

Dataset Integrity Check for the  
Diabetes Control and Complications Trial  
/ Epidemiology of Diabetes Intervention  
and Complications (DCCT/EDIC) CORE5  
Datasets (EDIC Years 19-24)

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August 24, 2021

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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 Diabetes Control and Complications Trial (DCCT) was a multicenter, randomized clinical trial designed to compare intensive with conventional diabetes therapy with regard to their effects on the development and progression of the early vascular and neurologic complications of type 1 insulin-dependent diabetes mellitus. The DCCT study involved 1,441 participants, ages 13 to 39, with type 1 diabetes and either no or minimal background retinopathy. Participants were required to have had diabetes for at least 1 year but no longer than 15 years.

Following DCCT, the Epidemiology of Diabetes Interventions and Complications (EDIC) study was initiated as follow-up to examine the long-term effects of the original DCCT interventions on diabetic complications such as cardiovascular events and advanced retinal and renal disease. Over 90 percent of participants from the DCCT study were followed by the EDIC study. Similar to the DCCT study, glycosylated hemoglobin values, fasting lipid levels, serum creatinine values, and other risk factors for cardiovascular disease were measured at different intervals for participants. Cardiovascular complications were assessed with standardized means and classified by an independent committee. The EDIC study has found that intensive diabetes therapy reduced risk of cardiovascular disease in patients with type 1 diabetes and that the differences in outcomes between the intensive and conventional therapy groups persist after long-term study.

## 3 Archived Datasets

All SAS data files, as provided by the Data Coordinating Center (DCC), are located in the DCCT/EDIC folder in the data package. For this replication, variables were taken from the “f0602\_2.sas7bdat”, and “cbl\_rep.sas7bdat” datasets.

## **4 Statistical Methods**

Analyses were performed to replicate statistics files provided by the DCC for DCCT/EDIC. To verify the integrity of the datasets, descriptive statistics were computed.

## **5 Results**

The replication of the descriptive statistics to the statistics files were an exact match.

## **6 Conclusions**

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

**Table A:** Variables used to replicate Statistics files: F0602\_2 and CBL\_REP

<b>STATS File Variable</b>	<b>dataset.variable</b>
<b>STATS.F0602_2.pdf</b>	
edicyear	f0602_2.edicyear
FOA1	f0602_2.foa1
FOA10	f0602_2.foa10
FOA11	f0602_2.foa11
FOA12	f0602_2.foa12
FOA13	f0602_2.foa13
FOA14	f0602_2.foa14
FOA15	f0602_2.foa15
FOA16	f0602_2.foa16
FOA17	f0602_2.foa17
FOA18	f0602_2.foa18
FOA19	f0602_2.foa19
FOA2	f0602_2.foa2
FOA3	f0602_2.foa3
FOA4	f0602_2.foa4
FOA5	f0602_2.foa5
FOA6	f0602_2.foa6
FOA7	f0602_2.foa7
FOA8	f0602_2.foa8
FOA9	f0602_2.foa9
FOB1	f0602_2.fob1
FOB10	f0602_2.fob10
FOB11	f0602_2.fob11
FOB12	f0602_2.fob12
FOB13	f0602_2.fob13
FOB14	f0602_2.fob14
FOB15	f0602_2.fob15
FOB16	f0602_2.fob16
FOB17	f0602_2.fob17
FOB18	f0602_2.fob18
FOB19	f0602_2.fob19
FOB2	f0602_2.fob2
FOB20	f0602_2.fob20
FOB21	f0602_2.fob21
FOB22	f0602_2.fob22
FOB23	f0602_2.fob23
FOB24	f0602_2.fob24
FOB25	f0602_2.fob25
FOB26	f0602_2.fob26
FOB27	f0602_2.fob27
FOB3	f0602_2.fob3
FOB4	f0602_2.fob4
FOB5	f0602_2.fob5

FOB6	f0602_2.fob6
FOB7	f0602_2.fob7
FOB8	f0602_2.fob8
FOB9	f0602_2.fob9
FOC1	f0602_2.foc1
FOC10	f0602_2.foc10
FOC11	f0602_2.foc11
FOC12	f0602_2.foc12
FOC13	f0602_2.foc13
FOC14	f0602_2.foc14
FOC2	f0602_2.foc2
FOC3	f0602_2.foc3
FOC4	f0602_2.foc4
FOC5	f0602_2.foc5
FOC6	f0602_2.foc6
FOC7	f0602_2.foc7
FOC8	f0602_2.foc8
FOC9	f0602_2.foc9
<b>STATS.CBL_REP</b>	
LIPID-TOTAL CHOLESTEROL (MG/DL)	cbl_rep.abval21
LIPID-TRIGLYCERIDE (MG/DL)	cbl_rep.abval22
LIPID-HDL CHOLESTEROL (MG/DL)	cbl_rep.abval23
LIPID-LDL CHOLESTEROL (MG/DL)	cbl_rep.abval24
LIPID-SERUM CREATININE (MD/DL)	cbl_rep.abval3
RANDOM ACR	cbl_rep.acr
HR REN-SERUM CREATININE (MG/DL)	cbl_rep.baval13
HR REN-URINE ALBUMIN (MG/L)	cbl_rep.baval14
HR REN-ALBUMIN EXCRETION (UG/MIN)	cbl_rep.baval15
HR REN-URINE CREATININE (MG/DL)	cbl_rep.baval16
HR REN-HEIGHT (CM)	cbl_rep.baval17
HR REN-WEIGHT (KG)	cbl_rep.baval18
HR REN-RAW CLEARANCE (ML/MIN)	cbl_rep.baval19
HR REN-STANDARD CLEARANCE	cbl_rep.baval20a
HR REN-DURATION (HOURS)	cbl_rep.baval20b
HR REN-VOLUME (ML)	cbl_rep.baval20c
SERUM CYSTATIC-C	cbl_rep.cystatin
HBA1C RESULTS (%)	cbl_rep.doresult
EDIC FOLLOW-UP YEAR	cbl_rep.edicyear
HBA1C IN SI UNITS (MMOL/MOL)	cbl_rep.hba1c_si
RANDOM RENAL SERUM CREATININE	cbl_rep.randmscr
RANDOM URINE ALBUMIN	cbl_rep.randomal
RANDOM URINE CREATININE	cbl_rep.randomcr
SERUM CREATININE	cbl_rep.serumcr

**Table B1:** Comparison of Statistics file “STATS.F0602\_2” to the “f0602\_2” dataset

Variable	STATS.F0602_2 File (n=3054)	DSIC (n= 3054)	Diff. (n=0)
EDICYEAR n (%)			
19	559 (18.3)	559 (18.3)	0 (0)
20	126 (4.1)	126 (4.1)	0 (0)
21	1132 (37.1)	1132 (37.1)	0 (0)
22	72 (2.4)	72 (2.4)	0 (0)
23	1112 (36.4)	1112 (36.4)	0 (0)
24	53 (1.7)	53 (1.7)	0 (0)
FOA1 n (%)			
1	1009 (33.1)	1009 (33.1)	0 (0)
2	1387 (45.6)	1387 (45.6)	0 (0)
3	387 (12.7)	387 (12.7)	0 (0)
4	234 (7.7)	234 (7.7)	0 (0)
5	28 (0.9)	28 (0.9)	0 (0)
FOA10 n (%)			
1	630 (20.8)	630 (20.8)	0 (0)
2	942 (31.1)	942 (31.1)	0 (0)
3	682 (22.5)	682 (22.5)	0 (0)
4	472 (15.6)	472 (15.6)	0 (0)
5	304 (10.0)	304 (10.0)	0 (0)
FOA11 n (%)			
1	898 (29.6)	898 (29.6)	0 (0)
2	1432 (47.1)	1432 (47.1)	0 (0)
3	370 (12.2)	370 (12.2)	0 (0)
4	274 (9.0)	274 (9.0)	0 (0)
5	64 (2.1)	64 (2.1)	0 (0)
FOA12 n (%)			
1	353 (11.6)	353 (11.6)	0 (0)
2	1288 (42.3)	1288 (42.3)	0 (0)
3	460 (15.1)	460 (15.1)	0 (0)
4	744 (24.4)	744 (24.4)	0 (0)
5	198 (6.5)	198 (6.5)	0 (0)
FOA13 n (%)			
1	337 (11.1)	337 (11.1)	0 (0)
2	905 (29.7)	905 (29.7)	0 (0)
3	582 (19.1)	582 (19.1)	0 (0)
4	920 (30.2)	920 (30.2)	0 (0)
5	299 (9.8)	299 (9.8)	0 (0)
FOA14 n (%)			
1	731 (24.0)	731 (24.0)	0 (0)
2	1435 (47.2)	1435 (47.2)	0 (0)
3	464 (15.3)	464 (15.3)	0 (0)
4	348 (11.4)	348 (11.4)	0 (0)
5	62 (2.0)	62 (2.0)	0 (0)

Variable	STATS.F0602_2 File (n=3054)	DSIC (n= 3054)	Diff. (n=0)
FOA15 n (%)			
1	1053 (34.7)	1053 (34.7)	0 (0)
2	1488 (49.0)	1488 (49.0)	0 (0)
3	255 (8.4)	255 (8.4)	0 (0)
4	191 (6.3)	191 (6.3)	0 (0)
5	49 (1.6)	49 (1.6)	0 (0)
FOA16 n (%)			
1	21 (41.2)	21 (41.2)	0 (0)
2	15 (29.4)	15 (29.4)	0 (0)
3	12 (23.5)	12 (23.5)	0 (0)
5	3 (5.9)	3 (5.9)	0 (0)
FOA17 n (%)			
1	12 (28.6)	12 (28.6)	0 (0)
2	10 (23.8)	10 (23.8)	0 (0)
3	19 (45.2)	19 (45.2)	0 (0)
5	1 (2.4)	1 (2.4)	0 (0)
FOA18 n (%)			
1	15 (35.7)	15 (35.7)	0 (0)
2	11 (26.2)	11 (26.2)	0 (0)
3	15 (35.7)	15 (35.7)	0 (0)
5	1 (2.4)	1 (2.4)	0 (0)
FOA19 n (%)			
1	560 (18.6)	560 (18.6)	0 (0)
2	1717 (57.0)	1717 (57.0)	0 (0)
3	601 (19.9)	601 (19.9)	0 (0)
4	135 (4.5)	135 (4.5)	0 (0)
FOA2 n (%)			
1	1203 (39.5)	1203 (39.5)	0 (0)
2	1252 (41.1)	1252 (41.1)	0 (0)
3	414 (13.6)	414 (13.6)	0 (0)
4	159 (5.2)	159 (5.2)	0 (0)
5	19 (0.6)	19 (0.6)	0 (0)
FOA3 n (%)			
1	1576 (51.8)	1576 (51.8)	0 (0)
2	1090 (35.8)	1090 (35.8)	0 (0)
3	249 (8.2)	249 (8.2)	0 (0)
4	107 (3.5)	107 (3.5)	0 (0)
5	20 (0.7)	20 (0.7)	0 (0)
FOA4 n (%)			
1	1437 (47.2)	1437 (47.2)	0 (0)
2	1241 (40.7)	1241 (40.7)	0 (0)
3	206 (6.8)	206 (6.8)	0 (0)
4	129 (4.2)	129 (4.2)	0 (0)
5	34 (1.1)	34 (1.1)	0 (0)



Variable	STATS.F0602_2 File (n=3054)	DSIC (n= 3054)	Diff. (n=0)
FOA5 n (%)			
1	1435 (47.2)	1435 (47.2)	0 (0)
2	1235 (40.7)	1235 (40.7)	0 (0)
3	220 (7.2)	220 (7.2)	0 (0)
4	118 (3.9)	118 (3.9)	0 (0)
5	30 (1.0)	30 (1.0)	0 (0)
FOA6 n (%)			
1	796 (26.2)	796 (26.2)	0 (0)
2	948 (31.2)	948 (31.2)	0 (0)
3	840 (27.6)	840 (27.6)	0 (0)
4	376 (12.4)	376 (12.4)	0 (0)
5	83 (2.7)	83 (2.7)	0 (0)
FOA7 n (%)			
1	1607 (52.8)	1607 (52.8)	0 (0)
2	1274 (41.8)	1274 (41.8)	0 (0)
3	104 (3.4)	104 (3.4)	0 (0)
4	46 (1.5)	46 (1.5)	0 (0)
5	14 (0.5)	14 (0.5)	0 (0)
FOA8 n (%)			
1	606 (19.9)	606 (19.9)	0 (0)
2	1263 (41.5)	1263 (41.5)	0 (0)
3	267 (8.8)	267 (8.8)	0 (0)
4	705 (23.2)	705 (23.2)	0 (0)
5	203 (6.7)	203 (6.7)	0 (0)
FOA9 n (%)			
1	1313 (43.2)	1313 (43.2)	0 (0)
2	1174 (38.6)	1174 (38.6)	0 (0)
3	289 (9.5)	289 (9.5)	0 (0)
4	207 (6.8)	207 (6.8)	0 (0)
5	58 (1.9)	58 (1.9)	0 (0)
FOB1 n (%)			
1	603 (19.8)	603 (19.8)	0 (0)
2	1762 (57.9)	1762 (57.9)	0 (0)
3	599 (19.7)	599 (19.7)	0 (0)
4	71 (2.3)	71 (2.3)	0 (0)
5	8 (0.3)	8 (0.3)	0 (0)
FOB10 n (%)			
1	1140 (37.6)	1140 (37.6)	0 (0)
2	1025 (33.9)	1025 (33.9)	0 (0)
3	482 (15.9)	482 (15.9)	0 (0)
4	225 (7.4)	225 (7.4)	0 (0)
5	156 (5.2)	156 (5.2)	0 (0)

Variable	STATS.F0602_2 File (n=3054)	DSIC (n= 3054)	Diff. (n=0)
FOB11 n (%)			
1	1707 (56.1)	1707 (56.1)	0 (0)
2	1088 (35.7)	1088 (35.7)	0 (0)
3	175 (5.7)	175 (5.7)	0 (0)
4	43 (1.4)	43 (1.4)	0 (0)
5	32 (1.1)	32 (1.1)	0 (0)
FOB12 n (%)			
1	977 (32.2)	977 (32.2)	0 (0)
2	1361 (44.9)	1361 (44.9)	0 (0)
3	592 (19.5)	592 (19.5)	0 (0)
4	87 (2.9)	87 (2.9)	0 (0)
5	16 (0.5)	16 (0.5)	0 (0)
FOB13 n (%)			
1	1695 (55.8)	1695 (55.8)	0 (0)
2	1061 (34.9)	1061 (34.9)	0 (0)
3	235 (7.7)	235 (7.7)	0 (0)
4	37 (1.2)	37 (1.2)	0 (0)
5	10 (0.3)	10 (0.3)	0 (0)
FOB14 n (%)			
1	344 (11.3)	344 (11.3)	0 (0)
2	1216 (40.0)	1216 (40.0)	0 (0)
3	1166 (38.3)	1166 (38.3)	0 (0)
4	286 (9.4)	286 (9.4)	0 (0)
5	30 (1.0)	30 (1.0)	0 (0)
FOB15 n (%)			
1	1037 (34.1)	1037 (34.1)	0 (0)
2	1488 (49.0)	1488 (49.0)	0 (0)
3	454 (14.9)	454 (14.9)	0 (0)
4	47 (1.5)	47 (1.5)	0 (0)
5	13 (0.4)	13 (0.4)	0 (0)
FOB16 n (%)			
1	131 (4.3)	131 (4.3)	0 (0)
2	828 (27.4)	828 (27.4)	0 (0)
3	1278 (42.2)	1278 (42.2)	0 (0)
4	616 (20.4)	616 (20.4)	0 (0)
5	173 (5.7)	173 (5.7)	0 (0)
FOB17 n (%)			
1	2689 (88.8)	2689 (88.8)	0 (0)
2	259 (8.6)	259 (8.6)	0 (0)
3	61 (2.0)	61 (2.0)	0 (0)
4	10 (0.3)	10 (0.3)	0 (0)
5	9 (0.3)	9 (0.3)	0 (0)

Variable	STATS.F0602_2 File (n=3054)	DSIC (n= 3054)	Diff. (n=0)
FOB18 n (%)			
1	1166 (38.3)	1166 (38.3)	0 (0)
2	918 (30.2)	918 (30.2)	0 (0)
3	652 (21.4)	652 (21.4)	0 (0)
4	249 (8.2)	249 (8.2)	0 (0)
5	59 (1.9)	59 (1.9)	0 (0)
FOB19 n (%)			
1	1822 (60.0)	1822 (60.0)	0 (0)
2	861 (28.4)	861 (28.4)	0 (0)
3	296 (9.7)	296 (9.7)	0 (0)
4	53 (1.7)	53 (1.7)	0 (0)
5	5 (0.2)	5 (0.2)	0 (0)
FOB2 n (%)			
1	1627 (53.4)	1627 (53.4)	0 (0)
2	1079 (35.4)	1079 (35.4)	0 (0)
3	310 (10.2)	310 (10.2)	0 (0)
4	21 (0.7)	21 (0.7)	0 (0)
5	7 (0.2)	7 (0.2)	0 (0)
FOB20 n (%)			
1	1185 (39.0)	1185 (39.0)	0 (0)
2	991 (32.6)	991 (32.6)	0 (0)
3	697 (22.9)	697 (22.9)	0 (0)
4	143 (4.7)	143 (4.7)	0 (0)
5	24 (0.8)	24 (0.8)	0 (0)
FOB21 n (%)			
1	56 (76.7)	56 (76.7)	0 (0)
2	12 (16.4)	12 (16.4)	0 (0)
3	3 (4.1)	3 (4.1)	0 (0)
4	1 (1.4)	1 (1.4)	0 (0)
5	1 (1.4)	1 (1.4)	0 (0)
FOB22 n (%)			
1	48 (76.2)	48 (76.2)	0 (0)
2	11 (17.5)	11 (17.5)	0 (0)
3	2 (3.2)	2 (3.2)	0 (0)
4	1 (1.6)	1 (1.6)	0 (0)
5	1 (1.6)	1 (1.6)	0 (0)
FOB23 n (%)			
1	41 (66.1)	41 (66.1)	0 (0)
2	12 (19.4)	12 (19.4)	0 (0)
3	7 (11.3)	7 (11.3)	0 (0)
4	1 (1.6)	1 (1.6)	0 (0)
5	1 (1.6)	1 (1.6)	0 (0)

Variable	STATS.F0602_2 File (n=3054)	DSIC (n= 3054)	Diff. (n=0)
FOB24 n (%)			
1	21 (44.7)	21 (44.7)	0 (0)
2	10 (21.3)	10 (21.3)	0 (0)
3	8 (17.0)	8 (17.0)	0 (0)
4	4 (8.5)	4 (8.5)	0 (0)
5	4 (8.5)	4 (8.5)	0 (0)
FOB25 n (%)			
1	19 (40.4)	19 (40.4)	0 (0)
2	7 (14.9)	7 (14.9)	0 (0)
3	11 (23.4)	11 (23.4)	0 (0)
4	6 (12.8)	6 (12.8)	0 (0)
5	4 (8.5)	4 (8.5)	0 (0)
FOB26 n (%)			
1	37 (77.1)	37 (77.1)	0 (0)
2	5 (10.4)	5 (10.4)	0 (0)
3	4 (8.3)	4 (8.3)	0 (0)
4	2 (4.2)	2 (4.2)	0 (0)
FOB27 n (%)			
1	31 (64.6)	31 (64.6)	0 (0)
2	6 (12.5)	6 (12.5)	0 (0)
3	5 (10.4)	5 (10.4)	0 (0)
4	2 (4.2)	2 (4.2)	0 (0)
5	4 (8.3)	4 (8.3)	0 (0)
FOB3 n (%)			
1	23 (0.8)	23 (0.8)	0 (0)
2	734 (24.2)	734 (24.2)	0 (0)
3	1961 (64.6)	1961 (64.6)	0 (0)
4	310 (10.2)	310 (10.2)	0 (0)
5	8 (0.3)	8 (0.3)	0 (0)
FOB4 n (%)			
1	447 (14.7)	447 (14.7)	0 (0)
2	1936 (63.7)	1936 (63.7)	0 (0)
3	531 (17.5)	531 (17.5)	0 (0)
4	108 (3.6)	108 (3.6)	0 (0)
5	15 (0.5)	15 (0.5)	0 (0)
FOB5 n (%)			
1	1104 (36.3)	1104 (36.3)	0 (0)
2	1423 (46.8)	1423 (46.8)	0 (0)
3	432 (14.2)	432 (14.2)	0 (0)
4	71 (2.3)	71 (2.3)	0 (0)
5	11 (0.4)	11 (0.4)	0 (0)
FOB6 n (%)			
1	258 (8.5)	258 (8.5)	0 (0)
2	1119 (36.9)	1119 (36.9)	0 (0)
3	993 (32.7)	993 (32.7)	0 (0)
4	549 (18.1)	549 (18.1)	0 (0)
5	117 (3.9)	117 (3.9)	0 (0)

Variable	STATS.F0602_2 File (n=3054)	DSIC (n= 3054)	Diff. (n=0)
FOB7 n (%)			
1	1956 (64.3)	1956 (64.3)	0 (0)
2	838 (27.6)	838 (27.6)	0 (0)
3	183 (6.0)	183 (6.0)	0 (0)
4	52 (1.7)	52 (1.7)	0 (0)
5	12 (0.4)	12 (0.4)	0 (0)
FOB8 n (%)			
1	58 (1.9)	58 (1.9)	0 (0)
2	227 (7.5)	227 (7.5)	0 (0)
3	730 (24.0)	730 (24.0)	0 (0)
4	1592 (52.4)	1592 (52.4)	0 (0)
5	432 (14.2)	432 (14.2)	0 (0)
FOB9 n (%)			
1	622 (20.5)	622 (20.5)	0 (0)
2	1287 (42.5)	1287 (42.5)	0 (0)
3	878 (29.0)	878 (29.0)	0 (0)
4	183 (6.0)	183 (6.0)	0 (0)
5	58 (1.9)	58 (1.9)	0 (0)
FOC1 n (%)			
0	2406 (79.9)	2406 (79.9)	0 (0)
1	406 (13.5)	406 (13.5)	0 (0)
2	91 (3.0)	91 (3.0)	0 (0)
3	78 (2.6)	78 (2.6)	0 (0)
4	20 (0.7)	20 (0.7)	0 (0)
5	11 (0.4)	11 (0.4)	0 (0)
FOC10 n (%)			
0	32 (1.1)	32 (1.1)	0 (0)
1	220 (7.3)	220 (7.3)	0 (0)
2	856 (28.4)	856 (28.4)	0 (0)
3	1351 (44.9)	1351 (44.9)	0 (0)
4	428 (14.2)	428 (14.2)	0 (0)
5	125 (4.2)	125 (4.2)	0 (0)
FOC11 n (%)			
0	1971 (65.8)	1971 (65.8)	0 (0)
1	797 (26.6)	797 (26.6)	0 (0)
2	138 (4.6)	138 (4.6)	0 (0)
3	68 (2.3)	68 (2.3)	0 (0)
4	13 (0.4)	13 (0.4)	0 (0)
5	8 (0.3)	8 (0.3)	0 (0)
FOC12 n (%)			
0	23 (39.7)	23 (39.7)	0 (0)
1	27 (46.6)	27 (46.6)	0 (0)
2	6 (10.3)	6 (10.3)	0 (0)
3	1 (1.7)	1 (1.7)	0 (0)
5	1 (1.7)	1 (1.7)	0 (0)

Variable	STATS.F0602_2 File (n=3054)	DSIC (n= 3054)	Diff. (n=0)
FOC13 n (%)			
0	23 (41.1)	23 (41.1)	0 (0)
1	26 (46.4)	26 (46.4)	0 (0)
2	3 (5.4)	3 (5.4)	0 (0)
3	3 (5.4)	3 (5.4)	0 (0)
5	1 (1.8)	1 (1.8)	0 (0)
FOC14 n (%)			
0	28 (51.9)	28 (51.9)	0 (0)
1	20 (37.0)	20 (37.0)	0 (0)
2	3 (5.6)	3 (5.6)	0 (0)
3	3 (5.6)	3 (5.6)	0 (0)
FOC2 n (%)			
0	2563 (85.2)	2563 (85.2)	0 (0)
1	376 (12.5)	376 (12.5)	0 (0)
2	35 (1.2)	35 (1.2)	0 (0)
3	22 (0.7)	22 (0.7)	0 (0)
4	8 (0.3)	8 (0.3)	0 (0)
5	4 (0.1)	4 (0.1)	0 (0)
FOC3 n (%)			
0	1612 (53.6)	1612 (53.6)	0 (0)
1	719 (23.9)	719 (23.9)	0 (0)
2	309 (10.3)	309 (10.3)	0 (0)
3	248 (8.3)	248 (8.3)	0 (0)
4	91 (3.0)	91 (3.0)	0 (0)
5	26 (0.9)	26 (0.9)	0 (0)
FOC4 n (%)			
0	149 (5.0)	149 (5.0)	0 (0)
1	1538 (51.2)	1538 (51.2)	0 (0)
2	1011 (33.7)	1011 (33.7)	0 (0)
3	269 (9.0)	269 (9.0)	0 (0)
4	30 (1.0)	30 (1.0)	0 (0)
5	7 (0.2)	7 (0.2)	0 (0)
FOC5 n (%)			
0	460 (15.3)	460 (15.3)	0 (0)
1	928 (30.9)	928 (30.9)	0 (0)
2	652 (21.7)	652 (21.7)	0 (0)
3	624 (20.8)	624 (20.8)	0 (0)
4	225 (7.5)	225 (7.5)	0 (0)
5	116 (3.9)	116 (3.9)	0 (0)
FOC6 n (%)			
0	2368 (78.7)	2368 (78.7)	0 (0)
1	513 (17.0)	513 (17.0)	0 (0)
2	78 (2.6)	78 (2.6)	0 (0)
3	32 (1.1)	32 (1.1)	0 (0)
4	11 (0.4)	11 (0.4)	0 (0)
5	8 (0.3)	8 (0.3)	0 (0)

Variable	STATS.F0602_2 File (n=3054)	DSIC (n= 3054)	Diff. (n=0)
FOC7 n (%)			
0	720 (23.9)	720 (23.9)	0 (0)
1	1408 (46.8)	1408 (46.8)	0 (0)
2	670 (22.3)	670 (22.3)	0 (0)
3	184 (6.1)	184 (6.1)	0 (0)
4	24 (0.8)	24 (0.8)	0 (0)
5	4 (0.1)	4 (0.1)	0 (0)
FOC8 n (%)			
0	118 (3.9)	118 (3.9)	0 (0)
1	1865 (61.8)	1865 (61.8)	0 (0)
2	682 (22.6)	682 (22.6)	0 (0)
3	281 (9.3)	281 (9.3)	0 (0)
4	62 (2.1)	62 (2.1)	0 (0)
5	9 (0.3)	9 (0.3)	0 (0)
FOC9 n (%)			
0	79 (2.6)	79 (2.6)	0 (0)
1	2026 (67.2)	2026 (67.2)	0 (0)
2	555 (18.4)	555 (18.4)	0 (0)
3	287 (9.5)	287 (9.5)	0 (0)
4	43 (1.4)	43 (1.4)	0 (0)
5	23 (0.8)	23 (0.8)	0 (0)

**Table B2:** Comparison of Statistics file “STATS.CBL\_REP” to the “cbl\_rep” dataset

Variable	STATS.CBL_REP File (n=5673)	DSIC (n= 5673)	Diff. (n=0)
Lipid-total Cholesterol (mg/dL)			
Mean	174	174	0 (0)
Std	35	35	0 (0)
Min	82	82	0 (0)
25 <sup>th</sup> pct	150	150	0 (0)
Median	171	171	0 (0)
75 <sup>th</sup> pct	194	194	0 (0)
Max	383	383	0 (0)
Lipid-Triglyceride (mg/dL)			
Mean	76	76	0 (0)
Std	55	55	0 (0)
Min	11	11	0 (0)
25 <sup>th</sup> pct	46	46	0 (0)
Median	62	62	0 (0)
75 <sup>th</sup> pct	88	88	0 (0)
Max	885	885	0 (0)
Lipid-HDL Cholesterol (mg/dL)			
Mean	63	63	0 (0)
Std	20	20	0 (0)
Min	18	18	0 (0)
25 <sup>th</sup> pct	48	48	0 (0)
Median	60	60	0 (0)
75 <sup>th</sup> pct	74	74	0 (0)
Max	157	157	0 (0)
Lipid-LDL Cholesterol (mg/dL)			
Mean	96	96	0 (0)
Std	29	29	0 (0)
Min	28	28	0 (0)
25 <sup>th</sup> pct	75	75	0 (0)
Median	91	91	0 (0)
75 <sup>th</sup> pct	111	111	0 (0)
Max	264	264	0 (0)
Lipid-Serum Creatinine (mg/dL)			
Mean	0.89	0.89	0 (0)
Std	0.45	0.45	0 (0)
Min	0.45	0.45	0 (0)
25 <sup>th</sup> pct	0.72	0.72	0 (0)
Median	0.83	0.83	0 (0)
75 <sup>th</sup> pct	0.96	0.96	0 (0)
Max	9.95	9.95	0 (0)



Variable	STATS.CBL_REP File (n=5673)	DSIC (n= 5673)	Diff. (n=0)
Random ACR			
Mean	59.17	59.17	0 (0)
Std	315.64	315.64	0 (0)
Min	-20.0	-20.0	0 (0)
25 <sup>th</sup> pct	2.20	2.20	0 (0)
Median	4.50	4.50	0 (0)
75 <sup>th</sup> pct	12.50	12.50	0 (0)
Max	6060.0	6060.0	0 (0)
HR Ren-Serum Creatinine (mg/dL)			
Mean	0.88	0.88	0 (0)
Std	0.22	0.22	0 (0)
Min	0.58	0.58	0 (0)
25 <sup>th</sup> pct	0.68	0.68	0 (0)
Median	0.87	0.87	0 (0)
75 <sup>th</sup> pct	0.98	0.98	0 (0)
Max	1.64	1.64	0 (0)
HR Ren-Urine Albumin (mg/L)			
Mean	29	29	0 (0)
Std	154	154	0 (0)
Min	1	1	0 (0)
25 <sup>th</sup> pct	1	1	0 (0)
Median	3	3	0 (0)
75 <sup>th</sup> pct	5	5	0 (0)
Max	1113	1113	0 (0)
HR Ren-Albumin Excretion (ug/min)			
Mean	103	103	0 (0)
Std	507	507	0 (0)
Min	4	4	0 (0)
25 <sup>th</sup> pct	6	6	0 (0)
Median	7	7	0 (0)
75 <sup>th</sup> pct	16	16	0 (0)
Max	3633	3633	0 (0)
HR Ren-Urine Creatinine (mg/dL)			
Mean	26	26	0 (0)
Std	17	17	0 (0)
Min	8	8	0 (0)
25 <sup>th</sup> pct	14	14	0 (0)
Median	21	21	0 (0)
75 <sup>th</sup> pct	32	32	0 (0)
Max	79	79	0 (0)

Variable		STATS.CBL_REP File (n=5673)	DSIC (n= 5673)	Diff. (n=0)
HR Ren-Height (cm)	Mean	172	172	0 (0)
	Std	30	30	0 (0)
	Min	58	58	0 (0)
	25 <sup>th</sup> pct	164	164	0 (0)
	Median	171	171	0 (0)
	75 <sup>th</sup> pct	178	178	0 (0)
	Max	1730	1730	0 (0)
	HR Ren-Weight (kg)	Mean	85.6	85.6
Std		25.0	25.0	0 (0)
Min		8.7	8.7	0 (0)
25 <sup>th</sup> pct		71.7	71.7	0 (0)
Median		83.7	83.7	0 (0)
75 <sup>th</sup> pct		96.6	96.6	0 (0)
Max		914.1	914.1	0 (0)
HR Ren-Raw Clearance (mL/min)		Mean	118.3	118.3
	Std	35.9	35.9	0 (0)
	Min	32.8	32.8	0 (0)
	25 <sup>th</sup> pct	96.5	96.5	0 (0)
	Median	115.0	115.0	0 (0)
	75 <sup>th</sup> pct	134.9	134.9	0 (0)
	Max	226.1	226.1	0 (0)
	HR Ren-Standard Clearance	Mean	102.7	102.7
Std		28.7	28.7	0 (0)
Min		35.3	35.3	0 (0)
25 <sup>th</sup> pct		87.0	87.0	0 (0)
Median		103.2	103.2	0 (0)
75 <sup>th</sup> pct		117.9	117.9	0 (0)
Max		181.2	181.2	0 (0)
HR Ren-Duration (hours)		Mean	4.0	4.0
	Std	0.5	0.5	0 (0)
	Min	2.2	2.2	0 (0)
	25 <sup>th</sup> pct	4.0	4.0	0 (0)
	Median	4.0	4.0	0 (0)
	75 <sup>th</sup> pct	4.1	4.1	0 (0)
	Max	5.3	5.3	0 (0)

Variable	STATS.CBL_REP File (n=5673)	DSIC (n= 5673)	Diff. (n=0)
HR Ren-Volume (mL)			
Mean	1141	1141	0 (0)
Std	479	479	0 (0)
Min	400	400	0 (0)
25 <sup>th</sup> pct	814	814	0 (0)
Median	1150	1150	0 (0)
75 <sup>th</sup> pct	1442	1442	0 (0)
Max	2146	2146	0 (0)
Serum Cystatin-C			
Mean	0.81	0.81	0 (0)
Std	0.21	0.21	0 (0)
Min	0.55	0.55	0 (0)
25 <sup>th</sup> pct	0.69	0.69	0 (0)
Median	0.77	0.77	0 (0)
75 <sup>th</sup> pct	0.86	0.86	0 (0)
Max	2.19	2.19	0 (0)
HBA1C Results (%)			
Mean	8.0	8.0	0 (0)
Std	1.2	1.2	0 (0)
Min	3.9	3.9	0 (0)
25 <sup>th</sup> pct	7.2	7.2	0 (0)
Median	7.8	7.8	0 (0)
75 <sup>th</sup> pct	8.6	8.6	0 (0)
Max	17.1	17.1	0 (0)
EDIC Follow-up Year n (%)			
19	589 (10.5)	589 (10.5)	0 (0)
20	1161 (20.5)	1161 (20.5)	0 (0)
21	1148 (20.2)	1148 (20.2)	0 (0)
22	1147 (20.2)	1147 (20.2)	0 (0)
23	1122 (19.8)	1122 (19.8)	0 (0)
24	506 (8.9)	506 (8.9)	0 (0)
HBA1C in SI Units (mmol/mol)			
Mean	63.4	63.4	0 (0)
Std	12.9	12.9	0 (0)
Min	19.1	19.1	0 (0)
25 <sup>th</sup> pct	55.2	55.2	0 (0)
Median	61.7	61.7	0 (0)
75 <sup>th</sup> pct	70.5	70.5	0 (0)
Max	163.4	163.4	0 (0)
Random Renal Serum Creatinine			
Mean	0.89	0.89	0 (0)
Std	0.43	0.43	0 (0)
Min	0.46	0.46	0 (0)
25 <sup>th</sup> pct	0.72	0.72	0 (0)
Median	0.82	0.82	0 (0)
75 <sup>th</sup> pct	0.95	0.95	0 (0)
Max	9.53	9.53	0 (0)

<b>Variable</b>	<b>STATS.CBL_REP File (n=5673)</b>	<b>DSIC (n= 5673)</b>	<b>Diff. (n=0)</b>
Random Urine Albumin			
Mean	41	41	0 (0)
Std	185	185	0 (0)
Min	-1	-1	0 (0)
25 <sup>th</sup> pct	1	1	0 (0)
Median	3	3	0 (0)
75 <sup>th</sup> pct	11	11	0 (0)
Max	2734	2734	0 (0)
Random Urine Creatinine			
Mean	94	94	0 (0)
Std	64	64	0 (0)
Min	5	5	0 (0)
25 <sup>th</sup> pct	44	44	0 (0)
Median	81	81	0 (0)
75 <sup>th</sup> pct	130	130	0 (0)
Max	508	508	0 (0)
Serum Creatinine			
Mean	0.89	0.89	0 (0)
Std	0.44	0.44	0 (0)
Min	0.45	0.45	0 (0)
25 <sup>th</sup> pct	0.72	0.72	0 (0)
Median	0.82	0.82	0 (0)
75 <sup>th</sup> pct	0.96	0.96	0 (0)
Max	9.95	9.95	0 (0)

## Attachment A: SAS Code

```
libname dsic "X:\NIDDK\niddk-dr_studies1\DCCT_EDIC\private_created_data\EDIC_Data_Through-2017";

*****;
* DSIC of CORE5 Datasets using STATS Files ;
*****;

*****;
*Calling Datasets ;
*****;
data life; set dsic.f0602_2;
run;

data labs; set dsic.cbl_rep;
run;

proc contents data=life;
run;

proc contents data=labs;
run;

*****;
*Replicating Quality of Life Questionnaire: F0602_2*;
*****;

*edicyear;
proc freq data=life;
tables edicyear;
run;

*FOA1;
proc freq data=life;
tables foa1;
run;

*FOA10;
proc freq data=life;
tables foa10;
run;

*FOA11;
proc freq data=life;
tables foa11;
run;

*FOA12;
proc freq data=life;
tables foa12;
run;

*FOA13;
proc freq data=life;
tables foa13;
run;

*FOA14;
proc freq data=life;
tables foa14;
run;

*FOA15;
proc freq data=life;
tables foa15;
run;

*FOA16;
proc freq data=life;
tables foa16;
```

```
run;

*FOA17;
proc freq data=life;
tables foa17;
run;

*FOA18;
proc freq data=life;
tables foa18;
run;

*FOA19;
proc freq data=life;
tables foa19;
run;

*FOA2;
proc freq data=life;
tables foa2;
run;

*FOA3;
proc freq data=life;
tables foa3;
run;

*FOA4;
proc freq data=life;
tables foa4;
run;

*FOA5;
proc freq data=life;
tables foa5;
run;

*FOA6;
proc freq data=life;
tables foa6;
run;

*FOA7;
proc freq data=life;
tables foa7;
run;

*FOA8;
proc freq data=life;
tables foa8;
run;

*FOA9;
proc freq data=life;
tables foa9;
run;

*FOB1;
proc freq data=life;
tables fob1;
run;

*FOB10;
proc freq data=life;
tables fob10;
run;

*FOB11;
proc freq data=life;
tables fob11;
run;
```

```
*FOB12;
proc freq data=life;
tables fob12;
run;

*FOB13;
proc freq data=life;
tables fob13;
run;

*FOB14;
proc freq data=life;
tables fob14;
run;

*FOB15;
proc freq data=life;
table fob15;
run;

*FOB16;
proc freq data=life;
table fob16;
run;

*FOB17;
proc freq data=life;
table fob17;
run;

*FOB18;
proc freq data=life;
table fob18;
run;

*FOB19;
proc freq data=life;
table fob19;
run;

*FOB2;
proc freq data=life;
table fob2;
run;

*FOB20;
proc freq data=life;
table fob20;
run;

*FOB21;
proc freq data=life;
table fob21;
run;

*FOB22;
proc freq data=life;
table fob22;
run;

*FOB23;
proc freq data=life;
table fob23;
run;

*FOB24;
proc freq data=life;
table fob24;
run;
```

```
*FOB25;
proc freq data=life;
table fob25;
run;

*FOB26;
proc freq data=life;
table fob26;
run;

*FOB27;
proc freq data=life;
table fob27;
run;

*FOB3;
proc freq data=life;
table fob3;
run;

*FOB4;
proc freq data=life;
table fob4;
run;

*FOB5;
proc freq data=life;
table fob5;
run;

*FOB6;
proc freq data=life;
table fob6;
run;

*FOB7;
proc freq data=life;
table fob7;
run;

*FOB8;
proc freq data=life;
table fob8;
run;

*FOB9;
proc freq data=life;
table fob9;
run;

*FOC1;
proc freq data=life;
table foc1;
run;

*FOC10;
proc freq data=life;
table foc10;
run;

*FOC11;
proc freq data=life;
table foc11;
run;

*FOC12;
proc freq data=life;
table foc12;
run;

*FOC13;
```



```

proc freq data=life;
table foc13;
run;

*FOC14;
proc freq data=life;
table foc14;
run;

*FOC2;
proc freq data=life;
table foc2;
run;

*FOC3;
proc freq data=life;
table foc3;
run;

*FOC4;
proc freq data=life;
table foc4;
run;

*FOC5;
proc freq data=life;
table foc5;
run;

*FOC6;
proc freq data=life;
table foc6;
run;

*FOC7;
proc freq data=life;
table foc7;
run;

*FOC8;
proc freq data=life;
table foc8;
run;

*FOC9;
proc freq data=life;
table foc9;
run;

*****;
*Replicating STATS.CBL_REP File      *;
*****;

proc contents data=labs;
run;

*Lipid total cholesterol;
proc means data=labs mean std min q1 median q3 max;
var abval21;
run;

*Lipid triglyceride;
proc means data=labs mean std min q1 median q3 max;
var abval22;
run;

*lipid HDL cholesterol;
proc means data=labs mean std min q1 median q3 max;
var abval23;
run;

```

```

*lipid LDL cholesterol;
proc means data=labs mean std min q1 median q3 max;
var abval24;
run;

*lipid serum creatinine;
proc means data=labs mean std min q1 median q3 max;
var abval3;
run;

*random acr;
proc means data=labs mean std min q1 median q3 max;
var acr;
run;

*hr ren-serum creatinine;
proc means data=labs mean std min q1 median q3 max;
var bavall3;
run;

*hr ren-urine albumin;
proc means data=labs mean std min q1 median q3 max;
var bavall4;
run;

*hr ren-albumin excretion;
proc means data=labs mean std min q1 median q3 max;
var bavall5;
run;

*hr ren-urine creatinine;
proc means data=labs mean std min q1 median q3 max;
var bavall6;
run;

*hr ren_height;
proc means data=labs mean std min q1 median q3 max;
var bavall7;
run;

*hr ren-weight;
proc means data=labs mean std min q1 median q3 max;
var bavall8;
run;

*hr ren-raw clearance;
proc means data=labs mean std min q1 median q3 max;
var bavall9;
run;

*hr ren-standard clearance;
proc means data=labs mean std min q1 median q3 max;
var baval20a;
run;

*hr ren-duration;
proc means data=labs mean std min q1 median q3 max;
var baval20b;
run;

*hr ren_volume;
proc means data=labs mean std min q1 median q3 max;
var baval20c;
run;

*serum cystatin-c;
proc means data=labs mean std min q1 median q3 max;
var cystatin;
run;

*HBA1c result;

```

```
proc means data=labs mean std min q1 median q3 max;
var doresult;
run;

*EDIC follow up year;
proc freq data=labs;
table edicyear;
run;

*hba1c in SI units;
proc means data=labs mean std min q1 median q3 max;
var hba1c_si;
run;

*random renal serum creatinine;
proc means data=labs mean std min q1 median q3 max;
var randmscr;
run;

*random urine albumin;
proc means data=labs mean std min q1 median q3 max;
var randomal;
run;

*random urine creatinine;
proc means data=labs mean std min q1 median q3 max;
var randomcr;
run;

*Serum creatinine;
proc means data=labs mean std min q1 median q3 max;
var serumcr;
run;
```