



**Agenda for the Metastatic Breast Cancer (MBC) Engagement Conference at  
Moffitt Cancer Center**

**June 22-23, 2018**

Note: \*\* Indicates the activity has been approved for *AMA PRA Category 1 Credit™* jointly provided by the University of Southern Florida and the Metastasis Research Society.

CER = comparative effectiveness research (research comparing the benefits and harms of existing approved MBC therapies to improve outcomes or quality of life)

MRS = Metastasis Research Society

MBC = metastatic breast cancer

**JUNE 22, 2018**

<i><b>Program</b></i>	<i><b>Speaker/Participants</b></i>
8-9:30 AM Registration in atrium of Stabile Research Building at Moffitt	
9:30-9:40AM Welcoming remarks and announcements	Kate Bankaitis, PhD (Project Lead for the MRS and Sonya Negley, Executive Director of METAvivor)
9:40-9:45AM Introduction to the Patient-Centered Outcomes Research Institute (PCORI)	Sonya Negley (Executive Director of METAvivor)
9:45-10:05AM <i>Session 1: Introduction to CER Trials**</i>	<b>Bill Dalton, MD, PhD</b> Founding Director of Moffitt's Personalized Medicine Institute CEO of M2Gen Past-president and CEO of Moffitt Moffitt Cancer Center, Tampa, FL
10:05-10:20 AM Break (registration still open)	

<p>10:20 AM-11AM <i>Session 2: MBC Patient-led Panel Presents Top Patient-Desired Outcomes**</i></p>	<p>Panel consisting of 4 male and female patients being treated for stage IV MBC (speaker names TBA)</p>
<p>11AM-12:10PM <i>Session 3: Needs Assessment Panel Discussion for Identifying Barriers to Engagement (patients, clinicians, and researchers)</i></p>	<p>Clinician Scientist:  <b>Brian Czerniecki, MD, PhD</b>  Chair and Senior Member of the Department of Breast Oncology  Moffitt Cancer Center, Tampa, FL</p> <p>Clinician:  <b>Catherine Lee, MD</b>  Surgeon  Assistant Professor  Moffitt Cancer Center, Tampa, FL</p> <p>Researcher and cancer survivor:  <b>Corrie Painter, PhD</b>  Associate Director of Operations and Scientific Outreach  Broad Institute of MIT and Harvard, Cambridge, MA  Vice President Angiosarcoma Awareness</p> <p>Male and female stage IV MBC patient panelists TBA</p>
<p>12:10-1:30 PM Lunch at roundtables with 1 hour engagement session from 12:30-1:30 for discussion of important barriers to engagement amongst stakeholders</p>	<p>All attendees participate</p>
<p><i>1:30 PM-2:45 PM Session 4: Introduction to the Biology of Breast Cancer Metastasis and Current Translational Research**</i></p>	<p><b>Danny Welch, PhD</b>  Professor and Chair  Adjunct faculty of Department of Molecular &amp; Integrative Physiology  University of Kansas Medical Center, Kansas City, KS</p>
<p>2:45 – 3PM Break</p>	

<p>3PM-4PM Engagement in working groups to order top translational/clinical research priorities</p> <p>4-4:05 PM Brief announcement about directory participation for research studies/trials and sustained engagement</p>	All attendees participate
<p>4:05-5PM Networking Reception (hors d'oeuvres provided)</p>	All attendees welcome, included with registration
<p>5PM Dinner at roundtables</p>	All attendees welcome, included with registration

**JUNE 23, 2018**

<b><i>Program</i></b>	<b><i>Speaker/Participants</i></b>
<p>8:30-9:30AM <i>Session 5: Insurance Coverage of Therapies in Clinical Studies (includes 15 min of Q&amp;A)</i></p>	<p>Speaker TBA (we anticipate a Blue Cross Blue Shield representative)</p>
<p>9:30-10:45AM <i>Session 6: Clinical Advances for MBC**</i></p>	<p><b>Ingrid Mayer, MD</b>  Co-Leader and Clinical Director, Breast Cancer Research Program  Chair, Data and Safety Monitoring Committee  Associate Professor of Medicine (Hematology/Oncology)  Vanderbilt University, Nashville, TN</p> <p>Male Metastatic Breast Cancer Focus:  <b>Pablo Leone, MD</b>  Medical Oncologist  Clinical Investigator in the Breast Oncology Center  Dana-Farber Cancer Institute  Susan F. Smith Center for Women's Cancers, Boston, MA</p> <p>Speakers on the use of liquid biopsy for management and treatment of MBC  <b>Klaus Pantel, MD</b>  Professor, Director, Department of Tumor Biology, University of Hamburg  University Medical Center Hamburg-Eppendorf, Germany</p>

	Potential industry short talk on liquid biopsy – TBA
<i>10:45-11AM Break</i>	
<i>11AM-12:00 PM Session 7: CER Trial Priorities for MBC**</i>	<b>Timothy Pluard, MD</b> Medical Director at St. Luke’s Hospital Associate professor of medicine, University of Missouri-Kansas City School of Medicine Kansas City, MO
<i>12:00-12:40 PM Lunch at roundtables</i>	
<i>12:40-2:40 PM National CER Priorities Engagement Session in Working Groups (15 min. break inside the 2-hour session)</i>	All attendees participate
<i>2:45-3:20 PM Session 8: Resources for MBC Stakeholders (includes patient resources and toolkits for physicians and researchers)</i>	Patient representative of METAvivor and two additional speakers - TBA
<i>3:20-4:15 PM Networking reception to facilitate creation of new peer-to-peer support groups (hors d’oeuvres provided)</i>	All attendees welcome, included in registration
<i>4:15-4:20 PM Closing Remarks</i>	

## **DESCRIPTION OF SESSIONS AND CONTINUING MEDICAL EDUCATION (CME) LEARNING OBJECTIVES**

**Introduction to PCORI (5-minute presentation):** Brief introduction to the goals of the Patient Centered Outcomes Research Institute and what they fund (engagement awards and comparative effectiveness research CER).

**Session 1: *Introduction to Clinical Comparative Effectiveness Research (CER) Trials\*\****  
Conference attendees (patients, clinicians and translational researchers) will be introduced to what CER is (a path forward for existing therapies to improve medical decisions) and how CER compares to phase III trials (describing the similarities and differences of CER and phase III trials for testing experimental therapies). MBC will be the example used. Attendees will also be introduced to the PICOT format for writing clinical CER questions that address patient-desired research outcomes. 17-minute presentation with 3 minutes for questions.

CME Learning Objective: Describe how clinical trials, including those testing experimental therapies or the novel use of existing therapies, can be applied to the treatment of metastatic breast cancer to improve outcomes and quality of life.

**Session 2: *MBC Patient-led Panel Presents Top Patient-Desired Outcomes\*\****

A panel consisting of 5 MBC patient advocates will present their top stage IV patient-desired outcomes including clinical and patient-reported outcomes. Each patient should expect to present for up to 6 minutes with slides. There will be 10 minutes following the panel for input from the audience. The project lead will collate a list of all top patient-desired outcomes discussed for publication.

CME Learning Objective: Identify how to optimize personalized medical decision making based upon a patients' desired outcomes.

**Session 3: *Needs Assessment Panel Discussion and Engagement Session for Identifying Barriers to Engagement Among Stakeholders*** (patients, researchers, clinicians)

This session will serve to identify and discuss current barriers that must be overcome for successful engagement amongst clinicians, researchers, and patients to ensure metastasis research in the lab and in clinical trials remains patient-centered. The panel will consist of 1 researcher, 1 clinician scientist, 1 oncologist, and 2 patients (one male and one female) to facilitate discussion of improving metastatic breast cancer studies through engagement from multiple perspectives.

Each panelist will present their barriers to engagement in an up to 6-minute presentation with slides. This will be followed by 30 minutes of discussion amongst panelists before input is opened to the audience for 20 minutes to conclude top barriers to engagement. The discussion will build upon barriers introduced during the first three webinars prior to the conference (these will be provided to speakers by the project lead by January of 2018, examples below).

Example barriers identified so far: Finding a way for patients who want to support and participate in research/trial planning to be matched with researchers/clinicians looking for their input, lack of researcher/clinician time, finding a balance between research needs and patient needs, etc.

**Session 4: The Biology of Breast Cancer Metastasis and Current Translational Research Priorities**

A metastatic breast cancer researcher of the MRS will introduce the top 5 translational metastatic breast cancer research priorities identified by a pre-conference survey and explain the basic biology of metastasis related to each in lay terms. Topics will be discussed and finalized with the speaker in January of 2018 after the survey closes (~6 months before the conference). The presentation will be followed by engagement amongst conference attendees (patients, researchers, and clinicians) collectively in

working groups to rank the top 3 research priorities from the list of 5 presented. There is one hour allotted for the presentation (up to 12 minutes per topic) with Q&A time to follow before the hour-long engagement session in working groups.

Related CME learning objective: Explain the molecular basis of breast cancer metastasis and discuss how new targets for therapy can be applied to the treatment of metastatic breast cancer to improve outcomes.

**Session 5: Insurance Coverage of Therapies in Clinical Studies**

A panel of representatives from healthcare insurance companies will describe their coverage of therapies in cancer clinical trials (what they do and do not cover).

**Session 6: Clinical Advances for MBC\*\***

Two leading oncologists will collectively cover the most recent clinical comparative effectiveness research findings (comparisons of existing therapies) for male or female metastatic breast cancer in lay terminology in order to disseminate information on the benefits and harms of current therapy options to all stakeholders. Oncologists will also briefly touch on clinical trials with new experimental treatments for metastatic breast cancer. An additional oncologist will present on how available blood tests (liquid biopsy) can be used to manage and treat MBC. Each oncologist will have 22 minutes to present and this session will be followed by 10 minutes of Q&A.

*Example CER topics (final session topics to be announced):* comparison of third line treatment options for metastatic breast cancer, hormonal therapies versus non-hormonal therapies for hormone positive metastatic breast cancer, partial versus whole-breast radiation, comparison of imaging modalities for diagnosing axillary lymph node metastasis, comparison of alternative mTOR inhibitors and alternative aromatase inhibitors.

CME learning objectives:

- 1) Describe how clinical trials, including those testing experimental therapies or the novel use of existing therapies, can be applied to the treatment of metastatic breast cancer to improve outcomes and quality of life.
- 2) Identify how liquid biopsy blood tests can help improve the treatment of metastatic breast cancer.

**Session 7: CER Trial Priorities for MBC\*\***

An oncologist will introduce the top 6 comparative effectiveness research (CER) topics in no special order, identified by all stakeholders as important on a pre-conference survey. The speaker will identify the question the CER topic is meant to address i.e. explain the significance of each topic prior to discussions meant to prioritize these topics amongst all stakeholders in engagement working groups. If topics mention certain drugs the speaker should explain what the drug is intended to treat and how. The list of the top 6 priorities will be provided to the speaker by February of 2018 to allow 5 months to prepare for the 45-minute talk (7.5 minutes per priority).

Stakeholder working groups of patients, clinicians, and researchers will then discuss the 6 topics and come up with specific CER questions meant to address at least 1 of the topics they feel as a group is the most important and addresses patient-desired outcomes. All stakeholders will be given a template for developing questions related to CER topics and sample questions. There will be at least 20 min. of discussion time for each of the 6 topics.

CME Learning Objective: Describe how clinical trials, including those testing experimental therapies or the novel use of existing therapies, can be applied to the treatment of metastatic breast cancer to improve outcomes and quality of life.

**Session 8:** *Resources for metastatic breast cancer stakeholders*

A patient representative of METAvivor will present on their established peer-to-peer support program for metastatic patients and clearly explain how individuals can set up these groups. Short presentations from two other patients will follow that highlight additional MBC patient resources (including information on trials) to physicians, researchers and patients (stakeholders).