

	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
	<p>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 Plevnar 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.</p>		
Recruiting	Study of Ad.p53 DC Vaccine and 1-MT in 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 IFNα 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	
	<p>Serum PSA levels, will be evaluated and antitumor responses .</p> <p>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.</p>		
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.	
	<p>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.</p> <p>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.</p> <p>Secondary: To compare the toxicities of these regimens in these patients.</p> <p>To compare the overall survival, progression-free survival, time to PSA progression, and duration of PSA-based response in patients treated with these regimens.</p> <p>To compare the quality of life of patients treated with these regimens.</p> <p>To evaluate the ability of the novel dendritic cell-APCC vaccination strategies to induce vaccine-specific immune response in these patients.</p> <p>OUTLINE: Patients are stratified according to 2-year survival probability (< 30% vs ≥ 30%). Patients are randomized to 1 of 2 treatment arms.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Patients complete quality-of-life questionnaires periodically.</p> <p>After completion of study treatment, patients are followed periodically for up to 3 years.</p>	
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:	

	<p>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.</p> <p>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.</p> <p>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.</p> <p><u>After completion of study treatment, patients are followed at 28 days and then periodically thereafter</u></p>	
Completed	<p>Vaccine Therapy With or Without Docetaxel in Treating Patients With Metastatic Prostate Cancer</p> <p>Condition: Prostate Cancer</p> <p>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</p>	<p>recombinant fowlpox-prostate specific antigen vaccine/ recombinant vaccinia prostate-specific antigen vaccine/ recombinant vaccinia-B7.1 vaccine with GM-CSF:</p>
	<p>(PSA)-specific T-cell precursors (CD8), the immunologic effects: Measure CD4 T-cell responses.</p> <p>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.</p> <p>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.</p> <p>OUTLINE: This is a randomized study. Patients are randomized to 1 of 2 treatment arms after receiving priming vaccinations.</p> <p>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.</p> <p>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.</p> <p>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.</p>	
Active, not recruiting	<p>Alpha-type-1 Dendritic Cell-based Vaccines in Patients With Metastatic Colorectal Cancer</p> <p>Condition: Metastatic Colorectal Cancer</p> <p>Intervention: Biological: DC-based vaccine 2007</p>	<p>Semi-continuous Alpha-type-1 Dendritic Cell-based Vaccines.</p>

	<p>Immunity results from either single injections or semi-continuous infusion [4-14 w], Detailed Description: Dendritic cell (DC)-based vaccination, usually administered by a traditional intradermal route, is a new treatment option for cancer patients. While the previous DC-based vaccination trials have shown the safety of this approach and its ability to induce objective clinical responses, the overall efficacy of DC-based vaccines is still disappointing (Rosenberg et al., 2004). We hypothesize that the two likely causes of such limited clinical activity are: A) suboptimal type of DCs used as a vaccine and B) suboptimal modes of use of such vaccines that do not allow the vaccinated patients to fully benefit from DC biology. We will conduct a pilot evaluation of the therapeutic vaccination with DC1s loaded with autologous tumor material, in patients with metastatic colorectal cancer that have been resected to no or minimal evidence of disease. The proposed evaluation of the novel intralymphatic route of DC-based vaccination will allow us to administer the vaccine in a way that is more physiologic with respect to the kinetics of antigen appearance to the lymph nodes and is feasible to be performed in repetitive fashion, without damaging local lymph nodes.</p>	
Active, not recruiting	<p>Vaccine Therapy in Treating Patients With Kidney Cancer</p> <p>Condition: Kidney Cancer</p> <p>Interventions: Biological: autologous tumor cell vaccine; Biological: therapeutic autologous dendritic cells 2001</p>	Autologous Tumor Cells And Dendritic Cells.
	<p>DTH, PR or CR as measured by RECIST at months 2 or 3 and 6. PFS as measured by RECIST at months 2 or 3 and 6. Event-free survival as measured by RECIST at months 2 or 3 and 6. OS. OUTLINE: Patients are stratified according to measurable disease at the time vaccine therapy is initiated (yes vs no). Patients undergo tumor cell harvest. Patients with multiple persistent sites of metastatic disease following harvest receive systemic therapy (biologic therapy and/or chemotherapy) during tumor cell line expansion. Over 2-4 months, the tumor cell line is expanded, treated with interferon gamma, and irradiated. Patients undergo leukapheresis to obtain peripheral blood mononuclear cells (PBMC). The PBMC are incubated over 7 days with sargramostim (GM-CSF) and interleukin-4 to produce dendritic cells (DC). The DC are incubated over 2-3 days with the irradiated tumor cells from the autologous tumor cell line for antigen loading of the DC. /Patients undergo delayed tumor hypersensitivity testing 1 week prior to vaccination and again at week 4. Patients receive vaccine therapy comprising autologous treated tumor cells and DC suspended in GM-CSF subcutaneously weekly for 3 weeks. Vaccine therapy continues monthly for 5 months in the absence of disease progression or unacceptable toxicity.</p>	
Completed	<p>Human Papilloma Virus (HPV) Vaccine Efficacy Trial Against Cervical Pre-cancer in Young Adults With GlaxoSmithKline (GSK) Biologicals HPV-16/18</p>	GSK Bio HPV Vaccine (580299) vs Hepatitis A Vaccine as Control in Prevention of Persistent HPV-16/18 Cervical Infection & Cervical Neoplasia
Has Results	<p>Conditions: Human Papillomavirus (HPV) Infection; Papillomavirus Vaccines; Cervical Neoplasia</p> <p>Interventions: Biological: Cervarix™; Biological: Havrix™-based investigational formulation 2005</p>	
	HPV DNA negative at Month 0 and Month 6 for the corresponding HPV-type and seronegative for HPV-16 and/or HPV-18 by ELISA	
Recruiting	<p>153Sm-EDTMP With or Without a PSA/TRICOM Vaccine To Treat Men With Androgen-Insensitive Prostate Cancer</p> <p>Condition: Prostate Cancer</p> <p>Interventions: Radiation: Samarium Sm 153 lexidronam pentasodium; Biological: Sargramostim; Biological: Recombinant vaccinia-TRICOM vaccine; Biological: Recombinant fowlpox-TRICOM vaccine 2007</p>	Recombinant vaccinia-TRICOM vaccine / Recombinant fowlpox-TRICOM vaccine contained genes for a protein(PSA) (PSA/TRICOM) :

	<p>4-month PFS. PSA-specific antigen outcomes. Immunologic response. PFS + OS.</p> <p>Background No treatment is known to improve survival for prostate cancer patients who have not been helped by previous treatments with hormones and chemotherapy.</p> <p>An experimental vaccine called PSA/TRICOM contains genes for a protein produced by prostate cancer cells called prostate-specific antigen (PSA). The vaccine can trigger the immune system to make cells that may be able to recognize and attack the cancer cells that make PSA.</p> <p>GM-CSF is an approved drug that is usually given to increase a patient's white blood cell count or to stimulate the immune system.</p> <p>153Sm-EDTMP is a radioactive drug that has been approved for many years to treat advanced prostate cancer. It is given through a vein and can be targeted directly to tumors in the bone where it can relieve pain caused by bone lesions. Radiation also increases the level of certain proteins inside the tumor, making it easier for the immune system to find and kill the tumor cells.</p> <p>When laboratory mice were given just vaccine, just radiation, or a combination of both, the combination was most effective in treating tumors.</p> <p>Objectives: -To determine if combined treatment with PSA/TRICOM vaccine and 153Sm-EDTMP radiation can delay progression of prostate cancer better than radiation alone.</p> <p>Eligibility: -Patients who have advanced prostate cancer that has worsened despite treatments with hormones, have two or more bone lesions related to their prostate cancer, and have had prior treatment with docetaxel chemotherapy.</p> <p>Design: Patients are randomly assigned to receive radiation alone (Arm A) or radiation with vaccine and sargramostim (Arm B).</p> <p>Arm A receives 153Sm-EDTMP radiation starting on study day 8 and repeated every 12 weeks.</p> <p>Arm B receives a priming vaccine on study day 1 and radiation on day 8. Radiation therapy is repeated every 12 weeks. Boosting vaccines are given on days 15 and 29 and then monthly. GM-CSF is given with each vaccination (on the day of the vaccination and for the next 3 days) to enhance the immune response. Vaccinations and GM-CSF are given as injections under the skin, usually in the thigh. Radiation therapy is given through a vein.</p> <p>Patients are monitored regularly with physical examinations, blood and urine tests, and scans to evaluate safety and treatment response.</p>							
Recruiting	<p>p53 Synthetic Long Peptides Vaccine With Cyclophosphamide for Ovarian Cancer</p> <table border="1"> <tr> <td data-bbox="257 848 432 879">Condition:</td> <td data-bbox="432 848 1630 879">Ovarian Cancer</td> </tr> <tr> <td data-bbox="257 879 432 997">Interventions:</td> <td data-bbox="432 879 1630 997">Drug: P53-SLP vaccine; Drug: Cyclophosphamide 2009</td> </tr> </table>	Condition:	Ovarian Cancer	Interventions:	Drug: P53-SLP vaccine; Drug: Cyclophosphamide 2009	<p>p53 Synthetic Long Peptides Vaccine With Cyclophosphamide.</p> <p>Clinical Resp. by measurement of serum CA-125 levels and CT-scan[day 105 – 126].</p> <p>p53-specific T cells by proliferation and IFN-γ ELISPOT [after fourth immunization] .</p>		
Condition:	Ovarian Cancer							
Interventions:	Drug: P53-SLP vaccine; Drug: Cyclophosphamide 2009							
Active, not recruiting	<p>Vaccine Therapy in Treating Patients With Pancreatic Cancer That Has Been Removed by Surgery</p> <table border="1"> <tr> <td data-bbox="257 1028 432 1090">Conditions:</td> <td colspan="2" data-bbox="432 1028 1630 1090">Anorexia; Fatigue; Pain; Pancreatic Cancer; Psychosocial Effects of Cancer and Its Treatment</td> </tr> <tr> <td data-bbox="257 1090 432 1124">Intervention:</td> <td colspan="2" data-bbox="432 1090 1630 1124">Biological: sargramostim plasmid DNA pancreatic tumor cell vaccine 2006</td> </tr> </table>		Conditions:	Anorexia; Fatigue; Pain; Pancreatic Cancer; Psychosocial Effects of Cancer and Its Treatment		Intervention:	Biological: sargramostim plasmid DNA pancreatic tumor cell vaccine 2006	
Conditions:	Anorexia; Fatigue; Pain; Pancreatic Cancer; Psychosocial Effects of Cancer and Its Treatment							
Intervention:	Biological: sargramostim plasmid DNA pancreatic tumor cell vaccine 2006							

Boosting With Lethally Irradiated Allogeneic Pancreatic Tumor Cells Transfected With the GM-CSF Gene:

	<p>PFS + OS. Immune response to prostate stem cell antigen, and mutated k-ras-specific T-cell responses, as measured by biopsy, histological analysis at 4 weeks post vaccination. GM-CSF serum level. 他多数</p> <p>Primary Determine the safety of primary and boost vaccinations with lethally irradiated allogeneic pancreatic tumor cells transfected with sargramostim (GM-CSF) gene vaccine in patients with surgically resected adenocarcinoma of the head, neck, or uncinat of the pancreas.</p> <p>Secondary Correlate specific in vivo parameters of immune response (e.g., mesothelin, prostate stem cell antigen, and mutated k-ras-specific T-cell responses) with clinical response in patients treated with this regimen.</p> <p>Determine the efficacy, in terms of overall and recurrence-free survival, of this regimen in these patients.</p> <p>Correlate serum GM-CSF levels with longevity of an allogeneic vaccine after semi-annual boosting in these patients.</p> <p>Determine the psychosocial (e.g., demographics, quality of life, hope, trust, social support, decision control, and advanced directives) and symptom (e.g., pain, anorexia, fatigue, and mood state) profiles in these patients and explore changes over time.</p> <p>OUTLINE: This is an open-label study. Patients are stratified according to prior vaccination with allogeneic sargramostim (GM-CSF)-secreting pancreatic tumor cell vaccine (yes [stratum I] vs no [stratum II]).</p> <p>Stratum I: Patients receive booster vaccination comprising allogeneic GM-CSF plasmid DNA pancreatic tumor cell vaccine subcutaneously (SC). Treatment repeats every 6 months in the absence of disease progression or unacceptable toxicity.</p> <p>Stratum II: Patients receive priming vaccinations SC once a month for 3 months and then receive booster vaccinations as in stratum I.</p> <p>Patients complete self-reported psychosocial (including quality of life, hope, and trust) and symptom (including pain, fatigue, anorexia, and mood) questionnaires at day 0 and day 28.</p> <p><i>After completion of study treatment, patients are followed at day 28 and then annually for 15 years.</i></p>					
Recruiting	<p>MUC1 Vaccine for Triple-negative Breast Cancer</p> <table border="1"> <tr> <td data-bbox="273 786 434 833">Conditions:</td> <td data-bbox="434 786 1630 833">Breast Cancer; Inflammatory Breast Cancer; Stage I Breast Cancer; Stage II Breast Cancer; Stage IIIA Breast Cancer; Stage IIIB Breast Cancer; Stage IIIC Breast Cancer; Triple-negative Breast Cancer</td> </tr> <tr> <td data-bbox="273 833 434 890">Interventions:</td> <td data-bbox="434 833 1630 890">Biological: MUC-1 peptide vaccine; Biological: poly ICLC; Biological: MUC1 peptide-poly-ICLC adjuvant vaccine; Other: laboratory biomarker analysis; Other: enzyme-linked immunosorbent assay; Other: flow</td> </tr> </table>	Conditions:	Breast Cancer; Inflammatory Breast Cancer; Stage I Breast Cancer; Stage II Breast Cancer; Stage IIIA Breast Cancer; Stage IIIB Breast Cancer; Stage IIIC Breast Cancer; Triple-negative Breast Cancer	Interventions:	Biological: MUC-1 peptide vaccine; Biological: poly ICLC; Biological: MUC1 peptide-poly-ICLC adjuvant vaccine; Other: laboratory biomarker analysis; Other: enzyme-linked immunosorbent assay; Other: flow	<p>MUC1 Peptide and Poly-ICLC Vaccine. Immunologic response [16 w following 4 injections] laboratory biomarker analysis by ELISA and flow-cytometry</p>
Conditions:	Breast Cancer; Inflammatory Breast Cancer; Stage I Breast Cancer; Stage II Breast Cancer; Stage IIIA Breast Cancer; Stage IIIB Breast Cancer; Stage IIIC Breast Cancer; Triple-negative Breast Cancer					
Interventions:	Biological: MUC-1 peptide vaccine; Biological: poly ICLC; Biological: MUC1 peptide-poly-ICLC adjuvant vaccine; Other: laboratory biomarker analysis; Other: enzyme-linked immunosorbent assay; Other: flow					
	<p>Primary: 1) Proportion of patients showing an immunologic response [Time Frame: At week 12 (2 weeks after the 3rd injection)]. 2) Defined as a ≥ 2-fold enhancement from baseline anti-MUC1 antibody immunity, or for subjects with no antibody to MUC1 at baseline, any detectable antibody immunity against MUC1. To test the hypothesis of a sufficient immunologic response, we will apply a Simon's optimum 2-stage design. The proportion of patients with an immunologic response will be calculated with a 95% confidence interval using method developed for multistage clinical trials.</p> <p>Secondary: •Safety and toxicity as assessed by NCI CTC [Time Frame: Weeks 0, 2, 4, 10, 12, 52, and 54 and then for 30 days after completion of study treatment]</p> <p>I. To evaluate the efficacy of MUC1 peptide-poly-ICLC adjuvant vaccine in boosting systemic immunity to MUC1 in women who have completed therapy for AJCC(American Joint Committee on Cancer) stage I-III 'triple-negative' [i.e., ER(-) PR(-) HER2/neu(-)] breast cancer.</p> <p>SECONDARY OBJECTIVES:</p> <p>I. To evaluate the safety and toxicity of the MUC1 peptide and poly-ICLC vaccine in this cohort of patients.</p> <p>OUTLINE:</p> <p>Patients receive MUC-1 peptide vaccine subcutaneously (SC) and poly-ICLC vaccine SC in weeks 0, 2, and 10 in the absence of disease progression or unacceptable toxicity. Some patients may receive a booster vaccine in week 52. Patients will be followed for study-related Serious Adverse Events (SAEs) for a period of 30 days after their last vaccination. If a patient experiences a SAE while participating in this study, they will be followed until the resolution of the SAE.</p> <p>•AJCC stage I-III infiltrating adenocarcinoma of the breast who have completed standard adjuvant or neoadjuvant therapy (surgery, radiation, biologic therapy, chemotherapy) for TNBC (ER-, PR-, HER-2/neu-)</p>					
Not yet	<p>Measles Vaccine in Patients With Measles Virus-Positive, Advanced Non-Small Cell Lung Cancer</p>	<p>Measles Vaccine (attenuated measles) in</p>				

recruiting	Conditions:	Non-Small Cell Lung Cancer; Measles	Patients With Measles Virus-Positive, Stage 3B/4 Non-Small Cell Lung Cancer: (PFS) + (OS) [Time Frame: 2-years]
	Intervention:	Biological: attenuated measles vaccine 2009	
Recruiting	Vaccination of Patients With Ovarian Cancer With Dendritic Cell/Tumor Fusions With Granulocyte Macrophage Colony-stimulating Factor (GM-CSF) and Imiquimod		Dendritic Cell/Tumor Fusions With GM-CSF and Imiquimod (drug): Cellular immunity and clinical response [2 years]. Patient cellular immune function and phenotypic characteristics
	Conditions:	Ovarian Cancer; Primary Peritoneal Cancer; Fallopian Tube Cancer	
	Interventions:	Drug: GM-CSF; Biological: Dendritic Cell/Tumor Fusion Vaccine; Drug: imiquimod 2008	
Recruiting	Docetaxel and Prednisone With or Without Vaccine Therapy in Treating Patients With Metastatic Hormone-Resistant Prostate Cancer		PSA-TRICOM (fowlpox-PSA-TRICOM vaccine + vaccinia-PSA-TRICOM vaccine) Vaccine: Median overall survival. Radiographic progression. PSA response. Association between PSA-specific immune responses, time to progression, and overall survival. Evaluate the association of predicted survival (by Halabi nomogram)
	Condition:	Prostate Cancer	
	Interventions:	Biological: fowlpox-PSA-TRICOM vaccine; Biological: vaccinia-PSA-TRICOM vaccine; Drug: docetaxel; Drug: prednisone 2010	
Recruiting	Vaccination of Patients With Breast Cancer With Dendritic Cell/Tumor Fusions and IL-12		Dendritic Cell/Tumor Fusions and IL-12 To determine if cellular and humoral immunity and clinically measurable disease responses [3 years].
	Condition:	Breast Cancer	
	Interventions:	Biological: Dendritic Cell/Tumor Fusion Vaccine; Drug: Interleukin-12 2008	
Active, not recruiting	Vaccine Therapy and GM-CSF in Treating Patients With Prostate Cancer That Progressed After Surgery and/or Radiation Therapy		PROSTVAC-V (Vaccinia)/TRICOM and PROSTVAC-F (Fowlpox)/TRICOM With GM-CSF: Free of PSA progression before 6 months. Characterization of PSA velocity. PSA response on vaccine. T-cell immune response
	Condition:	Prostate Cancer	
	Interventions:	Biological: fowlpox-PSA-TRICOM vaccine; Biological: sargramostim; Biological: vaccinia-PSA-TRICOM vaccine; Drug: bicalutamide; Drug: goserelin 2005	
Recruiting	Tumor Cell Vaccines With ISCOMATRIX(Trademark) Adjuvant and Celecoxib in Patients Undergoing Resection of Lung and Esophageal Cancers and Malignant Pleural Mesotheliomas		Epigenetically-Modified Autologous Tumor Cell Vaccines With ISCOMATRIX(TM) Adjuvant and Oral Celecoxib: Immunologic response [3 years]
	Conditions:	Mesothelioma; Esophageal Cancer; Lung Cancer	
	Interventions:	Drug: Celecoxib; Drug: ISCOMATRIX (TM) Adjuvant; Biological: Autologous Tumor Cell Vaccine 2010	
Not yet recruiting	Vaccine Therapy in Treating Patients With Colorectal, Stomach, or Pancreatic Cancer		
	Conditions:	Recurrent Colon Cancer; Recurrent Gastric Cancer; Recurrent Pancreatic Cancer; Recurrent Rectal Cancer; Stage III Colon Cancer; Stage III Gastric Cancer; Stage III Pancreatic Cancer; Stage III Rectal Cancer; Stage IV Colon Cancer; Stage IV Gastric Cancer; Stage IV Pancreatic Cancer; Stage IV Rectal	

	Interventions:	Other: laboratory biomarker analysis; Other: enzyme-linked immunosorbent assay; Other: flow cytometry; Other: immunoenzyme technique; Biological: modified vaccinia virus ankara vaccine expressing p53 2010
	<p>Modified vaccinia virus ankara vaccine expressing p53: Immunogenicity by using an ELISA assay for humoral response, lymphoproliferation for CD4+ T cell response and intracytoplasmic cytokine assays, and IFN-gamma and IL-4 by ELISPOT assays [1 years] PRIMARY OBJECTIVES:I. To establish whether 2 vaccine dose levels of MVAp53 vaccines are safe and well tolerated in patients with p53 over-expressing solid tumor malignancy. SECONDARY OBJECTIVES:I. To provide preliminary evidence of enhanced cellular and humoral immunity to p53. OUTLINE: This is a phase I, dose-escalation trial of modified vaccinia virus ankara vaccine expressing p53 (MVAp53). Patients receive MVAp53 subcutaneously (SC) on days 0, 21, and 42 in the absence of unacceptable toxicity. After completion of study treatment, patients are followed up annually for 5 years.</p> <ul style="list-style-type: none"> •Patients with unresectable and chemotherapy resistant primary or recurrent carcinoma of colorectal, gastric or pancreatic origin •There must be pathologic evidence for malignancy with a soft tissue component of tumor evident on CT scan imaging or physical examination 	
Active, not recruiting	<p>Vaccine Therapy With Sargramostim (GM-CSF) in Treating Patients With Her-2 Positive Stage III-IV Breast Cancer or Ovarian Cancer</p>	
	Conditions:	HER2-positive Breast Cancer; Stage III Ovarian Epithelial Cancer; Stage III Ovarian Germ Cell Tumor; Stage IIIA Breast Cancer; Stage IIIB Breast Cancer; Stage IIIC Breast Cancer; Stage IV Breast Cancer; Stage IV Ovarian Epithelial Cancer; Stage IV Ovarian Germ Cell Tumor
	Interventions:	Biological: pNGVL3-hICD vaccine; Biological: sargramostim; Other: flow cytometry; Other: immunologic technique; Other: immunoenzyme technique; Genetic: protein expression analysis; 2007
	<p>DNA Plasmid Based Vaccine Encoding the HER-2/Neu Intracellular Domain in Subjects With HER-2/Neu (HER2) Overexpressing Tumors: Dose on immunologic response [month 15]. Flow cytometry immunoenzyme technique Protein expression analysis Biopsy. Persistence of DNA at the injection site [: At 1 and 6 months after last vaccination] Biological: pNGVL3-hICD vaccine Plasmid-based DNA vaccine, given intradermally Biological: sargramostim, Given intradermally: Other Names: •GM-CSF, •granulocyte macrophage colony-stimulating factor, •Leukine, •Prokine, •rhu GM-CFS Other: flow cytometry Correlative studies Other: immunologic technique Correlative studies Other Names: •immunological laboratory methods, •laboratory methods, immunological Other: immunoenzyme technique 1) Undergo ELIspot (correlative studies), 2) Other Name: immunoenzyme techniques Genetic: protein expression analysis Undergo ELISA (correlative studies) Procedure: biopsy Undergo punch biopsy (correlative studies) Other Name: biopsies •Breast cancer: stage III or stage IV breast cancer with metastasis in remission and defined as NED (no evidence of disease); stable or healing bone disease by radiologic evaluation which may include, but is not limited to, bone scan, MRI, or PET scan documented within 90 days of enrollment to study and NED status for extraskelatal metastasis •Ovarian cancer: stage III or stage IV ovarian cancer in first complete remission with a normal AND stable CA-125; thus, two sequential normal CA-125 values will need to be documented; a minimum of 30 days between 2 sequential CA-125 values; the most recent will be within 2 weeks of enrollment into study •HER2 overexpression by immunohistochemistry (IHC) of 2+ or 3+ in their primary tumor or metastasis, and if overexpression is 2+ by IHC or in the absence of IHC, then patients must have documentation of HER2 gene amplification by FISH</p>	
Recruiting	<p>Autologous Tumor DRibble Vaccine in Patients With Non-Small Cell Lung Cancer</p>	
	Condition:	Non Small Cell Lung Cancer
	Autologous, unmodified tumor cells and DRibble Vaccine (highly immunogenic	

	Intervention:	Biological: DRibble vaccine 2009	accumulated short-lived proteins).
	<p>Ten patients will be enrolled. Study treatment is as follows: Docetaxel 75 mg/m² will be given on day 1. Intradermal vaccinations of DRibbles from 5-20 x 10⁶ cell equivalents per vaccine will begin 14 days after docetaxel. Immediately following vaccination, subcutaneous infusion of GM-CSF (50 micrograms/24 hrs) will be initiated. GM-CSF will be infused into the vaccination site for 6 days using the CADD-MS 3 pump.</p> <p>Immune response as measured by in vitro immune monitoring and by (DTH). [DTH on days 7-10 and days 77-80 and blood for immune monitoring (30-50 cc)].</p> <p>Tumor response (RECIST criteria) [Week 12]</p> <p>A second docetaxel injection will be given at day 29 followed by a second vaccination 14 days later and 3 additional vaccines will be given at 2-week intervals. Following each vaccination, GM-CSF will again be infused over 6 days via the CADD-MS 3 pump.</p> <p>Peripheral blood will be obtained for immune monitoring at each vaccination. DTH to autologous tumor and to DRibble vaccine will be tested before the first and fifth vaccines. A second leukapheresis for immune monitoring will be obtained at 12 weeks. Clinical tumor response will be assessed after the fifth vaccination unless clinical evidence of tumor progression occurs sooner.</p> <p>Immune response will be assessed by DTH, T-cell function, T-cell migration into the vaccine sites and cytokine release assays. Sophisticated flow cytometry assays will be used to detect active T-cell subsets. Safety will be monitored by physical and laboratory exams at each vaccine visit and adverse events will be recorded and reported as appropriate. Clinical response will be assessed by tumor measurements by CT scan and/or physical exam at study entry and after 12 weeks. PFS and</p>		
Recruiting	Prospective Trial of Vaccine Responses in Childhood Cancer Survivors		
	Conditions:	Childhood Cancer; Multiple Diseases 2007	I
	Interventions:	Biological: Immunization Schedule patients <7 years.; Biological: Immunization Schedule patients > or = to 7 years and <11 years of age; Biological: Immunization Schedule patients > or = to 11 years of age	
	<p>Immunization Schedule patients > or = to 7 years and <11 years of age</p> <ul style="list-style-type: none"> •Time 0 months: Hib #1, Pevnar 13 #1, Hepatitis B #1 •Time 1 month: Td#1, IPV #1(inactivated polio virus vaccine), Hepatitis B #2 •Time 2-3 months: Pevnar 13 #2, Hib #2 •Time 3-6 months: Td #2, Draw post vaccine titers Time 6-12 months: Administer Hepatitis #3 to patients not immunized prior to treatment for cancer, or with negative Hepatitis B titers after two immunizations 		
Recruiting	Vaccine Therapy, Temozolomide, and Radiation Therapy in Treating Patients With Newly Diagnosed Glioblastoma Multiforme		
	Condition:	Brain and Central Nervous System Tumors	IMA950 (A Novel Multi-Peptide Vaccine) Plus GM-CSF. glioblastoma multiform multi-antigen vaccine IMA950 and GM-CS..
	Interventions:	Biological: glioblastoma multiform multi-antigen vaccine IMA950; Biological: sargramostim; Drug: temozolomide; Other: laboratory biomarker analysis; Other: pharmacological study; Procedure: adjuvant	
	<p>T-cell responses against a single or multiple tumor-associated peptides (TUMAP) at one or more post-vaccination time points by HLA multimer analysis. (PSF) at 6 and 9 months post-surgery as assessed by the Macdonald criteria from conventional gadolinium-enhanced MRI and clinical assessment. Steroid levels and observed T-cell responses. O6-methyl-DNA-methyltransferase (MGMT) promoter methylation status in tumor tissue. •Kinetics of vaccine-induced TUMAP responses</p>		
Recruiting	Evaluating the T Cell Response to a Peptide-based Vaccine in Patients With Breast Cancer		CD8+ T Cell Activation and Infiltration Into Primary Breast Tumors Following Administration of a Peptide Vaccine:
	Condition:	Breast Neoplasms	
	Intervention:	Biological: 9 Peptides from Her-2/neu, CEA, & CTA 2009	

	<p>multi-peptide vaccine induces T cells that traffic to and penetrate into human primary breast cancers. (day22). Antigen specific T cell response to a peptide-based vaccine and the induction of differentiated effector cells, both in the peripheral blood and within the tumor microenvironment. [1 year]</p> <p>Just under 200,000 American women will be diagnosed with breast cancer this year. Standard breast cancer therapies have long included surgical resection, chemotherapy, radiation therapy, and hormonal therapy. However, other immune therapies are now being explored for the treatment of breast cancer, including peptide-based vaccines. In support of directed T cell therapies for breast cancer, antigenic epitopes from breast cancer-associated proteins such as Her-2/neu and the MAGE gene family have been identified, and vaccines containing peptides derived from these proteins have been shown to be safe and immunogenic in breast cancer patients.</p> <p>Results from successful immune therapy approaches, for various human and murine cancers, have shown that antitumor effects can be mediated by T cells, which is proof-of-principle that the immune system, and in particular, T cells, can reject tumor. Overall, however, the complete clinical response rate for T cell mediated immunotherapies has been low. There are at least two possibilities to explain why this may be the case. First, tumor reactive T cells may not traffic to tumors. Second, tumor reactive T cells may not have adequate effector function within the tumor microenvironment. Neither of these hypotheses has been adequately explored, though there are data suggesting that either or both may represent obstacles to successful immune therapy. In order to improve upon the clinical response rate with vaccines, we need to address the questions of whether vaccine-induced T cells traffic to tumor and exhibit effector function within the tumor.</p> <p>Specifically for breast cancer, there are opportunities for targeting T cells against primary tumors with the intent of providing immune protection early in the disease course. In the proposed clinical trial we will be administering a peptide-based vaccine and monitoring responses to the vaccine at the site of primary tumor. Peptide vaccines are unique in that they provide an opportunity to monitor directly the T cell response to defined antigens, enabling dissection of the immune response pre- and post-vaccination. The proposed analyses are designed to test the hypotheses that vaccination 1) enhances T cell infiltration into tumor and 2) induces T cells to become activated and fully differentiate into effector cells. The goals of this proposal are to define the extent to which these two processes occur following vaccination and to identify opportunities for improving tumor targeting and T cell effector function in human breast cancer.</p>	
Active, not recruiting	<p>Vaccine Therapy With Either Neoadjuvant or Adjuvant Chemotherapy and Adjuvant Radiation Therapy in Treating Women With p53-Overexpressing Stage III Breast Cancer</p> <p>Condition: Breast Cancer</p> <p>Intervention: Biological: autologous dendritic cell-adenovirus p53 vaccine 2004</p>	<p>Adenovirus p53 Infected DC Vaccine For Breast Cancer:</p> <p>Immune response, in terms of humoral and cellular response. antigen-specific immune</p>