Dataset Integrity Check for Anti-CD3 Mab (Teplizumab) for Prevention of Diabetes in Relatives At-Risk for Type 1 Diabetes Mellitus (TN10) Study

Prepared by NIDDK-CR
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Contents

1 Standard Disclaimer

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

2 Study Background

TrialNet 10 (TN10) was a phase 2 prevention trial of TrialNet, studying the effect of teplizumab on insulin production in the relatives of type 1 diabetics who were at high risk of developing the disease. Participants were randomly assigned to either the active or placebo group of the study, and monitored and tested over time until diagnosed with diabetes.

3 Archived Datasets

A full listing of the archived datasets included in the package can be found in the Roadmap document. All data files, as provided by the Data Coordinating Center (DCC), are located in the TN10 folder in the data package. For this replication, variables were taken from the “mastable.sas7bdat” dataset.

4 Statistical Methods

Analyses were performed to replicate results posted to ClinicalTrials.gov [1]. To verify the integrity of the data, only descriptive statistics were computed.

5 Results

For the table on ClinicalTrials.gov [1], Baseline Characteristics, Table A lists the variables that were used in the replication, and Table B compares the results calculated from the archived data files to the results in the table. The results of the replication are within expected variation to the published results.

6 Conclusions

The NIDDK Central Repository is confident that the TN10 data files to be distributed are a true copy of the study data.

7 References

[1] AntiCD3 Mab (Teplizumab) for Prevention of Diabetes in Relatives At-Risk for Type 1 Diabetes Mellitus (TN10). ClinicalTrials.gov, August 2020, https://www.clinicaltrials.gov/study/NCT01030861

Table A: Variables used to replicate results – Baseline Characteristics

Table Variable	**dataset.variable**
Age	mastable.age
Sex	mastable.sex mastable.rxdesc
Ethnicity	mastable.ethnic mastable.rxdesc
Race	mastable.race mastable.rxdesc
Relationship to person with type 1 diabetes	mastable.which_first mastable.rxdesc

Table B: Comparison of values computed in integrity check to reference website table

Baseline Characteristics	ClinicalTrials.gov Results: Teplizumab (n=44)	DSIC: Teplizumab (n=44)	Diff. (n=0)	ClinicalTrials.gov Results: Placebo (n=32)	DSIC: Placebo (n=32)	Diff. (n=0)
Age, median (min-max)	14 (8.5-49.5)	14 (8.5-49.5)	0 (0)	13 (8.6-45.0)	13 (8.6-45.0)	0 (0)
Sex, n (%)						
Female	19 (43.2)	19 (43.2)	0 (0)	15 (46.9)	15 (46.9)	0 (0)
Male	25 (56.8)	25 (56.8)	0 (0)	17 (53.1)	17 (53.1)	0 (0)
Ethnicity, n (%)						
Hispanic or Latino	1 (2.3)	1 (2.3)	0 (0)	1 (3.1)	1 (3.1)	0 (0)
Not Hispanic or Latino	43 (97.7)	43 (97.7)	0 (0)	31 (96.9)	31 (96.9)	0 (0)
Unknown or Not Reported	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Race, n (%)						
American Indian or Alaska Native	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Asian	0 (0)	0 (0)	0 (0)	2 (6.3)	2 (6.3)	0 (0)
Native Hawaiian or Other Pacific Islander	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Black or African American	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
White	44 (100)	44 (100)	0 (0)	30 (93.8)	30 (93.8)	0 (0)
More than one race	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Unknown or Not Reported	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Relationship to person with type 1 diabetes, n (%)						
Sibling(s)	24 (54.5)	24 (54.5)	0 (0)	16 (50.0)	16 (50.0)	0 (0)
Identical twin	4 (9.1)	4 (9.1)	0 (0)	0 (0)	0 (0)	0 (0)
Offspring	6 (13.6)	6 (13.6)	0 (0)	6 (18.8)	6 (18.8)	0 (0)
Parent	6 (13.6)	6 (13.6)	0 (0)	3 (9.4)	3 (9.4)	0 (0)
Sibling and another first degree relative	2 (4.5)	2 (4.5)	0 (0)	3 (9.4)	3 (9.4)	0 (0)
Second degree relative	2 (4.5)	2 (4.5)	0 (0)	3 (9.4)	4 (12.5)	1 (3.1)
Third degree relative or further removed	0 (0)	0	0 (0)	1 (3.1)	0 (0)	1 (3.1)

Attachment A: SAS Code

```
libname tn10 "X:\NIDDK\niddk-
dr_studies6\TrialNet_10\private_created_data\Trialnet10_V3\Data\Analysis\Secondary Outcomes";

/************************/
/* ClincalTrials.gov */
/************************/

*baseline participants;
proc freq data=tn10.mastable;
tables RxDesc;
run;

*age;
proc means data=tn10.mastable n median min max;
var age;
class RxDesc;
run;

*sex;
proc freq data=tn10.mastable;
tables Sex*RxDesc/norow nopercent;
run;

*ethnicity;
proc freq data=tn10.mastable;
tables ethnic*RxDesc/norow nopercent;
run;

*race;
proc freq data=tn10.mastable;
tables race*RxDesc/norow nopercent;
run;

*relationship to t1d;
proc freq data=tn10.mastable;
tables which_first*RxDesc/norow nopercent;
run;

data one; set tn10.mastable;
if which_first = "2nd/3rd Degree" then relative = 6;
if which_first = "FS=Brother/Sister" OR which_first = "FS=Brother/Sister,FS=Brother/Sister" OR
which_first = "NT=Non-identical Twin" then relative = 1;
if which_first = "IT=Identical Twin" then relative = 2;
if which_first = "CH=Child" then relative = 3;
if which_first = "P=Parent" then relative = 4;
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```
if which_first = "FS=Brother/Sister,P=Parent" or which_first = "CH=Child,FS=Brother/Sister" then relative
= 5;
run ;

proc freq data=one;
tables relative*rxdesc/norow nopercent missing;
run;
```