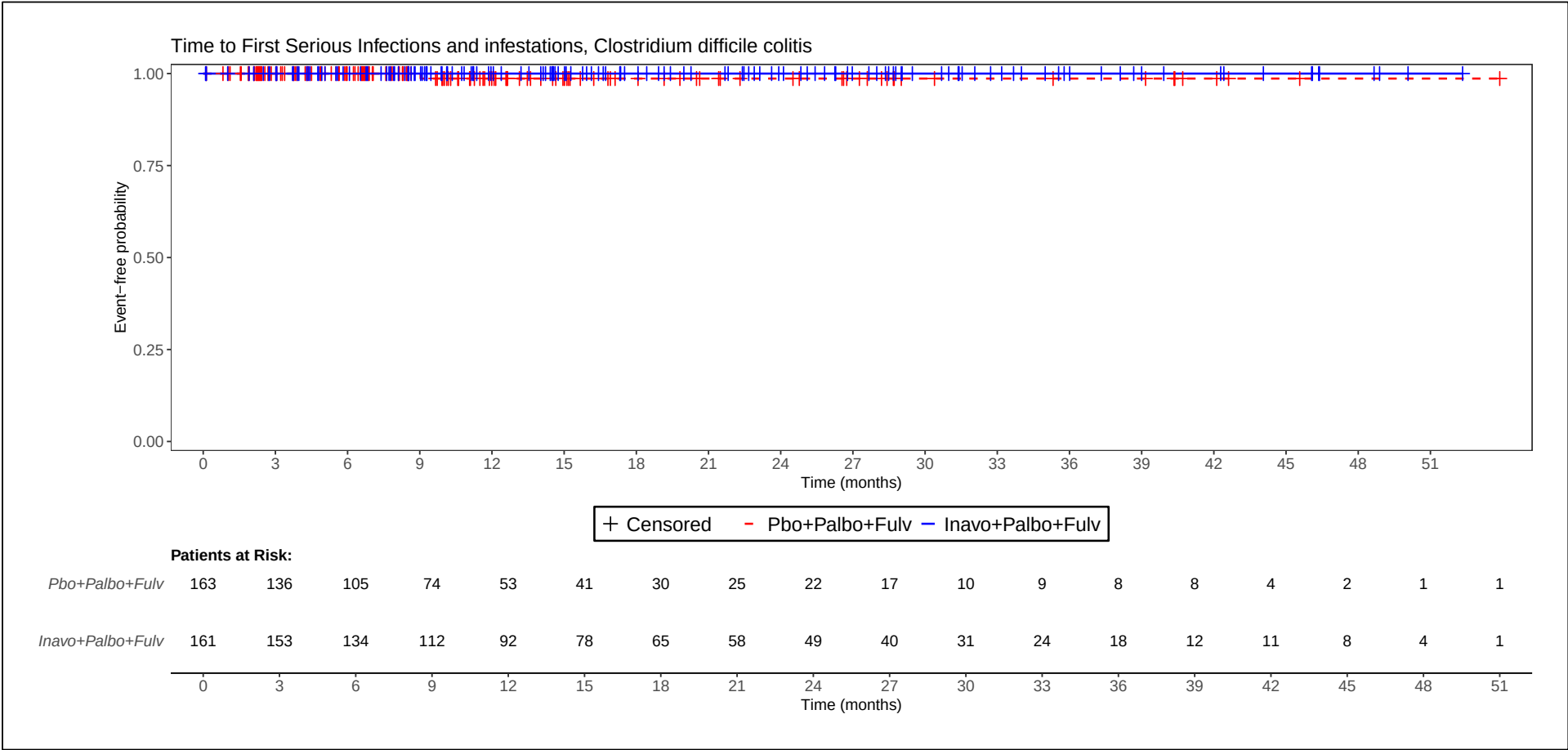
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

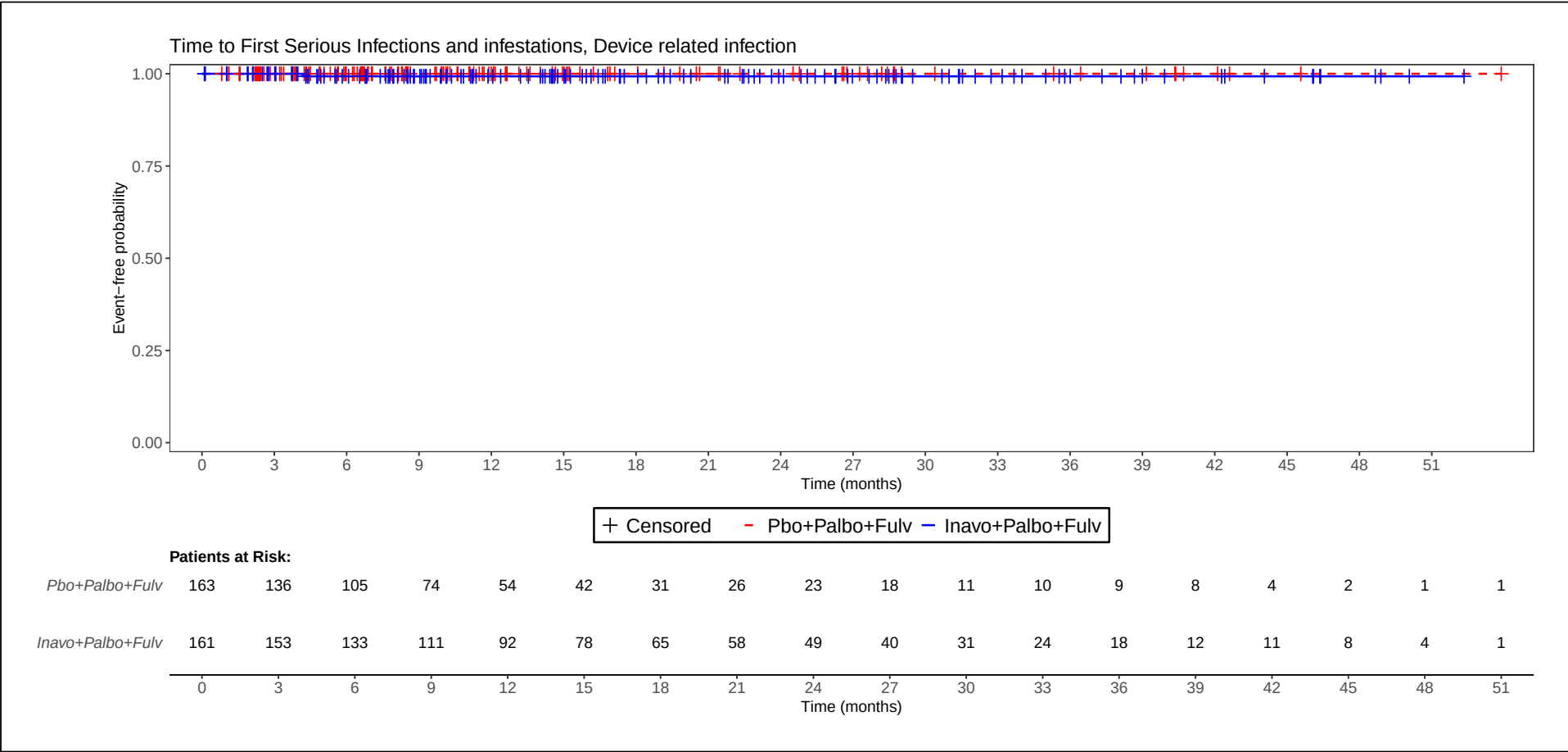
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

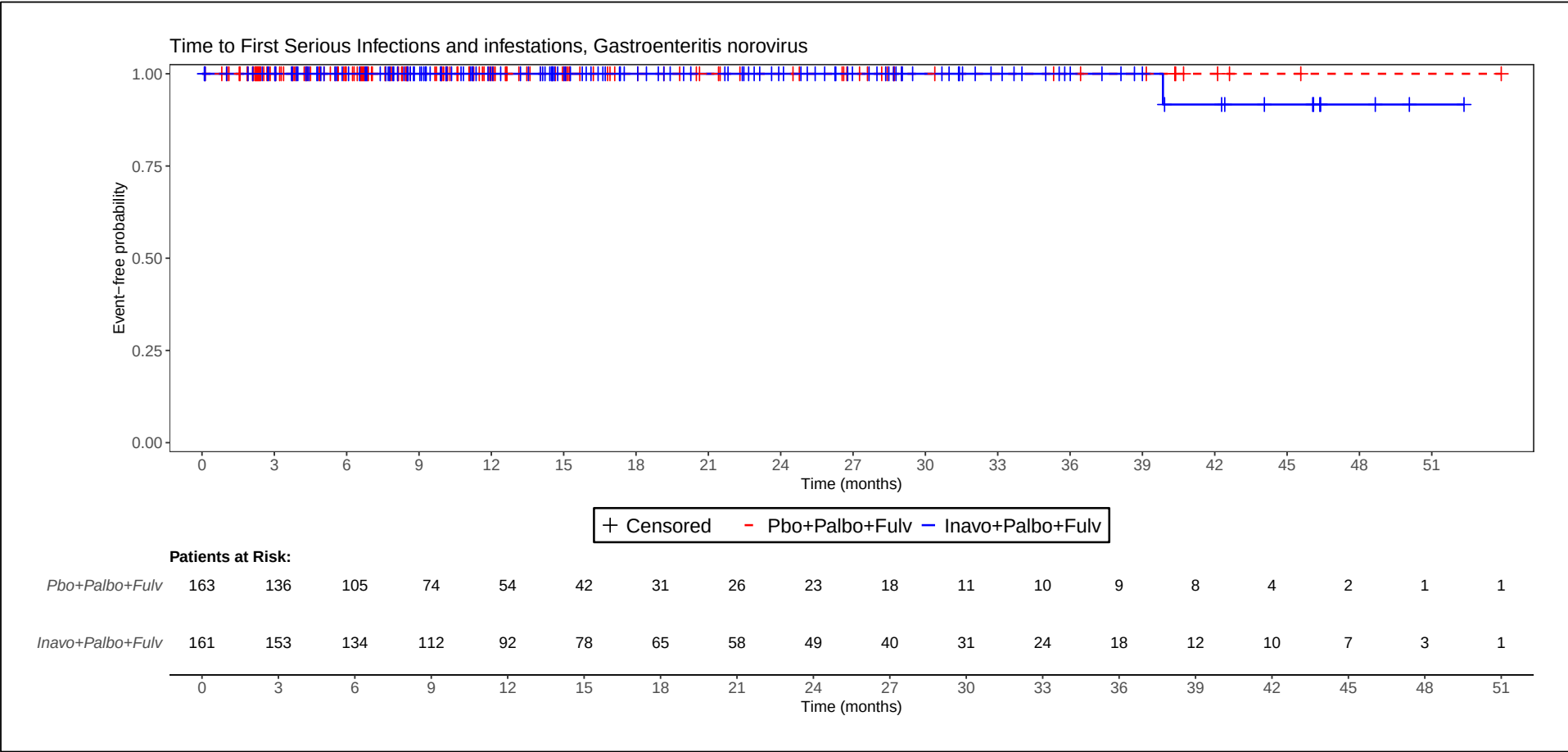
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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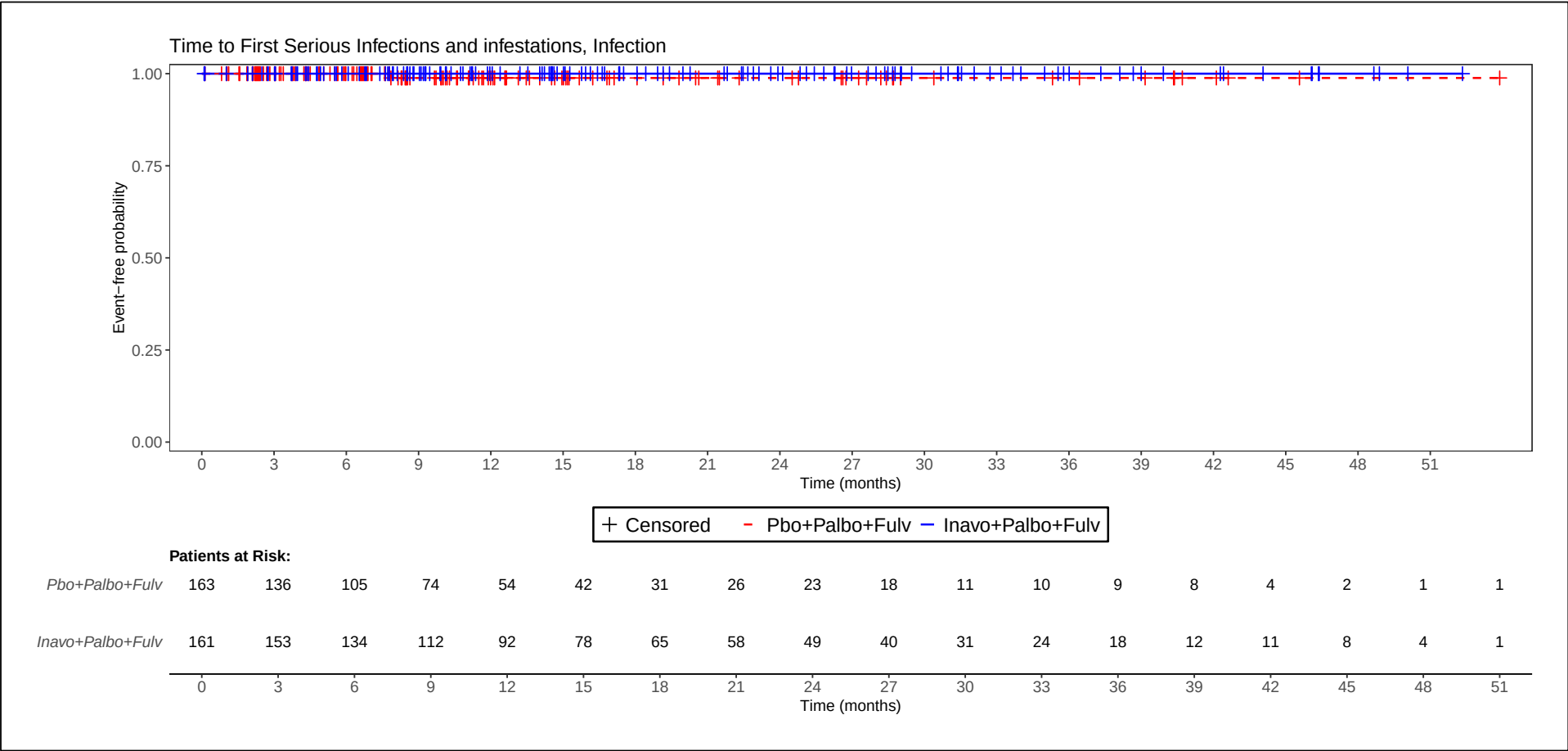
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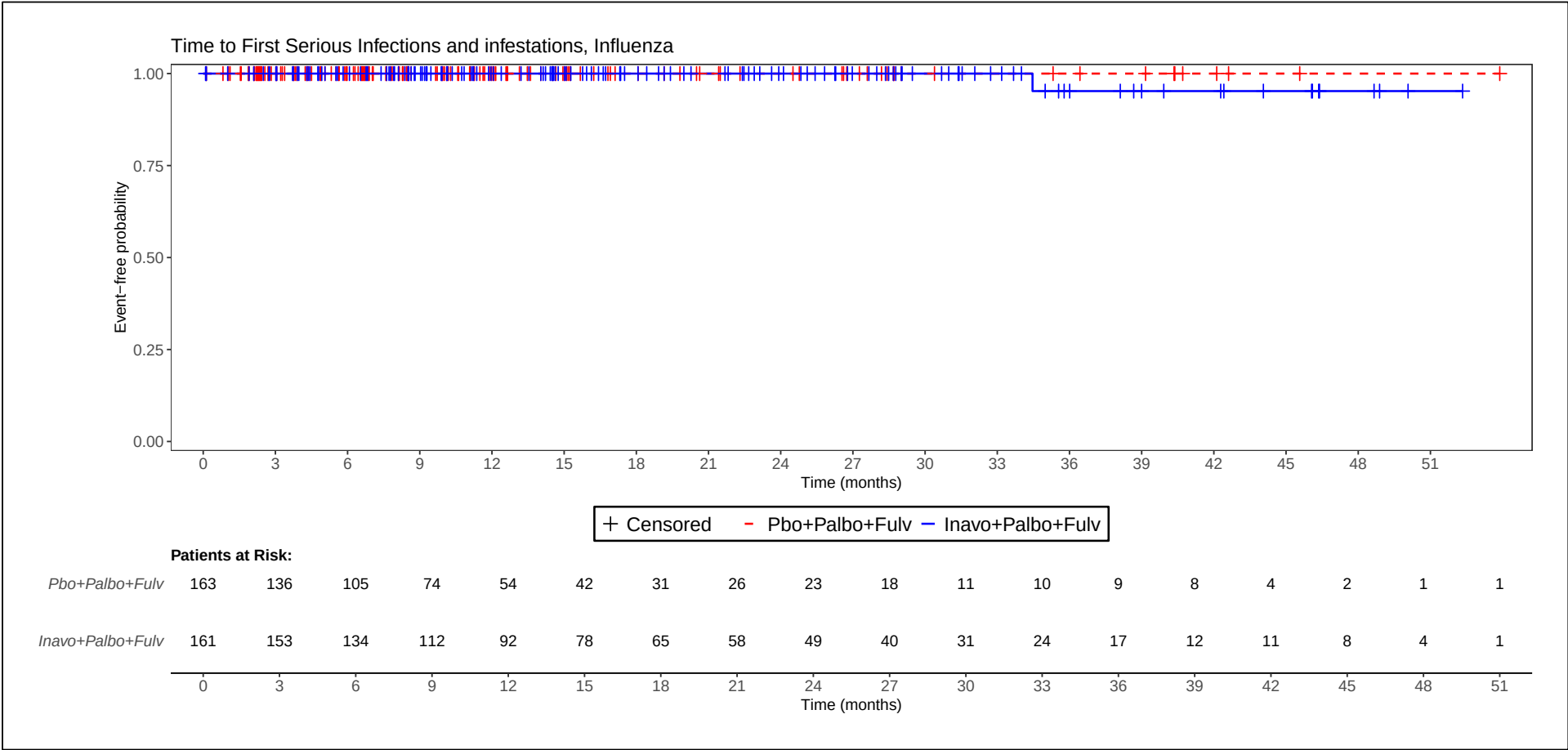
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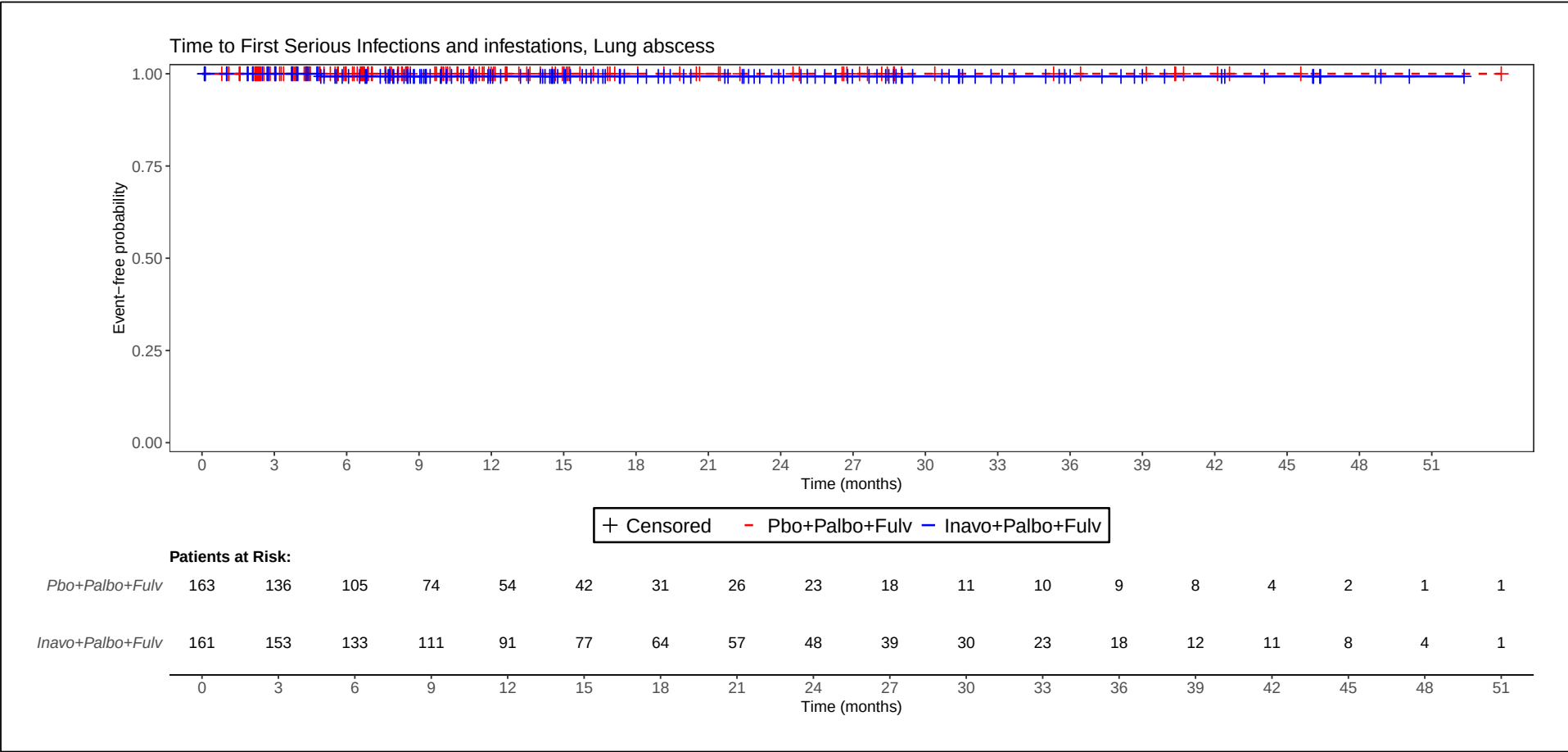
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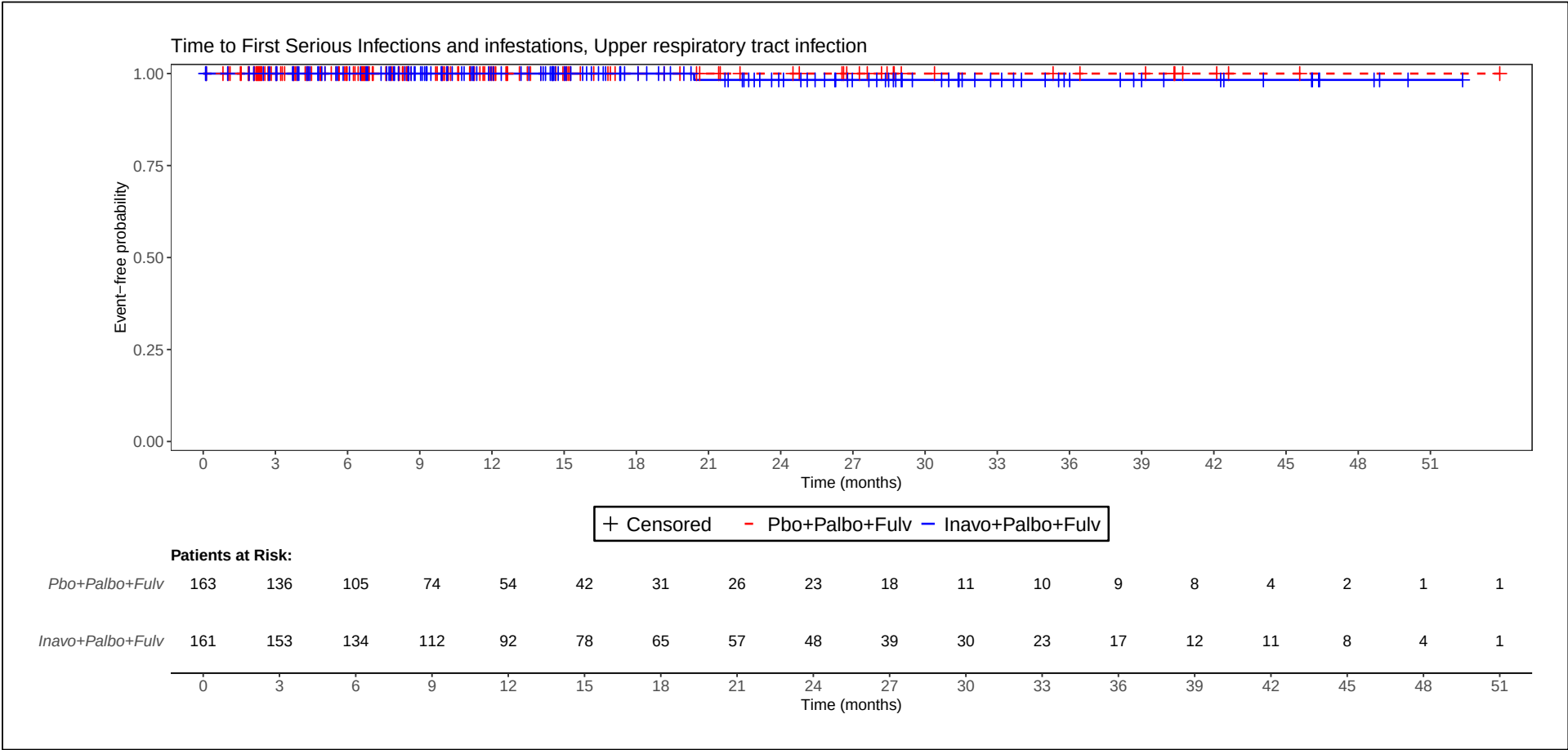
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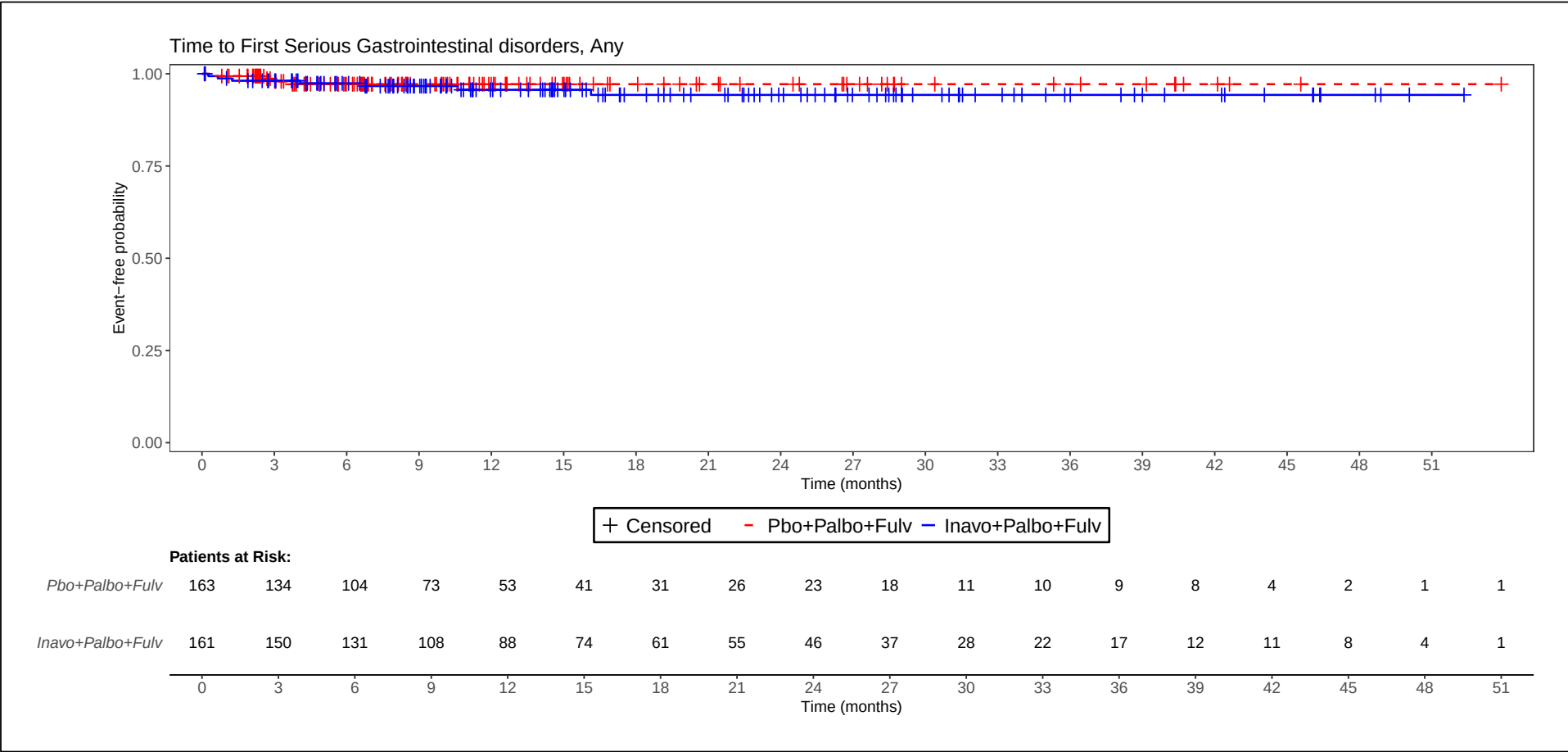
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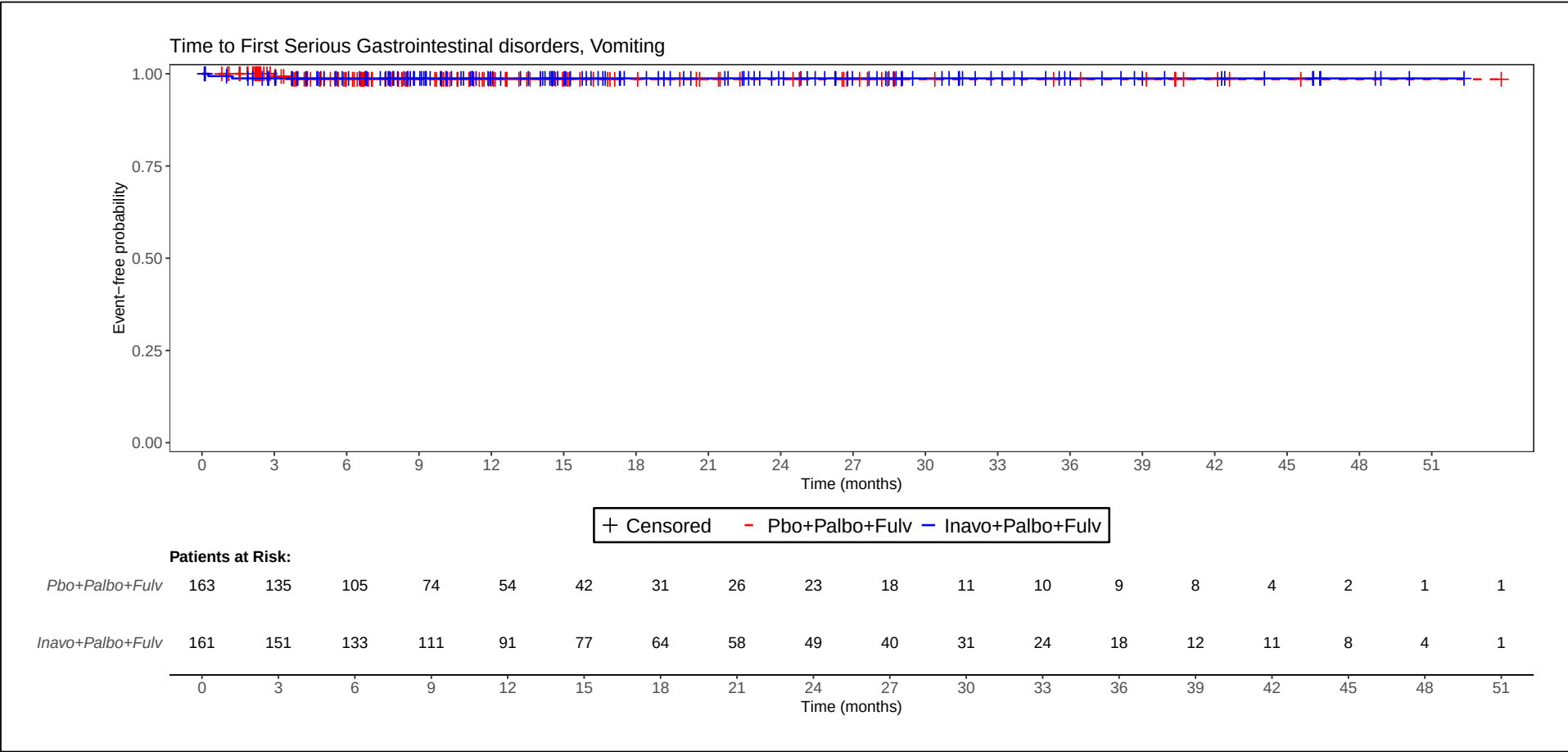
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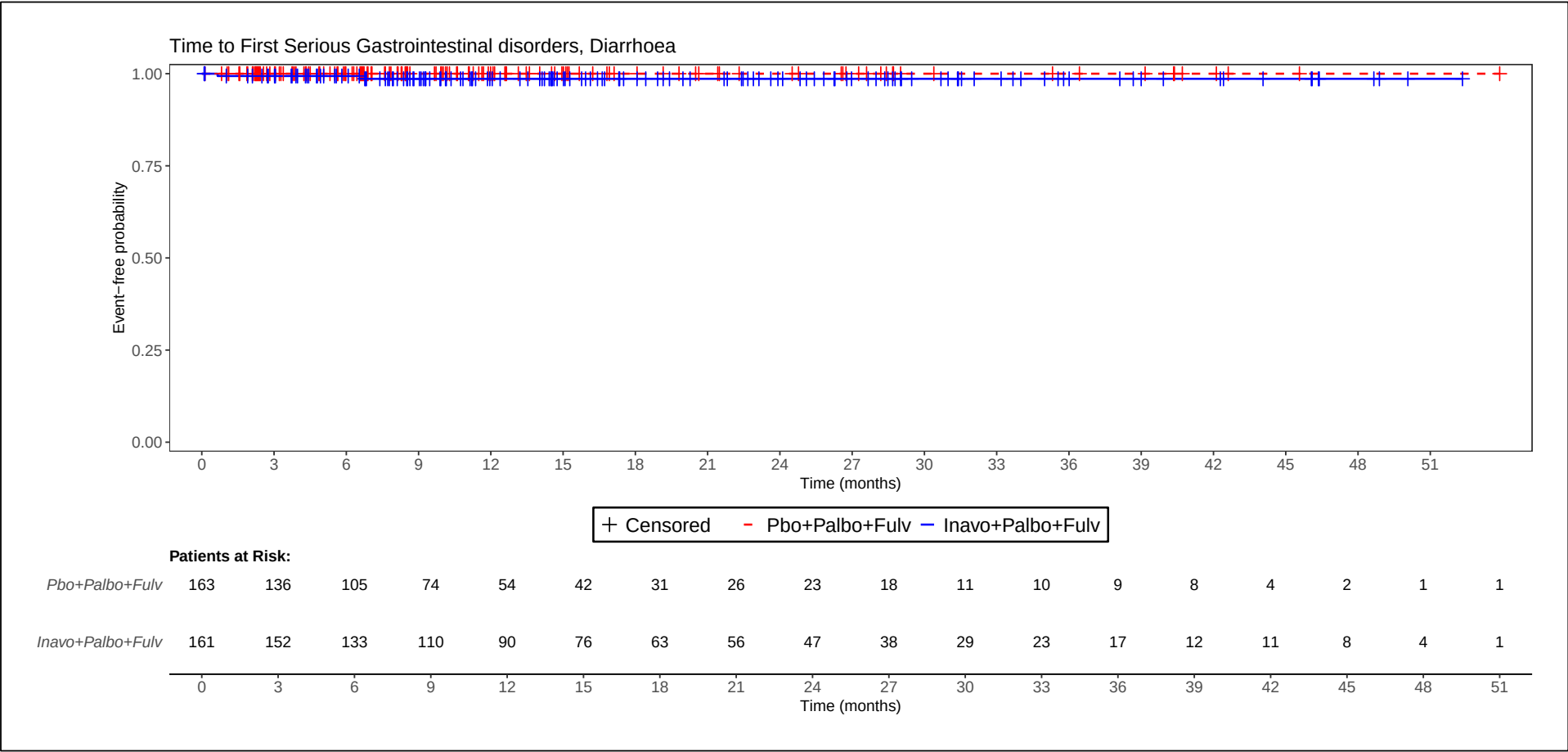
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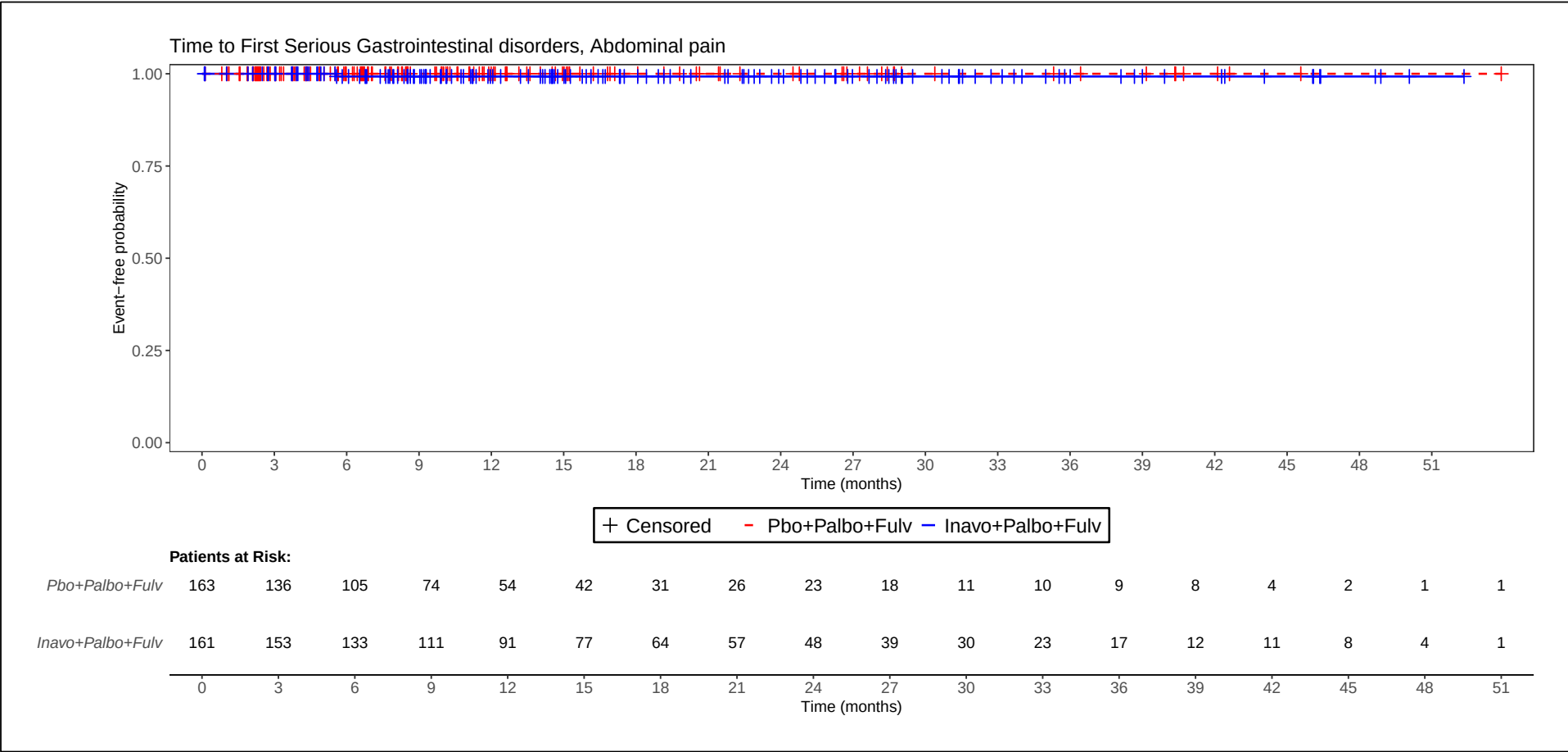
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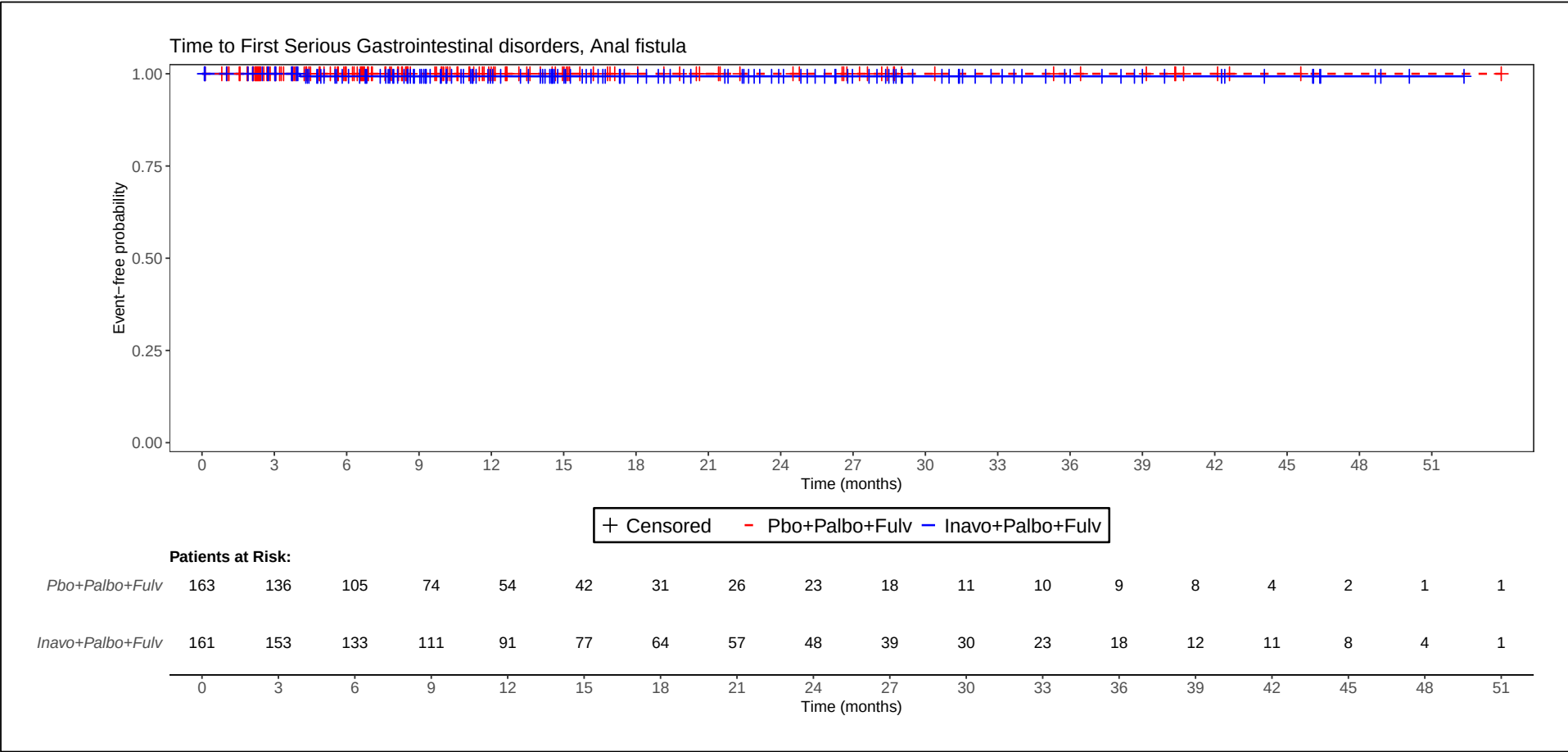
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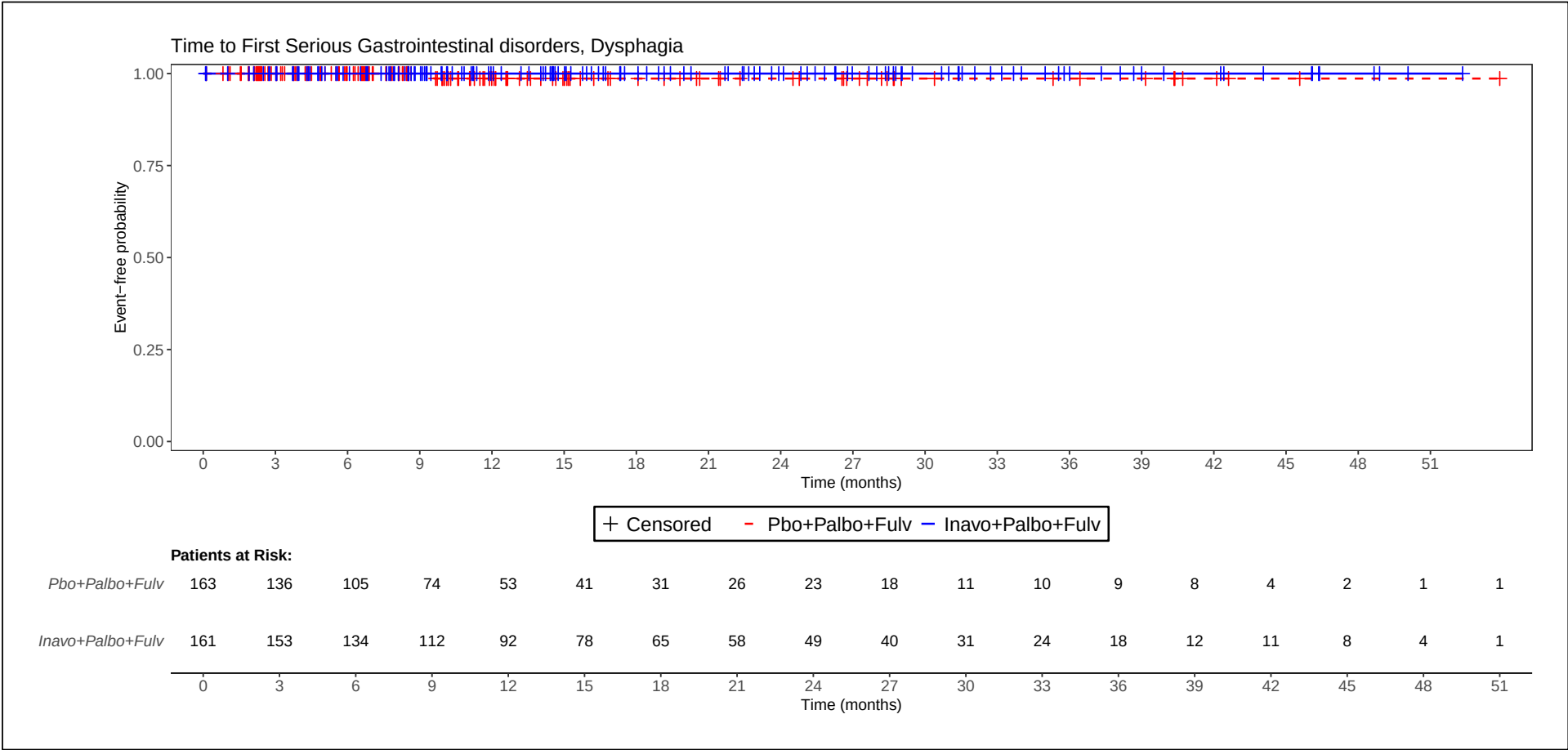
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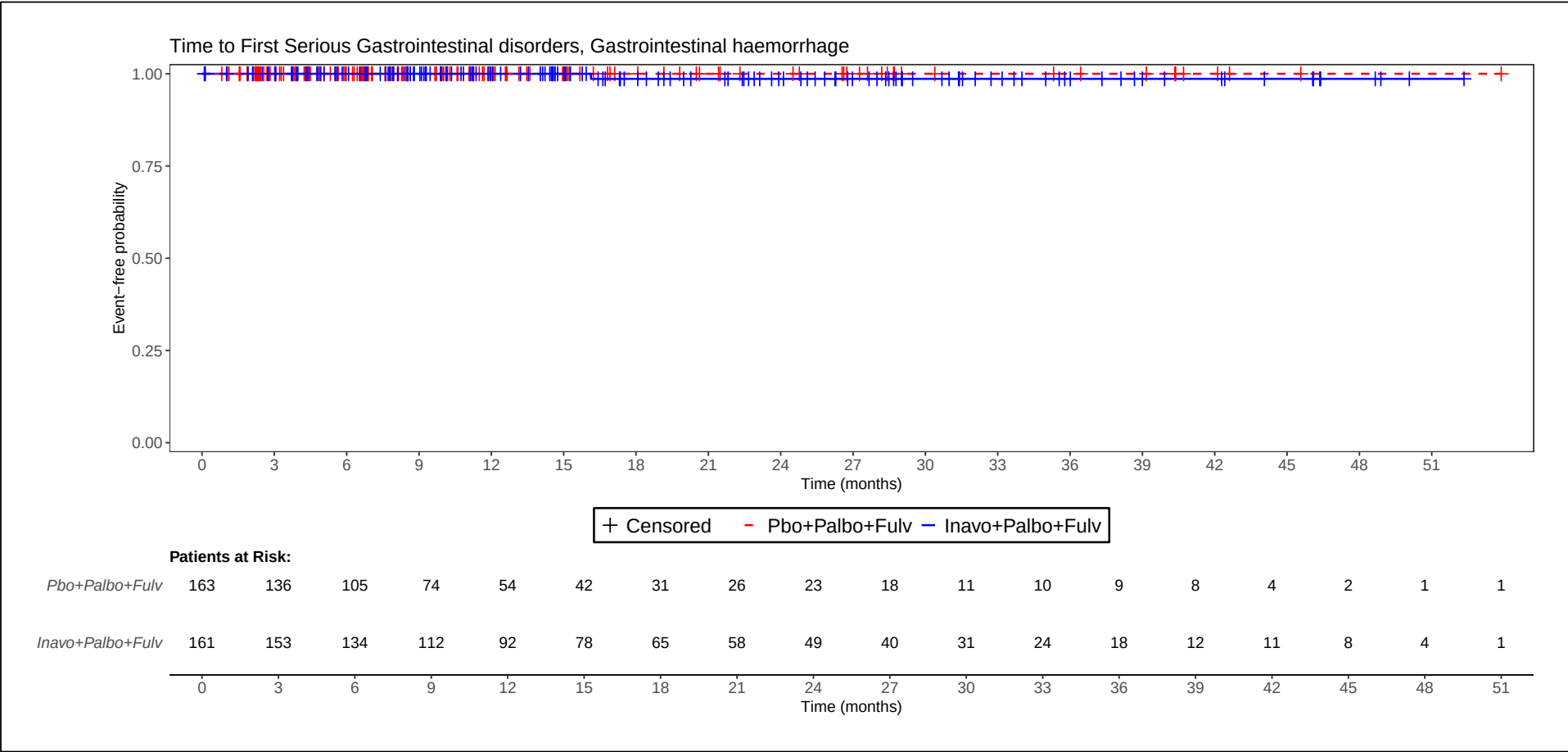
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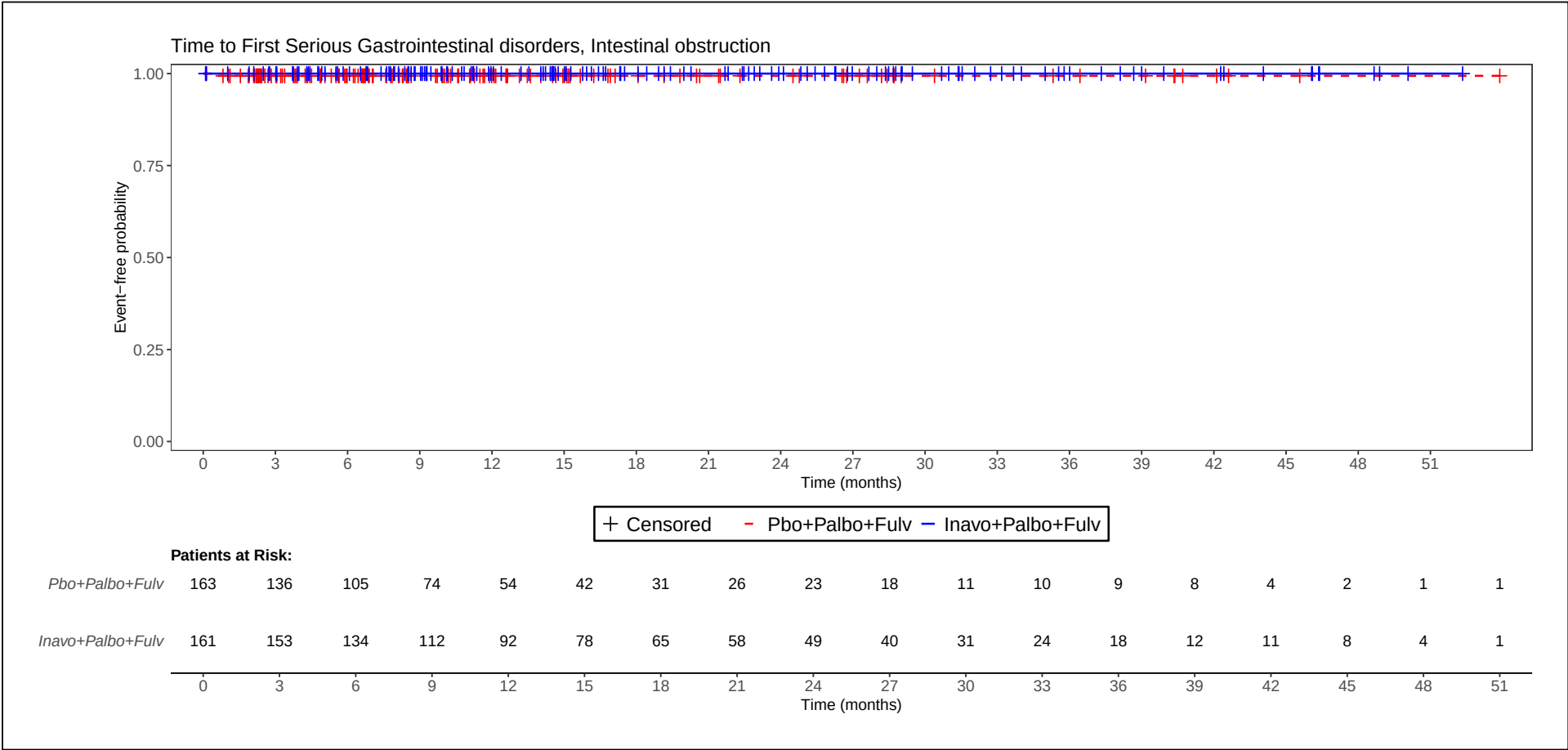
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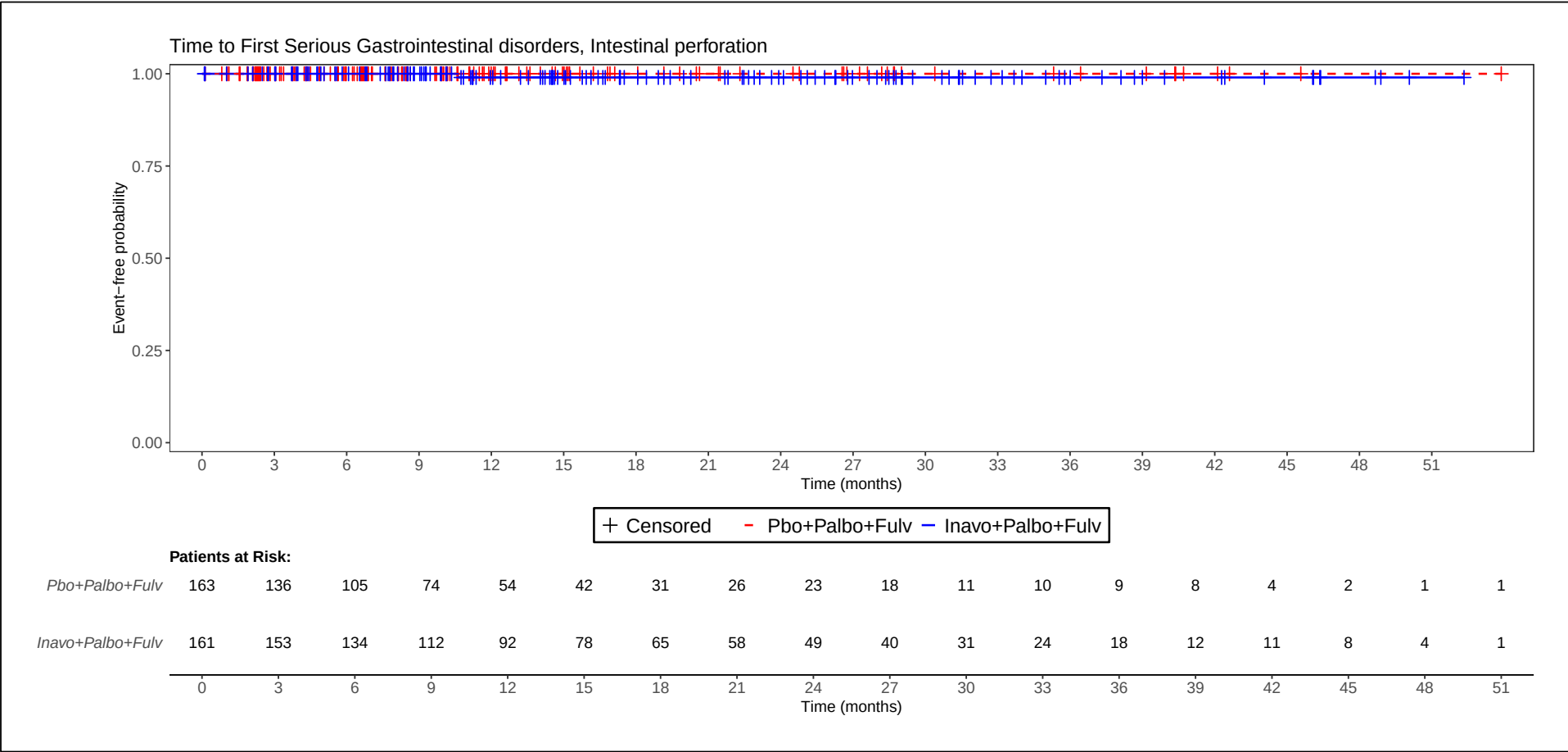
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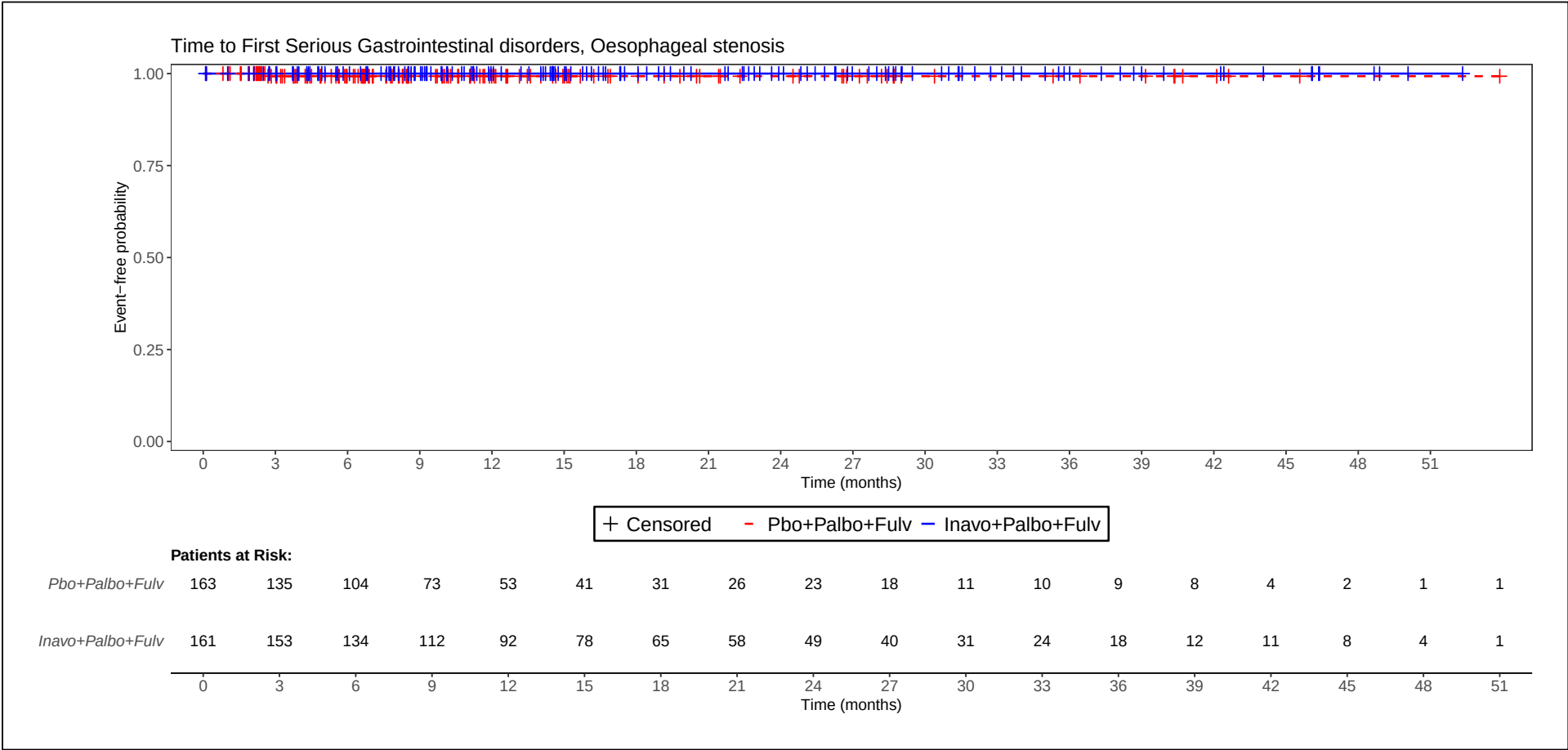
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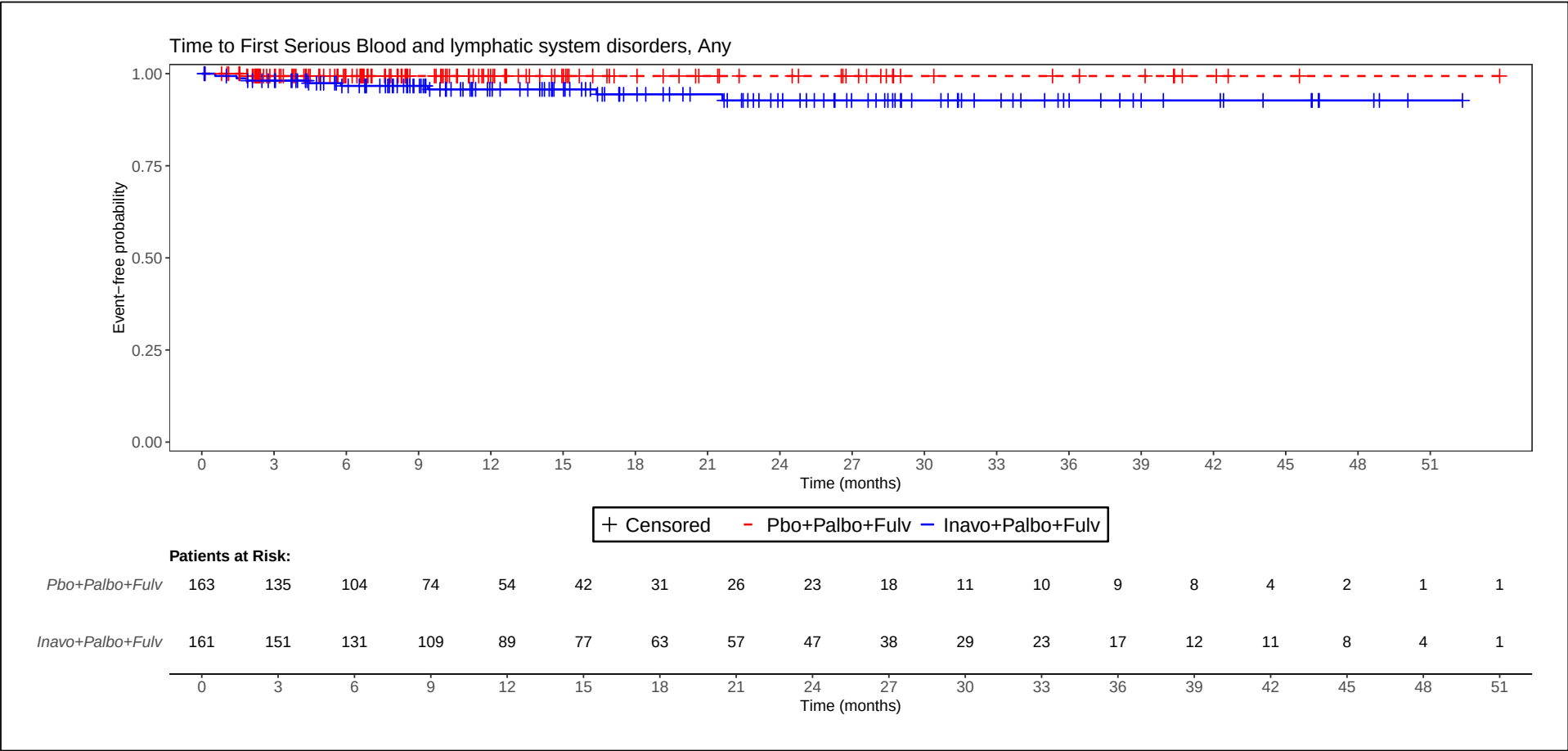
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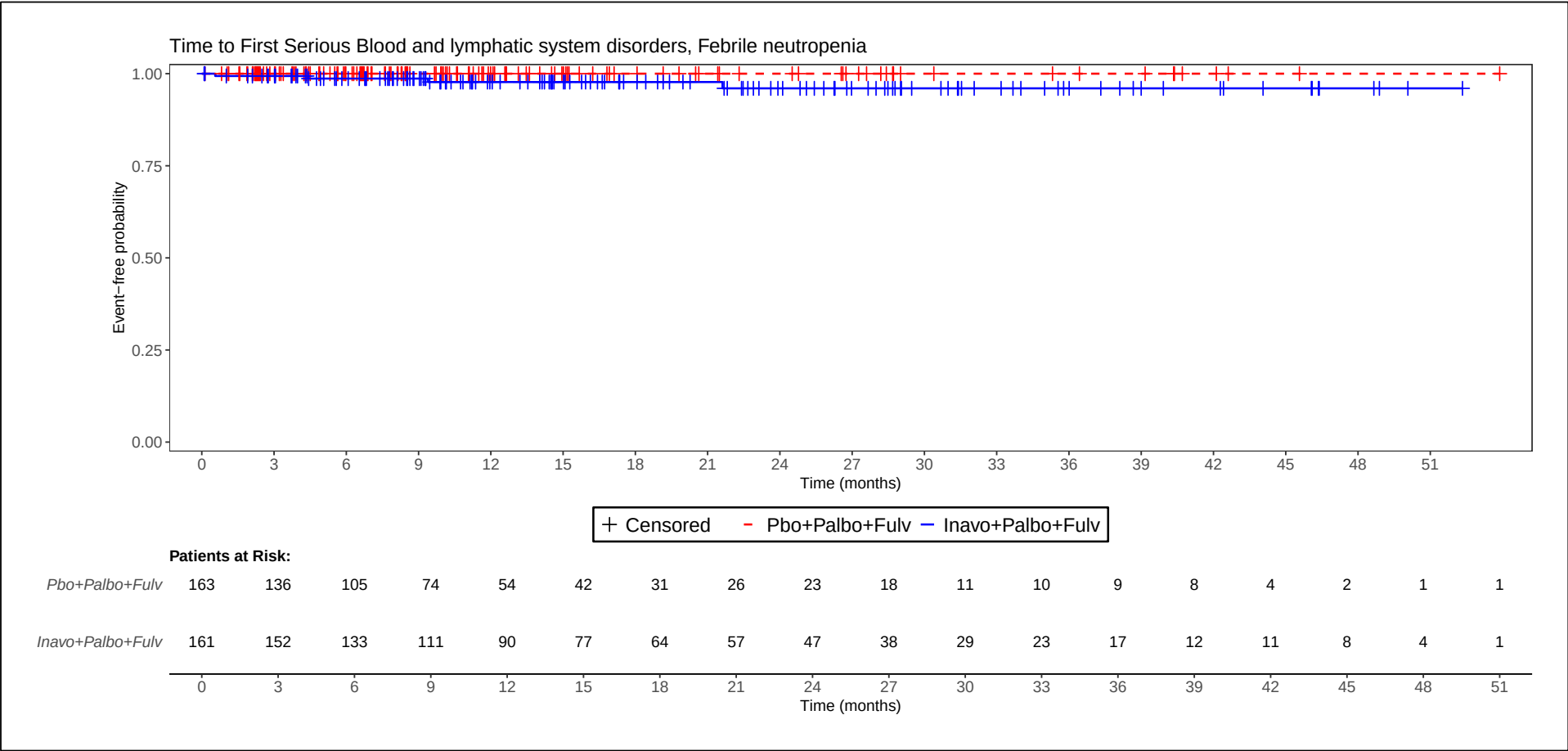
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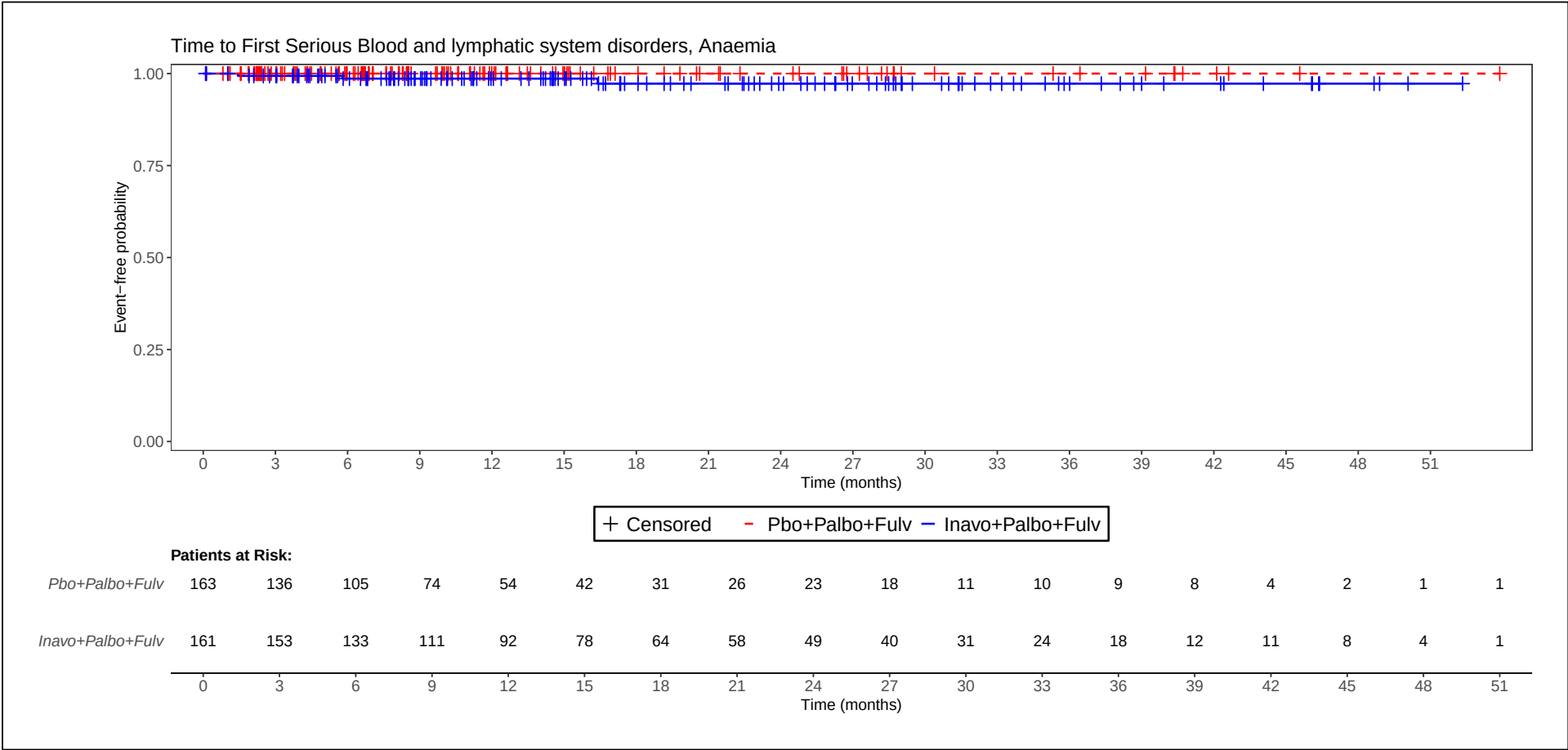
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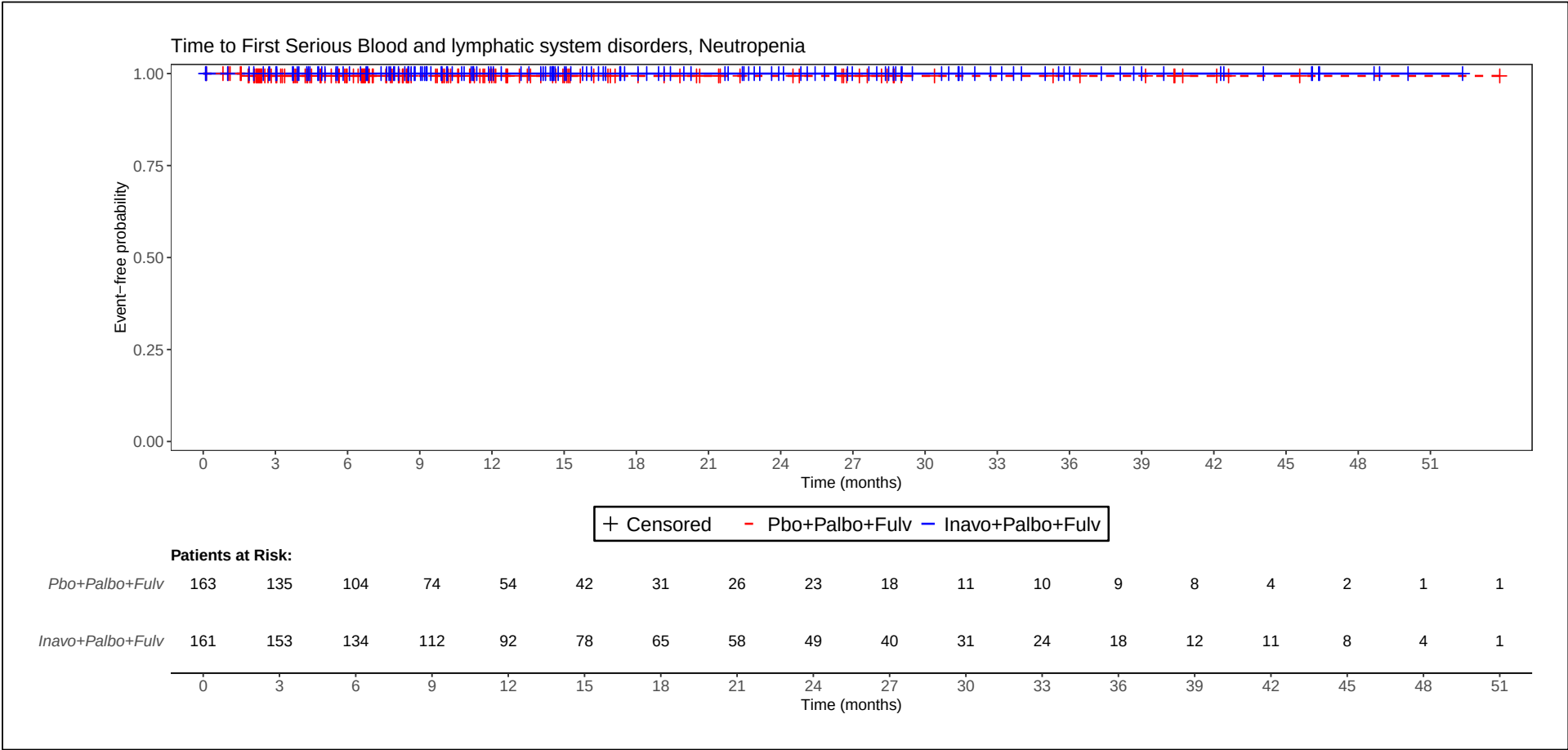
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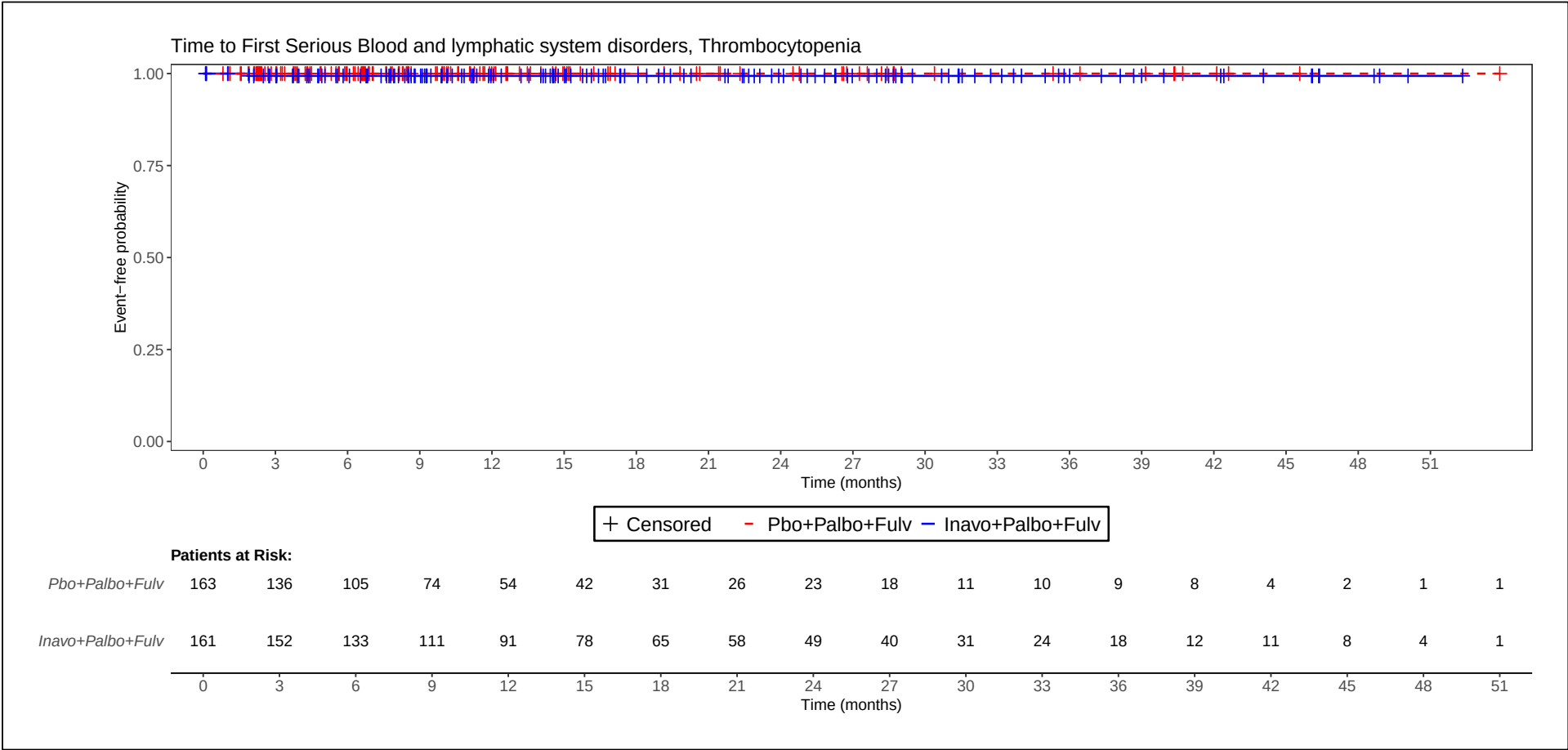
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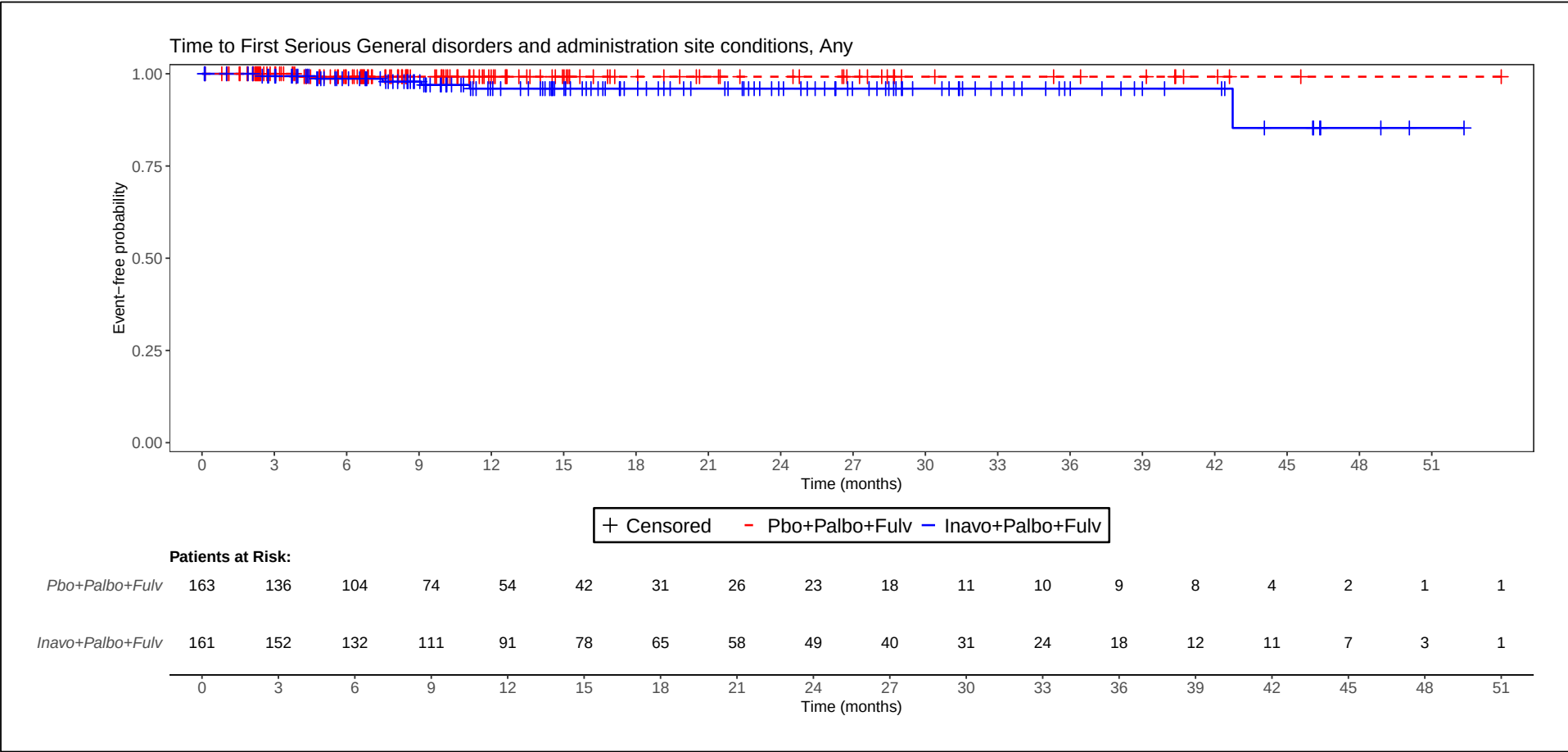
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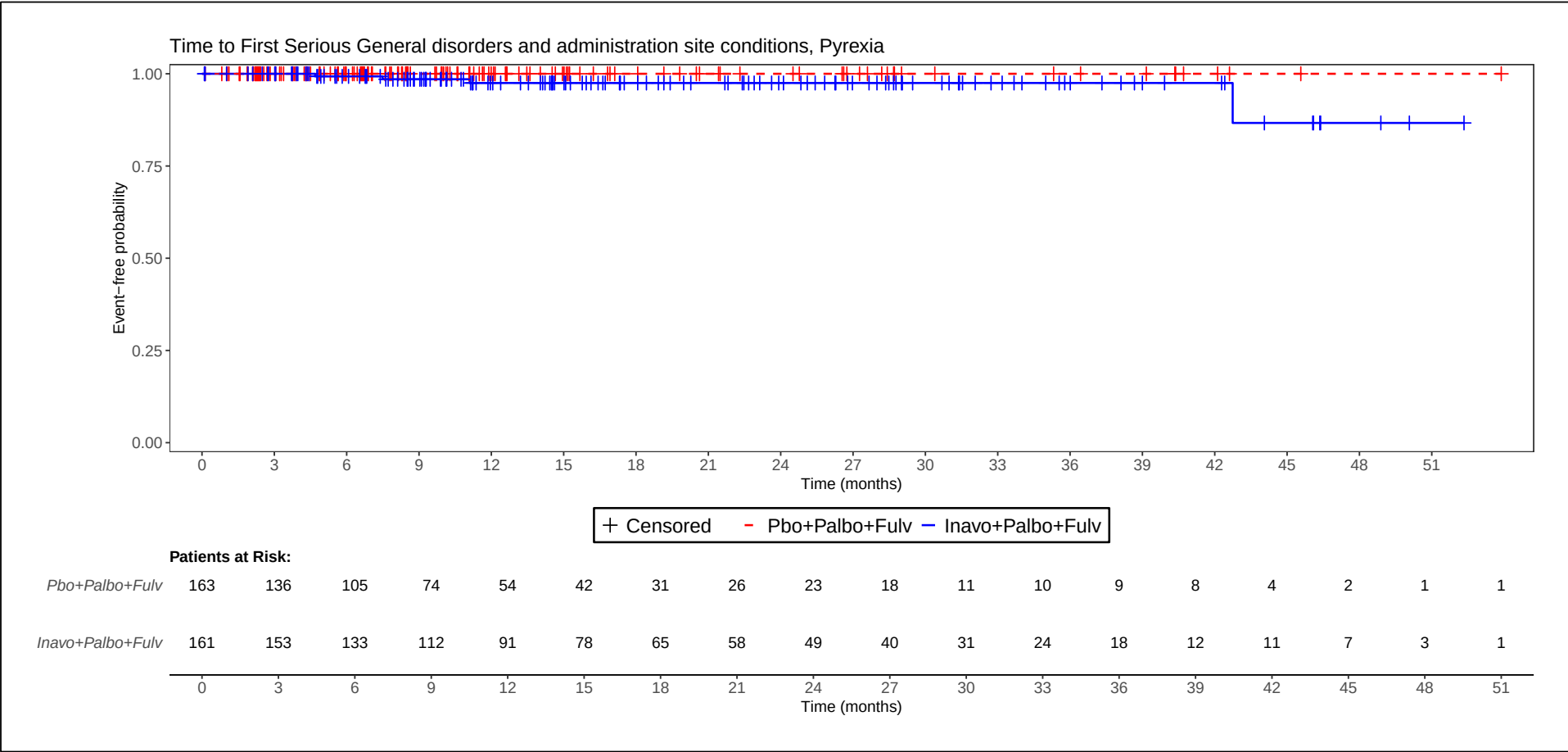
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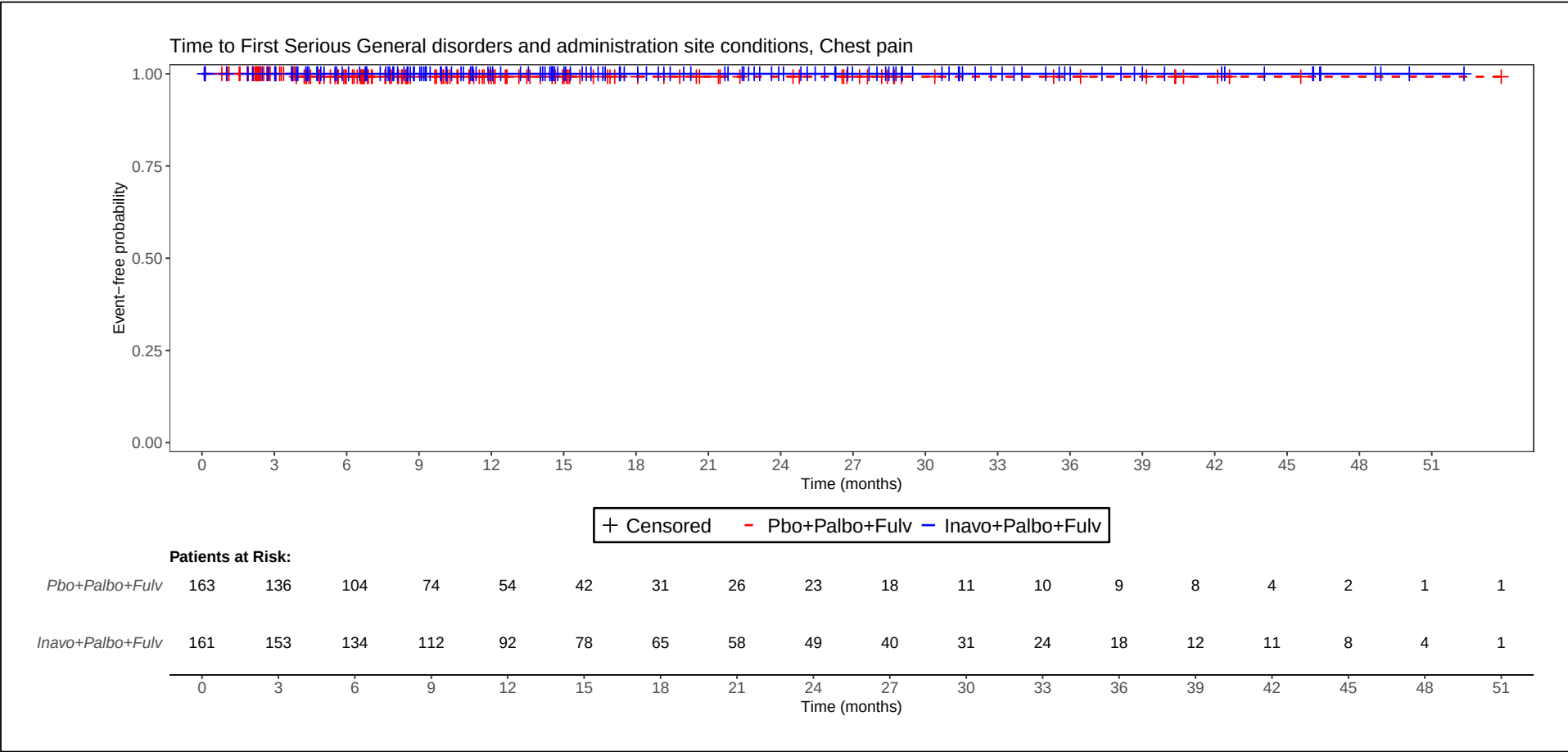
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

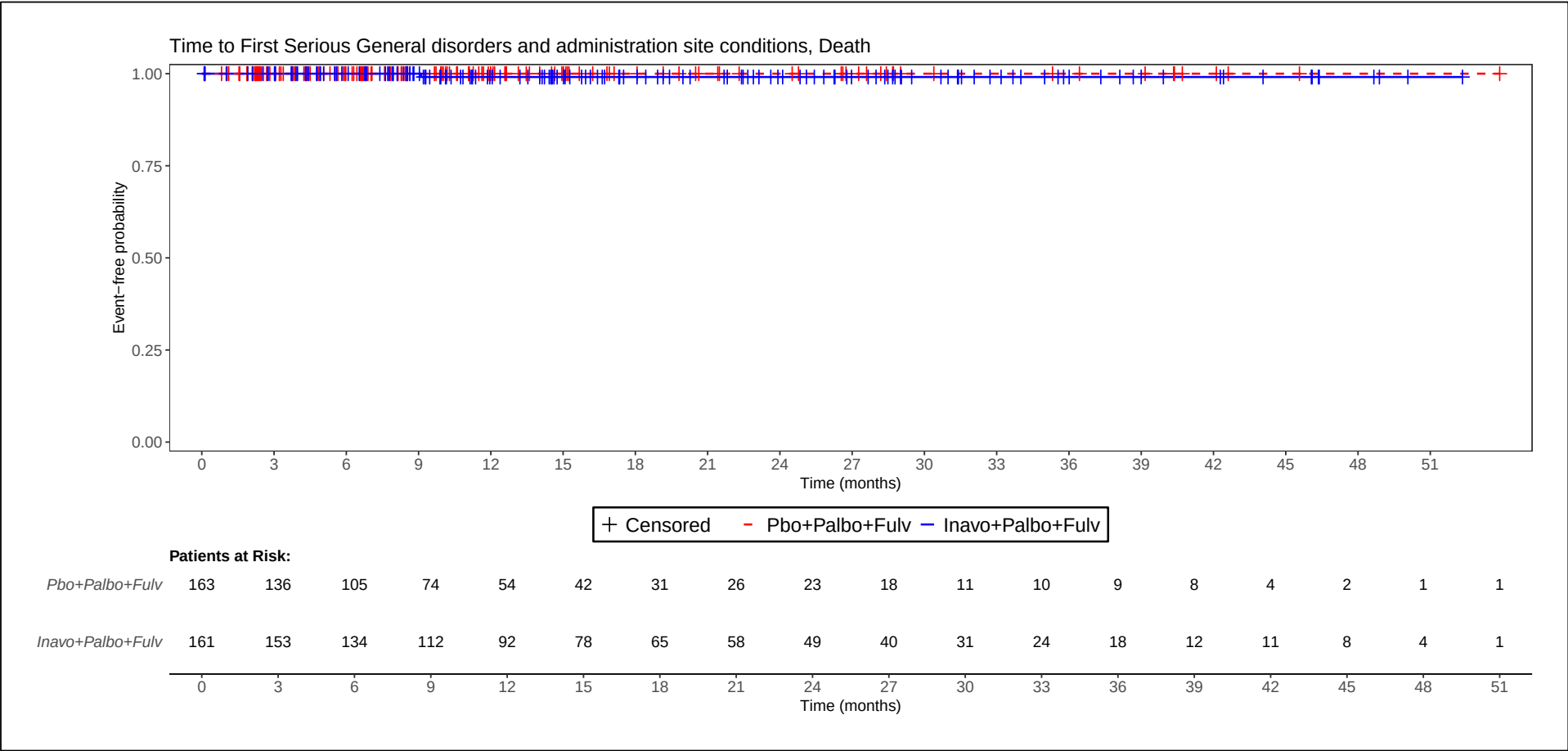
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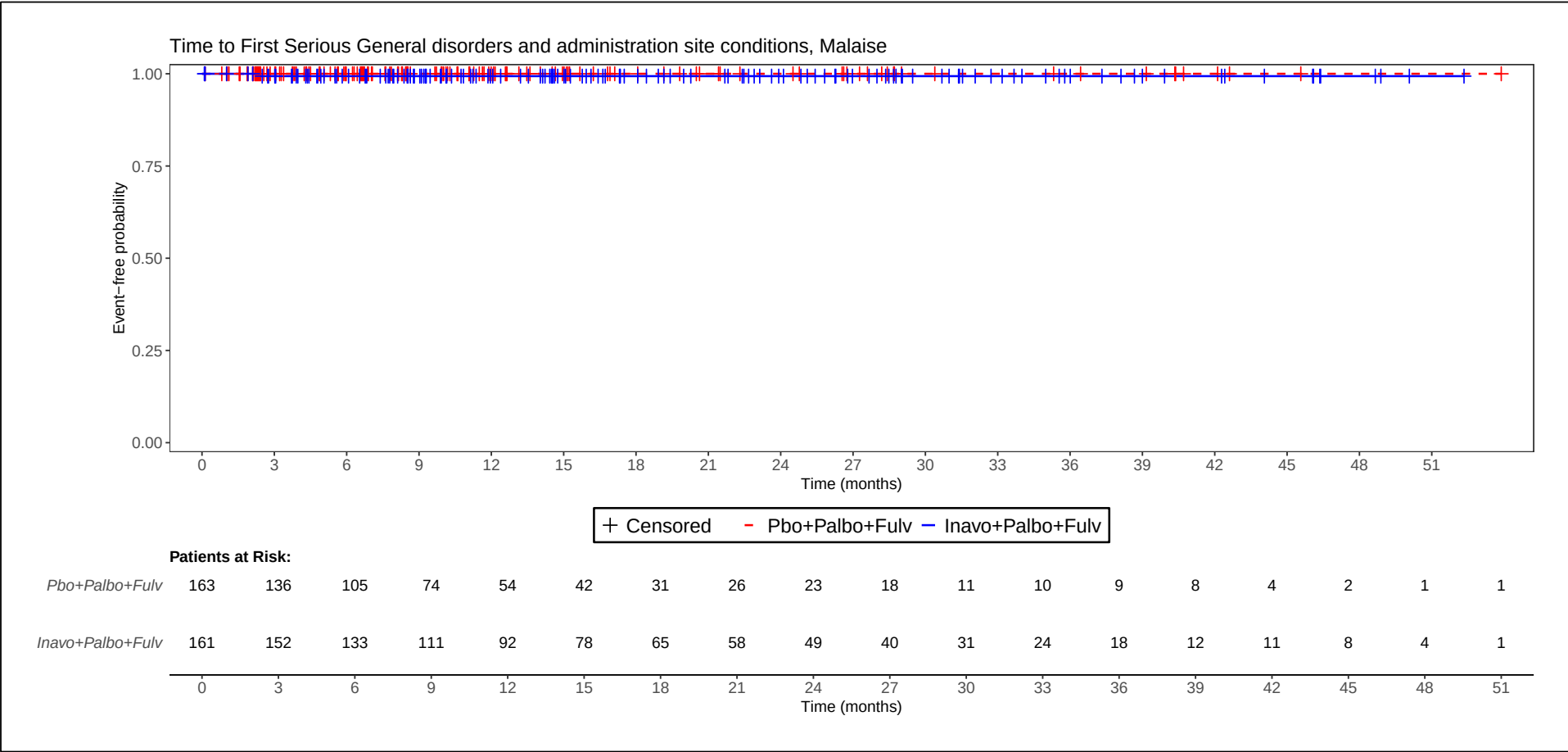
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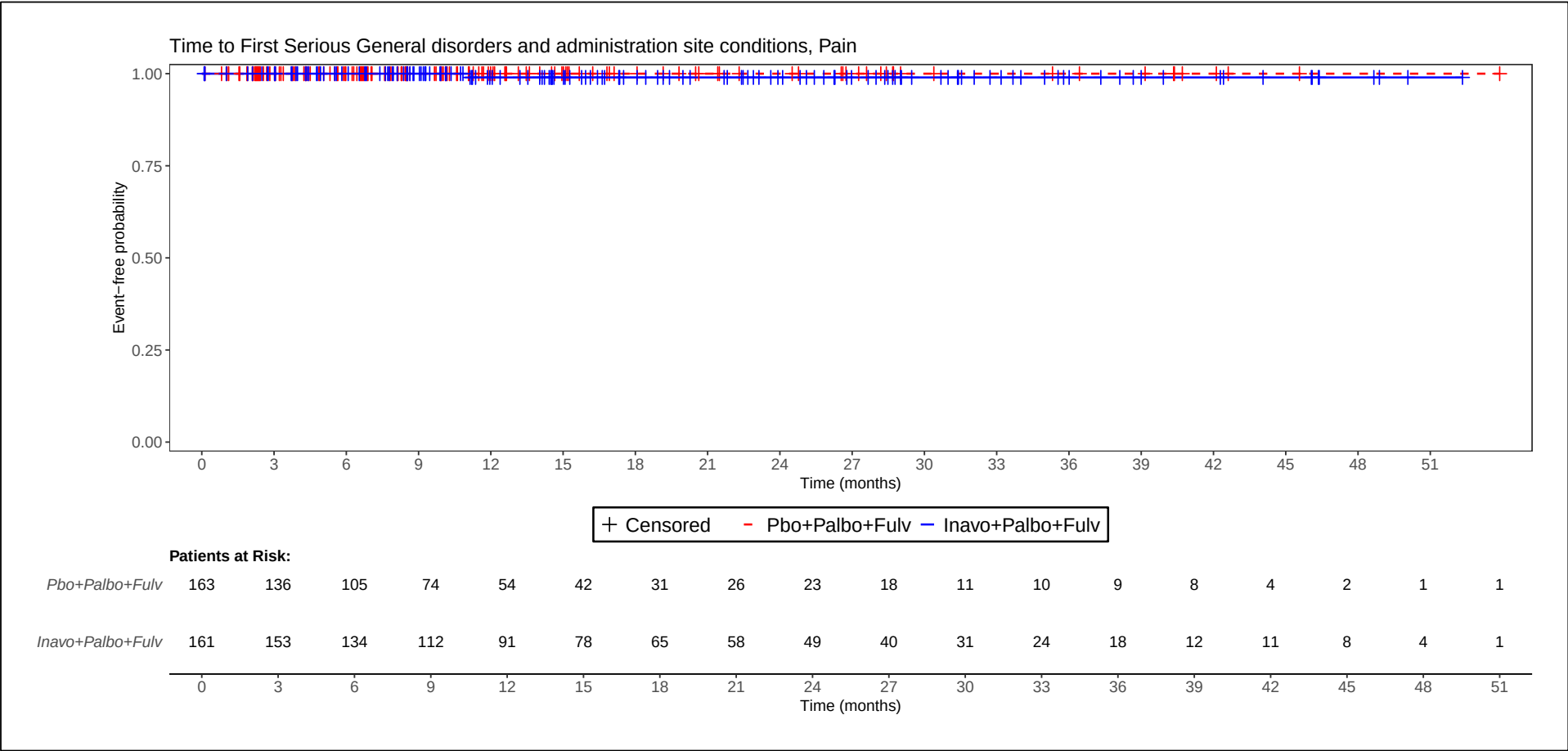
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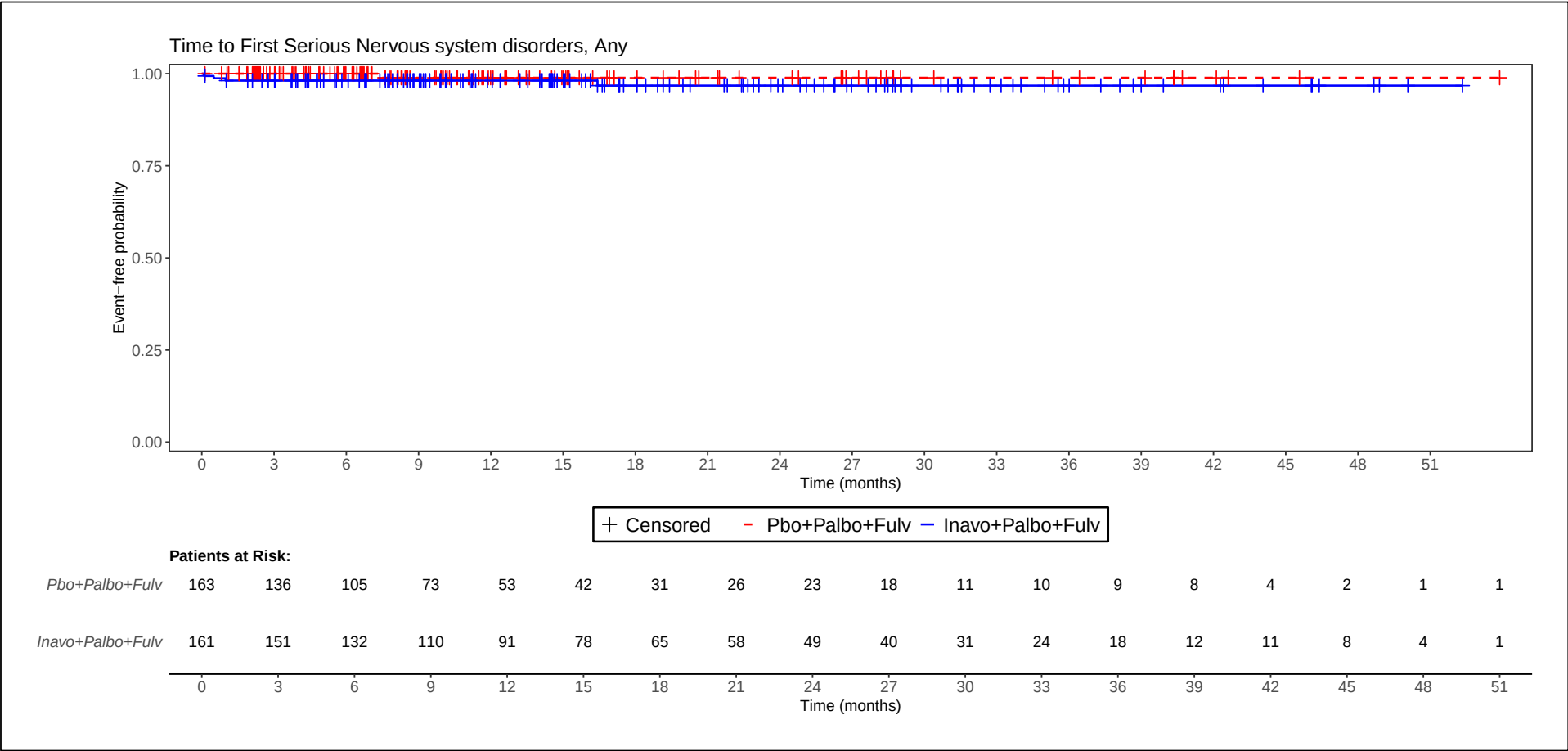
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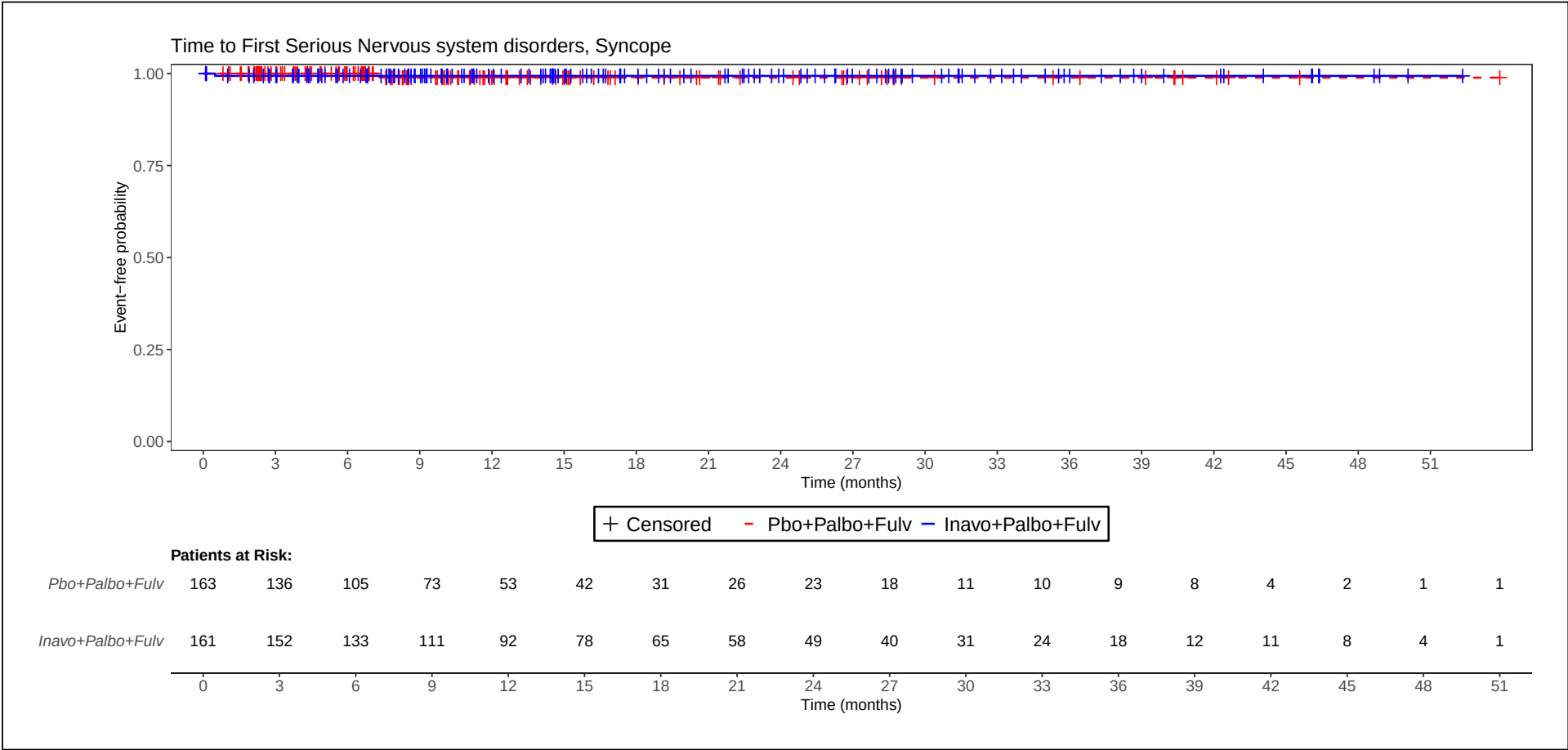
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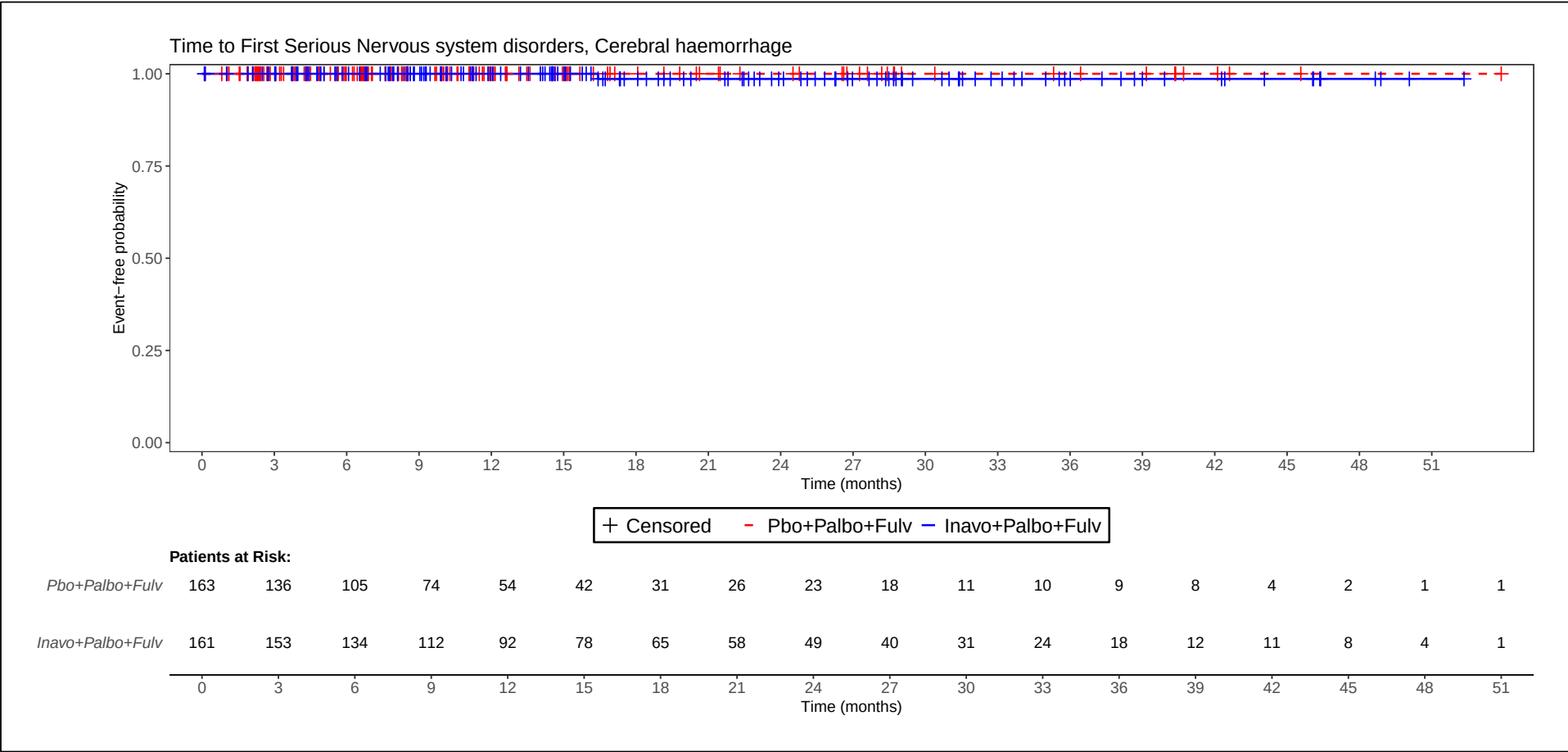
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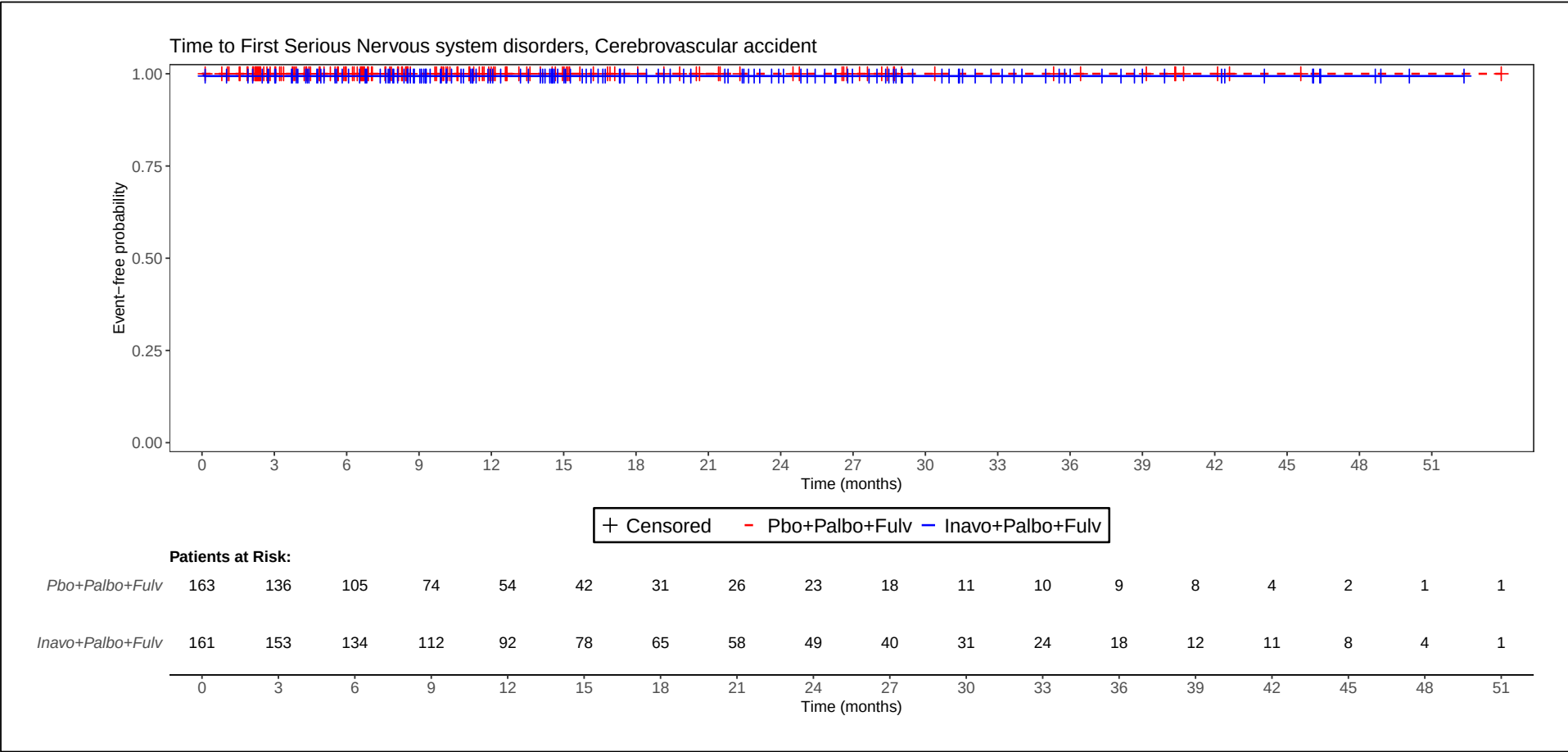
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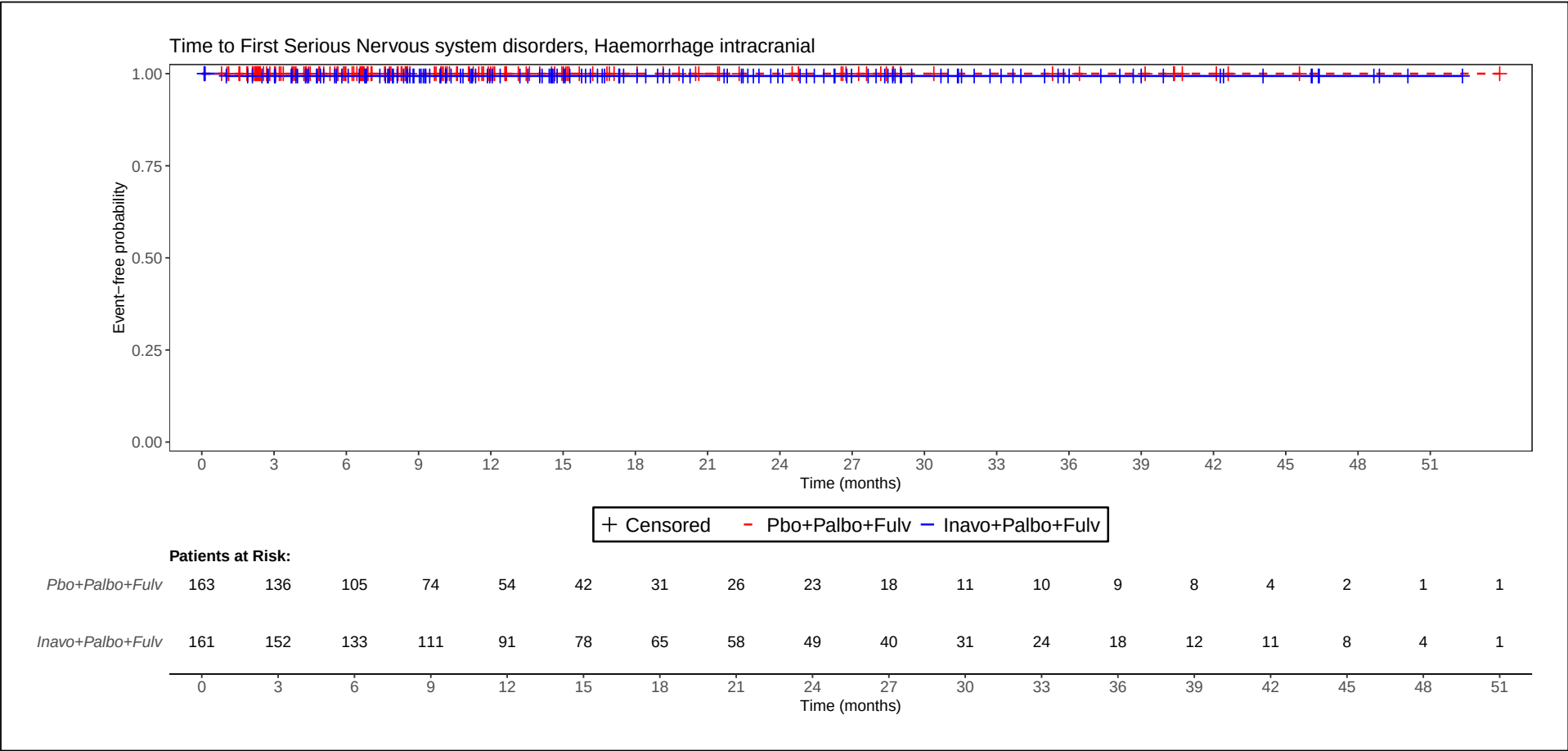
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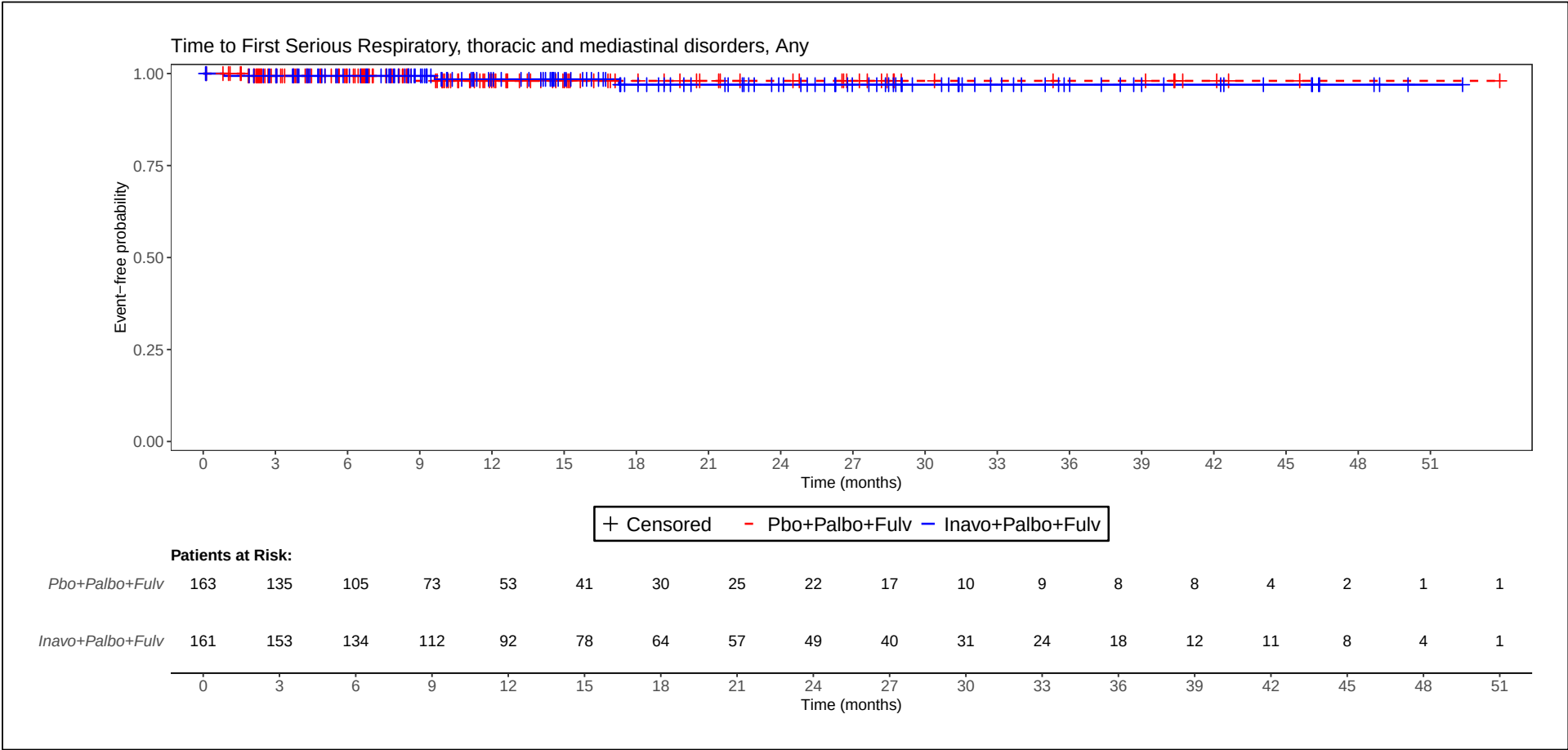
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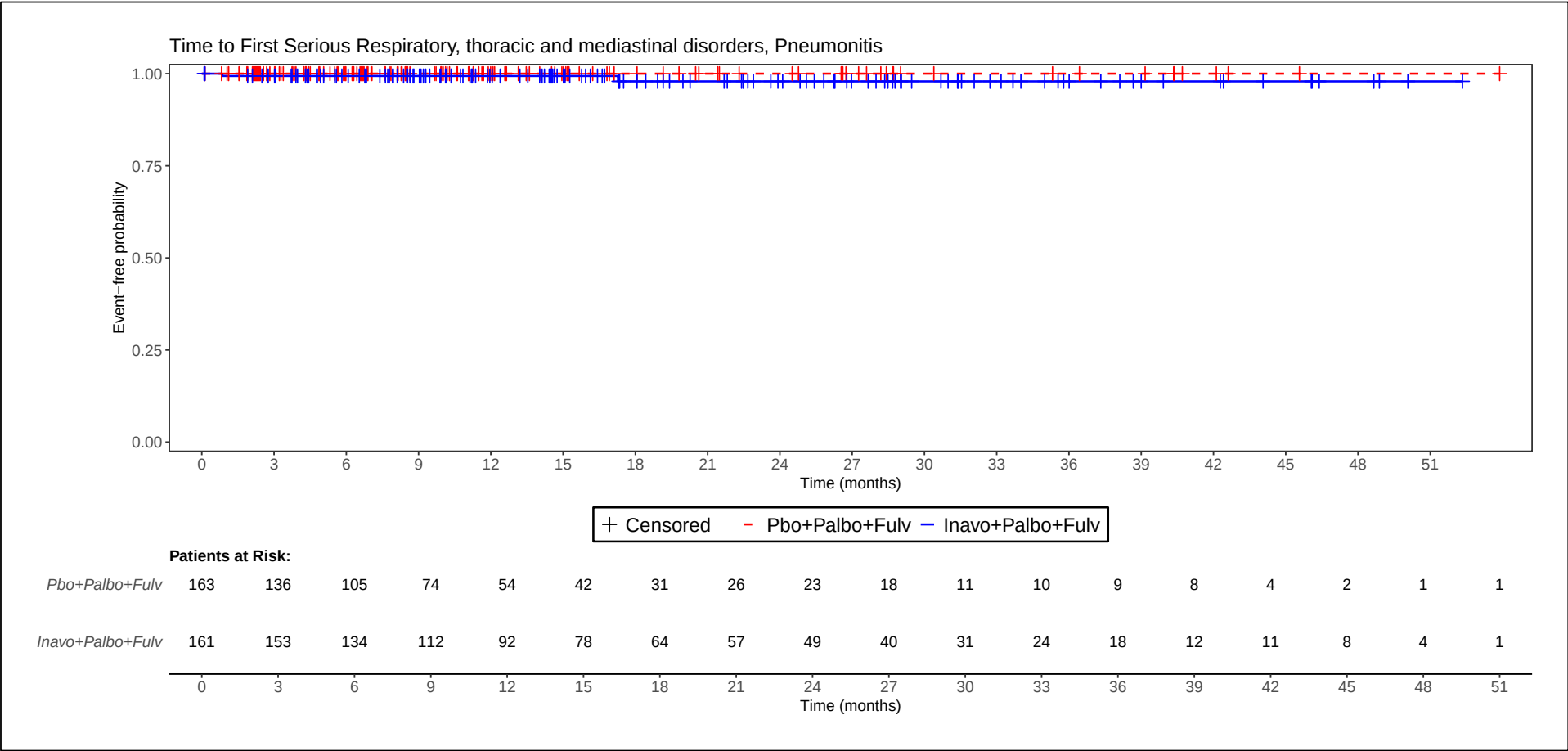
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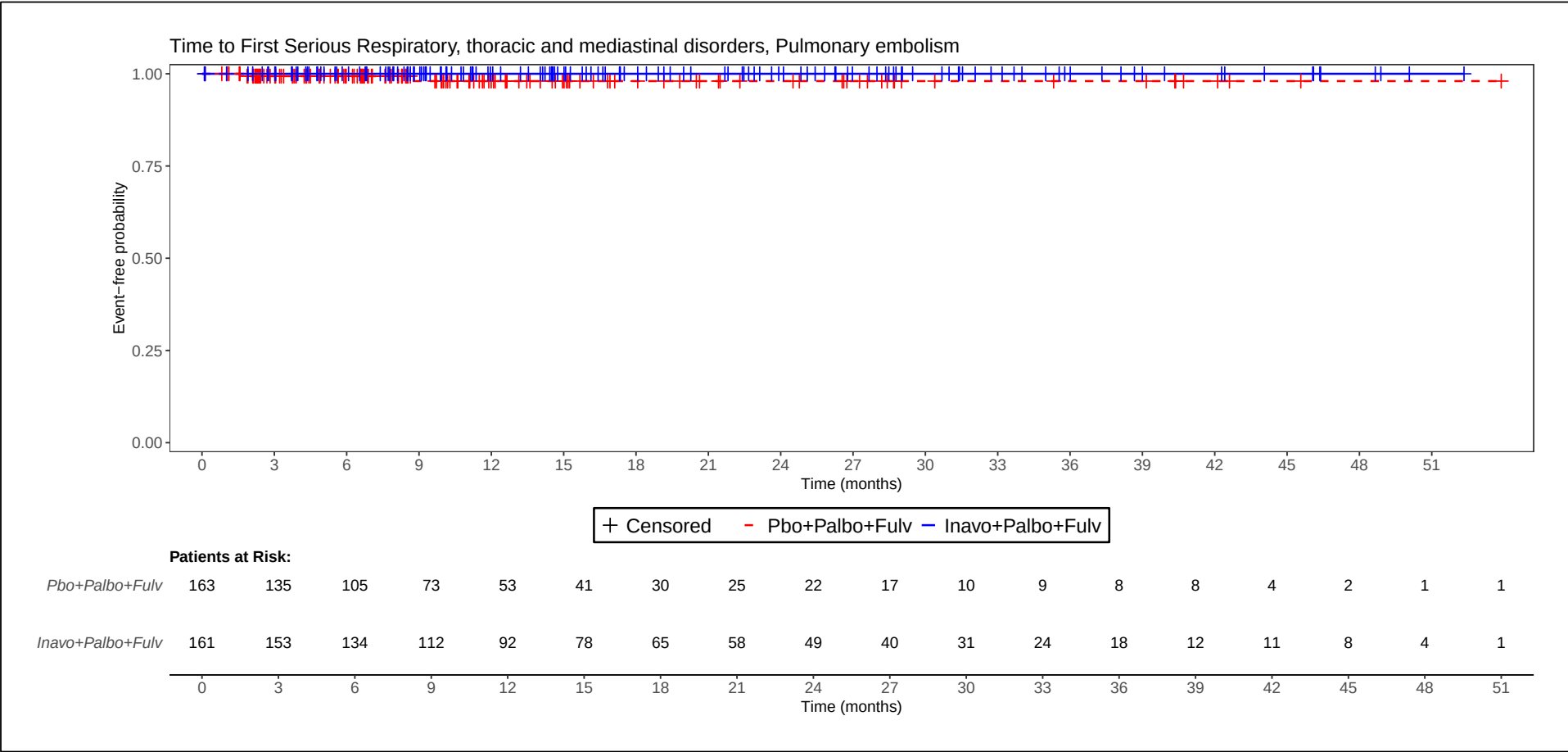
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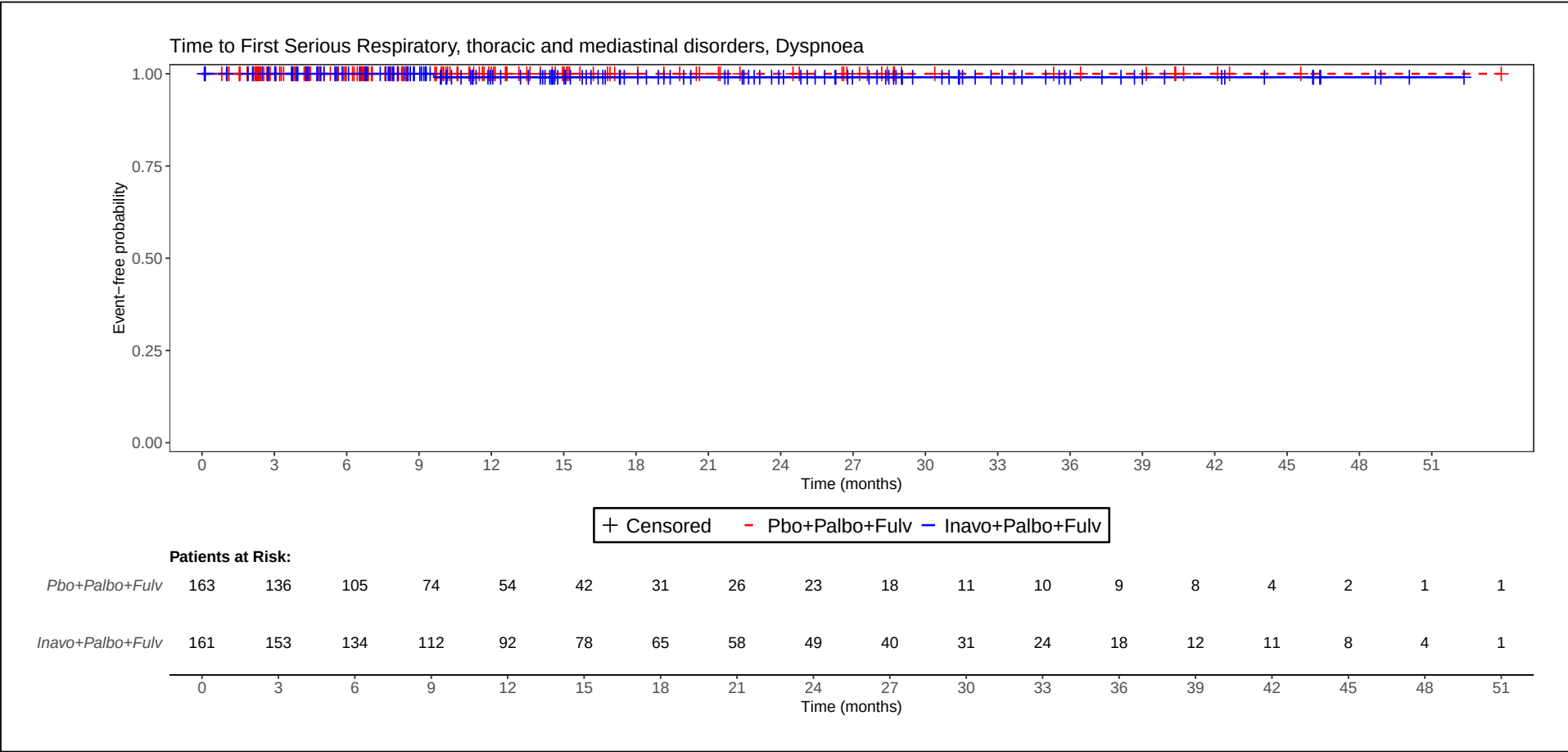
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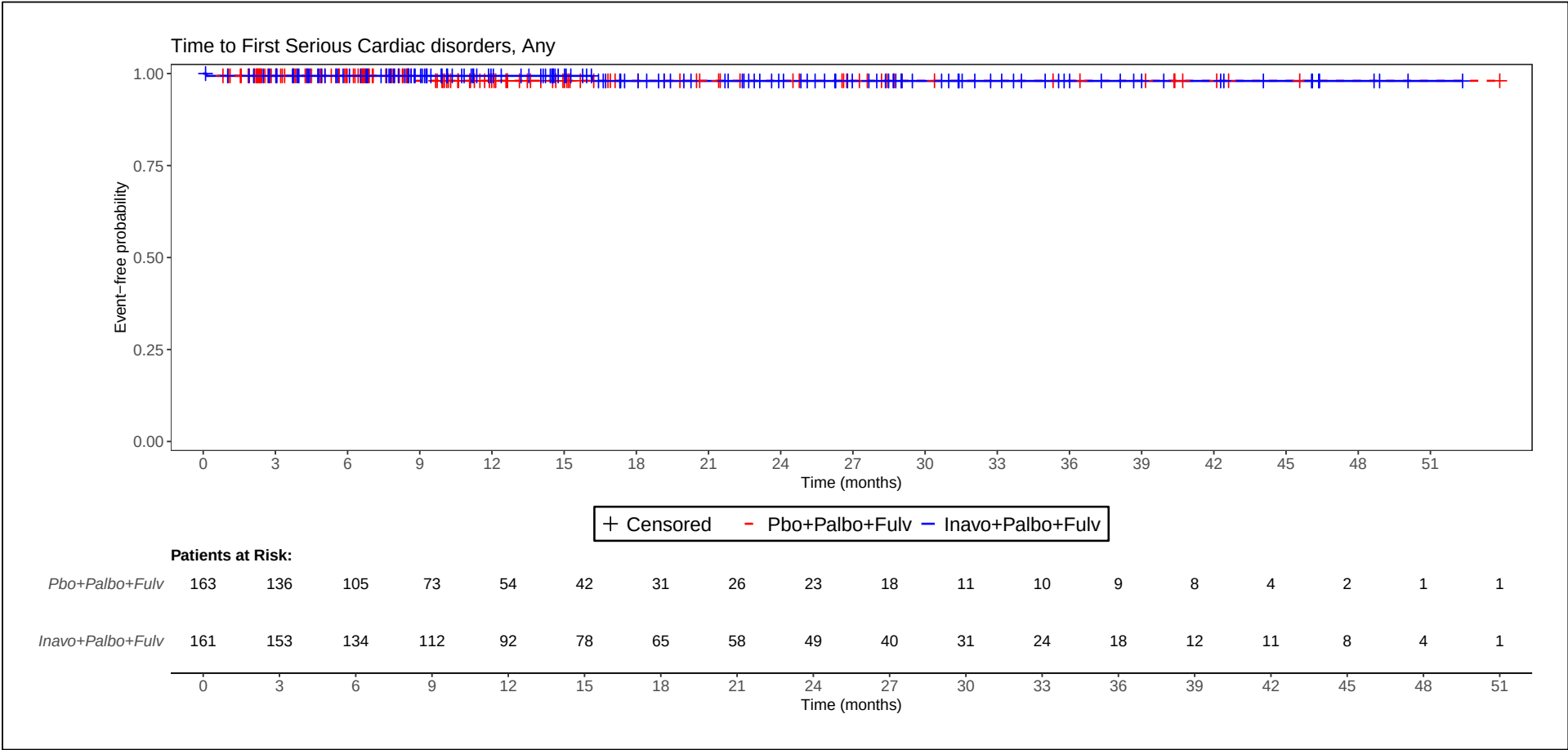
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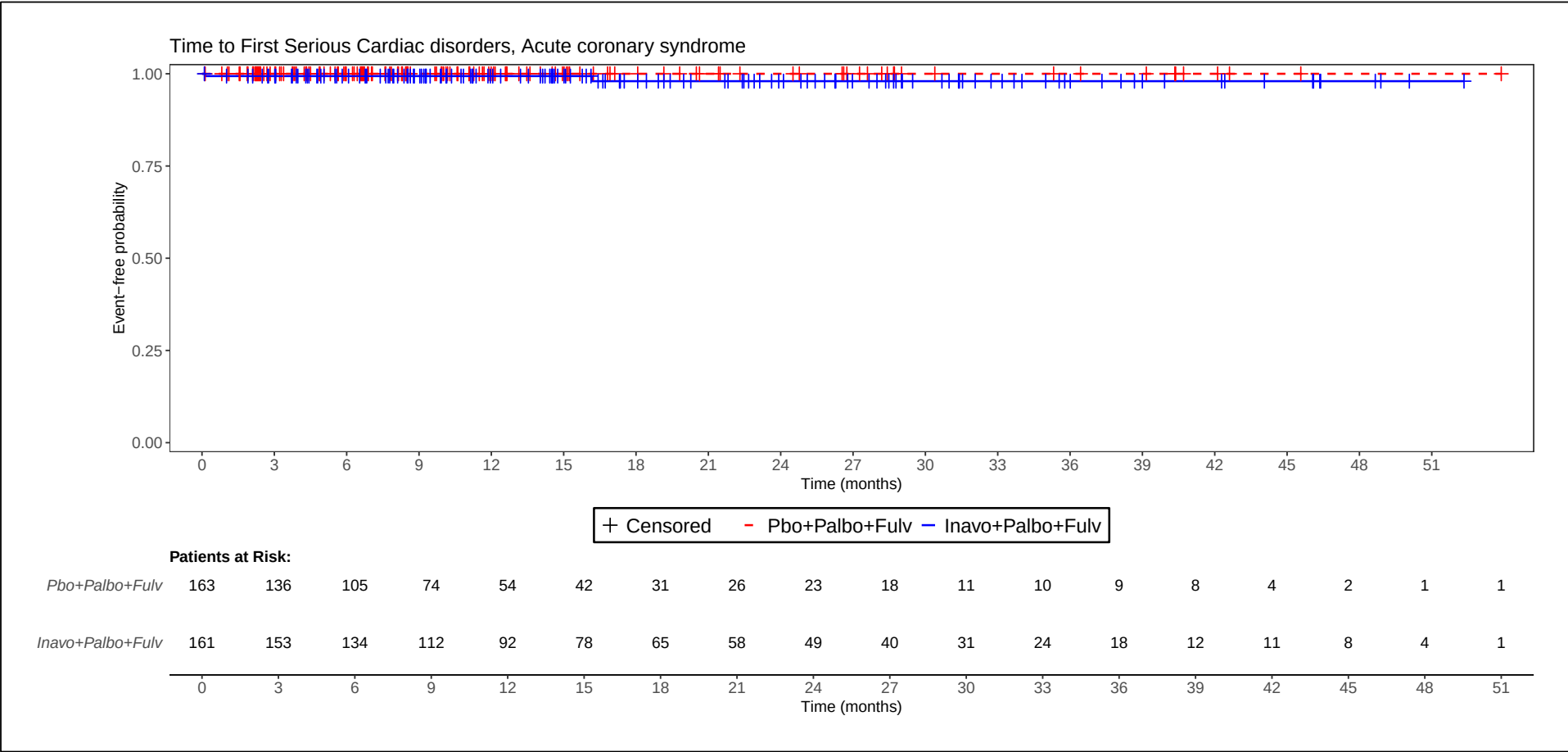
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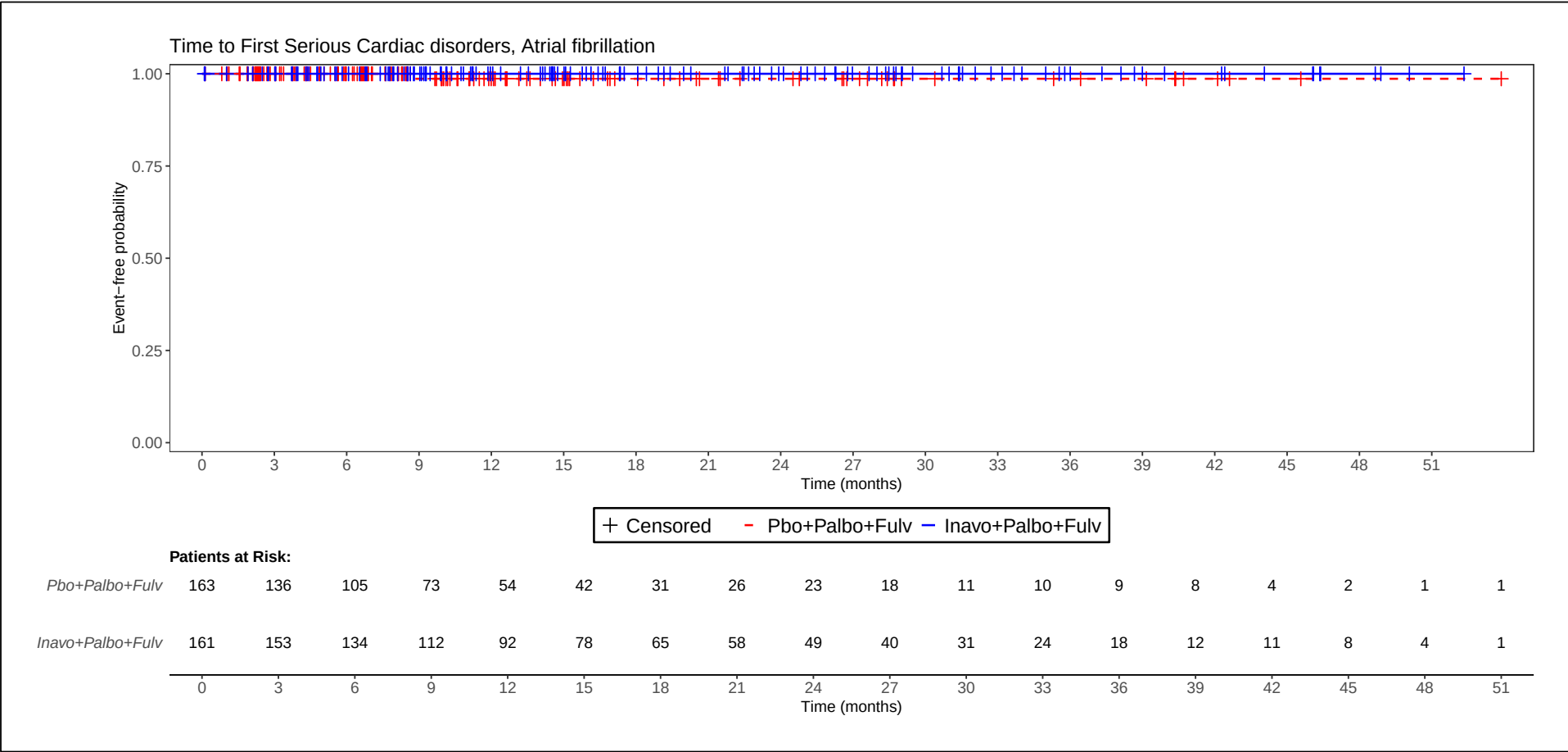
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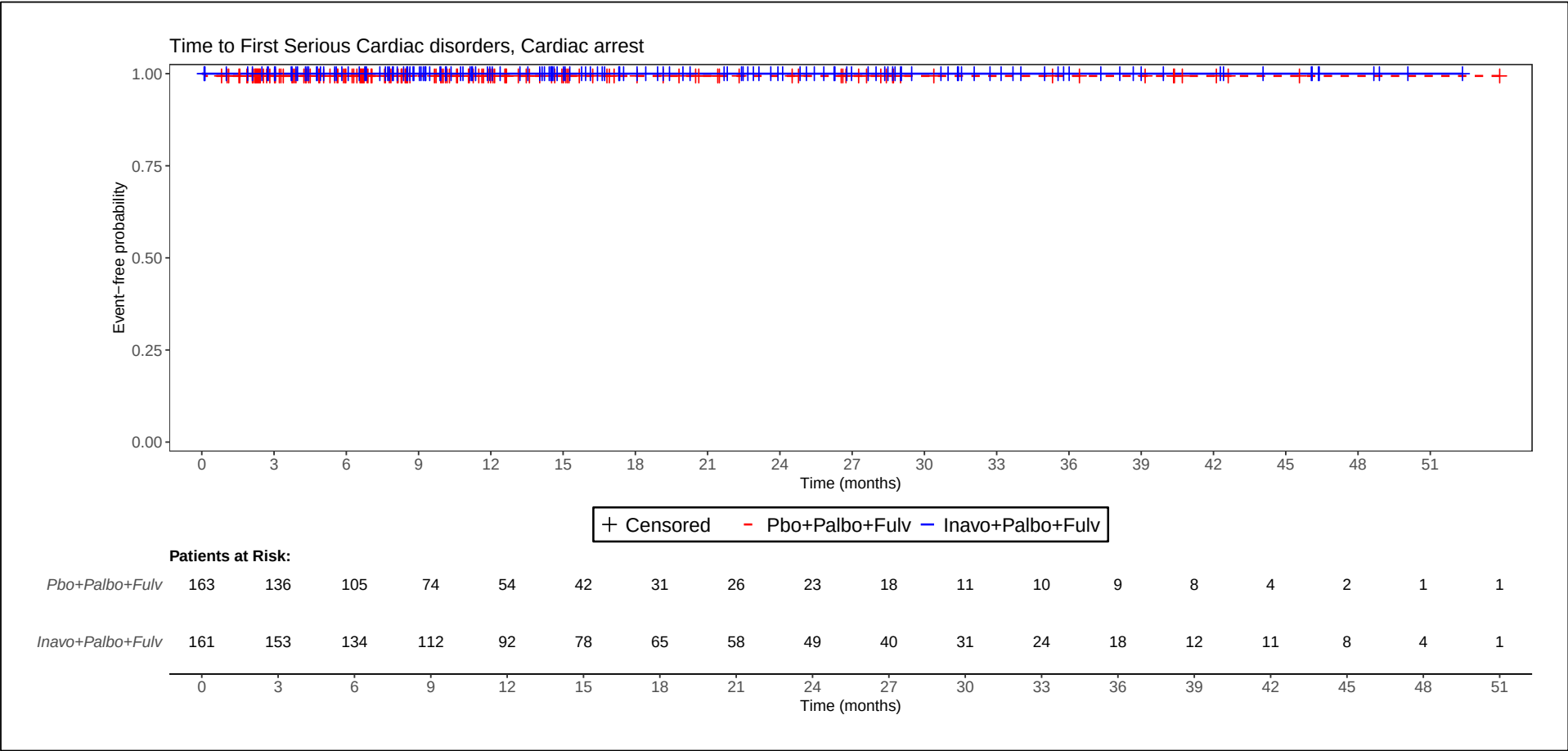
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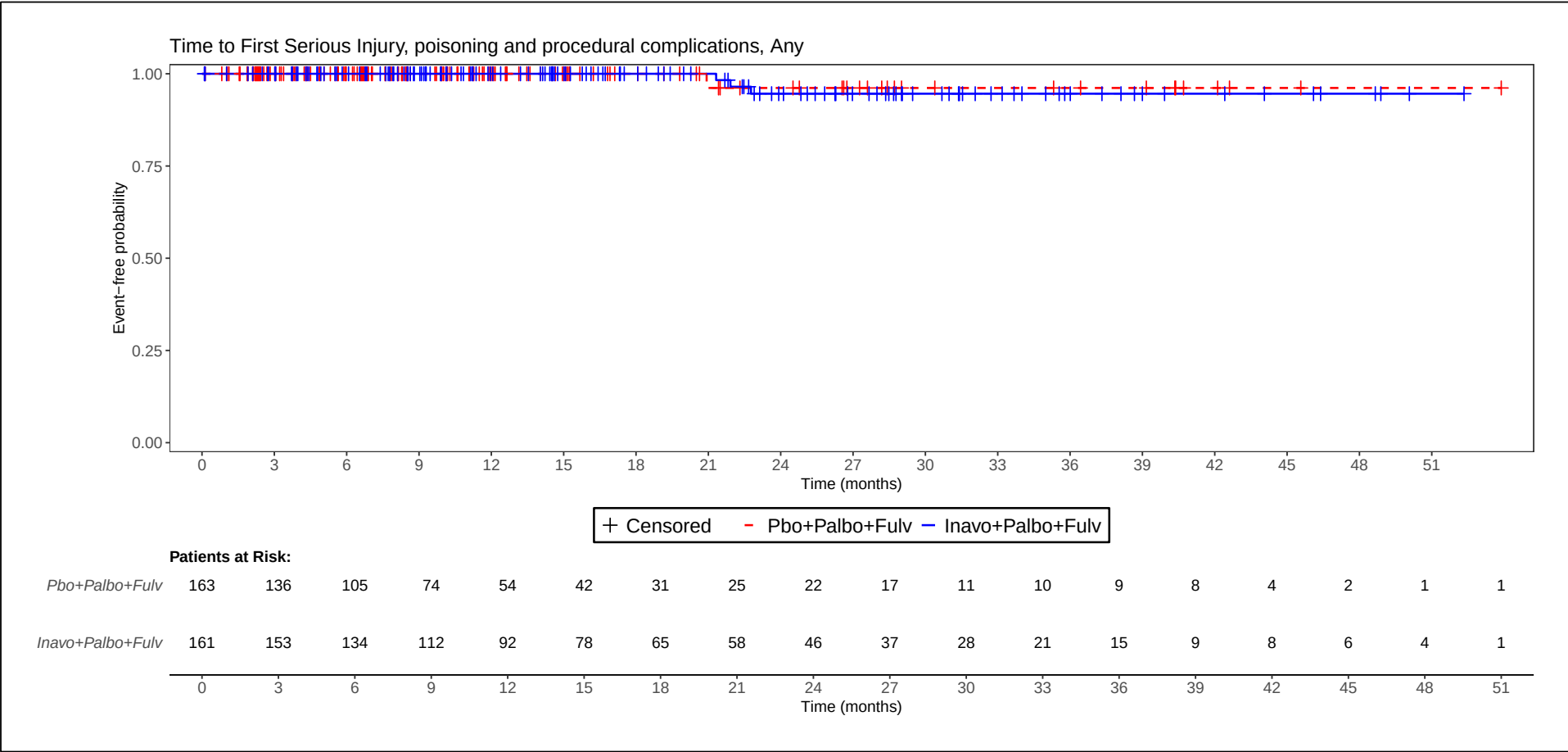
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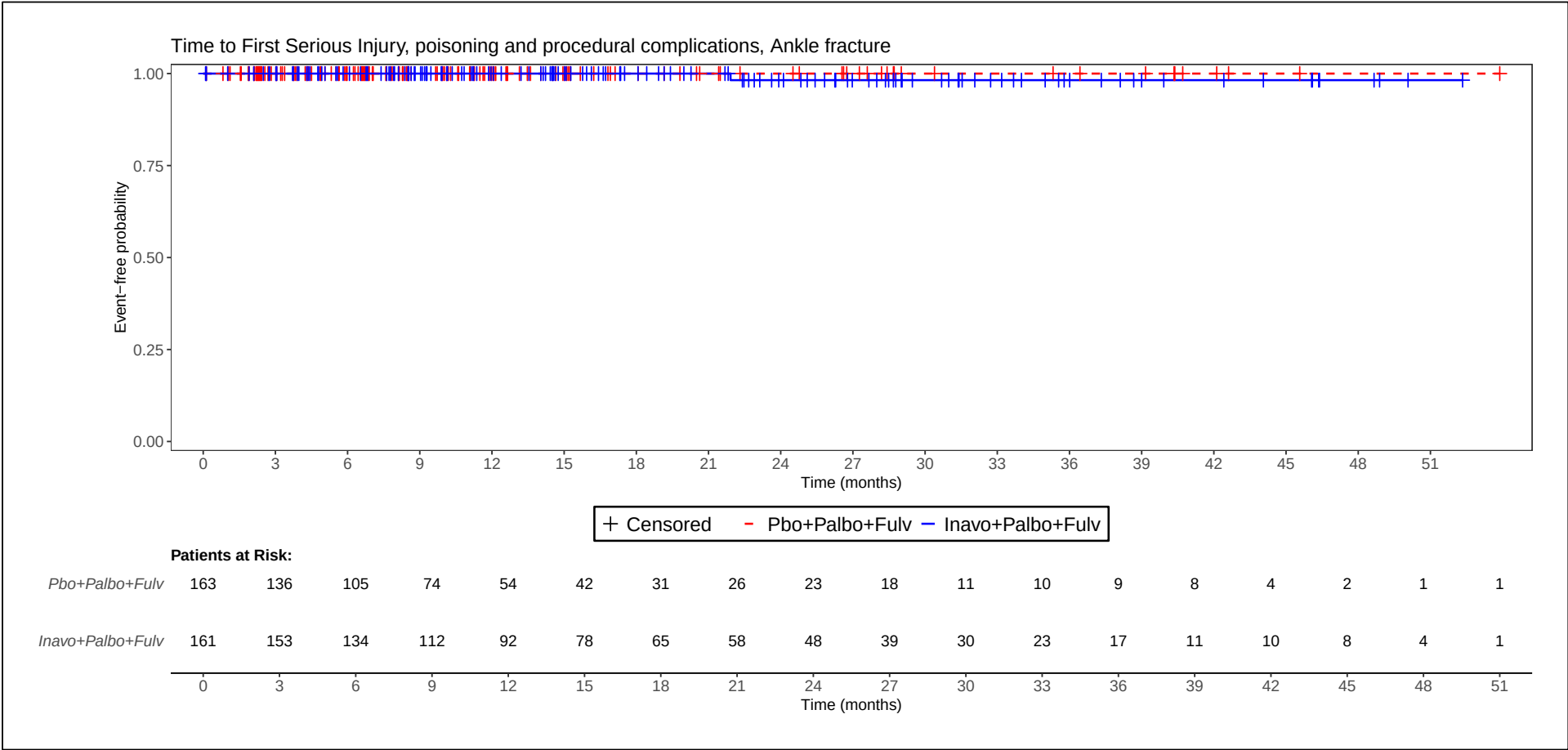
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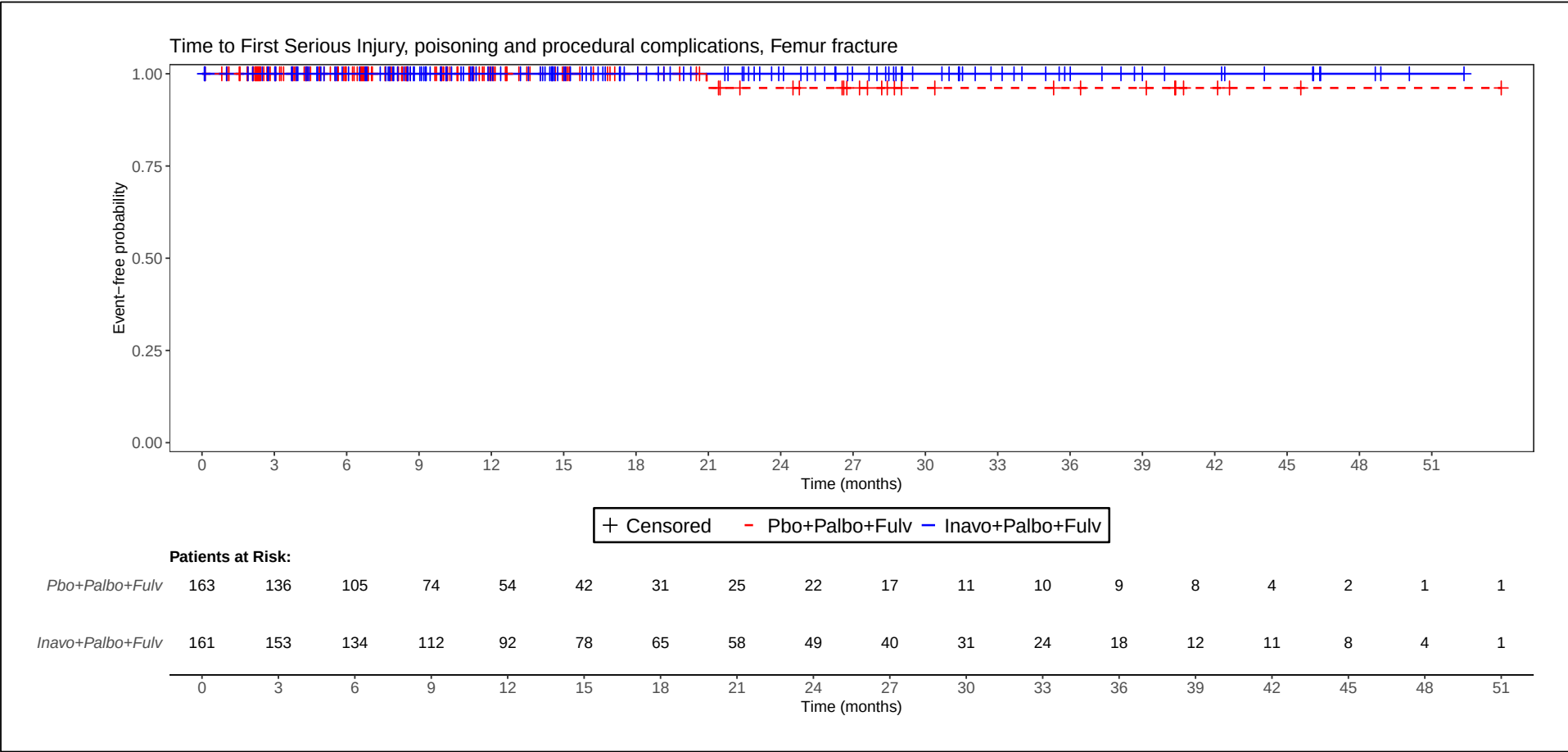
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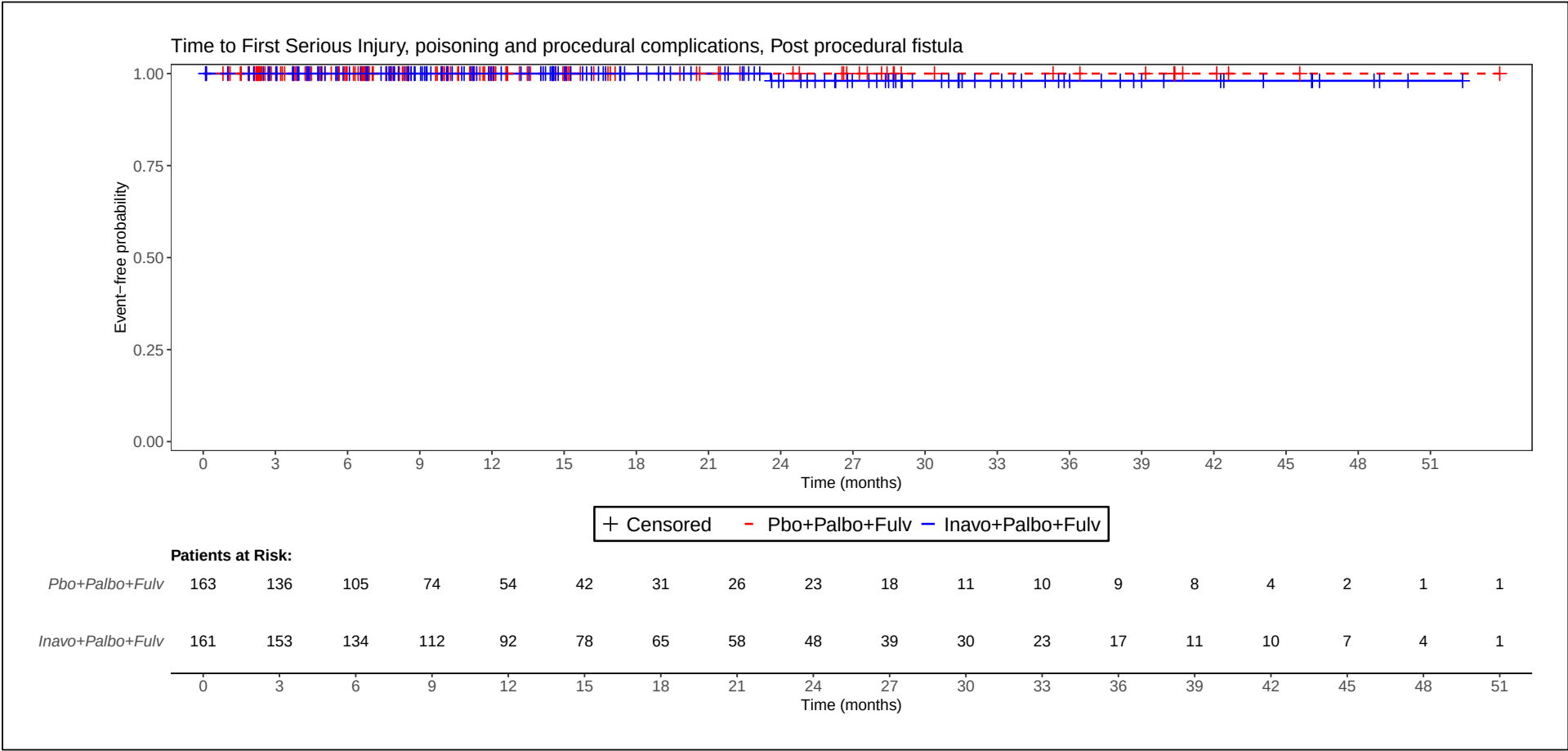
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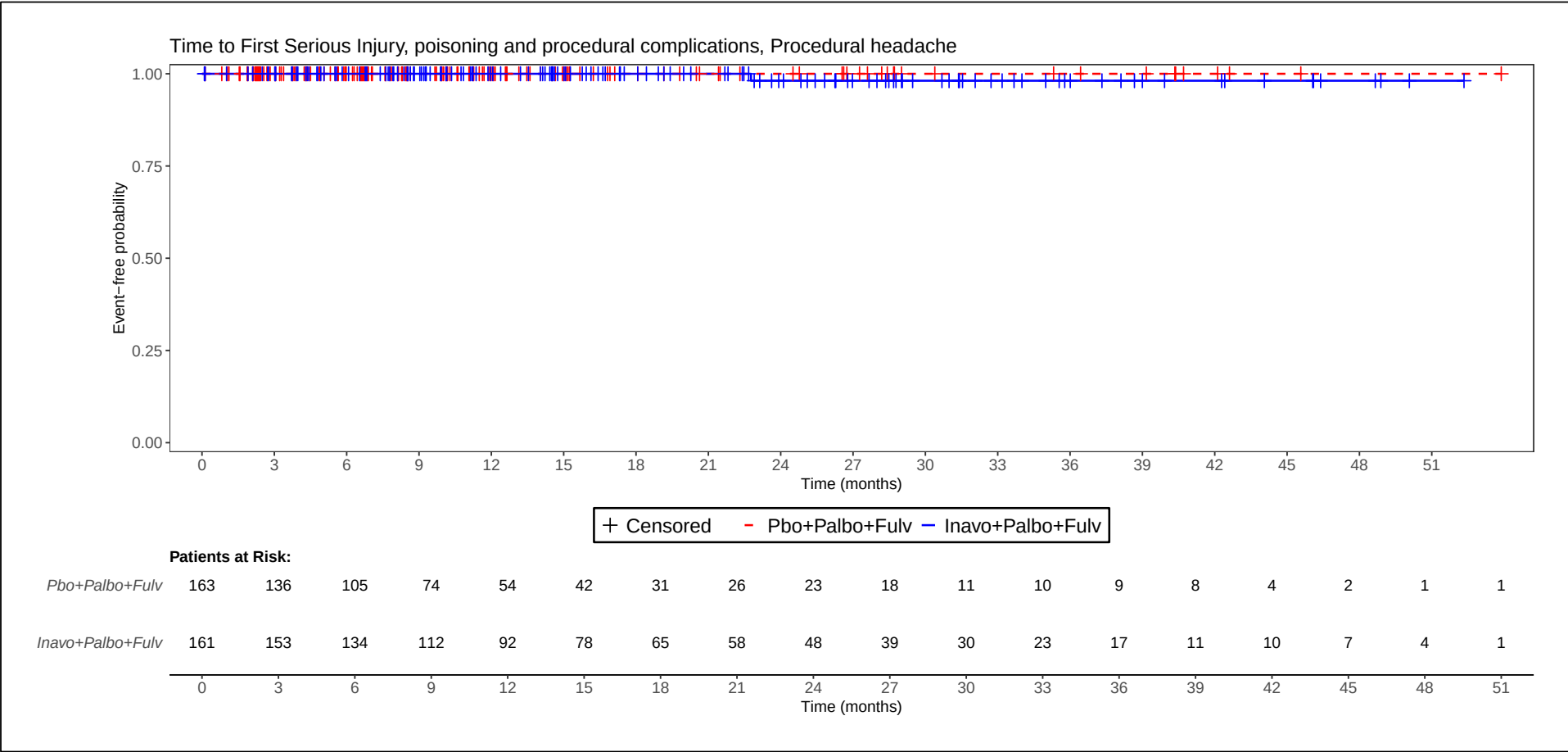
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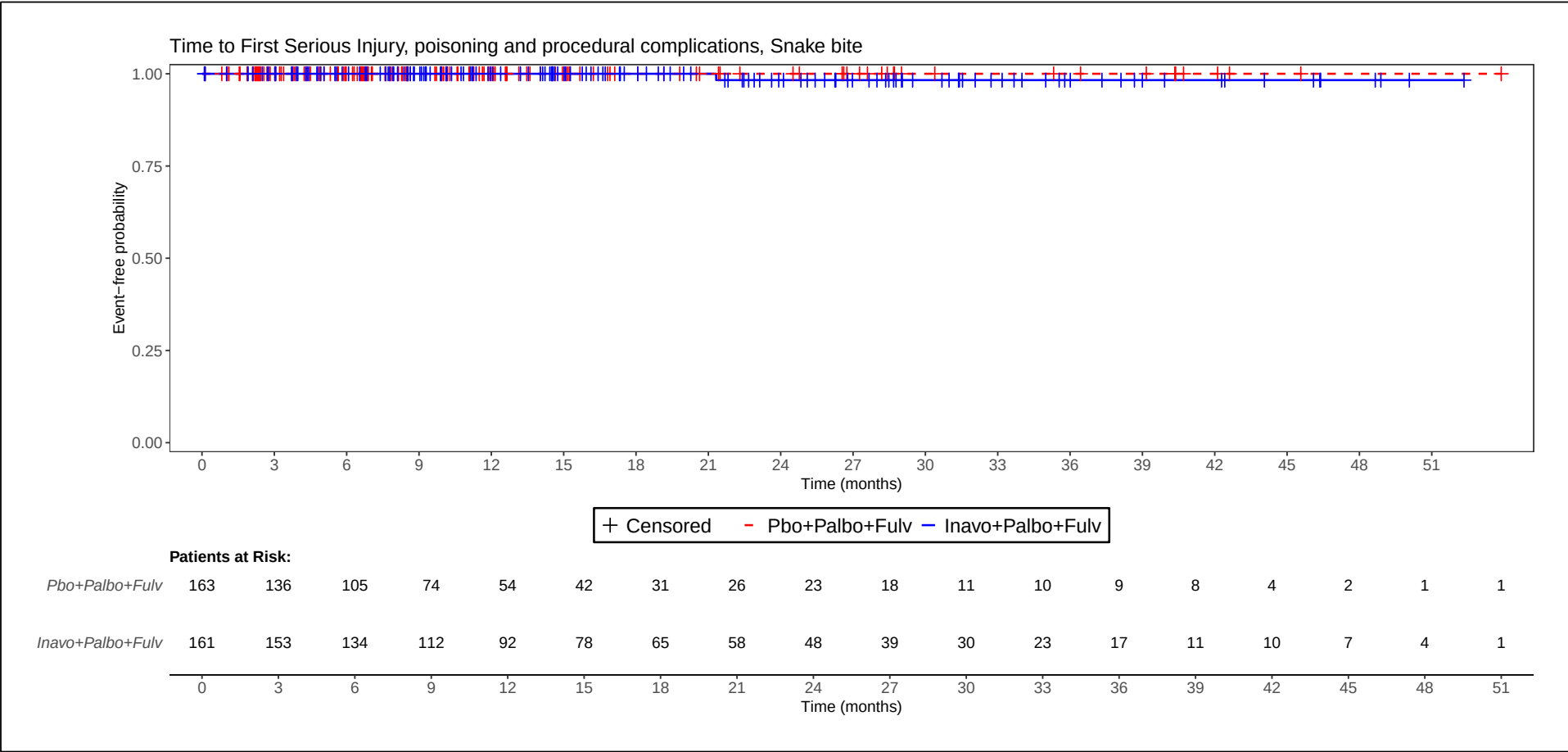
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

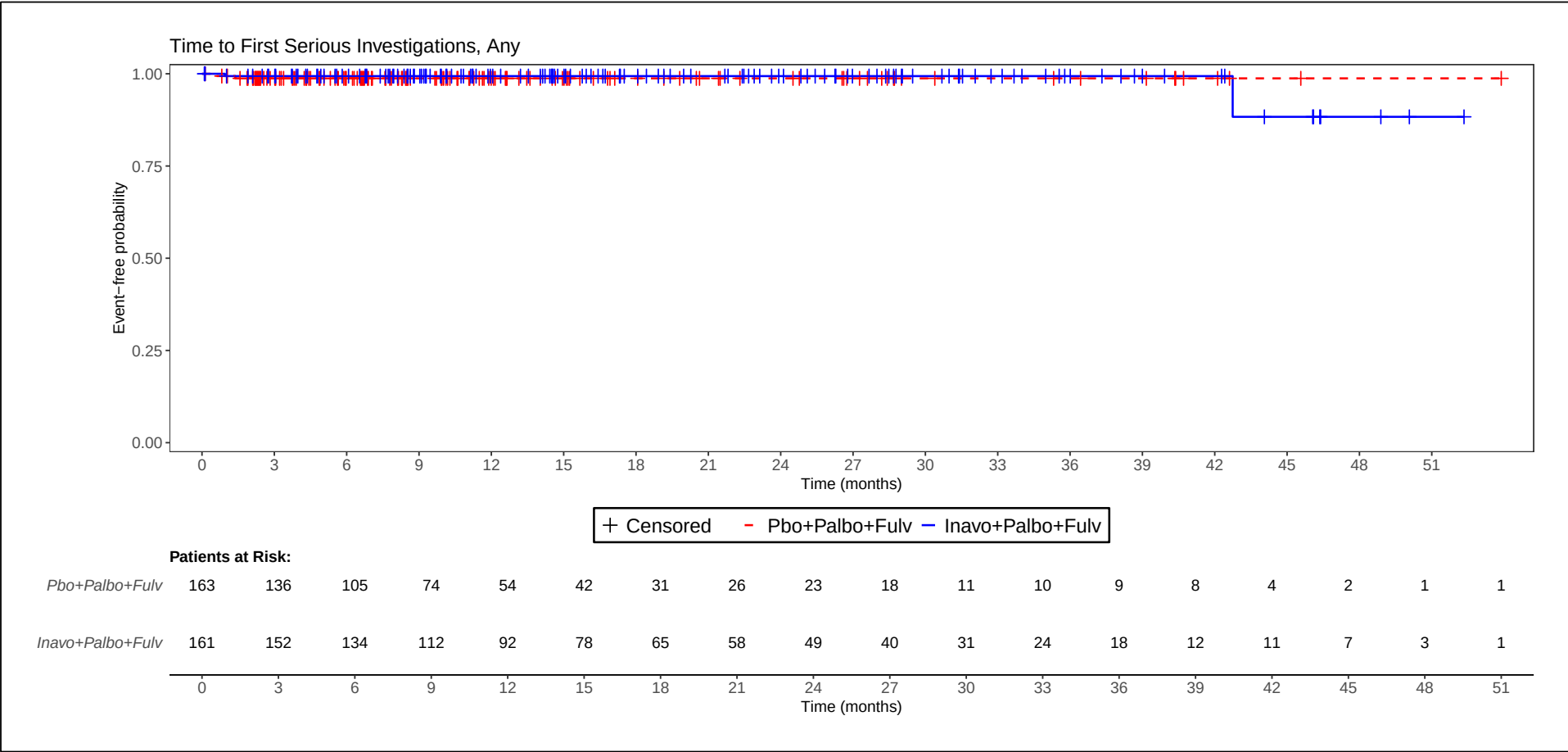
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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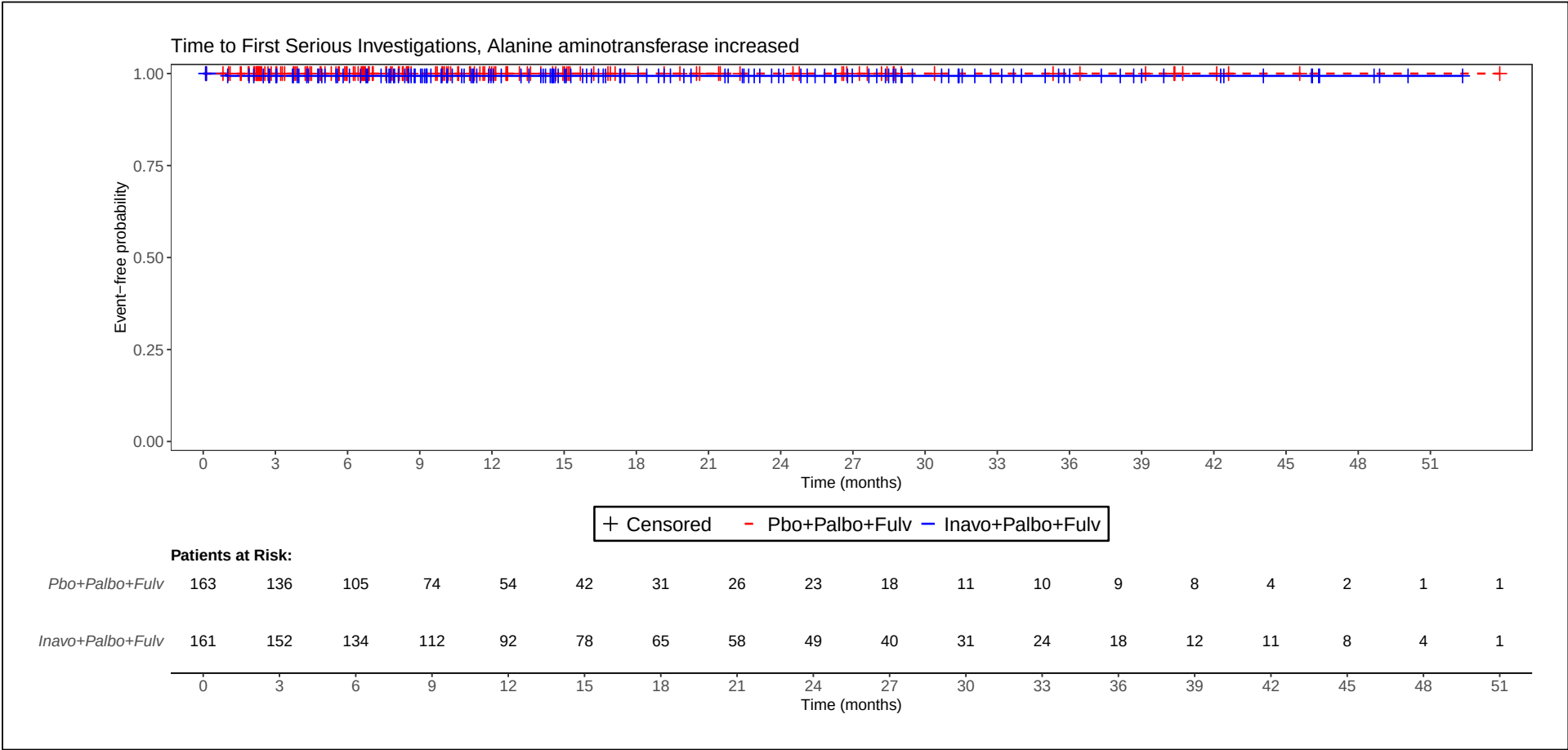
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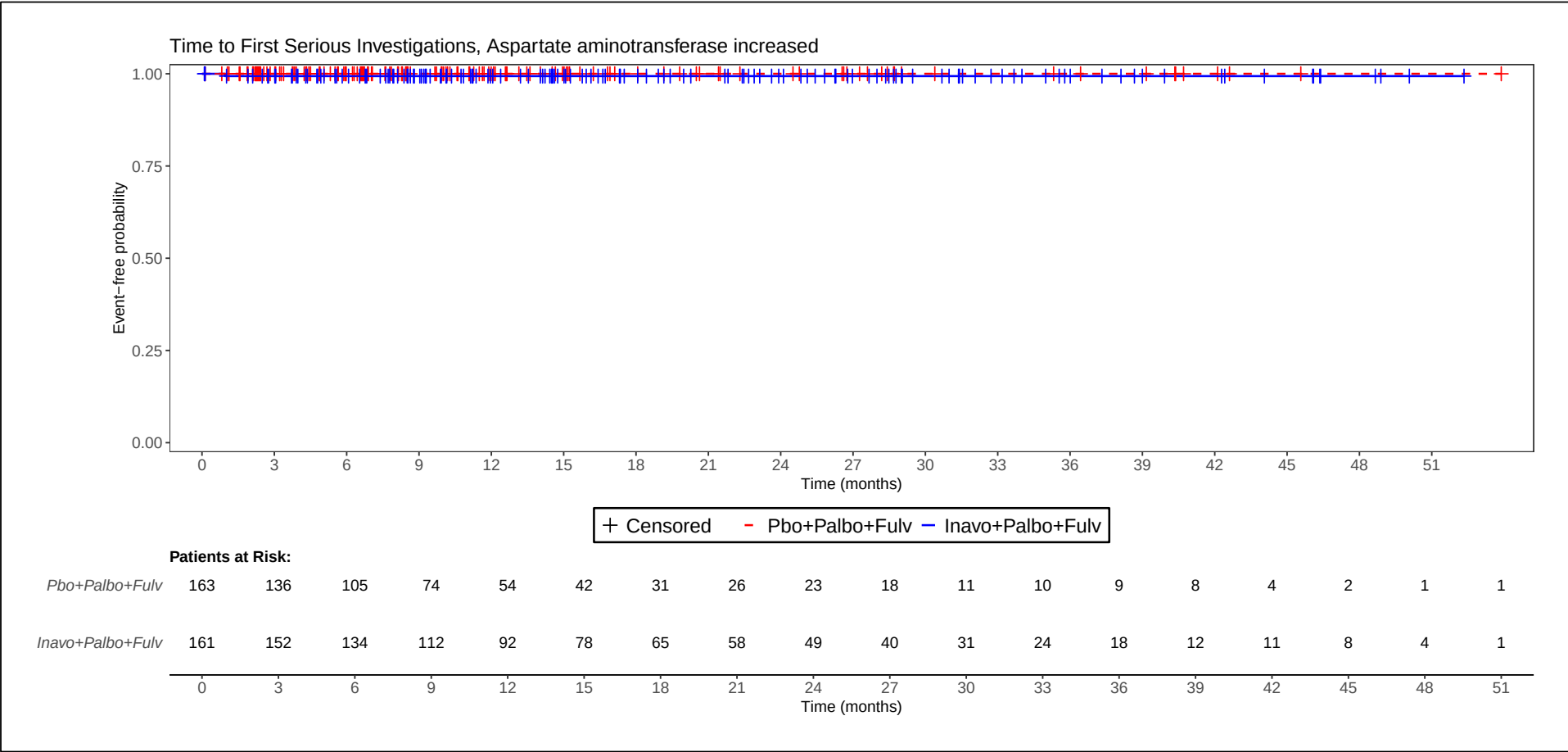
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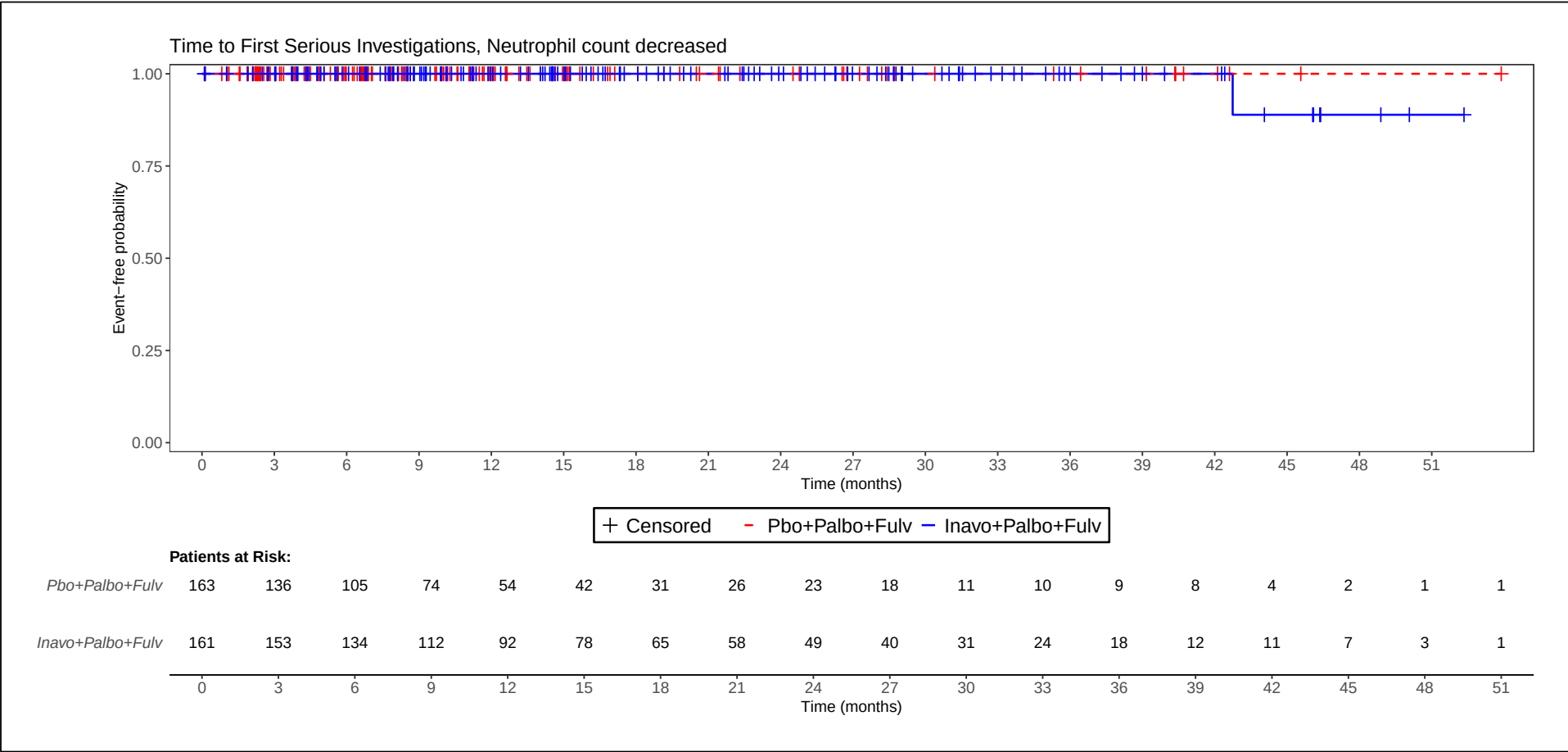
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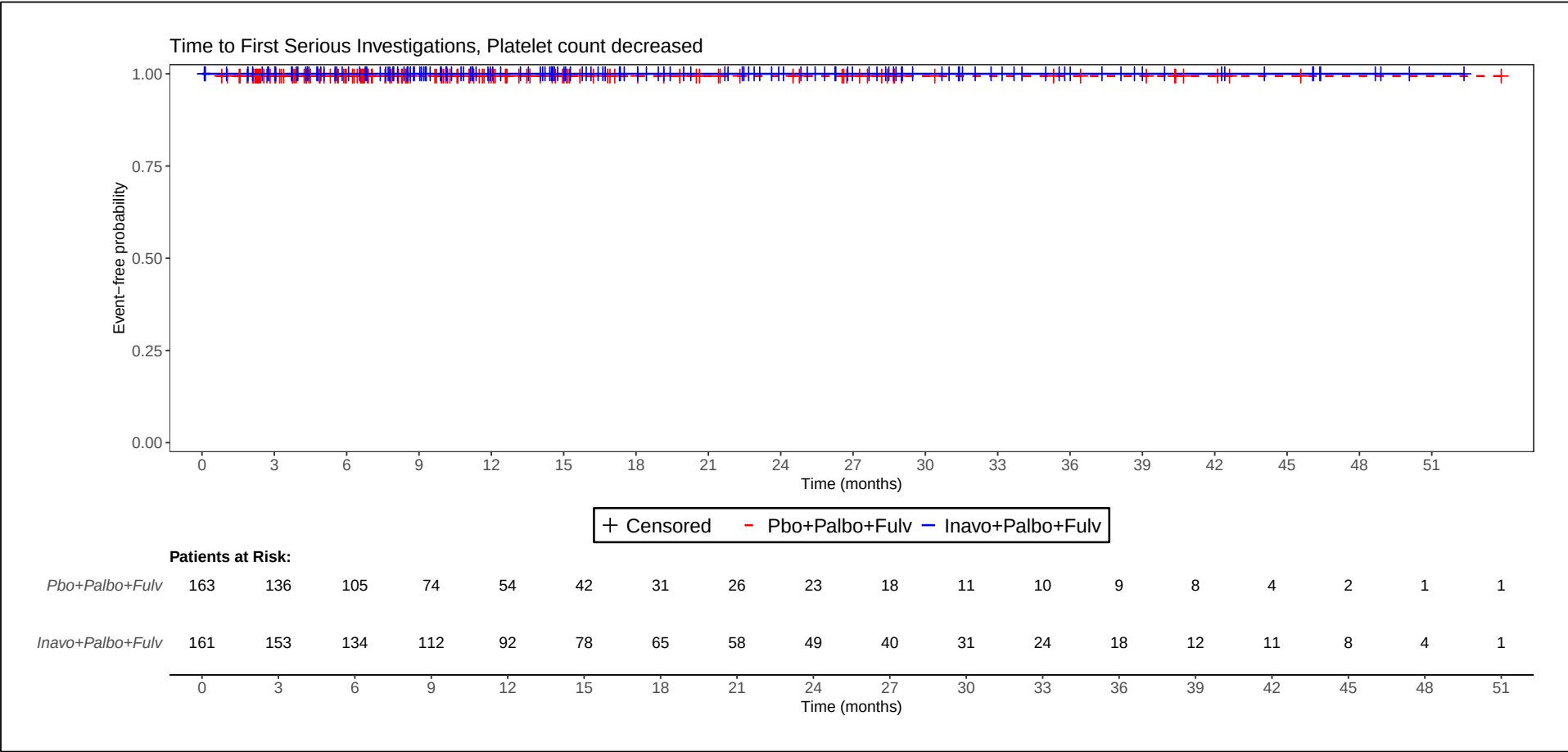
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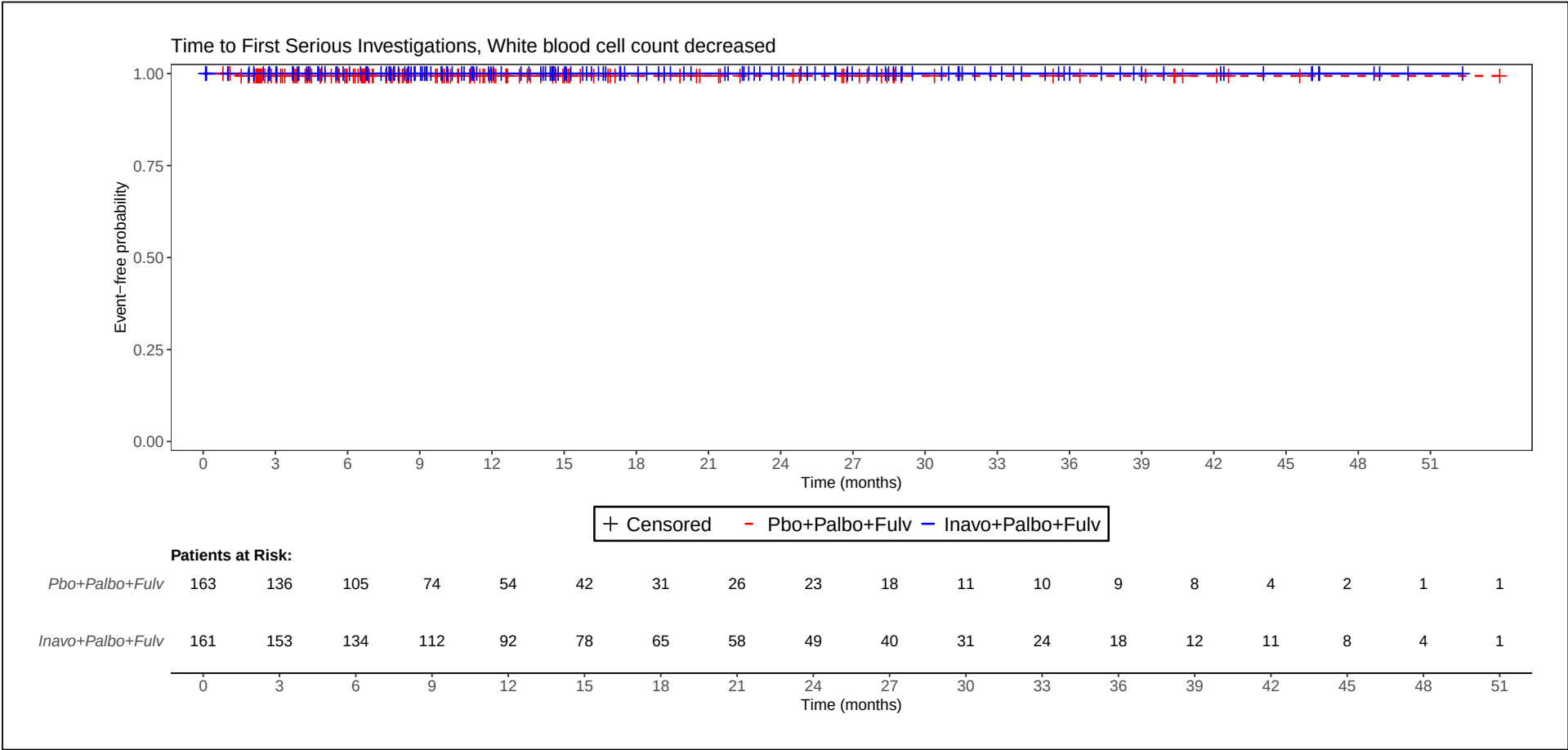
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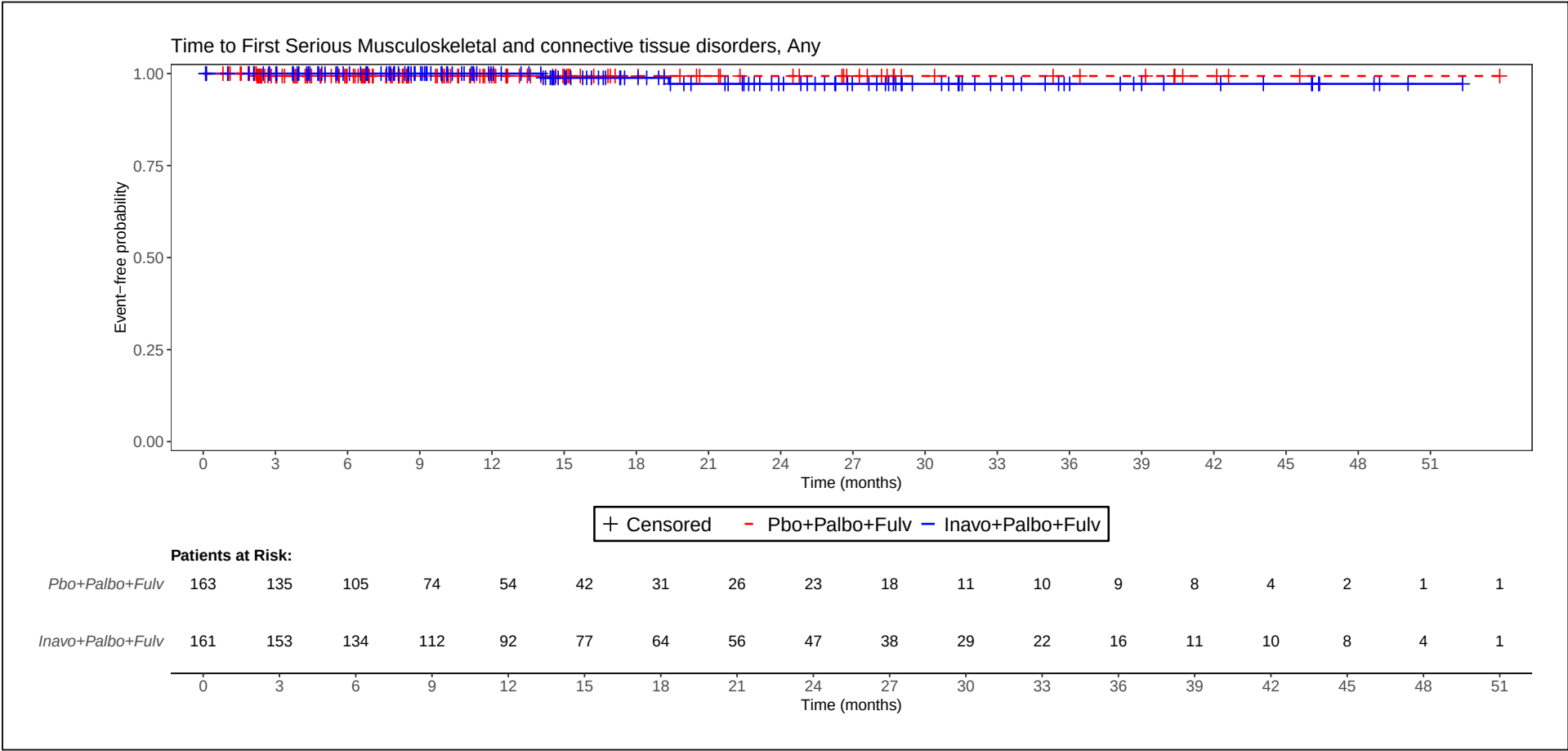
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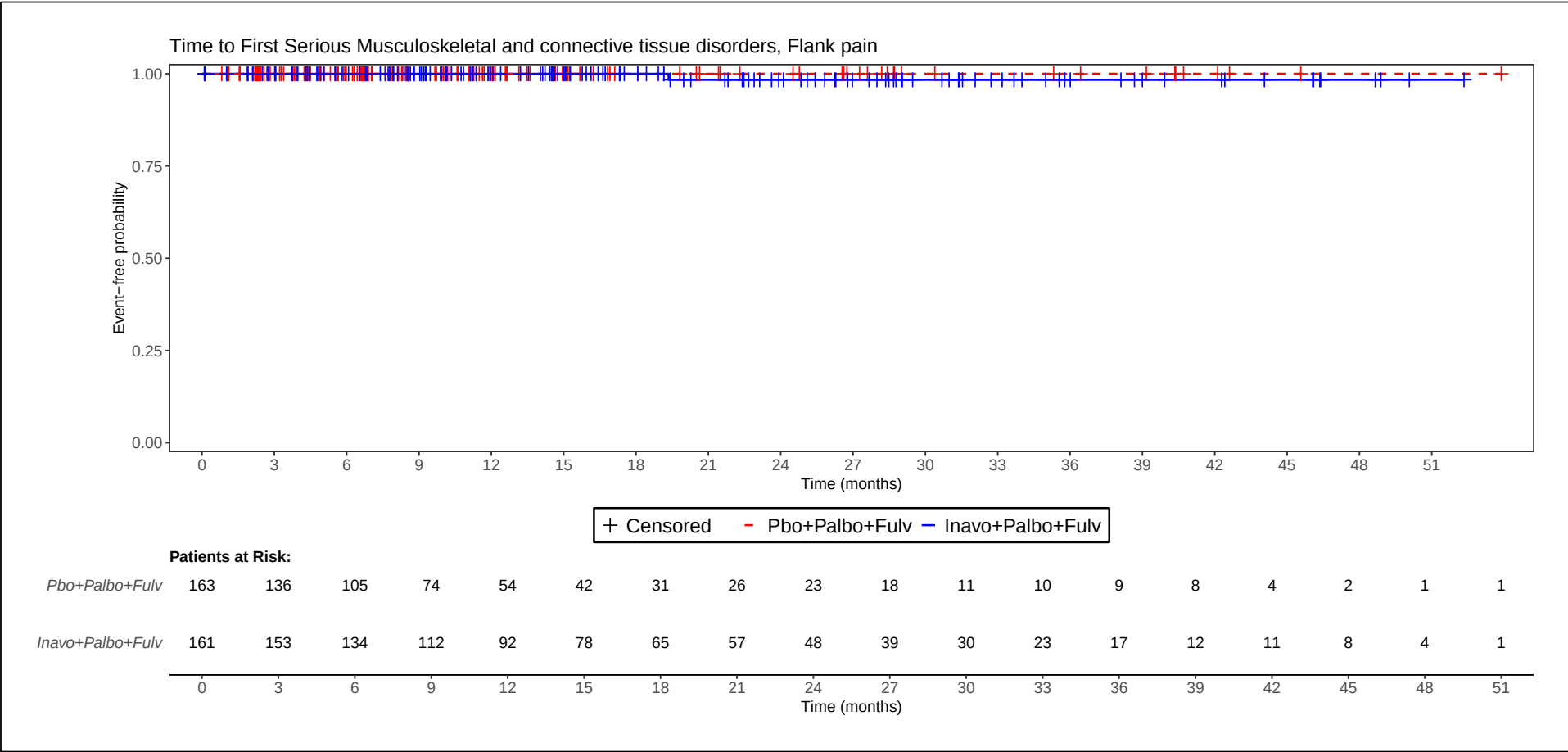
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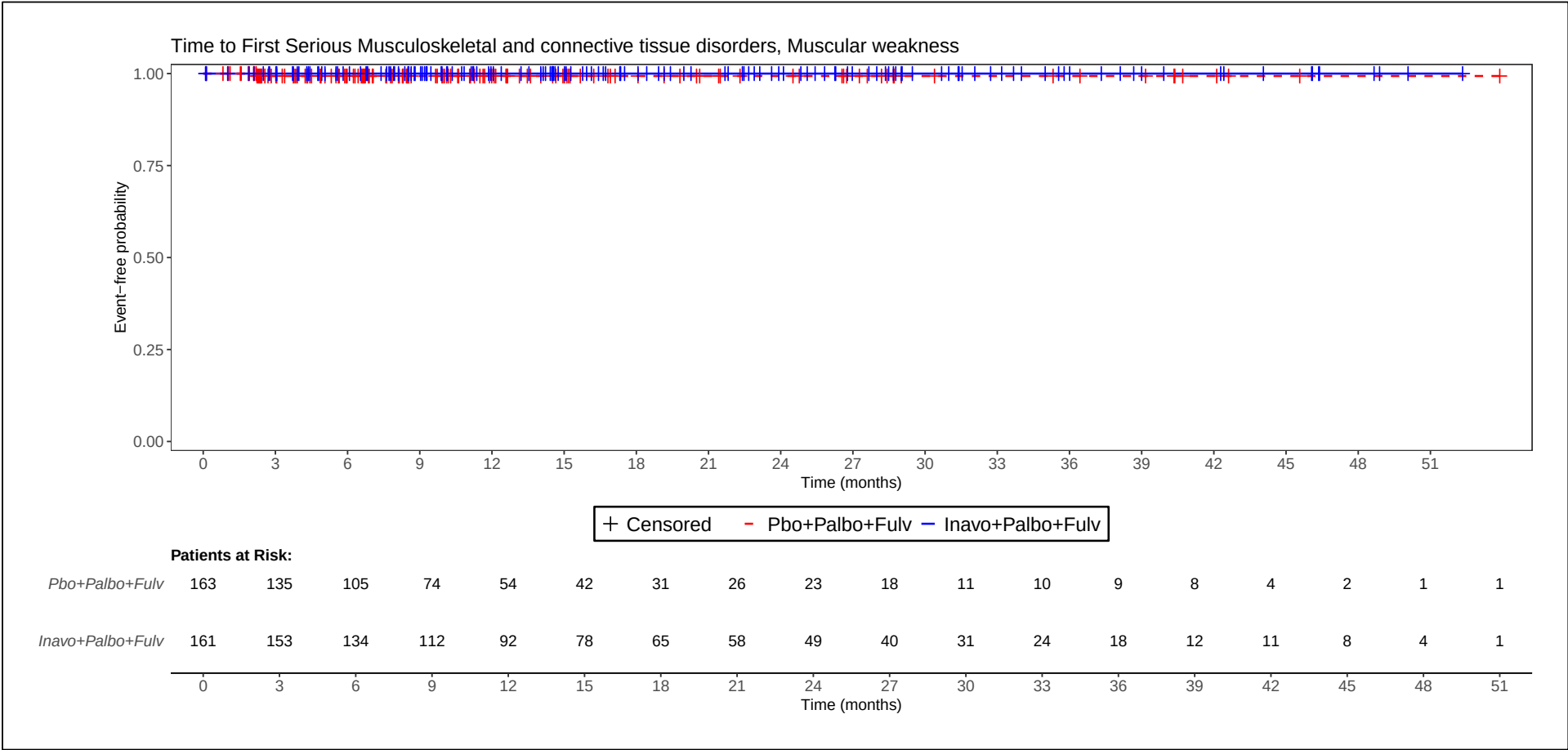
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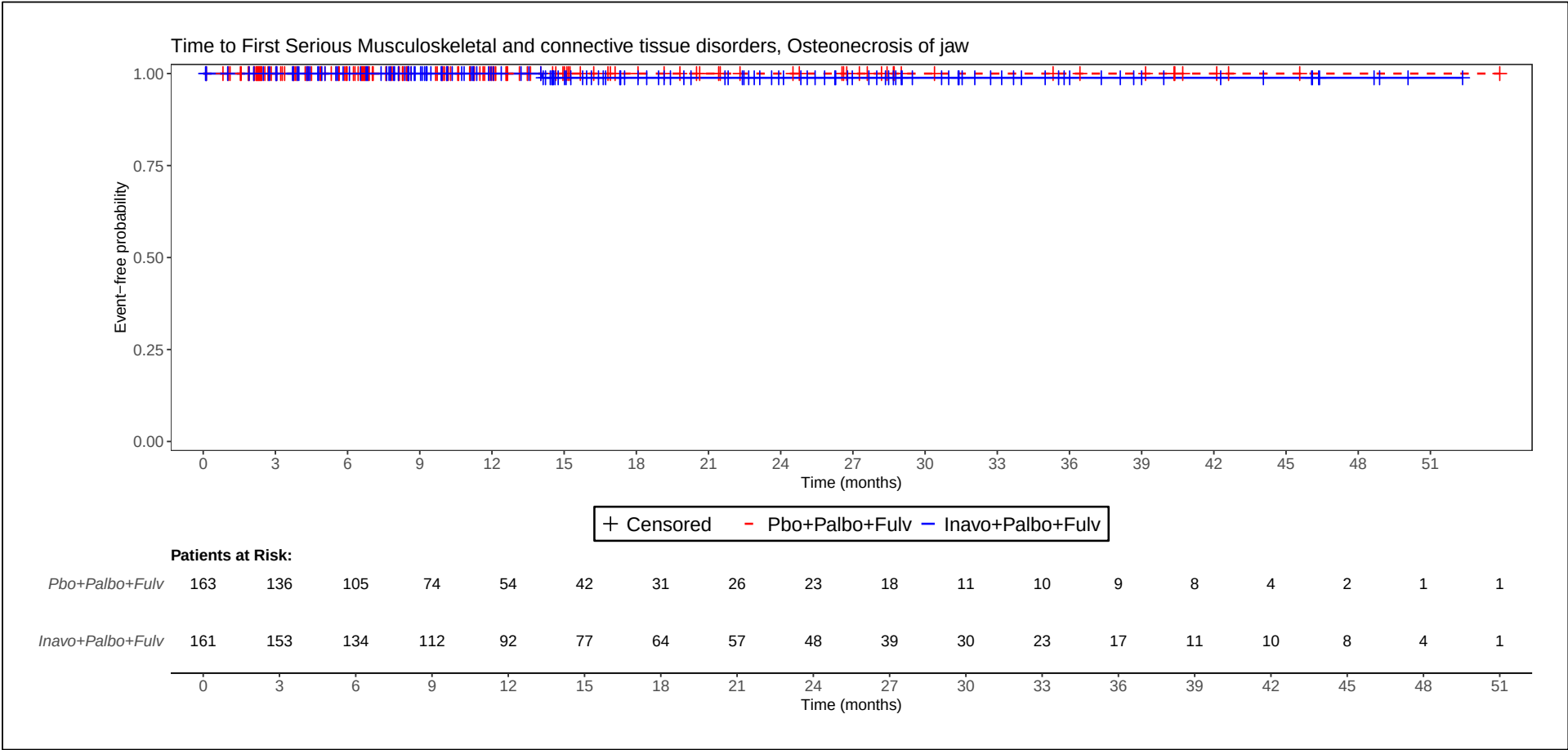
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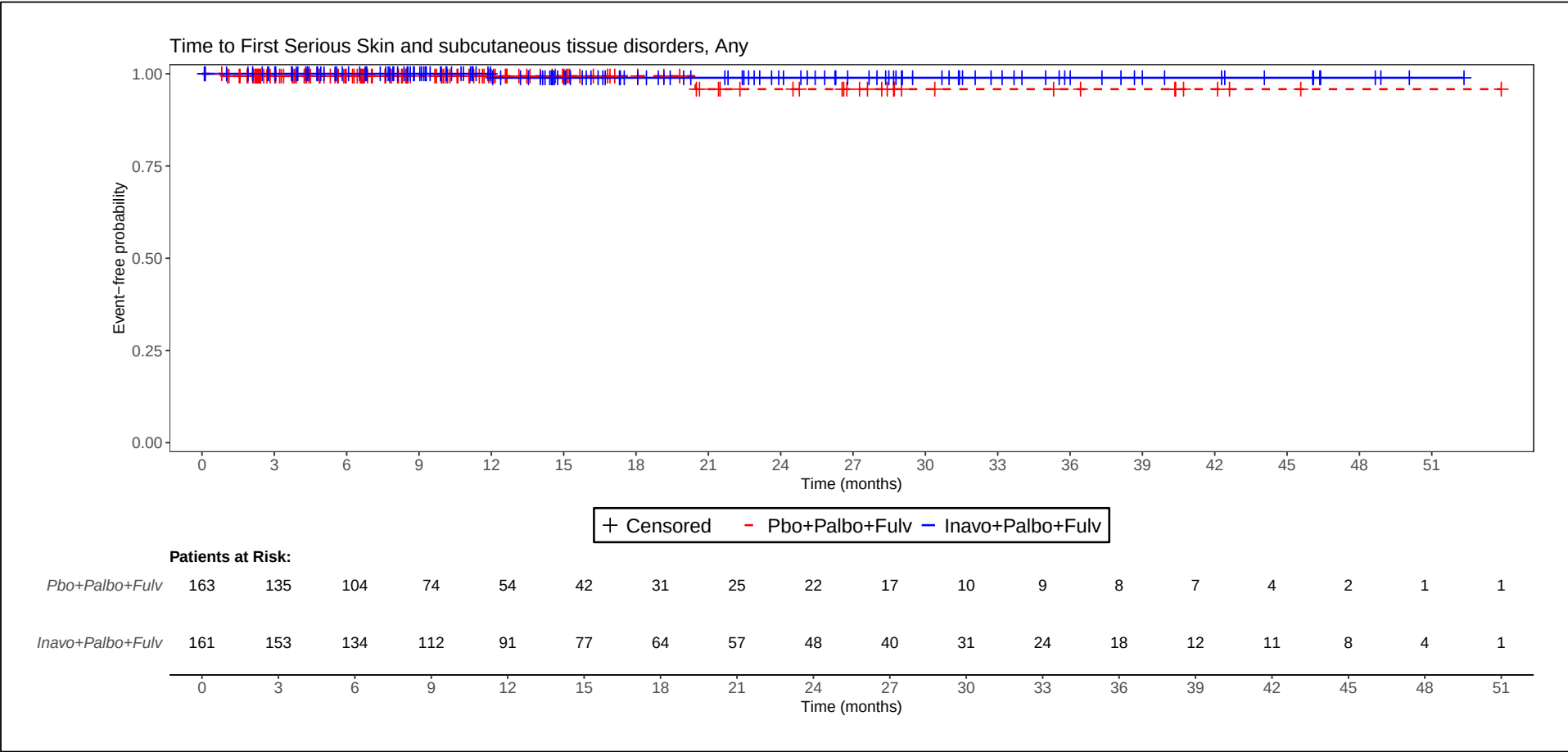
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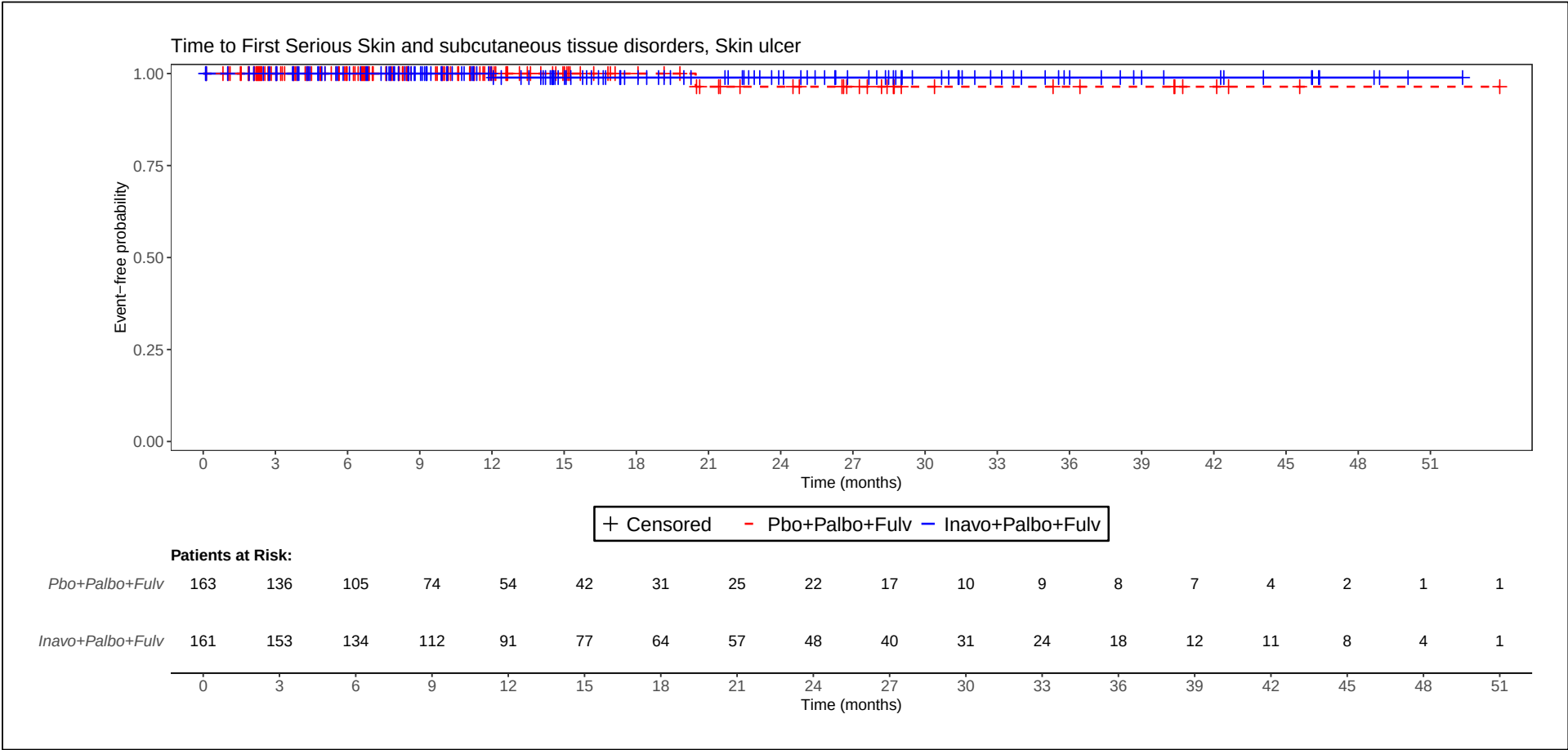
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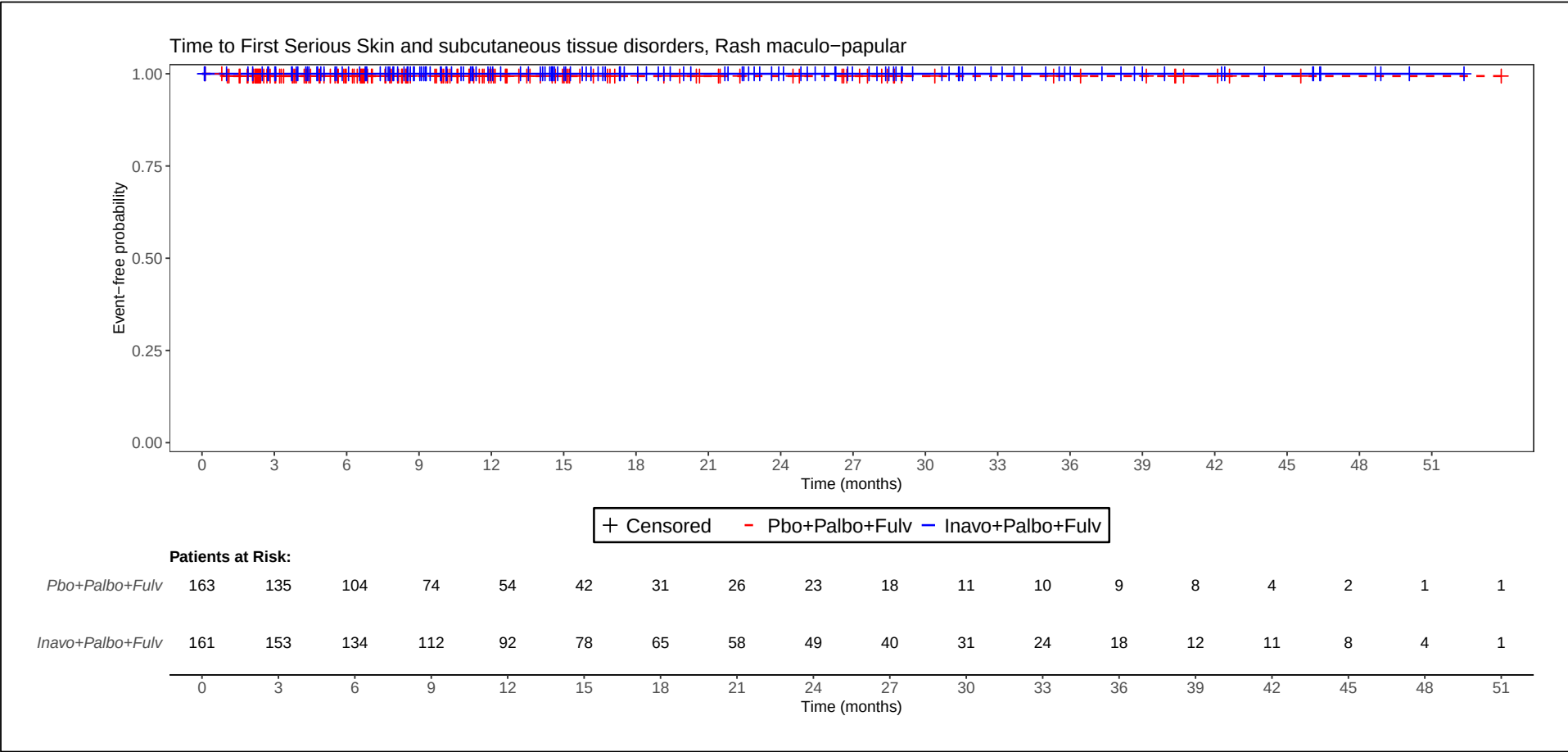
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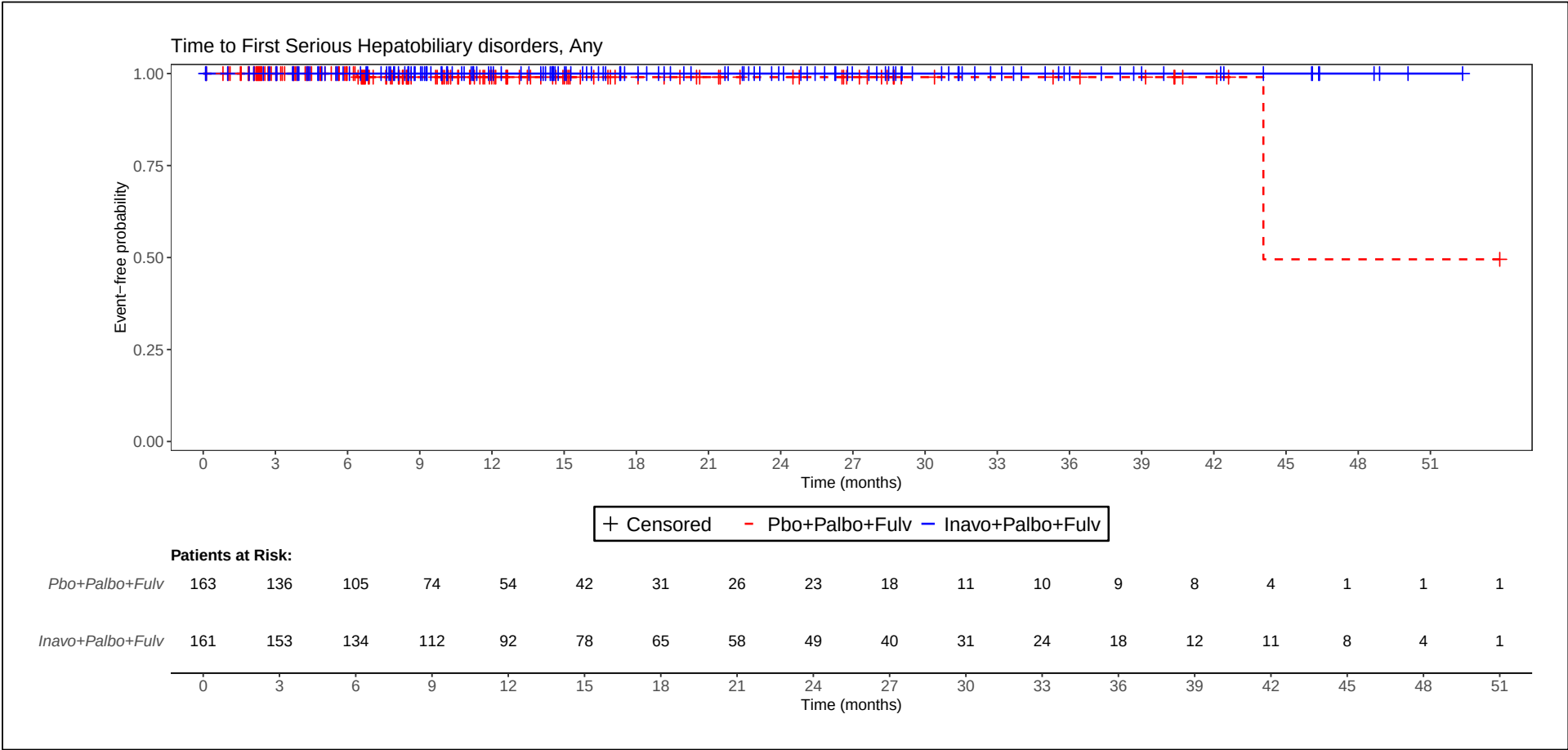
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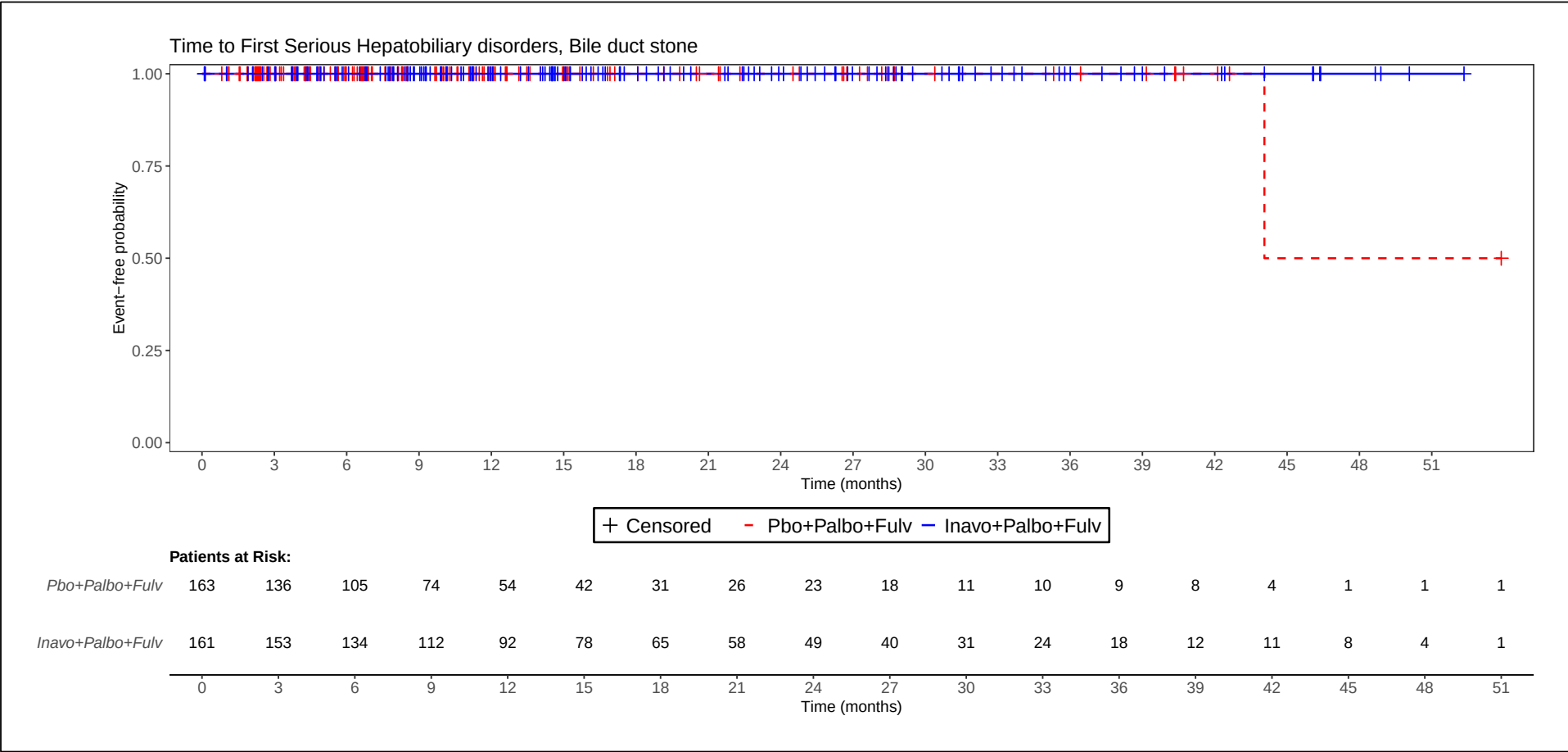
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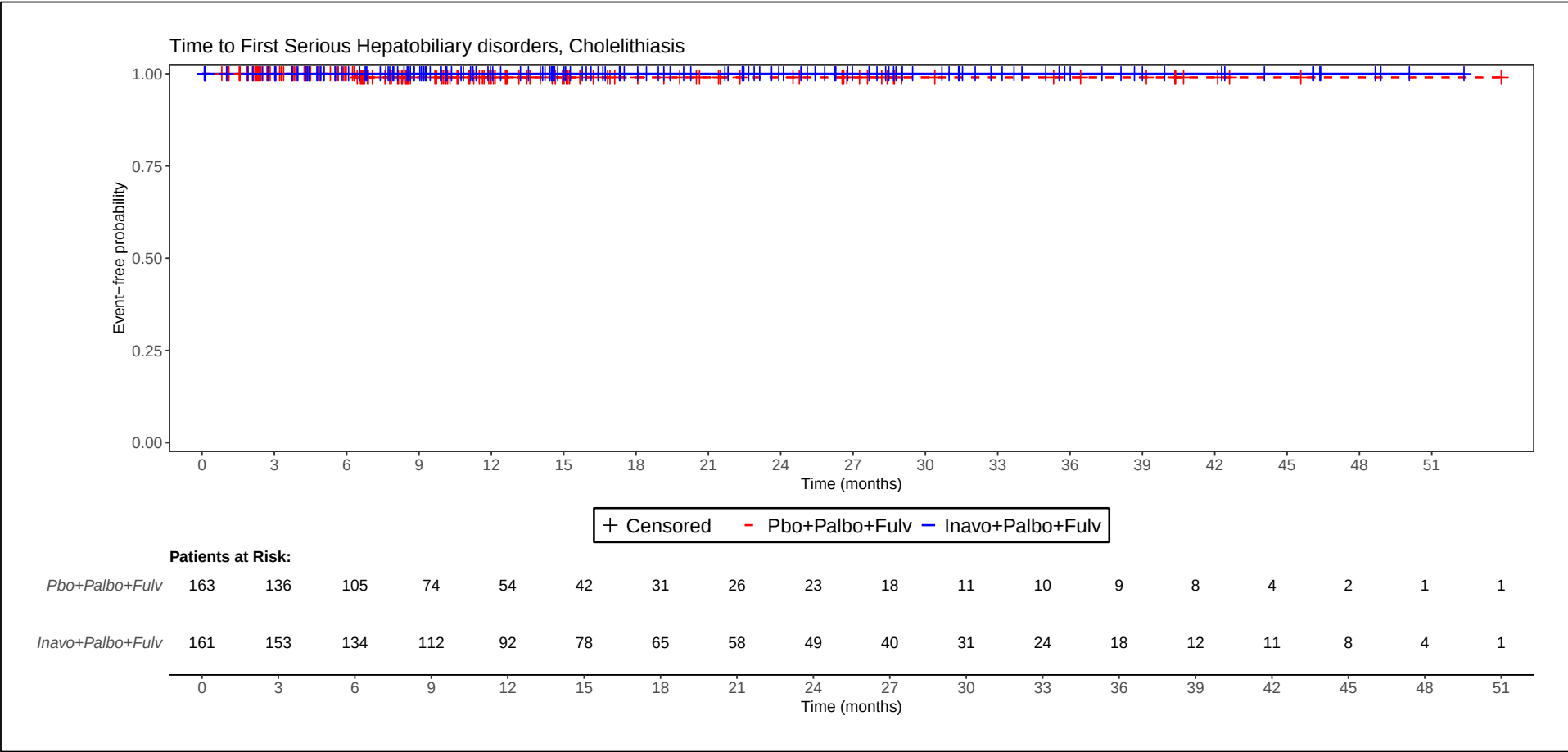
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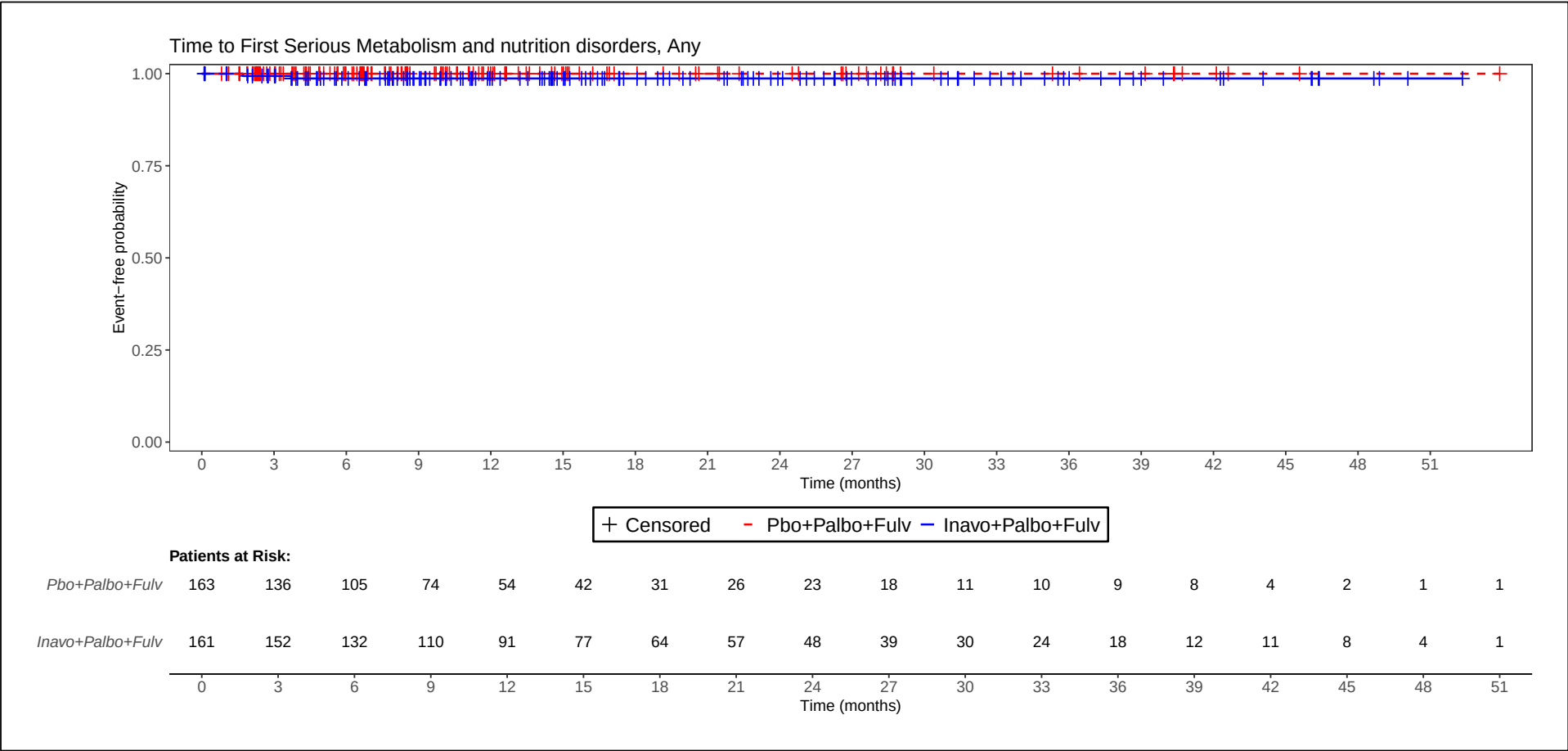
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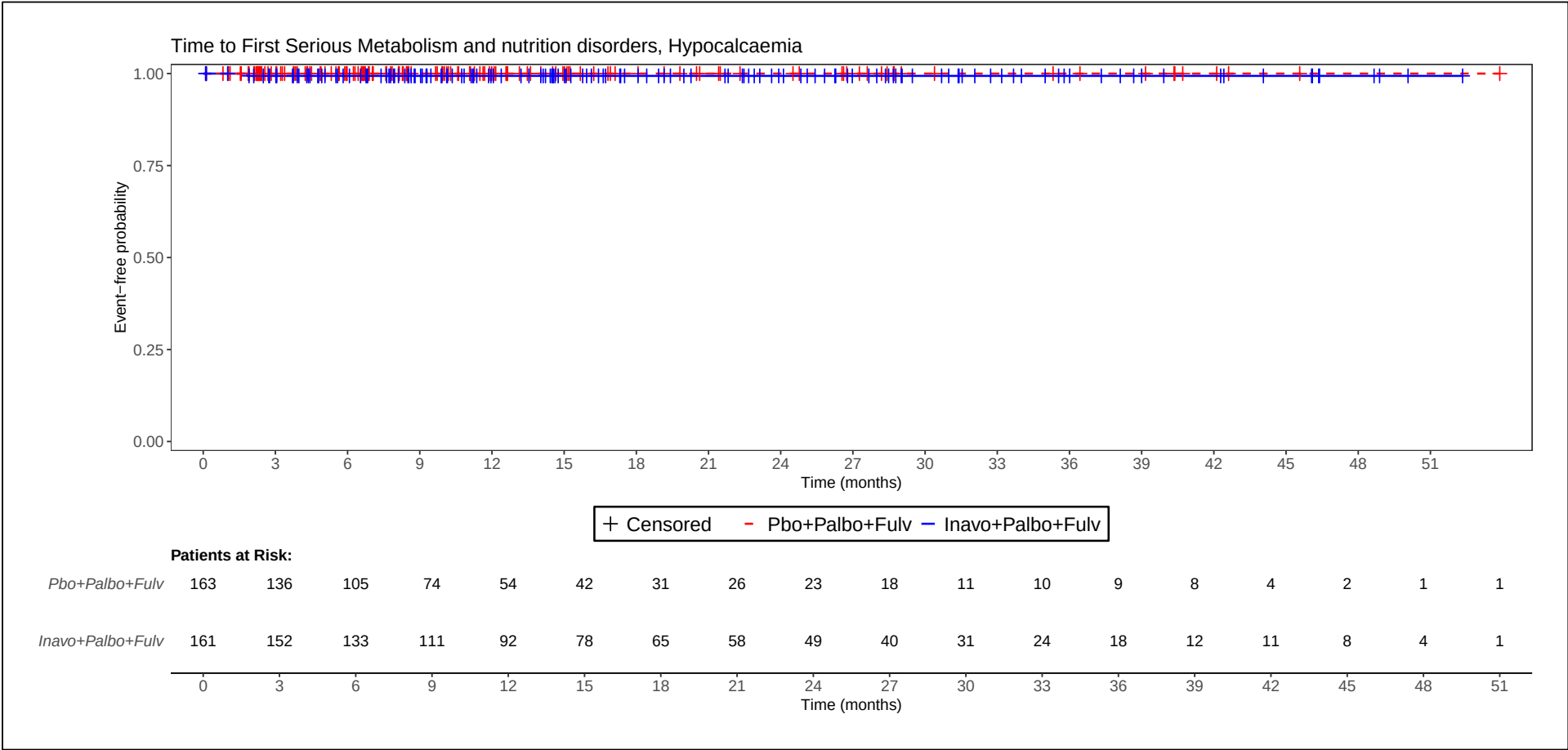
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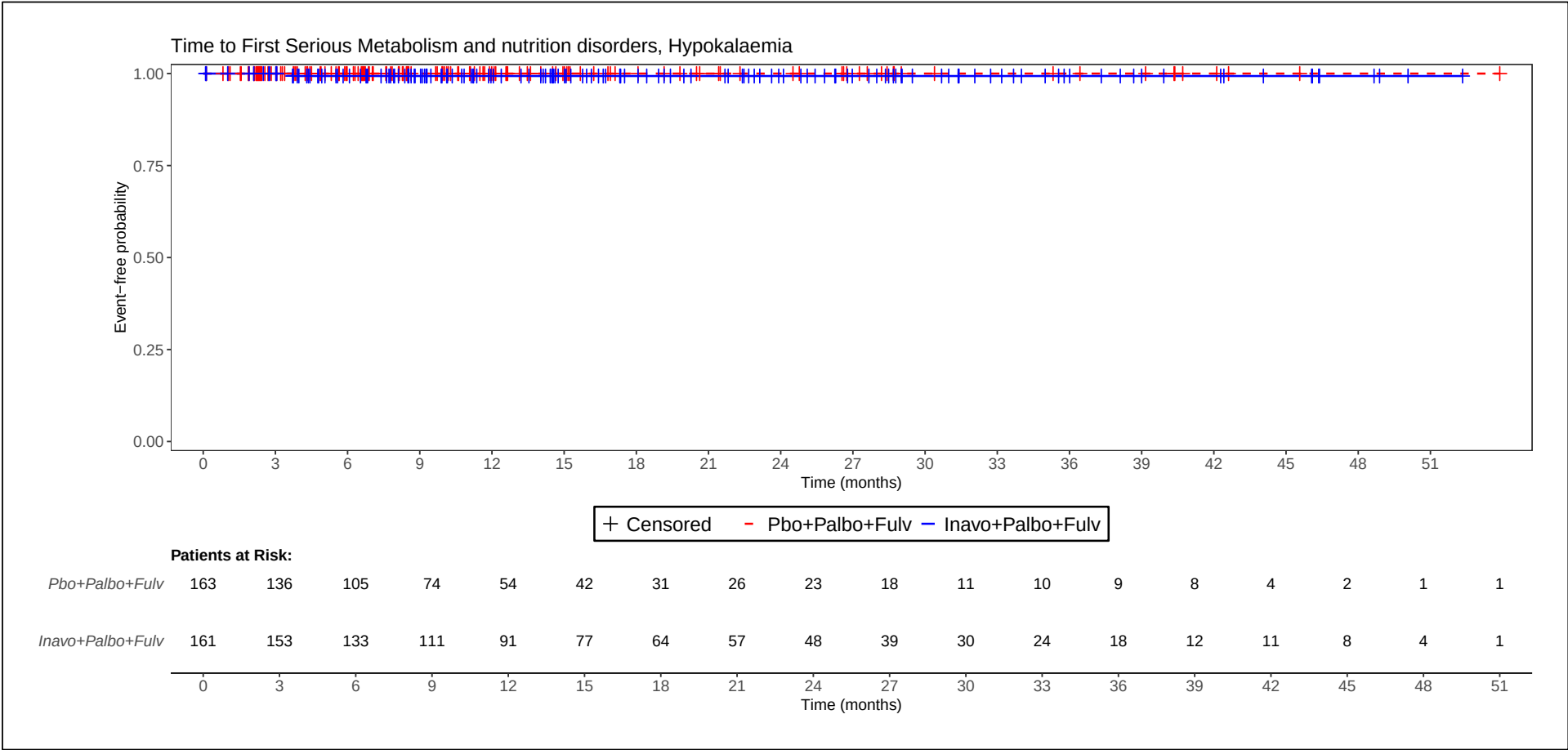
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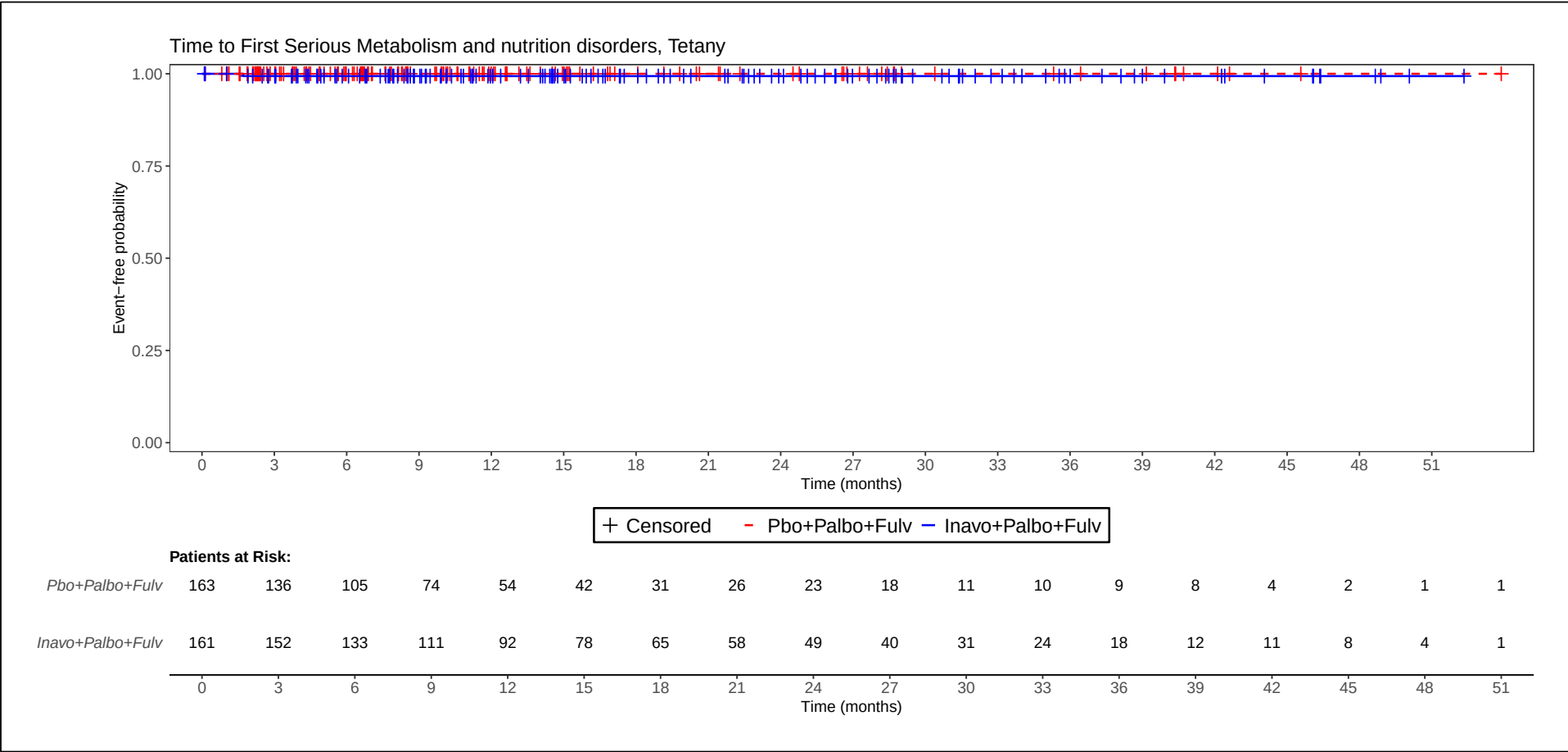
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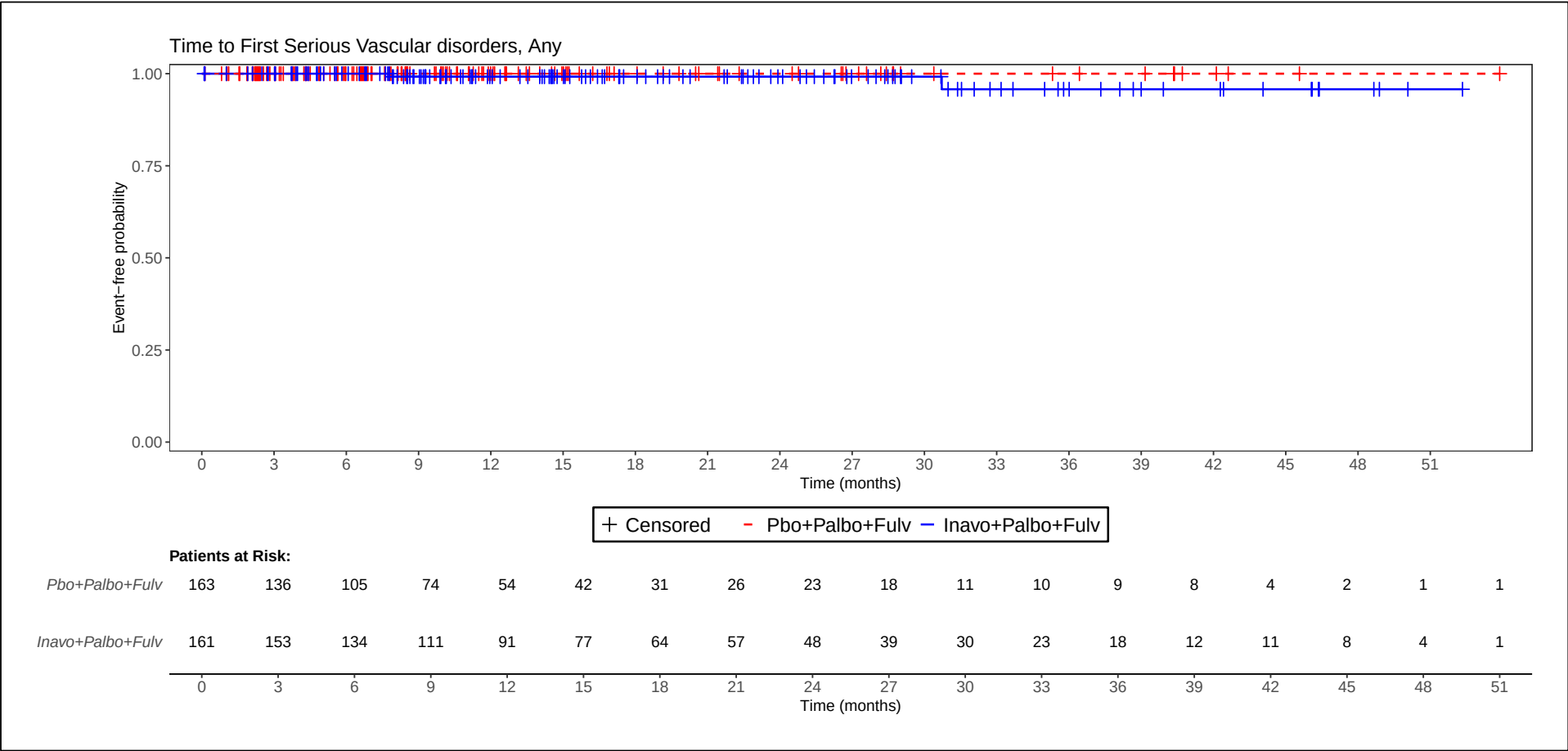
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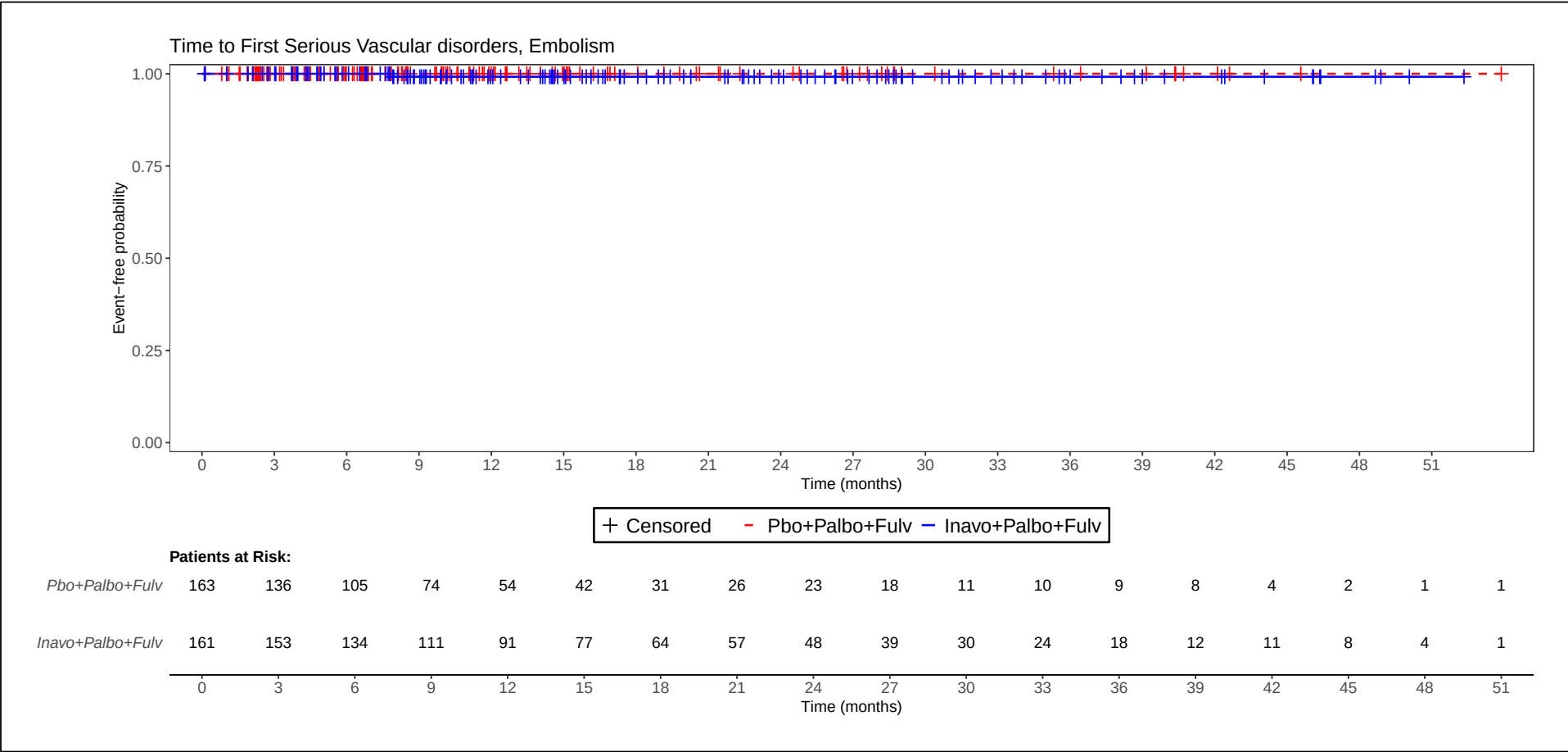
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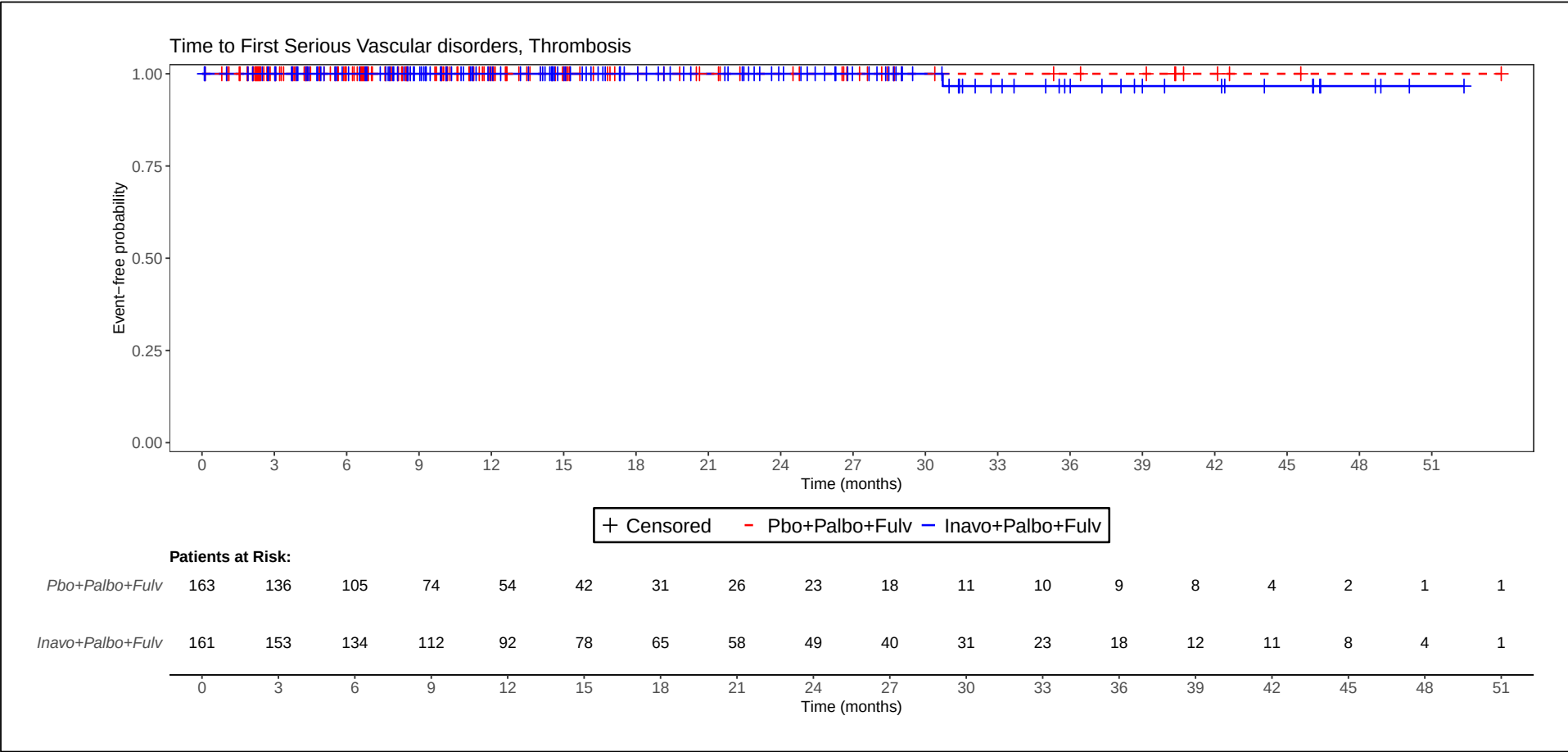
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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31 MAR 2025 06:19 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

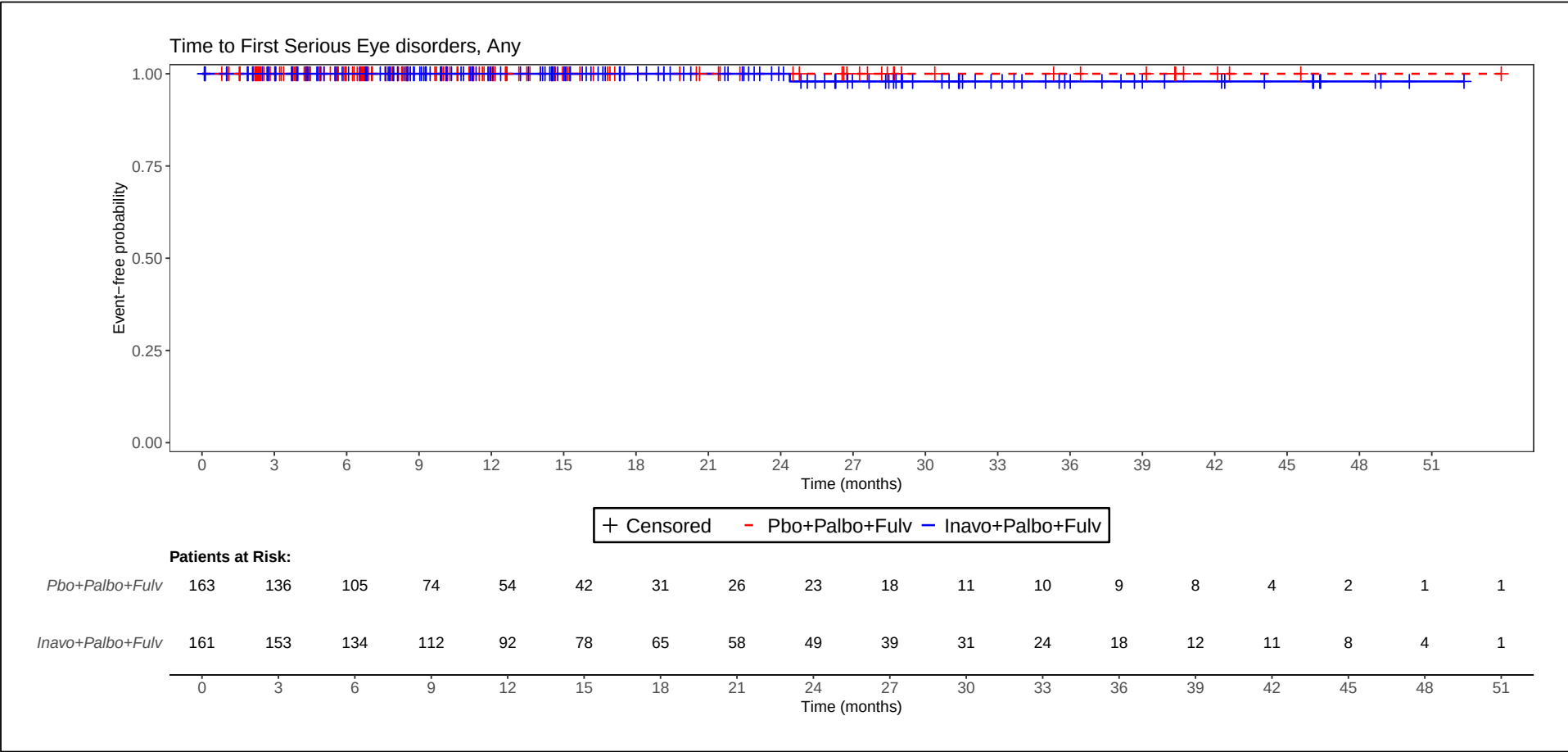
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

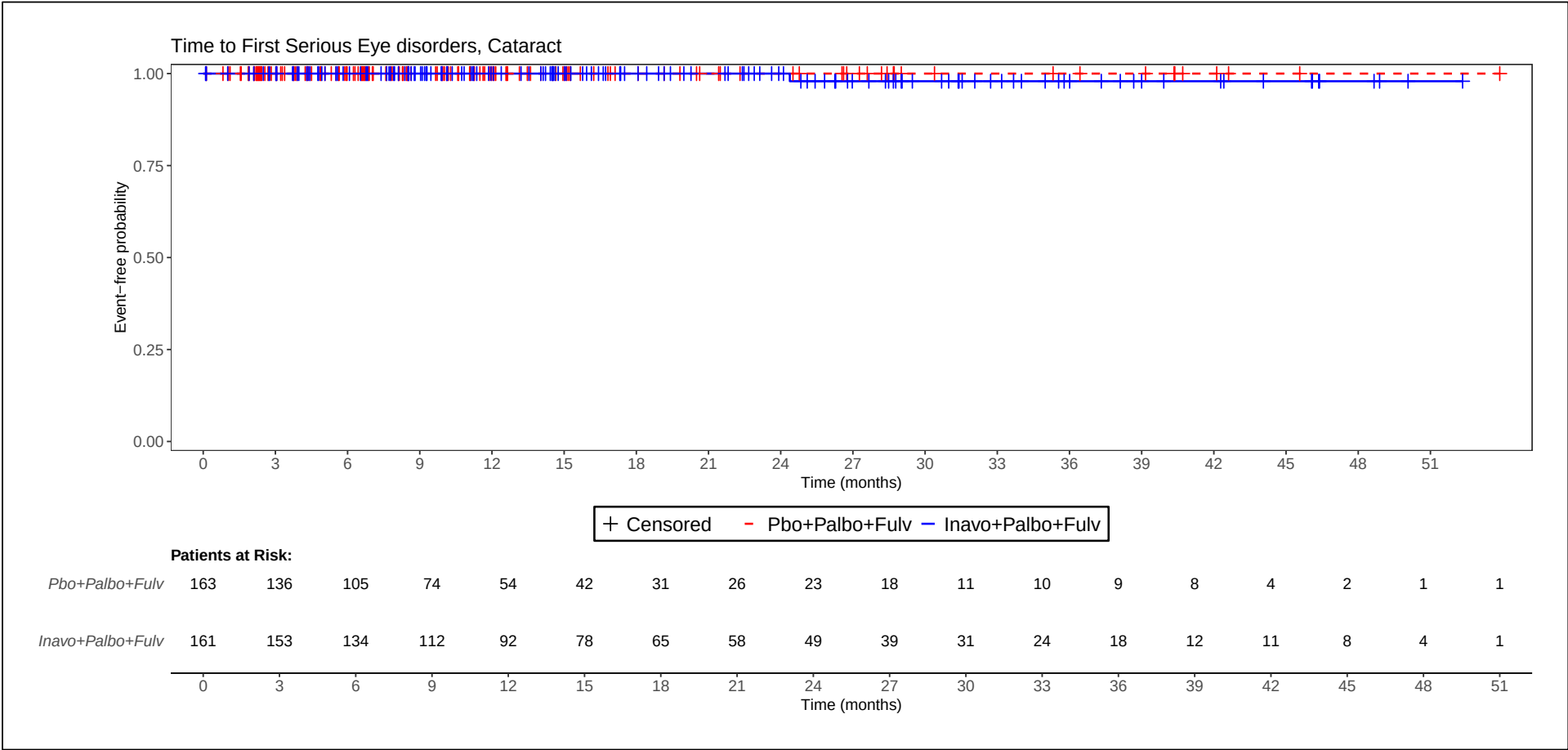
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

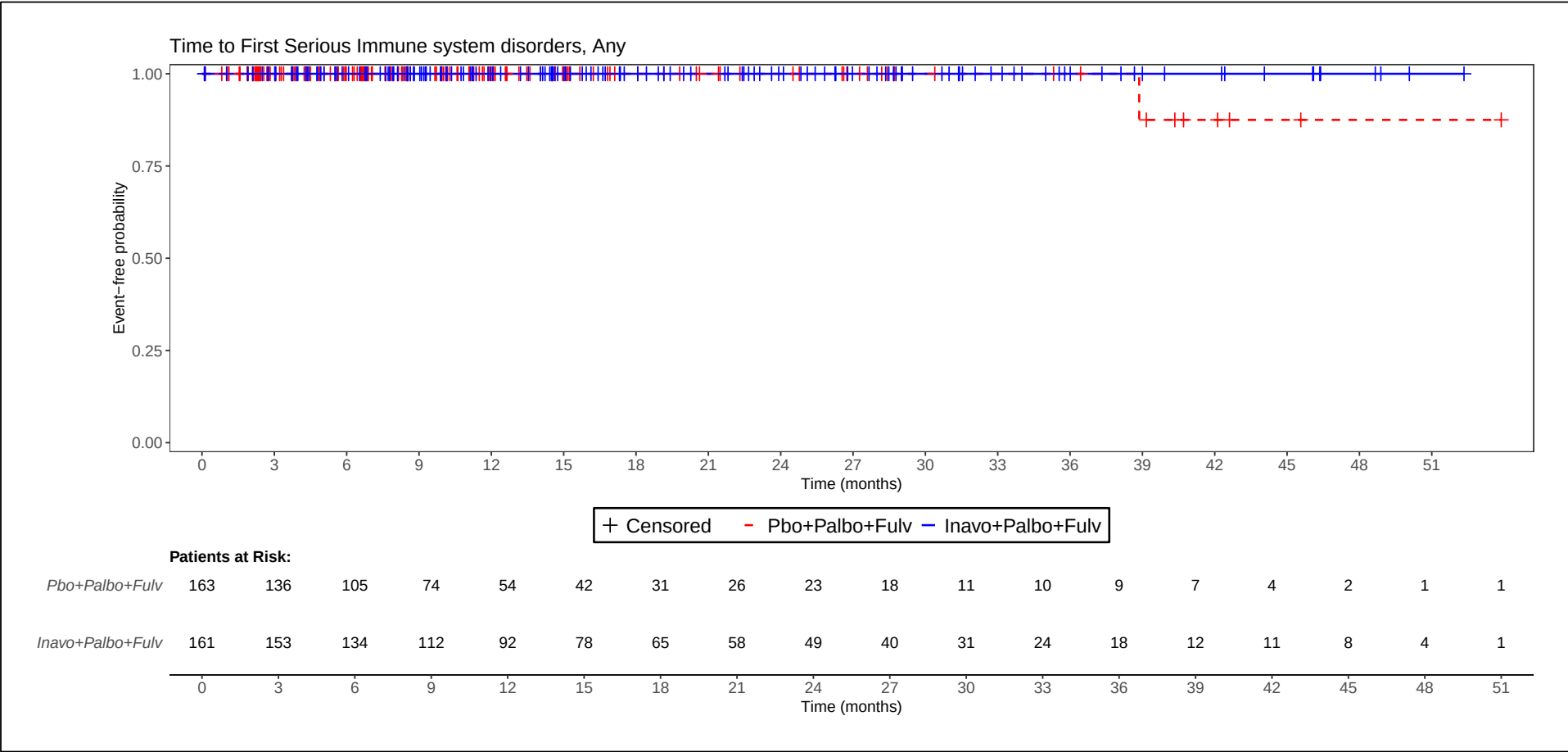
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_SERSPT_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

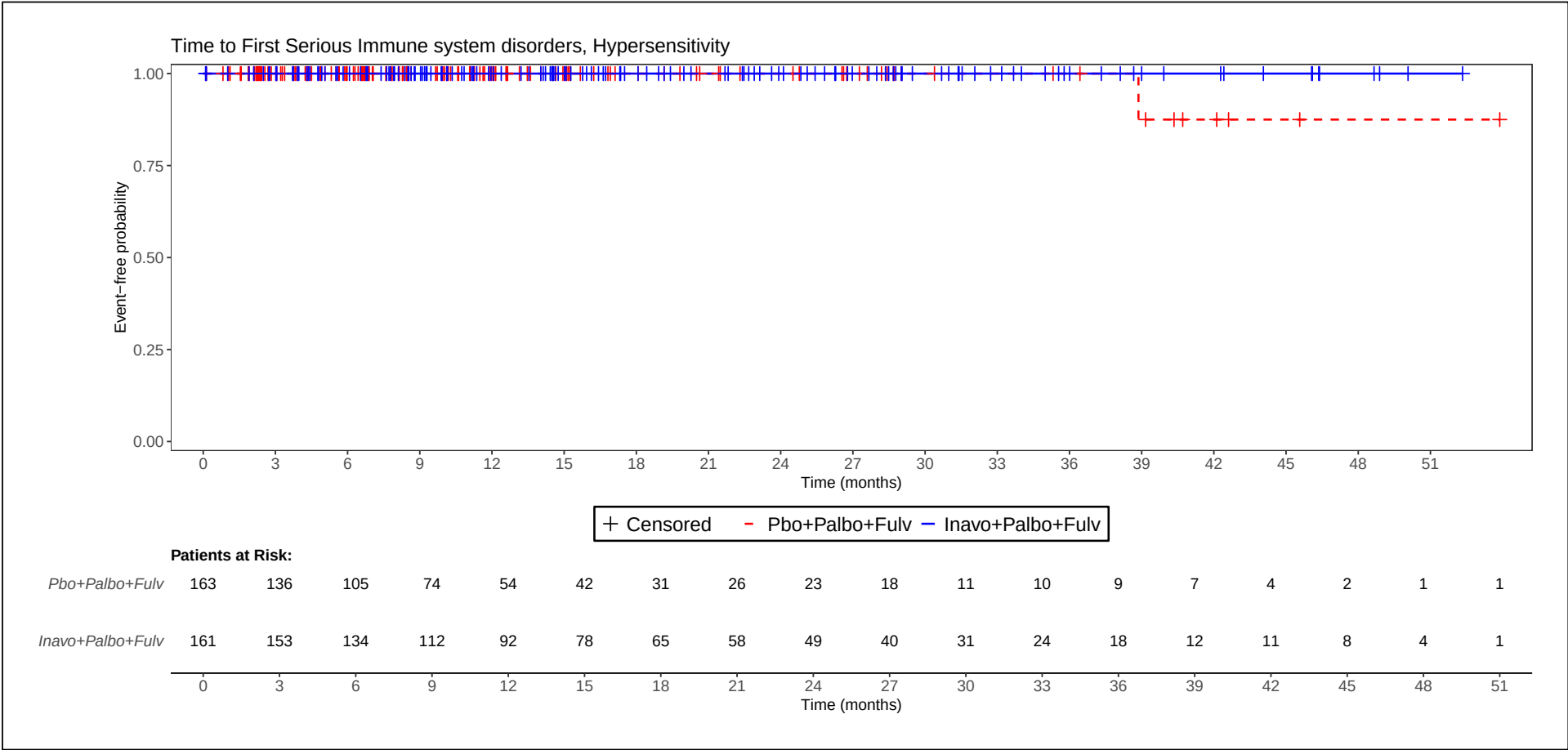
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Program name: programs/tlg/g_ae_km.R
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

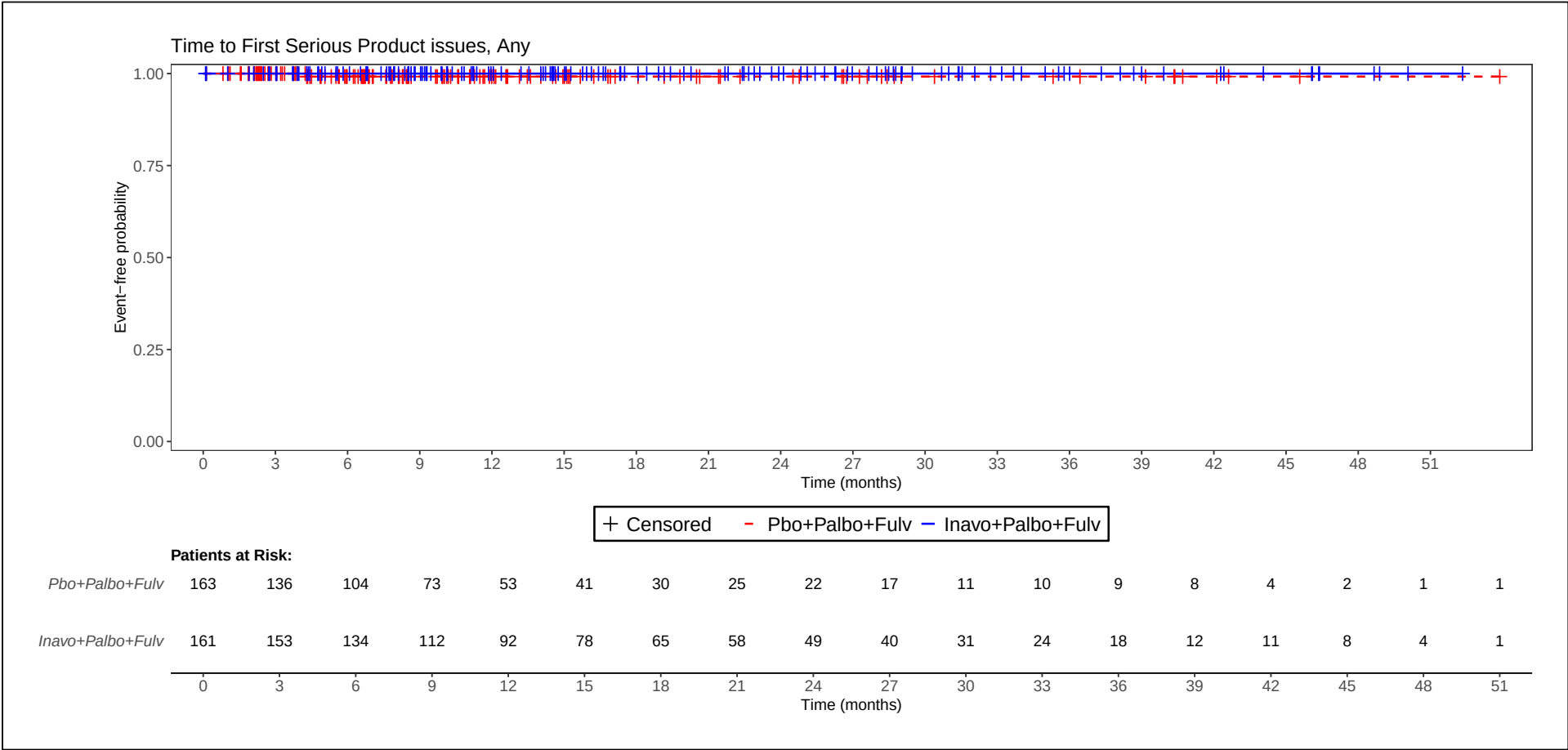
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_SERSPT_SAS_15NOV2024_41554.pdf
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

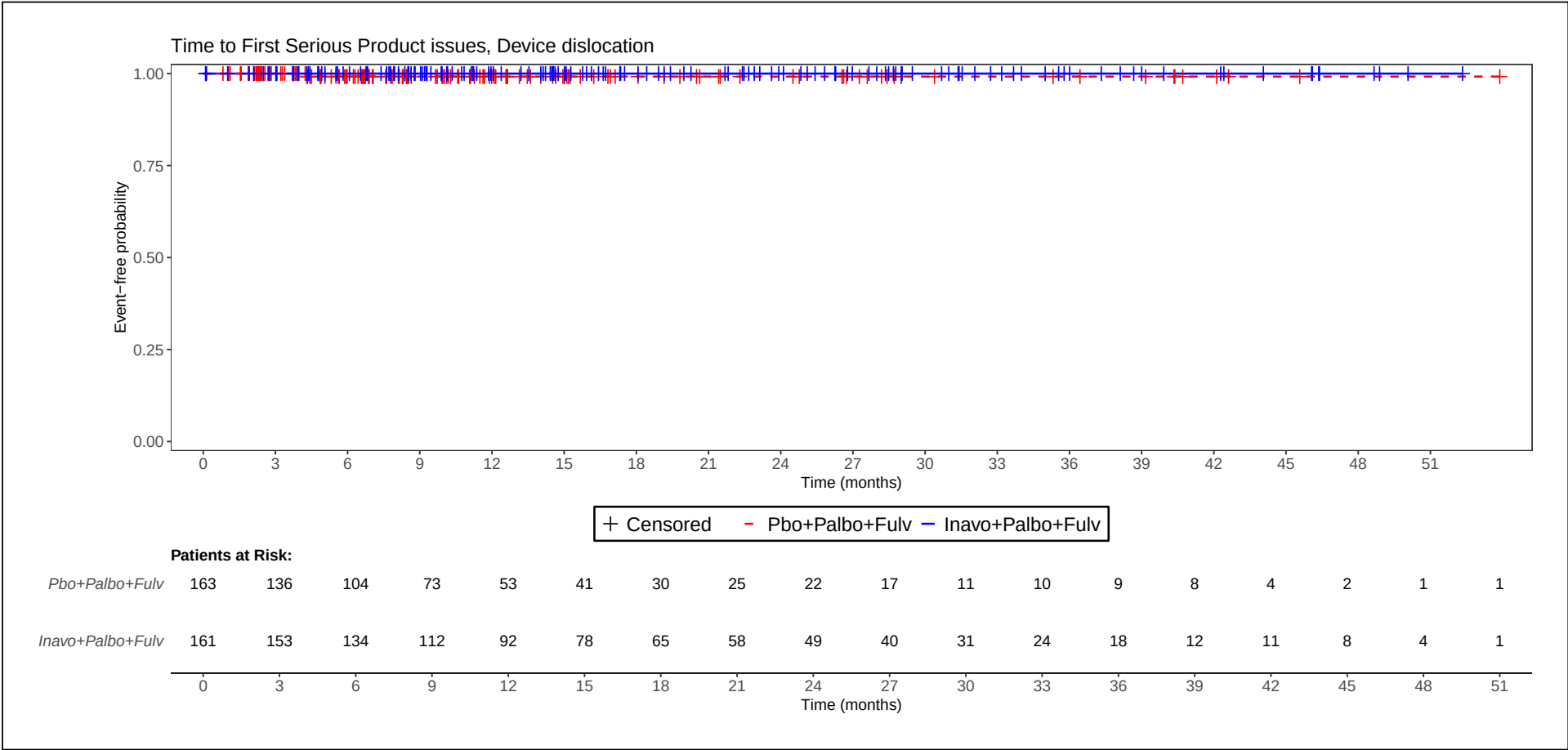
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

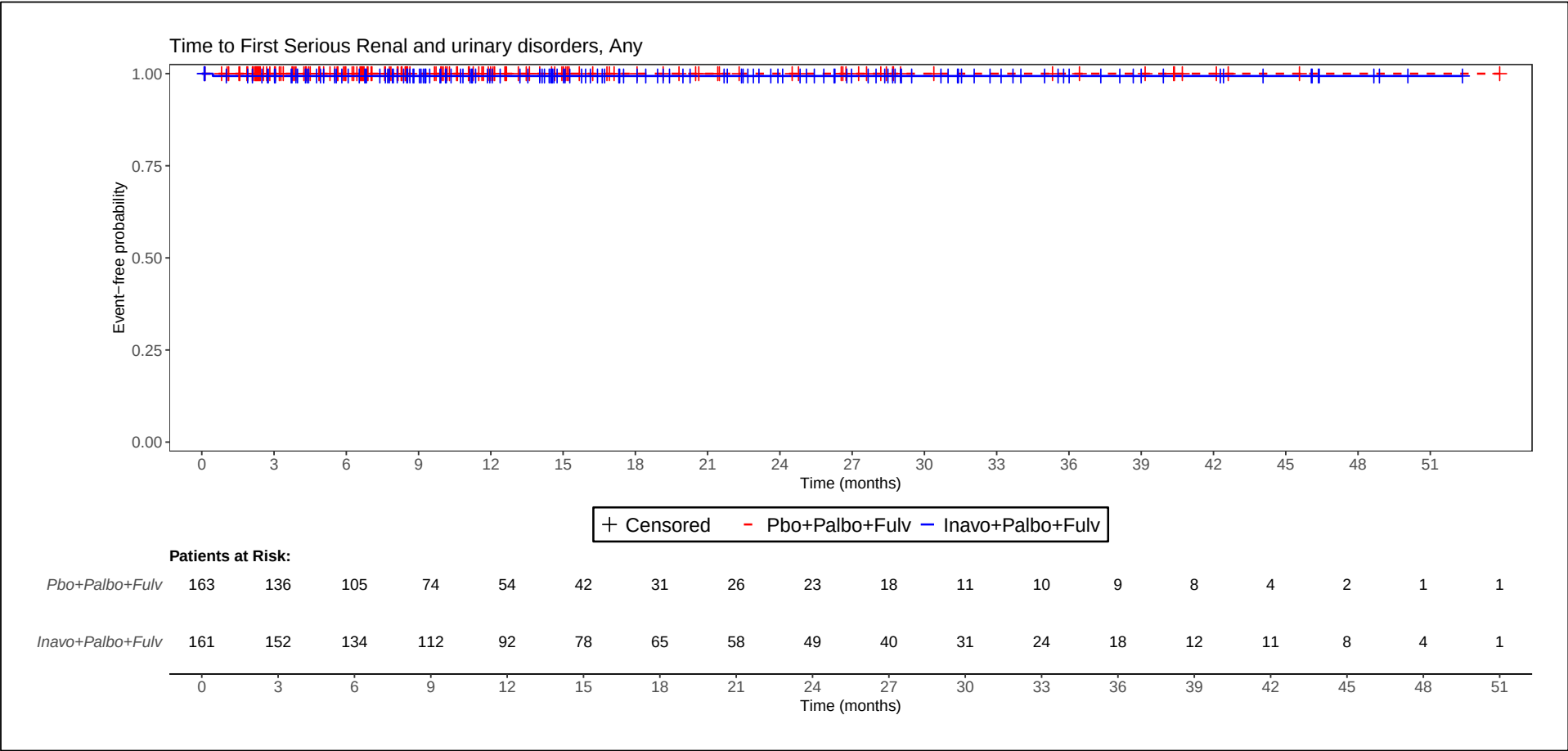
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

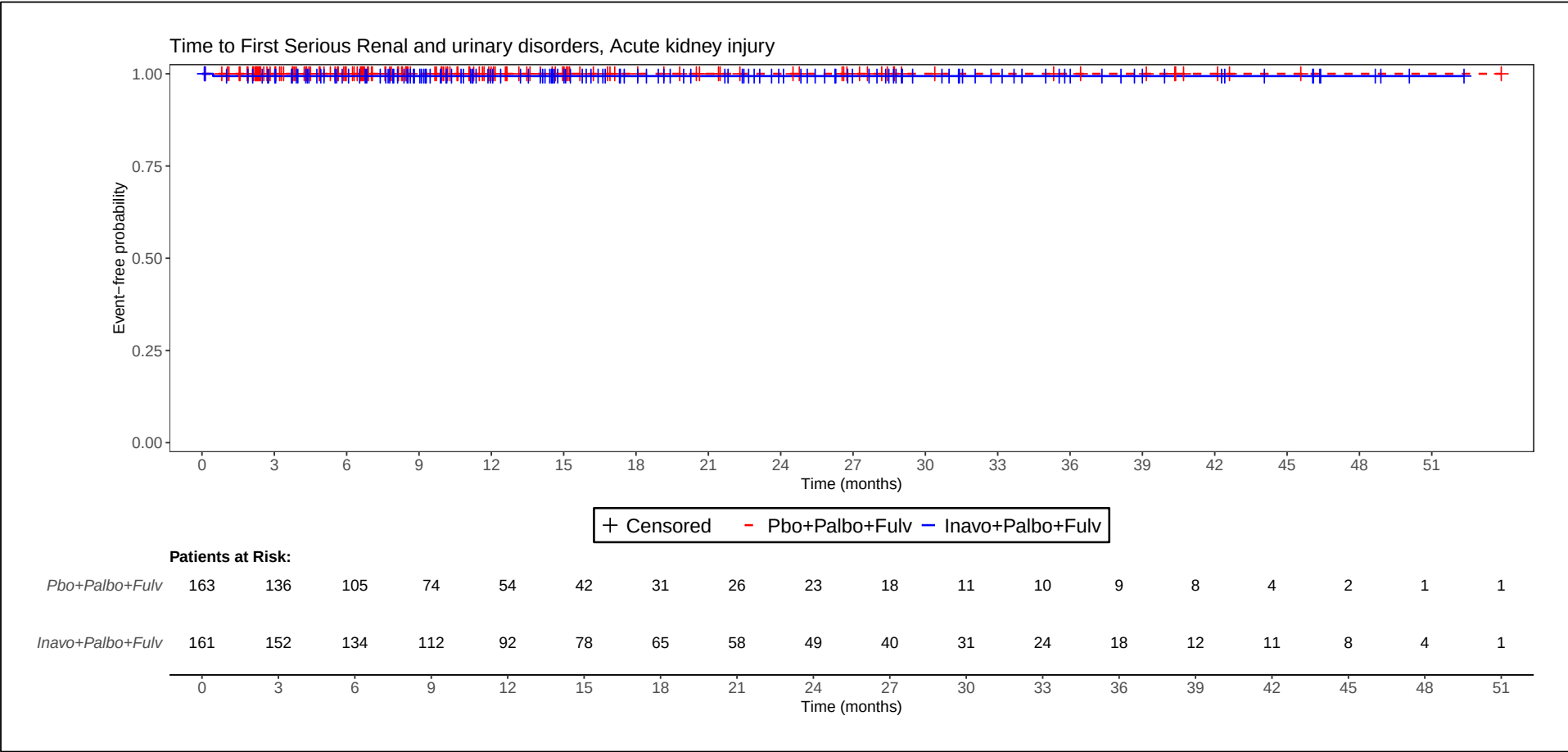
Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Safety, Serious Adverse Events by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
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Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.1 Generelle Verträglichkeit

3.1.2 Unerwünschte Ereignisse UE nach Systemorganklassen (SOC) und Preferred Terms (PT)

3.1.2.4 Patienten mit UE Grad 5 nach SOC/PT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis by SOC and PT Overall and with Subgroups (Safety), Adverse Events Grade 5 by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Grade 5 Cardiac disorders, Any											
All Patients	324	163	1	0.6	161	1	0.6	1.02	(0.06, 16.29)	0.9895	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3028	0.0708
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2240	0.0708
Sex											
F	318	162	1	0.6	156	1	0.6	1.05	(0.07, 16.71)	0.9750	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3334	0.2636
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.2636
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3297	0.2636
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.96	(0.06, 15.38)	0.9782	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	1.07	(0.07, 17.08)	0.9628	1.0000
Time to First Grade 5 Cardiac disorders, Acute coronary syndrome											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3128	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2240	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3066	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3297	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3267	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3014	1.0000
Time to First Grade 5 Cardiac disorders, Cardiac arrest											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3218	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.3028	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3280	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3334	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3080	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3332	1.0000
Time to First Grade 5 Infections and infestations, Any											
All Patients	324	163	1	0.6	161	1	0.6	0.82	(0.05, 13.22)	0.8858	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	0.0650
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2871	0.0650
Sex											
F	318	162	1	0.6	156	1	0.6	0.84	(0.05, 13.59)	0.9015	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4227	0.2224
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.2224
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3042	0.2224
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.76	(0.05, 12.28)	0.8445	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.88	(0.05, 14.25)	0.9310	1.0000
Time to First Grade 5 Infections and infestations, COVID-19											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4132	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2871	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4061	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.4227	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4307	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3833	1.0000
Time to First Grade 5 Infections and infestations, COVID-19 pneumonia											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3158	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2930	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3220	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3042	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.2981	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3243	1.0000
Time to First Grade 5 Nervous system disorders, Any											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2272	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5305	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.2200	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5541	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2652	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5002	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1972	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Grade 5 Nervous system disorders, Cerebral haemorrhage											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4889	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5305	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4795	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5541	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5002	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.4281	1.0000
Time to First Grade 5 Nervous system disorders, Cerebrovascular accident											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3082	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3173	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2652	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3037	1.0000
Time to First Grade 5 Gastrointestinal disorders, Any											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4857	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5338	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4762	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5186	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5040	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade 5 Gastrointestinal disorders, Gastrointestinal haemorrhage											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4857	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5338	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4762	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.5186	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5040	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6171	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade 5 General disorders and administration site conditions, Any											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4088	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4008	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5016	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4254	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3819	1.0000
Time to First Grade 5 General disorders and administration site conditions, Death											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4088	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2340	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4008	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5016	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4254	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3819	1.0000

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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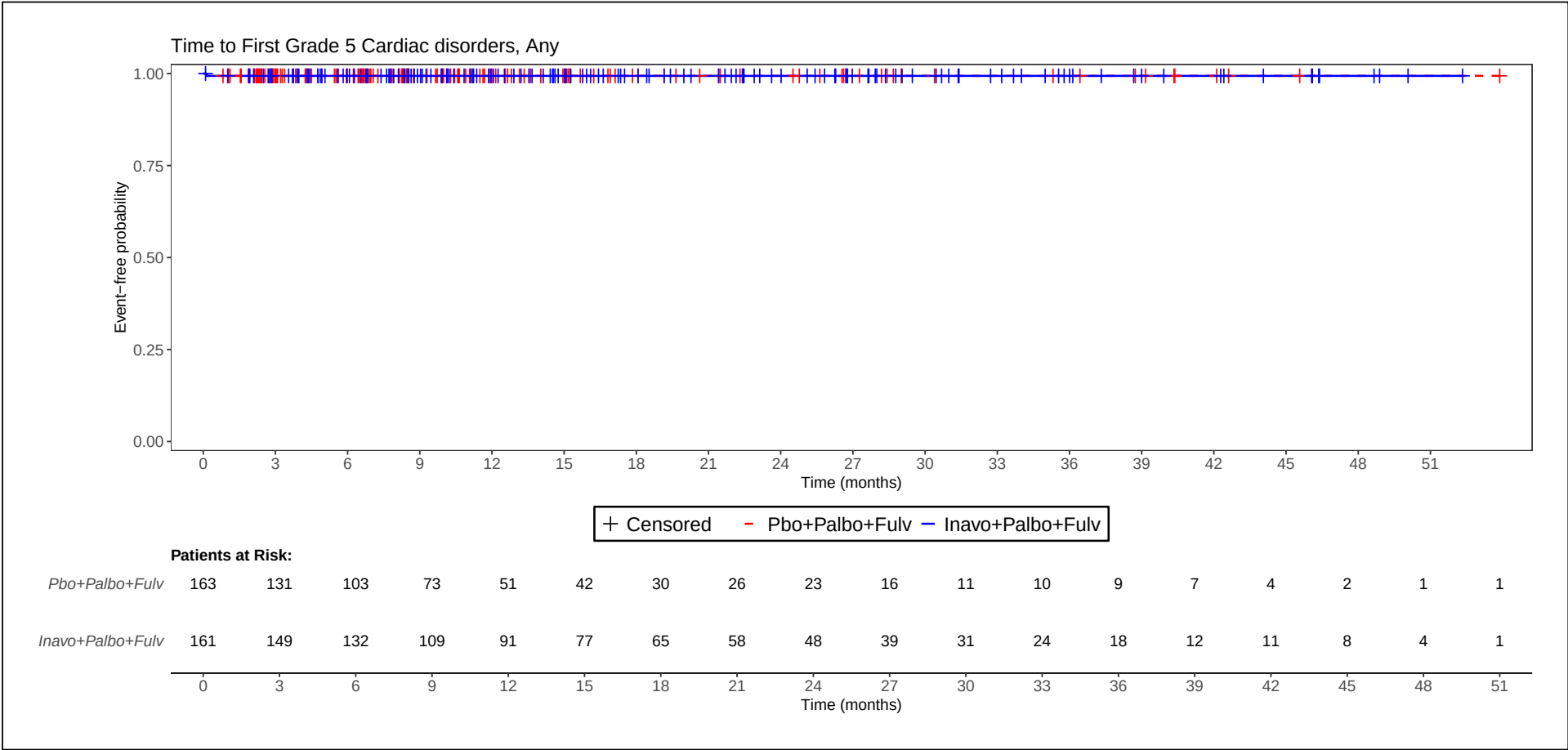
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08 APR 2025 17:33 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

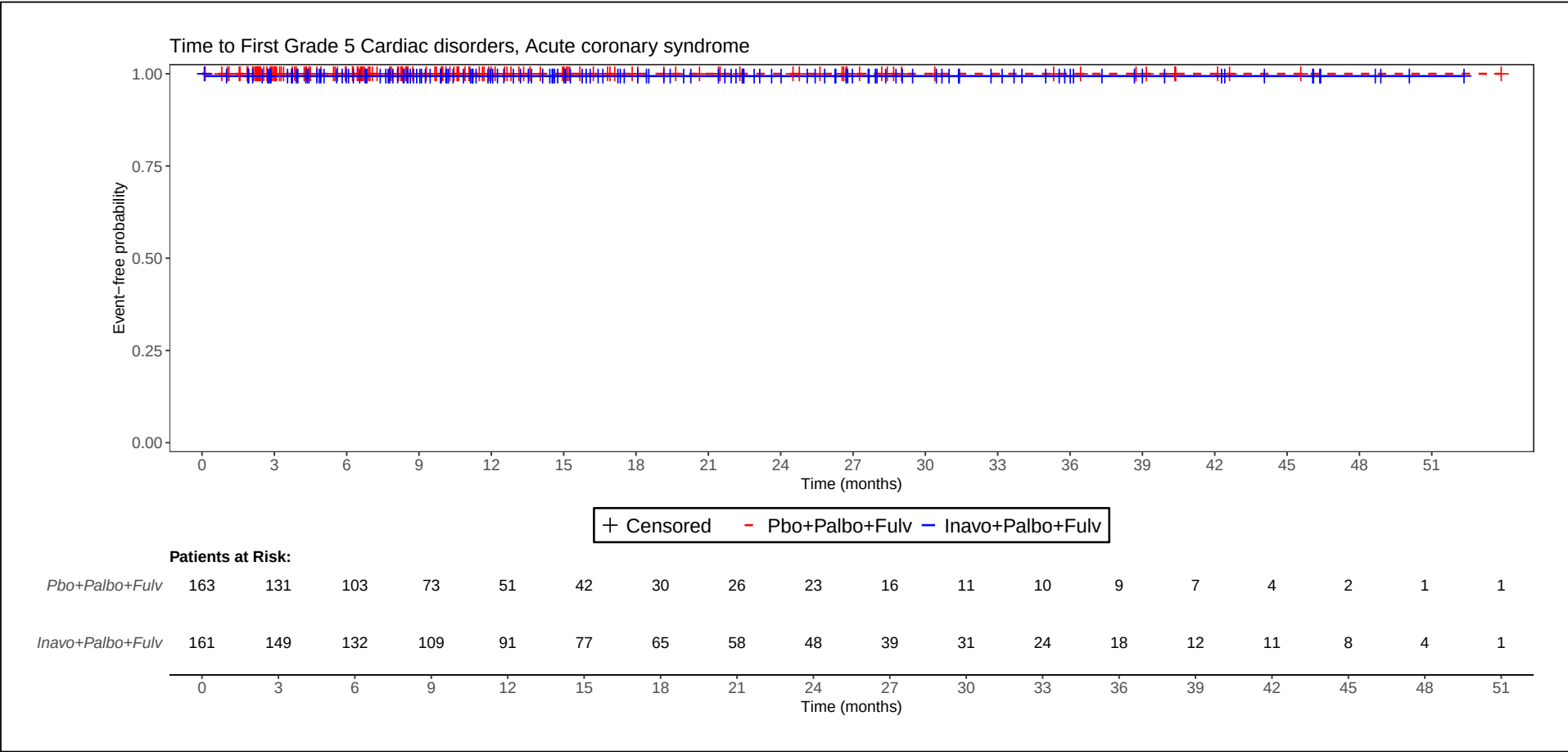
Kaplan Meier Plot for Safety, Adverse Events Grade 5 by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

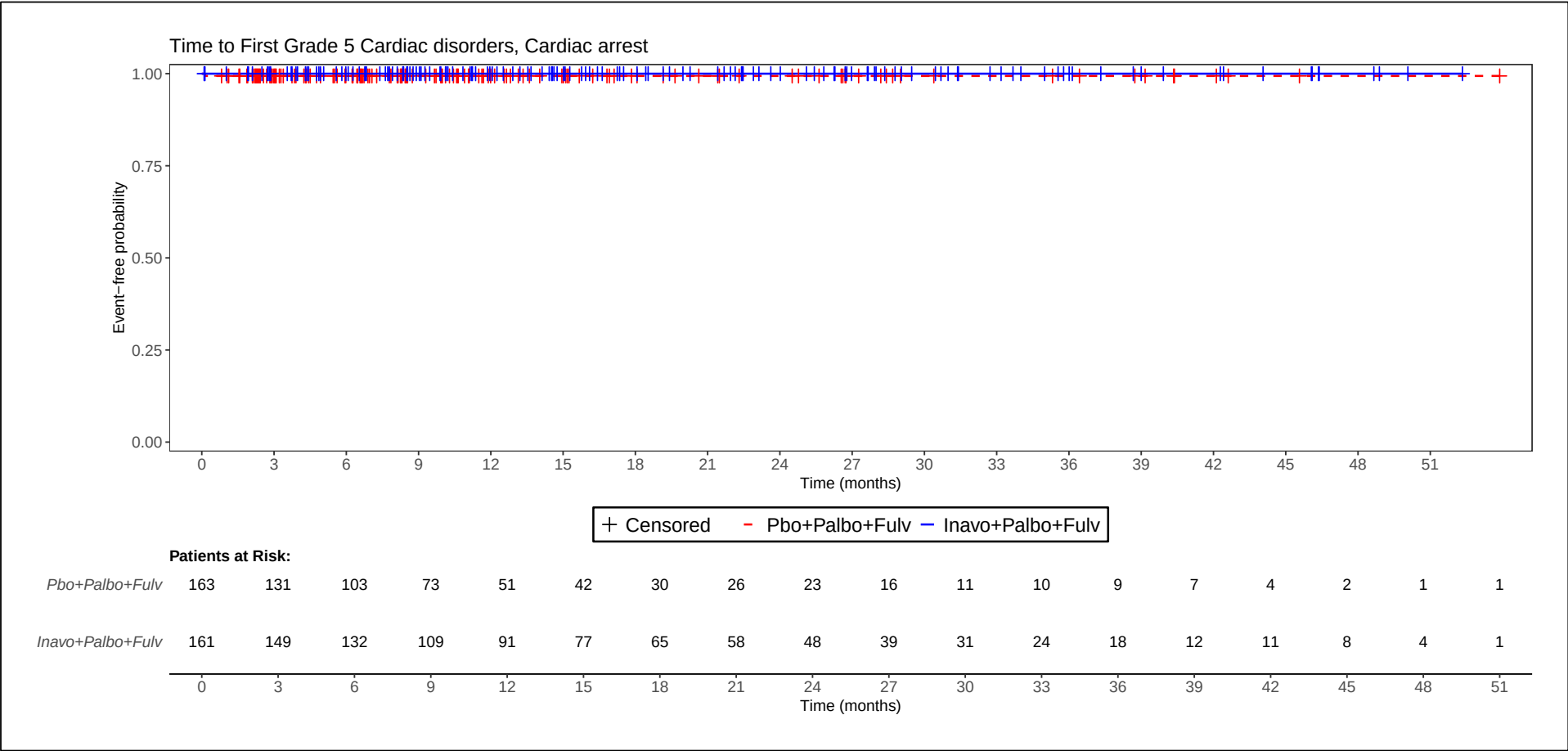
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

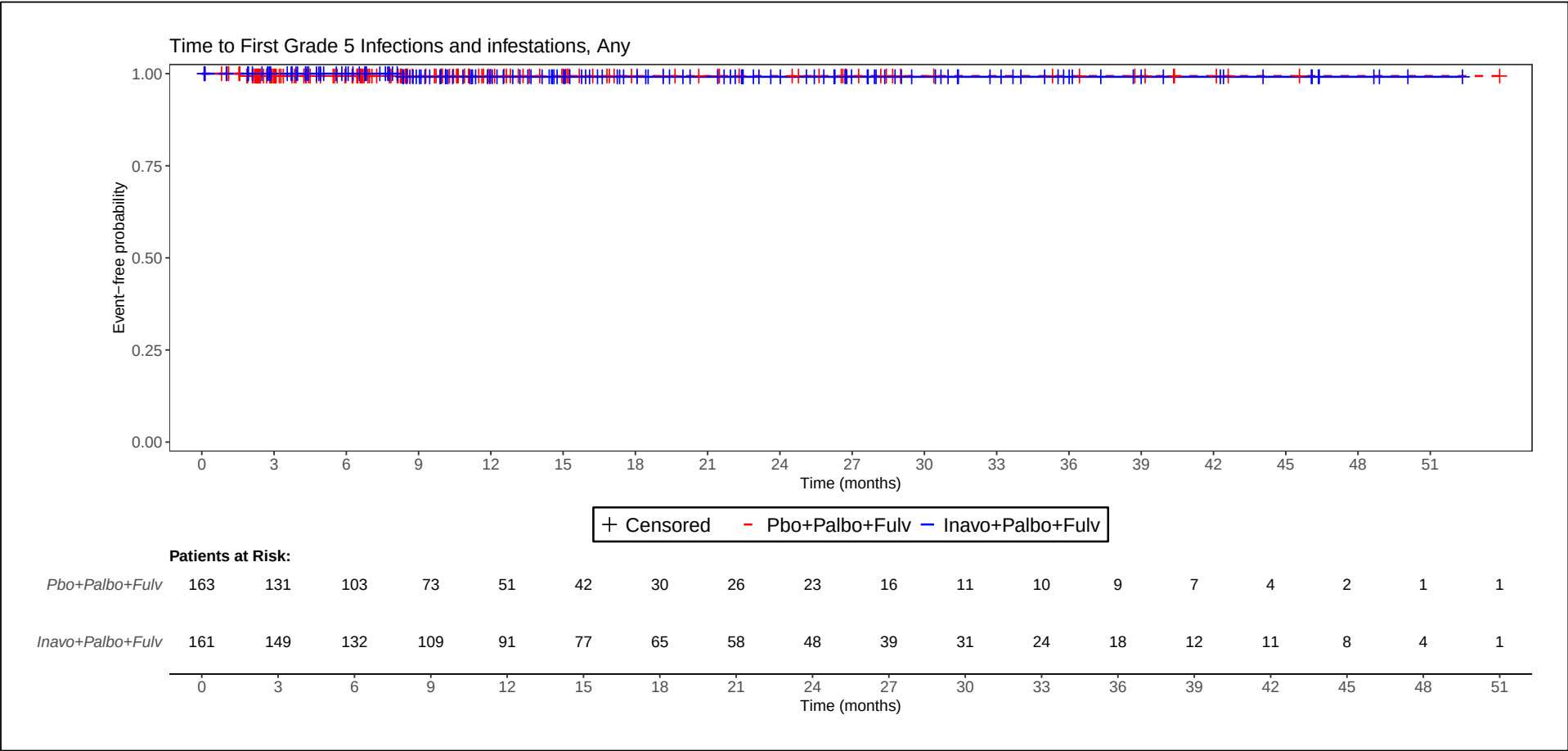
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

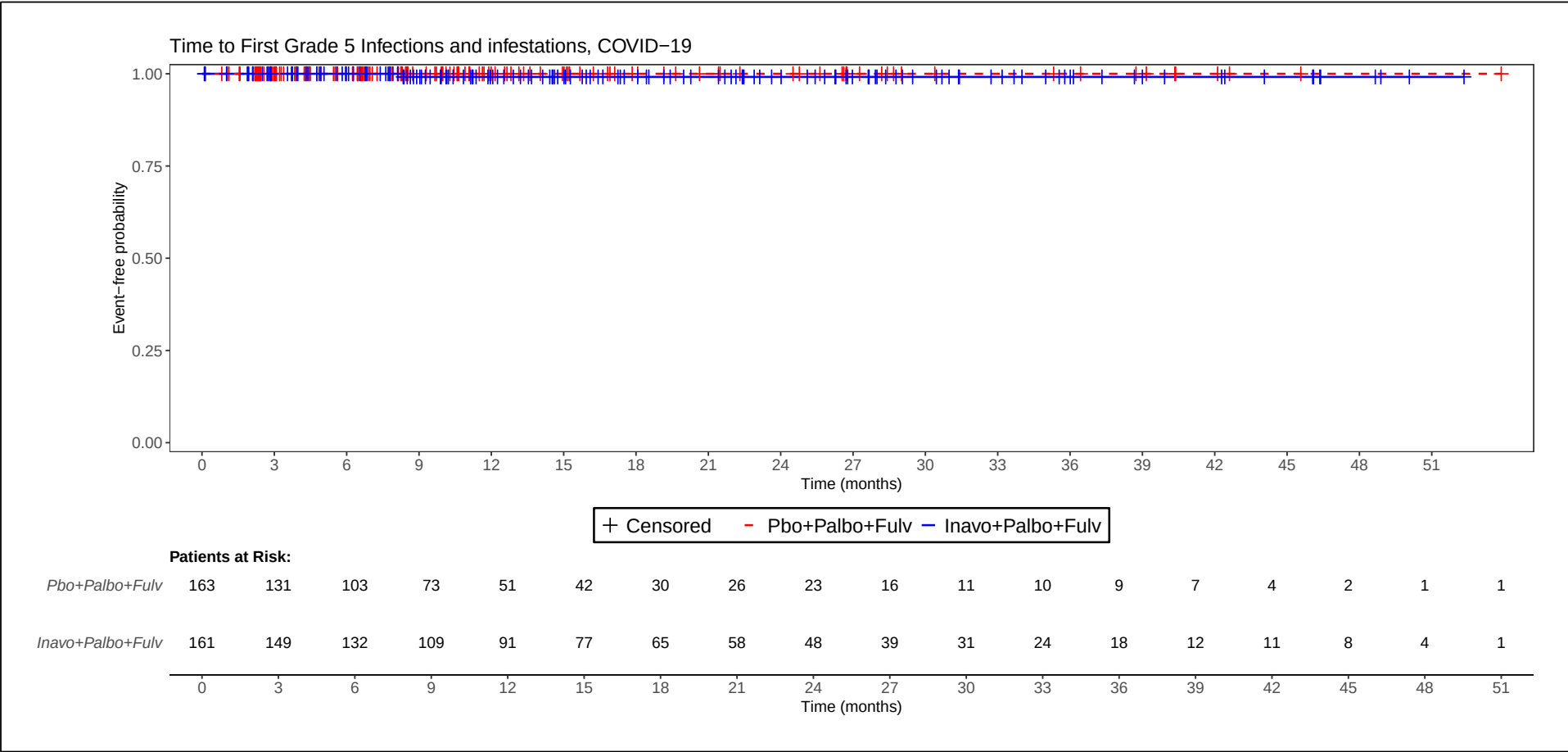
Kaplan Meier Plot for Safety, Adverse Events Grade 5 by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

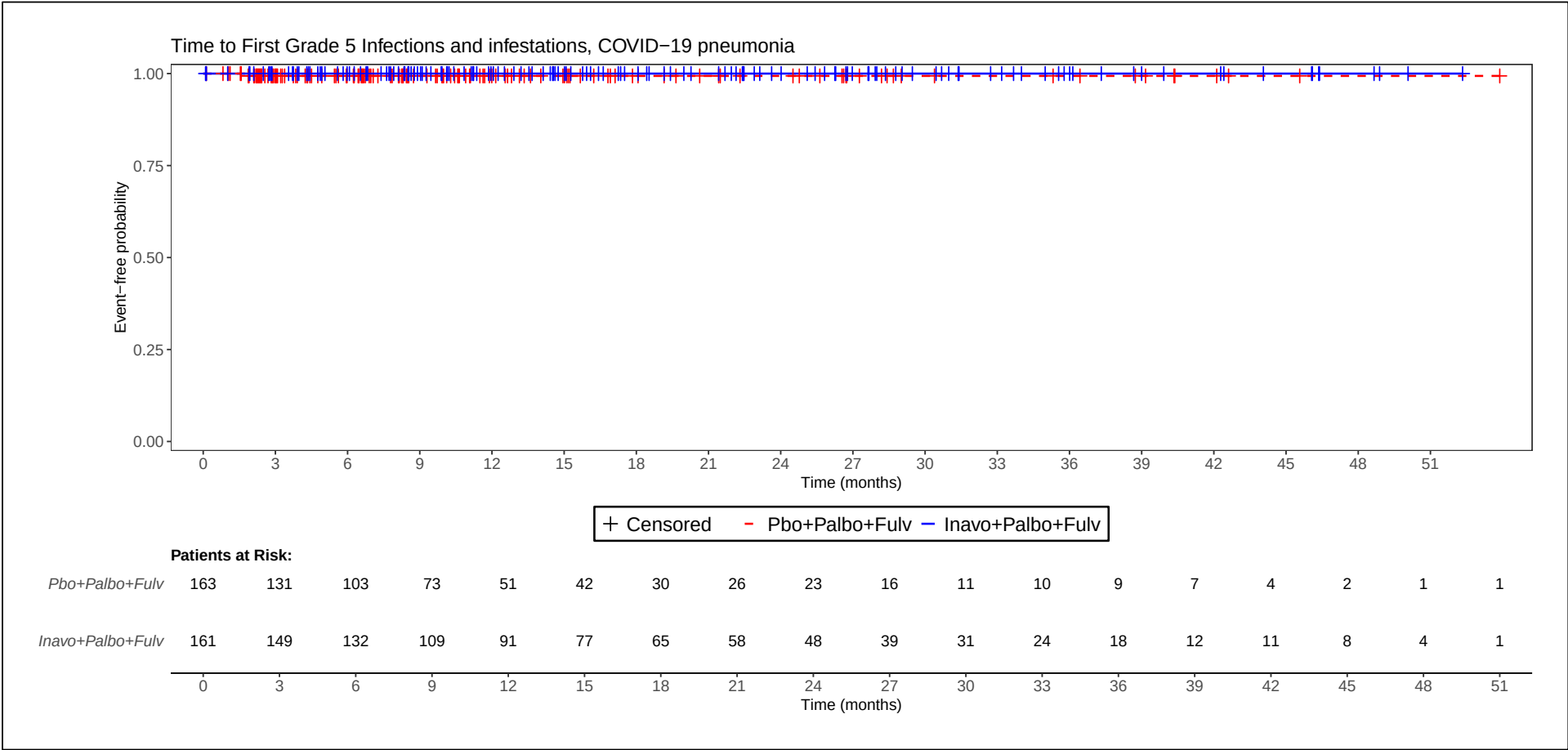
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

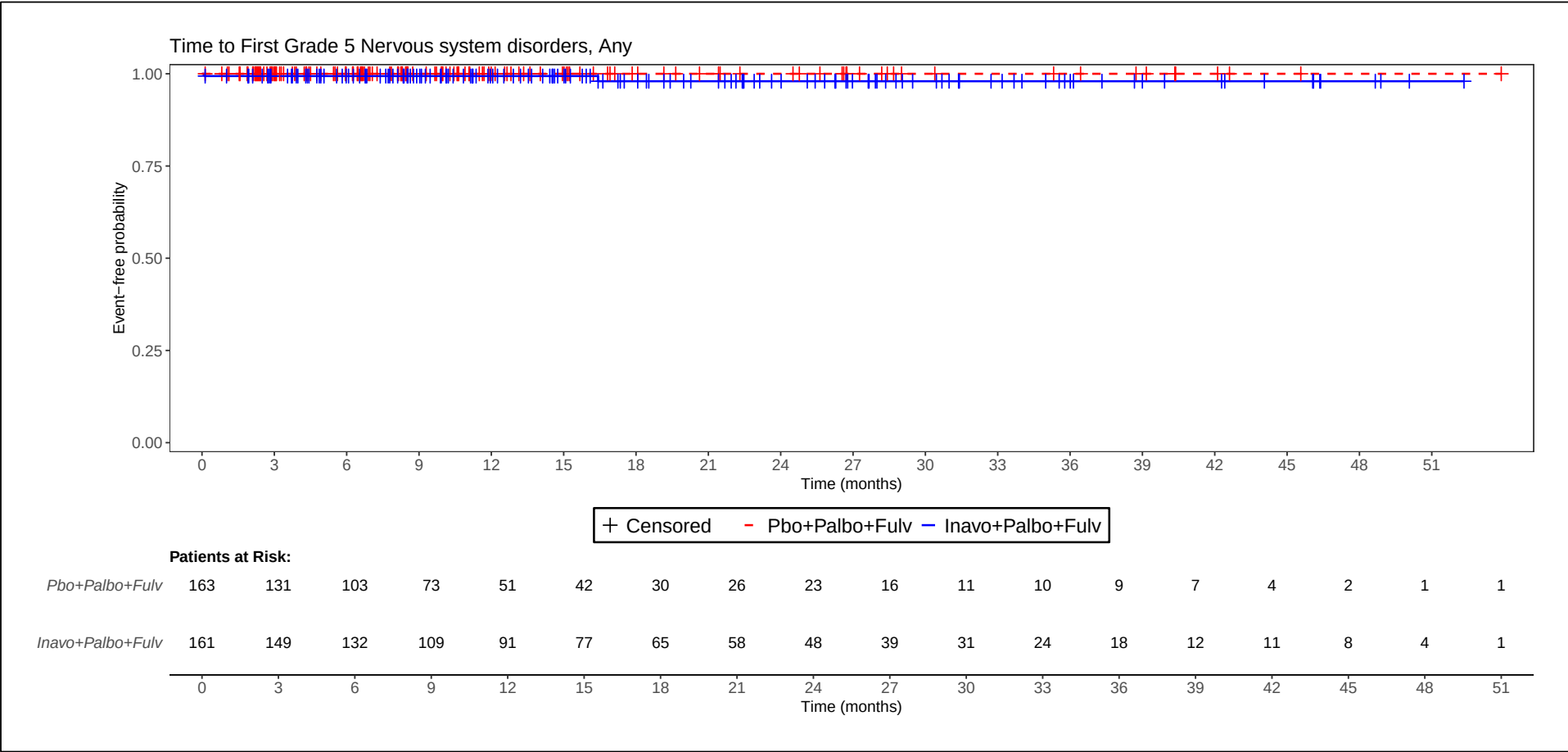
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

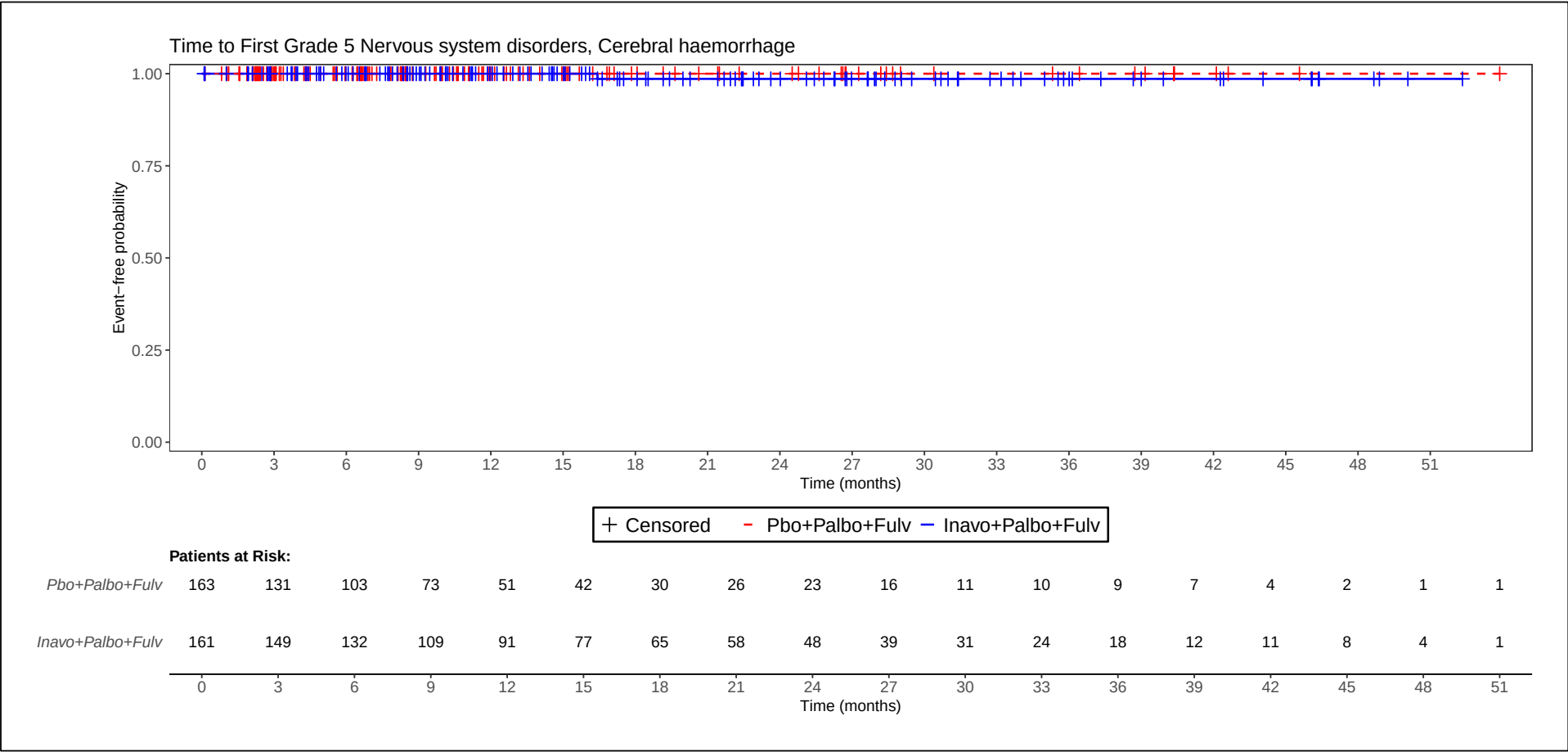
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

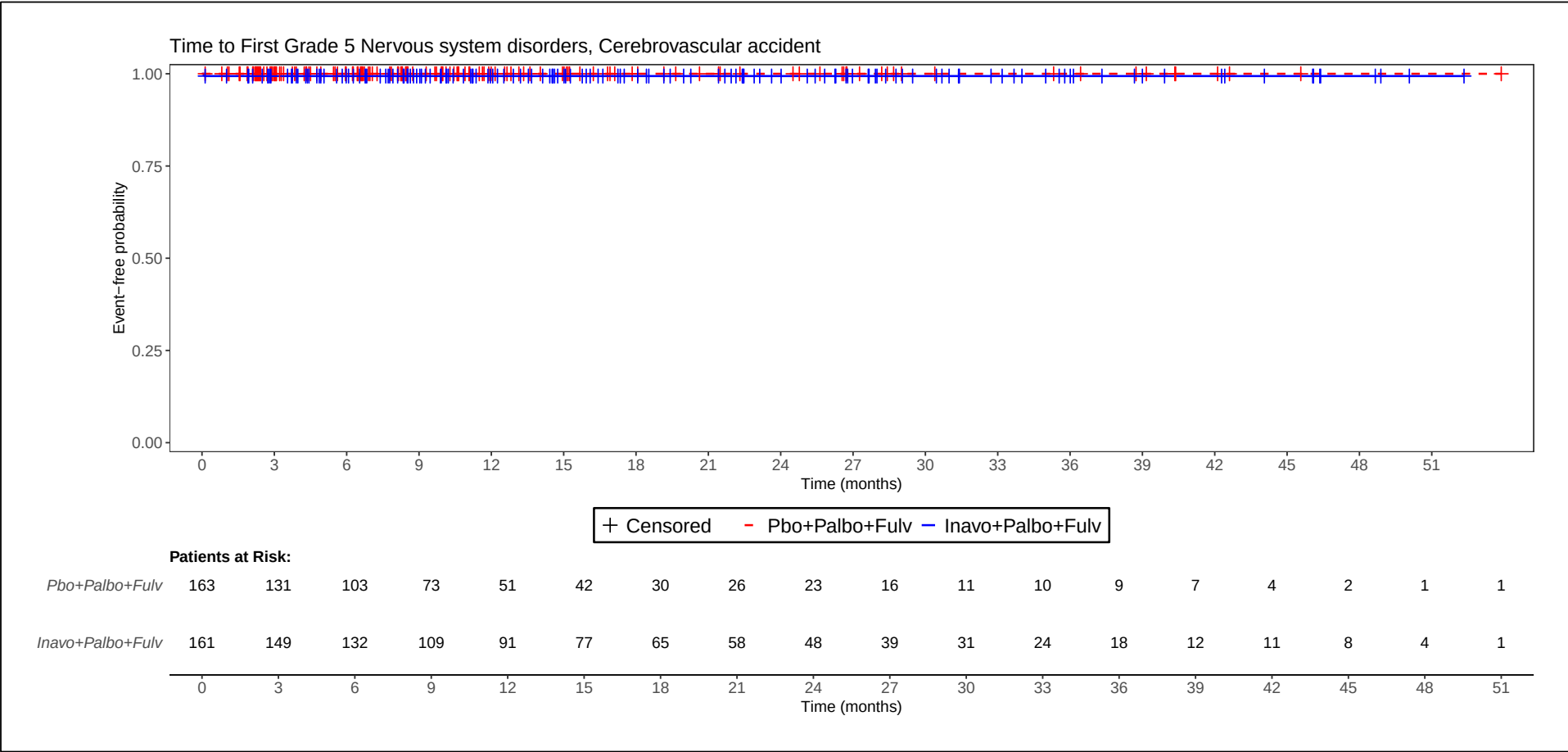
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

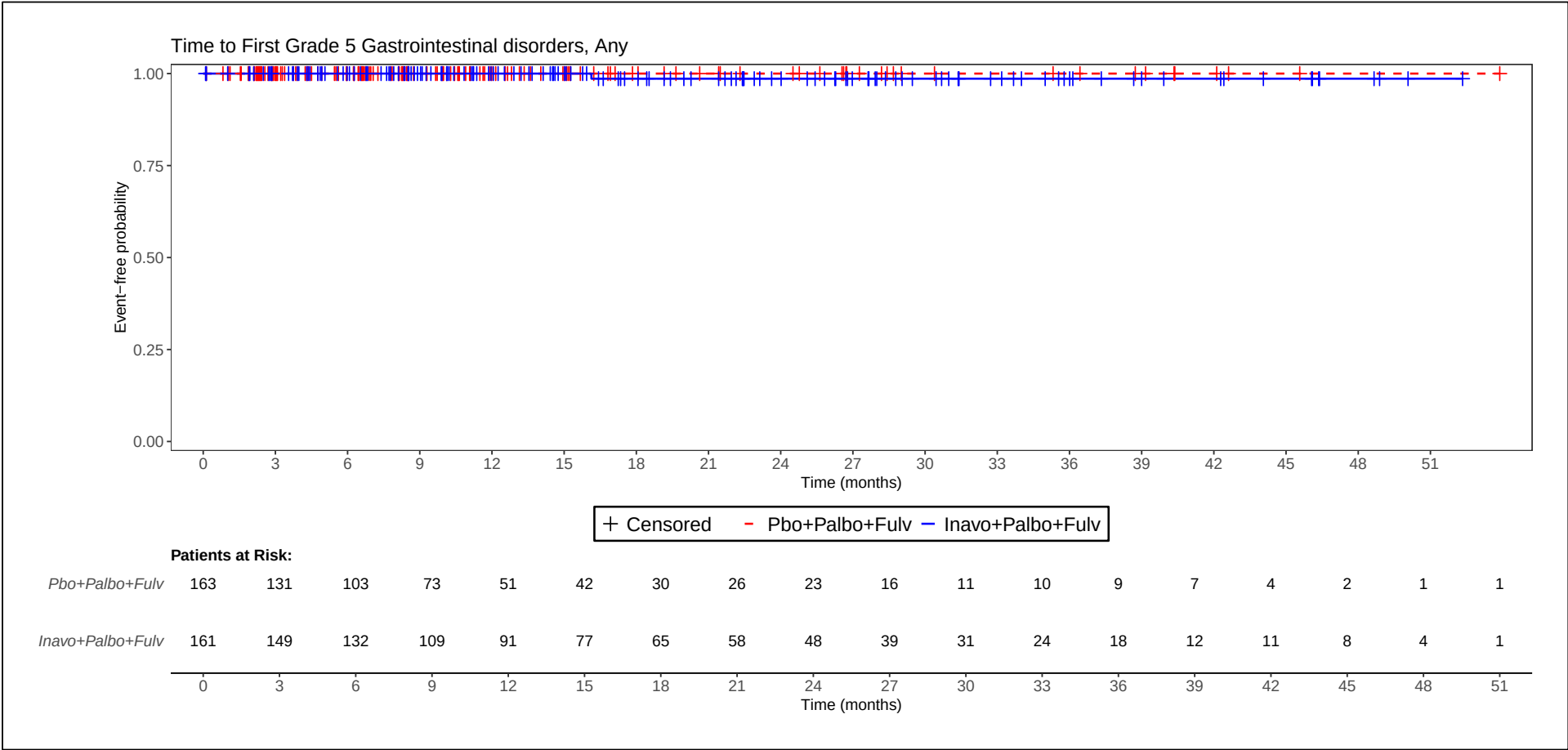
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

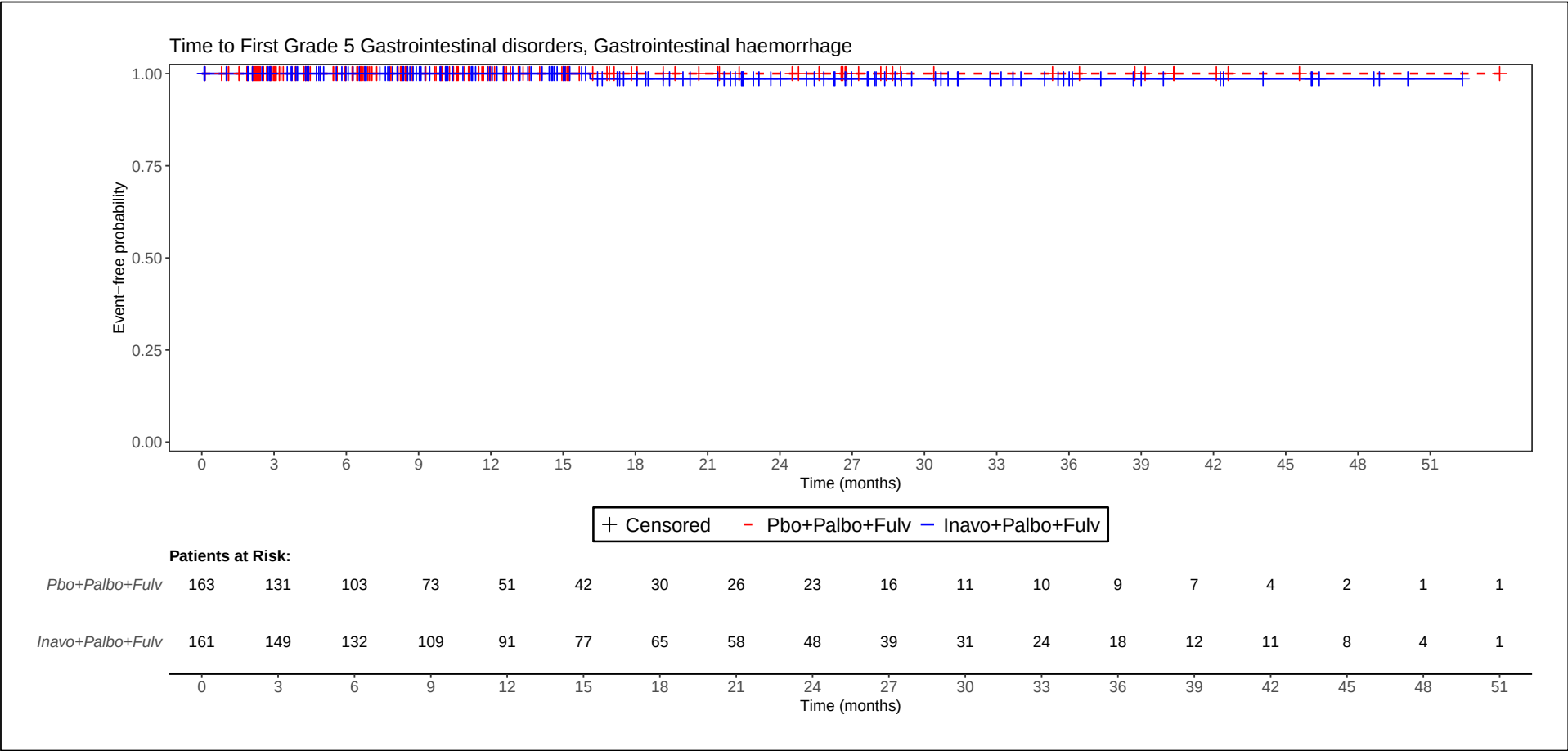
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

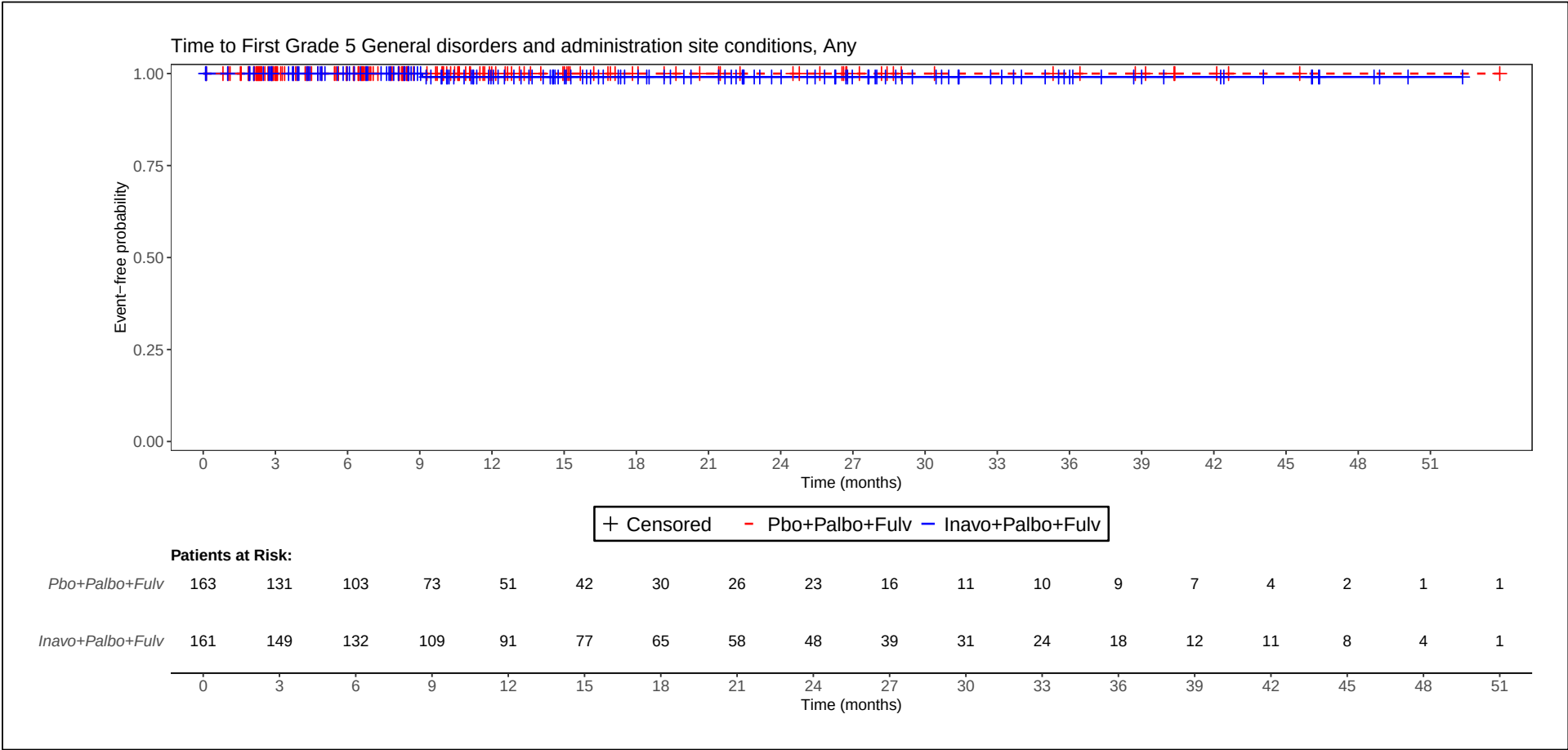
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

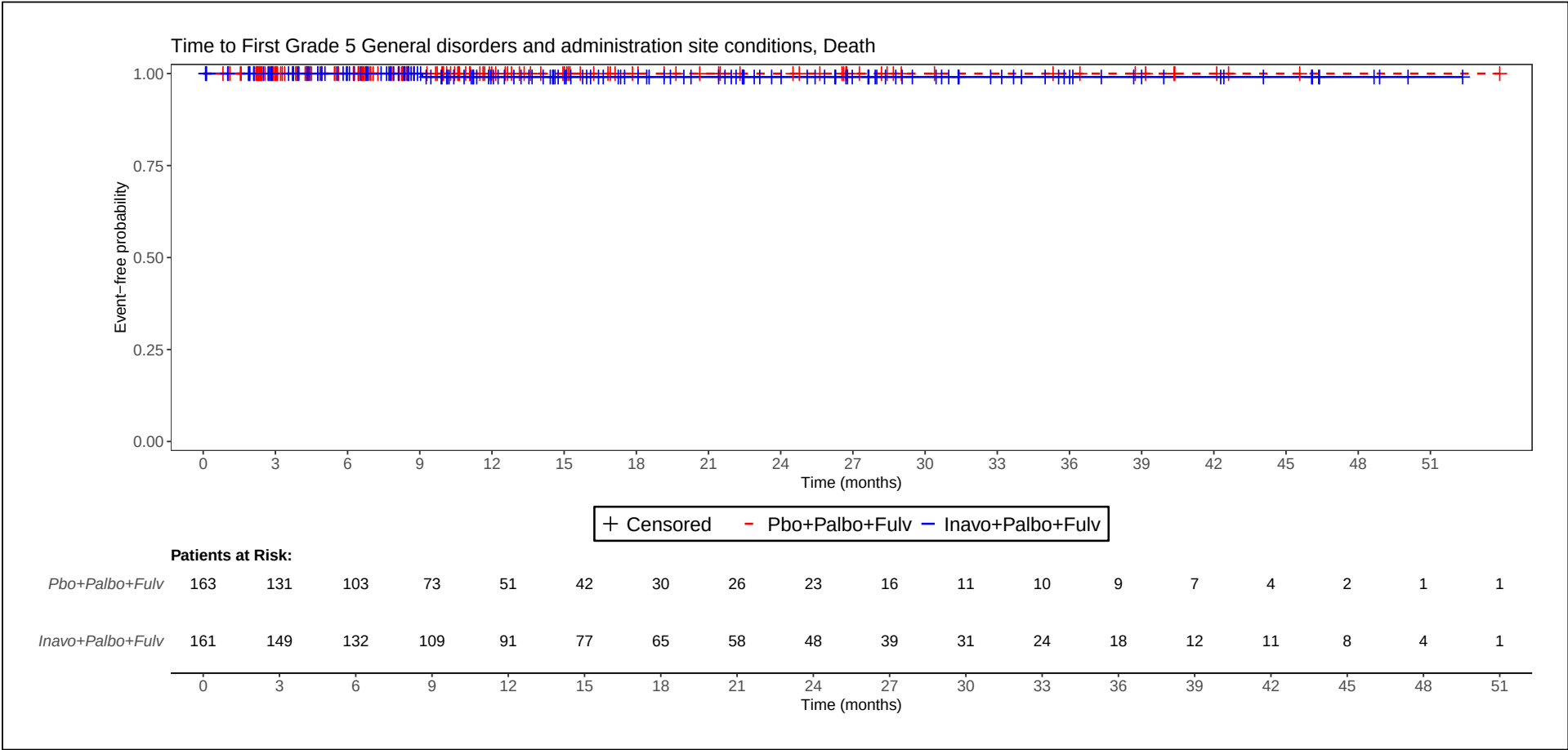
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Safety, Adverse Events Grade 5 by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v3/output/g_ae_km_GR5SPT_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 13:39 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.1 Generelle Verträglichkeit

3.1.2 Unerwünschte Ereignisse UE nach Systemorganklassen (SOC) und Preferred Terms (PT)

3.1.2.4 Patienten mit Therapieabbruch aufgrund Unerwünschter Ereignisse (UE) nach SOC/PT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Descriptive Analysis by SOC and PT Overall and with Subgroups (Safety), Adverse Events Leading to Discontinuation by SOC and PT, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv		
		n	Events	%	n	Events	%
Time to First AE Leading to Treatment Discontinuation: Investigations, Any							
All Patients	324	163	1	0.6	161	3	1.9
Age group (years)							
<65	266	129	1	0.8	137	2	1.5
>=65	58	34	0	0.0	24	1	4.2
Sex							
F	318	162	1	0.6	156	3	1.9
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	1	1.7
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	2	3.2
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	1	2.8	29	1	3.4
Y	259	127	0	0.0	132	2	1.5
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	3	2.9
Time to First AE Leading to Treatment Discontinuation: Investigations, Alanine aminotransferase increased							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Investigations, Blood creatinine increased							
All Patients	324	163	1	0.6	161	0	0.0
Age group (years)							
<65	266	129	1	0.8	137	0	0.0

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv		
		n	Events	%	n	Events	%
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	1	0.6	156	0	0.0
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	1	2.8	29	0	0.0
Y	259	127	0	0.0	132	0	0.0
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	1	1.9	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0
Time to First AE Leading to Treatment Discontinuation: Investigations, Neutrophil count decreased							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	0	0.0
>=65	58	34	0	0.0	24	1	4.2
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	1	1.7
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	1	3.4
Y	259	127	0	0.0	132	0	0.0
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Investigations, Weight decreased							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv		
		n	Events	%	n	Events	%
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Blood and lymphatic system disorders, Any							
All Patients	324	163	0	0.0	161	2	1.2
Age group (years)							
<65	266	129	0	0.0	137	2	1.5
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	2	1.3
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	1	2.5
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	1	3.4
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Blood and lymphatic system disorders, Neutropenia							
All Patients	324	163	0	0.0	161	2	1.2
Age group (years)							
<65	266	129	0	0.0	137	2	1.5
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	2	1.3
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	1	2.5
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	1	3.4
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv		
		n	Events	%	n	Events	%
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Gastrointestinal disorders, Any							
All Patients	324	163	0	0.0	161	2	1.2
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	1	4.2
Sex							
F	318	162	0	0.0	156	2	1.3
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	2	3.2
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	2	1.5
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Gastrointestinal disorders, Gastric ulcer							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Gastrointestinal disorders, Intestinal perforation							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv		
		n	Events	%	n	Events	%
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Gastrointestinal disorders, Stomatitis							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	0	0.0
>=65	58	34	0	0.0	24	1	4.2
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0
Time to First AE Leading to Treatment Discontinuation: Metabolism and nutrition disorders, Any							
All Patients	324	163	0	0.0	161	2	1.2
Age group (years)							
<65	266	129	0	0.0	137	2	1.5
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	2	1.3
M	6	1	0	0.0	5	0	0.0
Region							

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv		
		n	Events	%	n	Events	%
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0
OTHER	78	38	0	0.0	40	2	5.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	2	1.5
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9
Time to First AE Leading to Treatment Discontinuation: Metabolism and nutrition disorders, Hyperglycaemia							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0
OTHER	78	38	0	0.0	40	1	2.5
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Metabolism and nutrition disorders, Type 2 diabetes mellitus							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0
OTHER	78	38	0	0.0	40	1	2.5
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv		
		n	Events	%	n	Events	%
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Infections and infestations, Any							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0
Time to First AE Leading to Treatment Discontinuation: Infections and infestations, Anal abscess							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0
Time to First AE Leading to Treatment Discontinuation: Musculoskeletal and connective tissue disorders, Any							
All Patients	324	163	0	0.0	161	1	0.6

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv		
		n	Events	%	n	Events	%
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Musculoskeletal and connective tissue disorders, Bone pain							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Musculoskeletal and connective tissue disorders, Musculoskeletal pain							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv		
		n	Events	%	n	Events	%
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Neoplasms benign, malignant and unspecified (incl cysts and polyps), Any							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	1	1.7
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	1	3.4
Y	259	127	0	0.0	132	0	0.0
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Neoplasms benign, malignant and unspecified (incl cysts and polyps), Transitional cell carcinoma							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	1	0.7
>=65	58	34	0	0.0	24	0	0.0
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	1	1.7
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	1	3.4

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv		
		n	Events	%	n	Events	%
Y	259	127	0	0.0	132	0	0.0
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Renal and urinary disorders, Any							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	0	0.0
>=65	58	34	0	0.0	24	1	4.2
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	1	1.7
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Renal and urinary disorders, Acute kidney injury							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	0	0.0
>=65	58	34	0	0.0	24	1	4.2
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	1	1.7
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Skin and subcutaneous tissue disorders, Any							

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv		
		n	Events	%	n	Events	%
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	0	0.0
>=65	58	34	0	0.0	24	1	4.2
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0
Time to First AE Leading to Treatment Discontinuation: Skin and subcutaneous tissue disorders, Skin ulcer							
All Patients	324	163	0	0.0	161	1	0.6
Age group (years)							
<65	266	129	0	0.0	137	0	0.0
>=65	58	34	0	0.0	24	1	4.2
Sex							
F	318	162	0	0.0	156	1	0.6
M	6	1	0	0.0	5	0	0.0
Region							
ASIA	120	62	0	0.0	58	0	0.0
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6
OTHER	78	38	0	0.0	40	0	0.0
Visceral disease (per eCRF)							
N	65	36	0	0.0	29	0	0.0
Y	259	127	0	0.0	132	1	0.8
Menopausal Status at Randomization							
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0

Men are excluded from the subgroups of "Menopausal Status at Randomization"
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_tte.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_DSCSPT_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 8065628e23c1f16f1b9c5c76540f88be90f918fa
08 APR 2025 17:33 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.1 Generelle Verträglichkeit

3.1.3 Outcome Unerwünschter Ereignisse (UE)

Summary of Outcomes of Adverse Events, Any Adverse Event, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Outcome of AE	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade			
Any Adverse Event			
- Any Grade -	4013	2505	6518
Grade 1	2201 (54.8%)	1462 (58.4%)	3663 (56.2%)
Grade 2	1151 (28.7%)	557 (22.2%)	1708 (26.2%)
Grade 3	610 (15.2%)	435 (17.4%)	1045 (16%)
Grade 4	45 (1.1%)	49 (2%)	94 (1.4%)
Grade 5	6 (0.1%)	2 (0.1%)	8 (0.1%)
Missing	0	0	0
FATAL			
- Any Grade -	6	2	8
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	6 (100%)	2 (100%)	8 (100%)
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	553	379	932
Grade 1	345 (62.4%)	244 (64.4%)	589 (63.2%)
Grade 2	170 (30.7%)	102 (26.9%)	272 (29.2%)
Grade 3	34 (6.1%)	30 (7.9%)	64 (6.9%)
Grade 4	4 (0.7%)	3 (0.8%)	7 (0.8%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	3279	2038	5317
Grade 1	1760 (53.7%)	1167 (57.3%)	2927 (55%)
Grade 2	924 (28.2%)	433 (21.2%)	1357 (25.5%)
Grade 3	555 (16.9%)	393 (19.3%)	948 (17.8%)
Grade 4	40 (1.2%)	45 (2.2%)	85 (1.6%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED WITH SEQUELAE			
- Any Grade -	27	22	49
Grade 1	10 (37%)	12 (54.5%)	22 (44.9%)
Grade 2	11 (40.7%)	6 (27.3%)	17 (34.7%)
Grade 3	5 (18.5%)	4 (18.2%)	9 (18.4%)
Grade 4	1 (3.7%)	0	1 (2%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	139	62	201
Grade 1	81 (58.3%)	37 (59.7%)	118 (58.7%)
Grade 2	43 (30.9%)	16 (25.8%)	59 (29.4%)
Grade 3	15 (10.8%)	8 (12.9%)	23 (11.4%)
Grade 4	0	1 (1.6%)	1 (0.5%)
Grade 5	0	0	0
Missing	0	0	0
UNKNOWN			
- Any Grade -	9	2	11
Grade 1	5 (55.6%)	2 (100%)	7 (63.6%)
Grade 2	3 (33.3%)	0	3 (27.3%)
Grade 3	1 (11.1%)	0	1 (9.1%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0

All counts represent events.

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_ae_out.R

Output path:

/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v4/output/t_ae_out_ANYAE2_SAS_15NOV2024_41554.d
ocx

Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685

Git hash: d20c0145ff6351f556256891b738bb3ba354ec8e

01 APR 2025 20:57 GMT

Summary of Outcomes of Adverse Events, Any Adverse Event, Serious Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Outcome of AE			
Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Any Adverse Event			
- Any Grade -	73	28	101
Grade 1	5 (6.8%)	1 (3.6%)	6 (5.9%)
Grade 2	6 (8.2%)	1 (3.6%)	7 (6.9%)
Grade 3	52 (71.2%)	22 (78.6%)	74 (73.3%)
Grade 4	4 (5.5%)	2 (7.1%)	6 (5.9%)
Grade 5	6 (8.2%)	2 (7.1%)	8 (7.9%)
Missing	0	0	0
FATAL			
- Any Grade -	6	2	8
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	6 (100%)	2 (100%)	8 (100%)
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	6	4	10
Grade 1	0	1 (25%)	1 (10%)
Grade 2	1 (16.7%)	1 (25%)	2 (20%)
Grade 3	4 (66.7%)	2 (50%)	6 (60%)
Grade 4	1 (16.7%)	0	1 (10%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	57	22	79
Grade 1	5 (8.8%)	0	5 (6.3%)
Grade 2	5 (8.8%)	0	5 (6.3%)
Grade 3	44 (77.2%)	20 (90.9%)	64 (81%)
Grade 4	3 (5.3%)	2 (9.1%)	5 (6.3%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED WITH SEQUELAE			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (100%)	0	2 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (100%)	0	2 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0

All counts represent events.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_out.R
Output path:
/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v4/output/t_ae_out_ANYAE2_SER_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: d20c0145ff6351f556256891b738bb3ba354ec8e
01 APR 2025 20:57 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.2 Spezifische Verträglichkeit

3.2.1 Unerwünschte Ereignisse von speziellem Interesse (AESI)

3.2.1.1 Operationalisierung UE von speziellem Interesse (AESI)

Adverse Events of Special Interest (Immediately Reportable to the Sponsor)

Adverse events of special interest for this study are as follows:

- Grade ≥ 3 hyperglycemia
- Grade ≥ 3 rash
- Grade ≥ 3 diarrhea
- Grade ≥ 2 pneumonitis
- Grade ≥ 2 colitis or enterocolitis
- Grade ≥ 3 stomatitis or mucosal inflammation
- Grade ≥ 3 ALT or AST elevation

Adverse events of special interest for general drug development:

- Cases of potential drug-induced liver injury that include an elevated ALT or AST in combination with either an elevated bilirubin or clinical jaundice, as defined by Hy's Law
- Suspected transmission of an infectious agent by the study drug, as defined below:
Any organism, virus, or infectious particle (e.g., prion protein transmitting transmissible spongiform encephalopathy), pathogenic or non-pathogenic, is considered an infectious agent. A transmission of an infectious agent may be suspected from clinical symptoms or laboratory findings that indicate an infection in a patient exposed to a medicinal product. This term applies only when a contamination of the study drug is suspected.

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.2 Spezifische Verträglichkeit

3.2.1 Unerwünschte Ereignisse von speziellem Interesse (AESI)

3.2.1.2 Patienten mit UE von speziellem Interesse (AESI)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Safety), Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOd: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First AE of Special Interest (AESI): Grade >= 3 Hyperglycemia											
All Patients	324	163	0	0.0	161	11	6.8	>999.99	(0.00, >999.99)	0.0010	NE
Age group (years)											
<65	266	129	0	0.0	137	7	5.1	>999.99	(0.00, >999.99)	0.0095	1.0000
>=65	58	34	0	0.0	24	4	16.7	>999.99	(0.00, >999.99)	0.0125	1.0000
Sex											
F	318	162	0	0.0	156	11	7.1	>999.99	(0.00, >999.99)	0.0008	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3012	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	3	4.8	>999.99	(0.00, >999.99)	0.1085	1.0000
OTHER	78	38	0	0.0	40	7	17.5	>999.99	(0.00, >999.99)	0.0068	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	0.9999
Y	259	127	0	0.0	132	11	8.3	>999.99	(0.00, >999.99)	0.0013	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	4	7.7	>999.99	(0.00, >999.99)	0.0424	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	7	6.7	>999.99	(0.00, >999.99)	0.0076	1.0000
Time to First AE of Special Interest (AESI): Grade >= 3 Rash											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3266	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3311	1.0000
Time to First AE of Special Interest (AESI): Grade >= 3 Diarrhea											
All Patients	324	163	0	0.0	161	6	3.7	>999.99	(0.00, >999.99)	0.0162	NE
Age group (years)											
<65	266	129	0	0.0	137	4	2.9	>999.99	(0.00, >999.99)	0.0557	0.9999
>=65	58	34	0	0.0	24	2	8.3	>999.99	(0.00, >999.99)	0.0898	0.9999

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	6	3.8	>999.99	(0.00, >999.99)	0.0148	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	4	6.3	>999.99	(0.00, >999.99)	0.0451	1.0000
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.1785	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	5	3.8	>999.99	(0.00, >999.99)	0.0354	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	6	5.8	>999.99	(0.00, >999.99)	0.0133	1.0000
Time to First AE of Special Interest (AESI): Grade >= 2 Pneumonitis											
All Patients	324	163	2	1.2	161	3	1.9	1.26	(0.21, 7.65)	0.8050	NE
Age group (years)											
<65	266	129	1	0.8	137	3	2.2	2.17	(0.22, 21.34)	0.4963	0.2082
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.2082
Sex											
F	318	162	2	1.2	156	2	1.3	0.99	(0.14, 7.00)	0.9880	0.5230
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6171	0.5230
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.97	(0.06, 15.48)	0.9811	0.5832
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	0.72	(0.04, 11.95)	0.8180	0.5832
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	0.5832
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	1	3.4	1.31	(0.08, 20.93)	0.8484	0.8463
Y	259	127	1	0.8	132	2	1.5	1.36	(0.12, 15.46)	0.8027	0.8463
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.89	(0.06, 14.29)	0.9342	0.9745
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	1.03	(0.06, 16.46)	0.9835	0.9745
Time to First AE of Special Interest (AESI): Grade >= 2 Colitis or Enterocolitis											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First AE of Special Interest (AESI): Grade >= 3 Stomatitis or Mucosal Inflammation											
All Patients	324	163	0	0.0	161	9	5.6	>999.99	(0.00, >999.99)	0.0034	NE
Age group (years)											
<65	266	129	0	0.0	137	8	5.8	>999.99	(0.00, >999.99)	0.0090	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	8	5.1	>999.99	(0.00, >999.99)	0.0053	0.9999
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.9999
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.1452	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	6	9.5	>999.99	(0.00, >999.99)	0.0146	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5708	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	3	10.3	>999.99	(0.00, >999.99)	0.0435	0.9999
Y	259	127	0	0.0	132	6	4.5	>999.99	(0.00, >999.99)	0.0220	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	4	7.7	>999.99	(0.00, >999.99)	0.0662	0.9999
POST-MENOPAUSAL	214	110	0	0.0	104	4	3.8	>999.99	(0.00, >999.99)	0.0411	0.9999
Time to First AE of Special Interest (AESI): Grade >= 3 AST or ALT Elevation											
All Patients	324	163	4	2.5	161	7	4.3	1.37	(0.40, 4.74)	0.6193	NE
Age group (years)											
<65	266	129	4	3.1	137	5	3.6	0.88	(0.23, 3.32)	0.8454	0.0645
>=65	58	34	0	0.0	24	2	8.3	>999.99	(0.00, >999.99)	0.1132	0.0645
Sex											
F	318	162	4	2.5	156	7	4.5	1.40	(0.41, 4.86)	0.5913	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	3	5.2	1.37	(0.23, 8.30)	0.7294	0.2206
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	4	6.3	2.86	(0.32, 26.05)	0.3290	0.2206
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3110	0.2206
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.1243	0.1074
Y	259	127	4	3.1	132	5	3.8	0.87	(0.23, 3.31)	0.8417	0.1074
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	3	5.8	0.78	(0.16, 3.93)	0.7634	0.2416

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
POST-MENOPAUSAL	214	110	1	0.9	104	4	3.8	3.04	(0.33, 27.76)	0.3008	0.2416

Men are excluded from the subgroups of "Menopausal Status at Randomization"
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_tte.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_AESI_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 8065628e23c1f16f1b9c5c76540f88be90f918fa
08 APR 2025 17:32 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

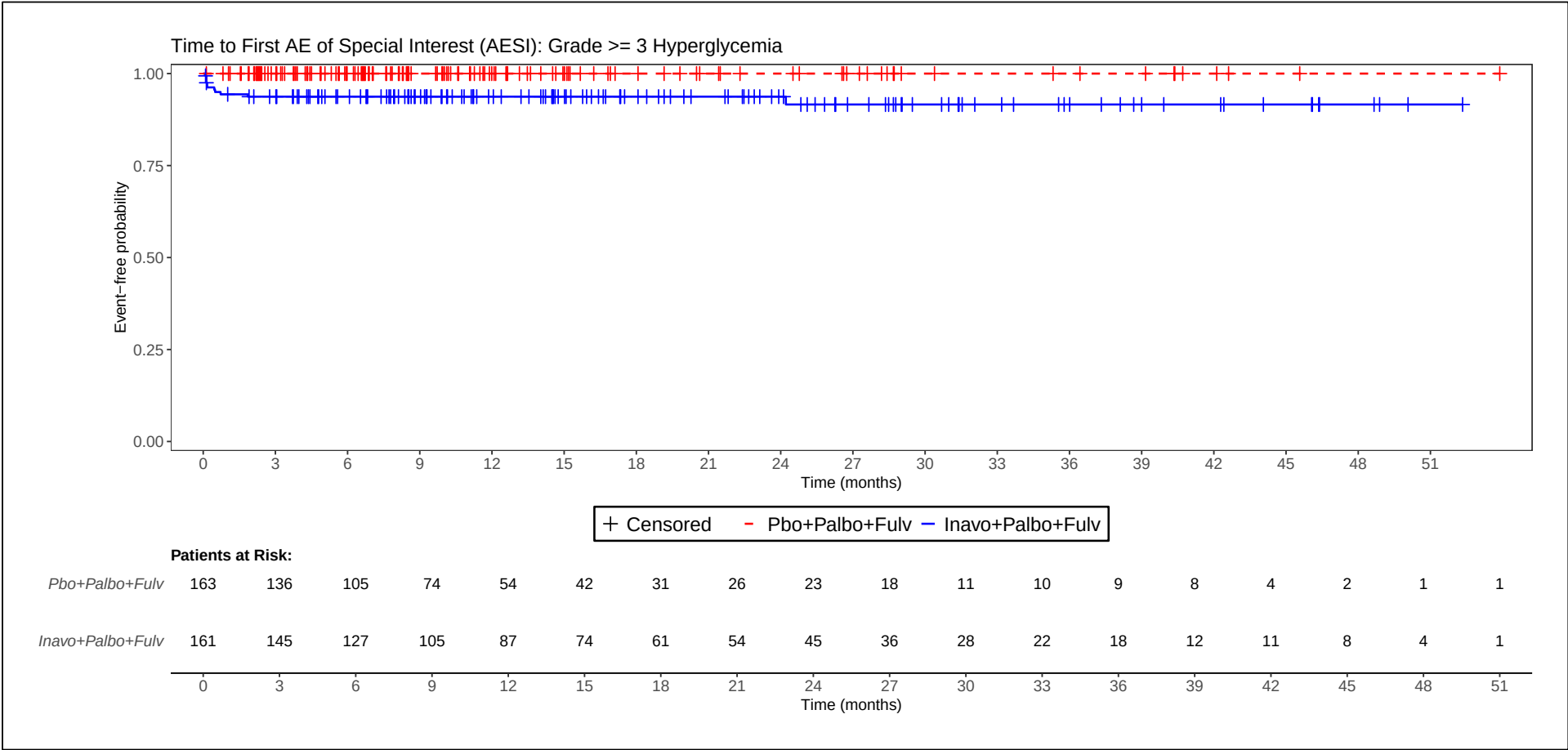
Time to Event Analysis Overall and with Subgroups (Safety), Adverse Events of Special Interest (AESI) >= Grade 3, Safety Analysis Set
Protocol: WO41554, CCOd: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First AE of Special Interest (AESI) >= Grade 3: Pneumonitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First AE of Special Interest (AESI) >= Grade 3: Colitis or Enterocolitis											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000

Men are excluded from the subgroups of "Menopausal Status at Randomization"
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlgt_ae_tte.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_G3AESI_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 8065628e23c1f16f1b9c5c76540f88be90f918fa
08 APR 2025 17:32 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

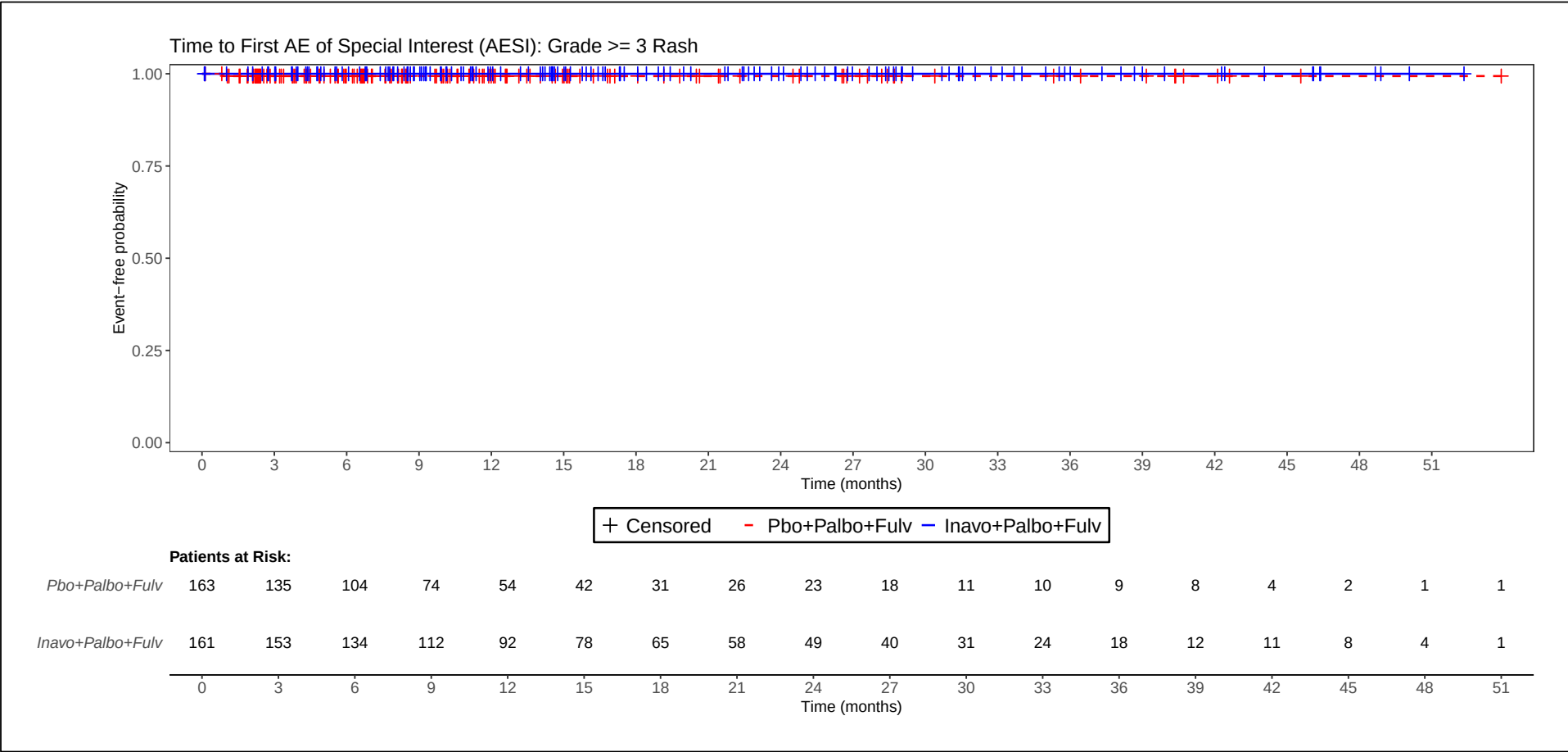
Kaplan Meier Plot for Safety, Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

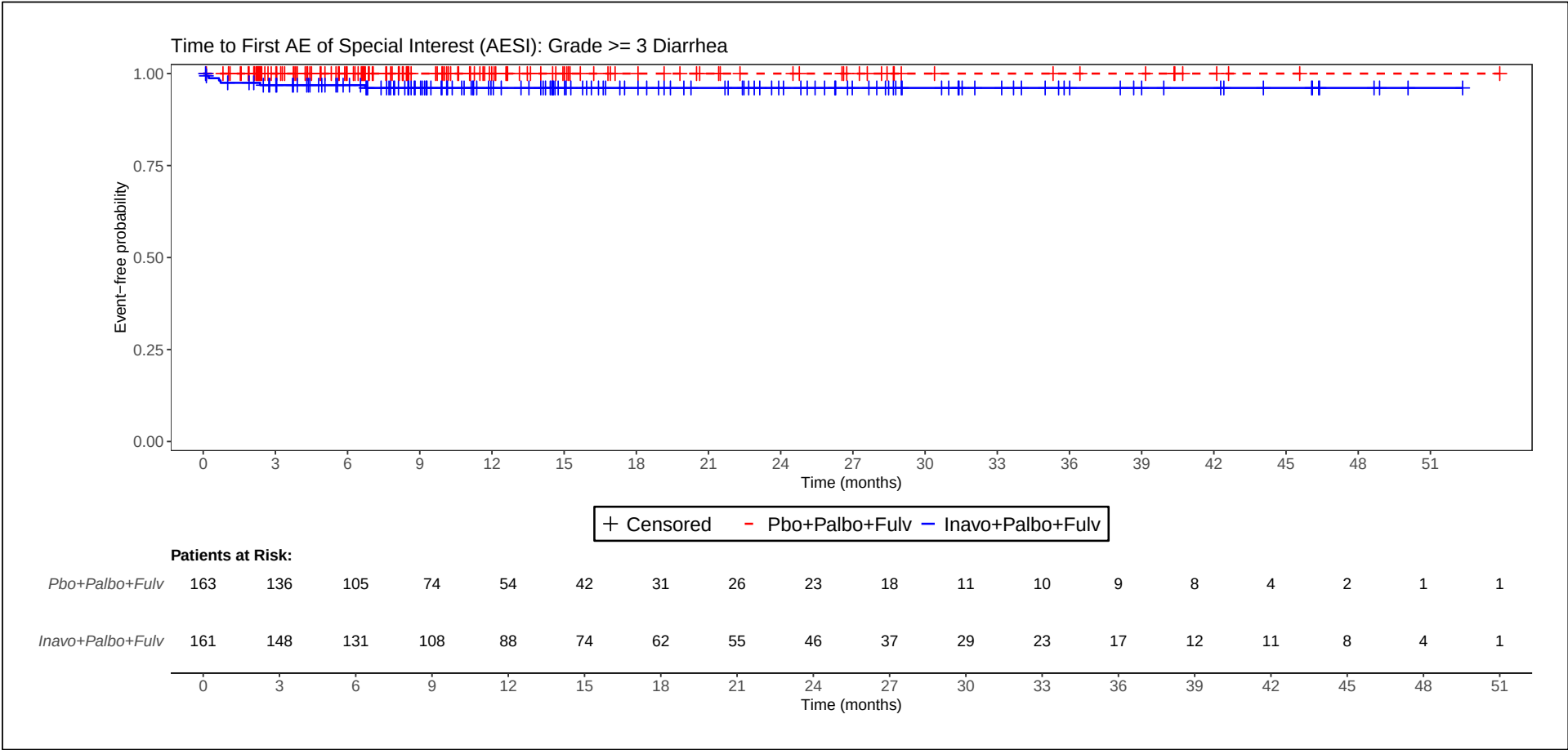
Kaplan Meier Plot for Safety, Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

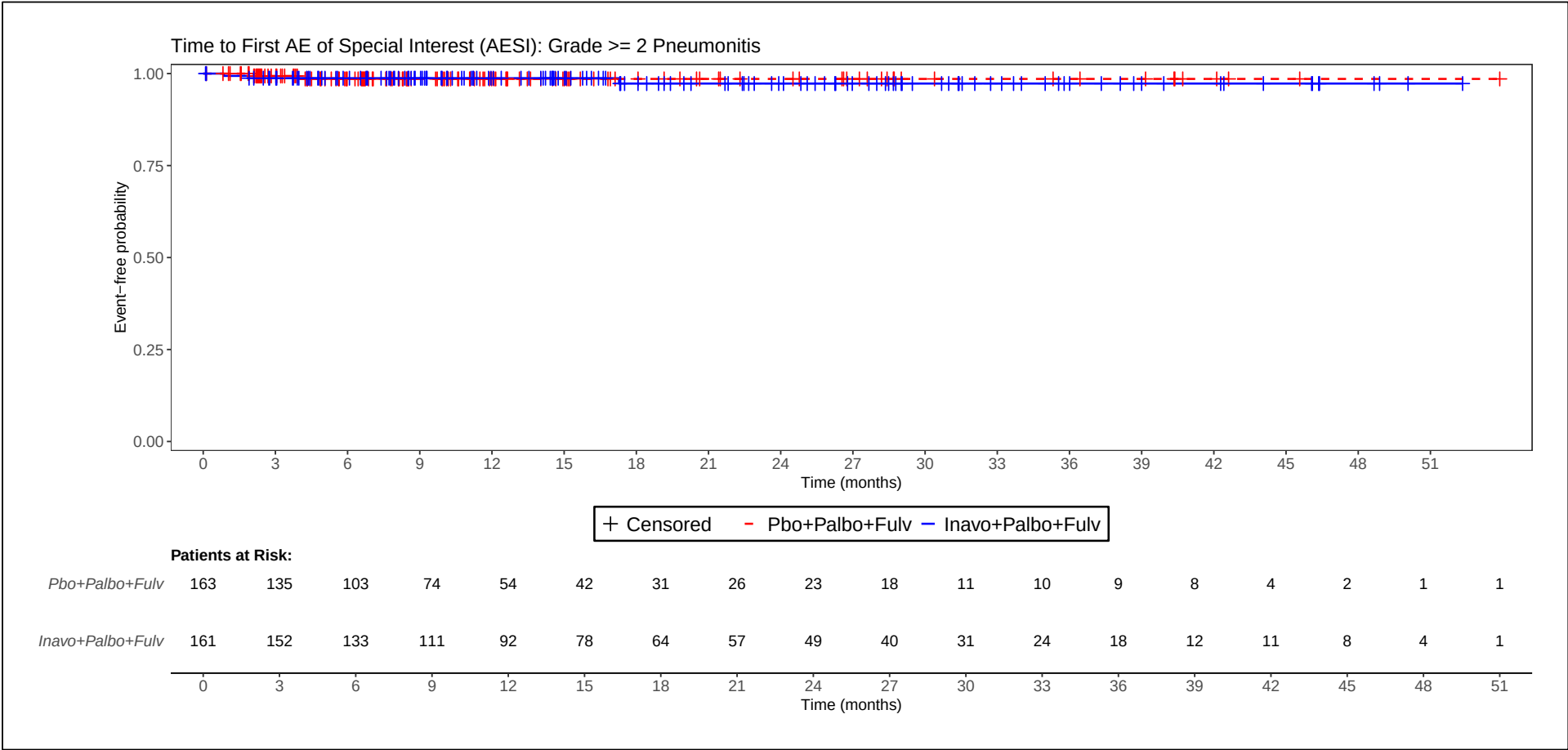
Kaplan Meier Plot for Safety, Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_AESI_SAS_15NOV2024_41554.pdf
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

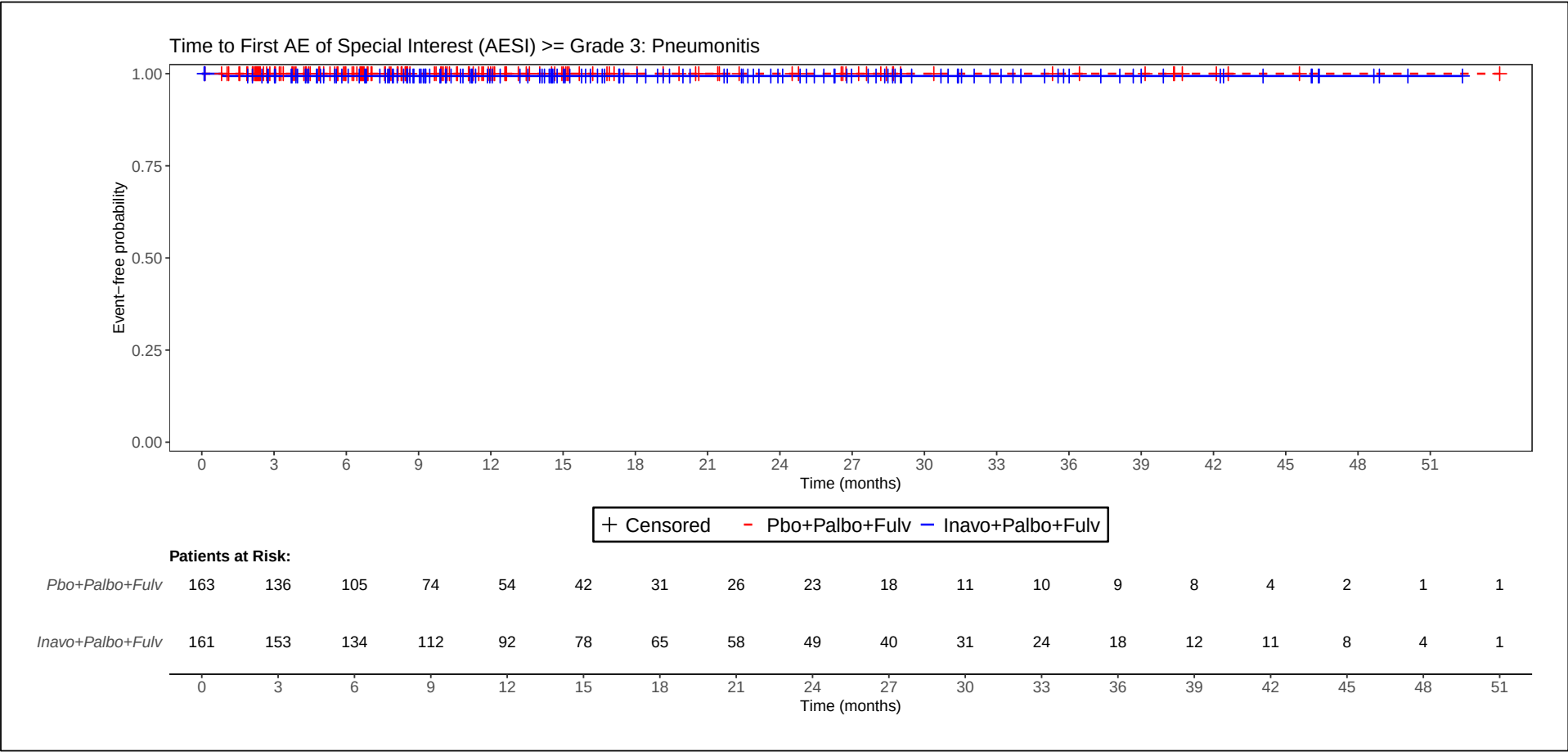
Kaplan Meier Plot for Safety, Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_AESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
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31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

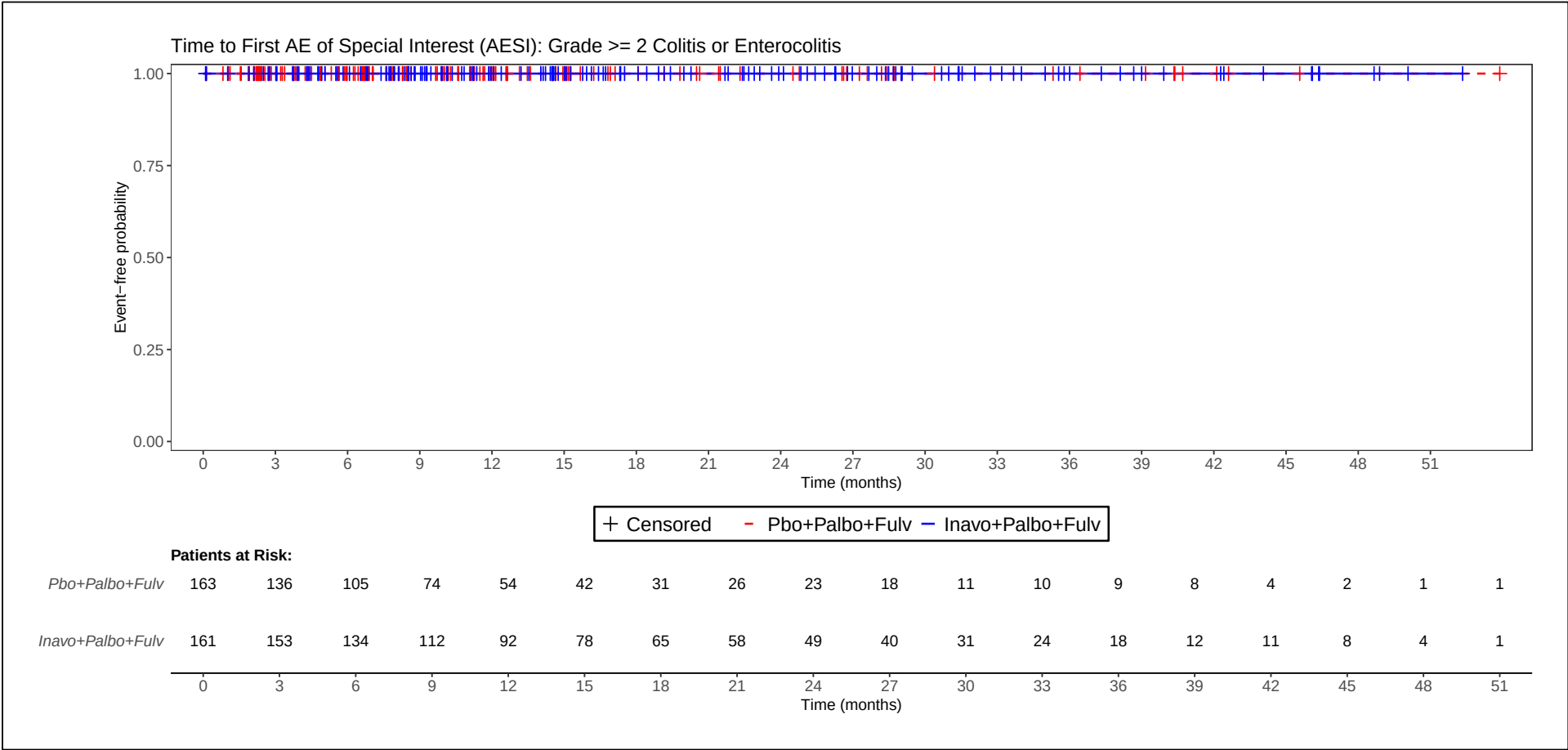
Kaplan Meier Plot for Safety, Adverse Events of Special Interest (AESI) >= Grade 3, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_G3AESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
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31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

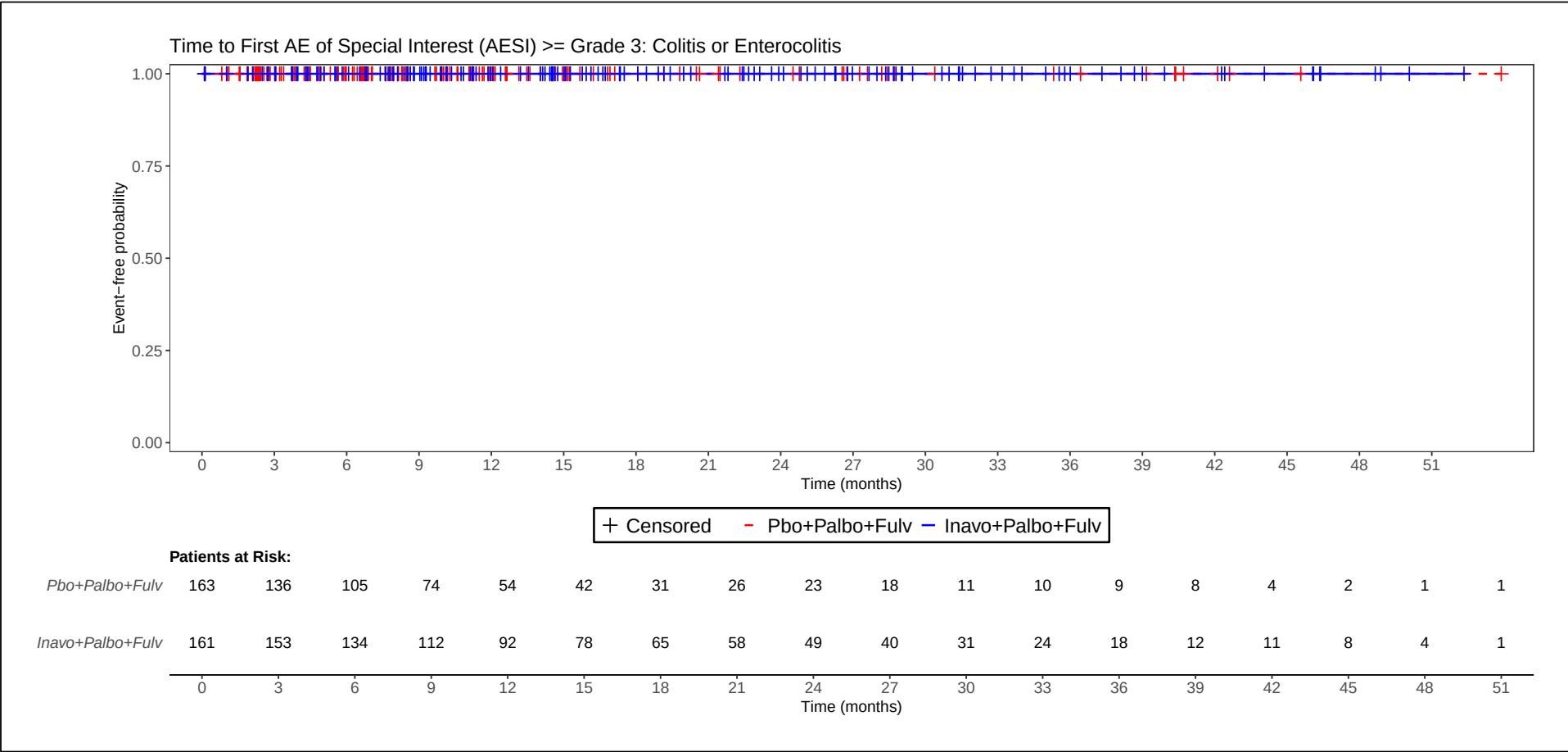
Kaplan Meier Plot for Safety, Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_AESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
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31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

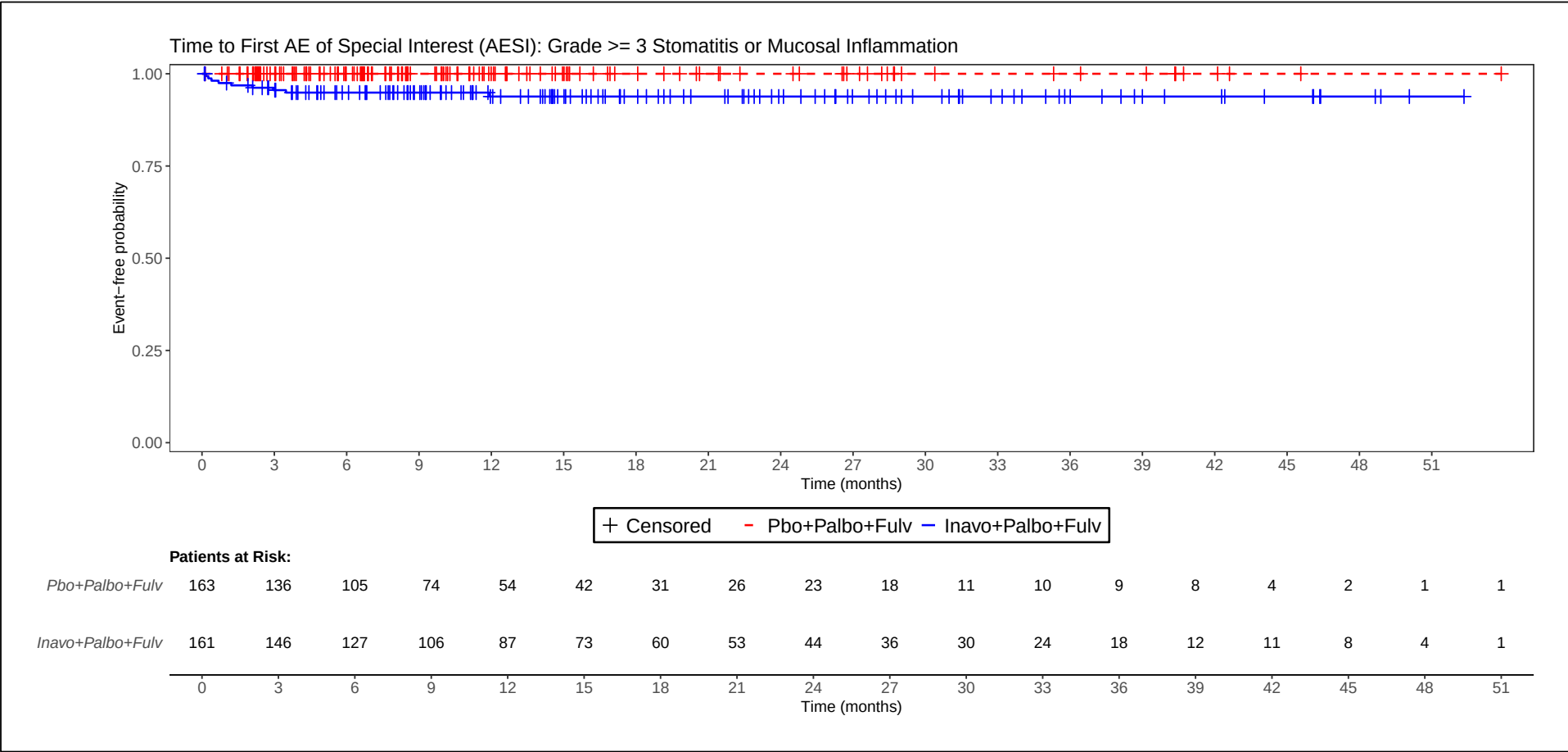
Kaplan Meier Plot for Safety, Adverse Events of Special Interest (AESI) >= Grade 3, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_G3AESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

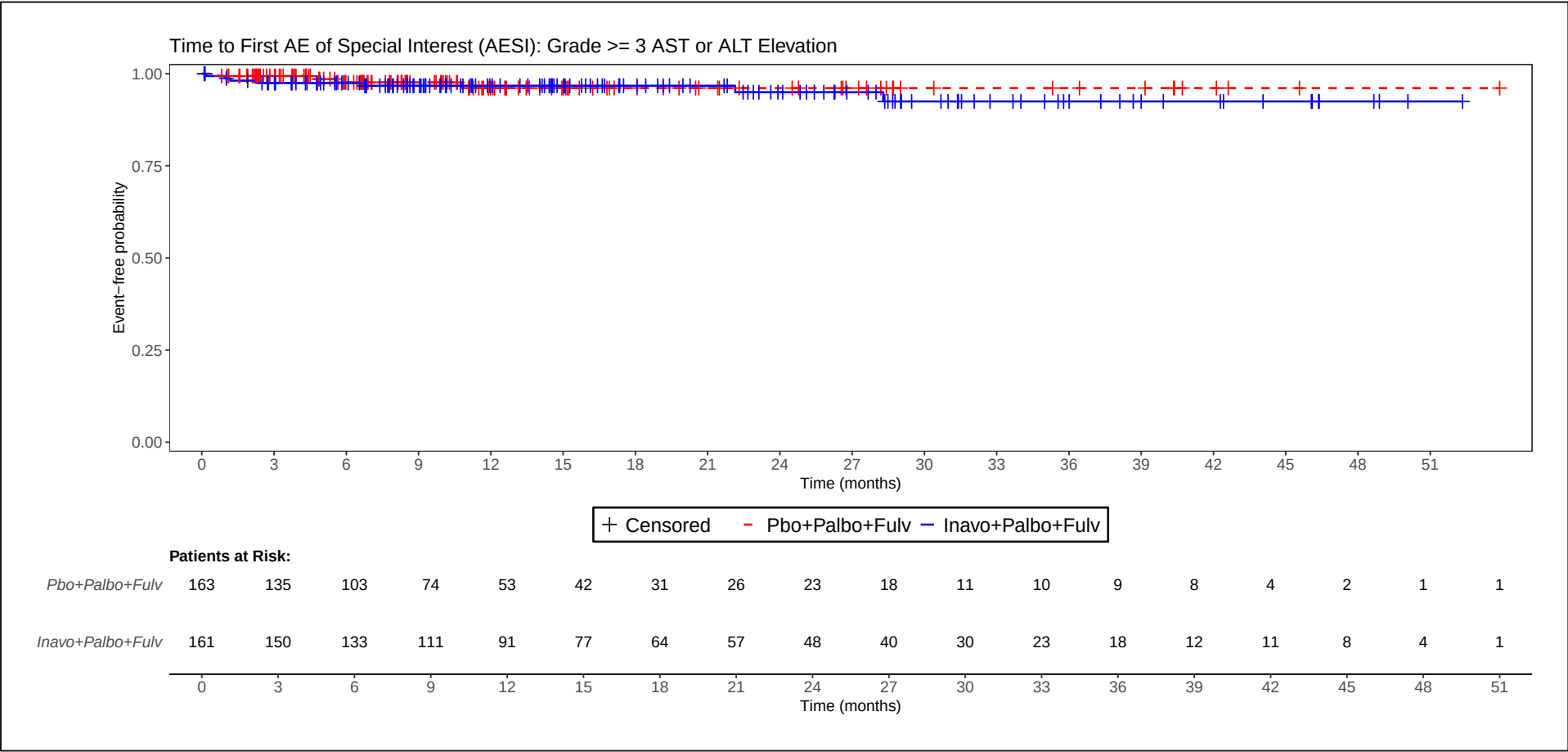
Kaplan Meier Plot for Safety, Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_AESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Safety, Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_AESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Safety), Serious Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOd: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Serious AE of Special Interest (AESI): Grade >= 3 Hyperglycemia											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious AE of Special Interest (AESI): Grade >= 3 Rash											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3266	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3311	1.0000
Time to First Serious AE of Special Interest (AESI): Grade >= 3 Diarrhea											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1880	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2367	1.0000
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1821	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3428	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4198	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1709	1.0000
Time to First Serious AE of Special Interest (AESI): Grade >= 2 Pneumonitis											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2313	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2592	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	0.9997
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6171	0.9997
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4715	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5194	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious AE of Special Interest (AESI): Grade >= 2 Colitis or Enterocolitis											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious AE of Special Interest (AESI): Grade >= 3 Stomatitis or Mucosal Inflammation											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious AE of Special Interest (AESI): Grade >= 3 AST or ALT Elevation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											

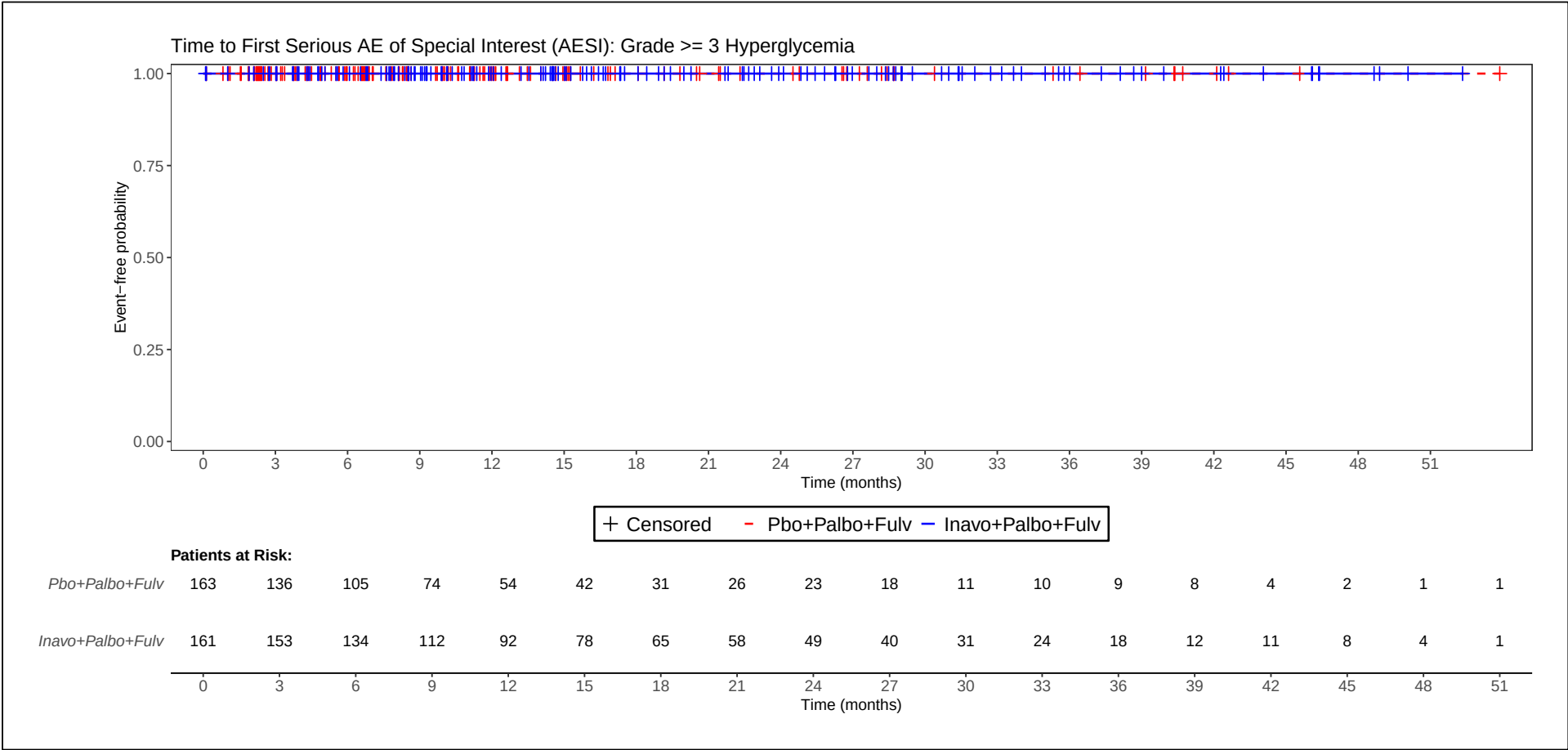
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log- rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000

Men are excluded from the subgroups of "Menopausal Status at Randomization"
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_tte.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_SAESI_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 8065628e23c1f16f1b9c5c76540f88be90f918fa
08 APR 2025 17:32 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

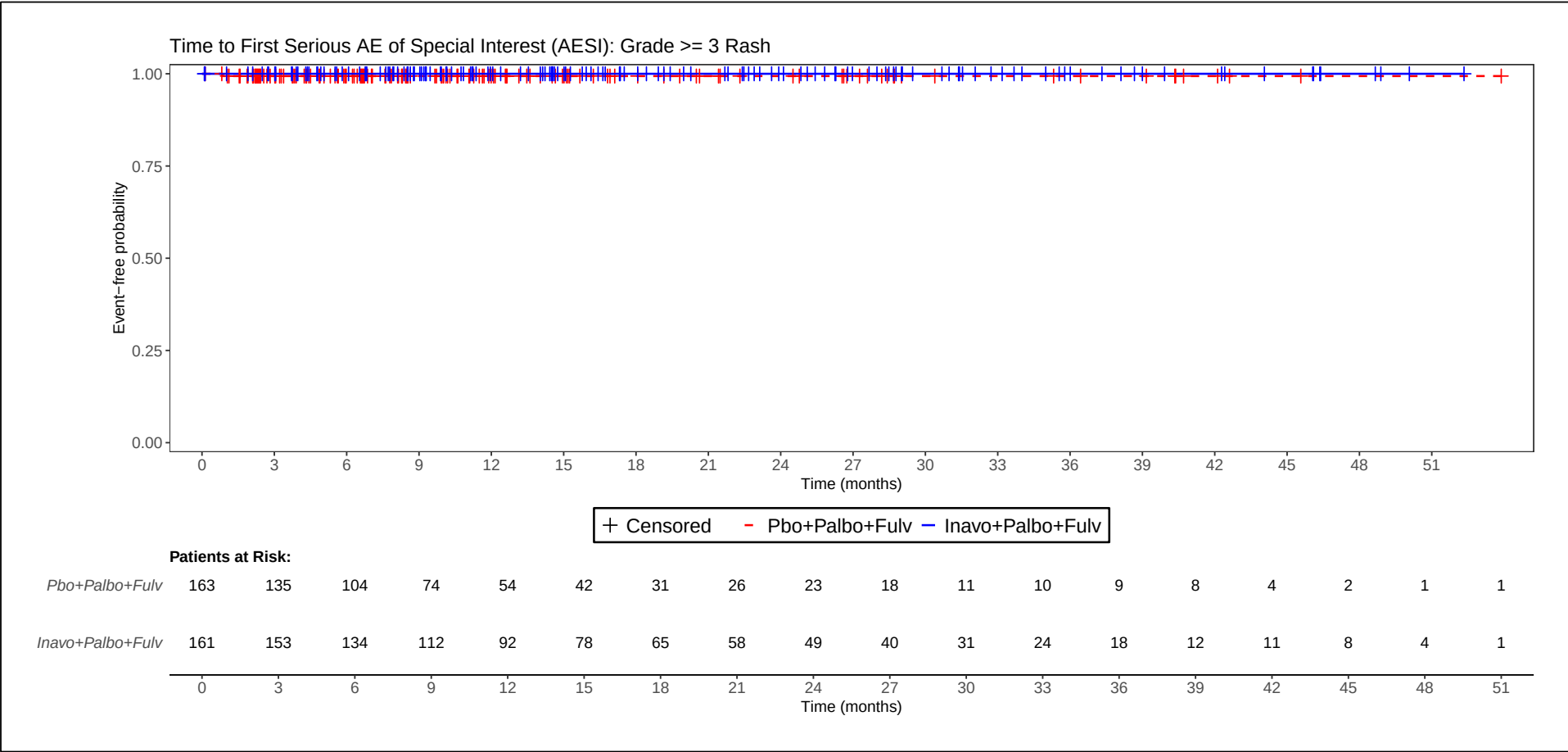
Kaplan Meier Plot for Safety, Serious Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_SAESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

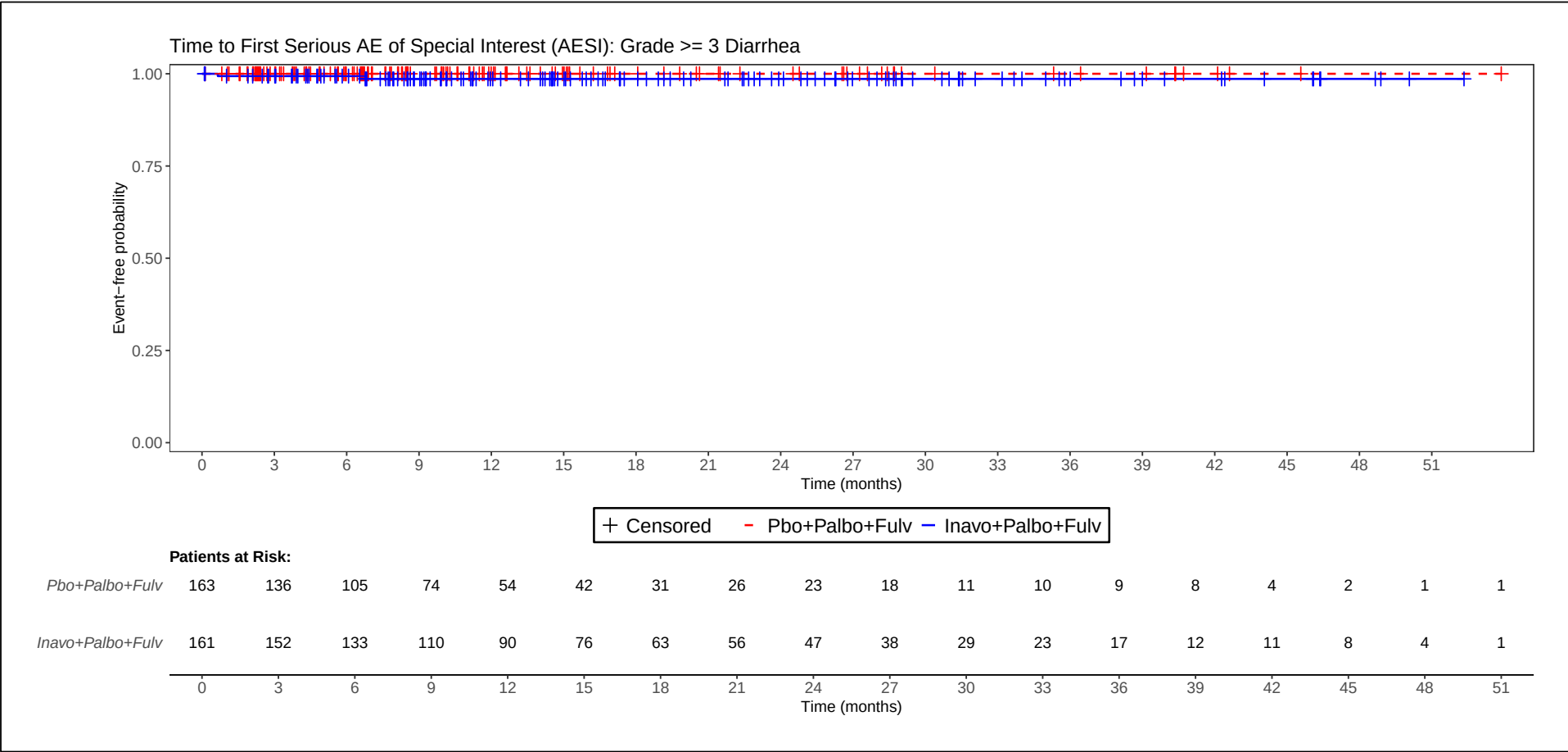
Kaplan Meier Plot for Safety, Serious Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_SAESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

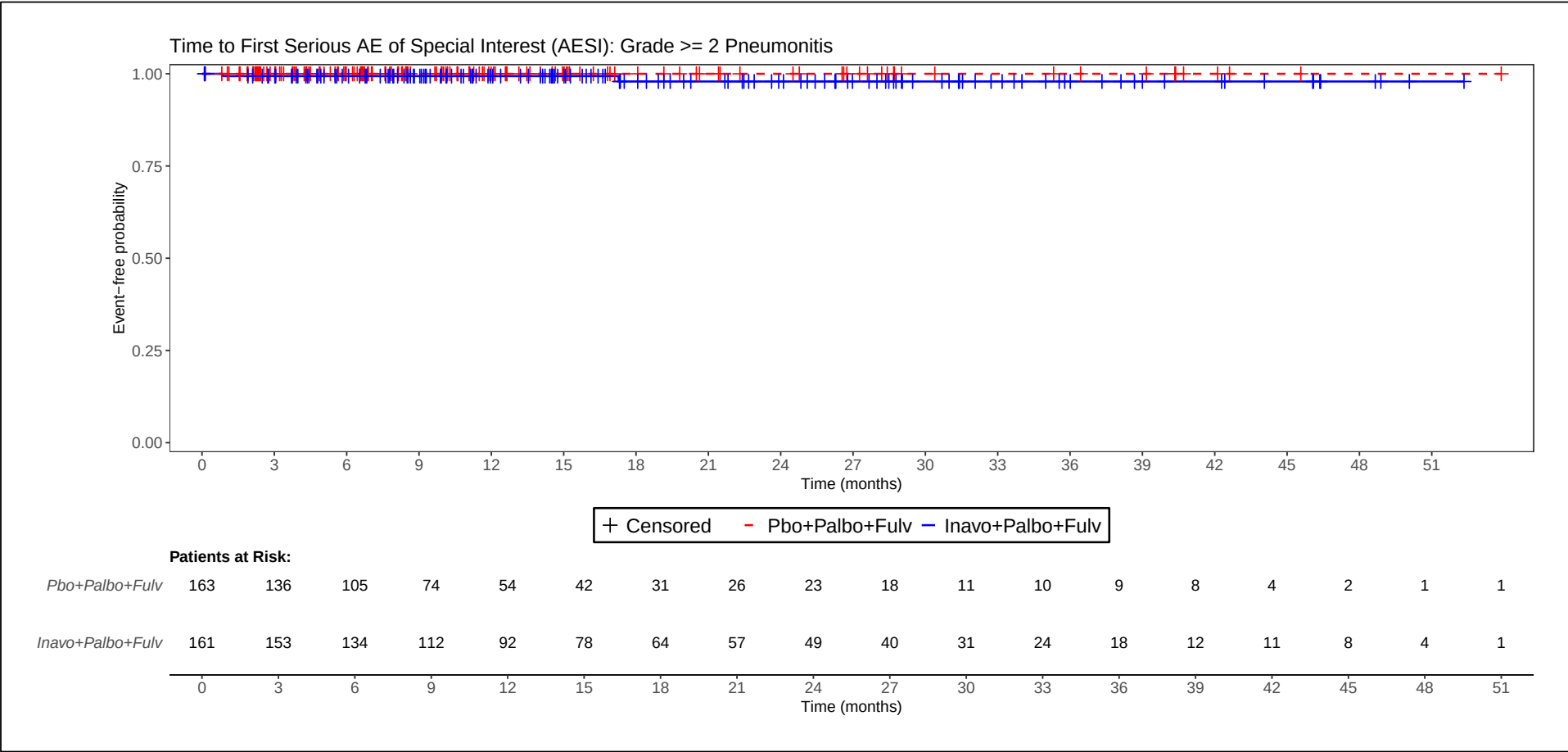
Kaplan Meier Plot for Safety, Serious Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_SAESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

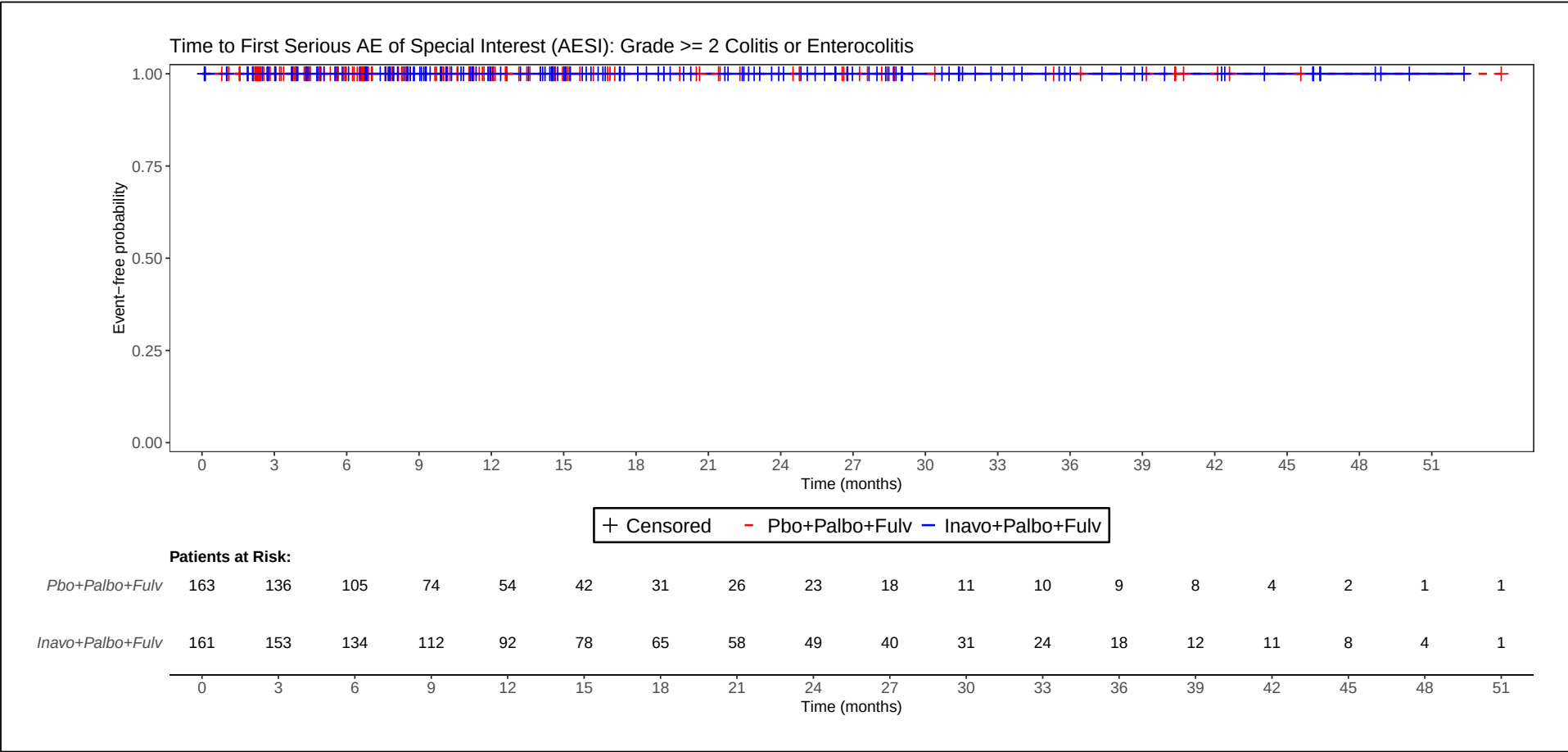
Kaplan Meier Plot for Safety, Serious Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_SAESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

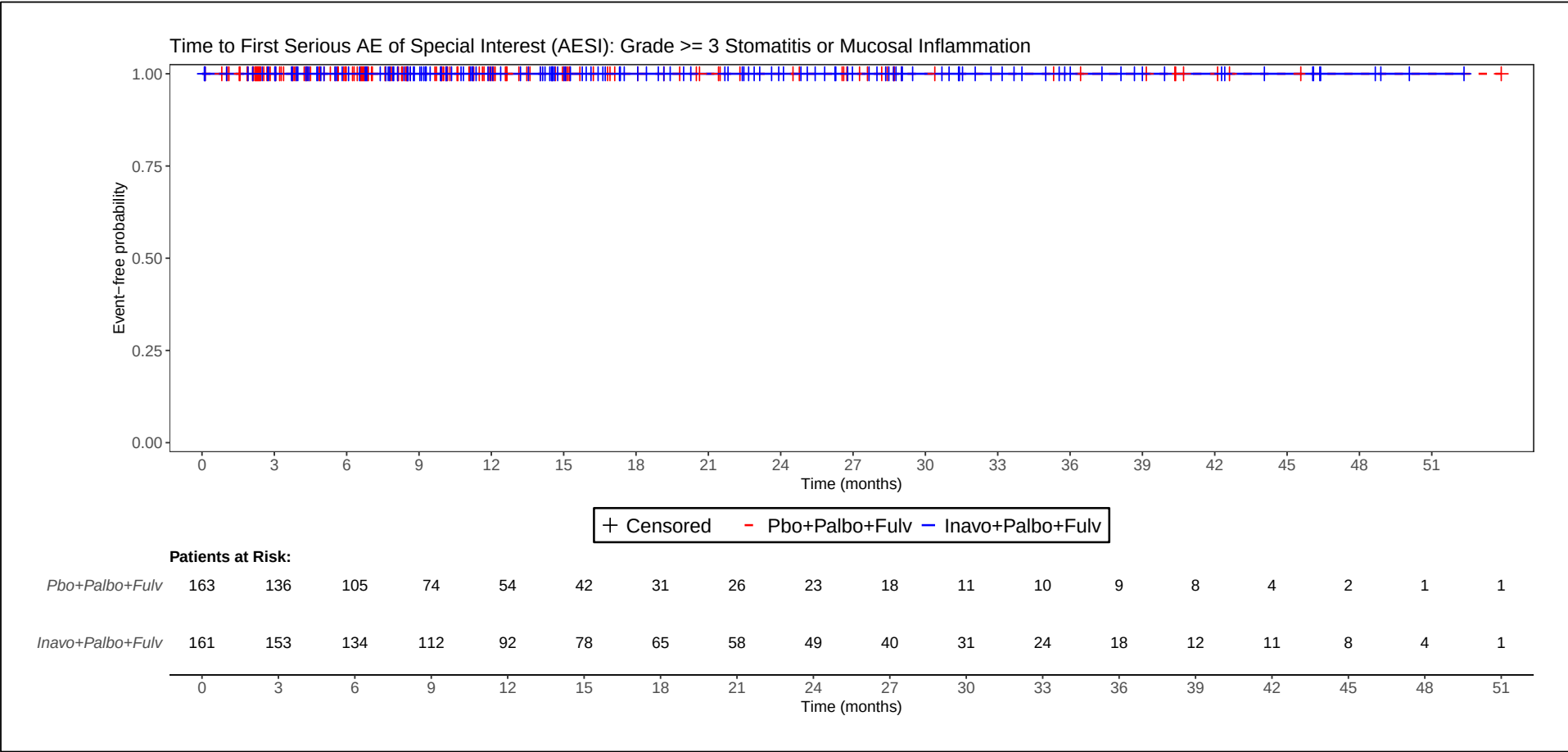
Kaplan Meier Plot for Safety, Serious Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_SAESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

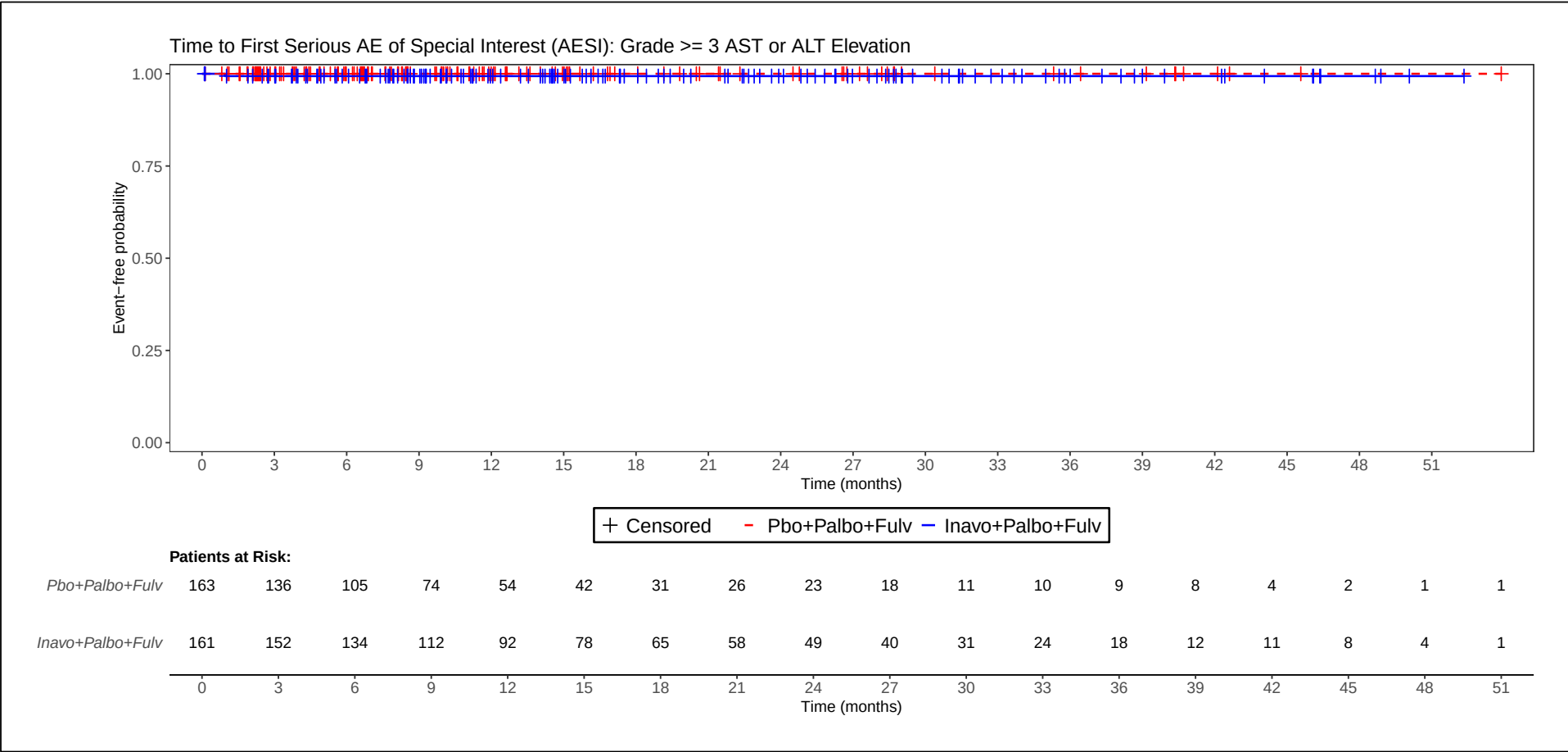
Kaplan Meier Plot for Safety, Serious Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_SAESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:14 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Safety, Serious Adverse Events of Special Interest (AESI), Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_SAESI_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:14 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.2 Spezifische Verträglichkeit

3.2.1 Unerwünschte Ereignisse von speziellem Interesse (AESI)

3.2.1.3 Outcome UE von speziellem Interesse (AESI)

Summary of Outcomes of Adverse Events, Adverse Events of Special Interest (AESI) by Event, Safety Analysis Set

Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

AE Group			
Outcome of AE			
Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade >= 3 Hyperglycemia			
Any Adverse Event			
- Any Grade -	11	0	11
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	11 (100%)	0	11 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	3	0	3
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	3 (100%)	0	3 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	6	0	6
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	6 (100%)	0	6 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (100%)	0	2 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Grade >= 3 Rash			
Any Adverse Event			
- Any Grade -	0	1	1
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (100%)	1 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	0	1	1
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (100%)	1 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Grade >= 3 Diarrhea			
Any Adverse Event			
- Any Grade -	8	0	8
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	8 (100%)	0	8 (100%)

AE Group Outcome of AE Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	8	0	8
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	8 (100%)	0	8 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Grade >= 2 Pneumonitis			
Any Adverse Event			
- Any Grade -	3	2	5
Grade 1	0	0	0
Grade 2	2 (66.7%)	2 (100%)	4 (80%)
Grade 3	1 (33.3%)	0	1 (20%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	1	1	2
Grade 1	0	0	0
Grade 2	0	1 (100%)	1 (50%)
Grade 3	1 (100%)	0	1 (50%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	2	1	3
Grade 1	0	0	0
Grade 2	2 (100%)	1 (100%)	3 (100%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Grade >= 3 Stomatitis or Mucosal Inflammation			
Any Adverse Event			
- Any Grade -	10	0	10
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	10 (100%)	0	10 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	10	0	10
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	10 (100%)	0	10 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Grade >= 3 AST or ALT Elevation			
Any Adverse Event			
- Any Grade -	12	5	17
Grade 1	0	0	0
Grade 2	0	0	0

AE Group			
Outcome of AE			
Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade 3	11 (91.7%)	5 (100%)	16 (94.1%)
Grade 4	1 (8.3%)	0	1 (5.9%)
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	2	3	5
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (100%)	3 (100%)	5 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	10	2	12
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	9 (90%)	2 (100%)	11 (91.7%)
Grade 4	1 (10%)	0	1 (8.3%)
Grade 5	0	0	0
Missing	0	0	0

All counts represent events.

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_ae_out.R

Output path:

/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v4/output/t_ae_out_AESIS_SAS_15NOV2024_41554.doc
x

Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685

Git hash: d20c0145ff6351f556256891b738bb3ba354ec8e

01 APR 2025 20:57 GMT

Summary of Outcomes of Adverse Events, Adverse Events of Special Interest (AESI) by Event, Serious Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

AE Group			
Outcome of AE			
Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade >= 3 Rash			
Any Adverse Event			
- Any Grade -	0	1	1
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (100%)	1 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	0	1	1
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (100%)	1 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Grade >= 3 Diarrhea			
Any Adverse Event			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (100%)	0	2 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (100%)	0	2 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Grade >= 2 Pneumonitis			
Any Adverse Event			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	1 (50%)	0	1 (50%)
Grade 3	1 (50%)	0	1 (50%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	1	0	1
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (100%)	0	1 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	1	0	1
Grade 1	0	0	0
Grade 2	1 (100%)	0	1 (100%)

AE Group Outcome of AE Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Grade >= 3 AST or ALT Elevation			
Any Adverse Event			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (50%)	0	1 (50%)
Grade 4	1 (50%)	0	1 (50%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (50%)	0	1 (50%)
Grade 4	1 (50%)	0	1 (50%)
Grade 5	0	0	0
Missing	0	0	0

All counts represent events.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_out.R
Output path:
/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v4/output/t_ae_out_AESIS_SER_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: d20c0145ff6351f556256891b738bb3ba354ec8e
01 APR 2025 20:57 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.2 Spezifische Verträglichkeit

3.2.2 Ausgewählte unerwünschte Ereignisse (selected AE)

3.2.2.1 Operationalisierung ausgewählter UE (selected AE)

Selected Adverse Events for Inavolisib

Selected Adverse Event	Search Strategy (MedDRA Preferred Terms, Roche AEGT or SMQ)
Hyperglycemia	Hyperglycemia; Blood glucose increased; Hyperglycemic crisis; Glycated serum protein increased, Glucose tolerance impaired, Diabetes mellitus, Type 2 diabetes mellitus, Glycosylated hemoglobin increased
Diarrhea	Non-infectious diarrhea SMQ (narrow)
Nausea	Nausea
Vomiting	Vomiting; Retching
Colitis	Roche colitis AEGT
Stomatitis or mucosal inflammation	Roche PI3K inhibitors stomatitis AEGT
Rash	Roche Standard AEGT for rash ^b
Ocular Toxicities	PTs mapped to the Eye Disorders SOC as a primary or secondary SOC
Pneumonitis	Interstitial lung disease SMQ (narrow)
Neutropenia	Neutropenia; Neutrophil count decreased
Thrombocytopenia	Thrombocytopenia; Platelet count decreased
AST/ALT elevation	Alanine aminotransferase increased; Alanine aminotransferase abnormal; Aspartate aminotransferase increased; Aspartate aminotransferase abnormal
Lymphopenia	Lymphopenia; Lymphocyte count decreased
Anemia	Anaemia; Haemoglobin decreased, Reticulocyte haemoglobin decreased; Reticulocyte haemoglobin increased

AEGT =adverse event group term; MedDRA =Medical Dictionary for Regulatory Activities;
PI3K =phosphatidylinositol 3-kinase; PT =preferred term; SMQ =standardized MedDRA query;
SOC =system organ class

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.2 Spezifische Verträglichkeit

3.2.2 Ausgewählte unerwünschte Ereignisse (selected AE)

3.2.2.2 Patienten mit ausgewählten UE (selected AE)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Safety), Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOd: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First ALT/AST elevation											
All Patients	324	163	37	22.7	161	34	21.1	0.78	(0.49, 1.24)	0.2963	NE
Age group (years)											
<65	266	129	31	24.0	137	28	20.4	0.66	(0.39, 1.10)	0.1084	0.1472
>=65	58	34	6	17.6	24	6	25.0	1.64	(0.53, 5.09)	0.3895	0.1472
Sex											
F	318	162	37	22.8	156	33	21.2	0.78	(0.49, 1.25)	0.3060	0.4672
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.4672
Region											
ASIA	120	62	17	27.4	58	17	29.3	0.94	(0.48, 1.85)	0.8528	0.7835
NORTH AMERICA/WESTERN EUROPE	126	63	15	23.8	63	13	20.6	0.72	(0.34, 1.52)	0.3853	0.7835
OTHER	78	38	5	13.2	40	4	10.0	0.68	(0.18, 2.56)	0.5692	0.7835
Visceral disease (per eCRF)											
N	65	36	7	19.4	29	7	24.1	1.12	(0.39, 3.20)	0.8282	0.4343
Y	259	127	30	23.6	132	27	20.5	0.71	(0.42, 1.19)	0.1909	0.4343
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	14	26.9	52	14	26.9	0.73	(0.34, 1.55)	0.4093	0.9917
POST-MENOPAUSAL	214	110	23	20.9	104	19	18.3	0.77	(0.42, 1.43)	0.4105	0.9917
Time to First Anemia											
All Patients	324	163	62	38.0	161	64	39.8	0.85	(0.60, 1.20)	0.3549	NE
Age group (years)											
<65	266	129	50	38.8	137	57	41.6	0.84	(0.58, 1.23)	0.3783	0.8512
>=65	58	34	12	35.3	24	7	29.2	0.76	(0.30, 1.94)	0.5616	0.8512
Sex											
F	318	162	61	37.7	156	63	40.4	0.88	(0.62, 1.26)	0.5003	0.0129
M	6	1	1	100.0	5	1	20.0	<0.01	(0.00, >999.99)	0.0253	0.0129
Region											
ASIA	120	62	24	38.7	58	27	46.6	1.03	(0.59, 1.79)	0.9261	0.5504
NORTH AMERICA/WESTERN EUROPE	126	63	22	34.9	63	18	28.6	0.67	(0.36, 1.25)	0.2123	0.5504
OTHER	78	38	16	42.1	40	19	47.5	0.81	(0.41, 1.58)	0.5261	0.5504
Visceral disease (per eCRF)											
N	65	36	13	36.1	29	14	48.3	1.18	(0.56, 2.52)	0.6472	0.2985
Y	259	127	49	38.6	132	50	37.9	0.78	(0.52, 1.15)	0.2098	0.2985
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	21	40.4	52	22	42.3	0.81	(0.44, 1.48)	0.4805	0.7690
POST-MENOPAUSAL	214	110	40	36.4	104	41	39.4	0.92	(0.59, 1.42)	0.7055	0.7690
Time to First Diarrhea											
All Patients	324	163	26	16.0	161	84	52.2	3.73	(2.40, 5.79)	<0.0001	NE
Age group (years)											
<65	266	129	17	13.2	137	75	54.7	4.71	(2.78, 7.98)	<0.0001	0.0564
>=65	58	34	9	26.5	24	9	37.5	1.66	(0.65, 4.19)	0.2750	0.0564

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	26	16.0	156	81	51.9	3.69	(2.37, 5.75)	<0.0001	0.4696
M	6	1	0	0.0	5	3	60.0	>999.99	(0.00, >999.99)	0.3766	0.4696
Region											
ASIA	120	62	6	9.7	58	28	48.3	5.29	(2.19, 12.81)	<0.0001	0.4649
NORTH AMERICA/WESTERN EUROPE	126	63	17	27.0	63	39	61.9	3.04	(1.72, 5.38)	<0.0001	0.4649
OTHER	78	38	3	7.9	40	17	42.5	4.98	(1.45, 17.16)	0.0049	0.4649
Visceral disease (per eCRF)											
N	65	36	5	13.9	29	15	51.7	4.40	(1.59, 12.13)	0.0017	0.7242
Y	259	127	21	16.5	132	69	52.3	3.55	(2.17, 5.79)	<0.0001	0.7242
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	26	50.0	9.12	(2.76, 30.20)	<0.0001	0.0496
POST-MENOPAUSAL	214	110	23	20.9	104	55	52.9	3.01	(1.85, 4.90)	<0.0001	0.0496
Time to First Hyperglycaemia											
All Patients	324	163	22	13.5	161	102	63.4	6.14	(3.87, 9.75)	<0.0001	NE
Age group (years)											
<65	266	129	20	15.5	137	89	65.0	5.25	(3.22, 8.54)	<0.0001	0.1544
>=65	58	34	2	5.9	24	13	54.2	13.63	(3.06, 60.71)	<0.0001	0.1544
Sex											
F	318	162	21	13.0	156	98	62.8	6.32	(3.94, 10.15)	<0.0001	0.3736
M	6	1	1	100.0	5	4	80.0	>999.99	(0.00, >999.99)	0.2591	0.3736
Region											
ASIA	120	62	7	11.3	58	38	65.5	7.36	(3.28, 16.52)	<0.0001	0.4425
NORTH AMERICA/WESTERN EUROPE	126	63	7	11.1	63	38	60.3	7.61	(3.39, 17.06)	<0.0001	0.4425
OTHER	78	38	8	21.1	40	26	65.0	4.12	(1.85, 9.18)	0.0002	0.4425
Visceral disease (per eCRF)											
N	65	36	4	11.1	29	22	75.9	12.32	(4.21, 36.11)	<0.0001	0.1708
Y	259	127	18	14.2	132	80	60.6	5.21	(3.11, 8.70)	<0.0001	0.1708
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	3	5.8	52	30	57.7	12.02	(3.66, 39.44)	<0.0001	0.2295
POST-MENOPAUSAL	214	110	18	16.4	104	68	65.4	5.65	(3.35, 9.53)	<0.0001	0.2295
Time to First Lymphopenia											
All Patients	324	163	15	9.2	161	6	3.7	0.36	(0.14, 0.92)	0.0259	NE
Age group (years)											
<65	266	129	13	10.1	137	6	4.4	0.36	(0.14, 0.96)	0.0338	0.3519
>=65	58	34	2	5.9	24	0	0.0	<0.01	(0.00, >999.99)	0.2517	0.3519
Sex											
F	318	162	15	9.3	156	6	3.8	0.37	(0.14, 0.95)	0.0304	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	1	1.6	58	2	3.4	2.09	(0.19, 23.08)	0.5364	0.2139
NORTH AMERICA/WESTERN EUROPE	126	63	5	7.9	63	2	3.2	0.39	(0.08, 2.00)	0.2385	0.2139
OTHER	78	38	9	23.7	40	2	5.0	0.15	(0.03, 0.69)	0.0054	0.2139

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	3	8.3	29	0	0.0	<0.01	(0.00, >999.99)	0.0943	0.1869
Y	259	127	12	9.4	132	6	4.5	0.42	(0.16, 1.13)	0.0772	0.1869
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	4	7.7	52	1	1.9	0.22	(0.02, 2.00)	0.1411	0.5264
POST-MENOPAUSAL	214	110	11	10.0	104	5	4.8	0.43	(0.15, 1.24)	0.1075	0.5264
Time to First Nausea											
All Patients	324	163	32	19.6	161	47	29.2	1.32	(0.84, 2.09)	0.2276	NE
Age group (years)											
<65	266	129	20	15.5	137	42	30.7	1.78	(1.04, 3.04)	0.0342	0.0298
>=65	58	34	12	35.3	24	5	20.8	0.51	(0.18, 1.46)	0.1985	0.0298
Sex											
F	318	162	32	19.8	156	47	30.1	1.37	(0.87, 2.15)	0.1793	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	4	6.5	58	14	24.1	3.26	(1.06, 9.99)	0.0290	0.1071
NORTH AMERICA/WESTERN EUROPE	126	63	21	33.3	63	25	39.7	1.14	(0.63, 2.04)	0.6869	0.1071
OTHER	78	38	7	18.4	40	8	20.0	0.80	(0.28, 2.28)	0.6782	0.1071
Visceral disease (per eCRF)											
N	65	36	12	33.3	29	5	17.2	0.39	(0.13, 1.15)	0.0793	0.0103
Y	259	127	20	15.7	132	42	31.8	1.84	(1.07, 3.14)	0.0249	0.0103
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	5	9.6	52	16	30.8	3.14	(1.14, 8.63)	0.0191	0.0538
POST-MENOPAUSAL	214	110	27	24.5	104	31	29.8	1.04	(0.62, 1.76)	0.8789	0.0538
Time to First Neutropenia											
All Patients	324	163	148	90.8	161	147	91.3	0.92	(0.73, 1.16)	0.4795	NE
Age group (years)											
<65	266	129	115	89.1	137	126	92.0	0.99	(0.76, 1.27)	0.8596	0.2305
>=65	58	34	33	97.1	24	21	87.5	0.66	(0.38, 1.15)	0.1540	0.2305
Sex											
F	318	162	147	90.7	156	142	91.0	0.92	(0.73, 1.16)	0.4549	0.7734
M	6	1	1	100.0	5	5	100.0	0.39	(0.03, 4.35)	0.4814	0.7734
Region											
ASIA	120	62	57	91.9	58	56	96.6	0.99	(0.68, 1.44)	0.9815	0.4235
NORTH AMERICA/WESTERN EUROPE	126	63	59	93.7	63	56	88.9	0.77	(0.53, 1.11)	0.1515	0.4235
OTHER	78	38	32	84.2	40	35	87.5	1.14	(0.70, 1.86)	0.6492	0.4235
Visceral disease (per eCRF)											
N	65	36	35	97.2	29	27	93.1	1.00	(0.60, 1.65)	0.9867	0.8300
Y	259	127	113	89.0	132	120	90.9	0.93	(0.72, 1.20)	0.5544	0.8300
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	48	92.3	52	49	94.2	0.81	(0.54, 1.21)	0.2986	0.3917
POST-MENOPAUSAL	214	110	99	90.0	104	93	89.4	0.98	(0.74, 1.30)	0.8562	0.3917
Time to First Ocular Toxicities											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
All Patients	324	163	26	16.0	161	47	29.2	1.66	(1.03, 2.68)	0.0372	NE
Age group (years)											
<65	266	129	23	17.8	137	43	31.4	1.50	(0.90, 2.49)	0.1178	0.6508
>=65	58	34	3	8.8	24	4	16.7	2.26	(0.51, 10.14)	0.2723	0.6508
Sex											
F	318	162	26	16.0	156	47	30.1	1.72	(1.06, 2.78)	0.0256	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	10	16.1	58	9	15.5	0.72	(0.29, 1.79)	0.4817	0.1110
NORTH AMERICA/WESTERN EUROPE	126	63	11	17.5	63	26	41.3	2.60	(1.29, 5.27)	0.0059	0.1110
OTHER	78	38	5	13.2	40	12	30.0	1.85	(0.65, 5.28)	0.2457	0.1110
Visceral disease (per eCRF)											
N	65	36	7	19.4	29	7	24.1	1.22	(0.42, 3.50)	0.7152	0.5397
Y	259	127	19	15.0	132	40	30.3	1.78	(1.03, 3.08)	0.0360	0.5397
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	12	23.1	52	15	28.8	0.95	(0.44, 2.05)	0.9004	0.0927
POST-MENOPAUSAL	214	110	14	12.7	104	32	30.8	2.37	(1.26, 4.45)	0.0055	0.0927
Time to First Pneumonitis											
All Patients	324	163	2	1.2	161	5	3.1	2.12	(0.41, 11.01)	0.3611	NE
Age group (years)											
<65	266	129	1	0.8	137	5	3.6	3.69	(0.43, 31.88)	0.2039	0.1428
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.1428
Sex											
F	318	162	2	1.2	156	2	1.3	0.99	(0.14, 7.00)	0.9880	0.2638
M	6	1	0	0.0	5	3	60.0	>999.99	(0.00, >999.99)	0.3322	0.2638
Region											
ASIA	120	62	1	1.6	58	1	1.7	0.97	(0.06, 15.48)	0.9811	0.6033
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	3	4.8	2.46	(0.25, 23.86)	0.4227	0.6033
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	0.6033
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	3	10.3	3.79	(0.39, 36.41)	0.2151	0.6323
Y	259	127	1	0.8	132	2	1.5	1.36	(0.12, 15.46)	0.8027	0.6323
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	1	1.9	0.89	(0.06, 14.29)	0.9342	0.9745
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	1.03	(0.06, 16.46)	0.9835	0.9745
Time to First Rash											
All Patients	324	163	32	19.6	161	43	26.7	1.27	(0.80, 2.01)	0.3079	NE
Age group (years)											
<65	266	129	25	19.4	137	41	29.9	1.41	(0.86, 2.33)	0.1747	0.1008
>=65	58	34	7	20.6	24	2	8.3	0.41	(0.08, 1.96)	0.2464	0.1008
Sex											
F	318	162	32	19.8	156	43	27.6	1.31	(0.83, 2.07)	0.2464	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	15	24.2	58	16	27.6	1.02	(0.50, 2.06)	0.9696	0.7240
NORTH AMERICA/WESTERN EUROPE	126	63	12	19.0	63	18	28.6	1.46	(0.70, 3.04)	0.3035	0.7240
OTHER	78	38	5	13.2	40	9	22.5	1.60	(0.53, 4.81)	0.4008	0.7240
Visceral disease (per eCRF)											
N	65	36	11	30.6	29	8	27.6	0.86	(0.34, 2.15)	0.7497	0.2759
Y	259	127	21	16.5	132	35	26.5	1.49	(0.86, 2.56)	0.1500	0.2759
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	10	19.2	52	14	26.9	1.15	(0.51, 2.63)	0.7321	0.8265
POST-MENOPAUSAL	214	110	22	20.0	104	29	27.9	1.38	(0.79, 2.41)	0.2511	0.8265
Time to First Stomatitis and mucosal inflammation											
All Patients	324	163	47	28.8	161	89	55.3	2.35	(1.65, 3.35)	<0.0001	NE
Age group (years)											
<65	266	129	35	27.1	137	82	59.9	2.75	(1.85, 4.09)	<0.0001	0.0272
>=65	58	34	12	35.3	24	7	29.2	0.97	(0.38, 2.47)	0.9310	0.0272
Sex											
F	318	162	46	28.4	156	87	55.8	2.46	(1.72, 3.51)	<0.0001	0.2426
M	6	1	1	100.0	5	2	40.0	0.60	(0.05, 6.89)	0.6777	0.2426
Region											
ASIA	120	62	21	33.9	58	39	67.2	2.61	(1.53, 4.44)	0.0003	0.4516
NORTH AMERICA/WESTERN EUROPE	126	63	21	33.3	63	32	50.8	1.91	(1.10, 3.32)	0.0188	0.4516
OTHER	78	38	5	13.2	40	18	45.0	3.62	(1.34, 9.82)	0.0069	0.4516
Visceral disease (per eCRF)											
N	65	36	14	38.9	29	16	55.2	1.78	(0.87, 3.65)	0.1124	0.2732
Y	259	127	33	26.0	132	73	55.3	2.62	(1.73, 3.95)	<0.0001	0.2732
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	16	30.8	52	33	63.5	2.60	(1.43, 4.74)	0.0012	0.7653
POST-MENOPAUSAL	214	110	30	27.3	104	54	51.9	2.38	(1.52, 3.72)	<0.0001	0.7653
Time to First Thrombocytopenia											
All Patients	324	163	75	46.0	161	80	49.7	1.18	(0.86, 1.62)	0.3116	NE
Age group (years)											
<65	266	129	57	44.2	137	65	47.4	1.16	(0.81, 1.66)	0.4107	0.6304
>=65	58	34	18	52.9	24	15	62.5	1.38	(0.69, 2.74)	0.3858	0.6304
Sex											
F	318	162	74	45.7	156	77	49.4	1.18	(0.86, 1.62)	0.3139	0.2062
M	6	1	1	100.0	5	3	60.0	0.39	(0.03, 4.35)	0.4814	0.2062
Region											
ASIA	120	62	31	50.0	58	43	74.1	1.98	(1.24, 3.14)	0.0031	0.0071
NORTH AMERICA/WESTERN EUROPE	126	63	23	36.5	63	24	38.1	1.08	(0.61, 1.92)	0.8067	0.0071
OTHER	78	38	21	55.3	40	13	32.5	0.55	(0.27, 1.10)	0.0821	0.0071
Visceral disease (per eCRF)											
N	65	36	11	30.6	29	17	58.6	2.64	(1.24, 5.65)	0.0101	0.0210
Y	259	127	64	50.4	132	63	47.7	0.97	(0.69, 1.38)	0.8638	0.0210

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	22	42.3	52	24	46.2	1.20	(0.67, 2.14)	0.5533	0.9883
POST-MENOPAUSAL	214	110	52	47.3	104	53	51.0	1.18	(0.80, 1.73)	0.3971	0.9883
Time to First Vomiting											
All Patients	324	163	10	6.1	161	26	16.1	2.44	(1.18, 5.08)	0.0134	NE
Age group (years)											
<65	266	129	7	5.4	137	23	16.8	2.73	(1.17, 6.38)	0.0158	0.5496
>=65	58	34	3	8.8	24	3	12.5	1.65	(0.33, 8.20)	0.5346	0.5496
Sex											
F	318	162	10	6.2	156	25	16.0	2.45	(1.18, 5.11)	0.0134	0.6783
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6171	0.6783
Region											
ASIA	120	62	2	3.2	58	8	13.8	4.10	(0.87, 19.33)	0.0534	0.4501
NORTH AMERICA/WESTERN EUROPE	126	63	8	12.7	63	16	25.4	2.05	(0.87, 4.79)	0.0916	0.4501
OTHER	78	38	0	0.0	40	2	5.0	>999.99	(0.00, >999.99)	0.2144	0.4501
Visceral disease (per eCRF)											
N	65	36	2	5.6	29	4	13.8	2.09	(0.38, 11.56)	0.3857	0.9981
Y	259	127	8	6.3	132	22	16.7	2.46	(1.09, 5.53)	0.0247	0.9981
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	9	17.3	>999.99	(0.00, >999.99)	0.0045	0.0094
POST-MENOPAUSAL	214	110	10	9.1	104	16	15.4	1.63	(0.74, 3.60)	0.2217	0.0094
Time to First Colitis or Enterocolitis											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_AESEL_SAS_15NOV2024_41554.docx

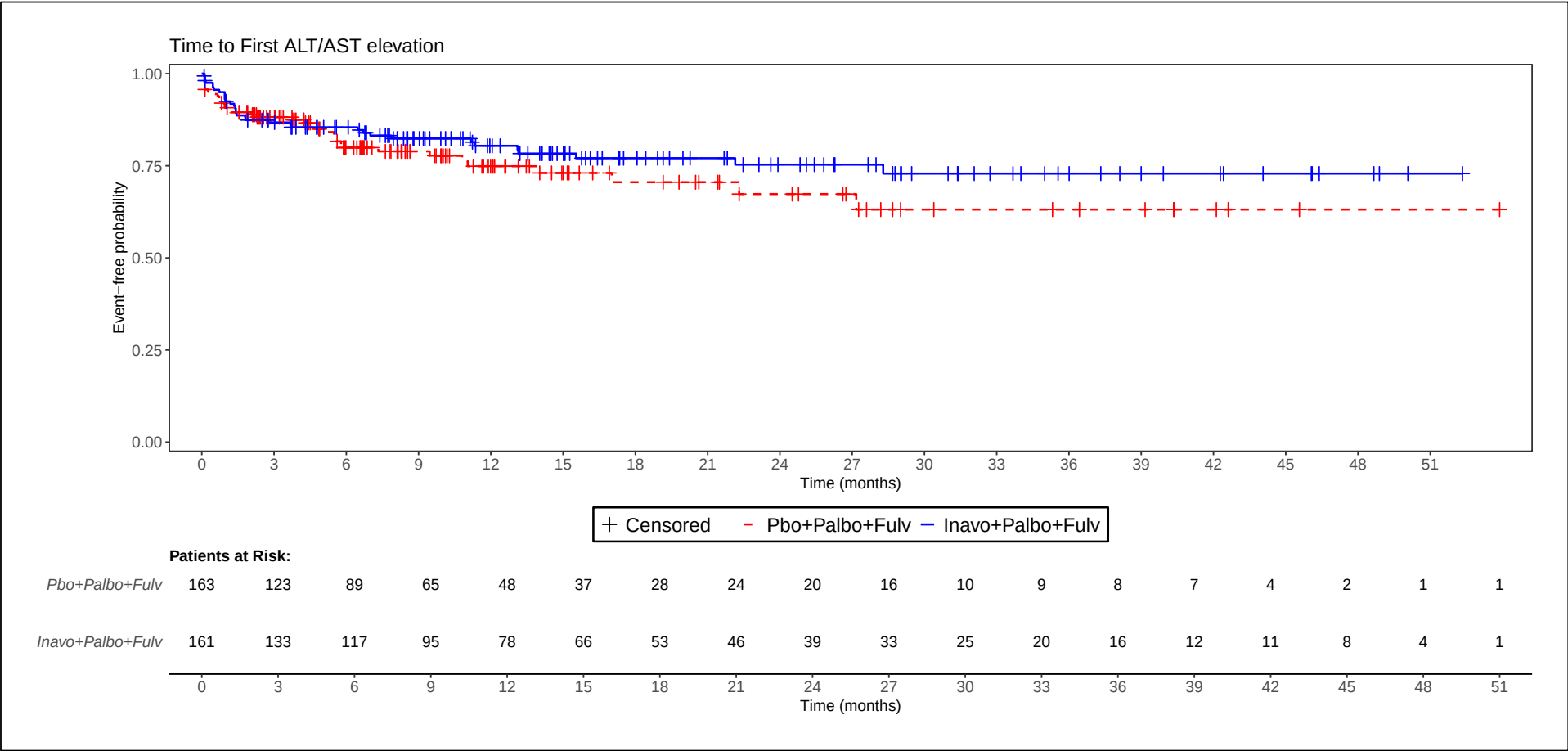
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08 APR 2025 17:32 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

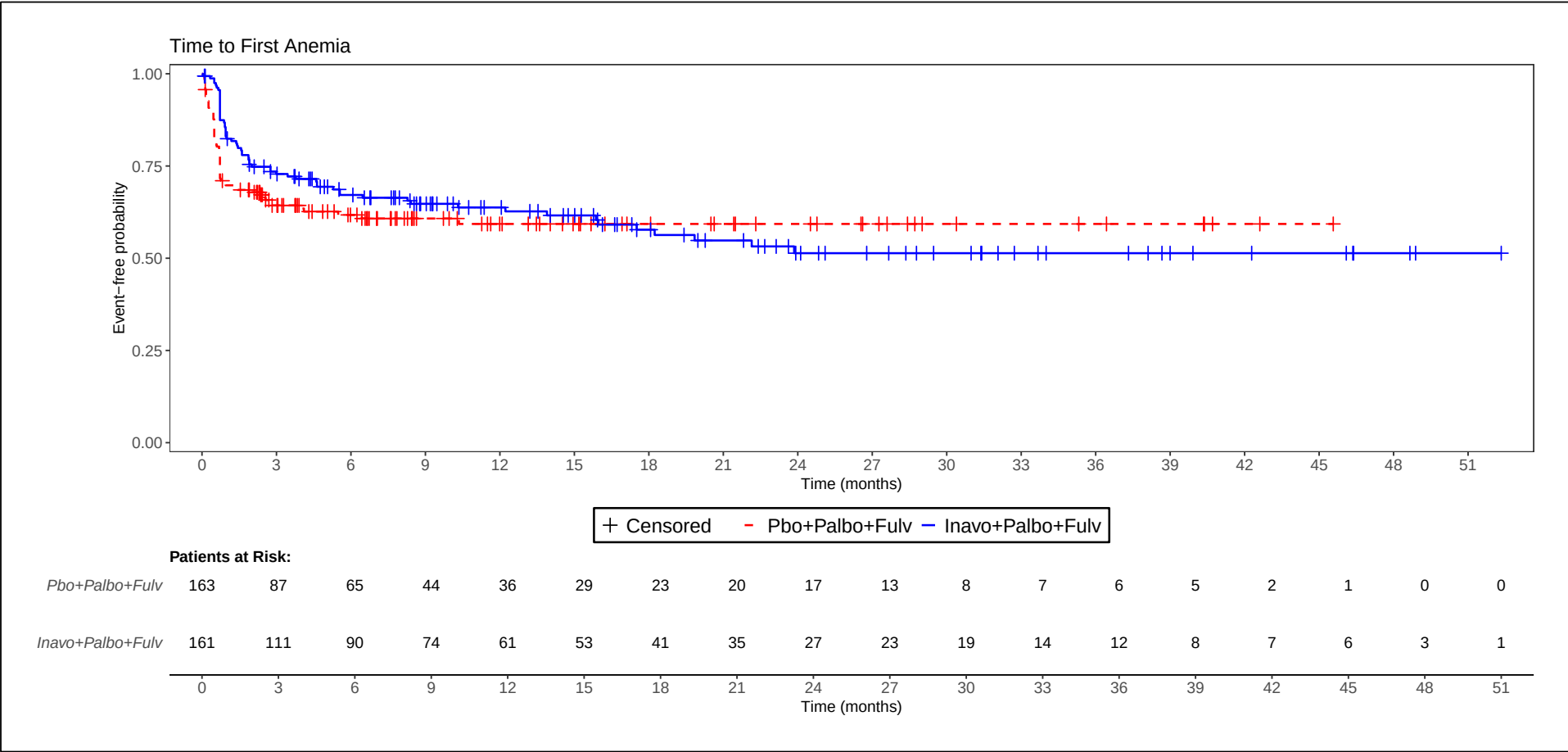
Kaplan Meier Plot for Safety, Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

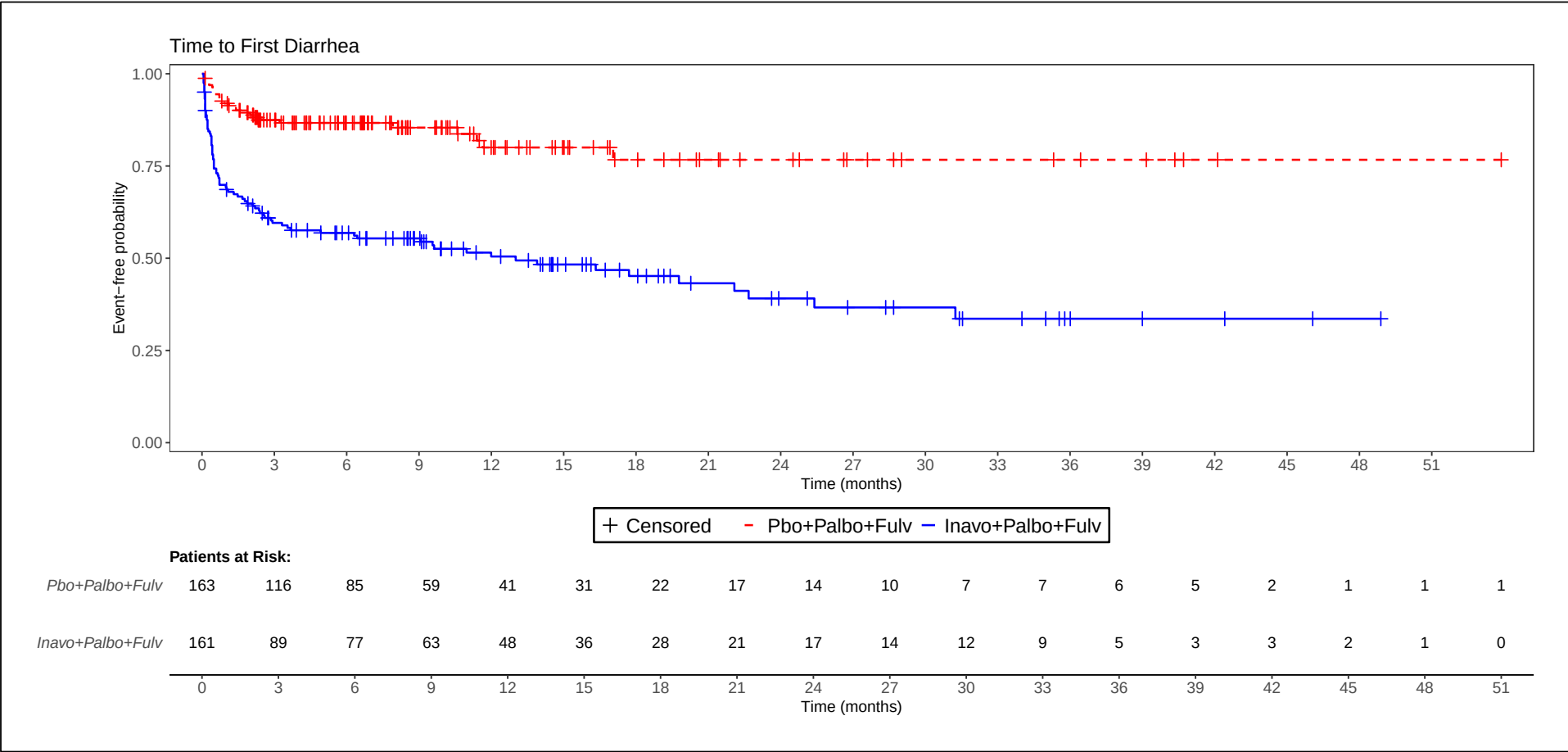
Kaplan Meier Plot for Safety, Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

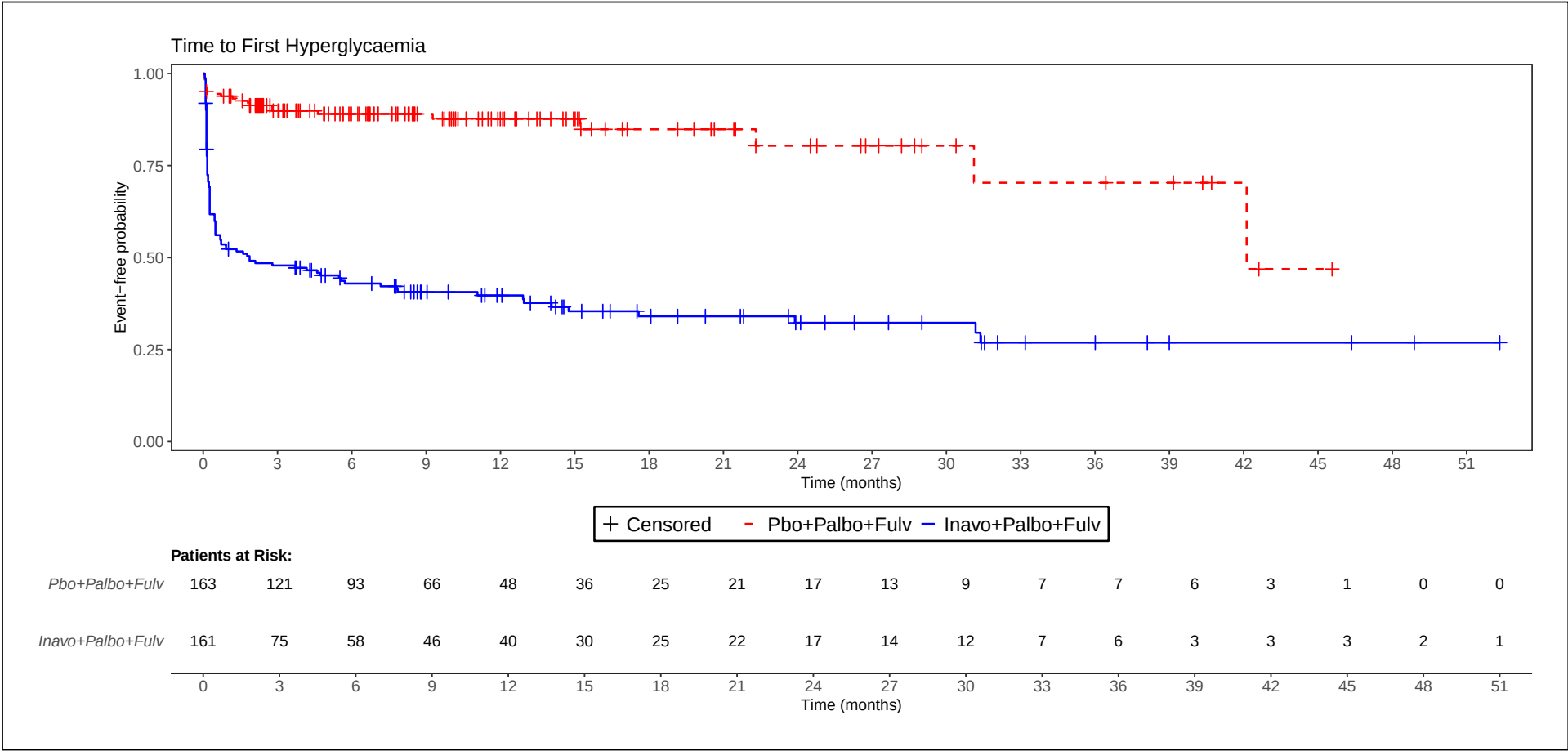
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

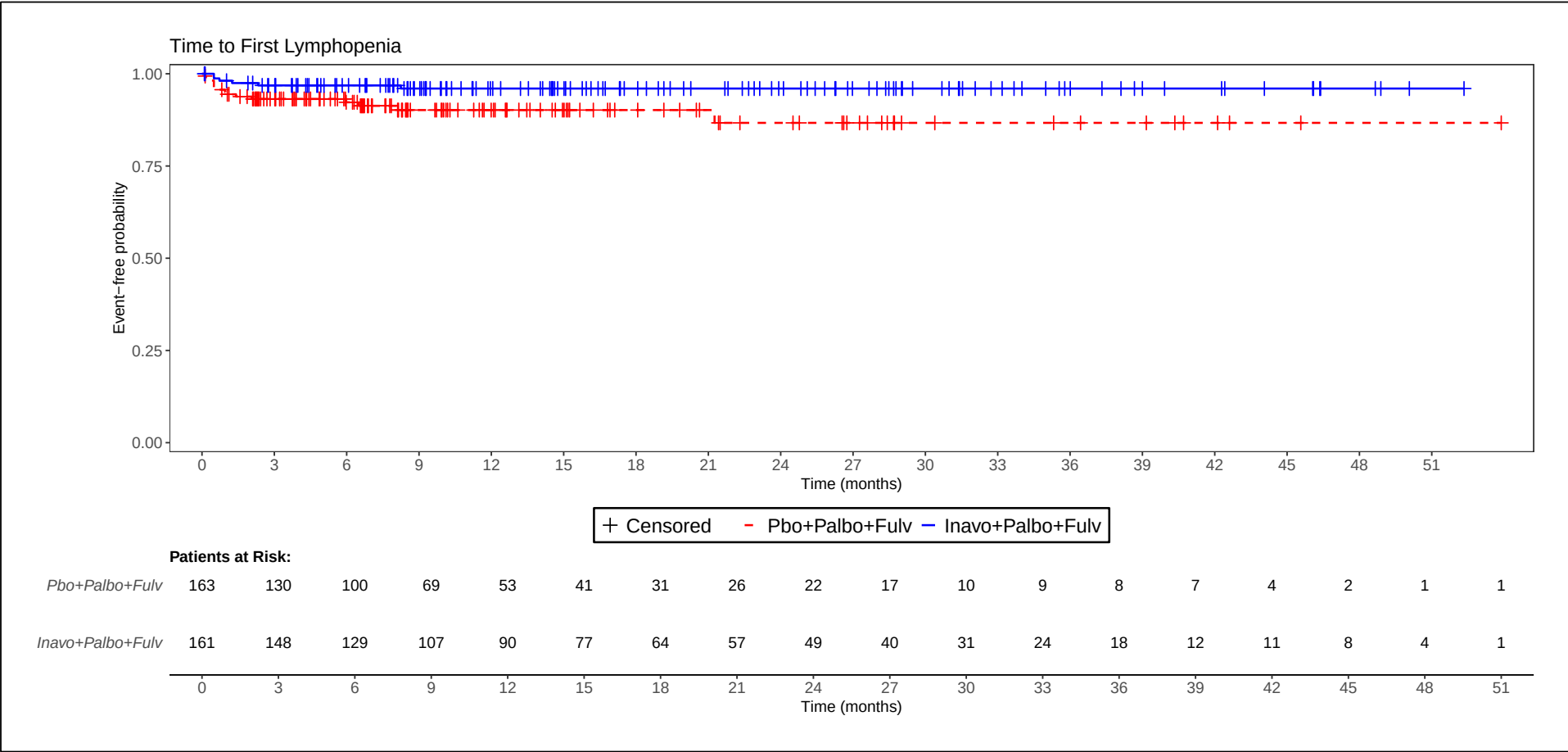
Kaplan Meier Plot for Safety, Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

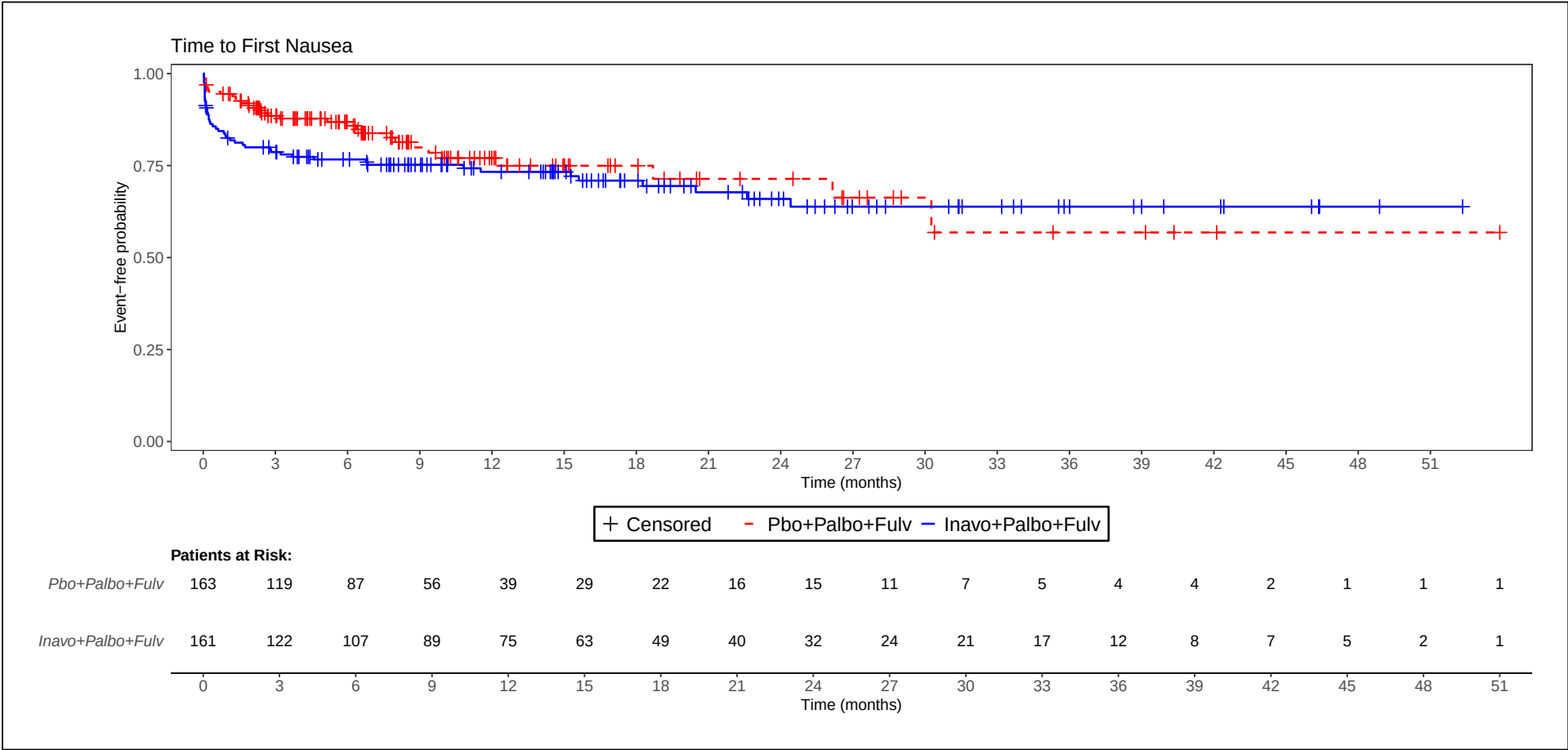
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

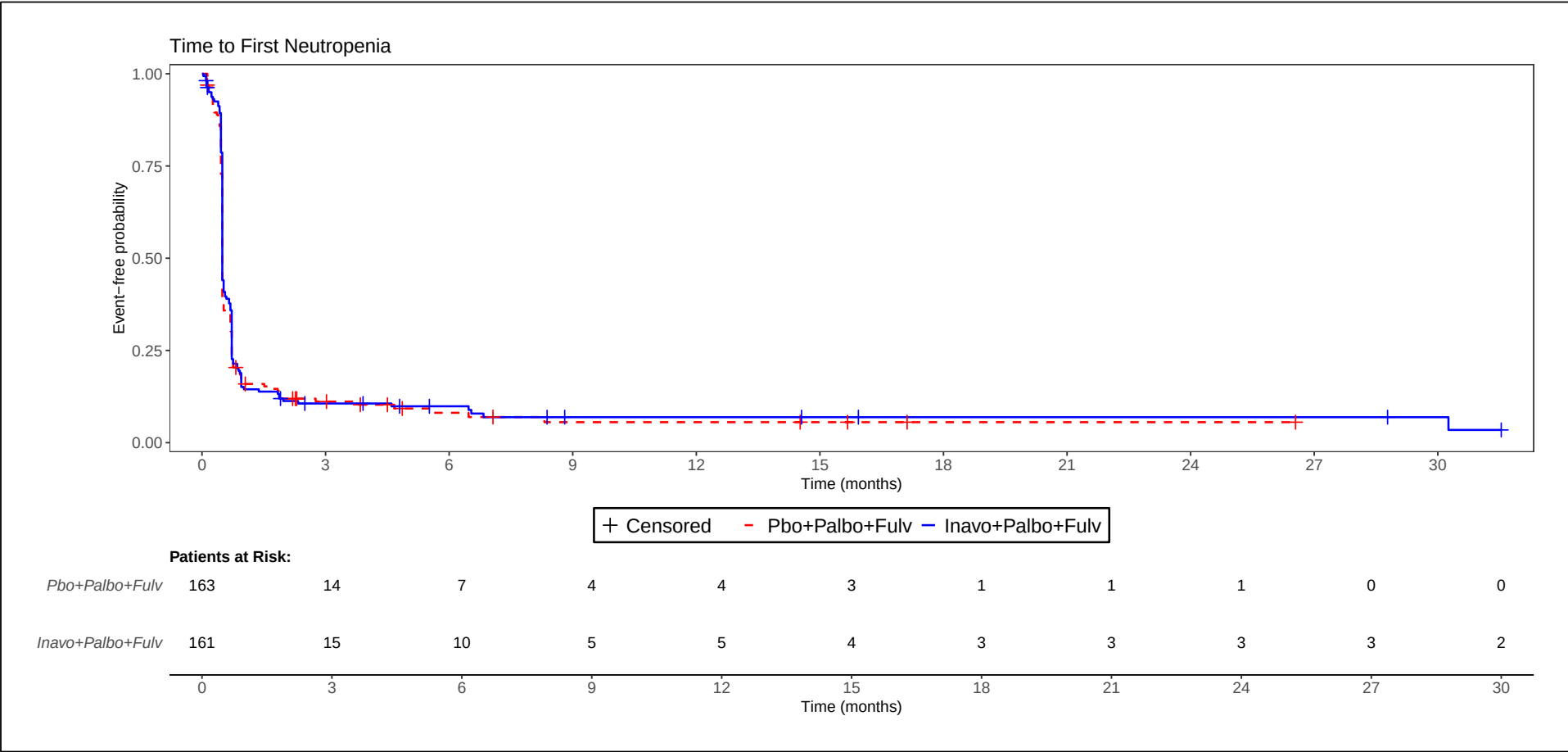
Kaplan Meier Plot for Safety, Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

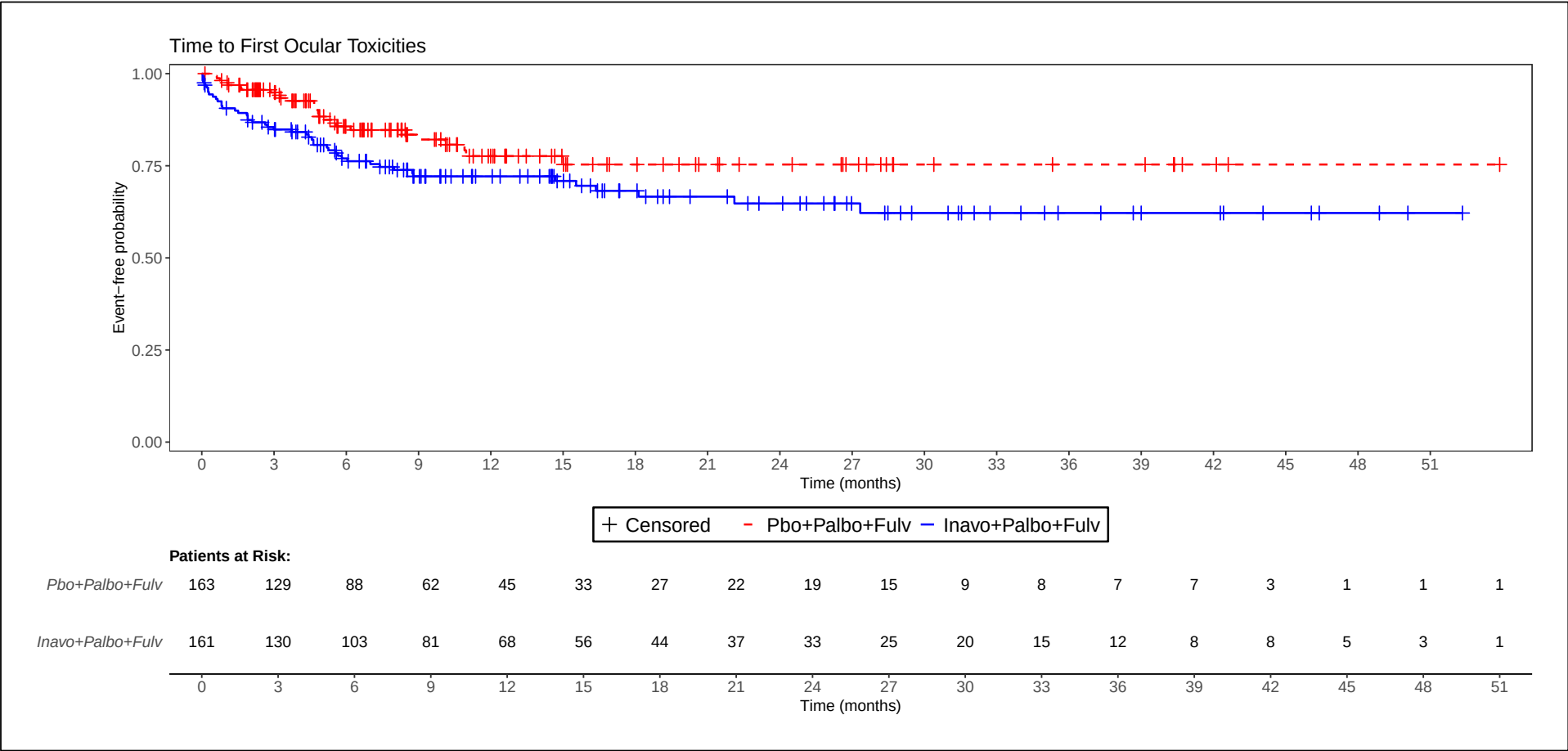
Kaplan Meier Plot for Safety, Selected Adverse Events, Safety Analysis Set
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

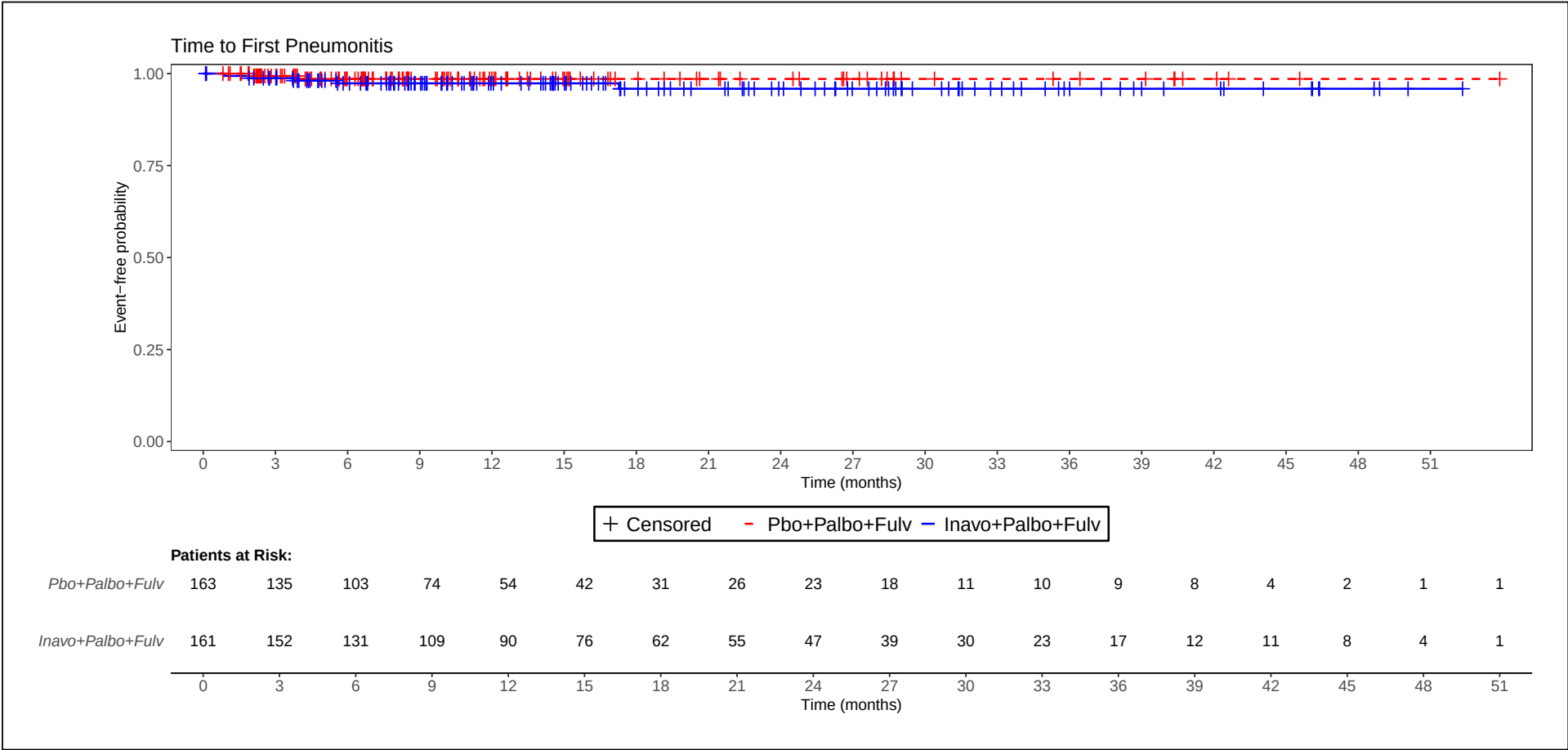
Kaplan Meier Plot for Safety, Selected Adverse Events, Safety Analysis Set
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

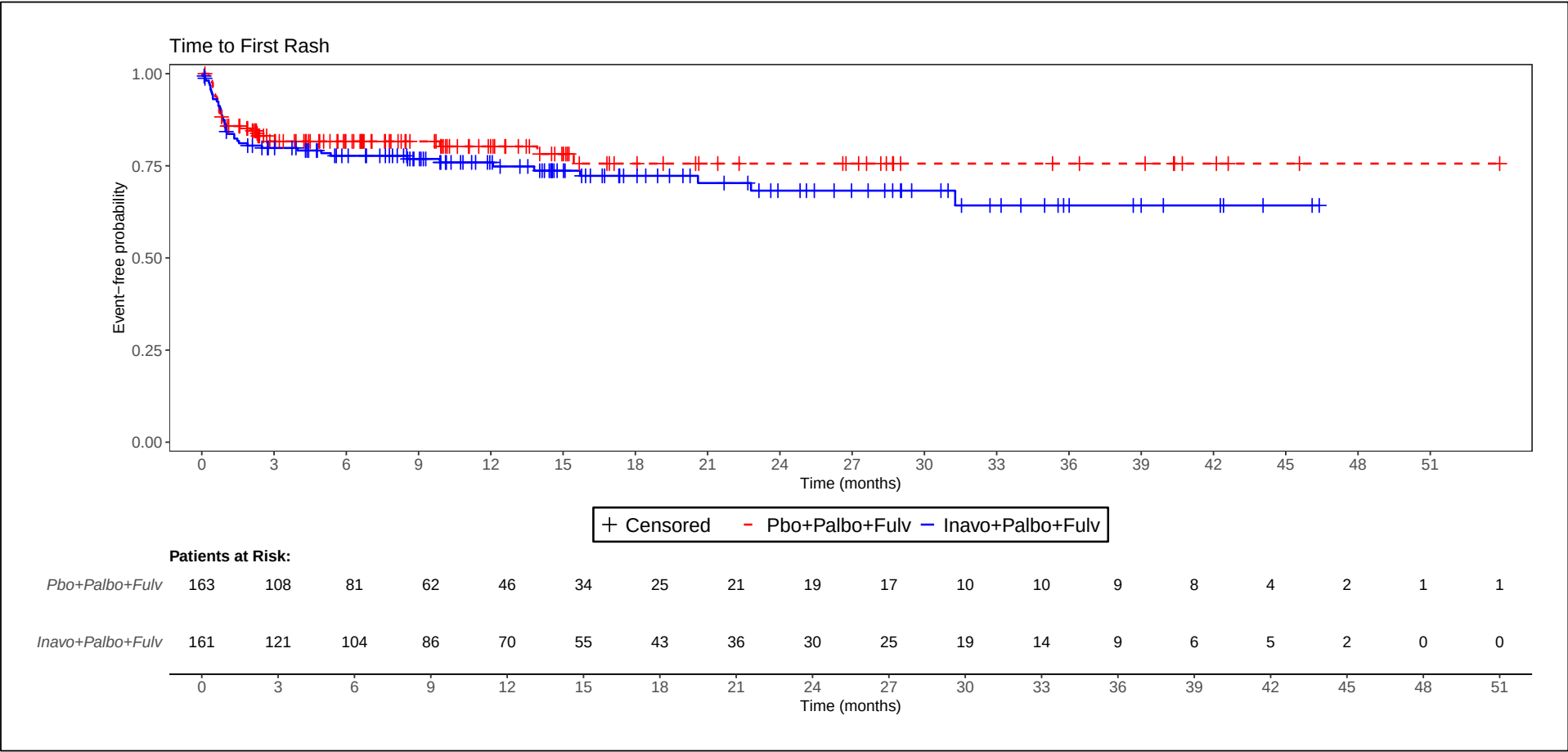
Kaplan Meier Plot for Safety, Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

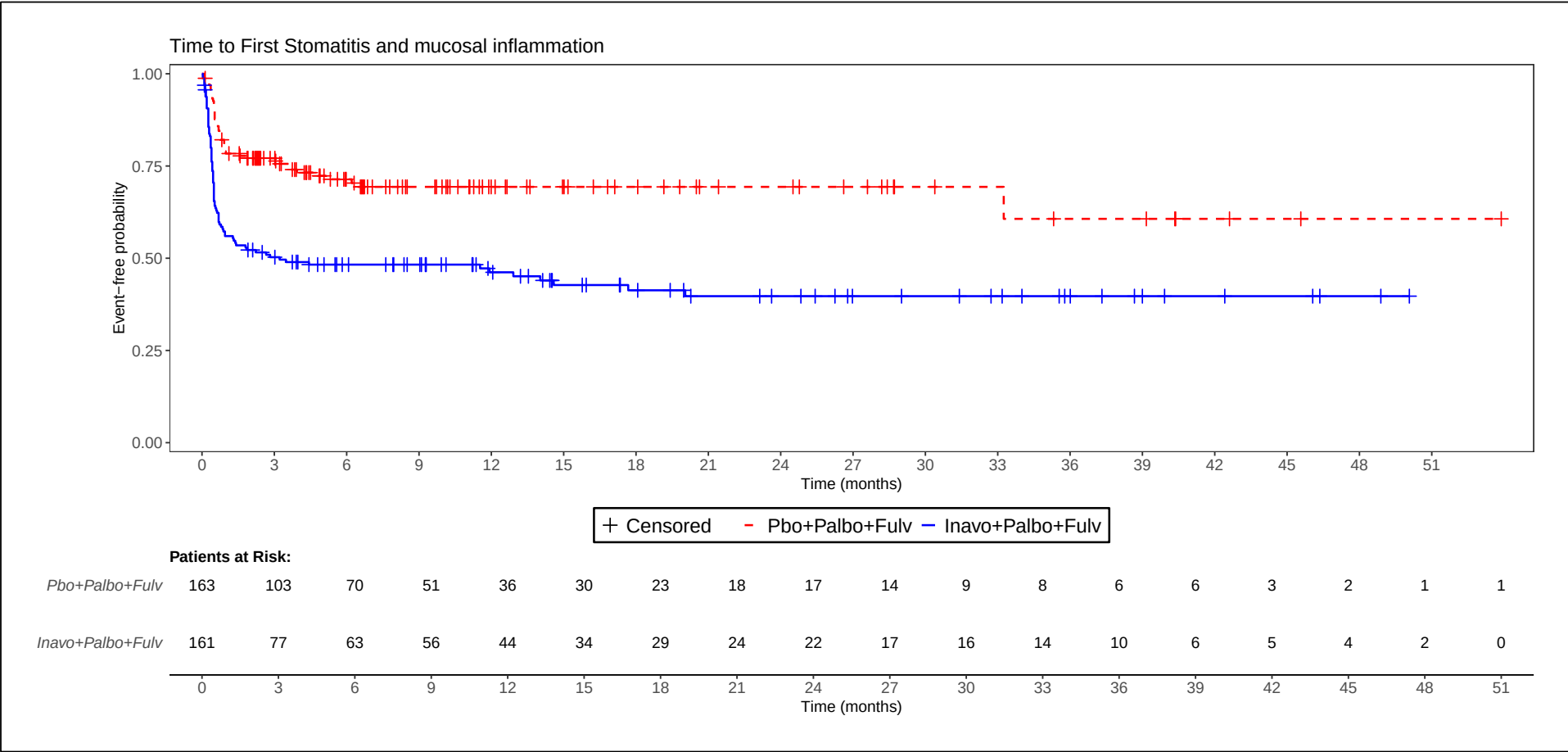
Kaplan Meier Plot for Safety, Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

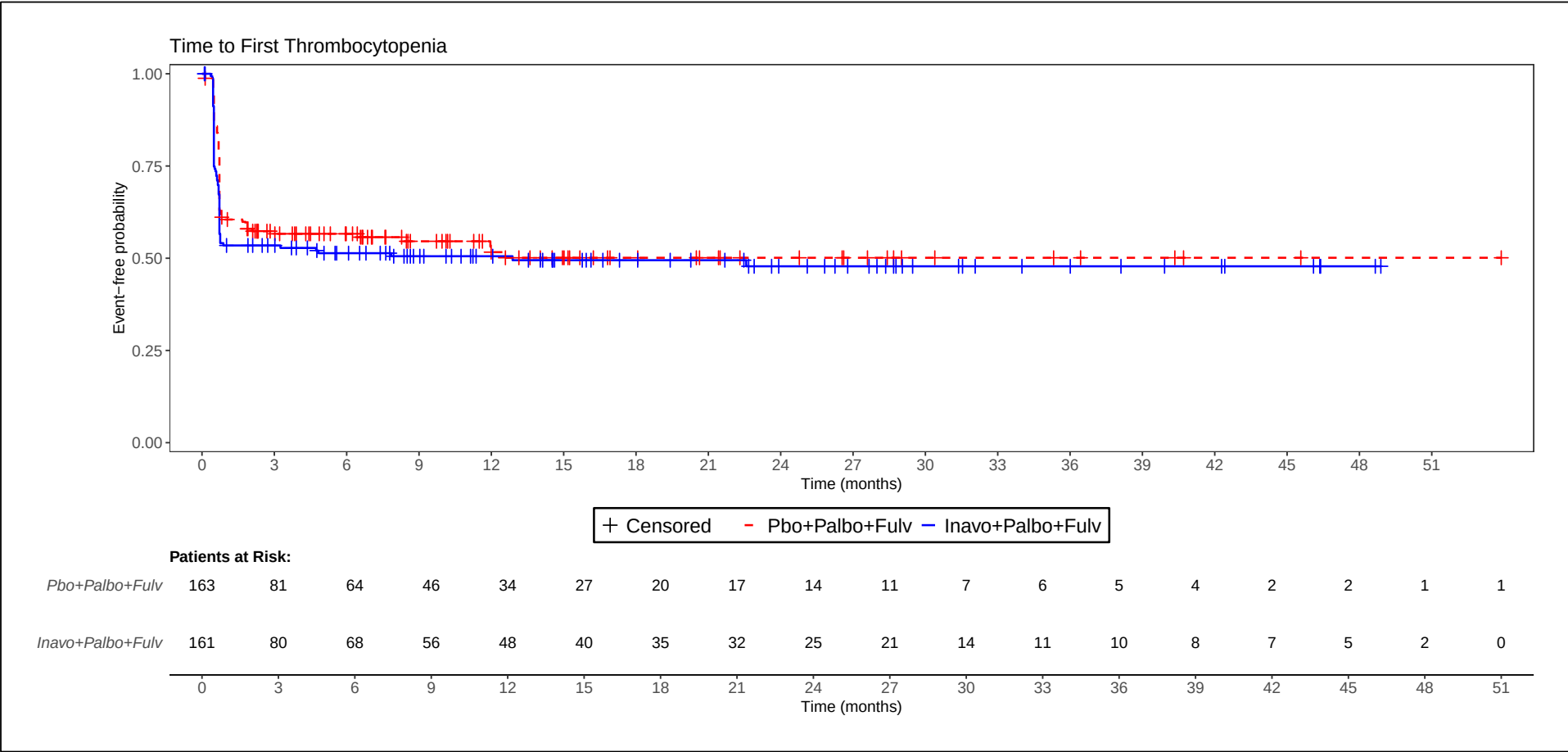
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

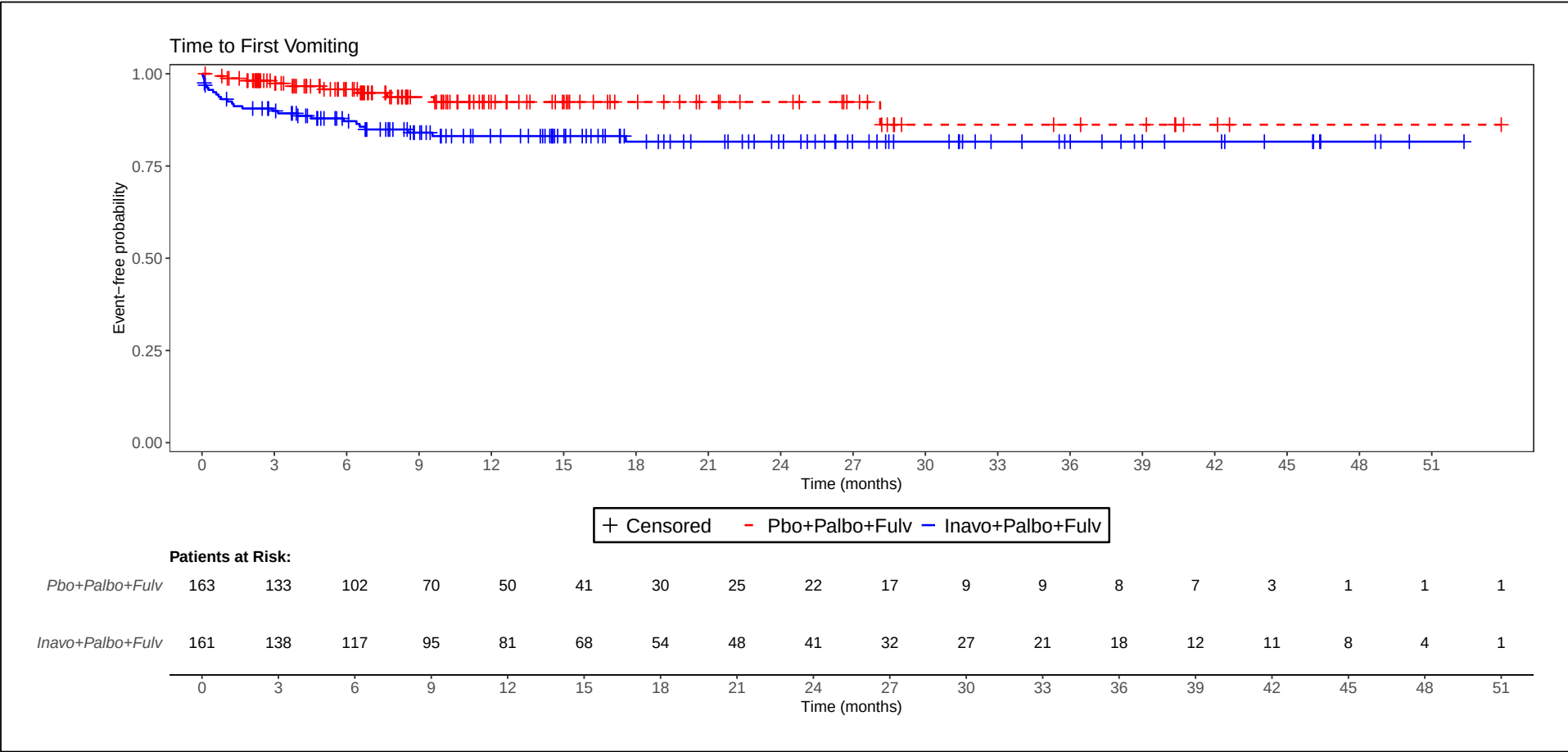
Kaplan Meier Plot for Safety, Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

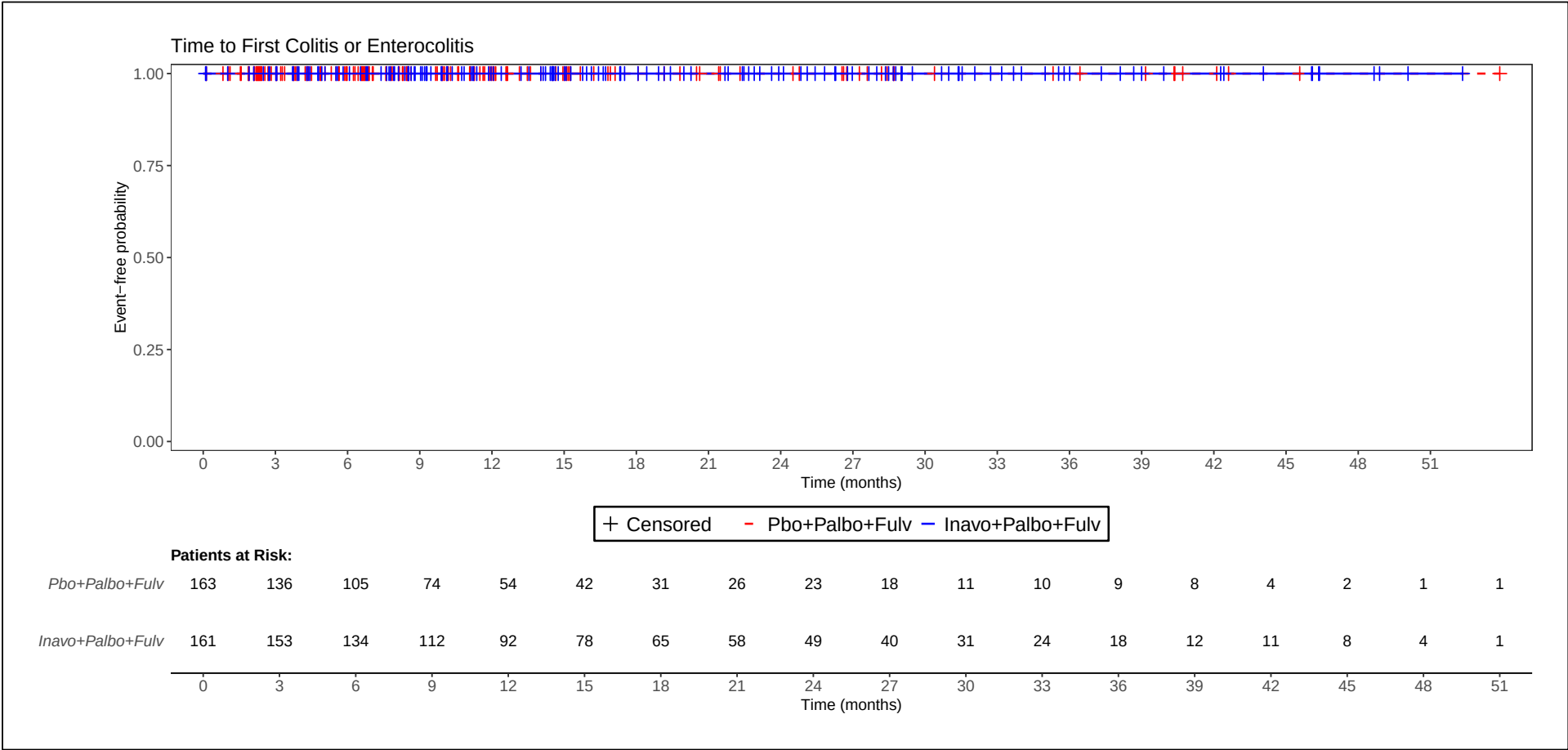
Kaplan Meier Plot for Safety, Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Safety, Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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31 MAR 2025 06:15 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Safety), Selected Adverse Events Grade >= 3, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Grade >= 3 Anemia											
All Patients	324	163	3	1.8	161	11	6.8	3.27	(0.91, 11.79)	0.0549	NE
Age group (years)											
<65	266	129	2	1.6	137	9	6.6	3.58	(0.77, 16.67)	0.0836	0.9346
>=65	58	34	1	2.9	24	2	8.3	3.41	(0.31, 37.68)	0.2866	0.9346
Sex											
F	318	162	3	1.9	156	11	7.1	3.37	(0.94, 12.13)	0.0487	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	1	1.6	58	8	13.8	7.20	(0.89, 58.07)	0.0309	0.1426
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	0.1426
OTHER	78	38	1	2.6	40	3	7.5	2.48	(0.26, 23.99)	0.4181	0.1426
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	5	17.2	5.28	(0.61, 45.74)	0.0921	0.5127
Y	259	127	2	1.6	132	6	4.5	2.80	(0.56, 13.87)	0.1884	0.5127
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	1	1.9	52	5	9.6	3.85	(0.44, 33.81)	0.1927	0.7842
POST-MENOPAUSAL	214	110	2	1.8	104	6	5.8	3.01	(0.61, 14.91)	0.1568	0.7842
Time to First Grade >= 3 Lymphopenia											
All Patients	324	163	3	1.8	161	1	0.6	0.30	(0.03, 2.95)	0.2774	NE
Age group (years)											
<65	266	129	2	1.6	137	1	0.7	0.40	(0.04, 4.50)	0.4459	0.5038
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.5038
Sex											
F	318	162	3	1.9	156	1	0.6	0.31	(0.03, 3.03)	0.2897	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3091	0.0898
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.0898
OTHER	78	38	3	7.9	40	0	0.0	<0.01	(0.00, >999.99)	0.0423	0.0898
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.2963	0.4640
Y	259	127	2	1.6	132	1	0.8	0.47	(0.04, 5.22)	0.5318	0.4640
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	3	2.7	104	1	1.0	0.33	(0.03, 3.15)	0.3081	1.0000
Time to First Grade >= 3 Nausea											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Neutropenia											
All Patients	324	163	131	80.4	161	133	82.6	0.96	(0.76, 1.23)	0.7506	NE
Age group (years)											
<65	266	129	101	78.3	137	117	85.4	1.06	(0.81, 1.38)	0.7209	0.1176
>=65	58	34	30	88.2	24	16	66.7	0.62	(0.34, 1.15)	0.1408	0.1176
Sex											
F	318	162	130	80.2	156	129	82.7	0.97	(0.76, 1.24)	0.7855	0.4534
M	6	1	1	100.0	5	4	80.0	0.22	(0.01, 3.59)	0.2467	0.4534
Region											
ASIA	120	62	52	83.9	58	55	94.8	1.18	(0.81, 1.73)	0.4110	0.2063
NORTH AMERICA/WESTERN EUROPE	126	63	52	82.5	63	47	74.6	0.76	(0.51, 1.13)	0.1722	0.2063
OTHER	78	38	27	71.1	40	31	77.5	1.07	(0.63, 1.81)	0.8544	0.2063
Visceral disease (per eCRF)											
N	65	36	31	86.1	29	25	86.2	0.92	(0.54, 1.56)	0.7480	0.9010
Y	259	127	100	78.7	132	108	81.8	0.98	(0.75, 1.29)	0.8823	0.9010
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	43	82.7	52	47	90.4	0.93	(0.61, 1.41)	0.7300	0.7241
POST-MENOPAUSAL	214	110	87	79.1	104	82	78.8	1.00	(0.74, 1.35)	0.9344	0.7241
Time to First Grade >= 3 Ocular Toxicities											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4888	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5371	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4844	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5271	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4979	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6056	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Pneumonitis											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3356	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Grade >= 3 Rash											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3266	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3311	1.0000
Time to First Grade >= 3 Stomatitis and mucosal inflammation											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
All Patients	324	163	0	0.0	161	9	5.6	>999.99	(0.00, >999.99)	0.0034	NE
Age group (years)											
<65	266	129	0	0.0	137	8	5.8	>999.99	(0.00, >999.99)	0.0090	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	8	5.1	>999.99	(0.00, >999.99)	0.0053	0.9999
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6547	0.9999
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.1452	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	6	9.5	>999.99	(0.00, >999.99)	0.0146	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5708	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	3	10.3	>999.99	(0.00, >999.99)	0.0435	0.9999
Y	259	127	0	0.0	132	6	4.5	>999.99	(0.00, >999.99)	0.0220	0.9999
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	4	7.7	>999.99	(0.00, >999.99)	0.0662	0.9999
POST-MENOPAUSAL	214	110	0	0.0	104	4	3.8	>999.99	(0.00, >999.99)	0.0411	0.9999
Time to First Grade >= 3 Thrombocytopenia											
All Patients	324	163	8	4.9	161	22	13.7	2.90	(1.29, 6.52)	0.0069	NE
Age group (years)											
<65	266	129	6	4.7	137	16	11.7	2.59	(1.01, 6.62)	0.0394	0.4570
>=65	58	34	2	5.9	24	6	25.0	4.95	(1.00, 24.56)	0.0301	0.4570
Sex											
F	318	162	8	4.9	156	22	14.1	2.99	(1.33, 6.71)	0.0054	0.9999
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	0.9999
Region											
ASIA	120	62	5	8.1	58	18	31.0	4.36	(1.62, 11.75)	0.0015	0.4153
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	1	1.6	1.02	(0.06, 16.38)	0.9864	0.4153
OTHER	78	38	2	5.3	40	3	7.5	1.14	(0.19, 7.03)	0.8869	0.4153
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	4	13.8	>999.99	(0.00, >999.99)	0.0190	0.0646
Y	259	127	8	6.3	132	18	13.6	2.22	(0.96, 5.11)	0.0546	0.0646
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	2	3.8	52	8	15.4	4.25	(0.90, 20.01)	0.0460	0.5996
POST-MENOPAUSAL	214	110	6	5.5	104	14	13.5	2.56	(0.98, 6.67)	0.0464	0.5996
Time to First Grade >= 3 Vomiting											
All Patients	324	163	2	1.2	161	2	1.2	0.95	(0.13, 6.76)	0.9596	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2560	0.1186
>=65	58	34	1	2.9	24	2	8.3	3.23	(0.29, 35.65)	0.3109	0.1186
Sex											
F	318	162	2	1.2	156	2	1.3	0.98	(0.14, 6.93)	0.9804	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	2	3.2	58	1	1.7	0.49	(0.04, 5.40)	0.5517	0.4349
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	0.4349
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.4349
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	2	1.5	0.88	(0.12, 6.25)	0.8968	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	1.00	(0.14, 7.11)	0.9990	1.0000
Time to First Grade >= 3 Colitis or Enterocolitis											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

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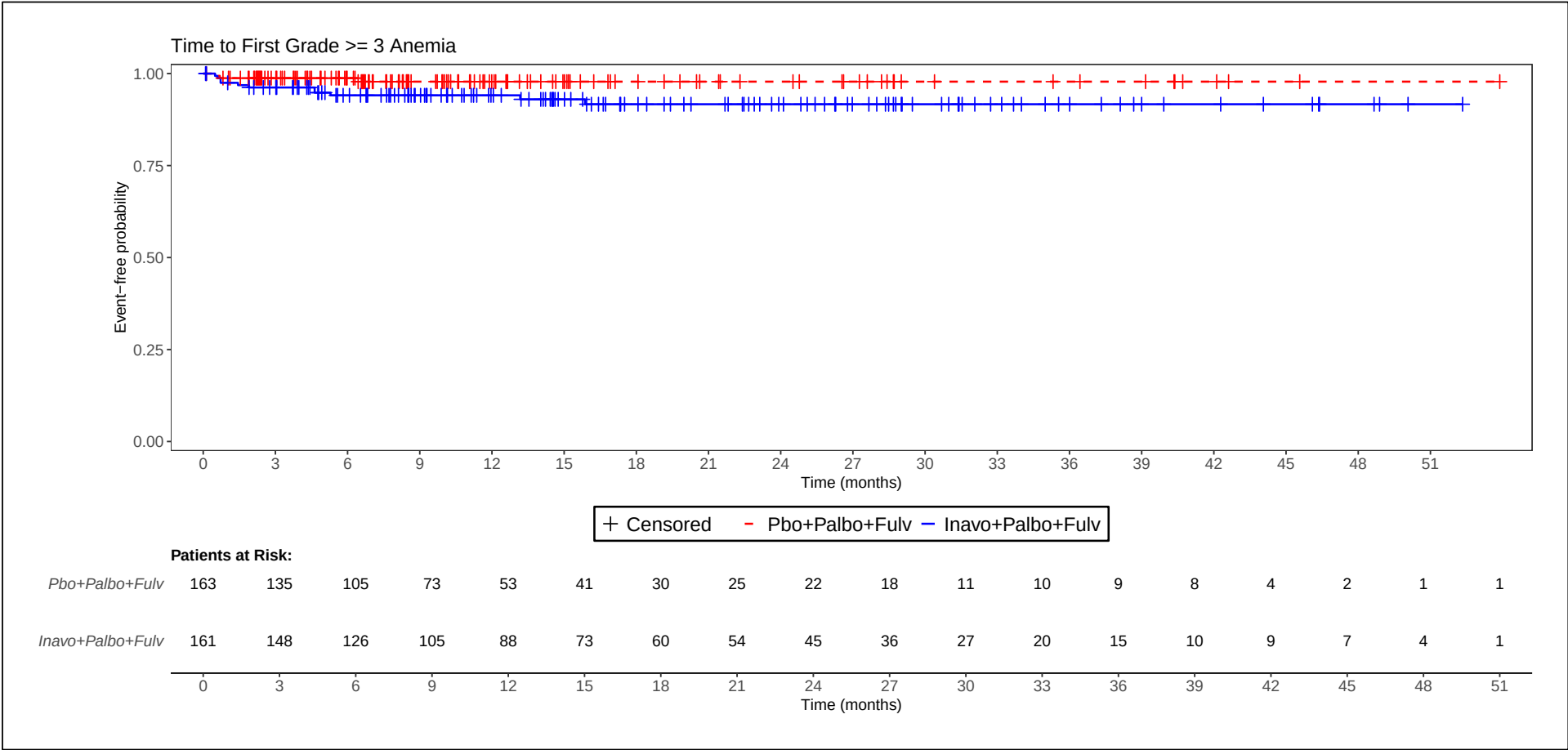
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08 APR 2025 17:32 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

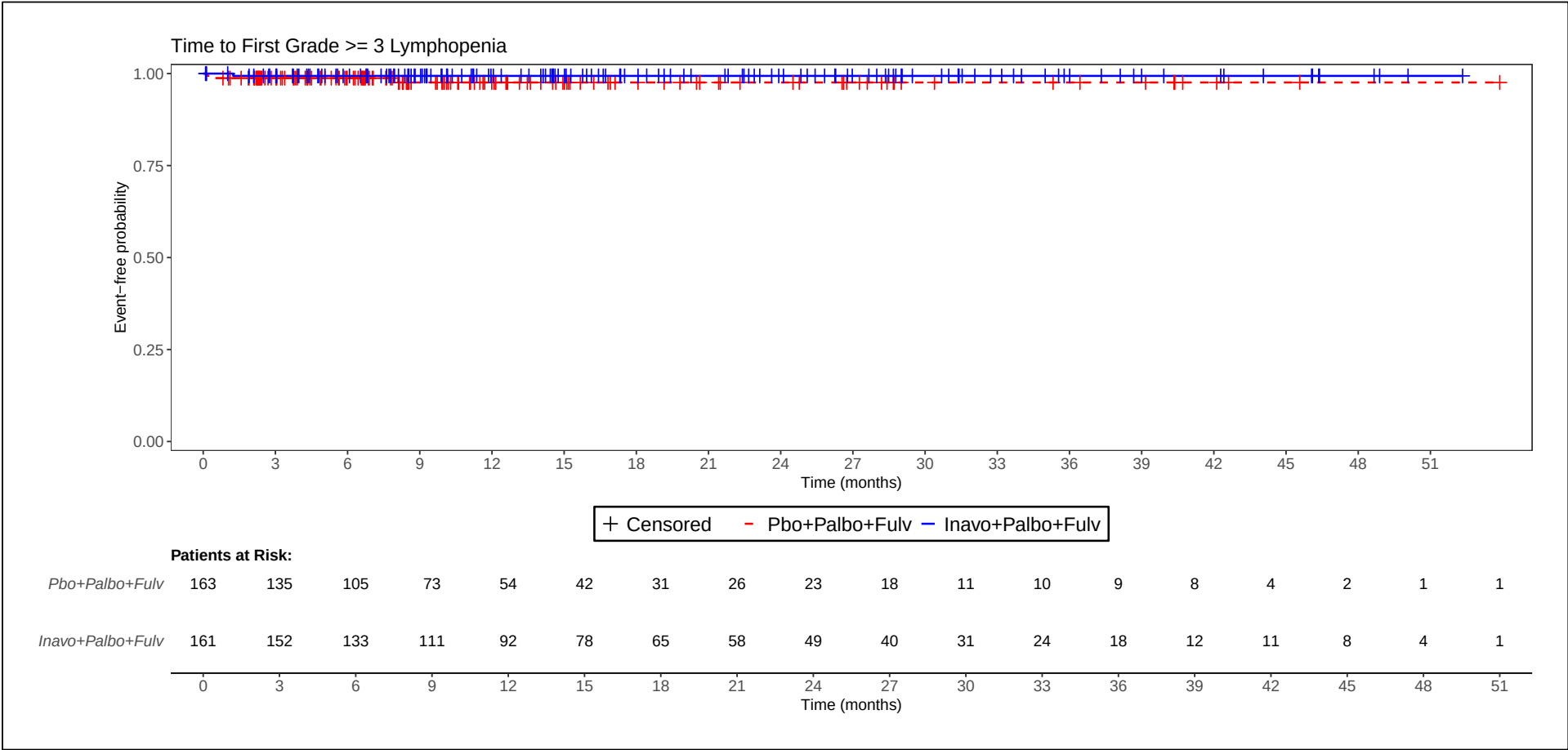
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

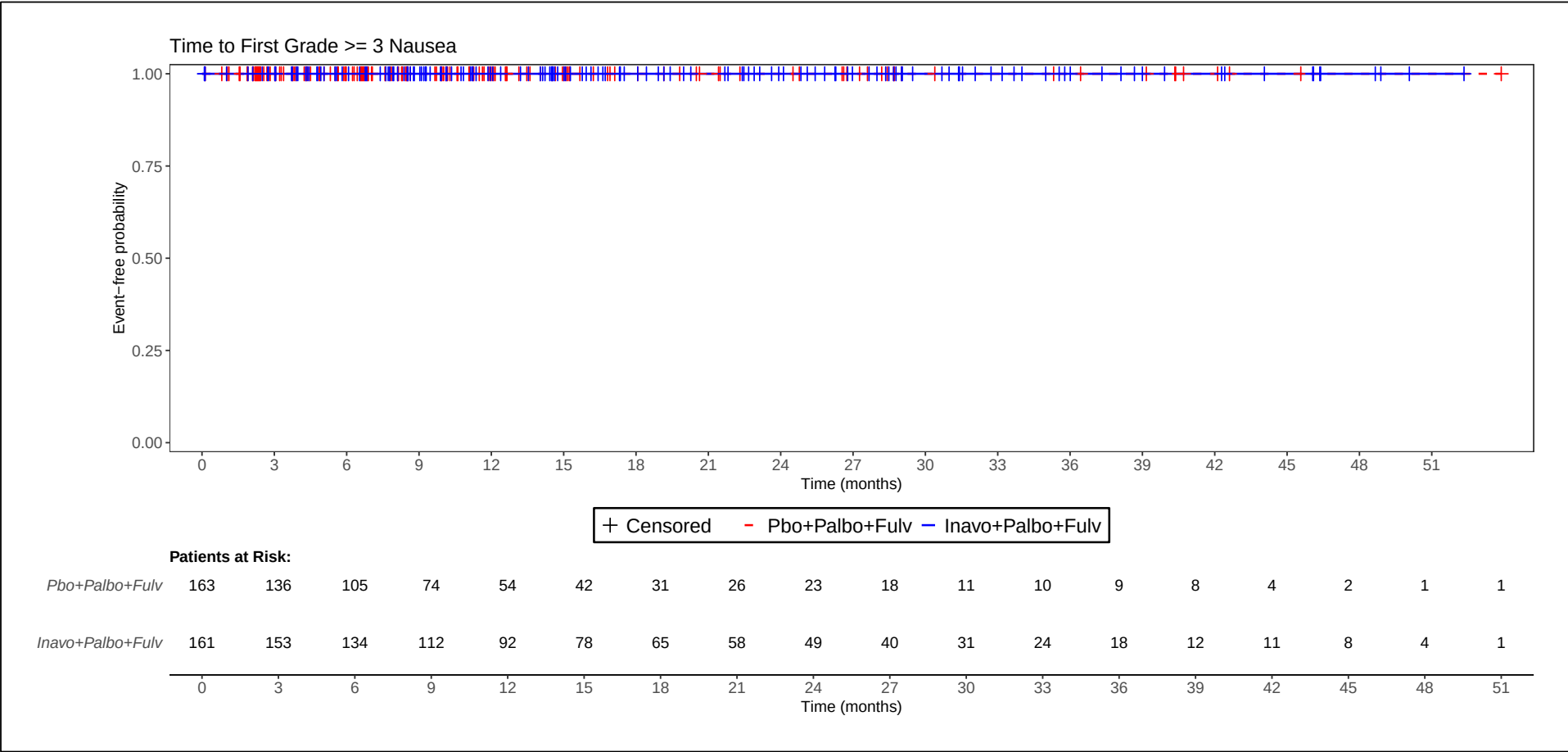
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

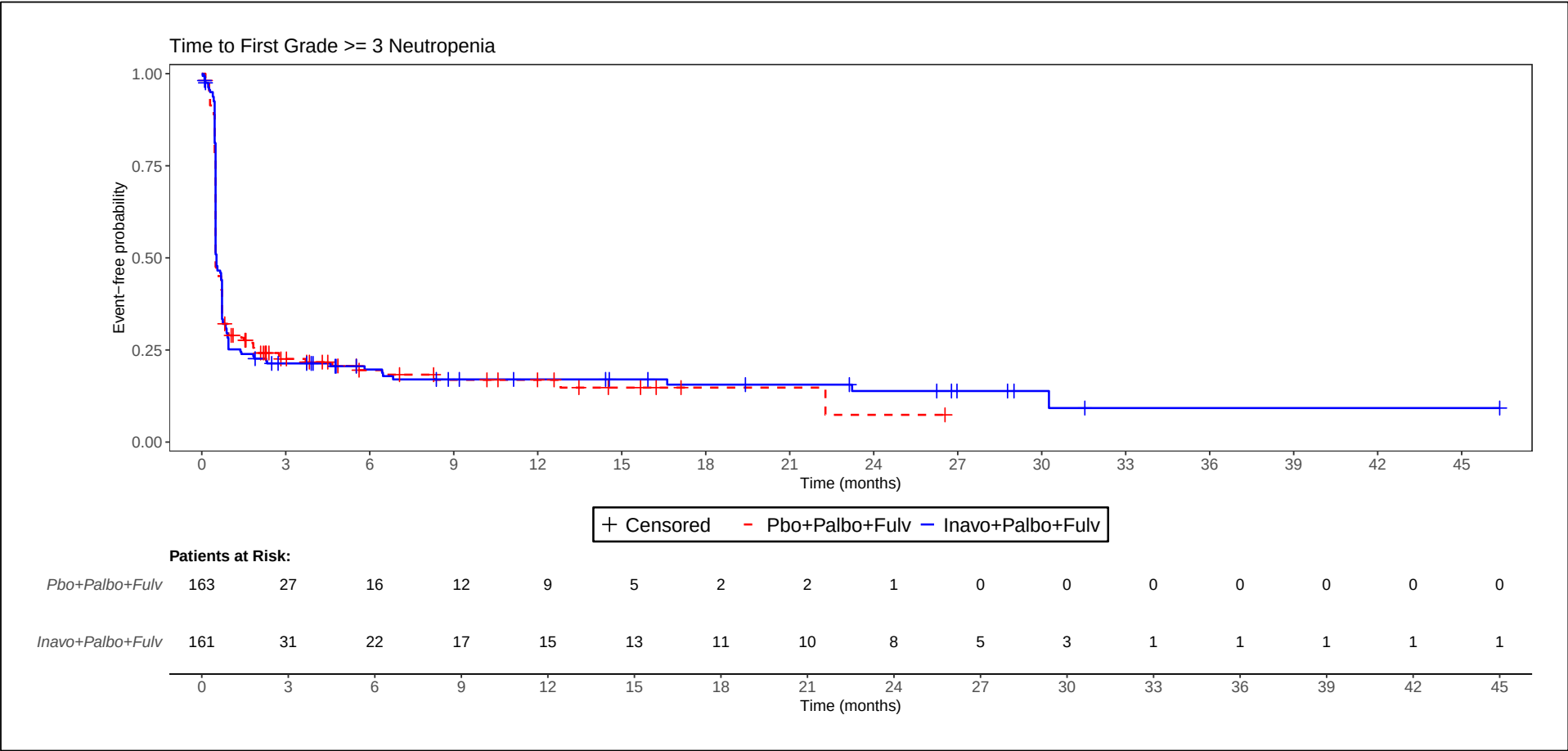
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

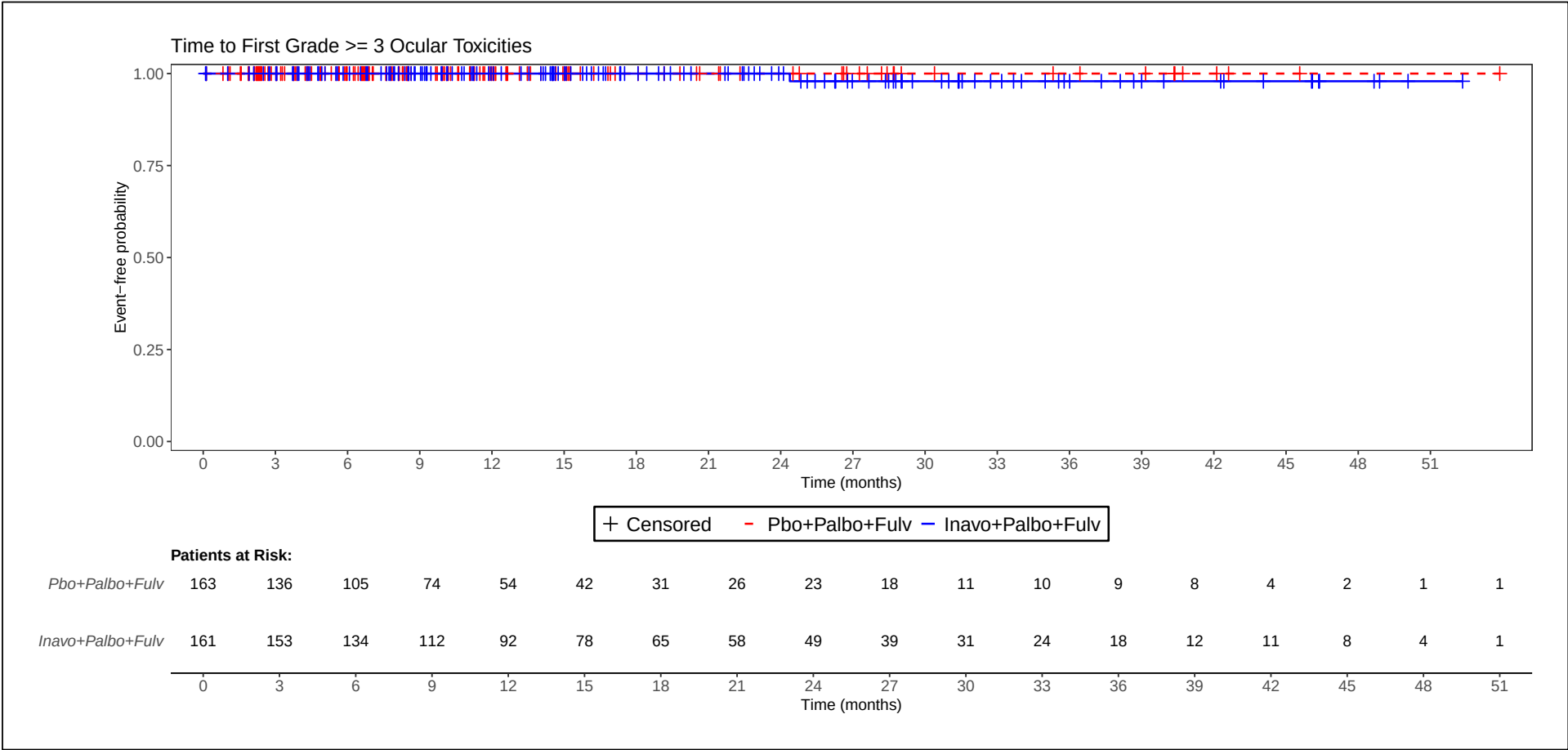
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

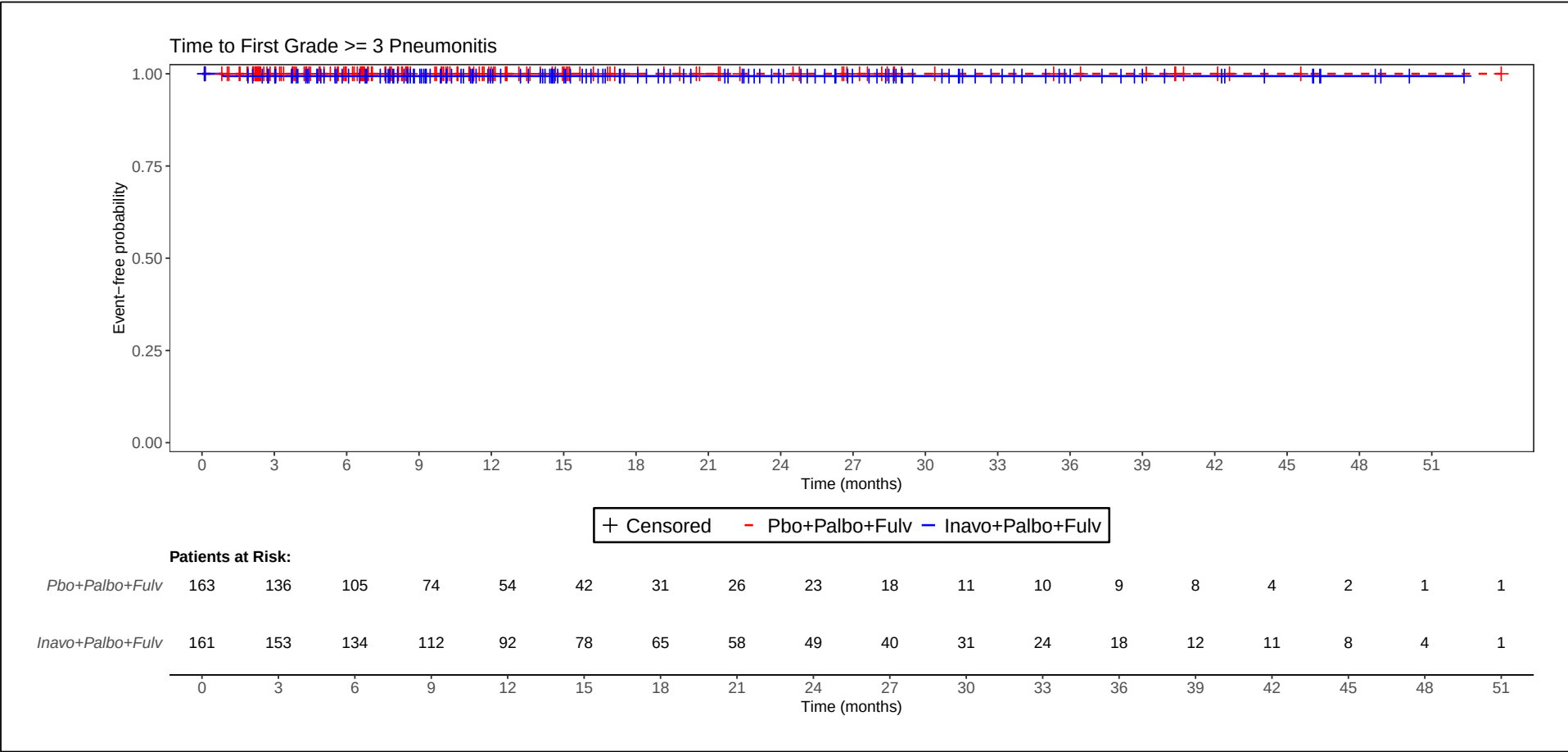
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

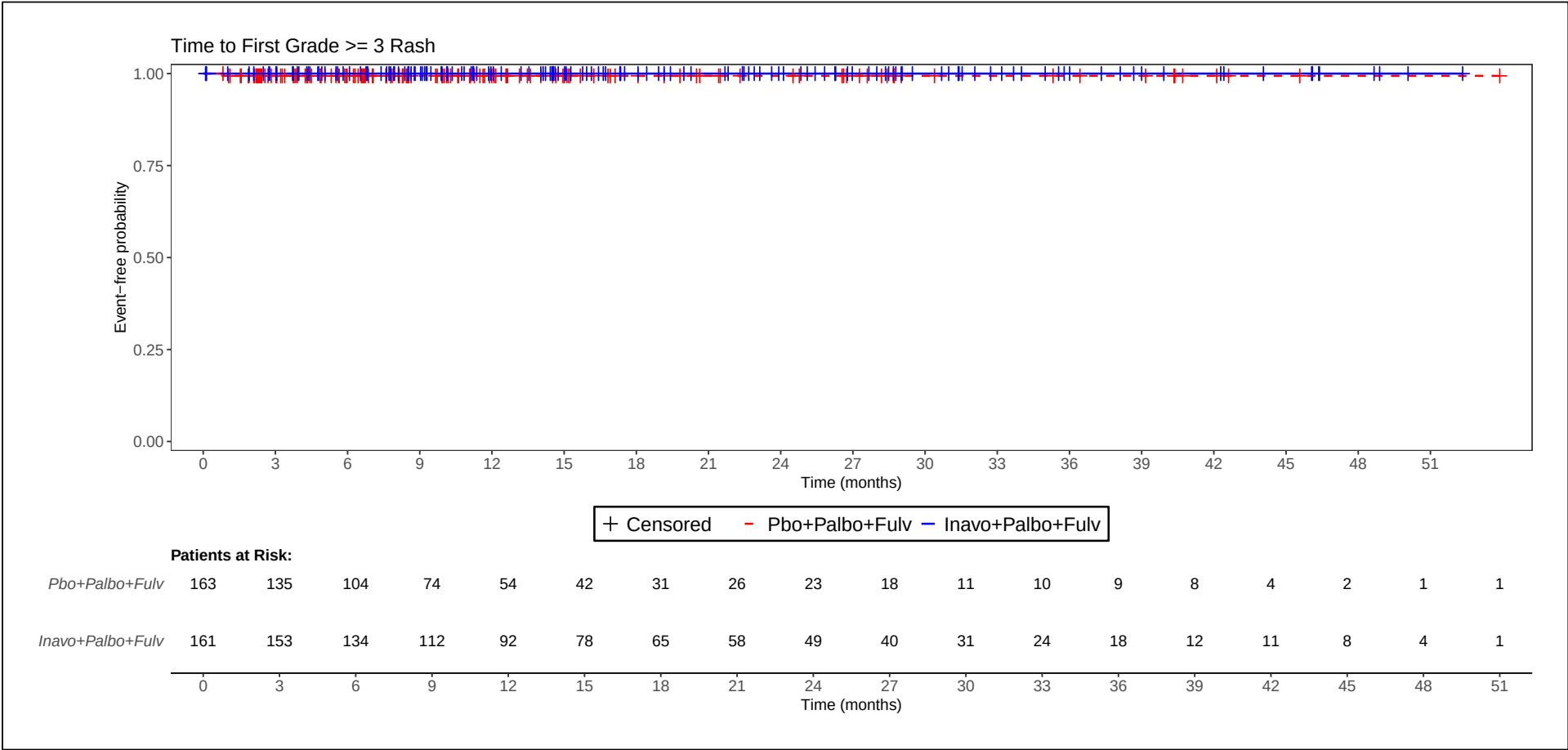
Kaplan Meier Plot for Safety, Selected Adverse Events Grade >= 3, Safety Analysis Set
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

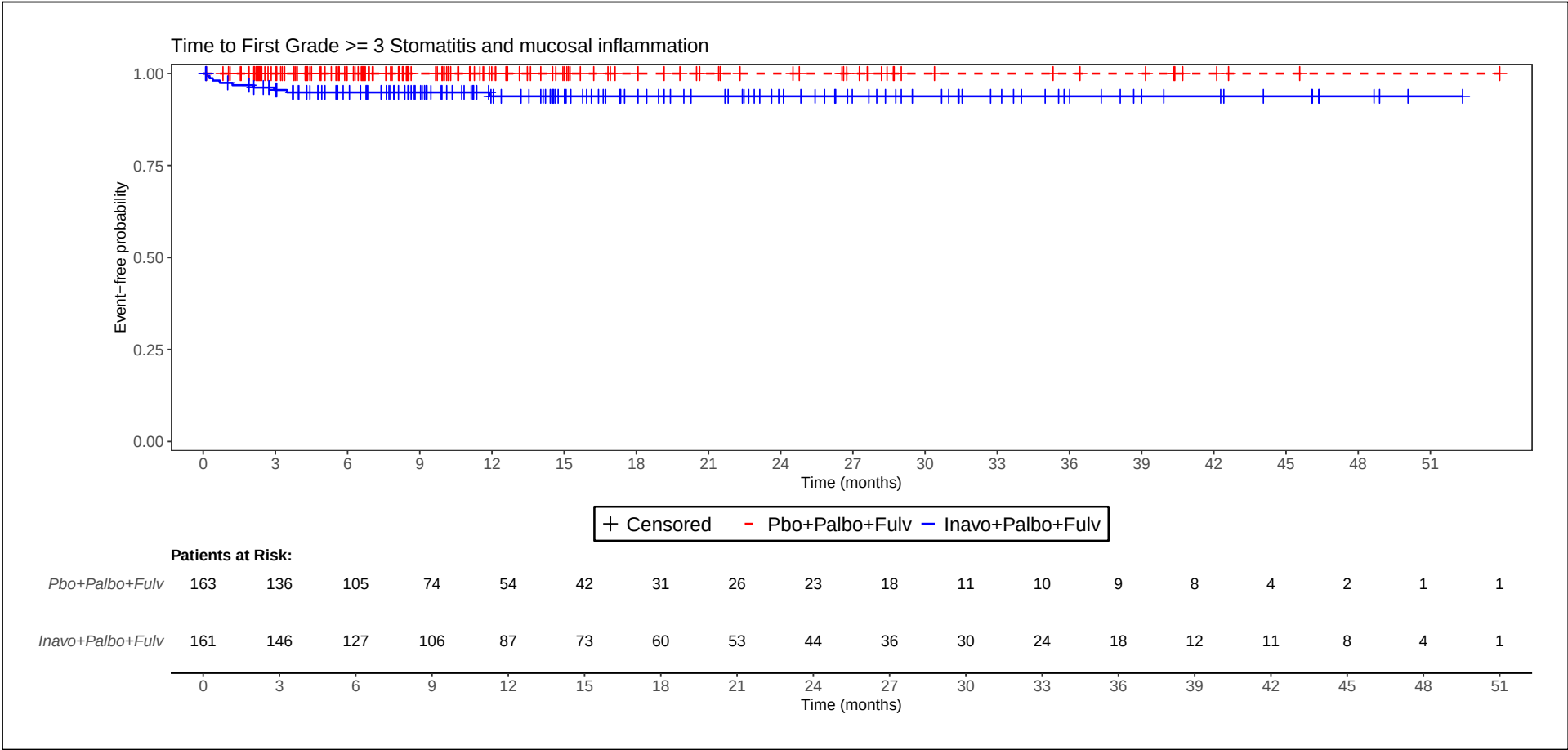
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31 MAR 2025 06:18 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

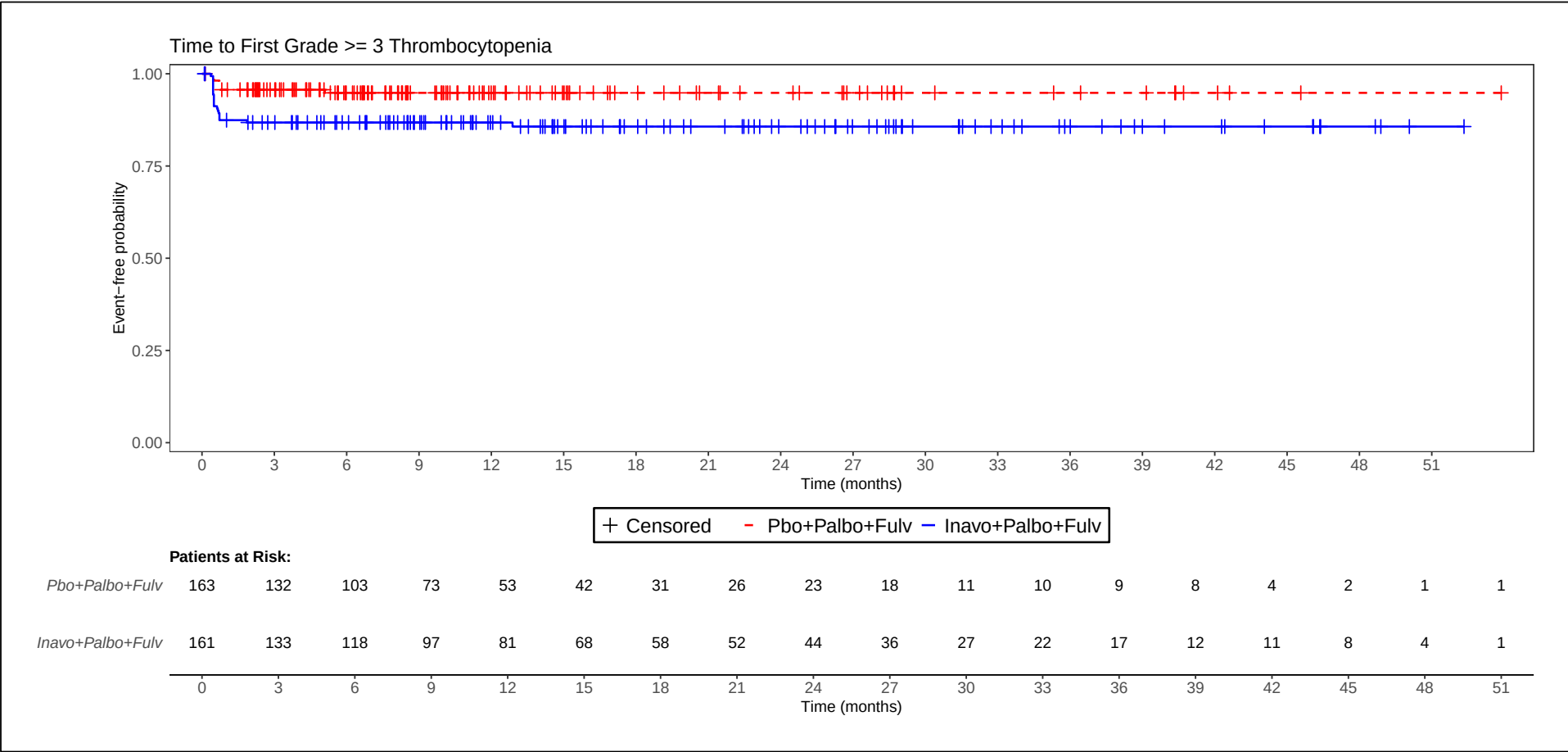
Kaplan Meier Plot for Safety, Selected Adverse Events Grade >= 3, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_GE3SEL_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:18 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

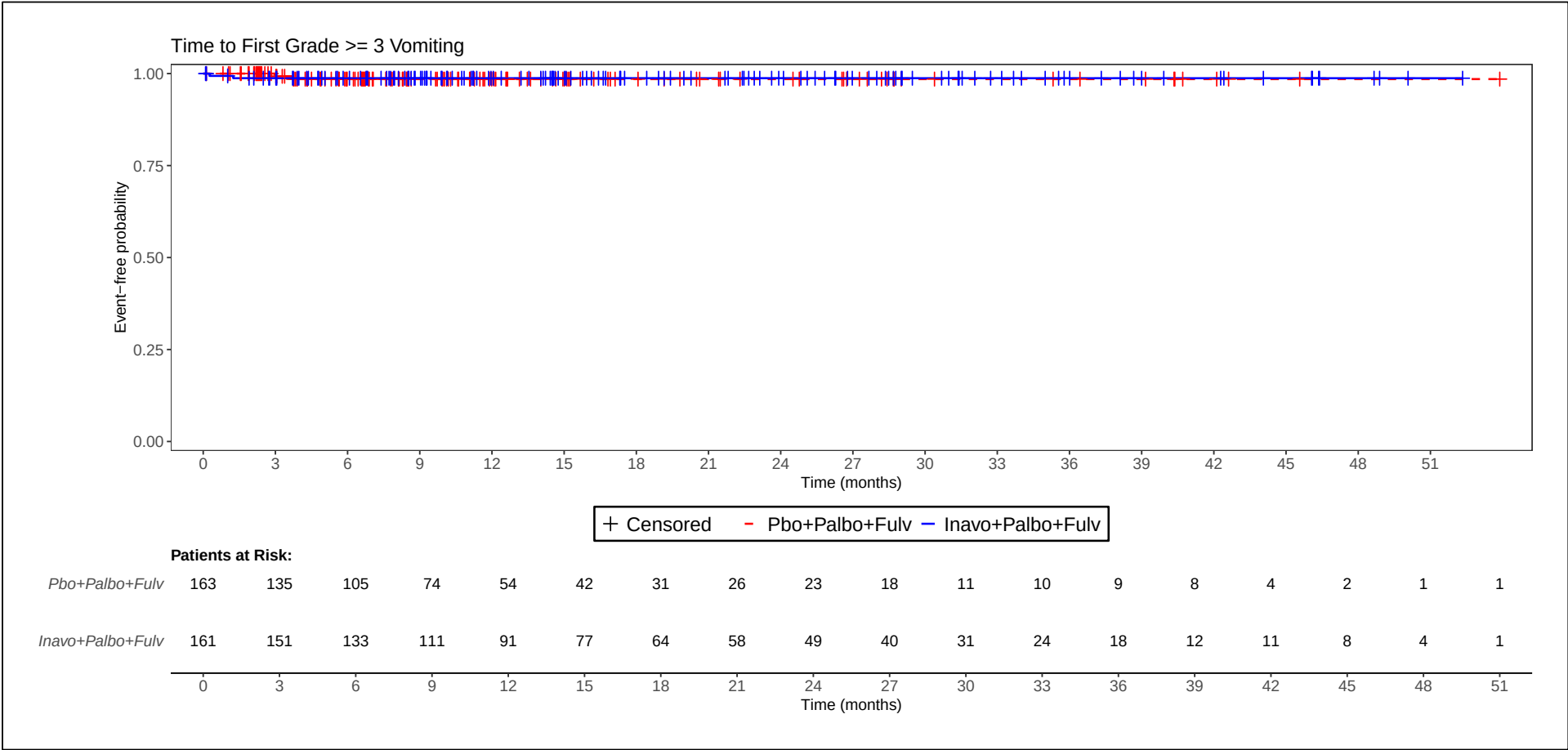
Kaplan Meier Plot for Safety, Selected Adverse Events Grade >= 3, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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31 MAR 2025 06:18 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

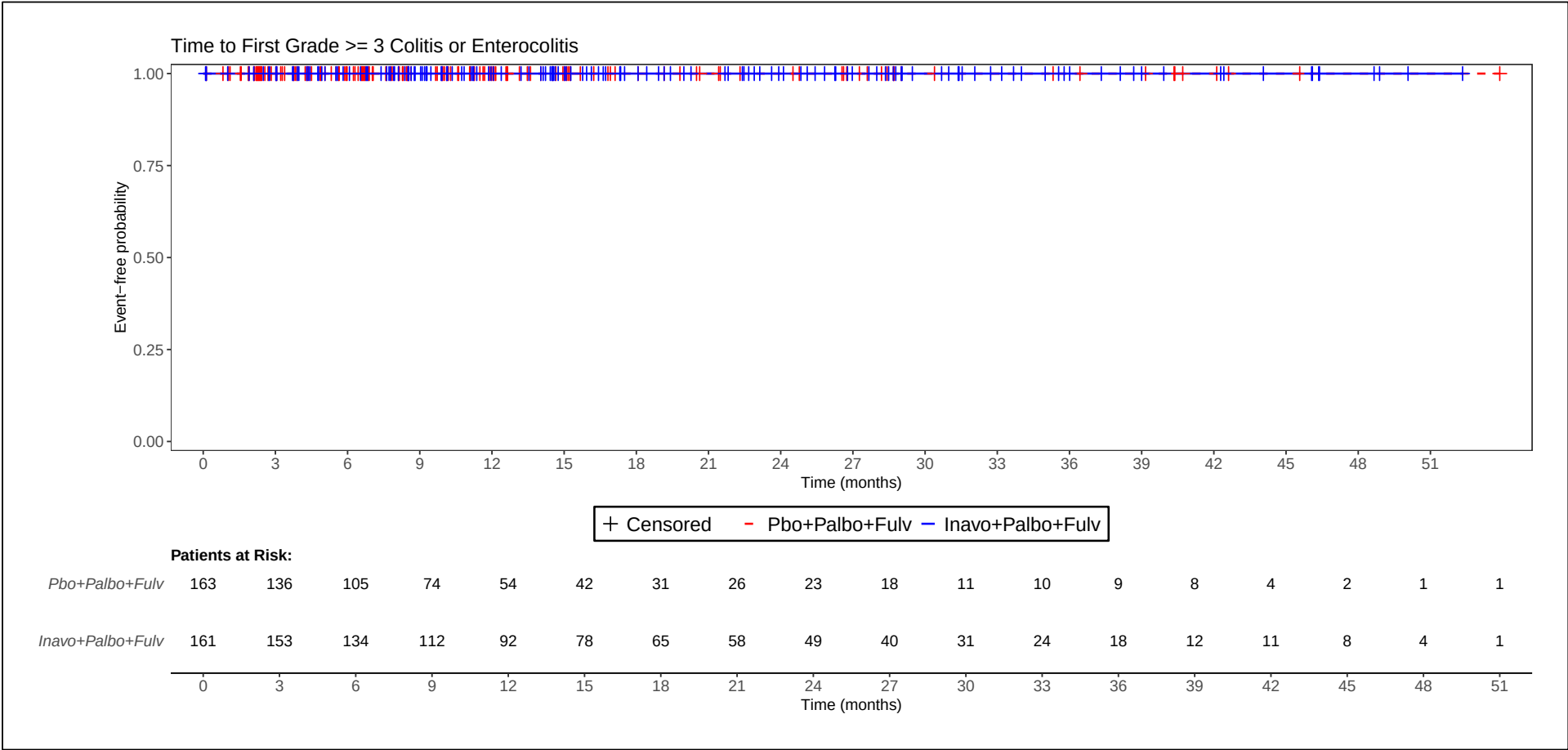
Kaplan Meier Plot for Safety, Selected Adverse Events Grade ≥ 3 , Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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31 MAR 2025 06:18 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Safety, Selected Adverse Events Grade >= 3, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_GE3SEL_SAS_15NOV2024_41554.pdf
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Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:18 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Time to Event Analysis Overall and with Subgroups (Safety), Serious Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Time to First Serious ALT/AST elevation											
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.3143	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2138	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	1	1.7	>999.99	(0.00, >999.99)	0.3051	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3287	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	1	1.0	>999.99	(0.00, >999.99)	0.3035	1.0000
Time to First Serious Anemia											
All Patients	324	163	0	0.0	161	3	1.9	>999.99	(0.00, >999.99)	0.1328	NE
Age group (years)											
<65	266	129	0	0.0	137	3	2.2	>999.99	(0.00, >999.99)	0.1600	0.9999
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	0.9999
Sex											
F	318	162	0	0.0	156	3	1.9	>999.99	(0.00, >999.99)	0.1270	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	2	3.4	>999.99	(0.00, >999.99)	0.2667	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3238	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	2	6.9	>999.99	(0.00, >999.99)	0.1957	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.3326	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6095	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1586	1.0000
Time to First Serious Diarrhea											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.1880	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.3337	1.0000
>=65	58	34	0	0.0	24	1	4.2	>999.99	(0.00, >999.99)	0.2367	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Sex											
F	318	162	0	0.0	156	2	1.3	>999.99	(0.00, >999.99)	0.1821	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3428	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3236	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4198	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	2	1.9	>999.99	(0.00, >999.99)	0.1709	1.0000
Time to First Serious Hyperglycaemia											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Lymphopenia											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Nausea											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Neutropenia											
All Patients	324	163	1	0.6	161	1	0.6	0.47	(0.02, 9.14)	0.6126	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.6374	0.2568
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	0.2568
Sex											
F	318	162	1	0.6	156	1	0.6	0.48	(0.02, 9.33)	0.6198	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	0.2643
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.5637	0.2643
OTHER	78	38	1	2.6	40	0	0.0	<0.01	(0.00, >999.99)	0.3042	0.2643
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	1	0.8	132	1	0.8	0.36	(0.02, 7.90)	0.5099	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	0.54	(0.03, 10.01)	0.6774	1.0000
Time to First Serious Ocular Toxicities											

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
All Patients	324	163	0	0.0	161	1	0.6	>999.99	(0.00, >999.99)	0.4888	NE
Age group (years)											
<65	266	129	0	0.0	137	1	0.7	>999.99	(0.00, >999.99)	0.5371	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.4844	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.5271	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.4979	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.6056	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Pneumonitis											
All Patients	324	163	0	0.0	161	2	1.2	>999.99	(0.00, >999.99)	0.2313	NE
Age group (years)											
<65	266	129	0	0.0	137	2	1.5	>999.99	(0.00, >999.99)	0.2592	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	1	0.6	>999.99	(0.00, >999.99)	0.3081	0.9997
M	6	1	0	0.0	5	1	20.0	>999.99	(0.00, >999.99)	0.6171	0.9997
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.4715	1.0000
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3300	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2568	1.0000
Y	259	127	0	0.0	132	1	0.8	>999.99	(0.00, >999.99)	0.5194	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	1	1.9	>999.99	(0.00, >999.99)	0.3173	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Rash											
All Patients	324	163	1	0.6	161	0	0.0	<0.01	(0.00, >999.99)	0.3203	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	1	2.9	24	0	0.0	<0.01	(0.00, >999.99)	0.4212	1.0000
Sex											
F	318	162	1	0.6	156	0	0.0	<0.01	(0.00, >999.99)	0.3266	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	1	1.6	63	0	0.0	<0.01	(0.00, >999.99)	0.3212	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	1	2.8	29	0	0.0	<0.01	(0.00, >999.99)	0.3778	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	0	0.0	<0.01	(0.00, >999.99)	0.3311	1.0000
Time to First Serious Stomatitis and mucosal inflammation											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000
Time to First Serious Thrombocytopenia											
All Patients	324	163	1	0.6	161	1	0.6	1.01	(0.06, 16.09)	0.9965	NE
Age group (years)											
<65	266	129	1	0.8	137	1	0.7	0.92	(0.06, 14.70)	0.9525	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	1	0.6	156	1	0.6	1.03	(0.06, 16.51)	0.9820	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	1	1.6	58	0	0.0	<0.01	(0.00, >999.99)	0.3295	0.2604
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	0.2604
OTHER	78	38	0	0.0	40	1	2.5	>999.99	(0.00, >999.99)	0.3304	0.2604
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	1	3.4	>999.99	(0.00, >999.99)	0.2482	0.0776
Y	259	127	1	0.8	132	0	0.0	<0.01	(0.00, >999.99)	0.3079	0.0776

Subgroups	Total n	Pbo+Palbo+Fulv			Inavo+Palbo+Fulv			Hazard Ratio	HR 95% Wald CI	p-value (log-rank)	p-value (likelihood ratio)
		n	Events	%	n	Events	%				
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	1	0.9	104	1	1.0	1.05	(0.07, 16.77)	0.9731	1.0000
Time to First Serious Vomiting											
All Patients	324	163	2	1.2	161	2	1.2	0.95	(0.13, 6.76)	0.9596	NE
Age group (years)											
<65	266	129	1	0.8	137	0	0.0	<0.01	(0.00, >999.99)	0.2560	0.1186
>=65	58	34	1	2.9	24	2	8.3	3.23	(0.29, 35.65)	0.3109	0.1186
Sex											
F	318	162	2	1.2	156	2	1.3	0.98	(0.14, 6.93)	0.9804	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	2	3.2	58	1	1.7	0.49	(0.04, 5.40)	0.5517	0.4349
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	1	1.6	>999.99	(0.00, >999.99)	0.3134	0.4349
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	0.4349
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	2	1.6	132	2	1.5	0.88	(0.12, 6.25)	0.8968	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	2	1.8	104	2	1.9	1.00	(0.14, 7.11)	0.9990	1.0000
Time to First Serious Colitis or Enterocolitis											
All Patients	324	163	0	0.0	161	0	0.0	NE	NE	1.0000	NE
Age group (years)											
<65	266	129	0	0.0	137	0	0.0	NE	NE	1.0000	1.0000
>=65	58	34	0	0.0	24	0	0.0	NE	NE	1.0000	1.0000
Sex											
F	318	162	0	0.0	156	0	0.0	NE	NE	1.0000	1.0000
M	6	1	0	0.0	5	0	0.0	NE	NE	1.0000	1.0000
Region											
ASIA	120	62	0	0.0	58	0	0.0	NE	NE	1.0000	1.0000
NORTH AMERICA/WESTERN EUROPE	126	63	0	0.0	63	0	0.0	NE	NE	1.0000	1.0000
OTHER	78	38	0	0.0	40	0	0.0	NE	NE	1.0000	1.0000
Visceral disease (per eCRF)											
N	65	36	0	0.0	29	0	0.0	NE	NE	1.0000	1.0000
Y	259	127	0	0.0	132	0	0.0	NE	NE	1.0000	1.0000
Menopausal Status at Randomization											
NOT POST-MENOPAUSAL	104	52	0	0.0	52	0	0.0	NE	NE	1.0000	1.0000
POST-MENOPAUSAL	214	110	0	0.0	104	0	0.0	NE	NE	1.0000	1.0000

Men are excluded from the subgroups of "Menopausal Status at Randomization"

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_ae_tte.R

Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v6/output/t_ae_tte_SERSEL_SAS_15NOV2024_41554.docx

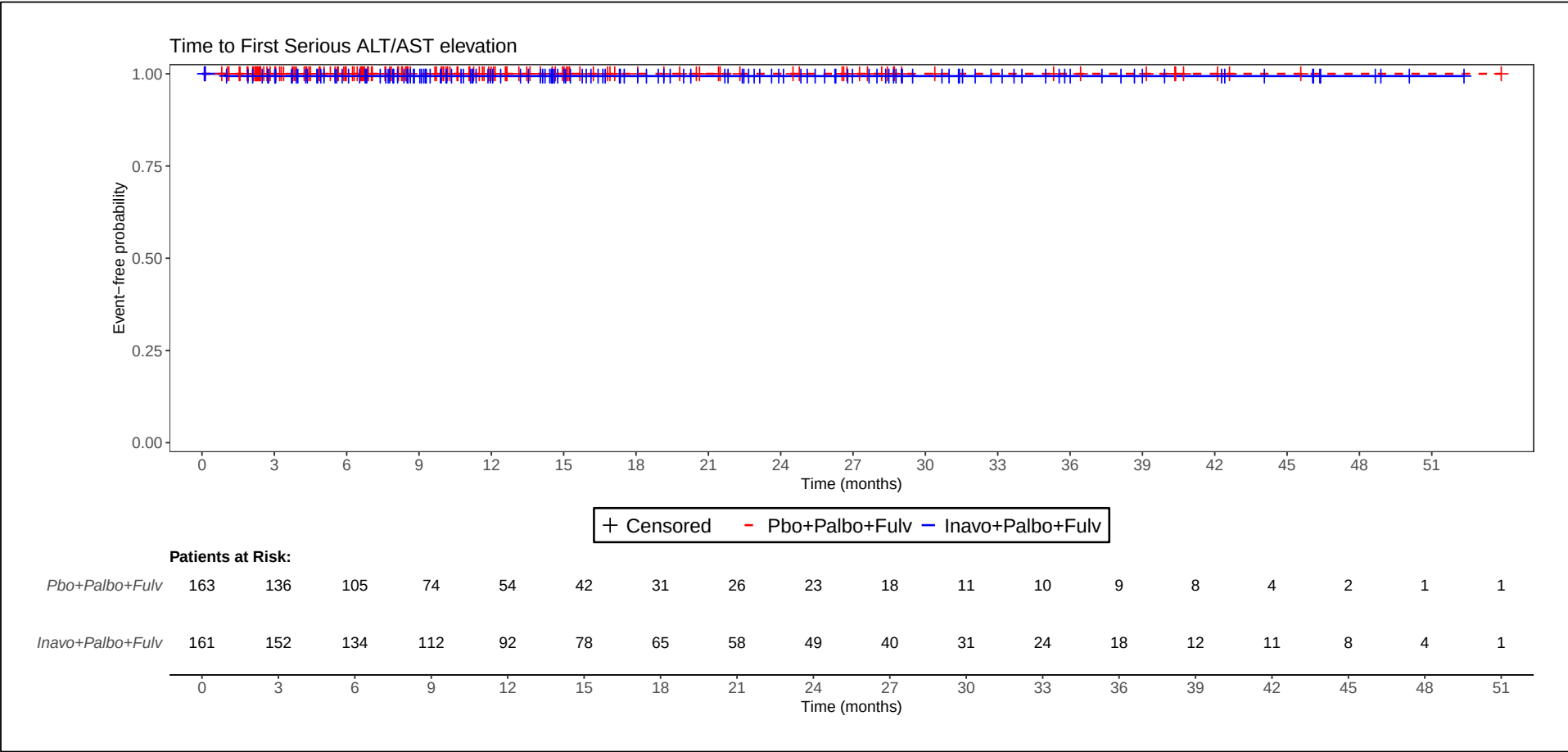
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08 APR 2025 17:33 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

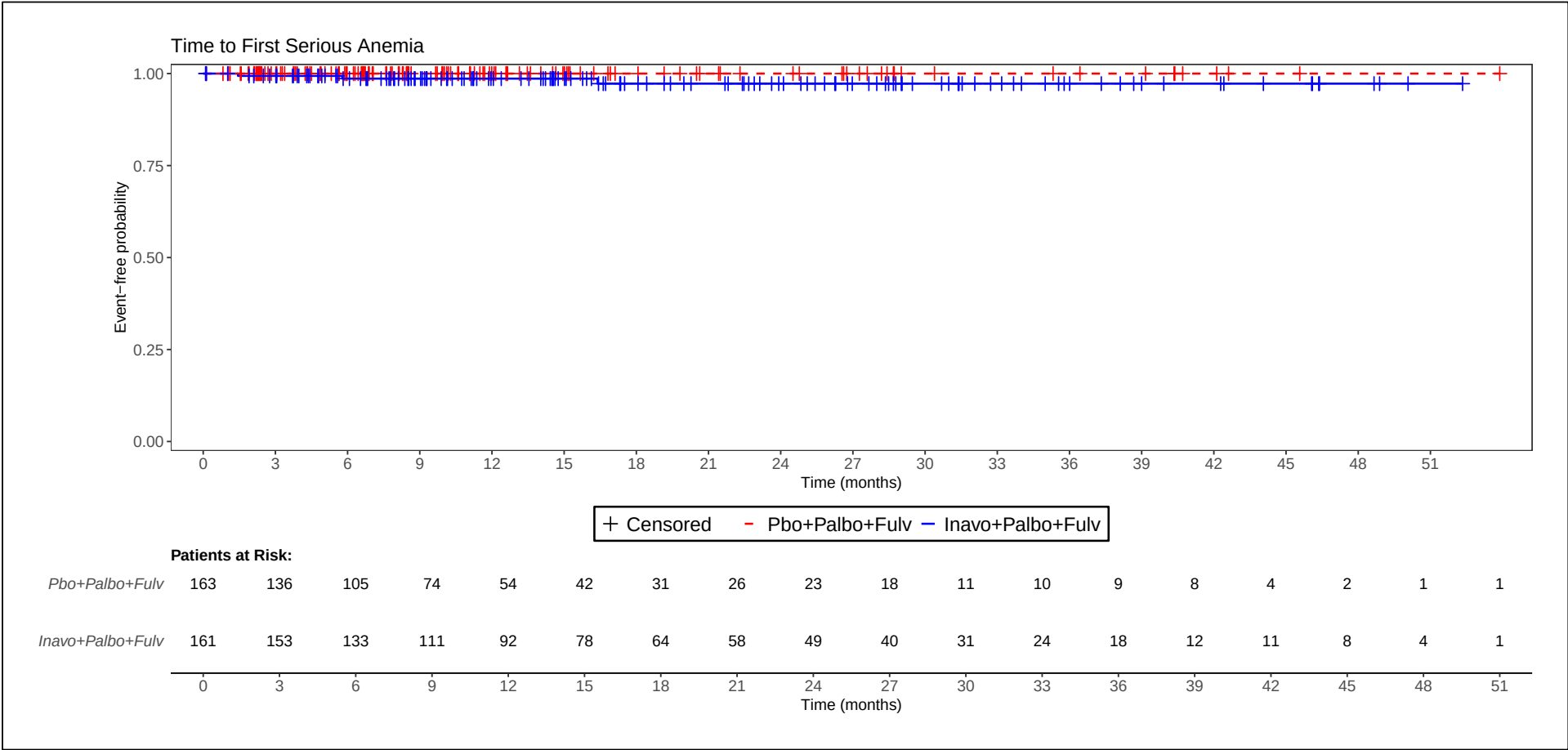
Kaplan Meier Plot for Safety, Serious Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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31 MAR 2025 06:18 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

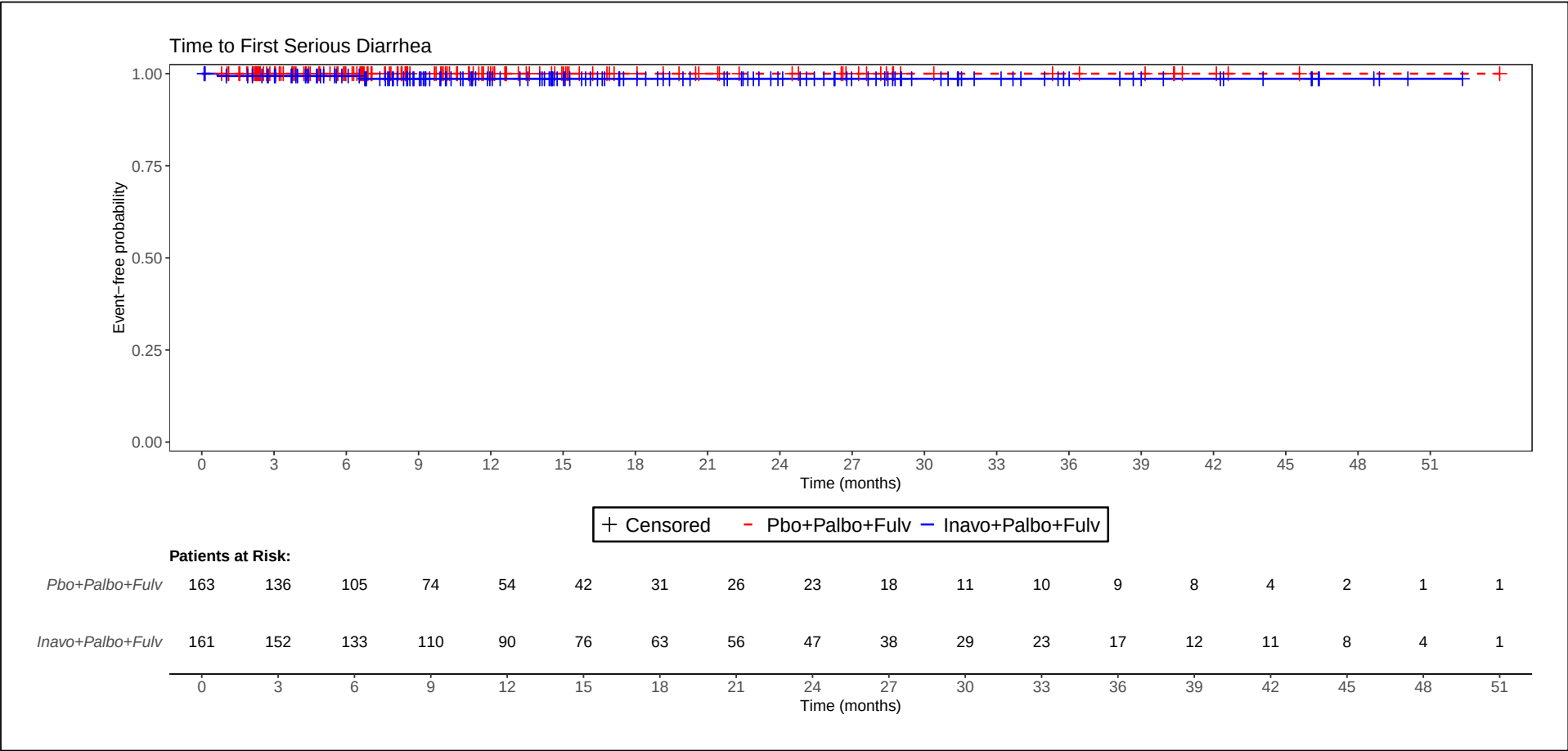
Kaplan Meier Plot for Safety, Serious Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/g_ae_km.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/g_ae_km_SERSEL_SAS_15NOV2024_41554.pdf
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

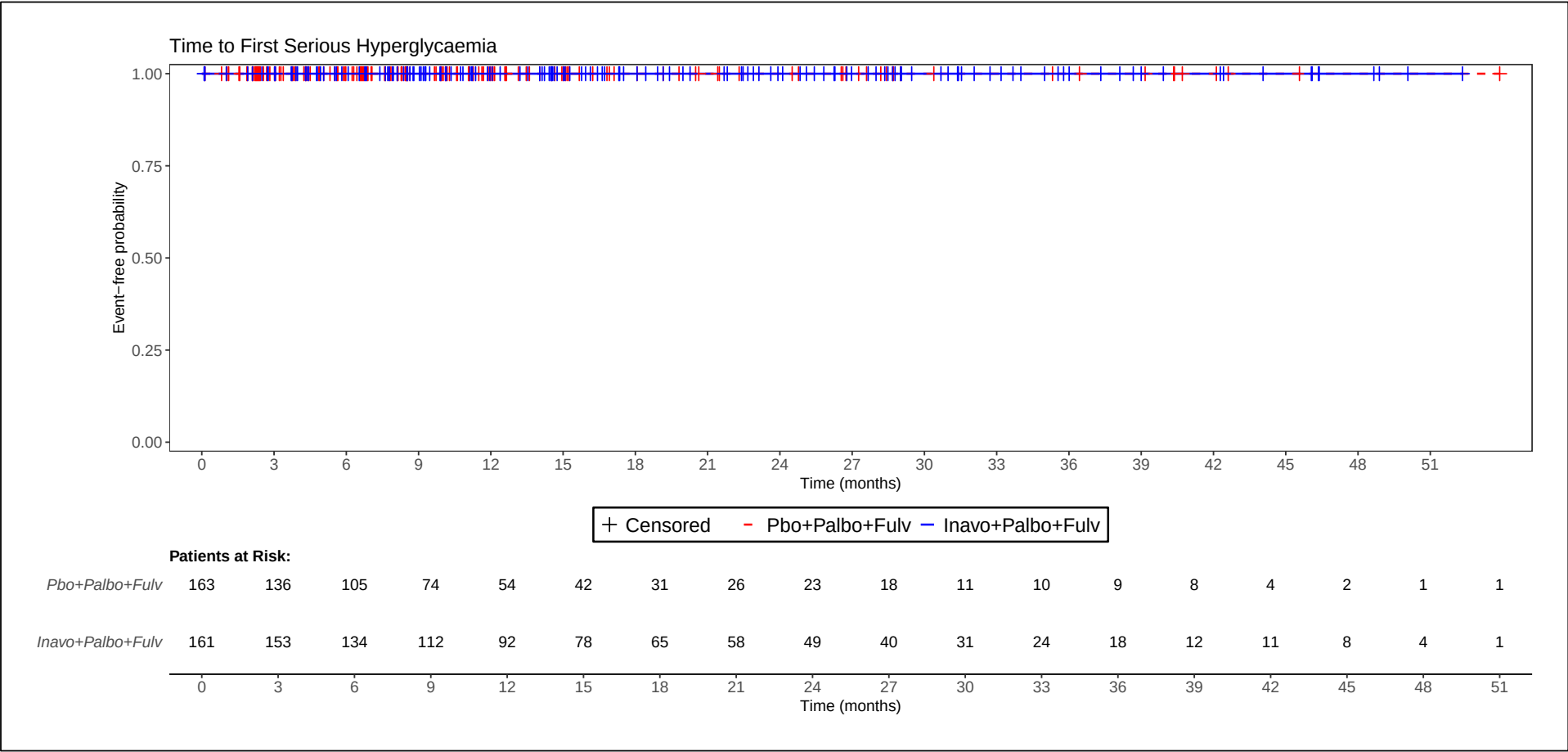
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

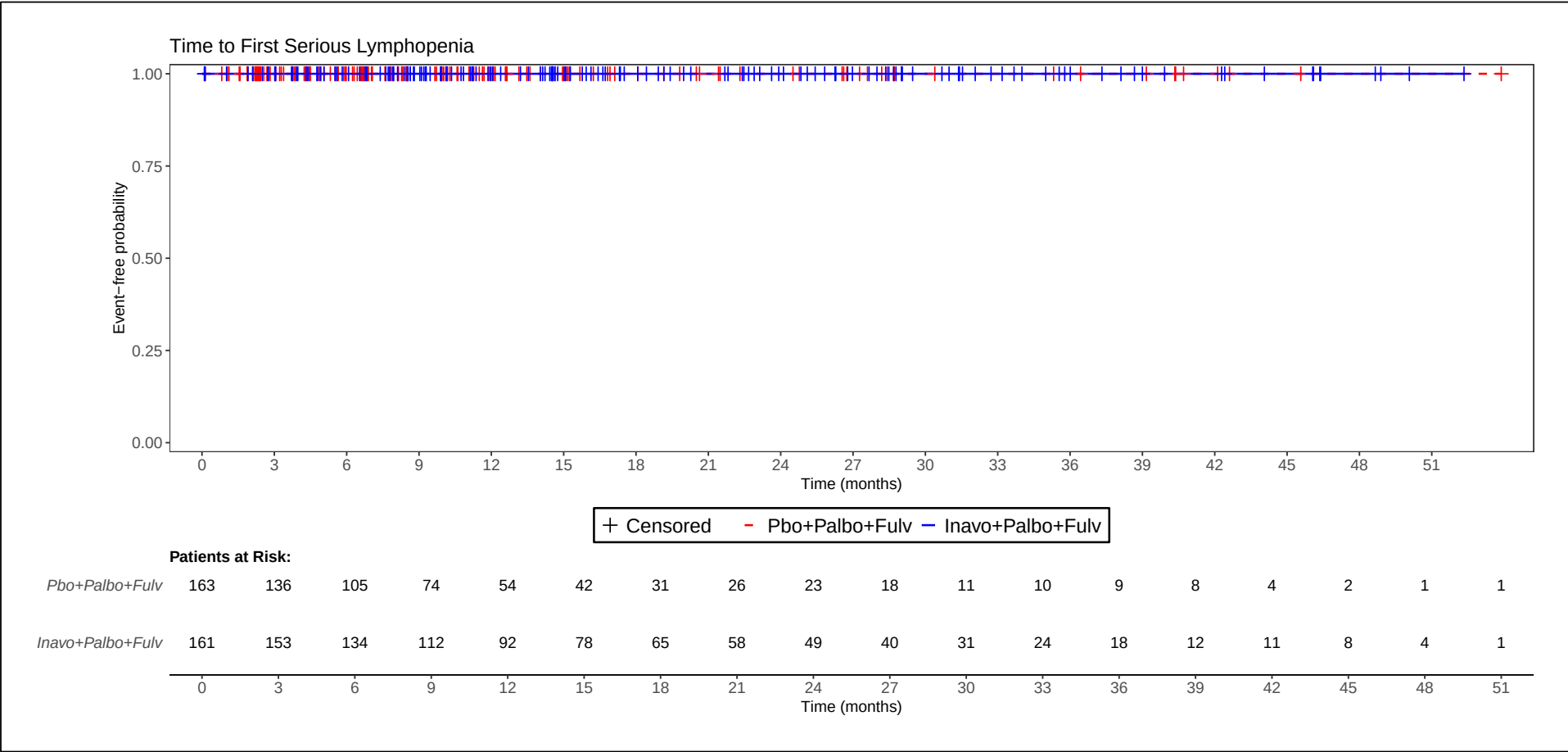
Kaplan Meier Plot for Safety, Serious Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

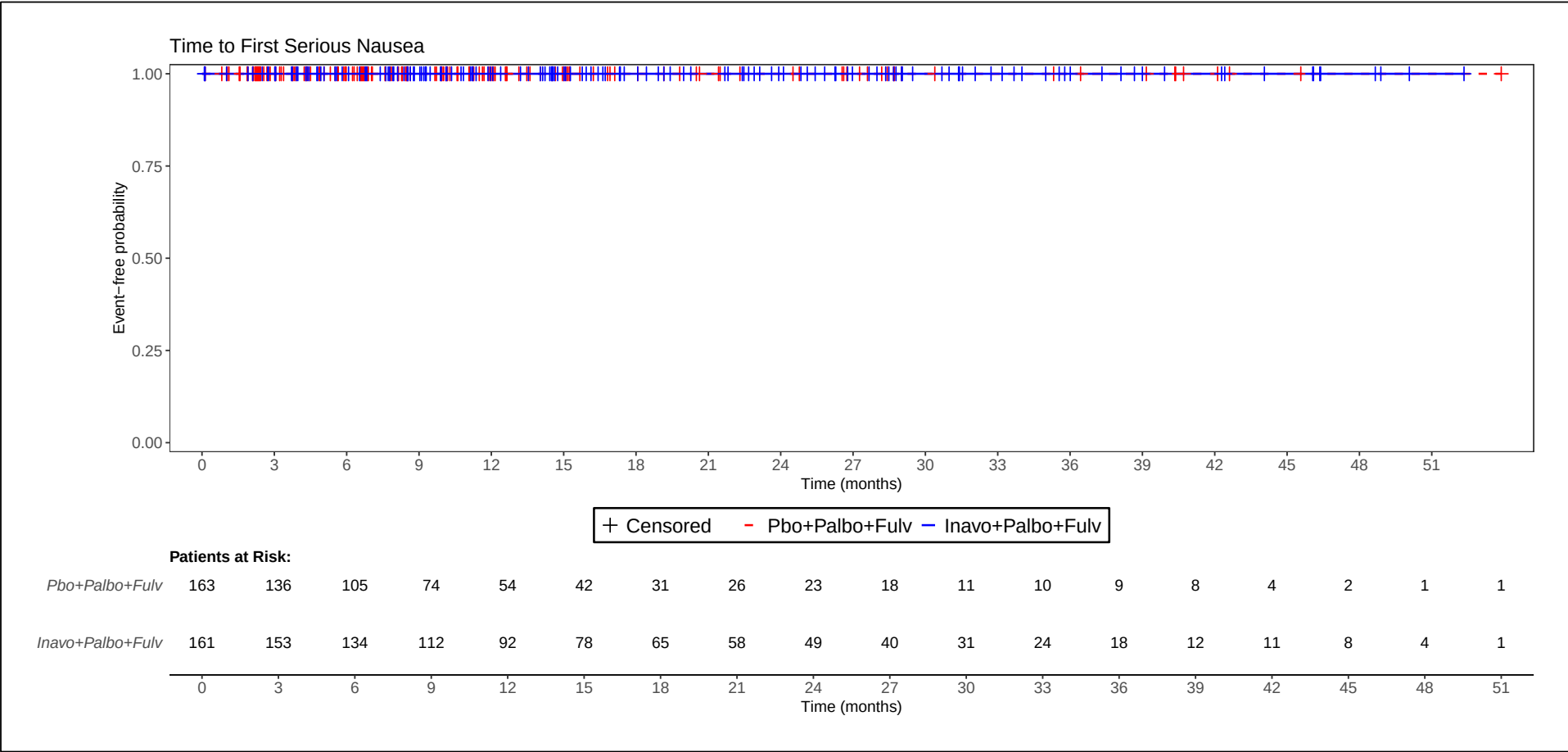
Kaplan Meier Plot for Safety, Serious Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

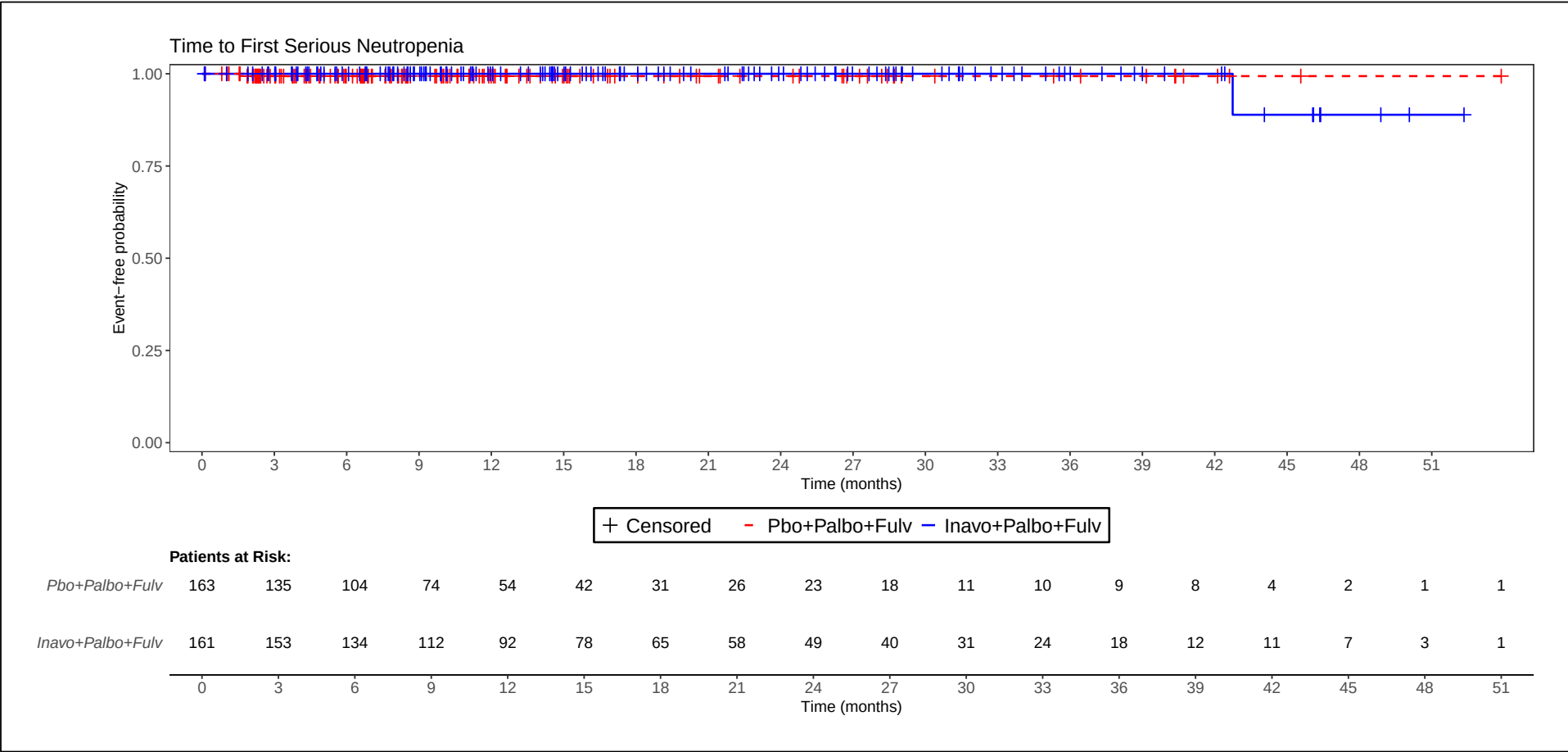
Kaplan Meier Plot for Safety, Serious Selected Adverse Events, Safety Analysis Set
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31 MAR 2025 06:18 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

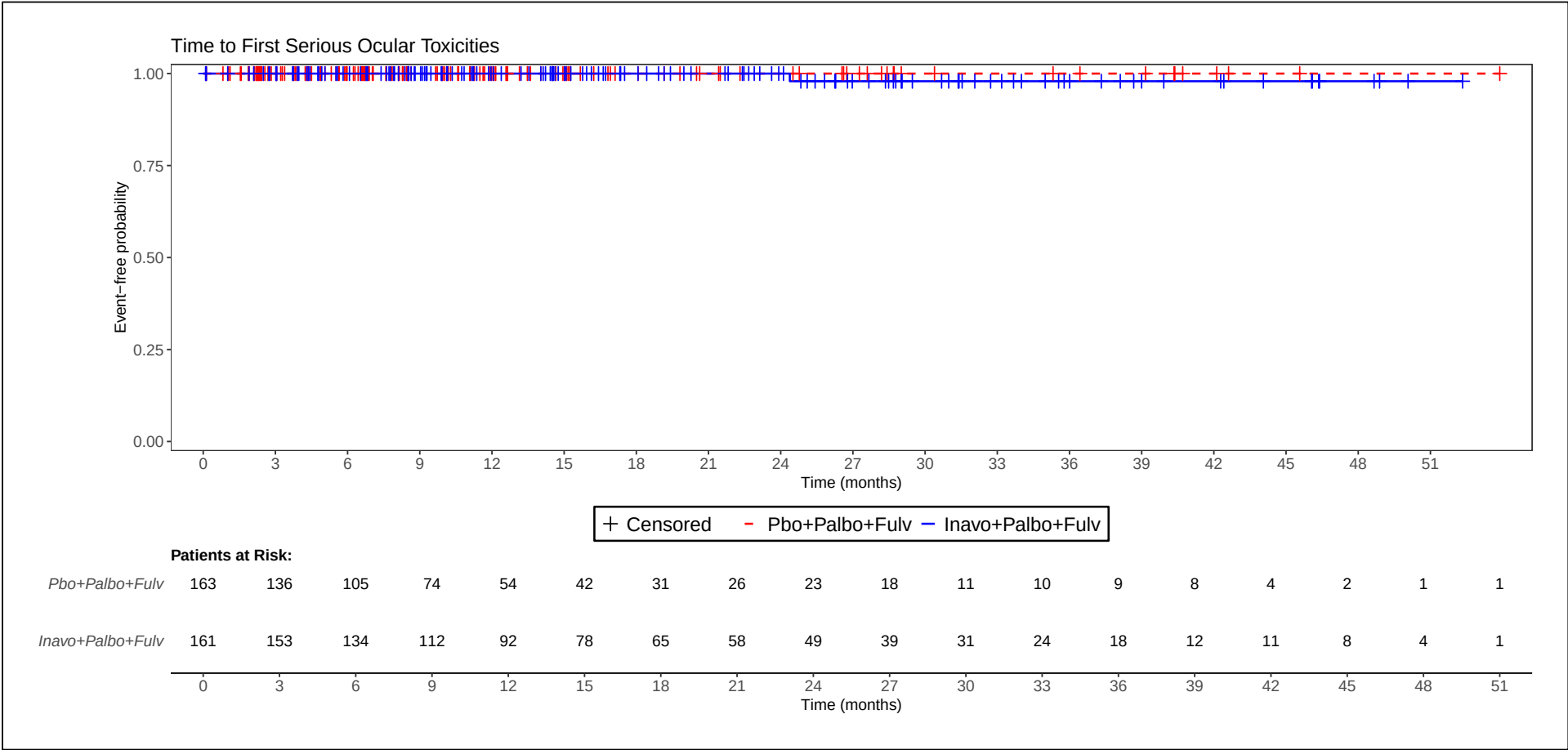
Kaplan Meier Plot for Safety, Serious Selected Adverse Events, Safety Analysis Set
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

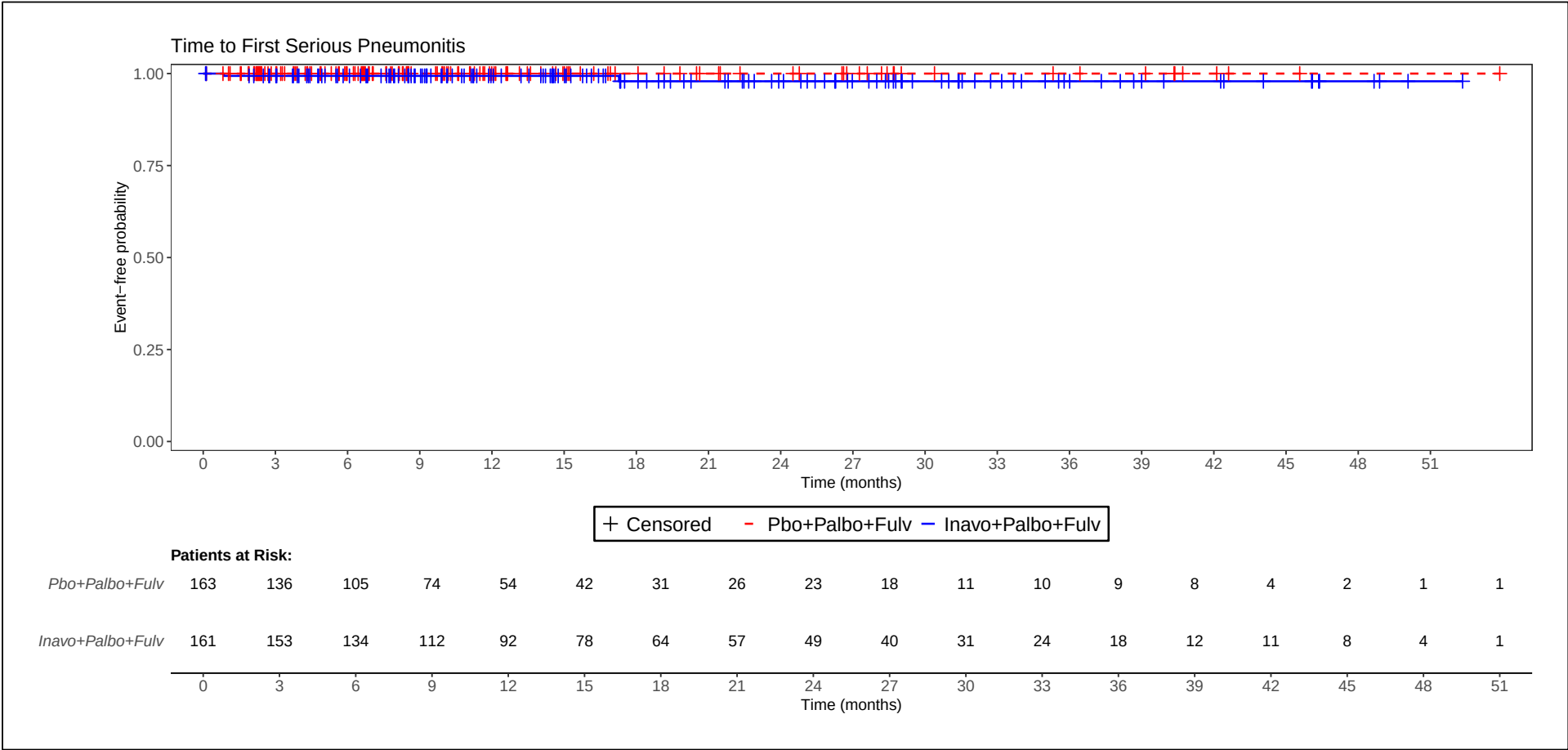
Kaplan Meier Plot for Safety, Serious Selected Adverse Events, Safety Analysis Set
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

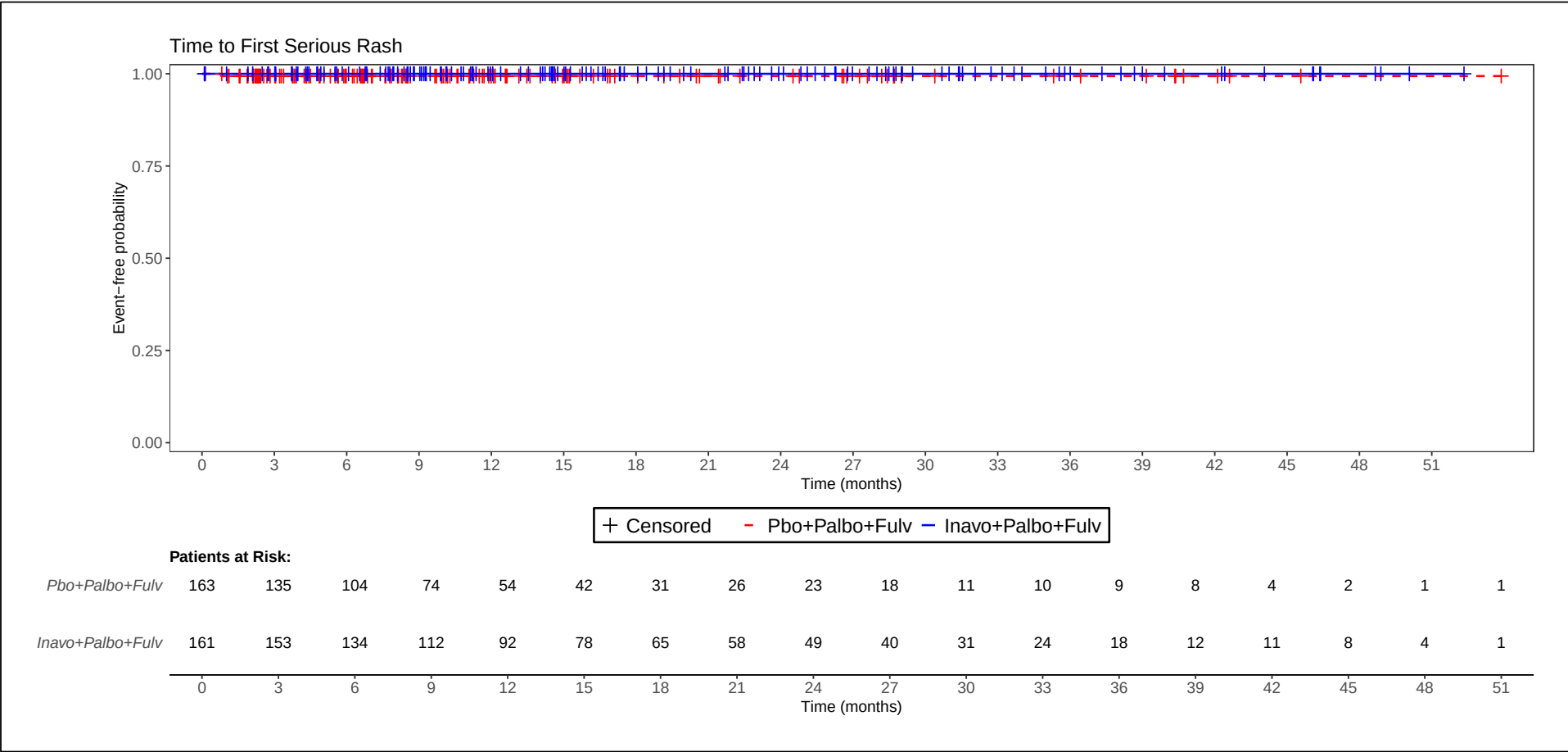
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Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

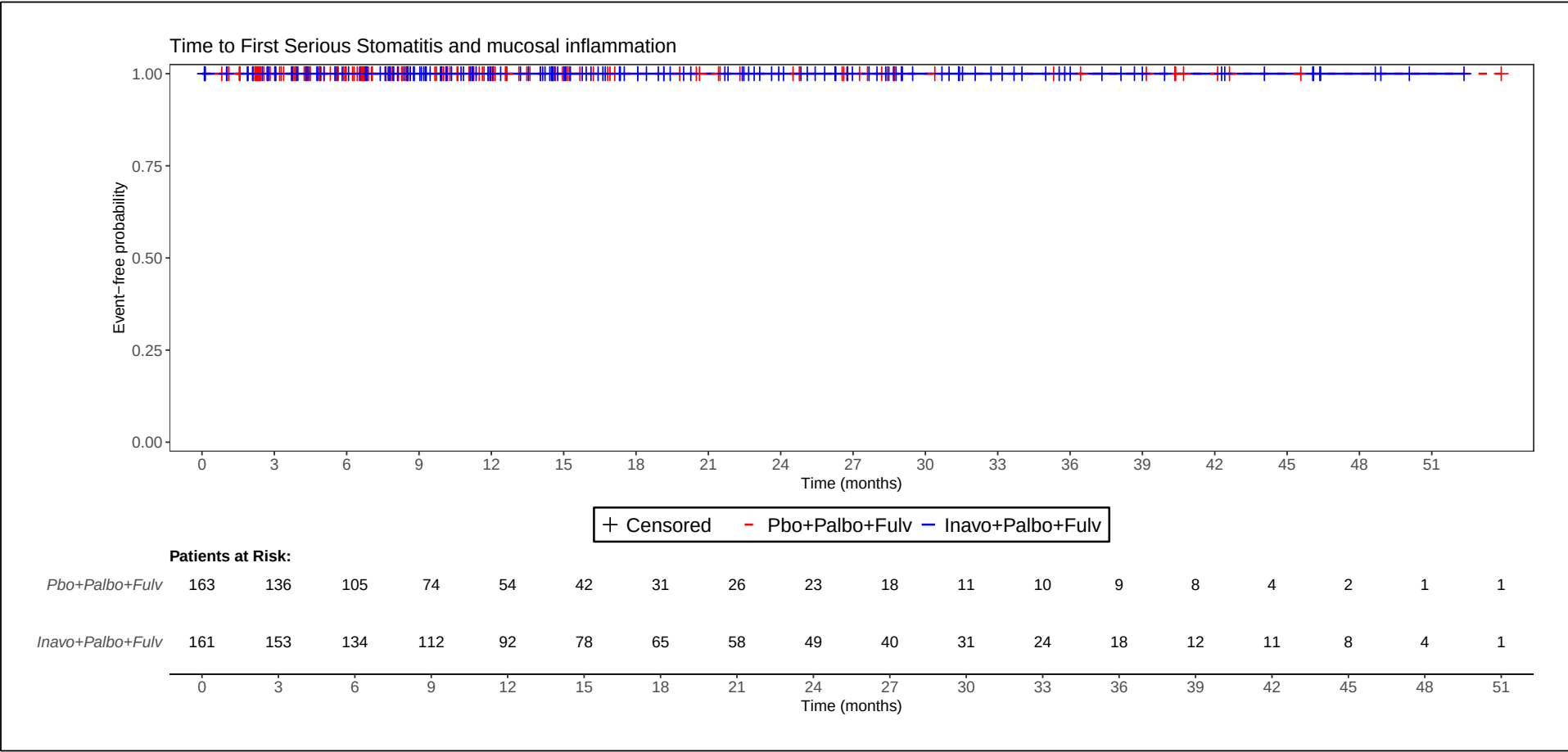
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31 MAR 2025 06:18 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

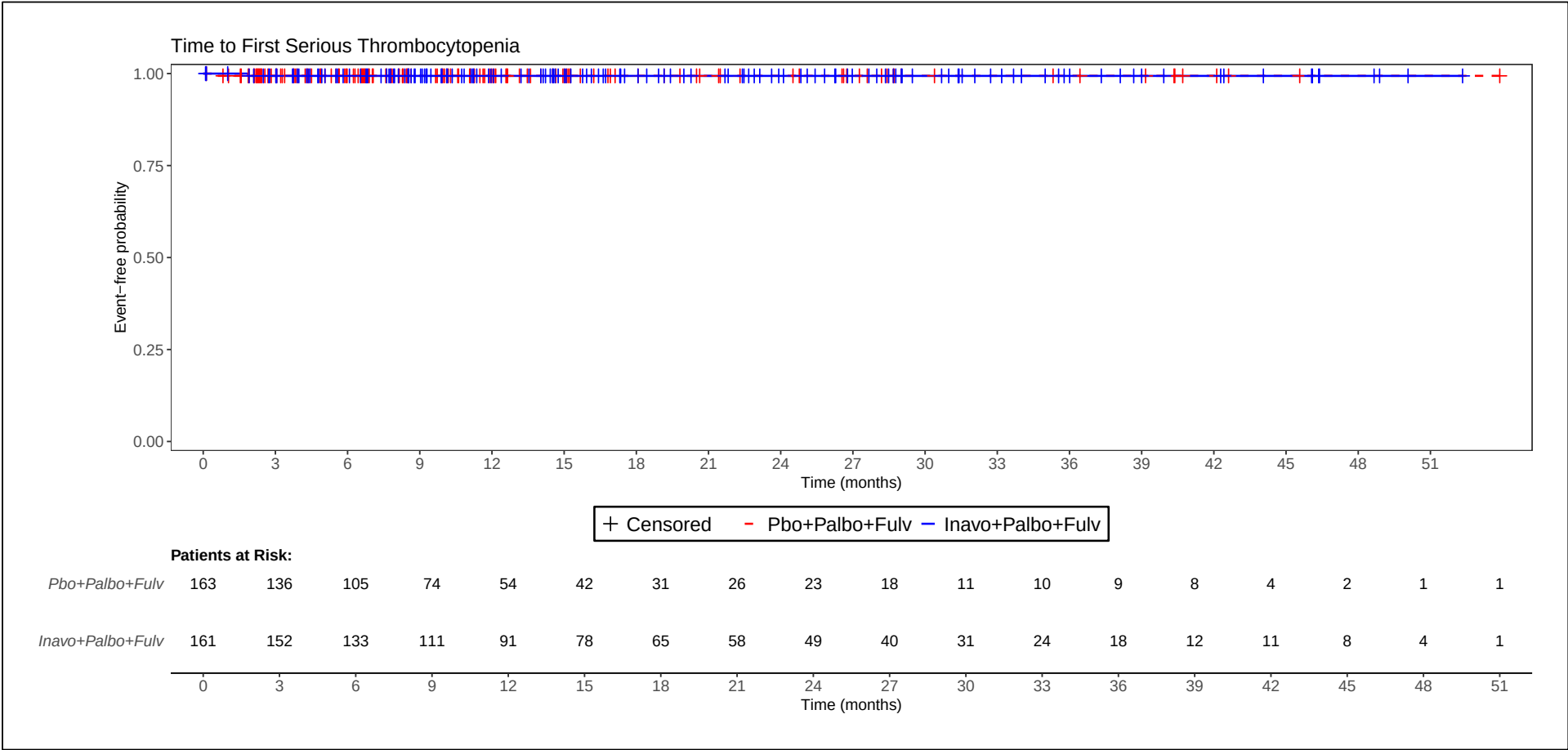
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31 MAR 2025 06:18 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

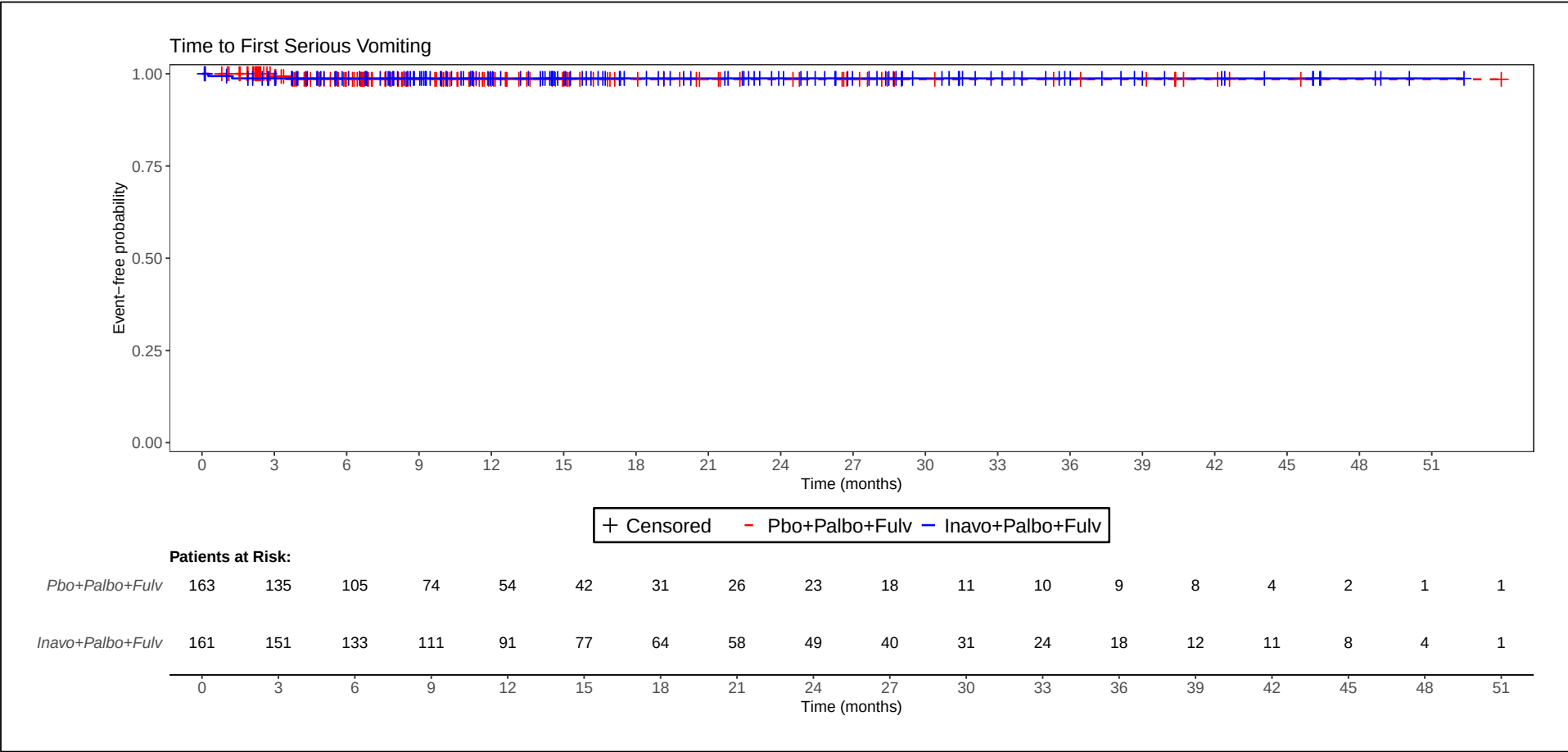
Kaplan Meier Plot for Safety, Serious Selected Adverse Events, Safety Analysis Set
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

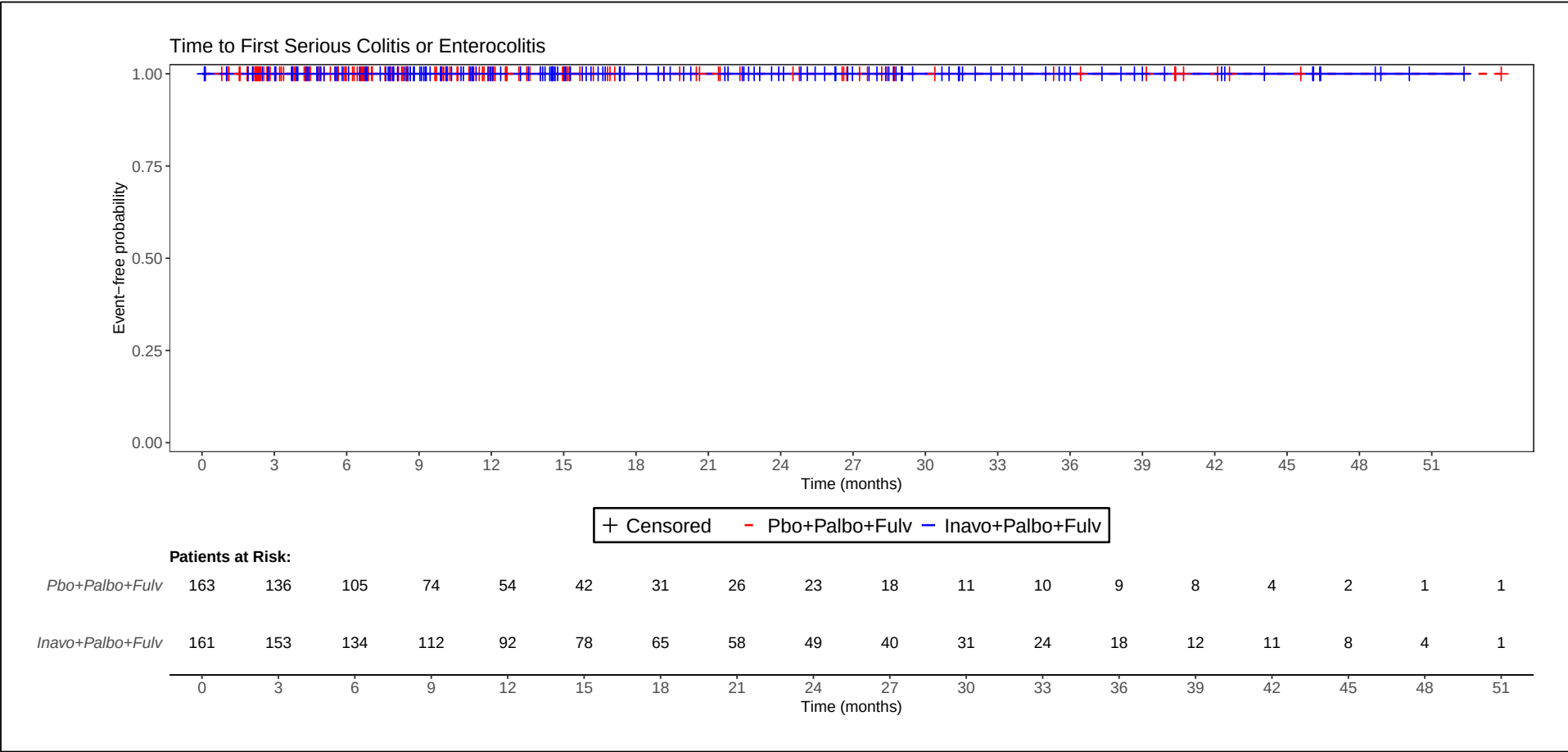
Kaplan Meier Plot for Safety, Serious Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



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Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
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31 MAR 2025 06:18 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Kaplan Meier Plot for Safety, Serious Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025



Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
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31 MAR 2025 06:18 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.2 Spezifische Verträglichkeit

3.2.2 Ausgewählte unerwünschte Ereignisse (selected AE)

3.2.2.3 Outcome ausgewählter UE (selected AE)

Summary of Outcomes of Adverse Events, Selected Adverse Events by Event, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

AE Group			
Outcome of AE			
Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
ALT/AST elevation			
Any Adverse Event			
- Any Grade -	84	81	165
Grade 1	55 (65.5%)	66 (81.5%)	121 (73.3%)
Grade 2	17 (20.2%)	10 (12.3%)	27 (16.4%)
Grade 3	11 (13.1%)	5 (6.2%)	16 (9.7%)
Grade 4	1 (1.2%)	0	1 (0.6%)
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	8	16	24
Grade 1	5 (62.5%)	10 (62.5%)	15 (62.5%)
Grade 2	1 (12.5%)	3 (18.8%)	4 (16.7%)
Grade 3	2 (25%)	3 (18.8%)	5 (20.8%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	76	60	136
Grade 1	50 (65.8%)	51 (85%)	101 (74.3%)
Grade 2	16 (21.1%)	7 (11.7%)	23 (16.9%)
Grade 3	9 (11.8%)	2 (3.3%)	11 (8.1%)
Grade 4	1 (1.3%)	0	1 (0.7%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED WITH SEQUELAE			
- Any Grade -	0	3	3
Grade 1	0	3 (100%)	3 (100%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	0	2	2
Grade 1	0	2 (100%)	2 (100%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Anemia			
Any Adverse Event			
- Any Grade -	129	113	242
Grade 1	78 (60.5%)	81 (71.7%)	159 (65.7%)
Grade 2	36 (27.9%)	29 (25.7%)	65 (26.9%)
Grade 3	15 (11.6%)	3 (2.7%)	18 (7.4%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	23	23	46
Grade 1	6 (26.1%)	9 (39.1%)	15 (32.6%)
Grade 2	12 (52.2%)	12 (52.2%)	24 (52.2%)
Grade 3	5 (21.7%)	2 (8.7%)	7 (15.2%)
Grade 4	0	0	0
Grade 5	0	0	0

AE Group			
Outcome of AE			
Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	98	85	183
Grade 1	69 (70.4%)	68 (80%)	137 (74.9%)
Grade 2	22 (22.4%)	16 (18.8%)	38 (20.8%)
Grade 3	7 (7.1%)	1 (1.2%)	8 (4.4%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED WITH SEQUELAE			
- Any Grade -	0	4	4
Grade 1	0	3 (75%)	3 (75%)
Grade 2	0	1 (25%)	1 (25%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	8	1	9
Grade 1	3 (37.5%)	1 (100%)	4 (44.4%)
Grade 2	2 (25%)	0	2 (22.2%)
Grade 3	3 (37.5%)	0	3 (33.3%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Diarrhea			
Any Adverse Event			
- Any Grade -	175	46	221
Grade 1	116 (66.3%)	38 (82.6%)	154 (69.7%)
Grade 2	51 (29.1%)	8 (17.4%)	59 (26.7%)
Grade 3	8 (4.6%)	0	8 (3.6%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	15	1	16
Grade 1	12 (80%)	1 (100%)	13 (81.2%)
Grade 2	3 (20%)	0	3 (18.8%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	157	45	202
Grade 1	104 (66.2%)	37 (82.2%)	141 (69.8%)
Grade 2	45 (28.7%)	8 (17.8%)	53 (26.2%)
Grade 3	8 (5.1%)	0	8 (4%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	3	0	3
Grade 1	0	0	0
Grade 2	3 (100%)	0	3 (100%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Hyperglycaemia			

AE Group Outcome of AE Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Any Adverse Event			
- Any Grade -	319	121	440
Grade 1	182 (57.1%)	115 (95%)	297 (67.5%)
Grade 2	126 (39.5%)	6 (5%)	132 (30%)
Grade 3	11 (3.4%)	0	11 (2.5%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	23	6	29
Grade 1	6 (26.1%)	4 (66.7%)	10 (34.5%)
Grade 2	14 (60.9%)	2 (33.3%)	16 (55.2%)
Grade 3	3 (13%)	0	3 (10.3%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	280	114	394
Grade 1	170 (60.7%)	110 (96.5%)	280 (71.1%)
Grade 2	104 (37.1%)	4 (3.5%)	108 (27.4%)
Grade 3	6 (2.1%)	0	6 (1.5%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED WITH SEQUELAE			
- Any Grade -	3	0	3
Grade 1	2 (66.7%)	0	2 (66.7%)
Grade 2	1 (33.3%)	0	1 (33.3%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	12	1	13
Grade 1	4 (33.3%)	1 (100%)	5 (38.5%)
Grade 2	6 (50%)	0	6 (46.2%)
Grade 3	2 (16.7%)	0	2 (15.4%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
UNKNOWN			
- Any Grade -	1	0	1
Grade 1	0	0	0
Grade 2	1 (100%)	0	1 (100%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Lymphopenia			
Any Adverse Event			
- Any Grade -	15	24	39
Grade 1	11 (73.3%)	10 (41.7%)	21 (53.8%)
Grade 2	3 (20%)	11 (45.8%)	14 (35.9%)
Grade 3	1 (6.7%)	3 (12.5%)	4 (10.3%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	0	7	7

AE Group Outcome of AE Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade 1	0	3 (42.9%)	3 (42.9%)
Grade 2	0	3 (42.9%)	3 (42.9%)
Grade 3	0	1 (14.3%)	1 (14.3%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	15	16	31
Grade 1	11 (73.3%)	7 (43.8%)	18 (58.1%)
Grade 2	3 (20%)	7 (43.8%)	10 (32.3%)
Grade 3	1 (6.7%)	2 (12.5%)	3 (9.7%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	0	1	1
Grade 1	0	0	0
Grade 2	0	1 (100%)	1 (100%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Nausea			
Any Adverse Event			
- Any Grade -	67	47	114
Grade 1	50 (74.6%)	41 (87.2%)	91 (79.8%)
Grade 2	17 (25.4%)	6 (12.8%)	23 (20.2%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	8	4	12
Grade 1	7 (87.5%)	3 (75%)	10 (83.3%)
Grade 2	1 (12.5%)	1 (25%)	2 (16.7%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	55	40	95
Grade 1	41 (74.5%)	36 (90%)	77 (81.1%)
Grade 2	14 (25.5%)	4 (10%)	18 (18.9%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	3	3	6
Grade 1	2 (66.7%)	2 (66.7%)	4 (66.7%)
Grade 2	1 (33.3%)	1 (33.3%)	2 (33.3%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
UNKNOWN			
- Any Grade -	1	0	1
Grade 1	0	0	0
Grade 2	1 (100%)	0	1 (100%)
Grade 3	0	0	0

AE Group			
Outcome of AE			
Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Neutropenia			
Any Adverse Event			
- Any Grade -	619	497	1116
Grade 1	38 (6.1%)	23 (4.6%)	61 (5.5%)
Grade 2	164 (26.5%)	119 (23.9%)	283 (25.4%)
Grade 3	381 (61.6%)	311 (62.6%)	692 (62%)
Grade 4	36 (5.8%)	44 (8.9%)	80 (7.2%)
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	24	21	45
Grade 1	4 (16.7%)	1 (4.8%)	5 (11.1%)
Grade 2	9 (37.5%)	10 (47.6%)	19 (42.2%)
Grade 3	9 (37.5%)	8 (38.1%)	17 (37.8%)
Grade 4	2 (8.3%)	2 (9.5%)	4 (8.9%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	580	458	1038
Grade 1	31 (5.3%)	19 (4.1%)	50 (4.8%)
Grade 2	149 (25.7%)	103 (22.5%)	252 (24.3%)
Grade 3	367 (63.3%)	295 (64.4%)	662 (63.8%)
Grade 4	33 (5.7%)	41 (9%)	74 (7.1%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED WITH SEQUELAE			
- Any Grade -	7	8	15
Grade 1	3 (42.9%)	1 (12.5%)	4 (26.7%)
Grade 2	0	4 (50%)	4 (26.7%)
Grade 3	3 (42.9%)	3 (37.5%)	6 (40%)
Grade 4	1 (14.3%)	0	1 (6.7%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	8	10	18
Grade 1	0	2 (20%)	2 (11.1%)
Grade 2	6 (75%)	2 (20%)	8 (44.4%)
Grade 3	2 (25%)	5 (50%)	7 (38.9%)
Grade 4	0	1 (10%)	1 (5.6%)
Grade 5	0	0	0
Missing	0	0	0
Ocular Toxicities			
Any Adverse Event			
- Any Grade -	79	38	117
Grade 1	62 (78.5%)	35 (92.1%)	97 (82.9%)
Grade 2	16 (20.3%)	3 (7.9%)	19 (16.2%)
Grade 3	1 (1.3%)	0	1 (0.9%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	30	8	38
Grade 1	22 (73.3%)	8 (100%)	30 (78.9%)
Grade 2	8 (26.7%)	0	8 (21.1%)
Grade 3	0	0	0
Grade 4	0	0	0

AE Group			
Outcome of AE			
Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	44	28	72
Grade 1	35 (79.5%)	25 (89.3%)	60 (83.3%)
Grade 2	8 (18.2%)	3 (10.7%)	11 (15.3%)
Grade 3	1 (2.3%)	0	1 (1.4%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	4	2	6
Grade 1	4 (100%)	2 (100%)	6 (100%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
UNKNOWN			
- Any Grade -	1	0	1
Grade 1	1 (100%)	0	1 (100%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Pneumonitis			
Any Adverse Event			
- Any Grade -	5	2	7
Grade 1	2 (40%)	0	2 (28.6%)
Grade 2	2 (40%)	2 (100%)	4 (57.1%)
Grade 3	1 (20%)	0	1 (14.3%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	1	1	2
Grade 1	0	0	0
Grade 2	0	1 (100%)	1 (50%)
Grade 3	1 (100%)	0	1 (50%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	4	1	5
Grade 1	2 (50%)	0	2 (40%)
Grade 2	2 (50%)	1 (100%)	3 (60%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Rash			
Any Adverse Event			
- Any Grade -	88	47	135
Grade 1	76 (86.4%)	38 (80.9%)	114 (84.4%)
Grade 2	12 (13.6%)	8 (17%)	20 (14.8%)
Grade 3	0	1 (2.1%)	1 (0.7%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0

AE Group Outcome of AE Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	5	2	7
Grade 1	5 (100%)	2 (100%)	7 (100%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	78	45	123
Grade 1	67 (85.9%)	36 (80%)	103 (83.7%)
Grade 2	11 (14.1%)	8 (17.8%)	19 (15.4%)
Grade 3	0	1 (2.2%)	1 (0.8%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED WITH SEQUELAE			
- Any Grade -	1	0	1
Grade 1	0	0	0
Grade 2	1 (100%)	0	1 (100%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	4	0	4
Grade 1	4 (100%)	0	4 (100%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Stomatitis and mucosal inflammation			
Any Adverse Event			
- Any Grade -	194	75	269
Grade 1	139 (71.6%)	60 (80%)	199 (74%)
Grade 2	45 (23.2%)	15 (20%)	60 (22.3%)
Grade 3	10 (5.2%)	0	10 (3.7%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	19	4	23
Grade 1	18 (94.7%)	4 (100%)	22 (95.7%)
Grade 2	1 (5.3%)	0	1 (4.3%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	165	70	235
Grade 1	112 (67.9%)	55 (78.6%)	167 (71.1%)
Grade 2	43 (26.1%)	15 (21.4%)	58 (24.7%)
Grade 3	10 (6.1%)	0	10 (4.3%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED WITH SEQUELAE			

AE Group Outcome of AE Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
- Any Grade -	0	1	1
Grade 1	0	1 (100%)	1 (100%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	9	0	9
Grade 1	8 (88.9%)	0	8 (88.9%)
Grade 2	1 (11.1%)	0	1 (11.1%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
UNKNOWN			
- Any Grade -	1	0	1
Grade 1	1 (100%)	0	1 (100%)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Thrombocytopenia			
Any Adverse Event			
- Any Grade -	227	143	370
Grade 1	132 (58.1%)	104 (72.7%)	236 (63.8%)
Grade 2	62 (27.3%)	31 (21.7%)	93 (25.1%)
Grade 3	28 (12.3%)	7 (4.9%)	35 (9.5%)
Grade 4	5 (2.2%)	1 (0.7%)	6 (1.6%)
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	6	11	17
Grade 1	3 (50%)	7 (63.6%)	10 (58.8%)
Grade 2	1 (16.7%)	3 (27.3%)	4 (23.5%)
Grade 3	1 (16.7%)	0	1 (5.9%)
Grade 4	1 (16.7%)	1 (9.1%)	2 (11.8%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	213	130	343
Grade 1	124 (58.2%)	95 (73.1%)	219 (63.8%)
Grade 2	58 (27.2%)	28 (21.5%)	86 (25.1%)
Grade 3	27 (12.7%)	7 (5.4%)	34 (9.9%)
Grade 4	4 (1.9%)	0	4 (1.2%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED WITH SEQUELAE			
- Any Grade -	4	0	4
Grade 1	2 (50%)	0	2 (50%)
Grade 2	2 (50%)	0	2 (50%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERING/RESOLVING			
- Any Grade -	4	2	6
Grade 1	3 (75%)	2 (100%)	5 (83.3%)

AE Group Outcome of AE Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade 2	1 (25%)	0	1 (16.7%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Vomiting			
Any Adverse Event			
- Any Grade -	55	11	66
Grade 1	42 (76.4%)	6 (54.5%)	48 (72.7%)
Grade 2	10 (18.2%)	3 (27.3%)	13 (19.7%)
Grade 3	3 (5.5%)	2 (18.2%)	5 (7.6%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	3	3	6
Grade 1	2 (66.7%)	0	2 (33.3%)
Grade 2	1 (33.3%)	2 (66.7%)	3 (50%)
Grade 3	0	1 (33.3%)	1 (16.7%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	52	8	60
Grade 1	40 (76.9%)	6 (75%)	46 (76.7%)
Grade 2	9 (17.3%)	1 (12.5%)	10 (16.7%)
Grade 3	3 (5.8%)	1 (12.5%)	4 (6.7%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0

All counts represent events.

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_ae_out.R

Output path:

/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v4/output/t_ae_out_AEELS_SAS_15NOV2024_41554.d

ocx

Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685

Git hash: d20c0145ff6351f556256891b738bb3ba354ec8e

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Summary of Outcomes of Adverse Events, Selected Adverse Events by Event, Serious Adverse Events, Safety Analysis Set

Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

AE Group			
Outcome of AE			
Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
ALT/AST elevation			
Any Adverse Event			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (50%)	0	1 (50%)
Grade 4	1 (50%)	0	1 (50%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (50%)	0	1 (50%)
Grade 4	1 (50%)	0	1 (50%)
Grade 5	0	0	0
Missing	0	0	0
Anemia			
Any Adverse Event			
- Any Grade -	3	0	3
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	3 (100%)	0	3 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	1	0	1
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (100%)	0	1 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (100%)	0	2 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Diarrhea			
Any Adverse Event			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	2 (100%)	0	2 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	0	0	0

AE Group Outcome of AE Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade 3	2 (100%)	0	2 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Neutropenia			
Any Adverse Event			
- Any Grade -	1	1	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (100%)	0	1 (50%)
Grade 4	0	1 (100%)	1 (50%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	1	1	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (100%)	0	1 (50%)
Grade 4	0	1 (100%)	1 (50%)
Grade 5	0	0	0
Missing	0	0	0
Ocular Toxicities			
Any Adverse Event			
- Any Grade -	1	0	1
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (100%)	0	1 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	1	0	1
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (100%)	0	1 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Pneumonitis			
Any Adverse Event			
- Any Grade -	2	0	2
Grade 1	0	0	0
Grade 2	1 (50%)	0	1 (50%)
Grade 3	1 (50%)	0	1 (50%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	1	0	1
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	1 (100%)	0	1 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	1	0	1
Grade 1	0	0	0

AE Group Outcome of AE Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade 2	1 (100%)	0	1 (100%)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Rash			
Any Adverse Event			
- Any Grade -	0	1	1
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (100%)	1 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	0	1	1
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (100%)	1 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
Thrombocytopenia			
Any Adverse Event			
- Any Grade -	2	1	3
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (100%)	1 (33.3%)
Grade 4	2 (100%)	0	2 (66.7%)
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	1	0	1
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	1 (100%)	0	1 (100%)
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	1	1	2
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (100%)	1 (50%)
Grade 4	1 (100%)	0	1 (50%)
Grade 5	0	0	0
Missing	0	0	0
Vomiting			
Any Adverse Event			
- Any Grade -	3	2	5
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	3 (100%)	2 (100%)	5 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
NOT RECOVERED/NOT RESOLVED			
- Any Grade -	0	1	1

AE Group Outcome of AE Grade	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (100%)	1 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0
RECOVERED/RESOLVED			
- Any Grade -	3	1	4
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	3 (100%)	1 (100%)	4 (100%)
Grade 4	0	0	0
Grade 5	0	0	0
Missing	0	0	0

All counts represent events.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_out.R
Output path:
/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v4/output/t_ae_out_AESELS_SER_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: d20c0145ff6351f556256891b738bb3ba354ec8e
01 APR 2025 20:57 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

3 Verträglichkeit

3.2 Spezifische Verträglichkeit

3.2.2 Ausgewählte unerwünschte Ereignisse (selected AE)

3.2.2.4 Zeit bis zum erstmaligen Auftreten ausgewählter unerwünschter Ereignisse (UE)

Time to Onset of First Occurrence of Selected Adverse Events, Key Selected Adverse Events, Safety Analysis Set

Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Time to First Diarrhea			
n	84	26	110
Mean (SD)	111.6 (199.7)	93.4 (139.1)	107.3 (186.8)
Median	18.0	31.0	22.0
Min - Max	2.0 - 951.0	3.0 - 519.0	2.0 - 951.0
Time to First Hyperglycaemia			
n	102	22	124
Mean (SD)	77.2 (177.3)	191.1 (347.5)	97.4 (219.9)
Median	8.0	38.5	8.0
Min - Max	2.0 - 955.0	2.0 - 1282.0	2.0 - 1282.0
Time to First Nausea			
n	47	32	79
Mean (SD)	118.1 (202.9)	168.3 (225.2)	138.4 (212.3)
Median	16.0	73.0	40.0
Min - Max	1.0 - 743.0	1.0 - 921.0	1.0 - 921.0
Time to First Ocular Toxicities			
n	47	26	73
Mean (SD)	154.4 (187.8)	152.8 (114.3)	153.9 (164.5)
Median	91.0	145.5	132.0
Min - Max	1.0 - 832.0	10.0 - 456.0	1.0 - 832.0
Time to First Rash			
n	43	32	75
Mean (SD)	124.1 (213.2)	64.6 (113.4)	98.7 (179.1)
Median	29.0	22.0	26.0
Min - Max	1.0 - 952.0	9.0 - 470.0	1.0 - 952.0
Time to First Stomatitis and mucosal inflammation			
n	89	47	136
Mean (SD)	54.3 (120.2)	62.5 (150.1)	57.2 (130.8)
Median	14.0	21.0	15.0
Min - Max	1.0 - 610.0	3.0 - 1012.0	1.0 - 1012.0
Time to First Thrombocytopenia			
n	80	75	155
Mean (SD)	37.7 (90.4)	42.0 (76.3)	39.8 (83.6)
Median	15.5	22.0	21.0
Min - Max	11.0 - 687.0	4.0 - 382.0	4.0 - 687.0
Time to First Vomiting			
n	26	10	36
Mean (SD)	99.0 (125.7)	203.1 (246.7)	127.9 (170.8)
Median	39.0	133.5	70.0
Min - Max	1.0 - 535.0	15.0 - 856.0	1.0 - 856.0

Investigator text for AEs is coded using MedDRA version 27.1.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_ae_onset2.R
Output path:
/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v7/output/t_ae_onset2_KAESEL_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: b6027dbd949ffd3bd010747913d30fe0e2c66bc9
14 APR 2025 06:17 GMT

Rate of Onset of Selected Adverse Events, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Selected Adverse Event Month	Inavo+Palbo+Fulv (N=161)			Pbo+Palbo+Fulv (N=163)		
	Number of AEs	Patients Month	Rate	Number of AEs	Patients Month	Rate
Diarrhea						
1	64	159.1	0.40	14	161.6	0.09
2	15	155.4	0.10	4	156.0	0.03
3	17	149.4	0.11	4	131.6	0.03
4	9	144.1	0.06	1	122.5	0.01
5	8	137.2	0.06	1	111.8	0.01
6	4	131.8	0.03	1	104.5	0.01
7	10	126.9	0.08	2	91.0	0.02
8	4	121.2	0.03	3	83.3	0.04
9	5	112.0	0.04	1	73.1	0.01
10	8	102.6	0.08	0	0.0	NE
11	3	97.2	0.03	3	58.7	0.05
12	4	91.0	0.04	2	53.5	0.04
13	1	86.7	0.01	0	0.0	NE
14	2	84.3	0.02	1	44.3	0.02
15	1	78.9	0.01	1	42.4	0.02
16	2	72.2	0.03	0	0.0	NE
17	2	68.9	0.03	1	32.4	0.03
18	2	65.4	0.03	1	30.0	0.03
19	2	62.5	0.03	1	28.7	0.03
20	1	59.7	0.02	0	0.0	NE
21	1	57.7	0.02	0	0.0	NE
22	0	0.0	NE	0	0.0	NE
23	2	51.5	0.04	1	23.0	0.04
24	1	47.8	0.02	0	0.0	NE
25	0	0.0	NE	0	0.0	NE
26	1	45.0	0.02	0	0.0	NE
27	0	0.0	NE	0	0.0	NE
28	0	0.0	NE	1	15.0	0.07
29	0	0.0	NE	0	0.0	NE
30	1	30.5	0.03	0	0.0	NE
31	0	0.0	NE	0	0.0	NE
32	3	25.4	0.12	0	0.0	NE
33	0	0.0	NE	0	0.0	NE
34	1	21.9	0.05	0	0.0	NE
35	0	0.0	NE	0	0.0	NE
36	0	0.0	NE	1	9.3	0.11
37	0	0.0	NE	0	0.0	NE
38	0	0.0	NE	0	0.0	NE
39	0	0.0	NE	0	0.0	NE
40	0	0.0	NE	1	6.2	0.16
41	0	0.0	NE	1	4.7	0.21
42	0	0.0	NE	0	0.0	NE
43	0	0.0	NE	0	0.0	NE
44	0	0.0	NE	0	0.0	NE
45	1	8.1	0.12	0	0.0	NE
46	0	0.0	NE	0	0.0	NE
47	0	0.0	NE	0	0.0	NE
48	0	0.0	NE	0	0.0	NE
49	0	0.0	NE	0	0.0	NE
Hyperglycaemia						
1	95	159.1	0.60	20	161.6	0.12
2	43	155.4	0.28	14	156.0	0.09
3	13	149.4	0.09	14	131.6	0.11
4	6	144.1	0.04	9	122.5	0.07
5	14	137.2	0.10	12	111.8	0.11
6	8	131.8	0.06	12	104.5	0.11

Selected Adverse Event Month	Inavo+Palbo+Fulv (N=161)			Pbo+Palbo+Fulv (N=163)		
	Number of AEs	Patients Month	Rate	Number of AEs	Patients Month	Rate
7	6	126.9	0.05	8	91.0	0.09
8	8	121.2	0.07	7	83.3	0.08
9	4	112.0	0.04	4	73.1	0.05
10	3	102.6	0.03	5	67.6	0.07
11	4	97.2	0.04	6	58.7	0.10
12	4	91.0	0.04	3	53.5	0.06
13	6	86.7	0.07	0	0.0	NE
14	4	84.3	0.05	0	0.0	NE
15	4	78.9	0.05	0	0.0	NE
16	8	72.2	0.11	1	35.7	0.03
17	3	68.9	0.04	0	0.0	NE
18	7	65.4	0.11	0	0.0	NE
19	3	62.5	0.05	0	0.0	NE
20	4	59.7	0.07	0	0.0	NE
21	6	57.7	0.10	0	0.0	NE
22	5	54.3	0.09	0	0.0	NE
23	5	51.5	0.10	1	23.0	0.04
24	5	47.8	0.10	0	0.0	NE
25	5	46.8	0.11	0	0.0	NE
26	6	45.0	0.13	0	0.0	NE
27	3	41.1	0.07	0	0.0	NE
28	4	36.7	0.11	0	0.0	NE
29	1	34.4	0.03	0	0.0	NE
30	6	30.5	0.20	0	0.0	NE
31	1	28.5	0.04	0	0.0	NE
32	3	25.4	0.12	1	10.0	0.10
33	1	24.6	0.04	0	0.0	NE
34	1	21.9	0.05	0	0.0	NE
35	2	21.0	0.10	0	0.0	NE
36	2	18.5	0.11	0	0.0	NE
37	1	16.0	0.06	1	8.4	0.12
38	1	15.3	0.07	0	0.0	NE
39	1	14.3	0.07	1	7.0	0.14
40	2	11.9	0.17	0	0.0	NE
41	2	11.0	0.18	1	4.7	0.21
42	2	11.0	0.18	0	0.0	NE
43	2	9.5	0.21	1	2.7	0.37
44	1	9.0	0.11	0	0.0	NE
45	3	8.1	0.37	0	0.0	NE
46	0	0.0	NE	0	0.0	NE
47	0	0.0	NE	0	0.0	NE
48	0	0.0	NE	0	0.0	NE
49	0	0.0	NE	0	0.0	NE
Nausea						
1	30	159.1	0.19	11	161.6	0.07
2	6	155.4	0.04	7	156.0	0.04
3	2	149.4	0.01	3	131.6	0.02
4	3	144.1	0.02	1	122.5	0.01
5	5	137.2	0.04	0	0.0	NE
6	1	131.8	0.01	2	104.5	0.02
7	3	126.9	0.02	6	91.0	0.07
8	2	121.2	0.02	2	83.3	0.02
9	0	0.0	NE	1	73.1	0.01
10	1	102.6	0.01	4	67.6	0.06
11	1	97.2	0.01	1	58.7	0.02
12	1	91.0	0.01	0	0.0	NE
13	0	0.0	NE	1	46.5	0.02
14	1	84.3	0.01	1	44.3	0.02
15	0	0.0	NE	0	0.0	NE

Selected Adverse Event Month	Inavo+Palbo+Fulv (N=161)			Pbo+Palbo+Fulv (N=163)		
	Number of AEs	Patients Month	Rate	Number of AEs	Patients Month	Rate
16	2	72.2	0.03	0	0.0	NE
17	1	68.9	0.01	0	0.0	NE
18	0	0.0	NE	2	30.0	0.07
19	1	62.5	0.02	1	28.7	0.03
20	1	59.7	0.02	0	0.0	NE
21	1	57.7	0.02	0	0.0	NE
22	0	0.0	NE	0	0.0	NE
23	1	51.5	0.02	0	0.0	NE
24	0	0.0	NE	0	0.0	NE
25	1	46.8	0.02	0	0.0	NE
26	0	0.0	NE	0	0.0	NE
27	1	41.1	0.02	1	17.9	0.06
28	0	0.0	NE	0	0.0	NE
29	0	0.0	NE	1	11.8	0.09
30	0	0.0	NE	0	0.0	NE
31	0	0.0	NE	1	10.2	0.10
32	0	0.0	NE	1	10.0	0.10
33	0	0.0	NE	0	0.0	NE
34	1	21.9	0.05	0	0.0	NE
35	0	0.0	NE	0	0.0	NE
36	0	0.0	NE	0	0.0	NE
37	0	0.0	NE	0	0.0	NE
38	0	0.0	NE	0	0.0	NE
39	0	0.0	NE	0	0.0	NE
40	0	0.0	NE	0	0.0	NE
41	0	0.0	NE	0	0.0	NE
42	0	0.0	NE	0	0.0	NE
43	1	9.5	0.11	0	0.0	NE
44	0	0.0	NE	0	0.0	NE
45	0	0.0	NE	0	0.0	NE
46	0	0.0	NE	0	0.0	NE
47	0	0.0	NE	0	0.0	NE
48	0	0.0	NE	0	0.0	NE
49	0	0.0	NE	0	0.0	NE
Ocular Toxicities						
1	19	159.1	0.12	4	161.6	0.02
2	9	155.4	0.06	3	156.0	0.02
3	6	149.4	0.04	3	131.6	0.02
4	2	144.1	0.01	4	122.5	0.03
5	9	137.2	0.07	6	111.8	0.05
6	6	131.8	0.05	4	104.5	0.04
7	2	126.9	0.02	1	91.0	0.01
8	3	121.2	0.02	0	0.0	NE
9	5	112.0	0.04	2	73.1	0.03
10	1	102.6	0.01	0	0.0	NE
11	1	97.2	0.01	7	58.7	0.12
12	0	0.0	NE	0	0.0	NE
13	0	0.0	NE	0	0.0	NE
14	0	0.0	NE	0	0.0	NE
15	2	78.9	0.03	1	42.4	0.02
16	1	72.2	0.01	0	0.0	NE
17	1	68.9	0.01	0	0.0	NE
18	0	0.0	NE	0	0.0	NE
19	1	62.5	0.02	0	0.0	NE
20	0	0.0	NE	0	0.0	NE
21	3	57.7	0.05	0	0.0	NE
22	1	54.3	0.02	0	0.0	NE
23	1	51.5	0.02	0	0.0	NE
24	0	0.0	NE	0	0.0	NE

Selected Adverse Event Month	Inavo+Palbo+Fulv (N=161)			Pbo+Palbo+Fulv (N=163)		
	Number of AEs	Patients Month	Rate	Number of AEs	Patients Month	Rate
25	1	46.8	0.02	0	0.0	NE
26	0	0.0	NE	0	0.0	NE
27	0	0.0	NE	0	0.0	NE
28	1	36.7	0.03	0	0.0	NE
29	0	0.0	NE	1	11.8	0.09
30	0	0.0	NE	0	0.0	NE
31	0	0.0	NE	0	0.0	NE
32	1	25.4	0.04	0	0.0	NE
33	0	0.0	NE	1	10.0	0.10
34	2	21.9	0.09	0	0.0	NE
35	0	0.0	NE	0	0.0	NE
36	0	0.0	NE	0	0.0	NE
37	0	0.0	NE	0	0.0	NE
38	0	0.0	NE	0	0.0	NE
39	0	0.0	NE	0	0.0	NE
40	0	0.0	NE	1	6.2	0.16
41	0	0.0	NE	0	0.0	NE
42	0	0.0	NE	0	0.0	NE
43	1	9.5	0.11	0	0.0	NE
44	0	0.0	NE	0	0.0	NE
45	0	0.0	NE	0	0.0	NE
46	0	0.0	NE	0	0.0	NE
47	0	0.0	NE	0	0.0	NE
48	0	0.0	NE	0	0.0	NE
49	0	0.0	NE	0	0.0	NE
Rash						
1	30	159.1	0.19	22	161.6	0.14
2	11	155.4	0.07	3	156.0	0.02
3	4	149.4	0.03	7	131.6	0.05
4	3	144.1	0.02	1	122.5	0.01
5	5	137.2	0.04	1	111.8	0.01
6	5	131.8	0.04	3	104.5	0.03
7	3	126.9	0.02	1	91.0	0.01
8	0	0.0	NE	1	83.3	0.01
9	2	112.0	0.02	1	73.1	0.01
10	3	102.6	0.03	3	67.6	0.04
11	0	0.0	NE	0	0.0	NE
12	0	0.0	NE	0	0.0	NE
13	2	86.7	0.02	0	0.0	NE
14	3	84.3	0.04	1	44.3	0.02
15	2	78.9	0.03	0	0.0	NE
16	2	72.2	0.03	1	35.7	0.03
17	0	0.0	NE	0	0.0	NE
18	1	65.4	0.02	0	0.0	NE
19	1	62.5	0.02	0	0.0	NE
20	0	0.0	NE	0	0.0	NE
21	3	57.7	0.05	0	0.0	NE
22	1	54.3	0.02	0	0.0	NE
23	1	51.5	0.02	0	0.0	NE
24	0	0.0	NE	0	0.0	NE
25	0	0.0	NE	0	0.0	NE
26	0	0.0	NE	0	0.0	NE
27	0	0.0	NE	0	0.0	NE
28	1	36.7	0.03	1	15.0	0.07
29	0	0.0	NE	0	0.0	NE
30	0	0.0	NE	0	0.0	NE
31	0	0.0	NE	0	0.0	NE
32	1	25.4	0.04	0	0.0	NE
33	1	24.6	0.04	0	0.0	NE

Selected Adverse Event Month	Inavo+Palbo+Fulv (N=161)			Pbo+Palbo+Fulv (N=163)		
	Number of AEs	Patients Month	Rate	Number of AEs	Patients Month	Rate
34	0	0.0	NE	0	0.0	NE
35	0	0.0	NE	0	0.0	NE
36	1	18.5	0.05	0	0.0	NE
37	0	0.0	NE	0	0.0	NE
38	0	0.0	NE	0	0.0	NE
39	0	0.0	NE	0	0.0	NE
40	0	0.0	NE	0	0.0	NE
41	1	11.0	0.09	0	0.0	NE
42	0	0.0	NE	0	0.0	NE
43	0	0.0	NE	0	0.0	NE
44	0	0.0	NE	0	0.0	NE
45	0	0.0	NE	0	0.0	NE
46	1	8.0	0.12	0	0.0	NE
47	0	0.0	NE	0	0.0	NE
48	0	0.0	NE	0	0.0	NE
49	0	0.0	NE	0	0.0	NE
Stomatitis and mucosal inflammation						
1	79	159.1	0.50	37	161.6	0.23
2	18	155.4	0.12	8	156.0	0.05
3	16	149.4	0.11	2	131.6	0.02
4	8	144.1	0.06	7	122.5	0.06
5	10	137.2	0.07	3	111.8	0.03
6	8	131.8	0.06	5	104.5	0.05
7	5	126.9	0.04	8	91.0	0.09
8	4	121.2	0.03	1	83.3	0.01
9	6	112.0	0.05	0	0.0	NE
10	3	102.6	0.03	1	67.6	0.01
11	3	97.2	0.03	1	58.7	0.02
12	5	91.0	0.05	0	0.0	NE
13	2	86.7	0.02	0	0.0	NE
14	1	84.3	0.01	0	0.0	NE
15	3	78.9	0.04	0	0.0	NE
16	1	72.2	0.01	0	0.0	NE
17	1	68.9	0.01	0	0.0	NE
18	2	65.4	0.03	0	0.0	NE
19	2	62.5	0.03	0	0.0	NE
20	0	0.0	NE	0	0.0	NE
21	2	57.7	0.03	0	0.0	NE
22	1	54.3	0.02	0	0.0	NE
23	1	51.5	0.02	0	0.0	NE
24	3	47.8	0.06	1	22.8	0.04
25	0	0.0	NE	0	0.0	NE
26	0	0.0	NE	0	0.0	NE
27	2	41.1	0.05	0	0.0	NE
28	0	0.0	NE	0	0.0	NE
29	2	34.4	0.06	0	0.0	NE
30	1	30.5	0.03	0	0.0	NE
31	1	28.5	0.04	0	0.0	NE
32	0	0.0	NE	0	0.0	NE
33	0	0.0	NE	0	0.0	NE
34	0	0.0	NE	1	10.0	0.10
35	0	0.0	NE	0	0.0	NE
36	0	0.0	NE	0	0.0	NE
37	0	0.0	NE	0	0.0	NE
38	1	15.3	0.07	0	0.0	NE
39	0	0.0	NE	0	0.0	NE
40	0	0.0	NE	0	0.0	NE
41	1	11.0	0.09	0	0.0	NE

Selected Adverse Event Month	Inavo+Palbo+Fulv (N=161)			Pbo+Palbo+Fulv (N=163)		
	Number of AEs	Patients Month	Rate	Number of AEs	Patients Month	Rate
42	0	0.0	NE	0	0.0	NE
43	0	0.0	NE	0	0.0	NE
44	0	0.0	NE	0	0.0	NE
45	0	0.0	NE	0	0.0	NE
46	0	0.0	NE	0	0.0	NE
47	0	0.0	NE	0	0.0	NE
48	0	0.0	NE	0	0.0	NE
49	1	3.5	0.28	0	0.0	NE
Thrombocytopenia						
1	75	159.1	0.47	64	161.6	0.40
2	14	155.4	0.09	15	156.0	0.10
3	17	149.4	0.11	10	131.6	0.08
4	6	144.1	0.04	7	122.5	0.06
5	10	137.2	0.07	6	111.8	0.05
6	10	131.8	0.08	6	104.5	0.06
7	10	126.9	0.08	7	91.0	0.08
8	6	121.2	0.05	4	83.3	0.05
9	9	112.0	0.08	4	73.1	0.05
10	6	102.6	0.06	3	67.6	0.04
11	8	97.2	0.08	1	58.7	0.02
12	5	91.0	0.05	5	53.5	0.09
13	4	86.7	0.05	2	46.5	0.04
14	2	84.3	0.02	0	0.0	NE
15	2	78.9	0.03	1	42.4	0.02
16	5	72.2	0.07	2	35.7	0.06
17	3	68.9	0.04	1	32.4	0.03
18	1	65.4	0.02	0	0.0	NE
19	1	62.5	0.02	1	28.7	0.03
20	3	59.7	0.05	1	27.2	0.04
21	4	57.7	0.07	1	26.6	0.04
22	1	54.3	0.02	0	0.0	NE
23	3	51.5	0.06	1	23.0	0.04
24	2	47.8	0.04	0	0.0	NE
25	1	46.8	0.02	0	0.0	NE
26	2	45.0	0.04	0	0.0	NE
27	2	41.1	0.05	0	0.0	NE
28	2	36.7	0.05	1	15.0	0.07
29	1	34.4	0.03	0	0.0	NE
30	2	30.5	0.07	0	0.0	NE
31	1	28.5	0.04	0	0.0	NE
32	1	25.4	0.04	0	0.0	NE
33	2	24.6	0.08	0	0.0	NE
34	1	21.9	0.05	0	0.0	NE
35	1	21.0	0.05	0	0.0	NE
36	0	0.0	NE	0	0.0	NE
37	1	16.0	0.06	0	0.0	NE
38	0	0.0	NE	0	0.0	NE
39	0	0.0	NE	0	0.0	NE
40	1	11.9	0.08	0	0.0	NE
41	0	0.0	NE	0	0.0	NE
42	1	11.0	0.09	0	0.0	NE
43	0	0.0	NE	0	0.0	NE
44	0	0.0	NE	0	0.0	NE
45	1	8.1	0.12	0	0.0	NE
46	0	0.0	NE	0	0.0	NE
47	0	0.0	NE	0	0.0	NE
48	0	0.0	NE	0	0.0	NE
49	0	0.0	NE	0	0.0	NE
Vomiting						

Selected Adverse Event Month	Inavo+Palbo+Fulv (N=161)			Pbo+Palbo+Fulv (N=163)		
	Number of AEs	Patients Month	Rate	Number of AEs	Patients Month	Rate
1	20	159.1	0.13	2	161.6	0.01
2	10	155.4	0.06	1	156.0	0.01
3	2	149.4	0.01	0	0.0	NE
4	3	144.1	0.02	1	122.5	0.01
5	2	137.2	0.01	0	0.0	NE
6	2	131.8	0.02	1	104.5	0.01
7	3	126.9	0.02	1	91.0	0.01
8	1	121.2	0.01	2	83.3	0.02
9	1	112.0	0.01	0	0.0	NE
10	3	102.6	0.03	1	67.6	0.01
11	0	0.0	NE	0	0.0	NE
12	0	0.0	NE	0	0.0	NE
13	0	0.0	NE	0	0.0	NE
14	0	0.0	NE	0	0.0	NE
15	0	0.0	NE	0	0.0	NE
16	1	72.2	0.01	0	0.0	NE
17	1	68.9	0.01	0	0.0	NE
18	1	65.4	0.02	0	0.0	NE
19	1	62.5	0.02	0	0.0	NE
20	1	59.7	0.02	0	0.0	NE
21	1	57.7	0.02	0	0.0	NE
22	0	0.0	NE	0	0.0	NE
23	0	0.0	NE	0	0.0	NE
24	1	47.8	0.02	0	0.0	NE
25	0	0.0	NE	0	0.0	NE
26	0	0.0	NE	0	0.0	NE
27	0	0.0	NE	0	0.0	NE
28	0	0.0	NE	0	0.0	NE
29	1	34.4	0.03	1	11.8	0.09
30	0	0.0	NE	0	0.0	NE
31	0	0.0	NE	0	0.0	NE
32	0	0.0	NE	0	0.0	NE
33	0	0.0	NE	0	0.0	NE
34	0	0.0	NE	0	0.0	NE
35	0	0.0	NE	0	0.0	NE
36	0	0.0	NE	0	0.0	NE
37	0	0.0	NE	0	0.0	NE
38	0	0.0	NE	0	0.0	NE
39	0	0.0	NE	0	0.0	NE
40	0	0.0	NE	0	0.0	NE
41	0	0.0	NE	0	0.0	NE
42	0	0.0	NE	0	0.0	NE
43	0	0.0	NE	0	0.0	NE
44	0	0.0	NE	0	0.0	NE
45	0	0.0	NE	0	0.0	NE
46	0	0.0	NE	0	0.0	NE
47	0	0.0	NE	0	0.0	NE
48	0	0.0	NE	0	0.0	NE
49	0	0.0	NE	0	0.0	NE

Treatment exposure time from the start of treatment to the end of treatment.

Rate of selected AE = number of selected AEs occurred during corresponding month / Patient-month of treatment exposure time.

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_ae_rate.R

Output path:

/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v7/output/t_ae_rate_SAS_15NOV2024_41554.docx

Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685

Git hash: b6027dbd949ffd3bd010747913d30fe0e2c66bc9

14 APR 2025 06:17 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

4 Sonstige Analysen

4.1 Anzahl Zentren, Länder, Regionen mit < 10 bzw. ≥ 10 Patienten pro Arm

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Number of Centers/Countries/Geographical Regions with <10, >=10 Patients per Arm
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Number in category			Patients Randomized		
	<10 patients per arm	>=10 patients per arm	Total	<10 patients per arm	>=10 patients per arm	Total
Center	123 (100%)	0 (0%)	123 (100%)	325 (100%)	0 (0%)	325 (100%)
Country	23 (82.1%)	5 (17.9%)	28 (100%)	171 (52.6%)	154 (47.4%)	325 (100%)
Geographical Region	0 (0%)	3 (100%)	3 (100%)	0 (0%)	325 (100%)	325 (100%)

"<10 patients" category if at least one treatment arm has <10 patients. ">=10 patients" category if all treatment arms have >=10 patients. Number of patients randomized in the corresponding category (e.g., number of patients randomized in centers with <10 pts per arm). % of randomized patients compared to overall number of randomized patients (e.g., % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients)

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/t_center.R

Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v1/output/t_center_FAS_15NOV2024_41554.docx

Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685

Git hash: 65ba890bf61ac3a2517ff79c20b7283a2af5911f

17 MAR 2025 23:33 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

4 Sonstige Analysen

4.2 Demographische und Krankheitscharakteristika zur Baseline

Demographic and Baseline Characteristics, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Age (years)			
n	161	164	325
Mean (SD)	53.8 (10.9)	54.1 (11.2)	54.0 (11.1)
Median	53.0	54.5	54.0
Min - Max	27 - 77	29 - 79	27 - 79
Age group (years)			
n	161	164	325
< 65	136 (84.5%)	130 (79.3%)	266 (81.8%)
>= 65	25 (15.5%)	34 (20.7%)	59 (18.2%)
Age group (years)			
n	161	164	325
< 65	136 (84.5%)	130 (79.3%)	266 (81.8%)
65 - 74	19 (11.8%)	28 (17.1%)	47 (14.5%)
>= 75	6 (3.7%)	6 (3.7%)	12 (3.7%)
Sex			
n	161	164	325
Male	5 (3.1%)	1 (0.6%)	6 (1.8%)
Female	156 (96.9%)	163 (99.4%)	319 (98.2%)
Race			
n	161	164	325
Asian	61 (37.9%)	63 (38.4%)	124 (38.2%)
Black or African American	1 (0.6%)	1 (0.6%)	2 (0.6%)
White	94 (58.4%)	97 (59.1%)	191 (58.8%)
Unknown	5 (3.1%)	3 (1.8%)	8 (2.5%)
Ethnicity			
n	161	164	325
HISPANIC OR LATINO	10 (6.2%)	10 (6.1%)	20 (6.2%)
NOT HISPANIC OR LATINO	145 (90.1%)	149 (90.9%)	294 (90.5%)
NOT REPORTED	2 (1.2%)	3 (1.8%)	5 (1.5%)
UNKNOWN	4 (2.5%)	2 (1.2%)	6 (1.8%)
Geographic region (per IxRS)			
n	161	164	325
Asia	58 (36.0%)	62 (37.8%)	120 (36.9%)
North America/Western Europe	62 (38.5%)	63 (38.4%)	125 (38.5%)
Other	41 (25.5%)	39 (23.8%)	80 (24.6%)
Weight (kg) at Baseline			
n	160	164	324
Mean (SD)	66.2 (15.9)	65.4 (14.3)	65.8 (15.1)
Median	62.5	64.0	63.0
Min - Max	39 - 124	38 - 111	38 - 124
BMI (kg/m2) at Baseline			
n	161	164	325
< 18.5	8 (5.0%)	10 (6.1%)	18 (5.5%)
>= 18.5 to < 25.0	78 (48.4%)	75 (45.7%)	153 (47.1%)
>= 25.0 to < 30.0	44 (27.3%)	50 (30.5%)	94 (28.9%)
>= 30	29 (18.0%)	28 (17.1%)	57 (17.5%)
Missing	2 (1.2%)	1 (0.6%)	3 (0.9%)

Endocrine resistance (primary or secondary according to European Society for Medical Oncology Advanced Breast Cancer 4 guidelines [Cardoso et al. 2018]).
HbA1c, hemoglobin A1c values by DCCT (Diabetes Control and Complications Trial) unit and by IFCC (International Federation of Clinical Chemistry) unit: 5.7% (DCCT) = 39 mmol/mol; 6.5% (DCCT) = 48 mmol/mol.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:25 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/t_dm_FAS_15NOV2024_41554.out

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Demographic and Baseline Characteristics, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Baseline ECOG			
n	161	164	325
0	100 (62.1%)	106 (64.6%)	206 (63.4%)
1	60 (37.3%)	58 (35.4%)	118 (36.3%)
Missing	1 (0.6%)	0	1 (0.3%)
Post-menopausal status at randomization			
n	161	164	325
NOT POST-MENOPAUSAL	52 (32.3%)	52 (31.7%)	104 (32.0%)
POST-MENOPAUSAL	104 (64.6%)	111 (67.7%)	215 (66.2%)
Missing	5 (3.1%)	1 (0.6%)	6 (1.8%)
HbA1c (%) at Baseline			
n	161	164	325
< 5.7	143 (88.8%)	143 (87.2%)	286 (88.0%)
>= 5.7 to <6.5	16 (9.9%)	20 (12.2%)	36 (11.1%)
>= 6.5	0	1 (0.6%)	1 (0.3%)
Missing	2 (1.2%)	0	2 (0.6%)
Fasting Glucose (mg/dL) at Baseline			
n	161	164	325
< 100	110 (68.3%)	121 (73.8%)	231 (71.1%)
>= 100 to < 126	45 (28.0%)	34 (20.7%)	79 (24.3%)
>= 126	1 (0.6%)	2 (1.2%)	3 (0.9%)
Missing	5 (3.1%)	7 (4.3%)	12 (3.7%)
Visceral Disease (per IxRS)			
n	161	164	325
Yes	127 (78.9%)	126 (76.8%)	253 (77.8%)
No	34 (21.1%)	38 (23.2%)	72 (22.2%)
Endocrine Resistance (per IxRS)			
n	161	164	325
PRIMARY	57 (35.4%)	59 (36.0%)	116 (35.7%)
SECONDARY	104 (64.6%)	105 (64.0%)	209 (64.3%)

Endocrine resistance (primary or secondary according to European Society for Medical Oncology Advanced Breast Cancer 4 guidelines [Cardoso et al. 2018]).
HbA1c, hemoglobin A1c values by DCCT (Diabetes Control and Complications Trial) unit and by IFCC (International Federation of Clinical Chemistry) unit: 5.7% (DCCT) = 39 mmol/mol; 6.5% (DCCT) = 48 mmol/mol.

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: <https://code.roche.com/studies/clinicalreporting/>

W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:25 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/
t_dm_FAS_15NOV2024_41554.out

Page 2 of 2

Breast Cancer History and Baseline Disease Characteristics, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Disease Stage (AJCC stage)*			
n	161	164	325
Stage I	19 (11.8%)	18 (11%)	37 (11.4%)
Stage IIA	32 (19.9%)	38 (23.2%)	70 (21.5%)
Stage IIB	35 (21.7%)	34 (20.7%)	69 (21.2%)
Stage IIIA	36 (22.4%)	35 (21.3%)	71 (21.8%)
Stage IIIB	12 (7.5%)	13 (7.9%)	25 (7.7%)
Stage IIIC	17 (10.6%)	20 (12.2%)	37 (11.4%)
Stage IV	7 (4.3%)	5 (3%)	12 (3.7%)
Missing	3 (1.9%)	1 (0.6%)	4 (1.2%)
Time from Initial Diagnosis (days)			
n	159	160	319
Mean (SD)	1773.1 (1316.4)	1607.0 (1053.6)	1689.8 (1192.9)
Median	1512.0	1431.5	1450.0
Min - Max	177.0 - 10319.0	41.0 - 6005.0	41.0 - 10319.0
Status of disease at Study entry			
n	161	164	325
Locally Advanced	1 (0.6%)	2 (1.2%)	3 (0.9%)
Metastatic	160 (99.4%)	162 (98.8%)	322 (99.1%)
Number of Organ Sites***			
n	161	164	325
1	21 (13%)	32 (19.5%)	53 (16.3%)
2	58 (36%)	46 (28%)	104 (32%)
>=3	82 (50.9%)	86 (52.4%)	168 (51.7%)
Visceral Disease (IxRS)**			
n	161	164	325
Yes	127 (78.9%)	126 (76.8%)	253 (77.8%)
No	34 (21.1%)	38 (23.2%)	72 (22.2%)
Visceral Disease (eCRF)**			
n	161	164	325
Yes	132 (82%)	128 (78%)	260 (80%)
No	29 (18%)	36 (22%)	65 (20%)
Liver**			
n	161	164	325
Yes	77 (47.8%)	91 (55.5%)	168 (51.7%)
No	84 (52.2%)	73 (44.5%)	157 (48.3%)
Lung**			
n	161	164	325
Yes	66 (41%)	66 (40.2%)	132 (40.6%)
No	95 (59%)	98 (59.8%)	193 (59.4%)
CNS**			
n	161	164	325
Yes	0	2 (1.2%)	2 (0.6%)
No	161 (100%)	162 (98.8%)	323 (99.4%)
Bone**			
n	161	164	325
Yes	108 (67.1%)	94 (57.3%)	202 (62.2%)
No	53 (32.9%)	70 (42.7%)	123 (37.8%)
Bone Only**, \$			
n	161	164	325
Yes	5 (3.1%)	6 (3.7%)	11 (3.4%)
No	156 (96.9%)	158 (96.3%)	314 (96.6%)
Prior (neo)-adjuvant chemotherapy			
n	161	164	325
Yes	132 (82%)	137 (83.5%)	269 (82.8%)
No	29 (18%)	27 (16.5%)	56 (17.2%)
Prior (neo)-adjuvant CDK 4/6 inhibitor			
n	161	164	325
Yes	2 (1.2%)	1 (0.6%)	3 (0.9%)
No	159 (98.8%)	163 (99.4%)	322 (99.1%)
Prior (neo)-adjuvant Endocrine Therapy			
n	161	164	325
Yes	160 (99.4%)	163 (99.4%)	323 (99.4%)
No	1 (0.6%)	1 (0.6%)	2 (0.6%)

* at initial diagnosis

** at screening

\$ Patients with evaluable bone-only disease are not eligible; disease that is limited to bone but has lytic or mixed lytic/blastic lesions and at least one measurable soft-tissue component per RECIST v1.1 may be eligible.

"Visceral Disease" (Yes/No) refers to lung, liver, brain, pleural, and peritoneal involvement.

*** "Number of Organ Sites" involved have been derived from target and non-target lesions at baseline.

"Endocrine Resistance" according to European Society for Medical Oncology Advanced Breast Cancer 4 guidelines [Cardoso et al. 2018]).

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:33 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/

t_mh_bch_FAS_15NOV2024_41554.out

Page 1 of 2

Breast Cancer History and Baseline Disease Characteristics, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
n	160	163	323
Aromatase inhibitor only	60 (37.3%)	71 (43.3%)	131 (40.3%)
Tamoxifen only	82 (50.9%)	73 (44.5%)	155 (47.7%)
Both aromatase inhibitor and tamoxifen	18 (11.2%)	19 (11.6%)	37 (11.4%)
HER2 Status			
n	161	164	325
HER2-	161 (100%)	164 (100%)	325 (100%)
Hormone receptor status			
n	161	164	325
ER+/PR-	45 (28%)	45 (27.4%)	90 (27.7%)
ER+/PR+	113 (70.2%)	113 (68.9%)	226 (69.5%)
Other	3 (1.9%)	6 (3.7%)	9 (2.8%)
Endocrine Resistance (IxRS)			
n	161	164	325
Primary	57 (35.4%)	59 (36%)	116 (35.7%)
Secondary	104 (64.6%)	105 (64%)	209 (64.3%)
Endocrine Resistance (eCRF)			
n	161	164	325
Primary	54 (33.5%)	58 (35.4%)	112 (34.5%)
Secondary	107 (66.5%)	105 (64%)	212 (65.2%)
Missing	0	1 (0.6%)	1 (0.3%)

* at initial diagnosis
** at screening
\$ Patients with evaluable bone-only disease are not eligible; disease that is limited to bone but has lytic or mixed lytic/blastic lesions and at least one measurable soft-tissue component per RECIST v1.1 may be eligible.
"Visceral Disease" (Yes/No) refers to lung, liver, brain, pleural, and peritoneal involvement.
*** "Number of Organ Sites" involved have been derived from target and non-target lesions at baseline.
"Endocrine Resistance" according to European Society for Medical Oncology Advanced Breast Cancer 4 guidelines [Cardoso et al. 2018]).
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:33 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/
t_mh_bch_FAS_15NOV2024_41554.out

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

All Lesions at Baseline (Investigator Assessed), Full Analysis Set
 Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Number of organ sites per patient			
Median	3.0	3.0	3.0
Range	1 - 7	1 - 6	1 - 7
1	21 (13%)	32 (19.5%)	53 (16.3%)
2	58 (36%)	46 (28%)	104 (32%)
3	44 (27.3%)	51 (31.1%)	95 (29.2%)
4	24 (14.9%)	18 (11%)	42 (12.9%)
5	9 (5.6%)	14 (8.5%)	23 (7.1%)
>5	5 (3.1%)	3 (1.8%)	8 (2.5%)
Number of patients with at least 1 lesion in organ site			
Bone	108 (67.1%)	94 (57.3%)	202 (62.2%)
Liver	77 (47.8%)	91 (55.5%)	168 (51.7%)
Lymph Nodes	81 (50.3%)	76 (46.3%)	157 (48.3%)
Lung	66 (41.0%)	66 (40.2%)	132 (40.6%)
Other	32 (19.9%)	39 (23.8%)	71 (21.8%)
Pleura or Peritoneum	38 (23.6%)	32 (19.5%)	70 (21.5%)
Skin or Soft Tissue	32 (19.9%)	34 (20.7%)	66 (20.3%)
Bone Only	5 (3.1%)	6 (3.7%)	11 (3.4%)
CNS	0	2 (1.2%)	2 (0.6%)

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: <https://code.roche.com/studies/clinicalreporting/>

W041554_Overall_Survival_Reporting_Event_8219953

Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa

03 FEB 2025 14:21 GMT

Output: /ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/

t_dm_les_INV_FAS_15NOV2024_41554.out

Page 1 of 1

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

4 Sonstige Analysen

4.3 Beobachtungsdauern

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Duration of Follow-up, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Duration of Follow-up (months)			
Median	34.2	32.3	34.2
95% CI	(30.2, 38.0)	(26.7, 36.8)	(30.3, 36.6)
25% and 75%-ile	22.6, 42.4	20.6, 40.0	21.5, 40.3
Range (censored)	0.1 to 50.9	0.1 to 50.0	0.1 to 50.9
Range (event)	0.0 to 52.3	2.1 to 53.9	0.0 to 53.9

Duration of follow-up is defined as the time from randomization to death or the last known alive date, whichever comes first.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:33 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIInterim_Ovrl_Surv/prod_srep_v1/output/t_ef_fudur_FAS_15NOV2024_41554.out Page 1 of 1

Duration of Safety Follow-up, Safety Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=163)	All Patients (N=324)
Safety Follow-Up Duration at 30 Days (Months)			
n	161	163	324
Mean (SD)	17.8 (12.9)	11.5 (10.6)	14.6 (12.2)
Median	14.5	8.1	10.4
Min - Max	0.1 - 52.3	0.1 - 53.9	0.1 - 53.9
Safety Follow-Up Duration at 90 Days (Months)			
n	161	163	324
Mean (SD)	18.1 (12.8)	11.7 (10.6)	14.9 (12.1)
Median	14.6	8.3	10.8
Min - Max	0.1 - 52.3	0.1 - 53.9	0.1 - 53.9

The duration of safety follow-up is defined as time from treatment start to the earliest of the following dates: data cut-off date, date of death, withdrawal of consent date, date of last dose of study treatment + 30 days or 90 days, initiation date of subsequent anti-cancer therapy.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_saf_dur.R
Output path:
/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v2/output/t_saf_dur_SAS_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ac46b26cbbffb3958547c52a8c216a191962c0b
31 MAR 2025 06:15 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

4 Sonstige Analysen

4.4 Folgetherapien nach Progression

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Post-progression therapies (for all lines post progression therapies), Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N = 161)		Pbo+Palbo+Fulv (N = 164)	
	Second Line	Third Line or Greater	Second Line	Third Line or Greater
Discontinued Treatment	111 (68.9%)	111 (68.9%)	144 (87.8%)	144 (87.8%)
No Subsequent Therapy - Death	17 (10.6%)	17 (10.6%)	22 (13.4%)	22 (13.4%)
Patient with Subsequent Therapy	83 (51.6%)	48 (29.8%)	109 (66.5%)	56 (34.1%)
CHEMOTHERAPY				
ANY	46 (55.4%)	41 (85.4%)	79 (72.5%)	49 (87.5%)
CAPECITABINE	26 (31.3%)	14 (29.2%)	37 (33.9%)	24 (42.9%)
PACLITAXEL	12 (14.5%)	17 (35.4%)	20 (18.3%)	16 (28.6%)
DOXORUBICIN	2 (2.4%)	4 (8.3%)	4 (3.7%)	7 (12.5%)
CARBOPLATIN	2 (2.4%)	5 (10.4%)	4 (3.7%)	16 (28.6%)
GEMCITABINE	3 (3.6%)	8 (16.7%)	8 (7.3%)	6 (10.7%)
ERIBULIN	1 (1.2%)	11 (22.9%)	6 (5.5%)	17 (30.4%)
VINORELBINE	1 (1.2%)	5 (10.4%)	3 (2.8%)	8 (14.3%)
ANTIHERMONAL AGENT				
ANY	26 (31.3%)	14 (29.2%)	31 (28.4%)	18 (32.1%)
AROMATASE INHIBITOR	16 (19.3%)	10 (20.8%)	20 (18.3%)	14 (25.0%)
SERD	10 (12.0%)	4 (8.3%)	10 (9.2%)	6 (10.7%)
LHRH AGONIST	3 (3.6%)	1 (2.1%)	2 (1.8%)	2 (3.6%)
TAMOXIFEN	1 (1.2%)	0 (0.0%)	1 (0.9%)	0 (0.0%)
ADC				
ANY	1 (1.2%)	8 (16.7%)	1 (0.9%)	20 (35.7%)
SACITUZUMAB GOVITECAN	0 (0.0%)	2 (4.2%)	0 (0.0%)	8 (14.3%)
TRASTUZUMAB DERUXTECAN	0 (0.0%)	6 (12.5%)	1 (0.9%)	16 (28.6%)
AZD 8205	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
DB 1303	1 (1.2%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
CDKi				
ANY	8 (9.6%)	3 (6.2%)	5 (4.6%)	3 (5.4%)
ABEMACICLIB	2 (2.4%)	2 (4.2%)	0 (0.0%)	2 (3.6%)
RIBOCICLIB	1 (1.2%)	1 (2.1%)	5 (4.6%)	0 (0.0%)
PALBOCICLIB	5 (6.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
HER2i				
ANY	0 (0.0%)	1 (2.1%)	0 (0.0%)	4 (7.1%)
TRASTUZUMAB	0 (0.0%)	1 (2.1%)	0 (0.0%)	4 (7.1%)
TUCATINIB	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
PERTUZUMAB;TRASTUZUMAB	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
mTOR KINASE INHIBITOR				
ANY	8 (9.6%)	4 (8.3%)	10 (9.2%)	9 (16.1%)
EVEROLIMUS	8 (9.6%)	4 (8.3%)	10 (9.2%)	8 (14.3%)
EVEROLIMUS;EXEMESTANE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
PI3Kinase inhibitor				
ANY	5 (6.0%)	2 (4.2%)	11 (10.1%)	3 (5.4%)
ALPELISIB	5 (6.0%)	2 (4.2%)	9 (8.3%)	2 (3.6%)
LOXO-783	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)
PI3K inhibitor	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
RLY 2608	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)
PARPi				
ANY	2 (2.4%)	0 (0.0%)	2 (1.8%)	0 (0.0%)
OLAPARIB	2 (2.4%)	0 (0.0%)	2 (1.8%)	0 (0.0%)
ANTI-VEGF AGENT				
ANY	3 (3.6%)	4 (8.3%)	6 (5.5%)	8 (14.3%)
LENVATINIB	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.6%)
BEVACIZUMAB	2 (2.4%)	3 (6.2%)	6 (5.5%)	6 (10.7%)
RIVOCERANIB	1 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
RAMUCIRUMAB	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)
IMMUNOTHERAPIES				
ANY	2 (2.4%)	0 (0.0%)	3 (2.8%)	2 (3.6%)
PEMBROLIZUMAB	1 (1.2%)	0 (0.0%)	3 (2.8%)	2 (3.6%)
NIVOLUMAB	1 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
OTHER				
ANY	6 (7.2%)	0 (0.0%)	3 (2.8%)	5 (8.9%)
METHOTREXATE	1 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MIRDAMETINIB	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
OTHER MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	4 (4.8%)	0 (0.0%)	2 (1.8%)	1 (1.8%)
MEGESTROL ACETATE	1 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ALL OTHER THERAPEUTIC PRODUCTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
CHIDAMIDE	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)
PROTEIN KINASE INHIBITORS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
INVESTIGATIONAL ANTINEOPLASTIC DRUGS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: <https://code.roche.com/studies/clinicalreporting/>
W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:21 GMT
Output:/ocean/harbour/CDT70123/W041554/CSRIinterim_Ovrl_Surv/prod_srep_v1/output/
t_cm_postpd_all_FAS_15NOV2024_41554.out

Page 1 of 1

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
Inavo+Palbo+Fulv	322980/10129	2ND LINE	309	CAPECITABINE	Y	235	Y
				PEMBROLIZUMAB		235	
		3RD LINE	548	CARBOPLATIN	Y	29	
		4TH LINE	577	VINORELBINE	Y	270	
	323127/10007	2ND LINE	150	DOCETAXEL	Y	152	Y
		3RD LINE	323	EVEROLIMUS		155	
				EVEROLIMUS		155	
				EVEROLIMUS		155	
	323131/10278	4TH LINE	478	EXEMESTANE		155	
				DOXORUBICIN	Y	21	
				CYCLOPHOSPHAMIDE	Y	21	
				CYCLOPHOSPHAMIDE	Y	21	
		5TH LINE	519	CISPLATIN	Y	44	
				GEMCITABINE	Y	44	
				EVEROLIMUS		63	
				EVEROLIMUS		63	
	323140/10114 323144/10037 323144/10113 323146/10141	2ND LINE	113	EXEMESTANE		63	
				PACLITAXEL	Y	132	
				PACLITAXEL	Y	132	
				PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	36	
		3RD LINE	176	FLUOROURACIL	Y	117	
				CISPLATIN	Y	117	
				PEGYLATED LIPOSOMAL DOXORUBICIN	Y	57	
				HYDROCHLORIDE			
	323144/10113	3RD LINE	400	CAPECITABINE	Y	225	Y
		4TH LINE	644	ERIBULIN	Y	125	
				ERIBULIN	Y	125	
		2ND LINE	711	TRIPTORELIN		NA	
				LETROZOLE		NA	

ASTDY is relative day calculated from the treatment start. The CHEMOTTE endpoint is calculated as time from randomization.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/l_fu_therapy.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v12/output/l_fu_therapy_FAS_15NOV2024_41554.out
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 3b4ed22d0616647521ed5b603a515231be7c34f7
03 JUN 2025 06:52 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
	323166/10059	2ND LINE	255	PALBOCICLIB		NA	
		3RD LINE	378	CAPECITABINE	Y	69	Y
				CARBOPLATIN	Y	75	
				GEMCITABINE	Y	75	
		4TH LINE	477	VINORELBINE TARTRATE	Y	1	
		5TH LINE	521	DOCETAXEL	Y	22	
		6TH LINE	577	FULVESTRANT		1	
	323396/10011	2ND LINE	976	OLAPARIB		421	
		3RD LINE	1462	TRASTUZUMAB DERUXTECAN		1	
		4TH LINE	1527	CAPECITABINE	Y	82	Y
	323401/10002	2ND LINE	206	CAPECITABINE	Y	78	Y
		3RD LINE	369	EXEMESTANE		NA	
	323401/10016	2ND LINE	154	CAPECITABINE	Y	NA	Y
	323401/10019	2ND LINE	119	CAPECITABINE	Y	15	Y
		3RD LINE	134	DOXORUBICIN	Y	1	
	323401/10147	2ND LINE	346	CAPECITABINE	Y	172	Y
		3RD LINE	525	PACLITAXEL	Y	113	
				PACLITAXEL	Y	113	
		4TH LINE	665	ERIBULIN	Y	43	
				ERIBULIN	Y	43	
	323414/10224	2ND LINE	697	PACLITAXEL	Y	NA	Y
				PACLITAXEL	Y	NA	Y
	323541/10153	2ND LINE	148	CAPECITABINE	Y	221	Y
				DOCETAXEL	Y	221	Y
	323572/10049	2ND LINE	430	FULVESTRANT		NA	
				GOSERELIN		NA	
		3RD LINE	521	ABEMACICLIB		NA	
	323572/10159	2ND LINE	232	FULVESTRANT		463	
				GOSERELIN		463	
				RIBOCICLIB		463	

ASTDY is relative day calculated from the treatment start. The CHEMOTTE endpoint is calculated as time from randomization.
Inavo = Inavolisib, Phbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/l_fu_therapy.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v12/output/l_fu_therapy_FAS_15NOV2024_41554.out
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 3b4ed22d0616647521ed5b603a515231be7c34f7
03 JUN 2025 06:52 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		3RD LINE	805	ALPELISIB		335	
				FULVESTRANT		335	
				GOSERELIN		335	
	323575/10066	2ND LINE	756	CAPECITABINE	Y	NA	Y
	323629/10073	2ND LINE	277	PACLITAXEL	Y	83	Y
				PACLITAXEL	Y	83	Y
		3RD LINE	383	CAPECITABINE	Y	12	
				TRASTUZUMAB		12	
				TUCATINIB		12	
	323629/10214	2ND LINE	867	DB 1303		78	
				DB 1303		78	
	323775/10263	2ND LINE	301	LETROZOLE		69	
		3RD LINE	370	PACLITAXEL	Y	22	Y
				PACLITAXEL	Y	22	Y
				CAPECITABINE	Y	12	
	323776/10031	4TH LINE	414	LETROZOLE		85	
	323776/10157	2ND LINE	225	ANASTROZOLE		17	
	323777/10102	2ND LINE	883	LETROZOLE		254	
	323807/10221	2ND LINE	255	LETROZOLE		36	
			207	EVEROLIMUS		36	
				EVEROLIMUS		36	
				EVEROLIMUS		36	
		3RD LINE	263	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	250	Y
		4TH LINE	523	LETROZOLE		64	
		5TH LINE	609	TRASTUZUMAB DERUXTECAN		NA	
	323897/10222	2ND LINE	664	CAPECITABINE	Y	190	Y
		3RD LINE	890	CISPLATIN	Y	NA	
				PACLITAXEL	Y	NA	
				PACLITAXEL	Y	NA	
	323897/10228	2ND LINE	64	CISPLATIN	Y	150	Y
				GEMCITABINE	Y	150	Y

ASTDY is relative day calculated from the treatment start. The CHEMOTTE endpoint is calculated as time from randomization.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/l_fu_therapy.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v12/output/l_fu_therapy_FAS_15NOV2024_41554.out
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 3b4ed22d0616647521ed5b603a515231be7c34f7
03 JUN 2025 06:52 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		3RD LINE	225	ERIBULIN	Y	329	
				ERIBULIN	Y	329	
	323897/10290	2ND LINE	402	CAPECITABINE	Y	NA	Y
	323898/10100	2ND LINE	412	CAPECITABINE	Y	35	Y
		3RD LINE	456	CISPLATIN	Y	504	
				PACLITAXEL	Y	504	
				PACLITAXEL	Y	504	
		4TH LINE	972	EVEROLIMUS		28	
				EVEROLIMUS		28	
				EVEROLIMUS		28	
				EXEMESTANE		28	
		5TH LINE	1052	ERIBULIN	Y	28	
				ERIBULIN	Y	28	
		6TH LINE	1093	CISPLATIN	Y	22	
				GEMCITABINE	Y	22	
	323953/10190	2ND LINE	288	ANASTROZOLE		29	
				PALBOCICLIB		29	
		3RD LINE	327	ANASTROZOLE		197	
				ERIBULIN MESILATE	Y	197	Y
		4TH LINE	530	EXEMESTANE		81	
				ERIBULIN MESILATE	Y	81	
		5TH LINE	614	EXEMESTANE		407	
				GEMCITABINE HYDROCHLORIDE	Y	407	
				PACLITAXEL	Y	407	
				PACLITAXEL	Y	407	
	323973/10077	2ND LINE	506	EVEROLIMUS		77	
				EVEROLIMUS		77	
				EVEROLIMUS		77	
		3RD LINE	583	BEVACIZUMAB		362	
				BEVACIZUMAB		362	

ASTDY is relative day calculated from the treatment start. The CHEMOTTE endpoint is calculated as time from randomization.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/l_fu_therapy.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v12/output/l_fu_therapy_FAS_15NOV2024_41554.out
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 3b4ed22d0616647521ed5b603a515231be7c34f7
03 JUN 2025 06:52 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
				PACLITAXEL	Y	362	Y
				PACLITAXEL	Y	362	Y
	323976/10050	2ND LINE	764	OLAPARIB		341	
		3RD LINE	1133	PACLITAXEL	Y	11	Y
				PACLITAXEL	Y	11	Y
	323976/10186	2ND LINE	114	FLUOROURACIL	Y	196	Y
				NIVOLUMAB		196	
				OXALIPLATIN	Y	196	Y
		3RD LINE	330	RAMUCIRUMAB		63	
				PACLITAXEL	Y	63	
				PACLITAXEL	Y	63	
	323985/10286	2ND LINE	235	CAPECITABINE	Y	103	Y
		3RD LINE	422	VINORELBINE	Y	86	
		4TH LINE	515	PACLITAXEL	Y	NA	
				PACLITAXEL	Y	NA	
	323988/10020	2ND LINE	1287	CAPECITABINE	Y	82	Y
		3RD LINE	1387	DOCETAXEL	Y	NA	
	323988/10032	2ND LINE	927	CAPECITABINE	Y	549	Y
	323992/10169	2ND LINE	485	ALPELISIB		85	
		3RD LINE	567	PACLITAXEL	Y	206	Y
				PACLITAXEL	Y	206	Y
		4TH LINE	785	CAPECITABINE	Y	NA	
	323997/10038	2ND LINE	806	PACLITAXEL	Y	106	
				PACLITAXEL	Y	106	
		3RD LINE	953	CYCLOPHOSPHAMIDE	Y	79	
				CYCLOPHOSPHAMIDE	Y	79	
				EPIRUBICIN	Y	79	
		4TH LINE	772	CAPECITABINE	Y	639	Y
	323997/10083	2ND LINE	661	EVEROLIMUS		261	
				EVEROLIMUS		261	

ASTDY is relative day calculated from the treatment start. The CHEMOTTE endpoint is calculated as time from randomization.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/l_fu_therapy.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v12/output/l_fu_therapy_FAS_15NOV2024_41554.out
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 3b4ed22d0616647521ed5b603a515231be7c34f7
03 JUN 2025 06:52 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		3RD LINE	936	EVEROLIMUS		261	
				LETROZOLE		366	
				RIBOCICLIB		366	
	324002/10143	2ND LINE	527	EXEMESTANE		204	
				FULVESTRANT		204	
	324033/10018	2ND LINE	312	EVEROLIMUS		153	
				EVEROLIMUS		153	
				EVEROLIMUS		153	
				EXEMESTANE		153	
		3RD LINE	434	CAPECITABINE	Y	396	Y
	324055/10218	2ND LINE	145	PACLITAXEL	Y	162	Y
				PACLITAXEL	Y	162	Y
	324063/10064	2ND LINE	427	ALPELISIB		157	
				FULVESTRANT		157	
		3RD LINE	556	DOCETAXEL	Y	142	Y
		4TH LINE	768	CAPECITABINE	Y	181	
	324063/10095	2ND LINE	83	FULVESTRANT		4	
				PALBOCICLIB		4	
		3RD LINE	272	CAPECITABINE	Y	65	Y
	324063/10193	2ND LINE	327	DOCETAXEL	Y	111	Y
		3RD LINE	441	ERIBULIN	Y	120	
				ERIBULIN	Y	120	
	324112/10127	2ND LINE	960	CAPECITABINE	Y	NA	Y
	324246/10072	2ND LINE	608	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	234	Y
	324249/10181	2ND LINE	259	BEVACIZUMAB		295	
				BEVACIZUMAB		295	
				CAPECITABINE	Y	295	Y
	324376/10001	2ND LINE	583	CAPECITABINE	Y	126	Y
		3RD LINE	709	ETOPOSIDE	Y	323	
		4TH LINE	1005	ERIBULIN	Y	132	

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Program name: programs/tlg/l_fu_therapy.R
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		5TH LINE	1164	ERIBULIN	Y	132	
				CARBOPLATIN	Y	134	
				GEMCITABINE	Y	134	
		6TH LINE	1339	VINORELBINE	Y	176	
	324376/10023	2ND LINE	617	LETROZOLE		141	
		3RD LINE	757	CAPECITABINE	Y	43	Y
				LETROZOLE		43	
		4TH LINE	799	CAPECITABINE	Y	63	
				EXEMESTANE		63	
		5TH LINE	862	ERIBULIN	Y	300	
				ERIBULIN	Y	300	
				EXEMESTANE		300	
	324376/10182	2ND LINE	302	ABEMACICLIB		57	
				EXEMESTANE		157	
		3RD LINE	379	CARBOPLATIN	Y	9	Y
				GEMCITABINE	Y	9	Y
		4TH LINE	393	ABEMACICLIB		127	
				CAPECITABINE	Y	127	
		5TH LINE	519	ERIBULIN	Y	99	
				ERIBULIN	Y	99	
	324508/10211	2ND LINE	263	PACLITAXEL	Y	138	Y
				PACLITAXEL	Y	138	Y
		3RD LINE	412	SACITUZUMAB GOVITECAN		52	
		4TH LINE	502	ELACESTRANT		44	
		5TH LINE	545	ALPELISIB		303	
				FULVESTRANT		303	
				TOPOTECAN	Y	303	
	324512/10065	2ND LINE	339	DOXORUBICIN	Y	854	Y
				FULVESTRANT		854	
				PALBOCICLIB		854	

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
	324513/10112	2ND LINE	29	CAPECITABINE	Y	295	Y
		3RD LINE	356	ERIBULIN MESILATE	Y	87	
		4TH LINE	456	TRASTUZUMAB DERUXTECAN		1	
		5TH LINE	498	SACITUZUMAB GOVITECAN		197	
	324513/10220	2ND LINE	275	TAMOXIFEN		178	
		3RD LINE	302	DB 1303		151	
				DB 1303		151	
	324798/10048	2ND LINE	135	CAPECITABINE	Y	87	Y
	324798/10175	2ND LINE	237	CARBOPLATIN	Y	74	Y
				GEMCITABINE	Y	74	Y
		3RD LINE	334	CAPECITABINE	Y	34	
	325824/10109	2ND LINE	361	CAPECITABINE	Y	87	Y
		3RD LINE	504	VINORELBINE	Y	68	
		4TH LINE	599	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	1	
	325824/10200	2ND LINE	367	BEVACIZUMAB		32	
				BEVACIZUMAB		32	
				PACLITAXEL	Y	32	Y
				PACLITAXEL	Y	32	Y
	330527/10090	2ND LINE	84	EVEROLIMUS		11	
				EVEROLIMUS		11	
				EVEROLIMUS		11	
				EXEMESTANE		11	
	331541/10067	2ND LINE	883	ALPELISIB		169	
				EXEMESTANE		169	
		3RD LINE	1051	CAPECITABINE	Y	64	Y
		4TH LINE	1122	TRASTUZUMAB DERUXTECAN		25	
	331541/10167	2ND LINE	289	CAPECITABINE	Y	224	Y
		3RD LINE	533	TRASTUZUMAB DERUXTECAN		64	
		4TH LINE	630	PACLITAXEL	Y	72	
				PACLITAXEL	Y	72	

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		5TH LINE	737	ERIBULIN	Y	132	
				ERIBULIN	Y	132	
	331893/10259	2ND LINE	462	FULVESTRANT		127	
				ALPELISIB		127	
	332071/10053	2ND LINE	170	CARBOPLATIN	Y	168	Y
				ERIBULIN	Y	168	Y
				ERIBULIN	Y	168	Y
				PACLITAXEL	Y	168	Y
				PACLITAXEL	Y	168	Y
	332071/10086	2ND LINE	502	ALPELISIB		242	
				FULVESTRANT		242	
	332072/10134	2ND LINE	76	FULVESTRANT		575	
				PALBOCICLIB		575	
		3RD LINE	664	FULVESTRANT		32	
	336753/10247	2ND LINE	241	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE		164	
		3RD LINE	374	CAPECITABINE	Y	NA	Y
				PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	NA	Y
		4TH LINE	526	BEVACIZUMAB		NA	
				BEVACIZUMAB		NA	
				DEPOXYTHILONE	Y	NA	
	336809/10131	2ND LINE	247	CAPECITABINE	Y	379	Y
				CYCLOPHOSPHAMIDE;PANAX GINSENG TOTAL	Y	379	Y
				GINSENOSEIDE EXTRACT			
				METHOTREXATE		379	
				METHOTREXATE		379	
				METHOTREXATE		379	
		3RD LINE	629	EVEROLIMUS		60	
				EVEROLIMUS		60	
				EVEROLIMUS		60	

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		4TH LINE	692	EXEMESTANE		60	
		5TH LINE	917	TRASTUZUMAB DERUXTECAN		206	
				BEVACIZUMAB		35	
				BEVACIZUMAB		35	
				CARBOPLATIN	Y	35	
				GEMCITABINE	Y	35	
	336809/10138	2ND LINE	188	UNSPECIFIED HERBAL AND TRADITIONAL		91	
				MEDICINE			
	336988/10154	2ND LINE	341	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	141	Y
				CAPECITABINE	Y	141	Y
		3RD LINE	497	CISPLATIN	Y	35	
				GEMCITABINE HYDROCHLORIDE	Y	35	
	337128/10070	2ND LINE	576	MEGESTROL ACETATE		394	
				MEGESTROL ACETATE		394	
				MEGESTROL ACETATE		394	
				MEGESTROL ACETATE		394	
		3RD LINE	996	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	62	Y
		4TH LINE	1056	EXEMESTANE		215	
	337128/10074	2ND LINE	177	RIVOCERANIB MESYLATE		94	
	337128/10081	2ND LINE	572	UNSPECIFIED HERBAL AND TRADITIONAL		59	
				MEDICINE			
	339022/10161	2ND LINE	131	ABEMACICLIB		NA	
				CAPECITABINE	Y	NA	Y
				FULVESTRANT		NA	
	339491/10088	2ND LINE	1082	CATEQUENTINIB		NA	
				GEMCITABINE	Y	NA	Y
	339491/10170	2ND LINE	330	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	NA	Y
	339491/10174	2ND LINE	275	CAPECITABINE	Y	1	Y
	339491/10298	2ND LINE	200	UNSPECIFIED HERBAL AND TRADITIONAL		NA	
				MEDICINE			

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
Pbo+Palbo+Fulv	344908/10189	2ND LINE	267	CAPECITABINE	Y	41	Y
				CYCLOPHOSPHAMIDE	Y	41	Y
				CYCLOPHOSPHAMIDE	Y	41	Y
				VINORELBINE	Y	41	Y
	346482/10196	2ND LINE	364	EVEROLIMUS		NA	
				EVEROLIMUS		NA	
				EVEROLIMUS		NA	
				EXEMESTANE		NA	
	357927/10308	3RD LINE	785	DOXORUBICIN	Y	NA	Y
		2ND LINE	280	ANASTROZOLE		55	
		3RD LINE	335	EVEROLIMUS		NA	
				EVEROLIMUS		NA	
	357961/10323	2ND LINE	185	EVEROLIMUS		NA	
				EVEROLIMUS		NA	
				EVEROLIMUS		NA	
				EXEMESTANE		NA	
	358193/10301	2ND LINE	93	PACLITAXEL	Y	NA	Y
				PACLITAXEL	Y	NA	Y
				PACLITAXEL	Y	183	Y
				PACLITAXEL	Y	183	Y
	323079/10057	2ND LINE	71	BEVACIZUMAB		NA	
				BEVACIZUMAB		NA	
				CAPECITABINE	Y	NA	Y
				TRASTUZUMAB DERUXTECAN		NA	
	323081/10126	2ND LINE	252	CAPECITABINE	Y	NA	Y
	323085/10179	2ND LINE	131	PACLITAXEL	Y	93	Y
				PACLITAXEL	Y	93	Y
		3RD LINE	302	ERIBULIN	Y	85	

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		4TH LINE	404	ERIBULIN	Y	85	
				CAPECITABINE	Y	77	
	323126/10319	2ND LINE	232	GEMCITABINE HYDROCHLORIDE	Y	NA	Y
				PEMBROLIZUMAB		NA	
				CARBOPLATIN	Y	NA	Y
	323131/10195	2ND LINE	119	LETROZOLE		308	
				RIBOCICLIB		308	
		3RD LINE	457	CAPECITABINE	Y	518	Y
		4TH LINE	986	PACLITAXEL	Y	NA	
				PACLITAXEL	Y	NA	
	323134/10004	2ND LINE	385	PACLITAXEL	Y	149	Y
				PACLITAXEL	Y	149	Y
	323140/10137	2ND LINE	260	CAPECITABINE	Y	85	Y
		3RD LINE	387	ERIBULIN	Y	308	
				ERIBULIN	Y	308	
		4TH LINE	722	EVEROLIMUS		29	
				EVEROLIMUS		29	
				EVEROLIMUS		29	
				EXEMESTANE		29	
		5TH LINE	778	CYCLOPHOSPHAMIDE	Y	29	
				CYCLOPHOSPHAMIDE	Y	29	
	323141/10052	2ND LINE	874	EVEROLIMUS		83	
				EVEROLIMUS		83	
				EVEROLIMUS		83	
				EXEMESTANE		83	
		3RD LINE	970	CARBOPLATIN	Y	343	Y
				PACLITAXEL	Y	343	Y
				PACLITAXEL	Y	343	Y
		4TH LINE	1338	CAPECITABINE	Y	NA	
	323144/10124	2ND LINE	370	EVEROLIMUS		261	

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Next Line Therapy by Line, Full Analysis Set
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Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
				EVEROLIMUS		261	
				EVEROLIMUS		261	
				EXEMESTANE		261	
		3RD LINE	641	CAPECITABINE	Y	337	Y
		4TH LINE	1030	TRASTUZUMAB DERUXTECAN		NA	
	323146/10091	2ND LINE	354	CAPECITABINE	Y	54	Y
				EVEROLIMUS		54	
				EVEROLIMUS		54	
				EVEROLIMUS		54	
				EXEMESTANE		54	
		3RD LINE	431	EXEMESTANE		767	
				LETROZOLE		767	
				PACLITAXEL	Y	767	
				PACLITAXEL	Y	767	
		4TH LINE	1213	TRASTUZUMAB		NA	
				TRASTUZUMAB DERUXTECAN		NA	
	323146/10239	2ND LINE	85	CAPECITABINE	Y	67	Y
	323146/10267	2ND LINE	64	ERIBULIN	Y	53	Y
				ERIBULIN	Y	53	Y
		3RD LINE	130	SACITUZUMAB GOVITECAN		60	
				SACITUZUMAB GOVITECAN		60	
	323166/10120	2ND LINE	239	CAPECITABINE	Y	232	Y
				FULVESTRANT		232	
		3RD LINE	465	EVEROLIMUS		175	
				EVEROLIMUS		175	
				EVEROLIMUS		175	
				EXEMESTANE		175	
		4TH LINE	655	GEMCITABINE	Y	221	
				PACLITAXEL	Y	221	
				PACLITAXEL	Y	221	

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Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		5TH LINE	896	CARBOPLATIN	Y	22	
				GEMCITABINE	Y	22	
		6TH LINE	945	PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	Y	60	
		7TH LINE	1040	DOCETAXEL	Y	25	
	323166/10315	2ND LINE	104	EXEMESTANE		NA	
				EVEROLIMUS		NA	
				EVEROLIMUS		NA	
				EVEROLIMUS		NA	
	323388/10274	2ND LINE	456	OLAPARIB		NA	
	323396/10188	2ND LINE	93	DOXORUBICIN	Y	1	Y
				DOXORUBICIN	Y	1	Y
	323401/10121	2ND LINE	303	CAPECITABINE	Y	3	Y
		3RD LINE	324	EXEMESTANE		6	
		4TH LINE	363	DOXORUBICIN	Y	1	
	323452/10273	2ND LINE	100	OLAPARIB		7	
	323463/10024	2ND LINE	1297	FULVESTRANT		NA	
	323572/10198	2ND LINE	313	EXEMESTANE		329	
				RIBOCICLIB		329	
	323572/10205	2ND LINE	202	GOSERELIN		333	
				LETROZOLE		333	
				RIBOCICLIB		333	
		3RD LINE	591	TRASTUZUMAB DERUXTECAN		NA	
	323572/10215	2ND LINE	679	CAPECITABINE	Y	85	Y
		3RD LINE	805	CARBOPLATIN	Y	64	
		4TH LINE	903	VINORELBINE	Y	NA	
	323629/10276	2ND LINE	73	CYCLOPHOSPHAMIDE	Y	43	Y
				CYCLOPHOSPHAMIDE	Y	43	Y
				EPIRUBICIN	Y	43	Y
		3RD LINE	155	TRASTUZUMAB DERUXTECAN		236	

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Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v12/output/l_fu_therapy_FAS_15NOV2024_41554.out
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554-HTAGBA_Ovrl_Surv_3382685
Git hash: 3b4ed22d0616647521ed5b603a515231be7c34f7
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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		4TH LINE	400	CAPECITABINE	Y	183	
		5TH LINE	579	SACITUZUMAB GOVITECAN		35	
	323633/10285	2ND LINE	82	CAPECITABINE	Y	65	Y
				PEMBROLIZUMAB		65	
		3RD LINE	153	DOCETAXEL	Y	141	
		4TH LINE	320	TRASTUZUMAB DERUXTECAN		86	
		5TH LINE	443	ABEMACICLIB		67	
				FULVESTRANT		67	
				TRASTUZUMAB		67	
		6TH LINE	538	PACLITAXEL	Y	NA	
				PACLITAXEL	Y	NA	
	323635/10194	2ND LINE	222	PACLITAXEL	Y	263	Y
				PACLITAXEL	Y	263	Y
	323635/10237	2ND LINE	462	PACLITAXEL	Y	183	Y
				PACLITAXEL	Y	183	Y
		3RD LINE	672	CYCLOPHOSPHAMIDE	Y	51	
				CYCLOPHOSPHAMIDE	Y	51	
				EPIRUBICIN	Y	51	
				FLUOROURACIL	Y	51	
		4TH LINE	751	SACITUZUMAB GOVITECAN		48	
		5TH LINE	819	ERIBULIN	Y	NA	
				ERIBULIN	Y	NA	
	323635/10280	2ND LINE	365	CAPECITABINE	Y	NA	Y
	323776/10013	2ND LINE	78	PACLITAXEL	Y	44	Y
				PACLITAXEL	Y	44	Y
		3RD LINE	141	CAPECITABINE	Y	45	
	323776/10051	NOT APPL ICABLE	814	TAMOXIFEN		NA	
	323776/10054	2ND LINE	294	PACLITAXEL	Y	106	Y
				PACLITAXEL	Y	106	Y

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		3RD LINE	423	CAPECITABINE	Y	184	
	323776/10229	2ND LINE	168	CAPECITABINE	Y	15	Y
	323776/10256	2ND LINE	248	PACLITAXEL	Y	135	Y
				PACLITAXEL	Y	135	Y
		3RD LINE	388	LETROZOLE		92	
	323777/10275	2ND LINE	457	CAPECITABINE	Y	NA	Y
	323777/10288	2ND LINE	179	DOCETAXEL	Y	42	Y
		3RD LINE	262	CAPECITABINE	Y	113	
	323897/10036	2ND LINE	192	EVEROLIMUS		249	
				EVEROLIMUS		249	
				EVEROLIMUS		249	
				EXEMESTANE		249	
		3RD LINE	428	CAPECITABINE	Y	470	Y
		4TH LINE	946	AZD 8205		217	
				AZD 8205		217	
		5TH LINE	1173	DOCETAXEL	Y	106	
		6TH LINE	1345	ERIBULIN	Y	NA	
				ERIBULIN	Y	NA	
	323897/10216	2ND LINE	92	GEMCITABINE	Y	135	Y
				PACLITAXEL	Y	135	Y
				PACLITAXEL	Y	135	Y
		3RD LINE	271	CAPECITABINE	Y	58	
		4TH LINE	335	CISPLATIN	Y	120	
				VINORELBINE	Y	120	
		5TH LINE	505	LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	Y	32	
		6TH LINE	542	EVEROLIMUS		22	
				EVEROLIMUS		22	
				EVEROLIMUS		22	
				EXEMESTANE		22	
		7TH LINE	570	LETROZOLE		50	

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
	323899/10097	2ND LINE	200	GOSERELIN ACETATE		50	
		3RD LINE	1101	TRASTUZUMAB DERUXTECAN		881	
		4TH LINE	1192	EVEROLIMUS;EXEMESTANE		77	
	323947/10282	2ND LINE	190	CAPECITABINE	Y	NA	Y
				BEVACIZUMAB		209	
				BEVACIZUMAB		209	
				GEMCITABINE	Y	209	Y
				PACLITAXEL	Y	209	Y
				PACLITAXEL	Y	209	Y
		3RD LINE	416	CARBOPLATIN	Y	NA	
				VINORELBINE	Y	NA	
		4TH LINE	442	TRASTUZUMAB DERUXTECAN		116	
		5TH LINE	580	CALCIUM FOLINATE		NA	
				CALCIUM FOLINATE		NA	
				CALCIUM FOLINATE		NA	
				CARBOPLATIN	Y	NA	
				ERIBULIN	Y	NA	
				ERIBULIN	Y	NA	
				FLUOROURACIL	Y	NA	
	323949/10251	2ND LINE	200	ANASTROZOLE		NA	
				RIBOCICLIB		NA	
	323973/10116	2ND LINE	258	CAPECITABINE	Y	44	Y
		3RD LINE	328	ERIBULIN	Y	184	
				ERIBULIN	Y	184	
		4TH LINE	548	CARBOPLATIN	Y	147	
	323976/10145	2ND LINE	1010	ALPELISIB		104	
				FULVESTRANT		104	
	323977/10029	2ND LINE	131	BEVACIZUMAB		217	
				BEVACIZUMAB		217	
				CAPECITABINE	Y	217	Y

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		3RD LINE	375	BEVACIZUMAB		134	
				BEVACIZUMAB		134	
				PACLITAXEL	Y	134	
				PACLITAXEL	Y	134	
		4TH LINE	692	VINORELBINE	Y	97	
		5TH LINE	820	SACITUZUMAB GOVITECAN		62	
		6TH LINE	922	ERIBULIN	Y	30	
				ERIBULIN	Y	30	
	323979/10106	2ND LINE	337	EVEROLIMUS		106	
				EVEROLIMUS		106	
				EVEROLIMUS		106	
				EXEMESTANE		106	
	323979/10115	2ND LINE	86	CAPECITABINE	Y	358	Y
	323979/10295	2ND LINE	239	EVEROLIMUS		65	
				EVEROLIMUS		65	
				EVEROLIMUS		65	
				EXEMESTANE		65	
		3RD LINE	316	CAPECITABINE	Y	57	Y
		4TH LINE	381	CARBOPLATIN	Y	29	
	323982/10089	2ND LINE	925	EVEROLIMUS		120	
				EVEROLIMUS		120	
				EVEROLIMUS		120	
				EXEMESTANE		120	
		3RD LINE	1065	CAPECITABINE	Y	NA	Y
	323983/10322	2ND LINE	210	CAPECITABINE	Y	NA	Y
	323986/10103	2ND LINE	302	CAPECITABINE	Y	85	Y
	323988/10076	2ND LINE	117	CAPECITABINE	Y	49	Y
		3RD LINE	177	CARBOPLATIN	Y	1	
	323988/10108	2ND LINE	350	ALPELISIB		26	
				FULVESTRANT		26	

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		3RD LINE	385	DOCETAXEL	Y	1	Y
		4TH LINE	427	CAPECITABINE	Y	140	
	323988/10144	2ND LINE	182	ALPELISIB		80	
				FULVESTRANT		80	
	323992/10008	2ND LINE	259	ERIBULIN	Y	143	Y
				ERIBULIN	Y	143	Y
		3RD LINE	471	EVEROLIMUS		171	
				EVEROLIMUS		171	
				EVEROLIMUS		171	
				EXEMESTANE		171	
		4TH LINE	646	ALPELISIB		601	
				FULVESTRANT		601	
	323998/10061	2ND LINE	322	DOCETAXEL	Y	106	Y
		3RD LINE	448	CAPECITABINE	Y	533	
		4TH LINE	1007	GEMCITABINE	Y	NA	
	324055/10245	2ND LINE	521	PACLITAXEL	Y	78	Y
				PACLITAXEL	Y	78	Y
	324063/10022	2ND LINE	58	ERIBULIN	Y	106	Y
				ERIBULIN	Y	106	Y
	324063/10163	2ND LINE	119	EVEROLIMUS		99	
				EVEROLIMUS		99	
				EVEROLIMUS		99	
				EXEMESTANE		99	
		3RD LINE	208	CARBOPLATIN	Y	102	Y
	324071/10025	2ND LINE	754	CAPECITABINE	Y	NA	Y
	324187/10125	2ND LINE	477	CAPECITABINE	Y	290	Y
		3RD LINE	799	TRASTUZUMAB DERUXTECAN		155	
		4TH LINE	974	ERIBULIN	Y	175	
				ERIBULIN	Y	175	
		5TH LINE	1170	SACITUZUMAB GOVITECAN		NA	

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
	324246/10111	2ND LINE	515	CAPECITABINE	Y	151	Y
	324248/10149	2ND LINE	69	BEVACIZUMAB		180	
				BEVACIZUMAB		180	
				PACLITAXEL	Y	180	Y
				PACLITAXEL	Y	180	Y
			282	LETROZOLE		169	
				RIBOCICLIB		169	
				TRIPTORELIN		169	
		3RD LINE	469	TRASTUZUMAB DERUXTECAN		233	
		4TH LINE	729	SACITUZUMAB GOVITECAN		50	
		5TH LINE	792	EPIRUBICIN	Y	29	
		6TH LINE	841	BEVACIZUMAB		211	
				BEVACIZUMAB		211	
				PACLITAXEL	Y	211	
				PACLITAXEL	Y	211	
				PERTUZUMAB;TRASTUZUMAB		211	
	324249/10104	7TH LINE	1072	TRASTUZUMAB		NA	
		2ND LINE	32	CARBOPLATIN	Y	90	Y
				PACLITAXEL	Y	90	Y
				PACLITAXEL	Y	90	Y
		3RD LINE	191	ERIBULIN	Y	118	
				ERIBULIN	Y	118	
		4TH LINE	320	CAPECITABINE	Y	53	
		5TH LINE	373	VINORELBINE TARTRATE	Y	7	
	324376/10000	2ND LINE	462	CAPECITABINE	Y	7	Y
		3RD LINE	487	CYCLOPHOSPHAMIDE	Y	112	
				CYCLOPHOSPHAMIDE	Y	112	
				PACLITAXEL	Y	112	
				PACLITAXEL	Y	112	
	324376/10082	2ND LINE	400	ANASTROZOLE		28	

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		3RD LINE	428	ANASTROZOLE		288	
				EVEROLIMUS		288	
				EVEROLIMUS		288	
				EVEROLIMUS		288	
				FULVESTRANT		288	
		4TH LINE	715	CAPECITABINE	Y	496	Y
				FULVESTRANT		496	
	324376/10250	2ND LINE	135	GEMCITABINE	Y	7	Y
				PACLITAXEL	Y	7	Y
				PACLITAXEL	Y	7	Y
	324508/10012	2ND LINE	205	ALPELISIB		144	
				FULVESTRANT		144	
		3RD LINE	319	CAPECITABINE	Y	97	Y
		4TH LINE	415	FULVESTRANT		62	
				MIRDAMETINIB		62	
				MIRDAMETINIB		62	
		5TH LINE	491	CARBOPLATIN	Y	152	
				PACLITAXEL	Y	152	
				PACLITAXEL	Y	152	
		6TH LINE	652	PAXALISIB		1	
				PAXALISIB		1	
		7TH LINE	684	DOXORUBICIN	Y	17	
	324513/10021	2ND LINE	368	ALPELISIB		209	
				ANASTROZOLE		209	
		3RD LINE	576	EVEROLIMUS		343	
				EVEROLIMUS		343	
				EVEROLIMUS		343	
				EXEMESTANE		343	
		4TH LINE	932	TRASTUZUMAB DERUXTECAN		182	
	324513/10060	2ND LINE	308	CAPECITABINE	Y	543	Y

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Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

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				DOCETAXEL	Y	543	Y
		3RD LINE	856	TRASTUZUMAB DERUXTECAN		138	
		4TH LINE	1004	SACITUZUMAB GOVITECAN		300	
		5TH LINE	1310	ERIBULIN	Y	NA	
				ERIBULIN	Y	NA	
	324798/10010	2ND LINE	296	TAMOXIFEN		12	
		3RD LINE	324	CARBOPLATIN	Y	45	Y
				PACLITAXEL	Y	45	Y
				PACLITAXEL	Y	45	Y
		4TH LINE	392	ERIBULIN	Y	43	
				ERIBULIN	Y	43	
	324798/10092	2ND LINE	260	ALPELISIB		NA	
				LETROZOLE		NA	
		3RD LINE	659	LENVATINIB		NA	
				LETROZOLE		NA	
				PEMBROLIZUMAB		NA	
		4TH LINE	831	CAPECITABINE	Y	NA	Y
		5TH LINE	1019	VINORELBINE	Y	NA	
		6TH LINE	1087	ERIBULIN	Y	NA	
				ERIBULIN	Y	NA	
		7TH LINE	1116	CARBOPLATIN	Y	44	
				GEMCITABINE	Y	44	
		8TH LINE	1172	TRASTUZUMAB DERUXTECAN		NA	
	324798/10101	2ND LINE	624	PHOSPHATIDYLINOSITOL-3-KINASE (PI3K) INHIBITORS		58	
		3RD LINE	715	LENVATINIB		189	
				LETROZOLE		189	
				PEMBROLIZUMAB		189	
		4TH LINE	909	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	208	Y

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Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		5TH LINE	1131	CARBOPLATIN	Y	NA	
				GEMCITABINE	Y	NA	
	324799/10063	2ND LINE	181	CAPECITABINE	Y	NA	Y
	324799/10165	2ND LINE	203	CAPECITABINE	Y	68	Y
				CISPLATIN	Y	68	Y
	325394/10035	2ND LINE	427	ALPELISIB		57	
				FULVESTRANT		57	
		3RD LINE	490	CAPECITABINE	Y	289	Y
		4TH LINE	763	TRASTUZUMAB DERUXTECAN		171	
		5TH LINE	959	ERIBULIN	Y	NA	
				ERIBULIN	Y	NA	
	325824/10148	2ND LINE	883	FULVESTRANT		NA	
				RLY 2608		NA	
				RLY 2608		NA	
	331800/10207	2ND LINE	71	CISPLATIN	Y	81	Y
				GEMCITABINE	Y	81	Y
	331800/10265	2ND LINE	362	GEMCITABINE	Y	290	Y
	331893/10269	2ND LINE	47	DOCETAXEL	Y	32	Y
				CAPECITABINE	Y	32	Y
	331893/10304	2ND LINE	310	GEMCITABINE HYDROCHLORIDE	Y	54	Y
				GEMCITABINE HYDROCHLORIDE	Y	54	Y
				GEMCITABINE HYDROCHLORIDE	Y	54	Y
				PACLITAXEL	Y	54	Y
				PACLITAXEL	Y	54	Y
	332071/10055	2ND LINE	201	PACLITAXEL	Y	64	Y
				PACLITAXEL	Y	64	Y
	332071/10202	2ND LINE	204	DOCETAXEL	Y	194	Y
		3RD LINE	448	CARBOPLATIN	Y	48	
		4TH LINE	522	BEVACIZUMAB		130	

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Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/l_fu_therapy.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v12/output/l_fu_therapy_FAS_15NOV2024_41554.out
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 3b4ed22d0616647521ed5b603a515231be7c34f7
03 JUN 2025 06:52 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
				BEVACIZUMAB		130	
				ERIBULIN	Y	130	
		5TH LINE	740	ERIBULIN	Y	130	
				IXABEPILONE	Y	18	
		6TH LINE	817	CAPECITABINE	Y	18	
				BEVACIZUMAB		8	
				BEVACIZUMAB		8	
				GEMCITABINE HYDROCHLORIDE	Y	8	
	332072/10028	2ND LINE	65	CAPECITABINE	Y	91	Y
	332072/10044	2ND LINE	68	CAPECITABINE	Y	11	Y
	332072/10047	2ND LINE	70	ERIBULIN	Y	NA	Y
				ERIBULIN	Y	NA	Y
	332072/10062	2ND LINE	237	CYCLOPHOSPHAMIDE	Y	21	Y
				CYCLOPHOSPHAMIDE	Y	21	Y
				DOCETAXEL	Y	21	Y
	332072/10094	2ND LINE	414	CAPECITABINE	Y	288	Y
		3RD LINE	833	CYCLOPHOSPHAMIDE	Y	24	
				CYCLOPHOSPHAMIDE	Y	24	
				EPIRUBICIN	Y	24	
		4TH LINE	890	BEVACIZUMAB		304	
				BEVACIZUMAB		304	
				PACLITAXEL	Y	304	
				PACLITAXEL	Y	304	
	332072/10133	2ND LINE	171	CYCLOPHOSPHAMIDE	Y	111	Y
				CYCLOPHOSPHAMIDE	Y	111	Y
				DOCETAXEL	Y	111	Y
		3RD LINE	307	VINORELBINE	Y	80	
		4TH LINE	401	IXABEPILONE	Y	50	
	332072/10199	2ND LINE	137	CARBOPLATIN	Y	122	Y
	333421/10254	2ND LINE	70	ALPELISIB		16	

ASTDY is relative day calculated from the treatment start. The CHEMOTTE endpoint is calculated as time from randomization.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/l_fu_therapy.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v12/output/l_fu_therapy_FAS_15NOV2024_41554.out
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554-HTAGBA_Ovrl_Surv_3382685
Git hash: 3b4ed22d0616647521ed5b603a515231be7c34f7
03 JUN 2025 06:52 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)	
	336753/10068	2ND LINE	323	FULVESTRANT		16		
				CISPLATIN	Y	1020	Y	
		3RD LINE	799	GEMCITABINE HYDROCHLORIDE	Y	1020	Y	
				BEVACIZUMAB		172		
				BEVACIZUMAB		172		
				CARBOPLATIN	Y	172		
		4TH LINE	1045	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	172		
				ERIBULIN	Y	67		
				ERIBULIN	Y	67		
				FULVESTRANT		67		
	PALBOCICLIB				67			
	5TH LINE	1111	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE		232			
	336753/10150	2ND LINE	209	ERIBULIN MESILATE	Y	28	Y	
		3RD LINE	270	OTHER MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES		239		
		4TH LINE	566	ABEMACICLIB		34		
				FULVESTRANT		34		
				GOSERELIN ACETATE		34		
		5TH LINE	631	CAPECITABINE	Y	85		
		6TH LINE	736	DEPOXYTHILONE	Y	85		
				CISPLATIN	Y	NA		
		336753/10180	2ND LINE	365	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	NA	
					BEVACIZUMAB		355	
	BEVACIZUMAB					355		
	LIPOSOMAL DOXORUBICIN HYDROCHLORIDE				Y	355	Y	
	3RD LINE		409	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	81		
	4TH LINE		532	TRASTUZUMAB DERUXTECAN		21		
	5TH LINE		574	CATEQUENTINIB		146		

ASTDY is relative day calculated from the treatment start. The CHEMOTTE endpoint is calculated as time from randomization.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/l_fu_therapy.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v12/output/l_fu_therapy_FAS_15NOV2024_41554.out
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 3b4ed22d0616647521ed5b603a515231be7c34f7
03 JUN 2025 06:52 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
	336753/10252	10TH LINE	679	ERIBULIN MESILATE	Y	NA	
		2ND LINE	78	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	22	Y
		3RD LINE	122	CARBOPLATIN	Y	NA	
				GEMCITABINE HYDROCHLORIDE	Y	NA	
		4TH LINE	159	TRASTUZUMAB DERUXTECAN		178	
				TRASTUZUMAB		178	
		5TH LINE	369	CISPLATIN	Y	26	
		6TH LINE	420	EVEROLIMUS		74	
				EVEROLIMUS		74	
				EVEROLIMUS		74	
				EXEMESTANE		74	
		7TH LINE	502	SACITUZUMAB GOVITECAN		NA	
		8TH LINE	432	BEVACIZUMAB		366	
				BEVACIZUMAB		366	
				CAPECITABINE	Y	366	
		9TH LINE	628	PROTEIN KINASE INHIBITORS		36	
				ALL OTHER THERAPEUTIC PRODUCTS		36	
				ALL OTHER THERAPEUTIC PRODUCTS		36	
	336809/10158	2ND LINE	196	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE		NA	
	336809/10320	2ND LINE	356	CAPECITABINE	Y	NA	Y
				CHIDAMIDE		NA	
				EXEMESTANE		NA	
	336988/10191	2ND LINE	305	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	416	Y
				CAPECITABINE	Y	416	Y
				EVEROLIMUS		416	
				EVEROLIMUS		416	
				EVEROLIMUS		416	
				EXEMESTANE		416	

ASTDY is relative day calculated from the treatment start. The CHEMOTTE endpoint is calculated as time from randomization.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/l_fu_therapy.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v12/output/l_fu_therapy_FAS_15NOV2024_41554.out
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 3b4ed22d0616647521ed5b603a515231be7c34f7
03 JUN 2025 06:52 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
		3RD LINE	722	DEPOXYTHILONE	Y	416	Y
				ERIBULIN	Y	169	
		4TH LINE	922	ERIBULIN	Y	169	
				CISPLATIN	Y	29	
		5TH LINE	974	VINORELBINE	Y	29	
				CATEQUENTINIB		NA	
				PIRARUBICIN	Y	NA	
	337128/10079	2ND LINE	457	LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	Y	232	Y
				VINORELBINE TARTRATE	Y	232	Y
	337128/10132	2ND LINE	34	PACLITAXEL LIPOSOME	Y	1	Y
	337128/10253	2ND LINE	69	CARBOPLATIN	Y	46	Y
				VINORELBINE TARTRATE	Y	46	Y
		3RD LINE	120	ALPELISIB		107	
				LETROZOLE		107	
		4TH LINE	212	TRASTUZUMAB DERUXTECAN		150	
				DEPOXYTHILONE	Y	150	
		5TH LINE	411	INVESTIGATIONAL ANTINEOPLASTIC DRUGS		40	
				INVESTIGATIONAL ANTINEOPLASTIC DRUGS		40	
	337370/10168	2ND LINE	132	BEVACIZUMAB		93	
				BEVACIZUMAB		93	
				CAPECITABINE	Y	93	Y
				ERIBULIN MESILATE	Y	93	Y
	337440/10130	2ND LINE	67	VINORELBINE	Y	197	Y
		3RD LINE	432	CAPECITABINE	Y	405	
	339020/10139	2ND LINE	57	CYTARABINE	Y	191	Y
				EXEMESTANE		191	
	339022/10203	2ND LINE	72	UNSPECIFIED HERBAL AND TRADITIONAL		128	
				MEDICINE			
				PACLITAXEL	Y	128	Y
				PACLITAXEL	Y	128	Y

ASTDY is relative day calculated from the treatment start. The CHEMOTTE endpoint is calculated as time from randomization.
Inavo = Inavolisib, Pho = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/l_fu_therapy.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v12/output/l_fu_therapy_FAS_15NOV2024_41554.out
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 3b4ed22d0616647521ed5b603a515231be7c34f7
03 JUN 2025 06:52 GMT

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Next Line Therapy by Line, Full Analysis Set
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

Treatment	Center/ Patient ID	Line of Therapy	Study Day of Start of Med.	Standardized Medication Name	Chemo Flag	Duratio n of Medicat ion (days)	CHEMOTTE Endpoint Event (s)
	339491/10135	2ND LINE	129	PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	Y	87	Y
		3RD LINE	273	EVEROLIMUS		167	
				EVEROLIMUS		167	
				EVEROLIMUS		167	
				EXEMESTANE		167	
	339491/10268	2ND LINE	86	PEMBROLIZUMAB		NA	
				CAPECITABINE	Y	NA	Y
	339491/10281	2ND LINE	-72	PACLITAXEL	Y	NA	Y
				PACLITAXEL	Y	NA	Y
	345707/10300	2ND LINE	115	ALPELISIB		NA	
				FULVESTRANT		NA	
	357926/10306	2ND LINE	313	CAPECITABINE	Y	NA	Y
	358498/10302	2ND LINE	350	CAPECITABINE	Y	163	Y
	358498/10310	2ND LINE	181	CAPECITABINE	Y	NA	Y
	358498/10313	2ND LINE	247	CAPECITABINE	Y	181	Y
		3RD LINE	441	CARBOPLATIN	Y	NA	
				PACLITAXEL	Y	NA	
				PACLITAXEL	Y	NA	

ASTDY is relative day calculated from the treatment start. The CHEMOTTE endpoint is calculated as time from randomization.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Program name: programs/tlg/l fu therapy.R
Output path: /ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v12/output/l_fu_therapy_FAS_15NOV2024_41554.out
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 3b4ed22d0616647521ed5b603a515231be7c34f7
03 JUN 2025 06:52 GMT

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

4 Sonstige Analysen

4.5 Studienabbruch unter Angabe der Gründe

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Disposition, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)	Pbo+Palbo+Fulv (N=164)	All Patients (N=325)
Received Any Study Drug	160 (99.4%)	164 (100%)	324 (99.7%)
On-study status	75 (46.6%)	65 (39.6%)	140 (43.1%)
Alive: On Treatment	49 (30.4%)	20 (12.2%)	69 (21.2%)
Alive: In Follow-up	26 (16.1%)	45 (27.4%)	71 (21.8%)
Discontinued the study	86 (53.4%)	99 (60.4%)	185 (56.9%)
ADVERSE EVENT	1 (0.6%)	0	1 (0.3%)
DEATH	71 (44.1%)	79 (48.2%)	150 (46.2%)
LOST TO FOLLOW-UP	4 (2.5%)	5 (3.0%)	9 (2.8%)
PHYSICIAN DECISION	1 (0.6%)	0	1 (0.3%)
PROGRESSIVE DISEASE	1 (0.6%)	0	1 (0.3%)
SYMPTOMATIC DETERIORATION	1 (0.6%)	0	1 (0.3%)
WITHDRAWAL BY SUBJECT	7 (4.3%)	15 (9.1%)	22 (6.8%)

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:44 GMT
Output: /ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/t_ds_FAS_15NOV2024_41554.out

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

4 Sonstige Analysen

4.6 Behandlungsabbrüche unter Angabe der Gründe

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Discontinuation from Individual Study Treatment Reasons by Trial Treatment, Full Analysis Set
Protocol: W041554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Inavo+Palbo+Fulv (N=161)			Pbo+Palbo+Fulv (N=164)		
	Inavo	Palbo	Fulv	Pbo	Palbo	Fulv
Received Study Drug	160 (99.4%)	160 (99.4%)	160 (99.4%)	164 (100%)	164 (100%)	164 (100%)
Discontinued Treatment	111 (68.9%)	113 (70.2%)	111 (68.9%)	144 (87.8%)	144 (87.8%)	144 (87.8%)
ADVERSE EVENT	9 (5.6%)	10 (6.2%)	6 (3.7%)	1 (0.6%)	0	0
DEATH	6 (3.7%)	5 (3.1%)	5 (3.1%)	3 (1.8%)	3 (1.8%)	3 (1.8%)
LOST TO FOLLOW-UP	1 (0.6%)	1 (0.6%)	1 (0.6%)	0	0	0
NON-COMPLIANCE WITH STUDY DRUG	2 (1.2%)	2 (1.2%)	2 (1.2%)	0	0	0
PHYSICIAN DECISION	1 (0.6%)	2 (1.2%)	2 (1.2%)	0	0	0
PROGRESSIVE DISEASE	86 (53.4%)	87 (54.0%)	89 (55.3%)	130 (79.3%)	130 (79.3%)	130 (79.3%)
SYMPTOMATIC DETERIORATION	1 (0.6%)	1 (0.6%)	1 (0.6%)	6 (3.7%)	6 (3.7%)	6 (3.7%)
WITHDRAWAL BY SUBJECT	5 (3.1%)	5 (3.1%)	5 (3.1%)	4 (2.4%)	5 (3.0%)	5 (3.0%)

Reasons for discontinuing individual trial treatments reported on the Study Drug Early Discontinuation CRF page.
Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant

Git repository: https://code.roche.com/studies/clinicalreporting/W041554_Overall_Survival_Reporting_Event_8219953
Git hash: 142631781fc0b756fa9e2423146b60eb622e69aa
03 FEB 2025 14:24 GMT
Output: /ocean/harbour/CDT70123/W041554/CSRInterim_Ovrl_Surv/prod_srep_v1/output/t_ds_tx_FAS_15NOV2024_41554.out

Anhang 4-G1 – Analysen Studie INAVO120; finaler OS-Datenschnitt vom 15. November 2024

4 Sonstige Analysen

4.7 Neue viszerale Metastasierung zum Zeitpunkt der Progression

Disease Characteristics at Progression, Patients who Discontinued Treatment, Patients who Received 2L
Protocol: WO41554, CCOD: 15NOV2024, Data Snapshot: 10JAN2025

	Did not Receive Chemotherapy in 2L (N=68)	Received Chemotherapy in 2L (N=125)	All Patients (N=193)
New Visceral Metastasis at Progression			
n	68	125	193
Yes	19 (27.9%)	56 (44.8%)	75 (38.9%)
No	49 (72.1%)	69 (55.2%)	118 (61.1%)

Inavo = Inavolisib, Pbo = Placebo, Palbo = Palbociclib, Fulv = Fulvestrant
Program name: programs/tlg/t_patchar2.R
Output path:
/ocean/harbour/CDT70123/WO41554/HTAGBA_Ovrl_Surv/prod_gba_v16/output/t_patchar2_TX_2L_15NOV2024_41554.docx
Git repository: https://code.roche.com/studies/clinicalreporting/WO41554_HTAGBA_Ovrl_Surv_3382685
Git hash: 1ce64ae7680efe91ab865341be3aa1b0c41f89ca
30 JUN 2025 16:35 GMT

Anhang 4-G2 – Analysen Studie INAVO120; erster Datenschnitt vom 29. September 2023

1 Wirksamkeit

1.1 Gesamtüberleben (OS)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

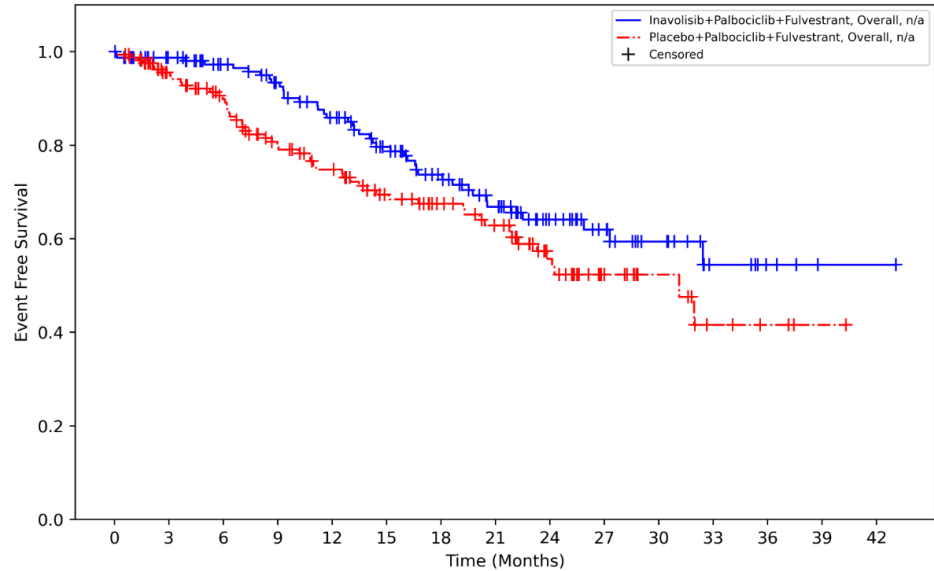
STUDY: WO41554
CLINICAL CUT-OFF: 2023-09-29
POPULATION: Intent-to-treat (ITT)|No specification
ENDPOINT: (Efficacy) Overall Survival|No specification
MODEL: Stratified(Stratification factor/s: Visceral Disease, Endocrine Resistance, Geographic Region)
REPORT: EFF_TTE Time to Event analysis

		Inavolisib+Palbociclib+Fulvestrant												Placebo+Palbociclib+Fulvestrant												Inavolisib+Palbociclib+Fulvestrant vs Placebo+Palbociclib+Fulvestrant					
		Patients		Patients with event		Patients censored		Time to event						Patients		Patients with event		Patients censored		Time to event						Time to event (log-rank)	Hazard ratio				Interaction test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% lower CI for Q1	95% upper CI for Q1	Median (months)	95% lower CI for Median	95% upper CI for Median	n	%	n	%	n	%	Q1 (months)	95% lower CI for Q1	95% upper CI for Q1	Median (months)	95% lower CI for Median	95% upper CI for Median	p-value	Hazard ratio	95% lower CI	95% upper CI	p-value (likelihood ratio)	
Overall	n/a	161	100.0	42	26.1	119	73.9	16.6	13.5	20.5	NE	27.3	NE	164	100.0	55	33.5	109	66.5	11.1	7.3	16.8	31.1	22.3	NE	0.0338	0.64	0.43	0.97	NE	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.

Program: sourced_repos/hta-global-share/inst/scripts/t_eff_tte.R
Git repository: https://ssh.code.roche.com/studies/clinicalreporting/WO41554_hta_csr-primary_3377334.git
Git hash: ca7e5d85245ee561e5b3ada65cf181aad101b838
Exported at: 2024-04-09 06:19:00

STUDY: W041554
CLINICAL CUT-OFF: 2023-09-29
POPULATION: Intent-to-treat (ITT)
ENDPOINT: (Efficacy) Overall Survival
MODEL: Unstratified
REPORT: KM_PLOT Kaplan-Meier analysis
SUBGROUP: All
SOC/PT: -/-



	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42
Patients at risk															
Inavolisib+Palbociclib+Fulvestrant Overall, n/a	161	143	127	114	101	85	69	56	38	26	17	8	4	1	1
Placebo+Palbociclib+Fulvestrant Overall, n/a	164	139	120	98	87	72	61	52	33	19	11	5	3	1	
Patients censored															
Inavolisib+Palbociclib+Fulvestrant Overall, n/a	0	16	30	38	42	51	61	68	84	95	103	111	115	118	118
Placebo+Palbociclib+Fulvestrant Overall, n/a	0	18	29	38	43	52	61	66	80	92	100	104	106	108	

Program: sourced_repos/hta-global-share/inst/scripts/g_km_plot.R
Git repository: https://ssh.code.roche.com/studies/clinicalreporting/W041554_hta_csr-primary_3377334.git
Git hash: 4e3c19430bc44bffa0c5b0f7e58e93b2378cd2741
Exported at: 2024-04-25 08:09:16
Output csv: /ocean/harbour/CDT70123/W041554/hta_csr-primary/dev/output/g_km_plot_SG_OS_FAS.csv

Anhang 4-G2 – Analysen Studie INAVO120; erster Datenschnitt vom 29. September 2023

1 Wirksamkeit

1.2 Progressionsfreies Überleben (PFS)

1.2.1 Progressionsfreies Überleben (PFS) (Prüfarzt-basiert)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

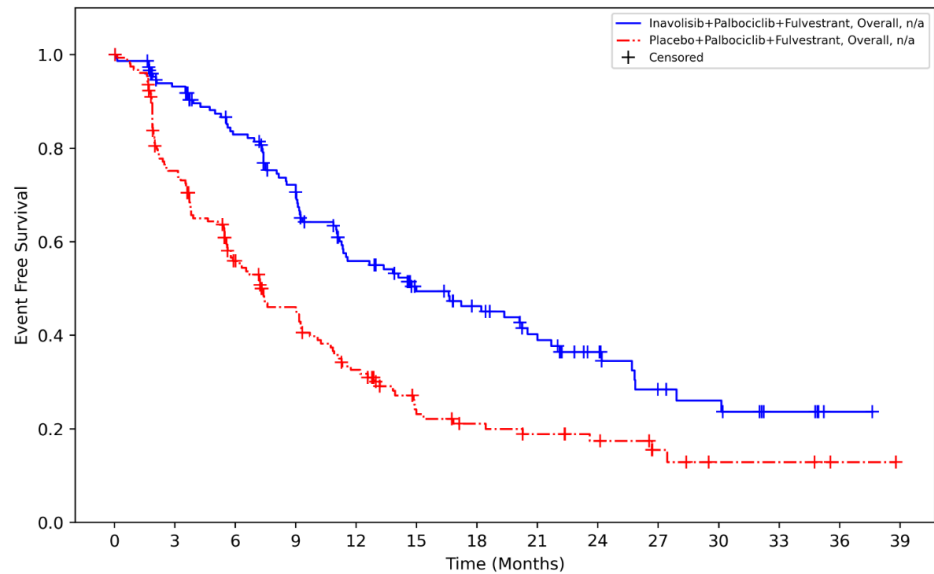
STUDY: WO41554
CLINICAL CUT-OFF: 2023-09-29
POPULATION: Intent-to-treat (ITT)|No specification
ENDPOINT: (Efficacy) Progression Free Survival|assessed by investigator per RECIST v1.1
MODEL: Stratified(Stratification factor/s: Visceral Disease, Endocrine Resistance, Geographic Region)
REPORT: EFF_TTE Time to Event analysis

		Inavolisib+Palbociclib+Fulvestrant												Placebo+Palbociclib+Fulvestrant												Inavolisib+Palbociclib+Fulvestrant vs Placebo+Palbociclib+Fulvestrant					
		Patients		Patients with event		Patients censored		Time to event						Patients		Patients with event		Patients censored		Time to event						Time to event (log-rank)	Hazard ratio				Interaction test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% lower CI for Q1	95% upper CI for Q1	Median (months)	95% lower CI for Median	95% upper CI for Median	n	%	n	%	n	%	Q1 (months)	95% lower CI for Q1	95% upper CI for Q1	Median (months)	95% lower CI for Median	95% upper CI for Median	p-value	Hazard ratio	95% lower CI	95% upper CI	p-value (likelihood ratio)	
Overall	n/a	161	100.0	82	50.9	79	49.1	8.0	6.6	9.1	15.0	11.3	20.5	164	100.0	113	68.9	51	31.1	3.2	2.0	3.7	7.3	5.6	9.3	<0.0001	0.43	0.32	0.59	NE	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.

Program: sourced_repos/hta-global-share/inst/scripts/t_eff_tte.R
Git repository: https://ssh.code.roche.com/studies/clinicalreporting/WO41554_hta_csr-primary_3377334.git
Git hash: ca7e5d85245ee561e5b3ada65cf181aad101b838
Exported at: 2024-04-09 06:27:50

STUDY: W041554
CLINICAL CUT-OFF: 2023-09-29
POPULATION: Intent-to-treat (ITT)
ENDPOINT: (Efficacy) Progression Free Survival|assessed by investigator per RECIST v1.1
MODEL: Unstratified
REPORT: KM_PLOT Kaplan-Meier analysis
SUBGROUP: All
SOC/PT: -/-



	0	3	6	9	12	15	18	21	24	27	30	33	36	39
Patients at risk														
Inavolisib+Palbociclib+Fulvestrant Overall, n/a	161	134	111	92	66	48	41	31	22	13	11	5	1	
Placebo+Palbociclib+Fulvestrant Overall, n/a	164	113	77	59	40	23	19	16	12	6	3	3	1	
Patients censored														
Inavolisib+Palbociclib+Fulvestrant Overall, n/a	0	17	26	31	37	48	52	56	63	68	69	74	78	
Placebo+Palbociclib+Fulvestrant Overall, n/a	0	13	21	26	28	35	37	38	41	46	48	48	50	

Program: sourced_repos/hta-global-share/inst/scripts/g_km_plot.R
Git repository: https://ssh.code.roche.com/studies/clinicalreporting/W041554_hta_csr-primary_3377334.git
Git hash: 4e3c19430bc44bff0c5b0f7e58e93b2378cd2741
Exported at: 2024-04-22 16:20:23
Output csv: /ocean/harbour/CDT70123/W041554/hta_csr-primary/dev/output/g_km_plot_SG_PFS_FAS.csv

Anhang 4-G2 – Analysen Studie INAVO120; erster Datenschnitt vom 29. September 2023

1 Wirksamkeit

1.2 Progressionsfreies Überleben (PFS)

1.2.2 Progressionsfreies Überleben (PFS) (BICR)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

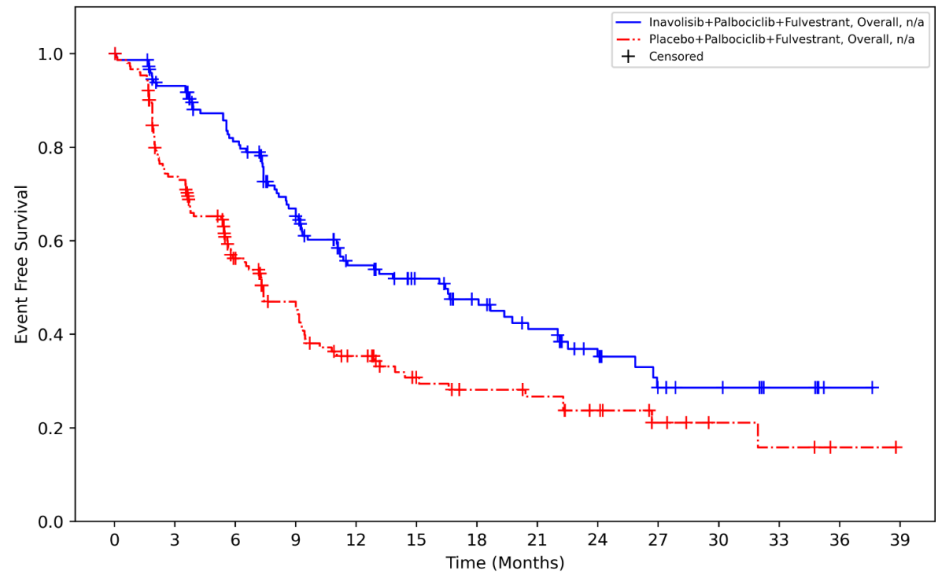
STUDY: WO41554
CLINICAL CUT-OFF: 2023-09-29
POPULATION: Intent-to-treat (ITT)|No specification
ENDPOINT: (Efficacy) Progression Free Survival|assessed by blinded independent central review (BICR) per RECIST v1.1
MODEL: Stratified(Stratification factor/s: Visceral Disease, Endocrine Resistance, Geographic Region)
REPORT: EFF_TTE Time to Event analysis

		Inavolisib+Palbociclib+Fulvestrant												Placebo+Palbociclib+Fulvestrant												Inavolisib+Palbociclib+Fulvestrant vs Placebo+Palbociclib+Fulvestrant				
		Patients		Patients with event		Patients censored		Time to event						Patients		Patients with event		Patients censored		Time to event						Time to event (log-rank)	Hazard ratio			Interaction test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% lower CI for Q1	95% upper CI for Q1	Median (months)	95% lower CI for Median	95% upper CI for Median	n	%	n	%	n	%	Q1 (months)	95% lower CI for Q1	95% upper CI for Q1	Median (months)	95% lower CI for Median	95% upper CI for Median	p-value	Hazard ratio	95% lower CI	95% upper CI	p-value (likelihood ratio)
Overall	n/a	161	100.0	77	47.8	84	52.2	7.4	5.7	8.6	16.4	11.1	22.0	164	100.0	98	59.8	66	40.2	2.5	2.0	3.7	7.4	5.8	9.2	<0.0001	0.50	0.36	0.68	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.

Program: sourced_repos/hta-global-share/inst/scripts/t_eff_tte.R
Git repository: https://ssh.code.roche.com/studies/clinicalreporting/WO41554_hta_csr-primary_3377334.git
Git hash: ca7e5d85245ee561e5b3ada65cf181aad101b838
Exported at: 2024-04-09 06:07:32

STUDY: W041554
CLINICAL CUT-OFF: 2023-09-29
POPULATION: Intent-to-treat (ITT)
ENDPOINT: (Efficacy) Progression Free Survival|assessed by blinded independent central review (BICR) per RECIST v1.1
MODEL: Unstratified
REPORT: KM_PLOT Kaplan-Meier analysis
SUBGROUP: All
SOC/PT: -/-



	0	3	6	9	12	15	18	21	24	27	30	33	36	39
Patients at risk														
Inavolisib+Palbociclib+Fulvestrant Overall, n/a	161	133	107	82	59	48	39	31	21	12	10	5	1	
Placebo+Palbociclib+Fulvestrant Overall, n/a	164	107	71	53	36	24	20	18	12	7	4	3	1	
Patients censored														
Inavolisib+Palbociclib+Fulvestrant Overall, n/a	0	18	28	35	44	52	57	60	66	72	74	79	83	
Placebo+Palbociclib+Fulvestrant Overall, n/a	0	18	30	37	41	49	51	52	56	60	63	63	65	

Program: sourced_repos/hta-global-share/inst/scripts/g_km_plot.R
Git repository: https://ssh.code.roche.com/studies/clinicalreporting/W041554_hta_csr-primary_3377334.git
Git hash: 4e3c19430bc44bff0c5b0f7e58e93b2378cd2741
Exported at: 2024-04-22 16:17:00
Output csv: /ocean/harbour/CDT70123/W041554/hta_csr-primary/dev/output/g_km_plot_SG_PFSB_FAS.csv