THE **TRIAL** BLAZER

UPMC HILLMAN CANCER CENTER

A quarterly newsletter from CLINICAL RESEARCH SERVICES

INTRODUCTION

Welcome to the first *Trial Blazer* edition of 2021. We continue to make concerted efforts to improve our operations and develop strategies in order to provide cutting-edge clinical trials for our cancer patients. We are constantly reviewing our day-to-day operations to identify areas where there is room for improvement or upgrading. In line with the efforts to modernize the Clinical Trials Management System (CTMA) at UPMC Hillman Cancer Center, CRS has initiated the implementation of OnCore and the regulatory software eReg for protocol processing and eSignatures, which will eventually replace CTMA. To complement this system overhaul, REDCap will be established as a database for investigator-initiated trials. The implementation process will unfold over the course of the next 18 months and we appreciate having all hands on deck to ensure a smooth transition. We plan to retire CTMA at the end of 2022.

We remain committed to identifying strategies to improve the accrual to clinical trials at our Hillman network locations and bring clinical trials to their clinics. Consequently, we have conducted several virtual meetings with leaders of the various Disease and Modality Centers (DMC) and community physicians to review the portfolio of clinical trials. Our focus is to identify gaps in the process and initiate the opening of more trials that are specifically tailored to meet the needs of the community we serve. We continue to solicit and appreciate your support in achieving our collective goal of at least 250 therapeutic accruals annually from our community locations.

Please take the time to go over the details of our Spotlight Trial, **HCC 20-149**, from the lung DMC, entitled **"A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status."** In addition, we would like to present the members of the lung CRS DMC team as the first Spotlight Team of 2021 and encourage you to get to know your co-workers and their interesting "quirks." We also have some interesting tidbits about the innovative expansion of the CTRC operations, particularly at Hillman's UPMC Magee-Womens Hospital location, to better serve our patients and clinical trials.

As we face the challenges of the "post-2020 era" and defining our "new normal," it will definitely not be business as usual and we are confident that the strength, innovation, and initiatives you have all shown will help us to continue to chart our collective course to meeting our goals this year.

Antoinette (Toni) Wozniak, MD, FACP, FASCO
Associate Director for Clinical Research
Division Chief, Hematology and Oncology (*ad interim*)

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

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POINTS OF INTEREST

Spotlight Trials

- Radiotherapy Followed by Atezolizumab in Stage II or III NSCLC

CRS Spotlight Team

- Lung Cancer Research Team

Priority Trials

- Genitourinary and Prostate Cancer
- Lung Cancer
- Hematological Malignancies
- Breast Cancers
- Gynecologic Cancers
- Biobehavioral Trials

Accrual Statistics for Fourth Quarter 2020

- 2020 Open Studies and Accruals

SPOTLIGHT TRIALS

Radiotherapy Followed by Atezolizumab in Stage II or III NSCLC

HCC 20-149: A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status

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:

- Pathologic (cytological or histological) proof of Stage III NSCLC with Zubrod Performance Status of 2 or Stage II NSCLC with Zubrod Performance Status of 0-2
- Not candidates for surgical resection or concurrent chemoradiation in treating investigator's opinion
- Have measurable or non-measurable disease documented using CT or MRI
- Have MRI or CT brain scan with contrast within 28 days prior to Registration Step 1
- Disease must fit radiation constraints specified by a local radiation oncologist
- Received prior treatment for their lung cancer, including surgery, chemotherapy, targeted agents, and/or radiation treatment. At least 12 months must have elapsed since last treatment.
- Had prior radiotherapy as long as the irradiated area does not overlap with the radiation field targeted for this study
- Meet specified clinical and laboratory criteria
- Satisfactorily recovered from any adverse effects of prior major surgery
- Have adequate bone marrow, liver, and renal function as evidenced by specified standard evaluations prior to Registration Step 1

CRS SPOTLIGHT TEAM: LUNG CANCER TEAM

Dr. Antoinette Wozniak enjoys cooking, travel, and visiting interesting restaurants.

Dr. Liza Villaruz says that while it's not exactly a "hobby," she is raising three boys with her husband Jason, and, thus, practices a lot of yoga to avoid losing her temper with said boys. She also loves cooking.

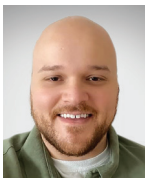
Dr. Timothy Burns is an avid sports fan who enjoys watching his sons play football, basketball, and lacrosse and hiking with his family. He's always willing to botch a field goal attempt for charity

Megan Hendricks is very interested in music, film, art history, antiques (especially old kitchen gadgets!), language, linguistics, and old buildings. She continues to discover new loves in all of these areas to keep her going. Her hobbies include cooking, cats, making bad jokes, and her newly discovered love of kayaking.

Danielle Bednarz enjoys baking, crafts, watching 90 Day Fiancé, and loves her dogs, bird, and fish.

Meagan McGrane is attempting to learn to cook and loves watching Bravo TV and telling bad dad jokes.

Deb Mayr loves cooking, crafts, and spending time with her grandkids.



Nick LaSota has a passion for cooking and golfing.

Jen Ruth enjoys cooking, reading, socializing, and stopping her kids from fighting.

Julie Simelis says her greatest passion is keeping her kids happy and alive.

PRIORITY TRIALS

Genitourinary/Prostate Cancer

HCC 20-001: A Phase I Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG 509 in Subjects with Metastatic Castration-resistant Prostate Cancer

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

AMG 509 is a novel humanized bi-specific STEAP1 x CD3 T cell recruiting XmAb® antibody cross-reactive to human and non-human primate (NHP) STEAP1 and CD3. AMG 509 monotherapy almost completely inhibited tumor growth in an established subcutaneous SK-N-MC Ewing's sarcoma tumor model and development of subcutaneous STEAP1-positive SNU5 tumors. The present first-in-human, open-label, ascending, multiple-dose study aims to evaluate AMG 509 administered as a short-term IV infusion (approximately 60 minutes) weekly on a 28-day cycle in patients with metastatic castration-resistant prostate cancer (mCRPC). We may also evaluate a once every two weeks (Q2W) dosing schedule in later cohorts. To reduce incidences of cytokine release syndrome (CRS), the cycle 1 dosing schedule may be adapted to include a run-in dose on cycle 1 day 1 followed by a higher maintenance dose ("step dose") for subsequent doses. This study will consist of dose exploration to estimate the mean tolerated dose (MTD), and the recommended phase II dose (RP2D) may be identified based on emerging safety, efficacy, PK, and PD data. The subsequent dose expansion phase will confirm safety, PK, and PD at the MTD or RP2D and obtain further efficacy and correlative biomarker data.

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

- Histologically or cytologically confirmed mCRPC refractory to a novel antiandrogen therapy (eg, abiraterone and/or enzalutamide) and failed at least 1 (but not more than 2) taxane regimens (or are deemed medically unsuitable for or actively refused a taxane regimen)
- Dose escalation: Novel antiandrogen therapy given for treatment of metastatic disease
- Dose expansion: Progression on novel antiandrogen therapy may have occurred in the non-metastatic or metastatic setting
- Have undergone bilateral orchiectomy or are on continuous androgen deprivation therapy (ADT) with a gonadotropin releasing hormone (GnRH) agonist or antagonist
- Total serum testosterone ≤ 50 ng/dL or 1.7 nmol/L
- Evidence of progressive disease with ≥ 1 Prostate Cancer Working Group 3 (PCWG3) criteria
- Eastern Cooperative Oncology Group (ECOG) performance status of 0–1
- Life expectancy < 3 months
- Adequate hematological, renal, hepatic, and cardiac function based on specific standard evaluations

Interested physicians should contact Dr. Appleman or Clare Grzejka, senior clinical research manager, 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

In non-squamous non-small cell lung cancer (NSCLC), newer agents including immunotherapy with antibodies targeting the programmed death-1 (PD-1) pathway have improved survival in the first-line setting, while current data support the idea that a combination of biomarkers including molecular and phenotypic factors may represent an "immunoprofile" or "immunosignature" with predictive value for PD-1/PD-L1 immunotherapy in NSCLC. Radiomics is an emerging field in imaging and initial studies of features in lung cancer on computed tomography (CT) have shown promise in predicting responses to anti-PD1/PD-L1 therapy. In this trial, patients will be enrolled into any one of three arms: A (1st line pembrolizumab followed by 2nd line pemetrexed/carboplatin), B (1st line pembrolizumab, followed by 2nd line pembrolizumab/pemetrexed/carboplatin), or C (pembrolizumab/pemetrexed/carboplatin induction followed by pemetrexed/pembrolizumab maintenance), and standard-of-care CT imaging scans will be collected before initiation of trial therapy and during the post treatment follow-up period. The scans will be used to calculate a comprehensive radiomic risk score as a CT biomarker for determining response to the immune checkpoint inhibitors (ICI).

This trial is open at the following UPMC Hillman Cancer Center locations: Arnold Palmer Pavilion in Greensburg, Beaver, UPMC McKeesport, UPMC Pinnacle, UPMC East, Upper St. Clair, UPMC Passavant, UPMC Altoona, UPMC St. Margaret, and Washington.

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 PS 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

HCC-19-046: An Investigator-sponsored, Phase I/II Trial of the Oral XPO1 Inhibitor Selinexor (KPT-330) in Combination with Docetaxel for Previously Treated, Advanced KRAS Mutant Non-small Cell Lung Cancer (NSCLC)

Principal Investigator: Dr. Timothy Burns, burnstf@upmc.edu

KRAS mutations, which are the most commonly identified driver mutation in non-small cell lung cancer (NSCLC), have been proposed to indicate poor response to conventional treatment and clinical outcomes, but attempts at inhibiting KRAS directly have proven unsuccessful. Preclinical studies in the search for novel approaches to improve treatment and outcomes in KRAS mutant NSCLC demonstrated the sensitivity of KRAS mutant NSCLC cell lines to the novel group of selective inhibitor of nuclear export (SINE) compounds. Selinexor (KPT-330) inhibits tumor cell growth, induces apoptotic cell death, and is specific to nuclear export machinery (XPO1 cargo transport) following temporary modification of target expression. In this present study, we aim to pharmacodynamically assess the effects of selinexor alone and in combination with chemotherapy with docetaxel, which is one of two FDA-approved cytotoxic agents for advanced NSCLC progressing after platinum doublet therapy, and the most feasible option for this indication. Selinexor will be administered once weekly starting 1 week before chemotherapy and docetaxel will be given once every 3 weeks. Treatment will be administered in 21-day cycles. Dose limiting toxicities (DLTs) will be assessed based on the first cycle using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events [NCI CTCAE] version 4.03.

Prospective participants must be ≥ 18 years and meet the following main, among other, eligibility criteria to enroll in this study:

- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Histologically or cytologically confirmed advanced (stage 4, according to the American Joint Committee Cancer [AJCC] version 7.0 Staging manual) NSCLC
- Molecular identification of a KRAS mutation (codons 12, 13, or 61 mutations detected by sequencing) by a CLIA-certified assay (source documentation required)
- Tissue available for analysis at time of enrollment for biomarker analysis
- At least one and up to two previous lines of systemic cytotoxic therapy for advanced NSCLC (one must have been a platinum-based doublet therapy). Up to four total previous lines of systemic therapy (including immunotherapy and molecularly targeted therapy).
- Radiographic or clinical disease recurrence or progression during or after the last line of systemic therapy
- Adequate hematologic, renal, and hepatic function based on specific standard laboratory evaluations
- Measurable disease according to RECIST v1.1

Interested physicians can contact the principal investigators or Jen Ruth, clinical research manager, at ruthj2@upmc.edu with inquiries.

Hematological Malignancies

HCC 19-129: A Randomized, Multicenter, Open-Label, Phase III Study to Compare the Efficacy and Safety of Acalabrutinib (ACP-196) in Combination with Venetoclax with and without Obinutuzumab Compared to Investigator's Choice of Chemoimmunotherapy in Subjects with Previously Untreated Chronic Lymphocytic Leukemia Without del(17p) or TP53 Mutation

Principal Investigator: Dr. Jing-Zhou Hou, houj@upmc.edu

Bruton tyrosine kinase (BTK) inhibition is an established therapeutic intervention for the treatment of CLL; however, data suggest that most patients who respond to a single-agent, such as ibrutinib, have ongoing persistent disease. The correlation of minimal residual disease (MRD)-negative status with longer remissions and the durable remissions that may be achieved with BTKi suggests the benefits of identifying combination regimens that may lead to deeper, MRD-negative responses. Early genetic studies demonstrating that BCL-2 overexpression rescues BTK-deficient XID murine B cells from spontaneous apoptosis has encouraged the investigation of combination therapy with a BTKi and a BCL-2 inhibitor. In this study, Arm A will be administered acalabrutinib, a selective, irreversible small molecule BTKi currently under clinical investigation with venetoclax, a highly selective small-molecule BCL-2 inhibitor that induces CLL cell apoptosis. In Arm B, obinutuzumab, which has the potential to further deepen responses and attain negative MRD status in both bone marrow and peripheral blood, will be added to the doublet of acalabrutinib and venetoclax, and Arm C consist of patients administered a chemoimmunotherapy of the Investigator's choice (fludarabine/cyclophosphamide/rituximab or bendamustine/rituximab).

Prospective male and female participants must be ≥ 18 years and meet the following main, among other, inclusion criteria to be eligible to enroll in this study:

- Eastern Cooperative Oncology Group (ECOG) performance status of 0-2
- Diagnosis of CLL that meets published diagnostic criteria
- Active disease per IWCLL 2018 criteria that requires treatment.
- Participants must use highly effective birth control throughout the study

HCC 16-073: A Phase 1, First-in-Human, Open-Label, Dose Escalation Study of JNJ-63709178, a Humanized CD123 x CD3 DuoBody in Subjects with Relapsed or Refractory AML

Principal Investigator: Dr. Michael Boyiadzis, boyiadzism@upmc.edu or boyimx@upmc.edu

Acute myeloid leukemia (AML) is a disorder of early hematopoietic progenitor cells, characterized by the proliferation and accumulation of immature, clonal, myeloid cells. JNJ-63709178 is a humanized IgG4-PAA bispecific DuoBody® antibody targeting the CD3 receptor complex on T cells and CD123 on myeloid cells, which brings the two cell types into close proximity, and subsequently promotes the activation of T cells with subsequent leukemic cell lysis. These effects are mediated by secreted perforin and various granzymes stored in the secretory vesicles of cytotoxic T cells, and result in the lysis of AML blasts. The purpose of the present two part study is to characterize the safety and tolerability of JNJ-63709178 and identify the recommended Phase II doses (RP2D) and schedule for JNJ-63709178 in Part 1 and characterize the safety and tolerability of JNJ-63709178 at the RP2D in Part 2.

Prospective male and female participants must be ≥ 18 years and meet the following main, among other, inclusion criteria to be eligible to enroll in this study:

- A diagnosis of AML according to the WHO 2008 criteria with relapsed or refractory disease and ineligible for or have exhausted standard therapeutic options
- Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1
- Hematology and chemistry laboratory parameters within the protocol specified range

For further trial information, including detailed information about the various sub-study treatments, interested physicians can contact the principal investigators or Linda Fukas, program manager, at fukaslj@upmc.edu.

Breast Cancer

HCC 20-029: An Open-label, Randomized, Multicenter Study Evaluating the Activity of Lasofoxifene Relative to Fulvestrant for the Treatment of Pre- and Postmenopausal Women with Locally Advanced or Metastatic ER+/HER2– Breast Cancer with an ESR1 Mutation

Principal Investigator: Dr. Adam Brufsky, brufskyam@upmc.edu

In this study, eligible pre- and postmenopausal women with locally advanced or metastatic estrogen receptor positive (ER+)/human epidermal growth factor 2 negative (HER2-) breast cancer with an estrogen receptor 1 (ESR1) mutation will first be stratified into those with and without visceral metastasis, and each of these stratified groups will then be further stratified into those with and without the Y537S ESR1 mutation. Each stratified groups will then be randomized 1:1 to receive either 5 mg/day of oral lasofoxifene or fulvestrant 500 mg intramuscular (IM) on Day 1, 15, and 29, and then every four weeks. Treatment will continue until radiographic or clinical evidence of disease progression.

This study is open at the following UPMC Hillman Cancer Center locations: UPMC Magee-Womens Hospital, Arnold Palmer Pavilion in Greensburg, UPMC East, UPMC Passavant, Upper St. Clair, Washington, UPMC Memorial, and UPMC Pinnacle and has the following, among other, main eligibility criteria that prospective participants are expected to meet:

- At least one or more of the following ESR1 point mutations as assessed in cell-free circulating tumor DNA (ctDNA) obtained from a blood (plasma) or tissue sample: Y537S, Y537C, D538G, E380Q, S463P, V534E, P535H, L536H, L536P, L536R, L536Q, or Y537N. The ctDNA sample collection must be obtained within 90 days prior to randomization to determine eligibility and baseline
- Subjects who have not received cytotoxic chemotherapy or who have received **one** cytotoxic chemotherapy regimen in the neo-adjuvant or adjuvant setting prior to entry into the trial; and/or no more than **one** chemotherapy regimen for metastatic breast cancer
- No prior use of everolimus or other mammalian target of rapamycin (mTOR) inhibitor or phosphoinositide 3-kinase inhibitor (PI3K) inhibitors are excluded unless discontinued due to reasons other than disease progression

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

Gynecologic Cancer

HCC 19-164: Phase IIA Trial of Delayed Initiation of Olaparib Maintenance Therapy in Platinum Sensitive Recurrent Ovarian Cancer

Principal Investigator: Dr. Sarah Taylor, taylorse2@upmc.edu

The purpose of this study is to test if delaying the start of the olaparib until there is a rise in a tumor marker called CA-125 will result in a longer time until the next or different treatment for the patient's cancer. The study will also evaluate how delaying the start of maintenance therapy will affect symptoms, physical functioning, quality of life, and impact on finances.

This study is open at the following UPMC Hillman Cancer Center locations: UPMC Magee-Womens Hospital, UPMC Hillman Cancer Center in Shadyside, Arnold Palmer Pavilion in Greensburg and Norwin, UPMC Altoona, Beaver, Erie, Greenville, UPMC Horizon, Indiana, John P. Murtha Pavilion in Johnstown, UPMC McKeesport, UPMC East, UPMC Northwest, UPMC Passavant, UPMC St. Margaret, Uniontown, Upper St. Clair, Washington, UPMC Mercy, and UPMC Pinnacle and has the following, among other, main eligibility criteria that prospective participants are expected to meet:

- Must have completed at least 2 courses of platinum-based chemotherapy with a PR or CR or CA-125 response
- BRCA required (but not needed for registration to trial)
- No prior PARP

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

Biobehavioral Trials

HCC 17-199: Collaborative Care Intervention for Cancer Patients and Their Family Caregiver

Principal Investigator: Jennifer Steel, steejl@upmc.edu

Socioeconomic disadvantage has been shown to result in a greater likelihood of being diagnosed with cancer, delays in cancer diagnoses, receiving less treatment, decreased access to palliative care and hospice services, and higher mortality rates. Our team has observed that people from socioeconomically disadvantaged backgrounds had a disproportionately higher prevalence of depression, pain, and fatigue in addition to a poorer quality of life compared to those with a reported higher socioeconomic status (SES). Specifically, we are interested in testing a web-based collaborative care intervention to reduce depression, pain, and fatigue. We are also interested in determining if changes in these symptoms are associated with reductions in inflammation and health outcomes as well as health care utilization and health care costs. Family caregivers are at increased risks for cardiovascular disease (CVD) and mortality. As a result, we are also examining if the reduction in patient reported outcomes also reduces the caregiver reported outcomes and metabolic syndrome, an intermediate endpoint to CVD.

Eligibility criteria for patients include:

- Age > 21 years
- Biopsy and/or radiograph proven diagnosis of cancer
- Score ≥ 16 on the Center for Epidemiological Studies-Depression scale or ≥ 3 (on a scale from 0-10) on fatigue or pain

Eligibility criteria for family caregivers:

- Aged ≥ 21 years and caring for someone diagnosed with cancer and enrolled in the study.

For more information regarding the study, please contact Dr. Steel; Josh Plassmeyer, Biobehavioral Cancer Control Program Supervisor, at plassmeyerj@upmc.edu; or Ella Choban, research coordinator, at chobane@upmc.edu.

ACHIEVEMENTS AND ACCOLADES

The UPMC Hillman Cancer Center Clinical and Translational Research Center (CTRC) outpatient unit operates in a dedicated space on the first floor of Hillman's Shadyside location, where research staff are met upon initiating new trials. CTRC nurses ensure patients are scheduled timely, have order entry completed, and diligently scrutinize protocols to prevent task misinterpretation, leading to deviations. Research for breast and gynecologic oncology patients of Hillman at UPMC Magee-Women's Hospital involve complex and detailed trials requiring specialized care and attention as laid out above; consequently, Magee has created a new specialized unit.

We now have two immunotherapy-oriented investigators, Dr. Leisha Emens (breast cancers) and Dr. Haider Mahdi (gynecologic cancers), who are working diligently to bring very innovative, novel trials to our patients. To execute these trials with the attention to detail they require, we recently hired an oncology nurse to specifically focus on the treatment and care of these patients. She has extensive oncology research and nursing experience and has completed the essential orientation with the HCC CTRC team. The project to create a Hillman/Magee CTRC in our current Women's Cancer Center on the fourth floor of Magee, where all Magee-based breast and gynecologic cancer patients are treated, has commenced. This unit has a large, very experienced group of oncology nurses in addition to APPs. The future plan is to expand the new CTRC to a permanent space, which will enable growth and provide patients greater opportunity for early phase I and II trials. We are very excited to see this longstanding goal of our physicians and our breast and gynecologic research team come to fruition. We have no doubt that our forward-thinking investigators and numerous exciting trials on the horizon will enable this unit to provide excellent opportunities and care for our patients.

2020 OPEN STUDIES AND ACCRUALS

Disease / Modality Center	Open Trials		Accruals	
	Interventional	Therapeutic	Interventional	Therapeutic
Biobehavioral Medicine in Oncology Program	6	0	359	0
Brain Tumor Center	16	16	28	28
Breast Center	27	23	302	54
Early Therapeutics Centers (Phase I and II)	51	51	72	72
GI/Esophageal Cancer Center	20	20	131	129
Gynecological Oncology Center	10	9	24	24
Head and Neck Center	34	33	78	78
Hematological Malignancies Center	28	28	52	43
Immune Therapy Center	46	46	114	114
Lung and Thoracic Malignancies Center	31	27	112	44
Melanoma Center	17	17	73	73
Multi-Disease/Modality Center Trials	3	3	1152	257
Pediatric Oncology	52	50	56	53
Prostate and Urologic Cancers	19	19	41	41
Sarcoma Center	11	11	11	11
Supportive Care	1	0	27	0
Total	**372**	**353**	**2632**	**1,021**
*Radiation Oncology Center	18	18	35	35

*Radiation Oncology accruals are distributed to disease center of care.
All Accruals are calculated from January 1 through December 31, 2020

Multi-disease/Modality Center Trials: HCC# 18-177
Accrual Total: 1,119, Therapeutic 20%: 224

2020 TOP PERFORMERS

INTERVENTIONAL TRIAL ACCRUALS

Physician	Treatment Site	Interventional
Kiefer, Gauri	Arnold Palmer Pavilion At Mt View - UPMCCC	209
Berg, Wendie	UPMC Magee-Womens Hospital - Breast Imaging	126
Marsh, Christopher	UPMC Cancer Center Upper St. Clair	106
Goel, Gaurav	UPMC Cancer Center Upper St. Clair	101
Evans, Terry	Arnold Palmer Pavilion At Mt View - UPMCCC	77
Thomas, Roby	UPMC Hillman Cancer Center	66
Sulecki, Matthew	Arnold Palmer Pavilion At Mt View - UPMCCC	64
Tageja, Nishant	UPMC Cancer Center At Upmc East, Oxford Drive	60
Sehgal, Rajesh	UPMC Cancer Center At Upmc East, Oxford Drive	59
Luke, Jason	UPMC Hillman Cancer Center	57
Ancevski Hunter, Katerina	Arnold Palmer Pavilion At Mt View - UPMCCC	44
Appleman, Leonard	UPMC Hillman Cancer Center	39
Luketich, James	UPMC Presbyterian	32
Sholi, Abdalla	UPMC Susquehanna Cancer Center At Divine Providence Hospital	32
Kirkwood, John	UPMC Hillman Cancer Center	31
Waas, John	Arnold Palmer Medical Oncology - Norwin	31

THERAPEUTIC TRIAL ACCRUALS

Physician	Treatment Site	Therapeutic
Davar, Diwakar	UPMC Hillman Cancer Center	63
Luke, Jason	UPMC Hillman Cancer Center	53
Ohr, James	UPMC Hillman Cancer Center	34
Luketich, James	UPMC Presbyterian	32
Kirkwood, John	UPMC Hillman Cancer Center	31
Najjar, Yana	UPMC Hillman Cancer Center	30
Zandberg, Dan	UPMC Hillman Cancer Center	26
Appleman, Leonard	UPMC Hillman Cancer Center	25
Rhee, John	UPMC Hillman Cancer Center	22
Drappatz, Jan	UPMC Hillman Cancer Center	19
Thomas, Roby	UPMC Hillman Cancer Center	19
Bahary, Nathan	UPMC Hillman Cancer Center	16
Villaruz, Liza	UPMC Hillman Cancer Center	15
Burgess, Melissa	UPMC Hillman Cancer Center	13
Kammula, Udai	UPMC Hillman Cancer Center	13

Clinical Research Services (CRS) is made up of over 200 staff members who facilitate development, implementation, coordination, internal data monitoring, and completion of approximately 400 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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