

A. Name and location of hospital

Christiana Care Health Services, Inc.

501 West 14th Street Wilmington, DE 19801

- B. Name of cancer center: Helen F Graham Cancer Center (HFGCC)
- C. Identify PI and key personnel with contact information (very brief bios) for each of the pilot focus areas:

• Principal Investigator

Nicholas Petrelli, M.D., Bank of America Endowed Medical Director of the HFGCC (npetrelli@christianacare.org). He spent 20 years at the Roswell Park Cancer Institute rising to Chief of Surgery and Professor of Surgery at SUNY Buffalo. He is presently Chair of the Colorectal Committee of the NSABP and President of the Society of Surgical Oncology.

• Vice President of Cancer Program

Patrick Grusenmeyer, ScD, FACHE (<u>pgrusenmeyer@christianacare.org</u>). Recruited from the Ochsner Clinic in New Orleans. He is a member of the Editorial Boards of the Journal of Clinical Oncology, Oncology Issues and Community Oncology. He has over 28 years of administrative experience, including over 20 years in management of complex health systems.

Disparities

Nora Katurakes, RN, MS, OCN (nkaturakes@christianacare.org). Director of the Community Outreach and Healthcare Disparities Program since 1998. Trained at MD Anderson Cancer Center and received the 2007 Cancer Outreach Award from the Philadelphia affiliate of the Susan Komen Foundation. Member of the Delaware Cancer Consortium and the City of Wilmington Health Planning Council.

• Clinical Trials

Stephen Grubbs, M.D., Chief of Medical Oncology (ssgrubbs@cbg.org), is the Principal Investigator for the Christiana Delaware CCOP and a practicing medical oncologist with 23 years of experience. He serves on the Board of Directors and Chairman of the Audit Committee for the CALGB Foundation. He received a special recognition award from the National Cancer Institute for his exceptional service to the Clinical Trials Working Group of the National Cancer Advisory Board, and in October of 2006, he received the Outstanding Clinical Researcher Award from the Association for Community Cancer Centers.

Kandie Price, MS, RN, OCN, CCRP (kprice@christianacare.org), is Director of the Cancer Research Office. She serves as the National Chair of the CALGB Clinical Research Associates Committee and on the Board of Directors Executive Committee and Institutional Performance Evaluation Committee. She is a member of the ONS Multi-Site Research Expert Panel.

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Steve Hess, Vice President and CIO, CCHS since 2003 (<a href="mailto:sheets-she

• Biospecimens

Gary Witkin, M.D., Chief of Pathology at CCHS since 1999 (gwitkin@christianacare.org). Residency in Clinical and Anatomic Pathology at the University of North Carolina. Pathology training as a Fellow at Yale University School of Medicine. Member of the American Society of Clinical Pathologists, College of American Pathologists and the United States and Canadian Academy of Pathology.

Mary Iacocca, M.D., Director of the Tissue Procurement Center at HFGCC (miacocca@christianacare.org). A member of the Department of Pathology, CCHS. Completed a residency in anatomic and clinical pathology at the University of North Carolina (UNC) and Surgical Pathology Fellowship at UNC.

Quality of Care

Tricia Strusowski, RN, BS, Director of the Care Management Department since 2000 (pstrusowski@christianacare.org). Prior to her directorship, she had 13 years of oncology nursing floor experience. She has worked as a registered nurse on a medical hematology unit, assistant nurse manager and manager on a bone marrow transplant unit. Presently obtaining her master's in health care administration.

• Survivorship

Jeff Kendall, PsyD, Director of Cancer Psychology (jkendall@christianacare.org). Clinical psychology degree at Indiana State University. Post-Doctoral fellowship/Psychosocial oncology at Roswell Park Cancer Institute. He is an Adjunct Associate Professor of Psychology at the University of Delaware. He has co-developed one of the first psychosocial cancer survivorship programs in the country. This program includes a Survivorship Multidisciplinary Center and a self-help style manual.

D. Describe the model for medical staff for cancer center (e.g., employed, private practice, contracts, specialty company contract, combination)

Most physicians in the HFGCC are private practice physicians. This includes the medical oncologists, radiation oncologists and most surgeons. The two medical oncology practices, one with seven medical oncologists and four nurse practitioners, and the other with five medical oncologists, are housed in the HFGCC. The radiation oncologists are a single group of seven radiation oncologists with a mutually exclusive relationship with the Christiana Care Cancer Program. They are also located in the Helen F. Graham Cancer Center. A group of 4 hematologic oncologists are located in offices on campus. Surgeons are located in a variety of private surgical practices often with a surgical subspecialty focus. The HFGCC joined one of the surgical practices in the recruitment of a Memorial Sloan-Kettering Cancer Center surgical oncologist to the HFGCC Program in July 2005.

Exceptions to the predominantly private practice model (that is, physicians employed by the Cancer Program) include two thoracic surgeons, an MD Anderson Cancer Center-trained physiatrist focusing on cancer rehabilitation, pain and palliative care and a gynecologic oncologist. A second gynecologic oncologist and a third thoracic surgeon are currently being recruited.

E. Provide the number of physicians in the cancer program – note cancer program specific medical staff credentialing if applicable

There are 62 physicians that participate in the Multidisciplinary Disease Site Centers (MDC's) at the HFGCC. The HFGCC has developed specific medical staff performance expectations to support patient care, quality, research and community outreach goals of the Cancer Program. The Medical Director and Vice President established a Cancer Program Participating Physicians Committee in 2002 including a medical oncologist, surgeon and radiation oncologist. The Participating Physician Committee developed and updates annually the Participating Physicians Criteria. All physicians must meet these criteria in order to participate in the HFGCC and multidisciplinary centers. A formal application process along with participating physician criteria has been established. Once a physician is accepted as a participating physician, there is a Participating Physician Agreement that must be signed by the physician. Performance expectations are monitored quarterly by the Cancer Center Medical Director. Physicians who fail to maintain performance at the expected level are notified by the Medical Director and given a chance to correct their performance. If they fail to correct their performance, they are removed as a participating physician in the MDC's.

F. Describe multi-disciplinary care model

14 Multidisciplinary Disease Site Centers (MDC's) where patients make one visit to see a surgeon, medical and radiation oncologist with all support services of genetic counseling, social service, nutrition, nurse navigator, clinical trials nurse, psychology, pastoral care and pain management have been established. Specific disease site centers are also staffed by gastroenterologists and interventional radiologists (Hepatobiliary Pancreatic MDC), pulmonologists (Thoracic MDC), dentists (Head and Neck MDC) as examples. Also a physician appointed by the medical director of the cancer program directs and coordinates the activities of each of the MDC's, and physicians from all 3 disciplines are physically present to discuss patient management along with all the support staff.

G. Provide a brief overview of community demographics

There are three counties in Delaware. New Castle is the northern-most county and largest where 62% of the population resides. Kent County is located in the center of the State, with Sussex County being the southern-most county. According to the 2005 U.S. Census/Claritas, Delaware's population is 842,652 with 526,575 in New Castle County, 134,411 in Kent County and 181,665 in Sussex County. The census reports that 76.6% of Delaware's population is White, 19.2% African-American and 4.8% Latino. Christiana Care provides 80% of the health care in New Castle County and 66% of health care in Delaware. It is known that 11.8% of Delaware's population is not covered by health insurance. The Medicare population is 122,792 & Medicaid population is 131,224 as of 2005. According to the U.S. Census, Delaware is 80% urban and 20% rural. The median household income is \$52,499.

County	White	African American	Latino
New Castle	70.9%	22.3%	6.8%
Kent	73.4%	19.9%	3.8%
Sussex	81.6%	13.0%	5.9%

H. Describe the philosophy on community outreach and list five major activities to reach disparate populations – note if the organization participates in a formal and ongoing community coalition to address unmet health need

Our philosophy centers on planning and coordination of all community efforts focused on reaching our neighbors in the high risk zip codes in the City of Wilmington (New Castle County). The population that resides in these areas represents vulnerable people with social, economic, and cultural barriers that impact access to care. Although our projects are targeted to these areas, our program touches many more people throughout New Castle County. Five major activities to reach disparate populations are: 1) A Cancer Outreach and Healthcare Disparities Program targeting the African-American and Hispanic population for the screening of cervical, breast, prostate, and colorectal cancer through a unique Chronic Disease Screening Program. This program is funded through the Delaware Division of Public Health, Chronic Disease Prevention Department. 2) There is a cancer screening partnership with the Henrietta Johnson Medical Center, federally funded, which serves uninsured, underinsured individuals from the African-American population and the Westside Health Center, another federally funded health care center which serves primarily the Hispanic population in Wilmington with increasing numbers of Asians, Russians, and African-Americans. 3) The Helping Hands for Breast Health program funded by the Avon Foundation Breast Care Fund focuses efforts in the African-American community. A minority outreach worker navigates women who may have failed to be screened. A Client Intake Form is completed for each woman who is enrolled and screened through this program. 4) There is a Prostate Cancer Screening and Warriors Against Prostate Cancer Program. This program is one of the original community-based education and screening programs. There are now 12 volunteers known as the Warriors Against Prostate Cancer. They attend community events, health fairs and provide one on one education to men they encounter who are interested in information about prostate cancer, screening and health. Annually, three community based prostate screening events are held. An oncology nurse navigator provides the necessary follow up to those screened and tracks outcomes. 5) Governor Minner's proposal to spend \$10 million in fiscal year 2005 to treat uninsured patients and promote cancer screening awareness was approved by the legislature. As a result, all uninsured Delawareans who were diagnosed with cancer on or after 7/01/04, lack comprehensive health insurance coverage including Medicaid, and earn less than 650% of the federal poverty level, are now eligible to receive one year of cancer care. A total of 248 Delawareans have received services through the Delaware Cancer Treatment Program from 7/01/04-10/31/06. Importantly, 43% of these individuals were racial and ethnic minorities. The program was approved for 2007-2008.

The HFGCC participates in the State coalition to address unmet health needs. Delaware Governor Ruth Ann Minner committed to reducing the State's cancer incidence and mortality and eliminating cancer disparity by appointing the Delaware Advisory Council on Cancer Incidence and Mortality in 2001. The Council has published in 2002 through 2007 a cancer control program with priorities and actions. The Advisory Council was maintained as the Delaware Cancer Consortium (DCC) in 2003 to oversee the implementation of the program in partnership with the Delaware Division of Public Health (DPH). The Council developed 7 subcommittees: Insurance, Colorectal Cancer, Tobacco, Quality of Care, Public Education, Environment, and Disparities.

I. 2006 new cancer cases – provide in RFP format SEE TABLE 1

J. 2006 patients on clinical trials – provide RFP format

Calen dar Year	Treatment	Cancer Control & Prevention	G O G	Pharma	Translatio nal	I- ELCAP=	Behavioral Health	Total Accrual	Analytic Cases	Percentage of Analytic Cases Accrued with I-ELCAP=	Percentage of Analytic Cases Accrued without I-ELCAP=
2006	204	130	#	56	*77	270	68	805	2729 +	29.3 +	19.6 +

*Includes University of Delaware, AI DuPont Children's Hospital, Kimmel Cancer Center at Jefferson, Fox Chase Cancer Center, ACOSOG and CALGB Tissue Bank #GOG accrual included in Treatment and Cancer Control/Prevention CCOP totals

- = International Early Lung Cancer Action Project
- + Estimated

K. Number of patients on clinical trials and % NCI-sponsored trials – provide in RFP format SEE TABLE 2

Total number of patients enrolled to NCI-sponsored trials in calendar year 2006, and percentage of total = 345 Patients on NCI trials/535 Patients total with no ELCAP = 67%

L. Describe the focus of linkages with NCI-designated cancer centers or other academic research institutions

CCHS is a major clinical affiliate of the Jefferson Medical College (JMC) of Thomas Jefferson University (TJU). All academic appointments at Christiana Care, including the Helen F. Graham Cancer Center, are in the appropriate departments at Thomas Jefferson University. Effective May 1, 2002, a Cancer Research Alliance Agreement was signed between Thomas Jefferson University through its Kimmel Cancer Center and Christiana Care Health Services through its Helen F. Graham Cancer Center. This Cancer Research Alliance Agreement continues to date in the areas of research cooperation, publication of information, marketing and public relations, and intellectual property. Several collaborative efforts have ensued since this agreement was completed. For example, the Helen F. Graham Cancer Center participates in an NIH RO1 of whom the Principal Investigator is Scott Waldman, M.D., Ph.D., Chair of the Department of Pharmacology and Experimental Therapeutics at Thomas Jefferson University/Kimmel Cancer Center. The overall goal of this project is to determine the diagnostic utility of a novel molecular biomarker, Guanylyl Cyclase C (GCC), in the surveillance of patients with colorectal cancer. Another example is the collaborative efforts with Ronald E. Myers, DSW, Ph.D., Director of the Division of Behavioral Epidemiology in the Department of Medicine at Thomas Jefferson University/Kimmel Cancer Center. These efforts have included an NCI R21 Tailored Messaging in Colorectal Cancer Screening and a second NCI R01 grant entitled, Tailored Navigation in CRC Screening. The overall goal of the projects is tailored navigation in colorectal cancer screening utilizing six community-based primary care practices that are part of the Christiana Care Health System.

A Center for Translational Cancer Research (CTCR) was officially launched on February 1, 2006, as a statewide partnership involving the University of Delaware (UD) including the Delaware Biotechnology Institute (DBI), the Nemours Research Institute at AI DuPont Hospital and the Helen F. Graham Cancer Center. The CTCR (www.udel.edu/ctcr) is directed by M.C. Farach-Carson, Ph.D., Professor of Biological Sciences at UD, who spent 2005-2006 on sabbatical at the HFGCC supported by a grant from CCHS. The basic approach for stimulating translational research in the CTCR is to match clinicians at the HFGCC with basic researchers with a common shared interest.

M. Describe the status of electronic medical records at the hospital and cancer center

The Christiana Care Health System is in transition to a fully electronic medical record. Many components are electronic including surgical reports, admit and discharge summaries, and pathology reports. Effective June 2007, the system went live for electronic physician signature of records. This develops the infrastructure necessary for fully electronic physician order entry to be implemented by the end of 2007.

In addition, CCHS is a founding and funding member of the Delaware Health Information Network (DHIN), a statewide electronic medical records system. DHIN went live with its first information sharing between hospitals, physician practices and laboratories in March 2007. In a predominantly private practice environment, DHIN will provide the infrastructure to share patient information between disparate electronic medical records systems in physician offices, hospital, radiology centers and laboratories.

N. Describe the experience with biospecimen collection and banking

A Tissue Procurement Facility is in place. Selected individuals from the Cancer Center and Department of Pathology and Laboratory Medicine received training at the Tissue Procurement Training Workshop hosted by the University of Alabama and the Cooperative Human Tissue Network, Southern Division in May of 2003. The Tissue Procurement Facility was constructed with the goal of banking tissue appropriate for DNA and RNA extraction, tissue arrays, laser capture microdissection and immunohistochemistry. Information Technology specialists at Christiana Care designed an Access database unique to the Tissue Procurement Facility in order to provide documentation of tumor characteristics (e.g. grade and stage), and non-identifying personal information (e.g. age or gender) while protecting patient confidentiality. The current system allows for the retrieval of a significant amount of pre-diagnostic and post-surgical information.

The process for collecting tissue is initiated when the patient is identified as a candidate for Tissue Procurement by their surgeon, based on criteria such as the size of their tumor and whether they will receive any treatment prior to surgery. A Helen F. Graham Cancer Center care coordinator obtains informed consent from the patient and notifies the Tissue Procurement technologist of the date and time of the surgery. A copy of the consent form is delivered to the Tissue Procurement Facility and maintained indefinitely on file. On the day of surgery, an insulated bucket, blood collection tubes, and instructions are sent to the operating room by the technologist. The technologist delivers everything to the Histology Laboratory and assigns the specimen a unique Tissue Procurement accession number in addition to the surgical pathology case number assigned by histology. The pathologist performs a gross examination to determine the quantity of tissue that may be directed to the Tissue Procurement Facility. Appropriately sized aliquots of both normal and tumor tissue are collected in sterile fashion and placed into labeled cryo vials as well as tissue cassettes (for quality control slides). The cryo vials are frozen in liquid nitrogen and stored at -70°C. The tubes of blood are spun down and the plasma and

buffy coat are aliquotted separately into labeled cryo vials which are also frozen in liquid nitrogen and stored at -70°C.

The quality control cassettes are processed by the Histology Lab, and on the following day, glass slides are delivered to the one pathologist responsible for quality control (Pathology Medical Director). The numbers of specimens collected to date are lung-84, colon-80, breast-8, esophagus-6, liver-5, parotid glands-4, brain-4, larynx-1, and kidney-1.

TABLE 1: 2006 NEW CANCER CASES (ANALYTIC)

	Total	ribution Case	TABLE
PRIMARY SITE	2006	Mix %	
ORAL	48	2.0%	
Lip	3	0.1%	
Tongue	16	0.7%	
Mouth	22	0.9%	
Pharynx	7	0.3%	
DIGESTIVE	359	14.6%	
Esophagus	19	0.8%	
Stomach	32	1.3%	
Small Intestine	8	0.3%	
Colon	158	6.4%	
Rectum/Rectosigmoid	56	2.3%	
Liver/Biliary/Gallbladder	31	1.3%	
Pancreas	50	2.0%	
Other Digestive	5	0.2%	
RESPIRATORY	376	15.3%	
Larynx	14	0.6%	
Lung	360	14.7%	
Other Respiratory	2	0.1%	
Bone & Conn. Tissue	21	0.9%	
Bone	4	0.2%	
Connective Tissue	17	0.7%	
Melanoma	97	3.9%	
Other Skin Cancer	6	0.2%	
BREAST	455	18.5%	
Female Organs	167	6.8%	
Cervix Uteri	24	1.0%	
Corpus Uteri	86	3.5%	
Ovary	42	1.7%	
Other Female Organs	15	0.6%	
Male Organs	326	13.3%	
Prostate	316	12.9%	
Testis	8	0.3%	
Other Male	2	0.1%	
URINARY	159	6.5%	
Bladder	93	3.8%	
Kidney/Renal Pelvis	56	2.3%	
Other Urinary	10	0.4%	
EYE	1	0.0%	
BRAIN/CNS	106	4.3%	-
ENDOCRINE	86	3.5%	
Thyroid	49	2.0%	
Endocrine/Other	13	0.5%	
LEUKEMIA	56	2.3%	
OTHER HEMATOPOIETIC	140	5.7%	•
Hodgkin's	17	0.7%	
Non-Hodgkin	96	3.9%	
Multiple Myeloma	27	1.1%	
All Other/Undefined	54	2.2%	

^{** 2006} cases are 81.2% complete as of the report on 5/29/07

Data Source-Oncology Data Center Prepared by R. McBride, CTR

^{*} Analytic cases are only cases that are newly diagnosed and/or newly treated at CCHS

TABLE 2: Information on Clinical Research Studies

Helen F. Graham Community Cancer Center Reporting Period: 1/1/2004 - 12/31/2006

Reporting Period: 1/1/2004 - 12/31/2006											
Sponsor (NCI/Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention)	Accrual Year 1	Accrual Year 2	Accrual Year 3	Total Accrual		
CALGB 40101	Breast	Cytoxan/Dox. Vs. Paclitaxel as Adj. Therapy for Breast CA in Women with 0-3 positive axillary nodes	7/8/02		Therapeutic	20	17	12	49		
CALGB 49907	Breast	Rand. Adj. Chemo with Standard Regimens CMF or AC vs. Capecitabine in Women with Breast CA over 65 yrs.	11/4/02	12/29/06	Therapeutic	1	7	2	10		
CALGB 49907	Breast	Rand. Adj. Chemo with Standard Regimens CMF or AC vs. Capecitabine in Women with Breast CA over 65 yrs.	11/4./02	12/29/06	Cancer Control	1	7	2	10		
CALGB 99904	Prostate	Adj Androgen Dep Vs Mitoxann Plus Pred. Plus Androgen Dep in High Risk Prostate Cancer Following Radical Prostatectomy	10/23/00		Therapeutic	1	1	2	4		
CALGB 40105	Breast	Evaluation of Novel Therapeutic Agents (Celebrex) in Breast Cancer	10/6/03	3/24/05	Therapeutic	1	0	0	1		
CALGB 50103	Lymphoma	EPOCH-R for Previously Untreated Aggressive B-Cell NHL	4/22/02	5/28/04	Therapeutic	4	0	0	4		
CALGB 500002	Melanoma	High-Dose Interferon vs. Cisplatin, Vinblastine and DTIC & IL-2 & Interferon for High Risk Melanoma	2/25/02	1/31/07	Therapeutic	0	1	1	2		
CALGB 90102	Bladder	Cisplatin, Gemcitabine and ZD1839 for Advanced Urothelial Cancer	8/2/02	4/8/05	Therapeutic	1	0	0	1		
CALGB 80003	Pancreatic	Phase II of Gemcitabine, 5FU and RT in Locally Adv. Non-Met. Pancreatic Adenocarcinoma	6/10/02	10/29/04	Therapeutic	2	0	0	2		
CALGB 59905	Hodgkin's	ABVD vs. Stanford V +/- RT in Locally Extensive and Adv. HD with 0-2 Risk Factors	7/27/01	6/15/06	Therapeutic	4	3	3	10		
CALGB 30103	SCLC	Rand. Phase II of Carboplatin & Etoposide with or without G3139 in Pts. With Extensive SCLC	7/14/03	10/29/04	Therapeutic	4	0	0	4		
CALGB 30105	NSCLC	Induction/Concurrent Chemo & Dose- Escalated Thoracic RT for Patients with Stage III NSCLC	10/20/03	11/30/04	Therapeutic	7	0	0	7		
CALGB 30402	NSCLC	Docetaxel/Cetuximab vs. Docetaxel/Bortezomib in PS 2 NSCLC	1/23/06	92806	Therapeutic	0	0	3	3		
CALGB 30406	NSCLC	Erlotinib with/without Taxol in Pts. with Advanced NSCLC	12/5/05		Therapeutic	0	0	3	3		
CALGB 30407	NSCLC	XRT, Pemetrexed and Carboplatin with/without Cetuximab for Stage 3 NSCLC	11/7/05		Therapeutic	0	0	4	4		
CALGB 70301	Breast	Quality of Life, Employment and Informal Care: Companion to 40101	12/19/05		Cancer Control	0	0	2	2		

Sponsor (NCI/Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention)	Accrual Year 1	Accrual Year 2	Accrual Year 3	Total Accrual
CALGB 100002	Hemat. Malignancy	Minimal Ablation and Cellular Immune Tx in Hematologic Malignancies	2/16/04	3/15/06	Therapeutic	0	0	1	1
CALGB 140202	Lung CA	CALGB Lung Cancer Tissue Bank	3/7/06		Translational	0	0	8	8
CALGB 9764	NHL	Genetic Changes in Diffuse Aggressive Non-Hodgkin's Lymphoma	9/25/00	5/23/05	Therapeutic	4	0	0	4
CALGB 9760	AML	Multidrug Resistance Studies in AML	5/5/97		Therapeutic	1	4	3	8
CALGB 9710	APL	Concurrent Tretinoin & Chemo w / wo Arsenic Trioxide as Initial Consolidation Therapy for Untreated APL, followed by Tretinoin vs Observation Maintenance	12/13/99	3/29/05	Therapeutic	1	0	0	1
CALGB 9665	Leukemia	CALGB Leukemia Tissue Bank	6/24/96		Therapeutic	6	16	8	30
CALGB 8461	Leukemia	Cytogenetics for Acute Leukemia	1/14/85		Therapeutic	7	17	6	30
CALGB 79809	Breast	IV Zoledronic Acid in the Prevention of Bone Loss in Localized Breast CA with Chemo-Induced Ovarian Failure	12/16/03	2/28/06	Cancer Control	6	4	1	11
CALGB 79805	Breast	Soy Protein to Treat Vasomotor Symptoms in Postmenopausal Women with Breast CA taking Tamoxifen	5/6/02	12/30/05	Cancer Control	3	1	0	4
CALGB 29801	CML	Molecular and Cytogenetic Monitoring of CML	2/8/99		Therapeutic	0	1	0	1
CALGB 9862	ALL	Molecular Genetic Features of ALL	9/27/99		Therapeutic	0	5	2	7
CALGB 100001	Multilple Myeloma	Autologous Followed by Non- Myeloablative Allogeneic Transplant For MM	2/26/93		Therapeutic	1	0	0	1
CALGB 19808	ALL	Induction Chemo w /wo MDR- Modulation Followed by Risk Adapted Intensification and Immunotherapy in AML ≤ 60 years.	1/22/01	3/31/06	Therapeutic	0	4	1	5
CALGB 59903	NHL	Early High Dose Chemo & ASCT to Conventional CHOP for Intermediate and High Risk Diffuse Aggressive NHL	6/12/00		Therapeutic	2	3	0	5
CALGB 99809	Prostate	Androgen Suppression plus External RT with a Brachytherapy Boost for Intermediate Risk Prostate CA	3/18/04	10/31/05	Therapeutic	0	1	0	1
CALGB 90207	Urothelial	PS-341 in Previously Treated Adv. Urothelial Tract Transitional Cell CA	2/10/04	4/8/05	Therapeutic	3	0	0	3
CALGB 90206	Renal Cell	Interferon Alfa-2B or Interferon alfa-2B plus Bevacizumab in Patients With Advanced Renal Cell	2/14/04	7/1/05	Therapeutic	6	6	0	12
CALGB 90202	Prostate	Early vs. Delayed Zoledronic Acid to Prevent Skeletal Related Events in Cancer of the Prostate	5/10/04		Therapeutic	0	0	3	3

Sponsor (NCI/Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention)	Accrual Year 1	Accrual Year 2	Accrual Year 3	Total Accrual
CALGB 90104	Bladder	Adj Sequential AG-TP vs Cisplatin and Gemcitabine after Cystectomy for Transitional Cell Carcinoma of Bladder	9/7/04	7/15/05	Therapeutic	0	1	0	1
CALGB 80101	Gastric	Phase III Trial of Adjuvant Chemo after Resection of Gastric Adenocarcinoma	6/9/03		Therapeutic	0	0	3	3
CALGB 80302	Esophagus	Pre-op Cisplatin + CPT11 followed by Post-op Cisplatin/CPT11/XRT for Locally Advanced Esophageal CA	6/26/06		Therapeutic	0	0	1	1
CALGB 80303	Pancreatic	Randomized Trial of Gemcitabine + Bevacizumab/Placebo in Pts. With Adv. Pancreatic Cancer	8/23/04	4/14/06	Therapeutic	6	12	2	20
CALGB 80405	Colon	FOLFOX/FOLFIRI + Bevacizumab + Cetuximab or +Bevacizumab or Cetuximab in Metastatic Colon CA	10/24/05		Therapeutic	0	0	9	9
CALGB 50203	Lymphoma	Phase II of Doxorubicin, Vinblastine, and Gemcitabine for Non-Bulky Stage I and II Hodgkin's Disease	9/27/04	9/29/06	Therapeutic	1	3	3	7
CALGB 500103	Melanoma	4 Weeks of High Dose Interferon in Stage T3-T4 or N1 Melanoma	9/27/04	1/31/07	Therapeutic	1	5	1	7
CALGB 500103	Melanoma	4 Weeks of High Dose Interferon in Stage T3-T4 or N1 Melanoma	9/27/04	1/31/07	Cancer Control	1	5	1	7
CALGB 500102	Melanoma	Temozolomide and Thalidomide in Patients with Met. Melanoma to the Brain	7/12/04	3/15/05	Therapeutic	1	0	0	1
CALGB 30304	SCLC	Single Agent Depsipeptide in Relapsed SCLC	10/11/04	2/15/06	Therapeutic	1	1	0	2
CALGB 30303	NSCLC	Dose-Dense Docetaxel and Cisplatin with Cytokine Support w / wo BNP7797 in Advanced NSCLC	11/8/04	3/10/06	Therapeutic	0	9	1	10
CALGB 30107	Meso- thelioma	PTK 7787 in Patients with Unresectable Malignant Mesothelioma	1/30/04	11/30/04	Therapeutic	5	0	0	5
CALGB 30203	NSCLC	Eicosanoid Pathway Modulators and Cytotoxic Chemo in Adv. NSCLC.	3/19/04	9/30/04	Therapeutic	11	0	0	11
CALGB 19902	Leukemia	Mylotarg + Cytarabine for Relapsed or Refractory AML	11/5/01	5/6/04	Therapeutic	2	0	0	2
CALGB 10201	AML	Daunorubicin & Cytarabine with or without Genasense in Previously Unterated AML ≥ 60 years	3/19/04	10/20/06	Therapeutic	1	2	2	5
CALGB 10105	MDS	Phase II Trial of an Oral VEGF Tyrosine Kinase Inhibitor in MDS	5/25/04	6/7/06	Therapeutic	4	1	1	6
CALGB 10102	ALL	Dose Escalation Study of Subq. Campath-1H during intensification in Adults with untreated ALL	1/12/05	5/2/07	Therapeutic	0	5	2	7
CALGB 90401	Prostate	Double-Blind Placebo Controlled Trial of Docetaxel/Prednisone w / wo Bavacizumab in HRPC	5/23/05		Therapeutic	0	1	5	6
CALGB 50303	NHL	R-CHOP vs. Dose-Adjusted EPOCH-R with Molecular Profiling in Untreated DeNovo Diffuse Large B-Cell Lymph.	7/11/05		Therapeutic	0	4	4	8
CALGB 50202	CNS Lymphoma	Intensive chemo and immunotherapy for Newly Diagnosed Primary CNS Lymphoma	3/21/05	_	Therapeutic	0	2	1	3

Sponsor (NCI/Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention)	Accrual Year 1	Accrual Year 2	Accrual Year 3	Total Accrual
CALGB 30206	SCLC	Induction Cisplatin/Irinotecan Followed by Carboplatin, Etoposide and RT in Limited Stage SCLC	4/11/05	9/30/05	Therapeutic	0	1	0	1
CALGB 20203	CLL	Molecular Markers of CLL	2/14/05		Therapeutic	0	1	2	3
CALGB 10301	Multiple Myeloma	Bortezomib and Liposomal Doxorubicin as Initial Therapy for Symptomatic Multiple Myeloma	11/22/04	10/25/05	Therapeutic	0	4	0	4
CALGB 10107	CML	Genasense and Gleevec in Gleevec- Resistant CML	4/13/04	3/29/05	Therapeutic	0	1	0	1
CALGB 10101	CLL	Fludarabine + Rituxan Induction Followed by Campaath Consolidation in Previously Untreated B-Cell CLL	2/14/05	12/15/06	Therapeutic	0	1	2	3
CALGB 10002	Burkitt's lymph/leuk.	Rituxan + Short Duration, High Intensity Chemo in Previously untreated Burkitt's lymph/leukemia	4/14/05		Therapeutic	0	1	0	1
CALGB 100101	Chronic GVHD	Intravenous Pentostatin for treatment of patients with Chronic GVHD	8/9/04		Therapeutic	0	1	0	1
ECOG E1201	Esophagus	Pre-op Paclitaxel /Cisplatin/RT or Irinotecan/Cisplatin/RT followed by post-op chemo in Esophageal CA	3/24/03	10/19/04	Therapeutic	3	0	0	3
ECOG E1804	Urothelial	Phase II Trial of Sorafenib in Pts. with Advanced Urothelial Cell CA	2/9/06		Therapeutic	0	0	1	1
ECOG E1905	Leukemia	Axacitadine with/without Histone Deacetylase Inhibitor MS275 for MDS, CML AML with Dysplasia	11/6/06		Therapeutic	0	0	1	1
ECOG E1B03	Meso- thelioma	Pemetrexed Plus Gemcitabine or Carboplatin for Patients with Advanced Malignant Mesothelioma	1/30/06		Therapeutic	0	0	1	1
ECOG E2100	Breast	Paclitaxel vs. Paclitaxel + Bevacizumab as First Line Therapy for Locally Recurrent or Met. Breast Cancer	3/11/02	5/26/04	Therapeutic	7	0	0	7
ECOG E2805	Renal	Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Cell Carcinoma	7/28/06		Therapeutic	0	0	1	1
ECOG E2903	CLL	Pentostatin, Cytoxan and Rituxan followed by Campath 1H for Previously Treated or Refractory CLL	6/1/05		Therapeutic	0	0	1	1
ECOG E2301	Head & Neck	BMS-247550 daily x 5 days every 3 Weeks or Weekly in Patients with Met or Recurrent Head/Neck Cancer	5/5/03	3/3/05	Therapeutic	1	0	0	1
ECOG E4599	NSCLC	Paclitaxel Plus Carboplatin with or without Bevacizumab in Advanced Non-Squamous NSCLC	1/14/02	4/7/04	Therapeutic	5	0	0	5
ECOG E5597	NSCLC	Chemoprevention of Selenium Supplementation in Patients With Resected Stage I NSCLC	4/9/01		Prevention	5	3	8	16
ECOG E5202	Colon	Phase III of FOLFOX vs. FOLFOX plus Bevacizumab in Stage II Colon CA at High Risk for Recurrence	10/27/06		Therapeutic	0	0	1	1
ECOG E5203	Gastric/ GE Junction	BAY 43-9006 with Docetaxel and Cisplatin or Oxaliplatin in Mets. Or Advanced Unresectable Gastric/GEJ.	6/29/06		Therapeutic	0	0	2	2

Sponsor (NCI/Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention)	Accrual Year 1	Accrual Year 2	Accrual Year 3	Total Accrual
ECOG E5204	Rectal	FOLFOX vs. FOLFOX plus Bevacizumab for Stage II or III Rectal CA receiving Pre-op Chemo/RT	5/8/06		Therapeutic	0	0	1	1
ECOG E5204	Rectal	FOLFOX vs. FOLFOX plus Bevacizumab for Stage II or III Rectal CA receiving Pre-op Chemo/RT	5/8/06		Cancer Control	0	0	1	1
ECOG E4402	NHL	Phase III Comparing 2 Different Rituxan Dosing Regimens for Low Tumor Burden Indolent NHL	4/7/04		Therapeutic	2	2	3	7
ECOG E4402	NHL	Phase III Comparing 2 Different Rituxan Dosing Regimens for Low Tumor Burden Indolent NHL	4/7/04		Cancer Control	2	2	3	7
ECOG E4101	Breast	Anastrozole + ZD1839 vs. Fulvestrant + ZD1839 in Postmenopausal Women with Hormone Receptor + Breast CA	4/7/04	12/11/06	Therapeutic	0	1	1	2
ECOG E3201	Rectal	FOLFIRI vs. FOLFOX vs. 5FU/LCV for Stage II/III Rectal CA receiving either Pre-Op or Post-Op 5FU/RT	2/10/04	10/28/05	Therapeutic	3	0	0	3
ECOG E3201	Rectal	FOLFIRI vs. FOLFOX vs. 5FU/LCV for Stage II/III Rectal CA receiving either Pre-Op or Post-Op 5FU/RT	2/10/04	10/28/05	Cancer Control	3	0	0	3
ECOG E2A02	Multiple Myeloma	Phase II Trial of PS-341 for High-Risk Newly Diagnosed Multiple Myeloma	4/7/04	3/7/05	Therapeutic	4	0	0	4
ECOG E5501	SCLC	Sequencing Topoisomerase Inhibitors for Extensive SCLC:	1/24/05		Therapeutic	0	4	0	4
ECOG E4802	Urothelial	Pemetrexed Disodium and Gemcitabine in Advanced Urothelial Cancer	10/11/04	10/20/05	Therapeutic	0	2	0	2
ECOG E3803	Prostate	Phase II Study of Wkly BMS-247550 for Refractory Prostate Cancer	1/24/05	8/18/06	Therapeutic	0	0	2	2
ECOG E2103	Breast	Herceptin Plus Weekly Ixabepilone & Carboplatin in Pts with Her2/Newu Positive Met. Breast Cancer	9/27/04	4/24/06	Therapeutic	0	3	0	3
ECOG E1A02	Macroglob ulinemia	Pilot Study of Rituxan + CHOP in Pts. With Newly Diagnosed Waldenstrom's Macroglobulinemia	11/22/04	4/26/07	Therapeutic	0	1	0	1
ECOG E1302	Head & Neck	Placebo Controlled Trial of Docetaxel +/- ZD1839 in PS 2 or Previously Treated Recurrent or Met Head & Neck	3/7/05		Therapeutic	0	2	1	3
ECOG E1302	Head & Neck	Placebo Controlled Trial of Docetaxel +/- ZD1839 in PS 2 or Previously Treated Recurrent or Met Head & Neck	3/7/05		Cancer Control	0	2	1	3
ECOG E1602	Melanoma	Multi-Epitpoe Vaccination w/ Melanoma Peptides for Cytotoxic T-Cells and Helper T Cells for Met. Melanoma	5/23/05		Therapeutic	0	1	3	4
ECOG PACCT-1	Breast	TAILORx Trial: Program for Assessment of Clinical Cancer Tests	7/24/06		Therapeutic	0	0	5	5
NSBAP B31	Breast	Safety/Efficacy of AC followed by Taxol in Node + Breast Cancer Patients who have Tumors that over-express Her2.	3/27/00	4/29/05	Therapeutic	5	2	0	7
NSABP B34	Breast	Adjuvant Clodronate vs. Placebo in Early Stage Breast Cancer Patients Receiving Chemo +/or TMX, or no TX	3/26/01	3/31/04	Therapeutic	2	0	0	2

Sponsor (NCI/Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention)	Accrual Year 1	Accrual Year 2	Accrual Year 3	Total Accrual
NSABP B35	Breast	Anastrozole With Tamoxifen in Postmenopausal Pts with DCIS Undergoing Lumpectomy with RT	3/10/03	6/15/06	Therapeutic	12	6	4	22
NSABP B35	Breast	Anastrozole With Tamoxifen in Postmenopausal Pts with DCIS Undergoing Lumpectomy with RT	3/10/03	1/13/05	Cancer Control	12	0	0	12
NSABP B36	Breast	Adjuvant Therapy Comparing 6 Cycles of FEC to 4 Cycles of AC w /wo Celecoxib in Node Neg. Breast CA	7/26/04		Therapeutic	0	1	0	1
NSABP B36	Breast	Adjuvant Therapy Comparing 6 Cycles of FEC to 4 Cycles of AC w /wo Celecoxib in Node Neg. Breast CA	7/26/04		Cancer Control	0	1	0	1
NSABP B38	Breast	Adjuvant Trial Comparing 3 Chemo Regimens in Women with Node- Positive Breast CA	10/25/04	5/3/07	Therapeutic	1	24	13	38
NSABP CI- 66	Hepatic Metastasis	Multiple Metastectomy Combined with Hepatic Arterial Infusion Alternating with Systemic Chemo for Met. Colon	2/24/03	9/15/04	Therapeutic	1	0	0	1
NSABP C08	Colon	FOLFOX with or without Bevacizumab every 2 weeks for Resected Stages II/III Colon Cancer	10/11/04	10/6/06	Therapeutic	0	12	8	20
NSABP C09	Colon	Oxaliplatin/Capecitabine/HAI of Fluxuridine vs Oxaliplatin/Capecitabine in CRC with resected liver mets	3/9/06		Therapeutic	0	0	1	1
NSABP C09	Colon	Oxaliplatin/Capecitabine/HAI of Fluxuridine vs Oxaliplatin/Capecitabine in CRC with resected liver mets	3/9/06		Cancer Control	0	0	1	1
NSABP R04	Rectal Cancer	Comparing Preop RT/Capecitabine with Pre-Op RT & CIVI 5FU in pts with Operable CA of the Rectum	8/23/04		Therapeutic	1	4	3	8
NSABP R04	Rectal Cancer	Comparing Preop RT/Capecitabine with Pre-Op RT & CIVI 5FU in pts with Operable CA of the Rectum	8/23/04		Cancer Control	1	4	3	8
NSABP P2	Breast	STAR- Study of Tamoxifen and Raloxifene in the Prevention of Breast Cancer	4/26/99	11/4/04	Prevention	9	0	0	9
NSABP CO-STAR	Breast	Effects of Selective Estrogen Receptor Modulators on Cognitive Aging.	1/14/02		Prevention	1	0	0	1
SWOG S0000	Prostate	Selenium and Vitamin E Cancer Prevention Trial (SELECT)	12/18/00	6/24/04	Prevention	1	0	0	1
SWOG S0000B	Prostate	Select Eye Endpoints: Follow-up trial to SELECT	12/30/04		Prevention	0	0	2	2
SWOG S0347	Prostate	PCPT Companion: Long Term Follow- up for Men Diagnosed with Prostate CA	3/10/06		Prevention	0	0	3	3
UMCC Flaxseed	Prostate	Impact of Fat and Flaxseed Modified Diets on Prostate Cancer	7/14/03	10/24/05	Prevention	1	0	0	1
GOG 0087L	GYN	Docetaxel & Gemcitabine Plus G-CSF in the Treatment of Recurrent of Adv. Leiomyosarcoma of Uterus	4/5/04	6/5/06	Therapeutic	1	0	0	1

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Sponsor (NCI/Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention)	Accrual Year 1	Accrual Year 2	Accrual Year 3	Total Accrual
GOG 0182	GYN	Paclitaxel/Carboplatin vs. Triplet or Doublet Combinations in Pts with Epithelial Ovarian or Peritoneal CA	3/15/04	9/1/04	Therapeutic	2	0	0	2
GOG 0209	GYN	Doxorubicin/Cisplatin/ Paclitaxel & G- CSF vs. Carbo/Paclitaxel in Stage III or IV or Recurrent Endometrial CA	3/8/04		Therapeutic	0	2	1	3
GOG 0209	GYN	Doxorubicin/Cisplatin/ Paclitaxel & G- CSF vs. Carbo/Paclitaxel in Stage III or IV or Recurrent Endometrial CA	3/8/04		Cancer Control	0	2	1	3
GOG 0204	GYN	Cisplatin + Paclitaxel or Gemcitabine or Topotecan in Stage IVB Recurrent or Persistent CA of the Cervix	2/23/04		Therapeutic	0	2	1	3
GOG 0204	GYN	Cisplatin + Paclitaxel or Gemcitabine or Topotecan in Stage IVB Recurrent or Persistent CA of the Cervix	2/23/04		Cancer Control	0	2	1	3
GOG 0199	GYN	Risk Reducing Salpingo-oophorectomy and CA-125 Screening in Women at Increased Risk of Ovarian Cancer	7/12/04	11/3/06	Prevention	3	27	28	58
GOG 0170F	GYN	Ph II Evaluation of BAY 43-9006 in Tx Of Persistent or Recurrent Epithelial Ovarian or Primary Peritoneal CA	10/4/04	1/23/06	Therapeutic	1	0	0	1
GOG 0146Q	GYN	Phase II of Irofulven in Recurrent or Resistant Platinum Sensitive Epithelial Ovarian or Primary Peritoneal CA	3/22/04		Therapeutic	0	0	1	1
GOG 0218	CYN	Combination Chemo/Bevacizumab regimens for Previously Untreated Stage III, or IV Epithelial Ovarian or Primary Peritoneal CA	1/30/06		Therapeutic	0	0	1	1
GOG 0218	CYN	Combination Chemo/Bevacizumab regimens for Previously Untreated Stage III, or IV Epithelial Ovarian or Primary Peritoneal CA	1/30/06		Cancer Control	0	0	1	1
GOG 0220	GYN	Pelvic Mass Study to develop Serum Proteomic Profiles for Epithelial Ovarian CA	1/9/06		Cancer Control	0	0	21	21
GOG 0170H	GYN	Vorinostat in Treatment of Persistent or Recurrent Epithelial Ovarian or Primary Peritoneal CA	11/21/05	4/3/06	Therapeutic	0	0	1	1
GOG 0188	GYN	Phase II Study of Faslodex in Advanced/Recurrent Endometrial CA	10/23/05		Therapeutic	0	0	1	1
RTOG 9811	GI	Ph III Rand. Study of 5-FU, Mitomycin & RT vs 5FU, Cisplatin & RT in Cancer of The Anal Canal	3/22/99	6/27/05	Therapeutic	2	0	0	2
RTOG 9902	Prostate	Ph III AS & RT VS AS & RT Followed By Chemo w/ Paclitaxel,, Estramustine & Etoposide for Localized High Risk	3/27/06	10/4/04	Therapeutic	4	0	0	4
RTOG 9910	Prostate	Ph III Trial to Evaluate the Duration of Neoadjuvant Total AS & RT in Intermediate Risk Prostate CA	4/10/00	5/3/04	Therapeutic	3	0	0	3
RTOG 0123	SCLC	Ph II Rand. Trial W/ Captopril for Patients Who Received RT+/- Chemo for Stage II-IIIB NSCLC, Stage I NSCLC or Limited SCLC	10/22/03	9/14/05	Therapeutic	1	0	0	1

Sponsor (NCI/Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention)	Accrual Year 1	Accrual Year 2	Accrual Year 3	Total Accrual
RTOG 0212	SCLC	Ph II/III Rand. Trial of 2 Doses (STND VS. HIGH) & 2 High Dose Schedules for PCI with Limited Stage SCLC	8/11/03		Therapeutic	2	1	2	5
RTOG 0212	SCLC	Ph II/III Rand. Trial of 2 Doses & 2 High Dose Schedules of PCI with limited Stage SCLC	8/11/03		Cancer Control	2	1	2	5
RTOG 0214	NSCLC	Ph III Comparison of PCI vs Observation in Pts. w Locally Advanced NSCLC	12/2/02		Therapeutic	2	4	0	6
RTOG 0214	Lung	Ph III Comparison of PCI vs. Observation in Pts. with Locally Adv. NSCLC	12/11/02		Cancer Control	2	4	0	6
RTOG 0241	SCLC	Ph I Study of CPT11 & Cisplatin in Combination w/ 2X Daily RT (45 Gy) or Once Daily RT(70 Gy) for Limited SCLC	8/25/03	11/29/05	Therapeutic	2	3	0	5
RTOG H0129	H&N	Ph II of Concurrent RT/Chemo Followed by Surgery for Residual Primary N2-3 Nodal Disease in Adv. H/N CA.	1/13/03	6/23/05	Therapeutic	10	8	0	18
RTOG 0122	Multiple	Double Blind Study of Nutritional Intervention for Tx of CA Cachexia with Juven Nutritional Supplement	3/24/03	10/12/04	Cancer Control	4	0	0	4
RTOG 0232	Prostate	ed Ext Beam RT and Transperineal hy. Vs. Brachy. Alone in Intermediate	2/9/04		Therapeutic	3	8	8	19
RTOG 0232	Prostate	Ph III Comparing Combined Ext. Beam RT & Transperineal Interstitial Perm. Brachy. Vs. Brachy Alone in Intermediate Risk Prostate	2/25/04		Cancer Control	3	8	8	19
RTOG 0234	H&N	Ph II Rand. Trial of Surgery Followed by ChemoRT plus C225 for Advanced Squamous Cell CA of the Head & Neck	9/13/04	12/1/06	Therapeutic	2	5	2	9
RTOG 0324	Lung	Ph II Study of C225 in Combination with ChemoRT in Pat. With Stage IIIA/B NSCLC	6/9/04	6/3/05	Therapeutic	0	3	0	3
RTOG S0132	GI	Ph II Trial of Neoadjuvant Gleevec for Primary and Recurrent Operable Malignant GIST Expressing TK CD117	4/5/04	6/2/06	Therapeutic	1	0	0	1
RTOG 0315	Gl	Rand. Dble-Blind Plac-Cont. Ph III to Determine the Efficacy of Sandostatin in Controlling Chemo-Induced Diarrhea	6/9/04	2/24/06	Cancer Control	5	2	0	7
RTOG 0320	NSCLC	Phase III Comparing WBRT & SRS Alone with Temozolomide or Erlotinib in NSCLC with 1-3 Brain Mets	7/25/05		Therapeutic	0	0	3	3
RTOG 0321	Prostate	Ph II Trial of Combined High-Dose Brachy Therapy & Ext. Beam RT for Adenocarcinoma of Prostate	1/13/05	5/26/06	Therapeutic	0	6	3	9
RTOG 0411	GI	Ph II Study of Bevacizumab w/ Concurrent Capecitabine/RT Followed by Maintenance Gemcitabine/Bev.	5/3/05	2/7/06	Therapeutic	0	7	0	7
RTOG 0412	NSCLC	Pre-Op Chemo vs. Pre-Op Comcurrent Chemo/RT followed by resection + consolidation in Favorable Stage IIIA	10/6/05	12/15/06	Therapeutic	0	0	2	2

Sponsor (NCI/Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention)	Accrual Year 1	Accrual Year 2	Accrual Year 3	Total Accrual
RTOG 0412	NSCLC	Pre-Op Chemo vs. Pre-Op Comcurrent Chemo/RT followed by resection + consolidation in Favorable Stage IIIA	10/6/05	12/15/06	Cancer Control	0	0	2	2
RTOG 0413	Breast	Conventional Whole Breast RT vs. Partial Breast RT for Stage 0, I, II Breast CA	7/26/05		Therapeutic	0	0	15	15
RTOG 0413	Breast	Conventional Whole Breast RT vs. Partial Breast RT for Stage 0, I, II Breast CA	7/26/05		Cancer Control	0	0	15	15
RTOG 0420	Brain	Ph II Study of RT & Low Dose Temozolomide Followed by Temozolomide & CPT11 for GBM	2/14/05	9/23/05	Therapeutic	0	4	0	4
RTOG 0424	Gliomas	Phase II of Temozolomide Based Chemo/RT for High Risk Low Grade Gliomas	3/8/05		Therapeutic	0	0	1	1
RTOG 0521	Prostate	Androgen Suppression and 3D CRT/IMRT vs. AS and 3D/CRT/IMRT Followed by Chemo for High Risk Prostate CA	3/7/06		Therapeutic	0	0	3	3
RTOG 0522	Head and Neck	Con. Acceler. RT + Cisplatin vs. Con Acceler RT, Cisplatin + Cetuximab for Stage III and IV Head & Neck Cancer	10/23/06		Therapeutic	0	0	2	2
RTOG 0522	Head and Neck	Con. Acceler. RT + Cisplatin vs. Con Acceler RT, Cisplatin + Cetuximab for Stage III and IV Head & Neck Cancer	10/23/06		Cancer Control	0	0	2	2
RTOG 0524	GU	Combined Paclitaxel & Trastuzumab w/Daily RT or Paclitaxel alone with Daily RT Following Transurethral Surgery in Bladder CA	11/08/05		Therapeutic	0	1	1	2
RTOG 0525	GBM	Comparing Conventional Adjuvant Temodar with Dose Intensive Temodar in Pts. with Newly Diagnosed GBM	3/21/06		Therapeutic	0	0	5	5
RTOG 0611	GBM	Urinary VEGF and MMP levels in Pts. receiving RT for GBM	2/23/06		Therapeutic	0	0	3	3
RTOG 0123	Lung	Ph II Rand. Trial W/ Captopril for Patients Who Received RT+/- Chemo for Stage II-IIIB NSCLC, Stage I NSCLC or Limited SCLC	10/22/03	9/14/05	Cancer Control	1	0	0	1
CTSU IBCSG 24-02	Breast	SOFT: Evaluation of Ovarian Function Suppression and Adjuvant Exemestane in Premenopausal ER/PR + Breast CA	10/11/04		Therapeutic	0	3	2	5
CTSU IBCSG 24-02	Breast	SOFT: Evaluation of Ovarian Function Suppression and Adjuvant Exemestane in Premenopausal ER/PR + Breast CA	10/11/04		Cancer Control	0	3	2	5
UMCC	Multiple	Trial of Encapsulized Ginger for Chemotherapy Induced Nausea/Vomiting	8/31/05	5/31/07	Cancer Control	0	2	9	11
CCCWFU 97102	Solid Tumors	Comparing Effects of Oxandrin vs. Megace on Lean Body Mass, Wt., Body Fat & QOL in Patients with Wt. Loss	6/26/06	5/1/07	Cancer Control	0	0	9	9

Sponsor (NCI/Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention)	Accrual Year 1	Accrual Year 2	Accrual Year 3	Total Accrual
CCCWFU 97202	Breast	Rand. Dbl-Blind Placebo Controlled Study of Oral Co-enzyme Q10 to Relieve Self-Reported Fatigue in Breast Cancer Pts.	4/10/06		Cancer Control	0	0	1	1
NOVARTIS	Colorectal	Rand. Double-Blind study in patients with met. colon or rectum adeno receiving FOLFOX +/- PTK787	4/7/03	8/21/04	Therapeutic	5	0	0	5
ASTRA ZENECA	NSCLC	Phase III of ZD1839 vs IV Docetaxel in Pts. with Metastatic Recurrent NSCLC after Failing Platinum Chemo	2/18/04	1/13/05	Therapeutic	9	0	0	9
ASTRA ZENECA	Lung	Pilot Study of Lung Function and Chemotherapeutic Tx of NSCLC and validation of a symptom survey	3/15/04	9/1/04	Cancer Control	4	0	0	4
BMS	Multiple	Effects of Esomeprazole on the Pharmacokinetics of BMS-275183 in Pts. with Advanced Malignancies	8/31/06	3/1/07	Therapeutic	0	0	1	1
BMS	Hepatic	Rand. Open Label Study of BMS- 582664 orally vs. Doxorubicin every 3 weeks in Adv. Or Mets Hepatocellular	12/18/06		Therapeutic	0	0	2	2
BMS	Multiple	Phase I Study of Cetuximab in Combination with Erlotinib in Pts with Advanced Solid Malignancies	6/15/06	2/12/07	Therapeutic	0	0	10	10
COLEY	Melanoma	ProMune with or without Chemotherapy for Stage IIIb/c or IB Melanoma	4/8/04	10/8/04	Therapeutic	4	0	0	4
Genentech	NSCLC	Bevacizumab in Combination with Tarceva Compared with Tarceva alone for Adv. NSCLC Failing First Line Tx	4/28/06		Therapeutic	0	0	4	4
Genentech	Colorectal	Observational Study of Avastin in Combination with Chemotherapy for First Line Tx of Colorectal Adenoca.	3/15/04	6/30/05	Cancer Control	16	7	0	23
GLAXO SMITHKLINE	Breast	Phse III of Lapatinib in Combination with Trastuzumab vs. Lapatinib alone in Mets. Breast CA progressing on Trastuzumab-Containing Regimen	1/12/06	12/20/06	Therapeutic	0	0	5	5
GLAXO SMITHKLINE	Multiple	Randomized Two Period Crossover Study to Investigate Interactions Between GW597559 and Cytoxan	6/24/04	3/28/05	Cancer Control	1	0	0	1
GLAXO SMITHKLINE	Multiple	Phase I of Liposomal Doxorubicin and Weekly Topotecan as Second Line Therapy in Adv. Solid Tumors	5/14/04	3/29/06	Therapeutic	1	16	3	20
HELEN F. GRAHAM Cancer Center	Colon	Cytoreductive Surgery, Intraperitoneal Hyperthermic & Systemiic Chemo in Small Bowel, Appendiceal or CRC	4/30/04		Therapeutic	1	0	0	1
HOOSIER ONCOLOGY GROUP	Breast	Phase II Trial of Capecitabine and Oxaliplatin in Patient with Previously Treated Metastatic Breast	91404	5/3/06	Therapeutic	0	8	3	11
AMGEN	Head & Neck	Phase III Double Blind Trial of Palifermin for Reduction of Oral Mucositis in H/N Patients receiving Chemo/RT	9/9/05	1/10/07	Cancer Control	0	4	6	10
AVENTIS	Breast	Phase III of RPR 109881 IV every 3 weeks vs Capecitabine fpr Met. Breast Cancer failing Taxanes/Anthracyclines	8/9/04	4/28/06	Therapeutic	0	2	0	2

Sponsor (NCI/Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention)	Accrual Year 1	Accrual Year 2	Accrual Year 3	Total Accrual
BMS	NSCLC	Randomized Trial of Two Dose Schedules of Carboplatin, Paclitaxel, and Cetuximab in Stage IIIB/IV NSCLC	7/13/05	1/26/06	Therapeutic	0	5	0	5
BMS	NSCLC	Exploratory Pharmacogenomics Study of Erbitux Monotherapy in Patients with Met. NSCLC	10/24/05	1/6/06	Therapeutic	0	4	1	5
GLAXO SMITH KLINE	Multiple	Two Period Crossover Study to Investigate Potential PK Interaction between Oral GW679769 and IV Cytoxan	7/15/05		Therapeutic	0	1	2	3
HOOSIER ONCOLOGY GROUP	Head & Neck	Single Arm Phase II Trial of Docetaxel and Capecitabine for Fist Line Tx of Recurrent/Met. Squamous Cell H/N	9/14/04	10/22/06	Therapeutic	0	5	2	7
HOOSIER ONCOLOGY GROUP	SCLC	Pemetrexed in Patients with Chemosensitive or Chemoresistant Relapsed SCLC	5/25/05	10/31/05	Therapeutic	0	2	0	2
IDERA	Renal	Randomized Open Label Study of Two Dose Levels of IMOxine in Patients with Met. or Recurrent Renal CA	7/14/05		Therapeutic	0	10	1	11
JOHNSON & JOHNSON	Breast	Randomized Study of Docetaxel Monotherapy or Doxil & Docetaxel for Advanced Breast Cancer	5/25/05	1/4/07	Therapeutic	0	1	4	5
NOVARTIS	NSCLC	Observational Registry of Stage IV NSCLC patients developing Bone Metastasis and initiating Zometa	5/25/05	1/2/06	Cancer Control	0	10	0	10
NSABP-FB-4	Breast	Phase II of Bevacizumab with Seq. AC followed by Docetaxel/Capecitabine Neoadjuvantly followed by Post-op Bev. for locally advanced Breast CA	9/20/06		Therapeutic	0	0	1	1
Pfizer	NSCLC	Phase II of SU011248 as Consolidation Therapy in Locally Advanced or Met. NSCLC	9/30/05	111406	Therapeutic	0	0	5	5
Pfizer	Breast	Phase II Efficacy and Safety Study of SU011248 in Combination with Trastuzumab in Met. Breast	1/11/06		Therapeutic	0	0	1	1
ROCHE	Colorectal	XELOX with Bevacizumab every 3 weeks vs. XELOX with Bevacizumab every 2 weeks in Met. Colorectal CA	11/14/05	9/1/06	Therapeutic	0	0	1	1
TAIHO	Breast	Efficacy and Safety Study of 3 Doses of TAS-108 Orally in Postmenopausal Patients Adv/recurrent/met. Breast CA	7/28/04	1/28/07	Therapeutic	0	1	1	2
VION	SCLC	Phase II Trial of Cloretazine for Pts. with Relapsed/Refractory SCLC	12/29/05		Therapeutic	0	0	3	3
FAVRILLE	NHL	Double Blind Placebo Controlled Trial of FAVID and GM-CSF vs. Placebo and GM-CSF after Rituxan for NHL	5/24/04	1/31/06	Therapeutic	0	5	0	5
LILLY	GYN	Induction Chemo with Carboplatin plus Gemcitabine or Paclitaxel followed by Paclitaxel Consolidation	10/6/04	10/18/05	Therapeutic	0	3	0	3
University of Delaware/ Helen F. Graham	Prostate	Pilot Study of Heparin Sulfate Dependent Interactions Between Met. Prostate Cancer Cells and Bone Marrow Stromal Cells	10/10/02	6/6/07	Translational	2	0	2	4

Sponsor (NCI/Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention)	Accrual Year 1	Accrual Year 2	Accrual Year 3	Total Accrual
Thomas Jefferson University	Colon	Guanylyl Cyclase C in blood and Colorectal Cancer	8/23/04		Translational	17	55	38	110
Fox Chase Cancer Center	Breast	Genomic Basis of Reproductive History on Breast Cancer	11/17/03		Translational	20	23	12	55
Fox Chase Cancer Center	Colon	Facilitating Informed Decisions for Microsatellite Instability Testing	7/15/05		Translational	0	0	17	17
NCI	Ovarian	Psychological Interventions for Gynecological Cancer Patients	7/27/04	4/18/06	Behavioral	13	0	0	13
DOD	Prostate	Evaluating an interactive, multimedia education and decision program for early stage prostate cancer patients in a RCT	6/18/04	6/21/06	Behavioral	13	16	1	30
None	Various	The effect of life marker review on affect in hospitalized cancer patients	10/14/05	6/15/06	Behavioral	0	0	50	50
NCI	Various	A comparison of two approaches to manage fatigue and insomnia in cancer patients: Energy and sleep enhancement, The EASE study.	12/23/05		Behavioral	0	0	11	11
University of Delaware	Breast	Couples Coping with Cancer	9/27/06		Behavioral	0	0	6	6
TOTAL						375	569	535	1479

Accrual Rate Calculation	Total Accrued	Number of New Cancer Cases	Percent Accrual		
Period 1: 1/1/04 - 12/31/-04	375	2681	13.9%		
Period 2: 1/1/05 – 12/31/05	569	2687	21.1%		
Period 3: 1/1/06 – 12/31/06	535	2729 est.	19.6%		