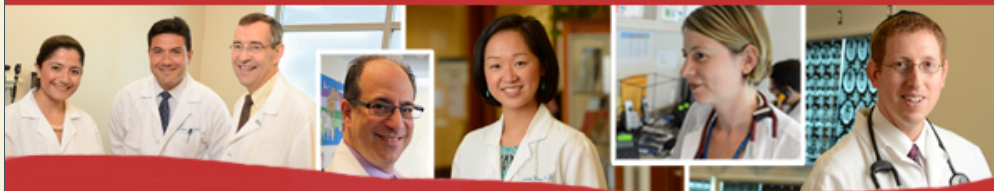



## Rutgers Cancer Institute of New Jersey




# Clinical Trials Connection

*A Cancer Resource for Healthcare Professionals* July 2014

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**Deborah Toppmeyer, MD,** is the director of the [Stacy Goldstein Breast Cancer Center](#) and chief medical officer at Rutgers Cancer Institute of New Jersey. Dr. Toppmeyer specializes in the management of patients with breast cancer, including high-risk cases, and is active in clinical research examining investigational therapeutics targeting this disease.

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### Clinical Trial Spotlight

#### Targeted Genomic Analysis of Human Cancers

The purpose of this study is to identify potentially "actionable" genomic alterations in cancers using next-generation sequencing technology, with a focus on rare cancers and cancers for which there is limited standard therapy.

[Learn more](#)

## Breast Cancer Clinical Trials

[View all related clinical trials](#)   [View printable version](#)

### Phase III LEE011 and Letrozole vs. Placebo and Letrozole in HR-positive Metastatic Breast Cancer

The study aims to:

- Compare progression free survival between LEE011 in combination with letrozole to placebo with letrozole among postmenopausal women with HR+, HER2-negative advanced breast cancer who received no prior therapy for advanced disease using RECIST 1.1.

[Learn more about this trial](#)

### A Single-Arm, Preoperative, Pilot Study of Oral Reparixin in Early Stage Breast Cancer Patients

The study aims to:

- Evaluate the effects of orally administered reparixin on CSCs in the primary tumor and the tumoral microenvironment.
- Evaluate the safety of oral reparixin administered t.i.d. for 21 consecutive days.

[Learn more about this trial](#)

### Phase III Neratinib and Capecitabine vs. Lapatinib and Capecitabine, HER2+ Metastatic Breast Cancer

The study aims to:

- Compare independently adjudicated PFS following treatment with neratinib plus capecitabine versus lapatinib plus capecitabine in patients with HER2+ metastatic breast cancer who have received two or more prior HER2-directed regimens in the metastatic setting.
- Compare overall survival following treatment with neratinib plus capecitabine versus lapatinib plus capecitabine in this population.

## Other Available Trials

[Gastrointestinal/  
Hepatobiliary](#)

[Gynecologic](#)

[Hematologic](#)

[Melanoma](#)

[Phase I](#)

[Prostate](#)

[Thoracic](#)



A Comprehensive Cancer  
Center Designated by the  
National Cancer Institute

[Learn more about this trial](#)

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### Phase III Study of the use of Everolimus in High-Risk, Hormone Receptor Positive HER2/neu Negative Breast Cancer

The study aims to:

- Compare whether the addition of one year of everolimus (10 mg daily) to standard adjuvant endocrine therapy improves invasive disease-free survival (IDFS) in patients with high-risk, hormone-receptor (HR) positive and HER2-negative breast cancer.
- Compare whether the addition of one year of everolimus to standard adjuvant endocrine therapy improves overall survival (OS) and distant recurrence-free survival (DRFS) in this patient population.
- Evaluate the safety, toxicities and tolerability of one year of everolimus in combination with standard adjuvant endocrine therapy and compare it with standard adjuvant endocrine therapy plus placebo in this patient population.

[Learn more about this trial](#)

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### Phase I Study of Pazopanib, Paclitaxel, and Carboplatin in Patients with Advanced Solid Tumors

The study aims to:

- Determine the safety and tolerability of pazopanib in combination with weekly paclitaxel and weekly carboplatin on Days 1, 8, and 15 every 28 days in patients with advanced solid tumors.
- Determine the maximum tolerated dose (MTD) of pazopanib in combination with weekly paclitaxel and weekly carboplatin on Days 1, 8, and 15 every 28 days in patients with advanced solid tumors.
- Determine the effect of pazopanib on the pharmacokinetics of paclitaxel and carboplatin.

[Learn more about this trial](#)

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### Phase III Fulvestrant with or without Palbociclib in Metastatic ER-positive Breast Cancer

The study aims to:

- Demonstrate the superiority of palbociclib in combination with fulvestrant (with or without goserelin) over fulvestrant (with or without goserelin) alone in prolonging investigator-assessed PFS in women with HR+/HER2- metastatic breast cancer whose disease has progressed on prior endocrine therapy.

[Learn more about this trial](#)

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## The INFORM Study: Randomized Phase II trial of Neoadjuvant Cisplatin vs. Doxorubicin/Cyclophosphamide in Women with Newly Diagnosed Breast Cancer and Germline BRCA Mutations

The study aims to:

- Determine if the pathologic complete response (pCR) rate (determined by the Miller-Payne method 1) to neoadjuvant cisplatin is at least 20% greater than the pCR to doxorubicin/ cyclophosphamide (AC) in women with newly diagnosed breast cancer and a germline BRCA mutation.

[Learn more about this trial](#)



As New Jersey's only National Cancer Institute-designated Comprehensive Cancer Center, Rutgers Cancer Institute of New Jersey offers patients access to treatment options not available at other institutions within the state. The Cancer Institute currently enrolls approximately 17 percent of all new adult cancer patients and approximately 70 percent of all pediatric cancer patients onto a clinical trial. Enrollment in these studies nationwide is fewer than five percent of all adult cancer patients.

[Learn more](#)

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