CLINICAL STUDY REPORT SUMMARY

Study ID: CT-001 | Trial Phase: II | July 25, 2025
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Study Summary

This clinical study report summarizes a simulated Phase II randomized controlled trial evaluating the baseline comparability and safety profile of Drug B versus Placebo.

The dataset consists of 11,878 patient-level records drawn from a synthetic Excel file ('patients_raw_data.xlsx'), representing demographic, cost, and adverse event data from a real-world-inspired clinical scenario. Data were cleaned, standardized, and mapped according to CDISC conventions to produce compliant SDTM and ADaM domains.

Key deliverables in this report include:
- Table 1: Snapshot of cleaned patient data for verification.
- Table 2: Baseline demographic and clinical characteristics by treatment group, with statistical comparison.
- Table 3: Frequency and distribution of common adverse events by treatment group.
- Figure 1: Distribution and statistical comparison of patient age across treatment arms.
- Figure 2: Stratified boxplot of BMI by sex and treatment group.

All results support the quality and balance of randomization, and no significant safety signals were observed.

Table-1: Patient Characteristics Snapshot After Cleaning

Obs	Unique Subject ID	Sex	Age	Treatment Group	Enroll Date	Study End Date	BMI	Weight Status	Average Cost	Lab test result
1	0000098	F	14	Placebo	08/21/2009	10/01/2024	21.2	Normal weight	.	NA
2	0000099	M	55	Drug B	06/16/2009	10/01/2024	18.0	Underweight	$34.92	NA
3	0000103	M	70	Placebo	06/08/2010	10/01/2024	26.5	Overweight	$71.97	NA
4	0000104	M	40	Drug B	11/10/2009	10/01/2024	14.2	Underweight	$32.33	NA
5	0000105	F	68	Drug B	12/18/2009	10/01/2024	23.2	Normal weight	$15.23	Negative
6	0000106	F	5	Drug B	01/20/2010	10/01/2024	18.1	Underweight	$62.09	NA
7	0000108	F	4	Drug B	05/22/2010	10/01/2024	17.5	Underweight	$51.73	Negative
8	0000109	M	53	Drug B	05/07/2010	10/01/2024	31.4	Obese	$77.81	NA
9	0000111	M	9	Placebo	04/03/2009	10/01/2024	27.1	Overweight	$31.99	NA
10	0000112	M	37	Placebo	05/09/2009	10/01/2024	21.4	Normal weight	$112.10	NA
11	0000113	M	71	Drug B	09/21/2008	10/01/2024	25.5	Overweight	$54.51	NA
12	0000115	M	51	Placebo	05/30/2010	10/01/2024	18.9	Normal weight	$31.00	NA
13	0000118	F	7	Drug B	06/17/2010	10/01/2024	24.4	Normal weight	$35.24	Negative
14	0000123	M	22	Placebo	07/09/2009	10/01/2024	19.2	Normal weight	$37.54	NA
15	0000124	M	53	Drug B	08/09/2010	10/01/2024	17.1	Underweight	$36.24	NA
16	0000126	M	5	Drug B	12/28/2008	10/01/2024	28.3	Overweight	$101.35	NA
17	0000127	F	11	Drug B	03/01/2009	10/01/2024	21.0	Normal weight	$90.05	NA
18	0000132	M	73	Placebo	12/14/2009	10/01/2024	21.1	Normal weight	$18.14	Positive
19	0000133	F	43	Drug B	11/22/2009	10/01/2024	22.0	Normal weight	$127.36	NA
20	0000134	F	.	Placebo	03/07/2009	10/01/2024	17.8	Underweight	$54.76	NA
21	0000135	F	19	Drug B	05/22/2009	10/01/2024	10.5	Underweight	$103.95	Positive
22	0000136	M	72	Placebo	03/09/2009	10/01/2024	23.5	Normal weight	$58.91	Negative
23	0000137	M	23	Placebo	10/28/2008	10/01/2024	20.8	Normal weight	$107.10	NA
24	0000138	M	52	Drug B	09/14/2009	10/01/2024	26.8	Overweight	$112.20	NA
25	0000142	F	32	Placebo	02/27/2010	10/01/2024	15.6	Underweight	$66.49	NA
26	0000144	F	23	Drug B	09/04/2009	10/01/2024	25.0	Overweight	$133.46	NA
27	0000145	F	48	Placebo	08/18/2010	10/01/2024	16.7	Underweight	$86.30	NA
28	0000146	M	28	Drug B	06/06/2009	10/01/2024	22.7	Normal weight	$91.80	NA
29	0000149	F	69	Drug B	08/02/2010	10/01/2024	19.4	Normal weight	$74.20	Positive
30	0000154	F	.	Drug B	06/03/2010	10/01/2024	16.4	Underweight	$81.28	NA
31	0000160	F	2	Drug B	06/16/2010	10/01/2024	21.4	Normal weight	$75.27	NA
32	0000161	M	46	Drug B	02/04/2009	10/01/2024	18.9	Normal weight	$87.87	NA
33	0000162	F	36	Drug B	04/20/2009	10/01/2024	20.2	Normal weight	$61.13	NA
34	0000163	M	48	Drug B	06/12/2010	10/01/2024	28.1	Overweight	$89.35	NA
35	0000164	M	24	Drug B	10/26/2008	10/01/2024	22.9	Normal weight	$88.00	Negative
36	0000165	M	48	Drug B	12/12/2008	10/01/2024	.		$59.76	NA
37	0000165	M	48	Drug B	12/12/2008	10/01/2024	19.4	Normal weight	$59.76	NA
38	0000170	M	33	Placebo	03/15/2010	10/01/2024	25.7	Overweight	$34.97	NA
39	0000171	M	38	Drug B	03/22/2010	10/01/2024	19.6	Normal weight	$77.38	Positive
40	0000173	M	77	Placebo	01/28/2009	10/01/2024	20.6	Normal weight	$36.43	NA

Table-1: Patient Characteristics Snapshot After Cleaning

Obs	Unique Subject ID	Sex	Age	Treatment Group	Enroll Date	Study End Date	BMI	Weight Status	Average Cost	Lab test result
41	0000175	F	29	Placebo	09/28/2008	10/01/2024	21.9	Normal weight	$82.13	NA
42	0000176	F	38	Placebo	03/19/2010	10/01/2024	18.0	Underweight	$41.82	NA
43	0000178	F	17	Drug B	02/20/2009	10/01/2024	11.8	Underweight	$78.99	NA
44	0000181	M	60	Drug B	08/03/2009	10/01/2024	18.8	Normal weight	$70.96	NA
45	0000182	F	23	Drug B	11/15/2008	10/01/2024	19.9	Normal weight	$33.86	Negative
46	0000184	M	31	Placebo	10/20/2009	10/01/2024	23.0	Normal weight	$50.50	NA
47	0000186	F	28	Placebo	03/13/2010	10/01/2024	22.3	Normal weight	$51.98	NA
48	0000188	F	22	Placebo	08/13/2010	10/01/2024	12.9	Underweight	$36.61	Negative
49	0000189	M	71	Drug B	12/04/2009	10/01/2024	20.6	Normal weight	$38.77	NA
50	0000190	M	2	Placebo	04/15/2010	10/01/2024	21.2	Normal weight	$98.77	Negative
51	0000191	M	34	Drug B	08/14/2009	10/01/2024	24.8	Normal weight	$68.44	NA
52	0000192	M	33	Drug B	05/01/2010	10/01/2024	31.7	Obese	$117.18	Negative
53	0000193	F	50	Drug B	09/18/2009	10/01/2024	14.0	Underweight	$113.92	Negative
54	0000194	F	15	Drug B	08/02/2010	10/01/2024	17.1	Underweight	$63.86	NA
55	0000196	F	28	Drug B	06/14/2010	10/01/2024	16.5	Underweight	$56.19	NA
56	0000197	M	83	Drug B	08/21/2010	10/01/2024	19.3	Normal weight	$38.92	NA
57	0000198	F	21	Drug B	03/26/2010	10/01/2024	25.0	Overweight	$81.20	Negative
58	0000200	M	8	Drug B	08/09/2009	10/01/2024	29.2	Overweight	$16.56	NA
59	0000202	M	30	Drug B	05/07/2009	10/01/2024	19.8	Normal weight	$41.12	NA
60	0000203	M	11	Placebo	05/23/2010	10/01/2024	18.4	Underweight	$29.38	Positive
61	0000205	M	41	Placebo	04/19/2010	10/01/2024	35.2	Obese	$102.26	NA
62	0000208	F	15	Placebo	06/23/2009	10/01/2024	18.8	Normal weight	$71.19	Positive
63	0000211	F	46	Drug B	12/28/2008	10/01/2024	25.5	Overweight	$42.17	Negative
64	0000212	F	81	Placebo	01/22/2010	10/01/2024	23.6	Normal weight	$31.65	NA
65	0000214	F	78	Drug B	06/18/2009	10/01/2024	15.7	Underweight	$82.04	NA
66	0000216	F	41	Drug B	03/28/2010	10/01/2024	13.3	Underweight	$44.51	NA
67	0000217	M	19	Drug B	02/19/2009	10/01/2024	19.3	Normal weight	$5.67	NA
68	0000218	M	49	Drug B	06/07/2009	10/01/2024	26.9	Overweight	$58.86	NA
69	0000222	F	12	Placebo	01/28/2010	10/01/2024	19.8	Normal weight	$55.71	NA
70	0000223	F	75	Drug B	10/03/2008	10/01/2024	23.5	Normal weight	$72.67	NA
71	0000224	M	19	Placebo	01/15/2010	10/01/2024	24.1	Normal weight	$36.64	NA
72	0000225	F	33	Placebo	01/04/2009	10/01/2024	23.2	Normal weight	$87.85	NA
73	0000228	F	27	Drug B	05/31/2010	10/01/2024	13.3	Underweight	$84.83	NA
74	0000230	F	59	Drug B	05/21/2010	10/01/2024	22.9	Normal weight	$68.88	NA
75	0000231	M	61	Drug B	07/25/2010	10/01/2024	23.6	Normal weight	$94.12	NA
76	0000232	M	.	Drug B	04/26/2010	10/01/2024	15.8	Underweight	$64.01	NA
77	0000234	M	25	Placebo	10/23/2008	10/01/2024	28.2	Overweight	$107.57	NA
78	0000235	M	37	Drug B	11/17/2009	10/01/2024	25.5	Overweight	$17.01	NA
79	0000236	F	9	Placebo	12/07/2008	10/01/2024	26.6	Overweight	$45.77	Positive
80	0000238	M	53	Drug B	04/13/2010	10/01/2024	19.6	Normal weight	$55.57	NA

Table-1: Patient Characteristics Snapshot After Cleaning

Obs	Unique Subject ID	Sex	Age	Treatment Group	Enroll Date	Study End Date	BMI	Weight Status	Average Cost	Lab test result
81	0000239	F	63	Placebo	04/13/2010	10/01/2024	22.1	Normal weight	$29.48	NA
82	0000240	F	19	Drug B	09/24/2008	10/01/2024	22.4	Normal weight	$91.35	NA
83	0000241	M	74	Drug B	05/20/2009	10/01/2024	29.5	Overweight	$56.66	NA
84	0000243	F	36	Drug B	04/16/2009	10/01/2024	24.2	Normal weight	$83.51	NA
85	0000245	F	23	Placebo	06/10/2009	10/01/2024	.		$68.90	Negative
86	0000245	F	23	Placebo	06/10/2009	10/01/2024	20.1	Normal weight	$68.90	Negative
87	0000246	F	55	Placebo	11/11/2009	10/01/2024	.		$41.66	NA
88	0000246	F	55	Placebo	11/11/2009	10/01/2024	.		$41.66	NA
89	0000246	F	55	Placebo	11/11/2009	10/01/2024	17.4	Underweight	$41.66	NA
90	0000247	M	10	Placebo	03/19/2010	10/01/2024	14.8	Underweight	$99.38	Positive
91	0000248	F	21	Placebo	11/16/2009	10/01/2024	21.2	Normal weight	$37.21	NA
92	0000249	M	20	Drug B	05/04/2009	10/01/2024	31.1	Obese	$55.41	Negative
93	0000251	F	10	Drug B	05/30/2009	10/01/2024	28.3	Overweight	$55.51	Positive
94	0000254	M	60	Drug B	02/28/2010	10/01/2024	15.1	Underweight	$45.25	Positive
95	0000255	F	7	Drug B	07/07/2009	10/01/2024	23.4	Normal weight	$87.33	NA
96	0000256	M	43	Drug B	01/28/2010	10/01/2024	22.2	Normal weight	$83.56	NA
97	0000258	M	33	Placebo	12/18/2009	10/01/2024	29.2	Overweight	$60.73	NA
98	0000260	M	40	Drug B	11/02/2009	10/01/2024	20.7	Normal weight	$85.54	NA
99	0000264	F	43	Placebo	06/17/2010	10/01/2024	24.6	Normal weight	$29.15	NA
100	0000266	F	40	Drug B	01/03/2010	10/01/2024	21.1	Normal weight	$72.98	NA

Table 1. Patient Characteristics Snapshot After Cleaning

This table lists the first 100 observations from the cleaned dataset. It includes key variables such as subject ID, sex, age, treatment group, enrollment dates, BMI, weight status, lab results, and cost information.

The data provides a quick validation of the standardization and deduplication steps performed during the preprocessing phase.

| | Treatment Group | | | | |
	Missing (N=112)	Drug B (N=5905)	Placebo (N=5973)	Total (N=11878)	P-value
Age					0.2732[1]
N (Missing)	111 (1)	5785 (120)	5855 (118)	11640 (238)	
Mean (SD)	38.7 (22.48)	41.2 (23.42)	41.7 (23.74)	41.4 (23.58)	
Median (Range)	36.0 (1.0, 80.0)	41.0 (0.0, 83.0)	41.0 (0.0, 84.0)	41.0 (0.0, 84.0)	
BMI					0.6165[1]
N (Missing)	110 (2)	5679 (226)	5753 (220)	11432 (446)	
Mean (SD)	21.2 (4.50)	21.3 (4.92)	21.3 (4.93)	21.3 (4.92)	
Median (Range)	21.2 (7.9, 34.2)	21.2 (4.0, 37.9)	21.3 (3.2, 40.3)	21.3 (3.2, 40.3)	
cWeight, n (%)					0.8479[2]
Morbidly Obese	0	0 (0.0%)	1 (0.0%)	1 (0.0%)	
Normal weight	63	2787 (49.1%)	2825 (49.1%)	5612 (49.1%)	
Obese	3	238 (4.2%)	238 (4.1%)	476 (4.2%)	
Overweight	16	1062 (18.7%)	1098 (19.1%)	2160 (18.9%)	
Underweight	28	1592 (28.0%)	1591 (27.7%)	3183 (27.8%)	
Missing	2	226	220	446	
Average Cost					0.5427[1]
N (Missing)	112 (0)	5905 (0)	5972 (1)	11877 (1)	

Table-2: Baseline Characteristics by Treatment Group

	Treatment Group				
	Missing (N=112)	Drug B (N=5905)	Placebo (N=5973)	Total (N=11878)	P-value
Mean (SD)	64.6 (25.04)	64.4 (24.04)	64.3 (24.43)	64.3 (24.23)	
Median (Range)	64.8 (11.6, 117.0)	64.5 (2.9, 195.3)	63.8 (3.1, 185.2)	64.2 (2.9, 195.3)	

[1]Kruskal-Wallis p-value; [2]Chi-Square p-value;

★ Table 2. Baseline Characteristics by Treatment Group

This table compares key baseline characteristics across three treatment groups: Missing (N=112), Drug B (N=5905), and Placebo (N=5973). A total of 11,878 patients were included in the analysis. Age was approximately balanced across groups, with a mean of 41.2 years in the Drug B group and 41.7 years in the Placebo group. The Kruskal-Wallis test showed no statistically significant difference in age (P=0.2732). BMI was also similar among groups, with a mean of 21.3 kg/m² across both Drug B and Placebo. No significant difference was observed (P=0.6165). In terms of BMI categories (cWeight), nearly half of the participants fell into the 'Normal weight' group across all arms (49.1%), and about 28% were classified as 'Underweight'. The proportion of 'Obese' and 'Morbidly Obese' subjects was low (<5%). Chi-square testing indicated no significant group difference (P=0.8479). The average cost variable was normally distributed with similar means across groups: 64.4 in Drug B and 64.3 in Placebo. There was no significant difference (P=0.5427). Overall, the randomization process appears to have achieved baseline balance across treatment groups, supporting the validity of downstream comparative analyses.

The FREQ Procedure

Frequency Row Pct	Table of AETERM by TRT01P		
	TRT01P		
AETERM	Drug B	Placebo	Total
Headache	2945 49.55	2999 50.45	5944
Nausea	2960 49.88	2974 50.12	5934
Total	5905	5973	11878

Frequency Missing = 112

Table-3: Adverse Events Summary by Treatment Group

The FREQ Procedure

Statistics for Table of AETERM by TRT01P

Statistic	DF	Value	Prob
Chi-Square	1	0.1343	0.7140
Likelihood Ratio Chi-Square	1	0.1343	0.7140
Continuity Adj. Chi-Square	1	0.1212	0.7277
Mantel-Haenszel Chi-Square	1	0.1343	0.7140
Phi Coefficient		-0.0034	
Contingency Coefficient		0.0034	
Cramer's V		-0.0034	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	2945
Left-sided Pr <= F	0.3639
Right-sided Pr >= F	0.6498
Table Probability (P)	0.0137
Two-sided Pr <= P	0.7273

Sample Size = 11878
Frequency Missing = 112

★ Table 3. Adverse Events Summary by Treatment Group

This table summarizes the frequency of two common adverse events (AEs) — Headache and Nausea — across the Drug B and Placebo treatment groups. A total of 11,878 observations were included (112 records had missing AE information). Headache was reported in 49.55% of Drug B and 50.45% of Placebo participants. Nausea occurred in 49.88% and 50.12% of participants in the respective groups. AE frequencies were nearly identical between groups. The Chi-square test yielded a non-significant result (χ^2=0.1343, df=1, P=0.7140), indicating no statistically significant difference in adverse event distribution between treatment groups. Other tests, including the likelihood ratio and Fisher's exact test, corroborated this conclusion (two-sided P=0.7273). The effect size measures (Phi coefficient, Cramer's V) were close to zero, reinforcing the interpretation that the observed differences are minimal and likely due to chance. Overall, no evidence was found of an association between treatment group and the occurrence of reported adverse events.
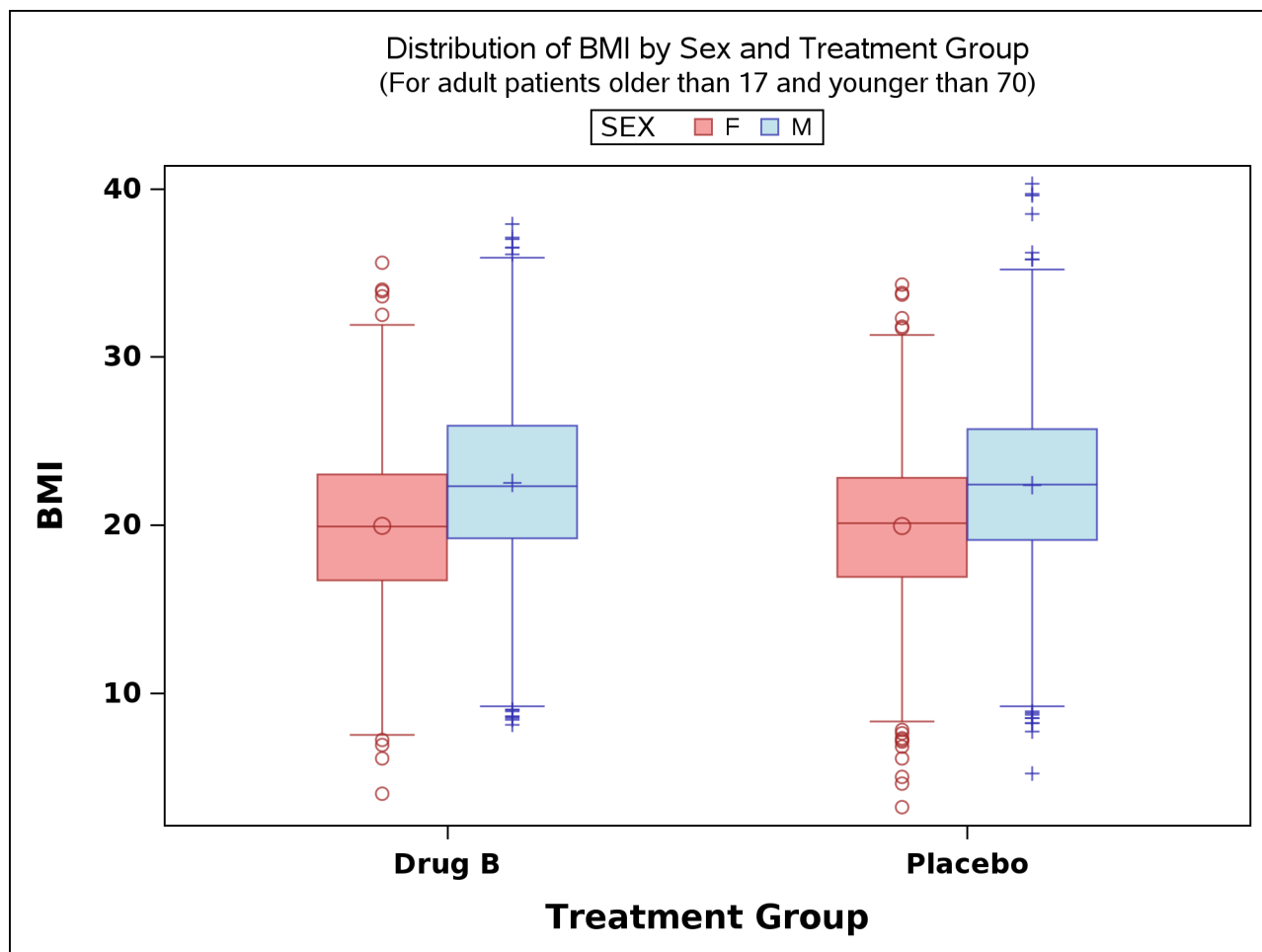
Figure-1
Distribution of Patient Age Stratified by Treatment Group

Variable: Age
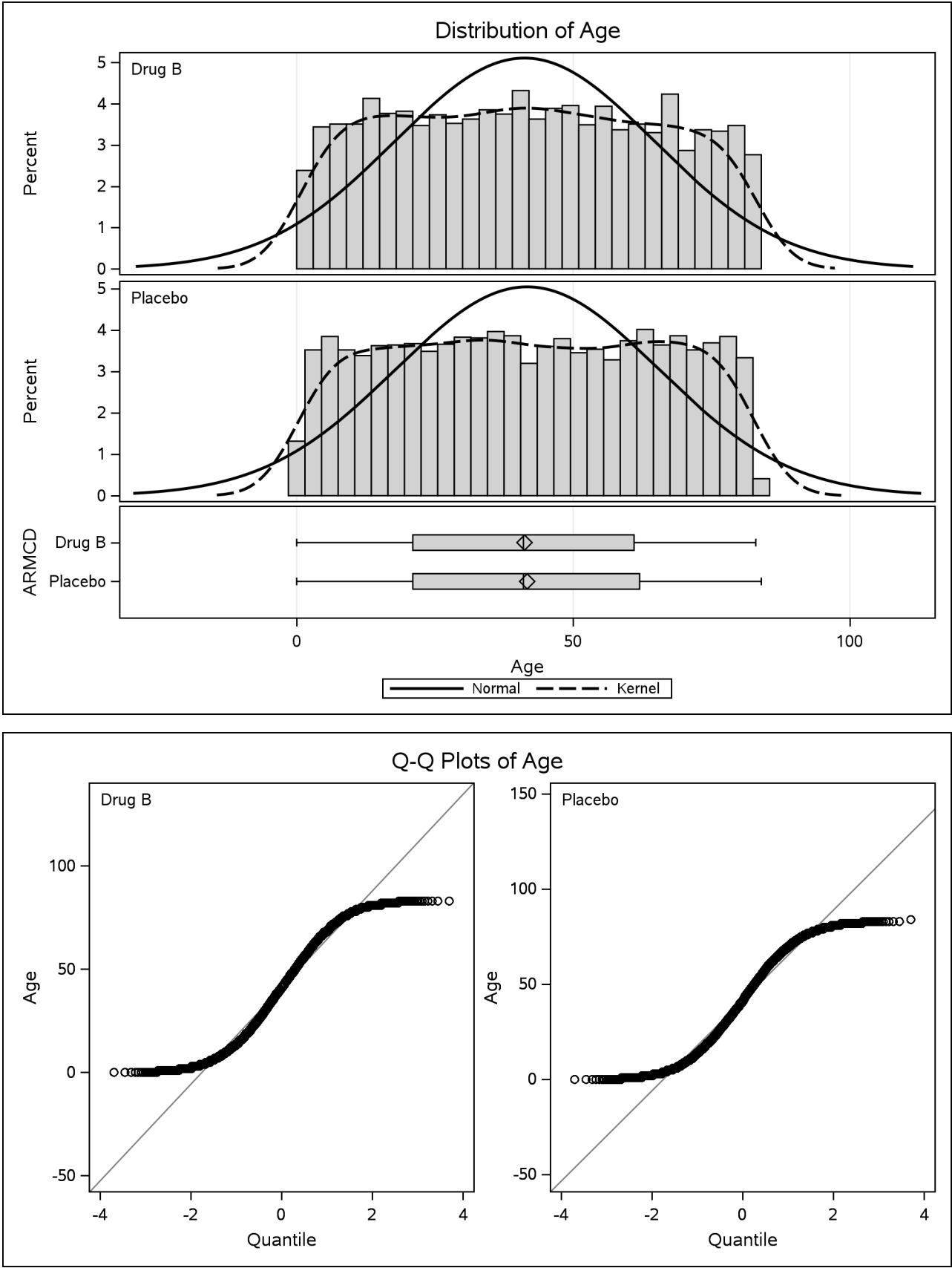
★ **Figure 1. Distribution of Patient Age Stratified by Treatment Group**

The figure illustrates the distribution of age by treatment arm using a combination of histogram, summary panel, and Q-Q plots. The TTEST procedure also provides statistical comparison between groups. The histogram, kernel density, and normal distribution overlays demonstrate that age is approximately uniformly distributed in both groups with similar ranges and central tendencies. The boxplots further confirm that age distributions are comparable, supporting the assumption of group balance for age.

★ **Figure 2. Boxplot of BMI by Sex and Treatment Group**

This boxplot shows BMI distributions across treatment groups, further stratified by sex. Adult patients aged 17–70 were included in this figure. Boxplots indicate that both males and females in the Drug B and Placebo groups show similar BMI medians and interquartile ranges. There are visible outliers, especially among males, but overall group-level BMI distributions appear balanced, suggesting no baseline BMI confounding between treatment groups.