References

Albain KS, Barlow WE, Shak S, et al. Prognostic and predictive value of the 21-gene recurrence score assay in postmenopausal women with node-positive, oestrogen-receptor-positive breast cancer on chemotherapy: a retrospective analysis of a randomised trial. *Lancet Oncol* 2010;11(1):55-65.

Bellman R. Dynamic Programming. Princeton University Press:Princeton, NY, 1957.

Cobo M, Isla D, Massuti B, et al. Customizing cisplatin based on quantitative excision repair cross-complementing 1 mRNA expression: A Phase III trial in non-small-cell lung cancer. *J Clin Oncol* 2007;25:2747-2754.

Cox DR. Regression models and life-tables. *J Royal Stat Soc Series B* 1972;24(2):187–220.

Efron B, Tibshirani R. An Introduction to the Bootstrap. New York: Chapman & Hall, 1994.

Freidlin B, Simon R. Adaptive signature design: An adaptive clinical trial design for generating and prospectively testing a gene expression signature for sensitive patients. *Clin Ca Res* 2005;1(11):7872–7878.

Friedlin B, Jiang W, Simon R. The cross-validated adaptive signature design. *Clin Ca Res* 2010;16:691–698.

Goldberg Y and Kosorok MR. Q-learning with censored data. *Ann of Stat* 2012;40:529–560.

Grant RM, Lama JR, Anderson PL, et al. Pre-exposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* 2010;363(27):2587–99.

Huang, Y, Pepe MS, and Feng Z. Evaluating the predictiveness of a continuous marker. *Biometrics* 2007;63:1181-8.

Huang Y, Gilbert PB, Janes H. Assessing treatment-selection markers using a potential outcomes framework. *Biometrics* 2012;68(3):687–96.

Janes H, Pepe MS, Bossuyt PM, et al. Measuring the performance of markers for guiding treatment decisions. *Ann Intern Med* 2011;154(4):253–9.

Janes H, Pepe MS, Huang Y. A framework for evaluating markers used to select patient treatment. *Med Decis Making* 2014;34(2):159–67.

Janes H, Brown MD, Pepe MS, et al. An approach to evaluating and comparing biomarkers for patient treatment selection. *Int J Biostat* 2014;10(1):99–121.

Janes H, Brown MD, Pepe MS. Designing a study to evaluate the benefit of a biomarker for selecting patient treatment. *Stat Med* 2015;34(27):3503–15.

Janes H, Pepe MS, McShane LM, et al. The fundamental difficulty with evaluating the accuracy of biomarkers for guiding treatment. *J Nat Cancer Inst* 2015;107(8). pii: djv157.

Kang C, Janes H, Huang Y. Combining biomarkers to optimize patient treatment recommendations. *Biometrics* 2014;70(3):695–707.

Keller MB, McCullough JP, Klein DN, et al. A comparison of nefazodone, the cognitive behavioral-analysis system of psychotherapy, and their combination for the treatment of chronic depression. *N Engl J Med* 2000;342:1462–70.

Kimmel SE, French B, Kasner SE, et al. A pharmacogenetic versus a clinical algorithm for warfarin dosing. *N Engl J Med* 2013;369:2283–93.

Mallal S, Phillips E, Carosi G, et al. HLA-B*5701 screening for hypersensitivity to abacavir. *N Engl J Med* 2008;358:568–579.

Laber EL, Zhao Y-Q, Regh T, et al. Using pilot data to size a two-arm randomized trial to find a nearly optimal personalized treatment strategy. *Stat Med* 2015;35(8):1245–56.

Mandrekar SJ, Sargent DJ. Clinical trial designs for predictive biomarker validation: theoretical considerations and practical challenges. *J Clin Onc* 2009;24(24):4027–4034.

Murphy S. Optimal dynamic treatment regimes. *JRSS B* 2003;65(2):331–355.

Murphy SA. An experimental design for the development of adaptive treatment strategies. *Stat Med* 2005;24:1455–81.

Romond EH, Perez EA, Bryant J, et al. Trastuzumab plus adjuvant chemotherapy for operable HER2-positive breast cancer. *N Engl J Med* 2005;353:1673–1684.

Ruczinski I, Kooperberg C, LeBlanc ML. Logic Regression. *J Comp Graph* 2003;12(3):475–511.

Sargent DJ, Allegra C. Issues in clinical trial design for tumor marker studies. *Sem in Onc* 2002;29(3):222–230.

Sargent D, Conley B, Allegra C, et al. Clinical trial designs for predictive marker validation in cancer treatment trials. *J Clin Onc* 2005;23:2020–2027.

Simon R, Maitournam A. Evaluating the efficiency of targeted designs for randomized clinical trials. *Clin Ca Res* 2004;10:6759–6763.

Simon, RM, Paik, S, and Hayes, DF. Use of archived specimens in evaluation of prognostic and predictive biomarkers. *J Natl Cancer Inst* 2010;101:1446–52.

Sparano JA. TAILORx: Trial assigning individualized options for treatment (Rx). *Clin Br Ca* 2006;7:347-50.

Simon R. Sensitivity, specificity, PPV, NPV for predictive biomarkers. *J Natl Cancer Inst* 2015;107(8). pii: djv153.

Sitlani CM, Heagerty PJ. Analyzing longitudinal data to characterize the accuracy of markers used to select treatment. *Stat Med* 2014;33(17):2881-2896.

Vickers AJ, Kattan MW, Daniel S. Method for evaluating prediction models that apply the results of randomized trials to individual patients. *Trials* 2007;8:14.

Zhang B, Tsiatis AA, Laber EB, et al. A robust method for estimating optimal treatment regimes. *Biometrics* 2012;68(4):1010-1018.

Zhang Z, Nie L, Soon G, et al. The use of covariates and random effects in evaluating predictive biomarkers under a potential outcomes framework. *Ann Appl Stat* 2014;8:2336-2355.

Zhao Y, Zeng D, Rush AJ, et al. Estimating individualized treatment rules using Outcome Weighted Learning. *J Am Stat Assoc* 2012;107(449):1106-1118.

Zhao YQ, Zheng D, Laber B, et al. Doubly robust learning for estimating individualized treatment with censored data. *Biometrika* 2015;102:151–68.