Dataset Integrity Check for the Immune Regulation and Costimulation in Natural History and Therapeutic Outcome of Chronic Hepatitis B Study (HBRN Immunology Treatment)

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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 Hepatitis B Research Network (HBRN) was a multicenter network to investigate the etiology and progression of the disease, and to test the safety and efficacy of current treatment approaches. The Immune Regulation and Costimulation in Natural History and Therapeutic Outcome of Chronic Hepatitis B (HBRN Immunology Treatment) study was designed to assess whether the balance between immune regulatory and effector responses in HBV-infected participants defined natural history and treatment outcomes in cases of chronic hepatitis B.

3 Archived Datasets

A full listing of 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 HBRN Immunology Treatment folder in the data package. For this replication, variables were taken from the “immuno_ia_ds.sas7bdat” dataset.

4 Statistical Methods

Analyses were performed to replicate results for the data in the presentation abstract by Traum et al. [1]. To verify the integrity of the data, results were computed from the presentation abstract. Since the abstract for this presentation contained the only published results for this study, very limited replication was possible.

5 Results

For the results in the presentation abstract [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 abstract results. The results of the replication are an exact match to the abstract results.

6 Conclusions

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

7 References

[1] Traum D, Wong D, Lau D, Sterling RK, Terrault N, Khalili M, Wahed A, Lee WM, Lok AS, Chang KM. HBV-Specific Proliferative T Cell Response is Not Restored by Therapeutic HBV Suppression or Correlate with HBsAg Titer. Hepatology, 76 (Suppl. 1), S29-S30, October 2022. doi: https://doi.org/10.1002/hep.32697

Table A: Variables used to replicate presentation abstract results

Variable	**dataset.variable**
Enrolled	immuno_ia_ds.armia immuno_ia_ds.id
Treatment Arm	immuno_ia_ds.armia
Stopped Treatment at Week 192	immuno_ia_ds.week

Table B: Comparison of values computed in integrity check to reference abstract results

Characteristic	**Abstract (n=34)**	**DSIC (n=34)**	**Diff. (n=0)**
Enrolled	34	34	0
Treatment Arm: Tenofovir (TDF)	21	21	0
Treatment Arm: Peginterferon + Tenofovir (PEG/TDF)	13	13	0
Stopped Treatment at Week 192	18	18	0

Attachment A: SAS Code

```
libname test "X:\NIDDK\niddk-dr_studies2\HBRN\private_created_data\HBRN Immunology
Treatment\Immunology Treatment\SAS Datasets";

*counting unique IDs in the dataset;
proc sql;
select count(distinct id) as distinct_var1
from test.immuno_ia_ds;
quit;

proc contents data=test.immuno_ia_ds;
run;

*assessing the treatment arm assignments;
proc freq data=test.immuno_ia_ds;
tables armia;
run;

*creating a temporary dataset to manipulate;
data one; set test.immuno_ia_ds;
run;

proc freq data=one;
tables armia*id;
run;

*reducing data to single observations per ID;
proc sort data=one nodupkey;
by id;
run;

*checking the split of treatment arm;
proc freq data=one;
tables armia;
run;
*there are 34 IDs w/ 21 on TNF alone and 13 on Peg/TNF;

*assessing the number of weeks;
proc freq data=test.immuno_ia_ds;
tables week*id;
run;
*18 at week 192;
```