THE **TRIAL** BLAZER

UPMC HILLMAN CANCER CENTER

A quarterly newsletter from **CLINICAL RESEARCH SERVICES**

INTRODUCTION

The past several months have demonstrated the incredible resilience of the UPMC Hillman Cancer Center staff in general and our CRS team in particular. We have learned to cope with the seemingly endless adjustments we have had to make, and have found new and creative ways to ensure maintenance of the world-class health care services to our patients for which we are known. We achieved an "Outstanding to Exceptional" score in the last National Cancer Institute (NCI) site visit for the Cancer Center Support Grant (CCSG) core grant, and we urge you to keep up the good work in maintaining this status.

We all know and, sadly, might have had personal experiences with the fact that COVID-19 "respects" no person and our cancer patients are an obvious high-risk population for the short- and long-term effects of this scourge. Consequently, we would like to highlight the opening of the HCC 20-175 trial titled NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study. This extremely relevant and timely observational study has the main objective of characterizing patient factors—such as pre-existing comorbidities, cancer type and treatment, and demographic factors—associated with short- and long-term outcomes of COVID-19, including symptoms, severity, and fatality, in adult and pediatric cancer patients undergoing treatment. For more details and enrollment contact information, please see the featured Spotlight Trial in this edition. This trial is open to the entire UPMC Hillman Cancer Center network. On a similar note, please see the equally relevant HCC 20-087: The Hillman Cancer Center COVID-19 Cohort trial featured under Biobehavioral Trials.

In organizational news updates, the CRS renovation project for our staff on the 3rd floor of the UPMC Cancer Pavilion has finally been completed and details of the changes are provided in the Achievements and Accolades section. While this extremely difficult but oddly rewarding year is indeed coming to an end, our challenges and goals are certainly not, and this would be a good time for us to reflect on just how we have managed to chart this new course as efficiently as possible. Even though we saw a significant decline in our clinical trial accruals from April to June, we have started seeing an uptrend in our accruals since July. We sincerely thank our faculty, community oncologists, and staff for their dedication to continuing to offer new therapeutic opportunities for our patients. In 2020, we are projected to cross 1,000 therapeutic accruals, despite the COVID-related slowdown, if we continue our momentum.

Patient and employee safety remains our top priority, hence we continue to stress the importance of wearing a mask, washing hands frequently, and maintaining social distancing. We as the CRS family are committed to adhering to these official COVID 19-related guidelines with a renewed resolve to keep each other safe by maintaining these practices. We appreciate all the incredible contributions you have all made, laud the "extra miles" you have all run, and encourage you to persevere in keeping up the sterling efforts.

Antoinette (Toni) Wozniak, MD, FACP, FASCO
Associate Director for Clinical Research

Bhanu P. Pappu, PhD, MHA
Vice President of Clinical Research Operations and Strategy

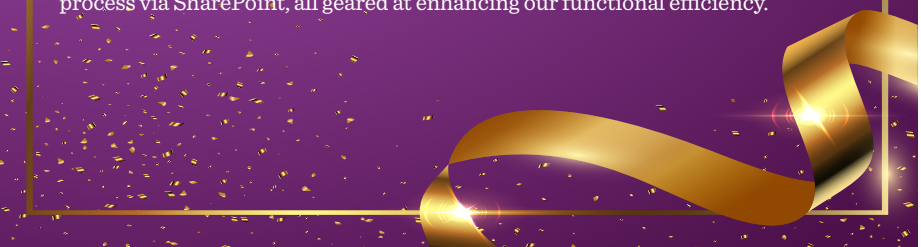
ACHIEVEMENTS AND ACCOLADES

Completed Construction

The CRS construction project has been successfully completed with a major overhaul of the staff seating/cubicle arrangements. To improve communication and smoothen the workflow interaction, members of various centers are now situated together. Thank you all for your patience while the project was underway.

New Research Role and Electronic Adverse Events (AE) Log Process

A new research coordinator role has been introduced in a few centers, while the operations team is working to pilot a new electronic adverse event (AE) log process via SharePoint, all geared at enhancing our functional efficiency.



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POINTS OF INTEREST

Spotlight Trials

- COVID-19 Observational Trial
- AZD1390 Plus Radiation Therapy in GBM/ Brain Metastases from Solid Tumors

CRS Spotlight Team

- Radiation Oncology Research Team

Priority Trials

- Melanoma and Cutaneous Tumors
- Genitourinary and Prostate Cancer
- Lung Cancer
- Head and Neck Cancer
- Breast Cancer
- Gynecologic Cancers

Accrual Statistics for Third Quarter 2020

- Open to Accrual (OTA) Studies

SPOTLIGHT TRIALS

COVID-19 Observational Trial

HCC 20-175: NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study

Principal Investigator: Dr. Antoinette Wozniak, wozniakaj@upmc.edu

The current global coronavirus 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) constitutes a particularly serious threat to high-risk populations. This includes cancer patients undergoing active therapy who may be at greater risk for more severe SARS-CoV-2 infection and worse long-term outcomes mainly because common risk factors for cancer, such as older age and a smoking history, are also associated with poorer outcomes of SARS-CoV-2 infections. Furthermore, immunosuppression from their underlying cancer and cancer-directed therapies may make these patients particularly vulnerable to some of the more severe SARS-CoV-2 sequelae. In light of the dearth of data on the course of COVID-19 in cancer patients, this observational trial primarily aims to characterize patient factors such as pre-existing comorbidities, cancer type and treatment, and demographic factors associated with short- and long-term outcomes of COVID-19, including symptoms, severity, and fatality, in adult and pediatric cancer patients undergoing treatment.

This trial is open at all UPMC sites and potential participants are expected to meet the following, among other, eligibility criteria:

- No age restrictions
- Diagnosis of cancer
- Pending or known positive SARS-CoV-2 test
- ≥ 18 years old: Specimens for first documented positive SARS-CoV-2 test collected within the last 14 days
- < 18 years old at enrollment: First documented positive SARS-CoV-2 test performed after January 31, 2020

Please contact the principal investigator or Julie Urban at urbanj2@upmc.edu with inquiries.

AZD1390 Plus Radiation Therapy in GBM/Brain Metastases from Solid Tumors

HCC 17-194: A Phase I, Multicenter Study to Assess the Safety, Tolerability, and Pharmacokinetics of Ascending Doses of AZD1390 in Combination with Radiation Therapy in Patients with Glioblastoma Multiforme and Brain Metastases from Solid Tumors

Principal Investigator: Dr. David Clump, clumpda2@upmc.edu

Glioblastoma as well as some brain metastases are resistant to conventional radiation therapy. Activated ataxia telangiectasia mutated (ATM) phosphorylates many substrates involved in DNA repair, checkpoint control, and cell death, making ATM and other DNA damage repair enzymes attractive targets for antitumor therapy. AZD1390 is a novel, highly potent and selective ATM kinase inhibitor and preliminary in vitro data, including evidence of profound survival improvement of a syngeneic glioblastoma multiforme (GBM) mouse model, provide a clinical rationale for its development as a radiosensitizer for use in combination with radiation therapy (RT) in brain malignancies. Therefore, this first-in-patient, phase I study consisting of three dose escalating cohorts (Arms A, B, and C) each targeting a different patient population, has been designed to assess the efficacy, tolerability, and safety of escalating cumulative doses of AZD1390 in the following settings with three different RT regimens: Arm A, 35 Gy over two weeks with intensity-modulated radiation therapy (IMRT); Arm B, 30 Gy over two weeks with whole brain radiation therapy (WBRT); and Arm C, 60 Gy over six weeks (IMRT). Each arm provides standard of care RT for the disease setting indicated, in combination with the experimental agent.

Prospective participants must be ≥ 18 years old and meet the following, among other, main eligibility criteria:

- Relapsed (recurrent) GBM eligible for re-irradiation (Arm A)
- Brain metastases, including leptomeningeal disease, from solid tumors not eligible for treatment with stereotactic radiosurgery (SRS, Arm B)
- Newly diagnosed GBM harboring unmethylated O-6-methylguanine-DNA methyltransferase (MGMT, Arm C)
- Willing to provide a formalin-fixed paraffin embedded (FFPE) tissue sample from their primary or metastatic disease
- Karnofsky Performance Score (KPS) ≥ 60
- Adequate organ system function
- Ability to swallow and retain oral medication.

Interested physicians can contact the principal investigator or Karen Holeva, clinical research manager, Radiation Oncology Research Program, at holevakd@upmc.edu.

CRS TEAM AND PHYSICIAN SPOTLIGHT: RADIATION ONCOLOGY RESEARCH TEAM

Radiation Oncology Research Oversight

Dr. David Clump
He's the medical director of the Mary Hillman Jennings Radiation Oncology Center at UPMC Shadyside and specializes in head and neck and lung malignancies as well as the utilization of stereotactic radiotherapy (SRS/SBRT) for primary and recurrent disease.

Dr. Heath Skinner
Despite current appearances, he once ran an ultramarathon in the middle of the Texas summer. However, he has not repeated that bit of insanity!

Dr. Adam Olson
Although he's pretty sure he doesn't have OCD, he can't stand to have the TV volume set to a prime number but doesn't really know why.

New Physicians at Mary Hillman Jennings Radiation Oncology Center at UPMC Shadyside

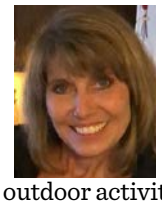
Dr. Tyler Wilhite
He enjoys walking around Oakland and Schenley Park with his dog Toby and wife Melissa.

Dr. Zaid Siddiqui
He avidly enjoys both indoor and Zwift cycling.

Dr. Susannah Ellsworth
She specializes in the treatment of gastrointestinal cancers with an interest in pancreatic and colorectal malignancies.

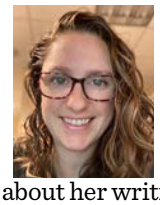
Dr. Ravi Patel
Outside of work, his hobbies and interests include sailing, woodworking, learning new recipes, and exploring new hiking trails.

Radiation Oncology Research Team Members



Karen Holeva
She spends most of her free time with her daughter Heather and grandson Haiden. Her other hobbies include baking, crafting, any outdoor activities, and spending time with close friends.

Samantha Demko
She and her husband love to go "glamping" at their camp in Tionesta. Her husband also has a Harley they enjoy riding and her most favorite things in the world, other than her family and her dog, are Christmas, Disney, and Steeler Sundays.



Alyssa Lombardo
Most of her free time is spent renovating her house and keeping her kids from (literally) climbing the walls. She is particular about her writing utensils and enjoys a good meme.

Karlotta Ashby
She enjoys reading and watching mystery movies.

Sydney Bader
She is a connoisseur of whiskey, rescued dogs, and blind cats.

Denise Ritter
She enjoys reading a good mystery, taking landscape/architecture photos, and revamping her 1920s house—by removing the wallpaper from every single surface.

PRIORITY TRIALS

Melanoma and Cutaneous Tumors

HCC 19-105: A Phase III, Randomized, Double-Blind Study of Adjuvant Immunotherapy with Nivolumab versus Placebo after Complete Resection of Stage IIB/C Melanoma

Principal Investigator: Dr. John Kirkwood, kirkwoodjm@upmc.edu

Currently, there is an unmet medical need for effective adjuvant therapies for patients diagnosed with stage IIB and IIC cutaneous melanoma and this study seeks to contribute data and information for establishing the role of nivolumab as an adjuvant immunotherapy in this patient population. Participants will be randomized (2:1), stratified by T stage to receive nivolumab (480 mg IV every four weeks) or the nivolumab-matched placebo until whichever of the following occurs first: recurrence, unacceptable toxicity, withdrawal of consent, or a maximum of 12 months from the treatment dose. After the first recurrence, participants may be eligible to receive optional open-label nivolumab for up to 12 or 24 months (resectable or unresctable/metastatic disease, respectively).

Prospective patients, both adults and pediatrics > 12 years old, will be expected to meet the following main, among other, eligibility criteria:

- Diagnosed with stage IIB/C cutaneous melanoma, histologically confirmed and completely surgically resected with documented negative margins (per local standard) for disease on resected specimens
- Complete resection performed within 12 weeks prior to randomization
- Negative sentinel lymph node biopsy
- Disease-free status documented by a complete physical examination and imaging studies (also ruling out brain metastases) before randomization
- Not treated for melanoma beyond complete surgical resection of lesion
- ECOG Performance Status of 0 or 1 at enrollment
- Available tumor tissue sample (minimum, 15 unstained slides or 1 FFPE block) from resected site

HCC 20-049: Randomized Neoadjuvant Phase II Study of TLR9 Agonist CMP-001 in Combination with Nivolumab vs. Nivolumab in Stage IIIB/C/D Melanoma Patients with an Integrated Imaging Biomarker

Principal Investigator: Dr. Diwakar Davar, davard@upmc.edu

In patients with advanced melanoma, the combination of a type C TLR9 agonist (SD-101) and PD-1 inhibitor (pembrolizumab) has been found to be associated with significant responses with minimal additional toxicity and based on its ability to pinpoint molecular activity, PET imaging has the potential to monitor response to therapeutic interventions such as PD-1 blockade. This is a 56-57-week study of nivolumab in combination with the Toll-like receptor 9 (TLR9) agonist CMP-001 vs. nivolumab in patients with PD-1 naïve stage IIIB-IIID cutaneous (or unknown primary) melanoma with clinically apparent lymph node (LN) and/or in-transit and/or satellite disease, which includes an integrated [18F]F-AraG imaging biomarker.

Prospective patients who are ≥ 18 years old must meet the following, among other, main eligibility criteria to participate:

- Willing to undergo [18F]F-AraG PET imaging at pre- and week five timepoints
- Histologically or cytologically confirmed diagnosis of cutaneous melanoma at specific AJCC TNM stages
- Primary melanoma with concurrent regional nodal and/or in-transit metastasis or at the time of clinical detected nodal and/or in-transit recurrence
- Injectable and measurable disease based on RECIST 1.1
- Willing to undergo tumor biopsy (core, punch, incisional or excisional); patients must undergo biopsy (core, punch) or open biopsy (incisional, excisional) within four weeks of registration on the study and at W4-5
- ECOG Performance Status of 0 or 1 at enrollment
- Demonstrate adequate organ function

Please contact the respective principal investigators or Amy Rose at kennaj@upmc.edu with inquiries.

Genitourinary/Prostate Cancer

HCC 20-002: An Open-Label, Randomized, Controlled Phase III Study of Enfortumab Vedotin in Combination with Pembrolizumab with or without Chemotherapy, versus Chemotherapy Alone in Previously Untreated Locally Advanced or Metastatic Urothelial Cancer

Principal Investigator: Dr. Leonard Appleman, applemanlj@upmc.edu

While cisplatin-containing chemotherapy offers a survival benefit in the first-line metastatic urothelial cancer (UC) setting, most patients do not achieve long-term disease-free survival and the outcome is even worse for those who are ineligible for cisplatin. Programmed cell death protein-1 (PD-1)/programmed cell death ligand-1 (PD-L1) inhibitors have demonstrated a survival benefit compared to chemotherapy in the management of late-line metastatic UC. Furthermore, nectin-4, a 66 kDa type I transmembrane protein of the nectin family of adhesion molecules, was identified as markedly upregulated in UC, which makes it an excellent treatment target and combining PD-1/PD-L1 inhibitors with these novel therapeutic agents, such as enfortumab vedotin, may be beneficial. This global phase III, randomized study will enroll an all-comer first-line metastatic UC population without pre-selection based on a tissue biomarker, who will be randomized in a 1:1:1 manner to one of the following study arms, Arm A: enfortumab vedotin plus pembrolizumab, Arm B (control arm): gemcitabine plus cisplatin or carboplatin, and Arm C: enfortumab vedotin plus pembrolizumab plus cisplatin or carboplatin.

Prospective participants who must be ≥ 18 years of age and have an anticipated life expectancy of ≥ 12 weeks are expected to meet the following main, among other, eligibility criteria:

- Histologically documented, unresectable locally advanced or metastatic urothelial carcinoma
- Have measurable disease by investigator assessment according to RECIST v1.1
- No prior systemic therapy for locally advanced or metastatic urothelial carcinoma with some exceptions
- Eligible to receive cisplatin- or carboplatin-containing chemotherapy
- Able to provide archival tumor tissue comprising muscle-invasive urothelial carcinoma or a biopsy of metastatic urothelial carcinoma for PD-L1 testing prior to randomization
- ECOG Performance Status score of 0, 1, or 2
- Adequate hematologic and organ function

Please contact the principal investigator or Clare Grzejka at grzejkac@upmc.edu with inquiries.

Lung Cancer

HCC 19-087: EA5163/S1709 INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy Alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis

Principal Investigator: Dr. Antoinette Wozniak, wozniakaj@upmc.edu

Arginine depletion has potential anticancer activity, as evidenced by monotherapy with the arginine deiminase (ADI) conjugated to polyethylene glycol-20 (ADI-PEG-20), which significantly prolonged progression free survival (PFS) compared to best supportive care in the phase II ADAM study of patients with malignant pleural mesothelioma (MPM) tumors that are argininosuccinate synthetase (ASS1)-deficient). The TRAP study investigating the applicability of combining ADI-PEG-20 36 mg/m^2 and systemic chemotherapy with pemetrexed 500 mg/m^2 and cisplatin 75 mg/m^2 (ADIPemCis) in MPM or non-squamous non-small cell lung carcinoma (NSCLC) patients with ASS1-deficient tumors has shown significant objective responses. While most of the study patients have a non-epithelioid histology with the poorest prognosis of the MPM histologies, the PFS and OS was apparently prolonged in treated MPM patients. Therefore, this present phase II/III study will enroll only non-epithelioid (biphasic and sarcomatoid) MPM patients who will be randomized at a 1:1 ratio to receive the same ADIPemCis regimen or PlaceboPemCis (placebo replaces ADI-PEG-20) weekly, both administered every three weeks as first-line chemotherapy. This study has the primary objective of determining the efficacy based on response rate (RR).

This trial is open at the following UPMC Hillman Cancer Center locations: Arnold Palmer Pavilion in Greensburg, Upper St. Clair, and UPMC Passavant and prospective participants ≥ 18 years of age are expected to meet the following main, among other, eligibility criteria:

- Histologically or cytologically confirmed stage IV non-squamous NSCLC
- PD-L1 expression Tumor Proportion Score (TPS) ≥ 1% in tumor cells
- Measurable or non-measurable disease as predefined

- ECOG Performance Status of 0–1
- No prior systemic chemotherapy or immunotherapy for advanced metastatic NSCLC
- No known EGFR mutations (except exon 20 insertion), BRAF mutations (V600), or ALK or ROS1 translocations that can be treated with oral tyrosine kinase inhibitors
- Adequate liver and renal function as determined by prespecified tests within 14 days of randomization

Interested physicians can contact principal investigator, Dr. Antoinette Wozniak, at wozniakaj@upmc.edu or Jen Ruth at ruthj2@upmc.edu.

Head and Neck Cancer

HCC-19-082: Phase II Study Evaluating HPV-16 vaccination (ISA101b) and Pembrolizumab plus Cisplatin Chemoradiotherapy for "Intermediate Risk" HPV-16 associated Head and Neck Squamous Cell Carcinoma

Principal Investigator: Dr. Robert L. Ferris, ferrrl@upmc.edu

Human papilloma virus (HPV)-associated oropharyngeal squamous cell cancers (OPSCC) more frequently present in a younger population and seem particularly responsive to treatment with a better overall survival, and attention is currently focused on reducing treatment toxicity. Improved control of local disease is critical to improve survival of patients with this and other head and neck squamous cell carcinomas (HNSCC), and transoral resection (TORS) dramatically limits the morbidity of surgical exposure and substantially reduces acute and late effects of resection. Immunotherapy has also emerged as an alternative approach based on recent success in other cancers with promising results. The dual primary objectives of this study are (1) to test the hypothesis that the proposed adjuvant de-escalation strategy of combining TORS surgery followed by de-escalated radiotherapy (RT) with 50 Gy accelerated fractionation and concurrent nivolumab immunotherapy (TORS + 50 Gy RT + nivolumab) is equivalent (non-inferior) to the current standard of care cisplatin chemotherapy + standard 60-66 Gy radiation and (2) to demonstrate a reduction in the rate of PEG tube dependence at one year.

This trial is open at the following UPMC Hillman Cancer Center locations: Arnold Palmer Pavilion in Greensburg, Norwin, and Mt. Pleasant, Beaver, Moon, John P. Murtha Pavilion in Johnstown, New Castle, UPMC Pinnacle, Upper St. Clair, Uniontown, UPMC East, UPMC Horizon, UPMC Northwest, UPMC Passavant, UPMC Altoona, UPMC St. Margaret, and Washington. Prospective male and female participants ≥ 18 years of age are expected to meet the following main, among other, eligibility criteria:

- Histologically-confirmed HNSCC with no evidence of distant metastasis and oropharynx primary site with intermediate risk disease as predefined.
- No prior systemic (chemotherapy or biologic/molecular targeted therapy) or radiation treatment for head and neck cancer.
- Patients with a history of curatively-treated non-HNSCC malignancy must be disease-free for at least two years.
- Consent to research biopsy at baseline and during week two of pembrolizumab/ISA101b vaccination, prior to start of cisplatin-IMRT, and another optional biopsy at week 2 after start of IMRT
- ECOG Performance Status of 0–1

Interested physicians can contact the principal investigator or Jen Ruth at ruthj2@upmc.edu with inquiries.

Breast Cancer

HCC 19-035: NIMBUS: A Phase II Study of nivolumab Plus Ipilimumab in Metastatic Hypermutated HER2-negative Breast Cancer

Principal Investigator: Dr. Leisha Emens, emensla@upmc.edu

Immunotherapy with PD-1/PD-1 inhibitors has revolutionized treatment for many cancers but most patients with metastatic breast cancer are refractory to this treatment, and PD-1 and PD-L1 expression has recently been shown to differ among breast tumors subtypes. Studies suggest that additional immunosuppressive factors likely cause resistance to immunotherapy in this population and, therefore, adding other agents to anti-PD-1/PD-L1 treatment might be necessary to enhance the benefit of immunotherapy in triple negative breast cancer (TNBC) while predictive biomarkers are needed to identify patients most likely to benefit from immunotherapy.

In this study, we aim to test our hypothesis that patients with hypermutated HER2-negative metastatic breast cancers are more likely to derive an objective response to the combination of nivolumab and ipilimumab, than monotherapy with either agent.

This trial is currently open at the following UPMC Hillman Cancer Center locations: UPMC Magee-Womens Hospital, Shadyside, Arnold Palmer Pavilion in Greensburg, Mt. Pleasant, and Norwin, Beaver, UPMC McKeesport, Uniontown, UPMC East, Upper St.

Clair, UPMC Passavant, UPMC St. Margaret, and Washington. Prospective patients are expected to fulfil the following main, among other, eligibility criteria:

- Must be HER2-negative and may be ER/PR positive or negative (HER2-/ER/PR +/-)
- Harbor tumors with total mutational burden of at least 10 mutations per megabase assessed by a cancer-gene panel containing > performed in a CLIA verified laboratory
- Measurable disease
- Two mandatory biopsy samples

Interested physicians can contact the principal investigator or Brenda Lee Steele, clinical research manager at the Women's Cancer Research Program, at steeleb@upmc.edu.

Gynecologic Cancer

HCC 19-188: GY021: A Phase II Randomized Trial of Olaparib versus Olaparib plus Tremelimumab in Platinum-sensitive Recurrent Ovarian Cancer

Principal Investigator: Dr. Alexander Olawaiye, olawwaiyea@upmc.edu

Platinum-based frontline chemotherapy is effective, but most patients experience disease recurrence and while additional platinum-based therapy is recommended, repeated courses result in cumulative toxicity and increased risks of allergic reaction to platinum. Consequently, alternative treatments to platinum-based chemotherapy for women with recurrent platinum-sensitive ovarian cancer are required. Despite evidence that ovarian cancer is a target for immunomodulatory regimens, there are currently no approved immune therapies for ovarian cancer. Furthermore, PARP inhibitors have recently demonstrated significant activity in the treatment of recurrent ovarian cancer in clinical trials while preclinical evidence indicates that PARP inhibition synergizes therapeutically with immunotherapy by CTLA-4 blockade. This trial has the primary objective of comparing the progression-free survival (PFS) duration of monotherapy with the PARP inhibitor olaparib versus olaparib plus tremelimumab, a human IgG2 monoclonal antibody against CTLA-4, in women with recurrent, platinum sensitive ovarian, primary peritoneal, or fallopian tube cancer.

This study, which is open at all UPMC sites, has the following, among other, main eligibility criteria that prospective participants will be expected to meet:

- Platinum-sensitive, recurrent high-grade serous or high-grade endometrioid (grade 3) ovarian, primary peritoneal, or fallopian tube cancer
- Prior chemotherapy must have included a first-line platinum-based regimen with or without consolidation chemotherapy
- Received up to one non-platinum-based line of therapy in the recurrent setting. Prior hormonal therapy will not be counted as this non-platinum-based line
- Women who received a PARP inhibitor for maintenance therapy in the frontline setting must have received at least one other chemotherapy regimen for recurrence prior to enrolling on this trial. Patients who demonstrated disease progression while on a PARP inhibitor are excluded.

Interested physicians can contact the principal investigator or Brenda Lee Steele, clinical research manager at the Women's Cancer Research Program, at steeleb@upmc.edu.

Biobehavioral Trials

HCC 20-087: The Hillman Cancer Center COVID-19 Cohort

Principal Investigator: Dr. Peg Rosenzweig, mros@pitt.edu, 412-383-7227

The COVID-19 illness represents a global pandemic with unprecedented societal impact. Individuals with cancer appear to be at risk for higher incidence and mortality related to the illness. Although our area has seen relatively low incidence of COVID-19, the worry and anxiety may influence patient's willingness to receive cancer treatment or follow-up.

UPMC Hillman Cancer Center established a cohort of patients who are undergoing active, neo-adjuvant or adjuvant of follow up treatment during the COVID-19 health emergency for immediate assessment of stress and anxiety with an opportunity for follow up at 6 and 12 months.

Drs. Peg Rosenzweig, Brenda Diergaarde, and Lyn Robertson led the study team. They hope to have the first wave of responses analyzed and submitted in a manuscript by the first of the year.

Please contact the principal investigator with inquiries.

OPEN STUDIES AND ACCRUALS AS OF OCTOBER 15, 2020

Disease / Modality Center	Current Int OTA Trials	Current Rx OTA Trials	Interventional Accruals	Treatment Accruals
Biobehavioral Medicine in Oncology Program	3	3	211	0
Brain Tumor Center	13	13	20	20
Breast Center	26	23	214	42
Early Therapeutics Centers (Phase I and II)	49	49	53	53
GI/Esophageal Cancer Center	22	22	98	96
Gynecological Oncology Center	11	11	19	19
Head and Neck Center	31	29	62	62
Hematological Malignancies Center	33	33	38	26
Immune Therapy Center	39	39	88	88
Lung and Thoracic Malignancies Center	30	27	87	36
Melanoma Center	16	16	56	56
Multi-Disease/Modality Center	4	4	968	215
Pediatric Oncology	54	52	46	43
Prostate and Urologic Cancers	21	21	34	34
Sarcoma Center	10	10	9	9
Supportive Care	2	0	9	0
Total	**364**	**352**	**2012**	**799**
*Radiation Oncology Center	17	17	30	30

*Bi-modality trial accruals are distributed based on the primary disease area.

Clinical Research Services (CRS) is made up of over 190 staff members who facilitate development, implementation, coordination, internal data monitoring, and completion of approximately 250 oncology-focused trials at Hillman each year. These trials include institutional (investigator-initiated), multi-center cooperative group/ National Clinical Trial Network (NCTN), consortium, and industry-sponsored trials. Using a disease-specific centers model for conducting clinical trials, CRS provides study development and implementation assistance, submissions to the FDA, IRB processing, patient recruitment, study coordination, study-specific training, data collection, and specimen collection and processing.

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