The Metastatic Breast Cancer Project

June 1 2016
What is metastatic breast cancer?

• Metastatic breast cancer (MBC) is breast cancer that has spread beyond the tissues of the breast

• An estimated 150,000 women and men are living with metastatic breast cancer in the U.S.

• 40,000 people in the U.S. die from metastatic breast cancer each year (7% of all cancer deaths in U.S.)

• Though treatments are improving, metastatic breast cancer is currently not curable
The Scientific Need in Cancer Research

• **Ultimate goal:** To understand what drives metastatic breast cancer so that we eventually can interpret every patient’s cancer genome, identify the optimal treatments, and anticipate and preempt resistance before it arises

• There’s been a lot of progress, but we are still far from the goal

• What will it take to get there? Detailed molecular and genomic characterization of **thousands** of tumor and germline samples along with medical information
Some questions we are trying to answer in metastatic breast cancer

- What are all changes at the molecular level that can lead to metastatic breast cancer?
- What explains why some patients show extraordinary responses to a particular treatment?
- What explains why some tumors never respond to a particular treatment, or why some tumors initially respond but later develop resistance?
- What are some factors that can lead to developing metastatic breast cancer at a young age?
- What are the genes involved in metastatic breast cancer for underrepresented and understudied groups?
- How can we improve the use of genomic information in the treatment of metastatic breast cancer?
- How can we develop better treatments for metastatic breast cancer?
Challenges of Studying Patient Tumor Samples

- Only 5% of U.S. cancer patients are enrolled in clinical trials
- 85% of U.S. cancer patients are treated in community settings

Most tumor samples have not been readily available for study

Technology, social media, and cultural changes now provide a new opportunity to engage cancer patients and directly partner with them in this research.
Do you want to help transform our understanding of metastatic breast cancer?

If you have metastatic breast cancer, join a nationwide movement of patients, doctors, and scientists by sharing your tumor samples, your medical information, and your voice. Together, we can speed the development of future therapies.
Your tumor and medical records could unlock discoveries.

The unique genetic information in your cancer could hold the key to rapid advances in cancer treatment. By looking at the DNA in your samples (using "genomic sequencing"), researchers can make discoveries to identify new ways to treat metastatic breast cancer. This information will be securely shared with researchers around the world. It will be invaluable to cancer research for years to come — and ultimately lead to a better understanding and faster advances in the treatment of metastatic breast cancer.
Become part of the research movement. Have a direct impact on the future.

By saying "Count Me In", you will partner with leading research institutes, hospitals, and patient advocacy groups by sharing part of your stored tumor tissue and copies of your medical records.

Here's how you can participate

1. Step 1. Tell us about yourself
   Click "Count Me In" and complete a simple online form to tell us about yourself and your cancer. Our goal is to perform many different studies within the metastatic breast cancer community, so allowing us to know a little bit about your experience will help us design future studies.

2. Step 2. Give us permission to collect your samples and data
   When we start a study that matches what you have told us about yourself, we will ask you to fill out an online consent form that requests your permission to obtain copies of your medical records and some of your stored tumor tissue. We will do the rest - we'll contact you.

3. Step 3. Learn with us along the way
   We are excited to learn with you! Throughout the project, we will provide you with regular updates about the status of the project and share any discoveries that you have enabled us to make. We also may ask you additional questions about your experience to help with...
Join the Movement: Tell Us about Yourself

Complete the form below to tell us about yourself and your cancer. Our goal is to perform many different studies within the metastatic breast cancer community, so allowing us to know a little bit about your experience will help us conduct our current projects and also to design future studies. We will be starting with some focused studies in metastatic breast cancer, and expanding over time based on what we learn from you. We are asking all patients with metastatic breast cancer to say Count Me In and fill out the form so that we can use the information you provide to plan our next studies.

Contact Info

First Name

Last Name

Email Address
Over 2200 women and men with metastatic breast cancer from all 50 states have joined the MBCproject in the 7 months since our launch in October 2015.
Metastatic Breast Cancer Project: Cumulative Enrollment

- Official Launch with Advocacy Partners
- Soft launch
- San Antonio Breast Cancer Symposium
- Facebook and Twitter posts by several advocates
- Facebook post by a metastatic breast cancer patient/advocate

>2200 patients enrolled as of 5/28/16.
Patient-Reported Data

95% submitted the 16-question survey

98% response rate to each question (all are optional)

6 minutes to complete

Disease Characteristics:
• Dates of initial diagnosis
• Date of diagnosis with metastatic disease
• ER+, PR+, and HER2+ status

Treatment Response:
• Questions about extraordinary responses
• Free text about treatments
• Date of most recent biopsy

Demographics:
• Year of birth
• Race and ethnicity

Free text about anything additional

Detailed patient reported data from >2000 patients
The average current age of respondents is 53 years (range 24-91)

As of April 2016, Based on 1750 responses (99.5% response rate)
Respondents were asked if at any time they had ER+/PR+, HER2+, triple negative, and/or inflammatory breast cancer.

As of April 2016, Based on 1758 responses

Hormone Receptor Positive?
- Yes: 81%
- No: 15%
- Don't Know: 4%
- No Response: 0%

HER2 Positive?
- Yes: 32%
- No: 61%
- Don't Know: 6%
- No Response: 1%

Triple Negative?
- Yes: 84%
- No: 11%
- Don't Know: 4%
- No Response: 1%

Inflammatory?
- Yes: 85%
- No: 7%
- Don't Know: 7%
- No Response: 1%

As of April 2016, Based on 1758 responses
Metastatic Breast Cancer Project: Approach

**ONLINE CONSENT**
Electronic consent form asks patients for permission to obtain a saliva sample, tumor tissue and medical records.

**SALIVA COLLECTION**
Consenting patients are sent a saliva kit and asked to mail back their saliva sample.

**MEDICAL HISTORY**
Medical records are obtained by the MBCproject team and centrally reviewed and abstracted.

**TISSUE COLLECTION**
Tumor blocks requested from local pathology departments by the MBCproject team.

**GENOMIC ANALYSIS**
Molecular characterization of tumor and saliva includes whole exome sequencing (WES) and transcriptome sequencing (RNASeq).

**INTERPRETATION**
Genomic data is interpreted in the context of clinical data (extraordinary response, de novo disease, age, etc) at the individual level and in aggregate across similar patients.

**REPORTING / DATA SHARING**
De-identified genomic & clinical data shared widely with research community. Overall progress, findings, and discoveries regularly communicated directly to patients.
“COUNT ME IN: The Metastatic Breast Cancer Project” is a patient-driven movement that empowers patients to directly transform research and treatment of disease by sharing their genomic data.

1. What is the purpose of this study?

We want to understand cancer better so that we can develop more effective therapies. By partnering directly with patients, we are able to study many more aspects of cancer than would otherwise be possible.

2. What will I have to do if I agree to participate in this study?

Participation requires little effort. You would answer some questions about your cancer and medical care, send a saliva sample to us in a pre-stamped package that
All 2000+ registrants have been sent a link for the online consent. To date, over 1200 patients have signed (>50% consent rate)

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MBCProject: Patients Enrolled, Consented, and Saliva Samples Received

- Registered
- Consented
- Saliva Received

In January, we started sending online consents sent to all registered patients.

In March, we started sending saliva kits to consenting patients, in batches of 100 kits per week.

Facebook post by a metastatic breast cancer patient/advocate

Facebook and Twitter posts by several advocates

San Antonio Breast Cancer Symposium

Official Launch With Advocacy Partners

Soft launch

>1200

>1500

>2000

>2200

>2500

>500

>1000

>1200

8/31/11

9/30/11

10/30/11

11/29/11

12/29/11

1/28/12

2/27/12

3/28/12

4/27/12

5/27/12

>1000

>1500

>2000

>2500

8/31/11

9/30/11

10/30/11

11/29/11

12/29/11

1/28/12

2/27/12

3/28/12

4/27/12

5/27/12

>1000

>1500

>2000

>2500

8/31/11

9/30/11

10/30/11

11/29/11

12/29/11

1/28/12

2/27/12

3/28/12

4/27/12

5/27/12
Identified groups of rare patients who have been challenging to study with traditional approaches:

- Patients with extraordinary responses to therapies
- Patients who present with advanced disease
- Patients diagnosed with MBC at a young age
- Underrepresented Populations

Each of these groups is readily identifiable based on the screening questions on the MBCProject.org website.
99% of those who responded “Yes” provided the drug names

98% of those who responded “Yes” provided drug names and additional “free text” details

Hundreds of patients with self-reported long-term and/or exceptional responses identified. For example:

- **Capecitabine (Xeloda):** 117
- **Platinums (Carboplatin, Cisplatin) and PARP inhibitors:** 63
- **Everolimus:** 36
100 respondents report living with metastatic disease for more than 10 years.
613 respondents (36%) report that they were diagnosed with metastatic disease less than 4 months after their initial diagnosis with breast cancer (representing Stage 4 or “de novo” metastatic disease).

As of April 2016, based on 1688 responses (96% response rate)
The average age of respondents when they were initially diagnosed with breast cancer is 45 yrs (range 23-74 yrs)!

As of April 2016, based on 1707 responses (97% response rate).

591 (35%) diagnosed before age 40
New MBCProject Initiative: Studying Resistance with Blood Biopsies

**In Progress:**
- IRB Approval
- Blood Draw Kits
- Logistics of blood draw

**Plan:**
- **Pilot 1 (Summer 2016):**
  - Test logistics with ~10-20 patients
- **Pilot 2 (Fall-Winter 2016):**
  - Send 500 kits
  - Collect 300 blood samples
  - Whole exome sequencing from 100+ samples with sufficient DNA
A Collaboration with Patients and Advocates

Patients and advocates have been involved from day 1 in conceiving, designing, implementing, testing, and refining this project.

More collaborations in the works
How do we interact with participants?

- **Regular updates** through the website and email about status of the project, progress to date, and any discoveries that have been made.

- **Educational information** and videos about metastatic breast cancer research, approaches we are using, and explanations of new discoveries.

- **Notifications** when we are starting to study new groups of patients with metastatic breast cancer.

- **Feedback** about questions and suggestions we receive through the surveys and direct emails – *we’re committed to listening to and learning from our patient-partners*.

*We are not at present returning individual genomic results - but this being worked on.*
#MBCproject on Facebook and Twitter

#BCSM twitter chat: > 2 million impressions; 1 Facebook post: 300 enrollments in 12 hours
Participants as drivers, not samples
Online to real life engagement

The San Antonio Breast Cancer Symposium 2015

MBCproject patient panel and lunch 2016

One of the most important days of my life. Thank you MBC Project.~ Jill Haagenson
Online to real life engagement
What the MBCproject means to patients

“I want to live and watch my children grow up, but if I can’t, then I want to leave a legacy and a cure.”
—Houston, TX

“As someone who does not live near a research center and therefore cannot easily participate in trials, I finally feel like I can contribute.”
—Lake Tahoe, CA

“The boy says, ‘Our family could be the key to unlocking a cure for cancer.’”
—Seattle, WA

“I have two daughters and my prayer is they never have to go through what they’ve watched me endure!”
—Clarkston, MI

“Amazing how happy that little box makes you feel! I felt like a 2 year old. Let me help! I feel a sense of pride and belonging because of this.”
—Minneapolis, MN

“Giving us HOPE for the future and if not for some of us, for our families.”
—Scottsdale, AZ
Ideas for Outreach / Expansion

1) Social Media
2) Advocacy Groups
3) Traditional print media
4) Patient Conferences / Meetings
5) Patient “Amplifiers” / Community Leaders
6) Community Oncologists
7) Television
8) Advertising

Major goal for 2016 to increase racial/ethnic diversity in MBCproject participants
MBCproject in the News

Breast cancer patients encouraged to share genetic data in new project

By Andrew Joseph | STAT | OCTOBER 28, 2015

#Cancer: Researchers Are Conducting Huge Studies Using Twitter, Facebook

Instead of relying on the small number of patients who go to research hospitals, doctors are recruiting huge numbers of participants online.

Researchers Take Aim at Metastatic Breast Cancer

Activists say the deadliest form of breast cancer has gotten short shrift until now

By AMY WESTERVELT | FEBRUARY 15, 2016
Best Of ASCO 2016

It’s @BBethJo presenting the #MBCproject at the asco16 poster session.

Eric Topol @EricTopol - Jun 7
The surprising power of smartphone apps to help patients w/ cancer thrive & survive on.wsj.com/1ZskHBH #ASCO16
WSJ Health News, WSJ Science, Ron Winslow and 2 others

Studies Rely on the Internet to Help Cancer Patients

Patients Are Contributing to Breast Cancer Research curetoday.com/articles/count...
#ASCO16

A nationwide effort could lead to new discoveries and better treatments for patients with breast cancer onclive.com/conference-cov... asco1

Male Breast Cancer
#MBC2014
He wouldn’t talk about his breast cancer dx at first. Now look @Bronxborn409!
#malebreastcancer #ASCO16 #MBCproject

Patient-Driven Research Project Aims to Advance Metastasis
Researchers are hoping that a new nationwide effort to encourage patients to share their tumor samples and clinical information will lead to new discoveries and better treatments oncive.com

Incredibly Rapid’ Enrollment in @MBC_Project Study. Why? #bcsn #ASCO16 @Nikhilwagle @corrie_painter

Via @Medscape
The many advocates and patients who have worked with us over the past year to develop and implement this project.

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