A. Cover Page

Project Title: EMBRACE (Ending Metastatic Breast Cancer for Everyone): A Comprehensive Approach to Improve the Care of Patients with Metastatic Breast Cancer

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ABSTRACT:
Overall goal: In contrast to early breast cancer, the quality of care for patients with metastatic breast cancer (MBC) has been relatively understudied. Little attention has been focused on leveraging the strengths of academic and community-based settings to provide optimal care for patients. Our overall goal is to advance the care of patients with MBC by designing and implementing a comprehensive program that combines clinical care, clinical research, physician engagement, and patient education.
Target Populations: 1) Academic breast medical oncology providers based at Dana-Farber Cancer Institute (DFCI), 2) Referring physicians, and 3) Patients with MBC seen at least once at DFCI.
Methods: We will build upon an existing, IRB-approved, prospective, longitudinal study that collects clinical data and bio-specimens in patients with MBC, and includes consent for tracking and re-contact. Each patient will be assigned an "EMBRACE navigator" who will facilitate care coordination through the continuum of care (including the interface between academic and referring oncologists), clinical trial matching, and psychosocial needs assessment. We will provide focused education and resources to both academic and community providers regarding standard of care approaches and clinical trial opportunities. We will provide an expanded program of communication, education, and supportive care resources for patients.
Assessment: We will utilize a variety of metrics to assess the proposed program, including the proportion of patients who return for ongoing consultation, referral/enrollment for molecular testing and clinical trials, and awareness of and use of supportive care resources. Using survey-based methods, we will assess patient and provider knowledge and satisfaction.

B. Table of Contents

C. Reviewer comments

Not applicable; no comments received

D. Detailed Proposal

D.1. Overall Goal & Objectives. Our overarching goal is to provide patients who have metastatic breast cancer (MBC) with individualized, high quality care beyond the traditional reach of an academic cancer center. In order to achieve this goal, we propose to design and implement a comprehensive program that combines clinical care, clinical research, provider engagement, and patient education and outreach in order to advance the care of current and future patients with metastatic breast cancer. While the proposed program will be based at Dana-Farber Cancer Institute (DFCI), we believe our approach has the potential for an impact far beyond the local/regional area by serving as a model for enhanced academic-community-patient partnerships more broadly.

Our proposed project aligns well with the missions of the National Comprehensive Cancer Network (NCCN) and Pfizer Independent Grants for Learning & Change (IGLC), and is in keeping with the focus of the RFP, that is, the design and implementation of programs to close clinical practice gaps and improve the quality of care for patients with MBC. In particular, we will focus on gaps in clinical practice related to clinician factors (e.g. knowledge of the most recent advances and standard of care in breast cancer treatment, barriers to clinical trial enrollment including knowledge of trial options and barriers to molecular testing and screening of patients for marker-specific trials, and familiarity with supportive care resources), patient factors (breast cancer knowledge, knowledge and use of supportive care resources, participation in shared decision-making, understanding of clinical trials), and health system factors (e.g. coordination between academic and community-based providers, access to clinical trials). We believe that our proposed interventions will allow patients to receive the best treatments at the optimal time in the optimal location.

In order to accomplish these goals, we will focus on the following specific aims:

- **Specific Aim 1.** To enhance the longitudinal care of patients with MBC seen at DFCI, through support and engagement of DFCI-based, multidisciplinary providers to deliver the most promising, individualized, high quality care.
- **Specific Aim 2.** To develop a robust, seamless, collaborative care model between DFCI-based providers and referring providers that will provide enhanced educational opportunities, communication, and opportunities for shared patient care.
- **Specific Aim 3.** To enhance quality of life and satisfaction with care and to facilitate shared decision-making among patients with MBC, with a combination of personalized follow-up, educational programs, and supportive care resources.

D.2. Background

D.2.1. Introduction. Breast cancer accounts for approximately 40,000 deaths in the United States per year, and over 500,000 deaths per year globally.[1] In contrast to early breast cancer, the quality of care for patients with metastatic breast cancer has been relatively understudied, as have interventions to improve care in the real-world setting.

Because of geographic, financial, and insurance-based considerations, the majority of cancer patients in the United States are seen in community settings. Community oncologists have considerable experience and can provide patients who have a life-threatening illness with the convenience and quality of life benefit of care closer to home with a skilled provider. Academic oncologists provide a deep level of disease-specific expertise and access to a wider selection of clinical trials. The current model in the U.S. generally results in three groups of patients: those cared for exclusively in community-based practices; those cared for exclusively in academic practices; and those who are cared for in the community with ad hoc consultations in academic cancer cancers. Only a small proportion of patients in the U.S. are cared for primarily within academic breast cancers; this has limited the diffusion of expertise and adversely affects clinical trial accrual and clinical-translational research. In addition, ad hoc consultations in academic practices are of variable utility because robust tracking and communication systems typically do not exist to maximize the value of academic-community partnerships. Harnessing the combined strengths of these two settings, together with patient empowerment through enhanced educational opportunities and supportive care resources has the potential to transform the delivery of care to patients with metastatic breast cancer, and if successful, be translated to other cancer types.

D.2.2. Variations in Oncologic Care for MBC in the United States. The existing data are concerning for significant variations in the care that patients receive, including variations in care concordant with national and international guidelines for standard-of-care treatments, and with respect to access to clinical trials. For example, among patients with hormone receptor-positive breast cancer, despite unanimity among national and international guidelines regarding the use of endocrine therapy, an analysis of nearly 20,000 women included in the MarketScan databases (2002-2012) indicated that only 60% were treated with first-line endocrine therapy, and only about one-quarter received a second-line endocrine agent.[2-4] With respect to HER2-positive breast cancer, among patients presenting with de novo stage IV breast cancer within SEER-Medicare, black race was associated with longer median time to trastuzumab initiation and lower likelihood of continuation of HER2-directed therapy over time. Of note, in this dataset, black patients with inferred HER2-positive breast cancer (based on trastuzumab use) also experienced significantly shorter median overall survival (1.3 years versus 2.7 years for black and white women, adjusted hazard ratio [HR] 1.45; 95% Confidence interval 1.01-2.08).[5] Collectively, the data support the need for enhanced educational and collaborative efforts to disseminate clinical practice guidelines, to speed the adoption of practice-changing discoveries, and to optimize patient care.

D.2.3. Barriers to Clinical Trial Participation. One of the results of the highly decentralized health structure in the United States is a low participation rate in clinical trials. It is estimated that less than 2% of adult cancer patients participate in clinical trials in the U.S.[6] The causes of low participation rates are multifactorial and include financial and insurance barriers, lack of patient awareness of trial options, misconceptions about clinical trials, and lack of physician awareness of trial options. Comis and colleagues surveyed nearly 6,000 adult cancer patients and reported that 85% were unaware of clinical trials.[7] Among the small fraction of patients who were aware of trials, clinical trial participation rate was 25%, far higher than the 2% rate that has been reported nationally. Notably, physician awareness of trials and encouragement

for trial participation were major factors distinguishing patients who did and did not participation in clinical trials.

D.2.4. Limitations of Available Patient Resources. A cancer diagnosis is stressful for most people and can be even more difficult for those with advanced disease. Accurate and realistic information helps patients prepare for threatening events and may lead to less emotional distress and better outcomes. A lack of information may negatively affect both decision making and quality of life. Patients with metastatic breast cancer have expressed feelings of being isolated and alone, and in need of accurate, in-depth information about their disease, treatment options, and approaches to symptom management.[8] Unfortunately, historically, much of the educational and supportive resources for women and men with breast cancer have focused on those with early-stage disease.

D.2.5. Current Assessment of Need in Target Area

Our overall goal is to provide the highest quality to care to patients with metastatic breast cancer and to extend the reach of our expertise beyond the traditional walls of an academic cancer center. To achieve this goal, we need to a) ensure the delivery of the most cutting-edge and compassionate care to patients seen at our academic institution, b) partner effectively with referring providers in order to allow patients to receive care at their preferred location while maintaining access to the expertise and clinical trial access at DFCI, c) partner with patients and patient advocates to develop and provide educational and supportive care resources that meet their needs. As a starting point, we have generated the following baseline data in order to identify gaps and barriers and to direct our efforts in the proposed project.

D.2.5.1. Variations in Care Provided to MBC Patients at DFCI. While we strive to provide the highest quality care to patients seen at our institution, we are aware that there is variation in the patient experience depending upon a number of factors, including the patient's medical team (MD, NP, PA, and RN), personal preferences, demographic, geographic, and financial factors, and overall health. While some degree of variation is desirable and is consistent with personalized care, other variation is the result of a lack of education, coordination and support. For example, with respect to clinical trials, we have identified a 10-fold difference in yearly accrual to therapeutic clinical trials by medical oncology provider that cannot be solely explained by differences in clinical volume or patient and/or tumor characteristics between providers. We also do not have a consistent approach to the common scenario of patients who would like to maintain the majority of their oncologic care locally, yet retain a connection to DFCI for advice at times of disease progression, in the case of significant symptom burden, or for consideration of clinical trials. Most commonly, DFCI-based oncologists ask patients and/or referring physicians to take on the task of scheduling return visits on an ad hoc basis, but there is not proactive reaching out to patients or referring providers on an ongoing, prospective basis. Finally, we have found that patients have significant knowledge gaps regarding the course and treatment of metastatic breast cancer (yet are very eager to close these gaps) and are also variably aware of the supportive care services available to them. We believe that these practice gaps offer a tremendous opportunity to improve the care we deliver to patients with metastatic breast cancer.

D.2.5.2. Survey of DFCI-based Medical Oncologists. We conducted a survey of medical oncologists who practice in the Breast Oncology Center at DFCI to understand the current state of the care offered to metastatic breast cancer patients and to identify areas for intervention.

Four main areas were covered in the survey: 1) quality and ease of communication with referring providers, 2) overall satisfaction with initial consultation and re-consultation, and 3) knowledge and use of clinical trial options, testing of markers for trial eligibility, and patient educational and supportive care resources, and 4) barriers to a collaborative care model with referring physicians. The response rate was high (92%). The survey highlighted key areas of improvement in our personal communication with referring providers where access to alternate modes of contact with these providers may prove to be helpful. In addition, 30% of oncologists stated that they were only 'slightly satisfied' with timing of initial consultation (e.g. occurring at appropriate time in a patient's disease course) and the availability of scans and records at time of consultation. Indeed, many oncologists reported that patients were frequently seen in consultation only after having received 3 or more lines of therapy for metastatic disease in the community. During consults, about 80% of the surveyed oncologists state they discuss clinical trial options; however the use of molecular testing was lower. Less than half routinely discussed supportive care and educational resources with their patients. In terms of knowledge of various resources for MBC patients, 95% of oncologists reported 'good to excellent' knowledge in regards to clinical trials and 86% for DFCI-based supportive care resources. Knowledge on educational resources was lower than expected (with about 40% reporting 'poor to fair' knowledge). Over 86% and 76% of surveyed oncologists, respectively, felt that inadequate administrative support and lack of a patient tracking system to be barriers in implementing a collaborative care model.

D.2.5.3. Key Informant Interviews with Referring Providers. We have begun key informant issues of referring providers to the Breast Oncology Center at DFCI (Table 1). The structured interviews cover three main areas: motivations for referring patients to DFCI, the experience with communication and collaboration, and their perceived patient experience. We anticipate that we will complete the interviews and analysis over the next 3 months. Initial themes based on preliminary analysis include: a) interest in access to clinical trials and knowledge of newer therapies as a prime motivator for referrals; b) importance of personal connection and communication in building and sustaining the relationship with referring providers; and c) wide variation in follow-up communication with referring provider across DFCI provider.

Table 1. Selected Quotations from Initial Key Informant Interviews

"Personal connections and knowing who to call make for an excellent experience."
"When I have to use the general number I have a less positive experience."
"Providers don't always get right back to the referring MD-it is very provider dependent"
"I think that it will help me ensure that my patients have full access to important clinical trials."

D.2.5.4. Survey of MBC Patients seen at DFCI. We conducted a cross-sectional, self-administered paper survey in our institution's outpatient oncology clinic.[9] We focused on adult patients (n=52) who had been diagnosed with metastatic breast cancer within the preceding 12 months. The survey included patient demographics, the Toronto Informational Needs Questionnaire-Breast Cancer (TINQ), the Hospital Anxiety and Depression Scale (HADS), and Medical Outcomes Study Short Form-36 (SF-36). High informational need was defined as a TINQ score >/=200. We found that 69% of patients had high informational needs; 20% met the criteria for anxiety, and 8% met the criteria for depression. With respect to informational

needs, we found that patients strongly desired treatment information, information about the disease, and management of side effects (Table 2).

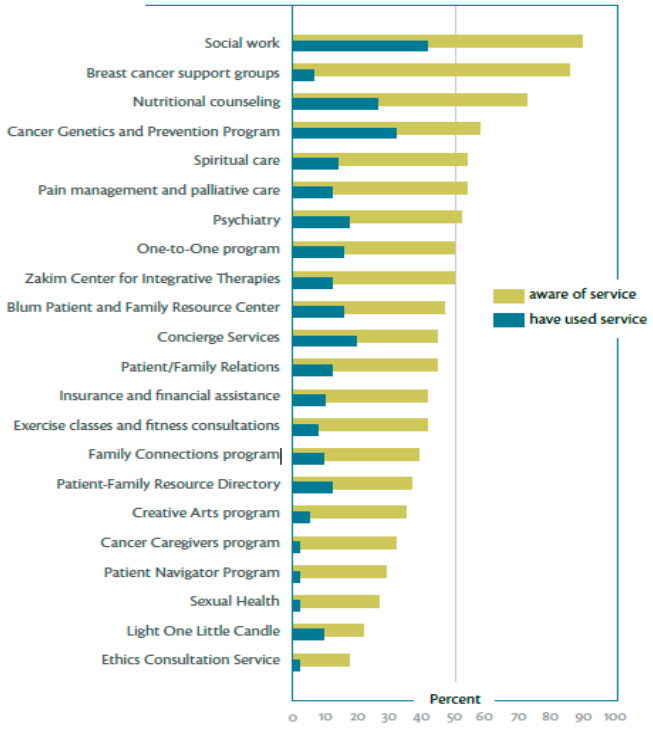
Table 2. Most important information as perceived by patients*

Rank	Question	Category	Mean Score	SD
1	If there is cancer anywhere else in my body	Disease	4.78	0.636
2	If I have side effects, how to deal with them	Treatment	4.78	0.456
3	If there are ways to prevent treatment side effects	Treatment	4.77	0.421
4	Who I should call if I have questions while I am still getting treatment	Treatment	4.73	0.485
5	What types of treatment are available	Treatment	4.73	0.563
6	Why the doctor suggested this treatment plan for me	Treatment	4.73	0.629
7	How to prepare for my treatment	Treatment	4.71	0.497
8	If the breast cancer will come back	Disease	4.67	0.809
9	The possible side effects of my treatment	Treatment	4.67	0.548
10	What side effects I should report to the doctor/nurse	Treatment	4.67	0.676

**Patients were asked to rank how important this information was on a 5-point Likert scale on which 1=not important and 5=extremely important. Means scores are reported here.*

We also surveyed patients on their awareness of and use of a variety of supportive care services. We found that although there was a high level of awareness of social workers, support groups, and nutritional counseling, there was much less awareness of the availability of pain and palliative care services, psychiatry, integrative medicine, the family connections program, and a number of other important programs (Figure 1). In addition, while around 40% of patients accessed social work services, a smaller proportion accessed other available services. Notably, among patients who accessed each of the services, the satisfaction level was high (data not shown).

Figure 1. Awareness and Use of Supportive Care Services among Patients with Metastatic Breast Cancer in the EMBRACE research cohort



Based on the informational needs we identified, we initiated a series of annual Metastatic Breast Cancer Forums. We conduct attendee surveys after each forum and adjust the content of the following year's event as well as interim web-based and other resources according to feedback. A high-level summary of the survey results are listed in Table 3. A selection of attendee written feedback is included in Table 4. Of note, 99% of attendees indicated they would recommend the event to another patient. In addition, selected talks from the event are available on-line and have each generated over 2,000 page views.

Table 3. Results of Attendee Survey after the 3rd Annual Metastatic Breast Cancer Forum

Item	% who found the session valuable
Overall event	98%
Research advances and clinical trials	95%
Special session on integrative oncology	75%
Learning about what happens to tissue	58%
Opportunity to meet with staff	49%
Opportunity to meet other patients	49%

Table 4. Selected Quotations from Patients after the 3rd Annual Metastatic Breast Cancer Forum

"There is so little support for MBC patients. This has been wonderful and I would love to see it continue."
"I think we feel that only survivors are embraced especially in October. Thank you so much."
"I learned about resources I may need in the future. It was encouraging to learn about the research."
"Thank you for doing this—it was deeply meaningful for me."

We believe that we have demonstrated a clear need for enhanced patient education, outreach, and supportive care services. Support from the NCCN will allow us to further expand and enhance our offerings, as well as to provide a more personalized patient experience via the establishment of an EMBRACE patient navigator who will be paired with every MBC patient seen in our practice, if the patient consents.

D.3. Target Audience

Our proposed project comprises three target audiences:

- Medical providers within the Breast Oncology Center at Dana-Farber Cancer Institute, including medical oncologists (MO), nurse practitioners (NP), physician's assistants (PA), and nurses (RN)
- Referring physicians, defined as medical oncologists who care for patients with metastatic breast cancer and with whom care could potentially be shared
- Patients with metastatic breast cancer who have at least one consultation visit with a DFCI provider.

D.3.1. Level of commitment from potential participants. As demonstrated in our needs assessment, there is a great desire and commitment by DFCI-based oncology providers to further improve the quality of care delivered to MBC patients. Furthermore, our proposal aligns with the goals of DFCI as a whole, and there is significant institutional incentive to encourage participation among DFCI-based providers. All DFCI-based providers who interact with MBC patients may be included in some or all of the quality initiatives outlined in this proposal. For medical oncology, all medical providers (MD, NP, PA, RN) will participate in educational programs designed to review the latest advances that may impact standard-of-care, and will participate in clinical trial training sessions. MD, NP/PA, and RNs will also receive additional training regarding the proposed collaborative care model and logistics. All DFCI-based providers in the Breast Oncology Center will have the opportunity to offer feedback and to actively participate in the planning and implementation of the initiatives described in our proposal.

We are in the process of conducting key informant interviews with referring physicians. We anticipate a moderate level of commitment that will increase over time as our proposal is rolled out. Specifically, our goal is to build a model that serves patients well and that optimizes collaborative care between referring physicians and DFCI-based medical oncologists. We anticipate that participating in such a program will allow referring physicians to increase their satisfaction with the consultation process at DFCI, strengthen relationships with DFCI-based providers, and expand the trial options available to their patients, while maintaining responsibility for the primary oncologic care of the majority of their patients, and thus provide a strong incentive for participation.

Based on the attendance at our annual Metastatic Breast Cancer Forum, results of our patient needs survey, and interest in our web-based materials (as assessed by page-views), we believe that patients will be highly motivated to participate in the proposed program. Currently, we approach patients with metastatic breast cancer for our EMBRACE prospective research cohort (DF/HCC IRB #09-204, PI: Nancy Lin), and the consent rate is extremely high (>95%) among approached patients. To date nearly 1,000 patients with metastatic breast

cancer have been enrolled in this prospective study that includes consent to biobanking, collection of detailed linked clinical data, receipt of patient education materials, permission to approach for surveys and additional studies, and consent for tracking by a clinical research coordinator. Of note, among the first ~300 patients enrolled onto the EMBRACE study, 60% had participated in at least one therapeutic clinical trial, further supporting the highly motivated nature of our target patient population. We anticipate that patients will be even more motivated to participate in the proposed EMBRACE clinical program (compared to the EMBRACE research cohort) given the potential for direct clinical benefit. Of note, the EMBRACE clinical program will be complementary and synergistic with our existing EMBRACE research cohort study. Patients will not be required to consent to the EMBRACE research cohort in order to participate in the EMBRACE clinical program. Finally, we plan to actively seek patient and patient advocate input in order to ensure the relevance of our offerings and effectiveness of our intervention, and we believe this will further strengthen the level of commitment of this group.

D.3.2. Scope of target audience

D.3.2.1. DFCI-based providers: The Breast Oncology Center at DFCI comprises 29 medical oncologists, 12 advanced practitioners (e.g. NP or PA), 5 research nurses, and 7 program nurses.

D.3.2.2. Referring physician network: Dana-Farber is the leading academic referral center in the New England area, and draws referrals from Massachusetts, New Hampshire, Maine, Rhode Island, New York, and Connecticut, as well as nationally and internationally.

D.3.2.3. Patients: The Breast Oncology Center at DFCI sees over 300 new patients with breast cancer each month. Of these, approximately 40 patients per month (~400-500 patients per year) carry a diagnosis of metastatic breast cancer. The existing EMBRACE research cohort (details under Project Design and Methods, below) already includes nearly 1,000 patients with metastatic breast cancer who have been seen at least once at DFCI since the study began in 2009. Excluding patients who present for one-time consultations only, at any one time, DFCI oncologists care for an active panel of approximately 600 patients with metastatic breast cancer.

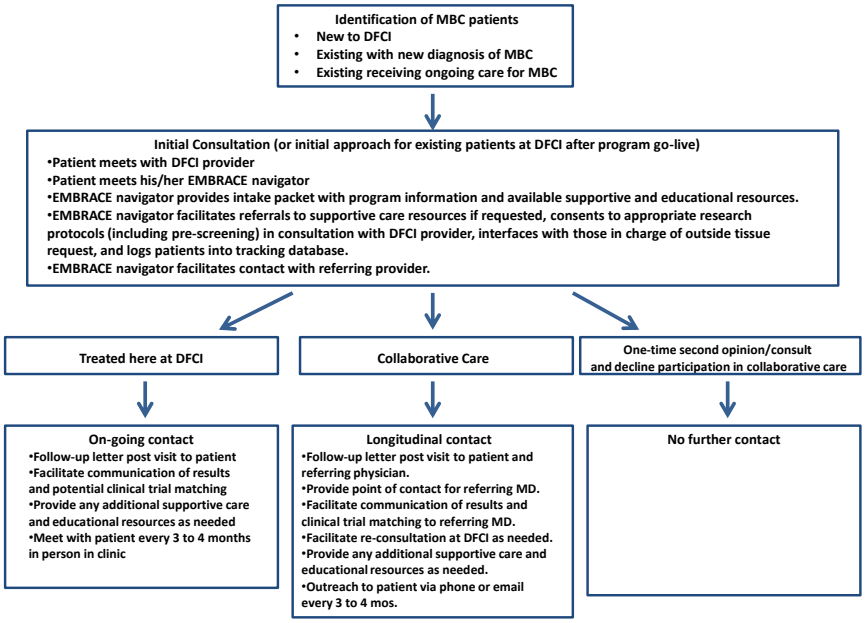
D.3.3. Potential benefits. We anticipate that each of the target audiences (DFCI providers, referring providers, and patients seen at DFCI) will directly benefit from the proposed interventions. In addition, we anticipate that the model of collaborative care that we are proposing can be replicated and/or expanded by other academic institutions and serve as a model of outreach to the community. With respect to patients, many of the enduring materials we create (e.g. webcasts, videos of forum lectures, educational materials) will be made available on-line and potentially benefit patients without a direct connection to DFCI.

D.4. Project Design and Methods

D.4.1. Overview of strategy, methodology, and analysis. Our overall strategy is to develop a unified, consistent, and comprehensive intake process and follow up approach for patients with metastatic breast cancer seen at least once at DFCI (Figure 2). We believe that our approach will allow us to achieve our specific aims of enhancing the longitudinal care we provide at DFCI, developing a robust collaborative care model with referring physicians, and maximally supporting patients with respect to educational and supportive care resources. A key component of our approach is the creating the position of an EMBRACE navigator. Each

navigator will take on a discrete patient panel, for whom they will be responsible for providing both clinical support and research support, to clinicians and to patients. We will also create patient intake materials, patient outreach materials, referring provider outreach materials, and educational materials for both patients and providers. Overall, the proposed project represents an original strategy within our group and does not duplicate other projects or materials already developed.

Figure 2. Flow Diagram of Proposed Patient Intake and Follow up Process



D.4.2. Specific Aim 1. Our first aim is to enhance the longitudinal care of patients with MBC seen at DFCI, through support and engagement of DFCI-based, multidisciplinary providers to deliver cutting-edge, individualized, high quality care. To accomplish this, we will focus on three main practice gaps:

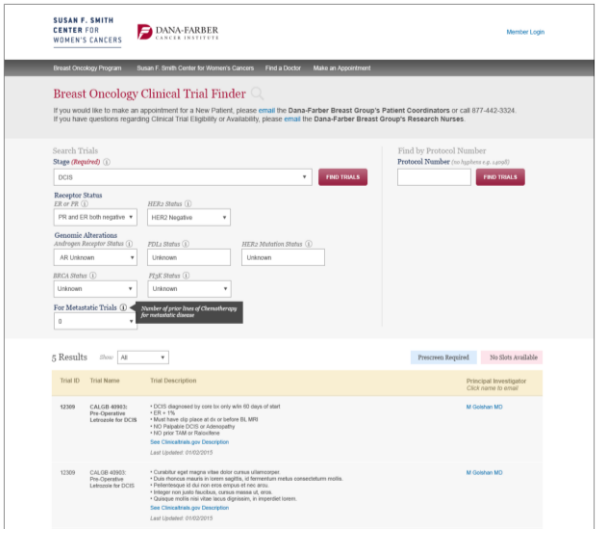
- Challenges in molecular testing for clinical trial eligibility
- Barriers to clinical trial enrollment
- Familiarity with supportive care resources

D.4.2.1. Support for molecular testing/pre-screening. An increasing number of trials require molecular testing upfront to determine whether a patient's tumor expresses particular markers and/or harbors specific genetic alterations. Such tests ideally will occur early in a patient's disease course, when possible, to allow time for tissue to be requested (often from outside pathology laboratories) and testing to be completed while a patient remains stable on their current regimen. This reduces time pressure for results for clinical decision-making and reduces the likelihood that patients will not be able to participate in trials because of the urgency in moving to next line of therapy at time of progression. We have already put into place a rudimentary infrastructure to aid clinicians in identifying potential candidates for pre-screening and to request tissue and manage results. However, creation of an EMBRACE navigator will allow for more personalized interactions with both clinicians and patients, and streamline the

prescreening process considerably. Each EMBRACE navigator will be assigned to a subset of physicians within our group, and to the patient panel of these physicians. He or she will be responsible for reviewing clinic schedules on a weekly basis and for working with the medical oncologist and mid-level providers (NP, PA) in identifying patients with metastatic breast cancer for whom a prescreening test is available and who would be appropriate to approach. Though it will remain the primary responsibility of the medical oncologist to discuss and consent patients, the EMBRACE navigator will facilitate consent and testing of patients by providing patient education, preparing consent documents, and coordination tissue requests and testing. The EMBRACE navigator will then collate results of prescreening tests (which, as research tests, generally cannot be directly placed into the medical record) so that they are readily available to the clinician upon request and in real time.

D.4.2.2. Clinical trial matching. We already review trials at a monthly clinical research meeting and at bi-monthly staff meetings which are attended by MD, NP, PA, and research RN, and will continue to do so moving forward. However, with an ever-increasing number of trials, complex eligibility requirements, and fluid slot availability, identifying the right trial at the right time for individual patients is increasingly difficult. We have previously developed a basic clinical trial "tracker" that allows clinicians to input key variables, such as ER, PR, and HER2 status, and number of lines of prior chemotherapy (www.dfcibreasttrials.org) (Figure 3). An innovation within the tracker compared to other matching websites already available on the web, is that it is continually (though manually) updated with matching protocols as well as slot availability. Recently, we have released a public-facing version of this basic tracker. Clinicians at DFCI can then access full protocol documents through our internal OncPro system. This two-tier system (public, outward facing tracker with matching algorithm and brief synopsis of trial design and key eligibility criteria; and internal website with detailed protocol documents) allows for broader access to trial options while maintaining confidentiality, when needed, of protocol documents. Response to the tracker has been uniformly positive. We will train both providers as well as the EMBRACE navigator in the use of this tool. The EMBRACE navigator will interact with research nurses and clinical research coordinators to assess slot availability and to facilitate the process of clinical trial matching.

FIGURE 3. Current clinical trials tracker (left panel) and proposed enhanced tracker (right panel)



D.4.2.3. Education and access to supportive care resources. As part of our needs survey, we identified gaps in provider knowledge with respect to supportive care resources available through DFCI, regionally, and via the internet. We plan to provide ongoing enhanced education at bimonthly staff meetings to improve awareness among providers. In addition, one of our goals is to empower patients. We will train the EMBRACE navigator and provide him/her with information, materials, and resources to share with both patients and providers in order to facilitate increased use of supportive care resources as need and appropriate.

D.4.3. Specific Aim 2. Our second aim is to develop a robust, seamless, collaborative care model between DFCI-based providers and referring providers that will provide enhanced educational opportunities, communication, and opportunities for shared patient care. To accomplish this, we will focus on three main practice gaps:

- Lack of infrastructure to support communication and teamwork between DFCI-based oncologists and referring providers
- Familiarity with the most recent advances in metastatic breast cancer management
- Knowledge of clinical trial opportunities

D.4.3.1. Initial consultation. The EMBRACE navigator will be responsible for facilitating communication between DFCI-based providers and referring providers. This will be accomplished by creating a comprehensive directory of referring providers and preferred mode of contact, a cover letter to the consultation letter explaining the collaborative care model (if a patient expresses interest in a shared care approach), a summary of any molecular testing ordered, and other information deemed important in the care of the patient.

D.4.3.2. Ongoing contact. The EMBRACE navigator will be responsible for facilitating interactions with referring providers and facilitating re-consultations as clinically appropriate. The navigator will work with administrative staff to ensure timely and complete receipt of medical records prior to re-consultation visits in order to maximize the value of such visits, facilitate communication from the referring provider to DFCI based provider ahead of visits, and

optimal communication back out to referring providers from the DFCI based provider at the conclusion of re-consultation visits.

D.4.3.3. Provider education and engagement. We will partner with referring physicians to develop best practices in collaborative oncology care. We will conduct key informant interviews to identify areas for improvement and to solicit feedback on ways we can best work together to provide optimal and coordinated care to patients. We will solicit feedback as part of key informant interviews, surveys, and/or focus groups with respect to our communication materials and communication plan. After we begin the proposed interventions, we will re-assess the satisfaction level of referring providers at regular intervals, so that we can adjust our practice model accordingly. With respect to education, we will build on existing DFCI-led CME courses, open houses, and web-based communications to share and extend our expertise with referring providers and to strengthen personal and professional connections and to build awareness and knowledge of clinical trial opportunities.

D.4.4.4. Clinical trial matching. We will provide access to our clinical trials tracker to referring physicians to that they can quickly identify potential clinical trials for patients, based on simple but relevant criteria, such as tumor subtype, line of therapy, and results of molecular testing. The EMBRACE navigator will also be responsible for working with the DFCI-based clinician to proactively communicate results of prescreening/molecular testing back to the referring provider and to facilitate interactions with DFCI-based clinicians, research nurses, and clinical research coordinators regarding trial options in a personalized and ongoing basis.

D.4.4. Specific Aim 3. Our third aim is to enhance quality of life and satisfaction with care, and to facilitate shared decision-making among patients with MBC, with a combination of personalized follow-up, educational programs, and supportive care resources. To accomplish this, we will focus on three main practice gaps:

- Knowledge about breast cancer and its treatment
- Knowledge about options for symptom management
- Familiarity with and access to supportive care resources

D.4.4.1. Initial consultation. We will engage patients at the time of initial consultation (for patients new to DFCI), initial recurrence (for existing DFCI patients), or at the first next visit after activation of our program (for existing DFCI patients receiving ongoing care). With their permission, all patients will be assigned an EMBRACE navigator and meet with him/her to review the EMBRACE clinical program, the range of available supportive care and educational resources, and the intake packet. The intake packet, which we will develop as part of this project, will include a description of the program and relevant informational materials (Figure 4). EMBRACE navigators will facilitate patients obtaining additional information about programs they are interested in, and in facilitating referrals to clinical and supportive care services as needed.

Figure 4. EMBRACE Welcome Packet

EMBRACE

Ending Metastatic Breast Cancer for Everyone

SUSAN F. SMITH CENTER FOR WOMEN'S CANCERS

DANA-FARBER CANCER INSTITUTE

Through our program, called EMBRACE (Ending Metastatic Breast Cancer for Everyone), you will receive world-class care with a personal touch.

You are not alone.

At the Susan F. Smith Center's Breast Oncology Program, you have a world-class care team behind you. Treating patients with metastatic breast cancer is a significant part of our practice. Our doctors, nurses, pharmacists, nutritionists, research staff, social workers, and others provide continuous care, support, and assistance. We offer each patient the best and most personalized treatment options available, taking advantage of the full range of services of a top-ranked cancer hospital and research center.

Your treatment is personalized just for you.

There is no "one size fits all" treatment for metastatic breast cancer – we create a personalized treatment plan based on your individual needs and the type of your particular cancer. Working closely with you, experts from medical oncology, surgical oncology, and radiation oncology coordinate your care to ensure that all feasible approaches to treatment are considered, and that you will receive the combination of treatments that is best for you.

We offer patient-and family centered care, which means that you and your family are the focus of our attention. Your health care team will take the time to listen, understand your needs and preferences, and help give you a better sense of control over your life.

We are at the forefront of research.

We conduct multiple clinical trials to study the effect of new targeted drugs in patients with metastatic disease. Our care team matches qualified patients with the trial that is the most relevant for their kind of breast cancer. Much of the research performed at Dana-Farber has resulted in treatment breakthroughs and new standards of care for patients with metastatic disease, particularly those with brain metastases.

Near or far, we are here for you.

As partners in your treatment, our care team can also collaborate with you and your local oncologist during the course of your treatment if you live a distance away. Near or far, we are here to provide active, continuous care to help you achieve the highest possible quality of life and make informed decisions about your care.

Contents of Welcome Packet

- EMBRACE program brochure
- What is EMBRACE Research Cohort Study
- EMBRACE newsletters
- Supportive Resource guide
- Overview of Social Work Consultations
- Schedule of Social Work Support Groups
- Overview of Zakim Center for Integrative Therapies and Calendar of Events

D.4.4.2. Longitudinal follow up. The EMBRACE navigator will follow up by phone or in person every 3-4 months, inquiring about the patient's disease status, overall health, psychosocial concerns, and supportive care needs. Any patient seen at least once by a breast medical oncologist at DFCI who gives permission for follow up will be included in this effort, regardless of whether they receive their primary oncologic care at DFCI or locally. We anticipate that this effort will increase patient satisfaction with respect to shared decision-making, facilitate re-consultations at appropriate time points in a patient's disease course, and facilitate awareness of and access to supportive care resources.

D.4.4.3. Educational offerings. We plan to expand and enhance our existing program of educational offerings for patients and their caregivers. We will host our 4th Annual Metastatic Breast Cancer Forum in October 2015, and will plan to continue to host annual forums thereafter. After each forum, we will survey attendees in order to identify knowledge gaps to inform the development of additional educational materials and programs. We plan to expand our offerings of webcasts on "special topics" (for example, new drug approvals, treatment of specific breast cancer subtypes or sites of disease, pain and symptom management, coping strategies, clinical trials, etc.). Lectures from each forum and webcasts will be available to public via the DFCI website (http://www.dana-farber.org/Adult-Care/Treatment-and-Support/Treatment-Centers-and-Clinical-Services/Breast-Cancer-Treatment-Center/Metastatic-Breast-Cancer-Forum.aspx). We will also continue to produce a bi-annual newsletter focused on issues of relevance to patients with metastatic breast cancer available to DFCI patients (for back issues, http://healthcommcore.org/resources/giving-back-study-participants-embrace). We are committed to providing different types of offerings (print, web-based, telephone-based, in-person) to accommodate different styles in learning and geographic access.

D.5. Evaluation Design

We plan to evaluate the impact of our proposed program using a combination of quantitative metrics, surveys, and focus groups/key informant interviews. As we plan to offer the intervention to all patients with metastatic breast cancer seen in our practice, and do not plan to randomize patients, we will focus on evaluation pre- and post-intervention. We recognize that this somewhat limits our ability to draw causal inferences, however, we believe that randomizing patients and/or providers raises significant logistical and ethical challenges and would also significantly affect the level of commitment from our target audiences. We will focus on the following areas:

D.5.1. Clinical trial awareness and accrual. We anticipate that our intervention will increase provider and patient awareness of clinical trial options, and potentially result in an increase in clinical trial enrollment of up to 20% over baseline. However, we acknowledge that clinical trial accrual is dependent on many factors, including patient volume, patient characteristics and preferences, the availability of trials for specific populations, and slot availability, particularly in the case of early phase trials. In addition, a clinical trial, even if available, may not be the most advisable option for a patient. In order to ameliorate some of the limitations that would be present in capturing only total enrollment to therapeutic trials, we will collect and tabulate the following data both pre- and post-intervention. Satisfaction levels will be measured using paper and web-based surveys and by tracking usage levels. Trial accrual will be measured using our central clinical trials database, supplemented by chart review:

- Satisfaction with and use of enhanced clinical trials tracker
- Satisfaction with prescreening process and turnaround time
- Confidence in knowledge of clinical trials
- Proportion of MBC patients who consent to the EMBRACE research cohort (DFCI IRB # 09-204) within 6 months of initial visit to DFCI
- Proportion of MBC patients who consent to biobanking protocols (DFCI IRB # 93-085 and DFCI IRB # 11-104) within 6 months of initial visit to DFCI
- Proportion of MBC patients who consent to at least one investigational pre-screening evaluation (of tumor tissue or blood) within 6 months of initial visit to DFCI
- Proportion of MBC patients in whom a specific trial option is discussed (based on chart review) within 6 months of initial visit to DFCI
- Proportion of MBC patients who consent to a therapeutic trial within 6 months of initial visit to DFCI
- Total number of MBC therapeutic trial accruals over 6-month period of time

D.5.2. Collaborative care model. We anticipate that our proposed collaborative care model will increase satisfaction among DFCI providers, referring providers, and patients. In addition, we expect that over time, if the model is successful, the number of referrals to DFCI will increase and the proportion of patients seen as one-time consultations will decrease. Overall, we anticipate that our intervention will increase the proportion of patients who are truly cared for in a collaborative fashion by 30% over baseline. We will collect the following data pre- and post-intervention. Satisfaction levels of DFCI providers, referring providers, and patients will be

measured using paper and web-based surveys. Administrative data will be used to generate metrics regarding patient volume and return visits.

- Satisfaction with collaborative care model – initial intake and follow up care
- Satisfaction with clinical trial communications (e.g. molecular testing results letters, clinical trial options)
- Evaluation of CME events
- Proportion and absolute number of new patients with metastatic breast who are referred in by a participating oncologist (versus patient self-referred)
- Proportion of patients who agree to participate in collaborative care model
- Proportion of patients who return to DFCI for re-consultation within 6 months, and within 1 year of initial consultation

D.5.3. Awareness of and Use of Supportive Care Services. We have already generated baseline data as part of our needs assessment regarding the awareness and use of supportive care resources among both patients and DFCI providers. We will plan to repeat this assessment following our proposed intervention. We anticipate that our intervention, including the assignment of an EMBRACE navigator to each patient, will increase awareness of key supportive care services by 20%-40%, depending upon the baseline level of awareness. In addition, we anticipate an increase in utilization of support services, though of a smaller absolute change. We will collect the following data:

- Proportion of patients who are aware of a variety of supportive care resources
- Proportion of patients who have utilized select supportive care resources
- Level of awareness of DFCI-based and referring providers regarding select supportive care resources

D.5.4. Patient knowledge and breast cancer and its treatment. We will assess patient confidence in their knowledge about breast cancer and its treatment through patient surveys conducted prior to and following the October 2016 and October 2017 metastatic breast cancer forums. We will also solicit feedback from patients regarding the content of our educational initiatives.

- Evaluation of educational events
- Knowledge about breast cancer and its treatment
- Knowledge about options for symptom management

D.5.5. Dissemination of Project Outcomes

We plan to present interim results of our project internally and to referring providers for process improvement. We will plan to submit results of initial project outcomes and final project outcomes to national meetings and subsequently for publication. Project outcomes may also be reported in EMBRACE newsletters and/or other patient-directed forums.

D.6. Detailed Workplan and Deliverables

Our plan is to implement the project over a 2-year period. We have already begun work on the planning phase of the project and our goal is to complete the initial planning and readiness phase by the end of March 2016. We expect to initiate our proposed intervention by April 2016, with a plan for formal assessment of the collaborative care model in October 2016, and

re-assessment in October 2017. We acknowledge that the scope of the proposed project and proposed timeline is ambitious, and we recognize that we may need to adjust our timelines somewhat depending upon issues that arise as we implement our proposed initiatives. However, the entire project team is very committed to pushing an aggressive timeline given the project's importance to our overall mission. Section F specifies the leadership plan and staff capacity for the proposed project.

A detailed schedule for completion of each deliverable is included below.

Table 5. Schedule for Completion of Each Deliverable

Item	Estimated Date of Completion
DFCI-based providers and services	
Hiring and training of EMBRACE navigators	January 2016
Training of research staff	January 2016
Pilot project among select providers	February 2016
Evaluation of pilot and adjustments to program	March 2016
Upgrade of internal clinical trials matching website	March 2016
Refinement of molecular results reporting mechanism	March 2016
Development of robust patient tracking mechanism	March 2016
Collection of baseline metrics	March 2016
Training of DFCI providers (MD, NP, PA, RN)	March 2016
Training of extended care team (e.g. social work, pharmacy, nutrition)	March 2016
Training of support staff	March 2016
Initiation of intervention across BOC	April 2016
Satisfaction surveys of new model – initial	October 2016
Collection of post-intervention metrics – Timepoint 1	October 2016
Adjustment of interventions based on feedback	December 2016
Satisfaction surveys of new model – subsequent	October 2017
Collection of post-intervention metrics – Timepoint 2	October 2017
Referring Physicians	
Key Informant Interviews-baseline	January 2016
Development of outreach materials – initial consultation	February 2016
Development of molecular results reporting letters	February 2016
Development of clinical trial outreach materials	February 2016
Development of outreach materials – ongoing care	February 2016
Development of "outward facing" clinical trials matching Website	March 2016
Key informant interviews and focus groups – outreach materials, letters, and communications	March 2016
Finalize outreach and communication materials	April 2016
Awareness campaign of new model of care	April 2016
Educational session Year 1 – MBC treatment and trials	July 2016

Evaluation – educational session Year 1	July 2016
Satisfaction surveys of new model – initial	October 2016
Adjustment of interventions based on feedback	October 2016
Educational session Year 2 – MBC treatment and trials	July 2017
Evaluation – educational session Year 2	
Satisfaction surveys of new model – subsequent	October 2017
Patients	
Host 4th Annual Metastatic Forum	October 2015
Analyze survey data from Forum	November 2015
Create inventory of supportive care resources	January 2016
Finalize patient intake materials	January 2016
Develop EMBRACE newsletter	~Every 6 months, ongoing
Develop and produce webcasts	~Every 3-6 months, ongoing
Develop scripts for patient follow up calls, train EMBRACE Navigators	March 2016
Develop patient educational materials (print and on-line)	April 2016 and ongoing
Develop patient surveys: intake and follow up	April 2016
Begin baseline patient intake surveys	May 2016
Host 5th Annual Metastatic Forum	October 2016
Analyze survey data from Forum	November 2016
Analysis of patient intake and follow up surveys – initial	October 2016
Adjust/develop supportive care programs in response to Surveys	March 2017
Host 6th Annual Metastatic Forum	October 2017
Analyze survey data from Forum	
Analysis of patient intake and follow up surveys – Subsequent	October 2017
Publication Strategy	
Submission of initial project outcomes to national meeting	December 2016
Submission of initial project outcomes for publication	June 2017
Submission of final project outcomes for publication	June 2018

E. References

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