

DUKE UNIVERSITY MEDICAL CENTER

CURRICULUM VITAE

Name: Susan Halabi, Ph.D.

Primary academic appointment: Professor (with Tenure)

Primary academic department: Department of Biostatistics and Bioinformatics

<u>Education</u>	<u>Institution</u>	<u>Date</u>	<u>Degree</u>
Graduate	The University of Texas Health Science Center at Houston, School of Public Health, Houston, Texas	1994	Ph.D in Biometry

Scholarly Societies:

American Statistical Association
International Biometric Society
Society for Clinical Trials
American Society of Clinical Oncology

Honors and Awards:

1990-94 Good Neighbor Scholarship, Houston, Texas
1994 Delta Omega, Honorary Society in Public Health
2014 *Fellow*, Society of Clinical Trials
2015 *Fellow*, American Statistical Association
2018 *Fellow*, American Society of Medical Oncology

Professional training and academic career:

<u>Institution</u>	<u>Position/Title</u>	<u>Dates</u>
Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham NC	Professor	2012-present
Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham NC	Associate Professor	2005-2012

Alliance in Clinical Trials in Oncology	Lead Faculty Statistician	2014- 2017
Cancer and Leukemia Group B (CALGB), GU Committee, Durham, NC	Lead Faculty Statistician	1996-2014
Department of Surgery, Duke University Medical Center, Durham NC	Associate Professor	2010-2012
Division of Biometry, Community And Family Medicine, Duke University Medical Center, Durham NC	Assistant Professor	1997-2005
Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, NC	Assistant Professor	07/00-02/05
Division of Biometry, Community And Family Medicine, Duke University Medical Center, Durham NC	Assistant Professor	1996-2000
Department of Biostatistics and Epidemiology, School of Public Health and Tropical Medicine, Tulane University, New Orleans, LA	Adjunct Assistant Professor	1997-2001
Department of Biostatistics and Epidemiology, School of Public Health and Tropical Medicine, Tulane University, New Orleans, LA	Assistant Professor	1994-1996
Department of Medicine, School of Medicine, Tulane University, New Orleans, LA	Adjunct Assistant Professor	1994-1996
Tulane Cancer Center Tulane University, New Orleans, LA	Assitant Director, Office of Clinical Research	1994-1996
Department of Epidemiology, MD Anderson Cancer Center, Houston, Texas	Pre-doctoral Fellow	1993-1994

Patents:

Biomarker Based Prognostic Model for Predicting Overall Survival in Patients with Metastatic Clear Cell Kidney Cancer (Int'l Patent Appln No PCT/US2016/016460 Appl# 4852-4365-44444)

Publications:

I. Refereed journals:

1. Khlat M, **Halabi S**, Khudr A, and Der Kaloustian V (1986). Perception of consanguineous marriage and their genetic effects among a sample of couples from Beirut. *American Journal of Medical Genetics* 25:299-306.
2. Khlat M and **Halabi S** (1986). Modernization and consanguineous marriages in Beirut. *Journal of Biosocial Sciences* 18:489-495.
3. Zurayk H, **Halabi S**, and Deeb M (1987). Measures of social class based on education for health studies in developing countries. *Journal of Epidemiology and Community Health* 41:173-179.
4. Armenian H, Lakkis N, Sibai A, and **Halabi S** (1988). Hospital visitors as controls. *American Journal of Epidemiology* 127:404-406.
5. Armenian HK, **Halabi S**, and Khlat M (1989). The epidemiology of primary health problems in Beirut. *Journal of Epidemiology and Community Health* 43:316-319.
6. Vernon SW, Vogel VG, **Halabi S**, Jackson GL, Lundy RO, and Peters GN (1992). Breast cancer screening behaviors and attitudes in three racial/ethnic groups. *Cancer* 69:165-174.
7. Bondy ML, Vogel VG, **Halabi S**, and Lustbader E (1992). Identification of women at increased risk for breast cancer in a population-based screening program. *Cancer Epidemiology, Biomarkers & Prevention* 1:143-147.
8. **Halabi S**, Zurayk H, Awaida R, Darwish M, and Saab B (1992). Reliability and validity of self and proxy reporting of morbidity data: A case study from Beirut, Lebanon. *International Journal of Epidemiology* 3:607-612.
9. Bondy ML, Spitz MR, **Halabi S**, Fueger JJ, Vogel VG (1992). Low incidence of familial breast cancer among Hispanic women. *Cancer Causes and Control* 3:337-382.
10. Bondy ML, Spitz MR, **Halabi S**, Fueger JJ, Schantz SP, Sample D, Hsu TC (1993). Association between family history of cancer and mutagen sensitivity in upper aerodigestive tract cancer patients. *Cancer Epidemiology, Biomarkers & Prevention* 2:103-106.
11. Peters GN, Vogel VG, Evans WP, Bondy ML, **Halabi S**, Lord J, Laville EA, and the Texas Breast Screening Project Scientific Review Committee (1993). The Texas Breast Screening Project: I. Mammographic and clinical results. *Southern Medical Journal* 86:385-390.

12. Vogel VG, Bondy ML, **Halabi S**, Lord J, Laville EA, and the Texas Breast Screening Project Scientific Review Committee (1993). The Texas Breast Screening Project II. Demographics, risk profiles, and health practices of participants. *Southern Medical Journal* 86:391-396.
13. Spitz MR, Fueger JJ, **Halabi S**, Schantz P, Sample D, Hsu TC (1993). Mutagen sensitivity in upper aerodigestive tract cancer: A case-control analysis. *Cancer Epidemiology, Biomarkers & Prevention* 2:329-333.
14. Schustermann MA, Kroll SS, Reece GP, Miller MJ, Ainslie N, **Halabi S**, Balch CM (1993). Incidence of autoimmune disease in patients after breast reconstruction with silicone gel implants versus autogenous tissue. *Annals of Plastic Surgery* 31:1-6.
15. **Halabi S**, Vogel VG, Bondy ML, Vernon SW (1993). Recruiting older women for screening mammography. *Cancer Detection and Prevention* 17:359-365.
16. Vernon SW, Vogel VG, **Halabi S**, Bondy ML (1993). Factors associated with perceived risk of breast cancer. *Breast Cancer Research and Treatment* 28:137-144.
17. Bondy ML, Lustbader E, **Halabi S**, Ross E, Vogel VG (1994). Validation of a breast cancer risk assessment model with a positive family history. *Journal of the National Cancer Institute* 86:620-625.
18. Ji W, Qu G, Ye P, Zhang X, **Halabi S**, Ehrlich M (1995). Frequent detection of bcl-2/JH translocations in human blood and organ samples by a quantitative PCR assay. *Cancer Research* 55:2876-2882.
19. Pillai MR, **Halabi S**, McKalip A, Jayaprakash PG, Rajalekshmi TN, Krishnan Nair M, Herman B (1996). The presence of human papillomavirus 16/18 E6, p53 and Bcl-2 protein expression in cervicovaginal smears from patients with cervical cancer. *Cancer Epidemiology, Biomarkers & Prevention* 5:329-335.
20. Crane MM, Strom SS, **Halabi S**, Berman EL, Fueger JJ, Spitz MR (1996). Correlation between selected environmental exposures and karyotype in acute myelocytic leukemia. *Cancer Epidemiology, Biomarkers & Prevention* 5:639-644.
21. Robinson WR, **Halabi S**, Roberts A, Adams J (1997). Risk factors for margin involvement in specimens generated by LEEP excision of the cervix. *Journal of Gynecologic Techniques* 3:17-20.
22. Coughlin SS, **Halabi S**, Metayer C (1998). Barriers to cardiac transplantation in idiopathic dilated cardiomyopathy: The Washington DC dilated Cardiomyopathy Study. *Journal of National Medical Association* 90(6):342-348.
23. Bublely GJ, Carducci M, Dahut W, Dawson N, Daliani D, Eisenberger M, Figg WD, Freidlin B, **Halabi S**, Hudes G, Hussain M, Kaplan R, Myers C, Oh W, Petrylak DP, Reed E, Roth B, Sartor O, Scher H, Simons J, Sinibaldi V, Small EJ, Smith MR, Trump DL, Vollmer R, Wilding G

- (1999). Eligibility and response guidelines for phase II clinical trials in androgen independent prostate cancer: Recommendations from the PSA working group. *Journal of Clinical Oncology* 17:3461-3467.
24. Savarese DM, Taplin ME, **Halabi S**, Kreis W, Hars V, Vogelzand NJ (1999). A phase II study of docetaxel, estramustine, and low dose hydrocortisone in men with hormone refractory prostate cancer: Preliminary results of CALGB 9780. *Seminars in Oncology* 26:39-44.
25. Anreder MB, Merogi A, Freeman SM, **Halabi S**, Marrogi AJ (1999). P53, C-erbB2 and PCNA Status in benign, Proliferative and malignant ovarian surface epithelial neoplasms: A study of 75 cases. *Archives of Pathology and Laboratory Medicine* 123(4):310-316.
26. Johnson ES, **Halabi S**, Netto G, Gladen B, Lucier G, Bechtold W, Henderson R (1999). Detection of low level benzene exposure in supermarket wrappers by urinary muconic acid. *Biomarkers* 4:106-117.
27. Rimer BK, **Halabi S**, Lipkus IM, Strigo TS, Crawford Y, Purcell C (1999). Confusion about mammography: prevalence and consequences. *Journal of Women's Health and Gender-Based Medicine* 8:509-520.
28. Kantoff PW, **Halabi S**, Conaway MR, Picus J, Hars V, Trump D, Winer E, Vogelzang NJ (1999). Hydrocortisone with or without mitoxantrone in men with hormone refractory prostate cancer: The results of CALGB 9182. *Journal of Clinical Oncology* 17:2506-2513.
29. Burns CP, **Halabi S**, Clamon GH, Hars V, Wagner BA, Hohl RJ, Lester E, Kirshner JJ, Vinciguerra V, Paskett E (1999). Phase I clinical study of fish oil fatty acid capsules for patients with cancer cachexia: Cancer and Leukemia Group B Study 9473. *Clinical Cancer Research* 5:3942-3947.
30. Bastian LA, McBride CM, **Halabi S**, Fish LJ, Skinner CS, Bosworth HA, Kaplan EB, Rimer BK, Siegler IC (1999). Attitudes and knowledge associated with being undecided about Hormone replacement therapy: Results from a community sample. *Women's Health Issues* 9:330-337.
31. Schildkraut JM, **Halabi S**, Bastos E, Marchbanks PA, McDonald JA, Berchuck A (2000). Prognostic significance of p53 overexpression in epithelial ovarian cancers diagnosed in women before age 55: A population-based study. *Obstetrics & Gynecology* 95:119-127.
32. Lipkus IM, Rimer BK, **Halabi S**, Strigo TS (2000). Can tailored interventions increase mammography use among HMO women? *American Journal of Preventive Medicine* 18:1-10.
33. Dawson NA, Conaway MR, **Halabi S**, Small EJ, Lake D, Winer EP, Cooper MR, Woliver TB, Ernstoff MS, Vogelzang NJ (2000). A randomized study comparing standard versus moderately high dose megestrol acetate in advanced prostate cancer: CALGB 9181. *Cancer* 88:825-834.
34. McBride CM, **Halabi S**, Bepler G, Lyna P, McIntyre L, Lipkus I, Albright J, O' Briant K (2000). Maximizing the motivational impact of feedback of lung cancer susceptibility on smokers' desire to quit. *Journal of Health Communication* 5: 229-241.

35. Lipkus IM, **Halabi S**, Strigo TS, Rimer BK (2000). The impact of abnormal mammograms on psychosocial outcomes and subsequent screening. *Psycho-Oncology* 9:402-410.
36. **Halabi S**, Skinner CS, Samsa GP, Strigo TS, Crawford Y, Rimer BK (2000). Factors associated with repeat mammography screening. *Journal of Family Practice* 49:1104-1112.
37. Sandler RS, **Halabi S**, Kaplan EB, Baron JA, Paskett ED, Petrelli NJ (2001). Use of vitamins, minerals and nutritional supplements by participants in a chemoprevention trial. *Cancer* 91:10401045.
38. Bok RA, **Halabi S**, Fei DT, Rodrigues CR, Hayes DF, Vogelzang NJ, Kantoff PW, Shuman MA, Small EJ (2001). Vascular endothelial growth factor and basic fibroblast growth factor urine levels as predictors of outcome in hormone refractory prostate cancer: A CALGB study. *Cancer Research* 61(6):2533-2536.
39. Savarese DM, **Halabi S**, Hars V, Akerley W, Godley P, Hussain A, Small E, Vogelzang NJ (2001). Phase II study of docetaxel, estramustine, and low-dose hydrocortisone in men with hormone-refractory prostate cancer: A final report of CALGB 9780. *Journal of Clinical Oncology* 19:2509-2516.
40. Rimer BK, **Halabi S**, Skinner CS, Kaplan EB, Crawford Y, Samsa GP, Strigo TS, Lipkus IM (2001). The short-term impact of a mammography decision-making intervention for women. *Patient Education and Counseling* 43:269-285.
41. Schildkraut J, Cooper G, **Halabi S**, Whittemore A, Hartge P, Berchuck A (2001). Age at natural menopause and the risk of developing invasive epithelial ovarian cancer. *Obstetrics & Gynecology* 98:85-90.
42. Bastian LA, Lipkus IM, Kuchibhatla MN, Haoling HW, **Halabi S**, Ryan PD, Skinner CS, Rimer BK (2001). Interest in chemoprevention for breast cancer: Results from a community sample. *Archives of Internal Medicine* 161:1565-1688.
43. George DJ, **Halabi S**, Shepard TF, Vogelzang NJ, Hayes DF, Small EJ, Kantoff PW (2001). Prognostic significance of plasma vascular endothelial growth factor (VEGF) levels in patients with hormone refractory prostate cancer: A CALGB study. *Cancer Clinical Research* 7:1932-1936.
44. Kantoff PW, **Halabi S**, Farmer DA, Hayes DF, Vogelzang NA, Small EJ (2001). Prognostic significance of reverse transcriptase polymerase chain reaction (RT-PCR) for prostate specific antigen (PSA) in men with androgen independent prostate cancer. *Journal of Clinical Oncology* 19:3025-3028.
45. **Halabi S**, Conaway MR, Small EJ, Vogelzang NJ, Dawson NA (2001). Serum prostate specific antigen as a predictor of survival in prostate cancer patients treated with second-line hormonal therapy (CALGB 9181). *The Prostate Journal* 3:18-25.

46. Levine EG, **Halabi S**, Roberts JD, Kaplan EB, Rago R, Atkins JN, Vogelzang NJ (2002). Higher doses of mitoxantrone among men with hormone refractory prostate cancer: A Cancer and Leukemia Group B study. *Cancer* 94:665-672.
47. Rimer BR, **Halabi S**, Skinner CS, Lipkus IM, Strigo TS, Kaplan EB, Glassman B, Farrell D, Samsa GP (2002). Effects of a mammography decision-making intervention at 12 and 24 months. *American Journal of Preventive Medicine* 22:247-257.
48. McBride CM, Bastian LA, **Halabi S**, Fish L, Lipkus IM, Bosworth HB, Rimer BK, Siegler I (2002). Efficacy of a tailored intervention to aid decision-making about hormone replacement therapy. *American Journal of Public Health* 92:1112-1114.
49. Small EJ, **Halabi S**, Rattain M, Rosner G, Stadler W, Palchak D, Marshall E, Rago R, Hars V, Wilding G, Petrylak D, Vogelzang NJ (2002). Randomized study of three different doses of suramin administered with a fixed dosing schedule in patients with advanced prostate cancer: Results of Intergroup 0159, Cancer and Leukemia Group B 9480. *Journal of Clinical Oncology* 20:3369-3375.
50. Moorman PG, Schildkraut JM, Calingaert B, Vine M, **Halabi S**, Berchuck A (2002). Ovulation and ovarian cancer: A comparison of two methods for calculating lifetime ovulatory cycles. *Cancer Causes and Control* 13:807-811.
51. **Halabi S**, Small EJ, Hayes DF, Vogelzang NJ, Kantoff PW (2003). Prognostic significance of reverse transcriptase polymerase chain reaction for prostate-specific antigen in metastatic prostate cancer. *Journal of Clinical Oncology* 21:490-495.
52. Sandler RS, **Halabi S**, Baron JA, Budinger S, Paskett E, Kereszates R, Petrelli N, Pipsa JM, Karp DD, Loprinzi CL, Steinback G, Schilsky R (2003). A randomized trial of aspirin to prevent colorectal adenomas in patients with previous colorectal cancer. *New England Journal of Medicine* 348:883-890.
53. **Halabi S**, Small EJ, Kantoff PW, Kattan MW, Kaplan EB, Dawson NA, Levine EG, Blumenstien BA, Vogelzang NJ (2003). Prognostic model for predicting survival in men with hormone-refractory metastatic prostate cancer. *Journal of Clinical Oncology* 21:1232-1237.
54. Small EJ, **Halabi S**, Dalbagni G, Pruthi R, Philips G, Edelman M, Bajorin D (2003). Overview of bladder cancer trials in the Cancer and Leukemia Group B. *Cancer* 97(8 Suppl):2090-2098.
55. **Halabi S**, Wun CC, Davis BR (2003). Analysis of survival data with missing measurements of a time-dependent binary covariate. *Journal of Biopharmaceutical Statistics* 13:253-270.
56. Lancaster JM, Wenham RM, **Halabi S**, Calingaert B, Marks JR, Moorman PG, Bentley RC, Berchuck A, Schildkraut JM (2003). No relationship between ovarian cancer risk and progesterone receptor gene polymorphism in a population-based, case-control study in North Carolina. *Cancer Epidemiology, Biomarkers & Prevention* 12:226-227.

57. Taplin, ME, Rajeshkumar B, **Halabi S**, Werner CP, Woda B A, Picus J, Stadler W, Hayes DF, Kantoff PW, Vogelzang NJ, Small EJ (2003). Androgen receptor mutations in androgen-independent prostate cancer: Cancer and Leukemia Group B Study 9663. *Journal of Clinical Oncology* 21:2673-2678.
58. Oh W, **Halabi S**, Kelly WK, Werner C, Godley PA, Vogelzang NJ, Small EJ (2003). A phase II study of estramustine, docetaxel and carboplatin with G-CSF support in patients with hormone refractory prostate cancer: Cancer and Leukemia Group B 99813. *Cancer* 98:2592-2598.
59. Sandler RS, **Halabi S**, Baron JA, Budinger S, Paskett E, Kereszates R, Petrelli N, Pipsa JM, Karp DD, Loprinzi CL, Steinback G, Schilsky R (2003). A randomized controlled trial of aspirin to prevent colorectal adenomas in patients with previous colorectal cancer. *Obstetrical and Gynecological Survey* 58:539-541.
60. Scher HI, Eisenberger M, D'Amico AV, **Halabi S**, Small EJ, Morris M, Kattan MW, Roach M, Kantoff P, Pienta KJ, Michael A, Carducci MA, Slovin SF, Heller G, Kelly WK, Lange PH, Petrylak D, Berg W, Wilding G, Moul JW, Partin AN, Logothetis C, Soule HR (2004). Eligibility and outcomes reporting guidelines for clinical trials for patients in the state of a rising PSA: Recommendations from the prostate-specific antigen working group. *Journal of Clinical Oncology* 22:537-556.
61. Small EJ, **Halabi S**, Dawson NA, Stadler WM, Rini BI, Picus J, Gable P, Torti F, Kaplan E, Vogelzang NJ (2004). A phase III trial of antiandrogen withdrawal alone or in combination with ketoconazole in androgen-independent prostate cancer patients: Results of CALGB 9583. *Journal of Clinical Oncology* 22:1025-1033.
62. **Halabi S**, Singh B (2004). Sample size determination for comparing several survival curves with unequal allocations. *Statistics in Medicine* 23:1793-1815.
63. Rini BI, **Halabi S**, Taylor S, Small EJ, Schilsky RL (2004). Cancer and Leukemia Group B 90206: A randomized phase III trial of interferon-alpha or interferon-alpha plus anti-vascular endothelial growth factor antibody (bevacizumab) in metastatic renal cell carcinoma. *Clinical Cancer Research* 10:2584-2586.
64. Burns SP, **Halabi S**, Clamon G, Kaplan E, Hohl RJ, Atkins JN, Schwartz MA, Wagner BA, Paskett E (2004). Phase II study of high-dose fish oil capsules for patients with cancer cachexia: A Cancer and Leukemia Group B study. *Cancer* 101:370-378.
65. **Halabi S**, Small EJ, Vogelzang NJ, Barrier RC, George SL, Gilligan TD (2004). Impact of race on survival in men with metastatic hormone refractory prostate cancer. *Urology* 64:212-217.
66. Amin A, **Halabi S**, Gleason EP, Stadler W, Vogelzang N, Small EJ (2004). 9-Nitrocimptothecin as second line chemotherapy for men with progressive, metastatic, hormone refractory prostate cancer: results of the CALGB 99901. *Urologic Oncology* 22:398-403.

67. Berchuck A, Schildkraut JM, Wenham RM, Calingaert B, Ali A, Henriott A, **Halabi S**, Rodriguez GC, Gertig D, Purdie DM, Kelemen L, Spurdle AB, Marks J, Chenevix-Trench G (2004). Progesterone receptor promoter +331A polymorphism is associated with a reduced risk of endometrioid and clear cell ovarian cancers. *Cancer Epidemiology, Biomarkers & Prevention* 13:2141-2171.
68. George DJ, **Halabi S**, Shepard TF, Sanford B, Vogelzang NJ, Small EJ, Kantoff PW (2005). The prognostic significance of plasma interleukin-6 (IL-6) levels in patients with metastatic hormonerefractory prostate cancer: Results from CALGB 9480. *Clinical Cancer Research* 11:1815-1820.
69. Moorman PG, Berchuck A, Calingaert B, **Halabi S**, Schildkraut JM (2005). Antidepressant medication use and risk of ovarian cancer. *Obstetrics and Gynecology* 105:725-730.
70. Spillman MA, Schildkraut JM, **Halabi S**, Moorman P, Calingaert B, Bentley RC, Marks JR, Murphy S, Berchuck A (2005). Transforming growth factor beta receptor I polyalanine repeat polymorphism does not increase ovarian cancer risk. *Gynecologic Oncology* 97:543-549.
71. Moorman PG, Schildkraut JM, Calingaert B, **Halabi S**, Berchuck A. Menopausal hormones and risk of ovarian cancer (2005). *American Journal of Obstetrics and Gynecology* 193:76-82.
72. Taplin ME, George DJ, **Halabi S**, Sanford B, Febbo PG, Hennessy KT, Mihos CG, Vogelzang NJ, Small EJ, Kantoff PW (2005). The prognostic significance of plasma chromogranin a levels in hormone-refractory prostate cancer patients treated on Cancer and Leukemia Group B (CALGB) 9480. *Urology* 66:386-391.
73. Hoyo C, Berchuck A, **Halabi S**, Bentley R, Moorman P, Calingaert B, Schildkraut J (2005). Anthropometric measurements and epithelial ovarian cancer risk in African American and white women. *Cancer Causes and Control* 16:955-963.
74. Ross R, **Halabi S**, Rajeshkumar B, Woda B, Vogelzang NJ, Small EJ, Taplin ME, Kantoff PW (2005). Predictors of prostate cancer tissue acquisition by an undirected core bone marrow biopsy in metastatic castration resistant prostate cancer - A cancer and leukemia group B study. *Clinical Cancer Research* 11:8109-8113.
75. Schildkraut JM, Moorman PG, **Halabi S**, Calingaert B, Marks JR, Berchuck A (2006). Analgesic drug use and risk of ovarian cancer. *Epidemiology* 17:104-107.
76. Humphrey PA, **Halabi S**, Picus J, Sanford B, Vogelzang NJ, Small EJ, Kantoff PW (2006). The prognostic significance of plasma scatter factor/hepatocyte growth factor levels in patients with metastatic hormone-refractory prostate cancer: Results from CALGB 150005/9480. *Clinical Genitourinary Cancer* 4:269-274.
77. **Halabi S**, Vogelzang NJ, Ou SS, Kelly WK, Small EJ (2006). Clinical outcomes by age in men with hormone refractory prostate cancer: A pooled analysis of eight Cancer and Leukemia Group B (CALGB) Studies. *Journal of Urology* 176:81-86.

78. Rini B, **Halabi S**, Barrier R, Margolin KA, Avigan D, Logan T, Stadler WM, McCarthy PL, Linker CA, Small EJ (2006). Adoptive immunotherapy by allogeneic stem cell transplantation for metastatic renal cell carcinoma: A CALGB intergroup phase II study. *Biology of Blood and Marrow Transplantation* 12:778-785.
79. Stadler W, **Halabi S**, Rini B, Ernstoff MS, Davila E, Picus J, Barrier R, Small E (2006). A phase II study of gemcitabine and capecitabine in metastatic renal cancer: A report of Cancer and Leukemia Group B protocol 90008. *Cancer* 107:1273-1279.
80. **Halabi S**, Vogelzang NJ, Ou SS, Small EJ (2007). The impact of prior radical prostatectomy in men with metastatic castration-recurrent prostate cancer: A pooled analysis of nine CALGB trials. *Journal of Urology* 177:531-534.
81. Schildkraut JM, Murphy SK, Palmieri RT, Iversen E, Moorman PG, Huang S, **Halabi S**, Calingaert B, Gusberg A, Marks J, Berchuck A (2007). Trinucleotide repeat polymorphisms in the androgen receptor gene and risk of ovarian cancer. *Cancer Epidemiology Biomarkers and Prevention* 16:473-80.
82. Ryan CJ, **Halabi S**, Ou SS, Vogelzang NJ, Kantoff P, Small EJ (2007). Adrenal androgen levels as predictors of outcome in prostate cancer patients treated with ketoconazole plus antiandrogen withdrawal: Results from a Cancer and Leukemia B Study. *Clinical Cancer Research* 13:2030-7.
83. Kyle RA, Yee GC, Somerfield MR, Flynn PJ, **Halabi S**, Jagannath S, Orlovski RZ, Roodman DG, Twilte P, Anderson K (2007). American Society of Clinical Oncology 2007 clinical practice guideline update on the role of bisphosphonates in multiple myeloma. *Journal of Clinical Oncology* 25:2464-72.
84. **Halabi S**, Ou SS, Vogelzang NJ, Small EJ (2007). Inverse relationship between body mass index and clinical outcomes in men with advanced castration-recurrent prostate cancer. *Cancer* 110:147884.
85. **Halabi S** (2008). Statistical considerations for the design and analysis of phase III clinical trials in prostate cancer. *Urologic Oncology* 26:300-307.
86. Philips GK, **Halabi S**, Sanford BL, Bajorin D, Small EJ (2008). A phase II trial of cisplatin, fixed dose-rate gemcitabine and gefitinib for advanced urothelial tract carcinoma: results of the Cancer and Leukemia Group B 90102. *British Journal of Urology International*. 101:20-25.
87. Kim S, Keku TO, Martin C, Galanko J, Woosley JT, Schroeder JC, Satia JA, **Halabi S**, Sandler RS (2008). Circulating levels of inflammatory cytokines and risk of colorectal adenomas. *Cancer Research* 68:323-328.
88. Garmey EG, Sartor O, **Halabi S**, Vogelzang NJ (2008). Second-line chemotherapy for advanced hormone-refractory prostate cancer. *Clinical Advances in Hematology and Oncology* 6: 118-132.

89. Scher HI, **Halabi S**, Tannock I, Morris M, Sternberg CN, Carducci MA, Eisenberger MA, Higano C, Bubley GJ, Driecer R, Petrylak D, Kantoff P, Basch E, Kelly WK, Figg WD, Small EJ, Beer TM, Wilding G, Martin A, Hussain M (2008). Design and endpoints of clinical trials for Patients with Progressive Prostate Cancer and Castrate levels of testosterone: Recommendations of the Prostate Cancer Clinical Trials Working Group (PCWG2). *Journal of Clinical Oncology* 26:1148-59.
90. **Halabi S**, Vogelzang NJ, Kornblith AB, Ou SS, Kantoff PW, Dawson NA, Small EJ (2008). Pain predicts overall survival in men with metastatic castrate refractory prostate cancer (CRPC). *Journal of Clinical Oncology* 26:2544-9.
91. Singh B, **Halabi S**, Schell M (2008). Sample size selection in clinical trials when population means are subject to a partial order. *Journal of Applied Statistics* 35: 583-600.
92. Schildkraut JM, Moorman PG, Bland A, **Halabi S**, Calingaert B, Whitaker R, Lee PS, ElkinsWilliams T, Bentley RC, Marks J, Berchuck A (2008). Cyclin E overexpression in epithelial ovarian cancer characterizes an etiologic subgroup. *Cancer Epidemiology Biomarkers Prevention* 17:585-93.
93. D'Amico AV, **Halabi S**, Tempany C, Titelbaum D, Philips GK, Loffredo M, McMahon E, Sanford B, Vogelzang NJ, Small EJ (2008). Tumor volume changes on 1.5 tesla endorectal MRI during neoadjuvant androgen suppression therapy for higher-risk prostate cancer and recurrence in men treated using radiation therapy results of the phase II CALGB 9682 study. *International Journal of Radiation Oncology, Biology, Physics* 71:9-15.
94. D'Amico AV, **Halabi S**, Vollmer R, Loffredo M, McMahon E, Sanford B, Archer L, Vogelzang NJ, Small EJ (2008). P53 protein expression status and recurrence in men treated with radiation and androgen suppression therapy for higher-risk prostate cancer : A prospective phase II Cancer and Leukemia Group B study (CALGB 9682). *Urology* 71:933-7.
95. Rosenberg JE, **Halabi S**, Sanford BL, Himelstein AL, Atkins JN, Hohl RJ, Millard F, Bajorin DF, Small EJ (2008). Phase II study of bortezomib in patients with previously treated advanced urothelial tract transitional cell carcinoma: CALGB 90207. *Annals of Oncology* 19:946-50.
96. Moorman PG, Calingaert B, Palmieri RT, Iversen ES, Bentley RC, **Halabi S**, Berchuck A, Schildkraut JM (2008). Hormonal risk factors for ovarian cancer in premenopausal and postmenopausal women. *American Journal of Epidemiology* 167:1059-69.
97. Hurwitz MD, **Halabi S**, Ou SS, McGinnis LS, Keuttel MR, DiBiase SJ, Small EJ (2008). Combination external beam radiation and brachytherapy boost with androgen suppression For treatment of intermediate risk prostate cancer: An initial report of CALGB 99809. *International Journal of Radiation Oncology, Biology, Physics* 72:814-9.
98. Dawson NA, **Halabi S**, Ou SS , Biggs DD, Kessinger A, Vogelzang N, Clamon GH, Nanus D, Kelly WK, Small EJ (2008). A phase II study of estramustine, docetaxel and exisulind in patients with hormone-refractory prostate cancer (HRPC): Results of Cancer and Leukemia Group B (CALGB) 90004. *Clinical Genitourinary Cancer* 6:110-116.

99. Armstrong AJ, **Halabi S**, de Wit R, Tannock IF, Eisenberger M (2008). The relationship of body mass index and serum testosterone with disease outcomes in men with castration-resistant metastatic prostate cancer. *Prostate Cancer and Prostatic Diseases*
100. Rini BI, **Halabi S**, Rosenberg JE, Stadler WM, Vaena DA, Ou SS, Archer L, Atkins JN, Picus J, Tanguay S, Dutcher J, Small EJ (2008). Bevacizumab plus interferon-alpha versus interferon-alpha monotherapy in patients with metastatic renal cell carcinoma: Results of CALGB 90206. *Journal of Clinical Oncology* 26:5422-8.
101. Kelly WK, **Halabi S**, Elfiky A, Ou SS, Bogart J, Zelefsky M, Small E (2008). Multicenter phase II study of neo-adjuvant paclitaxel, estramustine phosphate, and carboplatin (TEC) plus androgen deprivation prior to radiation therapy in patients with unfavorable-risk localized prostate cancer: Results of CALGB 99811. *Cancer* 113:3137-3145.
102. Kim S, Martin C, Galanko J, Woosley JT, Schroeder JC, Keku OT, Satia JA, **Halabi S**, Sandler RS (2008). Use of nonsteroidal antiinflammatory drugs and distal large bowel cancer in whites and African Americans. *American Journal of Epidemiology* 68:1292-300.
103. Potthoff RF, **Halabi S**, Schildkraut JM, Newman B (2008). Flexible frames and control sampling in case-control studies: Weighters (survey statisticians) versus anti-weighters (epidemiologists). *The American Statistician* 62, 307-313.
104. Philips GK, **Halabi S**, Sanford BL, Bajorin D, Small EJ (2009). A Phase II trial of cisplatin (C), gemcitabine (G) and gefitinib for advanced urothelial tract carcinoma: Results of Cancer and Leukemia Group B (CALGB) 90102. *Annals of Oncology* 20:1074-9.
106. Cole BF, Logan RF, **Halabi S**, Benamouzig R, Sandler RS, Grainge MJ, Chaussade S, Baron JA (2009). Aspirin for the chemoprevention of colorectal adenomas: Meta-analysis of the randomized trials. *Journal of the National Cancer Institute* 101:256-66.
107. Halabi S, Vogelzang NJ, Ou SS, Owzar K, Archer LA, Small EJ (2009). Progression-free survival as a predictor of overall survival in men with castrate resistant prostate cancer (CRPC). *Journal of Clinical Oncology* 27:2766-71. PMID: PMC2698015
108. Regan MM, O'Donnell EK, Kelly WK, **Halabi S**, Berry W, Urakami S, Kikuno N, Oh WK (2010). Efficacy of carboplatin-taxane combinations in the management of castration-resistant prostate cancer: A pooled analysis of 7 prospective clinical trials. *Annals of Oncology* 21:312-8
109. Sartor O, McLeod DG, **Halabi S**, Schellhammer PF, Scardino PT, D'Amico AV, Bennett C, Wei JT (2010). The COMPARE Registry: Design and Baseline Patterns of Care for Men with Biochemical Failure after Definitive Treatment of Localized Prostate Cancer. *Urology* 75:623-9.
110. Bajorin DF, **Halabi S**, Small E (2010). Arsenic trioxide in recurrent urothelial cancer: A CALGB phase II trial. *Clinical Genitourinary Cancer* 7:E66-70
111. Garber JE, **Halabi S**, Tolaney SM, Kaplan E, Archer L, Atkins JN, Edge S, Shapiro CL, Dressler

- L, Paskett EM, Kimmick G, Orcutt J, Scalzo A, Winer E, Levine E, Rotche R, Shahab N, Berliner N (2010). Factor V Leiden mutation and the risk of thromboembolic events in women receiving adjuvant tamoxifen for breast cancer: Results from CALGB 9872. *Journal of the National Cancer Institute* 102:942-9.
112. **Halabi S**, Owzar K (2010). The importance of identifying and validating prognostic factors in oncology. *Seminars in Oncology* 37:E9-18.
113. Armstrong AJ, Tannock IF, de Wit R, George DJ, Eisenberger M, **Halabi S** (2010). The development of risk groups in men with metastatic castration-resistant prostate cancer based on predictive risk factors for PSA decline and survival. *European Journal of Cancer* 46:517-25.
114. Rini BI, **Halabi S**, Rosenberg JE, Stadler WM, Vaena DA, Archer L, Atkins JN, Picus J, Czaykowski P, Dutcher J, Small ES (2010). A phase 3 study of bevacizumab plus interferon-alpha versus interferon-alpha monotherapy in patients with metastatic renal cell carcinoma-final results of CALGB 90206. *Journal of Clinical Oncology* 28:2137-43. (PMCID:PMC2860433)
115. Gulley JL, Arlen PM, Madan RA, Tsang KY, Pazdur MP, Skarupa L, Jones JL, Poole DJ, Higgins JP, Hodge JW, Cereda V, Vergati M, Steinberg SM, **Halabi S**, Jones E, Chen C, Parnes H, Wright JJ, Dahut WL, Schlom J (2010). Immunologic and prognostic factors associated with overall survival employing a poxviral-based PSA vaccine in metastatic castrate-resistant prostate cancer. *Cancer Immunology Immunotherapy* 59:663-74.
116. Armstrong AJ, Netto G, Rudek MA, **Halabi S**, Wood D, Creel P, Mundy K, Davis SL, Wang T, Albadine R, Schultz L, Partin A, Jimeno A, Fedor H, Febbo PG, George DJ, Gurganus R, De Marzo A, Carducci MA (2010). A pharmacodynamic study of rapamycin in men with advanced localized prostate cancer. *Clinical Cancer Research* 16:3057-66
117. Hagan N, Robins N, Hsu-Kim H, **Halabi S**, Morris M, Woodall G, Zhang T, Bacon A, Richter D, Vandenberg J (2010). Historical Atmospheric mercury concentrations from silver mining and their legacies in present-day Soils in Potosí, Bolivia. *Atmospheric Environment*, doi:10.1016/j.atmosenv.2010.10.009
118. Picus J, **Halabi S**, Kelly WK, Vogelzang NJ, Whang YE, Kaplan EB, Stadler WM, Small EJ (2011). A phase II study of estramustine, docetaxel, and bevacizumab in men with castrate resistant prostate cancer: Results of Cancer and Leukemia Group B (CALGB) 90006. *Cancer* 117:526-33.
119. Liu A, Liu C, **Halabi S** (2011). A min-max combination of biomarkers to improve diagnostic accuracy. *Statistics in Medicine* 30:2005–2014. PMCID: PMC3116024
120. Shapiro CL, **Halabi S**, Hars V, Archer L, Weckstein D, Kirshner J, Sikov W, Winer E, Burstein HJ, Hudis C, Isaacs C, Schilsky R, Paskett E (2011). Zoledronic acid preserves bone mineral density in premenopausal women who develop ovarian failure due to adjuvant chemotherapy: Final results from CALGB trial 79809. *European Journal of Cancer* 2011 47:683-9.

121. Hurwitz MD, **Halabi S**, Archer L, McGinnis LS, Kuettel MR, DiBiase SJ, Small EJ (2011). Combination external beam radiation and brachytherapy boost with androgen deprivation for treatment of intermediate-risk prostate cancer: long-term results of CALGB 99809. *Cancer* 117:5579-88.
122. **Halabi S***, Moser BK* (2012). Estimation and testing of the relative risk of disease in casecontrol studies with a set of k matched controls per case with known prevalence of disease. *Statistics in Medicine* 31(1):29-44. PMID: PMC3637965
*co-first authors
123. Monk JP, **Halabi S**, Picus J, Hussain A, Philips G, Kaplan E, Ahles T, Gu L, Vogelzang N, Kelly WK, Small EJ (2012). Efficacy of peripheral androgen blockade in prostate cancer patients with biochemical failure after definitive local therapy: Results of Cancer and Leukemia Group B (CALGB) 9782. *Cancer* 118(17):4139-47.
124. Armstrong AJ, Eisenberger MA, **Halabi S**, Oudard S, Nanus DM, Petrylak DP, Sartor AO, Scher HI (2012). Using biomarkers to guide therapy in men with metastatic castrate-resistant prostate cancer. *European Urology* 61:549-59.
125. Kelly WM, **Halabi S**, Carducci M, George D, Mahoney JF, Stadler WM, Morris M, Kantoff P, Monk P, Small EJ (2012). Randomized, double-blind, placebo-controlled phase III trial comparing docetaxel and prednisone with or without bevacizumab in men with metastatic castration-resistant prostate cancer: CALGB 90401. *Journal of Clinical Oncology* 30(13): 1534-40. PMID:PMC 3383121
126. Korn EL, Freidlin B, Abrams JS, **Halabi S** (2012). Design issues in randomized phase II/III trials. *Journal of Clinical Oncology* 30(6): 667-71.
127. Armstrong AJ, George DJ, **Halabi S** (2012). Serum lactate dehydrogenase predicts for overall survival benefit in patients with metastatic renal cell carcinoma treated with inhibition of mammalian target of rapamycin. *Journal of Clinical Oncology* 30:3402-7.
128. **Halabi S** (2012). Adjustment on the type I error rate for a clinical trial monitoring for both intermediate and primary endpoints *Journal of Biostatistics and Bioinformatics* 2155-6180, S7-S15. PMID: PMC3898520
129. Atkinson TM, **Halabi S**, Bennett AV, Rogak L, Sit L, Li Y, Kaplan E, Basch E (2012). Measurement of affective and activity pain interference using the Brief Pain Inventory (BPI): Cancer and Leukemia Group B 70903. *Pain Medicine* 13(11):1417-24.
130. Apolo AB, Ostrovnaya I, **Halabi S**, Iasonos A, Philips GK, Rosenberg JE, Riches J, Small EJ, Milowsky MI, Bajorin DF (2013). Prognostic model for predicting survival of patients with metastatic urothelial cancer treated with cisplatin-based chemotherapy. *Journal of the National Cancer Institute* 105(7):499-503.

131. Armstrong AJ, Shen T, **Halabi S**, Kemeny G, Bitting RL, Kartcheske P, Embree E, Morris K, Winters C, Jaffe T, Fleming M, George DJ (2013). A phase II trial of temsirolimus in men with castration-resistant metastatic prostate cancer. *Clin Genitourin Cancer*. pii: S1558-7673(13)00138-9.
doi: 10.1016/j.clgc.2013.05.007.
132. Aggarwal R, **Halabi S**, Kelly WK, George D, Carducci M, Mahoney J, Millard F, Stadler WM, Morris M, Kantoff PW, Monk P, Small EJ (2013). The Effect of Prior Androgen Synthesis Inhibition on Outcomes of Subsequent Therapy with Docetaxel in Patients with Metastatic Castrate Resistant Prostate Cancer: Results from a Retrospective Analysis of a Randomized Phase 3 Clinical Trial (CALGB 90401) (Alliance). *Cancer* 119(20):3636-43.
133. Lin CY, **Halabi S** (2013). On model specification and selection of the Cox proportional hazards model. *Statistics in Medicine* 32(26):4609-23.
134. **Halabi S**, Armstrong AJ, Sartor O, Kaplan E, de-Bono J, Lin CY, Solomon NC, Small EJ (2013). Prostate-specific antigen changes as surrogate of overall survival (OS) in men with metastatic castration-resistant prostate cancer (mCRPC) treated with second line chemotherapy. *Journal of Clinical Oncology* 31(31):3944-50.
135. **Halabi S**, Lin CY, Small EJ, Armstrong AJ, Kaplan E, Petrylak D, Sternberg CN, Shen L, Oudard S, de-Bono J, Sartor O (2013). Prognostic model for predicting overall survival in metastatic castration-resistant prostate cancer (mCRPC) men treated with second line chemotherapy. *Journal of the National Cancer Institute* 105(22):1729-37.
136. **Halabi S**, Rini R, Escudier B, Stadler WM, Small EJ (2014). Progression-free survival (PFS) as an intermediate endpoint of overall survival (OS) in patients with metastatic renal cell carcinoma (mRCC). *Cancer* 120(1):52-60.
137. **Halabi S**, Lin CY, Kelly WK, Fizazi KS, Moul JW, Kaplan EB, Morris MJ, Small EJ (2014). An updated prognostic model for predicting overall survival in first-line chemotherapy metastatic castration-resistant prostate cancer patients. *Journal of Clinical Oncology* 32(7):671-7.
138. Smith MR, **Halabi S**, Ryan CJ, Hussain A, Vogelzang V, Stadler W, Hauke RJ, Monk JP, Saylor P, Bhoopalam N, Saad F, Sanford B, Kelly WK, Morris, Small EJ (2014). Randomized controlled trial of early zoledronic acid in men with castration-sensitive prostate cancer and bone metastases: Results of CALGB 90202 (Alliance). *Journal of Clinical Oncology* 32(11):1143-50.
139. Liu C, Liu A, Hu J, Yuan VW, **Halabi S** (2014). Adjusting for misclassification in stratified biomarker clinical trials. *Statistics in Medicine* 33(18):3100-13

140. Moser BK, **Halabi S** (2015). Sample size requirements and length of study for testing main effects and interactions in completely randomized factorial designs when time to event is the outcome. *Communications in Statistics: Theory and Methods* 44(2):275-85.
141. Patel JN, Chen J, Hertz DH, Owzar K, Mulkey FA, **Halabi S**, Furukawa Y, Lassiter C, Dorsey SG, Friedman PN, Small EJ, Febbo PG, Shterev I, Kroetz DI, Carducci MA, Mahoney JF, Kelley MJ, Morris MJ, Nakamura Y, Kubo M, Ratain MJ, Kelly WK, McLeod HL (2015). A genome-wide association study (GWAS) and risk factor analysis of bevacizumab-related hemorrhage in CALGB 90401 (Alliance). *Cancer* 121(7):1025-31.
142. Hagan N, Robins N, Hsu-Kim H, **Halabi S**, Espinoza Gonzales RD, Ecos E, Richter D, Vandenberg J. Mercury hair levels and factors that influence exposure for residents of Huancavelica, Peru. *Environ Geochem Health* [Epub ahead of print]
143. Sartor O, **Halabi S** (2015). Independent data monitoring committees: An update and overview. *Urologic Oncology*: pii: S1078-1439(14)00466-9.
144. Bitting RL, Healy P, **Halabi S**, George DJ, Goodin M, Armstrong AJ (2015). Clinical phenotypes associated with circulating tumor cell enumeration in metastatic castration-resistant prostate cancer. *Urologic Oncology* pii: S1078-1439(14)00313-5.
145. Potthoff RF, **Halabi S** (2015). A novel test to compare two treatments based on endpoints involving both nonfatal and fatal events. *Pharmaceutical Statistics* 14(4):273-83.
146. Gillessen S, Omlin A, Attard G, de Bono JS, Efstathiou E, Fizazi K, **Halabi S**, Nelson PS, Sartor O, Smith MR, Soule HR, Akaza H, Beer TM, Beltran H, Chinnaiyan AM, Daugaard G, Davis ID, De Santis M, Drake CG, Eeles RA, Fanti S, Gleave ME, Heidenreich A, Hussain M, James ND, Lecouvet FE, Logothetis CJ, Mastris K, Nilsson S, Oh WK, Olmos D, Padhani AR, Parker C, Rubin MA, Schalken JA, Scher HI, Sella A, Shore ND, Small EJ, Sternberg CN, Suzuki H, Sweeney CJ, Tannock IF, Tombal B (2015). Management of patients with advanced prostate cancer: recommendations of the St Gallen Advanced Prostate Cancer Consensus Conference (APCCC) 2015. *Annals of Oncology* 26(8):1589-604.
147. Mahar AL, Compton C, McShane LM, **Halabi S**, Asamura H, Rami-Porta R, Groome PA; Molecular Modellers Working Group of the American Joint Committee on Cancer. Refining prognosis in lung cancer: A report on the quality and relevance of clinical prognostic tools. *J Thorac Oncol*. 2015 Aug 24. [Epub ahead of print]
148. Armstrong AJ, Healy P, Halabi S, Vollmer R, Lark A, Kemeny G, Ware K, Freedland SJ. Evaluation of an epithelial plasticity (EP) biomarker panel in men with localized prostate cancer. *In press* (Prostate Cancer and Prostatic Diseases).
149. Armstrong AJ, **Halabi S**, Healy P, Lee WM, Koontz BF, Moul JW, Mundy K, Creel P, Wood S, Davis K, Carducci MA, Stein M, Hobbs C, Reimer B, Nguyen M, , Anand M, Bratt L, Kim S, Tran PT, George DJ. A phase 2 multimodality trial of docetaxel/prednisone with sunitinib followed

by salvage radiation therapy in men with PSA recurrent prostate cancer after radical prostatectomy. *In press* (Prostate Cancer and Prostatic Diseases).

150. ICECaP Working group (Writing Committee: Coordinating Center: Sweeney C, Brandon B, Nakabayashi M, Regan M, Xie W, Hayes J, Keating, N, Li S, Philipson T, Members Independent of Coordinating Center over- seeing Statistical Analysis Plan: Buyse N, **Halabi S**, Kantoff P, Sartor AO, Soule H, Mahal B (2015). The development of intermediate clinical endpoints in cancer of the prostate (ICECaP). *Journal of the National Cancer Institute* 107(12):d1v261. doi: 10.1093/jnci/d1v261.

151. Armstrong AJ, **Halabi S**, Eisen T, Broderick S, Stadler WM, Jones RJ, Garcia JA, Vaishampayan UN, Picus J, Hawkins RE, Hainsworth JD, Kollmannsberger CK, Logan TF, Puzanov I, Pickering LM, Ryan CW, Protheroe A, Lusk CM, Oberg S, George DJ (2016). A randomized phase 2 international trial of everolimus vs. sunitinib in patients with metastatic nonclear cell renal cell carcinoma (ASPEN). *Lancet Oncology* 17(3):378-88.

152. Kim HL *, **Halabi S***, Li P, Mayhew G, Simko J, Nixon AJ, Small EJ, Rini B, Morris MJ, Taplin ME, George D (2015). A molecular model for predicting overall survival in patients with metastatic clear cell renal carcinoma: results from CALGB 90206 (Alliance) *EBioMedicine* 2(11):1814-20. *co-first authors

153. Scher HI, Morris MJ, Stadler W, Higano C, Basch E, Fizazi K, Antonarakis ES, Beer TM, Carducci MA, Chi KN, Corn PG, de Bono JS, Dreicer R, George DJ, Heath EI, Hussain M, Kelly WK, Liu G, Logothetis C, Nanus D, Stein MN, Rathkopf DE, Ryan CJ, Sartor O, Small EJ, Smith MR, Sternberg CN, Taplin ME, Wilding G, Nelson PS, Schwartz LH, **Halabi S**, Kantoff PW, Armstrong AJ (2016). Trial Design and Objectives for Castration-Resistant Prostate Cancer: Updated Recommendations from the Prostate Cancer Clinical Trials Working Group (PCWG3). *Journal of Clinical Oncology* 34(12):1402-18.

154. **Halabi S**, Kelly WK, Ma H, Zhou H, Solomon NC, Fizazi K, Tangen CM, Rosenthal M, Petrylak DP, Hussain M, Vogelzang NJ, Thompson IM, Chi KN, de Bono J, Armstrong AJ, Eisenberger MA, Fandi A, Li S, Araujo JC, Logothetis CJ, Quinn DI, Morris MJ, Higano CS, Tannock IF, Small EJ (2016). Meta-analysis evaluating the impact of site of metastasis on overall survival in men with castration-resistant prostate cancer. *Journal of Clinical Oncology* 34(14):16529.

155. Kattan MW, Hess KR, Amin M, Lu Y, Moons KG, Gershengwald JE, Gimotty PA, Guinney J, **Halabi S**, Lazar AJ, Mahar AL, Patel T, Sargent DJ, Weiser MR, Compton C (2016). American Joint Committee on Cancer acceptance criteria for inclusion of risk models for individualized prognosis in the practice of precision medicine. *CA: A Cancer Journal for Clinicians* doi: 10.3322/caac.21339. [Epub ahead of print] .

156. Mahar AL, Compton C, **Halabi S**, McShane LM, Hess KR, Gershengwald JE, Scolyer RA, Groome PA. Critical assessment of clinical prognostic tools in melanoma. *Annals of Surgical Oncology* 2016 Apr 6. [Epub ahead of print] .

157. McEwen AR, Hsu-Kim H, Robins NA, Hagan NA, **Halabi S**, Barras O, Richter Dd, Vandenberg JJ (2016). Residential metal contamination and potential health risks of exposure in adobe brick houses in Potosí, Bolivia. *Sci Total Environ* 15;562:237-46. doi: 10.1016/j.scitotenv.2016.03.152.
158. Hertz DL, Owzar K, Lessans S, Wing C, Jiang C, Kelly WK, Patel JN, **Halabi S**, Furukawa Y, Wheeler HE, Sibley A, Lassiter C, Weisman LS, Watson D, Krens SD, Mulkey F, Renn CL, Small EJ, Febbo PG, Shterev I, Kroetz D, Friedman PN, Mahoney JF, Carducci MA, Kelley MJ, Nakamura Y, Kubo M, Dorsey SG, Dolan ME, Morris MJ, Ratain MJ, McLeod HL (2016). Pharmacogenetic Discovery in CALGB (Alliance) 90401 and Mechanistic Validation of a VAC14 Polymorphism That Increases Risk of Docetaxel-Induced Neuropathy. *Clinical Cancer Research* 22(19):4890-4900.
159. Lin CY, **Halabi S**. A simple method for deriving the confidence regions for the penalized Cox's model via the minimand perturbation. *Communications in Statistics: Theory and Methods*, 46:4791808, 2017.
160. Kim S, **Halabi S**. High dimensional variable selection with error control. *In press* (Novel Computational Approaches and Applications in Cancer Research).
161. Choueiri TK, **Halabi S**, Sanford B, Hahn O, Dror Michaelson M, Walsh M, Feldman DR, Olencki T, Picus J, Small EJ, Dakhil S, George D, Morris MJ (2017). CABOZantinib versus SUNitinib (CABOSUN) as initial targeted therapy for patients with metastatic renal cell carcinoma of poor and intermediate risk: Alliance A031203 Trial. *Journal of Clinical Oncology* 35:591-597.
162. Armstrong AJ, Humeniuk MS, Healy P, Szmulewitz R, Winters C, Kephart J, Harrison MR, Martinez E, Mundy K, **Halabi S**, George D (2017). Phase Ib Trial of Cabazitaxel and Tasquinimod in Men With Heavily Pretreated Metastatic Castration Resistant Prostate Cancer (mCRPC): The CATCH Trial. *Prostate* 77(4):385-395
163. Gillessen S, Attard G, Beer TM, Beltran H, Bossi A, Bristow R, Carver B, Castellano D, Chung BH, Clarke N, Daugaard G, Davis ID, de Bono J, Dos Reis RB, Drake CG, Eeles R, Efstathiou E, Evans CP, Fanti S, Feng F, Fizazi K, Frydenberg M, Gleave M, **Halabi S**, Heidenreich A, Higano CS, James N, Kantoff P, Kellokumpu-Lehtinen PL, Khaulil RB, Kramer G, Logothetis C, Maluf F, Morgans AK, Morris MJ, Mottet N, Murthy V, Oh W, Ost P, Padhani AR, Parker C, Pritchard CC, Roach M, Rubin MA, Ryan C, Saad F, Sartor O, Scher H, Sella A, Shore N, Smith M, Soule H, Sternberg CN, Suzuki H, Sweeney C, Sydes MR, Tannock I, Tombal B, Valdagni R, Wiegel T, Omlin A. Management of patients with advanced prostate cancer: the report of the advanced prostate cancer consensus conference APCCC 2017. *Eur Urol.* 2017 Jun 24. pii: S0302-2838(17)30497-9.
164. Armstrong AJ, **Halabi S**, Healy P, Alumkal JJ, Winters C, Kephart J, Bitting RL, Hobbs C, Soleau CF, Beer TM, Slottke R, Mundy K, Yu EY, George DJ. Phase II trial of the PI3 kinase inhibitor buparlisib (BKM-120) with or without enzalutamide in men with metastatic castration resistant prostate cancer. *Eur J Cancer.* 2017 May 11. pii: S0959-8049(17)30892-4.

165. Mahar AL, Compton C, **Halabi S**, Hess KR, Weiser MR, Groome PA. Personalizing prognosis in colorectal cancer: A systematic review of the quality and nature of clinical prognostic tools for survival outcomes. *J Surg Oncol*. 2017 Aug 2. doi: 10.1002/jso.24774.
166. Xie W, Regan MM, Buyse M, **Halabi S**, Kantoff PW, Sartor O, Soule H, Clarke NW, Collette L, Dignam JJ, Fizazi K, Paruleker WR, Sandler HM, Sydes MR, Tombal B, Williams SG, Sweeney CJ. Metastasis-Free survival is a strong surrogate of overall survival in localized prostate cancer. *Journal of Clinical Oncology* 35(27):3097-3104, 2017. PMID: 28796587.
167. Beltran H, Wyatt AW, Chedgy EC, Donoghue A, Annala M, Warner EW, Beja K, Sigouros M, Mo F, Fazli L, Collins CC, Eastham J, Morris M, Taplin ME, Sboner A, **Halabi S**, Gleave ME. Impact of therapy on genomics and transcriptomics in high-risk prostate cancer treated with neoadjuvant docetaxel and androgen deprivation therapy: preliminary results from the CALGB 90203 (PUNCH) trial. *Clin Cancer Res*. 2017 Nov 15;23(22):6802-6811. doi: 10.1158/1078-0432.CCR-171034.
168. Anderson K, Ismaila N, Flynn PJ, **Halabi S**, Jagannath S, Ogaily MS, Omel J, Raje N, Roodman GD, Yee GC, Kyle RA. Role of Bone-Modifying Agents in Multiple Myeloma: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. 2018 Mar 10;36(8):812-818.
doi: 10.1200/JCO.2017.76.6402. Epub 2018 Jan 17.
169. Choueiri TK, Hessel C, **Halabi S**, Sanford B, Michaelson MD, Hahn O, Walsh M, Olencki T, Picus J, Small EJ, Dakhil S, Feldman DR, Mangeshkar M, Scheffold C, George D, Morris MJ. Cabozantinib versus sunitinib as initial therapy for metastatic renal cell carcinoma of intermediate or poor risk (Alliance A031203 CABOSUN randomised trial): Progression-free survival by independent review and overall survival update. *Eur J Cancer* 2018 Mar 20;94:115-125. doi: 10.1016/j.ejca.2018.02.012.
170. Mangat P, **Halabi S**, Bruinooge S, Garret-Mayer E, Aleva A, Janeway K, Stella P, Voest E, Yost K, Perlmutter J, Pinto N, Kim EW, Schilsky RL (2018). Rationale and design of the targeted agent and profiling utilization registry (TAPUR) Study. *Journal of Clinical Oncology Precision Oncology* 2:1-14, 2018.
171. Li M, Mulkey F, Jiang C, O'Neil BH, Schneider BP, Shen F, Friedman PN, Momozawa Y, Kubo M, Niedzwiecki D, Hochster HS, Lenz HJ, Atkins J, Rugo HS, **Halabi S**, Kelly WK, McLeod HL, Innocenti F, Ratain MJ, Venook AP, Owzar K, Kroetz DL (2018). Identification of a genomic region between *SLC29A1* and *HSP90AB1* associated with risk of bevacizumab-induced hypertension: CALGB 80405 (Alliance). *Cancer Clinical Research* 24(19):4734-4744. doi: 10.1158/1078-0432.
172. Pi L, **Halabi S** (2018). Combined Performance of Screening and Variable Selection Methods in Ultra-High Dimensional Data in Predicting Time-To-Event Outcomes. *Diagnostic and Prognostic Research*. doi: 10.1186/s41512-018-0043-4.

173. Mohler JL, **Halabi S**, Ryan ST, Al-Daghmin A, Sokoloff MH, Steinberg GD, Sanford BL, Eastham JA, Walther PJ, Morris MJ, Small EJ (2018). Management of recurrent prostate cancer after radiotherapy: long-term results from CALGB 9687 (alliance), a prospective multi-institutional salvage prostatectomy series. *Prostate Cancer and Prostatic Diseases* doi: 10.1038/s41391-0180106-1.
174. **Halabi S**, Dutta S, Tangen CM, Rosenthal M, Petrylak DP, Thompson IM Jr, Chi KN, Araujo JC, Logothetis C, Quinn DI, Fizazi K, Morris MJ, Eisenberger MA, George DJ, De Bono JS, Higano CS, Tannock IF, Small EJ, Kelly WK (2018). Overall survival of black and white men with metastatic castration-resistant prostate cancer treated with docetaxel. *Journal of Clinical Oncology* doi: 10.1200/JCO.18.01279.
175. Xie W, **Halabi S**, Tierney JF, Sydes MR, Collette L, Dignam JJ, Buyse M, Sweeney CJ, Regan MM. A systematic review and recommendation for reporting of surrogate endpoint evaluation using meta-analyses (ReSEEM). *In press* (Journal of the National Cancer Institute Cancer Spectrum)
176. Tierney J, Vale CL, Parelukar W, Rydzewska LH, **Halabi S**. Evidence synthesis to accelerate and improve the evaluation of therapies for metastatic hormone-sensitive prostate cancer. *In press* (European Urology Focus).
177. Ma H, **Halabi S**, Liu A (2019). On the use of min-max combination of biomarkers to maximize the partial area under the ROC curve. *J Probab Stat.* 2019;2019. doi: 10.1155/2019/8953530.
178. Armstrong AJ, **Halabi S**, Luo J, Nanus DM, Giannakakou P, Szmulewitz RZ, Danila DC, Healy P, Anand M, Rothwell CJ, Rasmussen J, Thornburg B, William R. Berry MD (1), Wilder RS, Lu C, Chen Y, Silberstein JL, Kemeny G, Galletti G, Somarelli JA, Gupta S, Gregory SG, Scher HI, Dittamore R, Tagawa ST, Antonarakis ES, George DJ. Prospective multicenter validation of AR-V7 and hormone therapy resistance in high risk castration resistant prostate cancer: the PROPHECY study. *In press* (Journal of Clinical Oncology).
179. Ryan CJ, Dutta S, Kelly WK, Russell C, Small EJ, Morris MJ, Taplin ME, **Halabi S**. Androgen decline and survival during docetaxel therapy in metastatic castration resistant prostate cancer (mCRPC). *In press* (*Prostate Cancer and Prostatic Diseases*)
180. Sugimoto T, Hamasaki T, Evans SR, **Halabi S**. Group-sequential logrank methods for trial designs using bivariate non-competing event-time outcomes. *In press* (Lifetime Data Analysis).
181. Dess RT, Hartman HE, Mahal BA, Soni PD, Jackson WC, Cooperberg MR, Amling CL, Aronson WJ, Kane CJ, Terris MK, Zumsteg ZS, Butler S, Osborne JR, Morgan TM, Mehra R, Salami SS, Kishan AU, Wang C, Schaeffer EM, Roach M 3rd, Pisansky TM, Shipley WU, Freedland SJ, Sandler HM, **Halabi S**, Feng FY, Dignam JJ, Nguyen PL, Schipper MJ, Spratt DE Association of Black Race With Prostate Cancer-Specific and Other-Cause Mortality. *JAMA Oncol.* 2019 May 23; doi: 10.1001/jamaoncol.2019.0826.

Editorials

Armstrong AJ, **Halabi S** (2015). Making progress on progression in metastatic prostate cancer. *Journal of Clinical Oncology*. Epub ahead of time 10.1200/JCO.2014.59.4283

Invited Non-peered Reviewed Articles

- 1) Small EJ, **Halabi S**, Kantoff P, D'Amico A, Stadler W, Kelly WK, Mohler J, Bajorin D, Vogelzang NJ (2006). Activities and accomplishments of the Cancer and Leukemia Group B Genitourinary Committee. *Clinical Cancer Research* 12:3596s-600s.
- 2) Fitzpatrick JM, Sternberg CN, Saad F, Extermann M, Caffo O, **Halabi S**, Kramer G, Oudard S, de Wit R (2009). Treatment decisions for advanced genitourinary cancers: From symptoms to risk assessment. *European Urology Supplements* 8: 738-746.

Chapters in Books:

- 1) Wodnicki P, Lockett S, Pillai R, **Halabi S**, McKalip A, Herman B (1996). Automated image microscopy in Fluorescence Imaging Spectroscopy and Microscopy, editors Herman B and Wang XF. John Wiley & Sons, Inc., New York.
- 2) **Halabi S**. Design considerations of randomized phase III trials in oncology in Encyclopedia of Medical Decision Making, editor Michael Kattan. Sage Publications, Inc., Thousand Oaks, CA 2009.
- 3) **Halabi S**, Kelly WK. Introduction to a clinical trial. *Oncology Clinical Trials: Successful Design, Conduct and Analysis*, editors Kevin Kelly, Susan Halabi. Demos Medical Publishing, New York, NY, 2010.
- 4) **Halabi S**. Statistical considerations for assessing prognostic factors in cancer. *Oncology Clinical Trials: Successful Design, Conduct and Analysis*, editors Kevin Kelly, Susan Halabi. Demos Medical Publishing, New York, NY, 2010.
- 5) **Halabi S**. Multiple arm trials. *Oncology Clinical Trials: Successful Design, Conduct and Analysis*, editors Kevin Kelly, Susan Halabi. Demos Medical Publishing, New York, NY, 2010.
- 6) **Halabi S**, Pi, L. Statistical considerations for developing and validating prognostic models of Clinical Outcomes. *Oncology Clinical Trials: Successful Design, Conduct and Analysis*, editors Kevin Kelly, Susan Halabi. Demos Medical Publishing, 2nd Edition, New York, NY, 2018.

Edited Books

Kelly WK, **Halabi S**. *Oncology Clinical Trials: Successful Design, Conduct and Analysis*. Demos Medical Publishing, New York, NY, 2010.

Kelly WK, **Halabi S**. *Oncology Clinical Trials: Successful Design, Conduct and Analysis*. Demos Medical Publishing, 2nd Edition, New York, NY, 2018.

Halabi S, Michiels S. *Textbook of Clinical Trials in Oncology*. Chapman & Hall/CRC Press, London: UK, 2019.

Others

A. Letters to the Editor:

1. Schildkraut JM, Bastos E, **Halabi S**, Berchuck A (1997). Relationship between lifetime ovulatory cycles and overexpression of mutant p53 in epithelial ovarian cancer. *Journal of the National Cancer Institute*, 89:1726-1727.
2. Demark-Wahnefried W, **Halabi S**, Paulson DF (1998). Serum androgens: associations with prostate cancer risk and hair patterning. *Journal of Andrology*, 19:631.
3. **Halabi S**, Small EJ, Vogelzang NJ (2005). An elevated body mass index predicts for longer overall survival duration in men with metastatic hormone refractory prostate cancer (HRPC). *Journal of Clinical Oncology* 23:2434-2435.
4. Scher HI, **Halabi S**, Tannock I, Morris M, Sternberg CN, Carducci MA, Eisenberger MA, Higano C, Bubley GJ, Driecer R, Petrylak D, Kantoff P, Basch E, Kelly WK, Figg WD, Small EJ, Beer TM, Wilding G, Martin A, Hussain M (2008). Reply to trial design for metastatic castration-resistant prostate cancer *Journal of Clinical Oncology* 26:3648-9.
5. **Halabi S**, Vogelzang NJ, Kornblith AB, Ou SS, Kantoff PW, Dawson NA, Small EJ (2008). Reply to "Pain interference items predication of cancer patients' survival is not the same as an evidence for that pain intensity is a survival predictor. *Journal of Clinical Oncology* 26: 4216-7.
6. Stadler WM, Phillips G, George DJ, **Halabi S**, Small E (2010). Bevacizumab and Everolimus in Renal Cancer: A rational way forward. *Journal of Clinical Oncology* 28:E692-3.
7. Armstrong AJ, George DJ, **Halabi S** (2013). Reply to Prognostic and predictive markers in metastatic renal cell carcinoma. *Journal of Clinical Oncology* 31(7):972-3.
8. Smith MR, **Halabi S**, Small EJ (2014). Reply to F. Valcamonico et al. *Journal of Clinical Oncology* 201 [Epub ahead of print]
9. **Halabi S**, Rini R, Escudier B, Stadler WM, Small EJ (2015). Reply to Progression-free survival: Does a correlation with survival justify its role as a surrogate clinical endpoint? *Cancer* 121(11):1906.
10. Choueiri TK, **Halabi S**, Morris MJ, George D. Reply to B. Rini et al and S. Buti et al. *J Clin Oncol*. 2017 Jun 1;35(16):1859-1860. doi: 10.1200/JCO.2017.72.2629.

Selected Invited and Contributed Talks

Halabi S. Validation of the Mitch Gail breast cancer risk model [(Invited) Presented at Boston University, February 1994].

Halabi S. Validation of the Gail breast cancer risk model [(Invited) Presented at Department of Biostatistics and Epidemiology, Memorial Sloan Kettering Cancer Center, NY, March 1994].

Halabi S. A Computer Program for Generating the Survival Distribution of a Cox Regression Model with a Time-Dependent Covariate [Presented at the International Biometric Society Eastern North American Region Annual Meeting, Richmond, VA, March 1995].

Halabi S. Validation of the Gail breast cancer risk model [(Invited) Presented at Community and Family Medicine, Duke University, Durham, NC, June 1996].

Halabi S. Analysis of Survival Data with Missing Measurements of a Binary Time-Dependent Covariate [Presented at the Presented at the International Biometric Society Eastern North American Region Annual Meeting, Chicago, IL, March 2000].

Halabi S. Results of CALGB 9480 (SWOG 9452, ECOG C9480, Intergroup 0159): A Phase III Trial of Three Different Doses of Suramin for the Treatment of Hormone Refractory Prostate Cancer (HRPC) [Presented at the American Society of Clinical Oncology Annual Meeting, New Orleans, LA, June 2000].

Halabi S. Innovative Designs in Phase II Oncology Clinical Trials. [(Invited) Presented at the Henry Ford System, Detroit, MI, October 2002].

Halabi S. Sample Size Determination for Comparing Several Survival Curves With Unequal Allocations [(Invited) Presented at the International Biometric Society Eastern North American Region Annual Meeting, Tampa, FL, March 2003].

Halabi S. The Impact of Age on Clinical Outcomes in Men with Hormone Refractory Prostate Cancer (HRPC) [(Invited) Presented at the Prostate Cancer Foundation Scientific Retreat, Lake Tahoe, NV, October 2004].

Halabi S. Sample Size Calculation for Longitudinal Data under Missing at Random (MAR). [Presented at the International Biometric Society Eastern North American Region Annual Meeting, Austin, TX, March 2005].

Halabi S. Implications in the Choice of Primary Endpoint and Alpha Allocation: A Statistician's Perspective. [(Invited) Presented at the Prostate Cancer Foundation Scientific Retreat, Lake Tahoe, NV, October 2005].

Halabi S. Sample Size Determination for Comparing Several Survival Curves with unequal allocations. [(Invited) Presented at the Cleveland Clinic Foundation, Cleveland, OH, December 2005].

Halabi S. On Sample Size Selection in Clinical trials With Both Accrual and Follow-up Periods for Comparing Several treatment Groups [(Invited) Presented at the Moffitt Cancer Center, Tampa, FL, March 2006].

Halabi S. Some Thoughts on Progression-Free Survival. [(Invited) Presented at the Prostate Cancer Foundation Scientific Retreat, Lake Tahoe, NV October 2006].

Halabi S. Adjustment on the Type I Error Rate for a Clinical Trial that Monitors for both an Intermediate and Primary Endpoints. [Presented at the Society of Clinical Trials Annual Meeting, Montreal, Canada, May 2007].

Halabi S. A Novel Intermediate Endpoint for Predicting Overall Survival in Men with Metastatic Castration-Recurrent Prostate Cancer (CRPC): An Analysis of nine CALGB Studies [Presented at the DOD Prostate Impact Meeting, Atlanta, GA, September 2007].

Halabi S. Challenges and Opportunities: Progression-Free Survival as an Endpoint in Phase III Clinical Trials. [(Invited) Presented at the Prostate Cancer Foundation Scientific Retreat, Lake Tahoe, NV, October 2007].

Halabi S. Predicting Overall Survival in Men with Castration-Resistant Prostate Cancer (CRPC). [(Invited) Plenary Presentation at the 1th Interactive Genitourinary Cancer Conference (IGUCC), Advances in Prostate Cancer: Lisbon, March 2009].

Halabi S. Two New Residuals In Survival Analysis With Full Likelihood Approach Using Proportional Hazards Model [Presented at the International Society of Clinical Biostatistics, Prague, August 2009].

Moser B, Halabi S. Estimation and testing of the relative risk of disease in retrospective case-control studies with a set of k matched controls per case. [Presented at the International Biometric Society Eastern North American Region Annual Meeting, New Orleans, LA, March 2010].

Halabi S. Prostate Cancer Clinical Trials: The Statistician's Perspective [(Invited) Presented at Thomas Jefferson University, Philadelphia, PA, March 2011].

Halabi S. Estimation and testing of the relative risk of disease in retrospective case-control studies with a set of k matched controls per case. [(Invited) Presented at Thomas Jefferson University, Philadelphia, PA, March 2011].

Halabi S. Enrichment Trials: Fact or Fiction? [(Invited) Presented at the Society of Clinical Trials Annual Meeting, Vancouver, Canada, May 2011].

Halabi S. Opportunities and Challenges in the Design and Implementation of Enrichment Trials. [(Invited) Presented at the Statistical Symposium Alliance Spring Meeting, Boston, MA, June 2011].

Halabi S. Debate on Prognostic models are a valuable tool for guiding treatment decisions in prostate cancer. [(Invited) Presented at the 4th Interactive Genitourinary Cancer Conference (IGUCC), Advances in Prostate Cancer: Integrating New Strategies in Clinical Practice, Prague, March 2012].
Halabi S. Successful Design, Conduct and Analysis of Clinical Trials in Oncology [(Invited) Plenary Presentation the 4th Interactive Genitourinary Cancer Conference, Advances in Prostate Cancer: Integrating New Strategies in Clinical Practice, Prague, March 2012].

Halabi S. Prostate-Specific Antigen Decline as a Surrogate for Overall Survival in Patients with Metastatic Castrate-Resistant Prostate Cancer Who Failed First-Line Chemotherapy. [Presented at the American Society of Clinical Oncology Annual Meeting, Chicago, IL, June 2012].

Halabi S. Results of COU-302: Paradigm Shift? [(Invited Discussant) Presented at the American Society of Clinical Oncology Annual Meeting, Chicago, June 2012].

Halabi S. Current Issues and Trends in Prognostic Models of Overall Survival in Men with Metastatic Castration Resistant Prostate Cancer. [(Invited) Presented at GU, Dana-Farber Cancer Institute, Boston, MA, November 2012].

Halabi S. Adjusting for Misclassification in Stratified Biomarker Trials [(Invited) Presented at the Johns Hopkins University, Baltimore, MD, February 2013].

Halabi S. A validated prognostic model for predicting overall survival in patients with metastatic chemotherapy naïve castrate-resistant prostate cancer [Presented at the European Society of Medical Oncology Annual Meeting, Amsterdam, September 2013].

Halabi S. Poster discussion for Abstracts 2863 (Ryan), 2864 (Scher), 2865 (Templeton). [(Invited Discussant) Presented at the European Society of Medical Oncology Annual Meeting, Amsterdam, September 2013].

Halabi S. Enrichment Trials: Worth their Weight? [(Invited) Presented at the Statistical Symposium Alliance Spring Meeting, Chicago, IL, November 2013].

Halabi S. Stratified Biomarker Design in the Presence of Classification Errors. [(Invited) Presented at the Society of Clinical Trials Annual Meeting, Philadelphia, PA, May 2014].

Halabi S. The Use of Penalized Regression Methods to Identify Subgroups [(Invited) Presented at the Society of Clinical Trials Annual Meeting, Philadelphia, PA, May 2014].

Halabi S. The Site of Visceral Metastases Predicts Overall Survival in Castration-Resistant Prostate Cancer Patients: A Meta-Analysis of 5 Phase III trials [Presented at the American Society of Clinical Oncology Annual Meeting, Chicago, IL, June 2014].

Halabi S. Adjusting for Misclassification in the Design and Analysis of Stratified Biomarker Clinical Trials. [Presented at the Joint Statistical Meetings, Boston, MA, August 2014].

Halabi S. Interpreting Clinical Trials: New concepts, old pitfalls [(Invited) Presented at the St Gallen Advanced Prostate Cancer Consensus Conference (APCCC) St. Gallen, Switzerland, March 2015].

Halabi S. Smarter Trials: Revolution or Evolution? [(Invited Discussant) Presented at the 36th Annual Meeting for the Society of Clinical Trials, Arlington, VA, May 2015].

Halabi S. Data Monitoring Committees: Reflections and Controversies [(Invited) Presented at the AACR Workshop Methods in Cancer Biostatistics: Clinical Trial Designs for Targeted Agent, Lake Tahoe, CA, June 2015]

Halabi S. A Novel Test to Compare Two Treatments Based on Endpoints Involving Both Nonfatal and Fatal Events. [Presented at the ISBS/IDA Joint Symposium on Biopharmaceutical Statistics, Beijing, China, June 2015]

Halabi S. Data Monitoring Committees: Uses and Abuses [(Invited) Presented at the Duke Industry Statistics Symposium, Durham, NC, October 2015]

Halabi S. On the Design of a Stratified Biomarker Trial in the Presence of Measurement Error. Department of Biostatistics [(Invited) University of Pennsylvania, Philadelphia, PA, April 2016].

Halabi S. Challenges in the Design and Implementation of Oncology Trials with Immunotherapy [(invited) Presented at the Duke Industry Statistics Symposium, Durham, NC, September 2016].

Halabi S. Lumpers or Slicers [(Invited) Presented at the second St Gallen Advanced Prostate Cancer Consensus Conference (APCCC) St. Gallen, Switzerland, March 2017].

Halabi S. Score Residuals In Survival Analysis With Full Likelihood Approach Using Proportional Hazards Model. [Presented at the ENAR Meeting in Washington DC, March 2017].

Halabi S. Innovative Designs for Early-Phase Clinical Trials [(Invited) Presented at the Centre for Quantitative Medicine, Duke-NUS Medical School, Singapore, March 2017].

Halabi S. On the Design of a Stratified Biomarker Trial in the Presence of Measurement Error [(Invited) Presented at the Quantitative Medicine Forum, Duke-NUS Medical School, Singapore, March 2017].

Halabi S. ASCO discussant for abstracts 5006-5008 [(Invited) the American Society of Clinical Oncology Annual Meeting, Chicago, IL, June 2017].

Halabi S. Real World Experiences in Futility Analysis. [(Invited) Cens-ISBS, Vienna, Austria, August 2017].

Halabi, S. SWOG-Latin America Clinical Trials Course, Mexico City, Mexico, November 2017.

Halabi, S. Challenges in the Analysis of Immunotherapy Trials with Non-Proportional Hazards Duke-FDA Workshop: Duke Margolis Institute of Public Policy, Washington, D.C, March 2018.

Halabi S. Estimating and Interpreting Treatment Effect in Oncology Trials with Immune Therapies [(Invited). IISA, Gainesville, FL May 2018].

Halabi, S. Monitoring Complicated Trials in Oncology. Annual Meeting Society of Clinical Trials, Portland, OR May 2018.

Halabi S. Overall Survival Between African-American and Caucasian Men with Metastatic Castration-Resistant Prostate Cancer [Presented at the American Society of Clinical Oncology Annual Meeting, Chicago, IL, June 2018].

Halabi S. Navigating Complicating Trials During Interim Analysis [(Invited) Presented at the Joint Statistical Meetings, Vancouver, British Columbia, Canada, August 2018].

Halabi S. Adjusting for misclassification in Stratified Biomarker Trials. [(Invited) Presented at the Department of Biostatistics, University of Michigan, October 2018].

Halabi S. The Promise and Power of Integrating Biomarkers into Clinical Trials [(Invited) Presented at the Department of Radiation Oncology, University of Michigan, October 2018].

Halabi S. Clinical Trials at NCI NCTN and beyond [(Invited) Presented at the AACR Cancer Health Disparities Think Tank, Washington, DC, October 2018].

Halabi S. Clinical Outcomes Between African-American and Caucasian Men with Metastatic Castration-Resistant Prostate Cancer (mCRPC) [(Invited) Presented at the Prostate Cancer Foundation Scientific Retreat, Carlsbad, CA, October 2018].

Halabi S. Design of stratified biomarker trials with measurement error [(Invited) Presented at the Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute, November 2018].

Consultant Appointments:

1995 Scientific Reviewer, United States Medical Research and Material
 Command, Scientific Peer Review for the Intramural Defense Women's
Health Research Program

1996 Scientific Reviewer, United States Medical Research and Material
 Command, Scientific Peer Review for the Extramural Defense Women's
Health Research Program

1996 Scientific Reviewer, United States Medical Research and Material
 Command, Scientific Peer Review for the Osteoporosis Research
Program

1998 Scientific Reviewer, Epidemiology and Disease Control-2 Study Section
National Institutes of Health

1998 Scientific Reviewer, Research Centers in Minority Institutions, Review
Committee, National Institutes of Health

1998 Scientific Reviewer, Epidemiology and Disease Control-2 Study Section National
Institutes of Health

1999 Statistical Consultant, Parke-Davis

1999 Participant in the NCI PSA consensus group

2000 Chair, Common Data Elements Committee for Bladder Cancer, National Cancer
Institute

2001-2002 Member, Clinical Trial Design in the State of Rising PSA Workshop

2001 Scientific Reviewer, Epidemiology and Disease Control-2 Study Section National
Institutes of Health

2001 Scientific Reviewer, Research Centers in Minority Institutions, Review
Committee, National Institutes of Health

2002 Scientific Reviewer of SPORE applications in Prostate Cancer, National
Institutes of Health

2003 Scientific Reviewer, National Institute of Arthritis and Musculoskeletal and Skin
Diseases, National Institutes of Health

2003-2006 Member of Compare Registry Steering Committee, Sanofi-Aventis

2003-2007 Member, Central Institutional Review Board, National Cancer Institute

2003-2007 Member, Cancer Biomarker Study Section, National Cancer Institute, National
Institutes of Health

2005 Participant, Clinical Trials Endpoints for Castration-Resistant/Hormone Refractory
Prostate Cancer II

2005-2007 Member, ASCO Multiple Myeloma Special Panel

2005-2007 Statistical Consultant, GPC-Biotech

2005 Member, Prostate Program for the Assessment of Clinical Cancer Tests Working

Group, NCI

- 2005-present Member, DOD Prostate Cancer Consortium External Advisory Board, Memorial Sloan Kettering Cancer Center
- 2006-2009 Member, Data Monitoring Committee, OncoGenex Technologies
- 2006-2009 Member, Data Monitoring Committee, Texas Heart Institute
- 2007-present Member, External Advisory Committee, Research Center for Minority Institutions, Meharry College of Medicine, Nashville, TN
- 2007-2009 Member, Data Monitoring Committee (TROPIC Trial), Sanofi
- 2007-2009 Member, Cougar Biotech Scientific Advisory Committee
- 2007-2015 Special Government Employee, General and Plastic Surgery Devices Panel, Food and Drug Administration
- 2007-2011 *Ad-hoc* reviewer, Subcommittee H, NCI
- 2008-present Genitourinary (GU) Steering Committee, NCI
- 2009-2013 American Joint Committee on Cancer Modeler Working Group
- 2009-present Reviewer, Standing Peer Review Panel, Prostate Cancer Foundation
- 2010- Member, Data Monitoring Committee, PROSTVAC, BNIT
- 2010- Member, Data Monitoring Committee, Affinity Trial, Oncogenex
- 2010-2014 Member, Data Monitoring Committee, SYNERGY Trial, Oncogenex
- 2011- Chair, Data Monitoring Committee, FirstAna Trial, Sanofi
- 2011- Chair, Data Monitoring Committee, Proselica Trial, Sanofi
- 2013 *Ad-hoc* reviewer, Epidemiology of Cancer (EPIC) Study Section, NIH
- 2013-present Independent Statistician, Intermediate Clinical Endpoints in Cancer of the Prostate (ICECaP) Working Group
- 2013-2014 Reviewer, Special Emphasis Panel (SEP), NCI
- 2014 Scientific Reviewer, Prostate Cancer Review Panel, Population Science Impact Award, Department of Defense

- 2014-present American Joint Committee on Cancer, Precision Medicine Core Committee
- 2014-2015 Member of the Scientific Committee: Advanced Prostate Cancer Consensus Conference (APCCC 2015) St. Gallen, Switzerland
- 2015-2016 Member, Data Monitoring Committee, ARMOR3-SV PRONOUNCE Trial, Tokai
- 2015-present Member, Data Monitoring Committee, PRONOUNCE Trial, Ferring
- 2015-present *Ad-hoc* reviewer, Cancer Center Support Grants, NCI
- 2015-present Statistician, TAPUR Registry, American Society of Clinical Oncology
- 2016- *Ad-hoc* reviewer, Clinical Oncology Panel (ONCA), VA
- 2016-2017 Member of the Scientific Committee: Advanced Prostate Cancer Consensus Conference (APCCC 2017) St. Gallen, Switzerland
- 2016-2017 Reviewer, General and Plastic Surgery Devices Panel, Food and Drug Administration
- 2016-present Member, Data Monitoring Committee, E7080-307 Trial, Eisai
- 2017-present Member, Oncology Drugs Advisory Committee (ODAC), Food and Drug Administration

Organizations and Participation:

- 1996-2000 ENAR Correspondent, Biometric Bulletin, International Biometric Society
- 2002-2004 Member of the Regional Advisory Board, ENAR, International Biometric Society
- 2003-2005 Representative, Council of Section, Biometrics Section, American Statistical Association
- 2004 Member, ENAR Spring Meeting Program Committee
- 2004-2005 Member and Chair (2004) of Biostatistics Track Committee, Scientific Program Committee, American Society of Clinical Oncology
- 2005 Students Awards Committee, ENAR Spring Meeting Program
- 2006-2008 Member, Committee on Career Development, American Statistical Association
- 2007-2011 Program Committee, Society of Clinical Trials

- 2007-2011 Education Committee, Society of Clinical Trials
- 2008-2011 Member, Grant Selection Committee, American Society of Clinical Oncology
- 2009-2011 Membership Committee, Society of Clinical Trials
- 2012-2014 Member, Board of Directors, Society of Clinical Trials
- 2012-2014 Member (2012) and Chair of Biostatistics Track (2013), Scientific Program Committee, American Society of Clinical Oncology
- 2015-2017 Member of the Regional Advisory Board, ENAR, International Biometric Society
- 2015-2016 Nomination Committee, Society of Clinical Trials
- 2016-present Member, TAPUR Steering Committee, American Society of Clinical Oncology
- 2016-present Fellows Committee, Chair, Society of Clinical Trials
- 2016-2019 Member of Biostatistics Track Committee, Scientific Program Committee, American Society of Clinical Oncology
- 2018- Member, Southwest Oncology Group (SWOG) NCORP External Advisory Committee
- 2018- Member, Updating Labels for Generic Oncology Drug, National Academies of Sciences, Engineering, and Medicine
- Participation in academic and administrative activities of the University and Medical Center:**
[at Duke only]
- 1996-2001 Biostatistics Core Director, Improving Cancer Risk Communication
- 2000 Cancer Protocol Committee, Duke University Comprehensive Cancer Center
- 2000-2001 Member, Search Committee, Cancer Center Biostatistics
- 2003-2004 Member, Scientific Committee, Critical Assessment of Microarray Data Analysis Conference, Duke University Medical Center
- 2005-2006 Member, Education and Training Committee, Department of Biostatistics and Bioinformatics
- 2005-2006 Member, Curriculum Subcommittee, Education and Training Committee, Department of Biostatistics and Bioinformatics

- 2005-2006 Chair, Mission Subcommittee, Education and Training Committee, Department of Biostatistics and Bioinformatics
- 2005- Member, Cancer Prevention and Control, Duke University Comprehensive Cancer Center
- 2005- Member, Appointments, Promotion and Tenure Committee, Department of Biostatistics and Bioinformatics
- 2006-present Biostatistics Core, DOD Prostate Cancer Clinical Trials Consortium
- 2006-2008 Member, Clinical Sciences Faculty Council on Academic Affairs, Duke University Medical Center
- 2006-2008 Member, Basic Science Faculty Steering Committee, Duke University Medical Center
- 2008-2011 Member, Search Committee, Department of Biostatistics and Bioinformatics, Duke University Medical Center
- 2010-2011 Member, Search Committee, Cancer Control, Duke University Medical Center
- 2012- Member, Professional Advisory Council, Department of Biostatistics and Bioinformatics, Duke University Medical Center
- 2018- Member, Doctoral Students Qualifying Exams, Department of Biostatistics and Bioinformatics, Duke University Medical Center
- 2018- Member, Doctoral Students Admissions Committee, Department of Biostatistics and Bioinformatics, Duke University Medical Center

Teaching responsibilities, including continuing education:

- 1994-1996 Introduction to Biostatistics, Categorical Data Analysis, Introduction to Medical Statistics, Tulane University School of Public Health and Tropical Medicine, and School of Medicine, New Orleans, LA
- 1999 Intuitive Biostatistics, Duke University Medical School, Duke University, Durham, NC
- 2002 Statistical Considerations in Clinical Trials in Oncology, The Henry Ford Systems, Detroit, MI
- 2003 Group Sequential Monitoring in Clinical Trials. Graduate course offered at Tulane

University School of Public Health, New Orleans, LA

- 2005-06 Duke University/FDA Workshop “Accelerating Anticancer Agent Development and Validation.” Bethesda, MD
- 2005-12 Course Co-Director (CRP248), Clinical Trials, Clinical Research Training Program, Duke University School of Medicine
- May 2011 Workshop co-Director: Essentials of Randomized Clinical Trials, 32 Annual Meeting, Society of Clinical Trials Vancouver, British Columbia, Canada
- May 2012 Workshop co-Director, Essentials of Randomized Clinical Trials, 33 Annual Meeting, Society of Clinical Trials, Miami, FL.
- May 2012 Course Director, Designs for Contemporary Early-Phase Clinical Trials, American Society of Clinical Oncology
- June 2012
- Fall 2013- Course Director, Clinical Trials, Clinical Research Training Program, Duke Present University School of Medicine
- June 2015 Faculty Member, American Association for Clinical Research Workshop Methods in Cancer Biostatistics: Clinical Trial Designs for Targeted Agent, Lake Tahoe, CA
- 11/ 2015 Faculty, Statistical Course, Latin America Cooperative Oncology Group, Mexico City, Mexico.
- 3/2016 Faculty Statistician, SWOG-Latin America Clinical Trials Course, Mexico City, Mexico.
- 11/2016 Faculty Statistician, SWOG-Latin America Clinical Trials Course, Bogota, Colombia
- 11/2017 Faculty Statistician, SWOG-Latin America Clinical Trials Course, Mexico City, Mexico
- 11/2018 Faculty Statistician, SWOG-Latin America Clinical Trials Course, Bogota, Colombia
- 2019- Course Co-Director, Statistical Analysis (CRP245), Clinical Research Training Program, Duke University School of Medicine

Editorial Activities

- 1/08-12/14 *Journal of Clinical Oncology* Editorial Board
- 11/11-present Associate Editor, *Clinical Trials*
- 1/14-present Statistical Advisor Consulting, *Nature Publishing Group*
- 1/15-present *Annals of Oncology* Editorial Board

2016-present Associate Editor, *Diagnostic and Prognostic Research* 2017-present
Associate Editor, *Statistics in Medicine*

Journal Peer Reviewer Activities

Statistics in Medicine, Biometrics, Biometrika, Biometrical Journal, Communication in Statistics, Clinical Trials, Biostatistics, Statistical Methods in Medical Research, Nature, Journal of the National Cancer Institute, Lancet Oncology, Journal of Clinical Oncology, Cancer Research, Clinical Cancer Research, Cancer, Annals of Oncology, Urology, Journal of Urology, British Journal of Urology, European Journal of Urology.

Students Advised

Amparo Gordillo -MPH in Epidemiology, School of Public Health, Tulane University, 1995-1996.
Lisa Cunningham- MS in Biostatistics, School of Public Health, Tulane University, 1995-1996.

Served on Thesis Committee

Nicole McCarthy, M.D., CRTP, Duke University Medical Center, 2002
Vidya Sankar, M.D., CRTP, Duke University Medical Center, 2003
Joseph Kay, CRTP, M.D., Duke University Medical Center, 2004
Ed Cowen, CRTP, M.D., Duke University Medical Center, 2006
Habib Ramadhani, M.D., CRTP, Duke University Medical Center, 2008
Mark W. Onaitis, M.D., CRTP, Duke University Medical Center, 2009
Anna Teeter, M.D., CRTP, Duke University Medical Center, 2010- Mazen
Noureddin, M.D., CRTP, NIH, 2011-2017
Laleh Amiri-Kordestani, M.D., CRTP, NIH 2012- Nan
Soon Wang, M.D., CRTP, CRTP, 2012-2015
Nicole Solomon (Chair), MS in Biostatistics, Duke University, 2012-2013
Rui Zou, MS in Biostatistics, Duke University, 2012-2013
Siyun Yang (Chair) , MS in Biostatistics, Duke University, 2014-2015
Stephanie (Xizi) Sun, MS in Biostatistics, Duke University, 2015-2016
Yao Song, MS in Biostatistics, Duke University, 2016-2017
Lina Yang, MS in Biostatistics, Duke University, 2016-2017 Paul
L. Feingold, M.D. CRTP, NIH, 2016-2018
Mengdi Xuan (Chair), MS in Biostatistics, Duke University, 2018-2019 Bohui
Zhang (Chair), MS in Biostatistics, Duke University, 2018-2019

Doctoral Dissertation Committee

Sangmi Kim, Department of Epidemiology, University of North Carolina, Chapel Hill, NC, 2006-07.
Tongrong Wang, Ph.D. in Biostatistics, Duke University, 2018-

Post-doctoral Fellows

Tong Shen, Ph.D., 2011-2012
Chen-Yen Lin, Ph.D., 2012-2013

Ivo Shterev, Ph.D., 2012-2013
Haojin Zhou, Ph.D., 2013-2014
Greg-Mayhew, Ph.D., 2013-2014
Zhenyu Wang, Ph.D., 2014-2015
Hua Ma, Ph.D., 2014-2016
Anna-Maria Masci, Ph.D., 2015-present
Lira Pi, Ph.D., 2015-2018
Sangjin Kim, Ph.D., 2015-2017
Sandipan Dutta, Ph.D., 2016-2019
Duy Thai, Ph.D., 2018

Areas of Research Interest

Data Science
Prognostic and Predictive Models
Personalized Medicine
Clinical Trial Methodology
Surrogate Endpoints
High dimensional data
Health disparity