Dataset Integrity Check for Rare and Atypical Diabetes Network (RADIANT) M003 Tosur

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

The Rare and Atypical DIAbetes NeTwork (RADIANT) is a multicenter prospective cohort study that is dedicated to characterizing (discovering and defining) rare and atypical forms of diabetes. Individuals will be screened for evaluation of suspected atypical diabetes of unknown origin. Among the pool of evaluated individuals, those found to have a known form of diabetes will be excluded from further study. The remaining participants will be prioritized for genetic/genomic analysis and further testing.

The M003 study sought to examine participation of underrepresented racial and ethnic groups (URG) across RADIANT study stages and describe strategies to enhance recruitment and retention of URG.

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 RADIANT folder in the data package. For this replication, variables were taken from the "m_003_mtosur_niddk_31mar2022_1.sas7bdat" dataset.

4 Statistical Methods

Analyses were performed to replicate results for the data in the publication by Tosur et al. [1]. To verify the integrity of the data, only descriptive statistics were computed.

5 Results

For Table 1 in the publication [1], Baseline characteristics of subjects at study participation, 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 Table 1. The results of the replication are within expected variation to the published results.

6 Conclusions

The NIDDK Central Repository is confident that the RADIANT M003 data files to be distributed are a true copy of the study data.

7 References

[1] Tosur M, Gandolfo L, Balasubramanyam A, Naylor RN, Pollin TI, Rasouli N, Cromer SJ, Buse JB, Redondo MJ. Enrollment of Underrepresented Racial and Ethnic Groups in the Rare and Atypical Diabetes Network (RADIANT). Journal of Clinical and Translational Science, 7(1), e47, January 2023. doi: https://doi.org/10.1017/cts.2022.529

Table A: Variables used to replicate Table 1 – Baseline characteristics of subjects at study participation

Table Variable	**dataset.variable**
Age at enrollment	m_003_mtosur_niddk_31mar2022_1.current_age
Age at diabetes diagnosis	m_003_mtosur_niddk_31mar2022_1.s1_diab_diag_age
Female	m_003_mtosur_niddk_31mar2022_1.sex_female
Hispanic	m_003_mtosur_niddk_31mar2022_1.eth_hisp
Race	m_003_mtosur_niddk_31mar2022_1.race
BMI at enrollment	m_003_mtosur_niddk_31mar2022_1.bmi
BMI at diabetes diagnosis	m_003_mtosur_niddk_31mar2022_1.bmi_diag
Most recent HbA1c	m_003_mtosur_niddk_31mar2022_1.s3_most_recent_a1c
Ever taken insulin	m_003_mtosur_niddk_31mar2022_1.s3_insulin_evr
Currently taking insulin	m_003_mtosur_niddk_31mar2022_1.s3_insulin_current
Islet autoantibody positivity	m_003_mtosur_niddk_31mar2022_1.baa_pos
Family history of diabetes or hyperglycemia	m_003_mtosur_niddk_31mar2022_1.s5_fam_hist_diab

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

Characteristic	**Pub: Mean ± SD or n (%) (n=601)**	**DSIC: Mean ± SD or n (%) (n=601)**	**Diff. (n=0)**
Age at enrollment, years	44 ± 16.8	44 ± 16.8	0 (0)
Age at diabetes diagnosis, years	31.5 ± 15.5	31.5 ± 15.5	0 (0)
Female, n (%)	383 (64.4%)	383 (63.7%)	0 (0.7)
Hispanic, n (%)	49 (8.4%)	49 (8.1%)	0 (0.3)
Race, n (%)			
American Indian/Alaska Native/Asian/Native Hawaiian or other Pacific Islander	46 (8.1%)	46 (7.7%)	0 (0.4)
Black or African American	41 (7.2%)	41 (6.8%)	0 (0.4)
White	458 (80.6%)	458 (76.2%)	0 (4.4)
More than one race	23 (4.1%)	23 (3.8%)	0 (0.3)
BMI at enrollment, kg/m^2	25.5 ± 6	25.5 ± 6	0 (0)
BMI at diabetes diagnosis, kg/m^2	25 ± 6.8	25 ± 6.8	0 (0)
Most recent HbA1c, %	6.9 ± 1.7	7.8 ± 10.5	0.9 (8.8)
Ever taken insulin, n (%)	260 (75.1%)	260 (75.1%)	0 (0)
Currently taking insulin, n (%)	223 (86.4%)	223 (86.4%)	0 (0)
Islet autoantibody positivity, n (%)	73 (19.6%)	73 (12.2%)	0 (7.4)
Family history of diabetes or hyperglycemia, n (%)	418 (81.6%)	418 (77.8%)	0 (3.8)

Attachment A: SAS Code

```
libname m3 "X:\NIDDK\niddk-
dr_studies6\RADIANT\private_orig_data\m_003_mtosur_niddk_submission";

*m003;
proc freq data=m3.m_003_mtosur_niddk_31mar2022_1;
run;

data one; set m3.m_003_mtosur_niddk_31mar2022_1;
if no_sec2 = .;
run;

*age at enrollment, age at diabetes diag;
proc means data=one n mean std;
var current_age s1_diab_diag_age;
run;

*sex, ethnicity, race;
proc freq data=one;
tables sex_female eth_hisp race/missing;
run;

*BMI at enrollment, BMI at diabetes diag, hba1c at diag, most recent hba1c;
proc means data=one n mean std;
var bmi bmi_diag  s3_most_recent_a1c ;
run;

*ever taken insulin, currently taking insulin, islet autoantibody positivity, family history of diabetes or
hyperglycemia;
proc freq data=one;
tables s3_diab_a1c_at_diag s3_insulin_current s3_insulin_evr baa_pos s5_fam_hist_diab;
run;
```