

LIVING BEYOND
BREAST CANCER®



Welcome to
Patient-centered dosing in
metastatic breast cancer:
Improving quality of life and
shared decision-making



Learning Objectives

To increase healthcare provider knowledge of:

- The role of patient-centered dosing in improving quality of life for people living with metastatic breast cancer
- The impact of altering treatment cadence and dosing protocols while providing effective supportive care
- New tools to enhance patient education and shared decision-making
- How to have open, actionable discussions with patients



THANK YOU TO OUR PARTNERS



THANK YOU TO OUR SPEAKERS



Amy Leader, DrPH, MPH

Professor, Thomas Jefferson University; Associate Director for Community Outreach and Engagement, Sidney Kimmel Comprehensive Cancer Center



Julia Maués

Patient Advocate, Co-founder of GRASP



Caroline Koffke, RN, BSN, OCN

Director, Educational and Healthcare Provider Programs, LBBC



Patient Centered Dosing Initiative

[THERIGHTDOSE.ORG](https://therightdose.org)

When Treatment Meets Real Life: Patients' Perspectives on Dosing

Julia Maués

Patient Centered Dosing Initiative (PCDI)

LBBC Webinar for HCPs

December 3, 2025



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Conflict of Interest

DISCLOSURE

- ☒ I have no potential conflict of interest to report
- ☐ I have the following potential conflict(s) of interest to report

Non-industry support to PCDI: Arnold Ventures, Steve Loeser

About Me



Diagnosed with breast cancer at 29 while pregnant



Living with (and in treatment for) metastatic breast cancer for 12 years



Advocate for centering lived experience in care & research



A founding member of PCDI to better understand the patient experience around drug dosing

Cancer drug dosing: More is better

often
not

- Cancer drug dosing has historically been determined using dose escalation studies, often by selecting the MTD, and using that dose in subsequent trial(s)
- Based on the premise that higher toxicity ➡ greater efficacy
- This premise is often not applicable for new treatments like targeted therapies & immunotherapies
- Does not consider long-term treatment-related SEs, especially for patients with metastatic cancer, on treatment for life
- TOLERATED by whom? For how long?

I can't take
it anymore!



What happens in real life?

Patients often:

- Push through side effects even when the quality of their life is terrible.
- Underreport symptoms due to fear that they'll be taken off a treatment that might be working.
- Fear dose changes mean “less effective care”.

This leads to delayed treatment adjustments and supportive care, and more suffering than necessary.

My kids say that every three weeks, I become “zombie mommy.”

I have to wear adult diapers if I will not have access to the bathroom for more than an hour.

I get asked how I feel on Day 1 of the treatment cycle, and by then, I'm feeling fine.

PCDI: Patient-Centered Dosing Initiative

We are a patient-led initiative questioning the practice of routinely treating Metastatic Breast Cancer patients **with the highest tolerable dose**.

- MBC isn't curable but can be treated, often for years, in some cases even decades.
- We don't just want to live LONGER. We also want to live WELL.
- Evidence suggests that lower allowed doses of some MBC drugs may be as effective as the Recommended Starting Dose (usually based on MTD).
- Anecdotally, we have seen that several long-term survivors are on reduced doses of medications for various reasons, and that has played a role in how they have been able to tolerate these treatments and stay on these treatments for long periods of time.

Patient Members

Julia Maués



Janice Cowden



Jo Lynn Collins



Martha Carlson



Amy Beumer



Kelly Shanahan



AJ Veach



Angela Rose

Medical Advisory Board Members



Aditya Bardia, MD



Mark Burkard, MD



Kevin Kalinsky, MD



Maryam Lustberg, MD



Elizabeth Papautsky, PhD



Mya Roberson, PhD



Hope Rugo, MD

In Loving Memory



Anne Loeser



Flori Hendron



Sheila Johnson



Chawnte Randall



Sandi Spivey

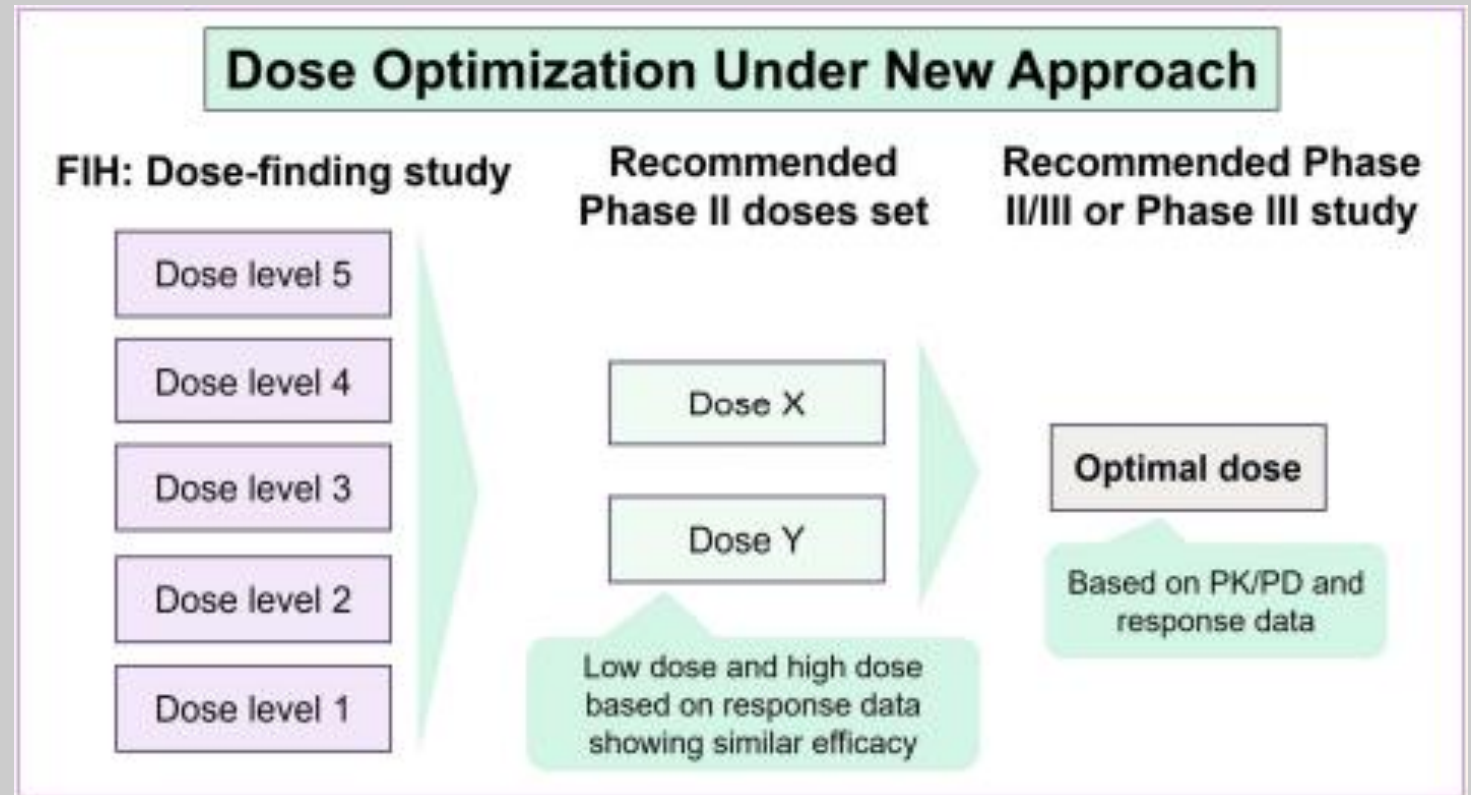
Recent Updates in Dosing

Caroline Koffke, RN, BSN, OCN

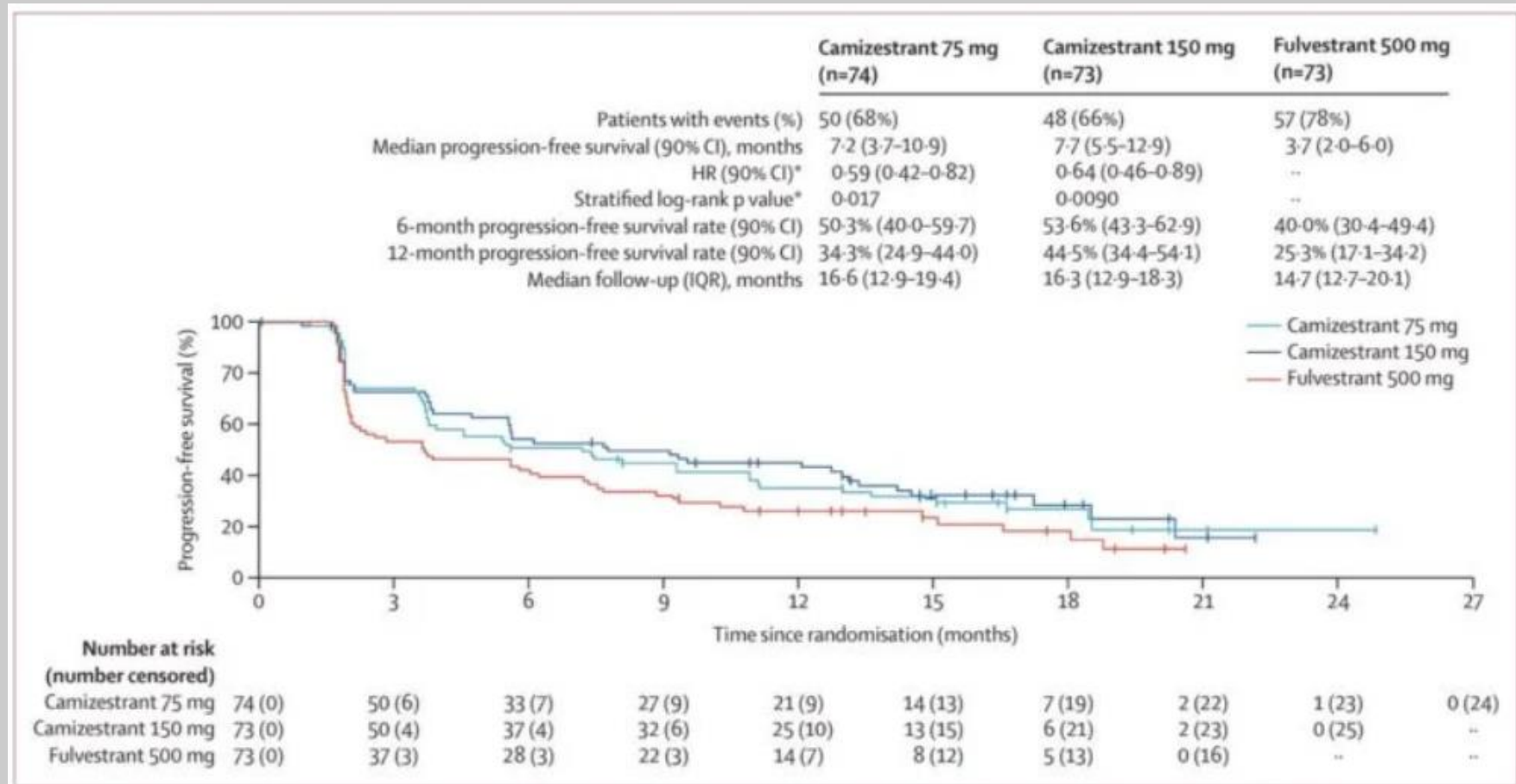
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Research Behind Dose Reductions

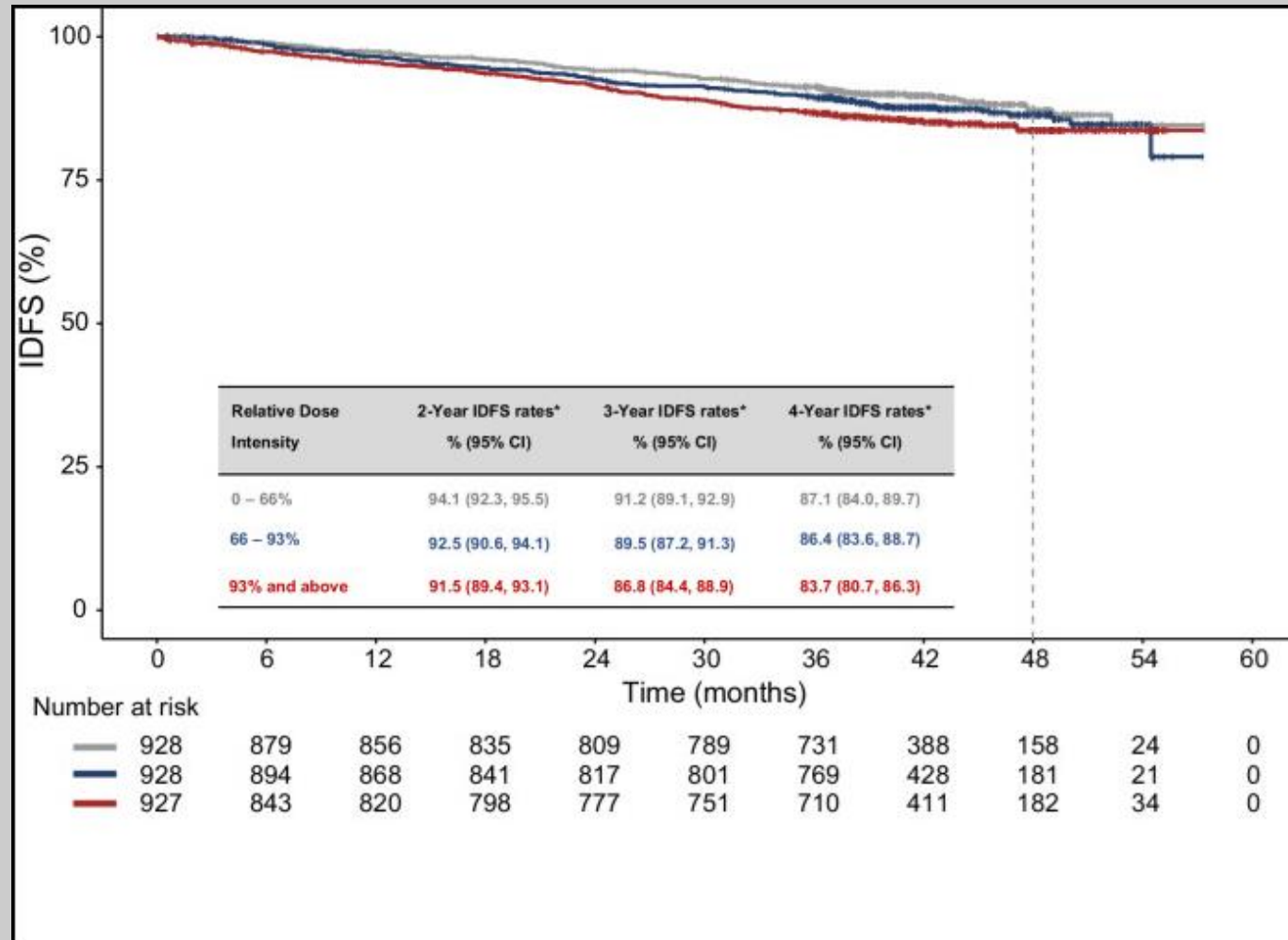
- Dose = AMOUNT of medication, SCHEDULE of medication and DURATION of medication
- Project Optimus
 - A shift at the FDA from "highest tolerable" to "optimal" dosing



SERENA-2



MonarchE (abemaciclib)



TRADE Study

- Focus: Investigated dose escalating (starting low and building) of abemaciclib in high risk, early stage patients with breast cancer
- Design: patients started at 50mg for 2 weeks, then increased to 100mg for 2 weeks, then went to the full dose of 150mg
- Preliminary Results: Dose reductions did not compromise effectiveness. Less patients discontinued their medication
- Patients reported less side effects Significance: Promotes personalized dosing strategies for better patient management.

Collaboration Between SKCC x LBBC

- Focus Groups
 - Participants: 2 English speaking focus groups (10 participants), 1 Spanish speaking focus group (4 participants)
- Materials Creation
- Testing in the Clinic
- Data Analysis

PCD Materials

Diarrhea. Headache. Nausea. Fatigue.



Are treatment side effects keeping you from living well with metastatic breast cancer?

Medicines for metastatic breast cancer (MBC) often come with side effects. But, did you know that many drugs that treat MBC can be just as effective at a lower dose, with fewer side effects? This approach to customizing your treatment is called **patient-centered dosing**.

Less struggle, more living

When treatment is too strong, it's hard to do normal things. A lower dose might help you:

- Stay on your medicine longer
- Do more of what you enjoy
- Spend more time with family and friends

Talk with your doctor about your side effects, what activities you like to do, and whether the medicines you take can be adjusted.

“We want to do things — be with friends, work, do chores around the house. We want to be here for a long time to enjoy our families. Immediately, I started noticing the difference with the new dosage.”
- Patient Advocate

You are not alone

Many people with metastatic breast cancer feel the same way. It's okay to talk about your side effects. Changing your dose does not mean your treatment won't work. It means you and your doctor are finding the best way for you to keep living your life.

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Start the conversation

Try our conversation guide to bring up patient-centered dosing with your doctor.

Say: “I want to live well while taking this medicine. My side effects are stopping me from doing the things I enjoy.”

Things I want to do:

My side effects that get in the way are:

I have these side effects:

___ more than once a day
___ every day
___ other: _____

Ask: “Can my dose be lowered to help with side effects?”

Looking for more information?

Scan the QR code to find more on this topic from LBBC.



Patient Engagement in Creating and Evaluating the PCD Materials

Two Phases:



Phase 1: Involve patients in the design of the materials



Phase 2: Involve patients in the evaluation of the materials

Phase 1: Focus Groups

- Involved patients living with MBC and who are a part of LBBC's network
- Conducted virtually with 14 participants (10 spoke English and 4 spoke Spanish)
- Discussion followed a pre-set moderator guide
- Discussion was audio recorded and transcribed for analysis
- Participants received \$75 in compensation



We need your help!

Living Beyond Breast Cancer is creating new patient education materials for patients living with metastatic breast cancer. Join a 90-minute virtual focus group discussion to shape the new patient education materials.

Find a group that fits your schedule

- Sunday, April 13th at 4p ET
- Monday, April 14th at 12p ET
- Thursday, April 24th at 7p ET
- Tuesday, April 29th at 7p ET

Compensation:
\$75 gift card

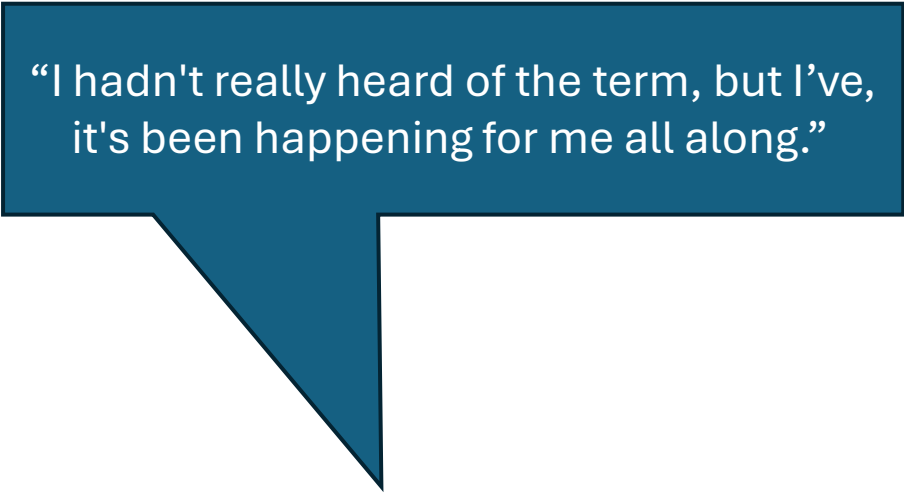
Sign up:
<https://tinyurl.com/LBBCRESEARCH>

Contact Caroline Koffke at ckoffke@lbbc.org with questions

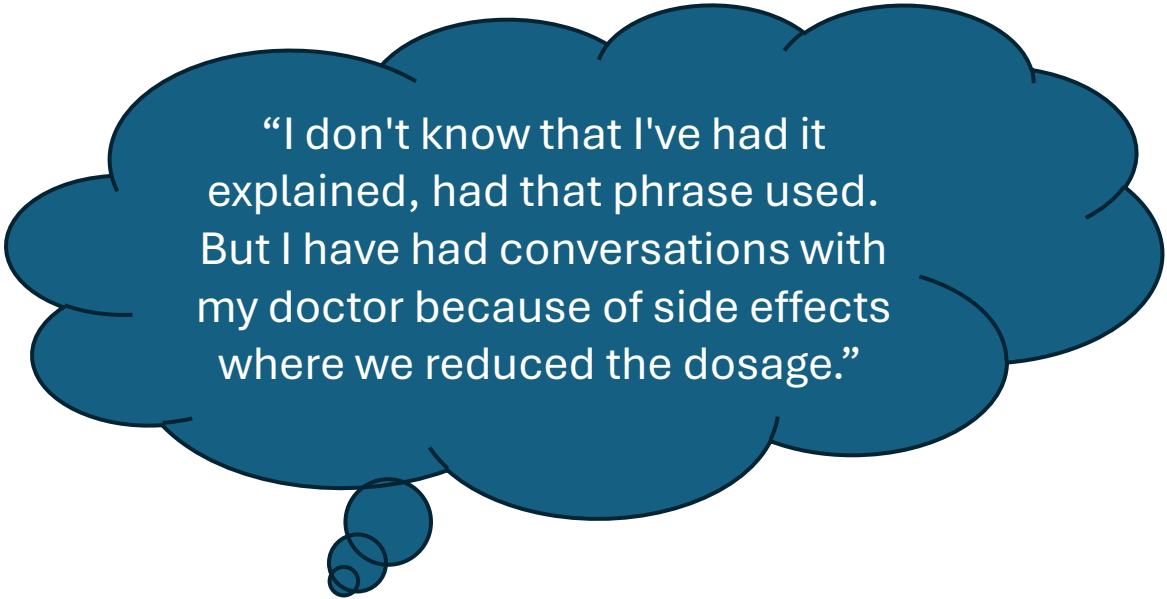


Experience with Patient Centered Dosing

There were mixed experiences with PCD – most were familiar with the idea, but not all knew it by this term; although a small minority of participants had not heard of the term:



“I hadn't really heard of the term, but I've, it's been happening for me all along.”



“I don't know that I've had it explained, had that phrase used. But I have had conversations with my doctor because of side effects where we reduced the dosage.”

Conversations with Care Teams about PCD

- For most patients, talking about dosing was a regular part of their treatment experience; but for a small number, they were hesitant to bring it up, for various reasons
- Every patient mentioned the role of advocacy in discussions about PCD
- Quality of life was the driving factor for considering changes in dosing

“There is this hesitancy like I don't want to be a bother, I don't want to complain.”

“I would say that it's important for patients to know that they are as much in control of the situation as the doctor is.”

“The concern is if we back down then, like with chemo, is it going to progress? Will it not be strong enough?”

“Why PCD? To continue living, you know? Not just continuing to exist.”

Suggestions for the PCD Materials

For material content, patients would like to see data, key terms/definitions, patient stories, and places to find additional resources:

“Short and sweet. With the direction to find out more. Because everybody does want to find out more.”


Also have a glossary, if possible, in English and Spanish, because this is a new language for those, that is, for us.”

“Present this information in different formats. Of course, YouTube videos, everybody seems to think that that's where it's at now. But written material as well. There are people who just need to see things on the paper to understand better.”

Other patient experiences are extremely valuable. The positive stories that, you know, people are 20 years out, still thriving”

Phase 2: Evaluate the Materials

- Any patient who is living with MBC is eligible to participate
- Available in-person (in Philadelphia) or entirely online
- Designed to be completed in one sitting, about 15 minutes
- Participants received \$25




ARE YOU LIVING WITH
METASTATIC BREAST CANCER?
WE NEED YOUR HELP!

We need your input on newly created
educational materials about treatment options


Two ways to help:

Scan here:



OR [CLICK HERE](#)

- All patients with metastatic breast cancer are eligible to help
- Involves reviewing the material and sharing your thoughts via 2 brief (5 minute) surveys
- Participants will be compensated \$25



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THIS STUDY WAS APPROVED BY THOMAS JEFFERSON UNIVERSITY
IN PARTNERSHIP WITH LIVING BEYOND BREAST CANCER

Study Design

Brief pre-survey about
knowledge, attitudes, and
intentions to talk to your care
team about PCD



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
Things I want to do:

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Brief post-survey about
knowledge, attitudes, and
intentions to talk to your care
team about PCD

(Participant reads
materials for as
long as they
desire)

Evaluation Results

- 20 English-speaking participants; 8 Spanish-speaking participants:
 - All currently in treatment
 - 50% receiving care at an NCI-designated cancer center
 - Diagnosed between 2006 and 2025, mean age 58 years old
 - High level of health literacy; varying levels of educational degrees
 - 75% had previously heard of Patient Centered Dosing

Changes in Knowledge, Attitudes and Intentions

| | PRE-TEST | POST-TEST |
|---|----------|-----------|
| Knowledge about Patient Centered Dosing (% Correct) | 71% | 80% |
| “I feel sure about the best dose of my cancer drug(s) for me” | 3.64 | 4.04 |
| “I understand the benefits and risks of adjusting the dose of my cancer drug(s)” | 3.68 | 4.32 |
| “I am clear about which benefits matter the most to me” | 3.48 | 4.32 |
| I have enough support to make a decision about the dosing of my cancer drug(s)” | 3.64 | 4.24 |
| “I plan to ask my doctors about the dosing level of my cancer drug(s) the next time I see them” | 2.88 | 3.36 |

Questions 2-5 based on a scale of 1-5, where 5 = Strongly Agree

Conclusions

- Involving patients living with MBC in the design of the PCD materials ensures that they meet the needs of patients
- Patients had important feedback on the content of the material, as well as the length, tone and ways to disseminate the materials
- Evaluation showed that those who viewed the materials, even for a short time, had increases in knowledge and felt more confident in PCD
- Future iterations of the PCD materials will be more interactive and more widely disseminated, per patient suggestions

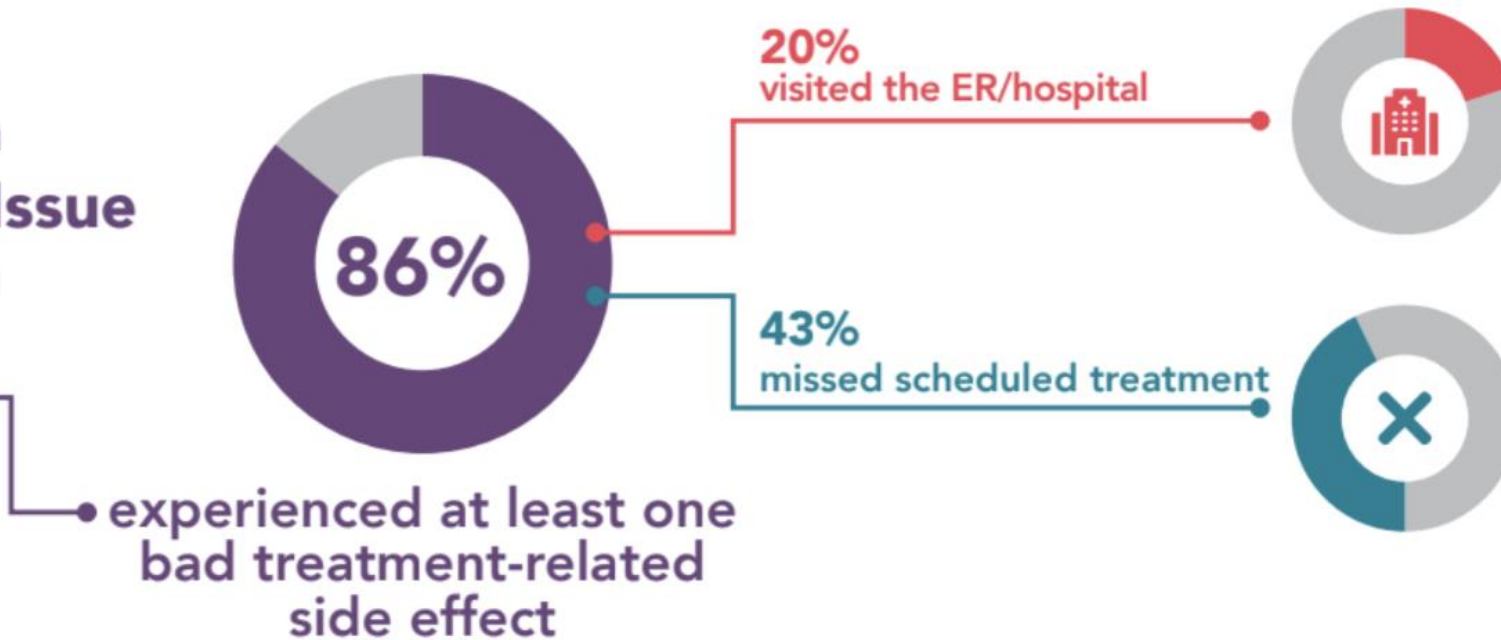
2020 Survey of people living with MBC

1,221 patient respondents




Toxicity Is a Significant Issue

Based on a survey¹ of 1,221 patients with MBC:














of patients felt better upon receiving dose reduction for side effect palliation

Patient-centered dosing: oncologists’ perspectives about treatment-related side effects and individualized dosing for patients with metastatic breast cancer (MBC)

Anne L. Loeser¹ · Lucy Gao²  · Aditya Bardia³ · Mark E. Burkard⁴ · Kevin M. Kalinsky⁵ · Jeffrey Peppercorn³ · Hope S. Rugo⁶ · Martha Carlson¹ · Janice Cowden¹ · Lesley Glenn¹ · Julia Maues¹ · Sheila McGlown¹ · Andy Ni⁷ · Natalia Padron¹ · Maryam Lustberg⁸

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The Right Dose: Results of a Patient Advocate–Led Survey of Individuals With Metastatic Breast Cancer Regarding Treatment-Related Side Effects and Views About Dosage Assessment to Optimize Quality of Life

Anne Loeser, BS^{1,*}; Janice S. Kim, MD² ; Jeffrey Peppercorn, MD, MPH² ; Mark E. Burkard, MD, PhD³ ; Andrzej Niemierko, PhD² ; Dejan Juric, MD² ; Kevin Kalinsky, MD, MS⁴ ; Hope Rugo, MD⁵ ; Lesley Glenn, BS¹ ; Christine Hodgdon, MS¹; Julia Maues, MA¹ ; Sheila Johnson, MBA¹; Natalia Padron, MS¹; Kimberly Parekh, EdD(c)¹; Maryam Lustberg, MD, MPH⁶ ; and Aditya Bardia, MD, MPH, FASCO⁷ 


DOI <https://doi.org/10.1200/OP.23.00539>

ABSTRACT

PURPOSE Although patients with metastatic breast cancer (MBC) have been living longer with the advent of more effective treatments such as targeted therapy and immunotherapy, the disease remains incurable, and most patients will undergo therapy indefinitely. When beginning therapy, patients are typically prescribed dose often based upon the maximum tolerated dose identified in phase I clinical trials. However, patients’ perspectives about tolerability and willingness to discuss individualized dosing of drugs upon initiation of a new regimen and throughout the course of treatment have not been comprehensively evaluated.

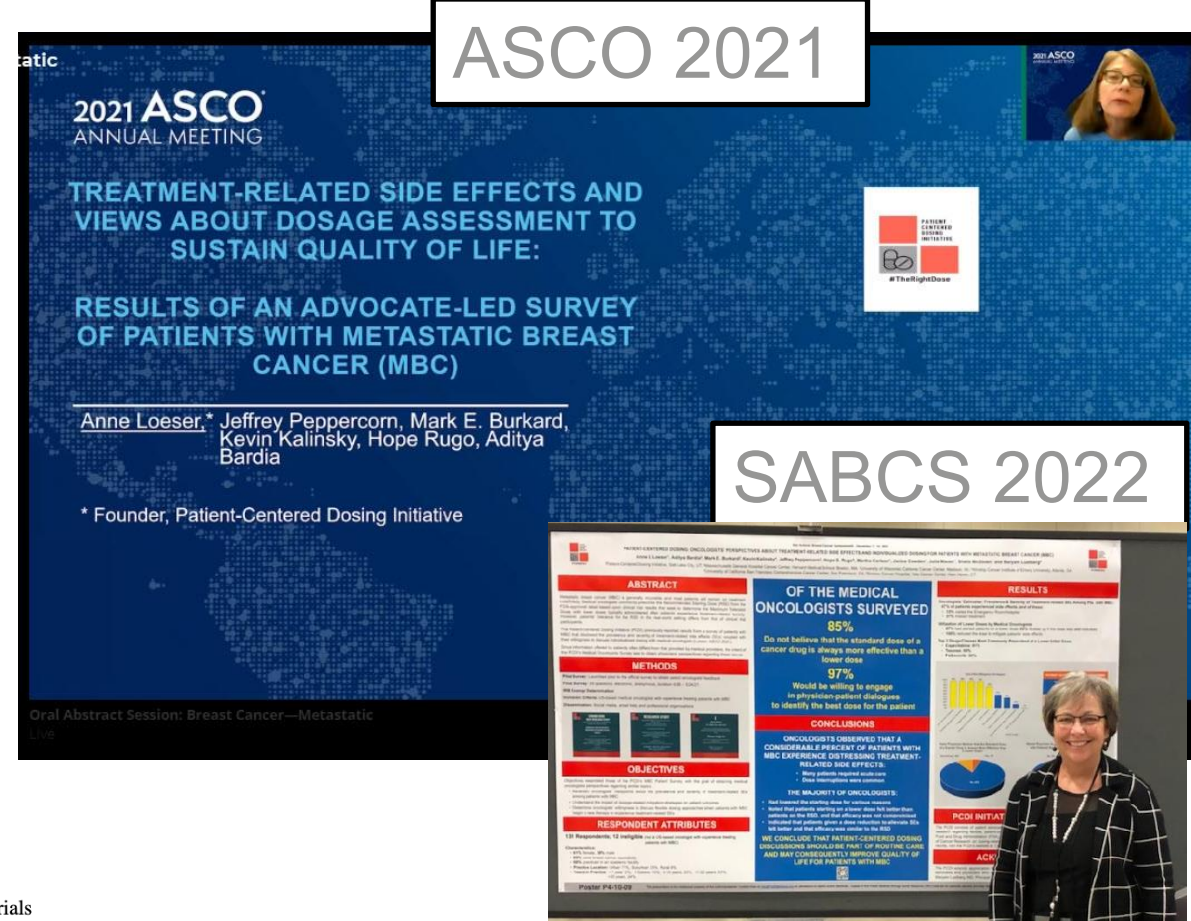
METHODS Patient advocates and medical oncologists from the Patient-Centered Dosing Initiative (PCDI) developed a survey to ascertain the prevalence and severity of MBC patients’ treatment-related side effects, the level of patient-physician communication, mitigation strategies, perception about the relative efficacy of

ACCOMPANYING CONTENT

 Appendix

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Clinical Trials
OnlineFirst
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<https://doi.org/10.1177/17407745241232428>

Article

The patient perspective on dose optimization for anticancer treatments: A new era of cancer drug dosing—Challenging the “more is better” dogma

Julia Maués ¹, Anne Loeser¹, Janice Cowden¹, Sheila Johnson¹, Martha Carlson¹, and Shing Lee²



The idea gained traction with the FDA

“It’s loud and clear from our patients that the drugs are **too toxic**... Patients deserve a more **tolerable** dose.”

FRIENDS of CANCER RESEARCH Annual Meeting

Dose Selection in Oncology

- Maximum tolerated dose (MTD) defined by Dose Limiting Toxicity
- Limitations of MTD approach:
 - Ignores target interactions – off target toxicity
 - Few patients evaluated at each dose
 - Short observation periods for dose-limiting toxicities (DLTs)
 - Limited consideration of safety information beyond DLTs
- Approved doses may be poorly-tolerated by patients, affecting quality-of-life and ability to remain on drug and experience benefit

Dr. Atik Rahman, FDA Division Director

Dr. Atik Rahman, FDA Division Director
Friends of Cancer Research Annual Meeting
Nov. 2021



The NEW ENGLAND
JOURNAL of MEDICINE

PERSPECTIVE



The Drug-Dosing Conundrum in Oncology — When Less Is More

Authors: Mirat Shah, M.D., Atiqur Rahman, Ph.D., Marc R. Theoret, M.D., and Richard Pazdur, M.D. [Author Info & Affiliations](#)

Published October 9, 2021 | N Engl J Med 2021;385:1445-1447 | DOI: 10.1056/NEJMp2109826

VOL. 385 NO. 16 | Copyright © 2021



We believe this practice should be reexamined for targeted drugs and biologic therapies.

With targeted drugs, increasing doses beyond a certain level may not enhance antitumor activity, dose-limiting toxic effects may not be observed at clinically active doses, and serious toxic effects may occur only after multiple cycles of experimental treatment. Patients may use targeted drugs for months or years, which increases the importance of evaluating long-term tolerability.

Real change is happening

FDA has **Project Optimus** (clinical trials) and **Project Renewal** (post-marketing requirements).

For the clinic, PCDI encourages **physician-patient discussions about the right dose for the right patient**. This will remain important because:

- Approved drugs currently on the market continue to be prescribed based upon the MTD.
- It will take time for drug development to actualize the new paradigm.
- Patients' responses in the real world can differ from those clinical trial participants because they are not subject to rigid inclusion/exclusion criteria.
- Patients have unique personal attributes (co-morbidities, drug sensitivities, etc.).

PCDI flyers to help guide conversations between patients and healthcare providers



Are you a patient experiencing treatment-related side effects?



A survey of 1,221 patients with metastatic breast cancer found 86% had at least one bad side effect. If you have side effects, speak with your health care professional.

1. Talk with your doctor who may be able to:

Prescribe medication for relief

Adjust your dose

Change your treatment schedule

Recommend a different treatment

Suggest something else to make you feel better

2. How to start the conversation:

"We both want the same things."

"I want to have the longest possible life, with the best possible quality of life."

"You want that for me too!"

"Let's work together to achieve this."

3. What to discuss together:

- Your personal goals and wishes
- Your general health situation
- History of side effects
- Current and past blood counts
- Whether the disease is slow- or fast-growing
- Whether any organs are severely affected, or the disease is in the brain
- Your body mass index (level of body fat)
- Affordability of medications to ease side effects
- If you need help at home, is anyone available?



NEVER change anything about your treatment on your own; always speak with your doctor!

Learn more at: TheRightDose.org or email info@TheRightDose.org.

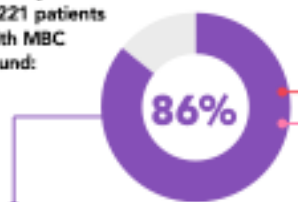
This postcard is solely for informational purposes and is not a substitute for professional medical advice or treatment. If you use and/or act upon any information included here, you assume full responsibility, and you understand and agree that the Patient-Centered Dosing Initiative is not responsible or liable for any claim, loss, or damage resulting from its use by you or any user.

PCDI flyers to help guide conversations between patients and healthcare providers

Are you a health care professional who treats patients with metastatic breast cancer?

MBC treatment is often disrupted by drug-related toxicities that impact therapeutic efficacy and patients' quality of life. But studies of some chemotherapy & targeted drugs found lower doses can be as effective as the recommended starting dose, with less toxicity.

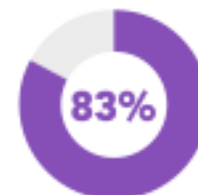
A study of 1,221 patients with MBC found:



experienced at least one bad treatment-related side effect

20% visited the ER/hospital

43% missed scheduled treatment



of patients felt better upon receiving dose reduction for side effect palliation

Talk with each patient to jointly determine an optimal dose.

For each individual patient, at the start of treatment and thereafter, consider these factors.

- The patient's personal goals & wishes
- Performance status
- History of side effects from other drugs
- Current and past blood counts
- Indolent vs. aggressive disease
- Organ dysfunction/CNS metastases
- Body Mass Index
- Ability to afford medications or specialists to ease side effects
- Availability of patients' at-home care



Side effect mitigation strategies may include:



- Dosage reduction
- Altering treatment frequency
- Palliative medications
- Switching treatments
- Referral to specialist
- Changing drug manufacturers
- Other supportive measures (e.g. acupuncture, yoga)



To optimize patients' quality of life, ask patients about side effects at every visit!
Learn more at: TheRightDose.org or email info@TheRightDose.org

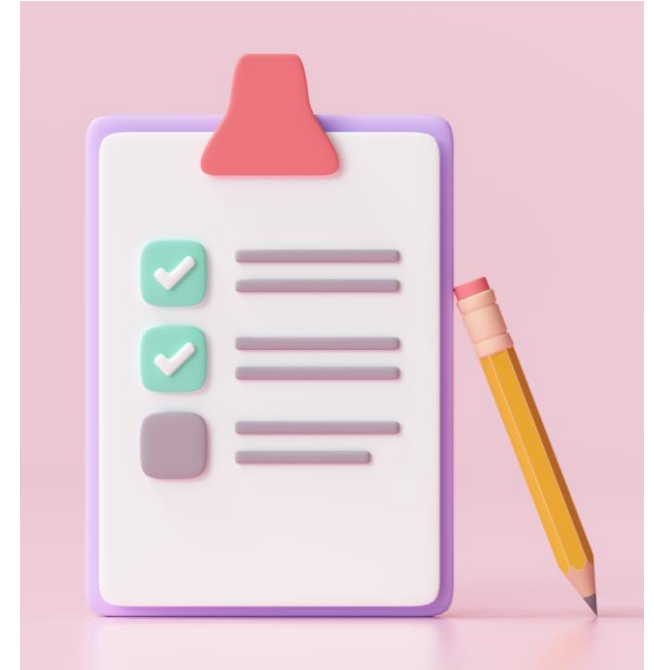


**Patient Centered
Dosing Initiative**

The latest from PCDI

Two new surveys in 2025!

1. **Antibody Drug Conjugates (ADCs) in People With Metastatic Breast Cancer**
 - Side Effects and Dosing
 - Survey completed and results presented at MASCC 2025
2. **Expansion and Update of 2020 Patient Survey**
 - The survey aims to fill gaps in knowledge from our previous research, particularly regarding:
 - **starting a new drug at a lower dose**
 - **underrepresented populations**
 - assessing the impact of dose reduction on **quality of life**
 - **Now open!**



New Patient Survey Closing Soon!

Tell your patients to email surveys@therightdose.org to request a unique survey link

Expansion and Update of 2020 Patient Survey

- The survey aims to fill gaps in knowledge from our previous research, particularly regarding:
 - **starting a new drug at a lower dose**
 - **underrepresented populations**
 - assessing the impact of dose reduction on **quality of life**
- Preliminary analysis will be presented at SABCS



Benefits for Patients

As a result of fewer toxicity-related side effects, patients may:

- Have less need for emergency care
- Miss fewer treatments
- Potentially remain on a working treatment longer
- Take broader advantage of the full complement of available treatments
- Experience a better Quality of Life

...And possibly,

just possibly,

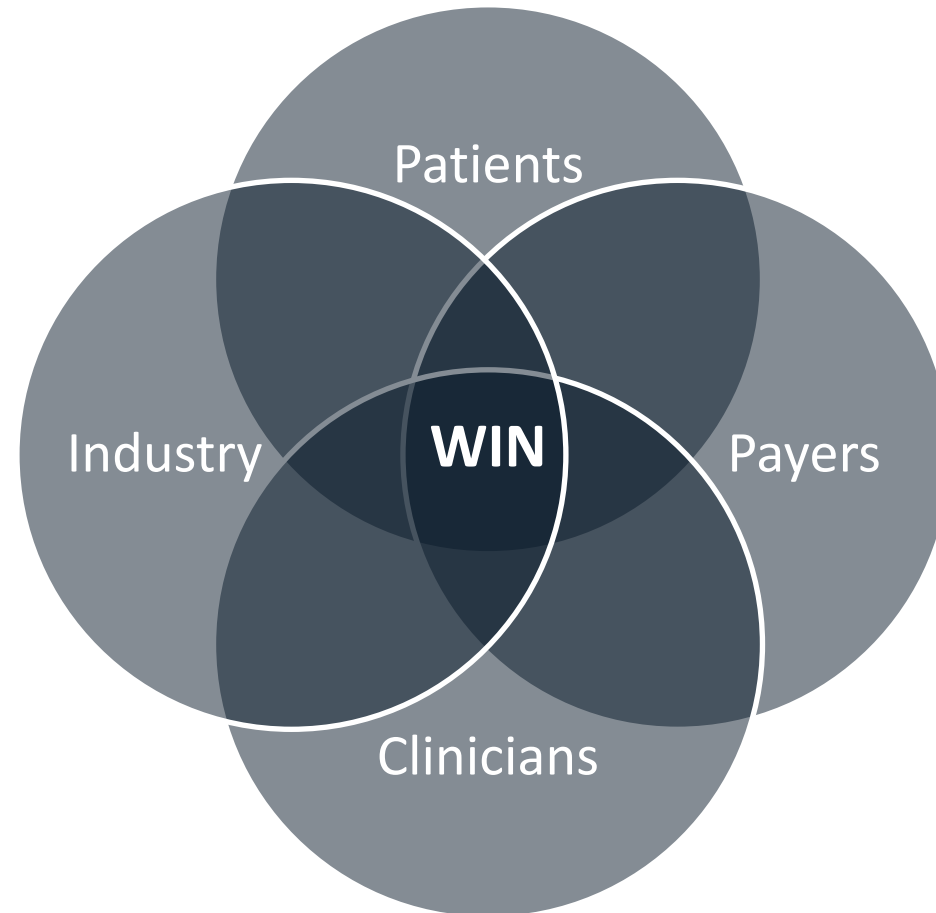
EVEN LIVE LONGER



PCDI Former Member Sheila Johnson and her oncologist of 13 years, Dr. Cynthia Ma.



Cancer Drug Dosing: A New Era



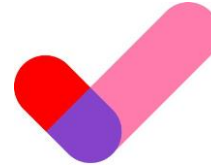
Thank you to PCDI's
funders and supporters



Steve Loeser

All patients and oncologists who have
taken our surveys

All partner organizations that have
helped us share the surveys, survey
results, and education materials



www.therightdose.org



info@therightdose.org



lead@therightdose.org

for providers

LIVING BEYOND BREAST CANCER RESOURCES

- [Patient-centered dosing one-pager](#)

Webpages

- [Patient-centered dosing](#)
- [Testing and precision medicine](#)
- [ctDNA testing](#)
- [Next-generation sequencing \(NGS\) tests](#)

Video

- [The right dose for you: Managing treatment & quality of life](#)

EXTERNAL RESOURCES

- [Patient Centered Dosing Initiative site](#)
- [Patient Centered Dosing Initiative flyer](#)

Resources

Free resources to help providers speak with patients about patient-centered dosing in metastatic breast cancer.



for providers



Healthcare provider resources

Your go-to webpage for resources for you and your patients.



Thank you for joining!

Please contact us at hcp@lbbsc.org with any questions.

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