

	Interventions:	Biological: HER-2/neu peptide vaccine; Biological: therapeutic autologous dendritic cells 2009	
	<p>HER-2/Neu Pulsed DC1 Vaccine:</p> <ul style="list-style-type: none"> •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	
	<ul style="list-style-type: none"> •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] <p>Secondary Outcome Measures:</p>		
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	
	<p>Primary Outcome Measures:</p> <ul style="list-style-type: none"> •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 $\geq 1.0 \log_{10}$ 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] <p>Secondary Outcome Measures:</p> <ul style="list-style-type: none"> •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
	<ul style="list-style-type: none"> •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 <p>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.</p>		
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 Hiltono1TM
	Condition:	Prostate Cancer	
	Intervention:	Drug: MUC_1 2005	
	<ul style="list-style-type: none"> •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	
	<p>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.</p> <p>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 intradermally 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.</p>		
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	

	<ul style="list-style-type: none"> •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. <p>OUTLINE: Patients are stratified according to type of metastatic cancer (melanoma or renal cell cancer vs all other cancers).</p> <ul style="list-style-type: none"> •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	
	<p>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.</p> <p>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.</p>		
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	
	<p>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</p>		
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	

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

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

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

	<p>Primary Outcome Measures: Document safety profile of 1000 µg of L-BLP25. [Time Frame: Day 0, Weeks 1, to Month 24. Additional inquires on survival until death.]</p> <p>Compare survival of patients who receive Best Supportive Care plus L-BLP25 to that of patients who receive Best Supportive Care alone. [Day 0, Weeks 1, to Month 24. Additional inquires on survival until death.]</p> <p>Secondary Outcome Measures: To evaluate the impact of L-BLP25 therapy on patients' health-related Quality of Life. [Day 0, Weeks 1, to Month 24. Additional inquires on survival until death.]/ To measure the immune responses elicited by L-BLP25. [Day 0, Weeks 1, to Month 24. Additional inquires on survival until death.]</p>	
Recruiting	<p>Vaccine Therapy in Treating Patients With Newly Diagnosed Stage IV Kidney Cancer</p>	
	Condition:	Kidney Cancer
	Interventions:	Biological: autologous dendritic cell-autologous tumor mRNA-human CD40L vaccine; Biological: therapeutic autologous dendritic cells 2006
	<p>Study Testing the Biologic Activity and Safety of Autologous Renal Cell Carcinoma Total mRNA and huCD40L</p>	
	<p>Primary Outcome Measures: T-cell response to RNA-loaded dendritic cells by the ELISpot assay on blood cells, weeks 6 and 14 and years 1 and 2</p> <p>Secondary Outcome Measures: Exploratory monitoring of T-cell functionality in terms of reverse-transcriptase polymerase chain reaction, cytokine/granzyme secretion, CD4/CD8 T cell proliferation, and CD4/CD8 T cell maturation. Exploratory assessment of immune response as assessed by delayed-type hypersensitivity</p> <p>Objective tumor response (complete and partial response) as assessed by RECIST criteria, Progression-free and overall survival as assessed by RECIST criteria</p>	
Active, not recruiting	<p>Lenalidomide and Vaccine Therapy in Treating Patients With Relapsed or Refractory Multiple Myeloma</p>	
	Condition:	Multiple Myeloma and Plasma Cell Neoplasm
	Interventions:	Biological: pneumococcal polyvalent vaccine; Drug: lenalidomide 2007
	<p>Primary Outcome Measures: Humoral and cellular response./ Efficacy of pneumococcal polyvalent vaccine.</p> <p>Secondary Outcome Measures: Changes in delayed-type hypersensitivity reactions to Candida and tetanus in the presence of lenalidomide /Immune responses to carrier protein CRM 197 in peripheral blood and bone marrow. /Effect of lenalidomide on T-cell activation in blood and bone marrow. /Correlation of immune responses to vaccination with myeloma responsiveness to lenalidomide</p> <p>Primary: Determine whether lenalidomide can augment the efficacy of pneumococcal polyvalent vaccine as it correlates with lenalidomide-induced antitumor efficacy in patients with relapsed or refractory multiple myeloma.</p> <p>Secondary Determine the antibody responses to pneumococcal serotypes in patients treated with this regimen.</p> <p>Determine T-cell responses to the carrier protein CRM 197 in patients treated with this regimen.</p> <p>Determine the ability of lenalidomide to augment in vivo immune responsiveness as measured by cutaneous delayed-type hypersensitivity (DTH) reactions to Candida and tetanus in these patients.</p> <p>Determine the ability of lenalidomide to prime and/or boost systemic vaccine responses in both peripheral blood lymphocytes and marrow lymphocytes in these patients</p>	
Completed	<p>Vaccine Therapy in Treating Patients With Ovarian, Fallopian Tube, or Peritoneal Cancer</p>	
	Conditions:	Fallopian Tube Cancer; Ovarian Cancer; Peritoneal Cavity Cancer
	Interventions:	Biological: MUC1-KLH conjugate vaccine; Biological: MUC1-KLH vaccine/QS21; Biological: QS21 2000
	<p>Vaccination oWith Glycosylated MUC-1-KLH Conjugate Plus the Immunological Adjuvant QS-21</p>	

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

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

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