

## Breast Cancer Clinical Trials in Georgia

### Breast Cancer in Georgia: The Facts

As the leading cause of cancer incidence among Georgia females, breast cancer accounts for 32 percent of all cancer incidence among women each year.

- Each year, an average of 1,014 women in Georgia die of breast cancer.
- Breast cancer is the most commonly diagnosed cancer among women in Georgia.
- Breast cancer is the second leading cause of cancer death in Georgia women.
- 16 percent of all cancer deaths in females in Georgia are attributable to breast cancer<sup>1</sup>.

### Priority Breast Cancer Clinical Trials

The Scientific Leadership Council in Breast Cancer, a leading panel of breast cancer experts, have identified 13 priority breast cancer clinical Trials that hope to increase the pace of diagnostic and treatment advances by resolving pertinent clinical questions. Georgia has 11 of the 13 priority breast cancer clinical trials. The priority trials include the following:

1. NSABP B-41 (NCT00486668)\*
2. ACOSOG-Z1031 (NCT00265759)\*
3. ACOSOG-Z1041 (NCT00513292) \*
4. NSABP B-39\*
5. EGF106708 (ALTTO) (NCT00490139)\*
6. SWOG S0307 (NCT00127205)\*
7. SOFT/IBCSG 24-02 (NCT00066690)\*
8. ECOG E5103 (NCT00433511)\*
9. NSABP B-42 (NCT00382070)\*
10. MA.17-R (NCT00754)
11. CZOL446E2352 (OPTIMIZE-2) (NCT00320710)\*
12. TAILORx (NCT00310180)\*
13. E2Z04 (NCT00309933)

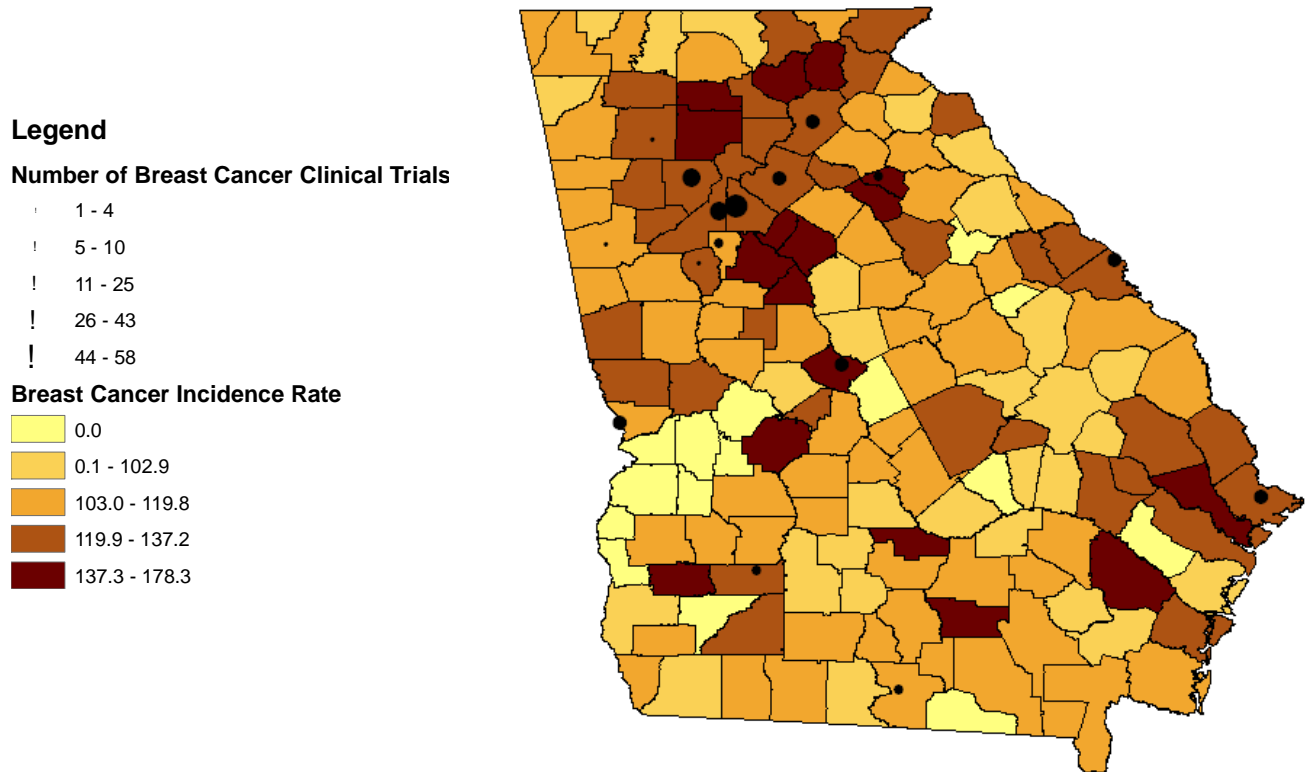
\* Indicates trial offered in a Georgia institution.

### Fast Facts

- 69 Breast Cancer Protocols offered in GA
- Trials available across 17 counties, 24 cities
- 57 percent of breast cancer trials in metro-Atlanta counties

The map in Figure 1.1 below displays the location of breast cancer clinical trials by county and the rates of new breast cancer cases.

**Figure 1.1 Breast Cancer Incidence Rates (1999-2004) and Breast Cancer Clinical Trials, by County** <sup>2,3</sup>



**Breast Cancer Clinical Trials Landscape in Georgia**

- Clinical Trials are important and help in the advancement and effectiveness of cancer treatment<sup>4</sup>.
- The need for breast cancer clinical trials in Georgia is evident, based on recent morbidity statistics.
- Clinical Trials appear to be most needed in North and Southeast Georgia, where the incidence rates are higher<sup>2, 3</sup>.
- There are 69 breast cancer protocols available in Georgia, across 17 counties and 24 cities.
- Approximately 57 percent of all breast cancer trials are located in metro Atlanta counties<sup>3</sup>.

**Table 1.1 Georgia Breast Cancer Protocols**

	<b>Cancer Type</b>	<b>Trial Number</b>	<b>Trial Description</b>
1.	Breast	011-015	Population PK Sub-Study of ASCENT-2
2.	Breast	0495-2006	Phase II Neoadjuvant Trial of Trastuzumab in Combination With Dose-Dense ABI-007 (Abraxane™)
3.	Breast	11271	TAC Versus TC for Adjuvant Breast Cancer
4.	Breast	20040213.	A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate Palifermin (rHuKGF) in the Reduction of Acute Graft Versus Host Disease in Subjects With Hematologic Malignancies Undergoing Allogeneic Marrow/PBPC Transplantation
5.	Breast	20060362	Amgen Protocol No. 20060362 - A Study of AMG 479 With Exemestane or Fulvestrant in Postmenopausal Women With Hormone Receptor Positive Locally Advanced or Metastatic Breast Cancer
6.	Breast	26866138CAN2007	Open-Label Study to Assess the Effect of Omeprazole on the Pharmacokinetics of VELCADE in Patients With Either Advanced Solid Tumors or Non-Hodgkin's Lymphoma.
7.	Breast	7792	A Phase II Trial of Gemcitabine and Oxaliplatin for Triple Negative Metastatic Breast Cancer
8.	Breast	7868	A Phase I-II Study of R115777 (Tipifarnib, Zarnestra(R)) Plus Sequential Weekly Paclitaxel Followed by Dose-Dense Doxorubicin and Cyclophosphamide in Patients with Stage IIB-IIIC Breast Cancer
9.	Breast	A6181077	Study Of SU011248 Versus Chemotherapy For Patients With Previously Treated Triple Receptor Negative Breast Cancer
10.	Breast	A6181094	A Study Of SU011248 Plus Paclitaxel Versus Bevacizumab Plus Paclitaxel In Patients With Advanced Breast Cancer
11.	Breast	ACORN AC01B07	1st or 2nd Line MBC (Metastatic Breast Cancer) With Previous Avastin (Bevacizumab) Therapy
12.	Breast	ACOSOG-Z1031	***Scientific Leadership Council in Breast Cancer High Priority Study*** A Randomized Phase III Trial Comparing 16 to 18 Weeks of Neoadjuvant Exemestane (25 mg daily), Letrozole (2.5 mg), or Anastrozole (1 mg) in Postmenopausal Women with Clinical Stage I
13.	Breast	ACOSOG-Z1041	***Scientific Leadership Council in Breast Cancer High Priority Study*** A Randomized Phase III Trial Comparing a Neoadjuvant Regimen of FEC-75 Followed by Paclitaxel Plus Trastuzumab with a Neoadjuvant Regimen of Paclitaxel Plus Trastuzumab Followed by F
14.	Breast	ALSSMBC0606	Phase II Trial of Capecitabine in Combination With Fulvestrant for Postmenopausal Women With Hormone Receptor Positive Metastatic Breast Cancer
15.	Breast	AVF3991n	A Study of Avastin in Combination With Chemotherapy for Treatment of Colorectal Cancer and Non-Small Cell Lung Cancer (ARIES)
16.	Breast	B9EUSS377	A Trial of Taxol and Bevacizumab vs. Gemcitabine, Taxol, and Bevacizumab in Advanced Breast Cancer
17.	Breast	BO20289	BEATRICE Study: A Study of Avastin (Bevacizumab) Adjuvant Therapy in Triple Negative Breast Cancer.
18.	Breast	CA163-131	This is a Study of Ixabepilone Plus Capecitabine or Docetaxel Plus Capecitabine in Metastatic Breast Cancer

19.	Breast	CALGB-40101	Cyclophosphamide And Doxorubicin (CA) (4 VS 6 Cycles) Versus Paclitaxel (4 VS 6 Cycles) As Adjuvant Therapy For Breast Cancer in Women With 0-3 Positive Axillary Lymph Nodes:A 2X2 Factorial Phase III Randomized Study
20.	Breast	CALGB-40503	Endocrine Therapy in Combination with Anti-VEGF Therapy: A Randomized, Double-Blind, Placebo-Controlled Phase III Trial of Endocrine Therapy Alone or Endocrine Therapy Plus Bevacizumab (NSC 704865; IND 7921) for Women with Hormone Receptor-Positive Advanced Breast Cancer
21.	Breast	CAN-NCIC-MA17	A Phase III Randomized Double Blind Study of Vorozole Versus Placebo in Women with Primary Breast Cancer Completing Five or More Years of Adjuvant Tamoxifen
22.	Breast	CAN-NCIC-MAP3	A Phase III Randomized Study of Exemestane Versus Placebo in Postmenopausal Women at Increased Risk of Developing Breast Cancer
23.	Breast	CAUY922A2101	Phase I-II Study to Determine the Maximum Tolerated Dose (MTD) of AU922 in Advanced Solid Malignancies, and Efficacy in HER2+ or ER+ Locally Advanced or Metastatic Breast Cancer Patients
24.	Breast	CIRG (TRIO) 001/ NSABP-44-1/ BO20906	A Multicenter Phase III Randomized Trial of Adjuvant Therapy for Patients With HER2-Positive Node-Positive or High Risk Node-Negative Breast Cancer Comparing Chemotherapy Plus Trastuzumab With Chemotherapy Plus Trastuzumab Plus Bevacizumab
25.	Breast	CR011-CLN-20	Study of CR011-vcMMAE to Treat Locally Advanced or Metastatic Breast Cancer
26.	Breast	CZOL446E2352	***Scientific Leadership Council in Breast Cancer High Priority Study*** Phase III Study of the Continued Efficacy and Safety of Zoledronic Acid in Patients With Documented Bone Metastases From Breast Cancer
27.	Breast	DMC #080304	Return To Wellness: A Study of the Effect of a Structured Exercise Program for Cancer Survivors Post Chemotherapy and/or Radiation Therapy Treatment
28.	Breast	DOCET_L_00712	Phase II Pilot Study of Docetaxel and Bevacizumab with and without Trastuzumab in First-Line Treatment of Patients With Metastatic Breast Cancer
29.	Breast	E7389-G000-305	E7389 Versus Treatment of Physician's Choice in Patients With Locally Recurrent or Metastatic Breast Cancer
30.	Breast	ECOG-E1105	E1105: A Randomized Phase III Double-Blind Placebo-Controlled Trial of First-Line Chemotherapy and Trastuzumab with or without Bevacizumab for Patients with HER-2/NEU Over-Expressing Metastatic Breast Cancer
31.	Breast	ECOG-E5103	***Scientific Leadership Council in Breast Cancer High Priority Study*** A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide Followed by Paclitaxel with Bevacizumab or Placebo in Patients with Lymph Node Positive and High Risk Lymph Node Ne
32.	Breast	ECOG-PACCT-1	***Scientific Leadership Council in Breast Cancer High Priority Study*** Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: The TAILORx Trial

33.	Breast	EGF104383	Phase III Study Of ErbB2 Over-Expressing Metastatic Breast Cancer Study Using Paclitaxel, Trastuzumab, and Lapatinib
34.	Breast	EGF106708	***Scientific Leadership Council in Breast Cancer High Priority Study*** ALTTO(Adjuvant Lapatinib And/Or Trastuzumab Treatment Optimisation)Study; BIG 2-06/N063D
35.	Breast	EU822-03	Randomized Phase II Trial of Sequential Docetaxel Followed by Capecitabine Versus Concomitant, Dose-Dense Docetaxel/Capecitabine as in Induction Therapy for Early Stage Breast Cancer
36.	Breast	GSK-EGF30008	Study Comparing GW572016 and Letrozole Versus Letrozole in Subjects with Advanced or Metastatic Breast Cancer
37.	Breast	IBCSG-24-02	***Scientific Leadership Council in Breast Cancer High Priority Study*** A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer
38.	Breast	IBCSG-27-02	A Randomized Clinical Trial Of Adjuvant Chemotherapy For Radically Resected Loco-Regional Relapse Of Breast Cancer
39.	Breast	LPT111110	Lapatinib + Vinorelbine in ErbB2 Overexpressing, First or Second Line Metastatic Breast Cancer Subjects
40.	Breast	LPT111111	A Single-Arm, Multicenter Phase II Study to Evaluate The Combination of Weekly Nanoparticle Albumin Bound Paclitaxel (Nab-Paclitaxel or ABRAXANE®) and Lapatinib (TYKERB®) in Women With No More Than One Prior Treatment for ErbB2 Overexpressing Metastatic B
41.	Breast	NCCTG-N0574	Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in Patients with One to Three Cerebral Metastases
42.	Breast	NSABP B-41	***Scientific Leadership Council in Breast Cancer High Priority Study*** A Randomized Phase III Trial of Neoadjuvant Therapy in Patients with Palpable and Operable HER2 Overexpressing Breast Cancer ComparingDoxorubicin/Cyclophosphamide (AC) Followed by We
43.	Breast	NSABP-B-39	***Scientific Leadership Council in Breast Cancer High Priority Study*** A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer
44.	Breast	NSABP-B-40	A Randomized Phase III Trial of Neoadjuvant Therapy in Patients with Palpable and Operable Breast Cancer Evaluating the Effect on Pathologic Complete Response (pCR) of Adding Capecitabine or Gemcitabine to Docetaxel when Administered Before AC with or without Bevacizumab and Correlative Science Studies Attempting to Identify Predictors of High Likelihood for pCR with Each of the Regimens
45.	Breast	NSABP-B-42	***Scientific Leadership Council in Breast Cancer High Priority Study*** A Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy Consisting of an Aromatase Inhibitor (
46.	Breast	NU-07B1	A Double-Blind, Randomized Phase IIB Study Evaluating the Efficacy and Safety of Sorafenib Compared to Placebo When Administered in Combination with Paclitaxel in Patients with Locally Recurrent or Metastatic Breast Cancer

47.	Breast	P04716	SCH 727965 in Patients With Advanced Breast and Lung Cancers (Study P04716)
48.	Breast	P05115	Oral Posaconazole in High Risk Patients With Gastrointestinal Dysfunction (Study P05115AM1)
49.	Breast	Perifosine211	Placebo-Controlled Study of Perifosine + Single Agent Chemotherapy for Metastatic Cancer Patients
50.	Breast	RTOG-0433	A Phase III International Randomized Trial of Single Versus Multiple Fractions for Re-Irradiation of Painful Bone Metastases
51.	Breast	RTOG-0517	Randomized Phase III Trial to Evaluate Radiopharmaceuticals and Zoledronic Acid in the Palliation of Osteoblastic Metastases from Lung, Breast, and Prostate Cancer
52.	Breast	RTOG-0614	A Randomized Phase III Double-Blind, Placebo Controlled Trial of Memantine for Prevention of Cognitive Dysfunction in Patients Receiving Whole-Brain Radiotherapy
53.	Breast	SCRI BRE 86	Phase II Study Of Bevacizumab Given With Either Anastrozole or Fulvestrant for Postmenopausal Metastatic Breast Cancer
54.	Breast	SNDX-275-0301	Study to Evaluate Exemestane With and Without SNDX-275 in Treatment of Postmenopausal Women With Advanced Breast Cancer
55.	Breast	STM01-102	Phase III Trial of Myocet , Paclitaxel, & Trastuzumab Versus Paclitaxel and Trastuzumab in Metastatic Breast Cancer
56.	Breast	SWOG-S0221	Phase III Trial of Continuous Schedule AC + G vs. Q 2 Week Schedule AC, Followed by Paclitaxel Given Either Every 2 Weeks or Weekly for 12 Weeks as Post-Operative Adjuvant Therapy in Node-Positive or High-Risk Node-Negative Breast Cancer
57.	Breast	SWOG-S0226	Phase III Randomized Trial of Anastrozole Versus Anastrozole and Fulvestrant as First Line Therapy for Post Menopausal Women with Metastatic Breast Cancer
58.	Breast	SWOG-S0230	Phase III Trial of LHRH Analog Administration During Chemotherapy to Reduce Ovarian Failure Following Chemotherapy in Early Stage, Hormone-Receptor Negative Breast Cancer
59.	Breast	SWOG-S0307	***Scientific Leadership Council in Breast Cancer High Priority Study*** Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer
60.	Breast	SWOG-S0500	A Randomized Phase III Trial to Test the Strategy of Changing Therapy Versus Maintaining Therapy for Metastatic Breast Cancer Patients Who Have Elevated Circulating Tumor Cell Levels at First Follow-Up Assessment
61.	Breast	SWOG-S0622	Phase II Studies of Two Different Schedules of Dasatinib (NSC-732517) in Bone-Metastasis Predominant Metastatic Breast Cancer
62.	Breast	TDM4258g	A Study of Trastuzumab-MCC-DM1 Administered Intravenously to Patients With HER2-Positive Metastatic Breast Cancer
63.	Breast	TDM4374g	A Study of of Trastuzumab-Mcc-DM1 Administered Intravenously to Patients With HER2-Positive Metastatic Breast Cancer
64.	Breast	TORI B-02	Neoadjuvant TAC Plus or Minus Bevacizumab(AVF3299)
65.	Breast	TORI B-03	Phase I/II Combined Biological Therapy Of Breast Cancer Using Monoclonal Antibodies Directed Against HER2/NEU Proto-oncogene And Vascular Endothelial Growth Factor (VEGF)

66.	Breast	TORI B-2	Phase II Study of Neoadjuvant Single-Agent Bevacizumab Followed by Docetaxel, Doxorubicin, and Cyclophosphamide With or Without Bevacizumab in Women With Early Stage II or Stage III Adenocarcinoma of the Breast
67.	Breast	TRIAD-BOI Mucositis	Risks and Outcomes of Mucositis in Subjects Being Treated for Breast, Colorectal, Head & Neck, Non-Small Cell Lung or Ovarian Cancer
68.	Breast	UAB 0461	Phase II Study of Avastin® to Reverse AEI in Metastatic Breast Cancer Patients Previously Responsive to Hormonal Therapy
69.	Breast	XRP9881B/3001	Breast Cancer Trial of an Investigational Drug (XRP9881) versus Capecitabine in Male or Female Patients with Advanced Breast Cancer

\*\*\*Shaded are indicates Scientific Leadership Council in Breast Cancer High Priority Study

<sup>1</sup>Singh S, Bayakly AR, McNamara C, Redding K, Thompson SK, Wall K. 2005. Georgia Cancer Data Report. Georgia Department of Human Resources, Division of Public Health, Chronic Disease, Injury and Environmental Epidemiology Section, and the American Cancer Society, Southeast Division, February 2006. Publication Number: DPH06/007HW.

<sup>2</sup> Georgia Comprehensive Cancer Registry, Georgia Department of Human Resources, Division of Public Health, 2007.

<sup>3</sup>Georgia Cancer Trials, powered by TrialCheck. 2008. Georgia Cancer Trials by Institution. [www.georgiacancertrials.org](http://www.georgiacancertrials.org).

<sup>4</sup> Bren, Linda. 2007. The Advancement of Controlled Clinical Trials. FDA Consumer Magazine, at [http://www.fda.gov/fdac/features/2007/207\\_trials.html](http://www.fda.gov/fdac/features/2007/207_trials.html).