

Dataset Integrity Check (DSIC) for the TrialNet TN-02 Mycophenolate Mofetil and Daclizumab Study



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Revision History

Version	Author/Title	Date	Comments
1.0	SM Rogers	November 2012	Original
1.1	SM Rogers	December 2012	QC revision
2.0	SM Rogers	February 2013	Revision based on addition of new variable to identify erroneous randomization group
2.1	SM Rogers	May 2013	Final revision based on new data supplied by DCC (2013May16)

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1 Standard Disclaimer

The TN-02 study was a three-arm, randomized, double-blind, placebo-controlled clinical trial conducted by Type 1 Diabetes TrialNet. This trial tested whether mycophenolate mofetil (MMF) alone or with daclizumab (DZB) could arrest the loss of insulin-producing β -cells in subjects with new-onset type 1 diabetes. As a partial check of the TN-02 data archived in the NIDDK data repository, a dataset integrity check (DSIC) was performed to verify that selected published results from the TN-02 study can be reproduced using the archived dataset. This DSIC consists of several analyses performed to duplicate selected results reported by Gottlieb et al [1] in Diabetes Care in 2010.

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 a first (or second) 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 data coordinating center (DCC), however this process is labor-intensive for both DCC and Repository staff. It is thus not our policy to resolve every discrepancy that is observed in an integrity check. Specifically, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses, *unless NIDDK Repository staff suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff*. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

2 Study Background

The objective of this study was to determine whether MMF alone or MMF combined with DZB could diminish progression of β -cell destruction in recent onset type 1 diabetes. The multi-center trial was conducted at 13 sites with subjects aged 8 to 45 years¹ with autoimmune type 1 diabetes for less than 3 months and with evidence of β -cell function. According to study protocol 126 subjects were randomized to receive MMF alone (with DZB placebo), MMF and DZB in combination, or control (MMF placebo and DZB placebo), stratified within clinical center. Among the last six sites to join the study, 12 subjects assigned to receive MMF alone inadvertently received DZB-alone, thus resulting in an imbalance in the group sample sizes (see RTI_01TN02Protocol/Version2.1 11Feb2008.pdf). The results from these 12 subjects are not presented in the published report and were excluded from these analyses (MMF01.dat, RNDERR=="YES").

MMF or matched placebo was administered daily at a dose of 600 mg/m² (maximum 2,000 mg/day) in 2–3 divided doses for 2 years. DZB or matched placebo was given by intravenous infusion at study day 0 and two weeks later at a dose of 1 mg/kg. All subjects were to be followed for at least 2 years under the intention-to-treat principle, including those who did not receive the full course of assigned therapy. Because both drugs reduce the ability to fight viral infections, screening for cytomegalovirus (CMV) and Epstein-Barr virus (EBV) was based on close surveillance rather than active prophylaxis. Visits included assessment of diabetes care, adverse events, and laboratory measurements to assess medication side effects. The paper by Gottlieb et al in *Diabetes Care* provides the main study results for the efficacy trial.

¹ We note that one subject aged 46 years (based on the variable, M01AGE) was included in the final analyses.

3 Archived Datasets

The DCC submitted 37 datasets which correspond with 35 of the study data collection forms plus a subject randomization file and study laboratory data. Contents of the archived forms datasets match dataset descriptions provided in the Data Dictionary (Protocol _2.Data Dictionary.rtf) provided by the DCC.

Analysis datasets to correspond with published results by the TN-02 study group were not provided. For our DSIC tabulations, we used the data files mmf01, mmf02, mmf03, mmf06, mmf_randlist, and mmf_labdata archived in the NIDDK repository.

4 Statistical Methods

We compare our DSIC results to the published results in

- Table 1. Baseline Characteristics of the treatment groups, including all 114 subjects correctly randomized, and
- Figure 2. Effect of MMF and MMF with DZB on glycemic control over time. A) Mean A1C (%) and 95% confidence limits over time. B) Mean insulin dose and 95% confidence limits over time within each group.

Our DSIC analyses were conducted in Stata v12 (Appendix 1). SAS datasets provided by the DCC were converted to Stata using Stat/Transfer (Circle Systems Inc).

Creating linkage between subject randomization number and treatment assignment. The randomization file, mmf_randlist, provides a study randomization number, RandomizationNumber, and treatment variables, MMF and DZB, for 1080 **screened** subjects. The Eligibility and Randomization Form data file, mmf03, provides indicators of patient randomization, M03PATRND=="Y", and randomization number, M03RNDNM, for the trial's 126 randomized subjects. Users should be aware that RandomizationNumber and M03PATRND can be linked to determine the treatment assignment of the randomized subjects.

As noted above, according to the study design 126 subjects were randomized to receive MMF alone, MMF and DZB in combination, or control (MMF placebo and DZB placebo), stratified within clinical center. Safety data in the manuscript are presented for 114 properly randomized subjects, excluding the 12 subjects who received DZB alone instead of MMF alone. Our DSIC analyses identify 126 subjects with a valid randomization number (M03RNDNM). The variable RNDERR in data file mmf01 identifies the 12 subjects who were improperly randomized. Our analyses were based on the 114 subjects who were identified as properly randomized (by dropping subjects with RNDERR=="Yes" in mmf01).

The manuscript notes that data from all 13 centers contributed to the primary and secondary effectiveness analysis of the MMF plus DZB combination and its respective control group. The center variable, *Site*, included in the randomization file provides data on 12 centers (Sites 1,2,4,5,7,8-11,13,16,17). When these data were merged with the baseline data, mmf_03, 7 of the 126 subjects randomized (M03PATRND="Y") were missing the Site variable.

The published manuscript notes also that due to a randomization error, subjects received MMF alone in only 7 centers; hence the published analyses compare the MMF alone subjects only with the concurrently randomized control subjects from these centers. *Our DSIC analyses, however, found only 6 centers where subjects received MMF alone. The published Ns and the DSIC Ns for tabulations of the number of control subjects randomized in Table 1 do not match.*

5 Results

Baseline Characteristics of the Treatment Groups. Table 1 presents the baseline characteristics for each active therapy group versus its respective control from the published manuscript and our DSIC analyses. The variables used in our DSIC analyses to replicate Table 1 are presented in Table 2. As noted above, we were unable to exactly match the published Ns of the MMF alone control subjects.. In addition, our analyses identified a few duplicate observations in the laboratory results file; for the duplicate pairs, we deleted the second duplicate observation for our analyses. Our DSIC results were generally similar to published demographic and physical measurements.

We were unable to replicate some of the published laboratory estimates as we were unable to identify the variables in the repository data files. These variables included the number of positive antibodies², the mean MPA level over 24 months, and the number (and percentage) of subjects who were MMF compliant. The 2-h C peptide area under the curve (AUC) (pmol/ml/120 min) was computed in the manuscript using the trapezoidal rule from timed measurements of C-peptide during each MMTT (including the basal); this calculation was not performed for this DSIC. Finally we note that z scores for BMI were estimated in the manuscript for subjects less than 20 years of age. Our DSIC analyses of the number of subjects within this age group did not match the published results and BMI z scores ((observed BMI minus mean BMI) / SD BMI)) were not estimated.

² The laboratory data, mmf.labdata, includes results for GAD65, MIAA, and ICA512; however, our tabulations of these variables did not resemble estimates presented in the published manuscript and are not presented.

Table 1 Baseline Characteristics of the treatment groups, including all 114 subjects correctly randomized‡ (From Gottlieb et al. (2010) *Failure to preserve β-cell function with MMF and DZB combined therapy in patients with new-onset Type 1 diabetes, Diabetes Care*).

	<i>from Gottlieb et al (2010) Diabetes Care</i>				<i>DSIC analysis</i>			
	MMF + DZB		MMF alone		MMF + DZB		MMF alone	
	Active	Control	Active	Control	Active	Control	Active	Control
N	41	42	31	28	41	42	31	30
Age (years)	18.3±9.1	18.8±10.5	17.1±6.7	15.8±8.0	18.3±9.1	18.8±10.5	17.2±6.7	16.4±8.1
Race (% white)	38 (93)	39 (93)	30 (97)	27 (96)	36 (88)	39 (93)	30 (97)	28 (97)
Non-Hispanic	40 (98)	39 (93)	29 (94)	26 (93)	40 (98)	39 (93)	29 (94)	28 (93)
Number of Ab+ (%)								
1	1 (2)	3 (7)	4 (13)	1 (4)	<i>not calculated</i>		<i>not calculated</i>	
2	11 (27)	8 (19)	7 (23)	7 (25)				
3	12 (29)	16 (38)	6 (19)	11 (39)				
4	17 (41)	15 (36)	14 (45)	9 (32)				
Male sex (%)	23 (56)	25 (60)	20 (65)	16 (57)	23 (56)	25 (60)	20 (65)	18 (60)
2-h C-peptide AUC means (pmol/ml)	0.71 ± 0.36	0.71 ± 0.34	0.65 ± 0.28	0.73 ± 0.36	<i>not calculated</i>		<i>not calculated</i>	
Baseline A1C (%)	7.5 ± 1.3	7.7 ± 1.6	7.4 ± 1.0	7.5 ± 1.5	7.6±1.2	7.7 ± 1.6	7.4±1.0	7.6±1.5
Baseline total insulin dose/kg	0.4 ± 0.26	0.36 ± 0.2	0.35 ± 0.15	0.39 ± 0.22	0.4 ± 0.26	0.36 ± 0.2	0.35 ± 0.15	0.39 ± 0.21
Weight (kg)	58.9 ± 16.6	59 ± 16.3	61.3 ± 18.3	57.2 ± 16.7	59.0±16.7	59.5±16.7	59.2±16.7	58.8±17.3
Height (cm)	162.4 ± 13.5	162.7 ± 13.7	164.4 ± 15.4	160.9 ± 13.4	161.9±13.3	163.2±13.7	163.7±15.7	161.9±13.5
BMI (km/m2)	22 ± 4.2	21.8 ± 3.6	22.1 ± 4.1	21.6 ± 4.0	21.8±4.2	21.7±3.7	21.6±3.5	21.9±4.0
zBMI (only on subjects <20 yrs)	0.44 ± 1.11	0.66 ± 0.79	0.42 ± 1.02	0.57 ± 0.74	<i>not calculated</i>		<i>not calculated</i>	
N	30	28	21	23	29	27	20	22
Mean A1C over 24 months (%)	7.2 ± 1.2	7.2 ± 1.0	7.0 ± 1.2	7.3 ± 0.9	7.3±1.2	7.2±1.0	7.0±1.1	7.3 ± 0.9
Mean insulin dose/kg over 24 months	0.56 ± 0.29	0.55 ± 0.32	0.59 ± 0.31	0.63 ± 0.34	0.55±0.27	0.55±0.31	0.56±0.29	0.60±0.32
Mean MPA level over 24 months (mcg/ml)*	4.5 ± 3.4	0.6 ± 0.6	5.8 ± 4.0	0.6 ± 0.2	<i>not calculated</i>		<i>not calculated</i>	
Received 2 full DZB infusions (%)	40 (98) **	42 (100)	31 (100)	28 (100)	40 (98)	42 (100)	31 (100)	30 (100)
% of subjects MMF compliant ***	36 (88)	41 (98)	27 (87)	27 (96)	<i>not calculated</i>		<i>not calculated</i>	

Note: Means ± SD are presented for continuous variables. *Limit of quantitation = 0.5 units. ** One subject did not receive the second infusion due to patient decision to continue study treatment. *** 80% or greater by capsule count up through last recorded visit starting with month 3.

The analysis for the AUC means for the 2-hr C-peptide were not calculated for this DSIC. In addition we were unable to calculate the mean MPA level and % of subjects MMF compliant as the proper variables could not be identified in the repository datasets.

Table 2. Variables used in DSIC calculations for Table 1.

Study Variable	Variable name
N	M03PATRND, M03RNDM, RNDERR mmf_randlist.RandomizationNumber,DZB,MMF
Age (years)	M01age
Race (% white)	M01white; M01asian; M01amind; M01blk;M01hawaii; M01ethn;M01otherad
Non-Hispanic	M01ethn
Number of Ab+ (%)	MMF_LABDATA.RESULTNAME=="GAD65" "ICA512" "MIAA", RESULTVALUE, VISITNO==1
Male sex (%)	M01sex
2-h C-peptide AUC means (pmol/ml)	MMF_LABDATA.RESULTNAME=="PEP120"
Baseline A1C (%)	M01HBG
Baseline total insulin dose/kg	M02 [9 TYPES]
Weight (kg)	M02WTKG
Height (cm)	M02HTCM
BMI (km/m2)	M02WTKG, M02HTCM
zBMI (only on subjects <20 yrs)	<i>not calculated</i>
Mean A1C over 24 months (%)	MMF_LABDATA.RESULTNAME=="HBA1C", VISITNO
Mean insulin dose/kg over 24 months	M02HUMDS,M02REGDS,M02NPHDS,M02ULTDS,M02DATM IRDS,M02NOTRDS,M02WTKG,M02NOVODS,M02LNTDS
Mean MPA level over 24 months (mcg/ml)	?
Received 2 full DZB infusions (%)	M06GIVINF2, M06VISIT
% of subjects MMF compliant	?

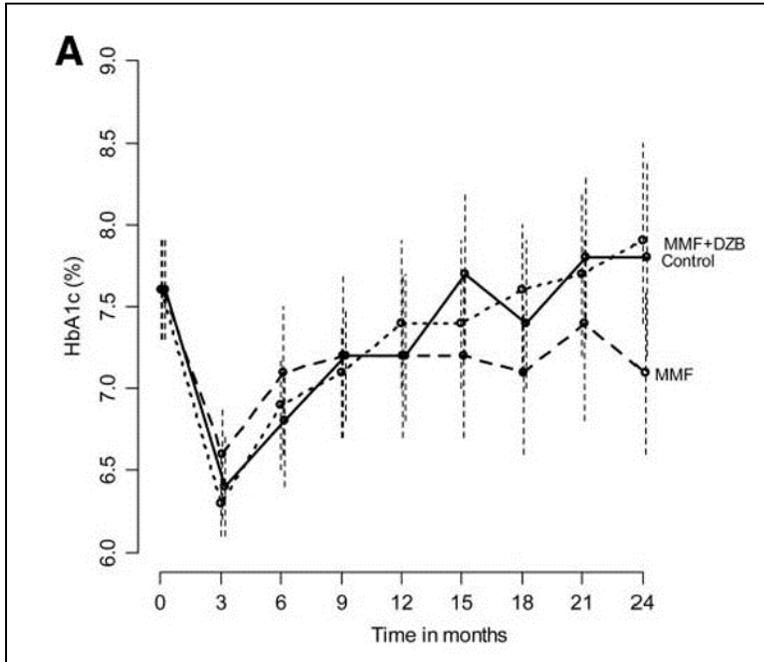
Figure 1. Effect of MMF and MMF plus DZB on glycemic control over time. Figure 1-A) Mean A1C (%) and 95% confidence limits over time. Figure 1-B) Mean insulin dose and 95% confidence limits over time within each group.

Figure 2 of the manuscript presents the mean HbA1c and mean insulin dose (units/kg) over the 24 month period for subjects assigned to MMF, MMF plus DZB, and controls. Our DSIC results are similar to results published in Figure 2 of Gottlieb et al. For all 3 groups, mean A1C declined at the 3 month follow-up and all groups achieved levels of 7.2 to 7.3. Daily insulin dose rose slowly from below 0.5 units/kg at baseline to nearly 0.7 units/kg for MMF alone and control subjects.

Our DSIC results present estimates of the mean values over time, 95% CIs, and sample Ns (see Appendix 1). Our sample Ns for the treatment groups match those presented in our DSIC calculations for Table 1.

Figure 1-A. Effect of MMF and MMF plus DZB on glycemic control over time: Mean A1C (%) and 95% confidence limits over time.

PUBLISHED (from Gottlieb P, Quinlan S, Krause-Steinrauf H et al for the Type 1 Diabetes TrialNet MMF/DZB Study Group (2010) Failure to preserve b-cell function with mycophenolate mofetil and daclizumab combined therapy in patients with new-onset type 1 diabetes. Diabetes Care 33(14): 826-832.)



DSIC Calculation for Figure 1-A.

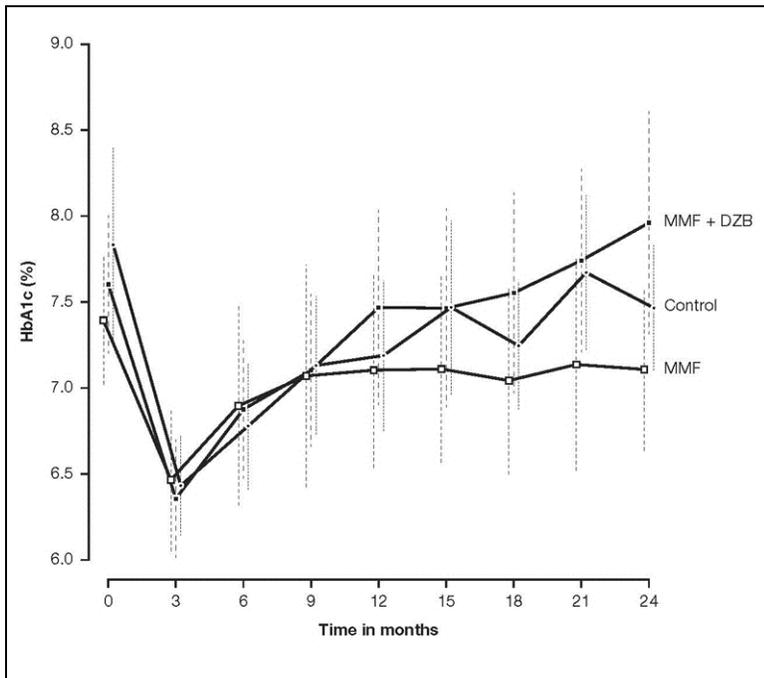
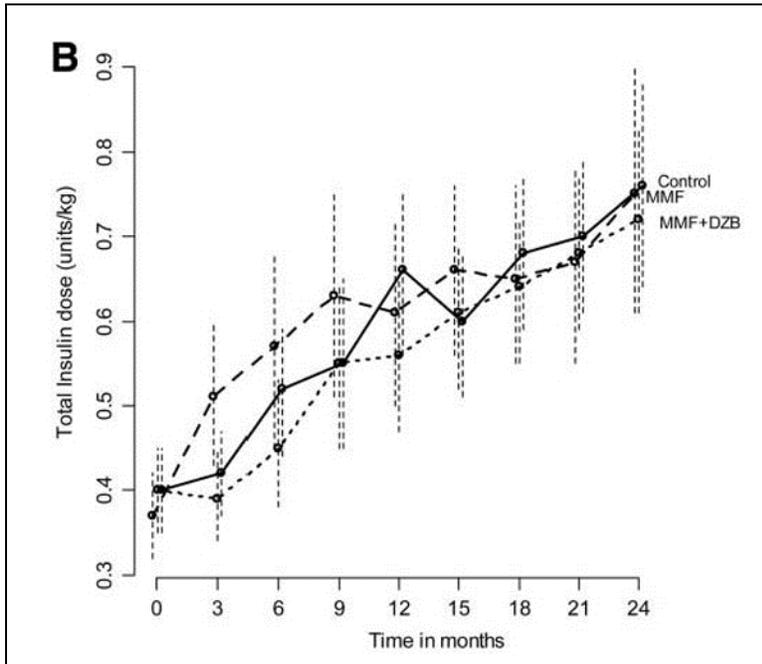
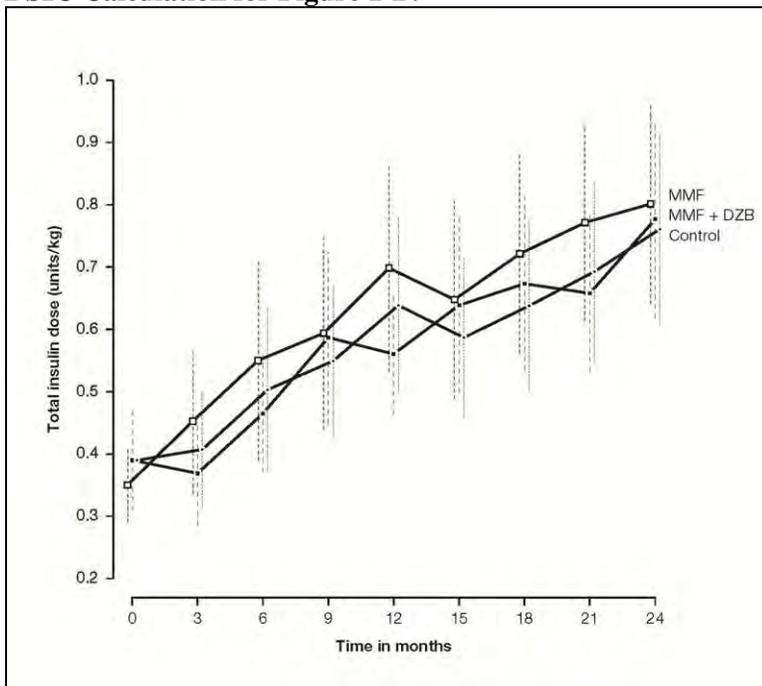


Figure 1-B. Comparison of published and calculated Effect of MMF and MMF plus DZB on glycemic control over time: Mean insulin dose and 95% confidence limits over time within each group.

PUBLISHED (from Gottlieb P, Quinlan S, Krausse-Steinrauf H et al for the Type 1 Diabetes TrialNet MMF/DZB Study Group (2010) Failure to preserve b-cell function with mycophenolate mofetil and daclizumab combined therapy in patients with new-onset type 1 diabetes. Diabetes Care 33(14): 826-832.)



DSIC Calculation for Figure 1-B.



7 Conclusions

Our DSIC analyses are similar to the results published by Gottlieb and colleagues (2010). We note, however, that we were unable to fully replicate laboratory results for several measures in part because of our inability to identify the proper study variables in the repository data.

8 References

1. Gottlieb P, Quinlan S, Krause-Steinrauf H et al for the Type 1 Diabetes TrialNet MMF/DZB Study Group (2010) Failure to preserve b-cell function with mycophenolate mofetil and daclizumab combined therapy in patients with new-onset type 1 diabetes. *Diabetes Care* 33(14): 826-832.

Appendix

[1] STATA v12 log of programming code for DSIC analysis of Gottlieb et al (2010) manuscript in *Diabetes Care*

9 Appendix 1.

```

-----
log: C:\Documents and Settings\smr\My Documents\Trial Net\MMD Study (TN-
02)\DSIC\FINAL\Gottlieb_final.log
log type: text
opened on: 30 May 2013, 12:54:18

. use "C:\Documents and Settings\smr\My Documents\Trial Net\MMD Study (TN-02)\DATA12
2013May16\mmf01.dta", clear

. keep MaskID RNDERR /**228 obs
RNDERR identifies 12 subjects incorrectly randomized**/
. merge 1:1 MaskID using "C:\Documents and Settings\smr\My Documents\Trial Net\MMD
Study (TN-02)\DATA12 2013May16\mmf03.dta", gen(_merge)

Result # of obs.
-----
not matched 93
    from master 93 (_merge==1)
    from using 0 (_merge==2)

matched 135 (_merge==3)
-----

. *tab M03RNDNM
. rename M03RNDNM RandomizationNumber

. sort RandomizationNumber

. *tab RandomizationNumber, missing
. keep if RandomizationNumber!=. /** 126 subjects w/ valid randomization
number**/
(102 observations deleted)

. drop if RNDERR=="YES"
(12 observations deleted)

. save "C:\Documents and Settings\smr\My Documents\Trial Net\MMD Study (TN-
02)\DSIC\FINAL\RANDOM", replace
file C:\Documents and Settings\smr\My Documents\Trial Net\MMD Study (TN-
02)\DSIC\FINAL\RANDOM.dta saved

. cd "C:\Documents and Settings\smr\My Documents\Trial Net\MMD Study (TN-02)\DATA12
2013May16\"
C:\Documents and Settings\smr\My Documents\Trial Net\MMD Study (TN-02)\DATA12 2013May16

. merge 1:m RandomizationNumber using "mmf_randlist.dta", gen(_merge2)

Result # of obs.
-----
not matched 973
    from master 0 (_merge2==1)
    from using 973 (_merge2==2)

matched 114 (_merge2==3)
-----

. keep if _merge2==3 /** 114 with match **/
(973 observations deleted)

. *tab1 M03PATRND M03DRNDNM, missing
. *list M03PATRND M03DRNDNM DZB MMF MaskID RandomizationNumber

```

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

. tab MMF DZB, mi ssi ng

MMF Treatment Assignment	DZB Treatment Assignment		Total
	Act	Pl a	
Act	41	31	72
Pl a	0	42	42
Total	41	73	114

```
. gen MMFDZB=.
(114 mi ssi ng val ues generated)
. repl ace MMFDZB=2 i f DZB=="Pl a" & MMF=="Pl a"
(42 real changes made)
. repl ace MMFDZB=1 i f DZB=="Act" & MMF=="Act"
(41 real changes made)
. label var MMFDZB "MMF+DZB"
. label defi ne MMFDZB 1"Act" 2"Control "
. label val ue MMFDZB MMFDZB
. tab MMFDZB, mi ssi ng
```

MMF+DZB	Freq.	Percent	Cum.
Act	41	35.96	35.96
Control	42	36.84	72.81
.	31	27.19	100.00
Total	114	100.00	

```
. *tab Si te MMF al one, mi ssi ng
. tab Si te i f MMF=="Act" & DZB=="Pl a"
```

Si te Number	Freq.	Percent	Cum.
01	5	16.13	16.13
05	5	16.13	32.26
07	6	19.35	51.61
09	8	25.81	77.42
10	4	12.90	90.32
16	3	9.68	100.00
Total	31	100.00	

. /**per ms, MMF al one subjects were compared only wi th concurrentl y randomi zed subjects at those centers.

> To repli cate, select centers wi th subjects randomi zed, centers 1, 5, 7, 9, 10, 16 **/

```
. gen center=real (Si te)
```

```
. recode center (01 05 07 09 10 16=1), gen(MMFsi te)
(74 di fferences between center and MMFsi te)
. gen MMF al one=.
(114 mi ssi ng val ues generated)
. repl ace MMF al one=2 i f DZB=="Pl a" & MMF=="Pl a" & MMFsi te==1
(30 real changes made)
. repl ace MMF al one=1 i f DZB=="Pl a" & MMF=="Act" & MMFsi te==1
(31 real changes made)
. tab MMF al one, mi ssi ng
```

MMF al one	Freq.	Percent	Cum.
1	31	27.19	27.19
2	30	26.32	53.51
.	53	46.49	100.00
Total	114	100.00	

```
. label val ue MMF al one MMFDZB
```

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

```
. keep M03PATRND RandomizationNumber M03DRNDNM DZB MMF MaskID MMFDZB MMFalone Site
center
. save "C:\Documents and Settings\smr\My Documents\TrialNet\MMD Study (TN-
02)\DSIC\FINAL\Random.dta", replace
file C:\Documents and Settings\smr\My Documents\TrialNet\MMD Study (TN-
02)\DSIC\FINAL\Random.dta saved
. use "mmf01.dta", clear
. *tab1 M01AGE M01AMIND M01WHITE M01ASIAN M01BLK M01HAWAII M01ETHN M01OTHERAD M01SEX
M01HBG DOB_Month DOB_Year
. keep MaskID M01AGE M01AMIND M01WHITE M01ASIAN M01BLK M01HAWAII M01ETHN M01OTHERAD
M01SEX M01HBG DOB_Month DOB_Year
. sort MaskID
. merge m:1 MaskID using "C:\Documents and Settings\smr\My Documents\TrialNet\MMD
Study (TN-02)\DSIC\FINAL\Random.dta", gen(_merge3)keep(match)
```

Result	# of obs.
not matched	0
matched	114 (_merge3==3)

```
. gen race=.
(114 missing values generated)
. replace race=1 if M01WHITE==1
(107 real changes made)
. replace race=2 if M01ASIAN=="1" | M01AMIND=="1" | M01BLK=="1" | M01HAWAII=="1" |
M01OTHERAD=="1"
(7 real changes made)
. label var race "RACE recode"
. label define race 1"white" 2"other"
. label value race race
. tab race, missing
```

RACE recode	Freq.	Percent	Cum.
white	105	92.11	92.11
other	7	6.14	98.25
.	2	1.75	100.00
Total	114	100.00	

```
. save "C:\Documents and Settings\smr\My Documents\TrialNet\MMD Study (TN-
02)\DSIC\FINAL\Random_m01.dta", replace
file C:\Documents and Settings\smr\My Documents\TrialNet\MMD Study (TN-
02)\DSIC\FINAL\Random_m01.dta saved
```

```
. use "mmf02.dta", clear

. /* 126 obs */
. *tab1 M02WTKG M02HTCM M02HUM M02HUMDS M02NOVO M02NOVODS M02REG M02REGDS M02NPH
M02NPHDS ///
> M02ULENT M02ULTDS M02LANT M02LNTDS M02LENTE M02LENTEDS
M02DTMI R M02DTMIRDS M02INOTR M02INOTRDS
. gen ins2=real(M02HUMDS)
(71 missing values generated)
. gen ins3=real(M02REGDS)
123 missing values generated)
. gen ins4=real(M02NPHDS)
(97 missing values generated)
. gen ins5=real(M02ULTDS)
(125 missing values generated)
. gen ins6=real(M02DTMIRDS)
(123 missing values generated)
. gen ins7=real(M02INOTRDS)
(121 missing values generated)
. gen ins8=M02NOVODS
(75 missing values generated)
. gen ins9=M02LNTDS
(37 missing values generated)
. egen ins=rowtotal(ins2 ins3 ins4 ins5 ins6 ins7 ins8 ins9)
. *tab ins
. label var ins "total insulin baseline"
```

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```
. gen insdoseb=ins/M02WTKG
(7 missing values generated)
. label var insdoseb "baseline total insulin dose"
. *tab insdoseb
. keep MaskID ins* ins M02WTKG M02HTCM
. merge 1:1 MaskID using "C:\Documents and Settings\smr\My Documents\TrialNet\MMD
Study (TN-02)\DSIC\FINAL\Random_m01.dta", gen(_merge5) keep(match)
```

Result	# of obs.
not matched	0
matched	114 (_merge5==3)

```
. /** Table 1 **/
. tab MMFDZB
```

MMF+DZB	Freq.	Percent	Cum.
Act	41	49.40	49.40
Control	42	50.60	100.00
Total	83	100.00	

```
. bysort MMFDZB: summ insdoseb /** Baseline insulin **/
```

-> MMFDZB = Act

Variab le	Obs	Mean	Std. Dev.	Min	Max
insdoseb	40	.4069389	.2568156	0	1.015873

-> MMFDZB = Control

Variab le	Obs	Mean	Std. Dev.	Min	Max
insdoseb	39	.3640621	.2026386	0	.8623853

-> MMFDZB = .

Variab le	Obs	Mean	Std. Dev.	Min	Max
insdoseb	29	.3500402	.1510903	.0590551	.6586826

```
. tab MMFalone
```

MMFalone	Freq.	Percent	Cum.
Act	31	50.82	50.82
Control	30	49.18	100.00
Total	61	100.00	

```
. bysort MMFalone: summ insdoseb
```

-> MMFalone = Act

Variab le	Obs	Mean	Std. Dev.	Min	Max
insdoseb	29	.3500402	.1510903	.0590551	.6586826

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

-> MMF alone = Control

Variable	Obs	Mean	Std. Dev.	Min	Max
insdoseb	30	.3881998	.2100326	0	.8623853

-> MMF alone = .

Variable	Obs	Mean	Std. Dev.	Min	Max
insdoseb	49	.3842855	.2453445	0	1.015873

. recode M01AGE (8/19=1) (20/46=0), gen(aged t20)
(114 differences between M01AGE and aged t20)

. *calculate BMI=wt(kg)/ht*ht(meters)
. gen bmi=M02WTKG/((M02HTCM/100)*(M02HTCM/100))
(7 missing values generated)

. bysort MMFDZB: tab1 race M01ETHN M01SEX aged t20

-> MMFDZB = Act

-> tabulation of race

RACE recode	Freq.	Percent	Cum.
white	36	87.80	87.80
other	5	12.20	100.00
Total	41	100.00	

-> tabulation of M01ETHN

M01ETHN	Freq.	Percent	Cum.
1	1	2.44	2.44
2	40	97.56	100.00
Total	41	100.00	

-> tabulation of M01SEX

M01SEX	Freq.	Percent	Cum.
1	23	56.10	56.10
2	18	43.90	100.00
Total	41	100.00	

-> tabulation of aged t20

RECODE of M01AGE (M01AGE)	Freq.	Percent	Cum.
0	12	29.27	29.27
1	29	70.73	100.00
Total	41	100.00	

-> MMFDZB = Control

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

-> tabulation of race

RACE recode	Freq.	Percent	Cum.
white	39	97.50	97.50
other	1	2.50	100.00
Total	40	100.00	

-> tabulation of M01ETHN

M01ETHN	Freq.	Percent	Cum.
1	3	7.14	7.14
2	39	92.86	100.00
Total	42	100.00	

-> tabulation of M01SEX

M01SEX	Freq.	Percent	Cum.
1	25	59.52	59.52
2	17	40.48	100.00
Total	42	100.00	

-> tabulation of age t20

RECODE of M01AGE (M01AGE)	Freq.	Percent	Cum.
0	15	35.71	35.71
1	27	64.29	100.00
Total	42	100.00	

-> MMFDZB = .

-> tabulation of race

RACE recode	Freq.	Percent	Cum.
white	30	96.77	96.77
other	1	3.23	100.00
Total	31	100.00	

-> tabulation of M01ETHN

M01ETHN	Freq.	Percent	Cum.
1	2	6.45	6.45
2	29	93.55	100.00
Total	31	100.00	

-> tabulation of M01SEX

M01SEX	Freq.	Percent	Cum.
1	20	64.52	64.52
2	11	35.48	100.00
Total	31	100.00	

-> tabulation of age t20

RECODE of |

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

MO1AGE (MO1AGE)	Freq.	Percent	Cum.
0	11	35.48	35.48
1	20	64.52	100.00
Total	31	100.00	

. by MMFDZB: summ MO1AGE MO1HBG MO2WTKG MO2HTCM bmi

-> MMFDZB = Act

Vari able	Obs	Mean	Std. Dev.	Min	Max
MO1AGE	41	18.31707	9.114382	8	43
MO1HBG	33	10.13939	2.508104	5.8	16.4
MO2WTKG	40	59.0275	16.75479	28.3	99.6
MO2HTCM	40	161.9375	13.28691	132.7	183
bmi	39	21.84849	4.210706	15.34571	32.15393

-> MMFDZB = Control

Vari able	Obs	Mean	Std. Dev.	Min	Max
MO1AGE	42	18.83333	10.45995	9	46
MO1HBG	33	10.0697	3.003902	5.8	16.6
MO2WTKG	39	59.50256	16.73489	27.2	89.1
MO2HTCM	40	163.2425	13.7215	128	186.5
bmi	39	21.74337	3.729694	15.74372	32.96659

-> MMFDZB = .

Vari able	Obs	Mean	Std. Dev.	Min	Max
MO1AGE	31	17.16129	6.743376	8	38
MO1HBG	19	8.610526	1.764116	5.9	12.5
MO2WTKG	29	59.17931	16.74164	27.5	87.4
MO2HTCM	29	163.7172	15.66156	128.5	186
bmi	29	21.56079	3.515626	14.93246	28.37639

. bysort MMFalone: tab1 race MO1ETHN MO1SEX agel t20

-> MMFalone = Act

-> tabulation of race

RACE recode	Freq.	Percent	Cum.
whi te	30	96.77	96.77
other	1	3.23	100.00
Total	31	100.00	

-> tabulation of MO1ETHN

MO1ETHN	Freq.	Percent	Cum.
1	2	6.45	6.45
2	29	93.55	100.00
Total	31	100.00	

-> tabulation of MO1SEX

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

M01SEX	Freq.	Percent	Cum.
1	20	64.52	64.52
2	11	35.48	100.00
Total	31	100.00	

-> tabulation of age1 t20

RECODE of M01AGE (M01AGE)	Freq.	Percent	Cum.
0	11	35.48	35.48
1	20	64.52	100.00
Total	31	100.00	

-> MMFalone = Control

-> tabulation of race

RACE recode	Freq.	Percent	Cum.
white	28	96.55	96.55
other	1	3.45	100.00
Total	29	100.00	

-> tabulation of M01ETHN

M01ETHN	Freq.	Percent	Cum.
1	2	6.67	6.67
2	28	93.33	100.00
Total	30	100.00	

-> tabulation of M01SEX

M01SEX	Freq.	Percent	Cum.
1	18	60.00	60.00
2	12	40.00	100.00
Total	30	100.00	

-> tabulation of age1 t20

RECODE of M01AGE (M01AGE)	Freq.	Percent	Cum.
0	8	26.67	26.67
1	22	73.33	100.00
Total	30	100.00	

. by MMFalone: summ M01AGE M01HBG M02WTKG M02HTCM bmi

-> MMFalone = Act

Variable	Obs	Mean	Std. Dev.	Min	Max
M01AGE	31	17.16129	6.743376	8	38
M01HBG	19	8.610526	1.764116	5.9	12.5

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

MO2WTKG	29	59.17931	16.74164	27.5	87.4
MO2HTCM	29	163.7172	15.66156	128.5	186
bmi	29	21.56079	3.515626	14.93246	28.37639

-> MMFalone = Control

Variable	Obs	Mean	Std. Dev.	Min	Max
MO1AGE	30	16.4	8.084041	9	46
MO1HBG	22	10.10455	3.199625	6.1	16.6
MO2WTKG	30	58.82	17.26117	27.2	89.1
MO2HTCM	30	161.9333	13.50503	128	183.5
bmi	30	21.9165	3.990383	15.74372	32.96659

-> MMFalone = .

Variable	Obs	Mean	Std. Dev.	Min	Max
MO1AGE	53	19.81132	10.46617	8	44
MO1HBG	44	10.10455	2.529542	5.8	16.4
MO2WTKG	49	59.53265	16.42208	28.3	99.6
MO2HTCM	50	162.984	13.51659	132.7	186.5
bmi	48	21.72057	3.968173	15.34571	32.15393

```
. *tabstat MO1AGE MO1HBG MO2WTKG MO2HTCM bmi, by (MMFDZB MMFonly) stat (mean sd)
. save "C:\Documents and Settings\smr\My Documents\TrialNet\MMD Study (TN-02)\DSI\C\FINAL\tabl e1. dta", replace
file C:\Documents and Settings\smr\My Documents\TrialNet\MMD Study (TN-02)\DSI\C\FINAL\tabl e1. dta saved
```

```
. use "mmf06.dta", clear
```

```
. keep if MO6VISIT==4 /*week 2*/
(1422 observations deleted)
```

```
. keep MaskID MO6VISIT MO6GIVINF2
```

```
. merge 1:1 MaskID using "C:\Documents and Settings\smr\My Documents\TrialNet\MMD Study (TN-02)\DSI\C\FINAL\tabl e1. dta", gen(_merge6) keep(match)
```

Result	# of obs.
not matched	0
matched	114 (_merge6==3)

```
. label var MO6GIVINF2 "received 2 DZB infusions"
```

```
. tab MO6GIVINF2 MMFDZB, col
```

Key	
frequency	column percentage

received 2 DZB infusions	MMF+DZB		Total
	Act	Control	
N	1 2.44	0 0.00	1 1.20
Y	40 97.56	42 100.00	82 98.80

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

Total	41	42	83
	100.00	100.00	100.00

. tab M06GI V I NF2 MMF al one, col

Key
frequency
column percentage

received 2 DZB infusions	MMF al one		Total
	Act	Control	
Y	31 100.00	30 100.00	61 100.00
Total	31 100.00	30 100.00	61 100.00

. save "C:\Documents and Settings\smr\My Documents\TrialNet\MMD Study (TN-02)\DSI\C\FINAL\table1a.dta", replace
file C:\Documents and Settings\smr\My Documents\TrialNet\MMD Study (TN-02)\DSI\C\FINAL\table1a.dta saved

. use "mmf06.dta", clear

. tab M06VI SIT

M06VI SIT	Freq.	Percent	Cum.
3	119	7.69	7.69
4	126	8.14	15.83
5	117	7.56	23.39
6	124	8.01	31.40
7	123	7.95	39.34
8	125	8.07	47.42
11	125	8.07	55.49
14	123	7.95	63.44
17	122	7.88	71.32
20	119	7.69	79.01
23	119	7.69	86.69
26	96	6.20	92.89
29	92	5.94	98.84
99	18	1.16	100.00
Total	1,548	100.00	

. drop if M06VI SIT<8 | M06VI SIT==99
(627 observations deleted)

```
. *tab1 M06WTKG M06HTCM M06HUM M06HUMDS M06NOVO M06NOVODS M06REG M06REGDS M06NPH
M06NPHDS ///
> M06ULENT M06ULTDS M06LANT M06LNTDS M06LENTE M06LENTEDS
M06DTMI R M06DTMI RDS M06I NOTR M06I NOTRDS
. gen HUM=real (M06HUMDS)
(576 missing values generated)
. gen REG=real (M06REGDS)
(908 missing values generated)
. gen NPH=real (M06NPHDS)
(846 missing values generated)
. gen ULT=real (M06ULTDS)
(912 missing values generated)
. gen DTMI R=real (M06DTMI RDS)
(895 missing values generated)
. gen OTR=real (M06I NOTRDS)
(892 missing values generated)
```

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

```
. gen NOVO=M06NOVODS
(413 missing values generated)
. gen LNT=M06LNTDS
(314 missing values generated)
. egen insf=rowtotal (HUM REG NPH ULT DTMI R OTR NOVO LNT)
. label var insf "total insulin followup"

. keep M06WTKG M06HTCM M06HUM M06HUMDS M06NOVO M06NOVODS M06REG M06REGDS M06NPH
M06NPHDS ///
> M06ULENT M06ULTDS M06LANT M06LNTDS M06LENTE M06LENTEDS
M06DTMI R M06DTMI RDS M06I NOTR M06I NOTRDS M06HBA1C M06VI SIT MaskID///
> HUM REG NPH ULT DTMI R OTR NOVO LNT insf
. *tab insf
. *bysort M06VI SIT: summ insf
. *by M06VI SIT: summ M06WTKG
. keep MaskID insf M06WTKG M06VI SIT

. reshape wide insf M06WTKG, i (MaskID) j (M06VI SIT)
(note: j = 8 11 14 17 20 23 26 29)
```

Data	long	->	wide
Number of obs.	921	->	125
Number of variables	4	->	17
j variable (8 values)	M06VI SIT	->	(dropped)
xij variables:	insf	->	insf8 insf11 ... insf29
	M06WTKG	->	M06WTKG8 M06WTKG11 ... M06WTKG29

```
. gen dose3=insf8/M06WTKG8
(13 missing values generated)
. gen dose6=insf11/M06WTKG11
(8 missing values generated)
. gen dose9=insf14/M06WTKG14
(17 missing values generated)
. gen dose12=insf17/M06WTKG17
(10 missing values generated)
. gen dose15=insf20/M06WTKG20
(28 missing values generated)
. gen dose18=insf23/M06WTKG23
(17 missing values generated)
. gen dose21=insf26/M06WTKG26
(43 missing values generated)
. gen dose24=insf29/M06WTKG29
(38 missing values generated)
. *summ dose*
. merge 1:1 MaskID using "C:\Documents and Settings\smr\My Documents\Tri al Net\MMD
Study (TN-02)\DSI C\FI NAL\tabl e1a.dta", gen(_merge7) keep(match)
```

Result	# of obs.
not matched	0
matched	113 (_merge7==3)

```
. save "C:\Documents and Settings\smr\My Documents\Tri al Net\MMD Study (TN-
02)\DSI C\FI NAL\fi g2.dta", repl ace
file C:\Documents and Settings\smr\My Documents\Tri al Net\MMD Study (TN-
02)\DSI C\FI NAL\fi g2.dta saved
```

```
. recode insdoseb dose3 dose6 dose9 dose12 dose15 dose18 dose21 dose24 (. =0)
(i nsdoseb: 6 changes made)
(dose3: 11 changes made)
(dose6: 6 changes made)
(dose9: 15 changes made)
(dose12: 8 changes made)
(dose15: 26 changes made)
(dose18: 15 changes made)
(dose21: 38 changes made)
(dose24: 30 changes made)
```

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

```
. egen averdose=rowmean(i nsdoseb dose3 dose6 dose9 dose12 dose15 dose18 dose21 dose24)
. bysort MMFDZB: summ averdose
```


 -> MMFDZB = Act

Vari able	Obs	Mean	Std. Dev.	Min	Max
averdose	41	.4725929	.2791221	.0792057	1.051528

 -> MMFDZB = Control

Vari able	Obs	Mean	Std. Dev.	Min	Max
averdose	42	.4546703	.3147442	0	1.233682

 -> MMFDZB = .

Vari able	Obs	Mean	Std. Dev.	Min	Max
averdose	30	.4943997	.2498591	.115639	1.004853

. by MMFDZB: ci dose*

 -> MMFDZB = Act

Vari able	Obs	Mean	Std. Err.	[95% Conf. Interval]
dose3	41	.3418619	.040913	.2591737 .4245501
dose6	41	.4421201	.0467231	.3476891 .536551
dose9	41	.5010295	.0666419	.3663411 .6357179
dose12	41	.5331133	.049485	.4331005 .6331262
dose15	41	.467318	.0670234	.3318587 .6027774
dose18	41	.5748903	.0680921	.437271 .7125096
dose21	41	.4332038	.0634051	.3050574 .5613503
dose24	41	.5627856	.0769164	.4073319 .7182394

 -> MMFDZB = Control

Vari able	Obs	Mean	Std. Err.	[95% Conf. Interval]
dose3	42	.3490608	.0450906	.2579985 .4401232
dose6	42	.4672219	.0630578	.3398741 .5945698
dose9	42	.4445378	.0594236	.3245295 .5645461
dose12	42	.5624758	.0688465	.4234375 .7015141
dose15	42	.4471817	.061757	.3224608 .5719026
dose18	42	.5313966	.0673958	.3952881 .6675051
dose21	42	.4448133	.0665878	.3103365 .5792901
dose24	42	.5072869	.075106	.3556072 .6589666

 -> MMFDZB = .

Vari able	Obs	Mean	Std. Err.	[95% Conf. Interval]
dose3	30	.4565869	.0595736	.3347452 .5784286
dose6	30	.51002	.0601299	.3870405 .6329995
dose9	30	.5656933	.0693738	.4238079 .7075787

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

dose12	30	.5544883	.0677	.4160263	.6929504
dose15	30	.483273	.0693091	.34152	.6250261
dose18	30	.6058559	.0763972	.4496061	.7621057
dose21	30	.4299442	.0757121	.2750956	.5847928
dose24	30	.5177415	.0747753	.3648089	.6706741

. bysort MMFalone: summ averdose

-> MMFalone = Act

Variabl e	Obs	Mean	Std. Dev.	Min	Max
averdose	30	.4943997	.2498591	.115639	1.004853

-> MMFalone = Control

Variabl e	Obs	Mean	Std. Dev.	Min	Max
averdose	30	.5406401	.3158151	.0605004	1.233682

-> MMFalone = .

Variabl e	Obs	Mean	Std. Dev.	Min	Max
averdose	53	.4198728	.2777942	0	1.051528

. by MMFalone: ci dose*

-> MMFalone = Act

Variabl e	Obs	Mean	Std. Err.	[95% Conf. Interval]
dose3	30	.4565869	.0595736	.3347452 .5784286
dose6	30	.51002	.0601299	.3870405 .6329995
dose9	30	.5656933	.0693738	.4238079 .7075787
dose12	30	.5544883	.0677	.4160263 .6929504
dose15	30	.483273	.0693091	.34152 .6250261
dose18	30	.6058559	.0763972	.4496061 .7621057
dose21	30	.4299442	.0757121	.2750956 .5847928
dose24	30	.5177415	.0747753	.3648089 .6706741

-> MMFalone = Control

Variabl e	Obs	Mean	Std. Err.	[95% Conf. Interval]
dose3	30	.4073555	.0565922	.2916115 .5230995
dose6	30	.5502476	.078491	.3897154 .7107798
dose9	30	.4949578	.0744139	.3427642 .6471514
dose12	30	.6753546	.0819354	.5077778 .8429313
dose15	30	.5183273	.0777641	.3592818 .6773728
dose18	30	.6490799	.0804365	.4845688 .813591
dose21	30	.5142923	.0839564	.3425821 .6860026
dose24	30	.6679459	.0853248	.493437 .8424548

-> MMFalone = .

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

Variable	Obs	Mean	Std. Err.	[95% Conf. Interval]	
dose3	53	.3104949	.034505	.2412556	.3797341
dose6	53	.4008078	.0410878	.3183592	.4832565
dose9	53	.4596993	.0558253	.3476777	.5717209
dose12	53	.4758678	.0450482	.3854721	.5662635
dose15	53	.4224877	.0555551	.3110083	.5339672
dose18	53	.4984295	.058405	.3812313	.6156278
dose21	53	.3965046	.0533121	.2895261	.5034831
dose24	53	.4592808	.0668382	.3251601	.5934016

```

. save "C:\Documents and Settings\smr\My Documents\TrialNet\MMD Study
(TN-02)\DSI\C\FINAL\fig2b.dta", replace
file C:\Documents and Settings\smr\My Documents\TrialNet\MMD Study (TN-
02)\DSI\C\FINAL\fig2b.dta saved
. use "mmf_labdata.dta"
. keep if RESULTNAME=="HBA1C"
(70844 observations deleted)

```

```

. tab VISITNO

```

VISITNO	Freq.	Percent	Cum.
1	218	17.83	17.83
8	126	10.30	28.13
11	123	10.06	38.18
14	126	10.30	48.49
17	121	9.89	58.38
20	120	9.81	68.19
23	116	9.48	77.68
26	96	7.85	85.53
29	91	7.44	92.97
31	48	3.92	96.89
32	23	1.88	98.77
33	14	1.14	99.92
99	1	0.08	100.00
Total	1,223	100.00	

```

. drop if VISITNO >29
(86 observations deleted)
. keep RESULTNAME MaskID RESULTVALUE VISITNO
. duplicates list
Duplicates in terms of all variables

```

group:	obs:	RESUL-ME	RESUL-UE	VISITNO	MaskID
1	424	HBA1C	5.5	14	1163818
1	425	HBA1C	5.5	14	1163818
2	692	HBA1C	6.1	1	1130140
2	693	HBA1C	6.1	1	1130140
3	847	HBA1C	6.6	8	1188995
3	848	HBA1C	6.6	8	1188995

```

. duplicates drop /* 3 duplicate observations */

```

Duplicates in terms of all variables
(3 observations deleted)

```

. reshape wide RESULTVALUE, i(MaskID) j(VISITNO)
(note: j = 1 8 11 14 17 20 23 26 29)
VISITNO not unique within MaskID;
there are multiple observations at the same VISITNO within MaskID.
Type "reshape error" for a listing of the problem observations.
. reshape error
(note: j = 1 8 11 14 17 20 23 26 29)

```

i (MaskID) indicates the top-level grouping such as subject id.

j (VISITNO) indicates the subgrouping such as time.
 The data are in the long form; j should be unique within i.

There are multiple observations on the same VISITNO within MaskID.
 The following 10 of 1134 observations have repeated VISITNO values:

	MaskID	VISITNO
105.	1106798	29
106.	1106798	29
157.	1110061	20
158.	1110061	20
693.	1159212	14
694.	1159212	14
723.	1163818	14
724.	1163818	14
873.	1178581	1
874.	1178581	1

```
(data now sorted by MaskID VISITNO)
. do "C:\DOCUME~1\smr\LOCALS~1\Temp\STD0a000000.tmp"
. drop in 874
(1 observation deleted)
. drop in 724
(1 observation deleted)
. drop in 694
(1 observation deleted)
. drop in 158
(1 observation deleted)
. drop in 106
(1 observation deleted)
. pause
```

```
. reshape wide RESULTVALUE, i(MaskID) j(VISITNO)
(note: j = 1 8 11 14 17 20 23 26 29)
```

Data	long	->	wide
Number of obs.	1129	->	217
Number of variables	4	->	11
j variable (9 values)	VISITNO	->	(dropped)
xij variables:	RESULTVALUE	->	RESULTVALUE1 RESULTVALUE8 ...
RESULTVALUE29			

```
. label var RESULTVALUE1 "base"
. label var RESULTVALUE8 "Month 3"
. label var RESULTVALUE11 "Month 6"
. label var RESULTVALUE14 "Month 9"
. label var RESULTVALUE17 "Month 12"
. label var RESULTVALUE20 "Month 15"
. label var RESULTVALUE23 "Month 18"
. label var RESULTVALUE26 "Month 21"
. label var RESULTVALUE29 "Month 24"
. summ RESULTVALUE*
```

Variable	Obs	Mean	Std. Dev.	Min	Max
RESULTVALUE1	214	7.679907	1.499301	5.1	14.7
RESULTVALUE8	125	6.4016	1.048192	4.8	9.9
RESULTVAL~11	123	6.801626	1.271567	4.9	10.9
RESULTVAL~14	122	7.035246	1.374077	4.7	12.3
RESULTVAL~17	121	7.214876	1.483389	4.9	12.9
RESULTVAL~20	119	7.405042	1.632553	4.7	12.8
RESULTVAL~23	116	7.282759	1.436316	4.9	12.9
RESULTVAL~26	96	7.601042	1.727212	5	17.2
RESULTVAL~29	90	7.577778	1.435801	5.4	12.6

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```
. sort MaskID
. merge 1:1 MaskID using "C:\Documents and Settings\smr\My Documents\TrialNet\MMD
Study (TN-02)\DSIC\FINAL\table1a.dta", gen(_merge8) keep(match)
```

Result	# of obs.
not matched	0
matched	114 (_merge8==3)

```
. /* 114 observations matched */
. bysort MMFDZB: ci RESULTVALUE*
```

-> MMFDZB = Act

Variable	Obs	Mean	Std. Err.	[95% Conf. Interval]	
RESULTVALUE1	41	7.526829	.1958417	7.131019	7.92264
RESULTVALUE8	41	6.339024	.1649419	6.005664	6.672384
RESULTVAL~11	39	6.892308	.1975007	6.492488	7.292127
RESULTVAL~14	41	7.043902	.2186446	6.602005	7.4858
RESULTVAL~17	41	7.404878	.2667087	6.86584	7.943917
RESULTVAL~20	40	7.4375	.2687265	6.893949	7.981051
RESULTVAL~23	38	7.505263	.2767405	6.944534	8.065993
RESULTVAL~26	33	7.648485	.2554008	7.12825	8.168719
RESULTVAL~29	32	7.859375	.3087063	7.229764	8.488986

-> MMFDZB = Control

Variable	Obs	Mean	Std. Err.	[95% Conf. Interval]	
RESULTVALUE1	42	7.67619	.244137	7.183146	8.169235
RESULTVALUE8	42	6.404762	.1380952	6.125873	6.683651
RESULTVAL~11	42	6.738095	.1776068	6.379411	7.096779
RESULTVAL~14	39	7.112821	.1822479	6.743879	7.481762
RESULTVAL~17	39	7.24359	.2107693	6.81691	7.67027
RESULTVAL~20	38	7.644737	.2607489	7.116409	8.173064
RESULTVAL~23	38	7.342105	.1849467	6.967368	7.716843
RESULTVAL~26	30	7.76	.2400958	7.268949	8.251051
RESULTVAL~29	30	7.57	.2006971	7.159528	7.980472

```
. by MMFDZB: summ RESULTVALUE*
```

-> MMFDZB = Act

Variable	Obs	Mean	Std. Dev.	Min	Max
RESULTVALUE1	41	7.526829	1.253998	5.6	10.3
RESULTVALUE8	41	6.339024	1.056143	4.9	9.6
RESULTVAL~11	39	6.892308	1.233392	5.3	9.8
RESULTVAL~14	41	7.043902	1.400009	5.3	11.5
RESULTVAL~17	41	7.404878	1.707769	5.2	12.9
RESULTVAL~20	40	7.4375	1.699576	5.5	12.8
RESULTVAL~23	38	7.505263	1.705943	5.4	12.9
RESULTVAL~26	33	7.648485	1.467166	5.4	11.6
RESULTVAL~29	32	7.859375	1.746307	5.4	12.6

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-> MMFDZB = Control

Variable	Obs	Mean	Std. Dev.	Min	Max
RESULTVALUE1	42	7.67619	1.582189	5.1	11.1
RESULTVALUE8	42	6.404762	.8949594	5.1	8.9
RESULTVAL~11	42	6.738095	1.151023	5	9.6
RESULTVAL~14	39	7.112821	1.138138	4.7	9.8
RESULTVAL~17	39	7.24359	1.316254	4.9	11
RESULTVAL~20	38	7.644737	1.607364	5.1	12.2
RESULTVAL~23	38	7.342105	1.140088	5	10
RESULTVAL~26	30	7.76	1.315059	5.5	11.3
RESULTVAL~29	30	7.57	1.099263	5.6	10.6

. ci RESULTVALUE* if MMFDZB==1

Variable	Obs	Mean	Std. Err.	[95% Conf. Interval]	
RESULTVALUE1	41	7.526829	.1958417	7.131019	7.92264
RESULTVALUE8	41	6.339024	.1649419	6.005664	6.672384
RESULTVAL~11	39	6.892308	.1975007	6.492488	7.292127
RESULTVAL~14	41	7.043902	.2186446	6.602005	7.4858
RESULTVAL~17	41	7.404878	.2667087	6.86584	7.943917
RESULTVAL~20	40	7.4375	.2687265	6.893949	7.981051
RESULTVAL~23	38	7.505263	.2767405	6.944534	8.065993
RESULTVAL~26	33	7.648485	.2554008	7.12825	8.168719
RESULTVAL~29	32	7.859375	.3087063	7.229764	8.488986

. egen avA1c=rowmean (RESULTVALUE1 RESULTVALUE8 RESULTVALUE11 RESULTVALUE14
RESULTVALUE17 RESULTVALUE20 RESULTVALUE23 RESULTVALUE26 RESULTVALUE29
>)

. by MMFDZB: summ avA1c /** for table 1**/

-> MMFDZB = Act

Variable	Obs	Mean	Std. Dev.	Min	Max
avA1c	41	7.276094	1.1891	5.477778	10.45556

-> MMFDZB = Control

Variable	Obs	Mean	Std. Dev.	Min	Max
avA1c	42	7.225671	.9628281	5.288889	9.344444

-> MMFDZB = .

Variable	Obs	Mean	Std. Dev.	Min	Max
avA1c	31	7.042582	1.12549	5.2625	10.4

. bysort MMFalone: ci RESULTVALUE*

-> MMFalone = Act

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Variabl e	Obs	Mean	Std. Err.	[95% Conf. Interval]	
RESULTVALUE1	31	7.393548	.1822757	7.021292	7.765805
RESULTVALUE8	30	6.466667	.2025319	6.052442	6.880891
RESULTVAL~11	30	6.896667	.2837549	6.316323	7.477011
RESULTVAL~14	30	7.07	.3164512	6.422785	7.717215
RESULTVAL~17	29	7.103448	.2773681	6.535285	7.671611
RESULTVAL~20	29	7.110345	.2655204	6.566451	7.654239
RESULTVAL~23	28	7.042857	.2660921	6.496881	7.588833
RESULTVAL~26	25	7.136	.2992702	6.518337	7.753663
RESULTVAL~29	24	7.108333	.2284888	6.635668	7.580998

-> MMFalone = Control

Variabl e	Obs	Mean	Std. Err.	[95% Conf. Interval]	
RESULTVALUE1	30	7.62	.2655898	7.076808	8.163192
RESULTVALUE8	30	6.526667	.1663629	6.186416	6.866917
RESULTVAL~11	30	6.81	.198694	6.403625	7.216375
RESULTVAL~14	27	7.262963	.2180036	6.81485	7.711076
RESULTVAL~17	28	7.332143	.248224	6.822829	7.841457
RESULTVAL~20	27	7.618519	.2875398	7.027472	8.209565
RESULTVAL~23	27	7.359259	.1839159	6.981215	7.737304
RESULTVAL~26	23	7.73913	.2367216	7.2482	8.230061
RESULTVAL~29	26	7.461538	.1743627	7.102432	7.820645

. by MMFalone: summ RESULTVALUE*

-> MMFalone = Act

Variabl e	Obs	Mean	Std. Dev.	Min	Max
RESULTVALUE1	31	7.393548	1.014868	5.5	10.3
RESULTVALUE8	30	6.466667	1.109313	4.8	9
RESULTVAL~11	30	6.896667	1.55419	4.9	10.9
RESULTVAL~14	30	7.07	1.733275	5	12.3
RESULTVAL~17	29	7.103448	1.493673	5	11
RESULTVAL~20	29	7.110345	1.429871	4.7	10.9
RESULTVAL~23	28	7.042857	1.408027	4.9	11.3
RESULTVAL~26	25	7.136	1.496351	5	11.6
RESULTVAL~29	24	7.108333	1.119362	5.4	10.2

-> MMFalone = Control

Variabl e	Obs	Mean	Std. Dev.	Min	Max
RESULTVALUE1	30	7.62	1.454695	5.2	11.1
RESULTVALUE8	30	6.526667	.9112074	5.4	8.9
RESULTVAL~11	30	6.81	1.088292	5.3	9.6
RESULTVAL~14	27	7.262963	1.13278	5.1	9.8
RESULTVAL~17	28	7.332143	1.313478	5.2	11
RESULTVAL~20	27	7.618519	1.4941	5.2	12.2
RESULTVAL~23	27	7.359259	.9556549	5.5	9.5
RESULTVAL~26	23	7.73913	1.135277	6	10.2
RESULTVAL~29	26	7.461538	.889079	5.6	9.4

TrialNet TN-02 Mycophenolate Mofetil and Daclizumab (MMF-DZB) Study

```
. by MMFalone: summ avA1c /** for table 1**/
```

```
-----  
-----  
-> MMFalone = Act
```

Variable	Obs	Mean	Std. Dev.	Min	Max
avA1c	31	7.042582	1.12549	5.2625	10.4

```
-----  
-----  
-> MMFalone = Control
```

Variable	Obs	Mean	Std. Dev.	Min	Max
avA1c	30	7.246118	.9180398	5.46	9.344444

```
-----  
-----  
end of do-file
```