

	<p>OBJECTIVES:•Compare the immunological effects of 2 different schedules of vaccinia-CEA-TRICOM vaccine, fowlpox-CEA-TRICOM vaccine, and sargramostim (GM-CSF) administered with standard adjuvant chemotherapy in women with high-risk stage II or III breast cancer.</p> <ul style="list-style-type: none"> •Compare the safety of these regimens in these patients. •Determine the feasibility of obtaining determinations of CD4 response in patients treated with these regimens. •Compare disease-free survival of patients treated with these regimens. <p>OUTLINE: This is a randomized study. Patients are randomized to 1 of 2 treatment arms.</p> <ul style="list-style-type: none"> •Vaccinia-CEA-TRICOM: Beginning 2-3 weeks after surgery and before initiation of standard adjuvant chemotherapy, all patients receive vaccinia-CEA-TRICOM vaccine subcutaneously (SC) on day 1 and sargramostim (GM-CSF) SC on days 1-4 of week 1. •Fowlpox-CEA-TRICOM: Patients are treated on 1 of the following schedules: <ul style="list-style-type: none"> •Arm I: During chemotherapy, patients receive fowlpox-CEA-TRICOM vaccine SC on day 1 and GM-CSF SC on days 1-4 of weeks 2, 5, 8, 11, 14, 17, 20, and 23. After chemotherapy, patients receive additional vaccinations on weeks 26, 38, and 50. •Arm II: Prior to chemotherapy, patients receive fowlpox-CEA-TRICOM vaccine SC on day 1 and GM-CSF SC on days 1-4 of week 2. After chemotherapy, patients receive additional vaccinations on weeks 26, 38, and 50. •Chemotherapy: Patients receive doxorubicin IV over 5-7 minutes and cyclophosphamide IV over 30 minutes on day 1 of weeks 3, 6, 9, and 12. Patients then receive paclitaxel IV over 3 hours on day 1 of weeks 15, 18, 21, and 24. Treatment continues in the absence of disease progression (after at least 1 course of chemotherapy) or unacceptable toxicity. •Radiotherapy: Patients undergo radiotherapy during weeks 26-32 in the absence of disease progression. Patients with hormone-receptor positive tumors receive oral tamoxifen for 5 years beginning on approximately week 32. 	
Recruiting	<p><u>Bevacizumab, Autologous Tumor/DC Vaccine, IL-2 and IFN α-2b in Metastatic Renal Cell Carcinoma (RCC) Patients</u></p> <p>Condition: Metastatic Renal Cell Carcinoma</p> <p>Interventions: Biological: DC vaccine; Drug: Bevacizumab; Biological: IL-2; Biological: IFN 2009</p>	<p>VEGF Blockade With Bevacizumab Combined With Autologous Tumor/Dendritic Cell Vaccine (DC Vaccine), IL-2 and IFN α-2b</p>
	<p>Primary Outcome Measures: To determine the objective clinical response rate and progression free survival (PFS) to this combined treatment regimen. [Time Frame: 3 years] To characterize the clinical and autoimmune related toxicity profile of the combined treatment regimen. [Time Frame: 3 years]</p> <p>Secondary Outcome Measures: In relevant immune pathways, to measure treatment-related tumor-specific immune responses and to examine the relationship between tumor-specific immune response and objective clinical response in RCC patients treated with this regimen [Time Frame: 3 years]</p>	
Active, not recruiting	<p><u>Vaccine Therapy, Cyclophosphamide, and Cetuximab in Treating Patients With Metastatic or Locally Advanced Pancreatic</u></p> <p>Condition: Pancreatic Cancer</p> <p>Interventions: Biological: Cetuximab; Biological: PANC 10.05 pcDNA-1/GM-Neo and PANC 6.03 pcDNA-1/GM-Neo vaccine; Drug: Cyclophosphamide; Other: laboratory biomarker analysis; Procedure: Biopsy</p>	<p>Lethally Irradiated Allogeneic Pancreatic Tumor Cells Transfected With the GM-CSF Gene in Combination With Erbitux (Cetuximab)</p>
	<p>Event-free survival [Time Frame: Continuous] . Secondary: Determine the overall, progression-free, and event-free survival of patients treated with this regimen. Correlate specific in vivo parameters of immune response (e.g., mesothelin, prostate stem cell antigen [PSCA], mutated k-ras-specific T-cell responses) with clinical response in patients treated with this regimen../Correlate downstream targets of epidermal growth factor receptor (EGFR) signaling (e.g., intratumor expression of Akt, Stat 3 and 5, mesothelin, mutated k-ras, and PSCA) with inhibition by cetuximab in patients treated with this regimen. /Correlate inhibition of EGFR signaling (e.g., Stat 3 and 5) with improved specific mesothelin, PSCA, and mutated k-ras-specific T-cell responses in patients treated with this regimen</p>	

Active, not recruiting	<u>A Phase 1 Study of Mixed Bacteria Vaccine (MBV) in Patients With Tumors Expressing NY-ESO-1 Antigen</u>		Mixed Bacteria Vaccine (MBV) in Patients With Tumors Expressing NY-ESO-1 Antigen
	Conditions:	Melanoma; Sarcoma; Gastrointestinal Stromal Tumor (GIST); Head and Neck Cancer; Transitional Cell Carcinoma; Prostate Cancer	
	Intervention:	Biological: Mixed Bacterial Vaccine (MBV) 2008	
	Primary Outcome Measures: •Toxicities and adverse events defined by National Cancer Institute Common Terminology Criteria for Adverse Events. [Time Frame: Duration of study] •Dose level(s) of MBV eliciting body temperature increase to 38C -39.5 C. [Time Frame: Weeks 1-5] Secondary Outcome Measures: •NY-ESO-1 specific immune responses [Time Frame: Duration of Study] •Tumor response as defined by RECIST [Time Frame: Duration of Study]		
Completed	<u>Vaccine Therapy With Tumor Specific Mutated VHL Peptides in Adult Cancer Patients With Renal Cell Carcinoma</u>		Tumor Specific Mutated VHL Peptides in Adult Cancer Patients
	Condition:	Renal Cell Carcinoma	
	Interventions:	Biological: aldesleukin; Biological: incomplete Freund's adjuvant; Biological: sargramostim; Biological: von Hippel-Lindau peptide vaccine 1999	
	Primary Outcome Measures: Presence of endogenous cellular or humoral immunity. /Induction of cellular immunity. Type and characteristics of cellular immunity. / Tolerability [Designated as safety issue: Yes]. Toxicity [Designated as safety issue: Yes] Feasibility of expanding specific T-cell clones		
Completed	<u>Vaccine Therapy Plus Sargramostim and Interleukin-2 Compared With Nilutamide Alone in Treating Patients With Prostate</u>		Immunotherapy With a Regimen of Recombinant Pox Viruses That Express PSA/B7.1 Plus Adjuvant GM-CSF and IL2 or Hormone Therapy With Nilutamide
	Condition:	Prostate Cancer	
	Interventions:	Biological: aldesleukin; Biological: recombinant fowlpox-prostate specific antigen vaccine; Biological: recombinant vaccinia prostate-specific antigen vaccine; Biological: recombinant vaccinia-B7.1 vaccine; Biological: sargramostim; Drug: nilutamide 2001	
	OBJECTIVES: Compare the difference in time to radiographic evidence of disease progression at 6 months in patients with hormone-refractory prostate cancer when treated with vaccine containing recombinant vaccinia-prostate-specific antigen (PSA) admixed with rV-B7.1 plus recombinant fowlpox-PSA vaccine, sargramostim (GM-CSF), and interleukin-2 vs nilutamide alone. Evaluate the vaccination therapy in relation to the change in T-cell precursor frequency and to the rise of serum PSA in this patient population. OUTLINE: This is a randomized study. Patients are stratified according to HLA-A2 typing (positive vs negative). Patients are randomized to one of two treatment arms. Arm I: Patients receive vaccine containing recombinant vaccinia-prostate-specific antigen (PSA) and rV-B7.1 subcutaneously (SC) on day 2 only. Beginning on day 30, patients receive recombinant fowlpox-PSA vaccine SC every 4 weeks for 12 vaccinations and then every 12 weeks thereafter. Patients also receive sargramostim (GM-CSF) SC daily on days 1-4 and interleukin-2 SC daily on days 8-12 with each vaccination		
Active, not recruiting	<u>Direct Tumor Injection KLH-Pulsed Dendritic Cells in Unresectable Pancreatic Cancer</u>		Apoptosis Induction Through Direct Tumor Injection of TNFerade(TM)or Radiation Alone Followed by KLH-Pulsed Autologous Dendritic Cells
	Condition:	Metastatic Pancreatic Cancer	
	Intervention:	Biological: KLH-pulsed autologous dendritic cell vaccine 2009	
	Overall Survival [Patients will be followed until death] .		
Recruiting	<u>Vaccine Therapy With or Without Imiquimod in Treating Patients With Grade 3 Cervical Intraepithelial Neoplasia</u>		HPV16-specific Therapeutic DNA-vaccinia Vaccination in Combination With Topical Imiquimod
	Conditions:	Cervical Cancer; Precancerous Condition	
	Interventions:	Biological: TA-HPV; Biological: pNGVL4a-Sig/E7(detox)/HSP70 DNA vaccine; Drug: imiquimod 2007	

	<p>Primary Outcome Measures: Safety (according to NCI CTCAE v3.0) and tolerability</p> <p>Secondary Outcome Measures: Change in histology (CIN3 or no CIN3) of biopsies between baseline and week 28. Quantitative changes in cervical HPV viral load in exfoliated cell samples. Changes in lesion size by serial digital colposcopy from week 0 to week 15 Characterization of peripheral and local tissue response to vaccination on serially obtained peripheral blood specimens and on tissue samples from therapeutic resection Correlation of immune response with clinical response.</p> <p>Correlation between measures of immune response and preclinical experimental data.</p> <p>Secondary</p> <p>To evaluate the effect of this regimen on histology, based on the regression of cervical intraepithelial neoplasia.</p> <p>To evaluate the feasibility and safety of study immunotherapy in these patients.</p> <p>To evaluate the quantitative changes in cervical HPV viral load in these patients following study immunotherapy.</p> <p>To evaluate changes in lesion size.</p> <p>To evaluate the cellular and humoral immune response to vaccination.</p> <p>To evaluate local tissue immune response.</p> <p>To correlate measures of immune response with clinical response.</p> <p>To correlate measures of immune response with those observed in the preclinical model.</p>					
Completed	<p><u>Vaccine Therapy in Treating Patients With Stage II, Stage IIIA, Stage IIIB, or Stage IVA Liver Cancer</u></p> <table border="1"> <tr> <td>Condition:</td> <td>Liver Cancer</td> </tr> <tr> <td>Interventions:</td> <td>Biological: alpha fetoprotein adenoviral vector vaccine; Biological: alpha fetoprotein plasmid DNA vaccine; Biological: sargramostim plasmid DNA hepatocellular carcinoma vaccine adjuvant 2004</td> </tr> </table>	Condition:	Liver Cancer	Interventions:	Biological: alpha fetoprotein adenoviral vector vaccine; Biological: alpha fetoprotein plasmid DNA vaccine; Biological: sargramostim plasmid DNA hepatocellular carcinoma vaccine adjuvant 2004	<p>Immunization With AFP + GM-CSF Plasmid Prime And AFP Adenoviral Vector Boost</p>
Condition:	Liver Cancer					
Interventions:	Biological: alpha fetoprotein adenoviral vector vaccine; Biological: alpha fetoprotein plasmid DNA vaccine; Biological: sargramostim plasmid DNA hepatocellular carcinoma vaccine adjuvant 2004					
	<p>Primary: Determine the dose-limiting toxicity and maximum tolerated dose of adjuvant vaccination comprising alpha fetoprotein (AFP) plasmid DNA and sargramostim (GM-CSF) plasmid DNA followed by AFP adenoviral vector boost in patients with HLA-A*0201-expressing stage II-IVA hepatocellular carcinoma.</p> <p>Secondary: Determine the optimal biological dose of this regimen, as defined by the generation of AFP-specific immunity, in these patients.</p> <p>Determine disease-free survival of patients treated with this regimen. Patients are followed monthly for 3 months and then every 6 months</p>					
Completed	<p><u>Vaccine Therapy Plus Immune Adjuvant in Treating Patients With Chronic Myeloid Leukemia, Acute Myeloid Leukemia, or</u></p> <table border="1"> <tr> <td>Conditions:</td> <td>Leukemia; Myelodysplastic Syndromes; Myelodysplastic/Myeloproliferative Neoplasms</td> </tr> <tr> <td>Interventions:</td> <td>Biological: PR1 leukemia peptide vaccine; Biological: incomplete Freund's adjuvant; Biological: sargramostim</td> </tr> </table>	Conditions:	Leukemia; Myelodysplastic Syndromes; Myelodysplastic/Myeloproliferative Neoplasms	Interventions:	Biological: PR1 leukemia peptide vaccine; Biological: incomplete Freund's adjuvant; Biological: sargramostim	<p>PR1 (NSC 698102) Human Leukemia Peptide Vaccine With Montanide ISA 51 (NSC 675756) or Montanide ISA 51 VG (NSC</p>
Conditions:	Leukemia; Myelodysplastic Syndromes; Myelodysplastic/Myeloproliferative Neoplasms					
Interventions:	Biological: PR1 leukemia peptide vaccine; Biological: incomplete Freund's adjuvant; Biological: sargramostim					
	<p>Primary Outcome Measures: Patient Immune response at 3 weeks after last vaccine [Time Frame: 21 weeks (3 weeks post vaccine)] . Patient Clinical response at 3 weeks after last vaccine [Time Frame: 21 weeks (3 weeks post vaccine)]</p> <p>Secondary Outcome Measures: Event-free survival as measured by Kaplan-Meier at 1 year [Time Frame: 1 year] Overall survival as measure by Kaplan-Meier at 1 year [Time Frame: 1 year]</p>					
Active, not recruiting	<p><u>Phase IIb Randomized Controlled Study of BLP25 Liposome Vaccine for Immunotherapy of Non-Small Cell Lung Cancer</u></p> <table border="1"> <tr> <td>Conditions:</td> <td>Lung Neoplasms; Carcinoma, Non-Small-Cell Lung 2005</td> </tr> <tr> <td>Interventions:</td> <td>Biological: BLP25 Liposome Vaccine plus best supportive care; Other: Best Supportive Care (BSC)</td> </tr> </table>	Conditions:	Lung Neoplasms; Carcinoma, Non-Small-Cell Lung 2005	Interventions:	Biological: BLP25 Liposome Vaccine plus best supportive care; Other: Best Supportive Care (BSC)	<p>BLP25 Liposome Vaccine for Active Specific Immunotherapy</p>
Conditions:	Lung Neoplasms; Carcinoma, Non-Small-Cell Lung 2005					
Interventions:	Biological: BLP25 Liposome Vaccine plus best supportive care; Other: Best Supportive Care (BSC)					

	<p>Primary Outcome Measures: Document safety profile of 1000 µg of L-BLP25. [Time Frame: Day 0, Weeks 1, to Month 24. Additional inquires on survival until death.] Compare survival of patients who receive Best Supportive Care plus L-BLP25 to that of patients who receive Best Supportive Care alone. [Day 0, Weeks 1, to Month 24. Additional inquires on survival until death.] Secondary Outcome Measures: To evaluate the impact of L-BLP25 therapy on patients' health-related Quality of Life. [Day 0, Weeks 1, to Month 244. Additional inquires on survival until death.]/ To measure the immune responses elicited by L-BLP25. [Day 0, Weeks 1, to Month 24. Additional inquires on survival until death.]</p>	
Recruiting	<u>Vaccine Therapy in Treating Patients With Newly Diagnosed Stage IV Kidney Cancer</u>	
	Condition:	Kidney Cancer
	Interventions:	Biological: autologous dendritic cell-autologous tumor mRNA-human CD40L vaccine; Biological: therapeutic autologous dendritic cells 2006
	<p>Primary Outcome Measures: T-cell response to RNA-loaded dendritic cells by the ELISpot assay on blood cells, weeks 6 and 14 and years 1 and 2 Secondary Outcome Measures: Exploratory monitoring of T-cell functionality in terms of reverse-transcriptase polymerase chain reaction, cytokine/granzyme secretion, CD4/CD8 T cell proliferation, and CD4/CD8 T cell maturation. Exploratory assessment of immune response as assessed by delayed-type hypersensitivity Objective tumor response (complete and partial response) as assessed by RECIST criteria, Progression-free and overall survival as assessed by RECIST criteria</p>	
Active, not recruiting	<u>Lenalidomide and Vaccine Therapy in Treating Patients With Relapsed or Refractory Multiple Myeloma</u>	
	Condition:	Multiple Myeloma and Plasma Cell Neoplasm
	Interventions:	Biological: pneumococcal polyvalent vaccine; Drug: lenalidomide 2007
	<p>Primary Outcome Measures: Humoral and cellular response./ Efficacy of pneumococcal polyvalent vaccine. Secondary Outcome Measures: Changes in delayed-type hypersensitivity reactions to Candida and tetanus in the presence of lenalidomide /Immune responses to carrier protein CRM 197 in peripheral blood and bone marrow. /Effect of lenalidomide on T-cell activation in blood and bone marrow. /Correlation of immune responses to vaccination with myeloma responsiveness to lenalidomide Primary: Determine whether lenalidomide can augment the efficacy of pneumococcal polyvalent vaccine as it correlates with lenalidomide-induced antitumor efficacy in patients with relapsed or refractory multiple myeloma. Secondary Determine the antibody responses to pneumococcal serotypes in patients treated with this regimen. Determine T-cell responses to the carrier protein CRM 197 in patients treated with this regimen. Determine the ability of lenalidomide to augment in vivo immune responsiveness as measured by cutaneous delayed-type hypersensitivity (DTH) reactions to Candida and tetanus in these patients. Determine the ability of lenalidomide to prime and/or boost systemic vaccine responses in both peripheral blood lymphocytes and marrow lymphocytes in these patients</p>	
Completed	<u>Vaccine Therapy in Treating Patients With Ovarian, Fallopian Tube, or Peritoneal Cancer</u>	
	Conditions:	Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer
	Interventions:	Biological: MUC1-KLH conjugate vaccine; Biological: MUC1-KLH vaccine/QS21; Biological: QS21 2000
	<p>Vaccination oWith Glycosylated MUC-1-KLH Conjugate Plus the Immunological Adjuvant QS-21</p>	

	<p>OBJECTIVES: I. Determine the safety of immunization with glycosylated MUC-1-KLH vaccine plus adjuvant QS21 in patients with ovarian, fallopian tube, or peritoneal epithelial cancer. II. Determine the dose of this treatment regimen for optimal antibody response in these patients. III. Determine the effect of immunization with this treatment regimen on the T-cell response in these patients.</p> <p>OUTLINE: This is a dose escalation study of glycosylated MUC-1-KLH vaccine. Patients receive glycosylated MUC-1-KLH vaccine and QS21 subcutaneously once a week on weeks 1-3, 7, and 19. Cohorts of 6 patients receive escalating doses of glycosylated MUC-1-KLH until the dose for optimal antibody response without unacceptable toxicity is determined. Patients are followed at 2 and 12 weeks, and then every 3 months thereafter as long as detectable immunity against MUC-1 persists.</p>	
Recruiting	<p><u>Therapy to Treat Ewing's Sarcoma, Rhabdomyosarcoma or Neuroblastoma</u></p> <p>Conditions: Neuroblastoma; Sarcoma; Rhabdomyosarcoma-Embryonal; Rhabdomyosarcoma- Alveolar;</p> <p>Interventions: Drug: Tumor Purged/CD25 Depleted Lymphocytes; Biological: Tumor Purged/CD25 Depleted Lymphocytes with Tumor Lysate/KLH Pulsed Dendritic Cell Vaccine; Drug: IL-4; Device: Miltenyi CliniMACS-System; Drug: Tumor Lysate/KLH Pulsed Dendritic Cell Vaccine; Drug: KLH; Drug: MAB 8H9; Drug: Endotoxin</p>	Tumor Vaccination and R-hIL-7 Following Standard Multimodality Therapy
	<p>Primary Outcome Measures: Immune response, feasibility, toxicity.</p> <p>Secondary Outcome Measures: Identify immunogenic tumor antigens, evaluate contamination after 8H9 purging, event-free and overall survival, evaluate diminished reconstitution, tumor-host immunobiology studies</p>	
Recruiting	<p><u>Pilot Trial of a WT-1 Analog Peptide Vaccine in Patients With Myeloid Neoplasms</u></p> <p>Condition: Leukemia</p> <p>Intervention: Biological: WT-1 2008</p>	Pilot Trial of a WT-1 Analog Peptide Vaccine
	<p>Primary Outcome Measures: Primary endpoints are safety, toxicity and immunogenicity of the WT1 vaccine.</p> <p>Secondary Outcome Measures: Secondary endpoint is the antitumor effect of the vaccine. [nterim analysis will be performed after enrollment of the first five evaluable patients.]. About 1 tablespoon of blood will be taken to measure the levels of WT-1 in their blood.</p> <p>Patients will receive 6 bi-weekly vaccinations over 10 weeks. Immune responses to be evaluated at weeks 6 and 12 via delayed-type hypersensitivity, CD4 T cell proliferation, CD4 and CD8 T cell interferon release, bone marrow cytogenetics including polymerase chain reaction (PCR) to look for molecular evidence of disease. Patients with an immunologic response and not disease progression may continue with up to 6 more vaccinations approximately every month. Such patients will be reevaluated with bone marrows/immunologic studies after the 9th and 12th vaccination. Patients will undergo evaluations for residual disease including immunohistochemistry and/or quantitative polymerase chain reaction (RQ-PCR) for WT-1 expression (selected patients), and multiparameter flow cytometry (AML/ MDS</p>	
Completed	<p><u>Vaccine Therapy in Treating Patients With Metastatic Breast Cancer</u></p> <p>Condition: Breast Cancer</p> <p>Interventions: Biological: recombinant vaccinia-MUC-1 vaccine; Biological: recombinant vaccinia-TRICOM vaccine; Biological: sargramostim 2003</p>	Admixture of Recombinant Vaccinia Virus That Express DF3/MUC1 and rV-TRICOM (B7.ICAM-1, and LFA-3)
	<p>Primary: Determine the toxicity of vaccination comprising recombinant vaccinia-MUC-1 and recombinant vaccinia-TRICOM vaccine in patients with metastatic breast cancer. /Determine the maximum tolerated dose of this regimen in these patients. /Determine the toxicity of this regimen when administered with sargramostim (GM-CSF) in these patients.</p> <p>Secondary: Determine the host immune reactivity in patients treated with this regimen with or without GM-CSF. /Determine the antitumor activity in patients treated with this regimen with or without GM-CSF. Patients are followed at 4 weeks, monthly until disease progression, and then annually for up to 15 years</p>	
Active, not recruiting	<p><u>Vaccine Therapy in Treating Patients With Kidney Cancer</u></p> <p>Condition: Kidney Cancer</p>	Injection of Renal Cell Carcinoma Patients With Human and Mouse Prostate Specific

	Interventions: Biological: human prostate-specific membrane antigen plasmid DNA vaccine; Biological: mouse prostate-specific membrane antigen plasmid DNA vaccine 2004	Human and mouse prostate-specific Membrane Antigen (PSMA) DNA:
	<p>Primary: Determine the safety and feasibility of vaccination with human and mouse prostate-specific membrane antigen DNA in patients with renal cell carcinoma. /Determine the maximum tolerated dose of this regimen in these patients. /Determine antibody responses to human PSMA in patients treated with this regimen.</p> <p>Secondary: Assess antitumor response in patients treated with this regimen /Patients are followed every 3 months for 2 years</p>	
Active, not recruiting	<u>Dendritic Cell Vaccine Study (DC/PC3) for Prostate Cancer</u>	Autologous Dendritic Cells Pulsed With Apoptotic Tumor Cells (DC/PC3)
	Condition: Prostate Cancer	
	Intervention: Biological: autologous dendritic cell vaccine (DC/PC3) 2004	
	<p>Primary Outcome Measures: Toxicity [Time Frame: throughout the study]</p> <p>Secondary Outcome Measures: Immunogenicity [Time Frame: Day 0, Week 3, 4, 5, 7, 9, 13, 17]/ Clinical Response [Time Frame: baseline, and at 5 weeks and 17 weeks after completion of]</p>	
Recruiting	<u>Docetaxel Alone or in Combination With Vaccine to Treat Breast Cancer</u>	Docetaxel Alone or in Combination With PANVAC(Trademark)-V (Vaccinia) and PANVAC(Trademark)-F (Fowlpox)
	Condition: Breast Cancer	
	Interventions: Drug: Docetaxel; Biological: Famimarev; Biological: Inalimarev; Biological: Sargramostim 2006	
	<p>Docetaxel Plus Vaccine: Participants receive the priming vaccination followed by monthly boosting vaccinations, along with the weekly docetaxel therapy. With every vaccination, patients also receive an injection of sargramostim to increase the number of immune cells at the vaccination site. Sargramostim injections are given the day of vaccination and daily for the next 3 days. All vaccine and sargramostim doses are given as injections under the skin, usually in the thigh. Patients are observed in the clinic for 1 hour after each injection.</p> <p>Patients have blood tests every four weeks to monitor drug side effects and before every vaccination to check blood counts. A bone scan or CT scan (or both) is done every 2 to 3 months to check the response to treatment.</p> <p>Patients may continue receiving treatment as long as their disease does not worsen and they can tolerate the treatment without significant side effects. Patients assigned to receive docetaxel alone whose disease progresses after 3 months on the drug may choose to receive the vaccine or come off the study to receive other treatment options. Patients are monitored with yearly telephone calls for up to 15 years.</p>	
Recruiting	<u>Study of the MUC1 Peptide-Poly-ICLC Adjuvant Vaccine in Individuals With Advanced Colorectal Adenoma</u>	MUC1 Peptide - Poly-ICLC Adjuvant Vaccine
	Condition: Risk for Colorectal Cancer	
	Intervention: Biological: MUC1 - Poly ICLC 2008	
	<p>Primary Outcome Measures: Evaluate the immune response to MUC1 peptide vaccine administered with Poly-ICLC, measured by Anti MUC1 antibody, in patients with a history of advanced colorectal adenoma. [Time Frame: 52 weeks]</p> <p>Secondary Outcome Measures: To monitor specific anti MUC1 isotypes such as anti-MUC1 IgM and IgG antibodies [Time Frame: 52 weeks] To monitor adverse events associated with the study agent [Time Frame: 52 weeks]/ To evaluate the correlation between the anti-MUC1 response (preexistent and/or induced by the vaccine) and polyp recurrence rate in patients with advanced adenoma [Time Frame: 52 weeks]</p>	
Active, not recruiting	<u>Vaccine Therapy in Treating Patients With Stage IIIB, Stage IV, or Recurrent Non-Small Cell Lung Cancer</u>	EP2101 Therapeutic Vaccine
	Condition: Lung Cancer	
	Interventions: Biological: EP-2101; Biological: incomplete Freund's adjuvant 2005	
	<p>Primary Outcome Measures: Comparison of overall survival with historical controls. /Safety [Designated as safety issue: Yes]</p> <p>Secondary Outcome Measures: Progression-free survival /Frequency, magnitude, and breadth of cytotoxic and helper T-cell response to vaccine epitopes</p>	
Active, not recruiting	<u>Immunogenicity of GlaxoSmithKline Biological's Human Papillomavirus (HPV) Vaccine (580299) Versus Merck's Gardasil® in Healthy Females 18-45 Years of Age</u>	Observer-blind Study to Compare Immunogenicity of GSK Biologicals' HPV-

Has Results	Conditions:	Cervical Cancer; Papillomavirus Vaccines; Papillomavirus Infection	16/18 L1/AS04 Vaccine Versus Gardasil® [Quadrivalent Human Papillomavirus (HPV-6,11,16,18 L1 VLP) Recombinant Vaccine
	Interventions:	Biological: GSK Biologicals HPV 16/18 vaccine 580299 (Cervarix™); Biological: Gardasil® (Merck & Co. Inc); Biological: Placebo	
Completed	<u>Vaccine Therapy in Treating Patients With Advanced Adenocarcinoma of the Prostate (Prostate Cancer)</u>		Recombinant Fowlpox and Recombinant Vaccinia Virus Expressing PSA for Adenocarcinoma of the Prostate
	Condition:	Prostate Cancer	
	Interventions:	Biological: recombinant fowlpox-prostate specific antigen vaccine; Biological: recombinant vaccinia prostate-specific antigen vaccine	
	<p>OBJECTIVES: Determine the toxicity and maximum tolerated dose of recombinant fowlpox prostate-specific antigen (PSA) vaccine in patients with advanced adenocarcinoma of the prostate. /Determine whether vaccination with recombinant fowlpox-PSA vaccine is associated with antitumor activity in these patients. Determine the efficacy of prime and boost regimens using recombinant fowlpox-PSA vaccine and recombinant vaccinia-PSA vaccine in these patients. /Compare the PSA-specific T-cell response in patients treated with recombinant fowlpox-PSA vaccine followed by recombinant vaccinia-PSA vaccine vs the same vaccines but in reverse order. OUTLINE: This is a randomized, open-label, multicenter, dose-escalation study of recombinant fowlpox prostate-specific antigen (PSA) vaccine</p>		
Completed	<u>Vaccine Therapy Plus Radiation Therapy in Treating Patients With Non-small Cell Lung Cancer That Has Been Completely</u>		Study of Postoperative Adjuvant Immunotherapy and Radiation (MoAb 11D10 anti-idiotype vaccine /3H1 anti-idiotype vaccine)
	Condition:	Lung Cancer	
	Interventions:	Biological: monoclonal antibody 11D10 anti-idiotype vaccine; Biological: monoclonal antibody 3H1 anti-idiotype vaccine; Radiation: radiation therapy	
	<p>OBJECTIVES: Determine the humoral and T-cell response to adjuvant monoclonal antibody 11D10 anti-idiotype vaccine and monoclonal antibody 3H1 anti-idiotype vaccine with radiotherapy in patients with completely resected stage II or IIIA non-small cell lung cancer. /Determine the qualitative and quantitative toxicity and reversibility of toxicity of this regimen in these patients. /Determine the progression-free and overall survival of patients treated with this regimen.</p>		
Active, not recruiting	<u>Clinical Trial to Compare the Immunogenicity, Safety, and Tolerability of an Adjuvanted A(H1N1) Influenza Vaccine Versus Non-</u>		
	Conditions:	H1N1 Influenza Virus; Invasive Solid Tumors	
	Interventions:	Biological: adjuvanted A(H1N1) influenza vaccine; Biological: non-adjuvanted A(H1N1) influenza vaccine	
Active, not recruiting	<u>Vaccine Therapy or Observation in Treating Patients With Nasopharyngeal Cancer at High Risk for Recurrence</u>		Latent Membrane Protein (LMP) - 2 Immunization for the Assessment of the Natural History and the Immunization-Induced Immunological Response (LMP-2:340-349 peptide / LMP-2:419-427 peptide
	Condition:	Head and Neck Cancer	
	Interventions:	Biological: LMP-2:340-349 peptide vaccine; Biological: LMP-2:419-427 peptide vaccine; Biological: incomplete Freund's adjuvant; Procedure: adjuvant therapy 2005	
	<p>Primary Outcome Measures: Response to MHC class I, HLA-A*-1101 restricted T cell epitopes of EBV encoded LMP-2/Response to MHC class I, HLA-A*-2404 restricted T cell epitopes of EBV encoded LMP-2. /Positive immune response. (in terms of inducing CD8+ T-cell responses,). Secondary Outcome Measures: Safety /Clinical activity / Surrogate marker. whether plasma anti-EBV titers can be used as surrogate markers to monitor the efficacy of these regimens</p>		
Withdrawn	<u>MVA-BN®-HER2 Vaccine in Locally Advanced & Advanced HER2+ Breast Cancer (Gene Transfer Protocol)</u>		Immunogenicity Trial of MVA-BN®-HER2 Vaccine (MVA-BN-HER2 Vaccine 0.5 ml (1x10 *TCID50MVA-BN-HER
	Condition:	Breast Cancer	
	Intervention:	Biological: MVA-BN-HER2 Vaccine 2010	

	Primary Outcome Measures: Safety and tolerability of MVA-BN®-HER2 [Time Frame: as assessed by the incidence of AEs, changes in ECOG performance status, ECGs, LVEF measurements (ECHO or MUGA scans), and lab tests.] comparing the ability of MVA-BN-HER2 to generate humoral and cellular immune responses to Her-2	
Recruiting	<u>Impaired Immunity in Patients With Cancer: Influence of Cancer Stage, Chemotherapy, and Cytomegalovirus Infection</u>	Optimal Immune System by Using Cytokine Cocktails Before Applying DC Vaccine
	Condition: Neoplasms	
	Intervention: Other: Immune profiling and DC vaccine 2007	
	<p>The strategy of enhance T cell is using well-known cytokines, such as IL2, and IL7 to expand the tumor-specific CD4 and CD8 T cells before DC-vaccine treatment. In the past, scientists utilized polyethyleneglycol to fuse cancer cells and dendritic cells. However, the results were devastating. Two new approaches of the DC vaccine will be applied to this study: DC-tumor fusion and DC phagocytosed apoptosed tumor cells. Whole tumor cells will be fused with DCs by combining hypotonic buffer and electrical-based fusion protocols.</p> <p>Primary Outcome Measures: Immune status [: 5 years] Secondary Outcome Measures: Tumor response [6 months]</p>	
Completed	<u>Stem Cell Transplant, Chemotherapy, and Biological Therapy in Treating Patients With High-Risk or Refractory Multiple</u>	Combination Immunotherapy After ASCT for Advanced Myeloma to Study HTERT Vaccination Followed by Adoptive Transfer of Vaccine-Primed Autologous T Cells
	Condition: Multiple Myeloma and Plasma Cell Neoplasm	
	Interventions: Biological: CMV pp65 peptide; Biological: hTERT I540/R572Y/D988Y multipeptide vaccine; Biological: pneumococcal polyvalent vaccine; Biological: survivin Sur1M2 peptide vaccine 2007	
	<p>Primary Outcome Measures: Toxicity at 21 and 28 days post-transplant / T-cell responses against the hTERT vaccine as measured by tetramer assays at 100 days post-transplant. /Paraprotein levels in the blood or urine and serum free light chain analyses at 60 days and at 6 months post-transplant</p> <p>Secondary Outcome Measures: Cytotoxic T-cell responses against autologous myeloma cell at day 100 post-transplant via chromium-51 release or flow-based assays. /Maximum clinical response. 1 and 2-year event-free survival. /Overall survival rates /CD4 and CD8 T-cell responses against cytomegalovirus (CMV) at days 60 and 100 post-transplantation by CFSE dye dilution assays /Composite binding antibody responses at days 60 and day 100 post-transplant by ELISA</p>	
Recruiting	<u>Neoadjuvant Intravesical Vaccine Therapy in Treating Patients With Bladder Carcinoma Who Are Undergoing Cystectomy</u>	Intravesical Recombinant Fowlpox – GM-CSF (rF-GM-CSF) and/or Recombinant Fowlpox-Tricom (rF-TRICOM)
	Condition: Bladder Cancer	
	Interventions: Biological: recombinant fowlpox GM-CSF vaccine adjuvant; Biological: recombinant fowlpox-TRICOM vaccine; Procedure: conventional surgery; Procedure: neoadjuvant therapy 2004	
	<p>Primary: Determine the maximum tolerated dose of neoadjuvant intravesical recombinant fowlpox-TRICOM vaccine and/or recombinant fowlpox-sargramostim vaccine in patients with bladder carcinoma who are scheduled for cystectomy./Determine the dose-limiting toxic effects of these regimens in these patients.</p> <p>Secondary: Determine the local and systemic immunologic response in patients treated with these regimens.</p> <p>Patients are followed every 6 months for 2 years and then annually for 3 years.</p>	
Active, not recruiting	<u>Study of the BiovaxId Tumor Derived Idiotypic Vaccine in Patients With Follicular Lymphoma</u>	
	Condition: Non-Hodgkins Lymphoma	
	Interventions: Biological: tumor specific immune response; Biological: control vaccine	
Recruiting	<u>CpG 7909/Montanide ISA 720 With or Without Cyclophosphamide in Combination Either With NY-ESO-1-derived Peptides or</u>	Patient-Specific Vaccination With Conjugated Follicular Lymphoma-Derived Idiotypic (FNHLId1
	Condition: NY-ESO-1-expressing Tumors	
	Interventions: Biological: Vaccine only; Biological: Vaccine + cyclophosphamide 2004	

	<p>Primary Outcome Measures: To demonstrate prolongation of the period of Disease Free Survival (significant prolongation of the period of complete remission) in idiotype vaccine treated patients.</p> <p>Secondary Outcome Measures: To determine the ability of the idiotype vaccine to produce a molecular complete remission /To determine the impact of molecular disease free survival [Time Frame: until relapse] /To assess the ability of the idiotype vaccine to generate an immunologic response against the NHL tumor [Time Frame: varies] /To compare the overall survival of subjects randomized to receive either treatment [Time Frame: minimum 5 years from last subject randomized] / To confirm the safety of 5 monthly injections of the vaccine with GM-CSF [Time Frame: 4 days]</p> <p>Patients with Stage III-IV follicular lymphoma and tumor > 2cm (Stage II allowed if tumor > 5cm), previously untreated by other than local radiation, provide tumor material by tissue biopsy for production of a patient-specific Ig idiotype vaccine conjugated to the immunogenic protein KLH. After completing PACE or CHOP-R chemotherapy and achieving a complete remission, followed by a waiting period to reconstitute the immune system, patients who remain in remission randomized to the active treatment arm receive a series of 5 idiotype vaccinations accompanied by the immune stimulant GM-CSF. Patients randomized to the control arm receive a time-matched series of KLH injections also accompanied by GM-CSF. Patients are subsequently studied to observe their immune responses both to the non-specific immune stimulating agents and for the specific immune response to the vaccine. Patients are followed for a minimum of 4 years post-randomization or until relapse.</p>	
Recruiting	<p><u>Vaccine Therapy and GM-CSF in Treating Patients With CNS Lymphoma</u></p>	
	<p>Conditions: Brain and Central Nervous System Tumors; Lymphoma; Lymphoproliferative Disorder; Small Intestine Cancer</p>	<p>Efficacy and Safety of Patient-Specific Immunotherapy, Recombinant Idiotype Conjugated to KLH (Id-KLH) and Administered With GM-CSF</p>
	<p>Interventions: Biological: autologous immunoglobulin idiotype-KLH conjugate vaccine; Biological: sargramostim; Drug: methotrexate; Drug: thiotepa; Radiation: radiation therapy 2008</p>	
	<p>Primary Outcome Measures: Anti-idiotype (Id) and anti-keyhole limpet hemocyanin (KLH) immune response rate in the CSF. Safety and tolerability</p> <p>Secondary Outcome Measures: Progression-free survival (PFS). /Time to receipt of first subsequent anti-lymphoma therapy after initiating immunization with the Id-KLH conjugate vaccine. /Correlation of anti-Id immune response in the CSF and/or serum with PFS and overall survival /Kinetics of humoral immune response development .</p> <p>Primary: To determine the proportion of patients with CNS lymphoma who develop anti-idiotype (Id) and anti-keyhole limpet hemocyanin (KLH) humoral immune responses in the serum and/or CSF following patient-specific immunotherapy comprising recombinant tumor-derived immunoglobulin Id-KLH conjugate vaccine and sargramostim (GM-CSF). / To assess the safety and tolerability of this regimen in these patients.</p> <p>Secondary: To evaluate the progression-free survival (PFS) of patients treated with this regimen. /To determine the time to receipt of first subsequent anti-lymphoma therapy after initiating immunization with the Id-KLH conjugate vaccine. /To assess the correlation of anti-Id immune response in the CSF and/or serum with PFS and overall survival. patients are followed periodically for up to 2 years</p>	
Recruiting	<p><u>NY-ESO Phase I Study for Prostate Cancer</u></p>	
	<p>Condition: Prostatic Neoplasms</p>	<p>Immunotherapy for Androgen-Independent Prostate Carcinoma Using NY-ESO-1/LAGE1 Peptide Vaccine (SPORE #: 11-01-30-14)</p>
	<p>Interventions: Biological: NY-ESO-1 class I and class II peptide vaccine; Biological: LAGE-1 class I and class II peptide vaccine 2008</p>	

	<p>Primary Outcome Measures:: Progressive disease is a new bone lesion on bone scan, progression of nodal or soft tissue, or a 50% increase in prostate specific antigen (PSA) level from the nadir PSA level confirm twice and measured at least two weeks apart. [1 (week 1) and every 12 weeks.]</p> <p>目的]There is a great need for new treatment options for prostate cancer that can be given safely. One alternative to widely used conventional cancer treatments is to utilize the ability of the patient's immune system to target and kill tumor cells. A vaccine is a compound designed to strengthen the immune system (the cells and substances that protect the body from infection and foreign matter) to fight an illness such as infections or cancer. This vaccine is called NY-ESO-1 protein. NY-ESO protein (an antigen, which is a compound that is recognized by the immune system) is found in many cancers. Proteins such as NY-ESO-1 and LAGE-1 and their fragments are the targets the immune system needs to recognize cancer cells. If the immune system can recognize these antigens (foreign substances) it may be able to kill the cells that carry them. NY-ESO-1 can be found at different stages of cancers, and is likely to be expressed (shown) at some point in the lifecycle of these types of cancer (that are eligible for this study). Therefore this study tries to boost (strengthen) the immune system toward NY-ESO-1 protein regardless of whether it is found in the tumor or not.</p>	
Recruiting	<p><u>Vaccine Therapy, GM-CSF, and Interferon Alfa-2b in Treating Patients With Locally Advanced or Metastatic Cancer That</u></p> <p>Condition: Unspecified Adult Solid Tumor, Protocol Specific</p> <p>Interventions: Biological: recombinant fowlpox-CEA(6D)/TRICOM vaccine; Biological: recombinant interferon alfa-2b; Biological: recombinant vaccinia-CEA(6D)-TRICOM vaccine; Biological: sargramostim 2006</p>	<p>Sequential Vaccinations With Fowlpox-CEA(6D)-Tricom (B7.1/ICAM/LFA3) and Vaccinia-CEA (6D)-Tricom, in Combination With GM-CSF and Interferon-Alfa-2B in Patients With CEA-Expressing Carcinomas</p>
	<p>Primary: Determine the maximum tolerated dose and recommended phase II dose of interferon alfa-2b (IFN-α-2b) when administered with recombinant vaccinia-CEA(6D)-TRICOM vaccine, recombinant fowlpox-CEA(6D)-TRICOM vaccine, and sargramostim (GM-CSF) in patients with locally advanced or metastatic carcinoembryonic antigen (CEA)-expressing carcinoma.</p> <p>Secondary: Determine the effect of IFN-α-2b on tumor cell expression of CEA and MHC class I antigens in patients treated with this regimen. Determine the immunologic effects of this regimen in these patients. /Determine any objective anti-tumor responses that may occur in response to this regimen in these patients. /Determine the time to tumor progression in patients treated with this regimen. After completion of study treatment, patients are followed monthly for 4 months and then every 6-12 months for up to 15 years</p>	
Active, not recruiting	<p><u>Vaccine Therapy in Treating Patients With Stage IV or Recurrent Melanoma</u></p> <p>Condition: Melanoma (Skin)</p> <p>Interventions: Biological: autologous tumor cell vaccine; Biological: therapeutic autologous dendritic cells 2001</p>	<p>Vaccine Biotherapy of Cancer: Tumor Cells and Dendritic Cells as Active Specific Immunotherapy</p>
	<p>OBJECTIVES: Determine the safety of immunization with autologous in vitro-treated tumor cells and dendritic cells in combination with sargramostim (GM-CSF) in patients with stage IV or recurrent melanoma. /Determine the frequency of conversion of delayed tumor hypersensitivity tests in patients treated with this regimen. Determine the progression-free and overall survival in patients treated with this regimen. /Determine the objective tumor response rate in patients with measurable melanoma treated with this regimen.</p> <p>Patients are followed every 2 months for 1 year and then every 3 months for 4 years.</p>	
Recruiting	<p><u>Protecting Young Special Risk Females From Cervical Cancer Through Human Papilloma Virus (HPV) Vaccination</u></p> <p>Condition: Cervical Cancer</p> <p>Intervention: Drug: Licensed quadrivalent HPV vaccine, Gardasil 2009</p>	<p>Prospective Non Controlled Study of Immunogenicity of Human Papilloma Virus (HPV) Vaccine in Groups at Special Risk of Poor Vaccine Result</p>
Recruiting	<p><u>Vaccine Therapy and GM-CSF in Treating Patients With Recurrent or Metastatic Melanoma</u></p> <p>Condition: Melanoma (Skin)</p>	<p>Autologous Vaccines Consisting of Adjuvant GM-CSF Plus Proliferating Tumor Cells</p>

	Interventions: Biological: autologous tumor cell vaccine; Biological: sargramostim; Biological: therapeutic autologous dendritic cells 2007	Versus GM-CSF Plus Dendritic Cells Loaded With Proliferating Tumor Cells in Patients
	<p>Primary Outcome Measures: Overall survival, progression-free survival, event-free survival, and failure-free survival /Frequency of immune response as measured by delayed-type hypersensitivity and serologic and cellular assays at baseline and during and after completion of study treatment /Safety</p> <p>Compare overall survival, progression-free survival, event-free survival, and failure-free survival of patients with metastatic melanoma treated with vaccine therapy comprising irradiated autologous tumor cells vs autologous dendritic cells loaded with irradiated autologous tumor cells in combination with sargramostim (GM-CSF). Compare the frequency of immune response based on delayed-type hypersensitivity to irradiated autologous tumor cells and serologic and cellular assays at baseline and during and after completion of autologous tumor cell-based vaccine therapy in these patients.</p>	
Terminated	GVAX® Vaccine for Prostate Cancer vs Docetaxel & Prednisone in Patients With Metastatic Hormone-Refractory Prostate	CG1940 and CG8711 Versus Docetaxel and Prednisone (Immunotherapy with allogeneic prostate vaccine)
	Condition: Prostate Cancer	
	Interventions: Biological: Immunotherapy with allogeneic prostate vaccine; Drug: Chemotherapy (Taxotere and prednisone)	
	Primary Outcome Measures: Survival [Time Frame: 0] Secondary Outcome Measures: Bone pain and bone related events [Time Frame: 0]	
Recruiting	Therapeutic Vaccination for Patients With HPV16+ Cervical Intraepithelial Neoplasia (CIN2/3)	Pilot Study of pnGVL4a-CRT/E7 (Detox) for HPV16+ Cervical Intraepithelial Neoplasia 2/3 (CIN2/3)
	Conditions: HPV16+; Cervical Intraepithelial Neoplasia (CIN 2/3)	Intra-lesional DNA vaccination
	Interventions: Biological: DNA vaccination; Device: Gene gun vaccine; Biological: intramuscular vaccination; Biological: intra-lesional vaccine administration; Procedure: therapeutic resection of the lesion 2009	
	<p>Primary Outcome Measures: To evaluate feasibility and toxicity in women with CIN2/3 caused by HPV16 [Time Frame: 2 years]</p> <p>Secondary Outcome Measures: To compare immunogenicity of three different routes of administration: intradermal , intramuscular, and intralesional[2 years]</p>	
Completed	Vaccine Therapy With or Without Sargramostim in Treating Patients With Cancer	Sequential Vaccinations With Fowlpox-CEA(6D)-Tricom(B7.1/ICAM/LFA3)Alone, And In Combination With Vaccinia-CEA(6D)-Tricom, And The Role Of GM-CSF
	Condition: Unspecified Adult Solid Tumor, Protocol Specific	
	Interventions: Biological: recombinant fowlpox-CEA(6D)/TRICOM vaccine; Biological: recombinant vaccinia-CEA(6D)-TRICOM vaccine; Biological: sargramostim	

	<p>Determine the impact of vaccine therapy on the quantity of circulating CEA-positive cells in patients treated with these regimens. V. Determine objective anti-tumor responses in patients treated with these regimens.</p> <p>OUTLINE: This is a dose-escalation study of fowlpox-CEA-TRICOM (fCEA-TRI) vaccine and vaccinia-CEA-TRICOM (vCEA-TRI) vaccine. Stage I: Patients receive fCEA-TRI vaccine subcutaneously (SC) once daily on days 1, 29, 57, and 85. Cohorts of 3-10 patients receive escalating doses of the fCEA-TRI vaccine until the maximum tolerated dose (MTD) is determined. The MTD is defined as the dose preceding that at which 2 of 6 patients experience dose-limiting toxicity (DLT). Stage II: Patients receive vCEA-TRI vaccine intradermally once on day 1 and fCEA-TRI vaccine SC at the MTD determined in stage I once daily on days 29, 57, and 85. Cohorts of 3-10 patients receive escalating doses of the vCEA-TRI vaccine until the MTD is determined. The MTD is defined as the dose preceding that at which 2 of 6 patients experience DLT. Stage III: A single cohort of 6-10 patients receive both vaccines as in stage II, at the MTDs determined in stages I and II, and sargramostim (GM-CSF) SC once daily on days 1-4, 29-32, 57-60, and 85-88. Patients in any stage of the study with responding disease may receive additional doses of the fCEA-TRI vaccine monthly for 2 months and then every 3 months thereafter. Patients who have objective evidence of response (including mixed response) and/or a fall in an elevated serum CEA level after the sixth vaccine and who subsequently develop disease progression while on the extended every 3-month treatment schedule and have no other potentially better treatment alternatives available may continue treatment as per the monthly vaccination schedule for 2 additional months. Patients with stable or responding disease after those two monthly vaccines may continue monthly vaccines at the discretion of the principal investigator. Patients are followed at 4 weeks and then monthly for 3 months. PROJECTED ACCRUAL: Approximately 12-42 patients will be accrued for this study within 4-14 months.</p>	
Active, not recruiting	<p><u>Partially Blind Study to Evaluate Immunogenicity & Safety of GSK Bio's HPV Vaccine 580299 in Healthy Women Aged 9-25 Yrs</u></p> <p>Conditions: Papillomavirus Infection; Cervical Cancer</p> <p>Intervention: Biological: GSK Bio's HPV vaccine 580299 (Cervarix TM) 2007</p>	<p>Immunogenicity of GSK Bio's HPV Vaccine 580299 When Administered in Healthy Females Aged 9 - 25 Years</p>
Recruiting	<p><u>Efficacy of Recombinant Epstein-Barr Virus (EBV) Vaccine in Patients With Nasopharyngeal Cancer Who Had Residual EBV</u></p> <p>Conditions: Nasopharyngeal Cancer; Epstein-Barr Virus Infections</p> <p>Intervention: Biological: MVA-EBNA1/LMP2 Inj. vaccine</p>	<p>Recombinant Epstein-Barr Virus (EBV) Vaccine in Patients With Nasopharyngeal Cancer Who Had Residual EBV DNA</p>
	<p>Primary Outcome Measures: Clinical Benefit Rate [Time Frame: 2 Years] /Clinical benefit rate (CBR, percent of patients experiencing complete response [CR], partial response [PR] or stable disease [SD] for at least 12 weeks from post cycle 2 to cycle 6 measurements) determined according to the Response Evaluation Criteria in Solid Tumours (RECIST), or on EBV genome levels in the absence of measurable disease.</p> <p>Secondary Outcome Measures: Objective Response Rate (ORR) [2 Years] /ORR is defined as the proportion of patients with confirmed complete response (CR) or confirmed partial response (PR) from post cycle 2 to cycle 6 measurements according to the Response Evaluation Criteria in Solid Tumours (RECIST), relative to the total evaluable patient population. /Duration of Response (DR) [2 Years] /DR is defined as the time from the first documentation of objective tumour response to the first documentation of objective tumour progression or to death due to any cause. /Progression-free survival (PFS) [3 Years] PFS is defined as the time from post cycle 2 measurement to first documentation of objective tumour progression, or to death due to any cause. Overall survival (OS) [3 Years] /Overall survival (OS) is defined as the time from start of study treatment to date of death due to any cause.</p>	
Completed	<p><u>Cyclophosphamide and Rituximab Followed By Vaccine Therapy in Treating Patients With Chronic Lymphocytic Leukemia</u></p> <p>Condition: Leukemia</p> <p>Interventions: Biological: autologous tumor cell vaccine; Biological: rituximab; Drug: cyclophosphamide 2006</p>	<p>Randomized Trial of Early Versus Late Vaccination in Patients With High Risk CLL</p>
	<p>Primary Outcome Measures: Efficacy and toxicity. /T-cell response to early versus late vaccine therapy comprising KGEL and autologous tumor cells. Compare the magnitude of the T-cell response to early vs delayed administration of this vaccine after rituximab and cyclophosphamide and correlate these responses with the extent of immune reconstruction.</p>	
Active, not	<p><u>A Phase I Study of Ovarian Cancer Peptides Plus GM-CSF and Adjuvant (Montanide ISA-51) as Consolidation Following</u></p>	<p>Ovarian Cancer Peptides Plus GM-CSF and</p>

recruiting	Condition:	Epithelial Ovarian, Tubal or Peritoneal Cancer	Adjuvant (Montanide ISA-51) as Consolidation Following Optimal Debulking and Systemic Chemotherapy
	Intervention:	Biological: OCPM Immunotherapeutic Vaccine 2007	
	<p>Primary Outcome Measures: Date of first objective finding will be used to define the date of relapse [From date of enrollment to date of confirmed relapse] The primary endpoint will be to determine the safety and feasibility of administering ovarian cancer peptides to women who have undergone debulking surgery and systemic chemotherapy, with the secondary objectives of evaluating immune response as measured by ELISPOT to the immunizations, to compare the immune response as measured by ELISPOT achieved by the two different dosing strategies and to assess disease relapse survival. Two cohorts of 9 patients each will be treated with different doses of the OCPM vaccine. They will receive the peptide vaccine subcutaneously on weeks 0,1,2,3,5 and6 and then receive the immunizations every 1 month for 6 months or disease recurrence. The first 9 patients will be entered into the first cohort; if 1 or fewer patients experience Dose-limiting toxicity (DLT) then the next 9 will be enrolled into the second cohort. DLT is defined as any Grade 3 or greater hematologic or non-hematologic toxicity or autoimmune disease (except for fever, skin reaction, or alopecia which would be grade 4) occurring at any time from the first immunization until 30 days after the last immunization. Toxicity will be assessed at each dose level using CTC toxicity criteria. Ovarian cancer peptide-specific immune response will be measured by ELISpot. Time to disease relapse will be based on composite assessment of clinical signs, objective exam findings, radiologic imaging, and CA125 results. A dosing scheme will be considered safe if <1 of the first 9 subjects treated at a dose level experience DLT (as described above). A subject will be considered evaluable for safety if treated with at least one immunization. A T cell response will be considered positive by ELISpot if: the mean number of spots in six wells with antigen exceeds the number of spots in six control wells by 10 and the difference between single values of the six wells containing antigen and the six control wells is statistically significant at a level of $p \leq 0.05$ using Student's t test.</p>		
Recruiting	<u>Vaccine Therapy in Treating Patients With Recurrent Stage III or Stage IV Melanoma That Cannot Be Removed by Surgery</u>		Immunogenicity of Vaccination With Multi-Epitope Peptide Vaccine Containing MART-1, gp100, and Tyrosinase Peptides Given With the Combination of GMCSF and CpG Oligonucleotide (CpG 7909) in ISA-Oil Adjuvant
	Conditions:	Intraocular Melanoma; Malignant Conjunctival Neoplasm; Melanoma (Skin)	
	Interventions:	Biological: MART-1:27-35 peptide vaccine; Biological: gp100:209-217(210M) peptide vaccine; Biological: incomplete Freund's adjuvant; Biological: sargramostim; Biological: tyrosinase peptide; Drug: agatolimod sodium; Other: flow cytometry; Other: immunologic technique; Other: laboratory biomarker analysis	
	<p>Secondary Outcome Measures: Immunologic response as measured by ELISPOT assays. /Breadth of the immune response as measured by the number of peptides to which the response is observed. /Depth of the immune response. /Objective tumor response (complete response and partial response) by RECIST criteria. /Anti-pigmentary response. / Time to disease progression. /Overall survival Determine the safety of a peptide vaccine comprising MART-1:27-35 peptide, gp100:209-217 (210M) peptide, and tyrosinase peptide with sargramostim (GM-CSF) and CpG 7909 emulsified in incomplete Freund's adjuvant in patients with unresectable recurrent stage III or IV melanoma. Determine the efficacy of immunoadjuvants CpG 7909 and GM-CSF, in terms of a strong antigen-specific CD8+ T-cell response, in these patients. Determine the anti-pigmentary response to this regimen in these patients. Determine the anti-tumor response, in terms of objective tumor regression, progression-free survival, and overall survival, in patients treated with this regimen.</p>		
Recruiting	<u>Vaccine Therapy With or Without Cryosurgery in Treating Patients With Residual, Relapsed, or Refractory B-Cell Non-Hodgkin</u>		"A Pilot Study of Dendritic Cell Therapy Delivered Intratumorally After Cryoablation or Intradermally
	Conditions:	Cutaneous B-cell Non-Hodgkin Lymphoma; Extranodal Marginal Zone B-cell Lymphoma of Mucosa-associated Lymphoid Tissue; Intraocular Lymphoma; Nodal Marginal Zone B-cell Lymphoma; Recurrent	
	Interventions:	Biological: dendritic cell vaccine therapy; Procedure: cryotherapy; Biological: pneumococcal polyvalent vaccine; Other: laboratory biomarker analysis; Other: immunoenzyme technique; Other: immunohistochemistry staining method; Biological: autologous dendritic cell-tumor fusion vaccine	

	<p>Primary Outcome Measures: Incidence of significant toxicity as assessed by the CTEP Active Version CTCAE [in week 2, every 3 months for 1 year,] Secondary Outcome Measures: Overall response rate [At week 4 (arm A) or 2 (arm B) and then every 3 months for 1 year starting at week 10] Feasibility as estimated by the number of patients receiving at least one dose of tumor antigen loading and vaccine delivery divided by the number receiving leukapheresis [Up to 2.5 years]. / Clinical benefit rate as estimated by the number of patients with an objective status of stable disease (SD) or an objective status of CR or PR [For at least 12 months] /Time to response [Time Frame: From the date of initiation of vaccination treatment to the date at which the patient's objective status is first noted to be either a CR or PR]/ Duration of response [Time Frame: From the date at which the patient's objective status is first noted to be either a CR or PR to the earliest date progression is documented] /Percent change from baseline in index lesion measurements as a marker of distant immune and treatment response [Time Frame: At day 1 of courses 1-4 (arm A) and 1-6 (arm B)] /Change in immunologic correlates before and after vaccination treatment [Time Frame: At day 1 of each course beginning in week 2, every 3 months for 1 year, and during documented progressive disease]/Correlation of immunologic markers with cancer and treatment-related outcomes (e.g., response, toxicities) [Time Frame: Up to 2.5 years]</p>	
Active, not recruiting	<u>Vaccine Therapy With or Without Fludarabine in Treating Patients With Stage IV Kidney Cancer</u>	
	Condition:	Kidney Cancer
	Interventions:	Biological: autologous tumor cell vaccine; Biological: keyhole limpet hemocyanin; Biological: therapeutic autologous dendritic cells; Drug: fludarabine phosphate; Procedure: conventional surgery 2004
	<p>Primary Outcome Measures: Safety as measured by NCI common toxicity table at completion of study. /Response as measured by RECIST guidelines and the Kaplan-Meier method at 5 years. /Survival as measured by the Kaplan-Meier method at 5 years Primary Compare the safety of vaccination comprising autologous dendritic cells loaded with autologous tumor lysate and keyhole limpet hemocyanin with vs without non-myeloablative fludarabine in patients with stage IV renal cell carcinoma. /Compare, preliminarily, the efficacy of these regimens in these patients. /Compare the overall survival of patients treated with these regimens. Secondary: Determine whether this vaccine induces tumor-reactive peripheral T-cell responses or delayed-type hypersensitivity in these patients.</p>	
Recruiting	<u>Vaccination of Patients With Renal Cell Cancer With Dendritic Cell Tumor Fusions and GM-CSF</u>	
	Condition:	Renal Cancer
	Interventions:	Biological: Dendritic Cell Tumor Fusion Vaccine; Drug: Granulocyte Macrophage Colony Stimulating Factor (GM-CSF) 2007
		Renal Cell Cancer With Dendritic Cell Tumor Fusions and GM-CSF

	<p>Primary Outcome Measures: To assess the toxicity associated with and to investigate the clinical impact of vaccination with mature DC/Tumor fusion and GM-CSF of this patient population. [Time Frame: 5 years]/ Secondary Outcome Measures: To determine if cellular and humoral immunity is induced by serial vaccination with DC/tumor fusion cells and GM-CSF [5 years] /to correlate immunologic response following vaccination. [Time Frame: 5 years] Tumor cells will be collected to make the study vaccine. Based on the location of the cancer, a decision will be made as to the best approach to obtain these cells. Participants will undergo a procedure known as leukapheresis in order to obtain their dendritic cells. Prior to this procedure they will receive 1 to 2 injection of GM-CSF to help increase their white blood cell count. If sufficient numbers of cells are obtained, tumor cells and dendritic cells will be fused (mixed) together in the laboratory and divided into the appropriate doses for administration. The treatment will consist of 3 vaccinations of fused cells given by an injection under your skin at 3-week intervals. The first six participants will receive only the study vaccine. The remaining participants will receive the study vaccine combined with GM-CSF. If enough vaccine cannot be made for the participant to receive 3 doses, the participant may receive only 2 doses of the study vaccine. Approximately 3 to 4 tablespoons of blood will be collected at certain times for testing the immune system and to determine if the study vaccine has increased the immune response against the tumor cells. Weekly visits for physical exam, assessment of adverse events and safety labs will be conducted. Regular blood draws will be done for at least 6 months following the completion of the study to follow safety labs and to monitor the immune response. Monthly physical exams will be performed following the last injection of the study vaccine. At one month, three months, and six months following the date the participant received the last study vaccine, they will have a CT scan to see if the study vaccine has affected their disease.</p>	
Completed	<u>Immunogenicity and Safety of GSK Biologicals' HPV Vaccine 580299 in Healthy Japanese Females 10-15 Years of Age</u>	
Has Results	Conditions: Papillomavirus Infection; Cervical Cancer	HPV Vaccine 580299 When Administered as a 3-dose Schedule in Healthy Japanese Pre-adolescent and Adolescent Female Subjects.
	Intervention: Biological: Cervarix TM (HPV-16/18 L1 VLP AS04) 2007	
Active, not recruiting	<u>Vaccine Therapy and QS21 in Treating Patients With Metastatic Breast Cancer</u>	
	Condition: Breast Cancer	Immunization of High Risk Breast Cancer Patients With a Sialyl Lewis ^a -Keyhole Limpet Hemocyanin Conjugate Plus the Immunological Adjuvant QS-21
	Interventions: Biological: QS21; Biological: sialyl Lewis ^a -keyhole limpet hemocyanin conjugate vaccine; Other: immunoenzyme technique; Other: immunologic technique; Other: laboratory biomarker analysis 2007	
	<p>Primary Outcome Measures: Safety + Immune response Secondary Outcome Measures: Presence of circulating tumor cells Primary : Determine the safety of sialyl Lewis^a -keyhole limpet hemocyanin conjugate vaccine and QS21 immunoadjuvant in patients with metastatic breast cancer. Determine the IgG and IgM antibody response in these patients. /Determine the proportion of breast cancer cells expressing this antigen in these patients. Secondary: Monitor the presence of circulating tumor cells prior to, during, and after this regimen in these patients. Blood samples are collected periodically and evaluated for circulating tumor cells and reactivity against sialyl Lewis^a antigen in ELISA and/or immunoprecipitation-western blot assays. After completion of study treatment, patients are followed every 3 months</p>	
Recruiting	<u>Dendritic Cell Vaccine in Treating Patients With Indolent B-Cell Lymphoma or Multiple Myeloma</u>	
	Conditions: Leukemia; Lymphoma; Multiple Myeloma and Plasma Cell Neoplasm	Lymphoma Patients With Dendritic Cell-Lymphoma Cell Hybrids and Dendritic Cells Pulsed With Tumor Lysates
	Interventions: Biological: autologous lymphoma cell lysate-pulsed autologous dendritic cell vaccine; Biological: autologous lymphoma cell/allogeneic dendritic cell electrofusion hybrid vaccine; Biological: autologous lymphoma cell/autologous dendritic cell electrofusion hybrid vaccine 2009	

	<p>Primary Outcome Measures: Immune response /Progression-free survival /Adverse events OBJECTIVES: Evaluation of feasibility of dendritic cell (DC)-based vaccination program using autologous tumor cells and/or lysates in patients with indolent B cell lymphomas or multiple myeloma as an adjuvant therapy to induce immune response in remission after cytoreductive treatment. /Evaluation of the immune response of patients /Evaluation the progression-free survival of patients treated this regimen. /Evaluate the adverse events of this regimen in these patients</p>	
Active, not recruiting	<p><u>Vaccine Plus Montanide ISA-51 and Sargramostim in Treating Patients With Stage IV Breast Cancer</u></p>	
	<p>Condition: Breast Cancer</p>	<p>Telomerase Peptide Vaccination For Patients With Advanced Breast Cancer</p>
	<p>Interventions: Biological: incomplete Freund's adjuvant; Biological: sargramostim; Biological: telomerase: 540-548 peptide</p>	
	<p>Primary: Determine the safety of telomerase: 540-548 peptide vaccine emulsified in Montanide ISA-51 and sargramostim (GM-CSF) in patients with HLA-A2-expressing stage IV breast cancer. Secondary: Compare the generation of human telomerase reverse transcriptase (hTERT) peptide-specific vs cytomegalovirus peptide-specific cytotoxic T-lymphocyte (CTL) immunity in patients treated with this regimen. /Correlate the dose level of this regimen with the generation of hTERT-specific CTL immunity and the development of hTERT-specific autoimmunity in these patients. /Determine the tumor response in patients treated with this regimen. OUTLINE: This is a dose-escalation study of the telomerase: 540-548 peptide and CMV 495 peptide portions of the vaccine</p>	
Active, not recruiting	<p><u>Vaccine Therapy in Preventing Cervical Cancer in Patients With Cervical Intraepithelial Neoplasia</u></p>	
	<p>Conditions: Cervical Cancer; Precancerous Condition</p>	<p>pNGVL4a-Sig/E7 (Detox)/HSP70 for the Treatment of Patients With HPV 16+ Cervical Intraepithelial Neoplasia 2/3</p>
	<p>Intervention: Biological: pNGVL4a-Sig/E7(detox)/HSP70 DNA vaccine 2005</p>	
	<p>Secondary Outcome Measures: Changes in lesion size and human papillomavirus viral load/ Cellular, humoral, and local tissue immune responses. /Correlate measures of immune response with clinical response. /Correlate measures of immune response with the preclinical model Determine changes in lesion size and HPV viral load in patients treated with this vaccine. / Determine the cellular, humoral, and local tissue immune responses in patients treated with this vaccine. /Correlate measures of immune response with clinical response in patients treated with this vaccine. /Correlate measures of immune response in patients treated with this vaccine with those observed in the preclinical model.</p>	
Completed	<p><u>Vaccine Therapy and Sargramostim in Treating Patients With Sarcoma or Brain Tumor</u></p>	
	<p>Conditions: Brain and Central Nervous System Tumors; Gastrointestinal Stromal Tumor; Sarcoma</p>	<p>Vaccination With Telomerase Peptide Plus GM-CSF</p>
	<p>Interventions: Biological: sargramostim; Biological: telomerase: 540-548 peptide vaccine</p>	
	<p>Determine the feasibility of treatment with telomerase: 540-548 peptide vaccine and sargramostim (GM-CSF) in patients with sarcoma or brain tumor. / Determine the safety and tolerability of this regimen in these patients. /Determine the frequency of T-cell specific vaccine antigens during and after administration of this regimen in these patients. /Determine, preliminarily, the clinical response, if any, of patients treated with this regimen. /OUTLINE: Patients receive telomerase: 540-548 peptide vaccine subcutaneously (SC) on day 3 and sargramostim (GM-CSF) SC on days 1-4 of weeks 1, 3, 5, 7, 9, 11, 15, 19, and 23 PROJECTED ACCRUAL: A total of 35 patients (20 adult and 15 pediatric) will be accrued for this study.</p>	
Completed	<p><u>Study to Test the Efficacy of the Vaccine GSK 249553 in Treating Non-small-cell Lung Cancer After Tumour Removal by</u></p>	
	<p>Condition: Non-Small-Cell Lung Cancer</p>	<p>Assess the Efficacy of GSK 249553 as Adjuvant Therapy Given to MAGE-3-Positive Patients With Non-Small-Cell Lung Cancer in Stage IB (T2/N0) or II (T1/N1 or T2/N1 or T3/N0).</p>
	<p>Interventions: Biological: GSK 249553 vaccine; Biological: Placebo 2006</p>	

	<p>Primary Outcome Measures: Number of days from surgical resection to the recurrence of NSCLC (all types of recurrence will be included). Secondary Outcome Measures: All serious adverse events. /Haematological, biochemical and urinalysis parameters. /Unsolicited non-serious adverse events. /Recurrence. /Disease-free survival /Time to death. /Time to lung cancer death. /Lung-cancer-related death. [30 months after enrolment] /Antibodies to MAGE-3 and protein D [Time Frame: At all points during treatment as specified in the study schedule] / In vitro cellular immune response. / Serum level of Cyfra21.1 and CEA [Time Frame: At all points during treatment as specified in the study schedule] /Level of plasma DNA and molecular characterisation by loss of heterozygosity and microsatellite instability /Number of circulating tumour cells in the blood. /MAGE-3 expression in circulating tumour cells in the blood. /Gene expression profiles of primary and relapsed tumour samples . /Proteomes of the patients' plasma. /Solicited local and general signs and symptoms recorded by the patients on diary cards</p>	
Recruiting	<u>Health SMART (Stress Management and Relaxation Training)</u>	
	Condition:	Breast Cancer
	Intervention:	Behavioral: Cognitive Behavioral Stress Management (CBSM) 2009
	<p>Primary Outcome Measures: Linear mixed models regression with an exchangeable covariance structure will be used to determine the average change in IgM, IgG and proliferative response to HA vaccine antibody response to HA vaccine following the intervention, as a function of time. [Time Frame: From post-intervention to 1-month post-intervention (primary antibody response) and from 6-months post-intervention to 7-months post-intervention (secondary antibody response)] Secondary Outcome Measures: Linear mixed model regression with an exchangeable covariance structure will be used to investigate the effects of change in distress on immune response as a function of time. We will include time as a random effect. [Time Frame: Length of the protocol (Baseline to 7 months post-intervention)]</p>	
Completed	<u>Vaccine Therapy Plus QS21 in Treating Patients With Prostate Cancer</u>	
	Condition:	Prostate Cancer
	Intervention:	Biological: MUC1-KLH vaccine/QS21 2000
	<p>Vaccination of Prostate Cancer Patients With MUC-1-KLH Conjugate Plus the Immunological Adjuvant QS21: A Trial Examining the Immunogenicity of MUC-1</p>	
	<p>OBJECTIVES: I. Determine if immunization with glycosylated MUC-1 antigen containing MUC-1 (106) with keyhole limpet hemocyanin conjugate plus immunological adjuvant QS21 induces an antibody, helper T cell and/or cytotoxic T cell response against MUC-1 in patients with prostate cancer expressing MUC-1. II. Determine post-immunization changes in PSA levels and other objective parameters or disease (radionuclide bone scan and/or measurable disease if present) in these patients after receiving this therapy. OUTLINE: Patients receive glycosylated MUC-1 antigen containing MUC-1 (106) with keyhole limpet hemocyanin conjugate subcutaneously (SQ) plus immunological adjuvant QS21 SQ on weeks 1-3, 7, 15, and 27 for a total of 6 vaccinations. Patients are followed every 3 months for 1 year or until documented disease progression. PROJECTED ACCRUAL: A total of 25 patients will be accrued for this study within 1 year.</p>	
Active, not recruiting	<u>Vaccine Therapy in Treating Patients With Newly Diagnosed Glioblastoma Multiforme</u>	
	Condition:	Brain and Central Nervous System Tumors
	Interventions:	Biological: PEP-3-KLH conjugate vaccine; Biological: sargramostim; Other: placebo 2008

	<p>Primary Outcome Measures: •Humoral and cellular immune response [Time Frame: 26 months] •Clinical efficacy of vaccination, in terms of progression-free survival [Time Frame: From date of surgery/diagnosis to date of progression.]</p> <p>Secondary Outcome Measures: Response to vaccination [Time Frame: 26 months] Toxicity [Time Frame: 26 months]</p> <p>Patients undergo delayed-type hypersensitivity (DTH) skin testing* at baseline, after the third vaccination, and then monthly thereafter. Patients also undergo leukapheresis to obtain sufficient peripheral blood lymphocytes for immunologic monitoring at baseline, after the third vaccination, and then, if applicable, at the time of positive DTH response, disease progression, or after the sixth course of post-radiotherapy temozolomide. Methods used for immunologic monitoring include ELISPOT assays, cytotoxicity assays, fluorescence activated cell sorting (FACS), and ELISA.</p> <p>NOTE: *Patients with positive DTH skin testing, also undergo skin punch biopsies.</p>	
Active, not recruiting	<p><u>Denileukin Diftitox Followed by Vaccine Therapy in Treating Patients With Metastatic Cancer</u></p> <p>Conditions: Breast Cancer; Colorectal Cancer; Lung Cancer; Pancreatic Cancer; Unspecified Adult Solid Tumor,</p> <p>Interventions: Biological: denileukin diftitox; Biological: recombinant fowlpox-CEA(6D)/TRICOM vaccine; Biological: therapeutic autologous dendritic cells 2006</p>	<p>Regulatory T Cell Depletion With Denileukin Diftitox Followed by Active Immunotherapy With Autologous Dendritic Cells Infected With CEA-6D Expressing Fowlpox-Tricom for Advanced or Metastatic Malignancies</p>
	<p>Rate of immune response as measured by ELISPot at week 10.</p> <p>Secondary: Determine the immune response to this regimen in these patients. /Determine, preliminarily, clinical response rate and/or time to progression in patients with assessable disease treated with this regimen. In both cohorts, treatment continues in the absence of disease progression or unacceptable toxicity. After completion of study treatment, patients are followed annually for up to 15 years.</p>	
Active, not recruiting	<p><u>Chemotherapy Followed By Vaccine Therapy in Treating Patients With Extensive-Stage Small Cell Lung Cancer</u></p> <p>Condition: Lung Cancer</p> <p>Interventions: Biological: autologous dendritic cell-adenovirus p53 vaccine; Drug: carboplatin; Drug: etoposide 2002</p>	<p>Dendritic Cells Transduced With An Adenoviral Vector Containing The p53 Gene To Immunize Patients With Extensive Stage</p>
	<p>Determine the maximum tolerated dose of autologous dendritic cell-adenovirus p53 vaccine, administered after standard chemotherapy, in patients with extensive stage small cell lung cancer. /Determine the toxicity of this regimen in these patients. /Determine the development of an anti-p53-specific immune response in these patients after treatment with this regimen. /Determine the tumor response rate, time to progression, and overall survival of patients treated with this regimen. /Determine the frequency of anti-adenovirus immune responses in these patients after treatment with this regimen. Patients are followed at day 140 and then every 3 months thereafter.</p>	
Terminated	<p><u>Vaccine Therapy in Treating Patients With Chronic Phase Chronic Myelogenous Leukemia</u></p> <p>Condition: Leukemia</p> <p>Interventions: Biological: bcr-abl peptide vaccine; Genetic: reverse transcriptase-polymerase chain reaction 2007</p>	<p>Synthetic Tumor-Specific Breakpoint Peptide Vaccine for CML and Minimal Residual Disease</p>
	<p>OBJECTIVES: Determine the antileukemic effects of tumor-specific BCR-ABL junction specific peptide vaccine, as measured by a decrease in circulating BCR-ABL transcripts by reverse-transcriptase polymerase chain reaction (RT-PCR), that persist for at least 3 months, in patients with chronic phase chronic myelogenous leukemia. /Determine the percentage of patients treated with this vaccine who become RT-PCR-negative for BCR-ABL transcripts. / Compare response in patients with B3A2 junctions vs B2A2 junctions when treated with this vaccine. /Determine the immunologic response over 1 year in patients treated with this vaccine. /Correlate response with specific HLA types in these patients. /Determine the safety of this vaccine in these patients.</p> <p>BCR-ABL transcript levels are assessed by quantitative reverse-transcriptase polymerase chain reaction at baseline</p>	
Completed	<p><u>Vaccine Therapy, Trastuzumab, and Vinorelbine in Treating Women With Locally Recurrent or Metastatic Breast Cancer</u></p> <p>Condition: Breast Cancer</p>	<p>A Multiepitope Dendritic Cell Vaccine Given With Trastuzumab And Vinorelbine For</p>

	Interventions:	Biological: therapeutic autologous dendritic cells; Biological: trastuzumab; Drug: vinorelbine ditartrate 2004	Metastatic Breast Cancer That Express HLA-A0201
	<p>Primary Outcome Measures: Response rate by RECIST criteria at 6 months following treatment</p> <p>Secondary Outcome Measures: Immune response by ELISPOT tetramer at 3 months following treatment</p> <p>Primary: Determine the efficacy of multiepitope autologous dendritic cell vaccine, trastuzumab (Herceptin®), and vinorelbine by measuring the change in the largest dimension of metastatic lesions, in women with locally recurrent or metastatic breast cancer that does not overexpress HER2/neu.</p> <p>Secondary: Determine the ability of this regimen to induce functional antigen-specific T cells in these patients by measuring ex-vivo antigen-specific T-cell activity against peptide-pulsed dendritic cells and tumor targets by tetramer staining and intracellular cytokine assays.</p>		
Completed	<u>Evaluation of Transgenic Lymphocyte Immunization Vaccine in Subjects With Prostate Adenocarcinoma</u>		Transgenic Lymphocyte Immunization Vaccine in Subjects With Prostate Adenocarcinoma
	Condition:	Prostatic Neoplasms	
	Intervention:	Biological: Transgenic Lymphocyte Immunization Vaccine (TLI) 2003	
	<p>Detailed Description: The goal of the study is to determine the safety, feasibility, and tolerability of transgenic lymphocyte immunization (TLI). In this process patient's lymphocytes are rendered transgenic for a gene coding for selected portion of telomerase an enzyme expressed in the vast majority of cancer cells. Transgenic cells are then returned to the patient to produce an immune response targeted at cancer cells expressing telomerase. The Phase 1 trial will evaluate TLI in patients with advanced, androgen-independent prostate cancer with metastases confined to lymph nodes or bones.</p>		
Recruiting	<u>Decitabine, Vaccine Therapy, and Doxorubicin Hydrochloride Liposome in Treating Patients With Recurrent Ovarian Epithelial</u>		NY-ESO-1 Protein Immunization in Combination With 5-AZA-2'-Deoxycytidine (Decitabine)
	Conditions:	Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer	
	Interventions:	Biological: NY-ESO-1 peptide vaccine; Biological: incomplete Freund's adjuvant; Biological: sargramostim; Drug: decitabine; Drug: pegylated liposomal doxorubicin hydrochloride; Genetic: DNA methylation analysis; Genetic: reverse transcriptase-polymerase chain reaction; Other: enzyme-linked immunosorbent assay; Other: immunoenzyme technique; Other: immunohistochemistry staining method; Other: laboratory biomarker analysis; Other: liquid chromatography; Other: mass spectrometry 2009	
	<p>Primary: Determine the safety of decitabine when administered in combination with NY-ESO-1 peptide vaccine (emulsified with incomplete Freund's adjuvant and sargramostim [GM-CSF]) and pegylated liposomal doxorubicin hydrochloride in patients with recurrent ovarian epithelial cancer, fallopian tube cancer, or primary peritoneal cancer.</p> <p>Secondary: /NY-ESO-1-specific cellular and humoral immunity as measured by NY-ESO-1-specific CD8+ and CD4+ T cells, NY-ESO-1-specific antibodies, and frequency of CD4+ CD25+ FOXP3+ regulatory T cells. /NY-ESO-1 expression as measured by quantitative RT-PCR and IHC. /Time to progression. /NY-ESO-1 promoter DNA methylation as measured by pyrosequencing. /Global genomic DNA methylation as measured by liquid chromatography-mass spectrometry and LINE-1 pyrosequencing.</p> <p>Determine the impact of decitabine on NY-ESO-1-specific expression, NY-ESO-1-promoter methylation, and global DNA methylation.</p> <p>Compare the time to progression in patients treated with this regimen vs patients treated with standard therapy (historical studies)</p>		
Recruiting	<u>Vaccine Therapy, Trastuzumab, and Vinorelbine in Treating Patients With Locally Recurrent or Metastatic Breast Cancer</u>		Multiepitope Dendritic Cell Vaccine Given With Trastuzumab and Vinorelbine Ditartrate for Metastatic Breast Cancer That Express HLA-A0201 and Tumors Overexpress HER-2/NEU
	Condition:	Breast Cancer	
	Interventions:	Biological: sargramostim; Biological: therapeutic autologous dendritic cells; Biological: trastuzumab; Drug: vinorelbine ditartrate 2005	

	<p>Primary: Determine the efficacy of multiepitope autologous dendritic cell vaccine in combination with trastuzumab (Herceptin®) and vinorelbine ditartrate in patients with locally recurrent or metastatic breast cancer whose tumors overexpress HER2/neu. Secondary: Determine if this regimen is effective in generating functional antigen-specific T cells. OUTLINE: Therapeutic autologous dendritic cell (DC) preparation: Patients undergo mobilization of DC and apheresis for production of therapeutic DC. DCs are expanded in vitro for 10-20 days and pulsed with E75 and E90 peptides. Treatment: Patients receive vinorelbine ditartrate IV over 6-10 minutes, therapeutic autologous DC intradermally over 2-5 minutes, and trastuzumab (Herceptin®) IV over 30-90 minutes on day 1. Patients receive sargramostim (GM-CSF) subcutaneously on days 2, 4, and 6, or until neutrophil counts recover. Treatment repeats every 14 days for up to 6 courses (or more at the discretion of the investigator) in the absence of disease progression or unacceptable toxicity. After completion of study treatment, patients are followed every 3 months.</p>	
Active, not recruiting	<u>Safety Study of BLP25 Liposome Vaccine in Non-Small Cell Lung Cancer Patients With Unresectable Stage III Disease</u>	
	Conditions:	Carcinoma, Non-Small-Cell Lung; Lung Neoplasms
	Intervention:	Biological: BLP25 Liposome Vaccine 2005
	<p>Open Label Safety Study of BLP25 Liposome Vaccine (L-BLP25) in Non-Small Cell Lung Cancer (NSCLC)</p>	
	<p>Patients will receive L BLP25 treatment following primary therapy. The primary treatment consists of: A single intravenous (I.V.) administration of 300 mg/m² of cyclophosphamide three days before the first vaccine treatment. The maximum dose to be administered is 600 mg of cyclophosphamide. Eight weekly subcutaneous vaccinations with 1,000 µg of L BLP25 at weeks 0, 1, 2, 3, 4, 5, 6 and 7. The 1,000 µg dose of L BLP25 will consist of four 0.5 mL subcutaneous injections each containing one fourth of the total dose and administered in the deltoid or triceps region of the upper arms, and the left and right anterolateral aspects of the abdomen. Best Standard of Care (BSC) will be provided at the investigator's discretion, and may include but not be limited to psychosocial support, nutritional support and other supportive therapies. Patients will be discontinued from the study drug upon documented clinical progression. Safety and Survival</p>	
Recruiting	<u>Influenza Vaccine in Preventing Flu in Patients Who Have Undergone Stem Cell Transplant and in Healthy Volunteers</u>	
	Conditions:	Brain and Central Nervous System Tumors; Chronic Myeloproliferative Disorders; Leukemia; Lymphoma; Lymphoproliferative Disorder; Multiple Myeloma and Plasma Cell Neoplasm; Myelodysplastic Syndromes;
	Interventions:	Other: cytology specimen collection procedure; Other: fluorescent antibody technique; Procedure: assessment of therapy complications 2009
	<p>Primary Outcome Measures: Incidence of influenza infection in patients and healthy volunteers [Designated as safety issue: No] Secondary Outcome Measures: Correlation of influenza infection with graft-vs-host disease, age, and transplant type in patients /Vaccine protection</p>	
Not yet recruiting	<u>Mother - Daughter Initiative (MDI) in Cervical Cancer Prevention</u>	
	Condition:	Cervical Cancer
	Intervention:	Biological: HPV Vaccine (Gardasil)
Active, not recruiting	<u>Health SMART (Stress Management and Relaxation Training) to Improve Vaccine Immune Response</u>	
	Condition:	Psychological Stress
	Intervention:	Behavioral: Cognitive Behavioral Stress Management (CBSM) group intervention
	<p>Can Stress Management Improve Vaccine Immune Response</p>	