Dataset Integrity Check for the Evaluation of the Intestinal Bile Acid Transport (IBAT) Inhibitor LUM001 in the Reduction of Pruritus in Alagille Syndrome, a Cholestatic Liver Disease (ITCH) Study

Prepared by NIDDK-CR
January 11, 2023

Contents

1 Standard Disclaimer

The intent of this DSIC is to provide confidence that the data distributed by the NIDDK repository is a true copy of the study data. Our intent is not to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected in secondary analysis. This occurs for a number of reasons including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, software coding used to define complex variables, etc. Experience suggests that most discrepancies can ordinarily be resolved by consultation with the study data coordinating center (DCC), however this process is labor-intensive for both DCC and Repository staff. It is thus not our policy to resolve every discrepancy that is observed in an integrity check. Specifically, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses, unless NIDDK Repository staff suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

2 Study Background

The ITCH study was a randomized, double-blind, placebo-controlled, parallel group, multi-center study in children with Alagille syndrome (ALGS). The study was designed to investigate the effects of LUM001, compared to placebo, on pruritus, serum bile acids, liver enzymes, and other biochemical markers associated with cholestatic liver disease, following daily dosing over a 13-week period.

3 Archived Datasets

All data files, as provided by the Data Coordinating Center (DCC), are located in the ITCH folder in the data package. For this replication, variables were taken from the “dm.sas7bdat” and “ ” datasets.

4 Statistical Methods

Analyses were performed to replicate results for the data in the publication by Schneider et al. [1]. To verify the integrity of the data, only descriptive statistics were computed.

5 Results

For Supplemental Table 6 in the publication [1], Demographic and Baseline Characteristics by Treatment Group, Table A lists the variables that were used in the replication, and Tables B1 and B2 compare the results calculated from the archived data files to the results in Supplemental Table 6. The results of the replication are within expected variation to the published results.

6 Conclusions

The NIDDK Central Repository is confident that the ITCH data files to be distributed are a true copy of the study data.

7 References

[1] Shneider BL, Spino C, Kamath BM, Magee JC, Bass LM, Setchell KD, Miethke A, Molleston JP, Mack CL, Squires RH, Murray KF, Loomes KM, Rosenthal P, Karpen SJ, Leung DH, Guthery SL, Thomas D, Sherker AH, Sokol RJ. Placebo-Controlled Randomized Trial of an Intestinal Bile Salt Transport Inhibitor for Pruritus in Alagille Syndrome. Hepatology Communications, 2(10), 1184-1198, September 2018. doi: https://doi.org/10.1002/hep4.1244

Table A: Variables used to replicate Supplemental Table 6 – Demographics and Baseline Characteristics by Treatment Group

Table Variable	**dataset.variable**
Age	dm.arm dm.age
Age category	dm.arm dm.age
Gender	dm.arm dm.sex
Ethnicity	dm.arm dm.ethnic
Race	dm.arm dm.race
Serum bile acid	adsl.arm adsl.bilebl
Alkaline phosphatase	adsl.arm adsl.alpbl
AST	adsl.arm adsl.astbl
ALT	adsl.arm adsl.altbl
GGT	adsl.arm adsl.ggtbl
Total bilirubin	adsl.arm adsl.bilibl
Direct bilirubin	adsl.arm adsl.bildirbl
Cholesterol	adsl.arm adsl.tcholbl
LDL cholesterol	adsl.arm adsl.ldlchbl
7 alpha-hydroxy-4-cholesten-3-one (C4)	adsl.arm adsl.hydrxbl

Table B1: Comparison of values computed in integrity check to reference article Supplemental Table 6 (70, 140, and 280 µg/kg/day)

Characteristic	Maralixibat (µg/kg/day)								
	Publication: 70 (n=8)	**DSIC: 70 (n=8)**	**Diff. (n=0)**	**Publication: 140 (n=11)**	**DSIC: 140 (n=11)**	**Diff. (n=0)**	**Publication: 280 (n=6)**	**DSIC: 280 (n=6)**	**Diff. (n=0)**
Age (years)									
Mean (SD)	7.4 (4.75)	7.4 (4.75)	0 (0)	8.6 (4.32)	8.5 (4.30)	0.1 (0.02)	5.5 (4.76)	5.5 (4.76)	0 (0)
Median	6.5	6.5	0	7.0	7.0	0	3.5	3.5	0
(Min, Max)	(2, 17)	(2, 17)	(0, 0)	(3, 17)	(3, 16)	(0, 1)	(1, 12)	(1, 12)	(0, 0)
Age Category, n (%)									
< 2 years	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)	1 (17%)	1 (17%)	0 (0)
2 to 4 years	2 (25%)	2 (25%)	0 (0)	2 (18%)	2 (18%)	0 (0)	3 (50%)	3 (50%)	0 (0)
5 to 7 years	3 (38%)	3 (38%)	0 (0)	5 (45%)	5 (45%)	0 (0)	0 (0%)	0 (0%)	0 (0)
8 to 12 years	2 (25%)	2 (25%)	0 (0)	2 (18%)	2 (18%)	0 (0)	2 (33%)	2 (33%)	0 (0)
13 to 18 years	1 (13%)	1 (13%)	0 (0)	2 (18%)	2 (18%)	0 (0)	0 (0%)	0 (0%)	0 (0)
Gender, n (%)									
Male	6 (75%)	6 (75%)	0 (0)	7 (64%)	7 (64%)	0 (0)	2 (33%)	2 (33%)	0 (0)
Female	2 (25%)	2 (25%)	0 (0)	4 (36%)	4 (36%)	0 (0)	4 (67%)	4 (67%)	0 (0)
Ethnicity, n (%)									
Hispanic or Latino	0 (0%)	0 (0%)	0 (0)	2 (18%)	2 (18%)	0 (0)	3 (50%)	3 (50%)	0 (0)
Not Hispanic or Latino	8 (100%)	8 (100%)	0 (0)	9 (82%)	9 (82%)	0 (0)	3 (50%)	3 (50%)	0 (0)
Race, n (%)									
American Indian or Alaska Native	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)
Asian	1 (13%)	1 (13%)	0 (0)	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)
Black or African American	1 (13%)	1 (13%)	0 (0)	1 (9%)	1 (9%)	0 (0)	1 (17%)	1 (17%)	0 (0)
Native Hawaiian or Other Pacific Islander	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)
White	6 (75%)	6 (75%)	0 (0)	10 (91%)	10 (91%)	0 (0)	4 (67%)	4 (67%)	0 (0)
More than one race	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)
Not reported	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)	1 (17%)	1 (17%)	0 (0)
Serum Bile Acid (umol/L)									
Mean (SD)	344.0 (338.6)	344.0 (338.6)	0 (0)	151.4 (123.6)	151.4 (123.6)	0 (0)	187.7 (107.8)	187.7 (107.8)	0 (0)
Median	213.0	213.0	0	143.9	143.9	0	153.4	153.4	0
(Min, Max)	(10, 1014)	(10, 1014)	(0, 0)	(21, 371)	(21, 371)	(0, 0)	(60, 329)	(60, 329)	(0, 0)

Characteristic	Maralixibat (µg/kg/day)								
	Publication: 70 (n=8)	DSIC: 70 (n=8)	Diff. (n=0)	Publication: 140 (n=11)	DSIC: 140 (n=11)	Diff. (n=0)	Publication: 280 (n=6)	DSIC: 280 (n=6)	Diff. (n=0)
Alkaline Phosphatase (U/L)									
Mean (SD)	522.3 (188.8)	522.3 (188.8)	0 (0)	622.1 (186.0)	622.1 (186.0)	0 (0)	538.3 (157.4)	538.3 (157.4)	0 (0)
Median	507.0	507.0	0	568.0	568.0	0	539.0	539.0	0
(Min, Max)	(286, 821)	(286, 821)	(0, 0)	(346, 911)	(346, 911)	(0, 0)	(361, 789)	(361, 789)	(0, 0)
AST (U/L)									
Mean (SD)	145.6 (97.52)	145.6 (97.52)	0 (0)	110.8 (53.09)	110.8 (53.09)	0 (0)	177.0 (97.66)	177.0 (97.66)	0 (0)
Median	99.5	99.5	0	120.0	120.0	0	166.5	166.5	0
(Min, Max)	(66, 338)	(66, 338)	(0, 0)	(43, 225)	(43, 225)	(0, 0)	(58, 342)	(58, 342)	(0, 0)
ALT (U/L)									
Mean (SD)	148.4 (84.38)	148.4 (84.38)	0 (0)	116.6 (57.58)	116.6 (57.58)	0 (0)	190.8 (103.9)	190.8 (103.9)	0 (0)
Median	126.0	126.0	0	95.0	95.0	0	182.0	182.0	0
(Min, Max)	(66, 335)	(66, 335)	(0, 0)	(44, 218)	(44, 218)	(0, 0)	(40, 329)	(40, 329)	(0, 0)
GGT (U/L)									
Mean (SD)	624.1 (518.1)	624.1 (518.1)	0 (0)	442.8 (362.3)	442.8 (362.3)	0 (0)	569.3 (405.3)	569.3 (405.3)	0 (0)
Median	450.5	450.5	0	253.0	253.0	0	538.0	538.0	0
(Min, Max)	(19, 1282)	(19, 1282)	(0, 0)	(131, 1260)	(131, 1260)	(0, 0)	(186, 1084)	(186, 1084)	(0, 0)
Total Bilirubin (mg/dL)									
Mean (SD)	7.0 (8.71)	7.0 (8.71)	0 (0)	3.4 (3.50)	3.4 (3.50)	0 (0)	4.2 (5.14)	4.2 (5.14)	0 (0)
Median	2.9	2.9	0	1.6	1.6	0	1.7	1.6	0.1
(Min, Max)	(1, 25)	(1, 25)	(0, 0)	(0, 11)	(0, 11)	(0, 0)	(1, 14)	(1, 14)	(0, 0)
Direct Bilirubin (mg/dL)									
N	8	8	0	11	11	0	6	6	0
Mean (SD)	3.9 (4.08)	3.9 (4.08)	0 (0)	2.5 (2.69)	2.5 (2.69)	0 (0)	2.9 (3.75)	2.9 (3.75)	0 (0)
Median	1.9	1.9	0	1.0	1.0	0	0.9	0.9	0
(Min, Max)	(0, 10)	(0, 10)	(0, 0)	(0, 8)	(0, 8)	(0, 0)	(1, 10)	(1, 10)	(0, 0)
Cholesterol (mg/dL)									
Mean (SD)	435.6 (379.5)	435.6 (379.5)	0 (0)	278.5 (97.78)	278.5 (97.78)	0 (0)	459.3 (311.6)	459.3 (311.6)	0 (0)
Median	263.0	263.0	0	234.0	234.0	0	350.0	350.0	0
(Min, Max)	(138, 1289)	(138, 1289)	(0, 0)	(179, 504)	(179, 504)	(0, 0)	(236, 1084)	(236, 1084)	(0, 0)
LDL Cholesterol (mg/dL)									
Mean (SD)	143.9 (89.56)	143.9 (89.56)	0 (0)	127.8 (26.24)	127.8 (26.24)	0 (0)	181.2 (29.42)	181.2 (29.42)	0 (0)
Median	153.5	153.5	0	119.0	119.0	0	174.5	174.5	0
(Min, Max)	(20, 311)	(20, 311)	(0, 0)	(78, 169)	(78, 169)	(0, 0)	(144, 222)	(144, 222)	(0, 0)

Characteristic	Maralixibat (µg/kg/day)								
	Publication: 70 (n=8)	DSIC: 70 (n=8)	Diff. (n=0)	Publication: 140 (n=11)	DSIC: 140 (n=11)	Diff. (n=0)	Publication: 280 (n=6)	DSIC: 280 (n=6)	Diff. (n=0)
7 alpha-hydroxy-4-cholesten-3-one (C4) (ng/mL)									
Mean (SD)	26.1 (55.46)	26.1 (55.46)	0 (0)	9.8 (14.67)	9.8 (14.67)	0 (0)	10.2 (15.75)	10.2 (15.75)	0 (0)
Median	3.1	3.1	0	3.5	3.5	0	2.9	2.9	0
(Min, Max)	(1, 162)	(1, 162)	(0, 0)	(0, 40)	(0, 40)	(0, 0)	(0, 41)	(0, 41)	(0, 0)

Table B2: Comparison of values computed in integrity check to reference article Supplemental Table 6 (Active, Placebo, and Overall)

Characteristic	Maralixibat (µg/kg/day)								
	Publication: All Active (n=25)	DSIC: All Active (n=25)	Diff. (n=0)	Publication: Placebo (n=12)	DSIC: Placebo (n=12)	Diff. (n=0)	Publication: Overall (n=37)	DSIC: Overall (n=37)	Diff. (n=0)
Age (years)									
Mean (SD)	7.5 (4.55)	7.4 (4.5)	0.1 (0.05)	5.5 (4.19)	5.5 (4.19)	0 (0)	6.8 (4.48)	6.8 (4.44)	0 (0.04)
Median	7.0	7.0	0	5.0	5.0	0	6.0	6.0	0
(Min, Max)	(1, 17)	(1, 17)	(0, 0)	(1, 15)	(1, 15)	(0, 0)	(1, 17)	(1, 17)	(0, 0)
Age Category, n (%)									
< 2 years	1 (4%)	1 (4%)	0 (0)	1 (8%)	1 (8%)	0 (0)	2 (5%)	2 (5%)	0 (0)
2 to 4 years	7 (28%)	7 (28%)	0 (0)	5 (42%)	5 (42%)	0 (0)	12 (32%)	12 (32%)	0 (0)
5 to 7 years	8 (32%)	8 (32%)	0 (0)	3 (25%)	3 (25%)	0 (0)	11 (30%)	11 (30%)	0 (0)
8 to 12 years	6 (24%)	6 (24%)	0 (0)	2 (17%)	2 (17%)	0 (0)	8 (22%)	8 (22%)	0 (0)
13 to 18 years	3 (12%)	3 (12%)	0 (0)	1 (8%)	1 (8%)	0 (0)	4 (11%)	4 (11%)	0 (0)
Gender, n (%)									
Male	15 (60%)	15 (60%)	0 (0)	6 (50%)	6 (50%)	0 (0)	21 (57%)	21 (57%)	0 (0)
Female	10 (40%)	10 (40%)	0 (0)	6 (50%)	6 (50%)	0 (0)	16 (43%)	16 (43%)	0 (0)
Ethnicity, n (%)									
Hispanic or Latino	5 (20%)	5 (20%)	0 (0)	2 (17%)	2 (17%)	0 (0)	7 (19%)	7 (19%)	0 (0)
Not Hispanic or Latino	20 (80%)	20 (80%)	0 (0)	10 (83%)	10 (83%)	0 (0)	30 (81%)	30 (81%)	0 (0)
Race, n (%)									
American Indian or Alaska Native	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)
Asian	1 (4%)	1 (4%)	0 (0)	0 (0%)	0 (0%)	0 (0)	1 (3%)	1 (3%)	0 (0)
Black or African American	3 (12%)	3 (12%)	0 (0)	2 (17%)	2 (17%)	0 (0)	5 (14%)	5 (14%)	0 (0)
Native Hawaiian or Other Pacific Islander	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)	0 (0%)	0 (0%)	0 (0)
White	20 (80%)	20 (80%)	0 (0)	9 (75%)	9 (75%)	0 (0)	29 (78%)	29 (78%)	0 (0)
More than one race	0 (0%)	0 (0%)	0 (0)	1 (8%)	1 (8%)	0 (0)	1 (3%)	1 (3%)	0 (0)
Not reported	1 (4%)	1 (4%)	0 (0)	0 (0%)	0 (0%)	0 (0)	1 (3%)	1 (3%)	0 (0)
Serum Bile Acid (umol/L)									
Mean (SD)	221.7 (223.1)	221.7 (223.1)	0 (0)	204.9 (162.5)	204.9 (162.5)	0 (0)	216.3 (203.3)	216.3 (203.3)	0 (0)
Median	155.5	155.5	0	162.3	162.3	0	155.5	155.5	0
(Min, Max)	(10, 1014)	(10, 1014)	(0, 0)	(27, 510)	(27, 510)	(0, 0)	(10, 1014)	(10, 1014)	(0, 0)

Characteristic	Maralixibat (µg/kg/day)								
	Publication: All Active (n=25)	DSIC: All Active (n=25)	Diff. (n=0)	Publication: Placebo (n=12)	DSIC: Placebo (n=12)	Diff. (n=0)	Publication: Overall (n=37)	DSIC: Overall (n=37)	Diff. (n=0)
Alkaline Phosphatase (U/L)									
Mean (SD)	570.0 (179.5)	570.0 (179.5)	0 (0)	685.4 (305.7)	685.4 (305.7)	0 (0)	607.5 (230.3)	607.5 (230.3)	0 (0)
Median	541.0	541.0	0	599.0	599.0	0	551.0	551.0	0
(Min, Max)	(286, 911)	(286, 911)	(0, 0)	(355, 1481)	(355, 1481)	(0, 0)	(286, 1481)	(286, 1481)	(0, 0)
AST (U/L)									
Mean (SD)	137.8 (81.69)	137.8 (81.69)	0 (0)	172.3 (93.97)	172.3 (93.97)	0 (0)	149.0 (86.11)	149.0 (86.11)	0 (0)
Median	120.0	120.0	0	161.0	161.0	0	123.0	123.0	0
(Min, Max)	(43, 342)	(43, 342)	(0, 0)	(60, 355)	(60, 355)	(0, 0)	(43, 355)	(43, 355)	(0, 0)
ALT (U/L)									
Mean (SD)	144.6 (81.28)	144.6 (81.28)	0 (0)	188.1 (93.05)	188.1 (93.05)	0 (0)	158.7 (86.46)	158.7 (86.46)	0 (0)
Median	124.0	124.0	0	180.0	180.0	0	137.0	137.0	0
(Min, Max)	(40, 335)	(40, 335)	(0, 0)	(65, 322)	(65, 322)	(0, 0)	(40, 335)	(40, 335)	(0, 0)
GGT (U/L)									
Mean (SD)	531.2 (417.1)	531.2 (417.1)	0 (0)	419.4 (288.3)	419.4 (288.3)	0 (0)	494.9 (379.8)	494.9 (379.8)	0 (0)
Median	304.0	304.0	0	339.0	339.0	0	329.0	329.0	0
(Min, Max)	(19, 1282)	(19, 1282)	(0, 0)	(113, 1049)	(113, 1049)	(0, 0)	(19, 1282)	(19, 1282)	(0, 0)
Total Bilirubin (mg/dL)									
Mean (SD)	4.7 (5.95)	4.7 (5.95)	0 (0)	6.4 (6.77)	6.4 (6.77)	0 (0)	5.3 (6.18)	5.3 (6.18)	0 (0)
Median	2.1	2.1	0	3.1	3.1	0	2.1	2.1	0
(Min, Max)	(0, 25)	(0, 25)	(0, 0)	(0, 20)	(0, 20)	(0, 0)	(0, 25)	(0, 25)	(0, 0)
Direct Bilirubin (mg/dL)									
N	25	25	0	12	12	0	37	37	0
Mean (SD)	3.0 (3.34)	3.0 (3.34)	0 (0)	4.1 (4.10)	4.1 (4.10)	0 (0)	3.4 (3.58)	3.4 (3.58)	0 (0)
Median	1.1	1.1	0	2.2	2.2	0	1.1	1.1	0
(Min, Max)	(0, 10)	(0, 10)	(0, 0)	(0, 10)	(0, 10)	(0, 0)	(0, 10)	(0, 10)	(0, 0)
Cholesterol (mg/dL)									
Mean (SD)	372.2 (271.1)	372.2 (271.1)	0 (0)	475.6 (392.0)	475.6 (392.0)	0 (0)	405.7 (313.6)	405.7 (313.6)	0 (0)
Median	281.0	281.0	0	357.0	357.0	0	320.0	320.0	0
(Min, Max)	(138, 1289)	(138, 1289)	(0, 0)	(158, 1601)	(158, 1601)	(0, 0)	(138, 1601)	(138, 1601)	(0, 0)
LDL Cholesterol (mg/dL)									
Mean (SD)	145.8 (57.17)	145.8 (57.17)	0 (0)	165.2 (61.35)	165.2 (61.35)	0 (0)	152.1 (58.43)	152.1 (58.43)	0 (0)
Median	152.0	152.0	0	142.5	142.5	0	144.0	144.0	0
(Min, Max)	(20, 311)	(20, 311)	(0, 0)	(93, 291)	(93, 291)	(0, 0)	(20, 311)	(20, 311)	(0, 0)

Characteristic	Maralixibat (µg/kg/day)								
	Publication: All Active (n=25)	DSIC: All Active (n=25)	Diff. (n=0)	Publication: Placebo (n=12)	DSIC: Placebo (n=12)	Diff. (n=0)	Publication: Overall (n=37)	DSIC: Overall (n=37)	Diff. (n=0)
7 alpha-hydroxy-4-cholesten-3-one (C4) (ng/mL)									
Mean (SD)	15.3 (33.68)	15.3 (33.68)	0 (0)	10.6 (12.17)	10.6 (12.17)	0 (0)	13.7 (28.23)	13.7 (28.23)	0 (0)
Median	3.1	3.1	0	6.4	6.4	0	4.0	4.0	0
(Min, Max)	(0, 162)	(0, 162)	(0, 0)	(1, 43)	(1, 43)	(0, 0)	(0, 162)	(0, 162)	(0, 0)

Attachment A: SAS Code

```
libname itch "X:\NIDDK\niddk-dr_studies2\ITCH\private_orig_data\ITCH Zipped Folder\SDTM data";
libname itch1 "X:\NIDDK\niddk-dr_studies2\ITCH\private_orig_data\ITCH Zipped Folder\ADaM data";

/******************/
/* DSIC for ITCH */
/* Schneider et al. */
/******************/

*Datasets;
data dm; set itch.dm;
if arm = "Screen Failure" then delete;
run;

data adsl; set itch1.adsl;
if arm="Screen Failure" then delete;
run;

*Age;
proc means data=dm n mean std median min max;
var age;
class arm;
run;

proc means data=dm n mean std median min max;
var age;
where arm ^= "Placebo";
run;

proc means data=dm n mean std median min max;
var age;
run;

*age cat;
data dm1; set dm;
agecat = 0;
if age < 2 then agecat = 1;
if age >= 2 AND age <=4 then agecat = 2;
if age > 4 AND age <= 7 then agecat = 3;
if age > 7 AND age <= 12 then agecat = 4;
if age > 12 AND age <= 18 then agecat = 5;
run;

proc freq data=dm1;
tables agecat*arm/norow;
run;
```

```
proc freq data=dm1;
tables agecat*arm/norow nocol;
where arm ^= "Placebo";
run;

*Gender;
proc freq data=dm1;
tables sex*arm/norow;
run;

proc freq data=dm1;
tables sex*arm/norow nocol;
where arm ^= "Placebo";
run;

*Ethnicity;
proc freq data=dm1;
tables ethnic*arm/norow;
run;

proc freq data=dm1;
tables ethnic*arm/norow nocol;
where arm ^= "Placebo";
run;

*Race;
proc freq data=dm1;
tables race*arm/norow missing;
run;

proc freq data=dm1;
tables race*arm/norow nocol missing;
where arm ^= "Placebo";
run;

*Serum Bile acid;
proc means data=adsl n mean std median min max;
var bilebl;
class arm;
run;

proc means data=adsl n mean std median min max;
var bilebl;
where arm ^= "Placebo";
run;

proc means data=adsl n mean std median min max;
```

```
var bilebl;
run;

*Alkaline Phosphatase;
proc means data=adsl n mean std median min max;
var alpbl;
class arm;
run;

proc means data=adsl n mean std median min max;
var alpbl;
where arm ^= "Placebo";
run;

proc means data=adsl n mean std median min max;
var alpbl;
run;

*AST;
proc means data=adsl n mean std median min max;
var astbl;
class arm;
run;

proc means data=adsl n mean std median min max;
var astbl;
where arm ^= "Placebo";
run;

proc means data=adsl n mean std median min max;
var astbl;
run;

*ALT;
proc means data=adsl n mean std median min max;
var altbl;
class arm;
run;

proc means data=adsl n mean std median min max;
var altbl;
where arm ^= "Placebo";
run;

proc means data=adsl n mean std median min max;
var altbl;
run;
```

```
*GGT;
proc means data=adsl n mean std median min max;
var ggtbl;
class arm;
run;

proc means data=adsl n mean std median min max;
var ggtbl;
where arm ^= "Placebo";
run;

proc means data=adsl n mean std median min max;
var ggtbl;
run;

*Total Bilirubin;
proc means data=adsl n mean std median min max;
var bilibl;
class arm;
run;

proc means data=adsl n mean std median min max;
var bilibl;
where arm ^= "Placebo";
run;

proc means data=adsl n mean std median min max;
var bilibl;
run;

*Direct bilirubin ;
proc means data=adsl n mean std median min max;
var bildirbl;
class arm;
run;

proc means data=adsl n mean std median min max;
var bildirbl;
where arm ^= "Placebo";
run;

proc means data=adsl n mean std median min max;
var bildirbl;
run;

*cholesterol;
proc means data=adsl n mean std median min max;
var tcholbl;
```

```
class arm;
run;

proc means data=adsl n mean std median min max;
var tcholbl;
where arm ^= "Placebo";
run;

proc means data=adsl n mean std median min max;
var tcholbl;
run;

*ldl;
proc means data=adsl n mean std median min max;
var ldlchbl;
class arm;
run;

proc means data=adsl n mean std median min max;
var ldlchbl;
where arm ^= "Placebo";
run;

proc means data=adsl n mean std median min max;
var ldlchbl;
run;

*7 alpha-hydroxy-4-cholesten-3-one ;
proc means data=adsl n mean std median min max;
var hydrxbl;
class arm;
run;

proc means data=adsl n mean std median min max;
var hydrxbl;
where arm ^= "Placebo";
run;

proc means data=adsl n mean std median min max;
var hydrxbl;
run;
```