

## **Scientific Leadership Council in Breast Cancer of the Coalition of Cancer Cooperative Groups Meeting Dallas, Texas--September 13-14**

The Coalition of Cancer Cooperative Groups (the Coalition) is a nonprofit organization whose mission is to improve the quality of life and survival of cancer patients by increasing participation in cancer clinical trials. One of their goals is to encourage and facilitate participation in clinical trials.

Because there are over 1400 breast cancer clinical trials and 526 stage III breast cancer trials, the organizations decided to form a Scientific Leadership Council (SLC) of the breast cancer thought leaders to prioritize the most important stage III trials in order to speed up accruals for those key trials.

The committee grouped trials into 9 different areas, screening, surgery, radiation therapy, adjuvant systemic therapy, chemoprevention, advanced disease, genomics, quality of life and special populations. The 14 *high priority* trials chosen are listed at the end of this report.

The meeting involved approximately 90 “stakeholders,” primarily advocates, but also community clinicians, researchers, and representatives of Pharma to “share the Council’s consensus-based clinical research recommendations and announce the *high priority* clinical trials.” The stated objectives of the meeting were:

1. Provide the cancer community with a contextual overview of the current state of breast cancer clinical research, future direction the research should take and how the community can keep the science on the correct course.
2. Stimulate discussion among stakeholders and the Council on the scientific trends and issues addressed in the Council’s consensus.
3. Present educational messages and tools on the *high priority* trials for attendees to carry forward to patients, the public and the medical community at large

Within the constraints of a one day meeting, these objectives were largely achieved. The educational materials (i.e., objective 3) will eventually be available on the coalition web site at

[http://www.cancertrialshelp.org/slc\\_content/slcMainContent.aspx?intAppMode=0](http://www.cancertrialshelp.org/slc_content/slcMainContent.aspx?intAppMode=0) .

The facilitated, interactive discussion was the primary session focused on obtaining stakeholder input (i.e., objective 2), and perhaps the most interesting. Several points will be summarized here:

1. The Coalition is trying to make a concerted effort in presenting clinical trials as “treatment options” as opposed to “experiments.” Some of the stakeholders expressed some concerns of the ethics of this change, while others endorsed it.

2. There was a clear consensus among the stakeholders that the Coalition should be very careful in their use of language to avoid the perception that they or stakeholders are “marketing” trials. Rather, the appropriate role is “to educate patients about all of their options and empower them to make informed decisions.”
3. A third point that was of particular concern to advocates was that the consensus recommendations were reached without their involvement. The Coalition representatives acknowledged this, but emphasized that they wanted stakeholder input at this point. As an aside, it was mentioned that Colon and Lung Cancer advocates were on their respective SLCs when a similar exercise was conducted. It was unclear, therefore, why they hadn’t been included on the Breast Cancer SLC. Some advocates interpreted this as a consequence of the size, complexity, and divisiveness of the Breast Advocacy Community.
4. There was some discussion about what selecting the consequence of selecting 14 *high priority* trials would or should be for those trials not selected. No one expressed the opinion that any trials should be stopped. Rather, the emphasis was on ensuring that the *high priority* trials accrue expeditiously.
5. There was a general acceptance of the fact that establishing principled criteria for prioritizing trials is very difficult and was probably not fully accomplished by this exercise. Nevertheless, there was a sense that the fact that current priorities were developed and endorsed by thought leaders should carry considerable weight.

This exercise raises other questions that were apparently not discussed but are should be of considerable importance to advocates. A few are mentioned here.

1. The advocacy community was not the only group not involved in the decision making process. The regional and community medical groups, key players in enrollment of clinical trials patients, were also excluded. They, like advocates, are likely to have important insights about which trials have the potential to lead to important change in clinical practice..
2. Also not discussed is that many members of the SLC are linked to many of the *high priority* trials selected (e.g., PI). This raises concerns about conflict of interest
3. What can be done to assist patients looking for trials, but deemed ineligible? Special populations such as minorities, the elderly, and triple negatives were mentioned but mostly not highlighted in the *high priority* trials.
4. Would more trials directed at quality of life (currently 1) or patients with advanced disease (currently 2) be included among the *high priority* trials if advocates were involved?

## 14 Priority Trials in Brief

**Name:** NSABP B-41

**Population:** HER2-positive

**Trial:** Preoperative combination CT regimens with trastuzumab and/or lapatinib

ACOSOG-Z1031

ER-positive/node-positive or – negative  
Preoperative efficacy of exemestane vs .letrozole vs. anastrozole

ACOSOG-Z1041

HER2-positive  
Preoperative CT ± trastuzumab

NSABP B-39/RTOG 0413

DCIS or Stage I/II breast cancer  
Conventional WBI vs. APBI

NCT00490139

HER2-positive  
Adjuvant lapatinib and/or trastuzumab:  
sequential vs. in combination

SWOG S0307

Stage I-III with no evidence of  
metastatic disease  
Bisphosphonates on bone metastases  
prevention

SOFT

ER-positive, premenopausal  
Ovarian suppression + tamoxifen or  
exemestane vs. tamoxifen alone

ECOG E5103

Lymph node-positive and high risk  
lymph node-negative  
Chemotherapy ± bevacizumab

NSABP B-42

ER-positive/node-positive or node-  
negative  
Letrozole vs. placebo following AI  
therapy or tamoxifen followed by an AI

MA.17-R

ER-positive/node-positive or node-  
negative  
Optimal duration of letrozole: additional  
5 y of letrozole therapy after 5 y of  
tamoxifen therapy

OPTIMIZE-2

Stage IV What is the optimal dosing  
schedule during the 2nd year or later  
years of bisphosphonate therapy?

New study concept

(to be approved) CT ± bevacizumab  
after progression on a bevacizumab-  
containing regimen

TAILORx

ER-positive, node negative  
Best therapy using Oncotype DX:  
hormonal therapy alone versus  
hormonal therapy plus chemotherapy in  
patients with RS 11-25.

E2Z04

Breast cancer survivors treated on  
studies C9741, E1199, E2197, E2198 and  
N9831 (or treated off protocol with  
similar regimens) and their spouses,  
partners or acquaintances  
Survivorship trial; results of this trial will  
help develop interventions for breast  
cancer survivors