THE TRIAL BLAZER

UPMC HILLMAN CANCER CENTER

A QUARTERLY NEWSLETTER FROM
CLINICAL RESEARCH SERVICES

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FAREWELL TRIBUTE TO DR. BHANU PAPPU

Dr. Bhanu Pappu was recruited in April 2018 from MD Anderson Cancer Center, where he served for more than 10 years in several leadership capacities. On his arrival, Dr. Pappu "hit the ground running" with numerous initiatives geared towards not only enhancing the day to day management strategies of CRS, but also improving the general work environment and boosting staff morale. Upon resuming his position at UPMC Hillman Cancer Center, Dr. Pappu initiated regular visits with CRS and medical oncology staff at network sites to determine the most pressing needs and review operations to identify the best way to improve our efficiency, and he endeavored to engage with community leadership. In a bid to increase physician engagement in the clinical trials, in September 2018, Dr. Pappu facilitated the first annual clinical research retreat attended by medical oncologists from all over the UMPC Hillman Cancer Center network, which has been a roaring success in encouraging higher levels of participation. These and other targeted programs have contributed to increasing the accrual of patients to the numerous high quality trials that are offered at UPMC Hillman Cancer Center. All of his efforts made a major contribution to the "Outstanding to Exceptional" score that was received on the CRS portion of the Cancer Center Support Grant. On identifying the gaps in steps for staff promotions, he established a new career

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INTRODUCING DR. TAOFEEK OWONIKOKO'S VISION

I am happy to return to UPMC Hillman Cancer Center and look forward to the opportunity to work with an outstanding team of clinical researchers that have made UPMC Hillman a leader among equals. The opportunity to engage in innovative clinical research in collaboration with world renowned basic scientists and across a large network anchored by academic and community oncologists was crucial to my decision to come back. I have spent the last three months interacting with various members of our cancer center including physicians, clinical and basic researchers, regulatory research support staff, and administrative leaders. I have a much greater appreciation of the commitment of the UPMC Hillman to drive innovative clinical research and to be at the forefront of cancer care for people in our immediate environment and worldwide.

I have spent the last decade of my career as a translational researcher and witnessed firsthand the successes in cancer care advances initiated by clinical research including targeted therapies, immunotherapies, minimally invasive surgical approaches, and advanced techniques in radiation delivery. I have also become very familiar with the challenges that we face in conducting human clinical research. It is my vision that the next few years would witness robust growth in investigator-initiated trials where we are

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Points of Interest

ACHIEVEMENTS AND ACCOLADES

- **UPMC Hillman Phase 1 program selected as Novartis First-in-Human site**

CRS TEAM SPOTLIGHT: Gynecologic Cancer Center

Physicians and CRS Members

Dr. Jessica Berger

Dr. Jessica Berger is an assistant professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh School of Medicine. Her research focus includes translational work on the impact of chemotherapy on reproductive health and fertility preservation options for reproductive age women undergoing gynecologic cancer treatment. In her leisure time, Dr. Berger enjoys exploring Pittsburgh with her three children, reading, and cooking.

Dr. Madeleine Courtney-Brooks

Dr. Madeleine Courtney-Brooks is an assistant professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh School of Medicine and the Division Director of Gynecologic Oncology. Dr. Courtney-Brooks has endeavored to highlight the current treatment paradigm of recurrent ovarian cancer. In her "down time," she enjoys attending the Pirates baseball games, spending time with family, reading, and planning vacations.

Dr. Haider Mahdi

Dr. Haider Mahdi is an assistant professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh School of Medicine and the Division Director of Gynecologic Oncology. He is a soccer enthusiast who also loves running and spending quality time with family.

Dr. Sarah Taylor

Dr. Sarah Taylor is an assistant professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh School of Medicine and the Division Director of Gynecologic Oncology. Her research interests include targeted and novel treatments of gynecologic cancer, correlated biomarker development for defining personalized cancer therapy, and screening and early detection of gynecologic cancers. Dr. Taylor enjoys spending time with family and friends, rowing, running, and reading in her personal "leisure time."

Dr. Jamie Lesnock

Dr. Jamie Lesnock is an assistant professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh School of Medicine, and she has over 16 years of diverse experience in the field. In her leisure time, she loves gardening, swimming, and baking with her four children.

Dr. Alexander Olawaiye

Dr. Alexander Olawaiye is an associate professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh School of Medicine and the Division Director of Gynecologic Oncology and the Director of Gynecologic Cancer Research at UPMC Magee-Womens Hospital. He has overseen numerous clinical research projects and his research focus include translational and clinical research in ovarian, cervical, and vulvar cancers. In his "spare time," Dr. Olawaiye enjoys soccer, tennis, fishing, hiking, and traveling.

Dr. Ronald Buckanovich

Dr. Ronald Buckanovich is a professor of medicine in the Department of Medicine, University of Pittsburgh and co-director of the Women's Cancer Research Center. His research interests are in ovarian cancer stem cells, mesenchymal stem cells, tumor vascular niche, ovarian cancer therapeutics, and ovarian cancer clinical trials. He is dedicated to improving the survival of gynecologic cancer patients and actively involved in basic laboratory research, new clinical trial development, and development of new screening tests. He loves hiking, biking, playing tennis and the folk guitar, and baking in his leisure time.

Dr. Lan Coffman

Dr. Lan Coffman is an assistant professor of hematology-oncology at the University of Pittsburgh School of Medicine. Her research focuses on the ovarian cancer microenvironment and understanding and targeting the cancer supporting stromal tissues which are critical to the survival, growth and spread of ovarian cancer running. In her leisure time, she enjoys reading and hiking with family.

Dr. Michelle Boisen

Dr. Michelle Boisen is an assistant professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh School of Medicine and her research has involved collaborations with other researchers in characterizing signatures of estrogen receptor signaling in both high grade serous and endometriosis-associated ovarian cancers. Dr. Boisen enjoys skiing, biking, hiking, travel, and cooking in her spare time.

Dr. Halina Zyczynski

Dr. Halina Zyczynski is a professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh School of Medicine and Medical Director of the Women's Center for Bladder and Pelvic Health. Her clinical research interest are focused on short- and long-term anatomic and functional outcomes of surgical and non-surgical treatments for pelvic organ prolapse, urinary and fecal incontinence, as well as cost-effectiveness of related diagnostic testing. In her spare time, she enjoys gardening, kayaking, and has just started sailing lessons and loves it.

Dr. Robert Edwards

Dr. Robert Edwards is a professor of medicine in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh School of Medicine , the Chair of Obstetrics, Gynecology, and Reproductive Sciences at Magee-Womens Hospital of UPMC, and the co-leader of the UPMC Gynecologic Cancer Program. His research interests are centered on novel therapeutic approaches to gynecologic malignancies, as well as translational research. In his leisure time, he loves hiking, running, and spending time with his kids.

Dr. Paniti Sukumvanich

Dr. Paniti Sukumvanich is an assistant professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of Pittsburgh School of Medicine. His research centers on the genetic causes of ovarian and breast cancers, and also cancer informatics (the science of analyzing large amounts of information). In his spare time, he loves traveling and spending time with his family.

Dr. Vikram Gorantla

Dr. Vikram Gorantla is an oncologist in Pittsburgh and specializes in internal medicine and hematology/oncology. Dr. Gorantla is affiliated with UPMC Shadyside, UPMC Presbyterian, and UPMC Magee Womens Hospitals.

Dr. John Comerci

Dr. John Comerci is a professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Pittsburgh School of Medicine and vice chair of Women's Health Service Line Specialty Services and Referral Physician Relations. Dr Comerci's research has been primarily focused on using photo-activated agents in the treatment of both pre-invasive and invasive gynecologic disease.

Joshua Plassmeyer

Joshua Plassmeyer has been with CRS for four and a half years serving as Operations Manager, and recently took over as the clinical research manager for breast and gynecological cancer centers in July 2021. He loves spending as much time as he can with his family, coaching his children in their sports and activities, and advocating for his eldest daughter- who is an epithelioid sarcoma cancer survivor.

Abigail Jackson

Abigail Jackson is a research associate who has been with CRS for about two and a half years. She enjoys hanging out with her husband and daughter, researching and practicing obsolete and historical crafts, and writing short stories.

Claire Berger

Claire Berger is a clinical research coordinator who has been with CRS for about a year and a half. She enjoys hanging out with her cats, making art, taking care of too many plants, and playing video games.

Emily Weber

Emily Weber is a clinical research coordinator who has been with CRS for about six months. She loves spending time with her cats, shopping, and getting her nails done

Sarah Miller

Sarah Miller is a research coordinator who has been with CRS for about a year and four months. She loves walking and hiking with her dogs Mollie and Sadie, planting, cooking new foods, crafting, and engaging in DIY projects on her house.

Jessica Yauch

Jessica Yauch is a research associate and has been with CRS for about five months. She enjoys chasing her son around, being outdoors, traveling to new places.

Hannah Stankus

Hannah Stankus is one of the newest research associates in the gyne center team and has been with CRS for about two months, She enjoys cooking and exploring new recipes, hiking, tennis, and embroidery

SPOTLIGHT TRIAL

TTFields in Recurrent Ovarian Cancer Treatment

HCC 19-137: ENGOT-ov50/INNOVATE-3: Pivotal, Randomized, Open-Label Study of Tumor Treating Fields (TTFields, 200kHz) Concomitant with Weekly Paclitaxel for the Treatment of Recurrent Ovarian Cancer

Principal Investigator: Dr. Alexander Olawaiye, olawaiyea@upmc.edu
Tumor-treating fields (TTFields) is a locoregional, antimitotic therapy, which can be applied to the abdominal and pelvic regions. The efficacy of TTFields in ovarian cancer has been shown using in vitro and in vivo models and the addition of taxanes was synergistic in preclinical ovarian models, potentially resulting from the mitotic spindle being a common target for both treatments. Simulations have also demonstrated that therapeutic level TTFields could be delivered to common sites of disease in ovarian cancer, including malignant ascites. These findings, in addition to the results of the INNOVATE pilot clinical study, which showed good compliance with TTFields and promising progression-free survival (PFS) outcomes in patients with platinum-resistant ovarian cancer, provide a strong rationale for further testing TTFields. In this present study, patients with recurrent ovarian cancer will be randomized 1:1 to receive TTFields applied at 200 kHz to the abdomen and pelvis using the NovoTTF-100L(O) system with weekly paclitaxel or weekly paclitaxel alone.

This study has the following, among other, main eligibility criteria that prospective participants ≥ 18 years old are expected to meet:

- Epithelial histology of ovarian/primary peritoneal or fallopian tube carcinoma at diagnosis
- Life expectancy of ≥ 12 weeks
- Maximum two prior lines of predefined systemic therapy following diagnosis of platinum resistance
- Maximum total of five prior lines of systemic therapy
- Amenable to receive weekly paclitaxel and able to operate the NovoTTF-100L(O) system
- Eastern Cooperative Oncology Group Performance Status (ECOG) 0-1
- Evaluable disease in the abdominal/pelvic region per RECIST V1.1

Study team contacts: Study Principal Investigator or Josh Plassmeyer (Breast/Gynecological Cancer Center Manager, plassmeyerjm@upmc.edu)

PRIORITY TRIALS

Genitourinary/Prostate Cancers

HCC 21-052: A Phase I, Open-Label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, and Antitumor Efficacy of DZD2269 in Patients with Metastatic Castration Resistant Prostate Cancer

Adenosine signaling, triggered through four distinct G-protein-coupled adenosine receptors including A2aR, has been recognized as a key mechanism mediating immunosurveillance evasion by tumors. Consequently, adenosine receptor inhibition has emerged as a promising approach for alleviating immunosuppression in tumors and several A2aR antagonists are currently in early clinical development. DZD2269 is an oral, potent, and selective A2aR antagonist and preclinical data have provided evidence to support its clinical development as a monotherapy and in combination with chemotherapy, radiotherapy, or other immunotherapies in patients with advanced cancers. In this first-in-human study, approximately 15–45 patients with metastatic castration resistant prostate cancer (mCRPC) will be enrolled to receive DZD2269 to investigate its safety and tolerability as monotherapy. Dose escalation with cohort 2 at 10 mg DZD2269 daily is currently ongoing, and the effect of food on DZD2269 pharmacokinetics will also be investigated at selected doses in a food effect cohort.

Potential male participants ≥ 18 years of age are expected to meet the following main, among other, eligibility criteria:

- Provide blood samples and paired tumor tissue
- Eastern Cooperative Oncology Group (ECOG) performance status 0–1 with no deterioration over previous two weeks
- Predicted life expectancy ≥ 12 weeks
- Histologically confirmed diagnosis of adenocarcinoma of the prostate, with metastatic disease and previous progression on standard-of-care (SoC) therapy despite castrate levels of testosterone.
- Total testosterone < 50 mg/dL at screening except those with prior orchiectomy
- Adequate bone marrow reserve and organ system functions LVEF ≥ 55% assessed using ECHO or MUGA

Study team contacts: Dr. Leonard Appleman (Study Principal Investigator, applemanlj@upmc.edu), Clare Grzejka (Senior Clinical Research Manager, (grzejkac@upmc.edu)

Gynecological Cancers

HCC 20-023: MIRASOL: A Randomized, Open-label, Phase III Study of Mirvetuximab Soravtansine vs. Investigator's Choice of Chemotherapy in Platinum-Resistant Advanced High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers with High Folate Receptor-Alpha Expression

Current data suggest that the folate receptor α (FRα) is a promising target in solid tumors, particularly epithelial ovarian cancer (EOC), and an emerging promising target for antibody drug conjugate (ADC) therapy. Mirvetuximab soravtansine (MIRV) is an ADC designed to target FRα and the selective upregulation of FRα in solid tumors provide a rationale for exploring the clinical benefits of MIRV. In this study, patients will be stratified based on the number of prior lines of therapy and enrolled 1:1 into one of the two following arms:

• Arm 1: MIRV 6 mg/kg adjusted ideal body weight (AIBW) every three weeks

• Arm 2: investigator's choice of chemotherapy (IC Chemo) with paclitaxel (Pac, 80 mg/m^2) weekly on a four-week cycle, pegylated liposomal doxorubicin (PLD, 40 mg/m^2) every four weeks, or topotecan (Topo, 4 mg/m^2) on Days 1, 8, and 15 every four weeks or for five consecutive days (1.25 mg/m^2 Days 1–5) every three weeks

This study has the following, among other, main eligibility criteria that prospective participants ≥ 18 years old are expected to meet:

- Confirmed diagnosis of high-grade serous EOC, primary peritoneal cancer, or fallopian tube cancer with platinum-resistance
- Radiographically confirmed progression on or after most recent line of therapy
- Provide archival tumor tissue block or slides or undergo procedure to obtain new biopsy for immunohistochemistry confirmation of FRα positivity
- Tumor must be FRα expression positive as defined by Ventana FOLR1 (FOLR-2.1) CDx assay
- Received at least one but no more than three prior systemic lines of anticancer therapy, and for whom single-agent therapy is appropriate as the next line of treatment:
- Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 or 1
- Systemic antineoplastic therapy (five half-lives or four weeks, whichever is shorter)
- Adequate hematologic, liver, and kidney functions based on pre-defined laboratory test

Study team contacts: Dr. Lan Coffman (Study Principal Investigator, coffmanl@mwri.magee.edu, coffmanl@upmc.edu) or Josh Plassmeyer (Breast/Gynecological Cancer Center Manager, plassmeyerjm@upmc.edu).

Biobehavioral

HCC 20-117: Cognitive Impairment in GIST Patients on Tyrosine Kinase Inhibitor Therapy: Cognitive-Behavioral Therapy to Improve Cognitive Symptoms

Cognitive-behavioral therapy (CBT) has been found to be efficacious for the treatment of cancer-related cognitive impairment (CRCI). Memory and Attention Adaptation Training (MAAT) has been evaluated in previous randomized clinical trials with samples of breast cancer survivors and found to be effective at reducing self-reported cognitive symptoms of CRCI and improve neurocognitive performance on objective measures of memory and processing speed. Moreover, MAAT is a telehealth-delivered CBT (designed and trialed years before the COVID-19 pandemic), which reduces costs, time, and travel burdens for survivors. In a recent international survey conducted by our team, up to 63% of patients with a diagnosis of gastrointestinal stromal tumor (GIST) report CRCI symptoms that have an adverse impact on quality of life. Given the success that TKI therapies have had on improving overall survival for people with GIST, addressing CRCI can have a strong positive impact on survivor quality of life. The primary aim of this small, one-group clinical trial is to evaluate feasibility, satisfaction, and initial efficacy of MAAT among survivors of GIST who report cognitive complaints.

Eligible participants will meet the following criteria:

- Diagnosis of GIST
- At least one year post-initiation of TKI therapy
- Report cognitive problems of memory and concentration attributed to GIST and/or treatment with a score of 10 or below on the FACT-Cog Impact on Quality-of-Life Scale

Study team contact: Dr. Robert Ferguson (Study Principal Investigator, fergusonrj2@upmc.edu), Dr. Anette Duensing (Study Principal Investigator, duensingau@upmc.edu), or Alicia Brindle (ALB330@pitt.edu).

Brain Malignancies

HCC 19-048: GBM AGILE: Global Adaptive Trial Master Protocol: An International, Seamless Phase II/III Response Adaptive Randomization Platform Trial Designed To Evaluate Multiple Regimens In Newly Diagnosed and Recurrent Glioblastoma (GBM)

Glioblastoma (GBM) adaptive, global, innovative learning environment (AGILE) is a biomarker-based, multi-arm, two-stage trial designed to evaluate multiple therapies in newly diagnosed and recurrent GBM. The goals of the trial are to identify effective therapies for GBM and match them with patient subtypes. In the initial screening stage, Bayesian response adaptive randomization is used within subtypes of the disease to assign patients to experimental arms, or a control based on their performance. Those with evidence of efficacy in at least one of several "biomarker signatures" will continue therapies in GBM AGILE uninterrupted. Furthermore, they will transition to a confirmatory stage with fixed randomization in an expansion cohort to control type I error, intended to support marketing approval. GBM AGILE provides an efficient mechanism to screen and develop robust information regarding the efficacy of proposed novel therapeutics and associated biomarkers for GBM and to quickly move therapies and biomarkers into the clinic.

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:

Newly Diagnosed GBM Criteria:

- Histologically confirmed Grade IV GBM, inclusive of gliosarcoma (WHO criteria; IDH wild-type by immunohistochemistry or sequencing for IDH) established by surgical resection or biopsy
- MRI scan with required imaging sequences performed within 21 days prior to randomization
- Post-operative MRI within 96 hours of surgery
- Use of dexamethasone ≤ 4 mg/per day within five days prior to randomization
- Karnofsky performance status ≥ 60% performed within a 14-day window prior to randomization
- Availability of GBM tumor tissue

Recurrent GBM Criteria

- Histologically confirmed Grade IV GBM inclusive of gliosarcoma (WHO criteria, IDH wild-type) at first or second recurrence after initial standard, control, or experimental therapy that includes radiotherapy, at a minimum
- Evidence of recurrent disease demonstrated by disease progression using slightly modified RANO criteria with post-chemoradiation time point as baseline
- Two scans to confirm progression
- Baseline MRI performed within 14 days prior to randomization
- Use of dexamethasone ≤ 4 mg/day within five days prior to randomization
- Karnofsky performance status ≥ 70% performed within a 14-day window prior to randomization
- Availability of GBM tumor tissue from initial definitive or recurrent surgery, if performed

Study team contacts: Dr. Jan Drappatz (Study Principal Investigator, drappatzj@upmc.edu) or Melinda Vargas-Jaffe (Clinical Research Supervisor, vargasjaffema@upmc.edu).

HCC 19-147: A Phase III, Multicenter, Randomized, Double-blind, Placebo-Controlled Study of AG-881 in Subjects With Residual or Recurrent Grade II Glioma With an IDH1 or IDH2 Mutation.

Isocitrate dehydrogenase (IDH) mutations are considered drivers of the genetic evolution of low-grade glioma (LGG) and their inhibition early in the disease course in low-risk patients who have undergone surgery only, may suppress tumor growth and disease transformation. Vorasidenib is a novel, orally available, brain-penetrant, targeted inhibitor of mutated IDH1 and IDH2 proteins, which has been extensively evaluated in nonclinical in vivo and in vitro studies, and effectively inhibits the gain-of-function activity of mutated IDH proteins. Moreover, safety and efficacy data in patients with glioma suggests that vorasidenib may serve as a novel molecularly targeted treatment for patients with residual or recurrent Grade 2 glioma who have only had surgical treatment and are under active observation, potentially delaying the need for more aggressive chemoradiation therapy. In this study, patients will be randomly assigned in a 1:1 ratio to receive vorasidenib orally at a dose of 40 mg once daily or vorasidenib–matched oral placebo daily. Randomization will be stratified by local 1p19q status (co-deleted or not) and baseline tumor size per local assessment.

This study has the following, among other, main eligibility criteria that prospective participants ≥ 18 years old are expected to meet:

- Grade 2 oligodendroglioma or astrocytoma per WHO 2016 criteria
- At least 1 prior surgery for glioma (biopsy, sub-total resection, gross-total resection), with the most recent surgery having occurred at least 1 year and not more than 5 years before the date of randomization, and no other prior anticancer therapy, including chemotherapy and radiotherapy
- Confirmed IDH1 (IDH1 R132H/C/G/S/L mutation variants tested) or IDH2 (IDH2 R172K/M/W/S/G mutation variants tested) gene mutation status disease by central laboratory
- MRI-evaluable, measurable, non-enhancing disease, at least 1 target lesion measuring ≥1 cm × ≥1 cm (bidimensional). Centrally confirmed, minimal, non-nodular, non-measurable enhancement that has not changed between the 2 most recent scans (including screening scan) will be permitted.

Study team contacts: Dr. Jan Drappatz (Study Principal Investigator, drappatzj@upmc.edu) or Melinda Vargas-Jaffe (Clinical Research Supervisor, vargasjaffema@upmc.edu)

ACHIEVEMENTS AND ACCOLADES

UPMC Hillman Phase 1 Program Selected as Novartis First-in-Human Site

The Novartis Early Trial Translational Oncology Program has selected the UPMC Hillman Cancer Center's Phase 1 Program with Dr. Taofeek Owonikoko as one of their First-in-Human sites. As part of this highly select group of institutes, UPMC Hillman Cancer Center will be in the position to provide patients with access to the very earliest cutting edge therapeutic innovations in the Novartis pipeline. Dr. Owonikoko will be leading a First-in-Human trial targeting the RAS pathway consisting of a dose escalation phase and several expansion cohorts further defining the pharmacology of the novel drug.

OPEN STUDIES AND ACCRUALS JAN–SEP 2021

	Open Trials		Accruals	
Disease / Modality Center	Interventional	Therapeutic	Interventional	Therapeutic
Biobehavioral Medicine in Oncology Program	14	0	202	0
Brain Tumor Center	14	14	22	22
Breast Center	39	34	397	54
Early Therapeutics Centers (Phase I and II)	73	73	83	83
GI/Esophageal Cancer Center	39	39	90	90
Gynecological Oncology Center	16	15	16	16
Head and Neck Center	29	26	147	56
Hematological Malignancies Center	49	49	29	29
Immune Therapy Center	63	63	100	100
Lung and Thoracic Malignancies Center	48	44	80	24
Melanoma Center	33	33	91	91
Multi-Disease/Modality Center Trials	2	1	40	40
Pediatric Oncology	64	60	27	26
Prostate and Urologic Cancers	26	24	68	32
Sarcoma Center	12	12	14	14
Supportive Care	1	0	0	0
Radiation Oncology Center	26	25	123	42
Total	**548**	**512**	**1529**	**719**

**All Accruals are calculated from January 1 through September 30, 2021.

OPEN STUDIES AND ACCRUALS JAN–SEP 2021

	Open Trials		Accruals	
Disease / Modality Center	Interventional	Therapeutic	Interventional	Therapeutic
Multi-Disease/Modality Center Trials	1	1	0	0
Brain Tumor Center	2	2	3	3
Breast Center	3	2	83	2
GI/Esophageal Cancer Center	1	1	0	0
Gynecological Oncology Center	2	2	2	2
Head and Neck Center	9	9	23	23
Lung and Thoracic Malignancies Center	2	2	9	9
Prostate and Urologic Cancers	6	6	3	3
Total	**26**	**25**	**123**	**42**

Multi-Disease/Modality Center Trials Accruals	**726**
Accruals to HCC#18-177	**686**

FAREWELL TRIBUTE TO DR. BHANU PAPPU (Continued from Page 1)

ladder that has provided CRS staff members with a clear pathway to achieving professional advancement, which has undoubtedly improved staff retention and morale. Dr. Pappu made it clear on his arrival that he was here to be a support to each and every one and no matter how "swamped" he was, he always maintained an "open door" policy with a listening ear to anyone who needed it. His annual "town hall" meetings provided an opportunity for every voice to be heard, and his humility in leadership service was phenomenally exemplary. His departure is indeed a huge loss to CRS, and a personal loss to many of us. He will be sorely missed and leaves some big shoes to fill. We wish him nothing but the very best as he makes this career move to the University of Texas – Southwestern, where he will have an even larger role in the clinical research done throughout the system.

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

INTRODUCING DR. TAOFEEK OWONIKOKO'S VISION (Continued from Page 1)

able to convert basic science findings into clinical interventions to help improve the outcome for our patients.

As a large cancer center network, we also want to make sure that clinical research operations and trials are made available at all of our community sites and as much as possible, to the same degree as is obtainable on the Shadyside campus. The COVID pandemic has shown us possibilities and how we can still conduct safe and effective clinical research while minimizing the laborious requirements for regulatory oversight without compromising the safety of our participants and patients. I envision a future where some of these initiatives will become part of our standard operating procedures. I hope that the ability to remotely consent patients and discuss the details of clinical trials with potential participants will be a tool that enable us to support our community-based practitioners. Also, remote evaluation of patients on study for safety has been a positive step to ensuring protocol compliance and overall quality of life for study participants.

In consultation with various disease site leaders, CRS administrative leaders, patient advocates, clinical research staff, and the entire UPMC Hillman Cancer Center leadership, I look forward to the opportunity to re-envision our programs with the goal to realigning them for synergy, efficiency, and productivity. We will also be bold and innovative in testing new initiatives that allow us to better leverage unique capabilities and expertise available within our basic science programs at UPMC Hillman and across various schools and departments of the university.

I am thankful for the opportunity to come back and be a part of UPMC Hillman Cancer Center and I look forward to a productive interaction with all our stakeholders. Thank you.

Taofeek Owonikoko, MD, PhD
Division Chief, Hematology and Oncology

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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