National Surgical Adjuvant Breast and Bowel Project (NSABP) Foundation

Research Development Report

Reporting Period:

July 1, 2011 – June 30, 2012

Commercial Development of Research

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. During this reporting period, the NSABP employed one research fellow in the pathology laboratory and one researcher who served as Biostatistician/Computational Biologist/Bioinformatics Specialist. The Biostatistician's responsibilities included 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**

Laboratory staff and research fellows actively participate in 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**

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.

*NSABP scientists have presented, or have been accepted for presentation, study results from NSABP clinical trials in the form of abstracts and posters:*

**ASTRO, Miami Beach (October 2-6, 2011)**


_San Antonio Breast Cancer Symposium (Dec 7-10, 2011)_


_American Society of Clinical Oncology (ASCO) Gastro Symposium, San Francisco (January 19-21, 2012)_
http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=115&abstractID=88085

American Association for Cancer Research (AACR) Annual Meeting (March 31-Apr 4, 2012)

http://www.abstractsonline.com/Plan/ViewAbstract.aspx?mID=2898&sKey=ee969019-3a07-429d-bf3c-919516e63d56&cKey=aa4ce99e-6dce-465f-9982-64d02c76f98&mKey=%7b2D8C569E-B72C-4E7D-AB3B-070BEC7EB280%7d

American Society of Clinical Oncology (ASCO) (June 1-5, 2012)

http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=114&abstractID=98794

http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=114&abstractID=99368

http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=114&abstractID=96720

comparing chemotherapy alone (six cycles of docetaxel plus cyclophosphamide or four cycles of doxorubicin plus cyclophosphamide followed by weekly paclitaxel) to chemotherapy plus trastuzumab in women with node-positive or high-risk, node-negative, HER2-low invasive breast cancer. Poster presentation. Presented. J Clin Oncol 30, 2012 (suppl; abstr TPS1142).
http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=114&abstractID=94083

http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=114&abstractID=99494

http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=114&abstractID=94683

http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=114&abstractID=97548

http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=114&abstractID=99870

http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=114&abstractID=97638
http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=114&abstractID=98385

http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=114&abstractID=94535

http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=114&abstractID=98446

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:


COMMENTARY.


**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.