

National Surgical Adjuvant Breast and Bowel Project (NSABP) Foundation

Research Development Report

Reporting Period:

July 1, 2013 – June 30, 2014

Commercial Development of Research

Efforts towards the commercialization of discoveries resulting from Health Research Formula funding have resulted in the submission of one provisional, one non-provisional and one international patent application related to: (1) using gene signatures to identify colon cancer patients who will benefit from treatment with oxaliplatin, and (2) defective mismatch repair and benefit from bevacizumab for colon cancer.

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 at a national law firm specializing in intellectual property 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 Ib/II, Phase II and Phase III clinical trials and have executed agreements providing opportunities for licensing partnerships. Over the past year, NSABP has developed a number of collaborative relationships in the preclinical space to bolster our early phase clinical trial effort. The preclinical research we are exploring through collaborations is both novel and exciting. We are hopeful this expanded scope will lead to further advancements in science with important opportunities for cancer patient care.

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

During this reporting period, the Foundation has recruited and employed two post-doctoral research scientists – a Biostatistician/Computational Biologist/Bioinformatics Specialist and a Molecular/Cellular Biologist. The Biostatistician's responsibilities include conducting statistically-justified genomic and correlative science projects, working closely with statisticians at the NSABP Biostatistical Center at the University of Pittsburgh, and developing prognostic and predictive models using pathological and/or molecular data to improve the treatment of breast and colorectal cancer patients. The Molecular Biologist's responsibilities include testing cancer cell lines for their response to agents and determining mechanisms of sensitivity or resistance to such agents.

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 ongoing training in the operation of sophisticated laboratory equipment used for a variety of genetic research applications.

Commercial Research Development Training

Laboratory staff 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.

These scientists have authored and published oncology articles and clinical trial results in well-respected, peer-reviewed journals. NSABP scientists continue to present clinical trial study results in the form of abstracts and posters 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.

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.