



# INDIANA UNIVERSITY

## MELVIN AND BREN SIMON CANCER CENTER

September 2009

Esteemed Colleagues,

The Indiana University Breast Care and Research Program continues to grow and offer a wide variety of treatment options. We hope that you and your patient's benefited from knowing what trials are available at the IU Simon Cancer Center. Please check out the Open Protocol list for more information. We will also be posting our Open Protocol list of trials on our website at [www.cancer.iu.edu/programs/breast](http://www.cancer.iu.edu/programs/breast), look for the Esteemed Colleagues tab. As always here are a few protocols that we would like to highlight for you and your patients.

- **Geron:** A Phase I/II study of GRN163L in combo with Taxol in patients with locally recurrent or MBC. Telomerase Inhibition in CTCs After Treatment with GRN163L on CPA14010. We are entering the Phase II portion of this study with continued excitement for this treatment.
- **IUCRO-0248:** Investigator initiated trial testing oral Pazopanib for lymphedema.

### Upcoming Trials:


- **ABCDE Study:** A randomized trial of adjuvant bevacizumab and metronomic chemotherapy with diet and exercise in the post-operative setting


The IUSCC Pink Newsletter is available at our website <http://cancer.iu.edu/programs/breast/iuccpink> for your patients and their families. If you would like hard copies for your patients please contact Casey via the information listed below.

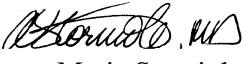
For questions and referrals contact us anytime at **(317) 274-5112**. New patient referrals can be accommodated within 1-2 weeks. If you have a patient for the High-Risk Screening Clinic please contact Laurie Carlson at (317) 278-7576. Lastly, our Spring Mill clinic conveniently located at Meridian and 103<sup>rd</sup> Street on Indianapolis' north side is a great alternative to driving downtown; for referrals call (317) 278-5000.


Your feedback is important, so let us know what you think!! Contact our Breast Cancer Clinical Research Coordinator-Casey Allen at 317-274-0594 or email her at [calallen@iupui.edu](mailto:calallen@iupui.edu).


Our best regard,

  
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Prevention									
Protocol No.	Title	PI Name	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN
MAP3	A Phase III Randomized Study of Exemestane Vs. Placebo in Postmenopausal Women at Increased Risk of Developing Breast Cancer	Storniolo, Anna Maria	Phase III	NCIC	MAP3/ ExCel	Exemestane	Inclusion: Woman must be postmenopausal (No menses or oophorectomy), If subject is > 35 years must be at risk DCIS is allowed. Exclusion: BRCA 1 or 2, tx w. HRT within 3 months prior Protocol treatment begins within 5 working days of subject randomization.	Arm 1:Exemestane 25mgs daily for 5yrs Arm 2:Placebo daily for 5yrs	<b>Cheri West</b> (317) 274-0930

Neoadjuvant									
IUCRO 0218	Lapatinib in the treatment of ductal carcinoma in situ of the breast	Rager			DCIS Surgery	lapatinib	For ER/PR neg, Her-2 OR EGFR positive DCIS. Pts MUST be identified in clinic- if Her-2/EGFR has not been done, this is ordered AFTER consent is signed	Lapatinib x 2-3 weeks prior to surgery	<b>Sarah Dutkevitch</b> (317) 274-5495
ALTTO/ N063D	Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation Trial	Storniolo, Anna Maria		CTSU	ALTTO	Herceptin/ Lapatinib / wkly Herceptin f/b `Lapatinib / q3wk Herc+ Lapat	HER2+, Tumor >= 1 cm with either + or - LN. Must have 4 cycles of anthracycline based therapy Must submit Tumor Block. 6 mm punch biopsy is acceptable	Design 1 (mainly for Europe) or Design 2 Design 2 included taxol to the 4 arm randomization	<b>Anita Rush-Taylor</b> (317) 278-6796
IUCRO-0215	An Exploratory Study of the Biological and Clinical Activity of SUNITINIB MALATE as a Component of Neoadjuvant Therapy for Breast Cancer. Oral Buccal Microscanner	Miller, Kathy		Pfizer-had 2 phase 3 trials not so good results.	Neo-adj Sutent	Sutent+Taxol+ AC	Inclusion: operable or inoperable stage 1c (primary tumor > 1.0 cm), II or III disease. Measurable disease by PE or diag imaging. Pre-treatment core or incisional biopsy. LVEF >LLN Exclusion: prior chemo, Stage IV disease, FNA	Segment 1: Oral Sunitinib day 1-14 Segment 2: Sunitinib + Taxol (C 2-5) Segment 3: A/C + GCSF (C 6-9) <b>Microscan on all pts</b>	<b>Nicki Coleman</b> (317) 630-7116
<a href="#">IUCRO-0096</a>	Cytochrome P450 Pharmacogenetics as a Predictor of Toxicity and Clinical Efficacy in Pre-Menopausal Women Receiving Doxorubicin and Cyclophosphamide in Loco-regional Breast Cancer	Schneider, Bryan	Pilot	IU	Baby AC		Inclusion: *Age <45 *Pre-menopausal Exclusion: *No distant metastatic disease *Not taking drugs to suppress ovarian function	*Receiving AC chemo *Subject will be followed one year post chemo	

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ADJUVANT									
Protocol No.	Title	PI Name	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS
IUCRO-0219	Women currently on tamoxifen either for prevention or adjuvant therapy who will be starting a SSRI for purposes of hot flashes	Flockhart, David		Mayo Clinic	TAM/SSRI	venlafaxine, citalopram, escitalopram, gabapentin, or sertraline	Inclusion: ≥18 years of age, tam use > 4 weeks, will be starting SSRI for hot flashes; Exclusion: Use of medications known to inhibit the CYP2D6 system or known to be a CYP2D6 poor metabolizer	One blood draw at each visit: baseline visit & one follow-up visit 8-16 weeks after SSRI started	<b>Suzanne Lemler</b> (317) 274-7841
ALTTO/N063D	Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation Trial	Storniolo, Anna Maria		CTSU	ALTTO	Herceptin/Lapatinib / wkly Herceptin f/b Lapatinib / q3wk Herc+ Lapat	HER2+, Tumor ≥/ = 1 cm with either + or - LN. Must have 4 cycles of anthracycline based therapy	Design 1 (mainly Europe) or Design 2 Design 2 included taxol to the 4 arm randomization	<b>Anita Rush-Taylor</b> (317) 278-6796
DFCI 07-199	Adjuvant Paclitaxel and Trastuzumab for Node-Negative HER2-Positive Breast Cancer	Miller, Kathy	II	DFCI	DFCI for Node Neg	Paclitaxel + Herceptin	Inclusion: Node neg, Her2 +, tumors ≤3cm, clear margins, LVEF ≥ 50%	Herceptin / taxol wkly X 12 wks f/b wkly or q 3 wks Herceptin X 40 wks	<b>Nicki Coleman</b> (317) 630-7116
<a href="#">IUCRO-0096</a>	Cytochrome P450 Pharmacogenetics as a Predictor of Toxicity and Clinical Efficacy in Pre-Menopausal Women Receiving Doxorubicin and Cyclophosphamide in Loco-regional Breast Cancer	Schneider, Bryan	Pilot	IU	Baby AC		Inclusion: *Age <45 *Pre-menopausal Exclusion: *No distant metastatic disease *Not taking drugs to suppress ovarian function	*Receiving AC chemo *Subject will be followed one year post chemo	<b>Suzanne Lemler</b> (317) 274-7841

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ADJUVANT									
Protocol No.	Title	PI Name	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS
<a href="#">S0307</a>	Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer	Miller, Kathy	Phase III	CTSU	SWOG Biphosphonate Study	Biphosphonate Zoledronic Clodronate Ibandronate	Inclusion: Primary disease resected <84 days, std adjuvant therapy, discontinue bisphosphonate, No mets. Include Neo-adj pts: S0215 & ALTTO	Zoledronic IV Monthly Clodronate PO daily Ibandronate PO Daily	<b>Christy Brown</b> (317) 278-3021
TAILORx	Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: The TAILORx Trial	Miller, Kathy	NA	ECOG	PACCT-1/ TAILORx	Standard chemo and hormonal treatment	Inclusion: Mastectomy or local excision/axillary procedure, ER/PR +, Her2 -, Negative axillary nodes, Tumor size 1.1-5.0 cm, no prior chemotherapy (standard chemo and hormonal therapy from protocol), tissue available	Secondary Study Group-1: Hormonal therapy Primary Study Group: Chemo + hormonal therapy or hormonal alone Secondary Study Group-2: chemo + hormonal	<b>Christy Brown</b> (317) 278-3021
E5103	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 Negative Breast Cancer	Miller, Kathy	Phase III	ECOG	5103	*Choice of classical versus dose dense AC Doxorubicin , Cyclophosphamide, Paclitaxel +/- Avastin	Inclusion: involvement of 1+ axillary lymph nodes or ER- tumor larger than 1 cm or ER+ tumor larger than 5 cm or ER+ with recurrence score 11+, Last breast surgery less than 84 days prior, Exclusion: HER2+, No radiation Therapy, stage N2 at diagnosis	Arm A: AC>T Arm B: BAC>BT Arm C: BAC>BT>B	<b>LaTrice Vaughn</b> (317) 278-3430

Metastatic									
GDC4627g	Study of safety, tolerability, pharmacokinetics, and activity of TDM-1(IV) + GDC-0941(PO) in HER2 pos MBC who progressed on previous Herceptin based Therapy.	Anna Maria Storniolo	Phase Ib	Genentech, DFCI and Hopkins	Oral GDC	TDM-1 + GDC-0941	HER2 +, with PD on at least prior heceptin therapy in the met setting or locally advanced setting. Hx of treated CNS met are eligible Exclusion: Known brain mets that are untreated, symptomatic, or require therapy to control symptoms	Dose escalation of GDC-0941. C1 D1 GDC-0941 C1 D2 TDM-1 f/b GDC-0941 daily. GDC-0941 PO daily x 14 days C2D1 GDC-0941 + TDM-1. Cycle= q 21d.	<b>LaTrice Vaughn</b> (317) 278-3430
TDM4373G/B022495	TDM4373g: An open Label Study of the safety and tolerability, and Efficacy of Trastuzumab-MCC-DM1 in combination with Pertuzumab in HER2 + locally advanced or MBC who have progressed while receiving prior therapy	Kathy Miller	Ib/II	Genentech	TDM + Pertuzumab	Trastuzumab-MCC-DM1 with Pertuzumab	locally adv or MBC HER2 +, prior heceptin therapy, no limits on # of prior therapies. No prior TDM or pertuzumab. Measurable disease, LVEF $\geq$ 55%	TDM-1 IV q 3 wks, pertuzumab IV loading dose then q3 wks	<b>Christy Brown</b> (317)278-3021
IUCRO-0239	A pilot trial of itraconazole pharmacokinetics in patients with metastatic breast cancer	Miller, Kathy	Pilot	IIT	Itraconazole	Itraconazole	Inclusion: can be HER2 + after Herceptin or lapatinib or HER2 - . Must carry the dx of MBC. CNS after tx for 2 wks Exclusion: Xanax, known pre-existing CHF or LV dysfunction. Concom meds w/ 14 days of beginning study-Cisapride, dofetilide, ergot derivatives, levomethadyl, lovastatin, midazolam, pimozone, quinidine,	Itraconazole PO 200mg daily until PD	<b>LaTrice Vaughn</b> (317) 278-3430
CP14A010 & IUCRO-0222	A Phase I/II study of GRN163L in combo c Taxol in pts c locally recurrent or MBC. Telomerase Inhibition in CTCs After Treatment with GRN163L on CPA14010.	Kathy Miller	I / II	Geron	GERON	Geron + Taxol + Bevacizumab	** Choice #1 for any met breast ca pt. 1st or 2nd line MBC. Allow 1 prior MBC tx (includes Correlative Consent)	*** High Priority <u>Accrual trial.</u> Taxol/Avastin + Telomerase inhibitor. Geron to be given on D1 & D15.	<b>Christy Brown</b> (317)278-3021

Metastatic									
Protocol No.	Title	PI Name	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS
SNDX-275-0301	A Phase 2, Randomized, Double-Blind, Multicenter Study of Exemestane With and Without SNDX-275 in Postmenopausal Women with Locally Recurrent or Metastatic Estrogen Receptor-Positive Breast Cancer, Progressing on Treatment with a Non-Steroidal Aromatase Inhibitor	Miller, Kathy	Phase II	Syndax	Syndax	Exemestane w or w/o SNDX-275	Inclusion: Locally Adv or MBC postmeno women confirmed ER+ BC, Relapse on tx with non-steroidal AI at least 12 mo for pts in the adj setting, PD after at least 3 mo tx with most recent AI for pts with met disease , Measureable disease, may have 1 prior chemo of 1st line therapy. Exclusion: Relapse on tx with non-steroidal AI after less than 12 mo for pts in the adj setting, PD after < 3 mo tx with most recent AI for pts with met	Arm A: Aromasin® (exemestane) 25 mg daily plus SNDX-275 (5 mg PO every week)  Arm B: Aromasin® (exemestane) 25 mg daily plus placebo PO every week	<b>LaTrice Vaughn</b> (317) 278-3430
IUCRO-0154	MPA Revisited: A Phase II Study of Anti-Metastatic, Anti-Angiogenic Therapy in Postmenopausal Patients with Hormone Receptor Negative Breast Cancer	Miller, Kathy	Phase II	IU	MPA/TBCRC	medroxyprogesterone acetate	Inclusion: metastatic, ER/PR negative, post-menopausal, NO PRIOR # of Therapies. Pts can be HER2 positive or Neg.	Cohort 1: 1000mg-MPA daily Cohort 2:1000mg-MPA daily, 50mg-Cytoxan daily, 2.5mg-Methotrexate days 1-2/week	<b>LaTrice Vaughn</b> (317) 278-3430
COE01	Predicting Response and Toxicity in Patients Receiving Chemotherapy for Breast Cancer; A Genomic, Proteomic and Pharmacogenomic Correlative Study	Miller, Kathy	Pilot	HOG	DOD	Choice of: Xeloda navelbine, gemzar	Inclusion: Incisional or core biopsies (1 or 2) MBC Measurable disease	Standard treatment regimen with chemo choice Biopsies and blood draws at various time points	<b>LaTrice Vaughn</b> (317) 278-3430
EGF103892	A Phase I, Dose Escalation Study to Assess the Safety and Tolerability of Lapatinib in Combination with Carboplatin, Paclitaxel, with and without Trastuzumab in Subjects with Metastatic Breast Cancer	Storniolo, Anna	Phase I	GSK	Lapatinib	Lapatinib, paclitaxel, carboplatin with/without Herceptin * May add growth factor	Inclusion: Group B: ErbB2 neg or positive, breast tissue available, measurable lesions CNS ok, normal MUGA, If prior taxane and herceptin for adjuvant or neoadjuvant if recurrence > 6 months after tx	Dose-Escalation Group A: Lapatinib, paclitaxel, carboplatin, trastuzumab Dose-Escalation Group B: Lapatinib, paclitaxel, carboplatin	<b>Anita Rush-Taylor</b> (317) 278-6796

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## Metastatic

Protocol No.	Title	PI Name	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS
DFCI 06-356	Phase 1 Study of Lapatinib in Combination with Radiation Therapy in Patients with Brain Metastases from HER2-Positive Breast Cancer	Storniolo, Anna Maria	Phase I	Dana Farber Cancer Center	Dana Farber Brain Mets	Lapatinib	Inclusion: HER2+, at least 1 parenchymal brain met, disease progression in the CNS, Exclusion: >2 weeks since RT or chemo without resolution of toxicity, prior WBRT, leptomeningeal carcinomatosis as the only site of CNS involvement. Measurable	Lapatinib 1 to 8 days then WBRT begins 24 hours to 8 days after the first dose. After completed WBRT, trastuzumab, at	<b>Anita Rush-Taylor</b> (317) 278-6796
COE-03 / BRE07-126	Predicting Response and Toxicity in Patients Receiving Oral Lonafarnib for Breast Cancer: A Multicenter Genomic, Proteomic and Pharmacogenomic Study	Sledge, George	II	HOG	DOD / HOG	Lonafarnib	No limit on # of prior therapies & no specific prior agents. MUST HAVE THE TUMOR BLOCKS	correlative blood and tissue c companion protocol	<b>Anita Rush-Taylor</b> (317) 278-6796
COE-03 BRE07-126	A Phase II Study of Lonafarnib in Pts with MBC- Correlative to COE-03	Sledge, George		HOG	DOD / HOG	Lonafarnib	Correlative to COE-03		<b>Anita Rush-Taylor</b> (317) 278-6796
PTC299-ONC-003-BRC	A Study to Assess the Safety, Feasibility, Pharmacokinetics, and Activity of PTC299 Monotherapy or Combination Therapy with Hormonal Agents in Patients with Metastatic Breast Cancer	Schneider	Phase 1b	PTC Therapeutics	PTC	Anti-Angiogenic agent PTC299 monotherapy and PTC299 combination therapy with hormonal agents in MBC	Measurable or non-measurable disease w/ MBC. must have received standard therapies. pt going on an AI as 1st line met disease	Stage 1, PTC299 in repeated 6 wk cycles; 3 successive cohorts of 3 to 6 subjects Stage 2=PTC299 + Anastrozole (Arimidex®), or Letrozole (Femara®), or Exemestane (Aromasin®)	<b>Anita Rush-Taylor</b> (317) 278-6796

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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	Miller, Kathy	Phase III	ECOG	E1105	Paclitaxel Carboplatin Trastuzumab Bevacizumab	Inclusion: HER2+, evaluable disease Exclusion: Prior treatment in metastatic setting, adjuvant trastuzumab and/or adjuvant or neo-adjuvant taxane less than 12 months prior, adjuvant or neo-adjuvant lapatinib less than 4 weeks prior, grade 2-4 neuropathy	Chemo- Paclitaxel 90 mg/m2 (6 cycles) or Paclitaxel 80mg/m2 + carboplatin AUC 2 (for 6 cycles) Arm A: Trastuzumab 2mg/kg weekly + Placebo for 6 cycles then maintenance q 3 weeks Arm B: Trastuzumab 2mg/kg weekly + Bevacizumab	<b>Nicki Coleman</b> (317) 630-7116
<b>CORRELATIVE/ANCILLARY</b>									
Protocol No.	Title	PI Name	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS
IUCRO-0269	Association of buccal mucosa vascular density with genotype and with outcome in the presence of anti-angiogenic therapy	Schneider		IIT	Monotherapy Microscanner + Blood Draws	N/A	Breast ca pts; Biopsy-proven br ca pts who are appropriate candidates for treatment with anti-angiogenic therapy (metastatic, adjuvant or neoadjuvant)	Microscanner done at BL, at C2, after 2mo of tx and end of study for br ca pts	<b>LaTrice Vaughn</b> (317) 278-3430
IUCRO-0248	Oral Pazopanib for Lymphedema	Miller, Kathy	II	GSK	Oral Lymphedema	pazopanib	Inclusion: unilateral lymphedema of the ipsilateral arm, > 3 cm total difference in arm circumference between affected and unaffected arm Exclusion: bilateral lymphedema. Pts on coumadin	Pilot study : oral pazopanib QD per 28day cycles for total of 24 wks	<b>Christy Brown</b> (317) 278-3021
PGE-M	A Screening Study to Evaluate Urine PGE-M Levels and Cyclooxygenase 2 Expression in Tumor Samples in Early stage or Met disease	Schneider, Bryan		Tragara	PGE-M	Correlatives of serum & tissue	Inclusion: Her2 + by IHC or FISH (any ER/PR) patients, ER/PR+/Her2 - , Triple neg pts, recently diagnosed pt post surgery, inflammatory BC. Must submit a tumor block	1 Urine sample and 1 tumor sample from tumor paraffin blocks	<b>Anita Rush-Taylor</b> (317) 278-6796
IUCRO-0162/ AVFD39805	VEGF Inhibition in Patients with Lymphedema Following Breast Cancer Treatment	Miller, Kathy	Pilot	IUCC	lymphedema	Avastin	Inclusion: unilateral lymphedema of the ipsilateral arm, > 3 cm total difference in arm circumference between affected and unaffected arm Exclusion: bilateral lymphedema	Avastin IV q 21 days	<b>Christy Brown</b> (317) 278-3021
COE05	Retro-Pro Tissue Study	Sledge	NA	HOG	Retro Pro	N/A	RHC pts		

PENDING									
Protocol No.	Title	PI Name	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS
TBCRC w MSKCC	A prospective analysis of surgery in pts presenting with Stage IV br ca	Storniolo					Stage IV newly diagnosed, intact tumor primary		
TBCRC -015	Investigational of Genetic Determinants of Capecitabine Toxicity	Storniolo		TBCRC		Capecitabine	Capecitabine Monotherapy	Cape 2000mg/m <sup>2</sup> /day x 14 days w/ 7 day rest	
Lilly JZAL	Phase 2 Evaluation of a Once Every 28 Days Dosing of LY573636 in MBC	Miller, Kathy	II	Lilly		ASAP-novel acylsulfonamide compound	MBC, must have received at least 2 or more prior chemo regimens, treated stable CNS,		
TBCRC - Triple neg WG	BiPar Phase III PARP-inhibitor trial	Miller, Kathy							
TBCRC w DFCI	A randomized trial of adj bev and metronomic chemo with diet and exercise in the post-op setting	Erica Mayer			ABCDE study		Triple Neg: pre-op stages I-III, ER+stage III at any point or stage IIB at time of surgery, Up to 6 mo after OR, if XRT 1st, 2 wks after XRT. No HER2 Pos, No prior bev		Nicki / ?
SKCCC-J0785 TBCRC 008	A Multi-Institutional Double-Blind Phase II Study Evaluating Response and Surrogate Biomarkers to Carboplatin and nab-Paclitaxel (CP) with or without Vorinostat as Preoperative Chemotherapy in HER2-negative Primary Operable Breast Cancer	Storniolo, Anna Maria		TBCRC		HER2 Neg, ER PR + or TNBC or High Grade ER+ with any PR	Neo-adj study (SMO pts)		Cheri/

