

# Use of Focus Groups to Inform Clinical Trial Design

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## BACKGROUND

Joseph Sparano, MD, principal investigator for the first trial from the National Cancer Institute (NCI) Program for the Assessment of Clinical Cancer Tests (PACCT) Committee contacted Research Advocacy Network. The trial is to test the Genomic Health 21-gene assay or Oncotype DX™ for early stage, node-negative, ER-positive breast cancer patients. The PACCT Committee was concerned that the number of participants (over 10,000 women) would make a randomized trial difficult to complete.



## COLLABORATION

Research Advocacy Network, Carol B. White & Associates, a market research consulting firm, and the Y-ME Breast Cancer Organization Illinois Affiliate proposed to conduct patient and advocate focus groups to inform the research and provide information for future participant education.

## MARKET RESEARCH

Focus groups are a powerful tool to learn about attitudes and opinions. They are in-depth interviews of 6-10 people at the same time in the same group. They are not surveys or polls and cannot be generalized or treated statistically. Focus groups have been used successfully in the past to provide qualitative data about how people think and why they think as they do. Y-ME was responsible for recruiting the patient focus group.

*“This was the first time a cooperative group used focus groups during the design stage. It influenced the design and informed the conversation about eligibility and how the trial would be presented to potential participants.”*

George Sledge, MD  
Professor of Medicine and Pathology  
Indiana University School of Medicine

## ACTIVITIES

The market research activities consisted of:

- One focus group of breast cancer patients
- One focus group of breast cancer advocates
- Three thought leader interviews
- Follow-up with advocates and advocate organizations after new research results about Oncotype DX were reported at the San Antonio Breast Cancer Symposium

## OUTLINE OF GROUP DISCUSSIONS

- Basic description of the test
- Reactions to the test (because the trial will not accrue without interest in and desire for the test)
- Basic description of trial
- Willingness to have (not have) chemotherapy
- Willingness to be randomized – with respect to the test
- Willingness to be randomized – with respect to treatment
- Impact of commercial availability of the test
- Outreach



## KEY FINDINGS

- Interest in the test is high
- Randomization to test is okay
- Randomization to treatment is problematic (both from an accrual standpoint and from an ethics standpoint)
- Commercial availability (especially if covered by payors) creates accrual challenges
- We learned about key points to include in education, as well as key audience members that should not be overlooked (i.e. family members)
- Adoption of this trial to physicians is also key to its success. In addition, other health professionals will be important in accrual and education



## OUTCOMES

For the first time a Cooperative Group used focus groups to inform the design of a Phase III trial they were proposing to conduct. The research leadership found the information helpful and hope to continue using market research techniques as they develop concepts and protocols in the future. They would like to use this technique earlier in the process — at the concept stage before too much time and money has been spent.

*“It (the market research) did have an effect. Not on the basic question but on how we thought about the design. We broadened our criteria and became more realistic about our accrual goals.”*

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## ABSTRACT

### Background

The National Cancer Institute Program for the Assessment of Cancer Clinical Tests and the Eastern Cooperative Oncology Group proposed a phase III, prospective, randomized, study to evaluate the use of a genomic test to determine treatment. The design and the number of participants (10,000 women) originally proposed raised concerns about the feasibility of completing such a trial.

### Methods

The Research Advocacy Network conducted focus groups of early stage breast cancer patients who matched the potential trial participants (node negative, ER positive tumors of 1 centimeter), and representatives from patient advocate organizations and breast cancer advocate thought leaders. The purpose was to gather feedback on: 1) interest in a test to determine response to chemotherapy, 2) willingness to be randomized, 3) input into the trial design and 4) information to explain trial design to potential participants.

### Results

Patients and advocates provided a rich source of information to test the trial design before activation. They expressed great excitement about the potential value of the test to the patient community. Randomization with respect to different treatments was found to be problematic because it ignores the complexity of their decision-making. The risk/benefit ratio for taking chemotherapy is highly individualized. The elements of different trial designs were discussed resulting in valuable information for the principal investigator. This discussion also provided key points to include in patient education materials.

### Conclusions

Focus groups involving patients and advocates can inform the design of research. These facilitated groups can provide insights into potential patient education materials needed to explain studies and potential recruitment strategies. This cost effective collaboration of patient advocates and researchers should serve as a model for future initiatives.