	Percentage of CD4+ T cells, CD8+ T cells, B cells, monocytes, and dendritic cells. peptide-specific IFN-gamma producing T cells and peptide-specific IL-5 producing T cells estimated by ELISPOT. Disease-free survival and OS. up to 2 years. In all arms, treatment repeats every 4 weeks for 6 courses in the absence of disease progression or unacceptable toxicity. Patients who complete 6 courses of treatment without disease recurrence or a second primary or intolerable toxicity will go to the observation phase of the study for up to 2 years. Patients who develop recurrent disease during the observational phase will go to the event monitoring phase for up to 2 years. Blood samples are collected periodically. Blood samples and tissue samples from the patient's most recent surgery are used for correlative studies including immune responses to T helper and CTL epitopes by Elispot and tetramer analysis; and antigenic profiling by expression analysis of class I HLA antigens, MUC1, and HER-2 in tumor tissue. After completion of study treatment, patients are followed periodically until disease recurrence or for up to 2 years	
Active, not recruiting	Vaccine Therapy of Prostate Cancer Patients With Recombinant Soluble Prostate-Specific Membrane Antigen (Rs-PSMA) Plus the Immunological Adjuvant Alhydrogel Condition: Prostate Cancer Intervention: Biological: rsPSMA protein plus Alhydrogel® vaccine 2008	Recombinant Soluble Prostate-Specific Membrane Antigen (Rs-PSMA) Plus the Immunological Adjuvant Alhydrogel:
	The immune response to increasing dose levels of rsPSMA protein. [Time: conclusion of study]. The pattern of change in PSA T. **Purpose** The purpose of this research is to help us study a vaccine treatment for patients with prostate cancer. A vaccine is a medicine that teaches the body to destroy harmful infections and other diseases, such as cancer. Your immune system is made up of many different types of cells which fight infection and disease in your body. A vaccine may stimulate the immune system to destroy the cancer cells. It may also help to slow the growth of the cancer. The vaccine is a solution given as an injection into or under the skin. It is made up of several parts. The first part is PSMA, a protein present in many cancers, especially prostate cancer. It is referred to as rsPSMA when made in a laboratory for this study and is mixed with a material called Alhydrogel® (aluminum hydroxide suspension) which helps the immune system to make more cancer fighting cells	
Recruiting	Phase I Trial of TGFB2-Antisense-GMCSF Gene Modified Autologous Tumor Cell (TAG) Vaccine for Advanced Cancer Condition: Advanced Metastatic Carcinoma Intervention:	TGFB2-Antisense-GMCSF Gene Modified Autologous Tumor Cell (TAG) Vaccine:
	Progression following the administration of TAG vaccine. [Time: survival] effect on immune stimulation. [baseline, Month 3, and Month 6]. Preliminary studies with a variety of vaccines suggest target accessibility (potential immunogenicity) in a variety of solid tumors to immune directed approaches. However, four primary factors limit the generation of effective immune mediated anticancer activity in therapeutic application: identifying and/or targeting cancer associated immunogen(s) in an individual patient insufficient or inhibited level of antigen presenting cell priming and/or presentation suboptimal T cell activation and proliferation cancer-induced inhibition of the anticancer immune response in both afferent and efferent limbs.	
Recruiting	Vaccine Therapy and Chemotherapy With or Without Tretinoin in Treating Patients With Extensive-Stage Small Cell Lung Cancer Condition: Lung Cancer Interventions: Biological: autologous dendritic cell-adenovirus p53 vaccine; Drug: tretinoin; Procedure: standard follow-up care 2008	Dendritic Cells Transduced With an Adenoviral Vector Containing the p53 Gene:

	Survival rate between all arms Tumor response rate/ survival of all patients. antigen-specific T-cell responses and reducing the number of immature myeloid cells in patients at least 30 days. **OUTLINE:** Standard first-line chemotherapy: Patients receive standard first-line chemotherapy comprising carboplatin IV over 1 hour on day 1 and etoposide IV over 1 hour on days 1-3. Treatment repeats every 21 days for up to 4 courses. Patients undergo restaging after completion of first-line chemotherapy. Patients with progressive disease do not receive any protocol treatment and are changed to second-line therapy. Adjuvant therapy: Patients with stable disease or better are then randomized to 1 of 3 arms of adjuvant therapy approximately 3 weeks after completion of first-line chemotherapy. Arm I (Observation only [standard care]): Patients undergo observation with serial CT scans. Arm II (Vaccine): Patients receive autologous dendritic cell-adenovirus p53 vaccine intradermally every 2 weeks for 3 doses. Patients with no sign of disease progression will undergo another leukapheresis and receive autologous dendritic cell-adenovirus p53 vaccine intradermally every 4 weeks for 3 doses. Arm III (Vaccine and tretinoin): Patients receive autologous dendritic cell-adenovirus p53 vaccine for up to 6 doses as in arm II. They also receive oral tretinoin for 3 days before receiving each dose of the vaccine. Patients who develops evidence of disease progression at any point proceed to second-line chemotherapy with paclitaxel once every 21 days in the absence of	
Active, not recruiting	HLA-A*0201 Restricted Peptide Vaccine Therapy With Gemcitabine With Gemcitabine in Patient Pancreatic Cancer (Phase1) Condition: Pancreatic Cancer Interventions: Biological: VEGFR1, VEGFR2; Drug: Gemcitabine 2010	HLA-A*0201 Restricted Antiangiogenic Peptide Vaccine Therapy Using Epitope Peptide Derived From VEGFR1 and VEGFR2 With Gemcitabine.
	Peptide specific CTL response/ CD8 population / level of regulatory T cells [3 months]. Response rate and OS [1 year] **Detailed Description:** The prognosis of pancreatic cancer is extremely poor even with extensive surgery, chemotherapy or radiation. It has been required development of new treatment modalities. Immunotherapy is one of the encouraging modalities for cancer patients. The investigators have to assess its toxicities and immune responsiveness	
Completed	Multivalent Conjugate Vaccine Trial for Patients With Biochem. Relapsed Prostate Cancer Conditions: Prostate; Cancer Intervention: Biological: QS21 2007	Multivalent Conjugate Vaccine (QS21):

	Overall antitumor assessment performed during weeks 19 and 3. monitored every 3 months with history, physical, performance status and bloodwork. Imaging studies every 6 mo. multivalent vaccine will consist of the lowest dose of synthetic glycoprotein and carbohydrate antigens shown to elicit high titer IgM and IgG antibodies. **Detailed Description:** This is a pilot trial designed to assess safety and immunogenicity of a multivalent conjugate vaccine for use in patients with biochemically relapsed prostate cancer. This trial is based on the results of eight dose-seeking phase I monovalent glycoprotein and carbohydrate conjugate vaccine trials in a patient population with minimal tumor burden despite a rising biomarker, PSA, who have failed primary therapy such as surgery or radiation. We know that a rising PSA is indicative of micrometastatic disease - a state to which the immune system may maximally respond. Based on these trials, we have identified three glycolipid antigens, Globo H, Lewisy and GM2 and three mucin antigens, glycosylated MUC-1, Tn(c), and TF(c) for inclusion into a multivalent trial. As a result of these vaccinations, most patients generated specific high titer IgM and IgG antibodies against the respective antigen-KLH conjugates. Our previous work has shown the monovalent vaccines to be safe with local erythema and edema but minimal systemic toxicities. Our data from approximately 160 men who participated in our earlier monovalent vaccine trials against the aforementioned antigens have shown that a treatment effect in the form of a decline in PSA log slopes compared with pretreatment values could be seen in patients with minimal tumor burden. The multivalent vaccine will consist of the lowest dose of synthetic glycoprotein and carbohydrate antigens shown to elicit high titer IgM and IgG antibodies in patients with biochemically relapsed prostate cancer. A phase III double blind randomized trial with two hundred forty patients is planned based on the safety and immunogenicity data accrued from this pilot trial. The primary endpoints of this study will be the safety of the vaccine and the humoral response to each of the antigens. The secondary endpoint will be to evaluate post-therapy changes in PSA.	
Recruiting	Mammaglobin-A DNA Vaccine for Metastatic Breast Cancer Condition: Metastatic Breast Cancer Intervention: Biological: Mammaglobin-A DNA vaccine 2008	Safety and Immunogenicity of a Mammaglobin-A DNA Vaccine:
	Immunogenicity of the mammaglobin-A DNA vaccine by ELISPOT analysis, a surrogate for CD8 T cell function. [52 weeks] , a naked plasmid DNA vaccine (WUSM-MGBA-01). **Detailed Description:** This is a phase I open-label study to evaluate the safety and immunogenicity of a plasmid mammaglobin-A DNA vaccine. The plasmid mammaglobin-A DNA vaccine will be formulated as a naked plasmid DNA vaccine (WUSM-MGBA-01). The hypothesis of this study is that the mammaglobin-A DNA vaccine will be safe for human administration and capable of generating measurable CD8 T cell responses to mammaglobin-A. The primary objective of this study is to demonstrate the safety of the mammaglobin-A DNA vaccine. The secondary objective is to evaluate the immunogenicity of the mammaglobin-A DNA vaccine as measured by ELISPOT analysis, a surrogate for CD8 T cell function.	
Recruiting	Phase II Study of Adenovirus/PSA Vaccine in Men With Hormone - Refractory Prostate Cancer Condition: Hormone Refractory Prostate Cancer Intervention: Biological: ADENOVIRUS/PSA VACCINE 2010	Adenovirus/PSA Vaccine: PSA doubling-time response [18 months]. · Serum PSA levels and Immune response

	Detailed Description: Subjects in this trial will be eligible if they have recent evidence of hormone refractory disease (D3) and either (a) have a positive bone scan or a positive CT scan (with obvious soft tissue metastasis or lymph nodes >1 cm), with a PSA doubling time of >/= 12 months, a total PSA of < 5 mg/ml, and are asymptomatic; or (b) have a negative bone scan with any PSA doubling time, are asymptomatic, and are not a candidate for chemotherapy. This is a virus vaccine in which the gene for prostate specific antigen (PSA) has been placed into a common cold virus termed adenovirus (Ad) to produce this Ad/PSA product. The purpose of this study is to determine whether vaccination with the Ad/PSA vaccine will induce an anti-PSA immunity that will result in the destruction of the remaining prostate cancer cells. Subjects will be vaccinated three times, each injection administered at 30-day intervals. Based upon our earlier clinical trial, the vaccine is considered safe and should not induce any major side effects. The investigators hope that vaccination with this PSA virus will cause the body to produce immunity to the PSA and that immunity will destroy any cell that produces PSA. Since the only cells left in the body that produce PSA will be the cancer cells, the investigators propose that the vaccination and ensuing anti-PSA immunity will kill the prostate cancer cells. Importantly, this treatment should not cause any major side effects as would treatment with anti-cancer drugs.		
Withdrawn	A Novel Vaccine for the Treatment of MUC1-expressing Tumor Malignancies		Peptide Vaccine (MUC-1) for MUC1-expressing Tumor Malignancies: anti-tumor response and immune response
	Conditions:	Multiple Myeloma; Tumors	
Completed	Safety & Activity of P501-AS15 Vaccine as a First-Line Treatment for Patients With Hormone-Sensitive Prostate Cancer Who Show Rising PSA		P501-AS15 vaccine CPC-P501 Protein Formulated With the Adjuvant AS15:
	Condition:	Prostate Cancer	
	Intervention:	Biological: P501-AS15 vaccine 2008	
	PSA response. Humoral immune response induced by P501-AS15 vaccine: Anti-CPC seropositivity. Anti-P501 seropositivity. Cellular immune response induced by P501-AS15 vaccine. Frequency of in vitro cellular immune response to CPC P501. This Phase I/II study will be conducted according to a multicenter, open-label, single-group design at approximately ten centers in Europe. At least 21 HSPC patients with rising PSA after primary tumor treatment will be enrolled in this study. All patients will be treated as out-patients and will receive the same treatment. The maximum dose will be 16 vaccinations. Follow-up: The patients' long-term safety and PSA status will be followed over a period of 48 weeks. The Protocol Posting has been updated in order to comply with the FDA Amendment Act. Sep 2007		
Recruiting	Phase II Study of Adenovirus/PSA Vaccine in Men With Recurrent Prostate Cancer After Local Therapy APP21		Adenovirus/PSA Vaccine: PSA doubling-time + ·Serum PSA levels and immune response [18 months].
	Condition:	Recurrent Prostate Cancer	
	Intervention:	Biological: Adenovirus/PSA Vaccine 2007	
Completed	Vaccine Therapy Plus Interleukin-2 in Treating Women With Stage IV, Recurrent, or Progressive Breast or Ovarian Cancer		aldesleukin/p53 peptide vaccine/in vitro-treated peripheral blood stem cell transplantation
	Conditions:	Breast Cancer; Ovarian Cancer	
	Interventions:	Biological: aldesleukin; Biological: p53 peptide vaccine; Procedure: in vitro-treated peripheral blood stem cell transplantation 2001-2009	

	•Cellular immunity as measured by Elipsot assay and 51 Cr-release assay every 3 weeks. Tumor response by CT scan every 3 months. **OBJECTIVES:** Determine whether endogenous cellular immunity to the p53 peptide vaccine is present in patients with stage IV, recurrent, or progressive breast or ovarian cancer and whether vaccination with these peptides and low-dose interleukin-2 can induce or boost the cellular immunity in these patients. Determine the type and characteristics of cellular immunity generated by this regimen in these patients. Determine the toxicity of this regimen in these patients. Correlate any immunologic response with any objective tumor response to this regimen in these patients. **OUTLINE:** This is a randomized, pilot study. Patients are randomized to 1 of 2 treatment arms. All patients undergo apheresis of autologous peripheral blood mononuclear cells, which are harvested and selected for monocytes on day -6. The monocyte fraction is cultured with sargramostim (GM-CSF) and interleukin-4 for 7 days and then pulsed with p53 peptide vaccine. Arm I: Patients receive p53 peptide vaccine subcutaneously (SC) on day 1. Arm II: Patients receive p53 peptide vaccine IV over 5 minutes on day 1. Treatment in both arms repeats every 3 weeks for a total of 4 vaccinations (4 courses). During courses 3 and 4, patients also receive low-dose interleukin-2 (IL-2) SC daily on days 3-7 and days 10-14. Patients with stable or responding disease may continue to receive vaccine and IL-2 treatment for up to 2 years. /Patients are followed at 1 month and then every 2-4 months for 2 years.	
Active, not recruiting	Vaccine Therapy and Interleukin-2 in Treating Patients With Stage IV Kidney Cancer Condition: Kidney Cancer Interventions: Biological: adenovirus B7-1; Biological: aldesleukin; Biological: autologous tumor cell vaccine; Procedure: conventional surgery 2002-2009	B7-1 Gene-Modified Autologous Tumor Cell Vaccine and Systemic IL-2: Reduction in tumor size. Immunogenicity, OS.
Completed	Vaccine Therapy Plus QS21 in Treating Patients With Prostate Cancer Condition: Prostate Cancer Interventions: Biological: MUC-2-Globo H-KLH conjugate vaccine; Biological: QS21 2002-2009	Bivalent MUC-2-Globo H-KLH conjugate vaccine/ QS21(Adjuvant):
	Antibody response. •Assess post-immunization changes in PSA levels and other objective parameters of disease (radionuclide bone scan) followed every 3 months for 1 year or until biochemical relapse. **OBJECTIVES:** Determine the safety of glycosylated MUC-2-Globo H-KLH conjugate vaccine with adjuvant QS21 in patients with prostate cancer. Determine the antibody response in patients treated with this vaccination therapy. Assess post-immunization changes in PSA levels and other objective parameters of disease (radionuclide bone scan) in patients treated with this vaccination therapy. OUTLINE: Patients receive glycosylated MUC-2-Globo H-KLH conjugate vaccine with adjuvant QS21 subcutaneously once weekly on weeks 0-2, 6, 14, and 26 in the absence of unacceptable toxicity. Patients whose antibody titers against Globo-H or MUC-2 antigens fall below 1/40 and who have no disease progression may receive a seventh vaccination after week 50. Patients are followed every 3 months for 1 year or until biochemical relapse or radiographic disease progression.	
Completed	Vaccine Therapy and GM-CSF in Treating Patients With Acute Myeloid Leukemia, Myelodysplastic Syndromes, Non-Small Cell Lung Cancer, or Mesothelioma Conditions: Leukemia; Lung Cancer; Malignant Mesothelioma; Myelodysplastic Syndromes; Peritoneal Cavity Cancer	WT-1 analog peptide vaccine/ incomplete Freund's adjuvant/GM-CSF PCR/flow cytometry/ immunoenzyme technique

	Interventions:	Biological: WT-1 analog peptide vaccine; Biological: incomplete Freund's adjuvant; Biological: sargramostim; Genetic: polymerase chain reaction; Other: flow cytometry; Other: immunoenzyme technique 2006	
	Immune response by T-cell proliferative response, DTH against WT-1 peptides, or ELISPOT. •Antileukemic effects. •Antitumor response as measured by CT scan based on RECIST criteria. Blood samples are collected at baseline, week 8, and week 14. Samples are examined by polymerase chain reaction (PCR) to measure levels of WT-1 and by T-cell proliferative response, delayed-type hypersensitivity against WT-1 peptides, or ELISPOT to measure immune response. **Primary** Determine the safety and immunogenicity of the Wilms tumor-1 analog peptide vaccine in patients with acute myeloid leukemia, myelodysplastic syndromes, non-small cell lung cancer, or mesothelioma. **Secondary:** Determine the antitumor effects of this vaccine in these patients. **OUTLINE:** This is a pilot study. Patients are stratified according to disease type (acute myeloid leukemia [AML] or myelodysplastic syndromes [MDS] vs non-small cell lung cancer or mesothelioma). **Patients** receive vaccine comprising Wilms-tumor 1 (WT-1) analog peptide emulsified in Montanide ISA-51 subcutaneously (SC) once in weeks 0, 4, 6, 8, 10, and 12 and sargramostim (GM-CSF) SC twice in weeks 0, 4, 6, 8, 10, and 12 (on the day of and 2 days prior to each vaccination). Patients who have an immunologic response and have no disease progression may receive up to 6 more vaccinations approximately 1 month apart. Blood samples are collected at baseline, week 8, and week 14. Samples are examined by polymerase chain reaction (PCR) to measure levels of WT-1 and by T-cell proliferative response, delayed-type hypersensitivity against WT-1 peptides, or ELISPOT to measure immune response. Bone marrow samples are collected from patients with AML or MDS at baseline and week 14. Samples are examined by PCR to measure levels of WT-1 and by multiparameter flow cytometry to measure residual disease. PROJECTED ACCRUAL: A total of 20 patients will be accrued for this study.	
Active, not recruiting	Vaccine To Prevent Cervical Intraepithelial Neoplasia or Cervical Cancer in Younger Healthy Participants		human papillomavirus 16/18 L1 virus-like particle/AS04 vaccine: HPV16/18 VLP Vaccine in the Prevention of Advanced Cervical Intraepithelial Neoplasia (CIN2, CIN3, Adenocarcinoma
	Conditions:	Cervical Cancer; Precancerous Condition	
	Intervention:	Biological: human papillomavirus 16/18 L1 virus-like particle/AS04 vaccine 2005	
Completed	Vaccine Therapy in Treating Women With Metastatic Breast Cancer		Detox-B adjuvant/ THERATOPE STn-KLH vaccine/KLH Measure the anti-STn, anti-OSM, and anti-KLH antibody titers
	Condition:	Breast Cancer	
	Interventions:	Biological: Detox-B adjuvant; Biological: THERATOPE STn-KLH vaccine; Biological: keyhole limpet hemocyanin; Drug: cyclophosphamide 1999	
Active, not recruiting	Vaccine Therapy and Interleukin-2 After Combination Chemotherapy in Treating Patients With Relapsed or De Novo Stage II, Stage III, or Stage IV Mantle Cell Lymphoma		Universal GM-CSF-Producing and CD40L-Expressing Bystander Cell Line (GM.CD40L) in the Formulation of Autologous Tumor Cell-Based Vaccines:
	Condition:	Lymphoma	
	Interventions:	Biological: GM.CD40L cell vaccine; Biological: aldesleukin; Biological: autologous tumor cell vaccine; Drug: CHOP regimen; Drug: cyclophosphamide; Drug: cytarabine; Drug: dexamethasone; Drug: doxorubicin hydrochloride; Drug: methotrexate; Drug: prednisone; Drug: vincristine sulfate 2005	

	Anti-tumor immune response by ELISPOT and DTH at 6 months. Tumor response rate and time to tumor progression by RECIST criteria at 6 months. • Disease-free and overall survival at 6, 9, and 12 months. DNA micro array analysis. **OUTLINE:** Patients undergo surgical resection of a malignant lymph node to collect autologous tumor cells for vaccine production. Vaccine is formulated by combining equal volumes of irradiated autologous tumor cells and irradiated cells from a cell line that produces sargramostim (GM-CSF) and expresses CD40L (GM.CD40L). Conventional chemotherapy: Patients receive conventional chemotherapy comprising 6 courses of cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) OR 3 courses of hyperfractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and cytarabine (hyper-CVAD) for patients who have relapsed after CHOP. Patients who achieve a partial or complete response after completion of chemotherapy proceed to vaccine therapy. Vaccine therapy: Patients receive vaccine comprising autologous tumor cells and GM.CD40L intradermally on day 1 and low-dose interleukin-2 (IL-2) subcutaneously twice daily on days 1-14. Treatment repeats every 28 days for 4 courses. Patients who have stable or responding disease at 12 months receive 4 additional courses of booster vaccine and low-dose IL-2 as above. Treatment continues in the absence of disease progression or unacceptable toxicity. Patients are followed every 3 months until disease progression and then annually thereafter.	
Recruiting	Multipeptide Vaccine for Advanced Breast Cancer Conditions: Breast Neoplasm; Breast Cancer; Cancer of the Breast; Carcinoma, Ductal Intervention: Biological: hTERT/Survivin Multi-Peptide Vaccine 2007	hTERT/Survivin Multi-Peptide Vaccine With Daclizumab (a-CD25) and Prevnar(augment T-helper cell immunity):
	•Immunologic response [After 4th vaccination, then after every 3-4 vaccinations, and then every 6 months]. **Target of daclizumab (a-CD25) including Treg cells, and inhibits its proliferation.** **[Detailed Description]:** Patients with advanced breast cancer may often fail standard of care treatments for metastatic disease. This research is studying a combinations of agents that impact the immune system. About >85% of all human cancers, including breast cancer, express telomerase (hTERT) activity. Targeting hTERT immunologically may also minimize immune escape due to antigen loss because mutation or deletion of hTERT may be incompatible with sustained tumor growth. hTERT Multi-Peptide Vaccine is made up of 1540 hTERT peptide and cryptic peptides selected for "low-affinity" binding to HLA-A2 in order to increase the likelihood that the host immune system would ignore them, and then they have been modified by changing the first amino acid of the peptides to tyrosine in order to increase HLA - A2 affinity. The two "heteroclitic" peptides are R572Y (YLFFYRKSV) and D988Y (YLQVNSLQTV), which bind HLA-A2 with high avidity and elicit specific CTL (cytotoxic T lymphocyte) responses using healthy donor mononuclear cells in vitro. In addition, in mouse models, these peptide vaccines elicit lytic CTL responses which are protective against tumor challenges using a TERT-expressing murine tumor. Subjects will also be immunized with a peptide vaccine derived from survivin, an important anti-apoptotic protein which is overexpressed in a broad range of malignancies including breast cancer. Survivin may be an ideal and "universal" tumor antigen since it is overexpressed in a wide variety of cancers yet terminally differentiated adult cells do not express the protein. CMV derived CTL epitopes will be used as positive control peptides. Daclizumab is a humanized anti-human CD25 monoclonal antibody that binds specifically to CD25 expressing cells, including Treg cells, and inhibits its proliferation. Prevnar is designed to augment T-helper cell immunity.	
Completed	Vaccine Therapy Plus Biological Therapy in Treating Patients With Relapsed Prostate Cancer Condition: Prostate Cancer	Multivalent Conjugate Vaccine (Globo H-GM2-Lewis-y-MUC1-32-mer-TF(c)-Tn(c)-

	Interventions:	Biological: Globo H-GM2-Lewis-y-MUC1-32-mer-TF(c)-Tn(c)-KLH conjugate vaccine; Biological: QS21 2001	KLH conjugate vaccine/ QS21) For Prostate Cancer.
	Antibody response. post-immunization changes in prostate-specific antigen levels and other objective parameters of the disease. **OBJECTIVES:** Determine the safety of a multivalent conjugate vaccine comprising Globo H, GM2, Lewis-y, MUC-1-32-mer, TF(c), and Tn(c) antigens conjugated to keyhole limpet hemocyanin (KLH) with adjuvant QS21 in patients with biochemically relapsed prostate cancer. Measure the antibody response against the individual components of the vaccine and correlate the response to subsequent clinical course in patients treated with this vaccine. Assess post-immunization changes in prostate-specific antigen levels and other objective parameters of the disease in these patients. OUTLINE: Patients receive Globo H, MUC-1-32mer, GM2, Lewis-y, Tn(c), TF(c)-KLH conjugate vaccine with adjuvant QS21 subcutaneously weekly on weeks 1, 2, 3, 7, 10, 21, 43, and 55. (Patients are followed every 3 months.		
Completed	Vaccine Therapy Plus Biological Therapy in Treating Patients With Prostate Cancer		Bivalent MUC-2-Globo H-KLH conjugate vaccine with GPI-0100 (Adjuvant).
	Condition:		
	Interventions:	Biological: GPI-0100; Biological: MUC-2-Globo H-KLH conjugate vaccine 2001	
	Optimal antibody response. post-immunization changes in prostate-specific antigen levels and other objective parameters of disease. **OBJECTIVES:** Determine the optimal (in terms of antibody response) and safe dose range of glycosylated MUC-2-Globo H-KLH conjugate vaccine with adjuvant GPI-0100 in patients with biochemically relapsed prostate cancer. Assess post-immunization changes in prostate-specific antigen levels and other objective parameters of disease in these patients. OUTLINE: This is a dose-escalation study of GPI-0100. Patients receive glycosylated MUC-2-Globo H-KLH conjugate vaccine with adjuvant GPI-0100 subcutaneously weekly on weeks 0-2, 6, 14, and 26 in the absence of unacceptable toxicity or disease progression. Cohorts of 5 patients receive escalating doses of GPI-0100 until the optimal dose, based on antibody response, is reached. Patients are followed every 3 months.		
Active, not recruiting	Vaccine Therapy in Treating Patients With Ovarian Epithelial or Primary Peritoneal Cancer		ovarian cancer peptide vaccine (ovarian cancer synthetic peptides)/ incomplete Freund's adjuvant/ GM-CSF /tetanus toxoid helper peptide emulsified in Montanide ISA-51
	Conditions:	Ovarian Cancer; Peritoneal Cavity Cancer	
	Interventions:	Biological: incomplete Freund's adjuvant; Biological: ovarian cancer peptide vaccine; Biological: sargramostim; Biological: tetanus toxoid helper peptide; Procedure: adjuvant therapy 2004	
	Immunogenicity Patients were followed at 1 week, 1 month, every 3 months for 9 months, every 6 months for 1 year, and then annually thereafter. **OBJECTIVES:** Determine the safety and immunogenicity of adjuvant vaccine comprising ovarian cancer synthetic peptides, tetanus toxoid helper peptide, and sargramostim (GM-CSF) emulsified in Montanide ISA-51 in patients with previously treated ovarian epithelial or primary peritoneal cancer. OUTLINE: This is an open-label study. Patients receive vaccine comprising ovarian cancer synthetic peptides, tetanus toxoid helper peptide, sargramostim (GM-CSF), and Montanide ISA-51 subcutaneously and intradermally to 2 different sites on days 1, 8, and 15. On day 22, patients undergo removal of the lymph node draining the vaccination site to determine whether the immune system is responding to the vaccine. Patients then receive additional vaccine as above only to the primary vaccination site on days 29, 36, and 43.		
Completed	Vaccine Therapy in Treating Patients With Metastatic Cancer		MAGE-12 Peptide Vaccine with GM-CSF emulsified in Montanide ISA-51.
	Conditions:	Lung Cancer; Adult Soft Tissue Sarcoma; Colorectal Cancer; Bone Cancer; Ovarian Sarcoma; Melanoma; Colon Cancer; Rectal Cancer; Breast Cancer; Eye Cancer; Uterine Sarcoma	
	Interventions:	Drug: interleukin-2; Drug: MAGE-12 peptide vaccine; Drug: Montanide ISA-51 2007	

	Immunologic response, as measured by an in vitro sensitization assay. Immunologic parameters and the clinical response rate. **OBJECTIVES:** I. Determine the toxicity profile of MAGE-12 peptide vaccine in patients with refractory metastatic cancer that expresses MAGE-12 antigen. II. Determine whether an immunologic response, as measured by an in vitro sensitization assay, can be obtained after administration of this regimen in these patients. III. Determine a frequency of administration for this regimen based on immunologic response in these patients. IV. Determine other immunologic parameters in these patients treated with this regimen. V. Determine the clinical response rate in these patients treated with this regimen. **PROTOCOL OUTLINE**: This is a randomized study. Patients are stratified according to disease (metastatic cutaneous melanoma vs other tumor types). Patients are randomized to one of two treatment arms. Arm I: Patients receive MAGE-12 peptide vaccine emulsified in Montanide ISA-51 adjuvant subcutaneously (SC) weekly for 4 doses. Arm II: Patients receive MAGE-12 peptide vaccine emulsified in Montanide ISA-51 adjuvant SC once every 3 weeks for 4 doses. Patients with progressive disease may receive interleukin-2 IV over 15 minutes every 8 hours, beginning on the day after each immunization and continuing for up to 4 days. Patients achieving stable disease or a mixed, partial, or complete response continue on vaccine therapy alone for up to 24 total doses. Patients are followed at 3 weeks.	
Completed	Vaccine Therapy in Treating Patients With Stage II, Stage III, or Stage IV Ovarian Epithelial, Fallopian Tube, or Peritoneal Conditions: Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer Interventions: Biological: fowlpox-NY-ESO-1 vaccine; Biological: recombinant vaccinia-NY-ESO-1 vaccine; Procedure: adjuvant therapy 2005	Recombinant Vaccinia-NY-ESO-1 (rF-NY-ESO-1) and Recombinant Fowlpox-NY-ESO-1 (rF-NY-ESO-1) for Patients Tumors Express NY-ESO-1 or LAGE-1 Antigen.
	Remission rate at 1 month, every 2 months for 1 year, and then annually post-treatment. •NY-ESO-1 specific cellular and humoral immunity at 1 month, every 2 months for 1 year. NY-ESO-1 antigen specific cellular or humoral immunity at 1 month, every 2 months for 1 year, and then annually post-treatment. NY-ESO-1 specific antibody and CD8+ T cells. ◦NY-ESO-1 by RT-PCR analysis OR immunohistochemistry. ◦LAGE-1 by RT-PCR. **OUTLINE: T**his is an open-label study. Patients receive vaccinia-NY-ESO-1 vaccine intradermally on day 1 and fowlpox-NY-ESO-1 vaccine subcutaneously on days 29, 57, 85, 113, 141, and 169 in the absence of disease progression or unacceptable toxicity. After completion of study treatment, patients are followed at 1 month, every 2 months for 1 year, and then annually thereafter.	
Recruiting	Gemcitabine and Capecitabine With or Without Vaccine Therapy in Treating Patients With Locally Advanced or Metastatic Condition: Pancreatic Cancer Interventions: Biological: GM-CSF; Biological: telomerase peptide vaccine GV1001; Drug: capecitabine; Drug: gemcitabine hydrochloride 2007	After chemotherapy, telomerase peptide vaccine GV1001[TELOVAC] with GM-CSF.

	•Objective response rate as assessed by RECIST criteria. •Survival and response as assessed by DTH. After completion of study treatment, patients are followed every 3 months. **OUTLINE:** This is a prospective, controlled, randomized, open-label, multicenter study. Patients are stratified according to stage of disease (locally advanced vs metastatic) and ECOG performance status (0 vs 1 vs 2). Patients are randomized to 1 of 3 treatment arms. Arm I: Patients receive gemcitabine hydrochloride IV over 30 minutes on days 1, 8, and 15 and oral capecitabine twice daily on days 1-21. Treatment repeats every 4 weeks in the absence of disease progression or unacceptable toxicity. Arm II: Patients receive gemcitabine hydrochloride and capecitabine as in arm I. Treatment repeats every 4 weeks for up to 2 courses in the absence of disease progression or unacceptable toxicity. Patients then receive sargramostim (GM-CSF) intradermally (ID) and telomerase peptide vaccine GV1001 ID on days 1, 3, and 5 in week 9, once a week in weeks 10-12 and 14, and then once a month in the absence of disease progression or unacceptable toxicity. Patients who develop disease progression while on vaccine therapy, discontinue vaccine therapy and then restart treatment with gemcitabine hydrochloride and capecitabine. Patients receive gemcitabine hydrochloride and capecitabine as above and continue treatment in the absence of further disease progression or unacceptable toxicity. Arm III: Patients receive gemcitabine hydrochloride and capecitabine as in arm I. Patients also receive GM-CSF ID and telomerase peptide vaccine GV1001 ID on days 1, 3, and 5 in week 1, once weekly in weeks 2, 3, 4 and 6, and then once a month in the absence of disease progression or unacceptable toxicity. Quality of life is assessed at baseline and at 8 weeks and then every 12 weeks during study treatment. After completion of study treatment, patients are followed every 3 months. Peer Reviewed and Funded or Endorsed by Cancer Research UK	
Completed	Vaccine Therapy Plus QS21 in Treating Patients With Progressive Prostate Cancer Condition: Prostate Cancer Interventions: Biological: MUC-2-KLH vaccine; Biological: QS21 2000	Glycosylated MUC-2-KLH Peptide Conjugate Vaccine Plus the Immunological Adjuvant QS21:
	An antibody, helper T cell, and/or cytotoxic T cell response against glycosylated MUC-2. Patients are followed every 3 months for 1 year or until disease progression. OBJECTIVES: I. Determine if immunization with glycosylated MUC-2 antigen with keyhole limpet hemocyanin (KLH) conjugate plus immunological adjuvant QS21 induces an antibody, helper T cell, and/or cytotoxic T cell response against glycosylated MUC-2 in patients with progressive prostate cancer. II. Determine the safety of this treatment regimen in this patient population. III. Determine the effect of glycosylated MUC-2 antigen with KLH conjugate on the T cell response against MUC-2 and by skin testing in these patients. IV. Assess the post immunization changes in prostate specific antigen levels and other objective parameters of disease including radionuclide bone scan and/or measurable disease in these patients. OUTLINE: Patients receive vaccination with glycosylated MUC-2 antigen 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 disease progression.	
Active, not recruiting	Vaccine Therapy in Treating Patients With Stage IIIC or Stage IV Malignant Melanoma Condition: Melanoma (Skin) Interventions: Biological: GM.CD40L cell vaccine; Biological: autologous tumor cell vaccine 2005	GM-CSF-Producing and CD40L-Expressing Bystander Cell Line (GM.CD40L) in the Formulation of Autologous Tumor Cell-Based

	Tumor response rate and time to tumor progression by RECIST criteria and DFS/OS at 3, 6, 9, and 12 months **•Anti-tumor immune response as assessed by ELISPOT assays, tetramer assays for T cell activity in peripheral blood mononuclear cells, and DTH skin test at 3 and 6 months.** **OUTLINE:** Patients undergo surgical resection of malignant lymph nodes or systemic metastases (isolated metastases or symptomatic lesions) for collection of autologous tumor cells for vaccine production. Vaccine is formulated by combining equal volumes of irradiated autologous tumor cells and irradiated cells from a cell line producing sargramostim (GM-CSF) and expressing CD40L (GM.CD40L). Patients receive vaccine comprising autologous tumor cells and GM.CD40L intradermally on day 1. Treatment repeats every 28 days for 3 courses. Patients with stable or responding disease at 3 months receive 3 additional courses of booster vaccine. Patients with no evidence of disease progression at 12 months receive 3 more courses of booster vaccine. Treatment continues in the absence of disease progression or unacceptable toxicity. Patients are followed every 3 months for 1 year, every 6 months for 1 year, and then annually thereafter.		
Suspended	Immunization of Patients With Non Small Cell Lung Cancer (NSCLC)		semi-allogeneic human fibroblasts (MRC-5) transfected with DNA:
	Condition:	Non Small Cell Lung Cancer (NSCLC)	
	Intervention:	Biological: semi-allogeneic human fibroblasts (MRC-5) transfected with DNA 2008	
	DNA-based vaccine to induce immune responses to the autologous tumor (if available) and/or the vaccine. [Time Frame: 14] All patients will be		
Active, not recruiting	Vaccine Therapy and Chemotherapy With or Without Tetanus Toxoid Compared With Chemotherapy Alone in Treating Patients With Metastatic Colorectal Cancer		ALVAC-CEA/B7.1 Vaccine Administered with or without tetanus toxoid, vs chemotherapy alone : Determine whether tetanus toxoid enhances the immune response
	Condition:	Colorectal Cancer	
	Interventions:	Biological: ALVAC-CEA-B7.1 vaccine; Biological: tetanus toxoid; Drug: FOLFIRI regimen; Drug: fluorouracil; Drug: irinotecan hydrochloride; Drug: leucovorin calcium 2001	
Recruiting	Tumor and Vaccine Site With a Toll Like Receptor (TLR) Agonist		pDCs at the Tumor and Vaccine Site With a Toll Like Receptor (TLR) Agonist (gp100 peptide, R848 gel, MAGE-3 peptide): vaccine, gp100, when given in combination with resiquimod (R848), can help to stimulate the immune system against melanoma.
	Condition:	Melanoma peptide vaccine	
	Interventions:	Drug: gp100; Drug: R848 gel; Drug: MAGE-3 2009	
	Immune Responses of Vaccine+R848 to Vaccine Alone [8 weeks] laboratory parameters of T-cell priming, T-cell migration to tumor, and inflammation at the vaccine and tumor sites. **The goal of this clinical research study is to learn if the vaccine, gp100, when given in combination with resiquimod (R848), can help to stimulate the immune system against melanoma.** **Primary:** To compare the ability of vaccine in combination with Toll Like Receptor (TLR) stimulation at the site of vaccine (R848; Resiquimod) to vaccine alone in the ability to enhance the generation of circulating antigen-specific T-cells (T-cell priming). **Secondary:** A. Evaluate the ability of locally administered TLR agonist (R848 gel) to activate innate immune cells at the vaccine site. **B**. Evaluate the ability of R848 gel, administered at the tumor site, to: Induce inflammation and upregulation of adhesion molecules on tumor vasculature Enhance T-cell infiltration into tumor / Generate T-cells against additional tumor antigens, not present in the vaccine (i.e., antigen spreading). **C.** To assess the association between clinical response with laboratory parameters of T-cell priming, T-cell migration to tumor, and inflammation at the vaccine and tumor sites.		

Active, not recruiting	An Immunotherapy Vaccine Against Grade IV Brain Tumors		Immunotherapy Vaccine Against Tumor-Specific EGFRvIII. Response Rate [Time Frame: Continous
	Condition:	Brain Neoplasms	
	Intervention:	Biological: PEP-3-KLH 2004	
Completed	Vaccine Therapy in Treating Patients With Stage II or Stage III Colon Cancer That Has Been Removed During Surgery		BCG vaccine by autologous tumor cell vaccine with chemotherapy: Immunogenicity of adjuvant autologous tumor cell vaccine. Patients are followed at 90 days and 6 months.
	Condition:	Colorectal Cancer	
	Interventions:	Biological: BCG vaccine; Biological: autologous tumor cell vaccine; Drug: fluorouracil; Drug: leucovorin calcium; Procedure: adjuvant therapy 2001	
Completed	Vaccine Therapy Plus Sargramostim in Treating Patients With Stage III or Stage IV Cancer		HER-2/Neu Peptide Incorporated Into PLG Microspheres with GM-CSF. cytotoxic T lymphocytes (CTL) specific for the HER-2 protein
	Conditions:	Breast Cancer; Lung Cancer; Ovarian Cancer	
	Interventions:	Biological: HER-2/neu peptide vaccine; Biological: sargramostim 2000	
Recruiting	Vaccine Therapy in Preventing Human Papillomavirus Infection in Young Participants Who Are Either HIV-Positive or HIV-Negative		Quadrivalent Human Papilloma Virus (HPV) (Types 6,11, 16, 18) Recombinant Vaccine in HIV-Infected and HIV-Negative Pre-Adolescents, Adolescents and Young Adults: Vaccine-induced antibody titer months 7, 12, 24, and 48. Vaccine-induced HIV-1 RNA levels. Correlation of increase in HPV titer
	Conditions:	Anal Cancer; Cervical Cancer; Nonneoplastic Condition; Penile Cancer; Precancerous Condition; Vulvar	
	Interventions:	Biological: quadrivalent human papillomavirus (types 6, 11, 16, 18) recombinant vaccine; Genetic: DNA analysis; Genetic: RNA analysis; Genetic: protein analysis; Other: immunologic technique; Other: laboratory biomarker analysis; Other: survey administration 2008	
Terminated	Vaccine Therapy and Sargramostim With or Without Docetaxel in Treating Patients With Metastatic Lung Cancer or Metastatic Colorectal Cancer		Recombinant fowlpox-CEA(6D)/TRICOM vaccine and recombinant vaccinia-CEA(6D)-TRICOM vaccine with docetaxel/ GM-CSF: Immune response as assessed by T-cells monthly; CEA-specific T-cell immune responses by ELISPOT assay. Antitumor response. Patients are followed every 6 months for 2 years and then annually for 13 years.
	Conditions:	Colorectal Cancer; Lung Cancer 2004	
	Interventions:	Drug: docetaxel; Drug: recombinant fowlpox-CEA(6D)/TRICOM vaccine; Drug: recombinant vaccinia-CEA(6D)-TRICOM vaccine; Drug: sargramostim; Procedure: biological therapy; Procedure: chemotherapy; Procedure: colony-stimulating factor therapy; Procedure: cytokine therapy; Procedure: non-specific immune-modulator therapy; Procedure: recombinant viral vaccine; Procedure: vaccine therapy	
Recruiting	Trial of Bi-shRNA-furin and Granulocyte Macrophage Colony Stimulating Factor (GMCSF) Augmented Autologous Tumor Cell Vaccine for Advanced Cancer		Bi-shRNAfurin and GMCSF Augmented Autologous Tumor Cell Vaccine: Bi-shRNAfurin and GMCSF Augmented Autologous Tumor Cell Vaccine. progression
	Condition:	Solid Tumors	
	Intervention:	Biological: FANG 2010	

	Preliminary studies with a variety of vaccines suggest target accessibility (potential immunogenicity) in a variety of solid tumors to immune directed approaches. In an effort to overcome limitations of immunostimulatory cancer vaccines, we have designed a novel autologous vaccine to address inability to fully identify cancer associated antigens, antigen recognition by the immune system (i.e. antigen to immunogen), effector potency, and cancer-induced resistance. We have completed clinical investigations using two different gene vaccine approaches to induce enhancement of tumor antigen recognition which have demonstrated therapeutic efficacy. Specifically, both the use of a GMCSF gene transduced vaccine (GVAX®) and a TGFβ2 antisense gene vaccine (Lucanix®), in separate trials, have demonstrated similar beneficial effects without any evidence of significant toxicity in advanced cancer patients. The GMCSF transgene directly stimulates increased expression of tumor antigen(s) and enhances dendritic cell migration to the vaccination site. TGFβ2 blockade following intracellular TGFβ2 antisense gene expression reduces production of immune inhibiting activity at the vaccine site. This appears to be one of the primary mechanisms of inhibition of immune responsiveness in glioblastoma and lung cancer. In a subsequent Phase I trial we combined both active principles in one autologous vaccine, TAG. TAG vaccine has an excellent safety profile in the first nineteen patients treated (enrollment open to any solid tumor) with one documented CR (melanoma). However, TGFβ1 is the dominant TGFβ family inhibitory effector in the majority of other solid tumors. We describe a unique method of inhibiting both TGFβ1 and TGFβ2 through RNA interference with Furin. We will harvest autologous cancer cells from patients with advanced refractory cancer. We have constructed a bi-shRNAfurin / GMCSF (FANG) expression vector plasmid and have successfully demonstrated preclinical activity of the vector function following transfection by electroporation and irradiation of ex vivo autologous tumor cells	
Completed	Vaccine Therapy in Treating Patients With Stage III Non-Small Cell Lung Cancer Condition: Lung Cancer Interventions: Biological: mutant p53 peptide pulsed dendritic cell vaccine; Procedure: adjuvant therapy 2001	mutant p53 peptide pulsed Cultured Autologous dendritic cell vaccine with adjuvant: DFS by CTEP CTC v2.x + OS by CTEP CTC v2.x. Immunological response by ELISPOT before and 2 weeks after last vaccine. Patients are followed for 5 years
Completed	Vaccine Therapy in Treating Patients With Transitional Cell Cancer of the Bladder Condition: Bladder Cancer Interventions: Biological: BCG vaccine; Biological: NY-ESO-1 peptide vaccine; Biological: sargramostim 2003	NY-ESO-1 Protein Immunization of Post-Cystectomy Patients Expressing NY-ESO-1 or LAGE-1 Antigen with BCG and GM-CSF. Immunological profile (NY-ESO-1 antibody, CD8+ cells, and delayed-type hypersensitivity / DTH). Patients are followed at 2 and 6 weeks.
Active, not recruiting	A Phase I Clinical Trial of Autologous Dendritic Cell Vaccine for Recurrent Ovarian or Primary Peritoneal Cancer Conditions: Ovarian Cancer; Peritoneal Cancer Intervention: Biological: DCVac-L 2008	Autologous Dendritic Cell Vaccine Leaded With Autologous Tumor Cell Lysate. Immunogenicity of DCVax-L administered intradermally in patients combined with intravenous bevacizumab and oral metronomic cyclophosphamide. [2 years]

	Detailed Description: Subjects with recurrent epithelial ovarian carcinoma or recurrent primary peritoneal cancer, for whom autologous tumor or malignant effusion has been harvested and is available for lysate preparation, are eligible, provided all other eligibility criteria are fulfilled. Harvested tumor or malignant effusion will be shipped to Cognate BioServices (Sunnyvale, CA) for preparation of lysate. If sufficient amount of lysate for vaccine can be generated, subjects will be enrolled to the study. Subjects will undergo apheresis on day -35 to -29 to harvest peripheral blood mononuclear cells (PBMC). The apheresis product will be shipped to Cognate BioServices, where DC will be prepared and pulsed with autologous lysate according to proprietary technology. Following apheresis, subjects will receive two cycles of biological antiangiogenesis/immunomodulatory therapy comprising intravenous bevacizumab at 10 mg/kg on day -28 and -14, which may be followed by 7 days of oral metronomic cyclophosphamide at 50 mg daily (days -28 to -21, and -14 to -7, respectively). Subjects will receive three doses of intradermal vaccination with ~5-10 x 106 dendritic cells (DCVax-L) on days 0, 14 and 28. Subjects will also receive intravenous bevacizumab at 10 mg/kg concurrently with intradermal DCVax-L on day 0 and 14, which may be followed by oral cyclophosphamide at 50 mg for 7 days (days 0 to 7, and 14 to 21, respectively). The last DCVax-L (day 28) may be followed by oral cyclophosphamide at 50 mg daily x 7 days (days 28 to 35), but no bevacizumab will be given on day 28. Prevnar, an FDA approved seven-valent vaccine against Pneumococcus pneumoniae, will be given intramuscularly on day 0 as positive control of immune responsiveness. Two weeks following third vaccine dose (day 42), patients will undergo immune assessment. Subjects will be contacted every 6 months for 5 years and then annually for survival. Subject will have the option of enrolling in other combinatorial immunotherapy trials when these are available, if they satisfy enrollment criteria. Subjects will have the option of continuing vaccination every two months till exhaustion of DCVax-L or disease progression, whichever occurs first.	
Recruiting	Ovarian Cancer and Immune Response to Flu Vaccine Condition: Ovarian Cancer Intervention: Biological: The current season's trivalent killed influenza vaccine 2008	Immunogenicity of Killed Influenza Vaccine in Patients With Ovarian, Fallopian Tube, and Primary Peritoneal Cancer:
Active, not recruiting	Vaccine Therapy in Treating Patients With Stage I, Stage II, or Stage III Non-Small Cell Lung Cancer Condition: Lung Cancer Interventions: Biological: allogeneic tumor cell vaccine; Biological: therapeutic autologous dendritic cells; Procedure: adjuvant therapy 2005	
	Allogeneic tumor cell vaccine + therapeutic autologous dendritic cells with adjuvant. Immunologic response and Immunologic response. Patients are followed monthly for 4 months, every 6 months for 2 years, and then periodically thereafter	
Active, not recruiting	Vaccine Therapy in Treating Patients With Epstein-Barr Virus-Related Cancer Conditions: Gastric Cancer; Head and Neck Cancer; Lymphoma; Lymphoproliferative Disorder; Nonneoplastic Interventions: Biological: EBNA1 C-terminal/LMP2 chimeric protein-expressing recombinant modified vaccinia Ankara vaccine; Other: laboratory biomarker analysis; Other: pharmacological study 2010	
	EBNA1 C-terminal/LMP2 chimeric protein-expressing recombinant modified vaccinia Ankara vaccine: local skin reactions considered related to the vaccination. ELIspot assays of the frequency of T-lymphocytes recognizing major histocompatibility complex (MHC) class I and II-restricted epitopes within EBNA1 and LMP2 in peripheral blood at sequential time-points before, during, and up to 9 mo. EBV-genome levels in plasma. patients are followed up at weeks 11 and 14, and at 6 months and 1 year.	
Completed	Vaccine Therapy in Treating Patients With Advanced Kidney Cancer	

	Condition:	Kidney Cancer	
	Interventions:	Biological: dendritic cell vaccine therapy; Procedure: conventional surgery 2000	
	Multi-Antigen Loaded Dendritic Cell Vaccine Evaluate the immunologic response to this regimen in this patient population. III. Evaluate the clinical response to this regimen in this patient population. Patients receive vaccination with irradiated autologous tumor lysate (TuLy) intradermally (ID) on day 0 followed by vaccination with multiantigen liposome loaded dendritic cells (DC) ID		
Active, not recruiting	HER-2/Neu Vaccine Plus GM-CSF in Treating Patients With Stage III or Stage IV Breast, Ovarian, or Non-Small Cell Lung Cancer		
	Conditions:	Breast Cancer; Lung Cancer; Ovarian Cancer	
	Interventions:	Biological: HER-2/neu peptide vaccine; Biological: sargramostim 1999	
	HER-2/Neu Peptide Based Vaccine With GM-CSF. Determine whether immunity can be elicited with peptides derived from the extracellular domain of the HER-2/neu protein. IV. Determine whether cytotoxic T cells specific for the HER-2/neu protein		
Recruiting	PSMA and TARP Peptide Vaccine With Poly IC-LC Adjuvant in HLA-A2 (+) Patients With Elevated PSA After Initial Definitive Treatment		
	Condition:	Prostate Cancer	
	Intervention:	Biological: peptide vaccine (PSMA and TARP peptide vaccine with Poly IC-LC adjuvant) 2008	
	Combination PSMA and TARP Peptide With Poly IC-LC Adjuvant in HLA-A2 (+) Patients. Impact of the vaccine on the pattern of PSA change [ap. 24 months]. 1.Estimate the frequency of immunological efficacy of the vaccine by comparison of the in vitro ELISPOT for each antigen (PSMA, TARP). 3.Describe the impact of the vaccine on the pattern of PSA change Detailed Objectives: 1.Estimate the frequency of immunological efficacy of the vaccine by comparison of the in vitro ELISPOT test results, for each antigen (PSMA, TARP) from peripheral blood specimens collected during the periods of time defined as "before", "during" and "after" vaccination. 2.Study the safety and toxicity of varying doses of polypeptide vaccines: PSMA27-35-PSMA687-701 (VLAGGFFLLYRHVIYAPSSHNKYA) and TARP13-35 (LQLLKQSSRRLEHTFMFLRNFSL) administered with a fixed dose of Poly IC-LC (2 mg total/treatment) as adjuvant. 3.Describe the impact of the vaccine on the pattern of PSA change in 2 subsets of patients: with castrate testosterone; with non-suppressed testosterone level/not on hormone therapy. 4.Identify if there is a basis for selection of a dose of the PSMA and the TARP polypeptide vaccines for future phase II development of this vaccination strategy, considering the dose range tested		
Completed	Prime-Boost Dose Scheduling Trial for Human GM-CSF Gene Transduced Irradiated Prostate Allogeneic Cancer Cell Vaccines (Allogeneic Prostate GVAX®)		Human GM-CSF Gene Transduced Irradiated Prostate Allogeneic Cancer Cell Vaccines
	Condition:	Prostate Cancer	
	Intervention:	Biological: Immunotherapy allogeneic GM-CSF secreting cellular vaccine 2005	
Recruiting	Wilm's Tumor 1 Protein Vaccine to Treat Cancers of the Blood		

	Conditions:	Leukemia, Acute Myelogenous (AML); Leukemia, Acute Lymphocytic (ALL); Leukemia, Chronic Myelogenous (CML); Myelodysplastic Syndrome (MDS); Non-Hodgkin's Lymphoma (NHL)	
	Interventions:	Drug: WT1 Peptide-Pulsed Dendritic Cells; Drug: Donor Lymphocytes; Drug: IL-4; Drug: KLH; Drug: WT1 Peptides; Drug: Endotoxin 2009	
	WT1 Peptide-Loaded Allogeneic Dendritic Cell Vaccine and Donor Lymphocyte Infusion immune response to the WT1 vaccine: Frequency and severity of GVHD. Whether immunologic responses to WT1-specific peptides. immunologic and/or clinical responses may be associated with the degree of WT1 expression by malignant cells or pre-existing donor The objective of this study is to evaluate the safety and efficacy of priming vaccinations, and subsequent boosting vaccinations with Human GM-CSF Gene Transduced Irradiated Prostate Allogeneic Cancer Cell Vaccines (Allogeneic Prostate GVAX®). Clinical observations and laboratory measurements will be monitored to evaluate safety and toxicity. Additionally, the antitumor effects of Allogeneic Prostate GVAX® on serum PSA levels will be evaluated and antitumor responses will be quantitated.	
Not yet recruiting	Vaccine Therapy in Preventing Human Papillomavirus Infection in Young HIV-Positive Male Patients Who Have Sex With Males		Quadrivalent Vaccine in Young HIV-Positive Males Who Have Sex With Males
	Conditions:	Anal Cancer; Nonneoplastic Condition; Penile Cancer; Precancerous Condition	
	Interventions:	Biological: quadrivalent human papillomavirus (types 6, 11, 16, 18) recombinant vaccine; Other: laboratory biomarker analysis 2010	
Recruiting	Vaccine Therapy in Treating Patients With Metastatic, Progressive Prostate Cancer		
	Condition:	Prostate Cancer	
	Intervention:	Biological: NY-ESO-1/LAGE-1 HLA class I/II peptide vaccine 2008	
	•Compare the response induced by immunotherapy with a combined class-I and class-II NY-ESO-1/LAGE-1 vaccine. inclusion of class-II epitopes in a peptide vaccine will result in a better antitumor immune response than class-I epitopes alone. Antitumor activity by antigen response assays including cytokine elaboration, changes in frequency of peripheral T cells that recognize tumor, and intra/peritumoral cellular infiltrates and cytokine expression Primary •Evaluate the safety and tolerance of NY-ESO-1/LAGE-1 class-I and class-II vaccine administered subcutaneously in patients with androgen-independent metastatic prostate cancer. Secondary •Compare the response induced by immunotherapy with a combined class-I and class-II NY-ESO-1/LAGE-1 vaccine to responses obtained to either class I or class II peptides alone. •Evaluate whether the inclusion of class-II epitopes in a peptide vaccine will result in a better antitumor immune response than class-I epitopes alone. •Determine antitumor activity by antigen response assays including cytokine elaboration, changes in frequency of peripheral T cells that recognize tumor, and intra/peritumoral cellular infiltrates and cytokine expression in responding and nonresponding metastasis. OUTLINE: Patients receive NY-ESO-1/LAGE-1 peptide vaccine subcutaneously every other week for 12 weeks in the absence of disease progression or unacceptable toxicity. The initial cohorts of patients are treated with one course of either MHC Class I-binding or MHC Class II-binding peptides. If these Class I or Class II binding peptides are safe individually, subsequent cohorts of patients with appropriate HLA type receive both types of peptides in combination.		
Recruiting	A Safety and Immunology Study of a Modified Vaccinia Vaccine for HER-2(+) Breast Cancer After Adjuvant Therapy		
	Condition:	Breast Cancer	

	Intervention: Biological: MVA-BN-HER2 2010	
	MVA-BN®-HER2 is a candidate breast cancer immunotherapy product comprised of a highly attenuated non-replicating vaccinia virus, MVA-BN®, engineered to encode a modified form of the HER-2 protein. Immune response [18 months].	
Completed	Study of the Feasibility to Derive Vaccine From Tumor Tissue in Patients With Non-Small Cell Lung Cancer Conditions: Non-Small-Cell Lung Carcinoma; Lung Cancer; Pulmonary Cancer Intervention: Biological: HSPPC-96 2004	
	Autologous Vaccine (HSPPC-96) From Tumor Tissue: efficacy profile, to evaluate disease recurrence in patients, and to evaluate overall survival. evaluate disease recurrence in patients receiving, and to evaluate overall survival in patients receiving HSPPC-96. Primary Outcome Measures: •The primary goal of this trial is to determine if HSPPC-96 can be made from the tumor tissue of patients with resectable non-small cell lung cancer. Secondary Outcome Measures: •The secondary goals are to further characterize the safety and efficacy profile, to evaluate disease recurrence in patients, and to evaluate overall survival in patients receiving HSPPC-96. Estimated Enrollment: 20 Study Start Date: September 2003 Primary Completion Date: November 2007 (Final data collection date for primary outcome measure) Detailed Description: Antigenics is enrolling patients in a Phase II study testing the feasibility to derive an autologous investigational vaccine (HSPPC-96) from the tumor tissue of patients with resectable non-small cell lung cancer. All patients will undergo surgery to remove the tumor and will be followed for recurrence and overall survival. The primary goal of this trial is to determine if HSPPC-96 can be made from the tumor tissue of patients with resectable non-small cell lung cancer. The secondary goals are to further characterize the safety and efficacy profile, to evaluate disease recurrence in patients receiving, and to evaluate overall survival in patients receiving HSPPC-96. HSPPC-96 is an investigational, immunotherapeutic agent made from an individual patient's own tumor, which is collected at the time of surgery. A portion of the tumor tissue is sent to Antigenics' manufacturing facility where it will undergo processing to create a vaccine. This vaccine may help the patient's immune system	
Active, not recruiting	Study of Cancer Peptides Vaccine Plus GM-CSF as Adjuvant Treatment for High Risk (TXN2-3M0) or Metastatic Breast Cancer With No Evidence of Disease Condition: Breast Cancer Intervention: Biological: OCPM Immunotherapeutic Vaccine	
	Cancer Peptides Plus GM-CSF and Adjuvant (Montanide ISA 51) Following Completion of Prescribed Chemotherapy or Trastuzumab: Tumor antigen specific immune response after 3 immunizations. They will receive the peptide vaccine subcutaneously on weeks 0,1,2,4,5, and 6 and then receive the immunizations every 1 month for 6 months or disease recurrence	
Recruiting	Vaccine Therapy in Treating Patients With Ductal Carcinoma In Situ of the Breast Condition: Breast Cancer	

	Interventions:	Biological: HER-2/neu peptide vaccine; Biological: therapeutic autologous dendritic cells 2009	
	HER-2/Neu Pulsed DC1 Vaccine: •Immune response + HER2/neu molecular expression pre-and post-vaccination. Clinical response pre-and post-vaccination. patients are followed up every 6 months for 5 years		
Completed	Prostatic Acid Phosphatase (PAP) Vaccine in Patients With Prostate Cancer		DNA-based Vaccine Targeting Prostatic Acid Phosphatase (PAP):
	Condition:	Prostate Cancer	
	Intervention:	Biological: pTVG-HP with rhGM-CSF 2007	
	•The primary objective of this phase I study is to determine if the vaccination with serial intradermal vaccinations of a DNA-based vaccine targeting PAP, with GM-CSF is safe (the investigators will be evaluating the degree of toxicity seen) [for 15 year follow-up] •To determine whether PAP-specific IFNγ-secreting CD8+ T cells can be generated in patients with stage D0 prostate cancer by means of immunization with a plasmid DNA vaccine encoding PAP. [Time Frame: 12 months] [Designated as safety issue: No] Secondary Outcome Measures:		
Recruiting	Vaccine Therapy in Preventing HPV in HIV-Positive Women in India		Safety and Immunogenicity of the Merck Quadrivalent Human Papillomavirus Vaccine:
	Conditions:	Cervical Cancer; Nonneoplastic Condition; Precancerous Condition	
	Interventions:	Biological: quadrivalent human papillomavirus (types 6, 11, 16, 18) recombinant vaccine; Genetic: DNA analysis; Genetic: polymerase chain reaction; Other: cytology specimen collection procedure; Procedure: colposcopic biopsy 2008	
	Primary Outcome Measures: •Safety, in terms of grade 3 or 4 adverse events attributed to the vaccine, according to NCI CTCAE v3.0 [as safety] •Significant decrease (at the 0.05 significance level) in CD4+ cell count or HIV RNA rise from baseline of≥ 1.0 log10 in the level of quantification (or > 200 copies/mL in patients < 50 years old at study entry) •Detectable HPV antibody to HPV 16, 18, 6 or 11 at 1 month after the completion of HPV vaccination series (week 28) [Designated as safety issue: No] Secondary Outcome Measures: •HPV antibody titers to types 6, 11, 16, and 18 at baseline and at weeks 8, 24, and 52		
Terminated	Vaccine Therapy in Treating Patients Who Are Undergoing Surgery for Stage IB, Stage II, or Stage IIIA Non-Small Cell Lung Cancer		Mature Autologous Dendritic Cells Loaded With Irradiated Autologous Tumor Cells !st safety. Secondary ·Determine the feasibility of this vaccine in these patients. ·Determine vaccine-specific and antitumor immunity in patients treated with this vaccine
	Condition:	Lung Cancer	
	Interventions:	Drug: autologous tumor cell vaccine; Drug: therapeutic autologous dendritic cells; Procedure: adjuvant therapy; Procedure: biological therapy; Procedure: conventional surgery; Procedure: surgery; Procedure: tumor cell derivative vaccine; Procedure: vaccine therapy 2004	
Recruiting	Vaccine Therapy, Tretinoin, and Cyclophosphamide in Treating Patients With Metastatic Lung Cancer		GM.CD40L cell vaccine/allogeneic tumor cell
	Condition:	Lung Cancer	

	Interventions:	Biological: GM.CD40L cell vaccine; Biological: allogeneic tumor cell vaccine; Drug: cyclophosphamide; Drug: tretinoin; Genetic: protein expression analysis; Other: flow cytometry; Other: immunoenzyme technique; Other: immunohistochemistry staining method 2008	vaccine tumor response rate in patients
	•To evaluate patients for the development of specific anti-tumor immune responses after immunization. •To quantitate the dendritic cell (DC):immature myeloid cell (ImC) ratio before and after treatment with tretinoin, vaccine therapy comprising allogeneic tumor cells and GM.CD40L, and cyclophosphamide. •To evaluate the survival of patients treated with this vaccine Patients undergo blood collection periodically during treatment for immune response testing, including determination of dendritic cell (DC):immature myeloid cell (ImC) ratios by flow cytometry and ELISPOT analysis. Archived diagnostic biopsy tissue is analyzed for the expression of WT1, CEA, and hTERT by immunohistochemistry.		
Suspended	MUC1 Vaccine in Conjunction With Poly-ICLC in Patients With Recurrent and/or Advanced Prostate Cancer		MUC1 Vaccine in Conjunction With Poly-ICLC (Polyinosinic-Polycytidylic Acid Stabilized With Polylysine and Carboxymethylcellulose) or HiltonolTM
	Condition:	Prostate Cancer	
	Intervention:	Drug: MUC_1 2005	
	•Proportion of patients showing an immunologic response at week 8 [Time Frame: 8weeks] •Measures of systemic immunosuppression [Time Frame: 8weeks] • Dendritic cell (DC) status [Time Frame: 7 weeks] •T cell subset analyses [Time Frame: 8weeks] •Clinical Response [Time Frame: weekly]		
Active, not recruiting	Vaccine Therapy, Interleukin-2, and Sargramostim in Treating Patients With Advanced Tumors		
	Conditions:	Breast Cancer; Esophageal Cancer; Gastric Cancer; Lung Cancer; Pancreatic Cancer; Unspecified Adult Solid Tumor, Protocol Specific	
	Interventions:	Biological: ALVAC-CEA vaccine; Biological: aldesleukin; Biological: sargramostim; Biological: vaccinia-CEA vaccine 1999	
	OBJECTIVES: I. Compare the CEA-specific cellular immune response in cancer patients randomized to receive a single vaccination with vaccinia-CEA vaccine followed by three boosts with ALVAC-CEA vaccine (V-A-A-A) or the reverse vaccination sequence (A-A-A-V). III. Determine whether the addition of GM-CSF alone or with IL-2 enhances the immune response to sequentially administered vaccinia-CEA vaccine and ALVAC-CEA vaccine. IV. Compare the enzyme linked immunosorbent assay ELISPOT with lymphoproliferative and cytotoxicity assays for measuring CEA-specific T lymphocyte immune response. OUTLINE: Patients receive **vaccinia-carcinoembryonic antigen (CEA) vaccine** intradermally on day 1 of course 1 and ALVAC-CEA vaccine (CEA-Avipox vaccine) intramuscularly (IM) on day 1 of courses 2-4. **Each course lasts 28 days**. Arm II: Patients receive ALVAC-CEA vaccine (CEA-Avipox vaccine) IM on day 1 of courses 1-3 and vaccinia-CEA vaccine ntradermally on day 1 of course 4. Each course lasts 28 days. **Patients in arms I and II continue 28-day courses through month 6** and then **receive 3-month courses for 2 years in the absence of disease progression or unacceptable toxicity**. In stage two, patients are enrolled successively into arms III and IV. Arm III: **Patients receive vaccines according to whichever schedule (arm I or II) was found to be superior plus sargramostim (GM-CSF) subcutaneously (SC) on days 1-4 of each course. Each course lasts 28 days.**		
Completed	Gene-Modified Lymphocytes, High-Dose Aldesleukin, and Vaccine Therapy in Treating Patients With Progressive or Recurrent Metastatic Cancer		aldesleukin / anti-p53 T-cell receptor-transduced peripheral blood lymphocytes /autologous dendritic cell-adenovirus p53 vaccine (Overexpresses p53 Using Lymphodepleting Conditioning Followed by Infusion of Anti-P53 TCR-Gene Engineered Lymphocytes and Dendritic Cell Vaccination
	Conditions:	Kidney Cancer; Melanoma (Skin); Unspecified Adult Solid Tumor, Protocol Specific	
	Interventions:	Biological: aldesleukin; Biological: anti-p53 T-cell receptor-transduced peripheral blood lymphocytes; Biological: autologous dendritic cell-adenovirus p53 vaccine; Biological: filgrastim; Drug: cyclophosphamide; Drug: fludarabine phosphate 2008	

	•Determine the in vivo survival of **TCR gene-engineered cells**. •Determine the ability of a DC vaccine to restimulate TCR gene-engineered cells in vivo. •Determine the toxicity profile of this treatment regimen. OUTLINE: Patients are stratified according to type of metastatic cancer (melanoma or renal cell cancer vs all other cancers). •Peripheral blood mononuclear cell (PBMC) collection: Patients undergo PBMC collection via leukapheresis for the generation of the adenovirus p53 dendritic cell vaccine as well as anti-p53 T-cell receptor (TCR) gene-engineered peripheral blood lymphocytes. •Nonmyeloablative lymphocyte-depleting preparative regimen: **Patients receive cyclophosphamide IV over 1 hour on days -7 and -6 and fludarabine phosphate IV over 30 minutes on days -5 to -1**. •Peripheral blood lymphocyte infusion: Patients receive anti-p53 TCR gene-engineered peripheral blood lymphocytes IV over 20-30 minutes on day 0. Patients receive filgrastim (G-CSF) subcutaneously (SC) once daily beginning on day 1 or 2 and continuing until blood counts recover. •High-dose aldesleukin: Patients receive high-dose aldesleukin IV over 15 minutes three times daily on days 0-4 for up to 15 doses.		
Active, not recruiting	Tumor Cell Vaccine in Treating Patients With Advanced Cancer		AUTOLOGOUS TUMOR CELL VACCINE:
	Condition:	Unspecified Adult Solid Tumor, Protocol Specific	
	Interventions:	Biological: filgrastim; Biological: recombinant interferon gamma; Biological: tumor cell lysate vaccine therapy	
	OBJECTIVES: I. Determine the toxic effects and side effects associated with administration of autologous tumor cell vaccine together with adjuvant interferon gamma or sargramostim (GM-CSF) in patients with advanced cancer. II. Determine the rate of conversion of delayed tumor hypersensitivity in patients receiving subcutaneous injections of irradiated autologous tumor cells (autologous vaccine). III. Determine the effect of autologous vaccines on in vitro assays of immune antitumor activity. IV. Determine the failure free survival associated with the use of autologous tumor cell line vaccines in patients with advanced cancer. OUTLINE: This is a randomized, multicenter study. Patients are stratified according to participating center, tumor type, disease stage, remission status (complete vs partial), prior therapy, progressive disease (yes vs no), and performance status (ECOG 0-1 vs 2). Patients are randomized into one of two treatment arms. Arm I: **Patients receive vaccination with irradiated autologous tumor cells subcutaneously (SQ) on week 1 and then autologous tumor cell vaccine plus interferon gamma SQ on weeks 2 and 3, and then monthly beginning on week 8 and continuing until week 24.** Arm II: Patients receive vaccination with irradiated autologous tumor cells as in arm I and then autologous tumor cell vaccine plus sargramostim (GM-CSF) SQ on weeks 2 and 3 and then monthly beginning on week 8 and continuing until week 24.		
Completed	Cyclophosphamide Plus Vaccine Therapy in Treating Patients With Advanced Cancer		allogeneic tumor cell vaccine Biological: autologous tumor cell vaccine ·Clinical response ·Duration of response · Survival (patients with evaluable disease) ·
	Conditions:	Breast Cancer; Colorectal Cancer; Kidney Cancer; Lung Cancer; Malignant Mesothelioma; Pancreatic	
	Interventions:	Biological: allogeneic tumor cell vaccine; Biological: autologous tumor cell vaccine; Biological: recombinant interferon alfa; Biological: recombinant interferon gamma; Biological: sargramostim; Drug: cyclophosphamide	
	Primary Outcome Measures: •Clinical response (patients with evaluable disease) •Duration of response (patients with evaluable disease) . • Survival (patients with evaluable disease) •Time to recurrence (patients without evaluable disease) •Survival (patients without evaluable disease) [Designated as safety issue: No		
Completed	Vaccine Therapy Plus Sargramostim and Chemotherapy in Treating Women With Stage II or Stage III Breast Cancer		Recombinant Vaccinia-CEA(6D)-TRICOM, And Recombinant Fowlpox-CEA(6D)-TRICOM (B7.1/ICIAM-1/LFA-3) With Sargramostim (GM-CSF), In Conjunction With Standard Adjuvant Chemotherapy
	Condition:	Breast Cancer	
	Interventions:	Biological: recombinant fowlpox-CEA(6D)/TRICOM vaccine; Biological: recombinant vaccinia-CEA(6D)-TRICOM vaccine; Biological: sargramostim; Drug: cyclophosphamide; Drug: doxorubicin hydrochloride; Drug: paclitaxel; Radiation: radiation therapy 2003	