

Dataset Integrity Check for Rare and Atypical Diabetes Network (RADIANT) M002 Krischer

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1 Standard Disclaimer

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

2 Study Background

The 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 M002 study used genotypic and phenotypic analyses to provide improved means of identifying cases with atypical 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 RADIANT folder in the data package. For this replication, variables were taken from the “m_002_jkrischer_niddk_19jul2022.sas7bdat” dataset.

4 Statistical Methods

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

5 Results

For Figure 2 in the publication [1], Consolidated Standards of Reporting Trials (CONSORT) diagram: stage 1, 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 Figure 2. The results of the replication are an exact match to the published results.

6 Conclusions

The NIDDK Central Repository is confident that the RADIANT M002 data files to be distributed are a true copy of the study data.

7 References

[1] Krischer JP, et al. The Rare and Atypical Diabetes Network (RADIANT) Study: Design and Early Results. *Diabetes Care*, 46(6), 1265-1270, June 2023. doi: <https://doi.org/10.2337/dc22-2440>

Table A: Variables used to replicate Figure 2 – Consolidated Standards of Reporting Trials (CONSORT) diagram: stage 1

Table Variable	dataset.variable
Consented, Stage 1	m_002_jkrischer_niddk_19jul2022.consent_stg1
Not Completed	m_002_jkrischer_niddk_19jul2022.radq1_notcomplete
Screen Pass	m_002_jkrischer_niddk_19jul2022.screen_pass
Screen Fail	m_002_jkrischer_niddk_19jul2022.screen_fail
Portal Account Created	m_002_jkrischer_niddk_19jul2022.portal_account
Questionnaire Completed	m_002_jkrischer_niddk_19jul2022.radq2_complete
Kit Requested	m_002_jkrischer_niddk_19jul2022.kit_requested
Awaiting Kit Shipment	m_002_jkrischer_niddk_19jul2022.kit_ship_pend
Awaiting Specimens	m_002_jkrischer_niddk_19jul2022.spec_pending
Specimens Received	m_002_jkrischer_niddk_19jul2022.spec_received
Drop Out	m_002_jkrischer_niddk_19jul2022.spec_drop
Results Reported	m_002_jkrischer_niddk_19jul2022.result_reported
Autoantibody Negative	m_002_jkrischer_niddk_19jul2022.baa_neg
Autoantibody Positive	m_002_jkrischer_niddk_19jul2022.baa_pos
Pre-Adjudication	m_002_jkrischer_niddk_19jul2022.preadjudication
Drop Out	m_002_jkrischer_niddk_19jul2022.curstat_adj_drop
Awaiting Review	m_002_jkrischer_niddk_19jul2022.curstat_adj_pending
Ineligible	m_002_jkrischer_niddk_19jul2022.curstat_adj_inelig
Keep in Reserve	m_002_jkrischer_niddk_19jul2022.curstat_keepinres
Need More Information	m_002_jkrischer_niddk_19jul2022.curstat_nmi
Eligible Stage 2	m_002_jkrischer_niddk_19jul2022.edligible_stg2
Pending Consent	m_002_jkrischer_niddk_19jul2022.curstat_stg2_pend
Consented, Stage 2	m_002_jkrischer_niddk_19jul2022.consent_stg2
Drop Out	m_002_jkrischer_niddk_19jul2022.curstat_stg2_drop

Table B: Comparison of values computed in integrity check to reference article Figure 2

Characteristics	Pub: Figure 2	DSIC: Figure 2	Diff.
Consented, Stage 1	878	878	0
Not Completed	19	19	0
Screen Pass	765	765	0
Screen Fail	94	94	0
Portal Account Created	721	721	0
Questionnaire Completed	628	628	0
Kit Requested	579	579	0
Awaiting Kit Shipment	2	2	0
Awaiting Specimens	37	37	0
Specimens Received	427	427	0
Drop Out	113	113	0
Results Reported	423	423	0
Autoantibody Negative	338	338	0
Autoantibody Positive	85	85	0
Pre-Adjudication	423	423	0
Drop Out	0	0	0
Awaiting Review	17	17	0
Ineligible	145	145	0
Keep in Reserve	22	22	0
Need More Information	45	45	0
Eligible Stage 2	194	194	0
Pending Consent	6	6	0
Consented, Stage 2	166	166	0
Drop Out	22	22	0

Attachment A: SAS Code

```
libname m2 "X:\NIDDK\niddk-  
dr_studies6\RADIANT\private_orig_data\m_002_jkrischer_niddk_submission";  
  
*M002;  
proc freq data=m2.m_002_jkrischer_niddk_19jul2022;  
tables consent_stg1 radq1_notcomplete screen_pass screen_fail portal_account  
radq2_complete kit_requested kit_ship_pend spec_pending spec_received spec_drop  
result_reported baa_neg baa_pos preadjudication curstat_adj_drop curstat_adj_pending  
curstat_adj_inelig eligible_stg2 curstat_keepinres curstat_nmi curstat_stg2_pend  
consent_stg2 curstat_stg2_drop;  
run;
```