Bayesian Analysis and Monitoring Plan for a Clinical Trial

Frank E Harrell Jr PhD

Department of Biostatistics

Vanderbilt University School of Medicine

f.harrell@vanderbilt.edu

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1 Background

The paper by Oettle *et al.*[1] provided evidence for efficacy of gemcitabine in improving disease-free survival for . . . The results are shown in the figure below.[1]

References

[1] H. Oettle, S. Post, P. Neuhaus, K. Gellert, J. Langrehr, K. Ridwelski, H. Schramm, J. Fahlke, C. Zuelke, C. Burkart, et al. Adjuvant chemotherapy with gemcitabine vs observation in patients undergoing curative-intent resection of pancreatic cancer: a randomized controlled trial. *Jama*, 297(3):267–277, 2007.

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[1]Knots were placed at 0.3, 0.5, 0.7, 1, 1.5, 3, and 4 years. Ordinary least squares was used to fit this cumulative hazard function. Simulations that follow are based on this fitted survival curve, by drawing random standard exponentially-distributed random variables and solving for time t so that the fitted spline function equals the exponential random variable.