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
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 Oncologicas (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)**


**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)**

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


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


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


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


**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**

**B-14, B-20**

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

**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,

**B-30**

**B-30-LETTER TO EDITOR**

**B-31/NCTG N9831**

**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.


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


C-06, C-07

C-08

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

MA-32

P-1, P-2


P-2


COMMENTARIES


CLINICAL TRIALS STUDY


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.