Completed	An Open Label Study of a Peptide Vaccine in Patients With Stage IIb or IIIa Non-Small Cell Lung Cancer Conditions: Carcinoma, Non-Small-Cell Lung; Lung Neoplasm Intervention: Biological: EP2101	EP2101: Safety and Tolerance Study of EP2101 Peptide Vaccine
	EP2101 is a new cancer vaccine containing 10 different peptide antigens. The vaccine is designed to activate the immune system to develop a response against tumor cells in order to delay or prevent the recurrence of cancer. This study will test the safety and measure the level of immune stimulating capability of EP2101 in patients with Non-Small Cell Lung Cancer.	
Recruiting	TroVax® In Subjects With Hormone Refractory Prostate Cancer (HRPC) Condition: Hormone Refractory Prostate Cancer Interventions: Drug: Docetaxel; Drug: TroVax + Docetaxel 2010	Docetaxel vs.TroVax + Docetaxel: EGF receptorであるvariant III(EGFRvIII)ワクシニアウィルスベクターMVAに組み込み. PFS, both RECIST and PCWG2 criteria
	Based on both pre-clinical and clinical data, it may be advantageous to administer a cancer vaccine before chemotherapy to enhance immune responses, thus leading to a more effective therapeutic approach for subjects with metastatic HRPC. This clinical study will evaluate the role of combination therapy of TroVax® plus Docetaxel vs. Docetaxel alone on the progression free survival (PFS) of subjects with HRPC. **Primary**: Progression-free survival [Time Frame: Week 37]. /To establish whether the incidence of progression-free survival (as defined by the absence of progression assessed by both RECIST and PCWG2 criteria) at week 37 in the TroVax® plus Docetaxel treatment arm is higher than the incidence in the Docetaxel alone treatment arm. **Secondary**: Clinical progression-free survival [Time Frame: 37 weeks]. /To establish whether the incidence of clinical progression-free survival (defined by the absence of progression assessed by RECIST criteria alone) at week 37 in the TroVax® plus Docetaxel treatment arm is higher than the incidence in the Docetaxel alone treatment arm	
Completed	IMA901 in Advanced Renal Cell Carcinoma Patients With Measurable Disease Condition: Renal Cell Carcinoma Interventions: Drug: Endoxana, IMA901, Leukine; Drug: IMA901 and Leukine 2007	Endoxana, Leukine, IMA910 Endoxana, Leukine, IMA910, Aldara. single agent with GM-CSF in combination with imiquimod following pre-treatment with low-dose
	This is a multicenter, open label, randomized phase 2 study which investigated the effect of a second-line systemic treatment with IMA901 plus GM-CSF in RCC patients. Randomization was done according to a pre-treatment with low-dose cyclophosphamide (CY). Secondary endpoints comprised tumor response parameters. The study population consisted of HLA-A*02-positive men or women with advanced RCC of the clear-cell type classified as having a favorable or intermediate risk after first-line systemic therapy for. Patients had to be aged 18 years or older, had at least have one measurable tumor lesion and had have received first-line tyrosine kinase inhibitor or cytokine systemic therapy for advanced disease, during or after which the patient had experienced disease progression. Patients in both arms received a total of 17 vaccinations with GM-CSF followed by IMA901 during the 9 month treatment period. At screening baseline tumor status was assessed by CT or MRI. During the study tumor assessments were performed every 6 weeks. Immunomonitoring (T-cell responses to peptides contained in IMA901 and analysis of other immune cell populations that may influence T-cell responses), serum levels of antibodies and molecules with suspected influence on immune response were assessed on several occasions during the study. Safety assessment comprised continuous adverse event reporting, regular physical examinations and regular assessments of vital signs, hematology, blood chemistry and urine. A 12-lead ECG was performed at screening and at the end of the study. Pregnancy testing was performed according to applicable legislation in the country where the trial was performed. At the very least, women of childbearing potential had have to undergo a pregnancy test during screening for the study, before the first dose was applied and at the end of the study.	

Recruiting	Dendritic Cell Vaccine for Head and Neck Cancer	dendritic cell vaccine: Dendritic Cells for the Recurrent or Metastatic Squamous Cell Carcinoma.
	Condition: Squamous Cell Carcinoma of Head and Neck	
	Intervention: Biological: dendritic cell vaccine 2007	
	Efficacy as measured by RECIST criteria [Time Frame: 5 years] immune response to the vaccine.White blood cells are part of the body's defense system. Sometimes when you have cancer, your body does not know that the cancer cells are making you sick. We hope to teach your white blood cells to find and destroy your cancer cells with a vaccine. The vaccine will be made from a special kind of blood cell called a dendritic cell. This is the cell that will carry the information about your cancer to your white blood cells in your body.	
Recruiting	Collection and Banking of Leukemia Cells for Vaccine Generation in Patients With Advanced Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML)	Collection of Leukemia Cells: Collection and Banking of Leukemia Cells for Vaccine Generation for Advanced MDS or AML. feasibility of banking leukemic blood
	Conditions: Myelodysplastic Syndrome; Acute Myeloid Leukemia	
	Intervention: Other: Collection of Leukemia Cells 2008	
	Leukemia cells will be collected by one or more of the following methods: 1)Routine blood draw 2)Bone marrow aspirate 3) Leukapheresis. The physician and study staff will determine which of the methods above is best suited for each participant. After collection, the leukemia cells will be transported to the Cell Manipulation Core Facility (CMCF) at the Dana-Farber Cancer Institute, where they will be frozen until the time of vaccine administration.	
Recruiting	A Study, Combination, Immunologic Study of LTX-315 as Adjunct to GV1001 in Patients Following Curative Surgery for Carcinoma	LTX-315: Immunologic Study of LTX-315 as Adjunct to GV1001. Outcome: T-cell function in peripheral blood
	Condition: Carcinoma	
	Intervention: Drug: LTX-315	
	This clinical study has two main aims which are: To measure the immunological effects of LTX-315 in combination with GV1001 Find out about the side effects of the combination of the two drugs This is an open label, single centre study assessing immunological effects and safety of LTX-315 given as an adjunct to GV1001. The LTX-315 dose will escalate while the GV1001 dose will be fixed. LTX-315 and GV1001 will be given as intradermal injections on days 1, 8, 15, 22 and 36. Investigational treatment: LTX-315 (0.10 mL) with escalating concentrations will be injected intradermally, followed, 1-2 hours later, by intradermal injection of 0.56 mg GV1001 (0.20 mL, 2.8 mg/mL) in the same site, in one arm. DTH-test control: 0.10 mg GV1001 (0.10 mL) will be injected intradermally in the contralateral arm without LTX-315, as a DTH skin reactivity test control.	
Active, not recruiting	PROSTVAC®-VF/TRICOM™ Vaccine for the Treatment of Metastatic Prostate Cancer After Failing Hormone Therapy	PROSTVAC®-VF/TRICOM™: consists of a pair of pox virus vectors specifically engineered to target PSA.
	Condition: Prostate Cancer	
	Intervention: Biological: PROSTVAC®-VF/TRICOM™: The trial had a sample of 122 men and its results showed a median overall survival of 25.1 months for men receiving, compared with 16.6 months for those receiving placebo (hazard ratio, 0.56; P = .006). 2004	

	PROSTVAC-VF is an investigational cancer vaccine. The vaccine is based on the theory that the immune system can be taught to fight cancer by directing the immune system to attack specific targets found on cancer cells. These targets are called Tumor Associated Antigens, or TAA's. This trial will help determine if this vaccine can help fight cancer. This multi-center, double-blind, randomized, empty vector-controlled trial is designed to evaluate the safety and efficacy of PROSTVAC-VF/TRICOM co-administered with GM-CSF versus the empty viral vector co-administered with placebo in the treatment of patients with androgen-independent prostate cancer (AIPC). All patients will be required to sign an informed consent prior to the performance of any on-study procedures. Patients will be screened for eligibility within 14 days prior to vaccine administration. Patients who meet all inclusion and exclusion criteria will be centrally randomized into the study and will receive a unique patient identification number and a blinded treatment assignment. The ratio of active treatment to empty vector control (placebo) is 2:1.	
Completed	NY-ESO-1 Protein Vaccine With Imiquimod in Melanoma (Adjuvant Setting) Condition: Malignant Melanoma Interventions: Biological: NY-ESO-1 protein; Drug: Imiquimod 2005	NY-ESO-1 protein / Imiquimod as Adjuvant: safety and Immunogenicity
	This study evaluates a cancer vaccine in melanoma patients who have resected melanoma but are at high risk for recurrence (stages IIB-III). This is a single arm, open label, pilot/phase I study evaluating safety and immunogenicity of NY-ESO-1 protein vaccination with Imiquimod as an adjuvant. Imiquimod is a FDA approved immune response modifier for the treatment of HPV associated genital warts (but used for a different indication here) and has been shown to attract and mature dendritic cells in areas of topical application. This will be utilized in this application to inject a protein vaccine into this site, to prime and boost anti-NY-ESO-1 immune responses. 9 patients will be treated to receive 4 vaccination cycles, 21 days apart. Each vaccination cycle consists of topical application of Imiquimod 250mg to healthy skin of extremities for the first five days of each cycle and intradermal injection of NY-ESO-1 protein 100mcg to the pretreated area on day 3. Immunization will be assessed by T-cell assays, NY-ESO-1 specific antibody titers, and evaluation of 3 small skin biopsies.	
Recruiting	Vaccine Therapy With PROSTVAC/TRICOM and Flutamide Versus Flutamide Alone to Treat Prostate Cancer Condition: Prostate Cancer Interventions: Drug: Flutamide; Biological: Sargramostim; Biological: recombinant fowlpox-prostate apecific antigen vaccine; Biological: recombinant vaccinia prostate specific antigen vaccine	PROSTVAC-V/TRICOM + Flutamide + GM-CSF. Time to development of metastatic disease
Recruiting	Immunotherapy of Recurrent Cervical Cancers Using Dendritic Cells (DCs) Condition: Cervical Cancer Intervention: Biological: HPV16 E7 peptide-pulsed autologous DCs	HPV16 E7 peptide-pulsed autologous DCs: Dendritic Cells (DCs) Pulsed With Human Papillomavirus Type 16 E7 Antigen. Immunologic responses to HPV16 E7 peptide
Active, not recruiting	Chemotherapy Plus Vaccination to Treat Mantle Cell Lymphoma Condition: Mantle Cell Lymphoma Interventions: Drug: Rituximab; Drug: autologous tumor cell vaccine; Drug: doxorubicin; Drug: cyclophosphamide; Drug: etoposide; Drug: filgrastim; Drug: keyhole limpet hemocyanin; Drug: prednisone; Drug: sargramostim; Drug: vincristine	Autologous tumor cell vaccine Rituximab + G-CSF + GM-CSF:Pilot Study of Idiotype Vaccine and EPOCH-Rituximab Chemotherapy in Untreated Mantle Cell Lymphoma.
Active, not	A Pilot Study of Tumor Cell Vaccine for High-risk Solid Tumor Patients Following Stem Cell Transplantation	tumor lysate-pulsed dendritic cell vaccine +

recruiting	Conditions:	Sarcoma; Neuroblastoma; Wilm's Tumor	tumor lysate-pulsed dendritic cell vaccine; Other: hematopoietic stem cell transplantation (HSCT):
	Interventions:	Biological: tumor lysate-pulsed dendritic cell vaccine; Other: hematopoietic stem cell transplantation (HSCT) 2006	
	immune response of this immunotherapy treatment [70 days]+ Immune response to the clinical response. [three years] Localized solid tumors such as, sarcoma, neuroblastoma, and Wilms' tumor, can generally be effectively treated with a combination of surgery, radiation and chemotherapy. However, patients with metastatic or relapsed disease have a very poor prognosis. New approaches to the management of these difficult groups of patients are needed. There is evidence to suggest that solid tumors may be good candidates for immunotherapy approaches. In fact, recent experimental evidence indicates that the period of lymphopenia that occurs after stem cell transplant may be an opportune time to use an immunotherapy treatment approach. In light of the very poor prognosis of young patients with advanced solid tumors, this treatment approach warrants further investigation.		
Completed	A Pilot Study of Autologous T-Cell Transplantation With Vaccine Driven Expansion of Anti-Tumor Effectors After Cytoreductive Therapy in Metastatic Pediatric Sarcomas		therapeutic autologous dendritic cells (Procedure: peripheral blood stem cell transplantation]:
	Conditions:	Ewing's Sarcoma; Rhabdomyosarcoma	
		Biological: therapeutic autologous dendritic cells; Drug: indinavir sulfate; Procedure: peripheral blood stem cell transplantation	
	This is a single arm study. The tumor specimen is analyzed for the presence of a fusion protein which corresponds to available peptides. Patients undergo T cell harvest 10 days after an initial priming peptide-pulsed antigen presenting cell (APC) vaccine is performed. Fresh APCs are utilized for initial priming vaccination. All subsequent vaccinations will use cryopreserved APCs. Minimum number of APCs administered per vaccination is 100,000/kg and maximum is 100,000,000/kg. Patients undergo cytoreductive therapy for the treatment of their particular malignancy. This therapy usually consists of multiagent chemotherapy in the context of a separate protocol. Following chemotherapy, infusion of harvested T cells followed by infusion of peptide-pulsed APC vaccinations occurs every 6 weeks for a total of 3 post-priming vaccinations. Influenza vaccine is administered by intramuscular injection concurrent to peptide-pulsed APC vaccines. IL-2 is administered as a continuous IV infusion for 4 days/week for 3 successive weeks starting on the same day as T cell /peptide-pulsed infusions.		
Recruiting	Dendritic Cells in Lung Cancer		Allogeneic Tumour Lysate (MelCancerVac): Dendritic Cells Pulsed With Allogeneic Tumour Lysate (MelCancerVac) .
	Condition:	Non Small Cell Lung Cancer	
	Intervention:	Biological: Allogeneic Tumour Lysate (MelCancerVac) 2007	
	Specific immunological reaction between vaccine antigens and the patients' immune system in vivo and in vitro. OS RECIST criteria. Vaccination with autologous dendritic cells pulsed with allogeneic melanoma cell lysate (MelCancerVac) in combination with the Cox-2 inhibitor of celecoxib for the treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC). Adjuvant Aldara cream will be used as adjuvant for induction of inflammation at the injection site, and the lymphocyte growth factor of interleukin-2 (IL-2) will be given as s.c. injection. The treatment aims at boosting the patient's specific immune system against the cancer cells. Patients with disseminated, inoperable NSCLC after chemotherapy and patients not wanting chemotherapy for which no other systemic treatments can be offered. Primary objective: to measure the antigen specific immunological reaction between vaccine antigens and the patients' immune system in vivo and in vitro. Secondary objectives: to estimate the patients' survival time, to estimate response according to RECIST criteria, and to estimate the patients' quality of life during the study period. The study is designed as an open, phase II, clinical study and will be carried out in accordance with the present protocol, ICH/GCP Guidelines and national		
Completed	A Pilot Study of Tumor-Specific Peptide Vaccination and IL-2 With or Without Autologous T Cell Transplantation in Recurrent Pediatric Sarcomas		EF-1 Peptide, EF-2 Peptide, PXFK Peptide

	Conditions:	Ewing's Sarcoma; Rhabdomyosarcoma	E7 Peptide + GM-CSF, IL-2/IL4
	Interventions:	Drug: EF-1 Peptide; Drug: EF-2 Peptide; Drug: PXFK Peptide; Drug: E7 Peptide; Drug: IL-2; Drug: IL-4; Drug: GM-CSF; Drug: CD40 Ligand 1999	
Recruiting	Administration of Autologous Dendritic Cells (DCs) Infected With an Adenovirus Expressing Her-2		CD34+ derived DCs: Autologous CD34+ Derived Dendritic Cells Transduced With an Adenovirus Vector Expressing Inactivated HER-2/Neu
	Condition:	Breast Neoplasms	
	Intervention:	Biological: CD34+ derived DCs 2005	
	clinical efficacy as measured by objective tumor reduction. Following written, informed consent, consecutive cohorts of 3-6 patients, up to a maximum of 18 patients, will be treated at increasing dose levels based on a modified Fibonacci scheme. Peripheral blood progenitor cells will be obtained from each patient following cytokine mobilization (with GM-CSF and G-CSF). Selected CD34+ cells are then cultured with human GM-CSF, human TNFα, Flt-3 ligand and human interleukin-4. The CD34+ derived dendritic cells are then transduced with an adenovirus expressing rat HER2/neu. These transduced DCs are then injected intradermally into the patient. Patients will be injected with the AdHER2/neu transduced DCs every 21 days for a total of three treatment cycles. The starting dose of dendritic cells will be 10 X 10^6 DCs. If none of the initial three patients treated at this dose experiences dose limiting toxicity (DLT) then a new cohort of three patients will be treated at a second dose level of 50 X 10^6 DCs. If any patient experiences DLT then up to six patients will be treated at the current dose level; if 2/6 or fewer patients experience DLT, we will escalate to the to the second dose level. If 3 or more patients experience DLT, the maximum tolerated dose will be deemed as exceeded and a second cohort of 3 patients will be treated at a 10 fold dose reduction of the initial dose level. The third dose level will consist of 100 x 10^6 DCs. All treatments will occur in the out-patient setting and patients will be seen prior to each injection and then monthly for at least three months following the last injection of AdHER2/neu DCs.		
Completed	Sequential Vaccinations in Prostate Cancer Patients		priming with rVaccinia-PSA(L155)-TRICOM (rV-PSA-(L155)-TRICOM) with subsequent monthly boosts using rFowlpox-PSA(L155)-TRICOM (rF-PSA(L155)-TRICOM) + GM-CSF.
	Condition:	Prostatic Neoplasms	
	Interventions:	Drug: Recombinant Vaccinia-PSA(L155)-TRICOM (PROSTVAC-V/TRICOM); Drug: Recombinant Fowlpox-PSA(L155)-TRICOM (PRSTVAC-F/TRICOM); Drug: Recombinant Fowlpox-GM-CSF 2003	
	PD: T cell precursor frequency as measured by Enzyme-linked ImmunoSpot Assay (ELISPOT) assay. " Adenocarcinoma of the prostate is the most common cancer diagnosis in American males and follows lung cancer as the leading cause of cancer death. " Vaccine strategies represent a novel therapeutic approach in the treatment for prostate cancer. One potential target for a prostate cancer vaccine is PSA, due to its restricted expression on prostate cancer and normal prostatic epithelial cells. Objectives:" The primary objective in Stage 1 is to evaluate the clinical safety and toxicity of a prime/boost vaccine strategy: priming with rVaccinia-PSA(L155)-TRICOM (rV-PSA-(L155)-TRICOM) with subsequent monthly boosts using rFowlpox-PSA(L155)-TRICOM (rF-PSA(L155)-TRICOM). " The primary objective in Stage 2 is to determine the impact of granulocyte-macrophage colony stimulating factor (GM-CSF) and rF-GM-CSF on the immunologic response in patients treated with these vaccines. " Secondary (both Stage 1 and Stage 2)-to determine the change in PSA-specific T cells in patients treated with these vaccines using ELISPOT assay analysis. " To document any objective anti-tumor responses that may occur		
Recruiting	AdV-tk Therapy With Surgery and Chemoradiation for Pancreas Cancer (PaTK01)		AdV-tk with Valacyclovir: OS [Time Frame: 2 years] PFS CA 19-9 response [Time Frame: 2 years]
	Conditions:	Pancreatic Adenocarcinoma; Pancreatic Cancer	
	Interventions:	Biological: AdV-tk; Drug: Valacyclovir 2008	

	The AdV-tk vector is injected into the tumor or tumor bed at the time of biopsy or standard tumor surgery after which valacyclovir pills are taken for 14 days. Two courses of AdV-tk, each followed by valacyclovir, are given as adjuvant to standard of care therapies (surgery and/or chemoradiation) which have been shown to work cooperatively with AdV-tk to kill tumor cells. Arm A is for resectable tumors in which the first course is given prior to surgery and the second is at the time of surgery. Arm B is for locally advanced disease in which both AdV-tk injections are administered by needle injection into the tumor before and during chemoradiation. The hypothesis is that this combination therapy can be safely delivered and will lead to improvement in the clinical outcome for patients with pancreatic cancer.	
Active, not recruiting	Phase 2a Study of AdV-tk With Standard Radiation Therapy for Malignant Glioma (BrTK02) Conditions: Malignant Glioma; Glioblastoma Multiforme; Anaplastic Astrocytoma Interventions: Biological: AdV-tk; Drug: Valacyclovir 2007	AdV-tk with Valacyclovir: OS [Time Frame: 2 years] PFS QOL
	Purpose The purpose of this study is to evaluate the safety and potential efficacy of Gene Mediated Cytotoxic Immunotherapy for malignant gliomas. The approach uses an adenoviral vector (disabled virus) engineered to express the Herpes thymidine kinase gene (AdV-tk), followed by an antiherpetic prodrug, valacyclovir. The AdV-tk vector is injected into the tumor bed after standard tumor surgery and valacyclovir pills are taken for 14 days. Standard radiation and chemotherapy are administered which have been shown to work cooperatively with AdV-tk + prodrug to kill tumor cells. The hypothesis is that this combination therapy can be safely delivered and will lead to improvement in the clinical outcome for patients with newly diagnosed malignant gliomas, including glioblastoma multiforme (WHO grade IV) and anaplastic astrocytomas (WHO grade III). In addition, re-treatment at recurrence is being evaluated in patients who previously received AdV-tk + prodrug on this study. Accrual of new patients has been completed. The study remains open for evaluation and re-treatment at recurrence.	
Active, not recruiting	Phase 1b Study of AdV-tk + Valacyclovir Combined With Radiation Therapy for Malignant Gliomas Conditions: Malignant Glioma; Glioblastoma Multiforme; Anaplastic Astrocytoma Interventions: Biological: AdV-tk; Drug: Valacyclovir	AdV-tk with Valacyclovir: OS [Time Frame: 2 years] PFS QOL
	Purpose This phase I study evaluated a Gene Mediated Cytotoxic Immunotherapy approach for malignant gliomas, including glioblastoma multiforme and anaplastic astrocytoma. The purpose of this study was to assess the safety and feasibility of delivering an experimental approach called GliAtak which uses AdV-tk, an adenoviral vector containing the Herpes Simplex thymidine kinase gene, plus an oral anti-herpetic prodrug, valacyclovir, in combination with standard of care	
	This study was designed to include patients with newly diagnosed unresectable (Arm A) and resectable (Arm B) malignant glioma. Three dose levels of AdV-tk were evaluated with a fixed dose level of valacyclovir prodrug. AdV-tk was delivered to tumor cells by stereotactic injection into the tumor at the time of biopsy (Arm A) or injection into the tumor bed following resection (Arm B). Oral valacyclovir began 1-3 days after the AdV-tk injection and continued for 14 days. Standard radiation therapy began 3-7 days following the AdV-tk injection to maximize synergy with radiation. Standard temozolomide could be administered after completion of valacyclovir	
Recruiting	Procurement of Follicular B Cell Lymphoma Cells for the Purpose of Possible Use in Future Clinical Trials Condition: Non-Hodgkin's Lymphoma Intervention: Procedure: Procurement of Follicular B Cell Lymphoma Cells 2007	Procurement of Follicular B Cell Lymphoma Cells From Blood, Tissue or Malignant Effusion for the Purpose of Possible Use in Future Clinical Trials:
	The following tests and procedures will be performed: Approximately 50 B600cc of peripheral blood will be drawn and stored in the tissue bank; patients who have follicular lymphoma cells circulating in the blood will have about 40cc's of blood drawn and stored for processing; patients undergoing a lymph node biopsy will have samples of the biopsy stored; patients having fluid drained from the abdomen or from around the lung will have some of their fluid saved to cell collection and processing; patients undergoing a bone marrow biopsy will have some of the sample stored for cell collection B599 and processing.A 600.	
Recruiting	A Trial of Boost Vaccinations of Pancreatic Tumor Cell Vaccine Condition: Pancreatic Cancer	PANC 10.05 pcDNA-1/GM-Neo and PANC 6.03 pcDNA-1 neo vaccine: Disease free

	Intervention:	Biological: PANC 10.05 pcDNA-1/GM-Neo and PANC 6.03 pcDNA-1 neo vaccine. 2010	overall survival. [Time Frame: total of 13 years with 6 months
	[Primary]: 1. To evaluate the safety and feasibility of long term boost vaccinations of a lethally irradiated, allogeneic pancreatic tumor cell vaccine transfected with the GM-CSF gene given alone or in combination with either a single intravenous dose or daily metronomic oral doses of cyclophosphamide for the treatment of patients with surgically resected adenocarcinoma of the head, neck, or uncinate process of the pancreas. [**Secondary**]: To assess the effect of boost vaccinations and long-term treatment of immune modulating doses of cyclophosphamide on the number, repertoire and avidity of peripheral mesothelin-specific CD8+ T cells. /To estimate disease-free and overall survival of surgically resected pancreatic adenocarcinoma patients treated with vaccine boosts with or without low dose cyclophosphamide. Eligible subjects will receive by intradermal administration the pancreatic tumor vaccine consisting of two irradiated, allogeneic pancreatic tumor cell lines transfected with the granulocyte macrophage-colony stimulating factor (GM-CSF) gene with or without low dose cyclophosphamide. Study participants will be recruited from our prior three arm neoadjuvant vaccination with or without low dose cyclophosphamide trial and vaccine naive patients. The vaccination boosts will be offered as a continuation of care. Patients from the J0810 study will remain on the same arm as the J0810 study where they have received the parental vaccine. The first vaccine boost will be given no sooner than six months (+/- 1 month) after the last prime vaccination. The vaccine will be administered for all arms once every six months (+/- 1 month) after the previous vaccine until ten years have passed, the subject no longer meets the eligibility criteria, no longer wishes to participate in the study, or the vaccine supply is exhausted. Arm A participants will receive the pancreatic cancer vaccine alone. Arm B participants will be vaccinated and receive a single low-dose of cyclophosphamide (200 mg/m2) intravenously one day prior to vaccination. Participants in Arm C will receive cyclophosphamide 50 mg once a day starting from 28 days prior to day 1 of vaccination till 28 days post vaccination. Vaccine naive patients will first receive three prime vaccines each one month apart and each in combination with a single low-dose of cyclophosphamide (200 mg/m2)intravenously one day prior to vaccination. Then they will receive the boost vaccines as the participant in Arm B from the J0810 study.		
Active, not recruiting	Immune Response in Patients Who Have Undergone Vaccine Therapy for Stage III or Stage IV Breast Cancer That Overexpresses HER2		HER-2/neu intracellular domain protein: Vaccination With a Plasmid Encoding HER2 ICD. Immunologic memory response to HER-2/neu (HER2) intracellular domain protein. memory T-cell population by intracellular cytokine staining. intracellular cytokine staining
	Condition:	Breast Cancer	
	Interventions:	Biological: HER-2/neu intracellular domain protein; Other: flow cytometry; Other: immunohistochemistry staining method; Procedure: biopsy; Other: Sterile water placement 2006	
Completed	Safety and Immunogenicity of CHP-HER2 and CHP-NY-ESO-1 Protein With OK-432 in Antigen-Expressing Cancers		CHP-HER2, CHP-NY-ESO-1: Cholesterol-Bearing Hydrophobized Pullulan HER2 Protein 146 (CHP-HER2) and NY-ESO-1 Protein (CHP-NY-ESO-1) in Combination With OK-432. Immune responses including HER2 and NY-ESO-1 specific IgG and T cells
	Conditions:	Esophageal Cancer; Lung Cancer; Stomach Cancer; Breast Cancer; Ovarian Cancer	
	Intervention:	Drug: CHP-HER2, CHP-NY-ESO-1 2006	
Active, not recruiting	Autologous PBHCT Followed by Dendritic Cell p53 Vaccination & Adoptive T Cell Transfer		PBHCT followed by Dendritic Vaccination and T Cell transfer: Autologous Peripheral
	Condition:	Small Cell Lung Cancer	

	Intervention:	Biological: PBHCT followed by Dendritic Vaccination and T Cell transfer 2008	Blood Hematopoietic Cell Transplantation (PBHCT) Followed by Dendritic Cell p53 Vaccination and Adoptive T Cell Transfer.
	1 year OS. 3 year progression-free survival; p53 immunity measured by ELISPOT for interferon-γ producing cells and by p53-specific tetramer in HLA-A. The purpose of this study is to find out if using high dose chemotherapy and hematopoietic cell transplant (HCT) in combination with lung cancer vaccines will improve survival in people with small cell lung cancer. Hematopoietic cells are blood cells that are responsible for making other blood cells (like red and white blood cells and platelets). When high doses of chemotherapy are given, the number of blood cells go way down and, by giving hematopoietic cells (a transplant), the numbers of blood cells come back up. This lessens the risk of having an infection or serious bleeding after high dose chemotherapy. High dose chemotherapy and HCT has been successful in some people with small cell lung cancer. In many cases, though, the cancer comes back over time. For this reason, other kinds of therapy are being tested in combination with high dose chemotherapy and HCT. In this research study, the study doctors will be testing a vaccine directed against lung cancer to see if it will keep the lung cancer from coming back after HCT.		
Recruiting	Blockage of PD-1 in Conjunction With the Dendritic Cell/Myeloma Vaccines Following Stem Cell Transplantation		Dendritic Cell Fusion Vaccine with CT-011: Blockage of PD-1 in Conjunction With the Dendritic Cell/Myeloma Vaccines Following Stem Cell Transplantation.
	Condition:	Multiple Myeloma	
	Interventions:	Drug: CT-011; Biological: Dendritic Cell Fusion Vaccine 2009	
	Immunological response to CT-011(MoAb). To correlate levels of circulating activated and regulatory T cells with immunologic response [3 years. serum marker. This study will collect tumor samples from people with cancers of the blood, bone marrow, or lymph glands for laboratory study of the biology of these conditions. Such studies contribute to a better understanding of cancer biology and to the development of new treatments. Planned studies include: Examination of individual cancer cells and to search for differences compared to other types of cancer and normal cells Examination of the chromosomes and genes in cancer cells and to search for differences compared to other types of cancer and normal cells Development of sensitive methods to detect small amounts of cancer that remain after treatment Search for new cancer proteins that might serve as targets for treatment Investigation of methods to develop cancer vaccines. Patients from birth to 75 years of age with acute lymphocytic leukemia, acute myelogenous leukemia, myelodysplastic syndrome, chronic myelogenous leukemia, juvenile myelomonocytic leukemia, non-Hodgkin's lymphoma, Hodgkin's disease, and other hematologic malignancies may be eligible for this study. Blood or bone marrow samples will be collected when sampling is required for the patient's medical care. Cells from some individuals will be grown in test tubes, establishing cell lines or in animals, establishing xenograft models. (A xenograft is transplantation of cells of one species to another species.)		
Recruiting	Biology Studies of Hematologic Cancers		This study will collect tumor samples from people with cancers of the blood, bone marrow, or lymph glands for laboratory study of the biology of these conditions.
	Condition:	Hematologic Malignancy 2009	
	Intervention:		
Recruiting	Vaccination With Tetanus and KLH to Assess Immune Responses.		Vaccination With Tetanus Toxoid and Keyhole Limpet Hemocyanin (KLH) to Assess
	Condition:	Cancer	

	Interventions:	Biological: Intracel KLH Vaccine; Biological: Biosyn KLH; Drug: Montanide ISA51; Biological: Tetanus toxoid 1999	Antigen-Specific Immune Responses. Tetanus Response and immune response
	[Purpose] The purpose of this study is to learn how the immune system works in response to vaccines. We will give the vaccines to subjects who have cancer but have not had treatment, and to patients who have had chemotherapy or stem cell transplant. Some patients will get vaccines while they are on treatments which boost the immune system (like the immune stimulating drug interleukin-2 or IL-2). Although we have safely treated many patients with immune boosting drugs, we do not yet know if they improve the body's immune system to respond better to a vaccine. Some healthy volunteers will also be given the vaccines in order to serve as control subjects to get a good measure of the normal immune response. We will compare the patients and the healthy volunteers to study how their immune systems respond to the vaccines. There are several different types of white cells in the blood. We are interested in immune cells in the blood called T-cells. These T-cells detect foreign substances in the body (like viruses and cancer cells). We are trying to learn more about how the body fights these foreign substances. Our goal is to develop cancer vaccines which would teach T-cells to detect and kill cancer cells better. We know that in healthy people the immune system effectively protects against recurrent virus infection. For example, that is why people only get "mono" (mononucleosis) once under normal circumstances. When the body is infected with the "mono" virus, the immune system remembers and prevents further infection. We are trying to use the immune system to prevent cancer relapse. To test this, we will give two vaccines which have been used to measure these immune responses. Blood samples will be studied from cancer patients and will be compared to similar samples from normal subjects		
Recruiting	Peptide Vaccination Associated With Tumoral Immunomodulation in Patients With Advanced Metastatic Melanoma		Vaccine MAGE-3.A1 peptide, or the NA17.A2 peptide + IL-2, IFN-α and GMCSF, Imiquimod. Tumor response will be assessed in accordance with the Modified RECIST version 1.1
	Condition:	Metastatic Melanoma	
	Intervention:	Drug: Vaccine MAGE-3.A1 peptide, or the NA17.A2 peptide + IL-2, IFN-α and GMCSF, Imiquimod. 2010	
	Cytolytic T lymphocyte responses to the vaccine antigens [Time Frame: at week 11, day 71] . CTL responses will be assessed by comparing either the anti-MAGE-3.A1 or the anti- NA17.A2 CTLp frequency in the pre- and post-immune blood of patients vaccinated with the respective antigen. Human cancers express tumor antigens that can be targeted by cytolytic T lymphocytes (CTL). These antigens consist of a small peptide, derived from endogenous proteins, that is presented at the cancer cell's surface by an HLA class I molecule. Such antigenic peptides, including MAGE-3.A1 and NA17.A2, have been tested in experimental therapeutic vaccines to elicit CTL responses in cancer patients, mainly with metastatic melanoma. Up to now, only rare tumor responses have been observed. Tumor resistance to CTL killing is the most likely explanation for the poor effectiveness of cancer vaccines. This resistance is probably acquired by the tumor during its development and selected by its repetitive challenge with spontaneous anti-tumoral immune responses. The precise molecular mechanisms of tumor resistance remain unknown. The observation that tumor-infiltrating lymphocytes (TIL) purified from melanoma metastases can recognize and kill autologous tumor cells in vitro, whilst they seem unable to control tumor growth in vivo, suggests that this resistance is hosted by the tumor environment, rather than being the result of a generalized immune suppression. The investigators have developed a murine model of cutaneous graft rejection that mimics the situation in melanoma. Female CBA mice do not reject syngeneic male skin grafts, even though they mount a spontaneous CTL response against H-Y, a male specific minor histocompatibility antigen, following grafting. The investigators have tested various experimental procedures aimed at inducing effective graft rejection in these mice. This was obtained with a combination of IFN-α, IL-2, GM-CSF, each administered separately under the skin graft, associated with topical applications of imiquimod. All these agents are available as registered drugs. Based on this murine model of cutaneous allograft rejection, the investigators postulate that local immunomodulation with this combination can trigger an effective tumor rejection process, and induce a more efficient and long-lasting anti-tumoral immune response following peptide vaccination.		
Recruiting	Surgical Resection With Gliadel Wafer Followed by Dendritic Cells Vaccination for Malignant Glioma Patients		Vaccination With Dendritic Cells Pulsed With Tumor Lysate for Patients With Malignant
	Condition:	Malignant Glioma	

	Intervention:	Biological: Dendritic cell Vaccine 2007	Glioma:
	To assess the survival of malignant glioma a, to assess the immunogenecity of patients who receive Dendritic cell vaccine , to assess progression free survival and to evaluate quality of life. [Time Frame: 1 year] Malignant gliomas are very aggressive and among the most common of brain tumors. A diagnosis carries with it a median survival of approximately 12 months, with 90 - 95% of patients surviving less than 2 years. The current standard treatment of surgical resection followed by radiation therapy and chemotherapy has not substabntially prolonged survival and even the few treatment options shown to exhibit small increases in survival primarily benefit certain (i.e., young) patient subpopulations. Cancer vaccines represent one novel therapy for malignant gliomas. The goal is for the body to recognize the tumor cells as foreign and produce its own response to fight off recurring tumor cells. A promising means of causing an immune response so the body can create this immunity is through the use of dendritic cell (DC) vaccines. Dendritic cells are a small group of cells contained in everyone's white blood cell population. These cells are responsible for letting the immune system know that something foreign, like bacteria, or a tumor, is in the body. Dendritic cells help the body ward off disease by alerting the immune system.		
Active, not recruiting	Dendritic Cells (DC) Vaccine for Metastatic Melanoma		Vaccination by Leukapheresis: Immunization Against Tumor Using Autologous Mature Dendritic Cells. (DTH) response to antigen-loaded autologous, [Time Frame: 12 mo]
	Condition:	Metastatic Melanoma	
	Interventions:	Biological: Vaccination; Procedure: Leukapheresis 2010	
Terminated	Active Immunization of Patients With Carcinoma of Oral Cavity or Oropharynx With Autologous Dendritic Cells Transfected With DNA From Autologous Tumor		autologous monocyte-derived dendritic cells (DC) transfected with DNA: Immunological responses to the vaccine and/or antitumor immune responses [Time Frame: 6 months
	Conditions:	Primary Advanced Carcinoma of the Oral Cavity or Oropharynx; Squamous Cell Carcinoma of the Head and	
	Intervention:	Biological: autologous monocyte-derived dendritic cells (DC) transfected with DNA 2006	
Recruiting	HLA-A2-Restricted Glioma Antigen-Peptides Vaccinations With Poly-ICLC for Recurrent WHO Grade II Gliomas		Peptide vaccine + Poly-ICLC: Vaccinations With HLA-A2-Restricted Glioma Antigen-Peptides in Combination With Poly-ICLC.
	Conditions:	Astrocytoma; Oligoastrocytoma; Oligodendroglioma	
	Intervention:	Biological: Peptide vaccine + Poly-ICLC 2009	
	Primary Outcome Measures: Induction of GAA-specific T-cell response [Time Frame: 2 year]. /The incidence and severity of adverse events associated with the vaccine regime will be assessed, with an early stopping rule based on the frequency of Regimen Limiting Toxicity (RLT). [Time Frame: 1 year] Secondary Outcome Measures: Clinical Response: Radiological response will be determined using the standard WHO response criteria. Based on serial magnetic resonance imaging (MRI) scans 2-year progression-free survival (PFS) will be evaluated in an exploratory manner. [Time Frame: 3 years] Biopsy/resection will be encouraged for patients who develop progression. Whenever post-vaccine tumor tissues are available, they will be analyzed for GAA expression status and infiltration of GAA-specific T-cells. [Time Frame: 3 years] Influence of RT on induction of GAA-specific immune response: we will compare the rate and magnitude of GAA-specific immune responses in Cohorts 1 and Cohort 2 using IFN-gamma-enzyme-linked immuno-spot (ELISPOT), and tetramer assays. [Time Frame: 3 years] All patients on the study will be followed for a minimum of 2 years		
Recruiting	Effects of Vaccinations With HLA-A2-Restricted Glioma Antigen-Peptides in Combination With Poly-ICLC for Adults With High-Risk WHO Grade II Astrocytomas and Oligo-Astrocytomas		GAA/TT-peptide vaccine and poly-ICLC: Vaccinations With HLA-A2-Restricted

	Conditions:	Astrocytoma; Oligo-astrocytoma; Glioma	Glioma Antigen-Peptides in Combination With Poly-ICLC .
	Intervention:	Biological: GAA/TT-peptide vaccine and poly-ICLC 2008	
	GAA-specific T-cell response [Time Frame: 2 year] . MRI) scans 2-year progression-free survival (PFS) . IFN-gamma-enzyme-linked immuno-spot (ELISPOT), and tetramer assays. [Time Frame: 3 years]Whenever post-vaccine tumor tissues are available, they will be analyzed for GAA expression status and infiltration of GAA-specific T-cells. [Time Frame: 3 years] This is a pilot vaccine study in adults with either WHO grade II astrocytoma or oligoastrocytoma. The purpose of this study is test the safety and efficacy of an experimental tumor vaccine made from peptides and Montanide ISA-51 in combination with the study drug Poly-ICLC. Poly-ICLC, manufactured by Oncovir, Inc., has already been received and generally well tolerated by subjects in earlier studies and has been shown to decrease the size of brain tumors in some cases. The immunological and safety data will be used to decide whether a larger study of clinical efficacy is warranted in each of two patient cohorts.		
Recruiting	Vaccination for the Treatment of Previously Untreated or Relapsed Follicular Lymphoma		Lethally Irradiated Lymphoma cells with GM-CSF K562 Cells: Vaccination With Lethally Irradiated Lymphoma Cells Admixed With GM-CSF Secreting K562 Cells.
	Condition:	Follicular Lymphoma	
	Intervention:	Biological: Lethally Irradiated Lymphoma cells with GM-CSF K562 Cells 2007	
	Tumor ORR complete + PRR [Time Frame: 2 years] PFS +AS. **[Detailed]** Description: The dose of vaccine will depend upon how many of the participant's own tumor cells are available and at which point they join study. This Phase I trial is a "dose escalation" study. This means that participants will be enrolled in groups. Group 2 will receive a larger dose than Group 1. Group 3 will receive a larger dose than Group 2. /The vaccine is administered in injections under and into the skin six times. Participants will receive vaccination shots once weekly for 3 vaccines, then every other week for 3 vaccines. /After the first and fifth vaccinations, a small amount of the participants own lymphoma cells (killed) will be injected under the skin to see if their immune system will react against it and cause redness and swelling. A punch skin biopsy will also be performed at these injection locations. During the course of the study, we will also be drawing blood to evaluate immune cells and the effect that the vaccinations have on the participants immune system. During all treatment cycles a physical exam and questions about the participants general health will be performed. After the final treatment (approximately week 10) the participant will undergo "re-staging" to assess the status of their disease. If after completion of six vaccines, evaluation of the participant's disease reveals that it is stable or responding to the vaccine, and there is still vaccine available, they may be eligible to continue to receive the vaccines every two weeks until their supply runs out. After completion of the vaccinations, participants will come back for physical exams and blood tests every 3 months for 1 year and then once a year for fifteen years to monitor the effects of the vaccine		
Not yet recruiting	Autologous Vaccination of Stage 4 Renal Cell Carcinoma Combined With Sunitinib		Autologous renal cell vaccine based on DNP modified cells: Vaccination With DNP Modified Autologous Renal Cell Carcinoma in Combination With Sunitinib in Stage 4 RCC.
	Condition:	Renal Cell Cancer	
	Intervention:	Biological: Autologous renal cell vaccine based on DNP modified cells	

	Immunological response to therapy [Time Frame: two years]. PFS. **Background:** Renal cell carcinoma (RCC) constitutes around 3% of all solid tumors and cure for metastatic sidease is reported for less than 5% of patients. Together with melanoma it is considered the most immune responsive tumor, moreover it is a common practice to resect primary tumor or large metastasis even in the metastatic settings. Antiangiogenesis treatments are currently the favored antitumor drugs, however their use has rarely resulted in complete response/ cure. Recently it has been demonstrated that these drugs can elicit a shift in the immune environment in RCC patients (improved T1 responses reduced Treg responses).Our department has experience in the treatment 200 melanoma patients with cellular vaccination and in the preparation of primary tumor cell lines from various tumors including RCC. Interestingly , immune modulators such as antiCTLA-4 Ab have demonstrated impressive activity in patients previously vaccinated with cellular vaccinations. Working hypothesis: Vaccination with autologous cellular vaccines of RCC patients will induce clinical and immunological responses and help in formulation of better combined vaccination strategies in this cancer. Our aims are: 1) Growth and characterization of primary RCC cell lines,2)vaccination with autologous cellular vaccines in combination with sunitinib. 3) Clinical and immunologic characterizations for derivation of prognostic and predictive factors. Methods: primary or metastatic tumor resected in one of several Israeli hospitals will be used to derive autologous cell lines used for vaccinations following DNP modifications in combination with the regular Sunitinib treatments. Immunological and clinical followup of the patients will be performed and primary cell lines will be grown for further in-vitro testing including possible future use for allogeneic vaccines. Expected result Good safety profile combined with significant clinical and immunological responses are expected. Importance: This research might result in clinical benefit to the treated patients and will be important in the formulation of effective immune strategies in kidney cancer.	
Recruiting	Blockade of PD-1 in Conjunction With the Dendritic Cell/AML Vaccine Following Chemotherapy Induced Remission Conditions: Acute Myelogenous Leukemia; AML Interventions: Biological: DC AML Vaccine; Drug: CT-011 2010	DC AML Vaccine with CT-011:
	Primary Outcome: Toxicity [2 years]. /First Stage: To assess the toxicity associated with treating AML patients with DC AML fusion cells in the post-chemotherapy setting. /Toxicity [2 Years]. /Second Stage: To assess the toxicity associated with treating AML patients with a combination of DC AML fusion cells and CT-011 following a chemotherapy induced remission **Secondary Outcome**: /Immune response [2 years]. /First Stage: To explore immunological response to DC AML Fusion vaccination in this patient population. Tumor regression [2 years]. /Second stage: To determine if cellular immunity is induced by treatment with monoclonal antibody CT-011 and DC/AML fusion cells in patients who have obtained a complete remission following induction chemotherapy. /Time to disease progression [2 Years]. /Second Stage: To define anti-tumor effects by determining time to disease progression.This study is divided into two groups: Group 1 participants will receive the DC AML Fusion Vaccine and Group 2 participants will receive the CT-011 and the DC AML vaccine. The first 10 participants will be in Group 1 and the remaining 25 will be in Group 2. Group 1 participants will receive the DC AML vaccine and GM-CSF 4-8 weeks after completion of chemotherapy for acute myelogenous leukemia (AML). GM-CSF is a drug that stimulates white blood cells and is given with the DC AML Vaccine in an effort to enhance the effect of the vaccine. Participants in this group will receive 3 doses of the vaccine at 4 week intervals. Group 2 participants will receive infusions of CT-011 4-8 weeks after completion of chemotherapy for AML. Participants in this group will receive a total of 3 doses of CT-011 at 6 week intervals. In addition, they will receive a vaccination of the DC AML vaccine two weeks following each infusion of CT-011. All participants will undergo the following procedures: Isolation of tumor cells by either bone marrow biopsy or blood draw; Initial chemotherapy for AML with standard therapy; Leukopheresis (collection of white blood cells from the blood). All participants will also have blood tests, a physical exam, and an electrocardiogram prior to each dose of vaccine. Four weeks following the final vaccination, participants will undergo a skin test called "delayed-type hypersensitivity" (DTH). This is an injection of the tumor cells under the skin to measure how the immune system responds. The tumor cells are broken up and irradiated to prevent their growth	
Recruiting	Allogeneic Tumor Cell Vaccination With Oral Metronomic Cytoxan in Patients With High-Risk Neuroblastoma	Allogeneic Tumor Cell Vaccination With Oral

	Conditions:	Neuroblastoma; Chemotherapy; Pediatrics	Allogeneic Tumor Cell Vaccination With Oral Metronomic Cytoxan in Patients With High-Risk Neuroblastoma (ATOMIC)
	Interventions:	Biological: Neuroblastoma Vaccine; Drug: Cytoxan 2010	
	Primary Outcome: Number of Participants with Adverse Events as a Measure of Safety and Tolerability [Time Frame: 5 years] [Designated as safety issue: Yes] Phase I Primary Objective: Evaluate the safety of fixed dose oral cytoxan administered metronomically to coincide with repeated immunizations of gene-modified, IL-2/lymphotactin secreting SJNB-JF-IL2 and SJNB-JF-LTN cells co-administered with unmodified SKNLP neuroblastoma cell lines in patients with a history of relapsed/refractory high-risk neuroblastoma. Number of Participants with Disease Progression as a Measure of Efficacy [Time Frame: 15 years] [Designated as safety issue: No] Phase II Primary Objective: Evaluate time to progression after administration of combination metronomic chemotherapy and allogeneic tumor cell immunizations in patients with a history of relapsed/refractory high-risk neuroblastoma. Secondary Outcome Measures: Participants with T-cell changes as a Measure of Immune Response [Time Frame: 15 years] [Designated as safety issue: No] Phase I Secondary Objective: Evaluate the immune response to combination metronomic chemotherapy and allogeneic tumor cell immunizations. Analysis of Immunologic Measurements [Time Frame: 15 years] [Designated as safety issue: No] Phase II Secondary Objectives: Evaluate changes in T regulatory cell absolute number, percentages, and suppressive function after the use of metronomic low-dose oral cytoxan with allogeneic neuroblastoma tumor cell immunizations. Evaluate the alterations in angiogenic biomarkers related to fixed dose oral cytoxan and repeated immunizations with allogeneic tumor cell immunizations.		
Not yet recruiting	How Our Immune System Can Help Fight Cancer		the association of indoleamine 2,3-dioxygenase (IDO) genetic polymorphisms with clinical outcomes of ovarian cancer
	Condition:	Ovarian Cancer: Indoleamine 2,3-dioxygenase (IDO), an enzyme that degrades an essential amino acid tryptophan that is necessary for T cells to multiply, however regulatory T cells are less susceptible to low levels of tryptophan, and can still multiply. This allows cancer growth and progression. This may be explained by genetic polymorphisms (changes) in the IDO gene, which may alter its function. Five of these changes in the IDO gene have been described. In this research project, we are asking if you would donate a small piece of your tumor and ascites to see if we can examine your IDO gene in the tumor cells and see if any of these gene changes are present. We hope that this will help us understand how the immune system works in EOC. We hypothesize that genetic polymorphisms within the IDO gene alter its enzymatic activity and affect the outcome of ovarian cancer patients. These findings have the potential to translate into a method for predicting successful immunotherapy. 2010	
	Intervention:		
Completed	Immune Responses To Antigen-Bearing Dendritic Cells in Patients With Malignancy		Antigen-Bearing Dendritic Cells in Patients (Ph-I)
	Condition:	Melanoma	
	Intervention:	Biological: dendritic cell vaccine 2007	

	Immunogenicity of tumor antigen-bearing dendritic cells, based on in vitro assays with class I MHC (influenza) and class II MHC (KLH) -restricted control antigens, **Purpose** Cancer cells make proteins called antigens that act as markers for the tumor cells. These antigens cannot cause the cancer itself. Special white blood cells, called T cells or T lymphocytes, recognize and respond to antigens. In many diseases, these and other cells in the immune system help your body get rid of the disease. However, T cells are normally resting, and they need other proteins on the diseased cell surface to begin working. Unfortunately, cancer cells do not usually make all the other proteins that T cells need to work. Therefore, T cells do not normally work against the cancer cells. We think this is one of the reasons that cancers grow and are not rejected by the body in the first place. Another white blood cell, called a dendritic cell, does have most if not all of the special proteins needed to make T cells work to destroy cancer cells. However, dendritic cells do not normally have the cancer proteins on their surface. The challenge then is to combine the cancer markers (antigens) with these dendritic cells to make a vaccine. We think that the body's T cells might then react against the tumor and help destroy it. This study will see if putting tumor antigens made in a lab onto dendritic cells will make T cells work against tumor cells. We want to answer this question by injecting you with dendritic cells loaded with the antigens. Then we will check for a response based on lab studies and your own clinical course. We will compare your response against melanoma with your response against a common antigen, to which almost everyone has already been exposed. Flu, for example, is a common antigen to which most people have been exposed. We also need to test your response to an antigen that your body has not likely seen before. For example, we plan to use KLH (keyhole limpet hemocyanin), which is a pigment or color protein made from a sea creature known as a keyhole limpet. Each of these, the flu and KLH antigens, which should be harmless to you, will be used along with the dendritic cell-tumor vaccine. This will help us find out if the vaccine is working, based on the lab studies we will check before and after the vaccinations.	
Completed	Augmentation of Dendritic Cell–Based Vaccines in Melanoma Patients by Depletion of Regulatory T Cells in Stage IV Melanoma Patients Condition: Melanoma Interventions: Drug: Daclizumab; Biological: Dendritic cells 2009	Daclizumab + Dendritic cells. Dendritic Cell Based Vaccines in Melanoma Pts by Depletion of Treg cells With an Anti-CD25 MoAb (Daclizumab).
	Immune reponse + Clinical Response. **Purpose** Dendritic cells (DC) are the professional antigen presenting cells of the immune system. Multiple distinct DC lineage's exist and it is now well appreciated that the DC subset and the maturation stage of the DC determines the type of immune response, ranging from a TH1 or TH2 response to immune tolerance. The extremely potent capacity of mature DC to initiate immune responses can be exploited to fight infectious diseases and cancer. Others and we are currently using tumor antigen loaded mature DC in clinical vaccination studies against cancer, and clinical as well as immunological responses have been observed. Exciting new insights accompany the revival of suppressor T cells, now referred to as **regulatory T cells (Treg)**, and implicate that also Treg play a key role in the control of immunity. Treg constitute a **sub-population of CD4+ T cells** constitutively expressing the **IL-2R alpha-chain (CD25)**. Treg show remarkably suppressive activities on different components of the immune system, including T lymphocytes and dendritic cells, suggesting they act both at the initiation phase (DC) and at the effector phase (activated T cells) of the immune response. Interestingly, temporal depletion of Treg has been shown to enhance anti-tumor immune responses and in case of prolonged absence of Treg even autoimmunity. Furthermore, data in mouse tumor models indicate that temporal depletion of Treg also results in improved vaccine efficiency in the therapeutic setting, e.g. in mice with a pre-existing tumor. These data imply that in tumor bearing patients depletion of Treg prior to vaccination will improve vaccine efficacy. In this study we investigate **the effect of regulatory T cell (Treg) depletion on the efficacy of DC-based anti-tumor vaccines** in a clinical study using melanoma associated antigens tyrosinase and **gp100-loaded DC** and a **depleting anti-CD25 mononuclear antibody (Daclizumab).** Our primary objective in this study is the induction of an effective anti-tumor immune response. Our secondary objective is the induction of a clinical response	
Active, not recruiting	Safety and Efficacy Study of HER2/Neu (E75) Vaccine in Breast Cancer Condition: Breast Cancer	E75 + GM-CSF vaccine: HER2/Neu Peptide (E75) Vaccine in Node Negative Breast

	Intervention:	Biological: E75 + GM-CSF vaccine 2009	Cancer Patients.
	Recurrence is measured as a secondary outcome measure. [Time Frame: 30 days] **Detailed Description:** Breast cancer is the most common malignancy and second most common cause of cancer-specific death among women in the United States. Despite advances in the diagnosis and treatment of breast cancer, one third of the women who develop the disease will die of the disease, accounting for approximately 46,300 deaths/year. While good primary therapies are available to treat early stage breast cancer, there is a substantial failure rate to these therapies in more advanced disease. Advances in the understanding of the immune response to cancer have led to the genesis of immunotherapeutic approaches. Specifically, the development of anti-cancer vaccines holds promise as an adjuvant and preventive therapy for patients after primary surgical and medical treatment for breast cancer, but who are at a high risk for recurrence. While patients with hormone receptor positive tumors have the option to undergo hormonal therapy, recurrence is especially high among estrogen receptor/progesterone receptor (ER/PR) negative patients. For these patients, currently there is no good treatment option after completion of primary therapy; close surveillance and watchful waiting is the standard. It is this population of patients that we have targeted with a vaccine strategy to induce cellular immunity. In our first vaccine study, (WU # 00-2005: **Phase Ib Trial of HER2/neu Peptide (E75) Vaccine** in Breast Cancer Patients at High Risk for Recurrence after Surgical and Medical Therapies) we have vaccinated node-positive, HER2/neu-positive breast cancer patients with an immunogenic peptide from the HER2/neu protein mixed with a FDA-approved immunoadjuvant, GM-CSF. The study is still enrolling patients, but to date the vaccine has been safe with very limited toxicity and has been very effective at inducing an immune response to the vaccinated peptide. However, it is too early to determine if this immunity will be protective against disease recurrence. However, with the early immunologic success of the trial, we now intend to more thoroughly study the optimal dose and schedule of vaccinations necessary to efficiently raise immunity against the peptide. In order to study these permeations, we will need to vaccinate significantly more patients; therefore, we propose to vaccinate node-negative breast patients since 75-80% of patients present with early stage breast cancer. Furthermore, we intend to vaccinate patients regardless of their HER2/neu status in order to determine the impact of prior exposure to this antigen on our ability to raise immunity against HER2/neu. Are patients with prior exposure to HER2/neu sensitized or tolerized to this antigen? This question must be answered in order to determine the usefulness of this vaccine as truly	
Recruiting	Vaccine Therapy in Treating Patients With Breast Cancer		
	Condition:	Breast Cancer	GP2 peptide + GM-CSF vaccine/ GM-CSF (sargramostim)/ AE37 + GM-CSF vaccine:
	Interventions:	Biological: GP2 peptide + GM-CSF vaccine; Biological: GM-CSF (sargramostim); Biological: AE37 + GM-CSF vaccine The HER2/Neu Peptide GP2 + GM-CSF Vaccine vs GM-CSF Alone in HLA-A2+ OR the Modified HER2/Neu Peptide AE37 + GM-CSF Vaccine vs GM-CSF Alone in HLA-A2- Node-Positive and High-Risk Node-Negative Breast Cancer Patients. 2007	
	Disease recurrence [until 2014]. Immune Response. proliferation assays, dimer assays, and ELISPOT. DTH **Purpose RATIONALE:** Vaccines made from peptides may help the body build an **effective immune response to kill tumor cells that express HER2/neu.** Biological therapies, such as **GM-CSF**, may stimulate the immune system in different ways and stop tumor cells from growing. It is not yet known whether vaccine therapy is more effective than GM-CSF in treating breast cancer. **PURPOSE:** This randomized phase II trial is studying vaccine therapy to see how well it works compared with GM-CSF in treating patients with breast cancer. After completion of study therapy, **patients are followed every 3 months for the first 24 months and then every 6 months for an additional 36 months.** **Booster** inoculations are administered at **12, 18, 24, and 30 months** from the date of patients' enrollment into the study. One booster inoculation is **administered at each timepoint (+/- 2 weeks)** and will be the same inoculation (vaccine or GM-CSF only) as what patients received during their regular inoculation series.		
Recruiting	Evaluate The Toxicity And Feasibility Of Intra-Tumoral Injection		Intra-Tumoral Injection Of Alpha-Gal

	Condition:	Neoplasm Metastases	Glycosphingolipids In Patients With Advanced Or Refractory Solid Tumors:
	Intervention:	Other: Alpha-Gal Glycosphingolipids 2008	
	Primary : Destruction of visible metastases [T11-12 weeks] **Secondary** : Induction of an immune response that will destroy invisible micrometastases. [11-12 weeks] **Detailed Description:** Recurring chemotherapy refractory tumor lesions are usually lethal in patients with solid tumors. Effective anti-tumor treatment in patients with such lesions needs to achieve two objectives: A.Destruction of visible metastases, and 2. Induction of an immune response that will destroy invisible micrometastases. Without such an immune response, micrometastases develop into lethal lesions. B.Since the majority of solid tumors are thought to express tumor associated antigens (TAA) that are shared between macro- and micrometastases, it is believed that immunotherapy for the induction of an anti-TAA immune response may help in eradication of micrometastases, provided that detectable lesions are effectively destroyed. C.Studies in experimental models have indicated that TAA on many tumors are "concealed" from the immune system by two major mechanisms: 1. The tumor microenvironment and local cytokine milieu are often suppressive toward immune function and can actively induce immune cell tolerance, anergy and death, and 2. Regulatory T cells (Treg) within the tumor and/or in the circulation suppress the development of an anti-TAA (i.e. anti-tumor) immune response. The researchers have developed a novel treatment modality to destroy such lesions and convert them into endogenous tumor vaccines by intratumoral injection of glycosphingolipids expressing alpha-gal epitope (designated GSL-alpha-GAL)		
Recruiting	Intratumoral Injection Of Alpha-Gal Glycosphingolipids		Intratumoral Injection Of Alpha-Gal Glycosphingolipids In Patients With Advanced Melanoma:
	Condition:	Metastatic Melanoma	
	Intervention:	Biological: Alpha-Gal Glycosphingolipids 2008	
	Immune response that will destroy invisible micrometastases. [11-12 w] **Detailed Description:** A standard Phase I dose escalation model will be used to define the maximum tolerated dose (MTD) of GSL alpha-GAL that can be administered directly into the tumor lesion on two separate injections separated by 4-weeks. This trial will serve as the basis for future Phase II trials utilizing multiple injections of GSL alpha-GAL in refractory solid tumors. Additionally, in this study we will look for histologic evidence of an immune response against the injected melanoma lesions which matches that seen in mice. Our hypothesis for this study is that a second injection of GSL alpha-GAL into a melanoma lesion will not precipitate an allergic or autoimmune reaction, but will cause a histologically evident immune response to the tumor		
Completed	Treatment of B-CLL With Human IL-2 and CD40 Ligand and Plasmid Gene Modified Autologous Tumor Cells		B-CLL with h-IL-2 and CD40 Ligand and Plasmid Gene Modified Autologous Tumor Cells (CLIPA): anti-tumor immune responses + anti-tumor effects [15 years] .
	Conditions:	Leukemia; Leukemia, B-Cell, Chronic	
	Intervention:	Biological: IL-2 AND HUMAN CD40 LIGAND PLASMID GENE MODIFIED AUTOLOGOUS TUMOR CELLS 2004	
Completed	Gene Modified Allogeneic Neuroblastoma Cells For Treatment of Relapsed/Refractory Neuroblastoma		Chemokine and Cytokine Gene Modified Allogeneic Neuroblastoma Cells: safety
	Condition:	Neuroblastoma	
	Intervention:	Drug: Interleukin-2 2005	
Withdrawn	Vaccine Therapy in Treating Patients With Stage IIIB or Stage IV Breast Cancer in Remission		recombinant modified vaccinia Ankara-(MVA) Vaccine (TROVAX) (adjuvant
	Condition:	Breast Cancer	

	Interventions:	Drug: recombinant modified vaccinia Ankara-5T4 vaccine; Procedure: adjuvant therapy; Procedure: recombinant viral vaccine therapy 2005	Vaccine (TROVAX) / adjuvant therapy/recombinant viral vaccine therapy:
	Determine the feasibility of conducting a live viral vaccine trial using adjuvant recombinant modified vaccinia Ankara-5T4 vaccine (TroVax®) in patients with stage IIIB-IV breast cancer in remission. Determine the progression-free survival of patients treated with this vaccine. Determine the 5T4-specific T-cell immune response in patients treated with this vaccine. Determine the toxicity of this vaccine in these patients. Determine the level of 5T4-specific antibody response in patients treated with this vaccine. Correlate, preliminarily, immune response with 3- and 12-month progression-free survival of patients treated with this vaccine. Correlate tumor 5T4 expression with overall survival and progression-free survival of patients treated with this vaccine. Correlate tumor infiltrating lymphocyte and CD1a-positive dendritic cell density with development of 5T4-specific T-cell immunity in patients treated with this vaccine.		
Active, not recruiting	Prospective Trial of Vaccine Responses Against Pneumococcus and Influenza in Adult Cancer Patients 65 Years of Age and Older		Inactivated influenza vaccine and the 23-valent pneumococcal vaccine/Inactivated influenza vaccine and the PPV23 vaccine (Pneumovax): 65 yrs diag with common adult tumors to the killed influenza including the killed H1N1 & or the 23-valent pure polysaccharide vaccine. Immune reconstitution od 65y-old Pts and vaccine response
	Conditions:	Breast Cancer; Lung Cancer; Prostate Cancer	
	Interventions:	Biological: inactivated influenza vaccine and the 23- valent pneumococcal vaccine; Biological: inactivated influenza vaccine and the PPV23 vaccine (Pneumovax) 2008	
Recruiting	Two-Arm Study of a DNA Vaccine Encoding Prostatic Acid Phosphatase (PAP) in Patients With Non-Metastatic Castrate-Resistant Prostate Cancer		pTVG-HP with rhGM-CSF: DNA Vaccine Encoding Prostatic Acid Phosphatase (PAP). Evaluate DNA Vaccine Encoding Prostatic Acid Phosphatase (PAP). immunization with a
	Condition:	Prostate Cancer	
	Intervention:	Biological: pTVG-HP with rhGM-CSF 2009	
	DNA vaccine encoding PAP prolongs PSA doubling time every 4-5w. 1-year metastasis-free survival. **Purpose** The investigators are trying to find new methods to treat prostate cancer. The approach is to try to enhance patients' own immune response against the cancer. In this study, the investigators will be testing the safety of a vaccine that may be able to help the body fight prostate cancer. The vaccine, called pTVG-HP, is a piece of DNA genetic material that contains genetic code for a protein that is made by the prostate gland, called prostatic acid phosphatase (PAP). The vaccine will be given together with a substance called an adjuvant. Adjuvants are typically given with vaccines and can improve the effect of the vaccine. The adjuvant that will be used in this study is called granulocyte-macrophage colony-stimulating factor (GM-CSF). The main purpose of this study is to find out whether the vaccine generates long-lived immune responses, and whether a better schedule of vaccination can be found by doing frequent laboratory testing for immune responses. The investigators also want to see if the vaccine stimulates any immune reaction against cancer cells.		
Withdrawn	GI-4000 With Adoptive Transfer in Pancreatic Cancer		GI-4000 Vaccine / GI-4000 Vaccine + Activated T Cells/ Surgical Evaluation after
	Condition:	Pancreatic Cancer	

	Interventions:	Other: Screening; Biological: GI-4000 Vaccine; Biological: GI-4000 Vaccine + Activated T Cells; Biological: Surgical Evaluation after Vaccine #4 2010	Vaccine #4:GI-4000, An Inactivated Recombinant Saccharomyces Cerevisiae Expressing Mutant Ras Protein. Ph-I
	Detailed Description: This Phase I/Pilot study will assess the safety and feasibility of the GI-4000 series vaccine with or without adoptive T cell transfer in subjects with locally advanced pancreatic cancer undergoing chemotherapy, radiotherapy, and surgical resection. Subjects will be randomized to either ARM A (GI-4000vaccine) or ARM B (GI-4000 vaccine and activated T cell transfer). All subjects will undergo apheresis of mononuclear cells immediately before receiving four cycles of gemcitabine/oxaliplatin (GemOx) chemotherapy ("immune preservation phase"). After the completion of chemotherapy, the apheresis product will be reinfused, and the subjects will enter the "priming phase," in which two biweekly doses (dose #1 and #2) of the appropriate GI-4000 vaccine (the one that best matches the mutations found in the patient's tumor) and a single dose of the Prevnar pneumococcal conjugate vaccine will be administered. At this time, those subjects who have not developed distant metastatic disease by CT/MRI will undergo chemoradiation, with ARM B subjects receiving a second apheresis immediately prior to the initiation of the chemoradiation. The pheresed product will be activated and expanded ex vivo and reinfused after chemoradiation is completed. All subjects will receive two more biweekly boosts of the GI-4000 vaccine (doses #3 and #4) while undergoing restaging with CT/MRI ("boosting phase"). Those who have not developed metastatic disease will undergo surgical evaluation for tumor resection. Patients who undergo R0 or R1 resection will receive up to three more weekly doses of GI-4000 prior to the initiation of adjuvant gemcitabine, monthly doses of GI-4000 during the four cycles of gemcitabine chemotherapy, and monthly GI-4000 doses thereafter. At the end of gemcitabine chemotherapy, apheresis will be performed for endpoint correlative studies. Those who are not candidates for surgery or whose tumors are not completely resected will continue to receive GI-4000 monthly booster vaccination.		
Recruiting	Study of Ad.p53 DC Vaccine and 1-MTin Metastatic Invasive Breast Cancer		Ad.p53 DC vaccine with 1-methyl-D-tryptophan (1-MT):
	Condition:	Breast Cancer	
	Interventions:	Biological: Ad.p53 DC vaccine; Drug: 1-methyl-D-tryptophan (1-MT) 2010	
	Ad.p53 DC vaccine with 1-methyl-D-tryptophan (1-MT): efficacy (objective response rate by RECIST) [16w]. The p53 specific IFNc ELISPOT measurement at baseline, week 7 and week 16. p53 specific IFNã ELISPOT responders at week 7 and 16, PFS, Response and progression-free survival , 16w to 12 mo.		
Completed	Vaccination Priming and Vaccine Boosting Trial of Allogeneic Human GM-CSF Gene Transduced Irradiated Prostate Cancer Cell Vaccines (GVAX® Vaccine for Prostate Cancer)		Allogeneic Human GM-CSF Gene Transduced Irradiated Prostate Cancer Cell Vaccines. GVAX® Vaccine for Prostate Cancer.
	Condition:	Prostate Cancer	
	Intervention:	Biological: Immunotherapy allogeneic GM-CSF secreting cellular vaccine 2005	
	Serum PSA levels, will be evaluated and antitumor responses . **Purpose** The objective of this study is to evaluate the safety and efficacy of priming vaccinations, and subsequent boosting vaccinations with GVAX® Vaccine for Prostate Cancer. Clinical observations and laboratory measurements will be monitored to evaluate safety and toxicity. Additionally, the antitumor effects of GVAX® Vaccine for Prostate Cancer on serum PSA levels, will be evaluated and antitumor responses will be quantitated.		
Recruiting	Polyvalent Vaccine-KLH Conjugate + Opt-821 Given in Combination With Bevacizumab		Allogeneic Colon Cancer Cell Vaccine Administered With a GM-CSF Producing Bystander Cell Line:
	Conditions:	Fallopian Tubes Cancer; Ovarian Cancer; Peritoneal Cancer	
	Intervention:	Biological: bevacizumab and the polyvalent vaccine-KLH conjugate + OPT-821 2008	

	T-cell responses to Ep-CAM as a potential surrogate as immune responses. Efficacy, disease-free, and overall survival. **Purpose** The immune system of the body has the ability to fight and eliminate infections and cancers. Immune treatments, such as in this study, seek to teach the immune system to find and destroy cancer cells. The purpose of this study is to test whether it is safe to treat the cancer with a vaccine and another drug called bevacizumab (also known as Avastin).	
Suspended	Vaccine Therapy in Treating Patients With Non-Metastatic Prostate Cancer Condition: Prostate Cancer Interventions: Biological: allogeneic tumor cell vaccine; Biological: therapeutic autologous dendritic cells 2008	Allogeneic Whole Cell Vaccine Administered With or Without Autologous Myeloid DCs: PFS rate at 1 year as assessed by radiographic studies and PSA levels.
	OS, PSA progression, PSA-based response, assessed by the EORTC QLQ-C30 questionnaire, vaccine-specific immune response as a function of time and number of vaccine administrations. **Primary:** To compare the progression-free survival rate at 1 year in patients with androgen-independent non-metastatic prostate cancer treated with allogeneic prostate cancer cell vaccine (APCC) with vs without autologous myeloid dendritic cells. **Secondary:** To compare the toxicities of these regimens in these patients. To compare the overall survival, progression-free survival, time to PSA progression, and duration of PSA-based response in patients treated with these regimens. To compare the quality of life of patients treated with these regimens. To evaluate the ability of the novel dendritic cell-APCC vaccination strategies to induce vaccine-specific immune response in these patients. OUTLINE: Patients are stratified according to 2-year survival probability (< 30% vs≥ 30%). Patients are randomized to 1 of 2 treatment arms. Arm I: Patients receive allogeneic prostate cancer cell vaccine (APCC) intradermally (ID) on days 0, 14, and 28 and then every 28 days for up to 14 courses in the absence of disease progression or unacceptable toxicity. Arm II: Patients undergo standard leukapheresis to harvest peripheral blood mononuclear cells for dendritic cell vaccine preparation. Patients receive the APCC vaccine and autologous dendritic cells derived from CD14-positive myeloid peripheral blood cells ID on days 0, 14, and 28 and then every 28 days for up to 14 courses in the absence of disease progression or unacceptable toxicity. Patients undergo blood sample collection periodically for translational studies. Samples are measured for a number of immune parameters by quantifying T-cell and dendritic cell populations by analysis of surface marker molecules by flow cytometry, T-cell proliferation assay, non-specific cytokine release, lysate-specific cytokine release, and cytokine expression measured by cytometric bead array and qPCR. Patients complete quality-of-life questionnaires periodically. After completion of study treatment, patients are followed periodically for up to 3 years.	
Recruiting	Vaccine Therapy and Cyclophosphamide in Treating Patients Who Have Undergone Surgery for Liver Metastases Due to Colorectal Cancer Conditions: Colorectal Cancer; Metastatic Cancer Interventions: Biological: GM-K562 cell vaccine; Biological: allogeneic tumor cell vaccine; Drug: cyclophosphamide; Genetic: gene expression analysis; Genetic: protein analysis; Other: immunoenzyme technique; Other: immunologic technique; Other: laboratory biomarker analysis 2008	an Allogeneic Colon Cancer Cell Vaccine Administered With a GM-CSF Producing Bystander Cell Line:

	Measuring T-cell responses to Ep-CAM. Efficacy, disease-free, and overall survival. Cellular vaccine response (one month after each (1st through 4th): analyzed by ELISPOT assays on peripheral blood mononuclear cells, for HLA typing and HLA-A2 expression by the standard NIH microlymphocytotoxicity test. OUTLINE: At least 1 month and no more than 3 months after the last course of adjuvant systemic chemotherapy or hepatic metastectomy, patients receive cyclophosphamide IV on day -1 and vaccine therapy comprising allogeneic colorectal carcinoma cells and K562/GM-CSF cells intradermally on day 0. Treatment repeats every month for up to 4 courses in the absence of disease progression or unacceptable toxicity. Blood is collected prior to the first vaccine administration, then one month after each (1st through 4th) immunization for correlative studies. Samples are analyzed by ELISPOT assays on peripheral blood mononuclear cells, for HLA typing and HLA-A2 expression by the standard NIH microlymphocytotoxicity test, for peptides by ELISPOT assays, and for immunologic response by other exploratory assays. After completion of study treatment, patients are followed at 28 days and then periodically thereafter	
Completed	Vaccine Therapy With or Without Docetaxel in Treating Patients With Metastatic Prostate Cancer Condition: Prostate Cancer Interventions: Biological: recombinant fowlpox-prostate specific antigen vaccine; Biological: recombinant vaccinia prostate-specific antigen vaccine; Biological: recombinant vaccinia-B7.1 vaccine; Biological: sargramostim; Drug: docetaxel 2002	recombinant fowlpox-prostate specific antigen vaccine/ recombinant vaccinia prostate-specific antigen vaccine/ recombinant vaccinia-B7.1 vaccine with GM-CSF:
	(PSA)-specific T-cell precursors (CD8), the immunologic effects: Measure CD4 T-cell responses. **OBJECTIVES:** Compare the relative change in prostate-specific antigen (PSA)-specific T-cell precursors (CD8) from baseline to day 85 in patients with metastatic androgen-independent prostate cancer treated with a vaccination regimen comprising fowlpox-PSA vaccine, recombinant rV-B7.1 vaccine, recombinant vaccinia-PSA vaccine, and sargramostim (GM-CSF) with or without docetaxel. Compare the safety of these regimens in these patients. / Compare clinical activity of these regimens in these patients. /Determine the immunologic effects in these patients after additional vaccine/chemotherapy courses. /Measure CD4 T-cell responses to the vaccine in these patients. OUTLINE: This is a randomized study. Patients are randomized to 1 of 2 treatment arms after receiving priming vaccinations. Priming vaccinations: All patients receive recombinant vaccinia-prostate-specific antigen (PSA) vaccine subcutaneously (SC) and recombinant rV-B7.1 vaccine SC on day 1 and sargramostim (GM-CSF) SC on days 1-4. Patients then receive fowlpox-PSA vaccine (F-PSA) SC on day 15 and GM-CSF SC on days 15-18. Arm I: Patients receive docetaxel IV over 30 minutes on days 29, 36, and 43; F-PSA SC on day 30; and GM-CSF SC on days 30-33. Treatment repeats beginning on day 56 for one more course. Patients who do not have disease progression at day 85 receive docetaxel weekly for 3 weeks and F-PSA on day 1 of each course. Courses repeat every 4 weeks in the absence of disease progression or unacceptable toxicity. Arm II: Patients receive F-PSA SC on days 29 and 57 and GM-CSF SC on days 29-32 and 57-60. Patients who show disease progression after day 85 either radiographically or by rising PSA stop receiving the vaccine and may receive docetaxel weekly for 3 weeks. Chemotherapy repeats every 4 weeks in the absence of disease progression or unacceptable toxicity.	
Active, not recruiting	Alpha-type-1 Dendritic Cell-based Vaccines in Patients With Metastatic Colorectal Cancer Condition: Metastatic Colorectal Cancer Intervention: Biological: DC-based vaccine 2007	Semi-continuous Alpha-type-1 Dendritic Cell-based Vaccines.