Subjects were enrolled in a study and were asked to take a pill daily for 8 weeks. Biomarker measurements (M1-M20) were collected before the subjects started taking the drug (week 0) and on weekly basis thereafter. Some subjects had an adverse event while on study. Subjects who had those events were taken off the drug, however, their biomarker data was still collected through the end of the study. You should therefore exclude all biomarker data that was collected after the occurrence of the event for the analyses.

Attached are two datasets. One contains the biomarker data, and the other contains the time of adverse events observed up to 8 weeks after the subject took the first dose of drug. The following questions are of interest:

- 1. Which biomarkers are changing as a result of treatment?
- 2. Can you come up with an algorithm/model that can predict the occurrence of adverse event based on one or a combination of biomarkers using their absolute values or fold changes at least one week prior?
- 3. Which biomarkers are related to the adverse event?

<u>Fold change</u> is calculated as: biomarker value at week t/ biomarker value at week 0

Summarize your final results by including the most important figures/tables along with the conclusions. Hint: Be mindful of stating your assumptions, intermediate steps to justify how you choose your final model and caveats to your conclusions, if any. You can summarize them on slides, word doc or pdf, to your preference.

Your codes should capture all the analyses done, not limiting to the final results, and they should be easy to follow, so include comments as necessary. All data manipulation should strictly be done by the code. No data will be manually entered or removed. If you need to combine the data from the two files, you should do that in a code.