NSABP Protocol Chart

January 2013

Legend of Abbreviations

Drug(s) Used				Type of Study	
‡	Rx had been extended beyond 5 years pending results of B-14; extension ended 10/28/95.	FUDR	Floxuridine	A	Node-Positive Adjuvant
5-FU	5-Fluorouracil	G-CSF	Granulocyte Colony-Stimulating Factor	B	Node-Negative Adjuvant
AC	Adriamycin-Cyclophosphamide	GET	Gemcitabine, Epirubicin, Taxol	C	Neo-Adjuvant Therapy
AC→Taxotere	Adriamycin-Cyclophosphamide followed by Taxotere	HER	Herceptin/trastuzumab	D	Advanced Disease
ATC (or TAC)	Adriamycin-Taxotere-Cyclophosphamide	L-PAM	L-Phenylalanine Mustard	E	Non-Invasive Breast Cancer (DCIS)
AC→Taxol	Adriamycin-Cyclophosphamide followed by Taxol	LV	Leucovorin	F	Estrogen Receptor (+)
AC→Taxol + HER	Adriamycin-Cyclophosphamide followed by Taxol plus Herceptin	M→F	Sequential MTX +5-FU	G	Estrogen Receptor (-)
AT	Adriamycin-Taxotere	MOF	MeCCNU, Vincristine, 5-FU	H	Adjuvant Colon
BCG	Bacillus Calmette-Guerin	MTX	Methotrexate	I	Adjuvant Rectal
CAPCIT	Capecitabine	OCT	Octreotide [SMS 201-995 pa LAR]	J	Breast Cancer Prevention
CMF	Cyclophosphamide, Methotrexate and 5-Fluorouracil	OXAL	Oxaliplatin	K	Tamoxifen Toxicity Study
DXM	Dexamethasone	PAN	Panitumumab	L	Surgical Treatment
EC	Epirubicin and Cyclophosphamide	RLX	Raloxifene	M	Quality of Life
FEC	Fluorouracil, Epirubicin and Cyclophosphamide	TAM	Tamoxifen	N	Biomarker
		UFT	Uracil/Ftorafur	O	Genetics
				P	Toxicity
				Q	Immunogenicity
				R	Radiation Therapy
				S	HER-2 Negative
				T	HER-2 Positive
				U	HER-2 Normal
				V	K-RAS Wild-type

NSABP BREAST PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
B-04	A Protocol for the Evaluation of Radical Mastectomy and Total Mastectomy With and Without Radiation in the Primary Treatment of Cancer of the Female Breast	N/A	L R	N/A	5	07/22/71	09/06/74	1765	Permanently closed to F/U effective 12/05/02
B-05	A Protocol for the Evaluation of Prolonged Therapy of Mammary Carcinoma With L-phenylalanine Mustard (L-PAM) as an Adjuvant to Surgery	L-PAM	A	N/A	2	09/22/72	02/05/75	418 (380)	Permanently closed to F/U effective 07/31/96
B-06	A Protocol to Compare Segmental Mastectomy and Axillary Dissection With and Without Radiation of the Breast and Total Mastectomy and Axillary Dissection	L-PAM 5-FU	L R	N/A	3	04/08/76	01/31/84	2163	Permanently closed to F/U effective 05/01/07
B-07	A Protocol to Compare Prolonged Therapy of Mammary Carcinoma by the Administration of L-phenylalanine Mustard (L-PAM) with L-PAM plus 5-Fluorouracil (5-FU)	L-PAM 5-FU	A	N/A	2	02/03/75	05/15/76	741	Permanently closed to F/U effective 07/31/96
B-08	A Protocol to Compare Prolonged Therapy of Mammary Carcinoma by the Administration of L-phenylalanine Mustard (L-PAM) plus 5-Fluorouracil (5-FU) with L-PAM plus Methotrexate (MTX)	L-PAM 5-FU MTX	A	N/A	2	04/12/76	04/29/77	737	Permanently closed to F/U effective 07/31/96
B-09	A Protocol to Compare Combined Chemotherapy With and Without Tamoxifen in the Management of Patients with Surgically Curable Breast Cancer	L-PAM 5-FU TAM	A	N/A	2	01/01/77	05/31/81	2697 (1891)	Permanently closed to F/U effective 04/14/04
B-10	A Protocol to Compare Combined Chemotherapy With and Without C.parvum+Hydrocortisone in the Management of Patients with Surgically Curable Breast Cancer	L-PAM 5-FU C.parvum Hydrocortisone	A	N/A	2	05/01/77	05/31/81	265	Permanently closed to F/U effective 07/31/96

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NSABP BREAST PROTOCOLS

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
B-11	A Protocol to Compare L-PAM and 5-FU With and Without Adriamycin in the Management of Primary Breast Cancer Patients With Positive Axillary Nodes Whose Tumors are Negative for Estrogen Receptors and/or Progesterone Receptors	L-PAM 5-FU Adriamycin	A G	N/A	2	06/01/81	09/30/84	707	Permanently closed to F/U effective 07/31/96
B-12	A Protocol to Compare L-PAM, 5-FU, and Tamoxifen With and Without Adriamycin in the Management of Primary Breast Cancer Patients With Positive Axillary Nodes Whose Tumors are Positive for Estrogen Receptors and/or Progesterone Receptors	L-PAM 5-FU TAM‡ Adriamycin	A F	N/A	2	06/01/81	09/30/84	1106	Permanently closed to F/U effective 04/14/04
B-13	A Protocol to Assess Sequential Methotrexate→ 5-Fluorouracil in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors are Negative for Estrogen Receptors	M→F LV	B G	N/A	2	08/01/81	10/17/88	1116 (760)	Permanently closed to F/U effective 04/14/04
B-14	A Clinical Trial to Assess Tamoxifen in Patients With Primary Breast Cancer and Negative Axillary Nodes Whose Tumors are Positive for Estrogen Receptors	TAM Placebo	B F	N/A	2	01/04/82	10/17/88	4127 (2892)	Permanently closed to F/U effective 05/01/07 Therapy unblinded 02/01/96
B-15	A Three-Arm Clinical Trial Comparing Short, Intensive Adriamycin-Cyclophosphamide Chemotherapy With and Without Interval Reinduction Chemotherapy (CMF) to "Conventional" CMF in Positive-Node Patients Having the Following Age and Receptor Criteria: ≤ 49 Years - All Patients; 50-59 Years - PR < 10 fmol, regardless of ER	AC CMF	A	N/A	3	10/01/84	10/14/88	2338	Permanently closed to F/U effective 04/14/04

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Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
B-16	A Three-Arm Clinical Trial Comparing Tamoxifen Alone with L-PAM, 5-FU, Adriamycin, and Tamoxifen or With Short, Intensive Adriamycin-Cyclophosphamide and Tamoxifen in Positive-Node Patients Having the Following Age and Receptor Criteria: 50-59 Years - PR ≥ 10 fmol, regardless of ER; 60-70 Years - All Patients	TAM‡ L-PAM 5-FU AC	A	N/A	3	10/01/84	04/14/89	1296	Permanently closed to F/U effective 04/14/04
B-17	A Protocol to Evaluate Natural History and Treatment of Patients with Noninvasive Intraductal Adenocarcinoma	N/A	E L	N/A	2	10/01/85	12/31/90	1087 (818)	Permanently closed to F/U effective 05/01/07
B-18	A "Unified" Trial to Compare Short, Intensive Preoperative Systemic Adriamycin-Cyclophosphamide Therapy With Similar Therapy Administered in Conventional Postoperative Fashion	AC TAM‡	A B C	N/A	2	10/17/88	04/30/93	1523	Permanently closed to F/U effective 05/01/07
B-19	A Clinical Trial to Compare Sequential Methotrexate, 5-Fluorouracil (M→F) with Conventional CMF in Primary Breast Cancer Patients With Negative Nodes and Estrogen-Receptor-Negative Tumors	M→F LV CMF	B G	N/A	2	10/17/88	07/31/90	1095	Permanently closed to F/U effective 03/02/06
B-20	A Clinical Trial to Determine the Worth of Chemotherapy and Tamoxifen Over Tamoxifen Alone in the Management of Patients with Primary Invasive Breast Cancer, Negative Axillary Nodes and Estrogen-Receptor-Positive Tumors	CMF TAM‡ M→F LV	B F	N/A	3	10/17/88	03/05/93	2363	Permanently closed to F/U effective 03/02/06
B-21	A Clinical Trial to Determine the Worth of Tamoxifen and the Worth of Breast Radiation in the Management of Patients with Node-Negative, Occult, Invasive Breast Cancer Treated by Lumpectomy	TAM Placebo	B R	N/A	3	06/01/89 Reopened 03/01/96	Temp. Closed 04/06/94 - 02/29/96 Closed 12/31/98	Goal = 1690 Actual = 1009	Permanently closed to F/U effective 05/01/07 Therapy unblinded 05/24/00

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NSABP BREAST PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
B-22	A Clinical Trial to Evaluate Dose Intensification and Increased Cumulative Dose on the Disease-Free Survival and Survival of Primary Breast Cancer Patients With Positive Axillary Nodes Receiving Postoperative Adriamycin-Cyclophosphamide (AC) Therapy	AC TAM‡	A	N/A	3	07/05/89	05/31/91	2305	Permanently closed to F/U effective 03/02/06
B-23	A Clinical Trial Comparing Short, Intensive AC ± Tamoxifen with Conventional CMF ± Tamoxifen in Node-Negative Breast Cancer Patients with ER-Negative Tumors	AC TAM CMF Placebo	B G	N/A	4	05/12/91	12/31/98	Goal = 2160 Actual = 2008	Permanently closed to F/U effective 03/02/06 Therapy unblinded 05/24/00
B-23QOL	A Study to Evaluate the Effect on Quality of Life of Adriamycin Cyclophosphamide (AC) Therapy versus Cyclophosphamide, Methotrexate, and 5-Fluorouracil (CMF) Therapy in Women with Axillary Node-Negative, Estrogen-Receptor-Negative, Primary Invasive Breast Cancer Being Treated on NSABP B-23	AC TAM CMF Placebo	M	N/A	4	05/15/97	12/31/98	Goal = 240 Actual = 167	Permanently closed to F/U effective 01/31/05
B-24	A Clinical Trial to Evaluate the Worth of Tamoxifen in Conjunction with Lumpectomy and Breast Irradiation for the Treatment of Noninvasive Intraductal Carcinoma (DCIS) of the Breast	TAM Placebo	E	N/A	2	05/09/91	04/29/94	1804	Permanently closed to F/U effective 05/01/07 Therapy unblinded 12/16/98
B-25	A Clinical Trial to Evaluate the Effect of Dose Intensification and Increased Cumulative Dose of Postoperative Adriamycin-Cyclophosphamide (AC) Therapy with G-CSF on the Disease-Free Survival and Survival of Patients with Primary Breast Cancer and Positive Axillary Nodes	AC G-CSF TAM	A	N/A	3	04/01/92	02/28/94	2548	Permanently closed to F/U effective 03/02/06

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NSABP BREAST PROTOCOLS

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
B-26	A Randomized Trial in Patients with Metastatic or Locally Advanced Breast Cancer Comparing the Effect of 3-hour vs 24-hour Infusion of High-Dose Taxol	Taxol	D	N/A	2	03/15/94	11/26/96	563	Permanently closed to F/U effective 02/28/02
B-27	A Randomized Trial Comparing Preoperative Doxorubicin (Adriamycin) Cyclophosphamide (AC) to Preoperative AC Followed by Preoperative Docetaxel (Taxotere) and to Preoperative AC Followed by Postoperative Docetaxel in Patients with Operable Carcinoma of the Breast	AC Taxotere TAM	C	Refer to Ancillary Trials	3	12/20/95	12/29/00	2411	Permanently closed to F/U effective 02/01/10
B-27.1	A Trial to Evaluate the Worth of Serum ErbB-2 Extracelluar Domain and Serum ErbB-2 Antibodies in Predicting Response to Preoperative Chemotherapy and Long-term Outcome in Patients with Operable Breast Cancer Who Are Participating in NSABP Protocol B-27	AC Taxotere TAM	N	YES	3	02/14/97	12/29/00	Goal =1200 Actual = 599	Permanently closed to F/U effective 02/01/10
B-27.2	A Trial to Evaluate the Worth of Tumor Biomarkers Obtained by FNA or Core Biopsy in Predicting Response to Preoperative Chemotherapy and Long-term Outcome in Patients with Operable Breast Cancer Who Are Participating in NSABP Protocol B-27	AC Taxotere TAM	N	YES	3	02/14/97	12/28/01	Goal = 720 Actual = 689	Permanently closed to F/U effective 02/01/10
B-28	A Randomized Trial Evaluating the Worth of Paclitaxel (Taxol) Following Doxorubicin (Adriamycin)/Cyclophosphamide in Breast Cancer Patients with Positive Axillary Nodes	AC Taxol TAM	A	YES	2	08/01/95	05/22/98	3060	Permanently closed to F/U effective 04/03/09
B-29	A Clinical Trial to Evaluate the Benefit of Adding Octreotide (SMS 201-995 pa LAR) to Tamoxifen Alone or to Tamoxifen and Chemotherapy in Patients with Axillary Node-Negative, Estrogen-Receptor-Positive, Primary Invasive Breast Cancer	TAM AC OCT	B F	YES	4	05/01/97	12/22/99	Goal = 3000 Actual = 893	Permanently closed to F/U effective 03/02/06

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NSABP BREAST PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
B-30	A Three-Arm Randomized Trial to Compare Adjuvant Adriamycin and Cyclophosphamide Followed by Taxotere (AC→T); Adriamycin and Taxotere (AT); and Adriamycin, Taxotere, and Cyclophosphamide (ATC) in Breast Cancer Patients with Positive Axillary Lymph Nodes	AC→Taxotere AT ATC TAM	A M	YES	3	03/15/99	03/31/04	5351	Permanently closed to F/U effective 12/31/12
B-31	A Randomized Trial Comparing the Safety and Efficacy of Adriamycin and Cyclophosphamide Followed by Taxol (AC→T) to that of Adriamycin and Cyclophosphamide Followed by Taxol Plus Herceptin (AC→T + H) in Node-Positive Breast Cancer Patients Who Have Tumors that Overexpress HER2	AC→Taxol AC→Taxol + HER TAM	A N T	YES	2	02/21/00	04/29/05	Goal = 2700 Actual = 2130	Closed to accrual
B-31.1	A Study to Determine the Correlation of Cardiac Function with Patient Characteristics and Blood Markers in Women Enrolled in NSABP B-31	N/A	N P	NO	2	11/01/01	04/29/05	Goal = 220 Actual = 45	Closed to accrual
B-32	A Randomized, Phase III Clinical Trial to Compare Sentinel Node Resection to Conventional Axillary Dissection in Clinically Node-Negative Breast Cancer Patients	N/A	L	YES	2	05/17/99	02/27/04	5611	Closed to accrual
B-33	A Randomized, Placebo-controlled, Double-blind Trial Evaluating the Effect of Exemestane in Clinical Stage T_{1-3} N_{0-1} M_0 Postmenopausal Breast Cancer Patients Completing at Least Five Years of Tamoxifen Therapy	Exemestane Placebo	A B F M N	YES (BBL substudy only)	2	05/01/01	10/09/03	Goal = 3000 Actual = 1598	Permanently closed to F/U effective 02/10/11 Therapy unblinded 10/14/03

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NSABP BREAST PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
B-34	A Clinical Trial Comparing Adjuvant Clodronate Therapy vs Placebo in Early-Stage Breast Cancer Patients Receiving Systemic Chemotherapy and/or Hormonal Therapy or No Therapy	Clodronate Placebo	A B N	YES	2	12/01/00	03/31/04	3323	Permanently closed to F/U effective 12/31/12 Therapy unblinded 12/07/11
B-35	A Clinical Trial Comparing Anastrozole with Tamoxifen in Postmenopausal Patients with Ductal Carcinoma In Situ (DCIS) Undergoing Lumpectomy with Radiation Therapy	Anastrozole TAM	E F M N	YES	2	01/06/03	06/15/06	3104	Closed to accrual
B-36	A Clinical Trial of Adjuvant Therapy Comparing Six Cycles of 5-Fluorouracil, Epirubicin and Cyclophosphamide (FEC) to Four Cycles of Adriamycin and Cyclophosphamide (AC) in Patients with Node-Negative Breast Cancer	FEC AC	B M N	YES	2	05/20/04	07/25/08	2722	Closed to accrual
B-37	IBCSG Trial 27-02 – A Randomized Clinical Trial of Adjuvant Chemotherapy for Radically Resected Loco-Regional Relapse of Breast Cancer	Chemo at physician's discretion HER	A B M T	NO (not for sites in North America)	2	01/14/05 NSABP 07/31/02 IBCSG	01/29/10	Goal = 265 Actual = 162	Closed to accrual
B-38	A Phase III, Adjuvant Trial Comparing Three Chemotherapy Regimens in Women With Node-Positive Breast Cancer: Docetaxel/ Doxorubicin/Cyclophosphamide (TAC); Dose-Dense (DD) Doxorubicin/Cyclophosphamide Followed by DD Paclitaxel (DD AC→P): DD AC Followed by DD Paclitaxel Plus Gemcitabine (DD AC→PG)	AC Taxotere Taxol Gemcitabine	A N P	YES	3	10/01/04	05/03/07	4894	Closed to accrual
B-39	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	N/A	M N R	YES	2	03/21/05	Still accruing	Goal = 4300	Open

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NSABP BREAST PROTOCOLS

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
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	AC Taxotere CAPCIT Gemcitabine Bevacizumab	C N P	YES	6	11/20/06	06/30/10	1206	Closed to accrual
B-41	A Randomized Phase III Trial of Neoadjuvant Therapy for Patients with Palpable and Operable HER2-Positive Breast Cancer Comparing the Combination of Trastuzumab Plus Lapatinib to Trastuzumab and to Lapatinib Administered with Weekly Paclitaxel Following AC Accompanied by Correlative Science Studies to Identify Predictors of Pathologic Complete Response	AC Taxol HER Paclitaxel Lapatinib	C N P T	YES	3	07/16/07	06/30/11	529	Closed to accrual
B-42	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 (AI) or Tamoxifen Followed by an AI in Prolonging Disease-Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast Cancer	Letrozole Placebo	F	YES	2	08/14/06	01/06/10	3966	Closed to accrual
B-43	A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma In Situ Resected by Lumpectomy	HER	B E N R T	YES	2	11/10/08	Still accruing	Goal=2000	Open

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NSABP BREAST PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
B-44-I (BETH)	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	Taxotere Carboplatin Bevacizumab HER	A B F G N P T	YES	2	04/25/08	12/10/10	3509	Closed to accrual
	BETH/Roche Pharmacogenetics Project in association with CIRG (TRIO) 011 / NSABP B-44-I / BO20906	N/A	N O	YES	N/A	06/12/09	Still accruing	Goal = 3500	Open
B-45	The protocol noted in a previous version of this chart will not be conducted								
B-46-I	A Phase III Clinical Trial Comparing the Combination of TC Plus Bevacizumab to TC Alone and to TAC for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer	Taxotere Doxorubicin Cyclophosphamide Bevacizumab	A B N P S	YES	3	05/08/09	01/11/12	Goal=3900 Actual=1613	Closed to accrual
B-47	A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer	Docetaxel Doxorubicin Cyclophosphamide HER Paclitaxel	A B N U	YES	2	01/06/11	Still accruing	Goal = 3260	Open
B-48	The protocol noted in a previous version of this chart will not be conducted								
B-49	A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer	Docetaxel Doxorubicin Cyclophosphamide Paclitaxel	A B N P S	YES	2	04/04/12	Still accruing	Goal = 1843	Open

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NSABP BREAST PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
B-50-I	A Randomized, Multicenter, Open-Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy for Patients with HER2-Positive Primary Breast Cancer Who Have Residual Tumor Present Pathologically in the Breast or Axillary Lymph Nodes Following Preoperative Therapy	Trastuzumab emtansine (T-DM1) HER	M T	YES	2	Pending	Pending	Goal = 1484	Pending
B-51	A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy	N/A	M N R	YES	2	Pending	Pending	Goal = 1636	Pending
BI-65 (N9431)	Menstrual Cycle and Surgical Treatment of Breast Cancer	N/A	L	N/A	N/A	03/28/97 NSABP 07/12/96 NCCTG	12/31/01	Total =1119 NSABP = 775	Permanently closed to F/U effective 10/09/09
BI-67 (S9927)	Randomized Trial of Post-Mastectomy Radiotherapy in Stage II Breast Cancer in Women With One to Three Positive Axillary Nodes, Phase III	N/A	A	YES	2	06/03/02 NSABP 06/15/00 SWOG	06/15/03	Goal = 2500 Actual = 98 NSABP = 0	Closed to accrual
BP-53	A Pilot Study in Patients With Metastatic or High-Risk Primary Breast Cancer to Evaluate the Worth of rHu GM-CSF in Permitting the Administration of Higher Doses of Cyclophosphamide in an AC Combination	GM-CSF AC	D	N/A	3 sequential	03/05/90	06/28/91	60	Permanently closed to F/U
BP-54	A Pilot Study in Patients With Metastatic or High-Risk Primary Breast Cancer to Evaluate the Worth of rHu G-CSF in Permitting the Administration of Higher Doses of Cyclophosphamide in an AC Combination	G-CSF AC	D	N/A	2 sequential	07/01/91	12/18/91	30	Permanently closed to F/U

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NSABP BREAST PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
BP-55	A Phase II Study in Patients with Metastatic or Locally Advanced Breast Cancer to Evaluate the Worth of High-Dose Taxol Administration as a 3-Hour Infusion with rHu G-CSF Support	G-CSF Taxol	D	N/A	1	08/01/93	03/03/94	100	Permanently closed to F/U
BP-56	A Pilot Study in Patients with Metastatic, Locally Advanced, or High Risk Breast Cancer to Evaluate the Feasibility of Sequential Administration of Standard-Dose Adriamycin-Cyclophosphamide Followed by High-Dose Taxol as a 3-Hour Infusion with rHu G-CSF Support	AC Taxol G-CSF	D	N/A	1	08/01/93	10/28/93	17	Permanently closed to F/U
BP-57	A Phase II Study in Patients with Metastatic or Locally Advanced Breast Cancer to Evaluate the Worth of the Combination of Doxorubicin (Adriamycin) and Docetaxel (Taxotere) (AT)	AT	D	NO	1	05/11/98	07/23/99	89	Permanently closed to F/U effective 12/05/02
BP-58	A Phase II Study in Patients with Metastatic or Locally Advanced Breast Cancer to Evaluate the Worth of the Combination of Adriamycin (doxorubicin), Taxotere (docetaxel), and Cyclophosphamide (ATC)	ATC	D	NO	1	06/01/98	01/18/00	89	Permanently closed to F/U effective 12/05/02
BP-59	Bone Marrow Analysis in Early-Stage Breast Cancer	N/A	N/A	YES	1	01/29/07	04/20/11	Goal = 1634 Actual = 1630	Closed to accrual
NSABP /NCIC-CTG									
MA-32F	Biobehavioral Mechanisms of Fatigue in Patients Treated on NCIC CTG MA.32: A Phase III Randomized Trial of Metformin Versus Placebo on Recurrence and Survival in Early Stage Breast Cancer	N/A	M N O Q	YES	1	07/11/11	Still accruing	Goal = 454	Open

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NSABP PREVENTION PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
P-1	A Clinical Trial to Determine the Worth of Tamoxifen for Preventing Breast Cancer	TAM Placebo	J M	YES	2	06/01/92	09/30/97	13,388	Permanently closed to F/U 05/23/06 Therapy Unblinded 3/31/98
P-1B	The Bone Mineral Density and Biochemical Marker Study to Determine the Effect of Tamoxifen on Bone in Premenopausal and Postmenopausal Women	TAM Placebo	N	YES	2	02/09/95	09/30/97	Goal = 384 Actual = 107	Permanently closed to F/U 05/23/06
P-1E	A Protocol to Evaluate the Prevalence and Detection of Ophthalmic Abnormalities Associated with Long-Term, Long-Dose Tamoxifen Administration	TAM Placebo	K	N/A	N/A	12/23/93	09/29/95	Goal = 558 Actual = 312	Permanently closed to F/U 05/23/06
P-1G	A Study of the Association Between Inherited Mutations and the Effect of Tamoxifen on Breast Cancer Incidence	TAM Placebo	O	YES	2	N/A	N/A	Goal = 784 to be genotyped	Trial initiated 01/05/99; analyses completed
P-1G2	A Study of the Association Between Inherited Mutations in Specific Clotting Factors and the Incidence of Blood Clots in Women Taking Tamoxifen	TAM Placebo	O	YES	N/A	N/A	N/A	Goal = 405	Trial initiated 12/00; analyses completed
P-1G3	Genetic Determinants of Invasive Breast Cancer in the Tamoxifen Breast Cancer Prevention Trial (NSABP P-1)	TAM Placebo	O	YES	N/A	N/A	N/A	Goal = 257 to be analyzed	Trial initiated 01/05; analyses completed
P-1G4	Sex Hormones and the Risk of Breast Cancer: an Ancillary Study in the Breast Cancer Prevention (P-1) Trial	TAM Placebo	O	YES	N/A	N/A	N/A	Goal = 330 to be analyzed	Trial initiated 01/22/04; analyses completed
P-2	Study of Tamoxifen and Raloxifene (STAR) for the Prevention of Breast Cancer	TAM Raloxifene Placebo	J M	YES	2	07/01/99	11/04/04	19,747	Permanently closed to F/U 05/31/12 Therapy Unblinded 04/17/06

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NSABP PREVENTION PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
P-3	Celecoxib Polyp Prevention Trial in Participants with Resected Stage I Colon Cancer	Celecoxib Placebo	M N	YES	2	07/01/04	04/03/06	1200 Actual=18	Therapy unblinded and permanently closed to F/U effective 04/03/06
P-5**	Statin Polyp Prevention Trial in Patients with Resected Colon Cancer	Rosuvastatin Placebo	M N P	YES	2	03/25/10	Still accruing	Goal = 1740	Open
DMP -1	A Study to Evaluate Different Decision-Making Approaches Used by Women Known to be at Increased Risk for Breast Cancer	N/A	M	NO	1	08/01/11	Still accruing	Goal = 1000	Open

**** The P-4 study noted in previous Protocol Charts will not be conducted.**

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NSABP COLON PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
C-01	A Clinical Trial to Evaluate Postoperative Immunotherapy and Postoperative Systemic Chemotherapy in the Management of Resectable Colon Cancer	BCG MOF	H	N/A	4	11/07/77	02/29/84	1817 (1166)	Permanently closed to F/U effective 02/03/99
C-02	A Protocol to Evaluate the Postoperative Portal Vein Infusion of 5-Fluorouracil and Heparin in Management of Patients with Resectable Adenocarcinoma of the Colon	5-FU Heparin	H	N/A	2	03/01/84	07/29/88	1158	Permanently closed to F/U effective 02/06/01
C-03	A Clinical Trial to Compare Adjuvant Leucovorin and 5-FU (LV+5-FU) With Adjuvant MeCCNU, Vincristine and 5-FU (MOF), in Patients with Dukes' B and C Carcinoma of the Colon	LV 5-FU MOF	H	N/A	2	08/01/87	04/14/89	1081	Permanently closed to F/U effective 04/14/04
C-04	A Clinical Trial to Assess the Relative Efficacy of 5-FU + Leucovorin, 5-FU + Levamisole, and 5-FU + Leucovorin + Levamisole in Patients with Dukes' B and C Carcinoma of the Colon	5-FU LV Levamisole	H	N/A	3	07/05/89	12/31/90	2151	Permanently closed to F/U effective 04/14/04
C-05	A Clinical Trial to Assess the Relative Efficacy of 5-FU + Leucovorin with or without Interferon Alfa-2a in Patients with Dukes' B and C Carcinoma of the Colon	5-FU LV Interferon Alfa-2a	H	N/A	2	10/01/91	02/28/94	2176	Permanently closed to F/U effective 03/02/06
C-06	A Clinical Trial Comparing Oral Uracil/Ftorafur (UFT) Plus Leucovorin (LV) with 5-Fluorouracil (5-FU) plus LV in the Treatment of Patients with Stages II and III Carcinoma of the Colon	UFT LV 5-FU	H M N	YES	2	02/14/97	03/31/99	1608	Permanently closed to F/U effective 04/03/09
C-07	A Clinical Trial Comparing 5-Fluorouracil (5-FU) plus Leucovorin (LV) and Oxaliplatin with 5-FU Plus LV for the Treatment of Patients with Stages II and III Carcinoma of the Colon	5-FU LV OXAL	H M N	YES	2	02/01/00	11/15/02	2492	Permanently closed to F/U effective 12/31/12
C-08	A Phase III Clinical Trial Comparing Infusional 5-Fluorouracil (5-FU), Leucovorin, and Oxaliplatin (mFOLFOX6) Every Two Weeks with Bevacizumab to the Same Regimen without Bevacizumab for the Treatment of Patients with Resected Stages II and III Carcinoma of the Colon	5-FU LV OXAL Bevacizumab	H P	YES	2	09/15/04	10/06/06	2710	Permanently closed to F/U effective 12/31/12

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NSABP COLON PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
C-09	A Phase III Clinical Trial Comparing Oxaliplatin, Capecitabine and Hepatic Arterial Infusion of Floxuridine to Oxaliplatin and Capecitabine in Patients with Resected or Ablated Liver Metastases from Colorectal Cancer	FUDR CAPCIT OXAL	M N P	YES	2	01/13/06 (U.S. only)	10/12/07	Goal=400 Actual = 22	Permanently closed to F/U effective 06/12/08
C-10	A Phase II Trial of 5-Fluorouracil, Leucovorin, and Oxaliplatin (mFOLFOX6) Chemotherapy Plus Bevacizumab for Patients with Unresectable Stage IV Colon Cancer and a Synchronous Asymptomatic Primary Tumor	5-FU LV OXAL Bevacizumab	D P	NO	1	03/20/06 (U.S. only)	06/16/09	Total =90	Permanently closed to F/U effective 12/31/12
C-11	A Phase III Study Evaluating the Role of Perioperative Chemotherapy in Patients with Potentially Resectable Hepatic Colorectal Metastases	OXAL 5-FU LV Irinotecan	D H I L P	YES	2	08/23/10	12/16/11	Goal = 670 Actual = 9	Permanently closed to F/U effective 12/21/11
CI-63	Phase III Intergroup Prospectively Randomized Trial of Perioperative 5-FU After Curative Resection, Followed by 5-FU/Leucovorin for Patients with Colon Cancer	5-FU LV	H	N/A	3	08/19/93 Intergroup 05/25/95 NSABP	05/19/00	Goal = 2000 Actual = 839 NSABP = 21	Closed to accrual
CI-64	A Phase III Prospective Randomized Trial Comparing Laparoscopic-Assisted Colectomy Versus Open Colectomy for Colon Cancer	N/A	L	N/A	2	08/02/94 Intergroup 04/25/97 NSABP	08/31/01	Goal =900 Actual = 870 NSABP= 22	Permanently closed to F/U effective 11/27/09
CI-66	A Phase II Trial Evaluating Multiple Metastasectomy Combined with Hepatic Artery Infusion of Floxuridine (FUDR) and Dexamethasone (DXM), Alternating with Systemic Oxaliplatin (OXAL) and Capecitabine (CAPCIT) for Colorectal Carcinoma Metastatic to the Liver	FUDR DXM OXAL CAPCIT	D I L	YES	1	02/22/02	04/08/05	Total = 76 NSABP = 47	Permanently closed to F/U effective 01/22/10

Refer to Long Term Survivor Protocol Section on the next page

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NSABP RECTAL PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
R-01	A Clinical Trial to Evaluate Postoperative Radiation and Postoperative Systemic Chemotherapy in the Management of Resectable Rectal Carcinoma	MOF	I R	N/A	3	11/07/77	11/01/86	574	Permanently closed to F/U effective 02/03/99
R-02	A Protocol to Compare Adjuvant MeCCNU, Vincristine, and 5-Fluorouracil (MOF) With and Without Radiation to Adjuvant Leucovorin and 5-Fluorouracil (LV+5-FU) With and Without Radiation in Patients with Dukes' B and C Carcinoma of the Rectum	MOF LV 5-FU	I R	N/A	Male - 4 Female - 2	08/01/87	12/31/92	741	Permanently closed to F/U effective 04/14/04
R-03	A Clinical Trial to Evaluate the Worth of Preoperative Multimodality Therapy (5-FU+LV+RTX) in Patients with Operable Carcinoma of the Rectum	5-FU LV	C I	N/A	2	06/01/93	06/30/99	Goal = 900 Actual = 267	Permanently closed to F/U effective 04/03/09
R-04	A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion of 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum	5-FU CAPCIT OXAL	C M N P R	YES	4	07/23/04 (2-arm version w/o OXAL) 01/31/06 (4-arm version w/ OXAL)	05/01/06 08/16/10	1608	Closed to accrual

LONG TERM SURVIVOR PROTOCOL

LTS-01	Patient Reported Outcomes in Long Term Survivors with Colon and Rectal Cancer	N/A	N/A	N/A	N/A	11/29/06	01/15/09	Goal = 1167 Actual = 744	Permanently closed to F/U effective 11/30/10

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NSABP DIVISION OF INDUSTRY TRIALS (DIT) PHASE I and PHASE II BREAST PROTOCOLS January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
FB-GE-001	A Phase 2 Study of Neoadjuvant Chemotherapy with Gemcitabine, Epirubicin, and Paclitaxel (Taxol) [GET] in Locally Advanced Breast Cancer	GET	D C	YES	1	01/09/02	06/19/03	76	Permanently closed to F/U effective 11/05
FB-IR-002	A Phase 2, Multi-center Trial of ZD1839 (IRESSA™) in Combination With Docetaxel as First-line Treatment in Patients With Advanced Breast Cancer	ZD1839 Docetaxel	D	YES	1	01/10/03	09/24/04	Goal = 49 Actual = 33	Permanently closed to F/U effective 09/06
FB-AX-003	A Phase 2 Study of Neoadjuvant Chemotherapy with Sequential Weekly Nanoparticle Albumin Bound Paclitaxel (Abraxane) Followed by 5-Fluorouracil, Epirubicin, Cyclophosphamide (FEC) in Locally Advanced Breast Cancer (LABC)	Abraxane FEC	C D N	YES	1	04/07/05	05/03/06	66	Permanently closed to F/U effective 07/01/08
FB-4	A Phase II Clinical Trial of Bevacizumab Beginning Concurrently with a Sequential Regimen of Doxorubicin and Cyclophosphamide Followed by Docetaxel and Capecitabine as Neoadjuvant Therapy Followed by Postoperative Bevacizumab Alone for Women with Locally Advanced Breast Cancer	Bevacizumab AC Taxotere CAPCIT	C D P	NO	1	08/15/06	08/28/07	45	Permanently closed to F/U effective 11/04/09
FB-5	A Phase II Clinical Trial of Epirubicin Plus Cyclophosphamide Followed by Docetaxel Plus Trastuzumab and Bevacizumab Given as Neoadjuvant Therapy for HER2-Positive Locally Advanced Breast Cancer or Given as Adjuvant Therapy for HER2-Positive Pathologic Stage III Breast Cancer	EC Docetaxel Bevacizumab Trastuzumab	D P T	NO	1 arm in each of 2 cohorts	04/20/07	05/18/09	105	Closed to Accrual

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Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
FB-6	A Phase II Clinical Trial of Four Cycles of Doxorubicin and Cyclophosphamide Followed by Weekly Paclitaxel Given Concurrently with Pazopanib as Neoadjuvant Therapy Followed by Postoperative Pazopanib for Women with Locally Advanced Breast Cancer	AC Paclitaxel Pazopanib	C D N O P	YES	1	01/06/09	03/17/11	101	Closed to Accrual
FB-7	A Phase II Randomized Clinical Trial Evaluating Neoadjuvant Therapy Regimens with Weekly Paclitaxel and Neratinib or Trastuzumab Followed by Doxorubicin and Cyclophosphamide with Postoperative Trastuzumab in Women with Locally Advanced HER2-Positive Breast Cancer	AC Neratinib HER Paclitaxel	C D N P T	YES	3	10/05/10 Reopened 09/10/12	Temp. Hold 12/16/11 - 09/09/12 Still accruing	Goal = 126	Open
FB-8	A Phase I Dose-Escalation Study Evaluating the Combination of Weekly Paclitaxel with Neratinib and Trastuzumab in Women with Metastatic HER2-Positive Breast Cancer	HER Neratinib Paclitaxel	D T	NO	1	05/17/11	7/18/12	21	Closed to Accrual
FB-9	A Phase II Randomized Clinical Trial Evaluating Neoadjuvant Chemotherapy Regimens with Weekly Paclitaxel or Eribulin Followed by Doxorubicin and Cyclophosphamide in Women with Locally Advanced HER2-Negative Breast Cancer	AC Paclitaxel Eribulin	C D S	NO	2	09/21/2012	Still accruing	Goal = 50	Open

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NSABP DIT PHASE I and PHASE II COLON and RECTAL PROTOCOLS

January 2013

Protocol		Drug(s) Used	Type of Study	Protocol Specified Specimen Banking	# of Arms	Date Open to Accrual	Date Closed to Accrual	Total Accrual*	Status
FC-AL-001	A Phase 2 Trial of ALIMTA Plus Oxaliplatin Administered Every 21 Days for First-Line Treatment of Patients with Advanced Colorectal Cancer	ALIMTA OXAL	D	NO	1	06/01/01	08/09/02	56 (54 evaluable)	Permanently closed to F/U effective 08/2004
FC-BV-003	Randomized Phase II Clinical Trial of Bevacizumab Combined With Capecitabine and Either Oxaliplatin or Irinotecan as First Line Treatment for Metastatic Colorectal Cancer	Bevacizumab CAPCIT OXAL Irinotecan	D	NO	2	03/30/06	02/07/07	Goal = 110 Actual = 7	Permanently closed to F/U effective 08/16/10
FC-4	A Randomized Phase II Clinical Trial Investigating Irinotecan Plus Cetuximab With or Without Anti-Insulin-Like Growth Factor-I Receptor Monoclonal Antibody (IMC-A12) for the Treatment of Patients with Metastatic Carcinoma of the Colon or Rectum that has Progressed on Oxaliplatin and Bevacizumab Given as First-Line Therapy	Irinotecan Cetuximab IMC-A12	D M P Q V	NO	2	01/12/09	02/22/10	Goal = 100 Actual = 4	Permanently closed to F/U effective 10/06/11
FC-6	A Phase II Study to Determine the Surgical Conversion Rate in Patients Receiving Neoadjuvant mFOLFOX7 Plus Cetuximab for Unresectable Wild-Type K-RAS Colorectal Cancer with Metastases Confined to the Liver	Oxaliplatin Leucovorin 5-FU Cetuximab	C D V	NO	1	01/20/10	Still accruing	Goal = 60	Open

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