

2015 Strategic Priorities

Breast Cancer Steering Committee (BCSC)

The Breast Cancer Steering Committee (BCSC) has developed the following strategic priorities for therapeutic trials* to be conducted in the National Clinical Trials Network (NCTN) based on recommendations from the NCTN WG (<http://deainfo.nci.nih.gov/advisory/ctac/0714/Sledge.pdf>).

The NCTN conducts a late phase clinical trials program. Trials should be innovative, scientifically/molecularly driven trials with clinically meaningful outcomes and should address high priority needs. Trials should be based upon adequate pre-clinical and early clinical data.

1) Decreasing breast cancer mortality

- a. Improve outcome in advanced triple negative breast cancer (TNBC) through elucidation of subtypes and associated molecular targets
 - Specific approaches in triple negative disease with a DNA damage repair deficiency
- b. Improve outcome in ER+ breast cancer
 - Restoration of responsiveness to anti-hormone therapy in advanced disease
 - Augment response to anti-hormonal therapy in adjuvant setting
 - Develop targeted agents against known ER mutations in advanced disease
- c. Improve outcome in advanced disease through immunotherapy
 - Study strategies to reduce the burden/development of metastatic disease

2) Decreasing toxicity/treatment/costs associated with therapy with negligible clinically meaningful benefits

- a. Decrease chemotherapy in some HER2+ patients
- b. Decrease radiation in some breast conserving therapy (BCT)

- c. Decrease surgery in some breast cancer patients with pathological complete response (pCR)

3) Understanding biology and translating biology into diagnostic and therapeutic strategies

- a. Develop targeted therapies in advanced triple negative disease
- b. Develop targeted agents against known ER mutations
- c. Predictors of relapse in ER+ disease
- d. Use of novel biomarkers to direct therapy or to assess therapeutic response
- e. Use of novel imaging to direct therapy
- f. Define novel therapeutics in metastases (e.g., through the use of persistent circulating tumor cells (CTCs))

* The above priorities were identified specifically for therapeutic clinical trials to be reviewed by the BCSC and funded by the Cancer Therapy Evaluation Program in the Division of Cancer Treatment and Diagnosis. Ductal carcinoma in situ (DCIS) is not included in the above priorities since DCIS trials are reviewed and funded through the Division of Cancer Prevention.