

# QOL Outcomes in Bria-ABC Late Stage Metastatic Phase 3 Trial



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## BACKGROUND

Bria-IMT is a combination immunotherapy comprising the allogeneic whole-cell vaccine SV-BR-1-GM, administered with low-dose cyclophosphamide (CTX), pegylated interferon alpha (IFN $\alpha$ ), and an immune checkpoint inhibitor (CPI). SV-BR-1-GM breast cancer cells are engineered to express both class I and II HLA molecules, secrete GM-CSF to enhance dendritic cell activation, and present tumor associated antigens such as HER2 and PRAME. Functioning as antigen presenting cells, these cells serve as a reservoir of shared tumor antigens capable of activating anti tumor immune responses. Enhancements to SV-BR-1-GM have improved in vitro immunologic characteristics (Lopez-Lago, SABC 2023)<sup>1</sup>. The addition of CPI is intended to potentiate SV-BR-1-GM induced immune activation by overcoming tumor induced immune suppression.

We present interim results from a randomized Phase 3 Bria-ABC study in patients with advanced metastatic breast cancer (aMBC).

## METHODS

Patients are randomized 1:1 to Bria-IMT+CPI or TPC. The Bria-IMT regimen includes Day -2 CTX (300 mg/m<sup>2</sup>), Day 0 intradermal SV-BR-1-GM (20x10<sup>6</sup>M irradiated cells), and Day 2-3 IFN $\alpha$  (0.1 mcg/site). CPI is administered q3w per protocol. ECOG2, CNS metastases, prior checkpoint inhibitor (CPI), antibody drug conjugate (ADC), or CDK4/6 inhibitor (CDK4/6i) exposure are eligible, with no limit on prior lines. Health related quality of life (HRQoL) was assessed at baseline (BL) and at each protocol specified treatment visit using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30), administered. QLQ-C30 raw item responses (scale: 1 - 4 for functional and symptom items; 1 - 7 for global health/QoL items) were aggregated into domain scores. For each patient and assessment, changes from BL in domain scores were quantified as absolute point differences on the item response scales and domain level scores were computed as the median of constituent items. Changes from BL were assessed using Wilcoxon matched-pairs signed-rank tests and the proportion of patients maintaining or improving scores was calculated for each domain. Time to deterioration was determined using Kaplan-Meier analysis with deterioration defined as a  $\geq 1$  raw-point Global Health Score decline or death, whichever first. Treatment emergent adverse events (TEAE) were recorded and graded according to CTCAE criteria. ECOG status was assessed at BL and at each treatment visit. Missing HRQoL data were handled using an observed cases approach. This interim analysis reports QoL outcomes in evaluable patients with available data, comparing baseline to visits 3, 6, and 9 to characterize patient experience during treatment.

## RESULTS

TABLE 1. PATIENT DEMOGRAPHICS (N= 151)

Characteristic	N (%)
Age, Median (Range)	60 (26–91)
BMI, Median (Range)	25.1 (8.7–45.7)
• White	118 (78)
• Other	33 (22)
• ECOG 0	71
• ECOG 1	68
• ECOG 2	12
Tumor Grade 1	6 (4)
Grade 2	46 (30)
Grade 3	66 (44)
• Undetermined or Not Reported	33 (22)
Prior systemic therapy, Median (Range)	6 (2–14)
Prior ADC Exposure	119
Prior CPI Exposure	40
Prior CDK4/6 inhibitor Exposure	90
Intracranial Metastases	11 (7)

TABLE 2. ADVERSE EVENTS

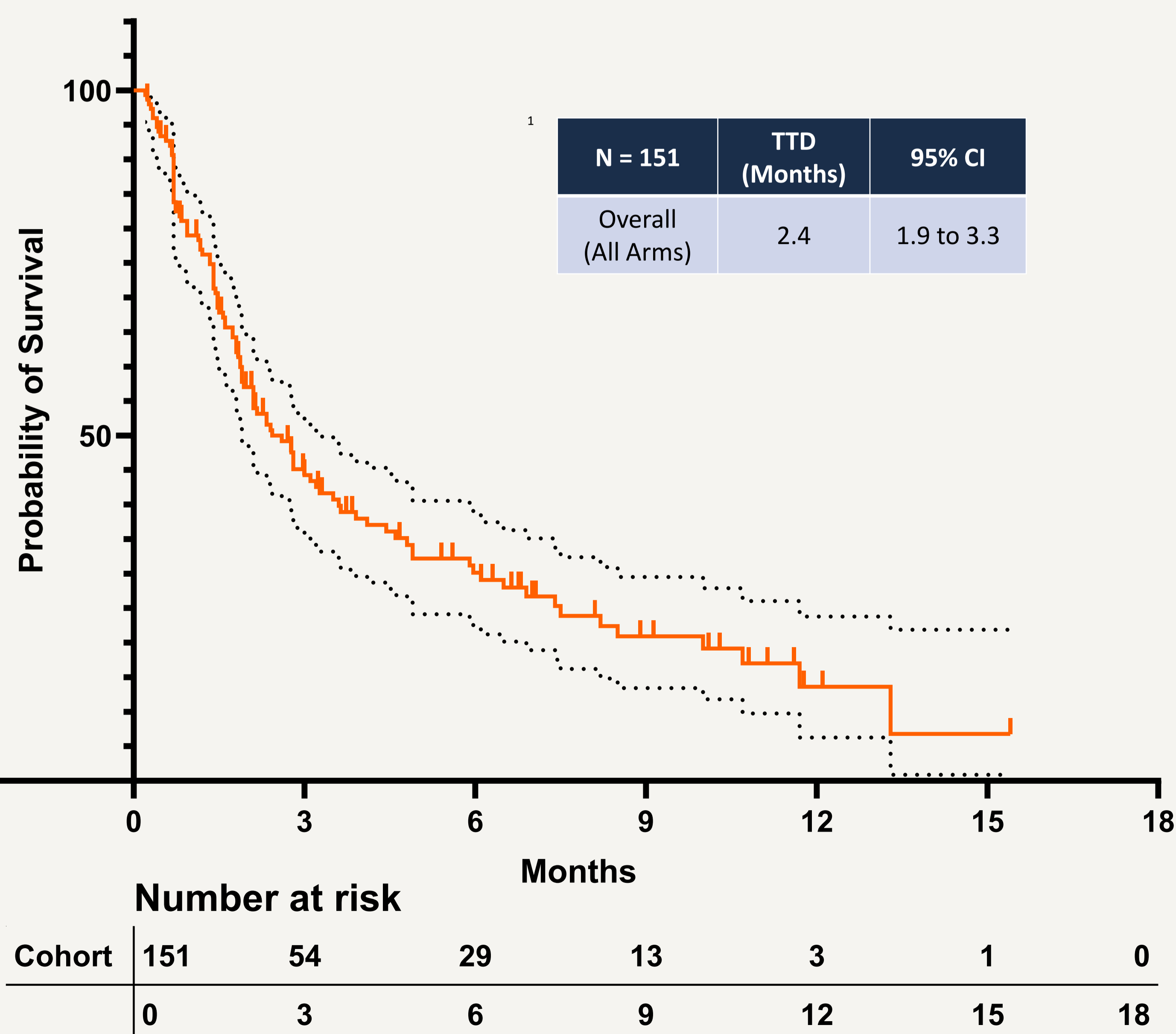
Adverse Event	Number of subjects (percent)				
	All Grades	Grade 1	Grade 2	Grade 3	Grade 4
Fatigue	53 (35.1%)	27 (17.9%)	22 (14.6%)	4 (2.6%)	0 (0.0%)
Nausea	43 (28.5%)	28 (18.5%)	13 (8.6%)	2 (1.3%)	0 (0.0%)
Anemia	38 (25.2%)	16 (10.6%)	12 (7.9%)	9 (6.0%)	1 (0.7%)
Constipation	34 (22.5%)	21 (13.9%)	12 (7.9%)	1 (0.7%)	0 (0.0%)
Vomiting	32 (21.2%)	18 (11.9%)	11 (7.3%)	3 (2.0%)	0 (0.0%)
Anorexia	22 (14.6%)	13 (8.6%)	9 (6.0%)	0 (0.0%)	0 (0.0%)
Lymphocyte count decrease	23 (15.2%)	7 (4.6%)	8 (5.3%)	8 (5.3%)	0 (0.0%)
Neutrophil count decreased	22 (14.6%)	7 (4.6%)	7 (4.6%)	4 (2.6%)	4 (2.6%)
Diarrhea	22 (14.6%)	20 (13.2%)	0 (0.0%)	2 (1.3%)	0 (0.0%)
Dyspnea	21 (13.9%)	7 (4.6%)	8 (5.3%)	6 (4.0%)	0 (0.0%)
Injection site reaction	20 (13.2%)	19 (12.6%)	1 (0.7%)	0 (0.0%)	0 (0.0%)
WBC count decreased	20 (13.2%)	9 (6.0%)	5 (3.3%)	5 (3.3%)	1 (0.7%)
Headache	20 (13.2%)	17 (11.3%)	2 (1.3%)	1 (0.7%)	0 (0.0%)
Rash	18 (11.9%)	16 (10.6%)	2 (1.3%)	0 (0.0%)	0 (0.0%)
Cough	18 (11.9%)	8 (5.3%)	10 (6.6%)	0 (0.0%)	0 (0.0%)
Hypokalemia	17 (11.3%)	12 (7.9%)	5 (3.3%)	0 (0.0%)	0 (0.0%)
Back pain	17 (11.3%)	7 (4.6%)	8 (5.3%)	2 (1.3%)	0 (0.0%)
Alkaline phosphatase increased	17 (11.3%)	7 (4.6%)	9 (6.0%)	1 (0.7%)	0 (0.0%)

Grade per CTCAE. TEAEs in  $\geq 5\%$  of patients shown.

## CONCLUSIONS

- QOL largely preserved in a heavily pretreated population with prior ADC, CPI, and CDK4/6 inhibitor exposure
- EORTC QLQ30 QOL Survey:
  - Global health status stable through early and mid-treatment
  - Emotional and cognitive functioning maintained; symptom burden stable
- Safety profile and time-to-deterioration analyses support durable tolerability in late-line setting
- Continued follow-up to further characterize QOL stability
- Results support feasibility of decentralized treatment approaches, including potential home self-administration strategies

FIGURE 1. TIME TO GLOBAL HEALTH SCORE DETERIORATION (TTD)



<sup>1</sup>Sakamaki K, Kawahara T. *BMC Med Res Methodol.* 2022;22(1):259.

Fig. 1. Kaplan-Meier estimate of the probability of remaining free from global health status deterioration or death. TTD was measured from the date of first treatment administration to deterioration defined as a  $\geq 1$  raw-point decline in GHS score (EORTC QLQ-C30 items 29–30) from baseline, or death, whichever occurred first. All treated patients contribute from time zero (date of first study drug administration). Median TTD [2.9 months; 95% CI: 2.4–3.3] shown with number at risk at 3-month intervals. Dashed line region = 95% CI.

FIGURE 2. GLOBAL HEALTH STATUS OVER TIME

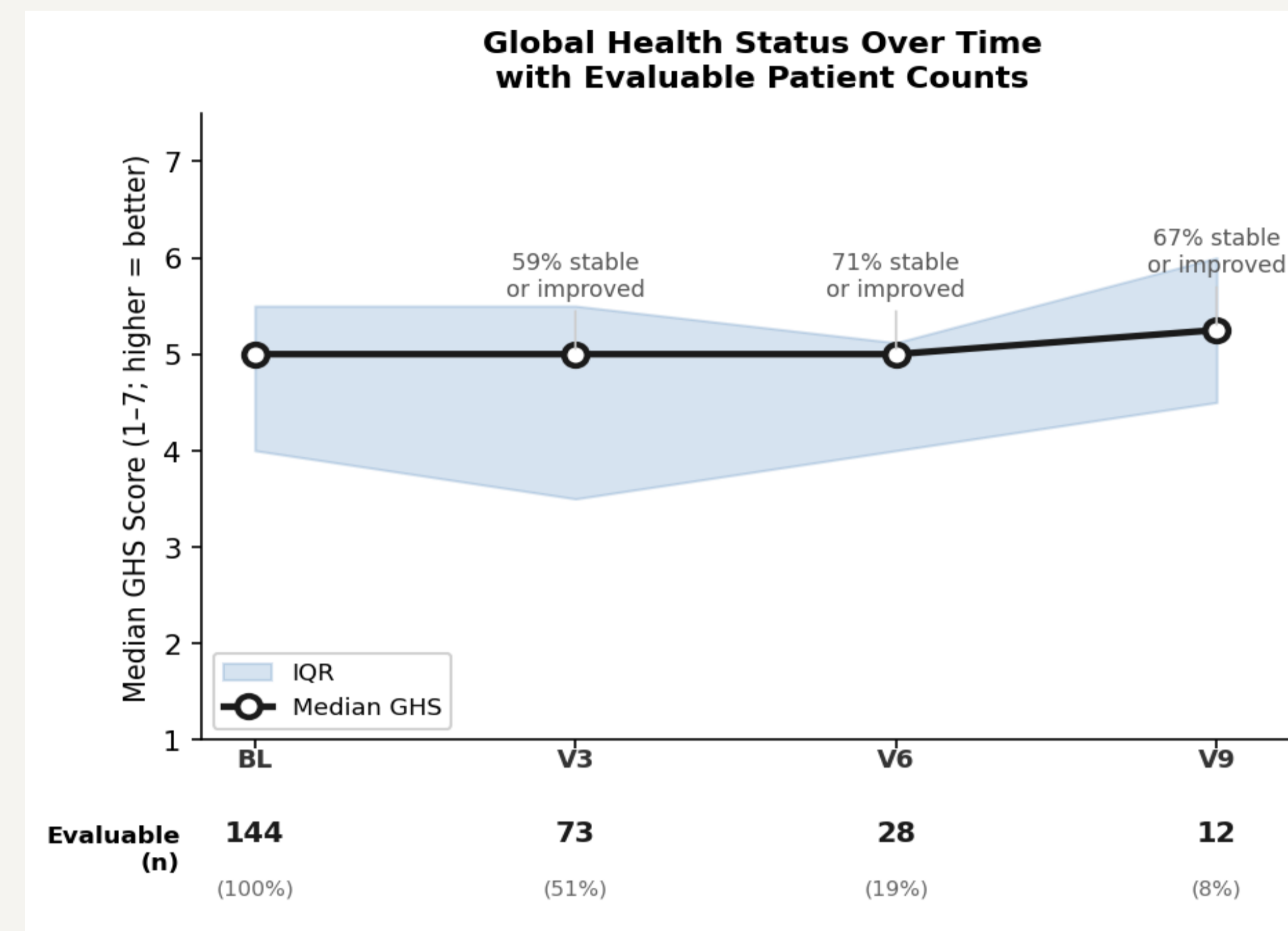


Fig. 2. Median EORTC QLQ-C30 global health status score (items 29–30; scale 1–7, higher = better) at each scheduled assessment. IQR band shown. Percentage of patients with stable or improved GHS relative to individual baseline annotated at each post-baseline visit. Wilcoxon matched-pairs signed-rank test vs baseline: V3 p=0.771, V6 p=0.416, V9 p=0.174. Evaluable patient counts shown below x-axis.

FIGURE 3. FUNCTIONAL DOMAIN SCORES

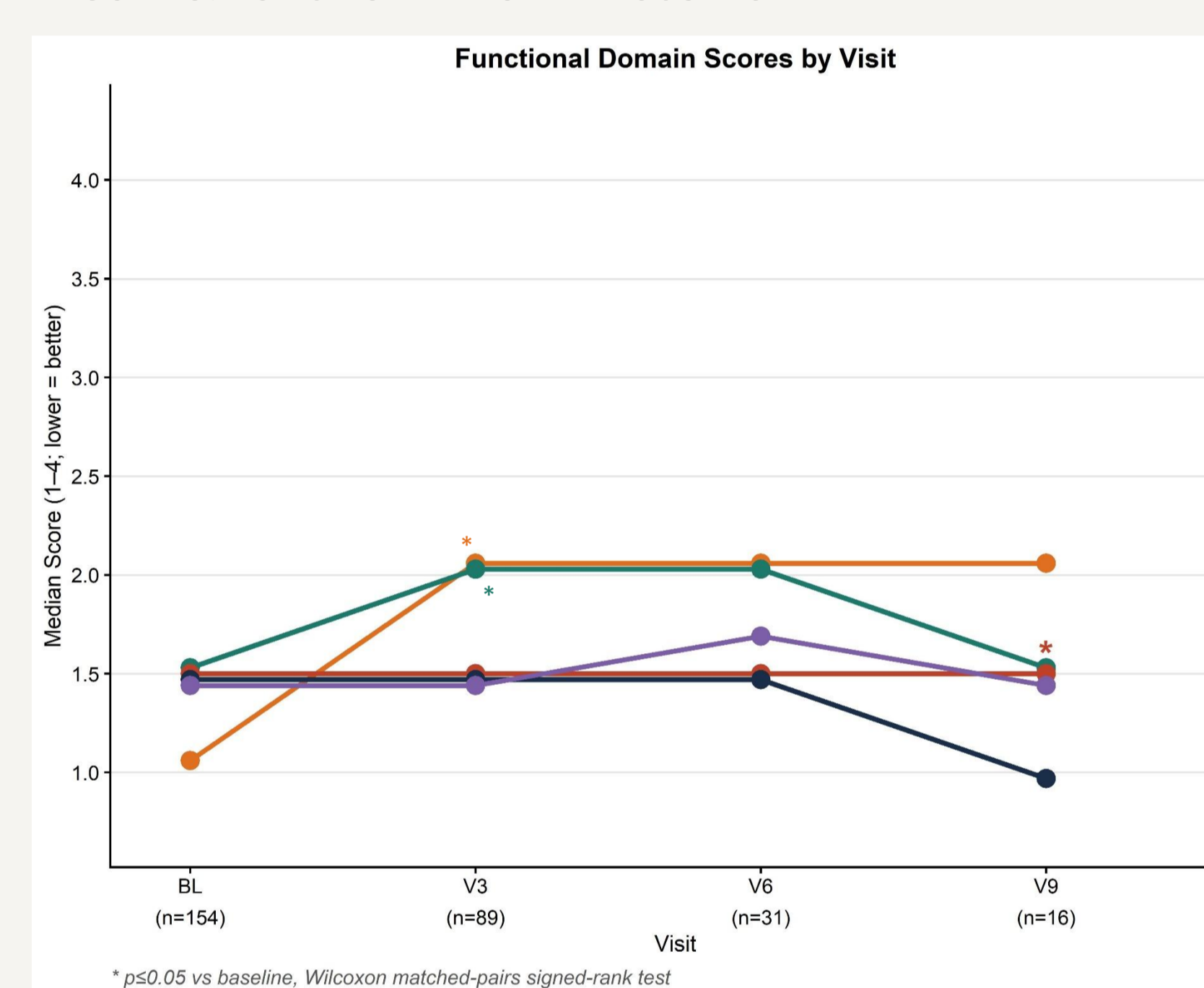


Fig. 3. Median EORTC QLQ-C30 functional domain scores at each scheduled assessment: Physical Functioning (items 1–5), Role Functioning (items 6–7), Emotional Functioning (items 21–24), Cognitive Functioning (items 20, 25), and Social Functioning (items 26–27). Scale 1–4; lower = better functioning. Per-patient domain scores calculated as the median of available raw item responses. V9\* reflects a decline in score among the 12 paired patients who remained evaluable at that timepoint, whose baseline median was higher than the overall cohort baseline.

TABLE 3. Prior Lines of Therapy by MBC Subtype

MBC Subtype	Patient Characteristics and Prior Treatment Burden by MBC Subtype								
	N	Median Prior Lines (Rang)	Prior ADC n (%)	Prior CPI n (%)	Prior CDK4/6i n (%)	ECOG 0 n (%)	ECOG 1 n (%)	ECOG 2 n (%)	Intracranial Mets n (%)
HR+/HER2–	84	6 (2-14)	70 (83)	9 (10)	74 (88)	35 (42)	42 (51)	5 (6)	8 (10)
TNBC	50	5 (2-12)	39 (78)	30 (60)	8 (16)	26 (52)	20 (40)	5 (10)	3 (6)
HER2+	16	6 (2-14)	9 (56)	1 (6)	8 (50)	8 (50)	6 (38)	2 (13)	0 (0)
Not Yet Reported	1	4	1 (100)	0 (0)	1 (100)	1 (100)	0 (0)	0 (0)	0 (0)
<b>Overall</b>	<b>151</b>	<b>6 (2-14)</b>	<b>119 (79)</b>	<b>40 (26)</b>	<b>90 (60)</b>	<b>71 (47)</b>	<b>68 (45)</b>	<b>12 (8)</b>	<b>11 (7)</b>

TABLE 4. PFS BY MBC SUBTYPE

MBC Subtype	PFS by MBC Subtype				
	N	PFS Events n (%)	Median PFS (months)	95% CI Lower	95% CI Upper
HR+/HER2–	83	62	3.0	2.3	4.0
TNBC (or HER2low)	50	39	3.7	2.7	3.9
HER2+	16	16	2.2	1.4	3.8
Not Yet Reported	2		N/A		
<b>Overall</b>	<b>151</b>	<b>121</b>	<b>3.0</b>	<b>2.4</b>	<b>3.7</b>

FIGURE 4. SYMPTOM BURDEN

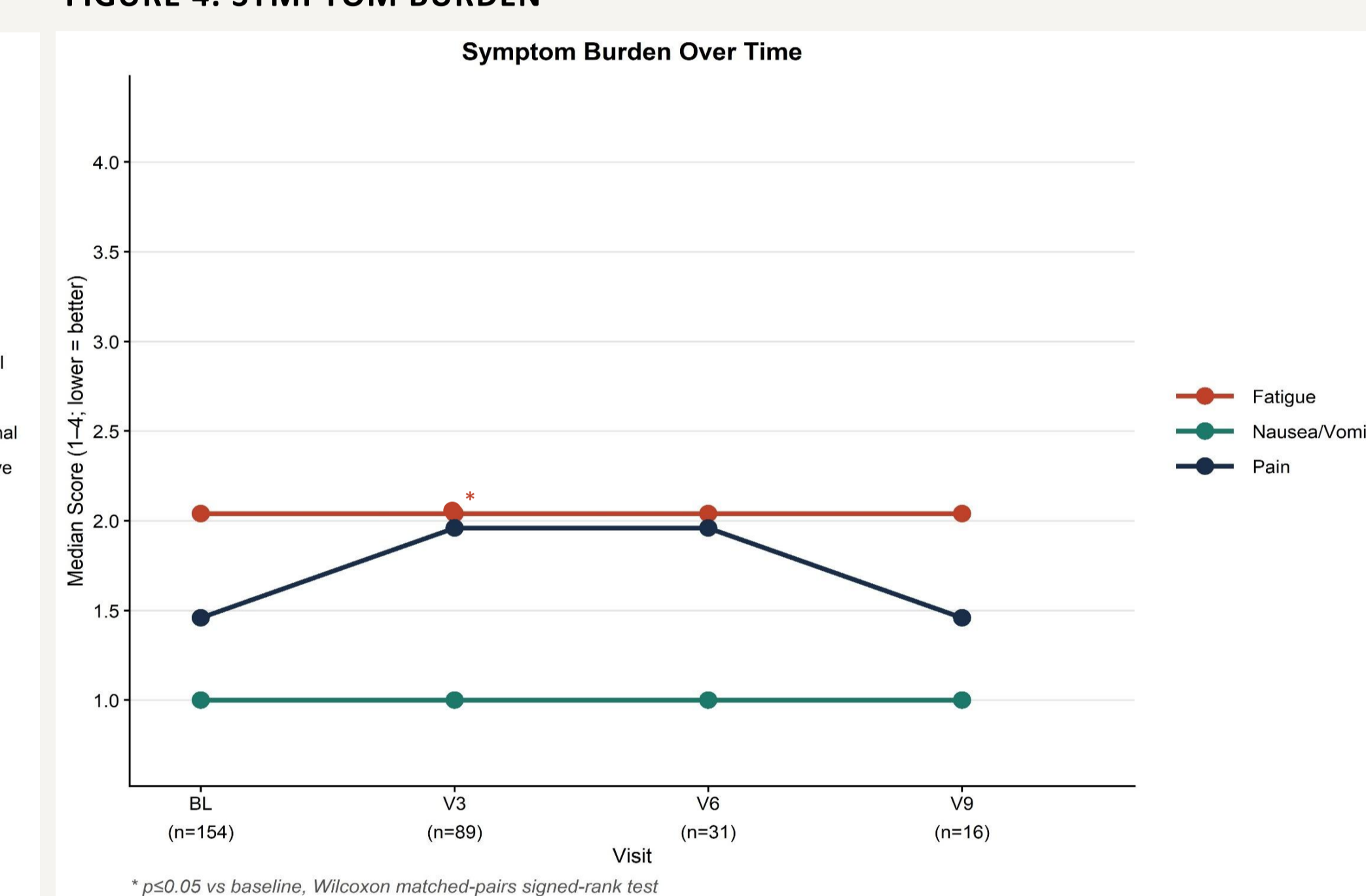


Fig. 4. Median EORTC QLQ-C30 symptom scores at each scheduled assessment: Fatigue (items 10, 12, 18), Nausea/Vomiting (items 14–15), and Pain (items 9, 19). Scale 1–4; lower = less symptom burden. Per-patient domain scores calculated as the median of available raw item responses.

FIGURE 5. OVERALL COHORT PROGRESSION-FREE SURVIVAL

