

Dataset Integrity Check for the FONT II Data Files

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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 Novel Therapies for Resistant FSGS (FONT II) trial was a randomized, multicenter Phase I/II clinical trial designed to investigate the potential efficacy of novel therapies for resistant FSGS. Two different therapies, adalimumab (a human anti-TNF- α antibody) and galactose, were evaluated against standard conservative therapy for resistant FSGS, which consists of the combination of lisinopril, losartan, and atorvastatin. Additional aims of the study included identification of one or more novel agents as candidates for evaluation in a future Phase III trial and creation of an infrastructure for the timely completion of clinical trials in patients with rare glomerular diseases such as FSGS.

Individuals with primary FSGS confirmed by renal biopsy who failed to respond to prior immunosuppressive therapy were eligible for the study. The primary outcome measure, evaluated at 6 months, was a composite of two end points, a reduction of proteinuria by 50% from the baseline value and an estimated GFR (eGFR) that was either $\geq 75\%$ of the value at time of randomization or that was persistently ≥ 75 mL/min/1.73 m² in those whose renal function was ≥ 75 mL/min/1.73 m². Thirty-two subjects were screened and 21 were assigned to one of the three study arms. While none of the adalimumab-treated subjects achieved the primary outcome, 2 subjects in the galactose and 2 in the standard medical therapy arm had a 50% reduction in proteinuria without a decline in eGFR.

3 Archived Datasets

All SAS data files, as provided by the Data Coordinating Center (DCC), are located in the Data folder of the data package. For this replication, variables were taken from the “font_primary.sas7bdat”, “form216.sas7bdat”, “form279.sas7bdat”, “font_ae.sas7bdat”, and “font_sae.sas7bdat” datasets.

4 Statistical Methods

Analyses were performed to duplicate results for the data published by Trachtman et al. in BMC Nephrology in 2015 [1].

To verify the integrity of the datasets, descriptive statistics were computed.

5 Results

For Table 1 in the publication [1], Font trial: demographic and clinical features of the subject Cohort, Table A lists the variables that were used in the replication and Table B compares the results calculated from the archived data files to the results published in Table 1. The results of the replication are an exact match to the published results.

For Table 2 in the publication [1], Font trial: Clinical outcomes, Table C lists the variables that were used in the replication and Table D compares the results calculated from the archived data files to the results published in Table 2. The results of the replication are similar to the published results.

For Table 3 in the publication [1], Font trial: outcomes by treatment arm, Table E lists the variables that were used in the replication and Table F compares the results calculated from the archived data files to the results published in Table 3. The results of the replication are an exact match to the published results.

For Table 4 in the publication [1], Font trial: serious adverse events, Table G lists the variables that were used in the replication and Table H compares the results calculated from the archived data files to the results published in Table 4. The results of the replication are an exact match to the published results.

For Table 5 in the publication [1], Font trial: adverse events, Table I lists the variables that were used in the replication and Table J compares the results calculated from the archived data files to the results published in Table 5. The results of the replication are an exact match to the published results.

6 Conclusions

The NIDDK repository are confident that the Font II data files to be distributed are a true copy of the study data.

7 References

[1] Trachtman H, Vento S, Herreshoff E, et al. Efficacy of galactose and adalimumab in patients with resistant focal segmental glomerulosclerosis: report of the font clinical trial group. BMC Nephrology. 2015;16:111. doi:10.1186/s12882-015-0094-5.

Table A: Variables used to replicate Table 1: Font trial: demographic and clinical features of the subject Cohort

Characteristic	dataset.variable(s)
Age at Consent (yr)	font_primary.age_cons
Female	font_primary.sex
Race (self-reported)	font_primary.race
Ethnicity (Self-reported)	font_primary.ethnic
Sitting Systolic BP	font_primary.bp_sys
Sitting Diastolic BP	font_primary.bpdia
Previous Rx with Cyclosporine	font_primary.csa
Cyclosporine Rx: Cumulative Exposure (mos)	font_primary.csamon
Previous Rx with Tacrolimus	font_primary.tacrol
Tacrolimus Rx: Cumulative Exposure (mos)	font_primary.tacmon
Previous Rx with Mycophenolate	font_primary.mmf
Mycophenolate Rx: Cumulative Exposure	font_primary.mmfmon
Edema	font_primary.edema
Serum Albumin (g/dL) at Screening	font_primary.rsl_alb_s
Total Cholesterol (mg/dL) at Screening	font_primary.rsl_chol_s
Up/c at Screening	font_primary.upc_avg_bsl
Baseline eGFR (ml/min/1.73 m ²)	font_primary.egfr_study
Duration of Follow up Post Randomization (yr)	font_primary.pt_fup_rand_yrs

Table B: Comparison of values computed in integrity check to reference article Table 1 values

Characteristic	Manuscript Overall (N=21) N (%) or Median (IQR)	DSIC Overall (N=21) N (%) or Median (IQR)	DIFF
Age at Consent (yr)	14.7 (13.0, 20.8)	14.7 (13.0, 20.8)	0 (0, 0)
Female	12 (57.1 %)	12 (57.1%)	0 (0%)
Race (self-reported)			
Black or African American	4 (19.0 %)	4 (19.0 %)	0 (0%)
White	12 (57.1 %)	12 (57.1 %)	0 (0%)
More than one race	1 (4.8 %)	1 (4.8 %)	0 (0%)
Unknown	4 (19.0 %)	4 (19.0 %)	0 (0%)
Ethnicity (Self-reported)	7 (33.3 %)	7 (33.3 %)	0 (0%)
Sitting Systolic BP	109 (104, 120)	109 (104, 120)	0 (0, 0)
Sitting Diastolic BP	66.0 (60.0, 74.0)	66.0 (60.0, 74.0)	0 (0, 0)
Previous Rx with Cyclosporine	12 (57.1 %)	12 (57.1 %)	0 (0%)
Cyclosporine Rx: Cumulative Exposure (mos)	6.00 (5.50, 12.0)	6.00 (5.50, 12.0)	0 (0, 0)
Previous Rx with Tacrolimus	13 (61.9 %)	13 (61.9 %)	0 (0%)
Tacrolimus Rx: Cumulative Exposure (mos)	7.00 (4.00, 24.0)	7.00 (4.00, 24.0)	0 (0, 0)

Characteristic	Manuscript Overall (N=21) N (%) or Median (IQR)	DSIC Overall (N=21) N (%) or Median (IQR)	DIFF
Previous Rx with Mycophenolate	11 (52.4 %)	11 (52.4 %)	0 (0%)
Mycophenolate Rx: Cumulative Exposure (mos)	6.00 (4.00, 17.0)	6.00 (4.00, 17.0)	0 (0, 0)
Edema			
None	14 (66.7 %)	14 (66.7 %)	0 (0%)
Pretibial	6 (28.6 %)	6 (28.6 %)	0 (0%)
Ascites	1 (4.8 %)	1 (4.8 %)	0 (0%)
Serum Albumin (g/dL) at Screening	2.40 (2.10, 3.50)	2.40 (2.10, 3.50)	0 (0, 0)
Total Cholesterol (mg/dL) at Screening	276 (198, 424)	276 (198, 424)	0 (0, 0)
Up/c at Screening	4.93 (3.30, 11.5)	4.93 (3.30, 11.5)	0 (0, 0)
Baseline eGFR (ml/min/1.73 m ²)	120 (81.1, 170)	120 (81.1, 170)	0 (0, 0)
Duration of Follow up Post Randomization (yr)	1.63 (1.27, 1.74)	1.63 (1.27, 1.74)	0 (0, 0)

Characteristic	Manuscript Age at consent <18 years (N=14) N (%) or Median (IQR)	DSIC Age at consent <18 years (N=14) N (%) or Median (IQR)	DIFF
Age at Consent (yr)	13.5 (12.8, 14.7)	13.5 (12.8, 14.7)	0 (0, 0)
Female	8 (57.1 %)	8 (57.1%)	0 (0%)
Race (self-reported)			
Black or African American	2 (14.3 %)	2 (14.3 %)	0 (0%)
White	7 (50.0 %)	7 (50.0 %)	0 (0%)
More than one race	1 (7.1 %)	1 (7.1 %)	0 (0%)
Unknown	4 (28.6 %)	4 (28.6 %)	0 (0%)
Ethnicity (Self-reported)	6 (42.9 %)	6 (42.9 %)	0 (0%)
Sitting Systolic BP	109 (88.0, 115)	109 (88.0, 115)	0 (0, 0)
Sitting Diastolic BP	62.5 (54.0, 71.0)	62.5 (54.0, 71.0)	0 (0, 0)
Previous Rx with Cyclosporine	6 (42.9 %)	6 (42.9 %)	0 (0%)
Cyclosporine Rx: Cumulative Exposure (mos)	5.50 (4.00, 12.0)	5.50 (4.00, 12.0)	0 (0, 0)
Previous Rx with Tacrolimus	8 (57.1 %)	8 (57.1 %)	0 (0%)
Tacrolimus Rx: Cumulative Exposure (mos)	9.50 (4.00, 31.0)	9.50 (4.00, 31.0)	0 (0, 0)
Previous Rx with Mycophenolate	9 (64.3 %)	9 (64.3 %)	0 (0%)
Mycophenolate Rx: Cumulative Exposure (mos)	6.00 (5.00, 12.0)	6.00 (5.00, 12.0)	0 (0, 0)
Edema			

Characteristic	Manuscript Age at consent <18 years (N=14) N (%) or Median (IQR)	DSIC Age at consent <18 years (N=14) N (%) or Median (IQR)	DIFF
None	9 (64.3 %)	9 (64.3 %)	0 (0%)
Pretibial	4 (28.6 %)	4 (28.6 %)	0 (0%)
Ascites	1 (7.1 %)	1 (7.1 %)	0 (0%)
Serum Albumin (g/dL) at Screening	2.40 (2.05, 3.60)	2.40 (2.05, 3.60)	0 (0, 0)
Total Cholesterol (mg/dL) at Screening	297 (163, 452)	297 (163, 452)	0 (0, 0)
Up/c at Screening	9.28 (3.30, 12.2)	9.28 (3.30, 12.2)	0 (0, 0)
Baseline eGFR (ml/min/1.73 m ²)	119 (88.2, 221)	119 (88.2, 221)	0 (0, 0)
Duration of Follow up Post Randomization (yr)	1.66 (1.48, 2.03)	1.66 (1.48, 2.03)	0 (0, 0)

Characteristic	Manuscript Age at consent ≥18 years (N=7) N (%) or Median (IQR)	DSIC Age at consent ≥18 years (N=7) N (%) or Median (IQR)	DIFF
Age at Consent (yr)	28.6 (20.8, 34.0)	28.6 (20.8, 34.0)	0 (0, 0)
Female	4 (57.1 %)	4 (57.1%)	0 (0%)
Race (self-reported)			
Black or African American	2 (28.6 %)	2 (28.6 %)	0 (0%)
White	5 (71.4 %)	5 (71.4 %)	0 (0%)
More than one race	--	--	--
Unknown	--	--	--
Ethnicity (Self-reported)	1 (14.3 %)	1 (14.3 %)	0 (0%)
Sitting Systolic BP	126 (107, 129)	126 (107, 129)	0 (0, 0)
Sitting Diastolic BP	74.0 (68.0, 79.0)	74.0 (68.0, 79.0)	0 (0, 0)
Previous Rx with Cyclosporine	6 (85.7 %)	6 (85.7 %)	0 (0%)
Cyclosporine Rx: Cumulative Exposure (mos)	6.00 (6.00, 12.0)	6.00 (6.00, 12.0)	0 (0, 0)
Previous Rx with Tacrolimus	5 (71.4 %)	5 (71.4 %)	0 (0%)
Tacrolimus Rx: Cumulative Exposure (mos)	6.00 (6.00, 24.0)	6.00 (6.00, 24.0)	0 (0, 0)
Previous Rx with Mycophenolate	2 (28.6 %)	2 (28.6 %)	0 (0%)
Mycophenolate Rx: Cumulative Exposure (mos)	9.50 (1.00, 18.0)	9.50 (1.00, 18.0)	0 (0, 0)
Edema			
None	5 (71.4 %)	5 (71.4 %)	0 (0%)
Pretibial	2 (28.6 %)	2 (28.6 %)	0 (0%)

Characteristic	Manuscript Age at consent ≥18 years (N=7) N (%) or Median (IQR)	DSIC Age at consent ≥18 years (N=7) N (%) or Median (IQR)	DIFF
Ascites	0 (0 %)	0 (0 %)	0 (0%)
Serum Albumin (g/dL) at Screening	2.50 (2.10, 3.50)	2.50 (2.10, 3.50)	0 (0, 0)
Total Cholesterol (mg/dL) at Screening	267 (198, 424)	267 (198, 424)	0 (0, 0)
Up/c at Screening	3.41 (3.23, 4.93)	3.41 (3.23, 4.93)	0 (0, 0)
Baseline eGFR (ml/min/1.73 m ²)	120 (71.5, 151)	120 (71.5, 151)	0 (0, 0)
Duration of Follow up Post Randomization (yr)	1.24 (1.06, 1.70)	1.24 (1.06, 1.70)	0 (0, 0)

Table C: Variables used to replicate Table 2: Font trial: Clinical outcomes

Characteristic	dataset.variable(s)
Up/c month 0	font_primary.upc_avg_bsl
Up/c month 6	font_primary.upc_avg_w26
% Change Up/c	font_primary.upc_rdt
Up/c responder	font_primary.upc_resp
eGFR month 0	font_primary.egfr_study
eGFR month 6	font_primary.egfr_w26, font_primary.age_cons, font_primary.sex, form216.weight, form216.height, form279.creat where cpevent = "W26"
eGFR preservation	font_primary.egfr_resp
Primary outcome met	font_primary.primary
Duration (yr) follow-up post randomization	font_primary.pt_fup_rand_yrs

Table D: Comparison of values computed in integrity check to reference article Table 2 values

Participant	Manuscript Up/c month 0	DSIC Up/c month 0	DIFF.	Manuscript Up/c month 6	DSIC Up/c month 6	DIFF.
RX=adalimumab						
1	2.1	2.1	0	12.3	12.3	0
2	6.3	6.3	0	6.6	6.6	0
3	14.9	14.9	0	8.4	8.4	0
4	4.7	4.7	0	6.1	6.1	0
5 ^{a,b}	3.4	3.4	0	.	.	.
6	2.3	2.3	0	1.6	1.6	0
7	2.1	2.1	0	5.2	5.2	0
RX = Galactose						
8	9.0	9.0	0	3.2	3.2	0
9	3.3	3.3	0	0.9	0.9	0
10	3.3	3.3	0	0.5	0.5	0
11	12.2	12.2	0	10.8	10.8	0
12 ^a	49.3	49.3	0	29.9	29.9	0
13	1.5	1.5	0	1.0	1.0	0
14	6.7	6.7	0	7.0	7.0	0
RX = Standard Therapy (lisinopril, losartan, atorvastatin)						
15	4.6	4.6	0	2.8	2.8	0
16	16.0	16.0	0	5.0	5.0	0
17 ^{a,b}	11.6	11.6	0	.	.	.
18	3.2	3.2	0	2.5	2.5	0
19	4.9	4.9	0	2.2	2.2	0
20	9.6	9.6	0	5.5	5.5	0
21	11.5	11.5	0	14.2	14.2	0

Participant	Manuscript % Change Up/c	DSIC % Change Up/c	DIFF.	Manuscript Up/c responder	DSIC Up/c responder	DIFF.
RX=adalimumab						
1	475.0	475.0	0	No	No	0
2	5.0	5.0	0	No	No	0
3	-43.8	-43.8	0	No	No	0
4	31.0	31.0	0	No	No	0
5 ^{a,b}	.	.	.	Never received study drug	N/A	N/A
6	-30.5	-30.5	0	No	No	0
7	142.5	142.5	0	No	No	0
RX = Galactose						
8	-64.5	-64.5	0	Yes	Yes	0
9	-72.8	-72.8	0	Yes	Yes	0
10	-86.0	-86.0	0	Yes	Yes	0
11	-11.4	-11.4	0	No	No	0
12 ^a	-39.2	-39.2	0	No	No	0
13	-29.9	-29.9	0	No	No	0
14	4.7	4.7	0	No	No	0
RX = Standard Therapy (lisinopril, losartan, atorvastatin)						
15	-40.3	-40.3	0	No	No	0
16	-68.5	-68.5	0	Yes	Yes	0
17 ^{a,b}	.	.	.	Never received study drug	N/A	N/A
18	-22.7	-22.7	0	No	No	0
19	-54.6	-54.6	0	Yes	Yes	0
20	-42.2	-42.2	0	No	No	0
21	23.2	23.2	0	No	No	0

Participant	Manuscript eGFR month 0	DSIC eGFR month 0	DIFF	Manuscript eGFR month 6	DSIC eGFR month 6	DIFF
RX=adalimumab						
1	325	325	0	41	41	0
2	140	140	0	155	155	0
3	88	88	0	116	116	0
4	120	120	0	93	93	0
5 ^{a,b}	81	81	0	.	.	.
6	37	37	0	29	29	0

Participant	Manuscript eGFR month 0	DSIC eGFR month 0	DIFF	Manuscript eGFR month 6	DSIC eGFR month 6	DIFF
7	58	58	0	24	24	0
RX = Galactose						
8	71	71	0	41	41	0
9	143	143	0	129	129	0
10	97	97	0	91	91	0
11	91	91	0	63	62	1
12 ^a	63	63	0	35	35	0
13	221	221	0	180	180	0
14	71	71	0	67	67	0
RX = Standard Therapy (lisinopril, losartan, atorvastatin)						
15	276	276	0	283	283	0
16	235	235	0	180	180	0
17 ^{a,b}	170	170	0	.	.	.
18	151	151	0	108	108	0
19	155	155	0	150	150	0
20	173	173	0	178	178	0
21	94	94	0	57	57	0

Participant	Manuscript eGFR preservation	DSIC eGFR preservation	DIFF	Manuscript Primary outcome met?	DSIC Primary outcome met?	DIFF
RX=adalimumab						
1	No	No	0	No	No	0
2	Yes	Yes	0	No	No	0
3	Yes	Yes	0	No	No	0
4	Yes	Yes	0	No	No	0
5 ^{a,b}	Never received study drug	N/A	N/A	No	No	0
6	Yes	Yes	0	No	No	0
7	No	No	0	No	No	0
RX = Galactose						
8	No	No	0	No	No	0
9	Yes	Yes	0	Yes	Yes	0
10	Yes	Yes	0	Yes	Yes	0
11	No	No	0	No	No	0
12 ^a	No	No	0	No	No	0
13	Yes	Yes	0	No	No	0
14	Yes	Yes	0	No	No	0

Participant	Manuscript eGFR preservation	DSIC eGFR preservation	DIFF	Manuscript Primary outcome met?	DSIC Primary outcome met?	DIFF
RX = Standard Therapy (lisinopril, losartan, atorvastatin)						
15	Yes	Yes	0	No	No	0
16	Yes	Yes	0	Yes	Yes	0
17 ^{a,b}	Never received study drug	N/A	N/A	No	No	0
18	Yes	Yes	0	No	No	0
19	Yes	Yes	0	Yes	Yes	0
20	Yes	Yes	0	No	No	0
21	No	No	0	No	No	0

Participant	Manuscript Duration (yr) follow-up post randomization	DSIC Duration (yr) follow-up post randomization	DIFF
RX=adalimumab			
1	2.5	2.5	0
2	2.0	2.0	0
3	1.6	1.6	0
4	1.7	1.7	0
5 ^{a,b}	0.1	0.1	0
6	1.5	1.5	0
7	1.7	1.7	0
RX = Galactose			
8	2.1	2.1	0
9	1.7	1.7	0
10	1.6	1.6	0
11	1.4	1.4	0
12 ^a	1.6	1.6	0
13	1.3	1.3	0
14	1.1	1.1	0
RX = Standard Therapy (lisinopril, losartan, atorvastatin)			
15	2.1	2.1	0
16	1.5	1.5	0
17 ^{a,b}	0.0	0.0	0
18	1.2	1.2	0
19	1.2	1.2	0
20	1.7	1.7	0
21	1.8	1.8	0

Table E: Variables used to replicate Table 3: Font trial: outcomes by treatment arm

Characteristic	dataset.variable(s)
Treatment Arm	font_primary.RX
Outcome	font_primary.primary

Table F: Comparison of values computed in integrity check to reference article Table 3 values

Outcome	(Manuscript) Adalimumab	(DSIC) Adalimumab	(Diff) Adalimumab	(Manuscript) Galactose	(DSIC) Galactose	(Diff) Galactose
Success	0	0	0	2	2	0
Failure	7	7	0	5	5	0
Total	7	7	0	7	7	0

Outcome	(Manuscript) Standard	(DSIC) Standard	(Diff) Standard	(Manuscript) Total	(DSIC) Total	(Diff) Total
Success	2	2	0	4	4	0
Failure	5	5	0	17	17	0
Total	7	7	0	21	21	0

Table G: Variables used to replicate Table 4: Font trial: serious adverse events

Characteristic	dataset.variable(s)
Treatment Arm	font_sae.rx
SAE Criteria: Fatal	font_sae.sercrt1
SAE Criteria: Immediately life-threatening	font_sae.sercrt2
SAE Criteria: Required hospitalization	font_sae.sercrt3
SAE Criteria: Prolonged existing hospitalization	font_sae.sercrt4
SAE Criteria: Persistent or significant disability/incapacity	font_sae.sercrt5
SAE Criteria: Congenital anomaly/birth defect	font_sae.sercrt6
SAE Criteria: Causes cancer	font_sae.sercrt7
SAE Criteria: Overdose of study medication	font_sae.sercrt8

Table H: Comparison of values computed in integrity check to reference article Table 4 values

Event	Manuscript Adalimumab (N=7) [PT,%,Events]	DSIC Adalimumab (N=7) [PT,%,Events]	Diff	Manuscript Galactose (N=7) [PT,%,Events]	DSIC Galactose [PT,%,Events]	Diff
Fatal	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0
Immediate Life Threatening	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0
Required Hospitalization	3,42.9,32	3,42.9,32	0,0,0	1,14.3,9	1,14.3,9	0,0,0
Prolonged Existing Hospitalization	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0
Persistent or Significant Disability/Incapacity	0,0,0	0,0,0	0,0,0	1,14.3,1	1,14.3,1	0,0,0
Congenital Anomaly / Birth Defect	1,14.3,1	1,14.3,1	0,0,0	1,14.3,1	1,14.3,1	0,0,0
Causes Cancer	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0
Overdose of Study Medication	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0

Event	Manuscript Standard [PT,%,Events]	DSIC Standard [PT,%,Events]	Diff
Fatal	0,0,0	0,0,0	0,0,0
Immediate Life Threatening	0,0,0	0,0,0	0,0,0
Required Hospitalization	1,14.3,1	1,14.3,1	0,0,0
Prolonged Existing Hospitalization	0,0,0	0,0,0	0,0,0
Persistent or Significant Disability/Incapacity	0,0,0	0,0,0	0,0,0
Congenital Anomaly / Birth Defect	0,0,0	0,0,0	0,0,0
Causes Cancer	0,0,0	0,0,0	0,0,0
Overdose of Study Medication	0,0,0	0,0,0	0,0,0

Table I: Variables used to replicate Table 5. Font trial: adverse events

Characteristic	dataset.variable(s)
Treatment Arm	font_ae_primary.rx
Symptom category	font_ae_primary.category

Table J: Comparison of values computed in integrity check to reference article Table 5 values

Event	Manuscript Adalimumab (N=7) [PT,%,Events]	DSIC Adalimumab (N=7) [PT,%,Events]	Diff	Manuscript Galactose (N=7) [PT,%,Events]	DSIC Galactose [PT,%,Events]	Diff
Allergy	1,14.3,1	1,14.3,1	0,0,0	2,28.6,2	2,28.6,2	0,0,0
Anorexia	2,28.6,4	2,28.6,4	0,0,0	1,14.3,1	1,14.3,1	0,0,0
CV	0,0,0	0,0,0	0,0,0	1,14.3,1	1,14.3,1	0,0,0
Cataract	0,0,0	0,0,0	0,0,0	1,14.3,1	1,14.3,1	0,0,0
Cosmetic	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0	0,0,0
Cough	3,42.9,3	3,42.9,3	0,0,0	2,28.6,3	2,28.6,3	0,0,0
Dehydration	2,28.6,5	2,28.6,5	0,0,0	1,14.3,5	1,14.3,5	0,0,0
Dizziness	0,0,0	0,0,0	0,0,0	4,57.1,6	4,57.1,6	0,0,0
Edema	6,85.7,100	6,85.7,100	0,0,0	5,71.4,57	5,71.4,57	0,0,0
Fatigue	5,71.4,8	5,71.4,8	0,0,0	2,28.6,5	2,28.6,5	0,0,0
GI	4,57.1,7	4,57.1,7	0,0,0	2,28.6,6	2,28.6,6	0,0,0
Headache	4,57.1,6	4,57.1,6	0,0,0	4,57.1,8	4,57.1,8	0,0,0
Hypotension	1,14.3,4	1,14.3,4	0,0,0	0,0,0	0,0,0	0,0,0
Infection	5,71.4,49	5,71.4,49	0,0,0	5,71.4,20	5,71.4,20	0,0,0
Miscellaneous	4,57.1,13	4,57.1,13	0,0,0	4,57.1,7	4,57.1,7	0,0,0
Musculoskeletal	3,42.9,8	3,42.9,8	0,0,0	1,14.3,2	1,14.3,2	0,0,0
Nausea	2,28.6,2	2,28.6,2	0,0,0	2,28.6,12	2,28.6,12	0,0,0
Pain	2,28.6,9	2,28.6,9	0,0,0	4,57.1,14	4,57.1,14	0,0,0
Renal	2,28.6,8	2,28.6,8	0,0,0	1,14.3,4	1,14.3,4	0,0,0
Respiratory	1,14.3,2	1,14.3,2	0,0,0	2,28.6,2	2,28.6,2	0,0,0
Skin	2,28.6,3	2,28.6,3	0,0,0	3,42.9,14	3,42.9,14	0,0,0
Vomiting	2,28.6,5	2,28.6,5	0,0,0	2,28.6,5	2,28.6,5	0,0,0

Event	Manuscript Standard [PT,%,Events]	DSIC Standard [PT,%,Events]	Diff
Allergy	1,14.3,1	1,14.3,1	0,0,0
Anorexia	0,0,0	0,0,0	0,0,0
CV	0,0,0	0,0,0	0,0,0
Cataract	0,0,0	0,0,0	0,0,0
Cosmetic	1,14.3,2	1,14.3,2	0,0,0
Cough	1,14.3,1	1,14.3,1	0,0,0
Dehydration	0,0,0	0,0,0	0,0,0
Dizziness	1,14.3,1	1,14.3,1	0,0,0
Edema	6,85.7,23	6,85.7,23	0,0,0
Fatigue	1,14.3,1	1,14.3,1	0,0,0
GI	1,14.3,2	1,14.3,2	0,0,0
Headache	1,14.3,1	1,14.3,1	0,0,0
Hypotension	0,0,0	0,0,0	0,0,0
Infection	4,57.1,10	4,57.1,10	0,0,0
Miscellaneous	4,57.1,13	4,57.1,13	0,0,0
Musculoskeletal	4,57.1,8	4,57.1,8	0,0,0
Nausea	0,0,0	0,0,0	0,0,0
Pain	3,42.9,3	3,42.9,3	0,0,0
Renal	1,14.3,1	1,14.3,1	0,0,0
Respiratory	2,28.6,2	2,28.6,2	0,0,0
Skin	3,42.9,8	3,42.9,8	0,0,0
Vomiting	0,0,0	0,0,0	0,0,0

Attachment A: SAS Code

```
*****
***Program: font_ii_redaction_review.sas
***Programmer: Corey Del Vecchio and Michael Spriggs
***Date Created: 1/31/2017 4:51:09 PM
***Purpose:
***
***
***Source of Request:
***Input Files:
***
***Output Files:
***
***History
***Updated by:
***Date Modified:
***Updated Task:
*****;

%include "/prj/niddk/ims_analysis/FONT_II/private_created_data/FONT_II_V1/formats/FONTII_formats_01102017.sas";

proc format ;

*** across forms";
value ynfmt
  0='No'
  1='Yes'
  8='N/A'
  9='Unknown'
  98="declines";

title1 "%sysfunc(getoption(sysin))";
title2 " ";

libname font "/prj/niddk/ims_analysis/FONT_II/private_created_data/FONT_II_V1/data";
libname anal "/prj/niddk/ims_analysis/FONT_II/private_created_data/FONT_II_V1/analysis_data";

ODS PATH RESET;
ODS PATH (PREPEND) WORK.Templat(UPDATE) ;

PROC TEMPLAT;
  EDIT Base.Freq.OneWayList;
  EDIT Frequency;
  FORMAT = COMMA6.;
END;
```

```

EDIT CumFrequency;
  FORMAT = COMMA6.;
END;
EDIT Percent;
  FORMAT = 5.1;
END;
EDIT CumPercent;
  FORMAT = 5.1;
END;
END;
RUN;

```

```

data form205          ; set font.form205          ;
data form210          ; set font.form210          ;
data form211          ; set font.form211          ;
data form216          ; set font.form216          ;
data form230          ; set font.form230          ;
data form231          ; set font.form231          ;
data form232          ; set font.form232          ;
data form236          ; set font.form236          ;
data form237          ; set font.form237          ;
data form238          ; set font.form238          ;
data form239          ; set font.form239          ;
data form240          ; set font.form240          ;
data form241          ; set font.form241          ;
data form242          ; set font.form242          ;
data form243          ; set font.form243          ;
data form244_concmeds ; set font.form244_concmeds ;
data form244_disp     ; set font.form244_disp     ;
data form244_studymeds ; set font.form244_studymeds ;
data form245          ; set font.form245          ;
data form252          ; set font.form252          ;
data form253          ; set font.form253          ;
data form254          ; set font.form254          ;
data form260          ; set font.form260          ;
data form261          ; set font.form261          ;
data form262          ; set font.form262          ;
data form263          ; set font.form263          ;
data form264          ; set font.form264          ;
data form271          ; set font.form271          ;
data form278          ; set font.form278          ;
data form279          ; set font.form279          ;
data form280          ; set font.form280          ;
data form283          ; set font.form283          ;
data form286          ; set font.form286          ;
data form287          ; set font.form287          ;
data form288          ; set font.form288          ;
data form294          ; set font.form294          ;
data form295          ; set font.form295          ;

```

```

data form296          ; set font.form296          ;

data cbl_serum        ; set anal.cbl_serum;
data cbl_urine        ; set anal.cbl_urine;
data font_ae          ; set anal.font_ae;
data font_palbap5supar ; set anal.font_palbap5supar;
data font_primary     ; set anal.font_primary;
data font_sae         ; set anal.font_sae;

data font_primary_2;
    set font_primary;

data font_primary;
    set font_primary;
    if 0 <= age_cons < 18 then age_cons_cat = 1;
    else if age_cons >= 18 then age_cons_cat = 2;

proc sort data = font_primary;
    by age_cons_cat;

*** Table 1 ***;
title3 "Table 1";

proc means data = font_primary MEDIAN P25 P75 maxdec=1;
    var age_cons;
    title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75 maxdec=1;
    var age_cons;
    by age_cons_cat;
    title4 "Means font_primary";

proc freq data = font_primary;
    table sex;

proc sort data = font_primary;
    by age_cons_cat;

proc freq data = font_primary;
    table sex;
    by age_cons_cat;

proc freq data = font_primary ;
    table RACE;

proc freq data = font_primary;
    table RACE;
    by age_cons_cat;

```

```

proc freq data = font_primary;
    table ETHNIC;

proc freq data = font_primary;
    table ETHNIC;
    by age_cons_cat;

proc means data = font_primary MEDIAN P25 P75;
    var BP_SYS;
    title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
    var BP_SYS;
    by age_cons_cat;
    title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
    var BPDIA;
    title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
    var BPDIA;
    by age_cons_cat;
    title4 "Means font_primary";

proc freq data = font_primary;
    table CSA;

proc freq data = font_primary;
    table CSA;
    by age_cons_cat;

proc means data = font_primary MEDIAN P25 P75;
    var CSAMON;
    title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
    var CSAMON;
    by age_cons_cat;
    title4 "Means font_primary";

proc freq data = font_primary;
    table TACROL;

proc freq data = font_primary;
    table TACROL;
    by age_cons_cat;

```

```

proc means data = font_primary MEDIAN P25 P75;
  var TACMON;
  title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
  var TACMON;
  by age_cons_cat;
  title4 "Means font_primary";

proc freq data = font_primary;
  table MMF;

proc freq data = font_primary;
  table MMF;
  by age_cons_cat;

proc means data = font_primary MEDIAN P25 P75;
  var MMFMON;
  title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
  var MMFMON;
  by age_cons_cat;
  title4 "Means font_primary";

proc freq data = font_primary;
  table EDEMA;

proc freq data = font_primary;
  table EDEMA;
  by age_cons_cat;

proc means data = font_primary MEDIAN P25 P75;
  var rsl_alb_s;
  title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
  var rsl_alb_s;
  by age_cons_cat;
  title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
  var rsl_chol_s;
  title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
  var rsl_chol_s;
  by age_cons_cat;

```

```

        title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
    var upc_avg_bsl;
    title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
    var upc_avg_bsl;
    by age_cons_cat;
    title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
    var egfr_study;
    title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
    var egfr_study;
    by age_cons_cat;
    title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
    var pt_fup_rand_yrs;
    title4 "Means font_primary";

proc means data = font_primary MEDIAN P25 P75;
    var pt_fup_rand_yrs;
    by age_cons_cat;
    title4 "Means font_primary";

proc sort data = font_primary;
    by RX pid;

proc sort data = font_primary_2;
    by RX;

/*
proc print data = font_primary_2;
    var rx upc_avg_bsl upc_avg_w26 upc_rdct upc_resp egfr_study egfr_w26 egfr_resp primary pt_fup_rand_yrs;
*/
data font_primary_table2;
    set font_primary;
    if RX = "ADALIMUMAB" then do;
        if round(upc_rdct, 0.1) = 475.0 then order_print = 1;
        else if round(upc_rdct, 0.1) = 5.0 then order_print = 2;
        else if round(upc_rdct, 0.1) = -43.8 then order_print = 3;
        else if round(upc_rdct, 0.1) = 31.0 then order_print = 4;
        else if round(upc_rdct, 0.1) = . then order_print = 5;
        else if round(upc_rdct, 0.1) = -30.5 then order_print = 6;
        else if round(upc_rdct, 0.1) = 142.5 then order_print = 7;
    end;
end;

```

```

else if RX = "GALACTOSE" then do;
  if round(upc_rdct, 0.1) = -64.5 then order_print = 8;
  else if round(upc_rdct, 0.1) = -72.8 then order_print = 9;
  else if round(upc_rdct, 0.1) = -86 then order_print = 10;
  else if round(upc_rdct, 0.1) = -11.4 then order_print = 11;
  else if round(upc_rdct, 0.1) = -39.2 then order_print = 12;
  else if round(upc_rdct, 0.1) = -29.9 then order_print = 13;
  else if round(upc_rdct, 0.1) = 4.7 then order_print = 14;
end;

else if RX = "STANDARD THERAPY" then do;
  if round(upc_rdct, 0.1) = -40.3 then order_print = 15;
  else if round(upc_rdct, 0.1) = -68.5 then order_print = 16;
  else if round(upc_rdct, 0.1) = . then order_print = 17;
  else if round(upc_rdct, 0.1) = -22.7 then order_print = 18;
  else if round(upc_rdct, 0.1) = -54.6 then order_print = 19;
  else if round(upc_rdct, 0.1) = -42.2 then order_print = 20;
  else if round(upc_rdct, 0.1) = 23.2 then order_print = 21;
end;

data form216_w26;
  set form216;
  if cpevent = 'W26';

proc sort data = form216_w26;
  by pid subevent_number;

data form216_w26;
  set form216_w26;
  by pid;
  if last.pid then output;

data form279_w26;
  set form279;
  if cpevent = 'W26';

proc sort data = form279_w26 nodupkey;
  by pid;

data form283_w26;
  set form283;
  if cpevent = 'W26';

proc sort data = form283_w26 nodupkey;
  by pid;

data w26_formdata;
  merge form216_w26 (in=val1 keep=pid height weight)
        form279_w26 (in=val2 keep=pid creat)
        form283_w26 (in=val3 keep=pid tstrq2);

```



```

    by pid;
    bsa = ((weight**0.425)*(height**0.725)*71.84)/10000;
    if val1 and (val2 or val3) then output;

proc sort data = font_primary_table2;
    by pid;

data font_primary_table2;
    merge font_primary_table2 (in=val1)
          w26_formdata        (in=val2);
    by pid;
    if egfr_w26 = . then do;
        if age_cons >= 18 then do;
            if sex=1 then egfr_w26 = (((140-(age_cons+0.5))*weight)/(72*creat))*(1.73/bsa);
            else if sex =2 then egfr_w26 = 0.85*(((140-(age_cons+0.5))*weight)/(72*creat));
        end;
        else if age_cons < 18 then do;
            if sex =2 or (sex =1 and age_cons < 13) then egfr_w26 = (0.55*height)/creat;
            else if (sex=1 and age_cons >= 13) then egfr_w26 = (0.7*height)/creat;
        end;
    end;
    if val1 then output;

proc sort data = font_primary_table2;
    by order_print;

proc print data = font_primary_table2;
    var /*PID*/ rx upc_avg_bsl upc_avg_w26 upc_rdct upc_resp egfr_study egfr_w26 egfr_resp primary pt_fup_rand_yrs;
    format upc_avg_bsl upc_avg_w26 upc_rdct pt_fup_rand_yrs 5.1 egfr_study egfr_w26 5.0;
    title3 "Table 2";

proc freq data = font_primary_2;
    table primary*RX / missing;
    title3 "Table 3";

proc sort data = font_sae;
    by RX;

data font_sae_per_RX;
    set font_sae;
    by RX;
    retain count_SERCRT1 count_SERCRT2 count_SERCRT3 count_SERCRT4 count_SERCRT5 count_SERCRT6 count_SERCRT7 count_SERCRT8 0;
    if first.RX then do;
        count_SERCRT1 = 0;
        count_SERCRT2 = 0;
        count_SERCRT3 = 0;
        count_SERCRT4 = 0;
        count_SERCRT5 = 0;
        count_SERCRT6 = 0;
    end;

```

```

        count_SERCRT7 = 0;
        count_SERCRT8 = 0;
end;

if SERCRT1 = "1" then do;
    count_SERCRT1 = count_SERCRT1 + 1;
end;

if SERCRT2 = "1" then do;
    count_SERCRT2 = count_SERCRT2 + 1;
end;

if SERCRT3 = "1" then do;
    count_SERCRT3 = count_SERCRT3 + 1;
end;

if SERCRT4 = "1" then do;
    count_SERCRT4 = count_SERCRT4 + 1;
end;

if SERCRT5 = "1" then do;
    count_SERCRT5 = count_SERCRT5 + 1;
end;

if SERCRT6 = "1" then do;
    count_SERCRT6 = count_SERCRT6 + 1;
end;

if SERCRT7 = "1" then do;
    count_SERCRT7 = count_SERCRT7 + 1;
end;

if SERCRT8 = "1" then do;
    count_SERCRT8 = count_SERCRT8 + 1;
end;

if last.RX then output font_sae_per_RX;

proc sort data = font_sae;
    by PID;

data font_sae_per_PID;
    set font_sae;
    by PID;
    retain ever_SERCRT1 ever_SERCRT2 ever_SERCRT3 ever_SERCRT4 ever_SERCRT5 ever_SERCRT6 ever_SERCRT7 ever_SERCRT8 0;
    if first.PID then do;
        ever_SERCRT1 = 0;
        ever_SERCRT2 = 0;
        ever_SERCRT3 = 0;

```

```

        ever_SERCRT4 = 0;
        ever_SERCRT5 = 0;
        ever_SERCRT6 = 0;
        ever_SERCRT7 = 0;
        ever_SERCRT8 = 0;
end;

if SERCRT1 = "1" then do;
    ever_SERCRT1 = 1;
end;

if SERCRT2 = "1" then do;
    ever_SERCRT2 = 1;
end;

if SERCRT3 = "1" then do;
    ever_SERCRT3 = 1;
end;

if SERCRT4 = "1" then do;
    ever_SERCRT4 = 1;
end;

if SERCRT5 = "1" then do;
    ever_SERCRT5 = 1;
end;

if SERCRT6 = "1" then do;
    ever_SERCRT6 = 1;
end;

if SERCRT7 = "1" then do;
    ever_SERCRT7 = 1;
end;

if SERCRT8 = "1" then do;
    ever_SERCRT8 = 1;
end;

if last.PID then output font_sae_per_PID;
run;

title3 "Table 4";

proc freq data = font_sae_per_RX;
    table count_SERCRT1*RX
          count_SERCRT2*RX
          count_SERCRT3*RX
          count_SERCRT4*RX

```

```

        count_SERCRT5*RX
        count_SERCRT6*RX
        count_SERCRT7*RX
        count_SERCRT8*RX / list missing;
    title4 "font_sae_per_RX";

proc freq data = font_sae_per_PID;
    table ever_SERCRT1*RX
          ever_SERCRT2*RX
          ever_SERCRT3*RX
          ever_SERCRT4*RX
          ever_SERCRT5*RX
          ever_SERCRT6*RX
          ever_SERCRT7*RX
          ever_SERCRT8*RX / list missing;
    title4 "font_sae_per_PID";

proc sort data = font_ae;
    by PID;

proc sort data = font_primary;
    by PID;

data font_ae_primary;
    merge font_ae      (in = in1)
          font_primary (in = in2 keep = PID);
    by PID;
    if in2 then output font_ae_primary;

run;
title3 "Table 5";

proc freq data = font_ae_primary;
    table category;

proc sort data = font_ae_primary;
    by RX;

data font_ae_primary_per_RX;
    set font_ae_primary;
    by RX;
    retain count_Allergy count_Anorexia count_CV count_Cataract count_Cosmetic count_Cough count_Dehydration count_Dizziness
count_Edema
           count_Fatigue count_GI count_Headache count_Hypotension count_Infection count_Miscellaneous
count_Musculoskeletal count_Nausea
           count_Pain count_Renal count_Respiratory count_Skin count_Vomiting 0;

    if first.RX then do;

```

```

count_Allergy          = 0;
count_Anorexia         = 0;
count_CV               = 0;
count_Cataract        = 0;
count_Cosmetic        = 0;
count_Cough           = 0;
count_Dehydration     = 0;
count_Dizziness       = 0;
count_Edema           = 0;
count_Fatigue         = 0;
count_GI              = 0;
count_Headache        = 0;
count_Hypotension    = 0;
count_Infection       = 0;
count_Miscellaneous   = 0;
count_Musculoskeletal = 0;
count_Nausea          = 0;
count_Pain            = 0;
count_Renal           = 0;
count_Respiratory     = 0;
count_Skin            = 0;
count_Vomiting        = 0;

end;
if category = "Allergy" then count_Allergy = count_Allergy + 1;
else if category = "Anorexia" then count_Anorexia = count_Anorexia + 1;

else if category = "CV"           " then count_CV           = count_CV           + 1;
else if category = "Cataract"    " then count_Cataract    = count_Cataract    + 1;
else if category = "Cosmetic"    " then count_Cosmetic    = count_Cosmetic    + 1;
else if category = "Cough"       " then count_Cough       = count_Cough       + 1;
else if category = "Dehydration" " then count_Dehydration = count_Dehydration + 1;
else if category = "Dizziness"   " then count_Dizziness = count_Dizziness   + 1;
else if category = "Edema"       " then count_Edema       = count_Edema       + 1;
else if category = "Fatigue"     " then count_Fatigue     = count_Fatigue     + 1;
else if category = "GI"          " then count_GI          = count_GI          + 1;
else if category = "Headache"    " then count_Headache    = count_Headache    + 1;
else if category = "Hypotension" " then count_Hypotension = count_Hypotension + 1;
else if category = "Infection"   " then count_Infection   = count_Infection   + 1;
else if category = "Miscellaneous" then count_Miscellaneous = count_Miscellaneous + 1;
else if category = "Musculoskeletal" then count_Musculoskeletal = count_Musculoskeletal + 1;
else if category = "Nausea"      " then count_Nausea      = count_Nausea      + 1;
else if category = "Pain"        " then count_Pain        = count_Pain        + 1;
else if category = "Renal"       " then count_Renal       = count_Renal       + 1;
else if category = "Respiratory" " then count_Respiratory = count_Respiratory + 1;
else if category = "Skin"        " then count_Skin        = count_Skin        + 1;
else if category = "Vomiting"    " then count_Vomiting    = count_Vomiting    + 1;

```

```

if last.RX then output font_ae_primary_per_RX;

proc freq data = font_ae_primary_per_RX;
  table RX*count_Allergy
        RX*count_Anorexia
        RX*count_CV
        RX*count_Cataract
        RX*count_Cosmetic
        RX*count_Cough
        RX*count_Dehydration
        RX*count_Dizziness
        RX*count_Edema
        RX*count_Fatigue
        RX*count_GI
        RX*count_Headache
        RX*count_Hypotension
        RX*count_Infection
        RX*count_Miscellaneous
        RX*count_Musculoskeletal
        RX*count_Nausea
        RX*count_Pain
        RX*count_Renal
        RX*count_Respiratory
        RX*count_Skin
        RX*count_Vomiting

        / list missing;

proc sort data = font_ae_primary;
  by PID;

data font_ae_primary_per_PID;
  set font_ae_primary;
  by PID;
  retain ever_Allergy ever_Anorexia ever_CV ever_Cataract ever_Cosmetic ever_Cough ever_Dehydration ever_Dizziness ever_Edema
        ever_Fatigue ever_GI ever_Headache ever_Hypotension ever_Infection ever_Miscellaneous
ever_Musculoskeletal ever_Nausea
        ever_Pain ever_Renal ever_Respiratory ever_Skin ever_Vomiting 0;

if first.PID then do;
  ever_Allergy          = 0;
  ever_Anorexia         = 0;
  ever_CV               = 0;
  ever_Cataract         = 0;
  ever_Cosmetic         = 0;
  ever_Cough            = 0;
  ever_Dehydration      = 0;

```

```

ever_Dizziness      = 0;
ever_Edema          = 0;
ever_Fatigue        = 0;
ever_GI             = 0;
ever_Headache       = 0;
ever_Hypotension    = 0;
ever_Infection       = 0;
ever_Miscellaneous  = 0;
ever_Musculoskeletal = 0;
ever_Nausea         = 0;
ever_Pain           = 0;
ever_Renal          = 0;
ever_Respiratory    = 0;
ever_Skin           = 0;
ever_Vomiting       = 0;

```

```
end;
```

```

if category = "Allergy" then ever_Allergy = 1;
else if category = "Anorexia" then ever_Anorexia = 1;
else if category = "CV"           " then ever_CV           = 1;
else if category = "Cataract"     " then ever_Cataract     = 1;
else if category = "Cosmetic"     " then ever_Cosmetic     = 1;
else if category = "Cough"        " then ever_Cough        = 1;
else if category = "Dehydration"  " then ever_Dehydration  = 1;
else if category = "Dizziness"    " then ever_Dizziness    = 1;
else if category = "Edema"        " then ever_Edema        = 1;
else if category = "Fatigue"      " then ever_Fatigue      = 1;
else if category = "GI"           " then ever_GI           = 1;
else if category = "Headache"     " then ever_Headache     = 1;
else if category = "Hypotension"  " then ever_Hypotension  = 1;
else if category = "Infection"    " then ever_Infection    = 1;
else if category = "Miscellaneous" then ever_Miscellaneous = 1;
else if category = "Musculoskeletal" then ever_Musculoskeletal = 1;
else if category = "Nausea"       " then ever_Nausea       = 1;
else if category = "Pain"         " then ever_Pain         = 1;
else if category = "Renal"        " then ever_Renal        = 1;
else if category = "Respiratory"  " then ever_Respiratory  = 1;
else if category = "Skin"         " then ever_Skin         = 1;
else if category = "Vomiting"     " then ever_Vomiting     = 1;

```

```
if last.PID then output font_ae_primary_per_PID;
```

```
proc freq data = font_ae_primary_per_PID;
```

```

table ever_Allergy      *RX
ever_Anorexia           *RX
ever_CV                 *RX
ever_Cataract           *RX
ever_Cosmetic           *RX

```

ever_Cough *RX
ever_Dehydration *RX
ever_Dizziness *RX
ever_Edema *RX
ever_Fatigue *RX
ever_GI *RX
ever_Headache *RX
ever_Hypotension *RX
ever_Infection *RX
ever_Miscellaneous *RX
ever_Musculoskeletal *RX
ever_Nausea *RX
ever_Pain *RX
ever_Renal *RX
ever_Respiratory *RX
ever_Skin *RX
ever_Vomiting *RX

/ missing;