Metastasis Research Society/METAvivor Metastatic Breast Cancer Engagement Conference
June 22-23, 2018

Venue: Vincent A. Stabile Research Building of the H. Lee Moffitt Cancer Center, Tampa, FL

Co-Chairs:

- Kate Bankaitis, PhD (Director of Programs and Engagement, Metastasis Research Society)
- Sonya Negley (Executive Director, METAvivor Research and Support Inc.)

Steering Committee:

- Dian “CJ” Corneliussen (METAvivor Research and Support Inc.)
- Kelli Davis (METAvivor Research and Support Inc.)
- Irwin Gelman, PhD (Roswell Park Cancer Institute, Buffalo, NY)
- Stan Leong, Stan Leong, MD, FACS, MS (California Pacific Medical Center Research Institute and University of California, San Francisco School of Medicine, San Francisco, CA)
- Conor Lynch, PhD (Moffitt Cancer Center, Tampa, FL)
- Lisa and Patrick Quinn (METAvivor Research and Support Inc.)
- Terlisa Sheppard (METAvivor Research and Support Inc.)
- Jonathan Zager, MD (Moffitt Cancer Center, Tampa, FL)

(listed by alphabetical order of last name)

Conference Medical Director
Kelly Shanahan, MD, FACOG
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PROGRAM

Common Acronyms:
MBC = metastatic breast cancer
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

Friday, June 22, 2018

08:00 – 09:30 AM  Registration
Room: Atrium of Vincent A. Stabile Research Building

09:30-09:40 AM  Welcoming Remarks and Important Announcements
Room: Auditorium of the Vincent A. Stabile Research Building
Kate Bankaitis, PhD (Metastasis Research Society) and Sonya Negley (METAvivor Research and Support Inc.)

09:40-09:45 AM  Introduction to the Patient-Centered Outcomes Research Institute
Sonya Negley, Executive Director, METAvivor Research and Support Inc.

09:45 – 10:00 AM  Introduction to Comparative Effectiveness Research (CER) Trials
Bill Dalton, MD, PhD, Moffitt Cancer Center, Tampa, FL
Chairpersons: Kate Bankaitis, PhD and Terlisa Sheppard

10:00 -10:05  Q &A

10:05 -10:25 AM  Coffee Break (registration still open)
Room: Atrium

10:25 -11:05 AM  MBC Patient-led Panel Presents Top Patient-Desired Outcomes
Room: Auditorium
Chairpersons: Beth Fairchild

10:26 -10:32 Marina Kaplan, PhD, Patient Advocate
10:32 -10:44 Kelli Davis, Patient Advocate, NWA Metsquerade
10:44-10:50 Michael Kovarik, Board Member, METAvivor Research and Support Inc.
10:50 -11:05 Input/questions from the audience regarding patient-desired outcomes
11:05 -12:25 PM *Needs Assessment Panel Discussion for Identifying Barriers to Engagement (patients, clinicians, and researchers)*  
*Room: Auditorium*  
*Chairperson: Kate Bankaitis, PhD and Dian “CJ” Corneliussen, MA*

11:06 -11:12 Corrie Painter, PhD, Broad Institute of MIT and Harvard, Cambridge, MA

11:12 -11:18 Catherine Lee, MD, Moffitt Cancer Center, Tampa, FL

11:18 -11:24 Timothy Pluard, MD, St. Luke’s Hospital, University of Missouri-Kansas City School of Medicine, Kansas City, MO

11:24 -11:30 Beth Fairchild, President, METAvivor Research and Support Inc.

11:30 -11:36 Kirby Lewis, MBC Patient Advocate

11:36 -12:06 Discussion including two topics selected from the preconference survey (Reference Appendix A page 8)

12:06-12:25 Panel Q &A and input on barriers from the audience

12:25–1:30 PM **Lunch Break**  
*Room: Atrium*

1:30–2:45 PM **Introduction to the Biology of Breast Cancer Metastasis and Current Translational Research**  
*Chairpersons: Barbara Fingleton, PhD and Kelly Lange*  
*Room: Auditorium*

1:30-2:15 Danny Welch, PhD, University of Kansas Medical Center, Kansas City, KS (Presentation research topics listed in Appendix B on page 8)

2:15-2:45 Q & A

2:45–3:00 PM **Coffee Break**  
*Room: Atrium*

3:00–4:00 PM **Engagement in Roundtable Working Groups to Rank Top Translational MBC Research Priorities**  
(Topics listed in Appendix B page 9)  
*Room: Atrium*
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<tr>
<td>4:00-5:00 PM</td>
<td>Networking Reception (hors d’oeuvres provided)</td>
<td>Atrium</td>
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<td>5:00-6:00 PM</td>
<td>Dinner at roundtables</td>
<td>Atrium</td>
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### Saturday June 23, 2018

<table>
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<tr>
<th>Time</th>
<th>Event</th>
<th>Room</th>
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<tr>
<td>9:00-9:30 AM</td>
<td><strong>Insurance Coverage of Therapies in Clinical Studies</strong>&lt;br&gt;&lt;br&gt;<em>Room:</em> Vincent A. Stabile Research Building Auditorium&lt;br&gt;<em>Chairpersons:</em> Kelly Lange&lt;br&gt;Paul Kaplan, MD, MBA, VP Medicare Quality and Stars, Florida Blue</td>
<td>Vincent A. Stabile Research Building Auditorium</td>
<td>Kelly Lange, Paul Kaplan, MD, MBA, VP Medicare Quality and Stars, Florida Blue</td>
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<td>9:20-9:30 AM</td>
<td>Q &amp;A</td>
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<td>9:30-10:50 AM</td>
<td><strong>Session on Clinical Advances for Metastatic Breast Cancer</strong>&lt;br&gt;&lt;br&gt;<em>Room:</em> Auditorium&lt;br&gt;<em>Chairperson:</em> Conor Lynch, PhD and Dian “CJ” Corneliussen, MA</td>
<td>Auditorium</td>
<td>Conor Lynch, PhD and Dian “CJ” Corneliussen, MA</td>
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<td>9:31-9:53 AM</td>
<td>Advances in Metastatic Breast Cancer&lt;br&gt;Senthil Damodaran, MD, PhD, The University of Texas MD Anderson Cancer Center, Houston, TX</td>
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<td>Senthil Damodaran, MD, PhD, The University of Texas MD Anderson Cancer Center, Houston, TX</td>
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<td>9:54-10:09 AM</td>
<td>Metastatic Breast Cancer in Men&lt;br&gt;Pablo Leone, MD, Dana-Farber Cancer Institute, Boston, MA</td>
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<td>Pablo Leone, MD, Dana-Farber Cancer Institute, Boston, MA</td>
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<td>10:10-10:32 AM</td>
<td>Liquid Biopsy in Metastatic Breast Cancer&lt;br&gt;Anna Bayaban, Dr. rer. biol. hum.&lt;br&gt;University Medical Center Hamburg-Eppendorf, Department of Tumor Biology, Hamburg, Germany</td>
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<td>Anna Bayaban, Dr. rer. biol. hum.&lt;br&gt;University Medical Center Hamburg-Eppendorf, Department of Tumor Biology, Hamburg, Germany</td>
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<td>10:32-10:45 AM</td>
<td>Q &amp; A with the speakers</td>
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<td>10:45-11:00 AM</td>
<td><strong>Coffee Break</strong>&lt;br&gt;&lt;br&gt;<em>Room:</em> Atrium</td>
<td>Atrium</td>
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<td>11:00-12:00 PM</td>
<td><strong>Comparative Effectiveness Research (CER) Trial Priorities for Metastatic Breast Cancer</strong>&lt;br&gt;&lt;br&gt;<em>Room:</em> Auditorium&lt;br&gt;<em>Chairpersons:</em> Irwin Gelman, PhD and Kelli Davis</td>
<td>Auditorium</td>
<td>Irwin Gelman, PhD and Kelli Davis</td>
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<td>11:00-11:40 PM</td>
<td>Timothy Pluard, MD, St. Luke’s Hospital, University of Missouri-Kansas City School of Medicine, Kansas City, MO&lt;br&gt;(Topics for presentation and discussion listed in Appendix C page 10)</td>
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<td>Timothy Pluard, MD, St. Luke’s Hospital, University of Missouri-Kansas City School of Medicine, Kansas City, MO</td>
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<td>11:40-12:00 PM</td>
<td>Q &amp; A</td>
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12:00-12:05  Brief explanation of how to write CER questions during the 12:45 PM Engagement Session  
Kate Bankaitis, PhD (Metastasis Research Society)

12:05-1:00 PM  Lunch  
Room: Atrium

1:00-2:40 PM  Engagement in Working Groups to Identify Top CER Priorities for MBC and Create CER Questions  
(Research topics in Appendix C page 10 and guide to writing CER questions in PICOT format in Appendix D page 11-12)  
**This session includes a 20 minute break from 1:50-2:10 PM**  
Room: Atrium

2:40-3:10 PM  Resources for MBC Stakeholders (patient resources and toolkits for physicians and researchers)  
Chairperson: Beth Fairchild  
Room: Auditorium

2:40-2:52  Kelly Lange, Treasurer, METAvivor Research and Support Inc.  
2:52-3:05  Dian “CJ” Corneliussen, Founder and Director Emeritus, METAvivor Research and Support Inc.  
3:05-3:00  Q & A

3:10-3:40 PM  Networking Reception (hors d’oeuvres provided)  
Room: Atrium

3:40-3:45 PM  Closing Remarks  
Room: Atrium  
Chairpersons: Kate Bankaitis, PhD (Metastasis Research Society); Sonya Negley (METAvivor Research and Support Inc.)
APPENDIX A

Panel Discussion Topics for Session Titled: Needs Assessment Discussion for Identifying Barriers to Engagement Amongst Stakeholders (patients, researchers, clinicians)

1) Lack of channels/opportunities for patients/researchers/clinicians to engage with each other

2) Clinical trial eligibility exclusions – excluding patients who want to participate in clinical trials but cannot due to “too strict” eligibility criteria.

These topics were the top two barriers to engagement identified by a pre-conference survey with 134 metastatic breast cancer patient, researcher, and clinician respondents.
APPENDIX B


Note: These topics were identified on a pre-conference survey with 134 metastatic breast cancer patient, researcher, and clinician respondents.

Translational Research Topics:

1) Researching the biology behind the hallmarks of metastasis to identify new ways to treat/target breast cancer metastasis.

2) Discovering new ways to limit breast cancer progression by researching how to target and destroy dormant metastatic breast cancer cells that have spread from the primary tumor or spread from metastatic tumors to seed new metastases.
   (Dormant cancer cells are cells that stop dividing and survive in a quiescent state until they receive environmental cues to begin dividing again)

3) Researching how primary breast cancer cells evolve into metastatic tumor cells and how metastatic tumors continue to progress rather than remain stable.

4) More pre-clinical testing of liquid biopsy as a non-invasive way to screen for metastatic breast cancer progression and response to treatments.

5) Research into organotropism and patterns of metastasis to better predict where breast cancer will spread or continue to spread.
   (organotropism refers to the affinity of cancer cells to metastasize to a specific organ such as the liver or bone).
APPENDIX C

Research Topics for Sessions Titled: Comparative Effectiveness Research (CER) Trial Priorities for Metastatic Breast Cancer and Engagement in Working Groups to Identify Top CER Priorities for MBC and Create CER Questions.

Note: These topics were identified on a pre-conference survey with 134 metastatic breast cancer patient, researcher, and clinician respondents.

CER = research comparing the benefits and harms of existing approved therapies to improve outcomes or quality of life

Comparative Effectiveness Research Topics:

1) What is the appropriate chemotherapy agent to combine with anti PD-1 immunotherapy in triple negative breast cancer.

2) A comparison of the three approved CDK4/6 inhibitors in combination with an aromatase inhibitor in women 70 and above.
   CDK4/6 inhibitor names: (Ibrance a.k.a palbociclib, Kisqali a.k.a ribociclib and Verzenio a.k.a abemaciclib)

3) Is there a role for continuing and/or switching CDK4/6 inhibitors after progression.

4) Should fulvestrant or an aromatase inhibitor be used first line with a CDK4/6 inhibitor in recurrent or denovo stage IV ER+ disease.

5) What is the role of liquid biopsy in: 1) replacing tissue biopsy and 2) monitoring treatment response (comparison of tissue vs liquid biopsy)

6) What is the effectiveness of acupuncture in pain management in MBC patients.
APPENDIX D

Guide to Writing Clinical Comparative Effectiveness Research (CER) Questions using the PICOT Format

PICOT stands for:

- **Population/ Patient Problem:** Who is your patient? (Disease or Health status, age, race, sex)  \( P = \text{patient} \)
- **Intervention:** What do you plan to do for the patient? (Specific tests, therapies, medications)  \( I = \text{intervention} \)
- **Comparison:** What is the alternative to your plan? (ie. No treatment, different type of treatment, etc.)  \( C = \text{comparison} \)
- **Outcome:** What outcome do you seek? (Less symptoms, no symptoms, full health, etc.)  \( O = \text{Outcome} \)
- **Time:** What is the time frame? (This element is not always included.)  \( T = \text{time} \)

*PICOT definition from the Lansing Community College Library: https://libguides.lcc.edu/c.php?g=167860&p=1102882*

Sample PICOT-Format Research Questions

Key: \( P = \text{patient} \), \( I = \text{intervention} \), \( C = \text{comparison} \), \( O = \text{outcome} \), \( T = \text{time} \) (optional)

**Intervention:** In African-American female adolescents with hepatitis B (P), what is the effect of splinting and casting (I) compared to constraint-induced therapy (C) on two-handed skill development (O)?

**Prognosis/Prediction:** For patients 65 years and older (P), how does use of the flu vaccine (I) compared to non-use (C) influence the risk of developing pneumonia (O) during flu season (T)?

**Diagnosis:** In middle-aged males with suspected myocardial infarction (P), are serial 12-lead ECGs (I) compared to one initial 12-lead ECG (C) more accurate in diagnosing an acute myocardial infarction (O)?

**Etiology:** Are 30-50 year old women (P) who have high blood pressure (I) compared with those without high blood pressure (C) at increased risk for an acute myocardial infarction (O) during the first year after hysterectomy (T)?

**Meaning:** How do young males (P) with a diagnosis of below the waist paralysis (I) perceive their interactions with their significant others (O) during the first year after diagnosis (T)?

*PICOT questions and templates were adapted from the PICOT Questions Template; Ellen Fineout-Overholt 2006. This information may be used for educational and research purposes without permission.*
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<thead>
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<th>模板内容</th>
<th>描述</th>
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<tr>
<td>INTERVENTION</td>
<td>在______(P)中，如何将______(I)与______(C)对比在______(O)中对______(T)的影响？</td>
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<tr>
<td>THERAPY</td>
<td>在______(P)中，治疗______(I)与______(C)对______(O)在______(T)中的影响是什么？</td>
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<tr>
<td>PROGNOSIS/PREDICTION</td>
<td>在______(P)中，如何将______(I)与______(C)对比对______(O)在______(T)中的影响？</td>
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<tr>
<td>DIAGNOSIS OR DIAGNOSTIC TEST</td>
<td>在______(P)中，<strong><strong><strong>(I)与</strong></strong></strong>(C)在诊断______(O)时更准确？</td>
</tr>
<tr>
<td>ETIOLOGY</td>
<td>在______(P)中，有______(I)与那些没有______(C)在______(T)中有什么不同？</td>
</tr>
<tr>
<td>MEANING</td>
<td>在______(P)中，<strong><strong><strong>(I)与</strong></strong></strong>(O)在______(T)中如何感知？</td>
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THANK YOU TO OUR SPONSORS:

This conference was funded in part through a Patient-Centered Outcomes Research Institute (PCORI) Eugene Washington PCORI Engagement Award (6102-MRS)