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

PRINCIPAL INVESTIGATOR: Eric Winer

RECIPIENT: Dana-Farber Cancer Institute, Inc.

REPORT DATE: 10/14/19

TYPE OF REPORT: Annual

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

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REPORT DOCUMENTATION PAGE

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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 (\geq 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					
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Unclassified	Unclassified	Unclassified	Unclassified	17	USAMRMC

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 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 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.

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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 37-48 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. However, the monthly accrual goal is now being met after changes in the eligibility criteria – 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
- *Milestone Achieved: Submit research grants on correlative works using biospecimens and epidemiologic data (months 50-60)* A sub-study evaluating changes in mammographic density among triple negative breast cancer patients enrolled on the aspirin stud was activated through the Alliance and is accruing subjects. The funding for the sub-study is through the National Cancer Institute

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. The Alliance Data Safety and Monitoring Board last met on May 10, 2019 and did not find any issues regarding adverse events or efficacy. Specifically, there were no grade 3 or 4 adverse events attributed to study drug. No interventions were recommended.
- We have assessed enrollment monthly
- As of August 31, 2019, 1171 sites have registered to enroll subjects, training of staff and local IRB approval is ongoing at those sites
- As of October 7, 2019, 1925 subjects have registered and been randomized
- Although total accrual was behind, we are now achieving target monthly accrual since November 2018 after changes in the eligibility criteria

Specific Aim 3: Biorepository

- As of September 25, 2019, 72% have submitted biospecimens (blood and/or tumor) and 89% have submitted a lifestyle questionnaire
- A sub-study evaluating changes in mammographic density among triple negative breast cancer patients enrolled on the aspirin stud was activated through the Alliance and is accruing subjects. The funding for the sub-study is through the National Cancer Institute

Additional Achievements, 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.
- December 2018 Patient Advocate Maggie Carvan publicized the trial at the San Antonio Breast Cancer Conference. The External Advisory Board met on December 10, 2018 and members were updated on study progress and protocol amendments. A trials in progress poster was presented at the annual American Society of Clinical Oncology meeting in June 2019

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 have successfully increased accrual such that we now have achieved target monthly accrual. 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.

During the current reporting period, we have not encountered any problems or delays. Our average patient accrual during the current reporting period is slightly over 100 subjects per month which was our original target accrual.

During the prior reporting period, our patient accrual had lagged behind what we had anticipated. In response to this and reported barriers to accrual, we implemented several changes in the eligibility criteria including: 1) inclusion of high risk node negative (T2-3N0 triple negative breast cancers), 2) decrease the washout periods for regular aspirin use, and 3) allow subjects within 10 years of diagnosis for hormone positive node positive subjects and within 18 months for triple negative cancers. Sample size and power were unchanged since the risks of recurrence for HER2 negative breast cancers are linear within these time frames. This resulted in a significant increase in accrual.

Furthermore, the study remains open in the other cooperative groups including ECOG, SWOG, and CCTG, and Health Canada. 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 maintain 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

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 was recommended to add a sentence to the consent form including the ASPREE results and to re-consent 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 was submitted to NCI CIRB and approved December 19, 2018. The Alliance DSMB was also 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, Ballman KV, 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 TPS599). 2019 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.

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.

Winer, Eric P.

New ACTIVE

P50CA168504-06A1 (Winer) 07/05/19 – 05/31/24 3.6 CM
NIH/NCI \$12,521,055 (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.

BCRF-18-184 (Winer) 10/01/2019 – 09/30/2020 0.24 CM
Breast Cancer Research Foundation \$250,000

Exploring de-escalated systemic therapy for patients with HER2-positive breast cancer who achieve pathologic complete response following neoadjuvant treatment

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 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.

No Num Available (Winer/Goel) 02/01/2019 – 01/31/2020 0.12 CM
Breast Cancer Alliance \$62,500

We aim to confirm our preliminary evidence that the mTOR pathway is hyper-activated in CDK4/6 inhibitor resistant breast cancers. We also aim to establish the importance of mTORC1 pathway activation as a mechanism of CDK4/6 inhibitor resistance.

Chen, Wendy Y.

New Active

2UMICA182913 (Buring) 9/1/2019-8/31/2024 0.48 Calendar
NIH/NCI \$835,161

Women's Health Study: Infrastructure support of continued cohort follow-up
This project is for continued follow-up for disease development in the Women's Health Study.
Role: Co-Investigator

Ended

R01CA184953 (Caan)
NIH/ NCI

06/01/2014 – 05/31/2019 (in ext.) 0.12 Calendar
\$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.