

National Surgical Adjuvant Breast and Bowel Project (NSABP) Foundation

Research Development Report

Reporting Period:

July 1, 2010 - June 30, 2011

Commercial Development of Research

Efforts towards the commercialization of discoveries resulting from Health Research Formula funding have resulted in the submission of two (2) non-provisional and international patent applications related to the identification and use of prognostic and predictive markers for improving cancer patient care.

Under confidential agreements, the NSABP conducts an ongoing exchange of ideas with current and potential commercial partners. Intellectual property (IP) policies provide for NSABP ownership and the sharing of IP revenues with employee inventors and member institutions of the Foundation. The use of biospecimens, which are collected during clinical trials conducted under NCI oversight, is governed by federal requirements and the policies of the Foundation. Discussions with, and final review by, scientific legal counsel specializing in intellectual property at a national law firm have resulted in contractual arrangements with commercial corporations.

The NSABP also continues to develop business relationships and opportunities in a variety of ways, including networking at scientific meetings with companies and individuals who have novel scientific ideas and interests common to NSABP; publication of results from projects supported by Health Research Formula funding; and through NSABP participation in business and scientific organizations, such as the Association of University Technology Managers (AUTM), Licensing Executives Society (LES), Society of Research Administrators (SRA), Oncology Nursing Society, National Histological Society, Council of Science Editors, and the American Association for Cancer Research.

The NSABP Foundation continues to meet with the major multi-national pharmaceutical and biotechnology companies offering oncology products and serving as potential sources for commercialization. We have established contractual relationships with many of these companies to perform Phase II and Phase III clinical trials and have executed agreements providing opportunities for licensing partnerships.

Research Licensing Agreements

The NSABP Foundation's license agreement template, which has been previously provided, is used as the basis of our negotiations with potential partners. The template undergoes periodic review by legal counsel to ensure continued compliance with all applicable laws and regulations.

Training Students and Health Professionals

The Foundation recruits visiting, post-doctoral research fellows, each engaged in State-funded projects during their tenure of one or more years. The fellows use their expertise in Medicine and Anatomic Pathology to perform complete microscopic and molecular analyses of breast and colon tumors based on NSABP clinical trial protocols; work to develop new prognostic and predictive tests for breast and colorectal cancer; and conduct research using various techniques including immunohistochemistry, fluorescence in-situ hybridization (FISH) and gene expression profiling using microarray. We currently have one research fellow working in the pathology laboratory and employ a visiting researcher with teaching and analysis experience in biostatistics, epidemiology and statistical genetics who has assumed the newly-created position of Biostatistician/Computational Biologist/Bioinformatics Specialist. This position contributes to the support of breast and colorectal cancer research by designing and conducting statistically-justified genomic and correlative science projects while working closely with statisticians at the NSABP Biostatistical Center at the University of Pittsburgh.

The NSABP encourages our laboratory scientists to participate in external educational symposiums to allow for an ongoing exchange of scientific information with oncology colleagues.

In addition to the standard laboratory training, research fellows and laboratory staff continue to participate in on-site training in the operation of sophisticated laboratory equipment used for a variety of genetic research applications.

Commercial Research Development Training

Active participation of laboratory staff and research fellows continues to be critical to scientific and development discussions where the design and examination of scientific data is discussed and finalized with potential business partners.

Senior faculty conference with legal and scientific counsel regarding inventions, intellectual property, licensing agreements, and potential patent opportunities.

Outreach to Businesses Regarding Recent Research Developments

The NSABP continues to develop business relationships and opportunities in a variety of ways, including networking at scientific meetings with pharmaceutical and biotechnology companies who have novel scientific ideas and interests common to NSABP, publication of results from projects supported by Health Research Formula funding, and through its participation in business organizations such as LES and AUTM. NSABP scientists serve as active members along with

cooperative group, government, academic, and pharmaceutical colleagues on national and international oncology committees and scientific advisory boards.

The NSABP continues to present its research findings in peer-reviewed journals and at local, national and international meetings attended by colleagues, collaborators and business partners. The Foundation's outreach efforts are an effective means of informing both the scientific community and businesses about our research developments and are employed to communicate findings that may result from research funded by the Health Research Formula Fund.

A partial list of conferences and NSABP presentations for this reporting period include:

Allegheny General Hosp: *Breast Cancer Genetics - The Many Faces of Breast Cancer*, Pittsburgh, PA

Allegheny General Hospital Grand Rounds: *Update on Women's Health Initiative*, Pittsburgh, PA

American Society of Breast Surgeons: *Clinical Community Oncology Programs*, Washington, DC

Aultman Cancer Center: *Advances in HER2-Positive Breast Cancer Treatment*, Canton, OH

Butler Memorial Hospital Symposium: *Breast Cancer Genetics*, Butler, PA

CancerCare Telephone Workshop: *Understanding the Importance of Clinical Trials: What You Need to Know*

KDKA Radio Medical Frontiers Show: *Breast Cancer*, Pittsburgh, PA

McGill University of Montreal Visiting Professorship Program, Visiting Speakers Program in Oncology: *Lapatinib in Palliation of Metastatic HER2-Positive Breast Cancer: Do Benefits Justify Toxicity and Costs*, Montreal and Toronto, Canada

North American Menopausal Society (NAMS) Annual Meeting: *Counseling Women on Ways to Prevent Breast Cancer*, Chicago, IL

NSABP Group Meeting Treatment Orientation: *NSABP History and Contributions to the Treatment of Breast and Colorectal Cancers*, Boca Raton, FL

NSABP Group Meeting: *NSABP Trastuzumab Trials Update*, Boca Raton, FL

Pennsylvania Breast Cancer Coalition: *P-2 Update*, Harrisburg, PA

Physicians' Education Resource, Controversies in Breast Cancer: Adjuvant and Neoadjuvant Therapy: *Indolent ER-Positive Breast Cancer (Counterpoint)*, New York, NY

Physicians' Education Resource, The Future of Breast Cancer: *Clinical Debates – Is Chemotherapy Still Standard for Indolent Hormone Receptor-Positive/Node-Positive Breast Cancer?*, La Jolla, CA

Sanford-Burnam Medical Research Institute: *Overview of the NSABP Breast Cancer Prevention Trials: Results and Biorepository Materials*, La Jolla, CA

Specialized Programs of Research Excellence (SPORE) Meeting: *Review of NSABP Biospecimen Bank and Correlative Science Projects*, Pittsburgh, PA

St. Gallen Cancer Conference: *Is Gene Array Testing to be Considered Routine Now?*, St. Gallen, Switzerland

The University of Texas MD Anderson Cancer Center, The First International Conference on Cancer and the Heart: *Cardiologist's Role in Cancer Trials*, Houston, TX

Washington Hospital Cancer Institute Oncology Grand Rounds: *Update on Breast Cancer Prevention*, Washington, DC

West Virginia University Fall Cancer Conference – Translating New Ideas into Cancer Care: *Breast Cancer Update: Emerging Targeted Therapies*, Morgantown, WV

Prediction of Benefit from Systemic Therapies for Breast Cancer was also presented at the following meetings: Breast Cancer Symposium, Seoul, Korea; University of Pittsburgh Institute (UPCI) Basic and Translational Research Seminar Series, Pittsburgh, PA; Human Genome Organization (HUGO) Meeting, Singapore, Singapore; GlaxoSmithKline Lapatinib Meeting, Singapore, Singapore; University of Miami Braman Breast Lecture Series, Miami, FL; Centro Nacional de Investigaciones Oncológicas (CNIO) meeting, Madrid, Spain; Massachusetts Institute of Technology, Cambridge, MA; Northwestern University, Evanston, IL; and the Breast Cancer Steering Committee (BCSC)/Clinical Trials Process Manager, Bethesda, MD.

NSABP scientists have also presented study results from NSABP clinical trials in the form of abstracts and posters:

2010 Breast Cancer Symposium (October 1-3, 2010)

Julian TB, Costantino JP, Vicini FA, White JR, Arthur DW, Kuske RR, Parda DS, Mamounas EP, Curran WJ Jr, Wolmark N. Early toxicity results with 3D conformal external beam therapy (CEBT) from the NSABP B-39/RTOG 0413 accelerated partial-breast irradiation (APBI) trial. Abstr 92. Oral presentation.

Mamounas EP, Anderson SJ, Bear HD, Julian TB, Geyer CE, Fisher B, Wickerham DL, Wolmark N. Predictors of loco-regional failure (LRF) in patients receiving neoadjuvant chemotherapy (NC): Results from combined analysis of NSABP B-18 and NSABP B-27. Abstr 90. Oral presentation.

ESMO (European Society for Medical Oncology, October 8-12, 2010 Milan)

Kerr DJ, O'Connell MJ, Lavery IC, Gray RG, Yothers G, Quirke P, Lopatin M, Clark-Langone KM, Lee, M, Wolmark N. Considerations in the development and validation of genomic tests for cancer recurrence and treatment benefit. Presented, poster disc #83PD.

American Society for Radiation Oncology (ASTRO) (Oct 31-Nov 4, 2010)

Thomas CR Jr, Glover KZ, Costantino JP, Feingold E, Wilson JW. Comparison of African American & Caucasian patients in radiotherapy delivery in National Surgical Adjuvant Breast & Bowel Project Breast Cancer treatment trials. *I J Radiat Oncol Biol Physics (ASTRO) 2010; 78(3 Suppl 1):S10-11. Abstr 22.* Presented.

San Antonio Breast Cancer Symposium (December 8-12, 2010)

Ingle J, Liu M, Wickerham L, Schaid D, Mushiroda T, Kubo M, Costantino J, Goetz M, Ames M, Vogel V, Paik S, Batzler A, Flockhart D, Wolmark N, Nakamura Y, Weinshilboum R. Genome-wide associations of breast events and functional genomic studies in high-risk women receiving tamoxifen or raloxifene on NSABP P1 and P2 prevention trials. A Pharmacogenomics Research Network-RIKEN-NSABP collaboration. Abstr 850333. Poster discussion presentation #PD05-02.

Julian TB, Anderson SJ, Golesorkhi N, Fouchotte V, Mamounas EP, Wolmark N. Prospective outcomes for patients with micrometastases and macrometastases in sentinel nodes: NSABP B-32 sentinel node trial. Oral presentation #S5-1.

Paik S. Invited talk, Prediction of benefit from systemic adjuvant therapies for breast cancer. Susan G Komen for the Cure Brinker Awards for Scientific Distinction lecture.

Tang G, Costantino JP, Crager M, Shak S, Wolmark N. Comparing the prediction of chemotherapy benefit in patients with node-negative, ER-positive breast cancer using the Recurrence Score and a new measure that integrates clinical and pathologic factors with the Recurrence Score. Oral presentation #S4-8.

Annual Society of Surgical Oncology (SSO) (March 2-5, 2011)

Goodwin MC, Stull TS, Collett AE, Chernick MR, Barrio AV, Frazier TG. A single institution review of lymphedema rates and locoregional recurrence in patients enrolled in NSABP B-32. *Ann Surg Oncol* 2011;18(Suppl 1):S19. Abstr 42.

American Association for Cancer Research (AACR) (April 2-6, 2011)

Liu M, Wang L, Schaid DJ, Wickerham DL, Costantino JP, Goetz MP, Ames MM, Vogel VG, Paik S, Batzler A, Wolmark N, Nakamura Y, Kubo M, Kamatani N, Ingle JN, Weinshilboum RM. Breast cancer prevention and selective estrogen response modulators (SERMs): Pharmacogenomics and differential estrogen and SERM regulation of BRCA1 and BRCA2 expression. Abstr 4727. Presented.

American Society of Clinical Oncology (ASCO) (June 3-7, 2011)

Allegra CJ, Yothers GA, O'Connell MJ, Sharif S, Petrelli NJ, Colangelo LH, Wolmark N. Overall survival and updated disease-free survival results of the NSABP C-08 trial assessing bevacizumab in stage II and III colon cancer. Abstr 3508. Oral presentation.

Amir E, Cecchini RS, Ganz PA, Costantino JP, Beddows S, Hood N, Goodwin PJ. 25-hydroxy vitamin D and associated variables as predictors of breast cancer risk and tamoxifen benefit in NSABP-P1. Abstr 1528. Poster discussion session.

Bear HD, Tang G, Rastogi P, Geyer CE, Robidoux A, Atkins JN, Baez-Diaz L, Brufsky A, Mehta RS, Fehrenbacher L, Pajon ER, Senecal FM, Gaur R, Margolese RG, Adams PT, Gross HM, Costantino JP, Swain SM, Mamounas EP, Wolmark N. The effect on pCR of bevacizumab and/or antimetabolites added to standard neoadjuvant chemotherapy: NSABP Protocol B-40. Abstr LBA 1005. Oral presentation. “Best of ASCO” selection.

Chapman JAW, O’Callaghan C, Hu N, Ding K, Yothers GA, Catalano PJ, Shi Q, Gray RG, O’Connell MJ, Sargent DJ, for the ACCENT collaborative group. Comparison of innovative estimation of efficacy to standard using the ACCENT database. Abstr 3616. General poster session.

Cheung WY, Shi Q, O’Connell M, Cassidy J, Blanke CD, Kerr DJ, Van Custem E, Alberts SR, Yothers GA, Sargent DJ. Predictive and prognostic value of gender in early stage colon cancer: A pooled analysis of 33,345 patients from the ACCENT database. Abstr 3619. General poster session.

Crager M, Tang G, Shak S. Using the 21-Gene Recurrence Score and the recently developed RSPC to assess recurrence risk in node-negative, ER-positive early-stage breast cancer patients receiving aromatase inhibitor treatment alone. Abstr 592. General poster session.

Foster NR, Sinicrope F, Yothers GA, Allegra CJ, Sargent DJ. Body mass index and DNA mismatch repair status in colon cancers from patients treated in adjuvant therapy trials. Abstr 10590. General poster session.

Julian TB, Costantino JP, Vincini FA, White JR, Winter KA, Arthur DW, Kuske R, Rabinovitch R, Parda DS, Mamounas EP, Curran WJ Jr, Wolmark N. Early toxicity results with 3-D conformal external beam therapy from the NSABP B-39/RTOG 0413 accelerated partial breast irradiation trial. Abstr 1011. Poster discussion session.

Land SR, Christian N, Wickerham DL, Costantino JP, Ganz PA. Cigarette smoking, fitness, and alcohol use as predictors of cancer outcomes among women in the National Surgical Adjuvant Breast and Bowel Project (NSABP) Breast Cancer Prevention Trial (BCPT). Abstr 1505. Oral presentation.

Parulekar W, Chen BE, Elliott C, Shepherd LE, Gelmon KA, Pritchard KI, Whelan TJ, Ligibel JA, Hershman DL, Mayer IA, Hobday TJ, Rastogi P, Lemieux J, Ganz PA, Stambolic V, Goodwin PJ. A phase III randomized trial of metformin versus placebo on recurrence and survival in early stage breast cancer (NCIC CLINICAL TRIALS GROUP MA.32). Abstr TPS103. Trials in Progress poster session.

Roh MS, Yothers G, O’Connell MJ, Beart RW, Pitot HC, Shields AF, Parda D, Sharif S, Allegra CJ, Petrelli N, Landry JC, Ryan DP, Arora A, Evans TL, Soori G, Chu L, Landes RV, Mohiuddin M, Lopa S, Wolmark N. The impact of capecitabine and oxaliplatin in the preoperative multimodality treatment of patients with carcinoma of the rectum: NSABP R-04. Abstr 3503. Oral presentation. “Best of ASCO” selection.

Shen K, Tang G, Costantino JP, Anderson SJ, Kim C, Pogue-Geile K, Song N, Gabrin MJ, Geyer CE, Wolmark N. Multigene predictors developed on breast cancer cell lines to predict patient chemotherapy response: A validation study on the NSABP B-27 trial. Abstr 1029. Poster discussion session.

Shi Q, Hubbard JM, Yothers GA, Andre T, Saltz L, Francini G, Bot BM, Twelves C, Buyse ME, Grothey A, Sargent DJ. Lymph node ratio risk classification in stage III colon cancer: A pooled analysis of 16,425 patients from the ACCENT database. Abstr 3556. General poster session.

Sinicrope F, Foster NR, Yothers GA, Benson AB, Haller DG, Seitz JF, Labianca R, Benedetti J, Goldberg RM, De Gramont A, Sargent DJ. Body mass index as a prognostic and predictive factor in Stage II/III colon cancer – an analysis of the ACCENT database. Abstr 221126. Electronic publication-only abstract e21126.

Siziopikou KP, Cobleigh MA, Anderson SJ, Julian TB, Arthur DW, Zheng P, Mamounas EP, Pajon ER, Behrens RJ, Chu L, Leasure NC, Atkins JN, Polikoff J, Seay TE, McCaskill-Stevens WJ, Rabinovitch R, Wolmark N. Preliminary results of centralized HER2 testing in DCIS of the breast: NSABP B-43. Abstr 588. General poster session.

Yothers GA, Allegra CJ, O’Connell MJ, George TJ, Sharif S, Petrelli NJ, Lopa S, Wolmark N. The efficacy of oxaliplatin when added to 5-fluorouracil/leucovorin in stage II colon cancer. Abstr 3507. Oral presentation. “Best of ASCO” selection.

NSABP scientists continue to author and publish oncology articles and NSABP clinical trial results in well-respected peer-reviewed journals. The following articles have appeared in oncology-related journals for this reporting period:

B-04

Empirical Likelihood Ratio Test for Median and Mean Residual Lifetime. Zhou M, Jeong JH. *Stat Med.* 2011 Jan 30;30(2):152-9. Epub 2010 Nov 5. PubMed ID: 21204121.

B-14, B-20

Comparison of the Prognostic and Predictive Utilities of the 21-Gene Recurrence Score Assay and Adjuvant! for Women with Node-Negative, ER-Positive Breast Cancer: Results from NSABP B-14 and NSABP B-20. Tang G, Shak S, Paik S, Anderson SJ, Costantino JP, Geyer CE Jr, Mamounas EP, Wickerham DL, Wolmark N. *Breast Cancer Res Treat.* 2011 May; 127(1): 133-42. Epub 2011 Jan 11. PubMed ID: 21221771.

B-15, B-16, B-22, B-25

Meta-Analysis Methodology for Combining Treatment Effects from Cox Proportional Hazard Models with Different Covariate Adjustments. Yuan X, Anderson SJ. *Biom J.* 2010 Aug;52(4): 519-37. Epub 2010 July 26. PubMed ID: 20661952.

B-17, B-24

Long-Term Outcomes of Invasive Ipsilateral Breast Tumor Recurrences After Lumpectomy in NSABP B-17 and B-24 Randomized Clinical Trials for DCIS. Wapnir IL, Dignam JJ, Fisher B,

Mamounas EP, Anderson SJ, Julian TB, Land SR, Margolese RG, Swain SM, Costantino J P, Wolmark N. *J Natl Cancer Inst.* 2011 Mar 16;103(6):478-88. Epub 2011 Mar 11. PubMed ID: 21398619.

B-30

Menstrual History and Quality-of-Life Outcomes in Women With Node-Positive Breast Cancer Treated With Adjuvant Therapy on the NSABP B-30 Trial. Ganz PA, Land SR, Geyer CE Jr, Cecchini RS, Costantino JP, Pajon ER, Fehrenbacher L, Atkins JN, Polikoff JA, Vogel VG, Erban JK, Livingston RB, Perez EA, Mamounas EP, Wolmark N, Swain SM. *J Clin Oncol.* 2011 Mar 20;29(9):1110-6. Epub 2011 Feb 7. PubMed ID: 21300930.

B-30-LETTER TO EDITOR

Amenorrhea from Breast Cancer Therapy—Not a Matter of Dose. Swain SM, Jeong JH, Wolmark N. *N Engl J Med.* 2010 Dec 2;363(23):2268-70. PubMed ID: 21121855. Comment on: Longer therapy, iatrogenic amenorrhea, and survival in early breast cancer. *N Engl J Med* 2010 Jun 3;362(22): 2053-65.

B-31/NCCTG N9831

Independent Adjudication of Symptomatic Heart Failure with the Use of Doxorubicin and Cyclophosphamide Followed by Trastuzumab Adjuvant Therapy: A Combined Review of Cardiac Data from the National Surgical Adjuvant Breast and Bowel Project B-31 and the North Central Cancer Treatment Group N9831 Clinical Trials. Russell SD, Blackwell KL, Lawrence J, Pippin JE Jr, Roe MT, Wood F, Paton V, Holmgren E, Mahaffey KW. *J Clin Oncol.* 2010 Jul 20;28(21):3416-21. Epub 2010 Jun 7. PubMed ID: 20530275.

B-32

Axillary recurrences following positive sentinel lymph node biopsy with individual tumor cells or micrometastases and no axillary dissection. Erb KM, Wright HM, Julian TB. *Breast Dis* 2011; 31:83-90.

Effect of Occult Metastases on Survival in Node-Negative Breast Cancer. Weaver DL, Ashikaga T, Krag DN, Skelly JM, Anderson SJ, Harlow SP, Julian TB, Mamounas EP, Wolmark N. *N Engl J Med.* 2011 Feb 3;364(5):412-21. Epub 2011 Jan 19. PubMed ID: 21247310.

Morbidity Results from the NSABP B-32 Trial Comparing Sentinel Lymph Node Dissection versus Axillary Dissection. Ashikaga T, Krag DN, Land SR, Julian TB, Anderson SJ, Brown AM, Skelly JM, Harlow SP, Weaver DL, Mamounas EP, Costantino JP, Wolmark N. *J Surg Oncol.* 2010 Aug 1;102(2):111-8. PubMed ID: 20648579.

Patient-Reported Outcomes in Sentinel-Node Negative Adjuvant Breast Cancer Patients Receiving Sentinel-Node Biopsy or Axillary Dissection: National Surgical Adjuvant Breast and Bowel Project Phase III Protocol B-32. Land SR, Kopec JA, Julian TB, Brown AM, Anderson SJ, Krag DN, Christian NJ, Costantino JP, Wolmark N, Ganz PA. *J Clin Oncol.* 2010 Sep 1;28(25):3929-36. Epub 2010 Aug 2. PubMed ID: 20679600.

Sentinel-Lymph-Node Resection Compared with Conventional Axillary-Lymph-Node Dissection in Clinically Node-Negative Patients with Breast Cancer: Overall Survival Findings from the NSABP B-32 Randomised Phase 3 Trial. Krag DN, Anderson SJ, Julian TB, Brown AM, Harlow SP, Costantino JP, Ashikaga T, Weaver DL, Mamounas EP, Jalovec LM, Frazier TG, Noyes RD, Robidoux A, Scarth HM, Wolmark N. *Lancet Oncol.* 2010 Oct;11(10):927-33. Epub 2010 Sep 20. PubMed ID: 20863759.

The Need for Axillary Dissection in Patients with Positive Axillary Sentinel Lymph Nodes. Croshaw RL, Erb KM, Shapiro-Wright HM, Julian TB. *Curr Oncol Rep.* 2011 Feb;13(1):5-10. PubMed ID: 20957459.

C-01, C-02, C-04, C-06

Relationship Between Tumor Gene Expression and Recurrence in Four Independent Studies of Patients with Stage II/III Colon Cancer Treated with Surgery Alone or Surgery plus Adjuvant Fluorouracil plus Leucovorin. O'Connell MJ, Lavery I, Yothers G, Paik S, Clark-Langone KM, Lopatin M, Watson D, Baehner FL, Shak S, Baker J, Cowens JW, Wolmark N. *J Clin Oncol.* 2010 Sep 1;28(25):3937-44. Epub 2010 Aug 2. PubMed ID: 20679606.

Accompanying editorial. "Multigene Assays to Improve Assessment of Recurrence Risk and Benefit from Chemotherapy in Early-Stage Colon Cancer: Has the Time Finally Arrived, or Are We Still Stage Locked?" Taberero J, Baselga J. *J Clin Oncol.* 2010 Sep 1;28(25):3904-7. Epub 2010 Aug 2. PubMed ID: 20679612.

C-06, C-07

Two or Three Year Disease-Free Survival (DFS) as a Primary End-Point in Stage III Adjuvant Colon Cancer Trials with Fluoropyrimidines With or Without Oxaliplatin or Irinotecan: Data from 12,676 Patients from MOSAIC, X-ACT, PETACC-3, C-06, C-07 and C89803. Sargent D, Shi Q, Yothers G, Van Cutsem E, Cassidy J, Saltz L, Wolmark N, Bot B, Grothey A, Buyse M, de Gramont A; for the Adjuvant Colon Cancer End-points (ACCENT) Group. *Eur J Cancer.* 2011 May;47(7):990-996. Epub 2011 Jan 21. PubMed ID: 21257306.

C-08

Phase III Trial Assessing Bevacizumab in Stages II and III Carcinoma of the Colon: Results of NSABP Protocol C-08. Allegra CJ, Yothers G, O'Connell MJ, Sharif S, Petrelli NJ, Colangelo LH, Atkins JN, Seay TE, Fehrenbacher L, Goldberg RM, O'Reilly S, Chu L, Azar CA, Lopa S, Wolmark N. *J Clin Oncol.* 2011 Jan 1;29(1):11-6. Epub 2010 Oct 12. PubMed ID: 20940184.

LTS-01 (C-05, C-06, C-07, R-02, R-03)

Routine Preventive Care and Cancer Surveillance in Long-Term Survivors of Colorectal Cancer: Results from National Surgical Adjuvant Breast and Bowel Project Protocol LTS-01. Kunitake H, Zheng P, Yothers G, Land SR, Fehrenbacher L, Giguere JK, Wickerham L, Ganz PA, Ko CY. *J Clin Oncol.* 2010 Dec 20;28(36):5274-9. Epub 2010 Nov 15. PubMed ID: 21079140.

MA-32

Evaluation of Metformin in Early Breast Cancer: a Modification of the Traditional Paradigm for Clinical Testing of Anti-Cancer Agents. Goodwin PJ, Stambolic V, Lemieux J, Chen BE, Parulekar WR, Gelmon KA, Hershman DL, Hobday TJ, Ligibel JA, Mayer IA, Pritchard KI,

Whelan TJ, Rastogi P, Shepherd LE. *Breast Cancer Res Treat.* 2010 Oct 26. Epub ahead of print. PubMed ID: 20976543.

P-1, P-2

Breast Cancer Chemoprevention: Progress and Controversy. Wickerham DL. *Surg Onco; Clin N Am.* 2010 Jul;19(3):463-73. PubMed ID: 206209210.

P-2

Estimated Risk of Invasive Breast Cancer in Postmenopausal Women With and Without Family History of the Disease. Sontag A, Wickerham DL, Ni X, Mitchell BD, Helt C, Muram D. *Menopause.* 2010 Dec 18. [Epub ahead of print]. PubMed ID: 21178791.

COMMENTARIES

Trastuzumab as Single Agent Therapy for HER2-Positive Metastatic Breast Cancer. Rastogi P, Davidson NE. *Onkologie.* 2010;33(8-9):420-21. Epub 2010 Jul 21. PubMed ID: 20838056.

Pitfalls of Using Composite Primary End Points in the Presence of Competing Tasks. Mell LK, Jeong JH. *J Clin Oncol.* 2010 Aug 16. [Epub ahead of print]. PubMed ID: 20713860.

CLINICAL TRIALS STUDY

Preliminary Evaluation of Factors Associated with Premature Trial Closure and Feasibility of Accrual Benchmarks in Phase III Oncology Trials. Schroen AT, Petroni GR, Wang H, Gray R, Wang XF, Cronin WM, Sargent DJ, Benedetti J, Wickerham DL, Djulbegovic B, Slingluff CL Jr. *Clin Trials.* 2010 Aug;7(4):312-21. Epub 2010 Jul 1. PubMed ID: 20595245.

Research Development Collaboration

The NSABP continues to meet with laboratory and biotechnology multi-national and Pennsylvania firms and has developed collaborative projects with academic institutions where we have material transfer agreements using tumor biospecimens from the NSABP Biospecimen Bank. Results of these collaborations are not yet available.

The Foundation continues to meet on a regular basis with pharmaceutical and biotechnology companies to review newly-developed drugs and laboratory techniques, and to explore opportunities for further investigation and potential commercialization. Such meetings are conducted under confidentiality agreements.