BIOSTAT724 Project 2: Student Rubric

Total Points: 100

1. Reproduce the safety monitoring rule described in the protocol **(40 points)** 
   1. Describe the Objective of the safety monitoring rule **(5 points)**
   2. Parameter to estimate and hypothesis **(10 points)** 
      1. Describe the parameter to be estimated by the safety monitoring rule *(3 points)*
      2. State the minimum clinically relevant value for this parameter *(3 points)*
      3. State the criterion related to this minimum clinically relevant value that should "trigger" a concern about the safety of the study participants *(4 points)*
   3. Describe the beta-binomial statistical model that will be used **(25 points)** 
      1. Include a general description of the model and how it will be used in the context of the problem *(3 points)*
      2. Define the prior distribution mathematically *(2 points)* and in plain English *(3 points)*
      3. Define the likelihood function mathematically *(2 points)* and in plain English *(3 points)*
      4. Show mathematically how the posterior distribution is specified *(2 points)*
      5. Show a table that illustrates how the monitoring rule critical boundary of 4 events was identified (include your code) *(10 points)*
2. Reproduce the simulation of frequentist operating characteristics of the Bayesian design as described in the excerpts from the study protocol **(60 points)**
   1. Describe the Objective of the efficacy analysis **(5 points)**
   2. Parameter to estimate and hypothesis **(10 points)** 
      1. Describe the parameter to be estimated in the efficacy analysis *(3 points)*
      2. State the minimum clinically relevant value for the parameter, and the hypothesis to be tested *(3 points)*
      3. State the success criteria for the efficacy analysis *(4 points)*
   3. Show the statistical model for the analysis **(13 points)** 
      1. *Prior (3 points)*
      2. Likelihood *(2 points)*
      3. Posterior *(3 points)*
      4. Discuss why priors are labeled as optimistic or pessimistic and what impact they might have on the posterior *(5 points)*
   4. Describe how the possibilities for drawing an incorrect conclusion are represented in the Bayesian framework for this trial (plain English) **(5 points)** 
      1. Try comparing what Type I error means under a frequentist hypothesis test to the formula you are using to calculate the "type I error" under the Bayesian framework
   5. Design of your program **(15 points)** 
      1. Describe input that goes into the program *(4 points)*
      2. Describe what the program creates as a final result (output) *(4 points)*
      3. Describe how the program operates to produce the output from the input (words, diagram, or both) *(7 points)*
   6. Include Program Code **(7 points)**
   7. Create two tables -- one for type I error and one for power -- that compare your results with those shown in the protocol **(10 points)** 
      1. Type I error table *(5 points)*
      2. Power table *(5 points)*