VERSATILE-002 – Consort Diagram

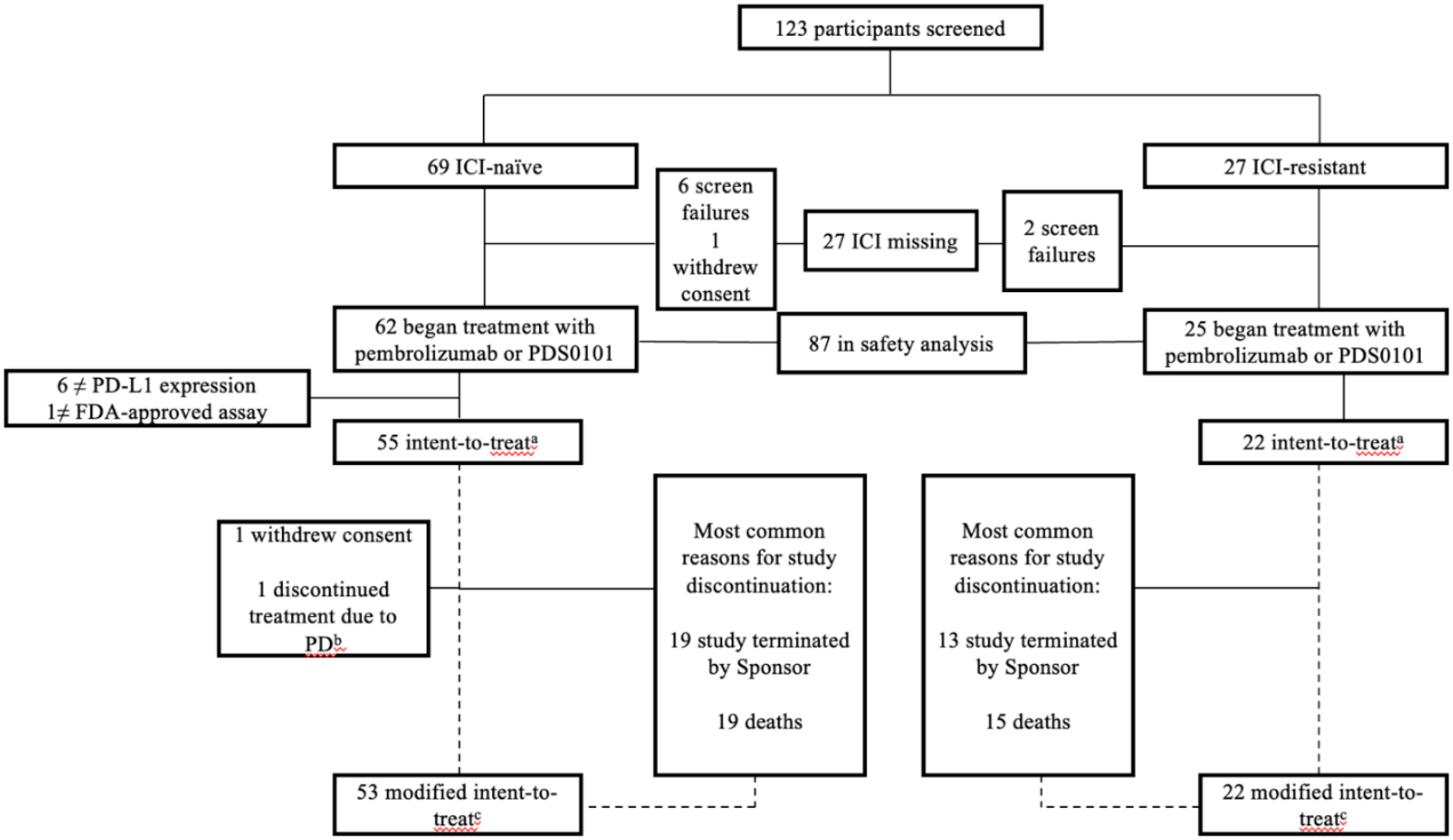

Table 1. *Participant characteristics.*

Characteristic	Overall (N = 75)	ICI-naïve (N = 53)	ICI-resistant (N = 22)
Age (years), *M (SD)*	64.0 (8.30)	64.0 (8.24)	63.9 (8.62)
Median	64.5	64.5	64.2
Range	47-83	47-83	49-78
Sex, *n (%)*			
Male	71/75 (95)	49/53 (93)	22/22 (100)
Female	4/75 (5)	4/53 (8)	0
Race, *n* (%)			
White	71/75 (95)	50/53 (94)	21/22 (96)
Black or African American	1/75 (1)	1/53 (2)	0
Asian	2/75 (3)	1/53 (2)	1/22 (5)
Other	1/75 (1)	1/53 (2)	0
Ethnicity, *n* (%)			
Not Hispanic or Latino	69/75 (92)	49/53 (93)	20/22 (91)
Hispanic or Latino	5/75 (7)	3/53 (6)	2/22 (9)
Not reported	1/75 (1)	1/53 (2)	0
ECOG Performance Score, *n (%)*			
0	43/75 (57)	30/53 (57)	13/22 (59)
1	32/75 (43)	23/53 (43)	9/22 (41)
PD-L1 expression status, *n (%)*			
CPS <1	6/75 (8)	0	6/22 (27)
CPS 1-19	42/75 (56)	33/53 (62)	9/22 (41)
CPS ≥20	27/75 (36)	20/53 (38)	7/22 (32)
Prior therapies for HNSCC, *n (%)*			
Chemotherapy	66/75 (88)	44/53 (83)	22/22 (100)
Radiation therapy	60/75 (80)	42/53 (79)	18/22 (82)
Immunotherapy	22/75 (29)	0	22/22 (100)

Table 2 . *Summary of efficacy by PD-L1 expression level – Investigator assessment.*

Group/Response category	CPS <1	CPS 1-19	CPS ≥20	Overall
ICI-naïve, n		33	20	53
CR, *n* (%)		2/33 (6)	3/20 (15)	5/53 (9)
PR, *n* (%)		8/33 (24)	6/20 (30)	14/53 (26)
SD, *n* (%)		15/33 (46)	7/20 (35)	22/53 (42)
PD, *n* (%)		6/33 (18)	3/20 (15)	9/53 (17)
Response not evaluable, *n* (%)		2/33 (6)	1/20 (5)	3/53 (6)
ORR (PR + CR)		10/33 (30)	9/20 (45)	19/53 (36)
DCR (%)		25/33 (76)%	16/20 (80)	41/53 (77)
Median DOR, months		21.8 (3.7, NE)	NE (9.00, NE)	21.8 (11.50, NE)
Median PFS, months (95% CI)		5.6 (3.50, 9.00)	13.8 (2.80, NE)	6.3 (4.20, 12.50)
Median OS, months (95% CI)		29.5 (15.60, NE)	29.3 (18.40, NE)	39.3 (23.90, NE)
ICI-resistant, n	6	9	7	22
CR, *n* (%)	0	0	0	0
PR, *n* (%)	0	0	0	0
SD, *n* (%)	1/6 (17)	3/9 (33)	3/7 (43)	7/22 (32)
PD, *n* (%)	4/6 (67)	5/9 (56)	4/7 (57)	13/22 (59)
Response not evaluable, *n* (%)	1/6 (17)	1/9 (11)	0	2/22 (9)
ORR (PR + CR)	0	0	0	0
DCR (%)	1/6 (17)	3/9 (33)	3/7 (43)	7/22 (32)
Median DOR, months	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Median PFS, months (95% CI)	2.0 (1.40, NE)	2.1 (0.30, 4.00)	1.5 (1.40 3.50)	2.0 (1.40, 2.10)
Median OS, months (95% CI)	15.6 (2.00, NE)	19.3 (0.30, NE)	13.7 (5.40, NE)	14.8 (8.50, 26.00)

Table 3 . *Summary of efficacy by PD-L1 expression level – central reviewer.*

Group/Response category	CPS <1	CPS 1-19	CPS ≥20	Overall
ICI-Naïve, n		33	20	53
CR, *n* (%)		2/33 (6)	4/20 (20)	6/53 (11)
PR, *n* (%)		7/33 (21)	5/20 (25)	12/53 (23)
SD, *n* (%)		8/33 (24)	6/20 (30)	14/53 (26)
PD, *n* (%)		14/33 (42)	4/20 (20)	18/53 (34)
Response not evaluable, *n* (%)		2/33 (6)	1/20 (5)	3/53 (6)
ORR (PR or CR)		9/33 (27)	9/20 (45)	18/53 (34)
DCR (%)		17/33 (52)	15/20 (75)	32/53 (60)
Median DOR, months		12.3 (5.60, NE)	NE (3.20, NE)	NE (6.90, NE)
Median PFS, months (95% CI)		2.3 (2.10, 6.30)	10.4 (2.10, NE)	5.3 (2.10, 9.00)
Median OS, months (95% CI)		29.5 (15.60, NE)	39.3 (18.40, NE)	39.3 (23.90, NE)
ICI-Resistant, n	6	9	7	22
CR, *n* (%)	0	0	0	0
PR, *n* (%)	0	0	0	0
SD, *n* (%)	1/6 (17)	3/9 (33)	2/7 (29)	6/22 (27)
PD, *n* (%)	4/6 (67)	5/9 (56)	5/7 (71)	14/22 (64)
Response not evaluable, *n* (%)	1/6 (17)	1/9 (11)	0	2/22 (9)
ORR (PR + CR)	0	0	0	0
DCR (%)	1/6 (17)	3/9 (33)	2/7 (29)	6/22 (27)
Median DOR, months	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Median PFS, months (95% CI)	2.0 (1.40, NE)	2.1 (0.30, 4.00)	1.5 (1.40, 2.20)	2.0 (1.40, 2.1)
Median OS, months (95% CI)	15.6 (2.00, NE)	19.3 (0.30, NE)	13.7 (5.40, NE)	14.8 (8.50, 26.00)

Table 4. *PDS0101 or pembrolizumab treatment related adverse events (TRAE) (≥5%).*

	Safety population (n = 87)	
Preferred term	ICI-naïve (n = 62)	ICI-resistant (n = 25)
Any PDS0101 or pembrolizumab TRAE, n (%)	55 (88)	21 (84)
General disorders and administration site conditions	51 (82)	20 (80)
Injection site pain	37 (60)	11 (44)
Fatigue	25 (40)	7 (28)
Injection site swelling	19 (31)	8 (32)
Injection site discoloration	9 (15)	7 (28)
Injection site erythema	13 (21)	3 (12)
Injection site warmth	11 (18)	3 (12)
Injection site pruritic	8 (12)	5 (20)
Injection site reaction	9 (15)	4 (16)
Injection site inflammation	8 (13)	3 (12)
Malaise	4 (7)	2 (8)
Injection site rash	4 (7)	
Skin and subcutaneous tissue disorders	20 (32)	2 (8)
Pruritus	9 (15)	0
Rash	6 (10)	1 (4)
Rash maculo-papular	4 (7)	0
Investigations	16 (26)	3 (12)
Alanine aminotransferase increased	5 (8)	0
Aspartate aminotransferase increased	4 (6.5)	0
Gastrointestinal disorders	12 (19)	5 (20)
Diarrhea	8 (13)	2 (8)
Nervous system disorders	14 (23)	1 (4)
Headache	12 (19)	1 (4)
Respiratory, thoracic, and mediastinal disorders	10 (16)	4 (16)
Cough	4 (7)	1 (4)
Musculoskeletal and connective tissue disorders	9 (15)	3 (12)
Arthralgia	5 (8)	0
Myalgia	4 (7)	0
Metabolism and nutrition disorders	5 (8)	2 (8)
Renal and urinary disorders	5 (8)	1 (4)
Endocrine disorders	4 (7)	1 (4)