**TFL Exercises**

You are in Production creating the outputs below. Produce an **rtf output** of each and save your completed code and outputs in your training area folder (code in TrainingCode\_20xx and outputs in Trial 1\20xx outputs). Prefix the names of your code and outputs with your initials and output number, for example “AC 6.01”.

I will review your code and outputs and offer feedback.

Ensure your code:

* works as a stand-alone program (running it from top to bottom)
* includes headers
* suitable comments
* simple to understand
* as good as you can make it
* adheres to Phastar Good Programming Guidelines (layout, indentation etc)

1. Table 6.01 Summary of Subjects by Population

* All analysis details in RAP-AVA102670 Final.doc in the Trial 1 folder
* Shells.doc provides a template of the output. The text in the RAP discusses APO4 cohort but ignore for this exercise as we weren’t provided with the data. The template TD01 has been customised for the purpose of this exercise
* All data required in P:\Training Area\Trial 1\Data
* Shell shows the denominator for the percentages

1. Table 6.08/6.09 Summary of Demographic Characteristics

* All analysis details in RAP-AVA102670 Final.doc in the Trial 1 folder
* Shells.doc provides a template of the output (some details may be in the text of the RAP)
* All data required in P:\Training Area\Trial 1\Data
* Shell shows the denominator for the percentages

1. Table 8.02 Summary of All Adverse Events (excluding treatment phase)

* All analysis details in RAP-AVA102670 Final.doc in the Trial 1 folder
* Shells.doc provides a template of the output (some details may be in the text of the RAP)
* All data required in P:\Training Area\Trial 1\Data
* Remember we are counting subjects, not adverse events
* Shell shows the denominator for the percentages
* Use AESOC and AEPT variables
* Order of AESOC is by the most common
* Order of AEPT within AESOC is by the most common
* For this example, ignore the treatment phase information

1. Table 8.02 Summary of All Adverse Events (including treatment phase)

* All analysis details in RAP-AVA102670 Final.doc in the Trial 1 folder
* Shells.doc provides a template of the output (some details may be in the text of the RAP)
* All data required in P:\Training Area\Trial 1\Data
* Remember we are counting subjects, not adverse events
* Shell shows the denominator for the percentages
* Use AESOC and AEPT variables
* Order of AESOC is by the most common
* Order of AEPT within AESOC is by the most common
* Separate the report into the different treatment phases
* Ensure a page break is included to put each treatment phase on a separate page

1. Table 8.36 Summary of ECG Values

* All analysis details in RAP-AVA102670 Final.doc in the Trial 1 folder
* Shells.doc provides a template of the output (some details may be in the text of the RAP)
* Only ECG values where the egevalcd = 1 should be used (as should be 12-Lead ECG)
* Present visit only, ignore time point
* If there are more than three readings per subject, per visit (RAP doesn’t account well enough for this), then take the average of the readings
* All data required in P:\Training Area\Trial 1\Data

You are now playing the role of QC and are required to QC the following outputs:

1. Listing 27: Listing of Anti-body Response to Vaccination

* Pop and Lab datasets are stored in P:\Training Area\Trial 1\Lab exercise
* Proc compare (see slides P:\Training area) required to compare production dataset stored in P:\Training Area\Trial 1\Lab exercise\Production data
* Antibody only to be included
* NOTE: You will have more patients than in the production dataset as the study is ongoing and more patients have been recruited since production created this output.

1. Listing 17: Listing of Laboratory Data Outside Normal Range

* Pop and Lab datasets are stored in P:\Training Area\Trial 1\Lab exercise
* Proc compare (see slides P:\Training area) required to compare production dataset stored in P:\Training Area\Trial 1\Lab exercise\Production data
* select where evalsafe/evalflag = 1
* include subjects that had a non-normal value
* NOTE: You will have more patients than in the production dataset as the study is ongoing and more patients have been recruited since production created this output.

1. Table 11.51: Summary Statistics for Serum Immunoglobulins

* Pop and Lab datasets are stored in P:\Training Area\Trial 1\Lab exercise
* Proc compare (see slides P:\Training area) required to compare production dataset stored in P:\Training Area\Trial 1\Lab exercise\Production data
* select where evalsafe/evalflag = 1
* select where lbcat = 'IMMU' and evalsafe/evalflag = 1
* use variables lbtestcd lbtest lbstunit
* include only lbtestcd of 'IGA\_PLC' 'IGE\_PLC' 'IGG\_PLC' 'IGM\_PLC'
* NOTE: You will have more patients than in the production dataset as the study is ongoing and more patients have been recruited since production created this output.