Exercise 1.

Phase II trials on a new treatment are completed, implying a 30% decrease on the hazard of death, compared to published data for the standard treatment.

You are asked to design a phase III clinical trial in order to examine the hypothesis of no difference between the standard and the experimental treatment. Median survival time under standard treatment is estimated by prior studies to be 1 year approximately. Assume we want a Type I error 0.05 and a power of 0.8. Accrual is estimated to be 30 patients per month.

Please design this superiority Phase III study assigning equal patients to the two treatment arms and taking into account 3 looks on the data (2 interim analyses and a final one). You should prefer the Lan-DeMets O’Brien Fleming stopping boundaries.