

Letter from Dr. Lin

First, many thanks for your suggestions and feedback about the first issue of this newsletter! There was lots of interest in learning more about clinical trials, so that's what we're dedicating this issue to—what clinical trials are in general, what it means to be in one, and a snapshot of some of the clinical trials happening here at DFCI.

If I could tell you only one thing about clinical trials, it would be that *it's very much your choice whether you participate or not*. We will always explain all of your options, and you should never feel like you're disappointing us if you decide not to take part.

But if it feels right, there are good reasons to participate. Clinical trials are how we make progress against cancer. Over the past decade, thanks to patients like you, a number of new drugs have been approved for treatment of metastatic breast cancer.

On a personal level, taking part in a clinical trial can provide new treatment options, and by participating in a clinical trial, you contribute to knowledge that can help future patients.

I also want to tell you about an exciting conference I attended with several Dana-Farber colleagues in November, 2011. For the first time ever, oncologists and patient advocates from around the world gathered to set guidelines for care for patients with advanced

LEARN MORE ABOUT THE METASTATIC BREAST CANCER CONFERENCE THAT TOOK PLACE IN PORTUGAL LAST NOVEMBER AT WWW.BIT.LY/NDBCC4

breast cancer and identify areas where more research needs to be done. This means that more patients with metastatic breast cancer can benefit from what we learn at institutions like DFCI. I think it has a symbolic meaning, too—it demonstrates that researchers, patient advocates, and clinicians all over are making the treatment and care of patients like you a priority.

Thanks again for your feedback, and let's keep the conversation going! Feel free to send any comments or questions to embrace@partners.org.

Warm regards,
Nancy Lin




A Closer Look at a Clinical Trial

IT'S AN EXCITING TIME IN CANCER RESEARCH. OVER THE PAST TEN YEARS, WE'VE REALLY STARTED TO UNDERSTAND WHAT MAKES CANCER TICK. OFTEN, IT'S A SERIES OF MOLECULES—CALLED A 'PATHWAY'—THAT ARE SWITCHED ON OR OFF. RESEARCHERS AT DFCI ARE WORKING TO LEARN MORE ABOUT THESE PATHWAYS.

One of these pathways is called the **PI3K pathway**. "It looks like this pathway is involved in many types of breast cancers," explains Dr. Nancy Lin. "But we need to learn more about how it works."

The PI3K pathway is named after the PI3K molecule. This molecule controls how cells grow, and is controlled by a certain set of genes. If the cancerous cell has a mutation in one of these genes, the pathway may become overactive, allowing tumors to resist standard treatments.

At Dana-Farber, many trials are testing drugs that turn off this pathway. The hope is that turning off the pathway will prevent tumors from growing and keep cancer under control.

For example, medical oncologist and researcher Dr. Sara Tolaney (see page 3) and her team are studying whether a drug called XL147 can help certain MBC patients when given together with a standard medicine called letrozole.

The study is a Phase 2 trial, which means that it's designed to find out more about whether the drug works

and what the side effects are. For this trial, Dr. Tolaney and her team:

1. Identify patients who are eligible and interested
2. Enroll them in the study
3. Perform tests to determine if a patient is able to receive the study treatment
4. Give them the new treatment
5. Record the side effects
6. Record how well the treatment works for each patient
7. Take a tissue sample to see what 'switches' were on or off
8. Enter the information in a database and analyze it for how effective the

continued on back page

“ I TRAVEL FROM SOUTH CAROLINA TO BOSTON FOR MY CLINICAL TRIAL TREATMENTS. SO FAR THE DRUG HAS BEEN WORKING VERY, VERY WELL. I HAVE FRIENDS WITH CANCER WHO CAN'T COME FOR THE TRIAL, SO I'M EAGER TO GET THE TREATMENT APPROVED. ”
— Leona Hydrick

INSIDE THIS ISSUE

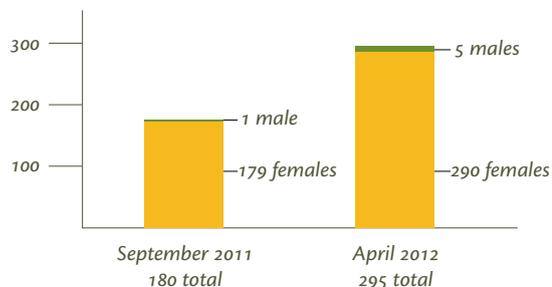


<i>EMBRACE at-a-glance</i>	2
<i>Questions and Answers</i>	2
<i>Meet: Sara M. Tolaney, MD, MPH</i>	3
<i>Ancient Healing, here and now</i>	3
<i>Resources</i>	4

EMBRACE at-a-glance

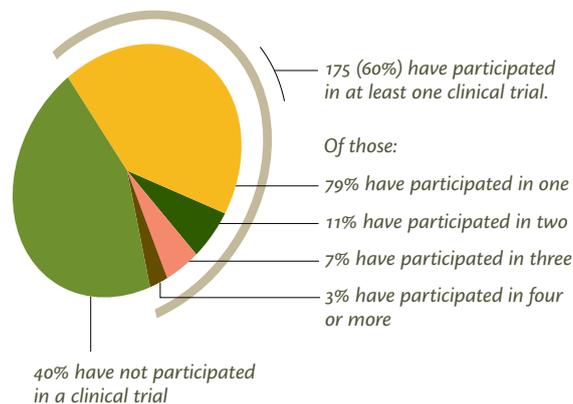
ENROLLMENT

Since the first issue of EMBRACE, 115 patients have joined the study.



PARTICIPATION IN CLINICAL TRIALS

Over half of all EMBRACE participants have participated in at least one clinical trial at Dana-Farber Cancer Institute.



Questions & Answers: Clinical Trials

WHAT IS A CLINICAL TRIAL?

A clinical trial is a carefully designed research study in which new treatments are tested in patients to learn about their side effects and evaluate their effectiveness.

patients are randomly assigned to receive either the new therapy or the current standard therapy.

WHY DO SOME CLINICAL TRIALS ASK FOR A RESEARCH BIOPSY?

Cancer treatments continue to improve. Many therapies now target specific molecules in hopes of causing changes in their activity. The only way researchers can learn whether a treatment had the desired effect on a molecule is by studying the genes and proteins in the tumor—which often requires a biopsy to obtain a tissue sample. This can help researchers understand why some cancers respond to treatment while others are resistant.

Health care practitioners take just as much care when performing a biopsy that's part of a clinical trial as they do for a biopsy that's used for diagnosis.

WHAT KINDS OF CLINICAL TRIALS ARE THERE?

In cancer research, there are three main types of clinical trials:

PHASE 1

Phase 1 trials often involve the fewest numbers of participants. New therapies are tested to learn:

- The best dose for future studies
- What side effects they might cause

PHASE 2

Through Phase 2 trials, researchers learn:

- How well a new medication works
- More about side effects

PHASE 3

Phase 3 trials typically compare new treatments with standard treatments. In most Phase 3 trials in cancer,

The National Institutes of Health provides a list of questions to ask your doctor if you're considering taking part in a clinical trial, available here:

www.cancer.gov/clinicaltrials/education/questions-to-ask-about-participating

To learn more about clinical trials, please visit www.dana-farber.org and click on Research, Clinical Trials.

“A CLINICAL TRIAL IS SOMETHING WE SHOULD ALL THINK ABOUT DOING. YOU DON'T JUST DO IT FOR YOURSELF, YOU DO IT FOR ALL THE PEOPLE WHO COME AFTER YOU.”
– Peter Devereaux

Meet:



Sara M. Tolaney, MD, MPH Medical Oncologist and Clinical Investigator

Sara Tolaney divides her time between caring for patients with breast cancer and working on developing new treatment options for them.

Dr. Tolaney became interested in oncology during medical school, where she found that the relationships she developed with patients with cancer were especially rewarding. "They're going through a challenging time, and you're able to help them through it. You build a relationship that's truly unique and special," she says.

In 2008, Dr. Tolaney joined the staff of Dana-Farber Cancer Institute and Brigham and Women's Hospital. She discovered that she enjoyed both seeing patients through the breast oncology center and working on clinical trials through the Early Drug Development Center (EDDC). "It's an incredible opportunity to be able to provide patients with excellent care and offer them cutting-edge treatment," she says.

The EDDC specializes in Phase 1 trials: carefully designed safety studies of new drugs. If a patient with metastatic breast cancer is interested in participating in a Phase 1 clinical trial, she or he may be referred to Dr. Tolaney. Together they discuss whether there are any trials that might be a good match, and talk about any concerns that he or she may have. If it seems like an EDDC clinical trial may be a good fit, Dr. Tolaney oversees his or her care during the time that the patient remains in the trial.

"Clinical trials are important not just because you're making a strong contribution to the breast cancer community, but also because it can expand your treatment options," Dr. Tolaney explains. "When one of my patients has a dramatic response to treatment, it feels great. We feel that together, we've really made a difference."

To see a video of Dr. Tolaney, please visit www.dana-farber.org/Health-Library/Sara-Tolaney,-MD,-MPH.aspx.

Ancient Healing, here and now

A WOODEN BOWL OFFERS SMOOTH STONES CARVED WITH WORDS—COMFORT, BREATHE—TO VISITORS. THIS IS NOT "MEDICINE AS USUAL." THIS IS THE ZAKIM CENTER FOR INTEGRATIVE THERAPIES.

The Zakim Center brings ancient healing practices to DFCI's state-of-the-art cancer care. Founded in 1999, the Center offers expert, oncology-focused therapies not typically part of medical services, such as acupuncture, massage, music therapy, and Reiki.



Photo by Sam Ogden, DFCI Communications

The Center's practitioners have extensive training in oncology. Staff members take patients' vital signs and review recent lab results before every appointment. Afterwards, notes are typed into the electronic medical record, so care is integrated on a logistical level, too.

Integrative therapies have been proven to be effective through centuries of human experience as well as through scientific research, much of it conducted by the Zakim Center. Integrative therapies may:

- Ease symptoms and side effects such as headaches, pain, nausea and vomiting, neutropenia, swelling, anxiety, depression, fatigue, and insomnia
- Increase relaxation
- Enhance quality of life

Patients may be referred to the Zakim Center by a health care provider or they can self-refer. Many services, like Qigong and music therapy, are free. Patients

pay for acupuncture, Reiki, and massage out-of-pocket because the therapies are typically not covered by health insurance.

"The Zakim Center is unique in New England," says Anne Doherty-Gilman, Director. "We encourage patients to explore what we offer and benefit from these therapies."

Acupuncture places super-thin needles (they're usually painless) in the skin's surface to balance energy flow through the body.

Massage therapy uses adaptive strokes and modified techniques to ensure safe, effective treatment of cancer patients. It can be done through clothing or on exposed skin, and patients can recline on a specialized chair or a table.

Reiki is an ancient healing technique in which a trained practitioner places his or her hands above or on various parts of the patient (with the patient sitting or reclining, and fully or partially clothed) to conduct "life force energy" through the body.

Nutrition counseling helps patients develop eating plans that address their health issues, and answers questions about the use of herbs and supplements to promote wellness.

Qigong—pronounced *chee-kung*—incorporates simple postures, like sitting or standing, and movement into a system of physical and mental exercises. Try *Sunset Qigong at DFCI, Tuesdays from 4:30–6:00 pm. Call 617-632-3322 to register. No charge.*

Music therapy is "guided by each patient's interest and comfort

continued on back page

Clinical Trials

continued from page 1

treatment was, what side effects were experienced, and clues as to why it might work in some cases but not all.

Many patients are eager to participate in clinical trials, since it can provide access to new therapies, but Lin is quick to point out that a patient is never 'trapped' in a study. "Usually, people continue the treatment as long as it is working and they don't have too many side effects," she explains. "But if it doesn't work out, for whatever reason, patients are always free to withdraw from the trial."

THINKING ONE STEP AHEAD

"A patient may want to join a clinical trial, but sometimes the trial only allows patients with a specific gene mutation or something else that requires a special test. Then we have to wait for the test results before we can know whether he or she can participate. That can be really stressful," says Lin. "Now we're testing for the PI3K mutation early on. This way, we know the result – so if the patient does become interested in the trial later on, it gives us a head start.

"Even if the patient decides not to participate," she adds, "we still know

whether his or her tumor has the mutation, and we can learn from that, too."

BETTER TREATMENTS

"Our goal is to be able to say 'If this combination of switches is turned on, the treatment is likely to work,'" explains Lin. "Instead of a trial-and-error approach to treatment, we want to be able to say 'Based on the results of your biopsy, we think this treatment will work for you.' We're not at this point quite yet, but we're heading in this direction, and we think it's a very reachable goal."

CLINICAL TRIALS

Listed below is a selection of some of the clinical trials available to patients with metastatic breast cancer at Dana-Farber. This is not a complete list, and the trials change frequently. Talk to your doctor if you're interested in participating in a clinical trial, and he or she can determine whether there is a trial that might be right for you.

PHASE 1

- Sapacitabine + seliciclib (chemotherapy + cdk inhibitor): metastatic breast cancer and a BRCA mutation
- GDC-0980 plus Taxol (PI3 kinase inhibitor): metastatic breast cancer
- LCL 161 + Taxol (apoptosis inhibitor): metastatic breast cancer

PHASE 2

- ARQ-197 (Met inhibitor): triple negative breast cancer
- Ruxolitinib (Jak inhibitor): triple negative or inflammatory breast cancer
- MK-2206 (Akt inhibitor): metastatic breast cancer
- Letrozole + XL147 (PI3 kinase inhibitor): ER+ breast cancer
- Herceptin and Lapatinib (HER2 inhibitor): HER2-positive breast cancer
- Neratinib (HER2 inhibitor): HER2-positive breast cancer brain metastases
- Fulvestrant (HSP90 inhibitor) with or without ganetespib: ER-positive breast cancer

PHASE 3

- TDM1 (HER2 inhibitor plus chemotherapy) versus standard chemotherapy: HER2-positive breast cancer

Resources

Learn more about clinical trials and search for studies that you might be eligible to participate in:

DANA-FARBER CANCER INSTITUTE

www.dana-farber.org/Research/About-Clinical-Trials.aspx

NATIONAL CANCER INSTITUTE

www.cancer.gov/clinicaltrials/education/main/Page1
www.cancer.gov/clinicaltrials

AMERICAN CANCER SOCIETY

www.cancer.org/Treatment/TreatmentsandSideEffects/ClinicalTrials/index

BREASTCANCERTRIALS.ORG

www.Breastcancertrials.org

AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO)

www.cancer.net/patient/All+About+Cancer/Clinical+Trials

US NATIONAL INSTITUTES OF HEALTH

www.clinicaltrials.gov/
www.nih.gov/health/clinicaltrials/findingatrial.htm

COALITION OF CANCER COOPERATIVE GROUPS

www.cancertrialshelp.org/cancer-trial-search/

EMERGING MED

www.emergingmed.com/pub_trial_match.asp

Ancient Healing

continued from page 3

level," says Brian Jantz, music therapist. It can take the form of listening, singing, chanting, playing (or learning to play) an instrument, writing songs, drumming, or bell ringing. *Drop in on the music program from 3:00-4:00 pm on Wednesdays in the Music/Art Studio in the back of Blum Resource Center on the first floor of the Yawkey Center for Cancer Care. No charge.*

Try on your own: Many complementary therapies are safe and easy to explore on your own, such as guided imagery, humor, meditation, and the relaxation response. More information is available by calling 617-632-3322, visiting www.danafarber.org/zakim, or through the Blum Center.

To learn more or arrange an integrative oncology consultation, call 617-632-3322 or email Zakim_Center@dfci.harvard.edu.

Save the date

METASTATIC BREAST CANCER FORUM

SATURDAY, OCTOBER 13, 2012, 9:00 AM — 12:00 NOON

Topics will include MBC research updates and sharing of results from the Metastatic Cohort Needs Assessment. You will receive an invitation in the mail prior to the event.

EMBRACE

ENDING METASTATIC BREAST CANCER
FOR EVERYONE

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