**FDA JUMPSTART SCRIPTS**

**TESTING USING FDA DATA AND ALSO ACCENTURE DATA**

**PROGRAM NAME**: DEMOGRAPHICS\_V1.SAS (Demographics Analysis Panel)

.

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**SAS VERSION**: 9.4

**DESCRIPTION**: The program was tested in Accenture’s SAS server in order to produce 15 Demographics Analysis displays (described in Table 1 below) using FDA-provided data (TEST) and also Accenture (ACN) datasets.

**TESTING STEPS**

1. All the necessary files were stored into the appropriate Accenture’s folder structure
2. CHANGES MADE TO THE SCRIPT TO MAKE IT RUN: the following parameters were defined in order to point to the right locations within Accenture’s environment:
   * Studypath: location of the drug study datasets.
   * Utilpath: location of external SAS programs.
   * Templatepath: filename of the template.
   * Outpath: location of the output.
   * Also, Text **ver=2003** was added to statement **libname xls pcfiles path="&demout.”;** which became **libname xls excel "&demout." ver=** **2003**;
   * No hardcoding was introduced into the program
3. Run the program.
4. Check that LOG file is free of ERRORS, WARNINGS, and other suspicious messages. It should be noted that some procedures used in this program require the LENGTH of variables like ARMCD to be, at the most, 16 bytes long otherwise a WARNING message is produced.
5. Output file name is **Demographics.xls** which must be manually renamed based on library name used. For example: if you are running TEST data, rename output to Demographics\_Test.xls so outputs won’t overwrite each other when generating output for ACN data.
6. Check that spreadsheet **Demographics Error Summary.xls** was NOT created for any of the program runs.
7. Spreadsheet **Demographics.xls** was created for every program ran and checked as follows:

Table 1: Review of the 15 tabs in Demographics.xls generated by running DEMOGRAPHICS\_V1.SAS using test data and also Accenture data

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Testing Result | |  |
| Tab | Description | Test Data | Accenture Data | Comments |
| 1 | Summary statistics for age per arm and overall and the counts and percentages per arm and overall for each age group, sex, race, and ethnicity that appears in the study | Pass | Pass |  |
| 2 | Counts of subjects and percentages per arm and overall for each age group that appears in the study, and a bar graph of the percentages | Pass | Pass |  |
| 3 | Counts of each age group by disposition term per arm and overall, and what percentage of the age groups in each arm experienced each disposition term. Age group is derived from the AGE variable from the demographics domain (DM) dataset using age groups defined by the user. | Pass | Pass | Overall column shows 0 (zero) for all rows of Test data. However, it shows the right numbers when using Accenture data. |
| 4 | Summary statistics and box plots of age per arm and overall, including the mean, median, maximum, minimum, and quartiles. | Pass | Pass |  |
| 5 | Counts of subjects and percentages per arm and overall for each sex that appears in the study, and a bar graph of the percentages. | Pass | Pass |  |
| 6 | Counts of each sex by disposition term per arm and overall, and what percentage of the sexes in each arm experienced each disposition term. Sex is taken from the SEX variable from the demographics domain (DM) dataset. | Pass | Pass | Overall column shows 0 (zero) for all rows of Test data. However, it shows the right numbers when using Accenture data. |
| 7 | Counts of subjects and percentages per arm and overall for each race that appears in the study, and a bar graph of the percentages. | Pass | Pass |  |
| 8 | Counts of each race by disposition term per arm and overall, and what percentage of the races in each arm experienced each disposition term. Race is taken from the RACE variable from the demographics domain (DM) dataset. | Pass | Pass | Overall column shows 0 (zero) for all rows of Test data. However, it shows the right numbers when using Accenture data. |
| 9 | Counts of subjects and percentages per arm and overall for each ethnicity that appears in the study, and a bar graph of the percentages. | Pass | Pass |  |
| 10 | Counts of each ethnicity by disposition term per arm and overall, and what percentage of the the ethnicities in each arm experienced each disposition term. Ethnicity is taken from the ETHNIC variable from the demographics domain (DM) dataset. | Pass | Pass | Overall column shows 0 (zero) for all rows of Test data. However, it shows the right numbers when using Accenture data. |
| 11 | Counts of subjects and percentages per arm and overall for each country that appears in the study, and a bar graph of the percentages. | Pass | Pass |  |
| 12 | Counts of each country by disposition term per arm and overall, and what percentage of the countries in each arm experienced each disposition term. Country is taken from the COUNTRY variable from the demographics domain (DM) dataset. | Pass | Pass | Overall column shows 0 (zero) for all rows of Test data. However, it shows the right numbers when using Accenture data. |
| 13 | Counts of subjects and percentages per arm and overall for each site ID that appears in the study, and a bar graph of the percentages. | Pass | Pass |  |
| 14 | Counts of each site ID by disposition term per arm and overall, and what percentage of the site IDs in each arm experienced each disposition term. Site ID is taken from the SITEID variable from the demographics domain (DM) dataset. | Pass | Pass | Overall column shows 0 (zero) for all rows of Test data. However, it shows the right numbers when using Accenture data. |
| 15 | Counts of subjects and percentages per arm and overall for each site ID and the country that the site ID is associated with. | Pass | Pass |  |

**ADDITIONAL WORK PERFORMED**

The testing described before checks only for results displays but not for the accuracy of the numbers being displayed. Therefore, Accenture created a validation program that confirmed that all numbers yielded by DEMOGRAPHICS\_V1.SAS are correct. Obviously, the only discrepancies are the ones entered in column COMMENTS of Table 1.

**SUGGESTION**

Some code of DEMOGRAPHICS\_V1.SAS should be reviewed to prevent the SAS NOTE which appears in Figure 1 below

Figure 1

NOTE: Numeric values have been converted to character values at the places given by: (Line): (Column).

1:1 1:1 1:1. (See screenshot below).

