

	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.
	<p>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, 24, 42, and 55. (Patients are followed every 2 months)</p>		
Completed	Vaccine Therapy Plus Biological Therapy in Treating Patients With Prostate Cancer		
	Condition:		Bivalent MUC-2-Globo H-KLH conjugate vaccine with GPI-0100 (Adjuvant).
	Interventions:	Biological: GPI-0100; Biological: MUC-2-Globo H-KLH conjugate vaccine 2001	
	<p>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 2 months)</p>		
Active, not recruiting	Vaccine Therapy in Treating Patients With Ovarian Epithelial or Primary Peritoneal Cancer		
	Conditions:	Ovarian Cancer; Peritoneal Cavity Cancer	ovarian cancer peptide vaccine (ovarian cancer synthetic peptides)/ incomplete Freund's adjuvant/ GM-CSF /tetanus toxoid helper peptide emulsified in Montanide ISA-51
	Interventions:	Biological: incomplete Freund's adjuvant; Biological: ovarian cancer peptide vaccine; Biological: sargramostim; Biological: tetanus toxoid helper peptide; Procedure: adjuvant therapy 2004	
	<p>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.</p>		
Completed	Vaccine Therapy in Treating Patients With Metastatic Cancer		
	Conditions:	Lung Cancer; Adult Soft Tissue Sarcoma; Colorectal Cancer; Bone Cancer; Ovarian Sarcoma; Melanoma; Colon Cancer; Rectal Cancer; Breast Cancer; Eye Cancer; Uterine Sarcoma	MAGE-12 Peptide Vaccine with GM-CSF emulsified in Montanide ISA-51.
	Interventions:	Drug: interleukin-2; Drug: MAGE-12 peptide vaccine; Drug: Montanide ISA-51 2007	

	<p>Immunologic response, as measured by an in vitro sensitization assay. Immunologic parameters and the clinical response rate.</p> <p>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.</p> <p>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.</p>	
Completed	<p>Vaccine Therapy in Treating Patients With Stage II, Stage III, or Stage IV Ovarian Epithelial, Fallopian Tube, or Peritoneal</p> <p>Conditions: Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer</p> <p>Interventions: Biological: fowlpox-NY-ESO-1 vaccine; Biological: recombinant vaccinia-NY-ESO-1 vaccine; Procedure: adjuvant therapy 2005</p>	<p>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.</p>
	<p>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.</p> <p>OUTLINE: This 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.</p>	
Recruiting	<p>Gemcitabine and Capecitabine With or Without Vaccine Therapy in Treating Patients With Locally Advanced or Metastatic</p> <p>Condition: Pancreatic Cancer</p> <p>Interventions: Biological: GM-CSF; Biological: telomerase peptide vaccine GV1001; Drug: capecitabine; Drug: gemcitabine hydrochloride 2007</p>	<p>After chemotherapy, telomerase peptide vaccine GV1001[TELOVAC] with GM-CSF.</p>

	<p>•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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Quality of life is assessed at baseline and at 8 weeks and then every 12 weeks during study treatment.</p> <p>After completion of study treatment, patients are followed every 3 months.</p> <p>Peer Reviewed and Funded or Endorsed by Cancer Research UK</p>		
Completed	Vaccine Therapy Plus QS21 in Treating Patients With Progressive Prostate Cancer	Glycosylated MUC-2-KLH Peptide Conjugate Vaccine Plus the Immunological Adjuvant QS21:	
	Condition: Prostate Cancer		
	Interventions: Biological: MUC-2-KLH vaccine; Biological: QS21 2000		
	<p>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.</p> <p>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.</p> <p>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.</p>		
Active, not recruiting	Vaccine Therapy in Treating Patients With Stage IIIC or Stage IV Malignant Melanoma	GM-CSF-Producing and CD40L-Expressing Bystander Cell Line (GM.CD40L) in the Formulation of Autologous Tumor Cell-Based	
	Condition: Melanoma (Skin)		
	Interventions: Biological: GM.CD40L cell vaccine; Biological: autologous tumor cell vaccine 2005		

	<p>Tumor response rate and time to tumor progression by RECIST criteria and DFS/OS at 3, 6, 9, and 12 months</p> <p>•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.</p> <p>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).</p> <p>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.</p> <p>Patients are followed every 3 months for 1 year, every 6 months for 1 year, and then annually thereafter.</p>	
Suspended	<p>Immunization of Patients With Non Small Cell Lung Cancer (NSCLC)</p> <p>Condition: Non Small Cell Lung Cancer (NSCLC)</p> <p>Intervention: Biological: semi-allogeneic human fibroblasts (MRC-5) transfected with DNA 2008</p>	semi-allogeneic human fibroblasts (MRC-5) transfected with DNA:
	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	<p>Vaccine Therapy and Chemotherapy With or Without Tetanus Toxoid Compared With Chemotherapy Alone in Treating Patients With Metastatic Colorectal Cancer</p> <p>Condition: Colorectal Cancer</p> <p>Interventions: Biological: ALVAC-CEA-B7.1 vaccine; Biological: tetanus toxoid; Drug: FOLFIRI regimen; Drug: fluorouracil; Drug: irinotecan hydrochloride; Drug: leucovorin calcium 2001</p>	ALVAC-CEA/B7.1 Vaccine Administered with or without tetanus toxoid, vs chemotherapy alone : Determine whether tetanus toxoid enhances the immune response
Recruiting	<p>Tumor and Vaccine Site With a Toll Like Receptor (TLR) Agonist</p> <p>Condition: Melanoma peptide vaccine</p> <p>Interventions: Drug: gp100; Drug: R848 gel; Drug: MAGE-3 2009</p>	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.
	<p>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.</p> <p>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.</p> <p>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).</p> <p>Secondary: <u>A.</u> Evaluate the ability of locally administered TLR agonist (R848 gel) to activate innate immune cells at the vaccine site.</p> <p><u>B.</u> 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).</p> <p><u>C.</u> 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.</p>	

Active, not recruiting	An Immunotherapy Vaccine Against Grade IV Brain Tumors		Immunotherapy Vaccine Against Tumor-Specific EGFRvIII. Response Rate [Time Frame: Continuous
	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	

	<p>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</p>		
Completed	Vaccine Therapy in Treating Patients With Stage III Non-Small Cell Lung Cancer		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
	Condition:	Lung Cancer	
	Interventions:	Biological: mutant p53 peptide pulsed dendritic cell vaccine; Procedure: adjuvant therapy 2001	
Completed	Vaccine Therapy in Treating Patients With Transitional Cell Cancer of the Bladder		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.
	Condition:	Bladder Cancer	
	Interventions:	Biological: BCG vaccine; Biological: NY-ESO-1 peptide vaccine; Biological: sargramostim 2003	
Active, not recruiting	A Phase I Clinical Trial of Autologous Dendritic Cell Vaccine for Recurrent Ovarian or Primary Peritoneal Cancer		Autologous Dendritic Cell Vaccine Leded With Autologous Tumor Cell Lysate. Immunogenicity of DCVax-L administered intradermally in patients combined with intravenous bevacizumab and oral metronomic cyclophosphamide. [2 years]
	Conditions:	Ovarian Cancer; Peritoneal Cancer	
	Intervention:	Biological: DCVax-L 2008	

	<p>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.</p> <p>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. Pevnar, an FDA approved seven-valent vaccine against <i>Pneumococcus pneumoniae</i>, 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.</p>	
Recruiting	<p>Ovarian Cancer and Immune Response to Flu Vaccine</p> <p>Condition: Ovarian Cancer</p> <p>Intervention: Biological: The current season's trivalent killed influenza vaccine 2008</p>	
	Immunogenicity of Killed Influenza Vaccine in Patients With Ovarian, Fallopian Tube, and Primary Peritoneal Cancer:	
Active, not recruiting	<p>Vaccine Therapy in Treating Patients With Stage I, Stage II, or Stage III Non-Small Cell Lung Cancer</p> <p>Condition: Lung Cancer</p> <p>Interventions: Biological: allogeneic tumor cell vaccine; Biological: therapeutic autologous dendritic cells; Procedure: adjuvant therapy 2005</p>	
	<p>Allogeneic tumor cell vaccine + therapeutic autologous dendritic cells with adjuvant.</p> <p>Immunologic response and Immunologic response. Patients are followed monthly for 4 months, every 6 months for 2 years, and then periodically thereafter</p>	
Active, not recruiting	<p>Vaccine Therapy in Treating Patients With Epstein-Barr Virus-Related Cancer</p> <p>Conditions: Gastric Cancer; Head and Neck Cancer; Lymphoma; Lymphoproliferative Disorder; Nonneoplastic</p> <p>Interventions: Biological: EBNA1 C-terminal/LMP2 chimeric protein-expressing recombinant modified vaccinia Ankara vaccine; Other: laboratory biomarker analysis; Other: pharmacological study 2010</p>	
	<p>EBNA1 C-terminal/LMP2 chimeric protein-expressing recombinant modified vaccinia Ankara vaccine:</p> <p>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.</p>	
Completed	<p>Vaccine Therapy in Treating Patients With Advanced Kidney Cancer</p>	

	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 (VLAGGFLLYRHVIYAPSSHNKYA) and TARP13-35 (LQLLKQSSRRLEHTFMFLRNFLS) 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, <u>considering the dose range tested</u>	
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	

	<p>Conditions: Leukemia, Acute Myelogenous (AML); Leukemia, Acute Lymphocytic (ALL); Leukemia, Chronic Myelogenous (CML); Myelodysplastic Syndrome (MDS); Non-Hodgkin's Lymphoma (NHL)</p> <p>Interventions: Drug: WT1 Peptide-Pulsed Dendritic Cells; Drug: Donor Lymphocytes; Drug: IL-4; Drug: KLH; Drug: WT1 Peptides; Drug: Endotoxin 2009</p>	
	<p>WT1 Peptide-Loaded Allogeneic Dendritic Cell Vaccine and Donor Lymphocyte Infusion</p> <p>immune response to the WT1 vaccine:</p> <p>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</p> <p>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.</p>	
Not yet recruiting	<p>Vaccine Therapy in Preventing Human Papillomavirus Infection in Young HIV-Positive Male Patients Who Have Sex With Males</p> <p>Conditions: Anal Cancer; Nonneoplastic Condition; Penile Cancer; Precancerous Condition</p> <p>Interventions: Biological: quadrivalent human papillomavirus (types 6, 11, 16, 18) recombinant vaccine; Other: laboratory biomarker analysis 2010</p>	<p>Quadrivalent Vaccine in Young HIV-Positive Males Who Have Sex With Males</p>
Recruiting	<p>Vaccine Therapy in Treating Patients With Metastatic, Progressive Prostate Cancer</p> <p>Condition: Prostate Cancer</p> <p>Intervention: Biological: NY-ESO-1/LAGE-1 HLA class I/II peptide vaccine 2008</p>	
	<ul style="list-style-type: none"> •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 <p>Primary</p> <ul style="list-style-type: none"> •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. <p>Secondary</p> <ul style="list-style-type: none"> •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. <p>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.</p>	
Recruiting	<p>A Safety and Immunology Study of a Modified Vaccinia Vaccine for HER-2(+) Breast Cancer After Adjuvant Therapy</p> <p>Condition: Breast Cancer</p>	

	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	
	<p>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</p>	
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	