AWARD NUMBER: W81XWH-15-1-0268

TITLE: Randomized Trial of Asprin as Adjuvant Therapy for Node-Positive Breast Cancer

PRINCIPAL INVESTIGATOR: Eric Winer

RECIPIENT: Dana-Farber Cancer Institute
Boston, MA 02215

REPORT DATE: October 2018

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2018	Annual	15 Sep 2017 - 14 Sep 2018

4. TITLE AND SUBTITLE
Randomized Trial of Asprin as Adjuvant Therapy for Node-Positive Breast Cancer

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-15-1-0268

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Eric Winer
Wendy Chen

E-Mail: Eric_Winer@dfci.harvard.edu; Wendy_Chen@dfci.harvard.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Dana-Farber Cancer Institute

450 Brookline Avenue
Boston, MA 02215-5450

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
In the United States, more than 3 million women are living after a breast cancer diagnosis. There is great need for additional breast cancer adjuvant treatments that are low-cost and low toxicity. These would not only save thousands of lives, but offer improved quality of life for those who do not tolerate current treatments, and treatment options to women in developing countries who currently get none.
We will enroll 3000 women with node-positive HER2 negative Stage II or III breast cancer with a 1:1 randomization to aspirin 325 mg daily versus placebo. Primary endpoint is invasive disease-free survival (including local and distant). Secondary endpoints include recurrence-free interval (local and distant), overall survival, cardiovascular disease, toxicity, and adherence. We will exclude those at high risk of bleeding complications with aspirin (≥age 70, history of prior stroke, significant gastrointestinal bleeding, anticoagulation) or those with indications for taking aspirin (history of myocardial infarction or atrial fibrillation) Breast cancer advocates will be involved in the creation of all recruitment letters, consent forms, and information sheets. We would conduct the trial in a multi-center collaboration of the Brigham and Women's Hospital, Dana Farber Harvard Cancer Institute, and the Alliance for Clinical Trials in Oncology. The research infrastructure, long-standing leadership roles in clinical trials, and ability to rapidly accrue subjects make the assembled research team ideal to lead a US trial within the proposed time frame.

15. SUBJECT TERMS
Breast cancer, adjuvant treatment, aspirin, randomized controlled trial

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	16	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

   There is great need for additional breast cancer adjuvant treatments that are low-cost and low toxicity. We believe aspirin holds great promise, and propose a randomized controlled trial to test that promise. There is compelling epidemiologic, in-vitro, and in-vivo, evidence of aspirin's potential. We will enroll 2936 women with HER2 negative non-metastatic breast cancer with a 1:1 randomization to aspirin 300 mg daily versus placebo. Primary endpoint is invasive disease-free survival (including local and distant). Secondary endpoints include recurrence-free interval (local and distant), overall survival, cardiovascular disease, toxicity, and adherence. We hypothesize that breast cancer survivors randomized to aspirin will have fewer recurrences and longer recurrence-free survival than those on placebo.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

   Breast cancer, adjuvant treatment, aspirin, randomized controlled trial

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

   What were the major goals of the project?
   List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

   The goals and milestones listed below pertain to months 25-36 in the approved SOW:

   Specific Aims 1 & 2: Clinical Trial
   - Screen subjects and consent eligible subjects to study (months 6-30) – Began December 2016, ongoing
   - Assign participants to one of two randomized groups study (months 6-30) – Began December 2016, ongoing
   - Distribute study medication for the first 6 months study (months 6-30) – Began December 2016, ongoing
   - Review accrual statistics to ensure that accrual goals will be met (every 6 months) – This is actually done every month. Began December 2016 and occurs on weekly basis
   - Assess participants every 6 months while on study (months 12-30) – Began December 2016, ongoing
   - Assess for toxicity and adverse events (ongoing) – Began December 2016, ongoing
   - Assess for need for dose reduction (ongoing) – Began December 2016, ongoing
   - Assess for need for proton pump inhibitor (ongoing) – Began December 2016, ongoing
   - Assess compliance with study drug (months 12-60) Began December 2016, ongoing

- Coordinate with sites and data for data collection (months 6-60) – Began December 2016, ongoing
- *Milestone achieved: Meet accrual goal for subjects (month 30)* - This was not achieved due to delay in subject accrual – see Section 5: Changes, Problems
- *Milestone Achieved: Report findings from characteristics of baseline population (month 30-32))* - This was not achieved due to delay in subject accrual – see Section 5: Changes, Problems

Specific Aim 3: Creation of biospecimen and epidemiologic biobank

- Collection of tumor specimens at baseline (months 6-30) – Began December 2016, ongoing
- Collection of blood and urine specimens at baseline (months 6-30) – Began December 2016, ongoing
- Storage and cataloguing of specimens (months 6-60) – Began December 2016, ongoing
- Collection of covariate data on sleep, stress, BMI, etc. (months 6-60) – Began December 2016, ongoing

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Referring to the SOW:

Specific Aims 1 & 2: Clinical Trial

- We began enrollment on Dec. 8, 2016. This included screening, randomization, distribution of study medication, collection of biospecimens, collection of epidemiologic data, collection of information on toxicity and adverse events, need for dose reduction, and need for proton pump inhibitor.
- We have assessed enrollment monthly
- As of August 31, 2018, 1175 sites have registered to enroll subjects, training of staff and local IRB approval is ongoing at those sites
- As of October 8, 2018, 723 subjects have registered and been randomized

Specific Aim 3: Biorepository

- As of September 24, 2018, 72% have submitted biospecimens (blood and/or tumor) and 91% have submitted a lifestyle questionnaire

Additional Achievement, not in the SOW

- The first External Advisory Board meeting was held 11/21/16 . A trials in progress poster was presented at the semi-annual Alliance for Clinical Trials Oncology meeting in May 2017 at the annual American Society for Clinical Oncology meeting in June 2017. Our Patient Advocates publicized the study at the National Advocate Leadership Summit for the National Breast Cancer Coalition in May 2017.
- The second External Advisory Board meeting was held on 11/13/17. During the meeting we discussed slow accrual. The advice was given to liberalize the inclusion criteria (please see Section 5 Problems and Changes to document what was suggested). A trials in progress poster was presented at the semi-annual Alliance for Clinical Trials Oncology meeting in November 2017 and May 2018 and at the annual American Society of Clinical Oncology meeting in June 2018. The advocates publicized the work at the San Antonio Breast Symposium in December 2017.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to report

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

We will continue to enroll and randomize subjects. Changes in the eligibility criteria to increase accrual were only recently approved by the National Cancer Institute IRB and activated by the Alliance and Clinical Trials Support Unit on September 4, 2018, the amendment still need to be approved and activated at the local IRB level, so the enrollment rate is estimated to increase greatly over the next few months, particularly given the changes in inclusion criteria. Please see Section 5: Problems and Changes for the changes we have made in the inclusion criteria.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Our patient accrual has been behind what we had anticipated by this time and we have aggressively addressed this. In December 2017, an amendment was approved and activated to change the eligibility criteria to include high risk node negative (T2-3N0 triple negative breast cancers) and to decrease the washout periods for regular aspirin use and end of chemotherapy/radiation which were all named as barriers to accrual. This resulted in an increase in accrual to almost 50 patients per month from 30 subjects per month. However, we recognize that this still lags behind our projected accrual, so another amendment was approved and activated in September 2018 to change the eligibility criteria to within 10 years of diagnosis for hormone

positive node positive subjects and within 18 months for triple negative cancers. Sample size and power are unchanged since the risks of recurrence for HER2 negative breast cancers are linear within these time frames. We anticipate that this will dramatically increase accrual for 2 reasons: 1) it will significantly increase the pool of eligible patients and 2) there are no competing trials for hormone positive breast cancers more than 18 months after diagnosis.

Furthermore, the study remains open in the other cooperative groups including ECOG, SWOG, and CCTG, and Health Canada is also considering opening the study. The study is promoted at all of the cooperative group meetings by the study champions and we have also engaged our advocates and their network to improve accrual
In addition, the trial is presented on the monthly Alliance breast conference calls and the biannual meetings and the American Society of Clinical Oncology annual meetings.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

A major cost of the trial is the $1400 per patient enrollment fee paid to the Alliance. As accrual is behind, these expenditures are lower than expected. We expect to catch up with patient enrollment (and expenditures) in coming years.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

An update was approved by the NCI central IRB and activated in December 2017. The main changes made to increase accrual were 1) to change the washout period after end or radiation/chemotherapy from 60 to 30 days, 2) to change the time from one year to 30 days that a subject needed to stop regular aspirin use prior to enrolling, 3) allow a +/- 14 day window for the 6 month visit, 4) allow high risk node negative (defined as T2-T4/N0) triple negative patients to enroll. Another amendment was approved by NCI CIRB and activated in September 2018 to change the eligibility criteria to within 18 months of diagnosis for triple negative breast cancer and within 10 years of diagnosis for hormone positive breast cancer. None of these changes impacted the risk/benefit ratio to subjects nor the statistical plan.

On September 16, 2018, the New England Journal of Medicine published 3 articles from the ASPREE (Aspirin in Reducing Events in the Elderly) trial, a randomized placebo-controlled study of aspirin (100 mg daily) among community dwelling adults aged 70 years of age or older, or ≥ 65 years of age among blacks and Hispanics in the US (for age 65-69, n=564). With median follow up of 4.7 years among 19,114 enrolled subjects (median age 74 years), there was an increase in average all-cause mortality with aspirin compared to placebo (12.7 vs 11.1 events/1000 person-years, HR 1.14; 95% CI 1.01-1.29). This mainly appeared to be driven by an increase in cancer related mortality (6.7 vs 5.1/1000 person-years (HR 1.31; 95% CI 1.10-1.56). As expected and has been seen in other studies, the rate of major hemorrhage was higher with aspirin (8.6 vs 6.2 events/person-years; HR1.38; 95% CI 1.18 to 1.62; P<0.001).

Some of the prior observational studies and pooled analyses of randomized trials of aspirin for primary and secondary prevention of cardiovascular disease have shown decreased cancer-related mortality. It should be noted that the ASPREE involved primarily an older population than that in prior studies, and that our current eligibility excludes patients >70 years of age. Additionally, only 19% of the ASPREE participants had a prior history of cancer, and the number of deaths from breast cancer on the ASPREE trial was very small (15 in aspirin treated patients and 7 in placebo treated patients).

The findings of the ASPREE trial were discussed with CTEP and it has been decided to add a sentence to the consent form including the ASPREE results and to reconsent subjects at the time of their next study visit. Given the differences in the patient populations, aspirin dose and primary endpoints of our aspirin study and the ASPREE study, CTEP did not feel that these results directly impacted on the conduct of our aspirin study which continues to address an important clinical question. The revised consent form and a patient information letter has been submitted to NCI CIRB. The Alliance DSMB will also be updated.

Significant changes in use or care of vertebrate animals.

Not applicable

Significant changes in use of biohazards and/or select agents

Not applicable

6. PRODUCTS: List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

Publications, conference papers, and presentations
Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report

Other publications, conference papers, and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Chen WY, Winer EP, Barry WT, Partridge AH, Carey LA, Openshaw TH, Visvanathan K, Symington B, Matyka C**,** Carvan M, Holmes MD**.** ABC trial (AO11502) A randomized phase III double blinded placebo controlled trial of aspirin as adjuvant therapy for breast cancer. (Abstract TPS597). 2018 Annual meeting of the American Society for Clinical Oncology.

Website(s) or other Internet site(s)
List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

http://abctrial.org/

This is the website for general information about the trial, for interested patients and clinicians. There are no results to disseminate yet.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

  Nothing to report

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

  Nothing to report

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *biospecimen collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

  Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

Example:

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award).*

Name: Project Role: Nearest person-month worked: Contribution to project:	Name: Eric Winer Role: Principal Investigator No change Contribution: Dr. Winer has had multiple meetings and conference calls with both the National Cancer Institute and Alliance for Clinical Trials in Oncology to secure approval for the protocol at both the NCI and Alliance. He has provided key input on the protocol and study design and has been a key liaison across the partnering organizations.
Name: Project Role: Nearest person-month worked: Contribution to project:	Name: Wendy Chen Role: Co-Investigator No change Contribution: Dr. Chen serves as study chair for the clinical trial at the Alliance for Clinical Trials in Oncology so has been in charge of writing and revising the protocol and securing approval through the Alliance and NCI. She has also been participating in regular conference calls on protocol revisions and approval.
Name: Project Role: Nearest person-month worked: Contribution to project:	Name: William Barry Role: Biostatistician 0.24 calendar months Contribution: Dr. Barry has helped to write the statistical analysis parts of the protocol and has also provided key input on study design. He has also participated in multiple conference calls to address questions about statistical issues relevant to the study. Dr. Barry left DFCI at the end of March, 2018. In the interim, Dr. Karla Ballman of Mayo Clinic (part of BWH contract) has been assisting, but a statistician at DFCI will be identified soon.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Yes. Changes in italics below:

Winer, Eric P.

P50CA168504 (Winer) *09/17/13 – 07/31/19 (in ext.)* 3.24 CM
NIH/NCI $1,498,227 (total SPORE)
Dana-Farber/ Harvard SPORE in Breast Cancer
The Dana-Farber/Harvard Cancer Center (DF/HCC) SPORE in Breast Cancer seeks to improve the prevention and treatment of breast cancer through four integrated, innovative, and highly translational Projects which span all of the major breast cancer subtypes and range in scope from basic and preclinical science to epidemiologic and clinical studies. The overarching goal of the DF/HCC SPORE in Breast Cancer is to promote translational research that can lead to tangible clinical benefit.
Role: SPORE Director

No Num Available (Winer) *10/1/18—9/30/19* *0.24 CM*
Breast Cancer Research Foundation *$208,333*
Exploring de-escalated systemic therapy for patients with HER2-positive breast cancer who achieve pathologic complete response following neoadjuvant treatment
Since over 90% of patients with non-metastatic HER2-positive breast cancer are cured with modern treatment regimens, it is imperative to explore ways to achieve cure with less toxic treatments. Scaling back the number of chemotherapy agents used will allow patients to maintain better quality of life and decrease the chance of rare but serious chemotherapy complications. Accordingly, we will conduct a clinical trial investigating less intensive chemotherapy for carefully selected patients with excellent prognosis and HER2-positive breast cancer. We aim (1) to assess the willingness of patients and doctors to adhere to this novel treatment approach, and (2) to understand patients' and doctors' attitudes about including or omitting post-surgery chemotherapy. The overarching goal of this small trial, which is a precursor to a large national/international trial investigating the same approach, is to help develop treatments for HER2-positive breast cancer that are highly effective but also minimize side effects for carefully selected patients.

Chen, Wendy Y.

R01CA184953 (Caan)	*06/01/2014 – 05/31/2019 (in ext.)*	0.12 Calendar
NIH/ NCI	$48,423	

(PQA2) Exploring the role of sarcopenia in obesity and breast cancer survival
The aims of the project are to understand how changes in lean/fat body mass as measured by CT scan are associated with changes in energy balance and survival among breast cancer survivors by integrating data from both Kaiser Permanente and DFCI.
Role: Subcontract PI

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.
Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Bayer Pharma AG, Mullerstr 178, 13353 Berlin, Germany is supplying both aspirin and placebo for this trial at no cost to the trial. We have executed a contract with them to do so on May 13, 2016.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

9. **APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.