INPUT SAMPLE DEMOGRAPHICS DATA AS CDISC ADaM ADSL

Obs	USUBJID	TRTPN	SEXN	RACEN	AGE
1	101	0	1	3	37
2	301	0	1	1	70
3	501	0	1	2	33
4	601	0	1	1	50
5	701	1	1	1	60
6	102	1	2	1	65
7	302	0	1	2	55
8	502	1	2	1	44
9	602	0	2	2	30
10	702	0	1	1	28
11	103	1	1	2	32
12	303	1	1	1	65
13	503	1	1	1	64
14	603	1	2	1	33
15	703	1	1	2	44
16	104	0	2	1	23
17	304	0	1	1	45
18	504	0	1	3	56
19	604	0	1	1	65
20	704	0	2	1	66
21	105	1	1	3	44
22	305	1	1	1	36
23	505	1	1	2	73
24	605	1	2	1	57
25	705	1	1	2	46
26	106	0	2	1	49
27	306	0	1	2	46
28	506	0	1	1	46
29	606	0	1	2	56
30	706	1	1	1	75
31	201	1	1	3	35
32	401	1	2	1	44
33	507	1	1	2	44
34	607	1	1	1	67
35	707	1	1	1	46
36	202	0	2	1	50

Company / Trial Name

INPUT SAMPLE DEMOGRAPHICS DATA AS CDISC ADaM ADSL

Obs	USUBJID	TRTPN	SEXN	RACEN	AGE
37	402	0	2	2	77
38	508	0	2	1	53
39	608	0	2	2	46
40	708	0	2	1	55
41	203	1	1	2	49
42	403	1	1	1	45
43	509	0	1	1	45
44	609	1	2	1	72
45	709	0	2	2	57
46	204	0	2	1	60
47	404	1	1	1	59
48	510	0	1	3	65
49	610	0	1	1	29
50	710	0	1	1	63
51	205	1	1	3	39
52	405	0	2	1	49
53	511	1	2	2	43
54	611	1	2	1	65
55	711	1	1	2	61
56	206	1	2	1	67
57	406	1	1	2	33
58	512	1	1	1	39
59	612	1	1	2	46
60	712	0		1	49

Table 5.1
Demographics and Baseline Characteristics

		Placebo	Active	Overall
Age	**n**	29	31	60
	Mean	50.1	51.4	50.8
	Median	50	46	49
	Standard Deviation	13.2	13.2	13.1
	Min	23	32	23
	Max	77	75	77
	Mode	46	44	46
Sex				
Missing	**n**	1		1
	%	3.4		1.7
Male	**n**	16	22	38
	%	55.2	71.0	63.3
Female	**n**	12	9	21
	%	41.4	29.0	35.0
Race				
White	**n**	18	18	36
	%	62.1	58.1	60.0
Black	**n**	8	10	18
	%	27.6	32.3	30.0
Other*	**n**	3	3	6
	%	10.3	9.7	10.0

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Table 5.1
Demographics and Baseline Characteristics

Active																	
					Sex						Race						
Age					Female		Male		Missing		Black		Other*		White		
N	Mean	SD	Min	Max	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
31	51.35	13.23	32	75	9	29%	22	71%			10	32%	3	10%	18	58%

Placebo																	
					Sex						Race						
Age					Female		Male		Missing		Black		Other*		White		
N	Mean	SD	Min	Max	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
29	50.10	13.22	23	77	12	43%	16	57%	0	0%	8	28%	3	10%	18	62%

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

INPUT SAMPLE DEMOGRAPHICS DATA AS CDISC ADaM ADSL

Obs	USUBJID	TRTPN	SEXN	RACEN	AGE
1	101	0	1	3	37
2	301	0	1	1	70
3	501	0	1	2	33
4	601	0	1	1	50
5	701	1	1	1	60
6	102	1	2	1	65
7	302	0	1	2	55
8	502	1	2	1	44
9	602	0	2	2	30
10	702	0	1	1	28
11	103	1	1	2	32
12	303	1	1	1	65
13	503	1	1	1	64
14	603	1	2	1	33
15	703	1	1	2	44
16	104	0	2	1	23
17	304	0	1	1	45
18	504	0	1	3	56
19	604	0	1	1	65
20	704	0	2	1	66
21	105	1	1	3	44
22	305	1	1	1	36
23	505	1	1	2	73
24	605	1	2	1	57
25	705	1	1	2	46
26	106	0	2	1	49
27	306	0	1	2	46
28	506	0	1	1	46
29	606	0	1	2	56
30	706	1	1	1	75
31	201	1	1	3	35
32	401	1	2	1	44
33	507	1	1	2	44
34	607	1	1	1	67
35	707	1	1	1	46
36	202	0	2	1	50

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

INPUT SAMPLE DEMOGRAPHICS DATA AS CDISC ADaM ADSL

Obs	USUBJID	TRTPN	SEXN	RACEN	AGE
37	402	0	2	2	77
38	508	0	2	1	53
39	608	0	2	2	46
40	708	0	2	1	55
41	203	1	1	2	49
42	403	1	1	1	45
43	509	0	1	1	45
44	609	1	2	1	72
45	709	0	2	2	57
46	204	0	2	1	60
47	404	1	1	1	59
48	510	0	1	3	65
49	610	0	1	1	29
50	710	0	1	1	63
51	205	1	1	3	39
52	405	0	2	1	49
53	511	1	2	2	43
54	611	1	2	1	65
55	711	1	1	2	61
56	206	1	2	1	67
57	406	1	1	2	33
58	512	1	1	1	39
59	612	1	1	2	46
60	712	0		1	49

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

ADSL data set with TRT HAS VALUES 0 = PLACEBO, 1 = ACTIVE, AND 2 = OVERALL

Obs	USUBJID	TRTPN	SEXN	RACEN	AGE
1	101	0	1	3	37
2	101	2	1	3	37
3	301	0	1	1	70
4	301	2	1	1	70
5	501	0	1	2	33
6	501	2	1	2	33
7	601	0	1	1	50
8	601	2	1	1	50
9	701	1	1	1	60
10	701	2	1	1	60
11	102	1	2	1	65
12	102	2	2	1	65
13	302	0	1	2	55
14	302	2	1	2	55
15	502	1	2	1	44
16	502	2	2	1	44
17	602	0	2	2	30
18	602	2	2	2	30
19	702	0	1	1	28
20	702	2	1	1	28
21	103	1	1	2	32
22	103	2	1	2	32
23	303	1	1	1	65
24	303	2	1	1	65
25	503	1	1	1	64
26	503	2	1	1	64
27	603	1	2	1	33
28	603	2	2	1	33
29	703	1	1	2	44
30	703	2	1	2	44
31	104	0	2	1	23
32	104	2	2	1	23
33	304	0	1	1	45
34	304	2	1	1	45
35	504	0	1	3	56
36	504	2	1	3	56

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

ADSL data set with TRT HAS VALUES 0 = PLACEBO, 1 = ACTIVE, AND 2 = OVERALL

Obs	USUBJID	TRTPN	SEXN	RACEN	AGE
37	604	0	1	1	65
38	604	2	1	1	65
39	704	0	2	1	66
40	704	2	2	1	66
41	105	1	1	3	44
42	105	2	1	3	44
43	305	1	1	1	36
44	305	2	1	1	36
45	505	1	1	2	73
46	505	2	1	2	73
47	605	1	2	1	57
48	605	2	2	1	57
49	705	1	1	2	46
50	705	2	1	2	46
51	106	0	2	1	49
52	106	2	2	1	49
53	306	0	1	2	46
54	306	2	1	2	46
55	506	0	1	1	46
56	506	2	1	1	46
57	606	0	1	2	56
58	606	2	1	2	56
59	706	1	1	1	75
60	706	2	1	1	75
61	201	1	1	3	35
62	201	2	1	3	35
63	401	1	2	1	44
64	401	2	2	1	44
65	507	1	1	2	44
66	507	2	1	2	44
67	607	1	1	1	67
68	607	2	1	1	67
69	707	1	1	1	46
70	707	2	1	1	46
71	202	0	2	1	50
72	202	2	2	1	50

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

ADSL data set with TRT HAS VALUES 0 = PLACEBO, 1 = ACTIVE, AND 2 = OVERALL

Obs	USUBJID	TRTPN	SEXN	RACEN	AGE
73	402	0	2	2	77
74	402	2	2	2	77
75	508	0	2	1	53
76	508	2	2	1	53
77	608	0	2	2	46
78	608	2	2	2	46
79	708	0	2	1	55
80	708	2	2	1	55
81	203	1	1	2	49
82	203	2	1	2	49
83	403	1	1	1	45
84	403	2	1	1	45
85	509	0	1	1	45
86	509	2	1	1	45
87	609	1	2	1	72
88	609	2	2	1	72
89	709	0	2	2	57
90	709	2	2	2	57
91	204	0	2	1	60
92	204	2	2	1	60
93	404	1	1	1	59
94	404	2	1	1	59
95	510	0	1	3	65
96	510	2	1	3	65
97	610	0	1	1	29
98	610	2	1	1	29
99	710	0	1	1	63
100	710	2	1	1	63
101	205	1	1	3	39
102	205	2	1	3	39
103	405	0	2	1	49
104	405	2	2	1	49
105	511	1	2	2	43
106	511	2	2	2	43
107	611	1	2	1	65
108	611	2	2	1	65

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

ADSL data set with TRT HAS VALUES 0 = PLACEBO, 1 = ACTIVE, AND 2 = OVERALL

Obs	USUBJID	TRTPN	SEXN	RACEN	AGE
109	711	1	1	2	61
110	711	2	1	2	61
111	206	1	2	1	67
112	206	2	2	1	67
113	406	1	1	2	33
114	406	2	1	2	33
115	512	1	1	1	39
116	512	2	1	1	39
117	612	1	1	2	46
118	612	2	1	2	46
119	712	0		1	49
120	712	2		1	49

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Sorted ADSL1 data set

Obs	USUBJID	TRTPN	SEXN	RACEN	AGE
1	101	0	1	3	37
2	301	0	1	1	70
3	501	0	1	2	33
4	601	0	1	1	50
5	302	0	1	2	55
6	602	0	2	2	30
7	702	0	1	1	28
8	104	0	2	1	23
9	304	0	1	1	45
10	504	0	1	3	56
11	604	0	1	1	65
12	704	0	2	1	66
13	106	0	2	1	49
14	306	0	1	2	46
15	506	0	1	1	46
16	606	0	1	2	56
17	202	0	2	1	50
18	402	0	2	2	77
19	508	0	2	1	53
20	608	0	2	2	46
21	708	0	2	1	55
22	509	0	1	1	45
23	709	0	2	2	57
24	204	0	2	1	60
25	510	0	1	3	65
26	610	0	1	1	29
27	710	0	1	1	63
28	405	0	2	1	49
29	712	0		1	49
30	701	1	1	1	60
31	102	1	2	1	65
32	502	1	2	1	44
33	103	1	1	2	32
34	303	1	1	1	65
35	503	1	1	1	64
36	603	1	2	1	33

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Sorted ADSL1 data set

Obs	USUBJID	TRTPN	SEXN	RACEN	AGE
37	703	1	1	2	44
38	105	1	1	3	44
39	305	1	1	1	36
40	505	1	1	2	73
41	605	1	2	1	57
42	705	1	1	2	46
43	706	1	1	1	75
44	201	1	1	3	35
45	401	1	2	1	44
46	507	1	1	2	44
47	607	1	1	1	67
48	707	1	1	1	46
49	203	1	1	2	49
50	403	1	1	1	45
51	609	1	2	1	72
52	404	1	1	1	59
53	205	1	1	3	39
54	511	1	2	2	43
55	611	1	2	1	65
56	711	1	1	2	61
57	206	1	2	1	67
58	406	1	1	2	33
59	512	1	1	1	39
60	612	1	1	2	46
61	101	2	1	3	37
62	301	2	1	1	70
63	501	2	1	2	33
64	601	2	1	1	50
65	701	2	1	1	60
66	102	2	2	1	65
67	302	2	1	2	55
68	502	2	2	1	44
69	602	2	2	2	30
70	702	2	1	1	28
71	103	2	1	2	32
72	303	2	1	1	65

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Sorted ADSL1 data set

Obs	USUBJID	TRTPN	SEXN	RACEN	AGE
73	503	2	1	1	64
74	603	2	2	1	33
75	703	2	1	2	44
76	104	2	2	1	23
77	304	2	1	1	45
78	504	2	1	3	56
79	604	2	1	1	65
80	704	2	2	1	66
81	105	2	1	3	44
82	305	2	1	1	36
83	505	2	1	2	73
84	605	2	2	1	57
85	705	2	1	2	46
86	106	2	2	1	49
87	306	2	1	2	46
88	506	2	1	1	46
89	606	2	1	2	56
90	706	2	1	1	75
91	201	2	1	3	35
92	401	2	2	1	44
93	507	2	1	2	44
94	607	2	1	1	67
95	707	2	1	1	46
96	202	2	2	1	50
97	402	2	2	2	77
98	508	2	2	1	53
99	608	2	2	2	46
100	708	2	2	1	55
101	203	2	1	2	49
102	403	2	1	1	45
103	509	2	1	1	45
104	609	2	2	1	72
105	709	2	2	2	57
106	204	2	2	1	60
107	404	2	1	1	59
108	510	2	1	3	65

Sorted ADSL1 data set

Obs	USUBJID	TRTPN	SEXN	RACEN	AGE
109	610	2	1	1	29
110	710	2	1	1	63
111	205	2	1	3	39
112	405	2	2	1	49
113	511	2	2	2	43
114	611	2	2	1	65
115	711	2	1	2	61
116	206	2	2	1	67
117	406	2	1	2	33
118	512	2	1	1	39
119	612	2	1	2	46
120	712	2		1	49

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Age data set

Obs	TRTPN	n	mean	std	min	max
1	0	29	50.1	13.22	23.0	77.0
2	1	31	51.4	13.23	32.0	75.0
3	2	60	50.8	13.13	23.0	77.0

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Denormalized (transposed) age data set

Obs	_NAME_	col0	col1	col2
1	n	29	31	60
2	mean	50.1	51.4	50.8
3	std	13.22	13.23	13.13
4	min	23.0	32.0	23.0
5	max	77.0	75.0	77.0

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Sexn data set

Obs	TRTPN	SEXN	COUNT	PERCENT	PCT_ROW	PCT_COL	value
1	0	1	16	13.3333	55.1724	21.0526	16 (55.2%)
2	1	1	22	18.3333	70.9677	28.9474	22 (71.0%)
3	2	1	38	31.6667	63.3333	50.0000	38 (63.3%)
4	0	2	12	10.0000	41.3793	28.5714	12 (41.4%)
5	1	2	9	7.5000	29.0323	21.4286	9 (29.0%)
6	2	2	21	17.5000	35.0000	50.0000	21 (35.0%)

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Sexn1 data set (de-normalized) or transposed data set

Obs	SEXN	col0	col1	col2
1	1	16 (55.2%)	22 (71.0%)	38 (63.3%)
2	2	12 (41.4%)	9 (29.0%)	21 (35.0%)

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Sex statistics

Obs	label	col0	col1	col2	pvalue
1	Sex				0.26808
2	Male	16 (55.2%)	22 (71.0%)	38 (63.3%)	
3	Female	12 (41.4%)	9 (29.0%)	21 (35.0%)	

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Sorted Racen data set

Obs	TRTPN	RACEN	COUNT	PERCENT	PCT_ROW	PCT_COL	value
1	0	1	18	15.0000	62.0690	25.0000	18 (62.1%)
2	1	1	18	15.0000	58.0645	25.0000	18 (58.1%)
3	2	1	36	30.0000	60.0000	50.0000	36 (60.0%)
4	0	2	8	6.6667	27.5862	22.2222	8 (27.6%)
5	1	2	10	8.3333	32.2581	27.7778	10 (32.3%)
6	2	2	18	15.0000	30.0000	50.0000	18 (30.0%)
7	0	3	3	2.5000	10.3448	25.0000	3 (10.3%)
8	1	3	3	2.5000	9.6774	25.0000	3 (9.7%)
9	2	3	6	5.0000	10.0000	50.0000	6 (10.0%)

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Transposed Racen data set

Obs	RACEN	col0	col1	col2
1	1	18 (62.1%)	18 (58.1%)	36 (60.0%)
2	2	8 (27.6%)	10 (32.3%)	18 (30.0%)
3	3	3 (10.3%)	3 (9.7%)	6 (10.0%)

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Racen statistics data set

Obs	label	col0	col1	col2	pvalue
1	**Race**				0.92695
2	White	18 (62.1%)	18 (58.1%)	36 (60.0%)	
3	Black	8 (27.6%)	10 (32.3%)	18 (30.0%)	
4	Other*	3 (10.3%)	3 (9.7%)	6 (10.0%)	

* Other includes Asian, Native American, and other races.
Created by on 05DEC2025.

Table 5.3
Demographics and Baseline Characteristics

	Active (N=31)	Placebo (N=29)	Overall (N=60)	P-value**
Age (years)				0.9528
N	31	29	60	
Mean	51.4	50.1	50.8	
Standard Deviation	13.23	13.22	13.13	
Minimum	32.0	23.0	23.0	
Maximum	75.0	77.0	77.0	
Sex				0.2681
Male	22 (71.0%)	16 (55.2%)	38 (63.3%)	
Female	9 (29.0%)	12 (41.4%)	21 (35.0%)	
Race				0.9270
White	18 (58.1%)	18 (62.1%)	36 (60.0%)	
Black	10 (32.3%)	8 (27.6%)	18 (30.0%)	
Other*	3 (9.7%)	3 (10.3%)	6 (10.0%)	

* Other includes Asian, Native American, and other races.
** P-values: Age = Wilcoxon rank-sum, Sex = Pearson's chi-square, Race = Fisher's exact test.
Created by on 05DEC2025.