

## Protocols by Specific Tumor Site

### Radiation +/- Chemotherapy

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### Chemotherapy or Other Only

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### BLADDER (Chemotherapy)

#### Phase II Study of Docetaxel and Oxaliplatin in Metastatic Transitional Cell Cancer (TCC) of the Urothelial Tract

**Summary:** Transitional cell carcinoma (TCC) of the urothelium is highly sensitive to treatment with chemotherapy. Multiple chemotherapy drugs and multiple combinations of chemotherapy drugs have activity in this disease. The frontline regimens in this disease include Gemcitabine-Cisplatin, MVAC, and Carboplatin-Taxol. Despite its sensitivity to chemotherapy, bladder cancer frequently relapses, and the impact of chemotherapy on survival is minimal. Furthermore, there are few additional drugs that can be given after recurrence. Single agent Taxotere has been reported to have response rates of 15 to 20% in the salvage setting, and oxaliplatin may also elicit responses in patients who have progressed after receiving cisplatin. Hence the combination of docetaxel and oxaliplatin may be useful in recurrent incurable disease.

**General Eligibility:** Participants must be 18 years of age and must have histologically or cytologically confirmed transitional cell carcinoma of the urothelial tract and metastatic disease. Measurable progressive disease is required.

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### BRAIN (Radiation Therapy)

#### Phase III Trial Comparing Conventional Adjuvant Temozolomide with Dose-Intensive Temozolomide in Patients with Newly Diagnosed Glioblastoma. (RTOG 0525)

**Summary:** This randomized protocol is studying two different schedules of temozolomide to compare how well they work when given together with radiation therapy in treating participants with newly diagnosed glioblastoma or gliosarcoma.

**General eligibility:** Biopsy proven diagnosis of glioblastoma or gliosarcoma. There must be enough tumor tissue remaining after diagnosis to allow for a second (central) review and analysis.

**Study Design:** Following registration to the protocol all participants receive the drug temozolomide (a pill they take by mouth every day) together with radiation therapy 5 days a week for 6 weeks. After completion of this combination treatment, participants are

randomized to one of two dosing schedules for treatment with additional temozolomide. Participants in Group 1 will follow the standard temozolomide dose and schedule for glioblastoma. Participants in Group 2 will follow a dose-escalation temozolomide schedule. This temozolomide schedule is considered experimental.

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### **Urinary VEGF and MMP Levels in Patients Receiving Radiation Therapy for Glioblastoma Multiforme: Prospective Determination of a Predictive Value for Recurrence. (RTOG 0611)**

**Summary:** This protocol is studying how well assessing urine protein levels works in predicting 1-year recurrence in participants who are undergoing radiation therapy (RT) for glioblastoma multiforme.

**General Eligibility:** Participants must be enrolled on an RTOG GBM protocol that uses RT

**Key Study Parameters:** Collection of a urine sample before beginning RT, at the end of RT, and one-month following the end of RT.

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### **BREAST (Radiation Therapy)**

#### **A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer (NSABP B-39)**

**Summary:** This protocol is studying whole breast radiation therapy to see how well it works compared to partial breast radiation therapy in treating women who have undergone surgery for ductal carcinoma or stage I or stage II breast cancer.

**General Eligibility:** To qualify for the protocol, participants must have had a lumpectomy or partial mastectomy for Stage 0 (DCIS) or Stage I or II invasive adenocarcinoma of the breast with no evidence of metastatic disease.

**Study Design:** Participants are randomized to receive either whole breast radiation (standard treatment) 5 days a week for approximately 6 weeks or partial breast radiation (experimental treatment) twice a day for 5 days. Partial breast radiation may be given by one of 3 methods: External Beam Irradiation; Mammosite®; or Multi-Catheter Brachytherapy.

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### **BREAST (Chemotherapy)**

#### **A Clinical Trial of Adjuvant Therapy Comparing Six Cycles of 5-Fluorouracil, Epirubicin and Cyclophosphamide (FEC) to Four Cycles of Adriamycin and**

## **Cyclophosphamide (AC) in Patients with Node-Negative Breast Cancer (NSABP B-36)**

**Summary:** This randomized phase III protocol is studying two combination chemotherapy regimens to compare how well they work in treating women who have undergone surgery for breast cancer that has not spread to the lymph nodes.

**General Eligibility:** Participants must have had either a lumpectomy or total mastectomy. The tumor must be diagnosed as an invasive adenocarcinoma and the tumor cells cannot have spread to the lymph nodes.

**Study Design:** Participants will be randomized to receive either combination chemotherapy with the drugs fluorouracil (5-FU), epirubicin, and cyclophosphamide for approximately 6 months or doxorubicin and cyclophosphamide for about 4 months.

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## **Phase III, Adjuvant Trial Comparing Three Chemotherapy Regimens in Women with Node-Positive Breast Cancer: Docetaxel/Doxorubicin/Cyclophosphamide (TAC); Dose-Dense (DD) Doxorubicin/Cyclophosphamide Followed by DD Paclitaxel (DD AC-P); AC Followed by DD Paclitaxel Plus Gemcitabine (DD AC-PG) (NSABP B-38)**

**Summary:** This randomized protocol is studying three different combination chemotherapy regimens and comparing how well they work in treating women who have undergone surgery for node-positive breast cancer.

**General Eligibility:** Women with operable, invasive carcinoma of the breast with tumor cells that have spread to the axillary lymph nodes.

**Study Design:** After surgery to remove the tumor and axillary lymph nodes, participants will be randomized to one of 3 treatment groups. Group 1 will receive the chemotherapy drugs doxorubicin, cyclophosphamide, and docetaxel every 3 weeks for 6 cycles. Group 2 will receive doxorubicin, cyclophosphamide, and docetaxel every 2 weeks for 4 cycles followed by paclitaxel every 2 weeks for 4 cycles. Group 3 will receive doxorubicin and cyclophosphamide every 2 weeks for 4 cycles followed by paclitaxel and gemcitabine every 2 weeks for 4 cycles.

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## **A Randomized Clinical Trial of Adjuvant Chemotherapy for Radically Resected Loco-Regional Relapse of Breast Cancer (NSABP B-37/IBSCG 27-02)**

**Summary:** Phase III protocol to determine the effectiveness of adjuvant chemotherapy in treating women who have undergone resection for local and/or regional relapsed breast cancer.

**General Eligibility:** Diagnosis of first recurrence of invasive breast cancer in the same breast or a lymph node on the same side following primary treatment with mastectomy or breast conserving surgery. Surgical resection of the recurrence with clear (no tumor) margins is required and, radiotherapy with  $\geq 50$  Gy will be given to participants who had no adjuvant radiation treatment.

**Study Design:** Participants are randomized to no adjuvant chemotherapy (with or without radiation therapy) or adjuvant chemotherapy (with or without radiation therapy.) The choice of chemotherapy, dose adjustments, and supportive therapy are left to the discretion of the study doctor.

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**A Multicenter, Phase III, Randomized, Placebo-Controlled Trial Evaluating the Efficacy and Safety of Bevacizumab in Combination with Chemotherapy Regimens in Subjects with Previously Untreated Metastatic Breast Cancer**

**Summary:** This protocol is designed to evaluate the efficacy and safety of bevacizumab in combination with chemotherapy compared with chemotherapy alone in participants with previously untreated metastatic breast cancer.

**General Eligibility:** Participants with previously untreated, advanced adenocarcinoma (locally recurrent or metastatic) of the breast are eligible and require histologically or cytologically confirmed adenocarcinoma of the breast with measurable or non-measurable locally recurrent or metastatic disease. Treatment with surgery to remove locally recurrent disease must not be possible.

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**A Phase III, Multicenter, Randomized, Placebo-Controlled Trial Evaluating the Efficacy and Safety of Bevacizumab in Combination with Chemotherapy Regimens in Subjects with Previously Treated Metastatic Breast Cancer**

**Summary:** This protocol is designed to evaluate the efficacy and safety of bevacizumab when combined with standard chemotherapy compared with chemotherapy alone in participants with previously treated metastatic breast cancer.

**General Eligibility:** Participants must have previously treated, metastatic adenocarcinoma of the breast that is histologically confirmed with measurable or non-measurable metastatic disease that has progressed.

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**Spectral Investigation of Human Tissue Using the Falcon-Ramon Molecular Imaging of Breast Cancer Samples Research Protocol**

**Summary:** This protocol is aimed at exploring the potential of molecular spectroscopy techniques applied to the study of breast cancer.

**General Eligibility:** Participants with non-cancerous breast tumors and microscopic features of DCIS with various amounts of invasive cancer and calcifications as noted on pre-op core biopsy.

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**A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer (SOFT trial)**

**Summary:** This protocol is studying ovarian suppression with either tamoxifen or exemestane to see how well they work compared to tamoxifen alone in treating premenopausal women who have undergone surgery for hormone-responsive breast cancer.

**General Eligibility:** Participants must have histologically confirmed breast cancer with the tumor confined to the breast and axillary nodes. Completely resected disease with no clinically detectable residual loco-regional axillary disease.

**Study Design:** Participants may have had surgery alone or may have had surgery followed by chemotherapy. Participants will be randomized into one of 3 treatment groups. Group 1 will take Tamoxifen alone for 5 years. Group 2 will undergo Ovarian Function Suppression (by taking triptorelin for 5 years OR surgical oophorectomy OR ovarian irradiation) plus take Tamoxifen for 5 years. Group 3 will undergo Ovarian Function Suppression (by taking triptorelin for 5 years OR surgical oophorectomy OR ovarian irradiation) plus take Exemestane for 5 years.

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### **Mammography Computer-Aided Detection (CAD) Study (Retrospective Study)**

**Summary:** The objective of this investigation is to obtain digital mammographic data for developing the formulas required for the development and testing of the Kodak Computer Aided Detection (CAD) System.

**General Eligibility:** Screening and diagnostic cancer participants for whom all pathology information is at Allegheny General Hospital.

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### **A Pilot Clinical Trial to Assess Percutaneous Segmental Mastectomy in Women with Malignant Tumors $\leq 1.0$ cm.**

**Summary:** The purpose of this protocol study is to determine if small invasive breast cancer can be completely and safely removed using a new biopsy device. This will be followed by a standard breast surgery.

**General Eligibility:** Participants have had a mammogram or sonogram, which showed a highly suspicious tumor that is equal to or less than 1.0 centimeter and have had a standard biopsy of the tumor that showed that the tumor was malignant.

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### **A Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease-Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast cancer.**

**Summary:** This protocol will determine if prolonged hormonal therapy with letrozole will improve disease-free survival. Neither the participant nor her study doctor will know if she is receiving the letrozole or the placebo.

**General Eligibility:** Participants must be postmenopausal women who have completed five years of hormonal therapy with either: 1) 5 years of an aromatase inhibitor (AI) or 2) up to 3 years of tamoxifen followed by an AI. Women who have taken 2 to 4.5 years of hormonal therapy may be eligible to receive letrozole at no cost through the study registration program until they have completed a total of 5 years.

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## **COLORECTAL (Radiation Therapy)**

### **A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion (CVI) of 5-Fluorouracil (5-FU) with or without oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum (NSABP R-04)**

**Summary:** This randomized protocol is studying radiation therapy and either capecitabine or fluorouracil with or without oxaliplatin and comparing them to see how well they work when given before surgery in treating patients with rectal cancer that can be removed by surgery.

**General Eligibility:** Participants must have a diagnosis of adenocarcinoma of the rectum obtained by a biopsy technique which leaves the major portion of the tumor intact.

**Study Design:** Participants are randomized to one of 4 treatment groups. Group 1 will receive 5-FU by continuous infusion for 5 days per week plus pelvic radiation on days of planned radiation therapy (RT). Group 2 will receive 5-FU by continuous infusion plus pelvic radiation for 5 days per week on days of planned RT plus oxaliplatin intravenously once a week for 5 weeks. Group 3 will receive capecitabine twice a day, 5 days per week throughout RT. Group 4 will receive capecitabine twice a day, 5 days per week throughout RT plus intravenous oxaliplatin once a week for 5 weeks..

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### **A Phase II Trial of Neoadjuvant Chemoradiation and Local Excision for uT2uN0 Rectal Cancer (ACOSOG Z6041)**

**Summary:** This protocol is studying how well giving capecitabine and oxaliplatin together with radiation therapy works in treating participants who are undergoing surgery for stage I rectal cancer.

**General Eligibility:** Participants must have histologically confirmed adenocarcinoma of the rectum, distal border within 8 cm from the anal verge. Tumor must be stage I as confirmed by transrectal ultrasound.

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## COLORECTAL (Chemotherapy)

### A Phase II Trial of 5-Fluorouracil , Leucovorin, and Oxaliplatin (mFOLFOX6) Chemotherapy Plus Bevacizumab for Patients with Unresectable stage IV Colon Cancer and a Synchronous Asymptomatic Primary Tumor. (NSABP C-10)

**Summary:** This protocol is studying how well giving combination chemotherapy together with bevacizumab works in treating patients with stage IV colon cancer that cannot be removed by surgery.

**General Eligibility:** The participant must have an unresected primary tumor of the colon and radiographically confirmed metastatic colon cancer (single or multiple sites of metastases) that the study doctor does not feel can be cured by surgery.

**Study Design:** This is a single arm protocol to establish the safety and efficacy data of mFOLFOX6 chemotherapy plus bevacizumab once every 14 days for participants presenting with stage IV colon cancer with distant metastases that are not resectable for cure and an asymptomatic primary tumor. Study therapy continues every 2 weeks until disease progression, toxicity requiring discontinuation, or clinical response sufficient for curative resection.

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### A Phase III Clinical Trial Comparing Oxaliplatin, Capecitabine, and Hepatic Arterial Infusion of Floxuridine to Oxaliplatin and Capecitabine in Patients with Resected or Ablated Liver Metastases from Colorectal Cancer (NSABP C-09)

**Summary:** This randomized protocol is studying oxaliplatin, capecitabine and, hepatic arterial infusion with floxuridine to see how well they work compared to oxaliplatin and capecitabine in treating participants who are undergoing surgery and/or ablation for liver metastases due to colorectal cancer.

**General Eligibility:** Participants must have a life expectancy of at least 5 years excluding their colorectal cancer. There must be documentation that the participant has evidence on preoperative evaluation of  $\leq 6$  hepatic metastatic lesions that can potentially be resected or ablated.

**Study Design:** Participants will be randomized into one of 2 study groups and all will undergo liver surgery to resect and/or ablate all hepatic metastases. Participants in Group 2 will also receive a hepatic arterial infusion pump during this surgery. Group 1 participants will receive oxaliplatin on Day 1 and capecitabine administered twice a day on days 1 through 14 every 3 weeks for 8 cycles. Group 2 participants will receive a total of 8 cycles of chemotherapy: Floxuridine on days 1 through 14 (through the hepatic arterial infusion pump), oxaliplatin on day 22, and capecitabine twice a day on days 22 through 35 every 42 days for 4 cycles followed by 4 cycles of the same regimen as Group 1 participants.

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### Genetic Determinants in Liver and Metastases Among Patients with Sporadic Colorectal Adenocarcinoma

**Summary:** This project attempts to identify genetic determinants for liver metastasis among participants with primary, sporadic colon carcinoma . Specifically, the gene expression patterns of tissue obtained from primary colon tumors in patients who also have liver metastasis will be compared to the gene expression patterns from primary colon tumors in patients without liver metastasis.

**General Eligibility:** All tissue samples used in this study will be left over from the primary tumor resection. Study groups will consist of one set of individuals where the primary colon carcinoma has already metastasized to liver and a matched set of individuals without liver metastasis.

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**“XENOX B,” A Multicenter, Randomized, Double-Blind, Placebo-controlled Phase III Study of the Efficacy of Xaliproden in Preventing the Neurotoxicity of Oxaliplatin in First-Line Treatment of Patients with Metastatic Colorectal Cancer Treated with Oxaliplatin/5-FU/LV**

**Summary:** This protocol will evaluate xaliproden in reducing the risk of occurrence peripheral sensory neuropathy (PSN) relative to the cumulative dose of oxaliplatin. The study will include nerve conduction studies to evaluate the duration, incidence, and time to onset of PSN and the incidence of dose reductions, dose delays, and treatment discontinuation due to PSN.

**General Eligibility:** Participants must have colon or rectal cancer with measurable metastatic/recurrent disease not able to be removed by surgery. No prior treatment or therapy for metastatic/recurrent disease is permitted.

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**A Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers.**

**Summary:** This protocol is studying oxaliplatin, leucovorin, fluorouracil, and bevacizumab to see how well they work compared to oxaliplatin, leucovorin, and fluorouracil or observation only in treating participants who have undergone surgery for stage II colon cancer.

**General Eligibility:** Participants diagnosed with Stage II colon cancer and who have a tumor specimen available for evaluation.

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**ESOPHAGEAL/HEAD AND NECK CANCER (Radiation Therapy)**

**A Randomized, Phase III Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Palifermin (NSC# 740548; IND #6370) For the Reduction of Oral Mucositis in Patients with Locally Advanced Head and Neck Cancer Receiving**

## **Radiation Therapy with Concurrent Chemotherapy (Followed by Surgery for Selected Patients) RTOG 0435**

**Summary:** This protocol is studying how well a new drug called palifermin works in controlling the mouth sores that usually develop when participants get chemotherapy and radiation therapy for the treatment of head and neck cancer. The experimental drug, palifermin, will be compared with a look-alike drug that does not contain any active ingredients (a placebo). The doctor, the participant, and the study team will know if the participant is getting the active drug or the placebo.

**General Eligibility:** Patients with Stage III or IVA-B squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, or larynx who will be receiving radiation treatment together with chemotherapy (RT/Chemo).

**Study Design:** Participants are randomized to one of two study groups. Participants in Group 1 will receive the drug Palifermin by intravenous (iv) injection. Participants in Group 2 will receive the placebo by intravenous injection. Twice a week, for up to 8 weeks after the end of RT/Chemo, participants will be evaluated for mouth sores and asked to answer questionnaires about their mouth sores, any pain they may be having, and any medications they may be taking for their pain

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### **LUNG (Radiation)**

#### **A Randomized Phase III Study of Sublobular Resection vs Sublobular Resection Plus Brachytherapy in High Risk Patients with NSCLC, 3 cm or Smaller (ACOSOG Z4032)**

**Summary:** This protocol studying surgery and internal radiation therapy to see how well they work compared to surgery alone in treating participants with Stage I non-small cell lung cancer (NSCLC).

**General Eligibility:** Suspicious lung nodule for early stage NSCLC, with the mass  $\leq 3$  cm maximum diameter by CT size estimate.

**Study Design:** Participants are randomized into one of two treatment groups. Participants are randomized to Group 1: surgery (sublobular resection) or Group 2: surgery + brachytherapy (vicryl mesh). Surgery to remove the cancer is performed. At the time of surgery, pathologic confirmation of the tumor diagnosis will be performed. In patients randomized to receive brachytherapy, radioactive ( $^{125}\text{I}$ ) seeds are implanted at the site where the tumor was removed.

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### **LUNG (Chemotherapy)**

#### **Molecular Epidemiology Case-Series Study of Non-Small Cell Lung Cancer in Smoking and Non-Smoking Women and Men**

**Summary:** This is a molecular epidemiology case – series study. It is an observational study and does not involve treatment. Biomarkers of exposure, susceptibility, and effect will be assayed in the blood and tumor tissue collected from these women and men and evaluated in relation to questionnaire data returned by the study participants.

**General Eligibility:** Participants must have newly-diagnosed, primary, histologically confirmed Stage I, II, IIA, or IIB non-small cell lung cancer. All males and females are eligible to participate, regardless of smoking status (never-smoker, or smoker.)

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## **LYMPHOMA (Chemotherapy)**

### **The National Lymphocare Study: An Observational Study of Treatment Outcomes, and Prognosis in Patients with Follicular Non-Hodgkin's Lymphoma (U2963n)**

**Summary:** Prospective, observational, longitudinal, multicenter study of participants with newly diagnosed follicular Non-Hodgkin's Lymphoma designed to look at differences in clinical outcome by comparing the effectiveness and safety of common treatment regimens.

**General Eligibility:** Histologic documentation of follicular Non-Hodgkin's Lymphoma.

**Study Design:** Enrolled participants will receive treatment and evaluations for follicular Non-Hodgkin's Lymphoma as determined by their treating physicians according to the standard of care and clinical practice at each study site.

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## **PROSTATE (Chemotherapy)**

### **Phase II Study of Oxaliplatin and Taxotere in Androgen Independent Prostate Cancer (AIPC)**

**Summary:** To evaluate the safety and efficacy oxaliplatin and docetaxel when given to participants with AIPC.

**General Eligibility:** Advanced prostate cancer. Prior Therapy for advanced disease allowed. Histologically proven adenocarcinoma of prostate and confirmed androgen independent prostate cancer.

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### **A Multicenter, Open-Label, Randomized Phase III Trial Comparing Immediate Adjuvant Hormonal Therapy (ELIGARD®-leuprolide acetate) in Combination with TAXOTERE® (docetaxel) Administered Every Three Weeks Versus Hormonal Therapy Alone Versus Deferred Therapy Followed by the Same Therapeutic**

## **Options in Patients with Prostate Cancer at High Risk of Relapse After Radical Prostatectomy**

**Summary:** This protocol is for participants at high risk of recurrent prostate cancer after surgery. Participants will receive study treatment either immediately after radical prostatectomy or when participants have a progression defined as PSA progression, or radiologically or histologically documented progression, whichever occurs first.

**General Eligibility:** Pathologically confirmed adenocarcinoma of the prostate based on central pathology review.

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## **COMBINED OR MULTIPLE TUMOR SITES (Radiation)**

### **Mega-Voltage Cone-Beam CT (CBCT) Image-Guided Radiotherapy**

**Summary:** This study will compare the results obtained from using Mega-Voltage CBCT with those obtained through ultrasound imaging, portal imaging or conventional simulation CT for radiotherapy treatment planning from participants scheduled to receive radiation therapy in the Allegheny General Hospital Department of Radiation Oncology.

**General Eligibility:** Male and female participants, 18 years of age and older, who are scheduled to receive CBCT in addition to conventional simulation CT for treatment planning. Particular emphasis will be given to individuals who will be receiving either intra-cranial stereotactic radiotherapy or radiation treatment for prostate cancer.

**Study Design:** This study collects and analyzes data obtained from different imaging techniques. There will be no changes to a participants' medical treatment, however, images obtained through the course of routine medical care will be compared with images obtained by other imaging techniques.

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