Request for Proposals (RFP)
Increasing Rates of *BRCA* Testing in Patients with Breast Cancer

Association of Community Cancer Centers and
Pfizer Independent Grants for Learning & Change

I. Introduction

Pfizer Inc. and the Association of Community Cancer Centers (ACCC) are collaborating to offer community cancer centers a grant opportunity for quality improvement initiatives focused on increasing the rates of *BRCA* testing for patients with either early or metastatic breast cancer. We are looking for community hospital-based programs and physician group practices that are interested in integrating *BRCA* mutation testing as a part of the care plan for all breast cancer patients and utilizing the results of the genetic test to help inform treatment plans for their patients. Only ACCC member institutions are eligible to apply.

The mission of Pfizer Independent Grants for Learning & Change (IGLC) is to partner with the global health care community to improve patient outcomes in areas of mutual interest through support of measurable learning and change strategies. "Independent" means that the projects funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the projects and only asks for reports about the results and the impact of the projects in order to share them publicly.

ACCC, a not-for-profit alliance of more than 24,000 multidisciplinary practitioners and 2,100 cancer programs and practices nationwide, is dedicated to providing education and advocacy support in adapting and responding to complex changes and challenges in the delivery of quality cancer care. ACCC provides resources on operations and management for programs and practices, reimbursement issues, policy and regulatory changes at the state and national levels, trends in cancer care, integrating new technologies and therapies, and more.

This Request for Proposals (RFP) is being issued by both organizations. ACCC is the lead organization for review and evaluation of applications. A review committee, led by ACCC, will make decisions on which proposals will receive funding. Grant funding will be provided by Pfizer Inc. Collectively, $1.5 million is available to fund at least ten proposals.

II. Background

Hereditary breast cancer accounts for 5-10% of all breast cancers diagnosed in the United States.[1] About 25-30% of inherited breast cancers are associated with mutations in Breast Cancer gene 1 (*BRCA1)* or Breast Cancer gene 2 (*BRCA2*).[2,3] The mean age of patients with *BRCA*-associated breast cancers is considerably lower compared to the mean age of patients with sporadic breast cancer (42 vs. 64 years). *BRCA1*-mutated cancers are most commonly of the more aggressive triple-negative subtype (ER-, PR-, HER2-negative) and higher grade, while *BRCA2*-associated cancers are most commonly ER+ and lower grade.[4] Also, *BRCA*-mutated patients have a higher risk of developing a second primary breast cancer as well as ovarian cancer.

The current National Comprehensive Cancer Network (NCCN) guidelines for genetic/familial high-risk assessment in breast and ovarian cancer recommends that all women who are diagnosed with breast cancer at age 45 years or younger be considered for *BRCA* testing, even in the absence of family history or any other risk factors.[5] Additionally, the NCCN Clinical Practice Guidelines for Breast Cancer recommend that for patients with HER2-negative tumors eligible for single-agent therapy, germline *BRCA* 1/2 testing be strongly considered.[6]

The mutational status of *BRCA* has the potential to influence treatment choices in patients with breast cancer. For example, when choosing between bilateral mastectomy versus breast-conserving surgery, the physician must consider that the chances of developing contralateral breast cancer after breast-conserving surgery are considerably increased in patients with *BRCA*-associated breast cancer.[7] The NCCN panel recommends multidisciplinary consultations prior to surgery in patients with *BRCA*-positive breast cancer, and a discussion of risks associated with the development of a contralateral breast cancer compared to the risk associated with recurrent disease from primary cancer.[6] Bilateral mastectomy substantially reduces the risk of developing contralateral breast cancer in these patients.[8]

In addition, most *BRCA*-associated breast cancers have a heightened sensitivity to chemotherapeutic agents that cause DNA breaks (e.g. alkylating-, platinum-), which can be attributed to the role of *BRCA* proteins in the repair of double-stranded DNA breaks.[9]

In the metastatic setting for *BRCA*-associated breast cancer, two recent randomized trials have demonstrated a greater benefit for the poly (ADP-ribose) polymerases (PARP) inhibitors, olaparib, and talazoparib, compared to chemotherapy.[10,11] PARPs are enzymes that play a crucial role in the DNA damage repair process. PARP inhibitors block the repair of damaged DNA leading to chromosomal instability, cell cycle arrest, and subsequent apoptosis. In a randomized, open-label, phase III study (OLYMPIAD trial) of patients with germline *BRCA* mutations (g*BRCA* mutations) and human epidermal growth factor receptor type 2 (HER2)-negative metastatic breast cancer who had received no more than two prior chemotherapy

regimens for metastatic disease, treatment with olaparib resulted in a median progression-free survival (PFS) of 7.0 months compared to 4.2 months for patients who received standard chemotherapy.[12] The risk of disease progression or death was calculated to be 42% lower with olaparib monotherapy compared with the standard chemotherapy. The median overall survival in the olaparib arm was 19.3 months versus 17.1 months in the chemotherapy arm (HR = 0.90; 95% CI 0.66-1.23; p=0.513). While this difference was not statistically significant, it is important to note that the trial was not powered to demonstrate an overall survival benefit. Patients receiving olaparib experienced a benefit in global health-related quality of life and a delay in time to deterioration in comparison to those in the chemotherapy arm. Olaparib demonstrated a favorable toxicity profile compared to chemotherapy; the most common adverse reactions (≥20%) in the OlympiAD trial of patients who received olaparib were nausea (58%), anemia (40%), fatigue (including asthenia) (37%), vomiting (30%), neutropenia (27%), respiratory tract infection (27%), leukopenia (25%), diarrhea (21%), and headache (20%). The rate of discontinuation in the olaparib arm was low (5%). Olaparib has received FDA-approval for the treatment of patients with g*BRCA*m, HER2- metastatic breast cancer based on the results of the OLYMPIAD trial.

Data from another phase III study (EMBRACA trial) were presented at the 2017 San Antonio Breast Cancer Symposium (SABCS) and demonstrated clinical benefit of another PARP inhibitor, talazoparib, an investigational agent, in locally-advanced or metastatic breast cancer patients with g*BRCA* mutations who either had responded to platinum-based treatment or had received at least 2 prior lines of nonplatinum chemotherapy.[10] The median PFS of patients treated with talazoparib was 5.6 months versus 2.6 months in those treated in the chemotherapy arm. Talazoparib reduced the risk of disease progression or death by 46% versus chemotherapy in this patient population. Although the data is immature (51% of projected events), the OS read-out presented at the 2017 SABCS showed a median OS of 22.3 months in talazoparib treated patients versus 19.5 months in the chemotherapy arm (HR = 0.76; 95% CI 0.54-1.06; p=0.105. Final OS results are pending. There also was a statistically significant delay in the time to clinically meaningful deterioration in global health status/quality of life with talazoparib versus chemotherapy (HR 0.38 [95% CI 0.26-0.55], p<0.0001), as measured by the EORTC QLQ-C30, a cancer-specific, patient-reported quality of life questionnaire. Talazoparib was generally well tolerated; the most common adverse events observed with talazoparib (any grade in at least 15% of patients) were anemia (52.8%), fatigue (50.3%), nausea (48.6%), neutropenia (34.6%), headache (32.5%), thrombocytopenia (26.9%), alopecia (25.2%), vomiting (24.8%), diarrhea (22%), constipation (22%), decreased appetite (21.3%), back pain (21%) and dyspnea (17.5%). 7.7 % of adverse events resulted in treatment discontinuation in the talazoparib arm. Talazoparib is not currently FDA-approved for any use. Some PARP inhibitors (olaparib, talazoparib, niraparib) are currently being investigated for early-stage breast cancer as well.

Current Trends in *BRCA* mutation testing:

Despite recent evidence supporting the role of *BRCA* 1/2 genetic testing in influencing treatment decisions for breast cancer patients, healthcare providers continue to lack clarity on which patients should be offered genetic testing. For patients with documented breast disease, personal and family history are crucial to generating empiric risk prediction models. Knowledge of the *BRCA* mutation status is also crucial to determine eligibility for clinical trials investigating agents, such as PARP inhibitors, in this specific patient population. Healthcare providers are also unclear about an optimal cut-off for the risk value which can be correlated with an increased percentage of an individual testing positive for a *BRCA* 1/2 mutation. In the absence of clear consensus, ≥10% mutational probability has remained a commonly cited reference point.

Given that *BRCA* mutation status can provide valuable insights when choosing treatment strategies, it is important that all patients with HER2-negative breast cancer undergo *BRCA* testing. Many large academic health centers have cancer risk assessment and counseling programs to provide patients with information about hereditary disease and the process of genetic testing, a personalized risk assessment, and evidence about the benefits, limitations, and risks of genetic testing for genetic mutations. However, community cancer centers may not offer genetic counseling and testing for all patients with breast cancer. According to the National Cancer Institute, over 80% of cancer patients in the United States receive treatment in the community setting. Therefore, it is crucial that the multidisciplinary cancer care teams practicing in community cancer centers are aware of the benefits of *BRCA* testing and are evaluating all their HER2-negative breast cancer patients for *BRCA1* and *BRCA2* mutations.

In a recent survey of community oncology practitioners conducted by ACCC to assess the status of *BRCA* mutation testing for patients with breast cancer, more than 80% of respondents reported that about 50% or less of their patients with early or metastatic breast cancer care have ever had germline *BRCA* mutation testing. Barriers to *BRCA* mutation testing include patient-related barriers (patient fear, patient refusal, concerns for future insurability following genetic testing), challenges with respect to identification of patients who meet criteria, reimbursement for testing and counseling, access to genetic counselors, turnaround time for *BRCA* mutation testing, systems-based challenges related to ordering tests and communicating test results, and lack of clarity regarding the clinical benefits of testing. Significant practice variations were also identified among the respondents in terms of the patients they selected for routine *BRCA* mutation testing. While most respondents indicated that genetic counselors most often ordered *BRCA* mutation testing at their centers, 16% of practitioners did not routinely utilize a genetic counselor. In terms of familiarity with targeted treatment options for patients harboring *BRCA1* or *BRCA2* mutations, 95% of the community practitioners who responded to the survey were at least somewhat familiar with the mechanism of action for PARP inhibitors in patients with metastatic breast cancer harboring *BRCA* mutations, and 67%

of the respondents reported to have prescribed a PARP inhibitor to patients with *BRCA*-mutated metastatic breast cancer.

For the detailed report on the ACCC survey results, please visit www.accc-cancer.org/BRCA-testing

III. Scope

ACCC and Pfizer encourage proposals for quality improvement initiatives focused on improving the rates of *BRCA* mutation testing in patients with breast cancer as recommended by NCCN Guidelines. Proposals should address any barriers that are identified to routine *BRCA* mutation testing in patients with either early or metastatic breast cancer. Quality improvement projects can use any accepted methodology such as PDSA (Plan Do Study Act) cycles, root cause analysis, and other data-driven approaches. Proposals can include continuing education or training for health care professionals. They may be pilot projects or build on already existing pilot projects.

ACCC will gather the outcomes data across all the projects with a goal of disseminating the results from the quality improvement projects to a larger audience. In order to gather consistent metrics across all projects, following notification of grant support, individual grantees will be contacted by ACCC to provide guidance on data collection for their project. Grantees will be required to capture and report this data back to ACCC at the end of the project. ACCC will have regular touch points with the individual grantees to monitor the progress of the projects.

The intent of this RFP is to encourage organizations to submit Letters of Intent (LOIs) detailing concepts and ideas for projects aimed at increasing the rates of *BRCA* testing in appropriate patients with early or metastatic breast cancer and using these data to guide treatment selection, with the goal to improve patient outcomes.

All proposals funded must:

- Be based on guidelines (NCCN or other)
- Promote evidence-based care
- Be sustainable after the award funding is complete
- Collect data and report outcomes, including improved testing rate in early stage BC and MBC settings
- Be flexible enough to address patient variability
- Promote administrative and system efficiency

Successful proposals will have a plan for improving the rates of *BRCA* mutation testing and integrating the results of the mutation testing to the treatment decision-making process.

Specific Areas of Interest:

1. Systems-based challenges related to ordering tests and communicating test results (For example, process improvement by integrating *BRCA* mutation testing into clinical pathways)
2. Access to genetic counselors
3. Turnaround time for *BRCA* mutation testing
4. Patient emotional needs, psychosocial support, and advocacy issues (For example, patient fear, patient concerns for future insurability following genetic testing)
5. Coordination of care within the multidisciplinary cancer care team

IV. Letters of Intent/Proposals

This RFP model employs a 2-stage process: Stage 1 is the submission of the 3-page LOI. If an LOI is selected, the applicant will be invited to Stage 2 to submit a full program proposal. Successful applicants will be able to describe the specific clinical practice gaps that exist for their own providers, health care system, or patient community and describe what they will do to close these gaps or problems. Site-specific obstacles to success should be identified and coupled with strategies to overcome the obstacles.

Programs must describe how the intervention, when implemented, will directly affect patient care and provide evidence of sustainability (e.g., integration with an electronic medical record system), scalability (e.g., plan for dissemination/applicability beyond the proposed institution), and can be completed within the timeframe specified.

Researchers seeking funding for clinical research projects will not be considered under this RFP.

The ACCC Peer Review of Proposals Committee (PRPC) has been formed to oversee this process and will utilize a formalized review procedure to accept LOIs and subsequently select the proposals of highest scientific merit. The ACCC PRPC has overseen the development of the RFP and will perform the peer review of applications.

The members of the ACCC PRPC are as follows:

Lillian Shahied Arruda, Ph.D., Medical Director, Women's Oncology, US Medical Affairs, Pfizer Inc.

Robert Buras, MD, Breast Surgeon, Anne Arundel Medical Center

Julie R. Gralow, MD, Jill Bennet Endowed Professor of Breast Medical Oncology and Professor of Global Health, University of Washington School of Medicine; Director, Breast Medical Oncology, Seattle Cancer Care Alliance

Joy Larsen Haidle, MS, LGC, Genetic Counselor, North Memorial Health

Timothy J. Pluard, MD, Director, Saint-Luke's Cancer Institute, Koontz Endowed Chair in Breast Disease, University of Missouri – KC School of Medicine

Lillie D Shockney, RN., BS., MAS, ONN-CG, University Distinguished Professor of Breast Cancer, Adm Director, the Johns Hopkins Breast Center Director, Johns Hopkins Cancer Survivorship Programs; Professor of Surgery and Oncology, JHU School of Medicine; Co-Creator, Work Stride-Managing Cancer at Work

Imee Unto, RN, MSN, OCN, Regional Administrator, Adventist Cancer Institute, Adventist Health System; Regional Administrator of the Oncology Service Line, Florida Hospital Central Division, North Region

Kari B. Wisinski, MD, FACS, Associate Professor of Medicine, Director of Medical Oncology Inpatient Service, University of Wisconsin Carbone Cancer Center

V. Requirements

Date RFP Issued:	Thursday, May 17, 2018
Clinical Area:	Breast Cancer
Target Audience:	Members of the health care team and administrators involved in the care of breast cancer patients
Applicant Eligibility Criteria:	ACCC member community hospital-based programs and physician group practices
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to $150,000 will be considered. The grant amounts requested must be proportional to the impact of the grant. For example, costs would be expected to be higher for multiple-site versus single-site projects. Smaller, lower-cost projects are strongly encouraged.
Estimated Key Dates:	LOI Deadline: June 26, 2018 Please note the deadline is 5:00 pm Eastern Time (New York, GMT -5). Anticipated LOI Notification Date: July 31, 2018 Full Proposal Deadline: September 28, 2018, * *Only accepted LOIs will be invited to submit full proposals. Please note the deadline is 5:00 pm Eastern Time (New York, GMT -5).

	Anticipated Full Proposal Notification Date: November 27, 2018 Grants distributed following execution of fully signed Letter of Agreement Period of Performance: January 2019 to December 2020 (2 year project maximum; projects may be shorter)
How to Submit:	Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click "REGISTER NOW". Select the following Area of Interest: Breast Cancer - Increasing Rates of *BRCA* Testing Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix). If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page. IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee. Questions: If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Jacqueline Waldrop (Jacqueline.Waldrop@pfizer.com) or to the ACCC at resources@accc-cancer.org, with the subject line "RFP - Increasing Rates of *BRCA* Testing in Patients with Breast Cancer"
Mechanism by which Applicants will be Notified:	All applicants will be notified via email by the anticipated dates noted above. Applicants may be asked for additional clarification or to make a summary presentation during the review period.

VI. Terms and Conditions

1. This RFP does not commit Pfizer or its partners to award a grant or a grant of any size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.

2. Pfizer reserves the right to accept or reject any or all applications received as a result of this request or to cancel this RFP in part or in its entirety, if it determines it is in the best interest of Pfizer to do so.

3. For compliance reasons and in fairness to all applicants, all communications about the RFP must come exclusively to Pfizer at the email address IGLC@Pfizer.com. Applicants should not contact other departments within Pfizer regarding this RFP. Failure to comply will disqualify applicants.

4. Complete Pfizer RFP Terms and Conditions are available for your review at www.pfizer.com/files/PfizerIGLC_RFP_TermsandConditions_2017Apr.pdf

VII. Appendix: Letter of Intent Submission Guidance

LOIs should be single-spaced using Calibri 12-point font and 1-inch margins. There is a 3-page limit for the main section and a 1-page limit for organizational detail. If extensive, references may be included on 1 additional page. Final submissions should not exceed 5 pages in total (3 pages for the main section, 1 page for organizational detail, and 1 page for references). LOIs not meeting these standards will not be reviewed. It is helpful to include a header on each page listing the requesting organization.

All required sections should be combined in one document (MS Word or Adobe PDF). There is no need to submit the organization detail or references in a document separate from the main section of the LOI.

Please note the formatting and page limit for the LOI. The LOI is inclusive of additional information of any kind. A submission exceeding the page limit WILL BE REJECTED and RETURNED UNREVIEWED.

LOIs should include the following sections:

Main Section (not to exceed 3 pages):

A. Title

B. Project Classification

1. There are multiple project types that are eligible for funding through this RFP. Please indicate which of the following best represents your project. More information on these

classifications can be found in the Decision Matrix posted on the Tips & Templates tab on the IGLC website.

- Dissemination and Implementation (D&I) Research
- Quality Improvement – **Preferred for this RFP**
- Education or Educational research

2. Background Information

- It is expected that D&I research projects follow generally accepted principals. For all research projects, the institution(s) must agree to assume all responsibilities as sponsor of the study as outlined in the proposal. These are listed in the RFP Terms and Conditions (#9).
    - At the time of approval of a full proposal, applicants will be required to sign a research contract, submit IRB approval and a research protocol.
- Quality improvement projects should be described in terms of generally accepted principles of improvement science such as those described by the IHI model for improvement or LEAN.
    - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.
- Educational projects should be planned using generally accepted principals of adult learning. More information on principals of learning and behavior change for health professionals can be found at www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf.
    - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.

C. Goal and Objectives

1. Briefly state the overall goal of the project. Also, describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s).

2. List the overall objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.

D. Assessment of Need for the Project

1. Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), or a project starting point (please cite data on gap analyses or relevant

patient-level data that informs the stated objectives) in your target area. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information. Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis, if appropriate.

E. Target Audience

1. Describe the primary audience(s) targeted for this project. Also, indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your sample population.

F. Project Design and Methods

1. Describe the planned project and the way it addresses the established need

2. If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.

G. Innovation

1. Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.

2. Describe how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.

H. Evaluation and Outcomes

1. In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data.

2. Quantify the amount of change expected from this project in terms of your target audience.

3. Describe how the project outcomes will be broadly disseminated.

I. Anticipated Project Timeline - Projects must complete in two years

J. Requested Budget

1. A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable.

2. The budget amount requested must be in U.S. dollars (USD).

3. While estimating your budget please keep the following items in mind:

• Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel.

• Pfizer does not provide funding for capital equipment.

• May not underwrite the entire cost of an electronic health record.

• May not include costs of buying already developed software or clinical care pathways.

• The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.

• It should be noted that grants awarded through IGLC cannot be used to purchase therapeutic agents (prescription or non-prescription).

• Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.

K. Additional Information

If there is any additional information you feel Pfizer or ACCC should be aware of concerning the importance of this project, please summarize it in within the page limitations.

Organizational Detail (not to exceed 1 page)

Describe the attributes of the institutions/organizations/associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project. Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.

Please note that any project partners listed in this section should also be listed within the online system. Tax-IDs of partner organizations will be requested when entering this information. If a partnership is only proposed, please indicate the nature of the relationship in the Organizational Detail section of your LOI.

References

1. Howlader N, Noone AM, Krapcho M, et al (eds). SEER Cancer Statistics Review, 1975-2014, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2014/, based on November 2016 SEER data submission, posted to the SEER web site, April 2017.
2. Kleibl Z, Kristensen VN. Women at high risk of breast cancer: Molecular characteristics, clinical presentation, and management. Breast 2016. Aug 28: 136-44.
3. Arpino G, Pensabene M, Condello C, et al. BMC. Cancer. 2016; Tumor characteristics and prognosis in familial breast cancer. BMS Cancer 2016;
4. van der Groep et al. J Clin Pathol 2006; 59(6): 611-617
5. Genetic/familial high-risk assessment: Breast and ovarian. NCCN clinical practice guidelines in oncology. Version 1.2018. Released Oct 3, 2017, accessed on Dec 1, 2017. All rights reserved.
6. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 1.2018. 03/30/18 © National Comprehensive Cancer Network, Inc. 2018. All rights reserved.
7. Van Sprundel TC, et al. Risk reduction of contralateral breast cancer and survival after contralateral prophylactic mastectomy in *BRCA1* or *BRCA2* mutation carriers. Br J Cancer. 2005; 93:287–292.
8. Ramaswami R, Morrow M, and Jagsi R. Contralateral Prophylactic Mastectomy. N Engl J Med 2017; 377: 1288-91.
9. Chappuis PO, Goffin J, Wong N, et al. A significant response to neoadjuvant chemotherapy in *BRCA*1/2 related breast cancer. J Med Genet 2002; 39: 608-10.
10. Litton J, et al. EMBRACA: A phase 3 trial comparing talazoparib, an oral PARP inhibitor, to physician's choice of therapy in patients with advanced breast cancer and a germline *BRCA* mutation. SABCS 2017, GS6-07.
11. Robson M, et al. Olaparib for metastatic breast cancer in patients with a germline *BRCA* mutation. N Engl J Med 2017; 377: 523-533.
12. Robson ME, Im S-A, Senkus E, et al. OlympiAD final overall survival: Olaparib versus chemotherapy treatment of physician's choice (TPC) in patients with HER2-negative metastatic breast cancer (mBC) and a germline *BRCA* mutation. Presented at: American Association for Cancer Research Annual Meeting, April 14-18, 2018, Chicago, IL. Abstract CT038.