

Prevention														
Protocol No.	Protocol Numbers	Title	PI Name	Current Status	Status Date	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS	Total Accrual U / L / A	Comment
MAP3	0709-06	A Phase III Randomized Study of Exemestane Vs. Placebo in Postmenopausal Women at Increased Risk of Developing Breast Cancer	Storniolo, Anna Maria	OPEN	9/20/2007	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	Cheri/ Shannon 4-8136	30/ 25/ 2	Brochure for High Risk Screening are available <u>Pts Completing the STAR TRIAL are ELIGIBLE</u>
Neoadjuvant														
IUCRO 0218	8LAP111 043	Lapatinib in the treatment of ductal carcinoma in situ of the breast	Rager	OPEN	4/23/2009			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	Sara Dutkevitch	30/- / 0	Study has been open for 6 mo without accrual
ALTTO/ N063D	0805-01	Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation Trial	Storniolo, Anna Maria	OPEN	8/21/2008		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	Anita/ Heidi 8-6144	25 /5/ 2	complete Neo-adj tx Likely to close by end of the yr.

Neoadjuvant

Protocol No.	Protocol Numbers	Title	PI Name	Current Status	Status Date	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS	Total Accrual U / L / A	Comment
IUCRO-0215	0802-15	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	OPEN	3/26/2008		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) Microscan on all pts	Nicki / Liz 4-5166	30/ 5/ 17	Will conflict w/ SKCCC-J0785. This trial is 1st choice for IU & Wishard. Abstract at SABC. EPC data looks good. MRI tests are ready

ADJUVANT

Protocol No.	IRB Number	Title	PI Name	Current Status	Status Date	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS	Total Accrual U / L / A	Comment
IUCRO-0219	0803-75	Women currently on tamoxifen either for prevention or adjuvant therapy who will be starting a SSRI for purposes of hot flashes	Flockhart, David	Open	2/8/2008		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	Suz 4-7841	20/1 /1	Nurse Coordinators to help identify pts. Women already on Tamoxifen are targeted
ALTTO/ N063D	0805-01	Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation Trial	Storniolo, Anna Maria	OPEN	8/21/2008		CTSUSU	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	Anita/ Heidi 8-6144	25 /5/ 2	complete Neo-adj tx
DFCI 07-199	0802-11	Adjuvant Paclitaxel and Trastuzumab for Node-Negative HER2-Positive Breast Cancer	Miller, Kathy.. Ask Kokomo as non affiliated invest.	OPEN	3/4/2008	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	Nikki/ Shannon 4-8136	5/ 4/ 3	pts are being tx locally. Study does not allow split institutions visits. Check on Non Affiliated Investigators..D r. Beckner

ADJUVANT

Protocol No.	IRB Number	Title	PI Name	Current Status	Status Date	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS	Total Accrual U / L / A	Comment
S0307	0602-18	Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer	Miller, Kathy	OPEN - pending IRB apprvl of amendment.	1/24/2006	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	Christy/ Jennifer 8-7792	48/ 12/ 23	
TAILORx	0605-09	Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: The TAILORx Trial	Miller, Kathy	OPEN	7/3/2006	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	Christy/ Liz 4-5166	45/ 5/ 34	Closing Next Year

ADJUVANT

Protocol No.	Protocol Numbers	Title	PI Name	Current Status	Status Date	Phase	Sponsor	Phase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS	Total Accrual U / L / A	Comment
E5103	0712-101	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	Suspended to Accrual	1/10/2008	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	LaTrice / Liz 4-5166	30/ 10/ 15	Amendment #4 will cont. to go thru IRB's for apprvl. This includes the QOL for all new pts.

Metastatic

GDC4627g	0906-04	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	OPEN		Phase Ib	Genentech, DFCl 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.	LaTrice/ Shannon 4-8136	18/6/2	ICRC for C1 and C2 PK's this will be a priority trial until we get 1 pt on per dose level.
----------	---------	---	----------------------	------	--	----------	-----------------------------	----------	------------------	--	--	----------------------------	--------	--

Breast Cancer Open Protocol List 10-08-09

TDM4373G/ B022495	0903-19	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	Open	5/4/2009	II	Genentech	TDM + Pertuzumab	Trastuzumab-MCC-DM1 with Pertuzumab	Newly dx locally adv or MBC HER2 +, Measurable disease, LVEF \geq 55%	TDM-1 IV q 3 wks, pertuzumab IV loading dose then q3 wks	Christy/ Shannon	6 / - / 16	Pts after 7/23 must have CBC on D3 of C1-C3. 11 other sites participating. We are leading Accruers!
----------------------	---------	--	--------------	------	----------	----	-----------	------------------	-------------------------------------	---	--	------------------	------------	---

Metastatic

Protocol No.	Protocol Numbers	Title	PI Name	Current Status	Status Date	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS	Total Accrual U / L / A	Comment
IUCRO-0239	0809-10	A pilot trial of itraconazole pharmacokinetics in patients with metastatic breast cancer	Miller, Kathy	Open	2/3/2009	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, simvastatin, or triazolam.	Itraconazole PO 200mg daily until PD	LaTrice/ Liz 4-5166	14/12/9	

Metastatic

Protocol No.	Protocol Numbers	Title	PI Name	Current Status	Status Date	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS	Total Accrual U / L / A	Comment
CP14A010 & IUCRO-0222	0805-41 & 0805-42	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	OPEN	8/7/2008	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 Accrual trial. Taxol/Avastin + Telomerase inhibitor. Geron to be given on D1 & D15.	Christy/Jennifer 8-7792	10/ - / 13	NEW Dose Schedule with Geron. Dr. Mark Kozloff in III participating
SNDX-275-0301	0803-24	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	OPEN	5/8/2008	Phase II	Syndax	Syndax	Exemestane w or w/o SNDX-275	Inclusion: Locally Adv or MBC post meno 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 disease	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	LaTrice/ Liz 4-5166	5/ 1/ 4	Aromasin will be reimbursed by the company.

IUCRO-0154	0607-18	MPA Revisited: A Phase II Study of Anti-Metastatic, Anti-Angiogenic Therapy in Postmenopausal Patients with Hormone Receptor Negative Breast Cancer	Miller, Kathy	OPEN	7/26/2006	Phase II	IU	MPA/ TBCRC	medroxyprogesterone acetate	Inclusion: metastatic, ER/PR negative, postmenopausal, NO PRIOR # of Therapies. Pts can be HER2 positive or Neg.	Cohort 1: Completed Cohort 2:1000mg- MPA daily, 50mg- Cytoxan daily, 2.5mg- Methotrexate days 1-2/week	LaTrice/ Jennifer 8-7792	50/ 30/ 22	participating sites UCSF, UNC, Duke, UAB, DFCI, MD Anderson NOW ON STAGE 2
Metastatic														
Protocol No.	Protocol Numbers	Title	PI Name	Current Status	Status Date	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS	Total Accrual U / L / A	Comment
COE01	0407-08	Predicting Response and Toxicity in Patients Receiving Chemotherapy for Breast Cancer; A Genomic, Proteomic and Pharmacogenomic Correlative Study	Miller, Kathy	OPEN	9/27/2005	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	LaTrice/ Jennifer 8-7792	30/ 30/ 15	Arm A is closed.
EGF103892	0606-09	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	OPEN	8/16/2006	Phase I	GSK	Lapatinib	Lapatinib, paclitaxel, carboplatin with/ or 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	Anita/ Shannon 4-8136	16/ 8/ 13 we are top accruers	Group A closed. Group B to close in Nov.? Abstract in SABC.
DFCI 06-356	0711-07	Phase 1 Study of Lapatinib in Combination with Radiation Therapy in Patients with Brain Metastases from HER2-Positive Breast Cancer	Storniolo, Anna Maria	OPEN	1/15/2008	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	Lapatinib 1 to 8 days then WBRT begins 24 hours to 8 days after the first dose. After completed WBRT, trastuzumab, at standard dose .	Anita / Liz 4-5166	5/ 5/ 3	Results of Audit: Created a form for XRT docs H&P's

Metastatic

Protocol No.	Protocol Numbers	Title	PI Name	Current Status	Status Date	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS	Total Accrual U / L / A	Comment
COE-03 / BRE07-126	0808-10	Predicting Response and Toxicity in Patients Receiving Oral Lonafarnib for Breast Cancer: A Multicenter Genomic, Proteomic and Pharmacogenomic Correlative Study	Sledge, George	OPEN	6/25/2009	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	Anita/ Heidi	20 / 15 / 4	Diarrhea is a major A/E requires prophylactic anti-diarrhea
COE-03 BRE07-126	0808-09	A Phase II Study of Lonafarnib in Pts with MBC- Correlative to COE-03	Sledge, George	OPEN	6/25/2009		HOG	DOD / HOG	Lonafarnib	Correlative to COE-03		Anita/ Heidi	20/15/4	
PTC299- ONC-003-BRC	0904-03	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	OPEN	Jun-09	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®)	Anita/ Liz 4-5166	6 / 3 / 1	

Breast Cancer Open Protocol List 10-08-09

E1105	0712-100	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	OPEN	//2008	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 10mg/kg every 2 weeks for 6 cycles then maintenance q 3 weeks	Nicki / Heidi 8-6144	9/ 3/ 4	** will have low accrual** National accrual is low. Amendment coming through ECOG to loosen up eligibility criteria.
-------	----------	--	---------------	------	--------	-----------	------	-------	---	--	---	----------------------	---------	---

CORRELATIVE/ANCILLARY

Protocol No.	Protocol Numbers	Title	PI Name	Current Status	Status Date	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS	Total Accrual U / L / A	Comment
IUCRO-0269	0905-13	Association of buccal mucosa vascular density with genotype and with outcome in the presence of anti-angiogenic therapy	Schneider	Approved Consent Amendment			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	LaTrice/ Jennifer 8-7792	70/70/1	Questionnaire included. 20 Healthy Volunteers-DONE
IUCRO-0248	0811-15	Oral Pazopanib for Lymphedema	Miller, Kathy	Open		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	Christy/ Carol 4-0757	15/0/9	Will include the Buccal Microvessel Density Scan
PGE-M	0805-81	A Screening Study to Evaluate Urine PGE-M Levels and Cyclooxygenase 2 Expression in Tumor Samples in Early stage or Met disease	Schneider , Bryan	Open	8/4/2008		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	Anita/ Liz 4-5166	180/ 75	Update on overall accrual
IUCRO-0162/ AVFD39805	0606-24	VEGF Inhibition in Patients with Lymphedema Following Breast Cancer Treatment	Miller, Kathy	OPEN	8/16/2006	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	Christy/ Heidi 8-6144	15/ 15/ 11	May HOLD accrual for data analysis and open oral pazopanib ASCO poster... manuscript

Breast Cancer Open Protocol List 10-08-09

COE05		Retro-Pro Tissue Study	Sledge	OPEN		NA	HOG	Retro Pro	N/A	RHC pts			~46	Please send e-mail to Janet H. or Kim Ziner when we here of RHC pts
-------	--	------------------------	--------	------	--	----	-----	-----------	-----	---------	--	--	-----	---

PENDING

Protocol No.	Protocol Numbers	Title	PI Name	Current Status	Status Date	Phase	Sponsor	Phrase	Drug	Inclusion/Exclusion	Treatment Plan	RN/CRS	Comment
BRE09-146		PARP Inhibition after Preoperative Chemotherapy in Patients with TNBC or Known BRCA1/2 Mutations	Miller, Kathy	To SRC						Triple neg BrCa or pts with ER+ and/or PR+ ONLY if known BRCA1 or 2 mutation, No HER2 positive disease		Christy, LaTrice /Heidi 8-6144	approx 250 pts
TBCRC w MSKCC		A prospective analysis of surgery in pts presenting with Stage IV br ca	Storniolo	SRC				The King Study		Stage IV newly diagnosed, intact tumor primary		Nicki, LaTrice	100-200 pt in 18-24 months
TBCRC -015		Investigational of Genetic Determinants of Capecitabine Toxicity	Storniolo	SRC provisionally apprvd			TBCRC	The O'Donnell Study	Capecitabine	Capecitabine Monotherapy	Cape 2000mg/m2/day x 14 days w/ 7 day rest	LaTrice/ Liz 4-5166	
Lilly JZAL		Phase 2 Evaluation of a Once Every 28 Days Dosing of LY573636 in MBC	Miller, Kathy	To IRB		II	Lilly		ASAP-novel acylsulfonamide compound	MBC, must have received at least 2 or more prior chemo regimens, treated stable CNS,		LaTrice, Nicki	Will need ICRC for PKs... 30-35 pts Waiting ICRC Orders
TBCRC - 013 Triple neg WG		BiPar Phase III PARP-inhibitor trial. Gem/Carbo, with or without BSI-201, in pts with Met TNBC	Miller, Kathy	To IRB		III	Sanofe Aventis					Anita/ Liz 4-5166	Waiting if TBCRC will participate Budget is done

SKCCC- J0785 TBCRC 008	pending	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	IRB Approved			TBCRC		HER2 Neg, ER PR + or TNBC or High Grade ER+ with any PR	Neo-adj study (SMO pts)		LaTrice,Cheri/	*Conflict w/ IUCRO 0215 Priority for SMO pts. All SMO pts to IU due to grant charges. Lead Site, JH. Waiting on phantom scan of PET requirements.
Proposals													
GSK		A randomized, open-label study of lapatinib + trastuzumab vs trastuzumab as continued HER2 suppression therapy after completion of 1st & 2nd line trastuzumab plus chemo in HER2 + pts		Undecided									
TBCRC correlative science WG		Leptomeningeal disease from solid tumors-investigating novel diagnostic markers		Undecided									
TBCRC correlative science WG		Genetic risk of osteonecrosis of the jaw (ONJ) in pt with met br ca: case control study		Undecided									

Novartis		TKI protocol for FGF+ pts		Interested										
TBCRC w DFCI		Phase II Double Blind of T-DM1 & GDC0941 + Placebo	Ian Krop/ Storniolo	committed		II				HER2 +, MBC, progressed on at least 1 herceptin based chemo regimen				approx 120 pts
TBCRC		Companion Study to BiPar Phase III PARP-inhibitor trial w/ Gem/Carbo		committed										
Imclone/Lilly		VEGFR1 correlatives proposal		Interested										
RIBBON 3		Randomized, placebo-controlled, to evaluate the efficacy & safety of continued tx w Bev in combo w chemo in advanced BC who have progressed after tx c 1st line chemo in combo w Bev	Miller, Kathy	committed			Genentech		AVF4343g	locally recurrent or MBC w PD after receiving chemo in combo w Bev in the first line setting, First line PFS (start of 1st line MBC tx to the first occurrence of documented PD) of at least 3 months				Sponsor Plan to activate 2010. Wait for Pre-study Evaluation later in the yr.