

	<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><a href="#">Denileukin Diftitox Followed by Vaccine Therapy in Treating Patients With Metastatic Cancer</a></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>	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>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><a href="#">Chemotherapy Followed By Vaccine Therapy in Treating Patients With Extensive-Stage Small Cell Lung Cancer</a></p> <p>Condition: Lung Cancer</p> <p>Interventions: Biological: autologous dendritic cell-adenovirus p53 vaccine; Drug: carboplatin; Drug: etoposide 2002</p>	Dendritic Cells Transduced With An Adenoviral Vector Containing The p53 Gene To Immunize Patients With Extensive Stage
	<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><a href="#">Vaccine Therapy in Treating Patients With Chronic Phase Chronic Myelogenous Leukemia</a></p> <p>Condition: Leukemia</p> <p>Interventions: Biological: bcr-abl peptide vaccine; Genetic: reverse transcriptase-polymerase chain reaction 2007</p>	Synthetic Tumor-Specific Breakpoint Peptide Vaccine for CML and Minimal Residual Disease
	<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. BCR-ABL transcript levels are assessed by quantitative reverse-transcriptase polymerase chain reaction at baseline</p>	
Completed	<p><a href="#">Vaccine Therapy, Trastuzumab, and Vinorelbine in Treating Women With Locally Recurrent or Metastatic Breast Cancer</a></p> <p>Condition: Breast Cancer</p>	A Multiepitope Dendritic Cell Vaccine Given With Trastuzumab And Vinorelbine For

	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	<a href="#">Evaluation of Transgenic Lymphocyte Immunization Vaccine in Subjects With Prostate Adenocarcinoma</a>		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	<a href="#">Decitabine, Vaccine Therapy, and Doxorubicin Hydrochloride Liposome in Treating Patients With Recurrent Ovarian Epithelial</a>		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	<a href="#">Vaccine Therapy, Trastuzumab, and Vinorelbine in Treating Patients With Locally Recurrent or Metastatic Breast Cancer</a>		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.</p> <p>Secondary: Determine if this regimen is effective in generating functional antigen-specific T cells.</p> <p>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.</p> <p>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.</p> <p>After completion of study treatment, patients are followed every 3 months.</p>		
Active, not recruiting	<a href="#">Safety Study of BLP25 Liposome Vaccine in Non-Small Cell Lung Cancer Patients With Unresectable Stage III Disease</a>		Open Label Safety Study of BLP25 Liposome Vaccine (L-BLP25) in Non-Small Cell Lung Cancer (NSCLC)
	Conditions:	Carcinoma, Non-Small-Cell Lung; Lung Neoplasms	
	Intervention:	Biological: BLP25 Liposome Vaccine 2005	
	<p>Patients will receive L BLP25 treatment following primary therapy. The primary treatment consists of: A single intravenous (I.V.) administration of 300 mg/m<sup>2</sup> of cyclophosphamide three days before the first vaccine treatment. The maximum dose to be administered is 600 mg of cyclophosphamide.</p> <p>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.</p> <p>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.</p> <p>Safety and Survival</p>		
Recruiting	<a href="#">Influenza Vaccine in Preventing Flu in Patients Who Have Undergone Stem Cell Transplant and in Healthy Volunteers</a>		
	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 ]</p> <p>Secondary Outcome Measures: Correlation of influenza infection with graft-vs-host disease, age, and transplant type in patients /Vaccine protection</p>		
Not yet recruiting	<a href="#">Mother - Daughter Initiative (MDI) in Cervical Cancer Prevention</a>		
	Condition:	Cervical Cancer	
	Intervention:	Biological: HPV Vaccine (Gardasil)	
Active, not recruiting	<a href="#">Health SMART (Stress Management and Relaxation Training) to Improve Vaccine Immune Response</a>		Can Stress Management Improve Vaccine Immune Response
	Condition:	Psychological Stress	
	Intervention:	Behavioral: Cognitive Behavioral Stress Management (CBSM) group intervention	

	<p>Primary Outcome Measures: Independent sample t-test will be used to compare 1) antibody change scores from before to after the first and second dose of vaccine, and 2) distress change scores from before to after the intervention [ Time Frame: length of protocol ]</p> <p>Secondary Outcome Measures: Multiple regression analyzes will be used to test changes in cortisol and changes in perceived risk of breast cancer; coping or social support mediate the effects of the intervention on antibody response to vaccine and distress [ Time Frame: length of protocol ] [ Designated as safety issue: No ]</p>	
Active, not recruiting	<a href="#">Vaccine Therapy in Treating Patients With Non-Small Cell Lung Cancer</a>	
	Condition:	Lung Cancer
	Interventions:	Biological: autologous tumor cell vaccine; Biological: therapeutic autologous dendritic cells; Procedure: conventional surgery 2001
	<p>Determine the safety and feasibility of immunization with autologous tumor lysate-pulsed dendritic cell vaccine in patients with non-small cell lung cancer. Determine the immunologic response in patients treated with this vaccine.</p> <p>OUTLINE: Patients undergo surgery to remove all or most of the gross evidence of tumor. Two months after surgery (or 4 months if chemotherapy and/or radiotherapy are required), patients undergo leukapheresis. Peripheral blood mononuclear cells are isolated and cultured with interleukin-4 and sargramostim (GM-CSF) to generate dendritic cells (DC). DC are then pulsed with tumor lysate prepared from previously removed tumor. Patients receive autologous tumor lysate-pulsed DC vaccine subcutaneously twice, 4 weeks apart. Patients are followed every 4 months for 2 years, every 6 months for 1 year, and then annually thereafter. PROJECTED ACCRUAL: A total of 10 patients will be accrued for this study within 2 years.</p>	
Recruiting	<a href="#">MTD Study of Vaccine BP-GMAX-CD1 Plus AP1903 to Treat Castrate Resistant Prostate Cancer</a>	
	Condition:	Castrate Resistant Prostate Cancer (CRPC)
	Interventions:	Biological: BPX-101; Drug: AP1903
	<p><b>Primary:</b> To determine the maximum tolerated dose (MTD) of BPX-101 and AP1903 when administered 24 hours apart [1 Year]/To determine other measures of safety and tolerability of BPX-101 and AP1903 when administered 24 hours apart to patients with castrate resistant prostate cancer (CRPC).</p> <p><b>Secondary:</b> To determine the pharmacokinetics of AP1903 when administered 24 hours after BPX-101 [1 Year] /To assess immune responses and their association with clinical outcome as measured by changes in levels of interferon gamma (IFN)-producing T cells, the cytotoxic T lymphocyte (CTL) response, cytokines (IFN, IL-4, IL-10), activation markers, and other [2 Years] /To assess PSA response and PSA dynamics (change in velocity, doubling time) [1 Year] /To assess reduction in the number of circulating tumor cells (CTC) [1 Year] /To assess cancer-related pain [1 Year] . /To assess pain medication usage [1 Year] . /To determine preliminary efficacy of BPX-101 at the maximum tolerated dose (MTD), based on tumor assessments using computed tomography (CT) or magnetic resonance imaging (MRI) and radionuclide bone scans [2 Years]</p>	
Completed	<a href="#">Vaccine Therapy in Treating Patients With Advanced or Recurrent Cancer</a>	
	Conditions:	Anal Cancer; Cervical Cancer; Esophageal Cancer; Head and Neck Cancer; Penile Cancer; Vulvar
	Interventions:	Biological: human papillomavirus 16 E7 peptide; Biological: synthetic human papillomavirus 16 E6 peptide 2001
	<p>IMMUNOLOGIC RESPONSES WITH HUMAN PAPILOMAVIRUS 16 E6 AND E7 PEPTIDES for METASTATIC OR LOCALLY ADVANCED CERVICAL CANCER</p>	
	<p>Determine whether endogenous cellular immunity to the viral oncoproteins human papilloma virus 16 (HPV16) E6 and E7 is present in patients with advanced or recurrent carcinoma of the cervix or other carcinomas that carry HPV16. /Determine whether vaccination with antigen-presenting cells pulsed with synthetic peptide corresponding to the tumor's HPV16 E6 or E7 peptide can induce or boost patient cellular immunity to that particular peptide. /Determine the type and characteristics of the cellular immunity generated in patients treated with this regimen. /Determine the toxicity of this regimen in these patients. /Determine the tumor response in patients treated with this regimen. /Determine whether in vivo T cells generated specifically against HPV16 E6 or E7 peptide can be cloned and expanded in vitro against the corresponding peptide. //Patients are followed at 1 month.</p>	
Not yet recruiting	<a href="#">Human Papillomavirus (HPV) Vaccination in Barretos (Pio XII Foundation - Barretos Cancer Hospital)</a>	
	Conditions:	Human Papillomavirus; HPV Infection; Vaccine

	Intervention:	2010	
	Evaluating the knowledge about the Pap test, cervical cancer, HPV, and vaccine in vaccinated girls and mothers (or legally responsible individuals) - before and after the vaccine program; Evaluating the vaccination program recruiting rate (school-based program); Evaluating adherence to the vaccination program.		
Not yet recruiting	<a href="#">BLP25 Liposome Vaccine and Bevacizumab After Chemotherapy and Radiation Therapy in Treating Patients With Newly Diagnosed Stage IIIA or Stage IIIB Non-Small Cell Lung Cancer That Cannot Be Removed by Surgery</a>		L-BLP25 and Bevacizumab in Unresectable Stage IIIA and IIIB Non-Squamous Non-Small Cell Lung Cancer After Definitive Chemoradiation
	Condition:	Lung Cancer	
	Interventions:	Biological: BLP25 liposome vaccine; Biological: bevacizumab; Drug: carboplatin; Drug: cyclophosphamide; Drug: paclitaxel; Radiation: radiation therapy 2009	
	<p>Primary: To determine the safety of BLP25 liposome vaccine and bevacizumab after definitive chemoradiotherapy and consolidation chemotherapy in patients with newly diagnosed, unresectable stage IIIA or IIIB nonsquamous cell non-small cell lung cancer.</p> <p>Secondary: To evaluate the overall survival and progression-free in patients treated with this regimen. To evaluate the toxicity of this regimen in these patients.</p> <p>Chemoradiotherapy: Patients receive paclitaxel IV over 1 hour and carboplatin IV over 15-30 minutes once a week for 6 weeks. Patients also undergo concurrent definitive radiotherapy 5 days a week for 6½ weeks. Patients with complete response (CR), partial response (PR), or stable disease (SD) proceed to consolidation chemotherapy. Patients are followed periodically for up to 5 years.</p>		
Completed	<a href="#">Vaccine Therapy Plus QS21 in Treating Patients With Progressive Prostate Cancer</a>		Thompson-Friedenreich [TF(c)]-KLH Conjugate Plus the Immunological Adjuvant QS21: A Trial Comparing TF(c)-KLH Doses
	Condition:	Prostate Cancer	
	Interventions:	Biological: QS21; Biological: TF(c)-KLH conjugate vaccine; Biological: Thomsen-Friedenreich antigen; Biological: keyhole limpet hemocyanin 1999	
	<p>OBJECTIVES: I. Determine the optimal dose of Thompson-Friedenreich [TF(c)]-keyhole limpet hemocyanin (KLH) conjugate plus adjuvant QS21 that induces an antibody response in patients with prostate cancer. II. Determine the safety of the TF(c)-KLH conjugate prepared using an MBS heterobifunctional linker plus QS21. III. Assess postimmunization changes in prostate specific antigen levels and other objective parameters of disease in these patients.</p> <p>OUTLINE: This is a dose escalation study. Patients receive TF(c)-KLH conjugate with adjuvant QS21 subcutaneously weekly for 3 weeks, then once during weeks 7 and 19. Cohorts of 5 patients each receive escalating doses of TF(c)-KLH vaccine until the optimal dose, based on antibody response, is reached. Patients are followed monthly for 6 months, then every 3 months for 1 year.</p> <p>PROJECTED ACCRUAL: A total of 20 patients will be accrued for this study within 6 months.</p>		
Completed	<a href="#">Vaccine Therapy in Treating Patients With Ovarian Epithelial, Primary Peritoneal, or Fallopian Tube Cancer</a>		NY-ESO-1b Peptide Plus Montanide ISA-51 In Patients With Ovarian, Primary Peritoneal, Or Fallopian Tube Cancer Expressing NY-ESO-1 or LAGE-1
	Conditions:	Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer	
	Interventions:	Biological: NY-ESO-1 peptide vaccine; Biological: incomplete Freund's adjuvant 2003	
	<p>OBJECTIVES: Determine the safety of NY-ESO-1b peptide vaccine and Montanide ISA-51 in patients with ovarian epithelial, primary peritoneal, or fallopian tube cancer expressing NY-ESO-1 or LAGE-1. /Determine the immunologic profile (NY-ESO-1 antibody, CD8+ cells, and delayed-type hypersensitivity) induced by this regimen in these patients.</p> <p>OUTLINE: This is an open-label study.</p> <p>Patients receive NY-ESO-1b peptide vaccine emulsified with Montanide ISA-51 subcutaneously once every 3 weeks on weeks 1, 4, 7, 10, and 13 in the absence of disease progression or unacceptable toxicity.</p> <p>Patients are followed at 3 weeks and then every 6-12 weeks for 2 years or until disease progression</p>		
Completed	<a href="#">Vaccine Therapy in Treating Patients With Recurrent Prostate Cancer</a>		Prostate Specific Antigen Peptide 3A (PSA: 154-163 (155L)) (NSC #722932, IND#9787)
	Condition:	Prostate Cancer	

	Interventions:	Biological: PSA:154-163(155L) peptide vaccine; Biological: incomplete Freund's adjuvant 2005	With Montanide ISA-51 (NSC #675756, IND # 9787) Vaccination
	<p>Primary Determine the T-lymphocyte immune response in patients with recurrent adenocarcinoma of the prostate treated with prostate-specific antigen (PSA) peptide vaccine (PSA-3A; PSA: 154-163 [155L]) emulsified in Montanide ISA-51.</p> <p>Secondary: Determine the toxicity of this vaccine in these patients. /Determine the effect of this vaccine on serum PSA level in these patients. patients are followed at 1 and 4 weeks. PROJECTED ACCRUAL: A total of 18-32 patients will be accrued for this study within 18-38 months.</p>		
Recruiting	<a href="#">Banking of Chronic Lymphocytic Leukemia Tumor Cells for Vaccine Generation</a>		Banking of Chronic Lymphocytic Leukemia Tumor Cells for Vaccine Generation
	Condition:	Chronic Lymphocytic Leukemia	
	Intervention:	Procedure: Leukemia cell harvest	
	<p>To collect up to 20 patient samples per year that could potentially be used to prepare autologous tumor cell vaccines. [ 2 years]It is important to understand that even if the participant consents to allow us to save their leukemia cells, we cannot guarantee that they will be able to receive a vaccine. First, we may not be able to make enough vaccine from the collected cells. Second, they may not be able to participate in a vaccine study in the future for reasons related to the status of your overall health. Third, an appropriate vaccine trial may not be available in the future.</p> <p>In order to make the vaccine, leukemia cells will be collected by one or more of the following methods: drawing blood during one of two visits to the clinic; leukapheresis; bone marrow aspiration; or, surgery to remove a lymph node.</p> <p>The physician will discuss with the participant which approach is best in their case to ensure the highest number of tumor cells collected.</p>		
Completed	<a href="#">Vaccine Therapy in Treating Patients With Advanced or Metastatic Cancer</a>		Immunotherapy With Autologous Dendritic Cells Infected With CEA-6D Expressing Fowlpox -Tricom In Patients With Advanced Or Metastatic Malignancies Expressing CEA
	Conditions:	Breast Cancer; Colorectal Cancer; Gallbladder Cancer; Gastric Cancer; Head and Neck Cancer; Liver	
	Interventions:	Biological: CMV pp65 peptide; Biological: autologous dendritic cells/CMV pp65 peptide mixture; Biological: recombinant fowlpox-CEA(6D)/TRICOM vaccine; Biological: tetanus toxoid; Biological: therapeutic autologous dendritic cells 2001	
	<p>Determine the safety and feasibility of active immunotherapy comprising autologous dendritic cells infected with recombinant fowlpox-CEA-TRICOM vaccine in patients with advanced or metastatic malignancies expressing CEA.</p> <p>Assess the CEA-specific immune response of patients treated with this regimen.</p> <p>Assess, in a preliminary manner, the clinical response rate of patients treated with this regimen.</p> <p>Patients are followed every 3 months for 1 year.</p>		
Active, not recruiting	<a href="#">Vaccine Therapy in Treating Patients With Metastatic or Recurrent Cancer</a>		Active Specific Immunotherapy With MVF-HER-2(628-647) and CRL1005 Copolymer Adjuvant in Patients With Metastatic Cancer
	Conditions:	Breast Cancer; Gastric Cancer; Lung Cancer; Ovarian Cancer; Unspecified Adult Solid Tumor, Protocol	
	Intervention:	Biological: MVF-HER-2(628-647)-CRL 1005 vaccine 2001	
	<p>OBJECTIVES: I. Determine the optimum biologic dose of MVF-HER-2(628-647)-CRL 1005 vaccine that will induce anti-HER-2 antibody in patients with metastatic or recurrent cancer. II. Characterize the nature and severity of toxicity of this drug in these patients. III. Document any clinical responses to this drug in these patients.</p> <p>OUTLINE: This is a dose-escalation study. Patients receive MVF-HER-2(628-647)-CRL 1005 vaccine intramuscularly on days 1 and 29. Cohorts of 5 patients receive escalating doses of MVF-HER-2(627-647)-CRL 1005 vaccine until at least 2 of 5 patients experience dose-limiting toxicity. Patients are followed on days 43 and 57 and every 2 months for at least 1 year.</p>		
Recruiting	<a href="#">Vaccine Therapy in Treating Patients With Head and Neck Cancer</a>		p53 Peptide Loaded DC-Based Therapy for Subjects With Squamous Cell Cancer of the Head and Neck
	Condition:	Head and Neck Cancer	
	Interventions:	Biological: mutant p53 peptide pulsed dendritic cell vaccine; Biological: tetanus toxoid helper peptide; Procedure: adjuvant therapy 2006	

	Primary Outcome Measures: Toxicity profile and overall toxicity rates. /Immunologic response rate as measured by ELISPOT assay prevaccination and at days 14 and 18. /Toxicologic response rate	
Active, not recruiting	<a href="#">Vaccine Therapy in Treating Patients With Metastatic Breast Cancer</a>	
	Condition:	Breast Cancer
	Intervention:	Biological: recombinant vaccinia DF3/MUC1 vaccine 1999
	<p>OBJECTIVES: I. Determine the toxicity associated with repeated vaccination with recombinant vaccinia DF3/MUC1 vaccine (rV-DF3/MUC1) in patients with metastatic breast cancer. II. Determine the maximum tolerated dose of rV-DF3/MUC1, based on cellular and humoral immunity, in these patients. III. Determine whether vaccination with rV-DF3/MUC1 is associated with antitumor activity in these patients.</p> <p>OUTLINE: This is an open label, dose escalation study. Patients receive recombinant vaccinia DF3/MUC1 vaccine (rV-DF3/MUC1) intradermally. Treatment repeats every month for 3 courses in the absence of disease progression or unacceptable toxicity. Cohorts of at least 6 patients receive escalating doses of rV-DF3/MUC1 until the maximum tolerated dose (MTD) or the highest dose level to be tested is reached. The MTD is defined as the dose preceding that at which 2 of 6 patients experience dose limiting toxicity. Patients are followed monthly for 6 months.</p>	
Completed	<a href="#">Vaccine Therapy in Treating Patients With Liver Cancer</a>	
	Condition:	Liver Cancer
	Intervention:	Biological: AFP gene hepatocellular carcinoma vaccine 2000
	<p>antigen-specific immune response [ Time Frame: 1 month ] /Determine the antigen-specific immune response to hAFP137-145 (PLFQVPEPV), hAFP158-166 (FMNKFIYEI), hAFP325-334 (GLSPNLNRFL) and hAFP542-550 (GVALQTMKQ), emulsified with Montanide ISA-51, in peripheral blood of patients with liver cancer.</p> <p>Survival [ Time Frame: 1 month ]</p> <p>Determine the overall survival, disease-free survival or progression-free survival of patients with HCC vaccinated with hAFP137-145 (PLFQVPEPV), hAFP158-166 (FMNKFIYEI), hAFP325-334 (GLSPNLNRFL) and hAFP542-550 (GVALQTMKQ), emulsified with Montanide ISA-51.</p>	
Completed	<a href="#">Vaccine Therapy Plus QS21 in Treating Women With Breast Cancer Who Have No Evidence of Disease</a>	
	Condition:	Breast Cancer
	Interventions:	Biological: GM2-KLH vaccine; Biological: QS21 1999
	Determine whether immunization with GM2-KLH vaccine plus the immunological adjuvant QS21 induces an antibody response against GM2 and cells expressing GM2 in disease free patients at high risk for recurrence of breast cancer.	
Completed	<a href="#">Vaccine Therapy, Chemotherapy, and GM-CSF in Treating Patients With Advanced Pancreatic Cancer</a>	
	Condition:	Pancreatic Cancer
	Interventions:	Biological: allogeneic tumor cell vaccine; Biological: recombinant interferon alfa; Biological: sargramostim; Drug: cyclophosphamide 1999
	<p>OBJECTIVES: I. Determine the feasibility, toxicity, and antitumor effects of active specific intralymphatic immunotherapy with allogeneic pancreatic cancer cells treated with interferon alfa plus low-dose adjuvant systemic sargramostim (GM-CSF) and cyclophosphamide in patients with incurable pancreatic adenocarcinoma. II. Assess the immunologic and biologic correlates of this treatment regimen in these patients.</p> <p>OUTLINE: Cultured allogeneic pancreatic cancer cells are incubated with interferon alfa for 72-96 hours. Autologous cell lines, if established, may be used as an alternative. The cells are irradiated immediately prior to use. Patients receive cyclophosphamide IV on day -3 and sargramostim (GM-CSF) subcutaneously on days 0-8. On day 0, patients receive viable tumor cells via dorsal pedal lymphatic cannulation. Treatment repeats every 2-4 weeks for a minimum of 8 weeks in the absence of disease progression or unacceptable toxicity. Patients are followed every 2-4 months.</p> <p>PROJECTED ACCRUAL: A total of 14 patients will be accrued for this study.</p>	

Recruiting	<a href="#">Trial of Vaccine Therapy in Curative Resected Prostate Cancer Patients Using Autologous Dendritic Cells Loaded With mRNA</a>		
	Condition:	Prostate Cancer	
	Intervention:	Biological: Dendritic cell vaccine 2010	
<p>Primary : Time to treatment failure defined by two different measurement of PSA levels &gt;0.5 µg/L with minimum of 4 weeks interval  Secondary Outcome Measures: Safety and toxicity of vaccination. Evaluation of immunological response.</p>			
Completed	<a href="#">Vaccine Therapy in Treating Patients With Breast Cancer</a>		Vaccination With MUC-1 (Glycosylated) Keyhole Limpet Hemocyanin Conjugates Plus the Immunological Adjuvant QS21
	Condition:	Breast Cancer	
	Intervention:	Biological: MUC1-KLH vaccine/QS21 1999	
<p>OBJECTIVES: I. Determine if immunization with glycosylated MUC-1 antigen containing MUC-1(106) or MUC-1(33) 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 high risk breast cancer (MUC-1+).  OUTLINE: Patients receive glycosylated MUC-1 antigen containing MUC-1(106) or MUC-1(33) with keyhole limpet hemocyanin conjugate subcutaneously (SQ) plus immunological adjuvant QS21 SQ on weeks 1-3, 7, and 19 for a total of 5 vaccinations. Patients are followed every 3 months.</p>			
Active, not recruiting	<a href="#">Vaccine Therapy in Treating Patients With Stage III or Stage IV Breast Cancer</a>		Vaccination With Multiple Synthetic Peptides in Participants With Advanced Breast Cancer
	Condition:	Breast Cancer	
	Intervention:	Biological: synthetic breast cancer peptides-tetanus toxoid-Montanide ISA-51 vaccine 2006	
<p>Primary Outcome Measures: Safety of the 9-peptide mixture if fewer than 33% of patients experience a dose-limiting toxicity at day 36  Secondary Outcome Measures: Frequency of immune responses by Elispot assay  Determine the safety of a vaccine comprising multiple synthetic breast cancer-associated peptides and a tetanus toxoid helper peptide emulsified in Montanide ISA-51 in patients with stage III or IV adenocarcinoma of the breast.  Determine, preliminarily, the frequency of immune responses against the 9 class I MHC-restricted peptides in patients treated with the vaccine.  Determine, preliminarily, the cytotoxic responses of T-cells to allogeneic breast cancer cells and autologous breast cancer cells (when available).  OUTLINE: This is an open-label study.</p>			
Completed	<a href="#">HER-2 Protein Vaccine in Treating Women With Breast Cancer</a>		Intramuscular Injections Of HER-2 Protein AUTOVAC (PX104.1.6) In Patients With Breast Cancer
	Condition:	Breast Cancer	
	Intervention:	Biological: HER-2/neu peptide vaccine 2003	
<p>Primary: Determine the safety of HER-2 protein AutoVac™ in women with breast cancer.  Secondary: Determine the ability of this drug to bypass the tolerance to the HER-2 self-protein by raising HER-2 antibodies in these patients.  Determine the kinetics of the immune response to HER-2/neu in patients treated with this drug.  OUTLINE: This is an open-label, multicenter study.  Patients receive HER-2 protein AutoVac™ intramuscularly at weeks 0, 2, 6, and 10 in the absence of unacceptable toxicity.  Patients are followed for up to 6 weeks.</p>			
Recruiting	<a href="#">Allogeneic Tumor Cell Vaccination in Patients With Solid Tumors</a>		Allogeneic Tumor Cell Vaccination in Patients With Solid Tumors
	Condition:	Metastatic Solid Tumors	
	Intervention:	Biological: Tumor Cell Vaccine 2005	
<p>Primary Outcome: Investigate the feasibility of anti-tumor immune response by allogeneic tumor cell vaccine using tumor cells that share MHC determinants with the patient.  Secondary Outcome: Investigate the feasibility of immune responses against cancer cells by combining allogeneic TCV with chemical drugs and rIL-2.</p>			

Active, not recruiting	<a href="#">Vaccine Therapy in Treating Patients With Advanced Refractory or Recurrent Non-Small Cell Lung Cancer</a>		Antitumor Vaccination Using $\alpha$ (1,3) Galactosyltransferase Expressing Allogeneic Tumor Cells
	Condition:	Lung Cancer	
	Interventions:	Biological: alpha-1,3-galactosyltransferase-expressing allogeneic lung tumor cell vaccine; Genetic: protein analysis; Genetic: western blotting; Other: enzyme-linked immunosorbent assay; Other: immunohistochemistry staining method 2004	
	<p>Primary Outcome: Adverse effects, dose-limiting toxicity, and maximum tolerated dose as measured by CTCAE v.3 and RECIST criteria pre-treatment, during study treatment, and 6 months after completion of study treatment (phase I) /Tumor response rate as measured by CTCAE v.3 and RECIST criteria pre-treatment, during study treatment, and 6 months after completion of study treatment (phase II)</p> <p>Secondary Outcome Measures: Immunological response as measured by an assay of serum anti-alpha-gal titers and enzyme-linked immunospot assay for interferon-gamma and interleukin-5 pre-treatment and at 6 months after completion of study treatment</p> <p>Determine the survival distribution and duration of response in patients treated with this vaccine. (phase II)</p> <p>Primary: Determine the side effects, dose-limiting toxicity, and maximum tolerated dose of vaccination comprising <math>\alpha</math>-1,3-galactosyltransferase-expressing allogeneic tumor cells (HyperAcute™ Lung Cancer Vaccine) in patients with advanced refractory or recurrent non-small cell lung cancer. (phase I, completed 10/06/09)</p> <p>Determine tumor response rate in patients treated with this vaccine. (phase II)</p> <p>Secondary: Determine the immunological response (phase II). /Determine the survival distribution and duration of response in patients treated with this vaccine. (phase II) /Some patients undergo tumor tissue biopsies at baseline and after 3 vaccinations for cellular immune response by IHC assays. Blood samples are also collected at baseline and periodically during study for immune response by ELISA, total immunophenotyping by FACS, and Western Blot.</p> <p>Patients are followed monthly for 1 year, every 3 months for 2 years, and then annually for 15 years.</p>		
Completed	<a href="#">Vaccine Therapy in Treating Patients With Metastatic Prostate Cancer</a>		RECOMBINANT VACCINIA VIRUS THAT EXPRESSES PSA IN PATIENTS WITH ADENOCARCINOMA OF THE PROSTATE
	Condition:	Prostate Cancer	
	Interventions:	Biological: recombinant viral vaccine therapy; Biological: sargramostim 1999	
	<p>OBJECTIVES: I. Assess the toxicity associated with repeated vaccination with recombinant vaccinia virus expressing prostate-specific antigen (rV-PSA) in patients with metastatic adenocarcinoma of the prostate. II. Determine the optimal dose of rV-PSA given at monthly intervals based on cellular and hormonal immunity. III. Determine whether vaccination with rV-PSA is associated with anti-tumor activity. IV. Determine whether granulocyte-macrophage colony-stimulating factor (GM-CSF) has an effect on cellular and humoral immunity different from rV-PSA, and whether the addition of GM-CSF has enhanced antitumor effect compared to rV-PSA alone.</p>		
Active, not recruiting	<a href="#">Vaccine Therapy in Treating Patients With Gastric, Prostate, or Ovarian Cancer</a>		EGFRvIII Peptide Based Vaccine in Patients With EGFRvIII Expressing Cancers
	Conditions:	Brain and Central Nervous System Tumors; Gastric Cancer; Ovarian Cancer; Prostate Cancer	
	Interventions:	Biological: EGFR antisense DNA; Biological: keyhole limpet hemocyanin; Biological: sargramostim 2001	
	<p>OBJECTIVES: Determine the toxicity of EGFRvIII peptide vaccine with sargramostim (GM-CSF) or keyhole limpet hemocyanin (KLH) as adjuvant in patients with EGFRvIII-expressing cancer. /Determine the preexisting antibody and T-cell responses to EGFRvIII in these patients.</p> <p>Determine the antibody and T-cell responses to EGFRvIII peptide after immunization with this vaccine with GM-CSF or KLH as adjuvant.</p> <p>OUTLINE: Patients are assigned to one of two treatment arms.</p> <p>Arm I: Patients receive a vaccine containing EGFRvIII peptide admixed with sargramostim (GM-CSF) intradermally monthly.</p> <p>Arm II: Patients receive a vaccine containing EGFRvIII peptide admixed with keyhole limpet hemocyanin subcutaneously monthly.</p> <p>Treatment in both arms continues for 6 months in the absence of disease progression or unacceptable toxicity.</p> <p>Patients are followed every 3 months for 1 year.</p>		

Recruiting	<a href="#">Vaccine Therapy in Treating Patients With Stage IIIB, Stage IV, or Recurrent Non-Small Cell Lung Cancer</a>		CCL21 Gene Modified Dendritic Cells In Non-Small Cell Lung Cancer
	Condition:	Lung Cancer	
	Interventions:	Biological: autologous dendritic cell-adenovirus CCL21 vaccine; Genetic: polymerase chain reaction; Genetic: reverse transcriptase-polymerase chain reaction; Other: flow cytometry; Other: immunoenzyme technique; Other: immunohistochemistry staining method 2008	
	<p>Primary Outcome: Safety. /Maximum tolerated dose /Toxicity as measured by NCI Common Toxicity Criteria</p> <p>Secondary Outcome: Disease status at days 28 and 56. /Immune response assessment by antigen-specific IFN<math>\gamma</math> ELISPOT assays on days 0, 28, and 56</p> <p>Primary: To determine the safety, toxicity, and maximum tolerated dose (MTD) of autologous dendritic cell-adenovirus CCL21 vaccine administered as an intratumoral injection in treating patients with stage IIIB, IV, or recurrent non-small cell lung cancer.</p> <p>Secondary: To determine the biologic and clinical responses to therapy. /To determine treatment-related toxicity using the NCI Common Toxicity Criteria. To identify the MTD. /To monitor patients for evidence of autologous dendritic cell-adenovirus CCL21 vaccine-induced cytokines and antigen-specific immune responses.</p> <p>To detect immune responses to tumor-associated antigens and vector. /To assess patients for objective signs of tumor regression (RECIST Criteria).</p> <p>OUTLINE: This is a dose-escalation study of autologous dendritic cell-adenovirus CCL21 vaccine.</p> <p>Tissue samples are analyzed for immune-modulating cytokines (i.e., IFN<math>\gamma</math>, CXCL9, and CXCL10) by quantitative RT-PCR; detection of tumor infiltrating leukocytes by immunohistochemistry; CD83+ DC, CXCR3, CCR7, CCL21 and CD3+ T-cells, CD4, and CD8 by flow cytometry; determination of tumor expression of tumor-</p>		
Active, not recruiting	<a href="#">Chemotherapy, Vaccine Therapy, and Peripheral Stem Cell Transplantation in Treating Patients With Newly Diagnosed Multiple</a>		Vaccination In Peripheral Stem Cell Transplant Setting For Multiple Myeloma: The Use Of Autologous Tumor Cells/An Allo PSCT
	Condition:	Multiple Myeloma and Plasma Cell Neoplasm	
	Interventions:	Biological: autologous tumor cell vaccine; Drug: chemotherapy; Procedure: autologous hematopoietic stem cell transplantation; Procedure: peripheral blood stem cell transplantation 2001	
	<p>OBJECTIVES: Determine the efficacy of induction chemotherapy followed by autologous tumor cell vaccine and autologous peripheral blood stem cell transplantation in patients with multiple myeloma. /Determine the safety of this regimen in these patients.</p> <p>OUTLINE: Autologous tumor cells are harvested. The vaccine is prepared in vitro by mixing autologous tumor cells with a bystander cell expressing sargramostim (GM-CSF). Patients receive induction chemotherapy followed by autologous tumor cell vaccination (ATCV) once. Patients then undergo autologous peripheral blood stem cell transplantation. <u>At 6 weeks after transplantation patients receive additional ATCVs every 3 weeks for a total of 8 vaccinations</u></p>		
Completed	<a href="#">Vaccine Therapy in Treating Patients With Metastatic Prostate Cancer</a>		Active Immunotherapy in Patients With Metastatic Prostate Carcinoma Using Autologous Dendritic Cells Pulsed With RNA Encoding Prostate Specific Antigen, PSA
	Condition:	Prostate Cancer	
	Intervention:	Biological: PSA RNA-pulsed dendritic cell vaccine 1999	