

AGENDA
NCI Breast Cancer Steering Committee (BCSC)
Clinical Trial Planning Meeting (CTPM) for
Lifestyle Intervention for Improving Disease Free Survival (DFS) in Early Stage Invasive Breast Cancer
February 10 – 11, 2014
The NIH Neuroscience Center Building, 6001 Executive Boulevard
Rockville, MD 20852

DAY 1: MONDAY, FEBRUARY 10, 2014

- 6:00 PM** **Welcome and introductions**
Nancy Davidson and Rachel Ballard-Barbash, Meeting Co-chairs
- 6:10 PM** **Meeting goals/intended outcomes of meeting**
Nancy Davidson and Rachel Ballard-Barbash
- 6:15 PM** **NCI coordination of trial and resources**
Lori Minasian
- 6:20 PM** **State of the science on weight loss trials in people without cancer**
Tom Wadden
- 6:40 PM** **State of the science on the effect of intentional weight loss in people with cancer and the feasibility of intervention approaches in the NCI clinical trials system**
Jennifer Ligibel
- 7:10 PM** **Adaptations using remote technologies and other innovations to enroll and maintain high risk and hard to reach population participants**
Gary Bennett
- 7:30 PM** **Panel and group discussion**
Moderator: Pam Goodwin
Panel Members: Tom Wadden, Jennifer Ligibel, Gary Bennett, Wortia McCaskill-Stevens
- 7:55 PM** **Issues to consider in trial design related to insurance companies covering clinical care provided for weight loss interventions among cancer patients (should the trial prove successful)**
Moderator: Catherine Alfano
Panel Members: Cay Loria, Kate Wolin, Gary Bennett, CMS

- 8:15 PM** **Trial monitoring, evaluation and breast cancer–specific endpoints**
Garnet Anderson
- 8:35 PM** **Group discussion**
Moderator: Rachel Ballard-Barbash
- 8:45 PM** **Closing remarks**
Nancy Davidson and Rachel Ballard-Barbash
- 8:50 PM** **ADJOURN**

DAY 2: TUESDAY, FEBRUARY 11, 2014

- 8:00 AM** **Welcome and overview of day 2**
Nancy Davidson and Rachel Ballard-Barbash
- 8:05 AM** **TRIAL DESIGN: What are the different types of overall design to consider for weight loss trials?**
Cay Loria and Mary Evans
- 8:20 AM** **TRIAL DESIGN: INTERVENTION: Weight loss**
Pam Goodwin
- 8:35 AM** **TRIAL DESIGN: INTERVENTION: Physical activity**
Kate Wolin
- 8:50 AM** **TRIAL DESIGN: INTERVENTION: Diet**
Marian Neuhouser
- 9:05 AM** **TRIAL DESIGN: INTERVENTION: Behavioral counseling**
Catherine Alfano
- 9:20 AM** **Panel discussion**
Moderator: Garnet Anderson
Panel Members: Tom Wadden, Cay Loria, Pam Goodwin, Kate Wolin, Marian Neuhouser, Catherine Alfano
- 9:50 AM** **Group discussion**
Moderator: Garnet Anderson

- 10:05 AM** **BREAK**
- 10:15 AM** **Intermediate Outcomes, Cost/Utilization, and Influence of Work/Productivity**
Kate Wolin
- 10:30 AM** **Group discussion**
Moderator: Garnet Anderson
- 10:45 AM** **TRIAL DESIGN: Eligibility**
Dawn Hershman
- 11:15 AM** **TRIAL DESIGN: Statistical considerations**
Mark Espeland
- 11:45 AM** **Panel discussion**
Moderator: Dawn Hershman
Panel Members: Tiffany Powell-Wiley, Mary Evans, Mark Espeland, Jennifer Ligibel
- 12:05 PM** **Group discussion**
Moderator: Dawn Hershman
- 12:35 PM** **BREAK**
- 1:35 PM** **Summation of proposed trial design and group discussion**
Nancy Davidson
- 2:15 PM** **Final thoughts on the data that insurance companies are seeking related to decisions to cover clinical care provided for weight loss interventions among cancer patients**
Moderator: Rachel Ballard-Barbash
- 2:25 PM** **Meeting summary and action plan**
Nancy Davidson and Rachel Ballard-Barbash
- 2:45 PM** **ADJOURN**