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Dataset Integrity Check for the EDIC 10-Year Retinopathy Study

[DCCT-EDIC Study on the Prolonged Effect of Intensive Therapy on the Risk of Retinopathy Complications in Patients with Type 1 Diabetes Mellitus, 10 years after the DCCT]

The Data Coordinating Center (DCC) of the DCCT-EDIC Research Group submitted an analysis dataset to the NIDDK Data Repository, pertaining to a study of the "Prolonged Effect of Intensive Therapy on the Risk of Retinopathy Complications in Patients with Type 1 Diabetes Mellitus: 10 Years After the Diabetes Control and Complications Trial", as published in *Archives of Ophthamology* [1]. As a partial check of the integrity of this dataset archived in the NIDDK data repository, a dataset integrity check (DSIC) was performed to verify that selected published results from the study could be reproduced using the archived dataset. Results of the DSIC are described below.

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 on an initial exercise 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 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. Thus, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses *unless staff of the NIDDK Repository 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 those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

DSIC Background. As stated in the publication, the DCCT demonstrated significant reductions in the risk of the development and progression of the early microvascular complications of diabetes over subjects administered intensive therapy as compared with conventional therapy. At the close of the DCCT, patients in the conventional therapy group were offered intensive therapy; 97% of the original DCCT cohort enrolled in the Epidemiology of Diabetes Interventions and Complications (EDIC) study, a longitudinal observational study. The analysis reported in the publication reports on continuing differences between the 2 original treatment groups in retinal complications, 10 years after the close of the DCCT.

DSIC Methods. The DCC submitted two SAS datasets in XPORT format. (XPORT format allows the data to be read in over a variety of *SAS* platforms). Per Repository operating procedures, the XPORT datasets were converted to *SAS* version 7-8-9 format. The converted SAS datasets were utilized for all DSIC analyses. The structure of the two SAS datasets are as follows:

1) dataset *EDRET10:* Longitudinal dataset containing many records per patient, for 1426 patients that had fundus photo data during DCCT closeout (EDIC year 0) *or* EDIC years 1-10. The unique record key is subject ID--EDIC year.

This dataset includes data on retinopathy outcomes attained through EDIC years 1- 10, such as proliferative diabetic retinopathy (PDR), severe nonproliferative diabetic retinopathy (SNPDR), presence of clinically significant macular edema (CSME), and photocoagulation therapy (focal or scatter).

Analysis indicators include: ANALYSIS (=1 for 1211 subjects with a year 10 retinopathy evaluation) and CSMEANAL(=1 for 1174 subjects with a year 10 CSME evaluation).

While performing the DSIC, we found that the indicators ANALYSIS and CSMEANAL were *only* programmed correctly for year 10 records. (The indicators are populated at other subject-years, but appear to select different subjects.) The dataset was fixed by isolating the data for these indicator variables at year 10 and re-merging them back into the entire longitudinal dataset via subject ID (see code in ***Appendix 2***).

Also, the DCC notes that "1426 patients with fundus photo data at any time during DCCT close (EDIC year 0) and EDIC year 1-10 are included (in the dataset)." We believe a better wording for this statement is "1426 patients with fundus photo data at any time during DCCT close (EDIC year 0) *or* EDIC year 1-10" are included in the dataset", as 3 of the 1426 patients were missing baseline data.

2*) dataset EDRETTAB:* Contains one record per patient, for 1211 patients with an EDIC year 10 retinopathy evaluation. This dataset primarily includes data on demographics and baseline clinical characteristics.

A portion of the analyses in the publication was selected for replication to assure the archived dataset is a true copy of the one analyzed for Publication. The methods of analysis emulated those described in the Publication text. To test for differences in characteristics between treatment groups, the Wilcoxon rank sum test was used for continuous measures, and the χ^2 test for categorical measures. The odds reduction associated with the intervention, for various retinopathy complications, was calculated using logistic regression. Odds reductions during EDIC are adjusted for the level of retinopathy at the end of the DCCT. Weibull proportional hazards regression was used to evaluate treatment group effects on the cumulative incidence of further retinopathy progression during EDIC, adjusting for other covariates as indicated by the publication. Hazard reduction for intensive versus conventional therapy was calculated using the formula "(1 – hazard ratio) x 100". Hazard models used all available photographs in all subjects, and excluded participants who had scatter photocoagulation in either eye during DCCT.

SAS software (Cary, NC) was used for all DSIC analyses, as also reported in the publication.

DSIC Results: Sample Characteristics. Table 1 presents characteristics of the 1211 patients evaluated for retinopathy after 10 years of EDIC follow-up, by original treatment group. Each patient characteristic derived from archived data is compared to the corresponding published result. Overall sample size by treatment group, from archived data, exactly matches the published sample size. The percent of women, calculated from archived data, is lower than what is published (46.5% [archived] versus 49.2% [published] women in the conventional treatment

group; 49.5% [archived] versus 50.8% [published] women in the intensive treatment group). We suspect this reflects a typographical error in the publication; i.e., that the article reports the distribution of women across treatment groups instead of within treatment group. (Archived data shows that, of 581 females in the analysis cohort, 49.2% were in the conventional group and 50.8% were in the intensive group, which are exactly the percents reported in the publication.)

In the conventional group, the standard deviation of glycosylated hemoglobin level is smaller in archived data (0.2) compared to its corresponding published result (1.3). All other percents, means, standard deviations, and *P* values in the Table, as calculated from archived data, closely matched published results. Observed differences are in the decimal points and may be attributable to rounding error.

Table 1. Characteristics of the 1211 Patients Evaluated for Retinopathy After 10 Years of EDIC Follow-up
[ARCH = from Archived Data; PUB = from Published data; DIFF = Difference between Archived and Published]

	DCCT Treatment Group, % (unless otherwise indicated)							
	Conventional			Intensive			*P* value*	
	ARCH	PUB	DIFF	ARCH	PUB	DIFF	ARCH	PUB
N	615	615	0	596	596	0		
At DCCT entry								
Women	46.5	49.2	2.7	49.5	50.8	1.3	0.30	0.30
Age, y, mean (SD)	27 (7.0)	27 (7.0)	0.0 (0.0)	27 (7.0)	27 (7.0)	0.0 (0.0)	0.13	0.13
Primary prevention cohort	51.2	51.2	0.0	49.2	49.2	0.0	0.47	0.47
Duration of diabetes, y, mean (SD)	5.7 (4.1)	5.7 (4.1)	0.0 (0.0)	6.0 (4.2)	6.0 (4.2)	0.0 (0.0)	0.27	0.27
Glycosylated hemoglobin level, %, mean (SD)	9 (1.6)	9 (1.6)	0.0 (0.0)	9.1 (1.6)	9.1 (1.6)	0.0 (0.0)	0.25	0.25
At DCCT closeout/EDIC baseline								
Age, y, mean (SD)	33 (7.0)	33 (7.0)	0.0 (0.0)	34 (7.0)	34 (7.0)	0.0 (0.0)	0.09	0.09
Duration of diabetes, y, mean (SD)	11.8 (4.9)	11.8 (4.9)	0.0 (0.0)	12.2 (4.9)	12.2 (4.9)	0.0 (0.0)	0.14	0.14
DCCT follow-up, y, mean (SD)	6.3 (1.6)	6.3 (1.6)	0.0 (0.0)	6.4 (1.7)	6.4 (1.7)	0.0 (0.0)	0.32	0.32
Glycosylated hemoglobin level, %, mean (SD)	9.1 (0.2)	9 (1.3)	-0.1 (1.2)	7.4 (0.9)	7.3 (1.0)	-0.1 (0.1)	<.001	<.001
Treatment								
Continuous subcutaneous insulin infusion (pump) or multiple daily injections	5.1	5.1	0.0	98.0	98.0	0.0	<.001	<.001
Self-monitoring of blood glucose level, ≥4 times/d	4.1	4.1	0.0	53.7	53.7	0.0	<.001	<.001
Arterial blood pressure, mm Hg, mean (SD)	88.2 (8.7)	88.2 (8.7)	0.0 (0.0)	88.7 (8.7)	88.7 (8.6)	0.0 (-0.1)	0.29	0.30
Hyperlipidemia	10.6	10.6	0.0	7.2	7.2	0.0	0.04	0.04
Level of retinopathy							<.001	<.001
None (10/10)	17.8	17.8	0.0	28.5	28.5	0.0		
Microaneurysms only (20/[<20])	31.7	31.7	0.0	39.8	39.8	0.0		
Mild nonproliferative retinopathy (35/[<35])	27.7	27.7	0.0	21.5	21.5	0.0		
Moderate or severe nonproliferative retinopathy (43/[<43])	22.8	22.8	0.0	10.2	10.2	0.0		
Photocoagulation during DCCT								
Scatter, for retinopathy	4.1	4.1	0.0	1.7	1.7	0.0	0.01	0.01
Focal, for macular edema	5.4	5.4	0.0	2.2	2.2	0.0	0.004	0.004
Treatment at EDIC year 10								
Continuous subcutaneous insulin infusion (pump) or multiple daily injections	92.2	92.2	0.0	96.6	96.6	0.0	0.001	0.001
Self-monitoring of blood glucose level, ≥4 times/d	61.5	61.5	0.0	53.7	53.6	-0.1	0.007	0.007

* P-values are from Wilcoxon rank-sum tests, as in the Publication.

DSIC Results: Retinopathy Complications. Table 2 presents the prevalence of various retinopathy complications at DCCT Closeout, EDIC Year 4, and EDIC Year 10, among the 1211 patients evaluated for retinopathy at EDIC Year 10. Odds reductions (for the intervention over conventional treatment) and *P* values are also presented. Odds reductions and *P* values at EDIC Year 4 and EDIC Year 10 are adjusted for the level of retinopathy at DCCT Closeout. Each prevalence, odds reduction, and *P* value derived from archived data is compared to the corresponding published result.

There is a small discrepancy in the analysis sample size at DCCT Closeout, for archived versus published data. In the conventional group, archived data shows a sample size of 614, while the publication reports that of 615. In spite of this discrepancy, all prevalences, odds reductions and *P* values calculated on archived data very closely match published results.

The largest discrepancy in estimated results is for the prevalence of Photocoagulation therapy at EDIC Year 4. For patients in the intervention group, the prevalence is 4.6% [archived] versus 4.2% [published]. For patients in the conventional group, the prevalence is 14.3% [archived] versus 13.7% [published]. The adjusted odds reduction and 95% confidence interval for the treatment versus conventional groups is 56 (25,74) in archived data, as compared to 54 (21,73) in published data.

All other prevalences, odds reductions and *P* values, estimated from archived data, closely match published results; observed differences are in the decimal points and may be attributable to rounding error.

Table 2. Prevalence of Various Retinopathy Complications at DCCT Closeout

[ARCH = from Archived Data; PUB = from Published data; DIFF = Difference between Archived and Published]

DCCT Closeout	Intervention (%)			Conventional (%)			Odds Reduction (95% CI)			*P* value	
	ARCH	PUB	DIFF	ARCH	PUB	DIFF	ARCH	PUB	DIFF	ARCH	PUB
Sample Size	596	596	0	614	615	1					
>3-step progression from DCCT Baseline	10.7	10.7	0	33.2	33.2	0	76 (67, 82)	76 (67, 82)	0 (0, 0)	<0.001	<0.001
SNPDR or worse	2.5	2.5	0	7	7	0	66 (38, 81)	66 (38, 81)	0 (0, 0)	<0.001	<0.001
PDR or worse	2.5	2.5	0	6.8	6.8	0	65 (36, 81)	64 (35, 81)	-1 (-1, 0)	<0.001	<0.001
CSME	3.9	3.9	0	7.7	7.7	0	51 (19, 71)	51 (19, 71)	0 (0, 0)	0.005	0.005
Photocoagulation therapy (focal or scatter)	3.4	3.4	0	8	8	0	60 (32, 76)	60 (32, 76)	0 (0, 0)	<0.001	<0.001

EDIC Year 4	Intervention (%)			Conventional (%)			Odds Reduction (95% CI)			*P* value	
	ARCH	PUB	DIFF	ARCH	PUB	DIFF	ARCH	PUB	DIFF	ARCH	PUB
Sample Size	541	541	0	553	553	0					
>3-step progression from DCCT Baseline	17.8	17.8	0	48.9	48.9	0	74 (64, 81)	74 (64, 80)	0 (0, -1)	<0.001	<0.001
SNPDR or worse	4.6	4.6	0	17.4	17.4	0	67 (44, 81)	68 (44, 81)	1 (0, 0)	<0.001	<0.001
PDR or worse	4.3	4.3	0	15.7	15.7	0	65 (39, 80)	65 (39, 80)	0 (0, 0)	<0.001	<0.001
CSME	3.8	3.8	0	13.3	13.3	0	63 (36, 78)	62 (35, 78)	-1 (-1, 0)	<0.001	<0.001
Photocoagulation therapy (focal or scatter)	4.6	4.2	-0.4	14.3	13.7	-0.6	56 (25, 74)	54 (21, 73)	-2 (-4, -1)	0.002	0.004

EDIC Year 10	Intervention (%)			Conventional (%)			Odds Reduction (95% CI)			*P* value	
	ARCH	PUB	DIFF	ARCH	PUB	DIFF	ARCH	PUB	DIFF	ARCH	PUB
Sample Size	596	596	0	615	615	0					
>3-step progression from DCCT Baseline	35.8	35.8	0	60.6	60.6	0	57 (46, 67)	57 (45, 66)	0 (-1, -1)	<0.001	<0.001
SNPDR or worse	9.1	9.1	0	25	25	0	58 (37, 71)	58 (38, 71)	0 (1, 0)	<0.001	<0.001
PDR or worse	8.9	8.9	0	24.7	24.7	0	58 (37, 71)	58 (38, 71)	0 (1, 0)	<0.001	<0.001
CSME	9	9	0	19	19	0	39 (12, 59)	38 (9, 59)	-1 (-3, 0)	0.009	0.009
Photocoagulation therapy (focal or scatter)	8.4	8.4	0	23.6	23.6	0	57 (36, 71)	57 (38, 71)	0 (2, 0)	<0.001	<0.001

KEY:
>3-step progression from DCCT Baseline = more than a three-step progression from DCCT Baseline in the early treatment diabetic retinopathy study (ETDRS) scale of diabetic retinopathy severity for individual eyes
PDR = proliferative diabetic retinopathy
SNPDR = severe nonproliferative diabetic retinopathy
CSME = presence of clinically significant macular edema

DSIC Results: Further Progression of Retinopathy between DCCT Closeout and EDIC Year 10. Table 3 presents an analysis of the cumulative incidence of further 3-step progression of retinopathy and PDR between DCCT closeout and EDIC year 10, stratified by the level of retinopathy at DCCT closeout. As previously described, the analysis was performed using multivariate Weibull proportional hazards regression models using evaluations at all years in subjects, excluding participants who had scatter photocoagulation in either eye during DCCT.

There is a small discrepancy in the number at risk for further 3-step retinopathy progression in archived versus published data. Archived data shows 1350 subjects at risk overall, while the publication reports 1349. Even so, adjusted hazard reduction of further 3-step progression (for treatment versus conventional groups) is similar in archived versus published data. For example, the overall adjusted hazard reduction is estimated at 52% in archived data versus 53% in published data (*P* value <.001 for both datasets).

There is an additional small discrepancy in the number at risk for proliferative diabetic retinopathy (PDR) during EDIC in archived versus published data. Archived data shows 1312 at risk overall, while the publication reports 1314. Even so, the adjusted hazard reduction of PDR is similar in archived versus published data. For example, the overall adjusted hazard reduction is estimated at 56% in archived data versus 56% in published data (*P* value <.001 for both datasets).

Conclusion. We suspect that minor differences in sample sizes in archived versus published data reflect possible small updates to the analysis dataset, implemented by the DCC post-publication, and/or small typographical errors in the publication. Since results of this DSIC are overall quite similar to published numbers, we are confident the archived data was not corrupted in storage, transmission, or processing by Repository staff.

Table 3. Incidence of Further 3-Step Progression of Retinopathy and PDR Between DCCT Closeout and EDIC Year 10, Stratified by the Level of Retinopathy at DCCT Closeout

[ARCH = from Archived Data; PUB = from Published data; DIFF = Difference between Archived and Published]

	No. at Risk			No. with Event			Adjusted Hazard Reduction, %			*P* value	
	ARCH	PUB	DIFF	ARCH	PUB	DIFF	ARCH	PUB	DIFF	ARCH	PUB
Further 3-Step Progression											
All Levels	1350	1349	-1				52	53	1	<0.001	<0.001
INT*	682	681	-1	188	187	-1					
CON**	668	668	0	321	322	1					
Stratum 1: no retinopathy							47	47	0	<0.001	<0.001
INT*	194	194	0	71	71	0					
CON**	123	123	0	68	68	0					
Stratum 2: microaneurysm only							62	63	1	<0.001	<0.001
INT*	275	274	-1	54	53	-1					
CON**	219	219	0	87	87	0					
Stratum 3: mild non-PDR							58	58	0	<0.001	<0.001
INT*	148	148	0	31	31	0					
CON**	200	200	0	82	83	1					
Stratum 4: moderate or severe non-PDR							41	40	-1	0.02	0.02
INT*	65	65	0	32	32	0					
CON**	126	126	0	84	84	0					
PDR[a]											
All Levels	1312	1314	2				56	56	0	<0.001	<0.001
INT*	667	666	-1	45	45	0					
CON**	645	648	3	119	121	2					
Stratum 1: no retinopathy							72	72	0	0.004	0.001
INT*	194	194	0	1	1	0					
CON**	122	122	0	2	2	0					
Stratum 2: microaneurysm only							a	a	a	a	a
INT*	274	273	-1	9	9	0					
CON**	219	219	0	20	20	0					
Stratum 3: mild non-PDR							57	58	1	0.01	0.009
INT*	148	148	0	15	15	0					
CON**	199	199	0	39	40	1					
Stratum 4: moderate or severe non-PDR							39	39	0	0.07	0.06
INT*	50	50	0	20	20	0					
CON**	104	104	0	58	59	1					

[a] For PDR, strata 1 and 2 were combined in stratified analysis and in adjustment for all-levels-combined analysis because of the low event rate in these 2 strata.

Reference.

[1] Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. **DCCT-EDIC Study on the Prolonged Effect of Intensive Therapy on the Risk of Retinopathy Complications in Patients with Type 1 Diabetes Mellitus, 10 years after the DCCT.** *Archives of Ophthalmology*, Vol 126(12), Dec 2008, pp. 1707-1715.

Appendices.

[1] Full Text of Original Article in *Archives of Ophthalmology*, Vol 126(12), Dec 2008, pp. 1707-1715 (for approved requestors only)

[2] SAS version 9.2 Log for programming code submitted for the replication of results of *Archives of Ophthalmology*, Vol 126(12), Dec 2008,
pp. 1707-1715

[3] SAS version 9.2 Log for programming code submitted for the replication of results of *Archives of Ophthalmology*, Vol 126(12), Dec 2008,
pp. 1707-1715

Attachment 1

Full Text of Article

Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. **DCCT-EDIC Study on the Prolonged Effect of Intensive Therapy on the Risk of Retinopathy Complications in Patients with Type 1 Diabetes Mellitus, 10 years after the DCCT.** *Archives of Ophthalmology*, Vol 126(12), Dec 2008, pp. 1707-1715.

SECTION EDITOR: LESLIE HYMAN, PhD

Prolonged Effect of Intensive Therapy on the Risk of Retinopathy Complications in Patients With Type 1 Diabetes Mellitus

10 Years After the Diabetes Control and Complications Trial

*Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group**

Objective: To examine the persistence of the original treatment effects 10 years after the Diabetes Control and Complications Trial (DCCT) in the follow-up Epidemiology of Diabetes Interventions and Complications (EDIC) study. In the DCCT, intensive therapy aimed at near-normal glycemia reduced the risk of microvascular complications of type 1 diabetes mellitus compared with conventional therapy.

Methods: Retinopathy was evaluated by fundus photography in 1211 subjects at EDIC year 10. Further 3-step progression on the Early Treatment Diabetic Retinopathy Study scale from DCCT closeout was the primary outcome.

Results: After 10 years of EDIC follow-up, there was no significant difference in mean glycated hemoglobin levels (8.07% vs 7.98%) between the original treatment groups. Nevertheless, compared with the former conventional treatment group, the former intensive group had significantly lower incidences from DCCT close of further retinopathy progression and proliferative retinopathy or worse (hazard reductions, 53%-56%; $P<.001$). The risk (hazard) reductions at 10 years of EDIC were attenuated compared with the 70% to 71% over the first 4 years of EDIC ($P<.001$). The persistent beneficial effects of former intensive therapy were largely explained by the difference in glycated hemoglobin levels during DCCT.

Conclusion: The persistent difference in diabetic retinopathy between former intensive and conventional therapy ("metabolic memory") continues for at least 10 years but may be waning.

Trial Registration: clinicaltrials.gov Identifiers: NCT00360815 and NCT00360893.

Arch Ophthalmol. 2008;126(12):1707-1715

THE DIABETES CONTROL AND Complications Trial (DCCT) was designed to determine whether intensive therapy with the aim of maintaining glycemic levels as close to the nondiabetic range as possible would prevent or delay the long-term complications of type 1 diabetes mellitus.[1] The DCCT demonstrated substantial reductions in the risk of development and progression of the early microvascular complications of diabetes over an average of 6.5 years of intensive therapy as compared with conventional therapy. At the close of the DCCT in 1993, patients in the conventional therapy group were offered intensive therapy and instructed in its use. All patients subsequently returned to their health care providers for further diabetes care and 97% of the original DCCT cohort (n=1394) was enrolled in the Epidemiology of Diabetes Interventions and Complications (EDIC), a long-term observational study.[2] An earlier report showed that the ongoing risk of all levels of retinopathy remained significantly reduced in the intensive compared with the conventional group during the first 4 years of EDIC, despite similar glycated hemoglobin (HbA_{1c}) levels over this period (called "metabolic memory").[3] Determining the duration of metabolic memory is important to quantify the long-term clinical effects of intensive diabetes therapy. The current report describes the continuing differences between the 2 original treatment groups in retinal complications 10 years after the close of the DCCT.

CME available online at www.jamaarchivescme.com and questions on page 1625

***Authors/Group Information:** A complete listing of the authors and Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) Research Group and their affiliations appears on page 1713.

Table 1. Characteristics of the 1211 Patients Evaluated for Retinopathy After 10 Years of EDIC Follow-up

Characteristic	DCCT Treatment Group, %[a] Conventional (n=615)[b]	Intensive (n=596)[b]	*P* Value[c]
At DCCT entry			
Women	49.2	50.8	.30
Age, y, mean (SD)	27 (7)	27 (7)	.13
Primary prevention cohort[d]	51.2	49.2	.47
Duration of diabetes mellitus, y, mean (SD)	5.7 (4.1)	6.0 (4.2)	.27
Glycated hemoglobin level, %, mean (SD)	9.0 (1.6)	9.1 (1.6)	.25
At DCCT closeout/EDIC baseline[e]			
Age, y, mean (SD)	33 (7)	34 (7)	.09
Duration of diabetes, y, mean (SD)	11.8 (4.9)	12.2 (4.9)	.14
DCCT follow-up, y, mean (SD)	6.3 (1.6)	6.4 (1.7)	.32
Glycosylated hemoglobin level, %, mean (SD)	9.0 (1.3)	7.3 (0.9)	<.001
Treatment			
Continuous subcutaneous insulin infusion (pump) or multiple daily injections	5.1	98.0	<.001
Self-monitoring of blood glucose level, ≥4 times/d	4.1	53.7	<.001
Arterial blood pressure,[f] mm Hg, mean (SD)	88.2 (8.7)	88.7 (8.6)	.30
Hyperlipidemia[g]	10.6	7.2	.04
Level of retinopathy			
None (10/10)	17.8	28.5	<.001
Microaneurysms only (20/[<]20)	31.7	39.8	
Mild nonproliferative retinopathy (35/[<]35)	27.7	21.5	
Moderate or severe nonproliferative retinopathy (43/[<]43)	22.8	10.2	
Photocoagulation during DCCT			
Scatter, for retinopathy	4.1	1.7	.01
Focal, for macular edema	5.4	2.2	.004
Treatment at EDIC year 10			
Continuous subcutaneous insulin infusion (pump) or multiple daily injections	92.2	96.6	.001
Self-monitoring of blood glucose level, ≥4 times/d	61.5	53.7	.007

Abbreviations: DCCT, Diabetes Control and Complications Trial; EDIC, Epidemiology of Diabetes Interventions and Complications.

SI conversion factors: To convert low-density lipoprotein cholesterol to micromoles per liter, multiply by 0.0259; triglycerides to micromoles per liter, multiply by 0.0113; hemoglobin to proportion of total hemoglobin, multiply by 0.01.

[a] Unless otherwise indicated.

[b] The numbers of patients who were alive, had gradable fundus photographs at EDIC year 10, or underwent scatter photocoagulation in one or both eyes during EDIC are included.

[c] *P* values were based on the Wilcoxon rank sum test for quantitative or ordinal variables or the χ^2 test for categorical variables.

[d] No retinopathy or microalbuminuria at baseline (see "Methods" section of the text).

[e] The baseline data in the EDIC study were the same as the data at the end of the DCCT.

[f] Arterial blood pressure = ⅔ diastolic blood pressure + ⅓ systolic blood pressure.

[g] Hyperlipidemia is defined as 2 consecutive reports of hypercholesterolemia (low-density lipoprotein cholesterol level >160 mg/dL) or hypertriglyceridemia (triglyceride level >500 mg/dL) within 1 month during DCCT.

METHODS

SUBJECTS

At baseline, the 1441 patients enrolled in the DCCT during 1983-1989 were 13 to 39 years of age, had type 1 diabetes mellitus for 1 to 15 years, and were in generally good health. The primary prevention (726 patients with no retinopathy, albumin excretion rates <28 µg/min [<40 mg/24 hours], and 1-5 years' diabetes duration) and secondary intervention (715 patients with diabetes duration of 1-15 years, minimal to moderate nonproliferative diabetic retinopathy [NPDR], and urinary albumin excretion rates <139 µg/min [≤200 mg/24 hours]) cohort participants were randomly assigned to either intensive therapy, with the goal of achieving glycemic levels as close to the nondiabetic range as safely possible, or to conventional therapy, as previously described.[1] Intensive therapy included at least 3 injections of insulin daily or continuous subcutaneous insulin infusion with pumps, with insulin dose adjustments based on frequent self-monitoring of capillary glucose levels, meal size and composition, and physical activity levels. Mean duration of follow-up in the DCCT was 6.5 years.

ASSESSMENT OF RETINOPATHY

During EDIC, retinopathy was assessed by 7-field stereo fundus photography in approximately one-quarter of the cohort each year and in the entire cohort at years 4 and 10. Photography was not conducted if a patient had previously undergone panretinal photocoagulation in both eyes. Retinopathy status was determined in 1211 patients at EDIC year 10, 1045 based on fundus photography and 166 living patients with a known history of panretinal photocoagulation in either eye during DCCT (35 patients) or EDIC (131 patients). All photographs were graded centrally, with graders masked to therapy assignment, using the final Early Treatment Diabetic Retinopathy Study (ETDRS) grading scale[4] and DCCT methods.[5] The primary outcome was the time to the first occurrence of further retinopathy progression during EDIC, defined as a 3-step or more progression from the level of retinopathy at DCCT closeout,[3] representing a reproducible measure of clinically important worsening. The secondary retinopathy outcome was the time to the first occurrence of proliferative diabetic retinopathy (PDR) or worse during EDIC. Other retinopathy outcomes were the prevalence of a 3-step or more progression from DCCT entry, severe NPDR (ETDRS level 53/<53) or worse, clinically significant macular edema (CSME),[6] and photocoagulation therapy (focal or scatter). Patients who received panretinal scatter photocoagulation (laser) therapy in either eye were counted as having worsened retinopathy for all of these outcomes thereafter, and patients who received focal photocoagulation for macular edema were counted as having CSME thereafter. Visual acuity was assessed by ETDRS methods.[7]

Interreader reliability during EDIC was evaluated by having different graders reread the same 50 fundus photographs at each EDIC year and comparing the results with the primary double reading at DCCT closeout. The individual weighted κ measure[8] of interrater agreement beyond chance ranged from 0.82 to 0.92 for ordinal ETDRS scores and from 0.71 to 0.90 for ordinal CSME scores over 10 years of measurements. The overall weighted κ[9] stratified for EDIC year was 0.91 for ETDRS scores and 0.84 for CSME scores.

ASSESSMENT OF GLYCEMIC CONTROL

Hemoglobin A_{1c} was measured annually in a central laboratory by high-performance liquid chromatography.[10] The mean HbA_{1c} value was calculated as the time-weighted average during the DCCT and EDIC.[11]

STATISTICAL ANALYSES

To test for differences between groups, the Wilcoxon rank sum test was used for quantitative or ordinal observations[12] and the

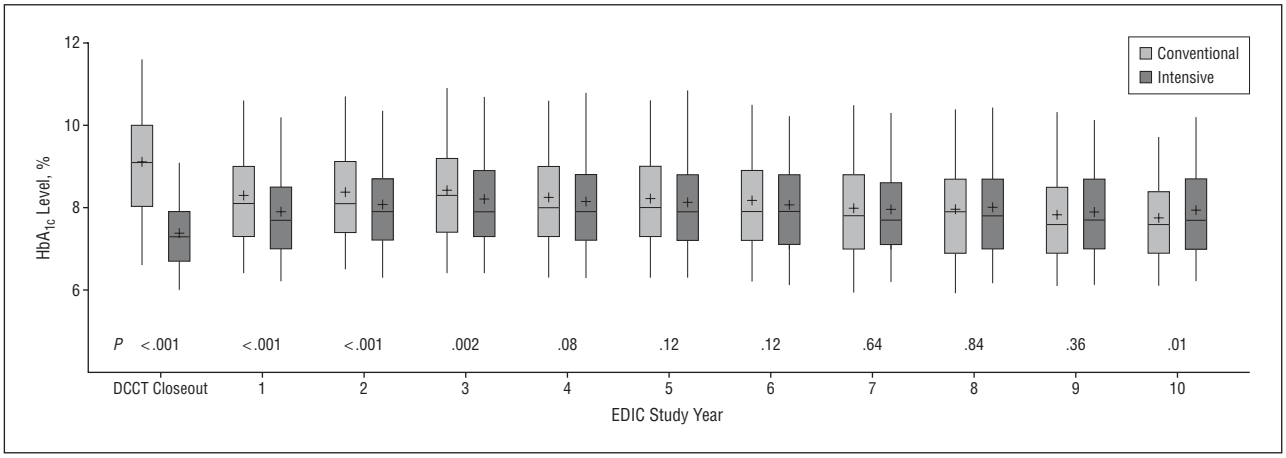

Figure 1. Distribution of glycated hemoglobin (HbA_{1c}) values by Diabetes Control and Complications Trial (DCCT) treatment group at the end of the DCCT and at each of the first 10 years of the Epidemiology of Diabetes Interventions and Complications (EDIC) study among 1211 subjects evaluated for retinopathy at year 10 of the EDIC study. The box presents the quartiles of the distribution, the vertical lines show the 95th and fifth percentiles, the horizontal line is the median, and the mean is shown as +.

Table 2. Prevalence of Various Retinopathy Complications at DCCT Closeout and EDIC Years 4 and 10 Among 1211 Patients Evaluated for Retinopathy at EDIC Year 10

	DCCT Closeout (n=1211)				EDIC Year 4 (n=1094)				EDIC Year 10 (n=1211)			
Retinopathy Complication[b]	INT, %	CON, %	Odds Reduction[a] (95% CI), %	*P* Value	INT, %	CON, %	Adjusted Odds Reduction[b] (95% CI), %	*P* Value	INT, %	CON, %	Adjusted Odds Reduction[b] (95% CI), %	*P* Value
Sample size	596	615			541	553			596	615		
≥3-step progression from DCCT baseline	10.7	33.2	76 (67-82)	<.001	17.8	48.9	74 (64-80)	<.001	35.8	60.6	57 (45-66)	<.001
SNPDR or worse	2.5	7.0	66 (38-81)	<.001	4.6	17.4	68 (44-81)	<.001	9.1	25.0	58 (38-71)	<.001
PDR or worse	2.5	6.8	64 (35-81)	<.001	4.3	15.7	65 (39-80)	<.001	8.9	24.7	58 (38-71)	<.001
CSME[c]	3.9	7.7	51 (19-71)	.005	3.8	13.3	62 (35-78)	<.001	9.0	19.0	38 (9-59)	.009
Photocoagulation therapy (focal or scatter)[d]	3.4	8.0	60 (32-76)	<.001	4.2	13.7	54 (21-73)	.004	8.4	23.6	57 (38-71)	<.001

Abbreviations: CI, confidence interval; CON, former DCCT conventional therapy group; CSME, clinical significant macular edema; DCCT, Diabetes Control and Complications Trial; EDIC, Epidemiology of Diabetes Interventions and Complications; INT, former DCCT intensive therapy group; PDR, proliferative diabetic retinopathy; SNPDR, severe nonproliferative diabetic retinopathy.

[a] The odds reduction is for INT as compared with CON.

[b] Adjusted odds reduction was computed after stratification by the level of retinopathy at the end of the DCCT as shown in Table 1. Since this Table is only limited to the 1121 patients with retinopathy evaluated at EDIC year 10 (except for CSME), the adjusted odds reduction at EDIC year 4 is slightly different from that previously published.[3]

[c] Based on 1174 patients who were evaluated for CSME at EDIC year 10, including 1173 at DCCT closeout (589 INT and 584 CON), 1068 at EDIC year 4 (534 INT and 534 CON), and 1174 at EDIC year 10 (589 INT and 585 CON).

[d] Patients with scatter photocoagulation after entry into the DCCT were counted as worse for retinopathy; those with focal photocoagulation were counted as worse for macular edema.

χ^2 test, for categorical data.[13] Generalized estimating equations with an unstructured working correlation matrix[14] were used to assess the aggregate HbA_{1c} level difference between groups over EDIC years and to test for differences in odds reduction in further 3-step or more progression and PDR between EDIC years 4 and 10.

Analyses of progression of retinopathy were stratified by, or included adjustment for, retinopathy severity at the end of DCCT, defined as no retinopathy (ETDRS grade 10/10), microaneurysms only (ETDRS grade 20), mild NPDR (ETDRS grade 30), moderate NPDR or greater (≥ETDRS grade 40), and any previous laser therapy (focal or scatter). The Mantel-Haenszel method provided a stratified adjusted odds ratio,[15] with test-based confidence intervals (CIs). Logistic regression models assessed the effects of covariates on the prevalence (odds) of a particular retinopathy outcome at a specific EDIC year.[15] *P* values were obtained from likelihood ratio tests. The percentage of reduction in the odds with intensive vs conventional therapy was computed as (1 – odds ratio) × 100.

The Weibull proportional hazards regression model for interval-censored data[16] evaluated the treatment group effects on the cumulative incidence of further retinopathy progression during EDIC adjusted for other covariates. The model used all photographs in all patients. The Weibull assumption was verified by empirical estimation of the survival function.[17] Risk (hazard) reduction with intensive vs conventional therapy was calculated as (1 – hazard ratio) × 100. *P* values were obtained from likelihood ratio tests. The proportion reduction in –log likelihood (R^2) was used to describe the proportion of variation in risk explained by the HbA_{1c} levels.[15] All analyses were performed using SAS (SAS Institute Inc, Cary, North Carolina).

RESULTS

SUBJECTS

Table 1 shows the characteristics at DCCT baseline and at the end of the DCCT (EDIC baseline) of the 1211 sub-

Table 3. Incidence of Further 3-Step Progression of Retinopathy and PDR Between DCCT Closeout and EDIC Year 10 Stratified by the Level of Retinopathy at DCCT Closeout

Retinopathy Level at DCCT Closeout	Further 3-Step Progression				PDR[a]			
	No. at Risk[b]	No. With Event	Adjusted Hazard Reduction[c] (95% CI), %	*P* Value[d]	No. at Risk[e]	No. With Event	Adjusted Hazard Reduction[c] (95% CI), %	*P* Value[d]
All levels	1349		53 (43 to 61)	<.001	1314		56 (37 to 70)	<.001
Intensive therapy	681	187			666	45		
Conventional therapy	668	322			648	121		
Stratum 1: no retinopathy			47 (26 to 62)	<.001			72 (42 to 87)	.001
Intensive therapy	194	71			194	1		
Conventional therapy	123	68			122	2		
Stratum 2: microaneurysm only			63 (47 to 74)	<.001				
Intensive therapy	274	53			273	9		
Conventional therapy	219	87			219	20		
Stratum 3: mild non-PDR			58 (34 to 73)	<.001			58 (19 to 78)	.009
Intensive therapy	148	31			148	15		
Conventional therapy	200	83			199	40		
Stratum 4: moderate or severe non-PDR			40 (9 to 60)	.02			39 (–3 to 64)	.06
Intensive therapy	65	32			50	20		
Conventional therapy	126	84			104	59		

Abbreviations: CI, confidence interval; DCCT, Diabetes Control and Complications Trial; EDIC, Epidemiology of Diabetes Interventions and Complications; PDR, proliferative diabetic retinopathy.

[a] For PDR, strata 1 and 2 were combined in stratified analysis and in adjustment for all-levels-combined analysis because of the low event rate in these 2 strata.

[b] The sample size for all levels is the same as in Figure 2A (n = 1349), based on all EDIC evaluations in all subjects, including those at EDIC years 4 and 10 and those in a quarter of these subjects at other EDIC years, among those patients who were free of scatter photocoagulation during DCCT.

[c] The Weibull model was performed for each stratum and for all levels combined after adjustment for primary/secondary cohort, glycated hemoglobin value at entry to the DCCT, and diabetes mellitus duration at DCCT baseline. Analysis of all levels combined was also adjusted for the level of retinopathy at the end of the DCCT. Hazard reduction is for intensive therapy as compared with conventional therapy.

[d] *P* values were based on the Wald χ^2 test from the Weibull model.

[e] The sample size for all levels is the same as in Figure 3A (n = 1314), based on all EDIC evaluations in all subjects, including those at EDIC years 4 and 10 and those in a quarter of these subjects at other EDIC years, among those patients who were free of PDR during DCCT. Among the 1314, 5 patients who did not have retinopathy evaluation at DCCT closeout were excluded from the stratified analysis.

jects with retinopathy status determined at EDIC year 10. At DCCT baseline, there were no significant differences between the intensive and conventional treatment groups. However, treatment group differences reflecting the beneficial effects of intensive therapy were seen at DCCT end for HbA_{1c} level, prevalence of hyperlipidemia, retinopathy level, and need for photocoagulation.

TREATMENT AND METABOLIC OUTCOMES

During 6.5 years of treatment in DCCT, intensive and conventional therapy groups adhered to their assigned therapies 98% and 97% of the time, respectively. At EDIC year 4, 95% of the former intensive therapy group were still being treated with multiple daily injections of insulin or an infusion pump, compared with 75% of the former conventional therapy group ($P<.001$). At EDIC year 10, the differences between the 2 groups had narrowed further with regard to insulin therapy and self-monitoring (Table 1).

At entry to the DCCT, the mean HbA_{1c} level in each treatment group was 9% (to convert to proportion of total hemoglobin, multiply by 0.01) (Table 1). Following 6.5 years of DCCT follow-up, the mean HbA_{1c} levels were 7.3% and 9.0% in the intensive and conventional therapy groups, respectively. At the first EDIC evaluation, 1 year after DCCT end, HbA_{1c} values in the 2 groups had converged (**Figure 1**). Over 10 years in EDIC, the mean HbA_{1c} levels in the 2 former treatment groups were almost the same (8.07% in the conventional therapy group vs 7.98% in the intensive therapy group; $P=.20$).

OPHTHALMOLOGIC OUTCOMES FROM DCCT BASELINE TO EDIC YEARS 4 AND 10

The prevalences of various levels of retinopathy and CSME were lower in the former intensive therapy group than in the former conventional therapy group at the end of DCCT and also at years 4 and 10 of EDIC (**Table 2**). The likelihood (odds) of a 3-step or more progression in retinopathy from DCCT baseline, the principal DCCT outcome, was 76% lower in the intensive than in the conventional therapy group at the end of DCCT (10.7% vs 33.2%). After 4 years of follow-up in EDIC, 48.9% of the former conventional therapy group had a 3-step or more progression in retinopathy from DCCT baseline compared with 17.8% of the former intensive therapy group; after 10 years, 60.6% had progressed in the conventional group vs 35.8% in the intensive group.

The overall prevalences during EDIC reflect, in part, retinopathy differences associated with intensive vs conventional therapy during DCCT. To eliminate the carryover of the treatment group differences at the end of the DCCT into EDIC, we performed logistic regression analysis adjusted for the level of retinopathy at the end of the DCCT. The adjusted odds of retinopathy progression from DCCT entry were reduced by 74% with intensive vs conventional therapy at 4 years of EDIC and 57%

at 10 years (each $P < .001$). Continued significant reductions at 4 and 10 years of EDIC follow-up were also observed in the adjusted odds of severe NPDR or worse, PDR or worse, CSME, and photocoagulation. However, the odds reductions at 10 years were less than that observed at 4 years, except for those for photocoagulation (Table 2).

OPHTHALMIC OUTCOMES FROM EDIC BASELINE TO EDIC YEARS 4 AND 10

To assess metabolic memory further, we examined the prevalence of further 3-step or more progression of retinopathy from the level of retinopathy at DCCT closeout, adjusted for the level at closeout, among those free of panretinal scatter laser therapy during the DCCT. There was a 71% (95% CI, 56%-81%) odds reduction ($P < .001$) with intensive vs conventional therapy at EDIC year 4 (6.6% and 21.8% prevalence, respectively) and 50% (95% CI, 35%-62%) reduction ($P < .001$) at EDIC year 10 (24.2% and 40.8% prevalence for intensive and conventional treatment groups, respectively). Generalized estimating equations analysis showed that the beneficial treatment effect in further 3-step or more progression waned ($P = .003$). We also examined the prevalence of PDR or worse among those free of PDR during the DCCT. The odds reduction with intensive therapy after adjustment for the retinopathy levels at DCCT closeout was 76% (95% CI, 45%-89%) at EDIC year 4 ($P < .001$), with prevalences of 1.5% and 8.9% in the intensive and conventional treatment groups, respectively. At year 10, the odds reduction of PDR or worse was 59% (95% CI, 37%-73%; $P < .001$), with prevalences of 6.5% and 19.2% in the intensive and conventional treatment groups, respectively. However, for PDR or worse, the generalized estimating equations analysis showed that the odds reduction was not significantly different between years 4 and 10 ($P = .12$).

An additional analysis examined the cumulative incidence of further 3-step or more progression during EDIC from the level at DCCT closeout in multivariate Weibull proportional hazards regression models using evaluations at all years in subjects, after excluding 36 participants who had scatter photocoagulation in either eye during DCCT (**Table 3**) (n = 1349). The Weibull model revealed a highly significant beneficial effect of DCCT intensive therapy up to 10 years after the end of DCCT. **Figure 2**A presents the estimated cumulative incidence of retinopathy further progression in each group derived from the Weibull model, reaching 51% at 10 years in the former conventional and 29% in the intensive treatment groups. The risk (hazard) of further retinopathy progression over the 10 years of EDIC was reduced by 53% ($P < .001$; 95% CI, 43%-61%). However, this beneficial effect was attenuated compared with the results over the first 4 years after the end of DCCT[3] (Figure 2B), when there was a 70% risk (hazard) reduction (95% CI, 59%-79%; $P < .001$) with intensive therapy. The Weibull model was further fit for the interval between EDIC year 4 and EDIC year 10 (Figure 2B) among those patients who were free of further 3-step progression from DCCT closeout as of EDIC year 4 (n = 1105). The risk reduction between EDIC years 4 and 10 verified the persistent and highly significant, albeit attenuated, beneficial effect of the former intensive therapy over this 6-year period (38% risk reduction; 95% CI, 22%-51%; $P < .001$).

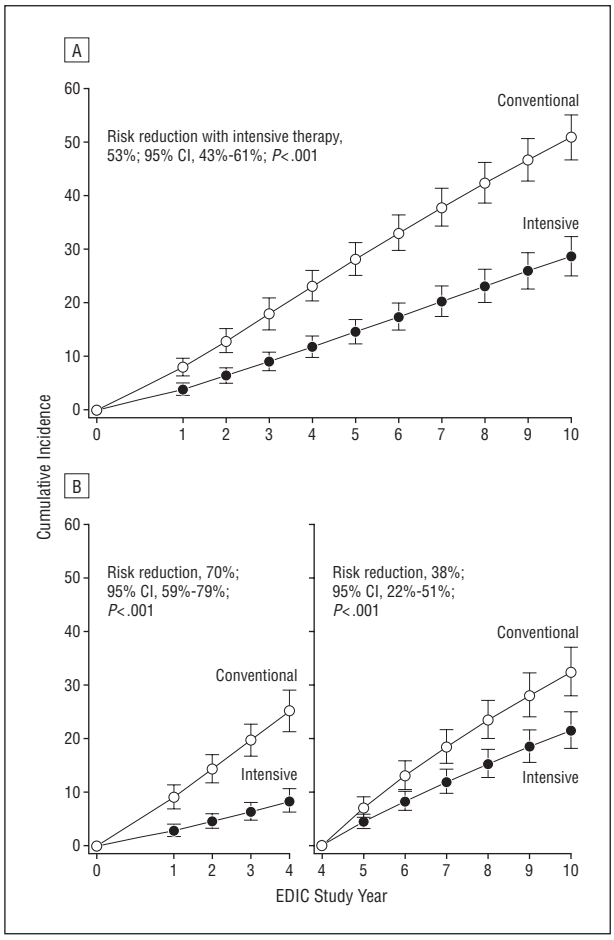

Figure 2. Estimated cumulative incidence of further 3-step progression of retinopathy from Diabetes Control and Complications Trial (DCCT) closeout to Epidemiology of Diabetes Interventions and Complications (EDIC) study year 10 (n = 1349) (A) and from DCCT closeout to EDIC year 4 (n = 1320) and from EDIC year 4 to EDIC year 10 (n = 1105) (B) based on Weibull regression models adjusted for the level of retinopathy at the end of the DCCT, primary vs secondary cohort, glycated hemoglobin value on entry to the DCCT, and diabetes mellitus duration at DCCT baseline. Retinopathy was evaluated in 369 patients during EDIC year 1, 448 in year 2, 430 in year 3, 1225 in year 4 (1997), 338 in year 5, 440 in year 6, 406 in year 7, 204 in year 8, 233 in year 9, and 1211 in year 10 (2003). Subjects with prior scatter photocoagulation during the DCCT were excluded from analyses (26 in the conventional therapy group and 10 in the intensive therapy group). Patients who had further 3-step progression from DCCT closeout as of EDIC year 4 (n = 212) and patients who were censored during the interval (n = 32) were excluded from the analysis of incidence over years 4 to 10. CI indicates confidence interval.

A Weibull model analysis of the cumulative incidence of PDR or worse among patients who were free of PDR or worse during DCCT had similar results (**Figure 3**). The risk (hazard) of PDR during the 10 years of EDIC follow-up was reduced by 56% (95% CI, 37%-70%; $P < .001$), 71% during the first 4 years of EDIC (95% CI, 44%-85%; $P < .001$), and 46% from EDIC year 4 to 10 (95% CI, 16%-65%; $P < .001$).

Table 3 presents separate Weibull models of the incidence of further 3-step progression and PDR over the 10 years of EDIC follow-up within the strata defined by retinopathy levels at DCCT closeout (EDIC baseline). For all DCCT closeout retinopathy levels, there was an overall benefit over the 10 years, but as the severity of retinopathy increased at DCCT closeout, the relative benefits of DCCT intensive therapy decreased. Whereas Table 3 examines

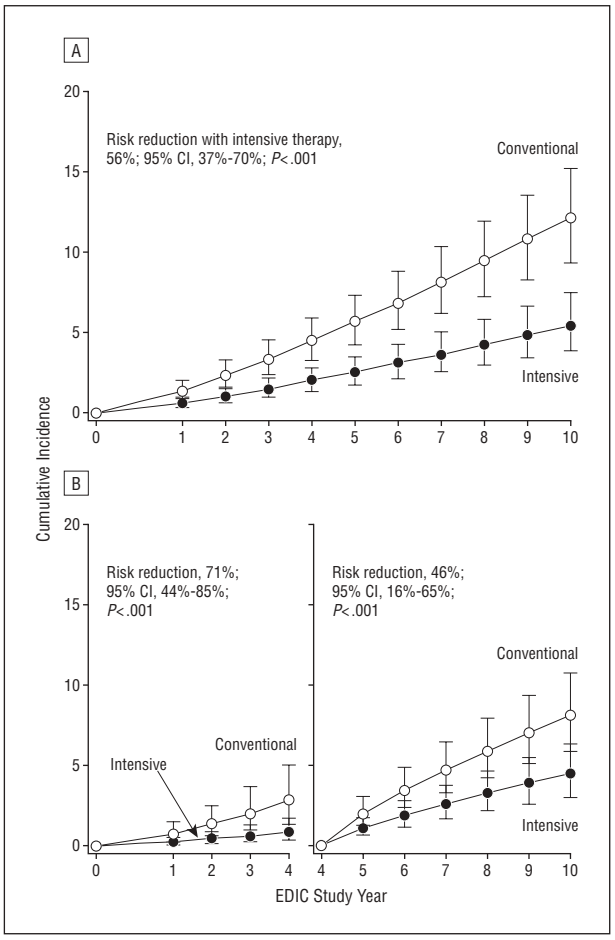

Figure 3. Estimated cumulative incidence of proliferative diabetic retinopathy (PDR) or worse from Diabetes Control and Complications Trial (DCCT) closeout to Epidemiology of Diabetes Interventions and Complications (EDIC) year 10 (n=1314) (A) and from DCCT closeout to EDIC year 4 (n=1285) and from EDIC year 4 to EDIC year 10 (n=1215) (B) based on Weibull regression models adjusted for the level of retinopathy at the end of the DCCT, primary vs secondary cohort, glycated hemoglobin value on entry to the DCCT, and diabetes mellitus duration at DCCT baseline. The sample size is based on all EDIC evaluations in all subjects, including those at EDIC years 4 and 10, and those in a quarter of these subjects at other EDIC years. Patients with prior PDR or worse during the DCCT were excluded from all the analyses (52 in the conventional therapy group and 26 in the intensive therapy group). Patients who had PDR during the first 4 years of EDIC follow-up (n=63) and patients who were censored during the interval (n=36) were excluded from the analysis of incidence over years 4 to 10. CI indicates confidence interval.

the prolonged protective effect of intensive vs conventional treatment at each retinopathy level, **Table 4** examines whether the inclusion of other risk factors attenuates the effects of intervention group. After adjusting for other DCCT baseline and DCCT closeout covariates, the differences between DCCT treatment groups in the risk of further progression of retinopathy remained highly significant (Table 4) ($P<.001$). Risk of further progression of retinopathy increased significantly with higher HbA_{1c} level at DCCT baseline (19% increase in risk per 1% increase in HbA_{1c} level; $P<.001$), higher mean blood pressure at DCCT closeout (11% increase in risk per 5 mm Hg–increase in the mean blood pressure; $P<.001$), and hyperlipidemia at DCCT closeout (70% increase in risk for those with hyperlipidemia vs those without; $P=.001$).

Table 4. Weibull Proportional Hazards Regression Model of Risk Factors for Further 3-Step Progression of Retinopathy From DCCT Closeout Over 10 Years of EDIC Follow-up in 1349 Patients[a]

Covariate	χ^2	*P* Value	Hazard Ratio (95% CI)[b]
At DCCT entry			
Glycated hemoglobin level at DCCT eligibility	39.74	<.001	1.19 (1.13-1.26)
Cohort (primary vs secondary)	0.02	.88	1.02 (0.78-1.33)
Type 1 diabetes mellitus duration	3.25	.07	0.97 (0.94-1.00)
At DCCT closeout			
Mean blood pressure	17.50	<.001	1.11 (1.06-1.17)
Hyperlipidemia ever[c]	15.65	.001	1.70 (1.31-2.21)
DCCT treatment group, intensive vs conventional	62.44	<.001	0.46 (0.38-0.56)

Abbreviations: See Table 3.
SI conversion factors: See Table 1.
[a] The sample size is based on all EDIC evaluations in all subjects, including those at EDIC years 4 and 10 and those in a quarter of these subjects at other EDIC years, among those patients who were free of scatter photocoagulation during DCCT. The model was also adjusted for the retinopathy levels at the DCCT closeout ($P<.001$). Significance levels were not affected after adjustment for body mass index, albumin excretion rate, smoking, or neuropathy at DCCT closeout, none of which contributed meaningfully when added to this model ($P>.053$ for all).
[b] Hazard ratio is the ratio of hazard of retinopathy progression per 1–percentage point increase in glycated hemoglobin level, 1-year increased duration of diabetes mellitus, 5–mm Hg increase in mean blood pressure, or for the dichotomous variable as noted.
[c] Hyperlipidemia is defined as 2 consecutive reports of hypercholesterolemia (low-density lipoprotein cholesterol level >160 mg/dL) or hypertriglyceridemia (triglyceride level >500 mg/dL) within 1 month during DCCT.

RELATION OF PROGRESSION OF RETINOPATHY TO HYPERGLYCEMIA

Another Weibull model assessed the effect of the combined DCCT and EDIC mean HbA_{1c} levels on the risk of further progression of retinopathy among those free of scatter photocoagulation during DCCT. Within each former therapy group, the hazard of further 3-step or more progression of retinopathy during EDIC increased as the mean HbA_{1c} values during the DCCT and EDIC increased, adjusting for cohort, diabetes duration, HbA_{1c} level at DCCT entry, and the level of retinopathy at the end of the DCCT. In the former conventional and intensive therapy groups, there was a 1.9 times greater risk and 2.0 times greater risk, respectively, of further progression of retinopathy for every 10% increase in HbA_{1c} level (eg, from 8.0% to 8.8%) during the DCCT and EDIC (95% CI, 1.8-2.2; $P<.001$ and 95% CI, 1.8-2.3; $P<.001$, respectively). The HbA_{1c} level effects on further progression of retinopathy were not significantly different for the 2 former DCCT treatment groups ($P=.40$).

In additional models that combined both treatment groups and adjusted for mean HbA_{1c} levels during DCCT or for mean HbA_{1c} levels during EDIC separately, 89% of the prolonged effect (R^2) of DCCT intensive therapy on further retinopathy progression was explained by the differences in the DCCT mean HbA_{1c} levels, whereas the EDIC mean HbA_{1c} levels explained only 1.6% of the prolonged intensive therapy effect.

DCCT/EDIC Study Research Group

The following persons and institutions participated in the DCCT/EDIC Study Research Group:

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Central Carotid Ultrasound Unit

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Central Electrocardiography Reading Unit

University of Minnesota: R. Crow (past), B. Gloeb (past), S. Thomas (past), C. O'Donnell (past); *Wake Forest University*: R. Prineas, C. Campbell.

Central Neuropsychological Coding Unit

C. Ryan; D. Sandstrom; T. Williams; M. Geckle; E. Cupelli; F. Thoma; B. Burzuk; T. Woodfill.

Central Autonomic Nervous System Reading Unit

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Computed Tomography Reading Center

Harbor UCLA Research and Education Institute: R. Detrano, N. Wong, M. Fox, L. Kim, R. Oudiz.

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Editor, EDIC Publications

D. M. Nathan.

VISUAL ACUITY 10 YEARS AFTER THE END OF THE DCCT

After 10 years of EDIC follow-up, 4 former intensive therapy patients had a visual acuity worse than 20/200 in 1 eye. None was so affected in both eyes. Only 1 of these 4 patients lost vision owing to diabetic retinopathy. One former conventional therapy group patient had a visual acuity worse than 20/200 in 1 eye at EDIC year 10 owing to PDR.

COMMENT

During the first 10 years of follow-up in the EDIC, the level of glycemic control in the former DCCT therapy groups converged. Based on previous epidemiologic assessments, the small difference in HbA_{1c} values between the former therapy groups would be expected to reduce the relative benefit of intensive therapy that occurred during the DCCT.[18] However, progression of retinopathy during the first 4 years of post-DCCT follow-up remained markedly less frequent in the former intensive therapy group, despite an increase in median HbA_{1c} value from 7.2% during the DCCT to 7.9% during the EDIC, than in the former conventional therapy group. Conversely, in the former conventional therapy group, the risk of progression of retinopathy during the first 4 years of EDIC[3] remained about the same as during the first 4 years of the DCCT,[19] despite a decrease in the median HbA_{1c} value from 9.1% during DCCT to 8.2% during EDIC. The continued separation in retinopathy of the former treatment groups was not merely a reflection of the differences in the severity of retinopathy between the 2 groups at the end of the DCCT, since the reductions in risk of further progression persisted after adjusting for the differences in complications between the 2 therapy groups at DCCT end. DCCT/EDIC has shown a similar prolonged effect of prior intensive therapy on microalbuminuria and albuminuria[11] and neuropathy.[20]

The likelihood of further progression of retinopathy in both groups was strongly associated with the mean HbA_{1c} value during the DCCT and EDIC combined, with a stronger effect of the mean HbA_{1c} value during the DCCT. In the Stockholm Diabetes Intervention Study, the prevalence of severe retinopathy after 7.5 years of follow-up was related to the mean HbA_{1c} value during the first 5 years of follow-up.[21]

Intensive therapy that maintains near-normal glycemic levels for an average of 6.5 years has a beneficial impact on long-term complications that extends at least 10 years beyond the actual period of such therapy. Moreover, therapy that maintains higher HbA_{1c} levels has adverse effects on complications that persist beyond the period of high HbA_{1c} levels. However, the DCCT/EDIC results should not be interpreted to mean that intensive therapy need only be applied for a limited period. Rather, the results support the implementation of intensive treatment as early in the course of the disease as possible. Stratified Weibull models fitted separately in the 4 retinopathy strata at DCCT closeout (Table 3) reveal that the metabolic memory is waning faster in patients with more severe retinopathy than in those with milder retinopathy, which reinforces the importance of implementing intensive glycemia control as early in the course of the disease as possible.

One potential limitation of the current study is that we did not adjust for other medication use, which might have confounded the results. However, we have shown in previously published analyses that the use of other medications, such as angiotensin-converting enzyme inhibitors and aspirin, was not significantly different between the treatment groups.[22]

The persistent adverse effects of hyperglycemia and the long-term beneficial effects of lowering glycemia on the development and progression of complications, also shown in animal models of diabetes,[23] has been termed *metabolic memory*. One possible explanation for this phenomenon is the slow accumulation, and subsequent slow degradation, of advanced glycation end products (AGEs).[24] DCCT patients in the intensive therapy group had lower concentrations of these substances in skin collagen than did patients in the conventional therapy group.[25] The levels of skin collagen AGEs were also associated with the subsequent incidence of progression of retinopathy (and nephropathy) over the first 10 years of EDIC.[26] Although the metabolic memory effect is present 10 years after the DCCT, the apparent waning of metabolic memory ("metabolic amnesia") between EDIC years 4 and 10 may be secondary to a combination of clearance of the long-lasting AGEs in the former conventional group and the accumulation of AGEs in the former intensive treatment group. There are currently no direct data to prove this speculation, and alternative explanations include epigenetic effects of hyperglycemia or a combination of effects.

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Ophthalmological Numismatics

Johann Gottlieb Fabini (Theofil Janos) (1791-1847) was one of the first Hungarian professors of ophthalmology. Fabini, a native of Transylvania, studied medicine in Vienna, Austria, where for 2 years he was assistant to George Beer. While in Vienna, he also had the opportunity to work with Carl von Graefe and William MacKenzie. Returning to Hungary in 1817, he was appointed chair of Ophthalmology at the University of Budapest, where he was to remain for the rest of his career. His primary interests were the diseases of the cornea, which is reflected in his publications in 1830 and 1831, respectively, of *Doctrina de morbus oculorum* and *Praecipius corneae morbis*.

In Hungary in 1982, a commemorative medal by Eszter Miro was cast in bronze, 105 mm in diameter. The medal is uniface and depicts Fabini's clothed facing bust, three-quarters to the left; within the curve at left: FABINI TEOFIL; and within the curve at lower right, the artist's initials: ME.

Courtesy of: Jay M. Galst, MD, clinical associate professor, New York Medical College, and Peter van Alfen, PhD, associate curator, American Numismatic Society.

Attachment 2

SAS version 9.2 Log
for programming code submitted for
the replication of results in
Archives of Ophthalmology, Vol 126(12), Dec 2008,
pp. 1707-1715

NOTE: SAS (r) Proprietary Software 9.2 (TS2M2)
Licensed to RTI INTL MAIN, Site 70006746.
NOTE: This session is executing on the XP_PRO platform.

NOTE: SAS initialization used:
real time 6.51 seconds
cpu time 1.10 seconds

```
1          options ps=55 ls=75 nonumber formchar='|----|+\---+=|-^<>*' mprint
1        ! orientation=portrait;
2
3            * directory with extracted SAS datasets *;
4          libname edic10sa 'C:\Documents and Settings\stan\My
4        ! Documents\DATA\NIDDK\EDIC\10-Year-Retinopathy\SAS_extract';
```
NOTE: Libref EDIC10SA was successfully assigned as follows:
Engine: V9
Physical Name: C:\Documents and Settings\stan\My
Documents\DATA\NIDDK\EDIC\10-Year-Retinopathy\SAS_extract

```
5
6          * EDRET10 -- one record per visit (Longitudinal dataset) -- with analysis
indicators
7            and longitudinal outcomes *;
8          data edic10re; set EDIC10SA.EDRET10; run;
```

NOTE: There were 6764 observations read from the data set EDIC10SA.EDRET10.
NOTE: The data set WORK.EDIC10RE has 6764 observations and 57 variables.
NOTE: DATA statement used (Total process time):
real time 0.12 seconds
cpu time 0.03 seconds

```
9
10         * EDRETTAB -- one record per subject (Baseline dataset) -- has mostly
10       ! baseline/demographic measures,
11           but also has DTCLSETD, which is one of the primary outcomes (not programmed in
12           longitudinal dataset ) *;
13         data edic10retab; set EDIC10SA.EDRETTAB;
14
15         ********************************************************;
16           * to replicate table 1*;
17         title To Replicate Table 1;
```

NOTE: There were 1211 observations read from the data set EDIC10SA.EDRETTAB.
NOTE: The data set WORK.EDIC10RETAB has 1211 observations and 28 variables.
NOTE: DATA statement used (Total process time):
real time 0.01 seconds
cpu time 0.00 seconds

```
18         proc freq data=edic10retab; tables group; run;
```

```
NOTE: There were 1211 observations read from the data set WORK.EDIC10RETAB.
NOTE: The PROCEDURE FREQ printed page 1.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.96 seconds
      cpu time            0.03 seconds


19         proc freq data=edic10retab; tables (sex retbase mdi99 gluc499 lipflg
20         mdi10 gluc410 dtclsetd anyscat anyfoca)*group/chisq exact; run;

NOTE: There were 1211 observations read from the data set WORK.EDIC10RETAB.
NOTE: The PROCEDURE FREQ printed pages 2-16.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.98 seconds
      cpu time            0.26 seconds


21            * evidently the regular chisq test was reported in the publication....
22              as stated in methods (nothing special ) *;
23
24         proc means data=edic10retab mean std maxdec=1;
25           class group;
26           var age0 duryr0 hbael
27           age99 duryr99 dcctyear hba99 mbp99 ; run;

NOTE: There were 1211 observations read from the data set WORK.EDIC10RETAB.
NOTE: The PROCEDURE MEANS printed page 17.
NOTE: PROCEDURE MEANS used (Total process time):
      real time           0.32 seconds
      cpu time            0.03 seconds


28         proc npar1way wilcoxon data=edic10retab;
29           class group;
30           var age0 duryr0 hbael
31           age99 duryr99 dcctyear hba99 mbp99 ; run;

NOTE: There were 1211 observations read from the data set WORK.EDIC10RETAB.
NOTE: The PROCEDURE NPAR1WAY printed pages 18-25.
NOTE: PROCEDURE NPAR1WAY used (Total process time):
      real time           0.23 seconds
      cpu time            0.03 seconds


32
33
34         ************************************************************;
35           * to replicate table 2*;
36         title To Replicate Table 2;
37         data edic10re; set edic10re;
38           * create focal or scatter indicator, reported in Table 2 *;
39           IF FOCAL=1 OR SCAT=1 THEN FOCALSCAT=1; ELSE IF FOCAL=0 AND SCAT=0 THEN
FOCALSCAT=0;
40
```

```
41          * create outcome in longitudinal dataset *;
42          DTCLSETD=.;
43          IF DCCT10=1 THEN DTCLSETD=1;
44          ELSE IF DCCT20=1 THEN DTCLSETD=2;
45          ELSE IF DCCT30=1 THEN DTCLSETD=3;
46          ELSE IF DCCT40=1 OR DCCT50=1 THEN DTCLSETD=4;
47
48          label DTCLSETD='DCCT closeout ETDRS level comb DCCT10-DCCT50';
49          * this was programmed in baseline dataset but not in longitudinal *;
50
51          if group='EXPERIMENTAL' then tgroup=1;
52          else if group='STANDARD' then tgroup=0;
53        run;

NOTE: There were 6764 observations read from the data set WORK.EDIC10RE.
NOTE: The data set WORK.EDIC10RE has 6764 observations and 60 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


54
55        proc sort data=edic10re; by mask_pat edicyr;
56
57        ************************************************************************;
58         * the analysis indicator is a little weird... it is only programmed correctly
59           for those with edicyr=10... at other years it includes too many people *;
60         * fix the indicators using below code *;

NOTE: There were 6764 observations read from the data set WORK.EDIC10RE.
NOTE: The data set WORK.EDIC10RE has 6764 observations and 60 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


61        data analysisre; set edic10re; if analysis=1 and edicyr=10;

NOTE: There were 6764 observations read from the data set WORK.EDIC10RE.
NOTE: The data set WORK.ANALYSISRE has 1211 observations and 60 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


62        data csmere; set edic10re; if csmeanal=1 and edicyr=10; run;

NOTE: There were 6764 observations read from the data set WORK.EDIC10RE.
NOTE: The data set WORK.CSMERE has 1174 observations and 60 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds
```

```
63
64          * main longitudinal analysis dataset *;
65         data edic10re_analy; merge edic10re analysisre(keep=mask_pat in=in2);
66           if in2; by mask_pat;
67
68          * csme longitudinal analysis dataset *;

NOTE: There were 6764 observations read from the data set WORK.EDIC10RE.
NOTE: There were 1211 observations read from the data set WORK.ANALYSISRE.
NOTE: The data set WORK.EDIC10RE_ANALY has 6084 observations and 60 variables.
NOTE: DATA statement used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


69         data edic10re_csme; merge edic10re csmere(keep=mask_pat in=in2);
70           if in2; by mask_pat; run;

NOTE: There were 6764 observations read from the data set WORK.EDIC10RE.
NOTE: There were 1174 observations read from the data set WORK.CSMERE.
NOTE: The data set WORK.EDIC10RE_CSME has 5910 observations and 60 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


71         ********************************************************************************;
72
73          * #s for table 2 *;
74         proc sort data=edic10re_analy; by edicyr;

NOTE: There were 6084 observations read from the data set WORK.EDIC10RE_ANALY.
NOTE: The data set WORK.EDIC10RE_ANALY has 6084 observations and 60 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.03 seconds
      cpu time            0.01 seconds


75         proc freq data=edic10re_analy; by edicyr; tables (step3 snpdr pdr
75       ! focalscat)*group/chisq exact; where edicyr in (0,4,10); run;

NOTE: There were 3524 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr in (0, 4, 10);
NOTE: The PROCEDURE FREQ printed pages 26-49.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           1.01 seconds
      cpu time            0.03 seconds


76
77         %macro logreganaly(out,adjust,edicyear,classvar);
78         proc logistic data=edic10re_analy descending; where edicyr=&edicyear;
```

```
79          class &classvar;
80          model &out=tgroup &adjust/risklimits; run;
81        %mend;
82        %logreganaly(step3,,0);
MPRINT(LOGREGANALY):   proc logistic data=edic10re_analy descending;
MPRINT(LOGREGANALY):   where edicyr=0;
MPRINT(LOGREGANALY):   class ;
MPRINT(LOGREGANALY):   model step3=tgroup /risklimits;
MPRINT(LOGREGANALY):   run;

NOTE: PROC LOGISTIC is modeling the probability that STEP3=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1210 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr=0;
NOTE: The PROCEDURE LOGISTIC printed pages 50-51.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.06 seconds
      cpu time            0.01 seconds


83        %logreganaly(snpdr,,0);
MPRINT(LOGREGANALY):   proc logistic data=edic10re_analy descending;
MPRINT(LOGREGANALY):   where edicyr=0;
MPRINT(LOGREGANALY):   class ;
MPRINT(LOGREGANALY):   model snpdr=tgroup /risklimits;
MPRINT(LOGREGANALY):   run;

NOTE: PROC LOGISTIC is modeling the probability that SNPDR=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1210 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr=0;
NOTE: The PROCEDURE LOGISTIC printed pages 52-53.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.06 seconds
      cpu time            0.01 seconds


84        %logreganaly(pdr,,0);
MPRINT(LOGREGANALY):   proc logistic data=edic10re_analy descending;
MPRINT(LOGREGANALY):   where edicyr=0;
MPRINT(LOGREGANALY):   class ;
MPRINT(LOGREGANALY):   model pdr=tgroup /risklimits;
MPRINT(LOGREGANALY):   run;

NOTE: PROC LOGISTIC is modeling the probability that PDR=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1210 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr=0;
NOTE: The PROCEDURE LOGISTIC printed pages 54-55.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.10 seconds
      cpu time            0.04 seconds
```

```
85         %logreganaly(focalscat,,0);
MPRINT(LOGREGANALY):   proc logistic data=edic10re_analy descending;
MPRINT(LOGREGANALY):   where edicyr=0;
MPRINT(LOGREGANALY):   class ;
MPRINT(LOGREGANALY):   model focalscat=tgroup /risklimits;
MPRINT(LOGREGANALY):   run;

NOTE: PROC LOGISTIC is modeling the probability that FOCALSCAT=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1210 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr=0;
NOTE: The PROCEDURE LOGISTIC printed pages 56-57.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.15 seconds
      cpu time            0.01 seconds


86         %logreganaly(step3,dtclsetd ,4,dtclsetd);
MPRINT(LOGREGANALY):   proc logistic data=edic10re_analy descending;
MPRINT(LOGREGANALY):   where edicyr=4;
MPRINT(LOGREGANALY):   class dtclsetd;
MPRINT(LOGREGANALY):   model step3=tgroup dtclsetd/risklimits;
MPRINT(LOGREGANALY):   run;

NOTE: PROC LOGISTIC is modeling the probability that STEP3=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1103 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr=4;
NOTE: The PROCEDURE LOGISTIC printed pages 58-60.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.09 seconds
      cpu time            0.04 seconds


87         %logreganaly(snpdr,dtclsetd ,4,dtclsetd);
MPRINT(LOGREGANALY):   proc logistic data=edic10re_analy descending;
MPRINT(LOGREGANALY):   where edicyr=4;
MPRINT(LOGREGANALY):   class dtclsetd;
MPRINT(LOGREGANALY):   model snpdr=tgroup dtclsetd/risklimits;
MPRINT(LOGREGANALY):   run;

NOTE: PROC LOGISTIC is modeling the probability that SNPDR=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1103 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr=4;
NOTE: The PROCEDURE LOGISTIC printed pages 61-63.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.09 seconds
      cpu time            0.01 seconds


88         %logreganaly(pdr,dtclsetd ,4,dtclsetd);
```

```
MPRINT(LOGREGANALY):   proc logistic data=edic10re_analy descending;
MPRINT(LOGREGANALY):   where edicyr=4;
MPRINT(LOGREGANALY):   class dtclsetd;
MPRINT(LOGREGANALY):   model pdr=tgroup dtclsetd/risklimits;
MPRINT(LOGREGANALY):   run;

NOTE: PROC LOGISTIC is modeling the probability that PDR=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1103 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr=4;
NOTE: The PROCEDURE LOGISTIC printed pages 64-66.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.17 seconds
      cpu time            0.03 seconds


89         %logreganaly(focalscat,dtclsetd,4,dtclsetd);
MPRINT(LOGREGANALY):   proc logistic data=edic10re_analy descending;
MPRINT(LOGREGANALY):   where edicyr=4;
MPRINT(LOGREGANALY):   class dtclsetd;
MPRINT(LOGREGANALY):   model focalscat=tgroup dtclsetd/risklimits;
MPRINT(LOGREGANALY):   run;

NOTE: PROC LOGISTIC is modeling the probability that FOCALSCAT=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1103 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr=4;
NOTE: The PROCEDURE LOGISTIC printed pages 67-69.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.07 seconds
      cpu time            0.04 seconds


90         %logreganaly(step3,dtclsetd ,10,dtclsetd);
MPRINT(LOGREGANALY):   proc logistic data=edic10re_analy descending;
MPRINT(LOGREGANALY):   where edicyr=10;
MPRINT(LOGREGANALY):   class dtclsetd;
MPRINT(LOGREGANALY):   model step3=tgroup dtclsetd/risklimits;
MPRINT(LOGREGANALY):   run;

NOTE: PROC LOGISTIC is modeling the probability that STEP3=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1211 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr=10;
NOTE: The PROCEDURE LOGISTIC printed pages 70-72.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.07 seconds
      cpu time            0.03 seconds


91         %logreganaly(snpdr,dtclsetd ,10,dtclsetd);
MPRINT(LOGREGANALY):   proc logistic data=edic10re_analy descending;
MPRINT(LOGREGANALY):   where edicyr=10;
```

```
MPRINT(LOGREGANALY):   class dtclsetd;
MPRINT(LOGREGANALY):   model snpdr=tgroup dtclsetd/risklimits;
MPRINT(LOGREGANALY):   run;

NOTE: PROC LOGISTIC is modeling the probability that SNPDR=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1211 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr=10;
NOTE: The PROCEDURE LOGISTIC printed pages 73-75.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.06 seconds
      cpu time            0.04 seconds


92         %logreganaly(pdr,dtclsetd ,10,dtclsetd);
MPRINT(LOGREGANALY):   proc logistic data=edic10re_analy descending;
MPRINT(LOGREGANALY):   where edicyr=10;
MPRINT(LOGREGANALY):   class dtclsetd;
MPRINT(LOGREGANALY):   model pdr=tgroup dtclsetd/risklimits;
MPRINT(LOGREGANALY):   run;

NOTE: PROC LOGISTIC is modeling the probability that PDR=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1211 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr=10;
NOTE: The PROCEDURE LOGISTIC printed pages 76-78.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.09 seconds
      cpu time            0.03 seconds


93         %logreganaly(focalscat,dtclsetd,10,dtclsetd);
MPRINT(LOGREGANALY):   proc logistic data=edic10re_analy descending;
MPRINT(LOGREGANALY):   where edicyr=10;
MPRINT(LOGREGANALY):   class dtclsetd;
MPRINT(LOGREGANALY):   model focalscat=tgroup dtclsetd/risklimits;
MPRINT(LOGREGANALY):   run;

NOTE: PROC LOGISTIC is modeling the probability that FOCALSCAT=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1211 observations read from the data set WORK.EDIC10RE_ANALY.
      WHERE edicyr=10;
NOTE: The PROCEDURE LOGISTIC printed pages 79-81.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.07 seconds
      cpu time            0.04 seconds


94
95         proc sort data=edic10re_csme; by edicyr;

NOTE: There were 5910 observations read from the data set WORK.EDIC10RE_CSME.
NOTE: The data set WORK.EDIC10RE_CSME has 5910 observations and 60 variables.
```

```
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


96         proc freq data=edic10re_csme; by edicyr; tables csme*group/chisq exact; where
edicyr
96       ! in (0,4,10); run;

NOTE: There were 3416 observations read from the data set WORK.EDIC10RE_CSME.
      WHERE edicyr in (0, 4, 10);
NOTE: The PROCEDURE FREQ printed pages 82-87.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.25 seconds
      cpu time            0.01 seconds


97
98         proc logistic data=edic10re_csme descending; where edicyr=0;
99           model csme=tgroup/risklimits; run;

NOTE: PROC LOGISTIC is modeling the probability that CSME=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1173 observations read from the data set WORK.EDIC10RE_CSME.
      WHERE edicyr=0;
NOTE: The PROCEDURE LOGISTIC printed pages 88-89.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.04 seconds
      cpu time            0.03 seconds


100        proc logistic data=edic10re_csme descending; where edicyr=4;
101          class dtclsetd;
102          model csme=tgroup dtclsetd /risklimits; run;

NOTE: PROC LOGISTIC is modeling the probability that CSME=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1069 observations read from the data set WORK.EDIC10RE_CSME.
      WHERE edicyr=4;
NOTE: The PROCEDURE LOGISTIC printed pages 90-92.
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.04 seconds
      cpu time            0.03 seconds


103        proc logistic data=edic10re_csme descending; where edicyr=10;
104          class dtclsetd;
105          model csme=tgroup dtclsetd /risklimits; run;

NOTE: PROC LOGISTIC is modeling the probability that CSME=1.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: There were 1174 observations read from the data set WORK.EDIC10RE_CSME.
      WHERE edicyr=10;
NOTE: The PROCEDURE LOGISTIC printed pages 93-95.
```

```
NOTE: PROCEDURE LOGISTIC used (Total process time):
      real time           0.06 seconds
      cpu time            0.04 seconds


106
107        ********************************************************;
108        * to replicate table 3*;
109        title To Replicate Table 3;
110
111        title2 Part 1:  Further 3-step Progression;
112
113        * get indicators for participants with at least followup retinopathy assessment
113      ! during EDIC
114          (EDIC years 1+) *;
115        * variable edic3stf = Any further 3 STEP change through EDIC (0=n 1=y) *;
116        proc freq data=edic10re noprint; where edic3stf in (0,1); tables
116      ! mask_pat/out=stf_assess; run;

NOTE: There were 5177 observations read from the data set WORK.EDIC10RE.
      WHERE edic3stf in (0, 1);
NOTE: The data set WORK.STF_ASSESS has 1350 observations and 3 variables.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.04 seconds
      cpu time            0.03 seconds


117        proc freq data=edic10re noprint; where edic3stf=1; tables
117      ! mask_pat/out=stf_edic_further; run;

NOTE: There were 1199 observations read from the data set WORK.EDIC10RE.
      WHERE edic3stf=1;
NOTE: The data set WORK.STF_EDIC_FURTHER has 509 observations and 3 variables.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.28 seconds
      cpu time            0.00 seconds


118
119        proc sort data=edic10re; by mask_pat;

NOTE: Input data set is already sorted, no sorting done.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.00 seconds
      cpu time            0.00 seconds


120        data edic10re; merge edic10re stf_assess(in=in3 keep=mask_pat)
120      ! stf_edic_further(in=in4 keep=mask_pat);
121          by mask_pat;
122          * at least one followup EDIC retinopathy assessment (denominator, indicator
122      ! variable) *;
123          if in3 then stf_assess=1; else stf_assess=0;
```

```
124
125          * subjects with further 3 STEP change (numerator) *;
126          if in4 then anystffurther=1; else anystffurther=0; run;

NOTE: There were 6764 observations read from the data set WORK.EDIC10RE.
NOTE: There were 1350 observations read from the data set WORK.STF_ASSESS.
NOTE: There were 509 observations read from the data set WORK.STF_EDIC_FURTHER.
NOTE: The data set WORK.EDIC10RE has 6764 observations and 62 variables.
NOTE: DATA statement used (Total process time):
      real time           0.23 seconds
      cpu time            0.03 seconds


127
128        ********************************************************;
129          ********* below:  we get approximate #s for numerator and denominator in table
3,
130                    further 3-step progression *********;
131          * #s at risk ... anyone with at least one followup STF assessment *;
132        proc freq data=edic10re; tables dtclsetd*group;
133          where DCCTSCAT=0 /* eliminate those with DCCT scatter */ AND STF_ASSESS=1
134          AND EDICYR=0; run;

NOTE: There were 1350 observations read from the data set WORK.EDIC10RE.
      WHERE (DCCTSCAT=0) and (STF_ASSESS=1) and (EDICYR=0);
NOTE: The PROCEDURE FREQ printed page 96.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.07 seconds
      cpu time            0.00 seconds


135
136          * #s with event *;
137        proc sort data=edic10re; by dtclsetd;

NOTE: There were 6764 observations read from the data set WORK.EDIC10RE.
NOTE: The data set WORK.EDIC10RE has 6764 observations and 62 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.04 seconds
      cpu time            0.03 seconds


138        proc freq data=edic10re; by dtclsetd; tables anystffurther*group;
139          where DCCTSCAT=0 /* eliminate those with DCCT scatter */ AND STF_ASSESS=1
140          AND EDICYR=0; run;

NOTE: There were 1350 observations read from the data set WORK.EDIC10RE.
      WHERE (DCCTSCAT=0) and (STF_ASSESS=1) and (EDICYR=0);
NOTE: The PROCEDURE FREQ printed pages 97-100.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.04 seconds
      cpu time            0.03 seconds
```

```
141
142        ************************************************************;
143          * create basic survival dataset for Further 3-step Progression *;
144        proc sort data=edic10re; by mask_pat edicyr;

NOTE: There were 6764 observations read from the data set WORK.EDIC10RE.
NOTE: The data set WORK.EDIC10RE has 6764 observations and 62 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


145        data base followup; set edic10re; by mask_pat edicyr;
146          if edicyr=0 then output base;
147          else if edicyr>0 AND edic3stf IN (0,1) then output followup; run;

NOTE: There were 6764 observations read from the data set WORK.EDIC10RE.
NOTE: The data set WORK.BASE has 1423 observations and 62 variables.
NOTE: The data set WORK.FOLLOWUP has 5177 observations and 62 variables.
NOTE: DATA statement used (Total process time):
      real time           0.03 seconds
      cpu time            0.01 seconds


148
149        data event noevent; set followup; if anystffurther=1 then output event;
150          else if anystffurther=0 then output noevent;
151          * EDIC3SFD (first event date) pops up when the event
152            actually happened (edic3stf=1), and then doesnt change *;

NOTE: There were 5177 observations read from the data set WORK.FOLLOWUP.
NOTE: The data set WORK.EVENT has 1980 observations and 62 variables.
NOTE: The data set WORK.NOEVENT has 3197 observations and 62 variables.
NOTE: DATA statement used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


153        data event; set event;
154          IF edic3stf=1;

NOTE: There were 1980 observations read from the data set WORK.EVENT.
NOTE: The data set WORK.EVENT has 1199 observations and 62 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


155        data event; set event;
156          ** if edic3sfd=fsasdate; * cant do it this way, wont pick up all events
(fsasdate
156      ! doesnt always match) *;
157          by mask_pat edicyr;
158          if first.mask_pat; run;
```

```
NOTE: There were 1199 observations read from the data set WORK.EVENT.
NOTE: The data set WORK.EVENT has 509 observations and 62 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


158      !                           * first visit with incident for those with event *;
159        /*  proc compare data=event; var edic3sfd; with fsasdate; run;
160            ** should always be the same? (it isn't always) */
161        data noevent; set noevent;
162          by mask_pat edicyr;
163          if last.mask_pat; run;

NOTE: There were 3197 observations read from the data set WORK.NOEVENT.
NOTE: The data set WORK.NOEVENT has 841 observations and 62 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.00 seconds


163      !                          * last visit for those who were event free, and had f/u
163      ! assessment taken *;
164        data survival; set event(in=in1) noevent(in=in2);
165          by mask_pat;
166          if in1 then do; event=1; lastdate=edic3sfd; end;
167          else if in2 then do; event=0; lastdate=fsasdate; end;
168          rename edicyr=lastedicyr; run;

NOTE: There were 509 observations read from the data set WORK.EVENT.
NOTE: There were 841 observations read from the data set WORK.NOEVENT.
NOTE: The data set WORK.SURVIVAL has 1350 observations and 64 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


169          * check:  frequencies are exactly the same *;
170        /*  proc freq; tables event*edic3stf/missing; run; */
171        data survival; merge survival(in=in1) base(keep=mask_pat fsasdate
171      ! rename=(fsasdate=edicbsdt))
172          edic10retab(keep=mask_pat hbael retbase dtclsetd);
173          by mask_pat;
174          if in1;
175          survdays=lastdate-edicbsdt; * all dates are represented as days since DCCT
175      ! randomization *;
176          if (lastdate=. or edicbsdt=.) then do; misslastdate=1;
survdays=lastedicyr*365.25;
176      ! end;
177          survyrs=round((survdays/365.25),0.01);
178          if retbase='PRIM' then retstratum=1; else if retbase='SCND' then retstratum=0;
run;

NOTE: Missing values were generated as a result of performing an operation on missing
values.
```

```
      Each place is given by: (Number of times) at (Line):(Column).
      1 at 175:20
NOTE: There were 1350 observations read from the data set WORK.SURVIVAL.
NOTE: There were 1423 observations read from the data set WORK.BASE.
NOTE: There were 1211 observations read from the data set WORK.EDIC10RETAB.
NOTE: The data set WORK.SURVIVAL has 1350 observations and 69 variables.
NOTE: DATA statement used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


179
180          proc freq; tables event*group; run;

NOTE: There were 1350 observations read from the data set WORK.SURVIVAL.
NOTE: The PROCEDURE FREQ printed page 101.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.07 seconds
      cpu time            0.03 seconds


181          proc print; where misslastdate=1; var survyrs lastedicyr lastdate event; run;

NOTE: There were 1 observations read from the data set WORK.SURVIVAL.
      WHERE misslastdate=1;
NOTE: The PROCEDURE PRINT printed page 102.
NOTE: PROCEDURE PRINT used (Total process time):
      real time           0.00 seconds
      cpu time            0.00 seconds


182               *n=1, did not reach outcome, lastdate missing *;
183          proc sort; by dtclsetd;

NOTE: There were 1350 observations read from the data set WORK.SURVIVAL.
NOTE: The data set WORK.SURVIVAL has 1350 observations and 69 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


184          proc freq; tables event*group; by dtclsetd; run;

NOTE: There were 1350 observations read from the data set WORK.SURVIVAL.
NOTE: The PROCEDURE FREQ printed pages 103-106.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.04 seconds
      cpu time            0.01 seconds


185          proc freq; tables DCCTSCAT; run;

NOTE: There were 1350 observations read from the data set WORK.SURVIVAL.
```

```
NOTE: The PROCEDURE FREQ printed page 107.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.00 seconds
      cpu time            0.00 seconds


185      !                                    *n=0. evidently programming this way
eliminates
186             those with DCCTSCAT=1 (those with DCCT scatter),
187            maybe because all missing <edic3stf> were eliminated *;
188
189        ************** to get survival/hazard/hazard reduction
**************************;
190        proc lifereg data=survival;
191          model survyrs*event(0)=tgroup/distribution=weibull; run;

NOTE: Algorithm converged.
NOTE: The PROCEDURE LIFEREG printed page 108.
NOTE: PROCEDURE LIFEREG used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


192        proc sort; by dtclsetd;

NOTE: Input data set is already sorted, no sorting done.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.00 seconds
      cpu time            0.00 seconds


193        proc lifereg data=survival; by dtclsetd;
194          model survyrs*event(0)=tgroup/distribution=weibull; run;

NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      DCCT closeout ETDRS level comb DCCT10-DCCT50=1
NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      DCCT closeout ETDRS level comb DCCT10-DCCT50=2
NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      DCCT closeout ETDRS level comb DCCT10-DCCT50=3
NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      DCCT closeout ETDRS level comb DCCT10-DCCT50=4
NOTE: The PROCEDURE LIFEREG printed pages 109-112.
NOTE: PROCEDURE LIFEREG used (Total process time):
      real time           0.18 seconds
      cpu time            0.01 seconds


195
196
197        ************** to get adjusted survival/hazard/hazard reduction
```

```
197      ! ************************;
198        proc lifereg data=survival; class dtclsetd;
199          model survyrs*event(0)=tgroup retstratum hbael duryr0
dtclsetd/distribution=weibull
199      ! ; run;

NOTE: Algorithm converged.
NOTE: The PROCEDURE LIFEREG printed pages 113-114.
NOTE: PROCEDURE LIFEREG used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


200        proc sort data=survival; by dtclsetd;

NOTE: Input data set is already sorted, no sorting done.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.00 seconds
      cpu time            0.00 seconds


201        proc lifereg data=survival; by dtclsetd;
202          model survyrs*event(0)=tgroup retstratum hbael duryr0/distribution=weibull;
run;

NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      DCCT closeout ETDRS level comb DCCT10-DCCT50=1
NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      DCCT closeout ETDRS level comb DCCT10-DCCT50=2
NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      DCCT closeout ETDRS level comb DCCT10-DCCT50=3
NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      DCCT closeout ETDRS level comb DCCT10-DCCT50=4
NOTE: The PROCEDURE LIFEREG printed pages 115-122.
NOTE: PROCEDURE LIFEREG used (Total process time):
      real time           0.21 seconds
      cpu time            0.03 seconds


203
204
205
206        title To Replicate Table 3;
207
208        title2 Part 2:  PDR;
209
210        ************************************************************;
211        * get indicators for participants with at least followup PDR assessment during
EDIC
212          (EDIC years 1+) *;
213        /*  proc print data=edic10re; by mask_pat; var edicyr anypdr anypdrd fsasdate
dcctpdr
```

```
213       ! ; run; */
```

```
214          * dcctpdr is a subject indicator, it doesnt change through time *;
215          * also, anypdr is populated at baseline, unlike edic3stf *;
216
217        data edic10_nodcpdr; set edic10re; if dcctpdr^=1;
218          if anypdr in (0,1); run;

NOTE: There were 6764 observations read from the data set WORK.EDIC10RE.
NOTE: The data set WORK.EDIC10_NODCPDR has 6373 observations and 62 variables.
NOTE: DATA statement used (Total process time):
      real time           0.03 seconds
      cpu time            0.01 seconds


219          proc sort; by mask_pat edicyr;

NOTE: There were 6373 observations read from the data set WORK.EDIC10_NODCPDR.
NOTE: The data set WORK.EDIC10_NODCPDR has 6373 observations and 62 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.07 seconds
      cpu time            0.03 seconds


220        data base; set edic10_nodcpdr; by mask_pat edicyr;
221          if first.mask_pat; run;

NOTE: There were 6373 observations read from the data set WORK.EDIC10_NODCPDR.
NOTE: The data set WORK.BASE has 1348 observations and 62 variables.
NOTE: DATA statement used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


222        data base; set base;
223          if edicyr=0; run;

NOTE: There were 1348 observations read from the data set WORK.BASE.
NOTE: The data set WORK.BASE has 1345 observations and 62 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.00 seconds


224        data edic10_nodcpdr; set edic10_nodcpdr; by mask_pat edicyr;
225          if first.mask_pat and last.mask_pat then flag=1; else flag=0; run;

NOTE: There were 6373 observations read from the data set WORK.EDIC10_NODCPDR.
NOTE: The data set WORK.EDIC10_NODCPDR has 6373 observations and 63 variables.
NOTE: DATA statement used (Total process time):
      real time           0.04 seconds
      cpu time            0.03 seconds


226        data edic10_nodcpdr; set edic10_nodcpdr; if flag=0; run;
```

```
NOTE: There were 6373 observations read from the data set WORK.EDIC10_NODCPDR.
NOTE: The data set WORK.EDIC10_NODCPDR has 6339 observations and 63 variables.
NOTE: DATA statement used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


227        data edic10_nodcpdr; merge edic10_nodcpdr(in=in1) base(in=in2 keep=mask_pat);
228          by mask_pat;
229          if in1 and in2; run;

NOTE: There were 6339 observations read from the data set WORK.EDIC10_NODCPDR.
NOTE: There were 1345 observations read from the data set WORK.BASE.
NOTE: The data set WORK.EDIC10_NODCPDR has 6331 observations and 63 variables.
NOTE: DATA statement used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


230
231        proc freq data=edic10_nodcpdr noprint; where anypdr=1; tables
mask_pat/out=pdr_edic;
231      ! run;

NOTE: There were 365 observations read from the data set WORK.EDIC10_NODCPDR.
      WHERE anypdr=1;
NOTE: The data set WORK.PDR_EDIC has 164 observations and 3 variables.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


232
233        data edic10_nodcpdr; merge edic10_nodcpdr pdr_edic(in=in4 keep=mask_pat);
234          by mask_pat;
235
236          * subjects with PDR during EDIC followup (numerator) *;
237          if in4 then pdr_edic=1; else pdr_edic=0; run;

NOTE: There were 6331 observations read from the data set WORK.EDIC10_NODCPDR.
NOTE: There were 164 observations read from the data set WORK.PDR_EDIC.
NOTE: The data set WORK.EDIC10_NODCPDR has 6331 observations and 64 variables.
NOTE: DATA statement used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


238
239        ********************************************************;
240          ********* below:  we get approximate #s for numerator and denominator in table
3,
241                    PDR during EDIC *********;
242          * #s at risk ... anyone with at least one followup PDR assessment *;
243        proc freq data=edic10_nodcpdr; tables dtclsetd*group/missing;
```

```
244          where EDICYR=0; run;

NOTE: There were 1312 observations read from the data set WORK.EDIC10_NODCPDR.
      WHERE EDICYR=0;
NOTE: The PROCEDURE FREQ printed page 123.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.01 seconds
      cpu time            0.00 seconds


245
246          * #s with event *;
247        proc sort data=edic10_nodcpdr; by dtclsetd;

NOTE: There were 6331 observations read from the data set WORK.EDIC10_NODCPDR.
NOTE: The data set WORK.EDIC10_NODCPDR has 6331 observations and 64 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.03 seconds
      cpu time            0.01 seconds


248        proc freq data=edic10_nodcpdr; tables pdr_edic*group;
249          where EDICYR=0; run;

NOTE: There were 1312 observations read from the data set WORK.EDIC10_NODCPDR.
      WHERE EDICYR=0;
NOTE: The PROCEDURE FREQ printed page 124.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.04 seconds
      cpu time            0.01 seconds


250        proc freq data=edic10_nodcpdr; by dtclsetd; tables pdr_edic*group; run;

NOTE: There were 6331 observations read from the data set WORK.EDIC10_NODCPDR.
NOTE: The PROCEDURE FREQ printed pages 125-129.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.03 seconds
      cpu time            0.01 seconds


251
252          ************************************************************;
253          * create basic survival dataset for PDR *;
254        proc sort data=edic10_nodcpdr; by mask_pat edicyr;

NOTE: There were 6331 observations read from the data set WORK.EDIC10_NODCPDR.
NOTE: The data set WORK.EDIC10_NODCPDR has 6331 observations and 64 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.04 seconds
      cpu time            0.01 seconds
```

```
255        data event noevent; set edic10_nodcpdr; if pdr_edic=1 then output event;
256          else if pdr_edic=0 then output noevent;

NOTE: There were 6331 observations read from the data set WORK.EDIC10_NODCPDR.
NOTE: The data set WORK.EVENT has 798 observations and 64 variables.
NOTE: The data set WORK.NOEVENT has 5533 observations and 64 variables.
NOTE: DATA statement used (Total process time):
      real time           0.04 seconds
      cpu time            0.01 seconds


257        data event; set event;
258          IF anypdr=1;

NOTE: There were 798 observations read from the data set WORK.EVENT.
NOTE: The data set WORK.EVENT has 365 observations and 64 variables.
NOTE: DATA statement used (Total process time):
      real time           0.00 seconds
      cpu time            0.00 seconds


259        data event; set event;
260          by mask_pat edicyr;
261          if first.mask_pat; run;

NOTE: There were 365 observations read from the data set WORK.EVENT.
NOTE: The data set WORK.EVENT has 164 observations and 64 variables.
NOTE: DATA statement used (Total process time):
      real time           0.00 seconds
      cpu time            0.00 seconds


261      !                           * first visit with incident for those with event *;
262        /*  proc compare data=event; var anypdrd; with fsasdate; run;
263            ** not always the same */
264        data noevent; set noevent;
265          by mask_pat edicyr;
266          if last.mask_pat; run;

NOTE: There were 5533 observations read from the data set WORK.NOEVENT.
NOTE: The data set WORK.NOEVENT has 1148 observations and 64 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.00 seconds


266      !                          * last visit for those who were event free, and had f/u
266      ! assessment taken *;
267        data survival_pdr; set event(in=in1) noevent(in=in2);
268          by mask_pat;
269          if in1 then do; event=1; lastdate=anypdrd; end;
270          else if in2 then do; event=0; lastdate=fsasdate; end;
271          rename edicyr=lastedicyr; run;
```

```
NOTE: There were 164 observations read from the data set WORK.EVENT.
NOTE: There were 1148 observations read from the data set WORK.NOEVENT.
NOTE: The data set WORK.SURVIVAL_PDR has 1312 observations and 66 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


272          * check:  frequencies are exactly the same *;
273        /*  proc freq; tables event*anypdr/missing; run; */
274        data survival_pdr; merge survival_pdr(in=in1) base(keep=mask_pat fsasdate
274      ! rename=(fsasdate=edicbsdt))
275          edic10retab(keep=mask_pat hbael retbase dtclsetd);
276          by mask_pat;
277          if in1;
278          survdays=lastdate-edicbsdt;
279          if (lastdate=. or edicbsdt=.) then do; misslastdate=1;
survdays=lastedicyr*365.25;
279      ! end;
280          survyrs=round((survdays/365.25),0.01);
281          if retbase='PRIM' then retstratum=1; else if retbase='SCND' then retstratum=0;
run;

NOTE: Missing values were generated as a result of performing an operation on missing
values.
      Each place is given by: (Number of times) at (Line):(Column).
      1 at 278:20
NOTE: There were 1312 observations read from the data set WORK.SURVIVAL_PDR.
NOTE: There were 1345 observations read from the data set WORK.BASE.
NOTE: There were 1211 observations read from the data set WORK.EDIC10RETAB.
NOTE: The data set WORK.SURVIVAL_PDR has 1312 observations and 71 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


282
283          proc freq; tables event*group; run;

NOTE: There were 1312 observations read from the data set WORK.SURVIVAL_PDR.
NOTE: The PROCEDURE FREQ printed page 130.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.04 seconds
      cpu time            0.00 seconds


284          proc print; where misslastdate=1; var survyrs lastedicyr lastdate event; run;

NOTE: There were 1 observations read from the data set WORK.SURVIVAL_PDR.
      WHERE misslastdate=1;
NOTE: The PROCEDURE PRINT printed page 131.
NOTE: PROCEDURE PRINT used (Total process time):
      real time           0.00 seconds
      cpu time            0.00 seconds
```

```
285              *n=1, did not reach outcome, lastdate missing *;
286          proc sort; by dtclsetd;

NOTE: There were 1312 observations read from the data set WORK.SURVIVAL_PDR.
NOTE: The data set WORK.SURVIVAL_PDR has 1312 observations and 71 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.03 seconds
      cpu time            0.00 seconds


287          proc freq; tables event*group; by dtclsetd; run;

NOTE: There were 1312 observations read from the data set WORK.SURVIVAL_PDR.
NOTE: The PROCEDURE FREQ printed pages 132-136.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.01 seconds
      cpu time            0.00 seconds


288          proc freq; tables DCCTSCAT; run;

NOTE: There were 1312 observations read from the data set WORK.SURVIVAL_PDR.
NOTE: The PROCEDURE FREQ printed page 137.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


288      !                                    *n=0. evidently programming this way
eliminates
289             those with DCCTSCAT=1 (those with DCCT scatter),
290            maybe because all missing <edic3stf> were eliminated *;
291
292        ************** to get survival/hazard/hazard reduction
**************************;
293        proc lifereg data=survival_pdr;
294          model survyrs*event(0)=tgroup/distribution=weibull; run;

NOTE: Algorithm converged.
NOTE: The PROCEDURE LIFEREG printed page 138.
NOTE: PROCEDURE LIFEREG used (Total process time):
      real time           0.03 seconds
      cpu time            0.01 seconds


295        data survival_pdr; set survival_pdr;
296          dtclsetd_cut3=dtclsetd;
297          if dtclsetd in (1,2) then dtclsetd_cut3=1;

NOTE: There were 1312 observations read from the data set WORK.SURVIVAL_PDR.
NOTE: The data set WORK.SURVIVAL_PDR has 1312 observations and 72 variables.
NOTE: DATA statement used (Total process time):
      real time           0.20 seconds
      cpu time            0.01 seconds
```

```
298          proc freq; tables dtclsetd*dtclsetd_cut3; run;

NOTE: There were 1312 observations read from the data set WORK.SURVIVAL_PDR.
NOTE: The PROCEDURE FREQ printed page 139.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.04 seconds
      cpu time            0.01 seconds


299        proc sort; by dtclsetd_cut3;

NOTE: There were 1312 observations read from the data set WORK.SURVIVAL_PDR.
NOTE: The data set WORK.SURVIVAL_PDR has 1312 observations and 72 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


300        proc lifereg data=survival_pdr; by dtclsetd_cut3;
301          model survyrs*event(0)=tgroup/distribution=weibull; run;

WARNING: The negative of the Hessian is not positive definite. The convergence is
questionable.
WARNING: The procedure is continuing in spite of the above warning. Results shown are based
on
         the last maximum likelihood iteration. Validity of the model fit is questionable.
NOTE: The above message was for the following BY group:
      dtclsetd_cut3=.
NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      dtclsetd_cut3=1
NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      dtclsetd_cut3=3
NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      dtclsetd_cut3=4
NOTE: The PROCEDURE LIFEREG printed pages 140-143.
NOTE: PROCEDURE LIFEREG used (Total process time):
      real time           0.34 seconds
      cpu time            0.01 seconds


302
303
304        ************** to get adjusted survival/hazard/hazard reduction
304      ! *************************;
305        proc lifereg data=survival_pdr; class dtclsetd_cut3;
306          model survyrs*event(0)=tgroup dtclsetd_cut3 retstratum hbael
306      ! duryr0/distribution=weibull; run;

NOTE: Algorithm converged.
NOTE: The PROCEDURE LIFEREG printed pages 144-145.
```

```
NOTE: PROCEDURE LIFEREG used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


307        proc sort; by dtclsetd_cut3;

NOTE: Input data set is already sorted, no sorting done.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.00 seconds
      cpu time            0.00 seconds


308        proc lifereg data=survival_pdr; by dtclsetd_cut3;
309          model survyrs*event(0)=tgroup retstratum hbael duryr0/distribution=weibull;
run;

WARNING: The negative of the Hessian is not positive definite. The convergence is
questionable.
WARNING: The procedure is continuing in spite of the above warning. Results shown are based
on
         the last maximum likelihood iteration. Validity of the model fit is questionable.
NOTE: The above message was for the following BY group:
      dtclsetd_cut3=.
NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      dtclsetd_cut3=1
NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      dtclsetd_cut3=3
NOTE: Algorithm converged.
NOTE: The above message was for the following BY group:
      dtclsetd_cut3=4
NOTE: The PROCEDURE LIFEREG printed pages 146-152.
NOTE: PROCEDURE LIFEREG used (Total process time):
      real time           0.26 seconds
      cpu time            0.04 seconds


310
311
312
313
314

NOTE: SAS Institute Inc., SAS Campus Drive, Cary, NC USA 27513-2414
NOTE: The SAS System used:
      real time           39.02 seconds
      cpu time            3.71 seconds
```

Attachment 3

SAS version 9.2 Log
for programming code submitted for
the replication of results in
Archives of Ophthalmology, Vol 126(12), Dec 2008,
pp. 1707-1715

The FREQ Procedure

GROUP Treatment Group (EXPERIMENTAL STANDARD)

GROUP	Frequency	Percent	Cumulative Frequency	Cumulative Percent
EXPERIMENTAL	596	49.22	596	49.22
STANDARD	615	50.78	1211	100.00

The FREQ Procedure

Table of SEX by GROUP

SEX(SEX Sex (F M))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
F	295 24.36 50.77 49.50	286 23.62 49.23 46.50	581 47.98
M	301 24.86 47.78 50.50	329 27.17 52.22 53.50	630 52.02
Total	596 49.22	615 50.78	1211 100.00

Statistics for Table of SEX by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	1.0860	0.2974
Likelihood Ratio Chi-Square	1	1.0862	0.2973
Continuity Adj. Chi-Square	1	0.9694	0.3248
Mantel-Haenszel Chi-Square	1	1.0851	0.2976
Phi Coefficient		0.0299	
Contingency Coefficient		0.0299	
Cramer's V		0.0299	

Fisher's Exact Test

Cell (1,1) Frequency (F)	295
Left-sided Pr <= F	0.8643
Right-sided Pr >= F	0.1624
Table Probability (P)	0.0267
Two-sided Pr <= P	0.3011

Sample Size = 1211

The FREQ Procedure

Table of RETBASE by GROUP

RETBASE(RETBASE RETINOPATHY AT BASELINE (PRIM SCND))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
PRIM	293 24.19 48.19 49.16	315 26.01 51.81 51.22	608 50.21
SCND	303 25.02 50.25 50.84	300 24.77 49.75 48.78	603 49.79
Total	596 49.22	615 50.78	1211 100.00

Statistics for Table of RETBASE by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	0.5130	0.4738
Likelihood Ratio Chi-Square	1	0.5130	0.4738
Continuity Adj. Chi-Square	1	0.4340	0.5100
Mantel-Haenszel Chi-Square	1	0.5126	0.4740
Phi Coefficient		-0.0206	
Contingency Coefficient		0.0206	
Cramer's V		-0.0206	

Fisher's Exact Test

Cell (1,1) Frequency (F)	293
Left-sided Pr <= F	0.2550
Right-sided Pr >= F	0.7804
Table Probability (P)	0.0355
Two-sided Pr <= P	0.4906

Sample Size = 1211

The FREQ Procedure

Table of MDI99 by GROUP

MDI99(MDI99 Pump or MDI @ DCCT closeout (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	12 0.99 2.02 2.01	583 48.18 97.98 94.95	595 49.17
1	584 48.26 94.96 97.99	31 2.56 5.04 5.05	615 50.83
Total	596 49.26	614 50.74	1210 100.00

Frequency Missing = 1

The FREQ Procedure

Statistics for Table of MDI99 by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	1045.1820	<.0001
Likelihood Ratio Chi-Square	1	1314.0605	<.0001
Continuity Adj. Chi-Square	1	1041.4668	<.0001
Mantel-Haenszel Chi-Square	1	1044.3182	<.0001
Phi Coefficient		-0.9294	
Contingency Coefficient		0.6808	
Cramer's V		-0.9294	

Fisher's Exact Test

Cell (1,1) Frequency (F)	12
Left-sided Pr <= F	1.673E-286
Right-sided Pr >= F	1.0000
Table Probability (P)	1.671E-286
Two-sided Pr <= P	1.806E-286

Effective Sample Size = 1210
Frequency Missing = 1

The FREQ Procedure

Table of GLUC499 by GROUP

GLUC499(GLUC499 BGSM >=4 times a day @ DCCT Close (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	276 22.81 31.91 46.31	589 48.68 68.09 95.93	865 71.49
1	320 26.45 92.75 53.69	25 2.07 7.25 4.07	345 28.51
Total	596 49.26	614 50.74	1210 100.00

Frequency Missing = 1

The FREQ Procedure

Statistics for Table of GLUC499 by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	365.3184	<.0001
Likelihood Ratio Chi-Square	1	414.4973	<.0001
Continuity Adj. Chi-Square	1	362.8881	<.0001
Mantel-Haenszel Chi-Square	1	365.0165	<.0001
Phi Coefficient		-0.5495	
Contingency Coefficient		0.4816	
Cramer's V		-0.5495	

Fisher's Exact Test

Cell (1,1) Frequency (F)	276
Left-sided Pr <= F	1.070E-91
Right-sided Pr >= F	1.0000
Table Probability (P)	1.031E-91
Two-sided Pr <= P	1.785E-91

Effective Sample Size = 1210
Frequency Missing = 1

Table of LIPFLG by GROUP

LIPFLG(LIPFLG HYPERLIPIDEMIA EVER (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	553 45.66 50.14 92.79	550 45.42 49.86 89.43	1103 91.08
1	43 3.55 39.81 7.21	65 5.37 60.19 10.57	108 8.92
Total	596 49.22	615 50.78	1211 100.00

The FREQ Procedure

Statistics for Table of LIPFLG by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	4.1926	0.0406
Likelihood Ratio Chi-Square	1	4.2230	0.0399
Continuity Adj. Chi-Square	1	3.7898	0.0516
Mantel-Haenszel Chi-Square	1	4.1891	0.0407
Phi Coefficient		0.0588	
Contingency Coefficient		0.0587	
Cramer's V		0.0588	

Fisher's Exact Test

Cell (1,1) Frequency (F)	553
Left-sided Pr <= F	0.9844
Right-sided Pr >= F	0.0255
Table Probability (P)	0.0099
Two-sided Pr <= P	0.0438

Sample Size = 1211

The FREQ Procedure

Table of MDI10 by GROUP

MDI10(MDI10 Pump or MDI @ EDIC Yr 10 (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	20 1.71 30.30 3.44	46 3.92 69.70 7.78	66 5.63
1	561 47.87 50.72 96.56	545 46.50 49.28 92.22	1106 94.37
Total	581 49.57	591 50.43	1172 100.00

Frequency Missing = 39

The FREQ Procedure

Statistics for Table of MDI10 by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	10.3893	0.0013
Likelihood Ratio Chi-Square	1	10.6714	0.0011
Continuity Adj. Chi-Square	1	9.5885	0.0020
Mantel-Haenszel Chi-Square	1	10.3805	0.0013
Phi Coefficient		-0.0942	
Contingency Coefficient		0.0937	
Cramer's V		-0.0942	

Fisher's Exact Test

Cell (1,1) Frequency (F)	20
Left-sided Pr <= F	8.711E-04
Right-sided Pr >= F	0.9997
Table Probability (P)	5.273E-04
Two-sided Pr <= P	0.0014

Effective Sample Size = 1172
Frequency Missing = 39

The FREQ Procedure

Table of GLUC410 by GROUP

GLUC410(GLUC410 BGSM >=4 times a day @ EDIC YR 10 (0=n 1=y .U=uncertain))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	267 22.96 54.16 46.35	226 19.43 45.84 38.50	493 42.39
1	309 26.57 46.12 53.65	361 31.04 53.88 61.50	670 57.61
Total	576 49.53	587 50.47	1163 100.00

Frequency Missing = 48

The FREQ Procedure

Statistics for Table of GLUC410 by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	7.3422	0.0067
Likelihood Ratio Chi-Square	1	7.3495	0.0067
Continuity Adj. Chi-Square	1	7.0241	0.0080
Mantel-Haenszel Chi-Square	1	7.3359	0.0068
Phi Coefficient		0.0795	
Contingency Coefficient		0.0792	
Cramer's V		0.0795	

Fisher's Exact Test

Cell (1,1) Frequency (F)	267
Left-sided Pr <= F	0.9972
Right-sided Pr >= F	0.0040
Table Probability (P)	0.0012
Two-sided Pr <= P	0.0076

Effective Sample Size = 1163
Frequency Missing = 48

The FREQ Procedure

Table of DTCLSETD by GROUP

DTCLSETD(DTCLSETD DCCT closeout ETDRS level comb DCCT10-DCCT50)

GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
1	170 14.06 60.93 28.52	109 9.02 39.07 17.78	279 23.08
2	237 19.60 54.99 39.77	194 16.05 45.01 31.65	431 35.65
3	128 10.59 42.95 21.48	170 14.06 57.05 27.73	298 24.65
4	61 5.05 30.35 10.23	140 11.58 69.65 22.84	201 16.63
Total	596 49.30	613 50.70	1209 100.00

Frequency Missing = 2

The FREQ Procedure

Statistics for Table of DTCLSETD by GROUP

Statistic	DF	Value	Prob
Chi-Square	3	54.3679	<.0001
Likelihood Ratio Chi-Square	3	55.3457	<.0001
Mantel-Haenszel Chi-Square	1	52.6774	<.0001
Phi Coefficient		0.2121	
Contingency Coefficient		0.2074	
Cramer's V		0.2121	

Fisher's Exact Test

Table Probability (P)	2.249E-16
Pr <= P	6.286E-12

Effective Sample Size = 1209
Frequency Missing = 2

Table of ANYSCAT by GROUP

ANYSCAT(ANYSCAT Any SCATTER DCCT/EDIC to date (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	586	590	1176
	48.39	48.72	97.11
	49.83	50.17	
	98.32	95.93	
1	10	25	35
	0.83	2.06	2.89
	28.57	71.43	
	1.68	4.07	
Total	596	615	1211
	49.22	50.78	100.00

The FREQ Procedure

Statistics for Table of ANYSCAT by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	6.1456	0.0132
Likelihood Ratio Chi-Square	1	6.3569	0.0117
Continuity Adj. Chi-Square	1	5.3245	0.0210
Mantel-Haenszel Chi-Square	1	6.1405	0.0132
Phi Coefficient		0.0712	
Contingency Coefficient		0.0711	
Cramer's V		0.0712	

Fisher's Exact Test

Cell (1,1) Frequency (F)	586
Left-sided Pr <= F	0.9965
Right-sided Pr >= F	0.0098
Table Probability (P)	0.0062
Two-sided Pr <= P	0.0156

Sample Size = 1211

Table of ANYFOCA by GROUP

ANYFOCA(ANYFOCA Any FOCAL DCCT/EDIC to date (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	583 48.14 50.04 97.82	582 48.06 49.96 94.63	1165 96.20
1	13 1.07 28.26 2.18	33 2.73 71.74 5.37	46 3.80
Total	596 49.22	615 50.78	1211 100.00

The FREQ Procedure

Statistics for Table of ANYFOCA by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	8.4005	0.0038
Likelihood Ratio Chi-Square	1	8.6955	0.0032
Continuity Adj. Chi-Square	1	7.5516	0.0060
Mantel-Haenszel Chi-Square	1	8.3935	0.0038
Phi Coefficient		0.0833	
Contingency Coefficient		0.0830	
Cramer's V		0.0833	

Fisher's Exact Test

Cell (1,1) Frequency (F)	583
Left-sided Pr <= F	0.9990
Right-sided Pr >= F	0.0027
Table Probability (P)	0.0017
Two-sided Pr <= P	0.0040

Sample Size = 1211

The MEANS Procedure

GROUP Treatment Group (EXPERIMENTAL STANDARD)	N Obs	Variable	Label	Mean
EXPERIMENTAL	596	AGE0	AGE0 AGE at DCCT baseline (years)	27.2
		DURYR0	DURYR0 IDDM duration (years): DCCT baseline	6.0
		HBAEL	HBAEL HBA1c at DCCT eligibility (%)	9.1
		AGE99	AGE99 AGE at DCCT closeout (years)	33.6
		DURYR99	DURYR99 IDDM duration (years): DCCT Closeout	12.2
		DCCTYEAR	DCCTYEAR Time on randomized treatment (Yr)	6.4
		HBA99	HBA99 HBA1c at DCCT closeout (%)	7.4
		MBP99	MBP99 Mean BP (CloseOut, F021)	88.7
STANDARD	615	AGE0	AGE0 AGE at DCCT baseline (years)	26.6
		DURYR0	DURYR0 IDDM duration (years): DCCT baseline	5.7
		HBAEL	HBAEL HBA1c at DCCT eligibility (%)	9.0
		AGE99	AGE99 AGE at DCCT closeout (years)	32.9
		DURYR99	DURYR99 IDDM duration (years): DCCT Closeout	11.8
		DCCTYEAR	DCCTYEAR Time on randomized treatment (Yr)	6.3
		HBA99	HBA99 HBA1c at DCCT closeout (%)	9.1
		MBP99	MBP99 Mean BP (CloseOut, F021)	88.2

GROUP Treatment Group (EXPERIMENTAL STANDARD)	N Obs	Variable	Label	Std Dev
EXPERIMENTAL	596	AGE0	AGE0 AGE at DCCT baseline (years)	7.0

		DURYR0	DURYR0	IDDM duration (years): DCCT baseline
4.2				
		HBAEL	HBAEL	HBA1c at DCCT eligibility (%)
1.6				
		AGE99	AGE99	AGE at DCCT closeout (years)
6.8				
		DURYR99	DURYR99	IDDM duration (years): DCCT Closeout
4.9				
		DCCTYEAR	DCCTYEAR	Time on randomized treatment (Yr)
1.7				
		HBA99	HBA99	HBA1c at DCCT closeout (%)
1.0				
		MBP99	MBP99	Mean BP (CloseOut, F021)
8.7				
STANDARD	615	AGE0	AGE0	AGE at DCCT baseline (years)
7.0				
		DURYR0	DURYR0	IDDM duration (years): DCCT baseline
4.1				
		HBAEL	HBAEL	HBA1c at DCCT eligibility (%)
1.6				
		AGE99	AGE99	AGE at DCCT closeout (years)
6.9				
		DURYR99	DURYR99	IDDM duration (years): DCCT Closeout
4.9				
		DCCTYEAR	DCCTYEAR	Time on randomized treatment (Yr)
1.6				
		HBA99	HBA99	HBA1c at DCCT closeout (%)
1.5				
		MBP99	MBP99	Mean BP (CloseOut, F021)
8.7				

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable AGE0
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
EXPERIMENTAL	596	370325.50	361176.0	6078.99535	621.351510
STANDARD	615	363540.50	372690.0	6078.99535	591.122764

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	370325.5000
Normal Approximation	
Z	1.5050
One-Sided Pr > Z	0.0662
Two-Sided Pr > |Z|	0.1323
t Approximation	
One-Sided Pr > Z	0.0663
Two-Sided Pr > |Z|	0.1326

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	2.2653
DF	1
Pr > Chi-Square	0.1323

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable DURYR0
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
EXPERIMENTAL	596	367876.0	361176.0	6052.40469	617.241611
STANDARD	615	365990.0	372690.0	6052.40469	595.105691

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	367876.0000
Normal Approximation	
Z	1.1069
One-Sided Pr > Z	0.1342
Two-Sided Pr > |Z|	0.2683
t Approximation	
One-Sided Pr > Z	0.1343
Two-Sided Pr > |Z|	0.2686

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	1.2254
DF	1
Pr > Chi-Square	0.2683

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable HBAEL
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
EXPERIMENTAL	596	368146.0	361176.0	6084.21271	617.694631
STANDARD	615	365720.0	372690.0	6084.21271	594.666667

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	368146.0000
Normal Approximation	
Z	1.1455
One-Sided Pr > Z	0.1260
Two-Sided Pr > |Z|	0.2520
t Approximation	
One-Sided Pr > Z	0.1261
Two-Sided Pr > |Z|	0.2522

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	1.3124
DF	1
Pr > Chi-Square	0.2520

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable AGE99
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
EXPERIMENTAL	596	371382.50	361176.0	6078.92457	623.125000
STANDARD	615	362483.50	372690.0	6078.92457	589.404065

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	371382.5000
Normal Approximation	
Z	1.6789
One-Sided Pr > Z	0.0466
Two-Sided Pr > |Z|	0.0932
t Approximation	
One-Sided Pr > Z	0.0467
Two-Sided Pr > |Z|	0.0934

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	2.8190
DF	1
Pr > Chi-Square	0.0932

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable DURYR99
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
EXPERIMENTAL	596	370063.50	361176.0	6069.97973	620.911913
STANDARD	615	363802.50	372690.0	6069.97973	591.548780

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	370063.5000
Normal Approximation	
Z	1.4641
One-Sided Pr > Z	0.0716
Two-Sided Pr > |Z|	0.1432
t Approximation	
One-Sided Pr > Z	0.0717
Two-Sided Pr > |Z|	0.1434

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	2.1438
DF	1
Pr > Chi-Square	0.1431

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable DCCTYEAR
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
EXPERIMENTAL	596	367092.50	361176.0	5957.73465	615.927013
STANDARD	615	366773.50	372690.0	5957.73465	596.379675

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	367092.5000
Normal Approximation	
Z	0.9930
One-Sided Pr > Z	0.1604
Two-Sided Pr > |Z|	0.3207
t Approximation	
One-Sided Pr > Z	0.1605
Two-Sided Pr > |Z|	0.3209

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	0.9862
DF	1
Pr > Chi-Square	0.3207

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable HBA99
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
EXPERIMENTAL	595	237885.50	359975.0	6067.94844	399.807563
STANDARD	614	493559.50	371470.0	6067.94844	803.842834

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	237885.5000
Normal Approximation	
Z	-20.1203
One-Sided Pr < Z	<.0001
Two-Sided Pr > |Z|	<.0001
t Approximation	
One-Sided Pr < Z	<.0001
Two-Sided Pr > |Z|	<.0001

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	404.8302
DF	1
Pr > Chi-Square	<.0001

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable MBP99
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
EXPERIMENTAL	594	364282.0	357885.0	6030.22509	613.269360
STANDARD	610	361128.0	367525.0	6030.22509	592.013115

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	364282.0000
Normal Approximation	
Z	1.0607
One-Sided Pr > Z	0.1444
Two-Sided Pr > |Z|	0.2888
t Approximation	
One-Sided Pr > Z	0.1445
Two-Sided Pr > |Z|	0.2890

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	1.1253
DF	1
Pr > Chi-Square	0.2888

---------- EDICYR EDIC year=0 ----------

The FREQ Procedure

Table of STEP3 by GROUP

STEP3(STEP3 3 Step change from DCCT baseline (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	532	410	942
	43.97	33.88	77.85
	56.48	43.52	
	89.26	66.78	
1	64	204	268
	5.29	16.86	22.15
	23.88	76.12	
	10.74	33.22	
Total	596	614	1210
	49.26	50.74	100.00

---------- EDICYR EDIC year=0 ----------

The FREQ Procedure

Statistics for Table of STEP3 by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	88.6866	<.0001
Likelihood Ratio Chi-Square	1	92.4650	<.0001
Continuity Adj. Chi-Square	1	87.3873	<.0001
Mantel-Haenszel Chi-Square	1	88.6133	<.0001
Phi Coefficient		0.2707	
Contingency Coefficient		0.2613	
Cramer's V		0.2707	

Fisher's Exact Test

Cell (1,1) Frequency (F)	532
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	7.147E-22
Table Probability (P)	2.212E-21
Two-sided Pr <= P	9.724E-22

Sample Size = 1210

---------- EDICYR EDIC year=0 ----------

The FREQ Procedure

Table of SNPDR by GROUP

SNPDR(SNPDR Severe Non-Proliferative Diabetic Retinopathy (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	581 48.02 50.43 97.48	571 47.19 49.57 93.00	1152 95.21
1	15 1.24 25.86 2.52	43 3.55 74.14 7.00	58 4.79
Total	596 49.26	614 50.74	1210 100.00

---------- EDICYR EDIC year=0 ----------

The FREQ Procedure

Statistics for Table of SNPDR by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	13.3392	0.0003
Likelihood Ratio Chi-Square	1	13.9174	0.0002
Continuity Adj. Chi-Square	1	12.3742	0.0004
Mantel-Haenszel Chi-Square	1	13.3282	0.0003
Phi Coefficient		0.1050	
Contingency Coefficient		0.1044	
Cramer's V		0.1050	

Fisher's Exact Test

Cell (1,1) Frequency (F)	581
Left-sided Pr <= F	0.9999
Right-sided Pr >= F	1.706E-04
Table Probability (P)	1.158E-04
Two-sided Pr <= P	2.398E-04

Sample Size = 1210

---------- EDICYR EDIC year=0 ----------

The FREQ Procedure

Table of PDR by GROUP

PDR(PDR Proliferative Diabetic Retinopathy (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	581	572	1153
	48.02	47.27	95.29
	50.39	49.61	
	97.48	93.16	
1	15	42	57
	1.24	3.47	4.71
	26.32	73.68	
	2.52	6.84	
Total	596	614	1210
	49.26	50.74	100.00

---------- EDICYR EDIC year=0 ----------

The FREQ Procedure

Statistics for Table of PDR by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	12.5947	0.0004
Likelihood Ratio Chi-Square	1	13.1192	0.0003
Continuity Adj. Chi-Square	1	11.6500	0.0006
Mantel-Haenszel Chi-Square	1	12.5843	0.0004
Phi Coefficient		0.1020	
Contingency Coefficient		0.1015	
Cramer's V		0.1020	

Fisher's Exact Test

Cell (1,1) Frequency (F)	581
Left-sided Pr <= F	0.9999
Right-sided Pr >= F	2.578E-04
Table Probability (P)	1.731E-04
Two-sided Pr <= P	3.658E-04

Sample Size = 1210

---------- EDICYR EDIC year=0 ----------

The FREQ Procedure

Table of FOCALSCAT by GROUP

FOCALSCAT
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	576 47.60 50.48 96.64	565 46.69 49.52 92.02	1141 94.30
1	20 1.65 28.99 3.36	49 4.05 71.01 7.98	69 5.70
Total	596 49.26	614 50.74	1210 100.00

---------- EDICYR EDIC year=0 ----------

The FREQ Procedure

Statistics for Table of FOCALSCAT by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	12.0293	0.0005
Likelihood Ratio Chi-Square	1	12.4136	0.0004
Continuity Adj. Chi-Square	1	11.1847	0.0008
Mantel-Haenszel Chi-Square	1	12.0194	0.0005
Phi Coefficient		0.0997	
Contingency Coefficient		0.0992	
Cramer's V		0.0997	

Fisher's Exact Test

Cell (1,1) Frequency (F)	576
Left-sided Pr <= F	0.9999
Right-sided Pr >= F	3.505E-04
Table Probability (P)	2.187E-04
Two-sided Pr <= P	4.862E-04

Sample Size = 1210

---------- EDICYR EDIC year=4 ----------

The FREQ Procedure

Table of STEP3 by GROUP

STEP3(STEP3 3 Step change from DCCT baseline (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	442	282	724
	40.55	25.87	66.42
	61.05	38.95	
	82.16	51.09	
1	96	270	366
	8.81	24.77	33.58
	26.23	73.77	
	17.84	48.91	
Total	538	552	1090
	49.36	50.64	100.00

Frequency Missing = 13

---------- EDICYR EDIC year=4 ----------

The FREQ Procedure

Statistics for Table of STEP3 by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	117.9201	<.0001
Likelihood Ratio Chi-Square	1	121.6317	<.0001
Continuity Adj. Chi-Square	1	116.5311	<.0001
Mantel-Haenszel Chi-Square	1	117.8119	<.0001
Phi Coefficient		0.3289	
Contingency Coefficient		0.3124	
Cramer's V		0.3289	

Fisher's Exact Test

Cell (1,1) Frequency (F)	442
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	2.974E-28
Table Probability (P)	1.003E-27
Two-sided Pr <= P	4.353E-28

Effective Sample Size = 1090
Frequency Missing = 13

---------- EDICYR EDIC year=4 ----------

The FREQ Procedure

Table of SNPDR by GROUP

SNPDR(SNPDR Severe Non-Proliferative Diabetic Retinopathy (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	516	457	973
	47.17	41.77	88.94
	53.03	46.97	
	95.38	82.64	
1	25	96	121
	2.29	8.78	11.06
	20.66	79.34	
	4.62	17.36	
Total	541	553	1094
	49.45	50.55	100.00

Frequency Missing = 9

---------- EDICYR EDIC year=4 ----------

The FREQ Procedure

Statistics for Table of SNPDR by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	45.1126	<.0001
Likelihood Ratio Chi-Square	1	47.9071	<.0001
Continuity Adj. Chi-Square	1	43.8269	<.0001
Mantel-Haenszel Chi-Square	1	45.0713	<.0001
Phi Coefficient		0.2031	
Contingency Coefficient		0.1990	
Cramer's V		0.2031	

Fisher's Exact Test

Cell (1,1) Frequency (F)	516
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	4.834E-12
Table Probability (P)	3.750E-12
Two-sided Pr <= P	8.501E-12

Effective Sample Size = 1094
Frequency Missing = 9

---------- EDICYR EDIC year=4 ----------

The FREQ Procedure

Table of PDR by GROUP

PDR(PDR Proliferative Diabetic Retinopathy (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	518	466	984
	47.35	42.60	89.95
	52.64	47.36	
	95.75	84.27	
1	23	87	110
	2.10	7.95	10.05
	20.91	79.09	
	4.25	15.73	
Total	541	553	1094
	49.45	50.55	100.00

Frequency Missing = 9

---------- EDICYR EDIC year=4 ----------

The FREQ Procedure

Statistics for Table of PDR by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	39.8575	<.0001
Likelihood Ratio Chi-Square	1	42.3051	<.0001
Continuity Adj. Chi-Square	1	38.5981	<.0001
Mantel-Haenszel Chi-Square	1	39.8211	<.0001
Phi Coefficient		0.1909	
Contingency Coefficient		0.1875	
Cramer's V		0.1909	

Fisher's Exact Test

Cell (1,1) Frequency (F)	518
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	8.325E-11
Table Probability (P)	6.404E-11
Two-sided Pr <= P	1.572E-10

Effective Sample Size = 1094
Frequency Missing = 9

---------- EDICYR EDIC year=4 ----------

The FREQ Procedure

Table of FOCALSCAT by GROUP

FOCALSCAT
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	517 46.87 52.01 95.39	477 43.25 47.99 85.03	994 90.12
1	25 2.27 22.94 4.61	84 7.62 77.06 14.97	109 9.88
Total	542 49.14	561 50.86	1103 100.00

---------- EDICYR EDIC year=4 ----------

The FREQ Procedure

Statistics for Table of FOCALSCAT by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	33.2280	<.0001
Likelihood Ratio Chi-Square	1	34.9960	<.0001
Continuity Adj. Chi-Square	1	32.0748	<.0001
Mantel-Haenszel Chi-Square	1	33.1979	<.0001
Phi Coefficient		0.1736	
Contingency Coefficient		0.1710	
Cramer's V		0.1736	

Fisher's Exact Test

Cell (1,1) Frequency (F)	517
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	3.271E-09
Table Probability (P)	2.402E-09
Two-sided Pr <= P	4.554E-09

Sample Size = 1103

---------- EDICYR EDIC year=10 ----------

The FREQ Procedure

Table of STEP3 by GROUP

STEP3(STEP3 3 Step change from DCCT baseline (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	380	242	622
	31.51	20.07	51.58
	61.09	38.91	
	64.19	39.41	
1	212	372	584
	17.58	30.85	48.42
	36.30	63.70	
	35.81	60.59	
Total	592	614	1206
	49.09	50.91	100.00

Frequency Missing = 5

---------- EDICYR EDIC year=10 ----------

The FREQ Procedure

Statistics for Table of STEP3 by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	74.0763	<.0001
Likelihood Ratio Chi-Square	1	74.8734	<.0001
Continuity Adj. Chi-Square	1	73.0876	<.0001
Mantel-Haenszel Chi-Square	1	74.0149	<.0001
Phi Coefficient		0.2478	
Contingency Coefficient		0.2406	
Cramer's V		0.2478	

Fisher's Exact Test

Cell (1,1) Frequency (F)	380
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	4.208E-18
Table Probability (P)	4.228E-18
Two-sided Pr <= P	6.397E-18

Effective Sample Size = 1206
Frequency Missing = 5

---------- EDICYR EDIC year=10 ----------

The FREQ Procedure

Table of SNPDR by GROUP

SNPDR(SNPDR Severe Non-Proliferative Diabetic Retinopathy (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	542	461	1003
	44.76	38.07	82.82
	54.04	45.96	
	90.94	74.96	
1	54	154	208
	4.46	12.72	17.18
	25.96	74.04	
	9.06	25.04	
Total	596	615	1211
	49.22	50.78	100.00

---------- EDICYR EDIC year=10 ----------

The FREQ Procedure

Statistics for Table of SNPDR by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	54.3336	<.0001
Likelihood Ratio Chi-Square	1	56.3755	<.0001
Continuity Adj. Chi-Square	1	53.2160	<.0001
Mantel-Haenszel Chi-Square	1	54.2887	<.0001
Phi Coefficient		0.2118	
Contingency Coefficient		0.2072	
Cramer's V		0.2118	

Fisher's Exact Test

Cell (1,1) Frequency (F)	542
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	5.622E-14
Table Probability (P)	3.979E-14
Two-sided Pr <= P	1.080E-13

Sample Size = 1211

---------- EDICYR EDIC year=10 ----------

The FREQ Procedure

Table of PDR by GROUP

PDR(PDR Proliferative Diabetic Retinopathy (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	543 44.84 53.98 91.11	463 38.23 46.02 75.28	1006 83.07
1	53 4.38 25.85 8.89	152 12.55 74.15 24.72	205 16.93
Total	596 49.22	615 50.78	1211 100.00

---------- EDICYR EDIC year=10 ----------

The FREQ Procedure

Statistics for Table of PDR by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	53.8867	<.0001
Likelihood Ratio Chi-Square	1	55.9373	<.0001
Continuity Adj. Chi-Square	1	52.7674	<.0001
Mantel-Haenszel Chi-Square	1	53.8423	<.0001
Phi Coefficient		0.2109	
Contingency Coefficient		0.2064	
Cramer's V		0.2109	

Fisher's Exact Test

Cell (1,1) Frequency (F)	543
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	7.039E-14
Table Probability (P)	4.985E-14
Two-sided Pr <= P	1.390E-13

Sample Size = 1211

---------- EDICYR EDIC year=10 ----------

The FREQ Procedure

Table of FOCALSCAT by GROUP

FOCALSCAT
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	546 45.09 53.74 91.61	470 38.81 46.26 76.42	1016 83.90
1	50 4.13 25.64 8.39	145 11.97 74.36 23.58	195 16.10
Total	596 49.22	615 50.78	1211 100.00

---------- EDICYR EDIC year=10 ----------

The FREQ Procedure

Statistics for Table of FOCALSCAT by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	51.6817	<.0001
Likelihood Ratio Chi-Square	1	53.7049	<.0001
Continuity Adj. Chi-Square	1	50.5636	<.0001
Mantel-Haenszel Chi-Square	1	51.6390	<.0001
Phi Coefficient		0.2066	
Contingency Coefficient		0.2023	
Cramer's V		0.2066	

Fisher's Exact Test

Cell (1,1) Frequency (F)	546
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	2.195E-13
Table Probability (P)	1.557E-13
Two-sided Pr <= P	2.956E-13

Sample Size = 1211

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_ANALY
Response Variable	STEP3
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Model Information

STEP3 3 Step change from DCCT baseline (0=n 1=y)

Number of Observations Read	1210
Number of Observations Used	1210

Response Profile

Ordered Value	STEP3	Total Frequency
1	1	268
2	0	942

Probability modeled is STEP3=1.

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	1281.658	1191.193
SC	1286.756	1201.390
-2 Log L	1279.658	1187.193

The LOGISTIC Procedure

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	92.4650	1	<.0001
Score	88.6866	1	<.0001
Wald	81.1198	1	<.0001

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-0.6980	0.0857	66.3747	<.0001
tgroup	1	-1.4196	0.1576	81.1198	<.0001

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.242	0.178	0.329

Association of Predicted Probabilities and Observed Responses

Percent Concordant	43.0	Somers' D	0.326
Percent Discordant	10.4	Gamma	0.611
Percent Tied	46.6	Tau-a	0.113
Pairs	252456	c	0.663

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.242	0.178	0.329

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_ANALY
Response Variable	SNPDR
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Model Information

SNPDR Severe Non-Proliferative Diabetic Retinopathy (0=n 1=y)

Number of Observations Read	1210
Number of Observations Used	1210

Response Profile

Ordered Value	SNPDR	Total Frequency
1	1	58
2	0	1152

Probability modeled is SNPDR=1.

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	467.575	455.657
SC	472.673	465.854
-2 Log L	465.575	451.657

The LOGISTIC Procedure

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	13.9174	1	0.0002
Score	13.3392	1	0.0003
Wald	12.2694	1	0.0005

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-2.5862	0.1581	267.4588	<.0001
tgroup	1	-1.0704	0.3056	12.2694	0.0005

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.343	0.188	0.624

Association of Predicted Probabilities and Observed Responses

Percent Concordant	37.4	Somers' D	0.246
Percent Discordant	12.8	Gamma	0.489
Percent Tied	49.8	Tau-a	0.022
Pairs	66816	c	0.623

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.343	0.188	0.624

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_ANALY
Response Variable	PDR
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Model Information

PDR Proliferative Diabetic Retinopathy (0=n 1=y)

Number of Observations Read	1210
Number of Observations Used	1210

Response Profile

Ordered Value	PDR	Total Frequency
1	1	57
2	0	1153

Probability modeled is PDR=1.

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	461.579	450.460
SC	466.677	460.656
-2 Log L	459.579	446.460

The LOGISTIC Procedure

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	13.1192	1	0.0003
Score	12.5947	1	0.0004
Wald	11.6283	1	0.0006

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-2.6115	0.1599	266.8376	<.0001
tgroup	1	-1.0452	0.3065	11.6283	0.0006

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.352	0.193	0.641

Association of Predicted Probabilities and Observed Responses

Percent Concordant	37.1	Somers' D	0.241
Percent Discordant	13.1	Gamma	0.480
Percent Tied	49.8	Tau-a	0.022
Pairs	65721	c	0.620

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.352	0.193	0.641

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_ANALY
Response Variable	FOCALSCAT
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Number of Observations Read	1210
Number of Observations Used	1210

Response Profile

Ordered Value	FOCALSCAT	Total Frequency
1	1	69
2	0	1141

Probability modeled is FOCALSCAT=1.

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	531.257	520.844
SC	536.356	531.041
-2 Log L	529.257	516.844

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	12.4136	1	0.0004
Score	12.0293	1	0.0005
Wald	11.3359	1	0.0008

The LOGISTIC Procedure

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-2.4450	0.1489	269.5478	<.0001
tgroup	1	-0.9154	0.2719	11.3359	0.0008

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.400	0.235	0.682

Association of Predicted Probabilities and Observed Responses

Percent Concordant	35.8	Somers' D	0.215
Percent Discordant	14.4	Gamma	0.428
Percent Tied	49.8	Tau-a	0.023
Pairs	78729	c	0.607

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.400	0.235	0.682

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_ANALY
Response Variable	STEP3
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Model Information

STEP3 3 Step change from DCCT baseline (0=n 1=y)

Number of Observations Read	1103
Number of Observations Used	1088

Response Profile

Ordered Value	STEP3	Total Frequency
1	1	364
2	0	724

Probability modeled is STEP3=1.

NOTE: 15 observations were deleted due to missing values for the response or explanatory variables.

Class Level Information

Class	Value	Design Variables		
DTCLSETD	1	1	0	0
	2	0	1	0
	3	0	0	1
	4	-1	-1	-1

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	1388.896	1093.024
SC	1393.888	1117.985
-2 Log L	1386.896	1083.024

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	303.8717	4	<.0001
Score	280.3627	4	<.0001
Wald	213.6273	4	<.0001

Type 3 Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	74.5450	<.0001
DTCLSETD	3	147.9164	<.0001

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	-0.1281	0.1019	1.5811	0.2086
tgroup		1	-1.3338	0.1545	74.5450	<.0001
DTCLSETD	1	1	-1.5423	0.1782	74.9162	<.0001
DTCLSETD	2	1	-0.3689	0.1214	9.2313	0.0024
DTCLSETD	3	1	0.3163	0.1237	6.5368	0.0106

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.263	0.195	0.357
DTCLSETD 1 vs 4	0.043	0.025	0.075
DTCLSETD 2 vs 4	0.140	0.093	0.212
DTCLSETD 3 vs 4	0.278	0.183	0.424

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	75.0	Somers' D	0.598
Percent Discordant	15.2	Gamma	0.664
Percent Tied	9.9	Tau-a	0.267
Pairs	263536	c	0.799

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.263	0.195	0.357
DTCLSETD 1 vs 4	1.0000	0.043	0.025	0.075
DTCLSETD 2 vs 4	1.0000	0.140	0.093	0.212
DTCLSETD 3 vs 4	1.0000	0.278	0.183	0.424

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_ANALY
Response Variable	SNPDR
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Model Information

SNPDR Severe Non-Proliferative Diabetic Retinopathy (0=n 1=y)

Number of Observations Read	1103
Number of Observations Used	1092

Response Profile

Ordered Value	SNPDR	Total Frequency
1	1	120
2	0	972

Probability modeled is SNPDR=1.

NOTE: 11 observations were deleted due to missing values for the response or explanatory variables.

Class Level Information

Class	Value	Design Variables		
DTCLSETD	1	1	0	0
	2	0	1	0
	3	0	0	1
	4	-1	-1	-1

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	758.288	443.778
SC	763.283	468.757
-2 Log L	756.288	433.778

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	322.5093	4	<.0001
Score	392.2473	4	<.0001
Wald	161.8183	4	<.0001

Type 3 Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	16.4210	<.0001
DTCLSETD	3	149.7795	<.0001

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	-2.7881	0.3083	81.8038	<.0001
tgroup		1	-1.1146	0.2751	16.4210	<.0001
DTCLSETD	1	1	-2.2206	0.7690	8.3372	0.0039
DTCLSETD	2	1	-1.5664	0.5070	9.5433	0.0020
DTCLSETD	3	1	0.6067	0.3413	3.1602	0.0755

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.328	0.191	0.562
DTCLSETD 1 vs 4	0.005	<0.001	0.033
DTCLSETD 2 vs 4	0.009	0.003	0.028
DTCLSETD 3 vs 4	0.076	0.044	0.132

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	88.5	Somers' D	0.841
Percent Discordant	4.5	Gamma	0.904
Percent Tied	7.0	Tau-a	0.165
Pairs	116640	c	0.920

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.328	0.191	0.562
DTCLSETD 1 vs 4	1.0000	0.005	<0.001	0.033
DTCLSETD 2 vs 4	1.0000	0.009	0.003	0.028
DTCLSETD 3 vs 4	1.0000	0.076	0.044	0.132

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_ANALY
Response Variable	PDR
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Model Information

PDR Proliferative Diabetic Retinopathy (0=n 1=y)

Number of Observations Read	1103
Number of Observations Used	1092

Response Profile

Ordered Value	PDR	Total Frequency
1	1	109
2	0	983

Probability modeled is PDR=1.

NOTE: 11 observations were deleted due to missing values for the response or explanatory variables.

Class Level Information

Class	Value	Design Variables		
DTCLSETD	1	1	0	0
	2	0	1	0
	3	0	0	1
	4	-1	-1	-1

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	711.102	425.242
SC	716.098	450.221
-2 Log L	709.102	415.242

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	293.8600	4	<.0001
Score	367.5658	4	<.0001
Wald	152.4423	4	<.0001

Type 3 Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	13.5905	0.0002
DTCLSETD	3	140.7458	<.0001

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	-2.9097	0.3105	87.8154	<.0001
tgroup		1	-1.0412	0.2824	13.5905	0.0002
DTCLSETD	1	1	-2.1249	0.7696	7.6242	0.0058
DTCLSETD	2	1	-1.4668	0.5078	8.3448	0.0039
DTCLSETD	3	1	0.4697	0.3513	1.7881	0.1812

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.353	0.203	0.614
DTCLSETD 1 vs 4	0.005	<0.001	0.038
DTCLSETD 2 vs 4	0.010	0.003	0.033
DTCLSETD 3 vs 4	0.070	0.039	0.127

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	88.2	Somers' D	0.835
Percent Discordant	4.6	Gamma	0.901
Percent Tied	7.2	Tau-a	0.150
Pairs	107147	c	0.918

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.353	0.203	0.614
DTCLSETD 1 vs 4	1.0000	0.005	<0.001	0.038
DTCLSETD 2 vs 4	1.0000	0.010	0.003	0.033
DTCLSETD 3 vs 4	1.0000	0.070	0.039	0.127

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_ANALY
Response Variable	FOCALSCAT
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Number of Observations Read	1103
Number of Observations Used	1101

Response Profile

Ordered Value	FOCALSCAT	Total Frequency
1	1	108
2	0	993

Probability modeled is FOCALSCAT=1.

NOTE: 2 observations were deleted due to missing values for the response or explanatory variables.

Class Level Information

Class	Value	Design Variables		
DTCLSETD	1	1	0	0
	2	0	1	0
	3	0	0	1
	4	-1	-1	-1

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	708.560	452.560
SC	713.564	477.580
-2 Log L	706.560	442.560

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	263.9999	4	<.0001
Score	333.2772	4	<.0001
Wald	152.9939	4	<.0001

Type 3 Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	9.2088	0.0024
DTCLSETD	3	141.6798	<.0001

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	-2.8813	0.2982	93.3743	<.0001
tgroup		1	-0.8249	0.2718	9.2088	0.0024
DTCLSETD	1	1	-2.2429	0.7641	8.6171	0.0033
DTCLSETD	2	1	-1.0590	0.4274	6.1402	0.0132
DTCLSETD	3	1	0.3831	0.3388	1.2788	0.2581

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.438	0.257	0.747
DTCLSETD 1 vs 4	0.006	<0.001	0.042
DTCLSETD 2 vs 4	0.019	0.007	0.047
DTCLSETD 3 vs 4	0.079	0.044	0.142

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	86.4	Somers' D	0.806
Percent Discordant	5.8	Gamma	0.875
Percent Tied	7.8	Tau-a	0.143
Pairs	107244	c	0.903

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.438	0.257	0.747
DTCLSETD 1 vs 4	1.0000	0.006	<0.001	0.042
DTCLSETD 2 vs 4	1.0000	0.019	0.007	0.047
DTCLSETD 3 vs 4	1.0000	0.079	0.044	0.142

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_ANALY
Response Variable	STEP3
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Model Information

STEP3 3 Step change from DCCT baseline (0=n 1=y)

Number of Observations Read	1211
Number of Observations Used	1204

Response Profile

Ordered Value	STEP3	Total Frequency
1	1	582
2	0	622

Probability modeled is STEP3=1.

NOTE: 7 observations were deleted due to missing values for the response or explanatory variables.

Class Level Information

Class	Value	Design Variables		
DTCLSETD	1	1	0	0
	2	0	1	0
	3	0	0	1
	4	-1	-1	-1

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	1669.769	1530.041
SC	1674.863	1555.508
-2 Log L	1667.769	1520.041

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	147.7278	4	<.0001
Score	140.7624	4	<.0001
Wald	126.1269	4	<.0001

Type 3 Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	47.3130	<.0001
DTCLSETD	3	66.3630	<.0001

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	0.4624	0.0881	27.5572	<.0001
tgroup		1	-0.8502	0.1236	47.3130	<.0001
DTCLSETD	1	1	-0.6897	0.1138	36.7444	<.0001
DTCLSETD	2	1	-0.2882	0.0967	8.8763	0.0029
DTCLSETD	3	1	-0.0344	0.1069	0.1034	0.7478

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.427	0.335	0.544
DTCLSETD 1 vs 4	0.182	0.120	0.278
DTCLSETD 2 vs 4	0.272	0.185	0.401
DTCLSETD 3 vs 4	0.351	0.234	0.527

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	62.8	Somers' D	0.378
Percent Discordant	25.0	Gamma	0.431
Percent Tied	12.3	Tau-a	0.189
Pairs	362004	c	0.689

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.427	0.335	0.544
DTCLSETD 1 vs 4	1.0000	0.182	0.120	0.278
DTCLSETD 2 vs 4	1.0000	0.272	0.185	0.401
DTCLSETD 3 vs 4	1.0000	0.351	0.234	0.527

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_ANALY
Response Variable	SNPDR
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Model Information

SNPDR Severe Non-Proliferative Diabetic Retinopathy (0=n 1=y)

Number of Observations Read	1211
Number of Observations Used	1209

Response Profile

Ordered Value	SNPDR	Total Frequency
1	1	207
2	0	1002

Probability modeled is SNPDR=1.

NOTE: 2 observations were deleted due to missing values for the response or explanatory variables.

Class Level Information

Class	Value	Design Variables		
DTCLSETD	1	1	0	0
	2	0	1	0
	3	0	0	1
	4	-1	-1	-1

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	1108.982	774.298
SC	1114.080	799.785
-2 Log L	1106.982	764.298

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	342.6844	4	<.0001
Score	379.4523	4	<.0001
Wald	227.4658	4	<.0001

Type 3 Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	18.7465	<.0001
DTCLSETD	3	206.3390	<.0001

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	-1.7145	0.1765	94.3692	<.0001
tgroup		1	-0.8552	0.1975	18.7465	<.0001
DTCLSETD	1	1	-2.3742	0.4419	28.8626	<.0001
DTCLSETD	2	1	-0.5609	0.2137	6.8857	0.0087
DTCLSETD	3	1	0.4702	0.1959	5.7585	0.0164

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.425	0.289	0.626
DTCLSETD 1 vs 4	0.008	0.002	0.026
DTCLSETD 2 vs 4	0.049	0.030	0.079
DTCLSETD 3 vs 4	0.136	0.089	0.207

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	81.8	Somers' D	0.721
Percent Discordant	9.7	Gamma	0.788
Percent Tied	8.5	Tau-a	0.205
Pairs	207414	c	0.860

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.425	0.289	0.626
DTCLSETD 1 vs 4	1.0000	0.008	0.002	0.026
DTCLSETD 2 vs 4	1.0000	0.049	0.030	0.079
DTCLSETD 3 vs 4	1.0000	0.136	0.089	0.207

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_ANALY
Response Variable	PDR
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Model Information

PDR Proliferative Diabetic Retinopathy (0=n 1=y)

Number of Observations Read	1211
Number of Observations Used	1209

Response Profile

Ordered Value	PDR	Total Frequency
1	1	204
2	0	1005

Probability modeled is PDR=1.

NOTE: 2 observations were deleted due to missing values for the response or explanatory variables.

Class Level Information

Class	Value	Design Variables		
DTCLSETD	1	1	0	0
	2	0	1	0
	3	0	0	1
	4	-1	-1	-1

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	1099.467	768.993
SC	1104.565	794.480
-2 Log L	1097.467	758.993

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	338.4745	4	<.0001
Score	377.3269	4	<.0001
Wald	226.5171	4	<.0001

Type 3 Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	18.6614	<.0001
DTCLSETD	3	205.4556	<.0001

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	-1.7307	0.1766	96.0609	<.0001
tgroup		1	-0.8582	0.1987	18.6614	<.0001
DTCLSETD	1	1	-2.3557	0.4418	28.4360	<.0001
DTCLSETD	2	1	-0.5435	0.2138	6.4636	0.0110
DTCLSETD	3	1	0.4390	0.1970	4.9672	0.0258

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.424	0.287	0.626
DTCLSETD 1 vs 4	0.008	0.003	0.026
DTCLSETD 2 vs 4	0.050	0.031	0.080
DTCLSETD 3 vs 4	0.132	0.087	0.202

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	81.7	Somers' D	0.719
Percent Discordant	9.8	Gamma	0.786
Percent Tied	8.5	Tau-a	0.202
Pairs	205020	c	0.860

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.424	0.287	0.626
DTCLSETD 1 vs 4	1.0000	0.008	0.003	0.026
DTCLSETD 2 vs 4	1.0000	0.050	0.031	0.080
DTCLSETD 3 vs 4	1.0000	0.132	0.087	0.202

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_ANALY
Response Variable	FOCALSCAT
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Number of Observations Read	1211
Number of Observations Used	1209

Response Profile

Ordered Value	FOCALSCAT	Total Frequency
1	1	194
2	0	1015

Probability modeled is FOCALSCAT=1.

NOTE: 2 observations were deleted due to missing values for the response or explanatory variables.

Class Level Information

Class	Value	Design Variables		
DTCLSETD	1	1	0	0
	2	0	1	0
	3	0	0	1
	4	-1	-1	-1

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	1066.977	755.203
SC	1072.075	780.691
-2 Log L	1064.977	745.203

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	319.7741	4	<.0001
Score	357.8739	4	<.0001
Wald	215.7823	4	<.0001

Type 3 Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	17.6128	<.0001
DTCLSETD	3	194.3539	<.0001

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	-1.8044	0.1775	103.3263	<.0001
tgroup		1	-0.8445	0.2012	17.6128	<.0001
DTCLSETD	1	1	-2.2877	0.4421	26.7756	<.0001
DTCLSETD	2	1	-0.5968	0.2193	7.4051	0.0065
DTCLSETD	3	1	0.4839	0.1981	5.9695	0.0146

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.430	0.290	0.638
DTCLSETD 1 vs 4	0.009	0.003	0.030
DTCLSETD 2 vs 4	0.050	0.030	0.082
DTCLSETD 3 vs 4	0.147	0.097	0.224

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	81.5	Somers' D	0.717
Percent Discordant	9.8	Gamma	0.785
Percent Tied	8.6	Tau-a	0.193
Pairs	196910	c	0.859

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.430	0.290	0.638
DTCLSETD 1 vs 4	1.0000	0.009	0.003	0.030
DTCLSETD 2 vs 4	1.0000	0.050	0.030	0.082
DTCLSETD 3 vs 4	1.0000	0.147	0.097	0.224

---------- EDICYR EDIC year=0 ----------

The FREQ Procedure

Table of CSME by GROUP

CSME(CSME Clinically Significant Macular Edema (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	566 48.25 51.22 96.10	539 45.95 48.78 92.29	1105 94.20
1	23 1.96 33.82 3.90	45 3.84 66.18 7.71	68 5.80
Total	589 50.21	584 49.79	1173 100.00

---------- EDICYR EDIC year=0 ----------

The FREQ Procedure

Statistics for Table of CSME by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	7.7562	0.0054
Likelihood Ratio Chi-Square	1	7.8858	0.0050
Continuity Adj. Chi-Square	1	7.0759	0.0078
Mantel-Haenszel Chi-Square	1	7.7496	0.0054
Phi Coefficient		0.0813	
Contingency Coefficient		0.0810	
Cramer's V		0.0813	

Fisher's Exact Test

Cell (1,1) Frequency (F)	566
Left-sided Pr <= F	0.9983
Right-sided Pr >= F	0.0037
Table Probability (P)	0.0020
Two-sided Pr <= P	0.0058

Sample Size = 1173

---------- EDICYR EDIC year=4 ----------

The FREQ Procedure

Table of CSME by GROUP

CSME(CSME Clinically Significant Macular Edema (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	514 48.13 52.61 96.25	463 43.35 47.39 86.70	977 91.48
1	20 1.87 21.98 3.75	71 6.65 78.02 13.30	91 8.52
Total	534 50.00	534 50.00	1068 100.00

Frequency Missing = 1

---------- EDICYR EDIC year=4 ----------

The FREQ Procedure

Statistics for Table of CSME by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	31.2446	<.0001
Likelihood Ratio Chi-Square	1	32.9696	<.0001
Continuity Adj. Chi-Square	1	30.0314	<.0001
Mantel-Haenszel Chi-Square	1	31.2154	<.0001
Phi Coefficient		0.1710	
Contingency Coefficient		0.1686	
Cramer's V		0.1710	

Fisher's Exact Test

Cell (1,1) Frequency (F)	514
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	9.656E-09
Table Probability (P)	7.295E-09
Two-sided Pr <= P	1.931E-08

Effective Sample Size = 1068
Frequency Missing = 1

---------- EDICYR EDIC year=10 ----------

The FREQ Procedure

Table of CSME by GROUP

CSME(CSME Clinically Significant Macular Edema (0=n 1=y))
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	536 45.66 53.07 91.00	474 40.37 46.93 81.03	1010 86.03
1	53 4.51 32.32 9.00	111 9.45 67.68 18.97	164 13.97
Total	589 50.17	585 49.83	1174 100.00

---------- EDICYR EDIC year=10 ----------

The FREQ Procedure

Statistics for Table of CSME by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	24.3048	<.0001
Likelihood Ratio Chi-Square	1	24.7574	<.0001
Continuity Adj. Chi-Square	1	23.4818	<.0001
Mantel-Haenszel Chi-Square	1	24.2841	<.0001
Phi Coefficient		0.1439	
Contingency Coefficient		0.1424	
Cramer's V		0.1439	

Fisher's Exact Test

Cell (1,1) Frequency (F)	536
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	5.113E-07
Table Probability (P)	3.021E-07
Two-sided Pr <= P	8.511E-07

Sample Size = 1174

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_CSME
Response Variable	CSME
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Model Information

CSME Clinically Significant Macular Edema (0=n 1=y)

Number of Observations Read	1173
Number of Observations Used	1173

Response Profile

Ordered Value	CSME	Total Frequency
1	1	68
2	0	1105

Probability modeled is CSME=1.

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	521.282	515.396
SC	526.349	525.531
-2 Log L	519.282	511.396

The LOGISTIC Procedure

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	7.8858	1	0.0050
Score	7.7562	1	0.0054
Wald	7.4790	1	0.0062

Analysis of Maximum Likelihood Estimates

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-2.4831	0.1552	256.0710	<.0001
tgroup	1	-0.7200	0.2633	7.4790	0.0062

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.487	0.291	0.815

Association of Predicted Probabilities and Observed Responses

Percent Concordant	33.9	Somers' D	0.174
Percent Discordant	16.5	Gamma	0.345
Percent Tied	49.6	Tau-a	0.019
Pairs	75140	c	0.587

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.487	0.291	0.815

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_CSME
Response Variable	CSME
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Model Information

CSME Clinically Significant Macular Edema (0=n 1=y)

Number of Observations Read	1069
Number of Observations Used	1065

Response Profile

Ordered Value	CSME	Total Frequency
1	1	90
2	0	975

Probability modeled is CSME=1.

NOTE: 4 observations were deleted due to missing values for the response or explanatory variables.

Class Level Information

Class	Value	Design Variables		
DTCLSETD	1	1	0	0
	2	0	1	0
	3	0	0	1
	4	-1	-1	-1

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	618.936	484.345
SC	623.907	509.199
-2 Log L	616.936	474.345

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	142.5911	4	<.0001
Score	170.9425	4	<.0001
Wald	104.7126	4	<.0001

Type 3 Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	12.7491	0.0004
DTCLSETD	3	86.3934	<.0001

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	-2.4749	0.2214	124.9890	<.0001
tgroup		1	-0.9894	0.2771	12.7491	0.0004
DTCLSETD	1	1	-1.8845	0.5432	12.0359	0.0005
DTCLSETD	2	1	-0.5943	0.2991	3.9491	0.0469
DTCLSETD	3	1	0.4472	0.2579	3.0062	0.0829

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.372	0.216	0.640
DTCLSETD 1 vs 4	0.020	0.005	0.084
DTCLSETD 2 vs 4	0.072	0.036	0.144
DTCLSETD 3 vs 4	0.205	0.119	0.353

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	79.5	Somers' D	0.684
Percent Discordant	11.1	Gamma	0.755
Percent Tied	9.5	Tau-a	0.106
Pairs	87750	c	0.842

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.372	0.216	0.640
DTCLSETD 1 vs 4	1.0000	0.020	0.005	0.084
DTCLSETD 2 vs 4	1.0000	0.072	0.036	0.144
DTCLSETD 3 vs 4	1.0000	0.205	0.119	0.353

The LOGISTIC Procedure

Model Information

Data Set	WORK.EDIC10RE_CSME
Response Variable	CSME
Number of Response Levels	2
Model	binary logit
Optimization Technique	Fisher's scoring

Model Information

CSME Clinically Significant Macular Edema (0=n 1=y)

Number of Observations Read	1174
Number of Observations Used	1171

Response Profile

Ordered Value	CSME	Total Frequency
1	1	161
2	0	1010

Probability modeled is CSME=1.

NOTE: 3 observations were deleted due to missing values for the response or explanatory variables.

Class Level Information

Class	Value	Design Variables		
DTCLSETD	1	1	0	0
	2	0	1	0
	3	0	0	1
	4	-1	-1	-1

Model Convergence Status

Convergence criterion (GCONV=1E-8) satisfied.

The LOGISTIC Procedure

Model Fit Statistics

Criterion	Intercept Only	Intercept and Covariates
AIC	939.689	797.505
SC	944.755	822.833
-2 Log L	937.689	787.505

Testing Global Null Hypothesis: BETA=0

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	150.1844	4	<.0001
Score	168.3959	4	<.0001
Wald	124.8389	4	<.0001

Type 3 Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	6.8125	0.0091
DTCLSETD	3	108.7178	<.0001

Analysis of Maximum Likelihood Estimates

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept		1	-1.7992	0.1420	160.5418	<.0001
tgroup		1	-0.5016	0.1922	6.8125	0.0091
DTCLSETD	1	1	-1.5807	0.2966	28.4021	<.0001
DTCLSETD	2	1	-0.4342	0.1757	6.1078	0.0135
DTCLSETD	3	1	0.3759	0.1641	5.2494	0.0220

Odds Ratio Estimates

Effect	Point Estimate	95% Wald Confidence Limits	
tgroup	0.606	0.415	0.883
DTCLSETD 1 vs 4	0.040	0.018	0.090
DTCLSETD 2 vs 4	0.126	0.079	0.201
DTCLSETD 3 vs 4	0.283	0.183	0.437

The LOGISTIC Procedure

Association of Predicted Probabilities and Observed Responses

Percent Concordant	72.6	Somers' D	0.558
Percent Discordant	16.8	Gamma	0.625
Percent Tied	10.7	Tau-a	0.132
Pairs	162610	c	0.779

Wald Confidence Interval for Odds Ratios

Effect	Unit	Estimate	95% Confidence Limits	
tgroup	1.0000	0.606	0.415	0.883
DTCLSETD 1 vs 4	1.0000	0.040	0.018	0.090
DTCLSETD 2 vs 4	1.0000	0.126	0.079	0.201
DTCLSETD 3 vs 4	1.0000	0.283	0.183	0.437

Part 1: Further 3-step Progression

The FREQ Procedure

Table of DTCLSETD by GROUP

DTCLSETD(DCCT closeout ETDRS level comb DCCT10-DCCT50)
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
1	194 14.37 61.20 28.45	123 9.11 38.80 18.41	317 23.48
2	275 20.37 55.67 40.32	219 16.22 44.33 32.78	494 36.59
3	148 10.96 42.53 21.70	200 14.81 57.47 29.94	348 25.78
4	65 4.81 34.03 9.53	126 9.33 65.97 18.86	191 14.15
Total	682 50.52	668 49.48	1350 100.00

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=1 ----------

The FREQ Procedure

Table of anystffurther by GROUP

anystffurther
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	123	55	178
	38.80	17.35	56.15
	69.10	30.90	
	63.40	44.72	
1	71	68	139
	22.40	21.45	43.85
	51.08	48.92	
	36.60	55.28	
Total	194	123	317
	61.20	38.80	100.00

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=2 ----------

The FREQ Procedure

Table of anystffurther by GROUP

anystffurther
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	221	132	353
	44.74	26.72	71.46
	62.61	37.39	
	80.36	60.27	
1	54	87	141
	10.93	17.61	28.54
	38.30	61.70	
	19.64	39.73	
Total	275	219	494
	55.67	44.33	100.00

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=3 ----------

The FREQ Procedure

Table of anystffurther by GROUP

anystffurther
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	117	118	235
	33.62	33.91	67.53
	49.79	50.21	
	79.05	59.00	
1	31	82	113
	8.91	23.56	32.47
	27.43	72.57	
	20.95	41.00	
Total	148	200	348
	42.53	57.47	100.00

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=4 ----------

The FREQ Procedure

Table of anystffurther by GROUP

anystffurther
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	33	42	75
	17.28	21.99	39.27
	44.00	56.00	
	50.77	33.33	
1	32	84	116
	16.75	43.98	60.73
	27.59	72.41	
	49.23	66.67	
Total	65	126	191
	34.03	65.97	100.00

Part 1: Further 3-step Progression

The FREQ Procedure

Table of event by GROUP

event
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	494 36.59 58.74 72.43	347 25.70 41.26 51.95	841 62.30
1	188 13.93 36.94 27.57	321 23.78 63.06 48.05	509 37.70
Total	682 50.52	668 49.48	1350 100.00

Part 1: Further 3-step Progression

Obs	survyrs	lastedicyr	lastdate	event
872	10	10	.	0

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=1 ----------

The FREQ Procedure

Table of event by GROUP

event
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	123 38.80 69.10 63.40	55 17.35 30.90 44.72	178 56.15
1	71 22.40 51.08 36.60	68 21.45 48.92 55.28	139 43.85
Total	194 61.20	123 38.80	317 100.00

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=2 ----------

The FREQ Procedure

Table of event by GROUP

event
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	221 44.74 62.61 80.36	132 26.72 37.39 60.27	353 71.46
1	54 10.93 38.30 19.64	87 17.61 61.70 39.73	141 28.54
Total	275 55.67	219 44.33	494 100.00

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=3 ----------

The FREQ Procedure

Table of event by GROUP

event
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	117 33.62 49.79 79.05	118 33.91 50.21 59.00	235 67.53
1	31 8.91 27.43 20.95	82 23.56 72.57 41.00	113 32.47
Total	148 42.53	200 57.47	348 100.00

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=4 ----------

The FREQ Procedure

Table of event by GROUP

event
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	33 17.28 44.00 50.77	42 21.99 56.00 33.33	75 39.27
1	32 16.75 27.59 49.23	84 43.98 72.41 66.67	116 60.73
Total	65 34.03	126 65.97	191 100.00

Part 1: Further 3-step Progression

The FREQ Procedure

DCCTSCAT Any SCATTER through DCCT (0=n 1=y)

DCCTSCAT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	1350	100.00	1350	100.00

Part 1: Further 3-step Progression

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	1350
Noncensored Values	509
Right Censored Values	841
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-1065.856528

Number of Observations Read	1350
Number of Observations Used	1350

Fit Statistics

-2 Log Likelihood	2131.713
AIC (smaller is better)	2137.713
AICC (smaller is better)	2137.731
BIC (smaller is better)	2153.337

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	63.6094	<.0001

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	2.5311	0.0303	2.4717	2.5905	6973.54	<.0001
tgroup	1	0.3873	0.0486	0.2921	0.4824	63.61	<.0001
Scale	1	0.5069	0.0206	0.4680	0.5490		
Weibull Shape	1	1.9727	0.0803	1.8213	2.1366		

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=1 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	317
Noncensored Values	139
Right Censored Values	178
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-226.8158407

Number of Observations Read	317
Number of Observations Used	317

Fit Statistics

-2 Log Likelihood	453.632
AIC (smaller is better)	459.632
AICC (smaller is better)	459.708
BIC (smaller is better)	470.908

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	13.5389	0.0002

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	2.4154	0.0461	2.3251	2.5057	2749.07	<.0001
tgroup	1	0.2380	0.0647	0.1112	0.3648	13.54	0.0002
Scale	1	0.3705	0.0288	0.3181	0.4314		
Weibull Shape	1	2.6994	0.2098	2.3179	3.1436		

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=2 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	494
Noncensored Values	141
Right Censored Values	353
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-320.7033933

Number of Observations Read	494
Number of Observations Used	494

Fit Statistics

-2 Log Likelihood	641.407
AIC (smaller is better)	647.407
AICC (smaller is better)	647.456
BIC (smaller is better)	660.014

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	22.1634	<.0001

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	2.6390	0.0561	2.5290	2.7490	2211.14	<.0001
tgroup	1	0.4001	0.0850	0.2335	0.5666	22.16	<.0001
Scale	1	0.4602	0.0362	0.3945	0.5369		
Weibull Shape	1	2.1730	0.1709	1.8626	2.5351		

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=3 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	348
Noncensored Values	113
Right Censored Values	235
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-250.5125401

Number of Observations Read	348
Number of Observations Used	348

Fit Statistics

-2 Log Likelihood	501.025
AIC (smaller is better)	507.025
AICC (smaller is better)	507.095
BIC (smaller is better)	518.582

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	14.9684	0.0001

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	2.6234	0.0625	2.5009	2.7459	1761.84	<.0001
tgroup	1	0.4213	0.1089	0.2079	0.6347	14.97	0.0001
Scale	1	0.4933	0.0428	0.4162	0.5846		
Weibull Shape	1	2.0273	0.1757	1.7105	2.4028		

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=4 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	191
Noncensored Values	116
Right Censored Values	75
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-215.8618775

Number of Observations Read	191
Number of Observations Used	191

Fit Statistics

-2 Log Likelihood	431.724
AIC (smaller is better)	437.724
AICC (smaller is better)	437.852
BIC (smaller is better)	447.481

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	5.9569	0.0147

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	2.2309	0.0745	2.0849	2.3769	896.78	<.0001
tgroup	1	0.3484	0.1428	0.0686	0.6282	5.96	0.0147
Scale	1	0.6792	0.0548	0.5800	0.7955		
Weibull Shape	1	1.4723	0.1187	1.2571	1.7243		

Part 1: Further 3-step Progression

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	1350
Noncensored Values	509
Right Censored Values	841
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-1006.6899

Number of Observations Read	1350
Number of Observations Used	1350

Class Level Information

Name	Levels	Values
DTCLSETD	4	1 2 3 4

Fit Statistics

-2 Log Likelihood	2013.380
AIC (smaller is better)	2031.380
AICC (smaller is better)	2031.514
BIC (smaller is better)	2078.251

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	54.7559	<.0001
retstratum	1	0.1217	0.7272
HBAEL	1	34.2179	<.0001
DURYR0	1	3.6932	0.0546
DTCLSETD	3	66.1963	<.0001

Part 1: Further 3-step Progression

The LIFEREG Procedure

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	2.8307	0.1751	2.4875	3.1739	261.37	<.0001
tgroup	1	0.3636	0.0491	0.2673	0.4599	54.76	<.0001
retstratum	1	0.0235	0.0672	-0.1083	0.1553	0.12	0.7272
HBAEL	1	-0.0799	0.0137	-0.1067	-0.0532	34.22	<.0001
DURYR0	1	0.0164	0.0085	-0.0003	0.0331	3.69	0.0546
DTCLSETD 1	1	0.2126	0.0849	0.0462	0.3790	6.27	0.0123
DTCLSETD 2	1	0.4925	0.0738	0.3479	0.6372	44.56	<.0001
DTCLSETD 3	1	0.4314	0.0694	0.2953	0.5674	38.62	<.0001
DTCLSETD 4	0	0.0000	.	.	.	.	.
Scale	1	0.4942	0.0198	0.4569	0.5345		
Weibull Shape	1	2.0236	0.0810	1.8709	2.1888		

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=1 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	317
Noncensored Values	139
Right Censored Values	178
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-223.5696632

Number of Observations Read	317
Number of Observations Used	317

Fit Statistics

-2 Log Likelihood	447.139
AIC (smaller is better)	459.139
AICC (smaller is better)	459.410
BIC (smaller is better)	481.693

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	12.7267	0.0004
retstratum	1	0.2301	0.6315
HBAEL	1	6.0013	0.0143
DURYR0	1	0.3661	0.5451

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	2.8062	0.2404	2.3350	3.2774	136.23	<.0001
tgroup	1	0.2339	0.0656	0.1054	0.3624	12.73	0.0004

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=1 ----------

The LIFEREG Procedure

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
retstratum	1	0.0530	0.1104	-0.1634	0.2693	0.23	0.6315
HBAEL	1	-0.0557	0.0227	-0.1003	-0.0111	6.00	0.0143
DURYR0	1	0.0121	0.0200	-0.0272	0.0514	0.37	0.5451
Scale	1	0.3692	0.0286	0.3171	0.4297		
Weibull Shape	1	2.7089	0.2100	2.3271	3.1534		

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=2 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	494
Noncensored Values	141
Right Censored Values	353
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-310.603071

Number of Observations Read	494
Number of Observations Used	494

Fit Statistics

-2 Log Likelihood	621.206
AIC (smaller is better)	633.206
AICC (smaller is better)	633.379
BIC (smaller is better)	658.421

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	25.4338	<.0001
retstratum	1	0.2458	0.6200
HBAEL	1	15.1387	<.0001
DURYR0	1	2.3745	0.1233

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	3.3102	0.2646	2.7916	3.8287	156.54	<.0001
tgroup	1	0.4391	0.0871	0.2684	0.6097	25.43	<.0001

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=2 ----------

The LIFEREG Procedure

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
retstratum	1	0.0554	0.1118	-0.1637	0.2746	0.25	0.6200
HBAEL	1	-0.0926	0.0238	-0.1392	-0.0460	15.14	<.0001
DURYR0	1	0.0260	0.0168	-0.0071	0.0590	2.37	0.1233
Scale	1	0.4577	0.0358	0.3926	0.5336		
Weibull Shape	1	2.1848	0.1711	1.8740	2.5472		

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=3 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	348
Noncensored Values	113
Right Censored Values	235
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-234.78881

Number of Observations Read	348
Number of Observations Used	348

Fit Statistics

-2 Log Likelihood	469.578
AIC (smaller is better)	481.578
AICC (smaller is better)	481.824
BIC (smaller is better)	504.691

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	13.3690	0.0003
retstratum	1	0.0512	0.8209
HBAEL	1	19.6266	<.0001
DURYR0	1	3.3786	0.0660

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	3.5234	0.3110	2.9138	4.1329	128.36	<.0001
tgroup	1	0.4152	0.1136	0.1926	0.6378	13.37	0.0003

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=3 ----------

The LIFEREG Procedure

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
retstratum	1	0.0275	0.1213	-0.2104	0.2653	0.05	0.8209
HBAEL	1	-0.1187	0.0268	-0.1713	-0.0662	19.63	<.0001
DURYR0	1	0.0294	0.0160	-0.0019	0.0607	3.38	0.0660
Scale	1	0.4752	0.0404	0.4022	0.5613		
Weibull Shape	1	2.1046	0.1790	1.7814	2.4863		

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=4 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	191
Noncensored Values	116
Right Censored Values	75
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-214.624944

Number of Observations Read	191
Number of Observations Used	191

Fit Statistics

-2 Log Likelihood	429.250
AIC (smaller is better)	441.250
AICC (smaller is better)	441.706
BIC (smaller is better)	460.764

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	5.8280	0.0158
retstratum	1	0.1670	0.6828
HBAEL	1	1.8727	0.1712
DURYR0	1	0.0937	0.7596

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	2.6673	0.4718	1.7427	3.5920	31.97	<.0001
tgroup	1	0.3499	0.1449	0.0658	0.6339	5.83	0.0158

Part 1: Further 3-step Progression

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=4 ----------

The LIFEREG Procedure

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
retstratum	1	0.0936	0.2290	-0.3553	0.5424	0.17	0.6828
HBAEL	1	-0.0524	0.0383	-0.1274	0.0226	1.87	0.1712
DURYR0	1	0.0062	0.0202	-0.0335	0.0458	0.09	0.7596
Scale	1	0.6739	0.0542	0.5755	0.7890		
Weibull Shape	1	1.4839	0.1194	1.2674	1.7375		

Part 2: PDR

The FREQ Procedure

Table of DTCLSETD by GROUP

DTCLSETD(DCCT closeout ETDRS level comb DCCT10-DCCT50)
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
.	1 0.08 50.00 0.15	1 0.08 50.00 0.16	2 0.15
1	194 14.79 61.39 29.09	122 9.30 38.61 18.91	316 24.09
2	274 20.88 55.58 41.08	219 16.69 44.42 33.95	493 37.58
3	148 11.28 42.65 22.19	199 15.17 57.35 30.85	347 26.45
4	50 3.81 32.47 7.50	104 7.93 67.53 16.12	154 11.74
Total	667 50.84	645 49.16	1312 100.00

Part 2: PDR

The FREQ Procedure

Table of pdr_edic by GROUP

pdr_edic
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	622 47.41 54.18 93.25	526 40.09 45.82 81.55	1148 87.50
1	45 3.43 27.44 6.75	119 9.07 72.56 18.45	164 12.50
Total	667 50.84	645 49.16	1312 100.00

Part 2: PDR

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=. ----------

The FREQ Procedure

Table of pdr_edic by GROUP

pdr_edic
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	4	2	6
	66.67	33.33	100.00
	66.67	33.33	
	100.00	100.00	
Total	4	2	6
	66.67	33.33	100.00

Part 2: PDR

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=1 ----------

The FREQ Procedure

Table of pdr_edic by GROUP

pdr_edic
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	924 61.56 62.10 99.46	564 37.57 37.90 98.60	1488 99.13
1	5 0.33 38.46 0.54	8 0.53 61.54 1.40	13 0.87
Total	929 61.89	572 38.11	1501 100.00

Part 2: PDR

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=2 ----------

The FREQ Procedure

Table of pdr_edic by GROUP

pdr_edic
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency| Percent | Row Pct | Col Pct	EXPERIMENTAL	STANDARD	Total
0	1279	949	2228
	54.03	40.09	94.13
	57.41	42.59	
	96.89	90.64	
1	41	98	139
	1.73	4.14	5.87
	29.50	70.50	
	3.11	9.36	
Total	1320	1047	2367
	55.77	44.23	100.00

Part 2: PDR

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=3 ----------

The FREQ Procedure

Table of pdr_edic by GROUP

pdr_edic
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	658 38.62 45.69 90.14	782 45.89 54.31 80.29	1440 84.51
1	72 4.23 27.27 9.86	192 11.27 72.73 19.71	264 15.49
Total	730 42.84	974 57.16	1704 100.00

Part 2: PDR

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=4 ----------

The FREQ Procedure

Table of pdr_edic by GROUP

pdr_edic
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	147 19.52 39.62 60.49	224 29.75 60.38 43.92	371 49.27
1	96 12.75 25.13 39.51	286 37.98 74.87 56.08	382 50.73
Total	243 32.27	510 67.73	753 100.00

Part 2: PDR

The FREQ Procedure

Table of event by GROUP

event
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	622 47.41 54.18 93.25	526 40.09 45.82 81.55	1148 87.50
1	45 3.43 27.44 6.75	119 9.07 72.56 18.45	164 12.50
Total	667 50.84	645 49.16	1312 100.00

Part 2: PDR

Obs	survyrs	lastedicyr	lastdate	event
839	10	10	.	0

Part 2: PDR

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=. ----------

The FREQ Procedure

Table of event by GROUP

event
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	1 50.00 50.00 100.00	1 50.00 50.00 100.00	2 100.00
Total	1 50.00	1 50.00	2 100.00

Part 2: PDR

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=1 ----------

The FREQ Procedure

Table of event by GROUP

event
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	193 61.08 61.66 99.48	120 37.97 38.34 98.36	313 99.05
1	1 0.32 33.33 0.52	2 0.63 66.67 1.64	3 0.95
Total	194 61.39	122 38.61	316 100.00

Part 2: PDR

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=2 ----------

The FREQ Procedure

Table of event by GROUP

event
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	265 53.75 57.11 96.72	199 40.37 42.89 90.87	464 94.12
1	9 1.83 31.03 3.28	20 4.06 68.97 9.13	29 5.88
Total	274 55.58	219 44.42	493 100.00

Part 2: PDR

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=3 ----------

The FREQ Procedure

Table of event by GROUP

event
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	133 38.33 45.39 89.86	160 46.11 54.61 80.40	293 84.44
1	15 4.32 27.78 10.14	39 11.24 72.22 19.60	54 15.56
Total	148 42.65	199 57.35	347 100.00

Part 2: PDR

---------- DCCT closeout ETDRS level comb DCCT10-DCCT50=4 ----------

The FREQ Procedure

Table of event by GROUP

event
GROUP(GROUP Treatment Group (EXPERIMENTAL STANDARD))

Frequency Percent Row Pct Col Pct	EXPERIMENTAL	STANDARD	Total
0	30 19.48 39.47 60.00	46 29.87 60.53 44.23	76 49.35
1	20 12.99 25.64 40.00	58 37.66 74.36 55.77	78 50.65
Total	50 32.47	104 67.53	154 100.00

Part 2: PDR

The FREQ Procedure

DCCTSCAT Any SCATTER through DCCT (0=n 1=y)

DCCTSCAT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	1312	100.00	1312	100.00

Part 2: PDR

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL_PDR
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	1312
Noncensored Values	164
Right Censored Values	1148
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-534.020551

Number of Observations Read	1312
Number of Observations Used	1312

Fit Statistics

-2 Log Likelihood	1068.041
AIC (smaller is better)	1074.041
AICC (smaller is better)	1074.059
BIC (smaller is better)	1089.579

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	31.8835	<.0001

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	3.1648	0.0802	3.0075	3.3220	1555.65	<.0001
tgroup	1	0.5753	0.1019	0.3756	0.7750	31.88	<.0001
Scale	1	0.5313	0.0398	0.4588	0.6154		
Weibull Shape	1	1.8821	0.1410	1.6250	2.1798		

Part 2: PDR

The FREQ Procedure

Table of DTCLSETD by dtclsetd_cut3

DTCLSETD(DCCT closeout ETDRS level comb DCCT10-DCCT50)
dtclsetd_cut3

Frequency Percent Row Pct Col Pct	1	3	4	Total
1	316 24.12 100.00 39.06	0 0.00 0.00 0.00	0 0.00 0.00 0.00	316 24.12
2	493 37.63 100.00 60.94	0 0.00 0.00 0.00	0 0.00 0.00 0.00	493 37.63
3	0 0.00 0.00 0.00	347 26.49 100.00 100.00	0 0.00 0.00 0.00	347 26.49
4	0 0.00 0.00 0.00	0 0.00 0.00 0.00	154 11.76 100.00 100.00	154 11.76
Total	809 61.76	347 26.49	154 11.76	1310 100.00

Frequency Missing = 2

Part 2: PDR

---------- dtclsetd_cut3=. ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL_PDR
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	2
Noncensored Values	0
Right Censored Values	2
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-2.2794E-12

Number of Observations Read	2
Number of Observations Used	2

Fit Statistics

-2 Log Likelihood	0.000
AIC (smaller is better)	6.000
AICC (smaller is better)	.
BIC (smaller is better)	2.079

WARNING: Negative of Hessian not positive definite.

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	1.5539	0.2042	1.1538	1.9541	57.93	<.0001
tgroup	1	0.3906	0.2887	-0.1754	0.9565	1.83	0.1762
Scale	0	0.0000	0.0000	0.0000	0.0000		
Weibull Shape	0	4587821	0.0000	4587821	4587821		

Part 2: PDR

---------- dtclsetd_cut3=1 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL_PDR
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	809
Noncensored Values	32
Right Censored Values	777
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-125.4764652

Number of Observations Read	809
Number of Observations Used	809

Fit Statistics

-2 Log Likelihood	250.953
AIC (smaller is better)	256.953
AICC (smaller is better)	256.983
BIC (smaller is better)	271.040

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	6.9593	0.0083

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	3.2356	0.1679	2.9065	3.5646	371.48	<.0001
tgroup	1	0.3740	0.1418	0.0961	0.6518	6.96	0.0083
Scale	1	0.3322	0.0569	0.2374	0.4647		
Weibull Shape	1	3.0105	0.5159	2.1517	4.2122		

Part 2: PDR

---------- dtclsetd_cut3=3 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL_PDR
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	347
Noncensored Values	54
Right Censored Values	293
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-160.0234836

Number of Observations Read	347
Number of Observations Used	347

Fit Statistics

-2 Log Likelihood	320.047
AIC (smaller is better)	326.047
AICC (smaller is better)	326.117
BIC (smaller is better)	337.595

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	5.4277	0.0198

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	3.0245	0.1194	2.7906	3.2585	642.09	<.0001
tgroup	1	0.3451	0.1481	0.0548	0.6353	5.43	0.0198
Scale	1	0.4678	0.0607	0.3628	0.6031		
Weibull Shape	1	2.1378	0.2772	1.6581	2.7564		

---------- dtclsetd_cut3=4 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL_PDR
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	154
Noncensored Values	78
Right Censored Values	76
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-149.2844722

Number of Observations Read	154
Number of Observations Used	154

Fit Statistics

-2 Log Likelihood	298.569
AIC (smaller is better)	304.569
AICC (smaller is better)	304.729
BIC (smaller is better)	313.680

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	3.2677	0.0707

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	2.4293	0.0790	2.2744	2.5842	944.47	<.0001
tgroup	1	0.2757	0.1525	-0.0232	0.5746	3.27	0.0707
Scale	1	0.5810	0.0586	0.4767	0.7080		
Weibull Shape	1	1.7212	0.1737	1.4124	2.0976		

Part 2: PDR

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL_PDR
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	1310
Noncensored Values	164
Right Censored Values	1146
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-428.075576

Number of Observations Read	1312
Number of Observations Used	1310
Missing Values	2

Class Level Information

Name	Levels	Values
dtclsetd_cut3	3	1 3 4

Fit Statistics

-2 Log Likelihood	856.151
AIC (smaller is better)	872.151
AICC (smaller is better)	872.262
BIC (smaller is better)	913.573

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	18.1614	<.0001
dtclsetd_cut3	2	70.9694	<.0001
retstratum	1	1.6376	0.2007
HBAEL	1	20.0618	<.0001
DURYR0	1	0.0315	0.8591

Part 2: PDR

The LIFEREG Procedure

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	3.3832	0.3050	2.7855	3.9810	123.06	<.0001
tgroup	1	0.4032	0.0946	0.2178	0.5887	18.16	<.0001
dtclsetd_cut3 1	1	1.2059	0.1483	0.9152	1.4965	66.11	<.0001
dtclsetd_cut3 3	1	0.6318	0.1001	0.4356	0.8280	39.84	<.0001
dtclsetd_cut3 4	0	0.0000	.	.	.	.	.
retstratum	1	0.1483	0.1159	-0.0788	0.3755	1.64	0.2007
HBAEL	1	-0.1093	0.0244	-0.1572	-0.0615	20.06	<.0001
DURYR0	1	0.0023	0.0132	-0.0235	0.0282	0.03	0.8591
Scale	1	0.4942	0.0353	0.4296	0.5684		
Weibull Shape	1	2.0237	0.1445	1.7594	2.3276		

Part 2: PDR

---------- dtclsetd_cut3=. ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL_PDR
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	2
Noncensored Values	0
Right Censored Values	2
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-2.2794E-12

Number of Observations Read	2
Number of Observations Used	2

Fit Statistics

-2 Log Likelihood	0.000
AIC (smaller is better)	6.000
AICC (smaller is better)	.
BIC (smaller is better)	2.079

WARNING: Negative of Hessian not positive definite.

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	1.5539	0.2042	1.1538	1.9541	57.93	<.0001
tgroup	1	0.3906	0.2887	-0.1754	0.9565	1.83	0.1762
retstratum	0	0.0000	.	.	.	.	.
HBAEL	0	0.0000	.	.	.	.	.
DURYR0	0	0.0000	.	.	.	.	.
Scale	0	0.0000	0.0000	0.0000	0.0000		
Weibull Shape	0	4587821	0.0000	4587821	4587821		

Part 2: PDR

---------- dtclsetd_cut3=1 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL_PDR
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	809
Noncensored Values	32
Right Censored Values	777
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-118.8425345

Number of Observations Read	809
Number of Observations Used	809

Fit Statistics

-2 Log Likelihood	237.685
AIC (smaller is better)	249.685
AICC (smaller is better)	249.790
BIC (smaller is better)	277.860

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	8.5082	0.0035
retstratum	1	2.3395	0.1261
HBAEL	1	8.8067	0.0030
DURYR0	1	0.0409	0.8397

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	4.0652	0.4683	3.1474	4.9830	75.37	<.0001
tgroup	1	0.4301	0.1475	0.1411	0.7191	8.51	0.0035

Part 2: PDR

---------- dtclsetd_cut3=1 ----------

The LIFEREG Procedure

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
retstratum	1	0.2536	0.1658	-0.0714	0.5786	2.34	0.1261
HBAEL	1	-0.1135	0.0382	-0.1884	-0.0385	8.81	0.0030
DURYR0	1	0.0048	0.0239	-0.0420	0.0516	0.04	0.8397
Scale	1	0.3336	0.0571	0.2385	0.4666		
Weibull Shape	1	2.9976	0.5131	2.1433	4.1925		

Part 2: PDR

---------- dtclsetd_cut3=3 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL_PDR
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	347
Noncensored Values	54
Right Censored Values	293
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-150.7546109

Number of Observations Read	347
Number of Observations Used	347

Fit Statistics

-2 Log Likelihood	301.509
AIC (smaller is better)	313.509
AICC (smaller is better)	313.756
BIC (smaller is better)	336.605

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	5.9356	0.0148
retstratum	1	0.2553	0.6134
HBAEL	1	14.3300	0.0002
DURYR0	1	0.0142	0.9052

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	4.4294	0.4925	3.4641	5.3947	80.88	<.0001
tgroup	1	0.3840	0.1576	0.0751	0.6930	5.94	0.0148

Part 2: PDR

---------- dtclsetd_cut3=3 ----------

The LIFEREG Procedure

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
retstratum	1	-0.0897	0.1776	-0.4377	0.2583	0.26	0.6134
HBAEL	1	-0.1455	0.0384	-0.2208	-0.0702	14.33	0.0002
DURYR0	1	-0.0027	0.0223	-0.0463	0.0410	0.01	0.9052
Scale	1	0.4534	0.0579	0.3530	0.5822		
Weibull Shape	1	2.2058	0.2816	1.7176	2.8328		

Part 2: PDR

---------- dtclsetd_cut3=4 ----------

The LIFEREG Procedure

Model Information

Data Set	WORK.SURVIVAL_PDR
Dependent Variable	Log(survyrs)
Censoring Variable	event
Censoring Value(s)	0
Number of Observations	154
Noncensored Values	78
Right Censored Values	76
Left Censored Values	0
Interval Censored Values	0
Name of Distribution	Weibull
Log Likelihood	-147.7133211

Number of Observations Read	154
Number of Observations Used	154

Fit Statistics

-2 Log Likelihood	295.427
AIC (smaller is better)	307.427
AICC (smaller is better)	307.998
BIC (smaller is better)	325.648

Algorithm converged.

Type III Analysis of Effects

Effect	DF	Wald Chi-Square	Pr > ChiSq
tgroup	1	3.2764	0.0703
retstratum	1	1.6496	0.1990
HBAEL	1	1.0956	0.2952
DURYR0	1	0.7337	0.3917

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
Intercept	1	2.6565	0.5194	1.6385	3.6746	26.16	<.0001
tgroup	1	0.2794	0.1544	-0.0231	0.5819	3.28	0.0703

---------- dtclsetd_cut3=4 ----------

The LIFEREG Procedure

Analysis of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	95% Confidence Limits		Chi-Square	Pr > ChiSq
retstratum	1	0.2909	0.2265	-0.1530	0.7347	1.65	0.1990
HBAEL	1	-0.0454	0.0434	-0.1305	0.0396	1.10	0.2952
DURYR0	1	0.0179	0.0210	-0.0231	0.0590	0.73	0.3917
Scale	1	0.5740	0.0577	0.4714	0.6989		
Weibull Shape	1	1.7421	0.1750	1.4308	2.1212		