

Quality of life and treatment tolerability of Bria-IMT + CPI in metastatic breast cancer

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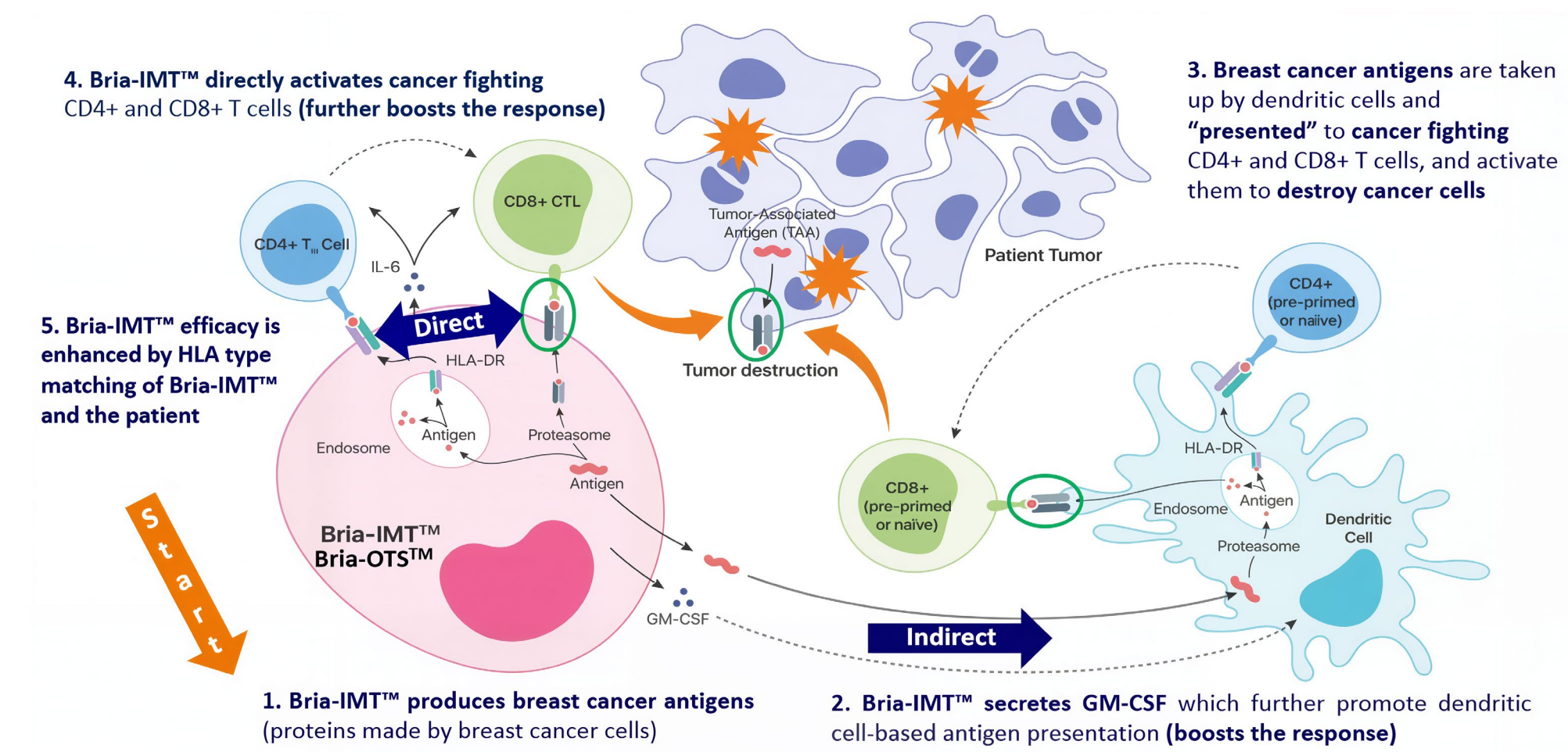
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Background

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 α), and an immune checkpoint inhibitor (CPI). SV-BR-1-GM breast cancer cells are engineered to secrete GM-CSF to enhance dendritic cell activation, express both class I and II HLA molecules and present tumor associated antigens such as HER2 and PRAME. Exhibiting antigen presenting cell activity, these cells serve as a reservoir of shared tumor antigens capable of enhancing anti-tumor immune responses. Subsequent enhancements to SV-BR-1-GM have improved in vitro immunologic characteristics (Lopez-Lago, SABC 2023)¹. The addition of CPI is intended to potentiate SV-BR-1-GM-induced immune activation by overcoming tumor-induced immune suppression. We present updated findings from prospective randomized and post hoc exploratory analyses in patients with advanced metastatic breast cancer (aMBC) treated with the Bria-IMT regimen.

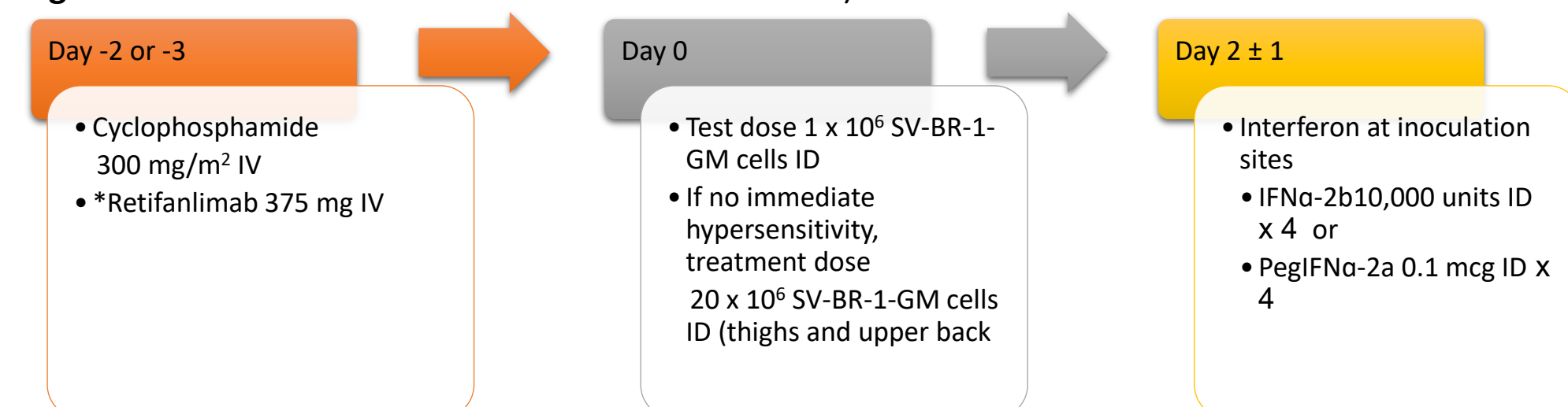
Figure 1. Mechanism of action of SV-BR-1-GM (Bria-IMT)



Methods

Patients are randomized 1:1 to Bria-IMT+CPI or TPC. 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 (HRQL) assessed with European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30), at baseline (BL) and each treatment visit. QLQ-C30 raw item responses (scale: 1 - 4 for functional and symptom items; 1 - 7 for global health/QoL items) aggregated into domain scores. For each pt and assessment, changes from BL in domain scores quantified as absolute point differences on the item response scales and domain level scores computed as the median of constituent items. Changes from BL assessed using Wilcoxon matched-pairs signed-rank tests and the proportion of patients maintaining or improving scores was calculated for each domain. Time without symptoms or toxicities (TWiST), toxicity (TOX), and "relapse state" (REL) were quantified as restricted mean durations derived from partitioned Kaplan-Meier survival curves using the Q-TWiST methodology¹. "Q" utility weights not yet applied (pending derivation from trial PRO data at full enrollment). Time spent in "TOX" state was total time that a patient spent experiencing a grade 3 or higher AE.

Figure 2. SV-BR-1-GM + CPI Arm Treatment Schedule



The first author and presenting author declare no undisclosed conflicts of interest or financial relationships. For further correspondence please reach out to gdelpriore@msm.edu

Conclusions

- Heavily pretreated MBC pts in Bria-ABC demonstrated stable global health status and preservation of key functional domains.
- Findings support sustained QoL in advanced disease despite poor prognostic characteristics.
- TWiST analysis demonstrated meaningful clinical benefit without significant toxicity burden.
- Ongoing follow-up will further characterize durability of patient reported outcomes and correlation with clinical outcomes.
- Results support the feasibility of decentralized care and potential future home self-administration strategies.

Results

Figure 3. TWiST Partitioned Survival Analyses

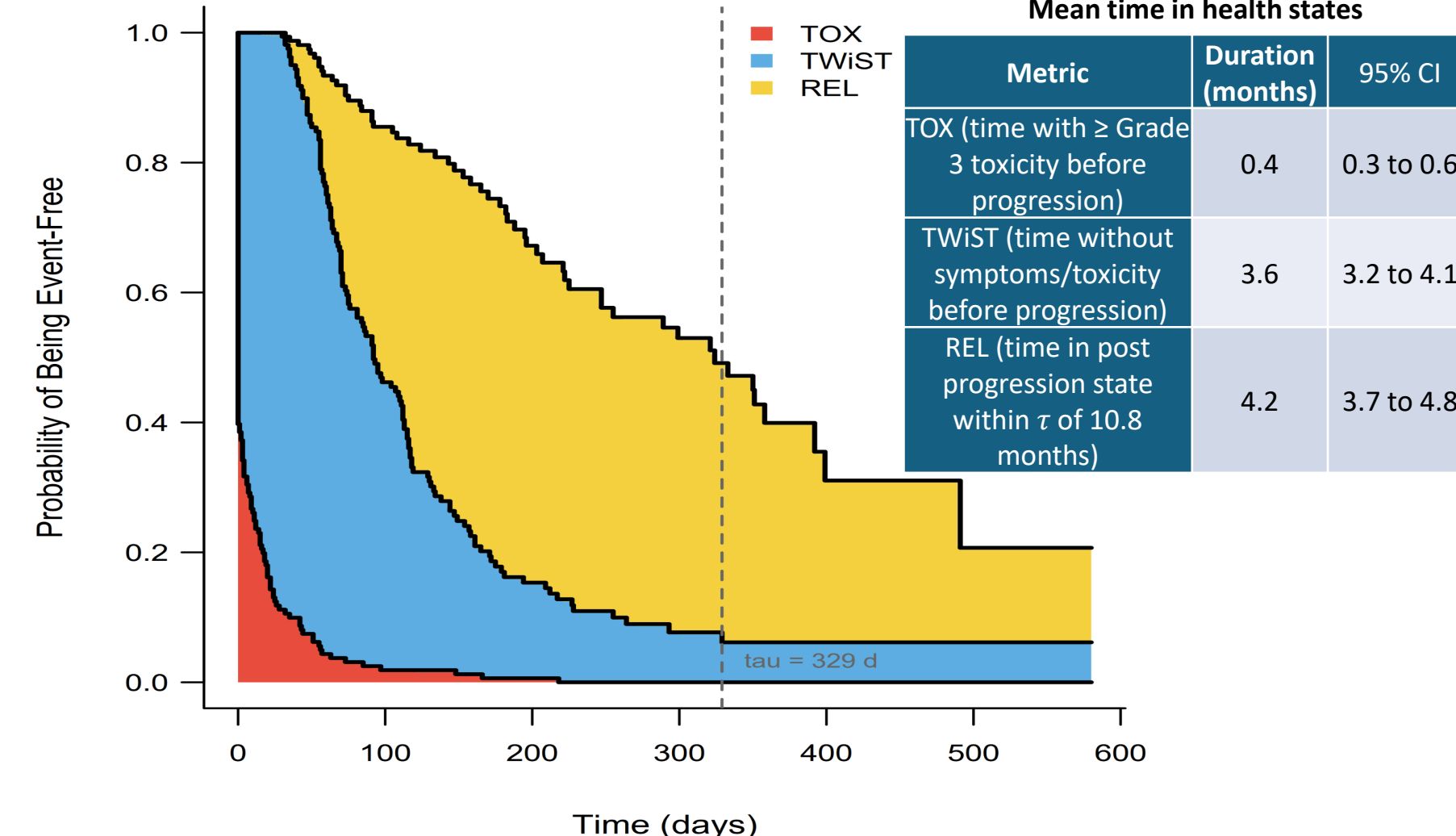


Fig. 3 Partitioned survival analysis of patient health state durations (N=161). Shaded areas represent mean restricted time spent in each health state up to tau (τ = 329 days): toxicity (TOX, red), time without symptoms or toxicity (TWiST, blue), and relapse (REL, yellow). Dashed vertical line indicates the restriction horizon (τ). Health state durations derived using Q-TWiST methodology¹. Utility weights not yet applied (pending derivation from trial PRO data at full enrollment). 1. Bogart E, et al. *Comput Methods Programs Biomed.* 2016;125:79-87.

Table 1. Patient Demographics

Characteristic	N (%)
Age, Median (Range)	60 (26–91)
BMI, Median (Range)	25.1 (8.7–45.7)
• White	125 (78)
• Other	36 (22)
• ECOG 0	77 (48)
• ECOG 1	74 (46)
• ECOG 2	10 (6)
Intracranial Metastases	11 (7)
Tumor Grade 1	7 (4)
Grade 2	49 (30)
Grade 3	71 (44)
Undetermined or Not Reported	34 (21)
Prior systemic therapy, Median (Range)	6 (2–14)
Prior ADC Exposure	136 (84)
Prior CPI Exposure	43 (27)
Prior CDK4/6 inhibitor Exposure	98 (61)

Figure 4. Symptom Burden by Visit

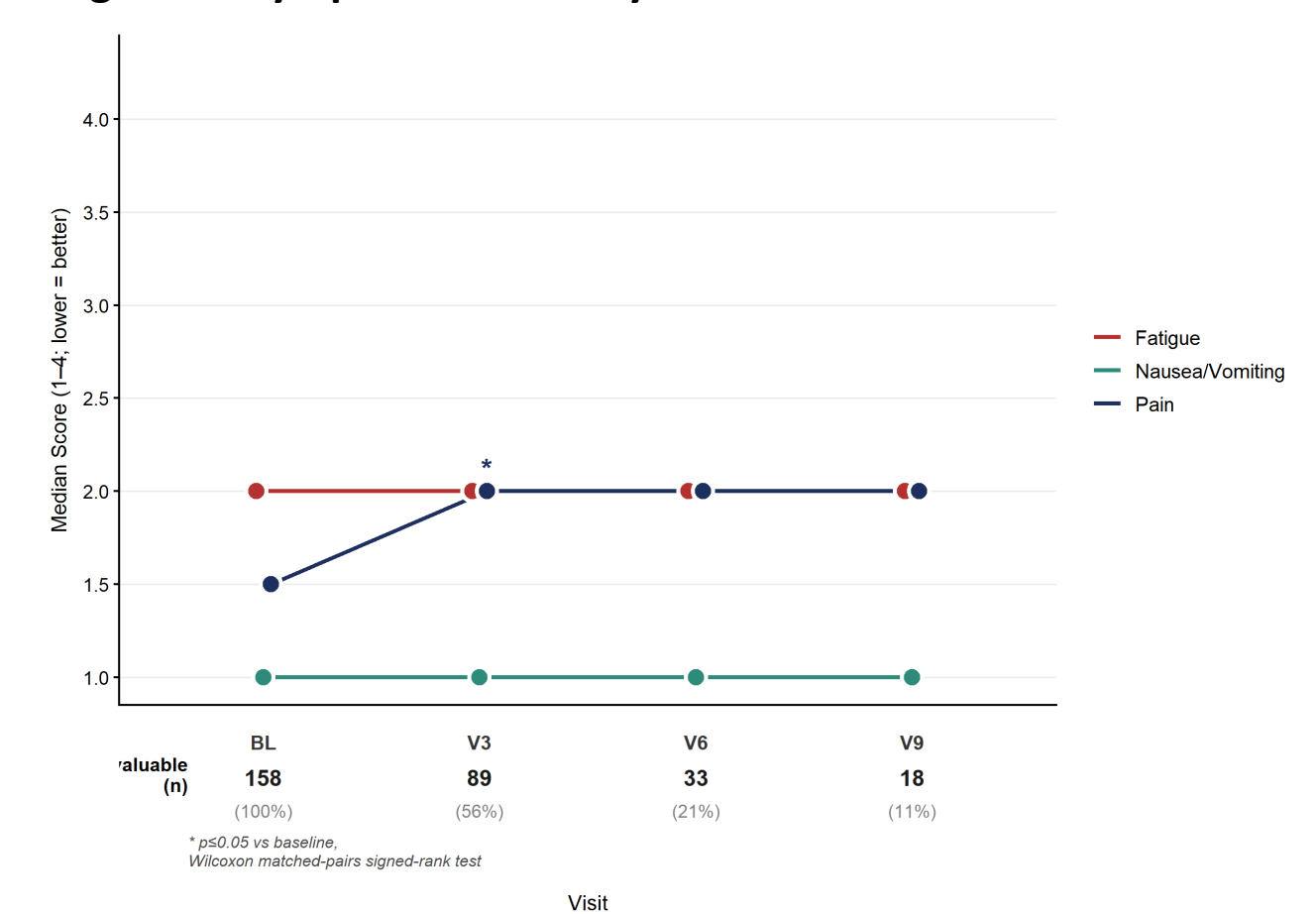


Fig. 4 Median EORTC QLQ-C30 symptom scores at each scheduled assessment: Fatigue (items 10, 12, 18), Nausea/Vomiting (items 14–15), and Pain (items 9, 19). Scale 1–4; lower = less symptom burden. Per-patient domain scores calculated as the median of available raw item responses.

Figure 5. Functional Domain Scores

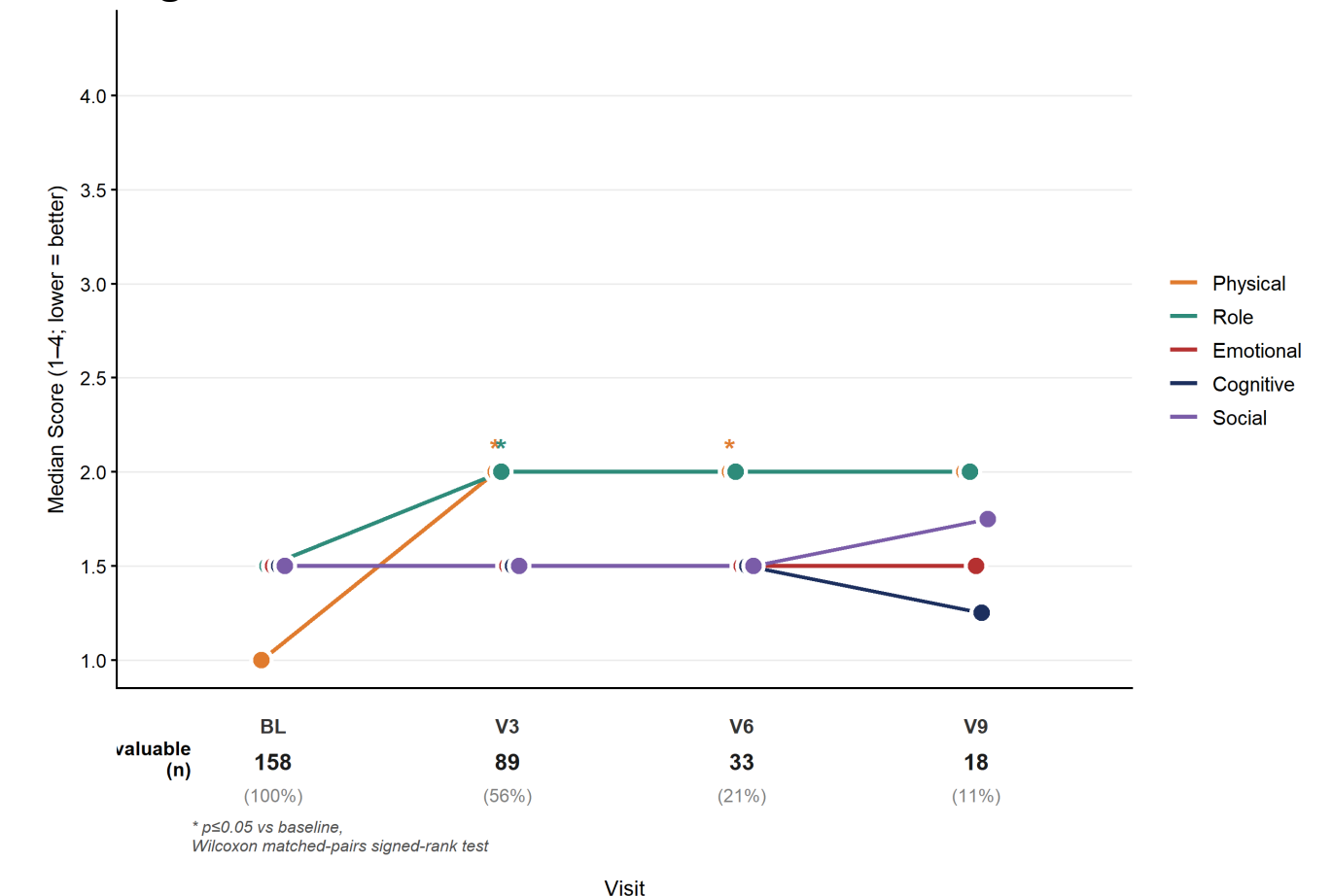


Fig. 5. Median EORTC QLQ-C30 functional domain scores at each scheduled assessment: Physical Functioning (items 1–5), Role Functioning (items 6–7), Emotional Functioning (items 21–24), Cognitive Functioning (items 20, 25), and Social Functioning (items 26–27). Scale 1–4; lower = better functioning. Per-patient domain scores calculated as the median of available raw item responses.

Figure 6. QLQ30 Global Health Status Over Time

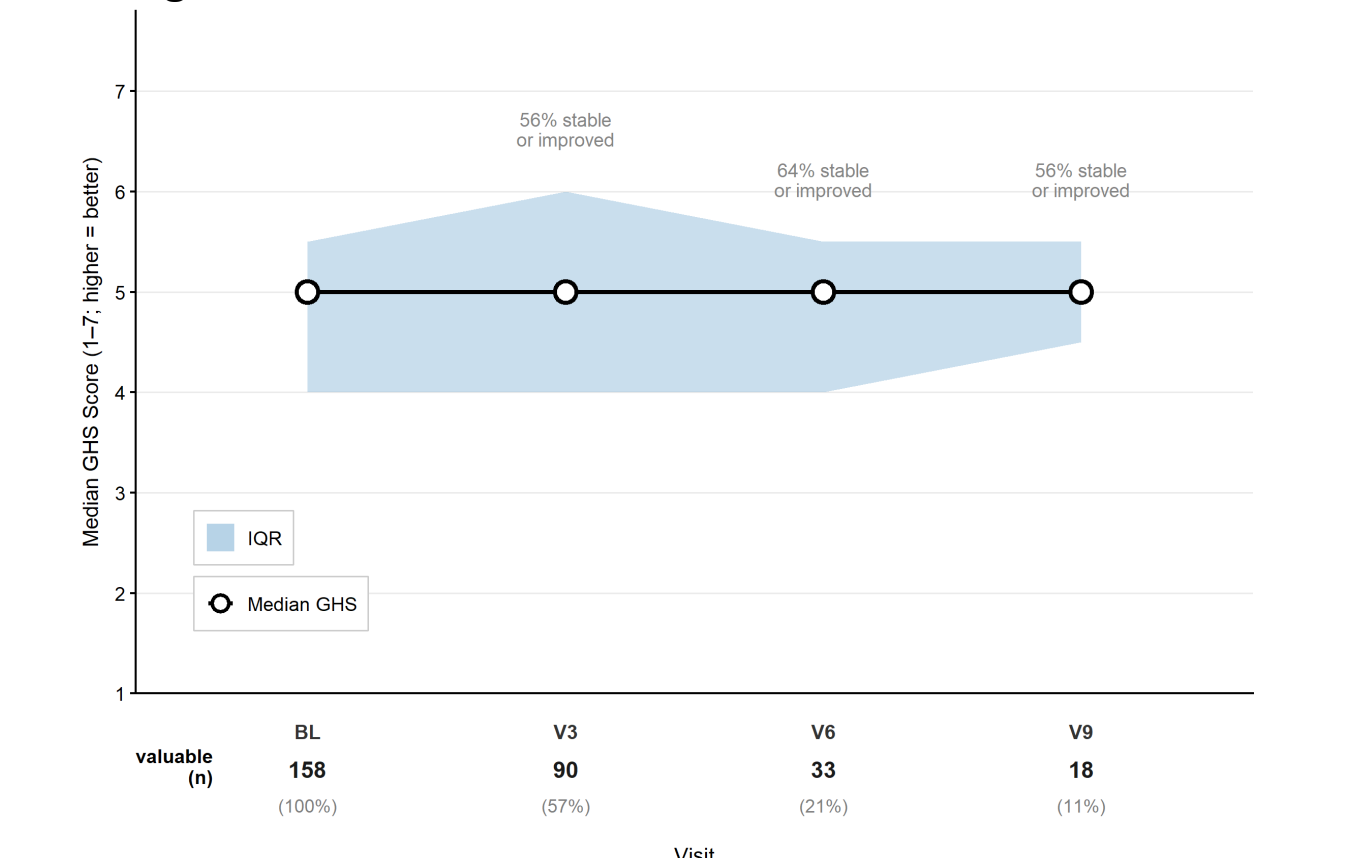


Fig. 6. Median EORTC QLQ-C30 global health status score (items 29–30; scale 1–7, higher = better) at each scheduled assessment. IQR band shown. Percentage of patients with stable or improved GHS relative to individual baseline annotated at each post-baseline visit. Wilcoxon matched-pairs signed-rank test vs baseline: V3 p=0.80, V6 p=0.36, V9 p=0.36. Evaluable patient counts shown below x-axis.

Table 2. Adverse Events

Adverse Event	All Grades	Most Common Adverse Events (\geq 10%)			
		Grade 1	Grade 2	Grade 3	Grade 4
Fatigue	60 (26.3%)	31 (13.6%)	24 (10.5%)	5 (2.2%)	0 (0.0%)
Nausea	48 (21.1%)	31 (13.6%)	13 (5.7%)	4 (1.8%)	0 (0.0%)
Anemia	39 (17.1%)	16 (7.0%)	13 (5.7%)	9 (3.9%)	1 (0.4%)
Constipation	39 (17.1%)	26 (11.4%)	12 (5.3%)	1 (0.4%)	0 (0.0%)
Vomiting	37 (16.2%)	21 (9.2%)	12 (5.3%)	4 (1.8%)	0 (0.0%)
Anorexia	27 (11.8%)	15 (6.6%)	12 (5.3%)	0 (0.0%)	0 (0.0%)
Neutrophil count decreased	27 (11.8%)	7 (3.1%)	9 (3.9%)	4 (1.8%)	7 (3.1%)
Lymphocyte count decreased	26 (11.4%)	9 (3.9%)	9 (3.9%)	8 (3.5%)	0 (0.0%)
Dyspnea	25 (11.0%)	9 (3.9%)	8 (3.5%)	8 (3.5%)	0 (0.0%)
Headache	25 (11.0%)	20 (8.8%)	3 (1.3%)	2 (0.9%)	0 (0.0%)
Diarrhea	24 (10.5%)	21 (9.2%)	1 (0.4%)	2 (0.9%)	0 (0.0%)
White blood cell count decreased	23 (10.1%)	9 (3.9%)	6 (2.6%)	7 (3.1%)	1 (0.4%)
Injection site reaction*	22 (9.6%)	21 (9.2%)	1 (0.4%)	0 (0.0%)	0 (0.0%)

AEs with start date after 30 April 2026 excluded. AE terms normalised for case variants. Each subject counted once per AE at highest grade only. Grade 5 (Death) excluded. n = 228 subjects. * Injection site reaction included as a pre-specified exception (9.6%).