UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS

BY DISEASE TYPE

October 2017

- Leukemia
- Lymphoma - Hodgkin
- Lymphoma - Non-Hodgkin
- Multiple Myeloma
- Myelodysplastic Syndrome (MDS)
- Hematologic / Bone Marrow Diseases
- Stem Cell Transplant
- Brain and Nervous System
- Breast
- Gastrointestinal
- Genitourinary
- Gynecological
- Melanoma
- Thoracic/Head and Neck
- Pediatric Oncology

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UFHealth CANCER CENTER

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Acute lymphoblastic leukemia (ALL)			
Newly Diagnosed			
18424-269 A Phase 2 Study of the JAK1/JAK2 Inhibitor Ruxolitinib With Chemotherapy in Children With De Novo High-Risk CRLF2-Rearranged and/or JAK Pathway-Mutant Acute Lymphoblastic Leukemia	http://clinicaltrials.gov/ct2/show/NCT02723994 To evaluate intial safety and tolerability and to define the recommended Part 2 dose of ruxolitnub in combination with multi-agent chemotherapy in children and adolescents or young adults wiht de novo high-risk Philadelphia Chromosome-like (ph-like) cytokine receptor-like factor 2 rearranged and/or Janus kinase pathway-mutant B-cell ALL.	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu
<opening soon> AALL15P1 A Groupwide Pilot Study to Test the Tolerability and Biologic Activity of the Addition of Azacitidine (NSC# 102816) to Chemotherapy in Infants With Acute Lymphoblastic Leukemia (ALL) and KMT2A(MLL) Gene Rearrangement	http://clinicaltrials.gov/ct2/show/NCT02828358 1. Incidence of adverse events of azacitidine and combination chemotherapy, graded according to Common Terminology Criteria for Adverse Events 4.0 2. Biologic activity, defined as global DNA methylation change in PBMCs 3. Calculate the mean long interspersed nucleotide element-1 (LINE-1) methylation for all patients before and after azacitidine and perform paired t-test analysis to determine if there is significant demethylation in the study population for the tested dose level.	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu
AALL1231 A Phase III Randomized Trial Investigating Bortezomib (NSC# 681239; IND# 58443) on a Modified Augmented BFM (ABFM) Backbone in Newly Diagnosed T- Lymphoblastic Leukemia (T-ALL) and T-Lymphoblastic Lymphoma (T-LLy)	http://clinicaltrials.gov/ct2/show/NCT02112916 To compare EFS in patients with newly diagnosed T-ALL and T-LLy who are randomized to a modified ABFM backbone versus bortezomib plus the modified ABFM backbone.	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu

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ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Acute lymphoblastic leukemia (ALL)			
Newly Diagnosed			
AALL0932 Treatment of Patients with Newly Diagnosed Standard Risk B - Lymphoblastic Leukemia or Localized B-Lineage Lymphoblastic Lymphoma (B-LLY)	http://clinicaltrials.gov/ct2/show/NCT01190930 This partially randomized phase III clinical trial is studying different combinations of risk-adapted chemotherapy regimens and their side effects and comparing how well they work in treating younger patients with newly diagnosed standard-risk acute lymphoblastic leukemia. Drugs used in chemotherapy work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Giving more than one drug (combination chemotherapy), giving the drugs in different doses, and giving the drugs in different combinations may kill more cancer cells.	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu
Supportive Care			
UF-BMT-LDND-101 A Phase III, Randomized, Clinical Trial Comparing Two Diets in Patients undergoing Hematopoietic Stem Cell Transplant (HSCT) or Remission Induction Chemotherapy for Acute Leukemia and Myelodysplastic Syndrome	http://clinicaltrials.gov/ct2/show/NCT03016130 To determine if the incidence of major infections in patients undergoing HSCT or receiving induction chemotherapy for acute leukemia with prolonged neutropenia (>= 7 days) who are receiving Diet A (LD) is non-inferior to patients receiving Diet B (ND).	,	Zachary Hudson 352-273-5263 zachary.hudson@medicine.ufl.edu
<opening soon> MDA 2013-0039 A Phase 3, Multi-Center, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Mino-Lok Therapy (MLT) in Combination with Systemic Antibiotics in the Treatment of Catheter-Related or Central Line-Associated Bloodstream Infection	http://clinicaltrials.gov/ct2/show/NCT02901717 This is a Phase 3, multi-center, randomized, double-blind study to determine the efficacy and safety of MLT, a novel antibiotic lock therapy that combines minocycline with edetate disodium in 25% ethanol solution.	,	Denise Praither 352-265-0680 Ext. 87669 dpraithe@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Transplant			
1101 A Multi-Center, Phase III, Randomized Trial of Reduced Intensity (RIC) Conditioning and Transplantation of Double Unrelated Umbilical Cord Blood (dUCB) versus HLA-Haploidentical Related Bone Marrow (haplo-BM) for Patients with Hematologic Malignancies	http://clinicaltrials.gov/ct2/show/NCT01597778 Hematopoietic cell transplants (HCT) are one treatment option for people with leukemia or lymphoma. Family members, unrelated donors or banked umbilical cord blood units with similar tissue type can be used for HCT. This study will compare the effectiveness of two new types of bone marrow transplants in people with leukemia or lymphoma: one that uses bone marrow donated from family members with only partially matched bone marrow; and, one that uses two partially matched cord blood units.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Acute myeloid leukemia (AML)			
CR1 or CR2			
<opening soon> 2215-CL-0304 A Multi-center, Randomized, Double-blind, Placebo-controlled Phase III Trial of the FLT3 Inhibitor Gilteritinib Administered as Maintenance Therapy Following Allogeneic Transplant for Patients with FLT3/ITD AML	http://clinicaltrials.gov/ct2/show/NCT02997202 The purpose of this study is to compare relapse-free survival between participants with FLT3/ITD AML in first morphologic complete remission (CR1) who undergo hematopoietic stem cell transplant (HCT) and are randomized to receive gilteritinib or placebo beginning after the time of engraftment for a two year period.	,	Alina Thompson a.thompson@ufl.edu
2215-CL-0302 A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of the FLT3 Inhibitor Gilteritinib (ASP2215) Administered as Maintenance Therapy Following Induction/Consolidation Therapy for Subjects with FLT3/ITD AML in First Complete Remission	http://clinicaltrials.gov/ct2/show/NCT02927262 To compare relapse free survival between subjects with FLT3 AML in first complete remission without transplant after completion of induction/consolidation chemotherapy.	,	Alina Thompson a.thompson@ufl.edu
Correlative			
BEATAML Beat AML: Personalized Medicine for Acute Myeloid Leukemia Based on Functional Genomics	http://clinicaltrials.gov/ct2/show/NCT02927106 The purpose of this study is to profile AML cancer cell molecular diagnostics and patient pharmacogenetics to simulate cancer cell function and screen for FDA approved drugs with anti-neoplastic activity and predict adverse events to prescribed treatments.	,	Barry Sawicki 352-273-9148 bswcki@ufl.edu
iCare iCare for Cancer Patients	http://clinicaltrials.gov/ct2/show/NCT02435550 The purpose of this study is to profile cancer cell molecular diagnostics and patient pharmacogenetics to simulate cancer cell function and screen for FDA approved drugs with anti-neoplastic activity and predict adverse events to prescribed treatments.	,	Barry Sawicki 352-273-9148 bswcki@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Acute myeloid leukemia (AML)			
Newly Diagnosed			
AC220-A-U302 A Phase 3, Double-Blind, Placebo-Controlled Study of Quizartinib (AC220) Administered in Combination with Induction and Consolidation Chemotherapy, and Administered as Maintenance Therapy in Subjects 18 to 75 Years Old with Newly Diagnosed FLT3-ITD (+) Acute Myeloid Leukemia	http://clinicaltrials.gov/ct2/show/NCT02668653 This is a phase 3, randomized, double-blind, placebo-control global study. The purpose of this study is to compare the effect of quizartinib versus placebo (administered with standard induction and consolidation chemotherapy, then administered as maintenance therapy for up to 12 cycles) on event-free survival in subjects with FLT3-ITD positive AML.	,	Alina Thompson a.thompson@ufl.edu
AAML1531 Risk-stratified Therapy for Acute Myeloid Leukemia in Down Syndrome	http://clinicaltrials.gov/ct2/show/NCT02521493 1. To determine the 2-year event-free-survival (EFS) for children with standard risk DS AML (MRD-negative after one cycle of induction therapy) after elimination of HD Ara-C from the treatment regimen. 2. To determine the 2-year EFS for children with high risk DS AML (MRD-positive after one cycle of induction therapy) after intensification of treatment equivalent to that used for high risk AML in children without DS	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Newly Diagnosed - Elderly			
2215-CL-0201 A Phase 2/3 Multicenter, Open-label, 3-arm, 2-stage Randomized Study of ASP2215 (Gliteritinib), Combination of ASP2215 Plus Azacitidine and Azacitidine Alone in the Treatment of Newly Diagnosed Acute Myeloid Leukemia with FLT3 Mutation in Patients Not Eligible for Intensive Induction Chemotherapy	http://clinicaltrials.gov/ct2/show/NCT02752035 The primary objective is to determine the efficacy superiority of ASP2215 and/or ASP2215 plus azacitidine versus azacitidine as measured by overall survival.	,	Alina Thompson a.thompson@ufl.edu
AC220-A-U302 A Phase 3, Double-Blind, Placebo-Controlled Study of Quizartinib (AC220) Administered in Combination with Induction and Consolidation Chemotherapy, and Administered as Maintenance Therapy in Subjects 18 to 75 Years Old with Newly Diagnosed FLT3-ITD (+) Acute Myeloid Leukemia	http://clinicaltrials.gov/ct2/show/NCT02668653 This is a phase 3, randomized, double-blind, placebo-control global study. The purpose of this study is to compare the effect of quizartinib versus placebo (administered with standard induction and consolidation chemotherapy, then administered as maintenance therapy for up to 12 cycles) on event-free survival in subjects with FLT3-ITD positive AML.	,	Alina Thompson a.thompson@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Relapsed / Refractory			
UF-AML-CE-101 A Phase Ib/II Clinical Trial of Oral Ciprofloxacin and Etoposide in Subjects with Resistant Acute Myeloid Leukemia (AML)	http://clinicaltrials.gov/ct2/show/NCT02773732 Phase Ib: Establish the maximum tolerated dose (MTD) of oral ciprofloxacin when given in combination with a fixed dose of oral etoposide. Phase II: Determine the rate of complete remission following treatment with the MTD.	,	Christina Cline 352-273-6840 clcline@ufl.edu
<opening soon> AAML1421 A Phase 1/2 Study of CPX-351 (NSC# 775341) Alone Followed by Fludarabine, Cytarabine, and G-CSF (FLAG) for Children With Relapsed Acute Myeloid Leukemia (AML)	http://clinicaltrials.gov/ct2/show/NCT02642965 1. To determine a recommended phase 2 dose (RP2D) and the toxicities associated with CPX-351 in pediatric and young adult patients with relapsed/refractory acute myeloid leukemia (AML). The phase 1 portion of the study has been completed as of 12/12/2016 and dose level #1 (135 Units/m2/dose) was found to be the recommended phase 2 dose. II. To estimate the response rate (complete remission [CR] plus complete remission with partial platelet recovery [CRp]) after CPX-351 (cycle 1) followed by fludarabine phosphate, cytarabine, and filgrastim (FLAG) (cycle 2) in children with AML in first relapse.	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu
2215-CL-0301 A Phase 3 Open-label, Multicenter, Randomized Study of ASP2215 versus Salvage Chemotherapy in Patients with Relapsed or Refractory Acute Myeloid Leukemia (AML) with FLT3 Mutation	http://clinicaltrials.gov/ct2/show/NCT02421939 The purpose of this study is to determine the clinical benefit of ASP2215 therapy in patients with FMS-like tyrosine kinase (FLT3) mutated acute myeloid leukemia (AML) who are refractory to or have relapsed after first-line AML therapy as shown with overall survival compared to salvage chemotherapy. This study will also determine the overall efficacy in event-free survival (EFS) and complete remission (CR) rate of ASP2215 compared to salvage chemotherapy.	,	Alina Thompson a.thompson@ufl.edu

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Study Title	Study Summary	Study Physician	Study Contact
Supportive Care			
UF-BMT-LDND-101 A Phase III, Randomized, Clinical Trial Comparing Two Diets in Patients undergoing Hematopoietic Stem Cell Transplant (HSCT) or Remission Induction Chemotherapy for Acute Leukemia and Myelodysplastic Syndrome	http://clinicaltrials.gov/ct2/show/NCT03016130 To determine if the incidence of major infections in patients undergoing HSCT or receiving induction chemotherapy for acute leukemia with prolonged neutropenia (>= 7 days) who are receiving Diet A (LD) is non-inferior to patients receiving Diet B (ND).	,	Zachary Hudson 352-273-5263 zachary.hudson@medicine.ufl.edu
<opening soon> MDA 2013-0039 A Phase 3, Multi-Center, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Mino-Lok Therapy (MLT) in Combination with Systemic Antibiotics in the Treatment of Catheter-Related or Central Line-Associated Bloodstream Infection	http://clinicaltrials.gov/ct2/show/NCT02901717 This is a Phase 3, multi-center, randomized, double-blind study to determine the efficacy and safety of MLT, a novel antibiotic lock therapy that combines minocycline with edetate disodium in 25% ethanol solution.	,	Denise Praither 352-265-0680 Ext. 87669 dpraithe@ufl.edu

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Study Title	Study Summary	Study Physician	Study Contact
Transplant			
<opening soon> 2215-CL-0304 A Multi-center, Randomized, Double-blind, Placebo-controlled Phase III Trial of the FLT3 Inhibitor Gilteritinib Administered as Maintenance Therapy Following Allogeneic Transplant for Patients with FLT3/ITD AML	http://clinicaltrials.gov/ct2/show/NCT02997202 The purpose of this study is to compare relapse-free survival between participants with FLT3/ITD AML in first morphologic complete remission (CR1) who undergo hematopoietic stem cell transplant (HCT) and are randomized to receive gilteritinib or placebo beginning after the time of engraftment for a two year period.	,	Alina Thompson a.thompson@ufl.edu
UF-BMT-MRD-101 A phase I clinical trial to evaluate the maximally tolerated dose (MTD), dose limiting toxicities (DLTs) and safety profiles of increasing doses of lenalidomide after allo-HCT in AML and MDS subjects with minimal residual disease (MRD) detected by the CD34+ mixed chimerism analysis	http://clinicaltrials.gov/ct2/show/NCT02370888 The purpose of this study is to determine the maximum tolerated dose, dose limiting side effects, and the safety of increasing doses of lenalidomide in patients with AML and MDS who have a small amount of detectable disease after allogeneic stem cell transplant.	,	Christina Cline 352-273-6840 clcline@ufl.edu
1101 A Multi-Center, Phase III, Randomized Trial of Reduced Intensity (RIC) Conditioning and Transplantation of Double Unrelated Umbilical Cord Blood (dUCB) versus HLA-Haploidentical Related Bone Marrow (haplo-BM) for Patients with Hematologic Malignancies	http://clinicaltrials.gov/ct2/show/NCT01597778 Hematopoietic cell transplants (HCT) are one treatment option for people with leukemia or lymphoma. Family members, unrelated donors or banked umbilical cord blood units with similar tissue type can be used for HCT. This study will compare the effectiveness of two new types of bone marrow transplants in people with leukemia or lymphoma: one that uses bone marrow donated from family members with only partially matched bone marrow; and, one that uses two partially matched cord blood units.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Chronic lymphocytic leukemia (CLL)			
Relapsed / Refractory			
MEDI4736-NHL-001; Celgene A Phase 1/2, open label, multicentre study to assess the safety and tolerability of durvalumab (anti-PD-L1 antibody) as monotherapy and in combination therapy in subjects with lymphoma or chronic lymphocytic leukemia	http://clinicaltrials.gov/ct2/show/NCT02733042 This open-label, multicenter, global study is designed to determine the recommended phase 2 dose, safety, efficacy, and pharmacokinetics/pharmacodynamics of durvalumab in subjects with certain lymphoma subtypes or CLL. Globally, 253 subjects may be enrolled into 4 treatment arms, including durvalumab monotherapy; durvalumab in combination with lenalidomide± rituximab; ibrutinib; or rituximab ± bendamustine. The study will have 3 parts: dose finding, dose confirmation, and dose expansion. Subjects receiving monotherapy may receive combination therapy or involved-field radiation to a single nodal site at time of progressive disease.	,	Ashton Monismith amonismith@ufl.edu
<opening soon> MK-3475-155; Phase Ib Trial of Pembrolizumab (MK-3475) in Combination with Dinaciclib (MK-7965) in Subjects with Hematologic Malignancies (KEYNOTE-155)	http://clinicaltrials.gov/ct2/show/NCT02684617 (1) Objective: In both the Dose Evaluation and Signal Detection phases, evaluate the safety and tolerability of the treatment combination. (2) Objective: Within each disease type of the Signal Detection phase, evaluate objective response rate (ORR) according to investigator assessment using the disease specific criteria.	,	Ashton Monismith amonismith@ufl.edu

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ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Relapsed / Refractory			
MEDI4736-NHL-001; Celgene A Phase 1/2, open label, multicentre study to assess the safety and tolerability of durvalumab (anti-PD-L1 antibody) as monotherapy and in combination therapy in subjects with lymphoma or chronic lymphocytic leukemia	http://clinicaltrials.gov/ct2/show/NCT02733042 This open-label, multicenter, global study is designed to determine the recommended phase 2 dose, safety, efficacy, and pharmacokinetics/pharmacodynamics of durvalumab in subjects with certain lymphoma subtypes or CLL. Globally, 253 subjects may be enrolled into 4 treatment arms, including durvalumab monotherapy; durvalumab in combination with lenalidomide± rituximab; ibrutinib; or rituximab ± bendamustine. The study will have 3 parts: dose finding, dose confirmation, and dose expansion. Subjects receiving monotherapy may receive combination therapy or involved-field radiation to a single nodal site at time of progressive disease.	,	Ashton Monismith amonismith@ufl.edu
Supportive Care			
39039039 STM4001 Efficacy and Safety of Rivaroxaban Prophylaxis Compared with Placebo in Ambulatory Cancer Patients Initiating Systemic Cancer Therapy and at High Risk for Venous Thromboembolism	http://clinicaltrials.gov/ct2/show/NCT02555878 The primary efficacy objective is to demonstrate that rivaroxaban is superior to placebo for reducing the risk of the primary composite outcome as defined by objectively confirmed symptomatic lower extremity proximal DVT, asymptomatic lower extremity proximal DVT, symptomatic upper extremity DVT, symptomatic non-fatal PE, incidental PE, and VTE-related death in ambulatory adult subjects with various cancer types receiving systemic cancer therapy who are at high risk of developing a VTE.	,	Anita Rajasekhar 352-273-8699 anita.rajasekhar@medicine.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Burkitt's			
Transplant			
1101 A Multi-Center, Phase III, Randomized Trial of Reduced Intensity (RIC) Conditioning and Transplantation of Double Unrelated Umbilical Cord Blood (dUCB) versus HLA-Haploidentical Related Bone Marrow (haplo-BM) for Patients with Hematologic Malignancies	http://clinicaltrials.gov/ct2/show/NCT01597778 Hematopoietic cell transplants (HCT) are one treatment option for people with leukemia or lymphoma. Family members, unrelated donors or banked umbilical cord blood units with similar tissue type can be used for HCT. This study will compare the effectiveness of two new types of bone marrow transplants in people with leukemia or lymphoma: one that uses bone marrow donated from family members with only partially matched bone marrow; and, one that uses two partially matched cord blood units.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Diffuse Large B-cell			
Relapsed / Refractory			
SGN19A-003 A randomized, open-label phase 2 study of denintuzumab mafodotin (SGN-CD19A) plus rituximab, ifosfamide, carboplatin, and etoposide (19A+RICE) chemotherapy vs. RICE in the treatment of patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are candidates for autologous stem cell transplant	http://clinicaltrials.gov/ct2/show/NCT02592876 The primary objective is to compare the complete remission (CR) rates in patients with relapsed/refractory DLBCL who are candidates for autologous stem cell transplant (ASCT) treated with denintuzumab mafodotin plus RICE (19A+RICE) versus RICE.	,	
PCYC-1123-CA A Multicenter Open-Label Phase 1 b/2 Study of the Brutons Tyrosine Kinase (BTK) Inhibitor, Ibrutinib, in Combination with Lenalidomide and Rituximab in Subjects with Relapsed or Refractory Diffuse Large B-Cell Lymphoma	http://clinicaltrials.gov/ct2/show/NCT02077166 This Phase 1 b/2 study is designed to assess the safety and efficacy of ibrutinib in combination with lenalidomide and rituximab in subjects with relapsed/refractory Diffuse Large B-Cell Lymphoma (DLBCL) not eligible for transplant.	,	Ashton Monismith amonismith@ufl.edu
<opening soon> MK-3475-155; Phase Ib Trial of Pembrolizumab (MK-3475) in Combination with Dinaciclib (MK-7965) in Subjects with Hematologic Malignancies (KEYNOTE-155)	http://clinicaltrials.gov/ct2/show/NCT02684617 (1) Objective: In both the Dose Evaluation and Signal Detection phases, evaluate the safety and tolerability of the treatment combination. (2) Objective: Within each disease type of the Signal Detection phase, evaluate objective response rate (ORR) according to investigator assessment using the disease specific criteria.	,	Ashton Monismith amonismith@ufl.edu
IGN002-101; Valor A Phase 1, Open-Label, Dose-Escalation Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Multiple Intravenous Doses of IGN002 Administered Weekly to Subjects	http://clinicaltrials.gov/ct2/show/NCT02519270 To evaluate the safety and tolerability of multiple doses of IGN002 administered weekly as an IV infusion to subjects with refractory NHL. To determine the maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D)	,	Ashton Monismith amonismith@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Diffuse Large B-cell			
Relapsed / Refractory			
with Refractory Non-Hodgkin Lymphoma (NHL)	of IGN002 administered weekly as an IV infusion to subjects with refractory NHL (Dose-Escalation Stage)		
MEDI4736-NHL-001; Celgene A Phase 1/2, open label, multicentre study to assess the safety and tolerability of durvalumab (anti-PD-L1 antibody) as monotherapy and in combination therapy in subjects with lymphoma or chronic lymphocytic leukemia	http://clinicaltrials.gov/ct2/show/NCT02733042 This open-label, multicenter, global study is designed to determine the recommended phase 2 dose, safety, efficacy, and pharmacokinetics/pharmacodynamics of durvalumab in subjects with certain lymphoma subtypes or CLL. Globally, 253 subjects may be enrolled into 4 treatment arms, including durvalumab monotherapy; durvalumab in combination with lenalidomide± rituximab; ibrutinib; or rituximab ± bendamustine. The study will have 3 parts: dose finding, dose confirmation, and dose expansion. Subjects receiving monotherapy may receive combination therapy or involved-field radiation to a single nodal site at time of progressive disease.	,	Ashton Monismith amonismith@ufl.edu
A051301 A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation Versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma of the Activated B-Cell Subtype	http://clinicaltrials.gov/ct2/show/NCT02443077 This randomized phase III trial studies ibrutinib to see how well it works compared to placebo when given before and after stem cell transplant in treating patients with diffuse large B-cell lymphoma that has returned after a period of improvement (relapsed) or does not respond to treatment (refractory). Before transplant, stem cells are taken from patients and stored. Patients then receive high doses of chemotherapy to kill cancer cells and make room for healthy cells. After treatment, the stem cells are then returned to the patient to replace the blood-forming cells that were destroyed by the chemotherapy. Ibrutinib is a drug that may stop the growth of cancer cells by blocking a protein that is needed for cell growth. It is not yet known whether adding ibrutinib to chemotherapy before and after stem cell transplant may help the transplant work better in patients with relapsed or refractory diffuse large B-cell lymphoma.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu

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ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Diffuse Large B-cell			
Transplant			
A051301 A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation Versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma of the Activated B-Cell Subtype	http://clinicaltrials.gov/ct2/show/NCT02443077 This randomized phase III trial studies ibrutinib to see how well it works compared to placebo when given before and after stem cell transplant in treating patients with diffuse large B-cell lymphoma that has returned after a period of improvement (relapsed) or does not respond to treatment (refractory). Before transplant, stem cells are taken from patients and stored. Patients then receive high doses of chemotherapy to kill cancer cells and make room for healthy cells. After treatment, the stem cells are then returned to the patient to replace the blood-forming cells that were destroyed by the chemotherapy. Ibrutinib is a drug that may stop the growth of cancer cells by blocking a protein that is needed for cell growth. It is not yet known whether adding ibrutinib to chemotherapy before and after stem cell transplant may help the transplant work better in patients with relapsed or refractory diffuse large B-cell lymphoma.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu
1101 A Multi-Center, Phase III, Randomized Trial of Reduced Intensity (RIC) Conditioning and Transplantation of Double Unrelated Umbilical Cord Blood (dUCB) versus HLA-Haploidentical Related Bone Marrow (haplo-BM) for Patients with Hematologic Malignancies	http://clinicaltrials.gov/ct2/show/NCT01597778 Hematopoietic cell transplants (HCT) are one treatment option for people with leukemia or lymphoma. Family members, unrelated donors or banked umbilical cord blood units with similar tissue type can be used for HCT. This study will compare the effectiveness of two new types of bone marrow transplants in people with leukemia or lymphoma: one that uses bone marrow donated from family members with only partially matched bone marrow; and, one that uses two partially matched cord blood units.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Follicular			
Relapsed / Refractory			
MEDI4736-NHL-001; Celgene A Phase 1/2, open label, multicentre study to assess the safety and tolerability of durvalumab (anti-PD-L1 antibody) as monotherapy and in combination therapy in subjects with lymphoma or chronic lymphocytic leukemia	http://clinicaltrials.gov/ct2/show/NCT02733042 This open-label, multicenter, global study is designed to determine the recommended phase 2 dose, safety, efficacy, and pharmacokinetics/pharmacodynamics of durvalumab in subjects with certain lymphoma subtypes or CLL. Globally, 253 subjects may be enrolled into 4 treatment arms, including durvalumab monotherapy; durvalumab in combination with lenalidomide± rituximab; ibrutinib; or rituximab ± bendamustine. The study will have 3 parts: dose finding, dose confirmation, and dose expansion. Subjects receiving monotherapy may receive combination therapy or involved-field radiation to a single nodal site at time of progressive disease.	,	Ashton Monismith amonismith@ufl.edu
IGN002-101; Valor A Phase 1, Open-Label, Dose-Escalation Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Multiple Intravenous Doses of IGN002 Administered Weekly to Subjects with Refractory Non-Hodgkin Lymphoma (NHL)	http://clinicaltrials.gov/ct2/show/NCT02519270 To evaluate the safety and tolerability of multiple doses of IGN002 administered weekly as an IV infusion to subjects with refractory NHL. To determine the maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D) of IGN002 administered weekly as an IV infusion to subjects with refractory NHL (Dose-Escalation Stage)	,	Ashton Monismith amonismith@ufl.edu
<opening soon> S1608 RANDOMIZED PHASE II TRIAL IN EARLY RELAPSING OR REFRACTORY FOLLICULAR LYMPHOMA	To compare the complete response rate at 6 cycles after randomization as defined by centrally read PET/CT (integral biomarker) of 2 targeted therapeutic regimens (obinutuzumab + TGR-1202 or obinutuzumab + lenalidomide) with obinutuzumab + CHOP in patients with early relapsing or refractory follicular lymphoma.	,	Ashton Monismith amonismith@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Mantle Cell			
Relapsed / Refractory			
MEDI4736-NHL-001; Celgene A Phase 1/2, open label, multicentre study to assess the safety and tolerability of durvalumab (anti-PD-L1 antibody) as monotherapy and in combination therapy in subjects with lymphoma or chronic lymphocytic leukemia	http://clinicaltrials.gov/ct2/show/NCT02733042 This open-label, multicenter, global study is designed to determine the recommended phase 2 dose, safety, efficacy, and pharmacokinetics/pharmacodynamics of durvalumab in subjects with certain lymphoma subtypes or CLL. Globally, 253 subjects may be enrolled into 4 treatment arms, including durvalumab monotherapy; durvalumab in combination with lenalidomide± rituximab; ibrutinib; or rituximab ± bendamustine. The study will have 3 parts: dose finding, dose confirmation, and dose expansion. Subjects receiving monotherapy may receive combination therapy or involved-field radiation to a single nodal site at time of progressive disease.	,	Ashton Monismith amonismith@ufl.edu
Supportive Care			
39039039 STM4001 Efficacy and Safety of Rivaroxaban Prophylaxis Compared with Placebo in Ambulatory Cancer Patients Initiating Systemic Cancer Therapy and at High Risk for Venous Thromboembolism	http://clinicaltrials.gov/ct2/show/NCT02555878 The primary efficacy objective is to demonstrate that rivaroxaban is superior to placebo for reducing the risk of the primary composite outcome as defined by objectively confirmed symptomatic lower extremity proximal DVT, asymptomatic lower extremity proximal DVT, symptomatic upper extremity DVT, symptomatic non-fatal PE, incidental PE, and VTE-related death in ambulatory adult subjects with various cancer types receiving systemic cancer therapy who are at high risk of developing a VTE.	,	Anita Rajasekhar 352-273-8699 anita.rajasekhar@medicine.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Relapsed / Refractory			
<opening soon> OP-103 OP-103 A Randomized, Controlled, Open-Label, Phase 3 Study of Melflufen/Dexamethasone Compared with Pomalidomide/Dexamethasone for Patients with Relapsed Refractory Multiple Myeloma who are Refractory to Lenalidomide (OP-103)	http://clinicaltrials.gov/ct2/show/NCT03151811 This is a randomized, controlled, open-label, Phase 3 multicenter study which will enroll patients with RRMM following 2-4 lines of prior therapy and who are refractory to lenalidomide in the last line of therapy as demonstrated by disease progression on or within 60 days of completion of the last dose of lenalidomide. Patients will receive either melflufen+dex or pomalidomide+dex.	,	Diane Richardson 352-273-6844 drichardson@ufl.edu
<opening soon> C16029 A Phase 2/3, Randomized, Open-Label Study Comparing Oral Ixazomib/Dexamethasone and Oral Pomalidomide/Dexamethasone in Relapsed and/or Refractory Multiple Myeloma	http://clinicaltrials.gov/ct2/show/NCT03170882 The purpose of this study is to compare the effect of ixazomib+dexamethasone (ixa+dex) versus pomalidomide+dexamethasone (pom+dex) on progression-free survival (PFS) in participants with relapsed and/or refractory multiple myeloma (RRMM) who have received at least 2 prior lines of therapy, including lenalidomide and a proteasome inhibitor, and are refractory to lenalidomide but not refractory to proteasome inhibitors.	,	Diane Richardson 352-273-6844 drichardson@ufl.edu
CLBH589D2222 A Multicenter, Randomized, Open-Label Phase 2 Study Evaluating the Safety and Efficacy of Three Different Regimens of Oral Panobinostat in Combination with Subcutaneous Bortezomib and Oral Dexamethasone in Patients with Relapsed or Relapsed/Refractory Multiple Myeloma Who Have Been Previously Exposed to Immunomodulatory Agents	http://clinicaltrials.gov/ct2/show/NCT02654990 The purpose of this study is to investigate the safety and efficacy of three different regimens of PAN (20 mg TIW, 20 mg BIW, and 10 mg TIW) in combination with s.c. BTZ and Dex and to provide exposure, safety and efficacy data to identify the optimal regimen of PAN in a randomized, 3-arm parallel design. This study will also assess the impact of administering s.c. BTZ (in combination with PAN and Dex) twice weekly for 4 cycles, and then weekly starting from Cycle 5 until disease progression in patients ≤ 75 years of age. Patients > 75 years of age will receive for the entire treatment period s.c. BTZ weekly (in combination with PAN and Dex) until disease progression.	,	Diane Richardson 352-273-6844 drichardson@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Relapsed / Refractory			
OP-106 A Single Arm, Open-Label, Phase 2 Study of Melflufen in Combination with Dexamethasone in Patients with Relapsed Refractory Multiple Myeloma who are Refractory to Pomalidomide and/or Daratumumab	http://clinicaltrials.gov/ct2/show/NCT02963493 To assess overall response rate (ORR), as best response in patients treated with Melflufen.	,	Diane Richardson 352-273-6844 drichardson@ufl.edu
<opening soon> KCP-330-012 A Phase 2b, Open-Label, Single-Arm Study of Selinexor (KPT-330) Plus Low-Dose Dexamethasone (Sd) in Patients with Multiple Myeloma Previously Treated with Lenalidomide, Pomalidomide, Bortezomib, Carfilzomib, and Daratumumab, and Refractory to Prior Treatment with Glucocorticoids, an Immunomodulatory Agent, a Proteasome Inhibitor and the anti-CD38 mAb Daratumumab	http://clinicaltrials.gov/ct2/show/NCT02336815 This is a Phase 2b, single-arm, open-label, multicenter study of selinexor 80 mg plus dexamethasone 20 mg (Sd) dosed twice weekly in four-week cycles, in patients with penta-refractory MM (Parts 1 and 2) or quad refractory MM (Part 1 only).	,	Diane Richardson 352-273-6844 drichardson@ufl.edu
<opening soon> MK-3475-155; Phase Ib Trial of Pembrolizumab (MK-3475) in Combination with Dinaciclib (MK-7965) in Subjects with Hematologic Malignancies (KEYNOTE-155)	http://clinicaltrials.gov/ct2/show/NCT02684617 (1) Objective: In both the Dose Evaluation and Signal Detection phases, evaluate the safety and tolerability of the treatment combination. (2) Objective: Within each disease type of the Signal Detection phase, evaluate objective response rate (ORR) according to investigator assessment using the disease specific criteria.	,	Ashton Monismith amonismith@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Supportive Care			
<opening soon> MDA 2013-0039 A Phase 3, Multi-Center, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Mino-Lok Therapy (MLT) in Combination with Systemic Antibiotics in the Treatment of Catheter-Related or Central Line-Associated Bloodstream Infection	http://clinicaltrials.gov/ct2/show/NCT02901717 This is a Phase 3, multi-center, randomized, double-blind study to determine the efficacy and safety of MLT, a novel antibiotic lock therapy that combines minocycline with edetate disodium in 25% ethanol solution.	,	Denise Praither 352-265-0680 Ext. 87669 dpraithe@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Correlative			
iCare iCare for Cancer Patients	http://clinicaltrials.gov/ct2/show/NCT02435550 The purpose of this study is to profile cancer cell molecular diagnostics and patient pharmacogenetics to simulate cancer cell function and screen for FDA approved drugs with anti-neoplastic activity and predict adverse events to prescribed treatments.	,	Barry Sawicki 352-273-9148 bswcki@ufl.edu
Intermediate-2 / High Risk			
1102 A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Intermediate-2 and High Risk Myelodysplastic Syndrome (BMT CTN #1102)	http://clinicaltrials.gov/ct2/show/NCT02016781 MDS is a clonal disorder of hematopoietic precursors and stem cells, which may evolve to a terminal phase resembling acute leukemia. A subject of clinical urgency for researchers, clinicians, patients, and health care underwriters such as Medicare, is the role of allogeneic hematopoietic cell transplantation (alloHCT) in the treatment of older patients with higher risk myelodysplastic syndromes (MDS). The use of reduced intensity conditioning (RIC) regimens has extended HCT to the care of older patients with acute myelogenous leukemia (AML) and lymphoma and a number of retrospective and phase II trials for patients with MDS now show the curative potential of RIC alloHCT in selected patients. This protocol is designed evaluate the relative benefits of RIC alloHCT compared to non-transplant therapies focusing on overall survival. This will be done by having patients biologically assigned to the alloHCT arm or the hypomethylating therapy/best supportive care arm and following them for survival at 3 years.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Relapsed / Refractory			
04-30 A Phase III, International, Randomized, Controlled Study of Rigosertib versus Physicians Choice of Treatment in Patients with Myelodysplastic Syndrome after Failure of a Hypomethylating Agent	http://clinicaltrials.gov/ct2/show/NCT02562443 The primary objective of this study is to compare the overall survival (OS) of patients receiving intravenous (IV) rigosertib to the OS of patients receiving the physician's choice of treatment (PC) in a population of patients with myelodysplastic syndrome (MDS) after failure of treatment with a hypomethylating agent (HMA), azacitidine (AZA) or decitabine (DEC).	,	Denise Praither 352-265-0680 Ext. 87669 dpraithe@ufl.edu
<opening soon> iCARE2 iCare 2: Personalized Genomic Mutation Informed Treatment of Patients with Myelodysplastic Syndromes		,	
Supportive Care			
UF-BMT-LDND-101 A Phase III, Randomized, Clinical Trial Comparing Two Diets in Patients undergoing Hematopoietic Stem Cell Transplant (HSCT) or Remission Induction Chemotherapy for Acute Leukemia and Myelodysplastic Syndrome	http://clinicaltrials.gov/ct2/show/NCT03016130 To determine if the incidence of major infections in patients undergoing HSCT or receiving induction chemotherapy for acute leukemia with prolonged neutropenia (>= 7 days) who are receiving Diet A (LD) is non-inferior to patients receiving Diet B (ND).	,	Zachary Hudson 352-273-5263 zachary.hudson@medicine.ufl.edu
<opening soon> MDA 2013-0039 A Phase 3, Multi-Center, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Mino-Lok Therapy (MLT) in Combination with Systemic Antibiotics in the Treatment of Catheter-Related or Central Line-Associated Bloodstream Infection	http://clinicaltrials.gov/ct2/show/NCT02901717 This is a Phase 3, multi-center, randomized, double-blind study to determine the efficacy and safety of MLT, a novel antibiotic lock therapy that combines minocycline with edetate disodium in 25% ethanol solution.	,	Denise Praither 352-265-0680 Ext. 87669 dpraithe@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Transplant			
1102 A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Intermediate-2 and High Risk Myelodysplastic Syndrome (BMT CTN #1102)	http://clinicaltrials.gov/ct2/show/NCT02016781 MDS is a clonal disorder of hematopoietic precursors and stem cells, which may evolve to a terminal phase resembling acute leukemia. A subject of clinical urgency for researchers, clinicians, patients, and health care underwriters such as Medicare, is the role of allogeneic hematopoietic cell transplantation (alloHCT) in the treatment of older patients with higher risk myelodysplastic syndromes (MDS). The use of reduced intensity conditioning (RIC) regimens has extended HCT to the care of older patients with acute myelogenous leukemia (AML) and lymphoma and a number of retrospective and phase II trials for patients with MDS now show the curative potential of RIC alloHCT in selected patients. This protocol is designed evaluate the relative benefits of RIC alloHCT compared to non-transplant therapies focusing on overall survival. This will be done by having patients biologically assigned to the alloHCT arm or the hypomethylating therapy/best supportive care arm and following them for survival at 3 years.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu
UF-BMT-MRD-101 A phase I clinical trial to evaluate the maximally tolerated dose (MTD), dose limiting toxicities (DLTs) and safety profiles of increasing doses of lenalidomide after allo-HCT in AML and MDS subjects with minimal residual disease (MRD) detected by the CD34+ mixed chimerism analysis	http://clinicaltrials.gov/ct2/show/NCT02370888 The purpose of this study is to determine the maximum tolerated dose, dose limiting side effects, and the safety of increasing doses of lenalidomide in patients with AML and MDS who have a small amount of detectable disease after allogeneic stem cell transplant.	,	Christina Cline 352-273-6840 clcline@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Correlative			
<opening soon> iCare3 Predicting Disease Relapse by Monitoring Circulating Cancer DNA After Chemotherapy in Patients with MDS and AML (iCare3)	http://clinicaltrials.gov/ct2/show/NCT03138395 Develop and optimize assays to track up to five myeloid mutations in hematological oncology patients using droplet digital PCR (ddPCR). Collect serial samples from AML and MDS patients to track their myeloid mutations through ctDNA to determine MRD or relapse free survival. Compare fingerstick and saliva specimen ctDNA MAF to peripheral blood and bone marrow MAF.	,	Leylah Drusbosky ldrusbosky@ufl.edu
Severe Aplastic Anemia			
<opening soon> BMT CTN 1502 Optimizing Cord Blood and Haploidentical Aplastic Anemia Transplantation (CHAMP)	http://clinicaltrials.gov/ct2/show/NCT02918292 This study is a prospective, simultaneous, parallel phase II study with one arm receiving unrelated cord blood transplantation and the other arm receiving haploidentical transplantation for Severe Aplastic Anemia (SAA) patients. The primary objective is to assess overall survival (OS) separately in the 2 arms at 1 year post-hematopoietic stem cell transplantation (HSCT).	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu

UF HEALTH CANCER CENTER ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
GVHD - Prevention			
Abatacept Combined with a Calcineurin Inhibitor and Methotrexate for Graft Versus Host Disease Prophylaxis	http://clinicaltrials.gov/ct2/show/NCT01743131 The investigators are doing this study to see if a new drug, abatacept, can be used together with a calcieneurin inhibitor (cyclosporine or tacrolimus) and methotrexate to provide better protection against Acute Graft versus Host Disease (aGvHD) without causing more infections.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu
15-MMUD A Multi-Center, Phase II Trial of HLA-Mismatched Unrelated Donor Bone Marrow Transplantation with Post-Transplantation Cyclophosphamide for Patients with Hematologic Malignancies	http://clinicaltrials.gov/ct2/show/NCT02793544 This is a multi-center, single arm Phase II study of hematopoietic cell transplantation (HCT) using human leukocyte antigen (HLA)-mismatched unrelated bone marrow transplantation donors and post-transplantation cyclophosphamide (PTCy), sirolimus and mycophenolate mofetil (MMF) for graft versus host disease (GVHD) prophylaxis in patients with hematologic malignancies.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu
CTN 1301 A Randomized, Multi-Center, Phase III Trial of Calcineurin Inhibitor-Free Interventions for Prevention of Graft-versus Host-Disease	http://clinicaltrials.gov/ct2/show/NCT02345850 The study is designed as a three arm randomized Phase III, multicenter trial comparing two calcineurin inhibitor (CNI)-free strategies for GVHD prophylaxis to standard calcineurin inhibitor tacrolimus and methotrexate (Tac/Mtx) in patients with acute leukemia or myelodysplasia undergoing myeloablative conditioning hematopoietic stem cell transplantation.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu

UF HEALTH CANCER CENTER ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
GVHD - Treatment			
Acute			
<opening soon> INCB 39110-301 A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Itacitinib or Placebo in Combination With Corticosteroids for the Treatment of First-Line Acute Graft-Versus-Host Disease	http://clinicaltrials.gov/ct2/show/NCT03139604 The purpose of this study is to evaluate itacitinib or placebo in combination with corticosteroids as first-line treatment of participants with Grade II to IV acute graft-versus-host disease (aGVHD).	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu
BMT CTN 1501 A Randomized, Phase II, Multicenter, Open Label, Study Evaluating Sirolimus and Prednisone in Patients with Refined Minnesota Standard Risk, Ann Arbor 1/2 Confirmed Acute Graft-Versus-Host Disease	http://clinicaltrials.gov/ct2/show/NCT02806947 The primary objective is to assess the rate of complete remission (CR)/partial remission (PR) on day 28 post-randomization in patients with standard-risk acute GVHD.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu
INCB 18424-271 A Single-Cohort, Phase 2 Study of Ruxolitinib in Combination With Corticosteroids for the Treatment of Steroid-Refractory Acute Graft-Versus-Host Disease	http://clinicaltrials.gov/ct2/show/NCT02953678 The purpose of this study is to assess the efficacy of ruxolitinib in combination with corticosteroids in subjects with Grades II to IV steroid-refractory acute graft-versus-host disease (GVHD).	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Chronic			
GS-US-406-1840 A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Tolerability of Entospletinib, a Selective SYK Inhibitor, in Combination with Systemic Corticosteroids as First-Line Therapy in Subjects with Chronic Graft Versus Host Disease (cGVHD)	http://clinicaltrials.gov/ct2/show/NCT02701634 This study will evaluate the effect of entospletinib on the best overall response rate in adults with chronic graft versus host disease (cGVHD) who are currently receiving systemic corticosteroids as first-line therapy for cGVHD.	,	Denise Praither 352-265-0680 Ext. 87669 dpraithe@ufl.edu
<opening soon> 18424-365 A phase III randomized open-label multi-center study of ruxolitinib vs. best available therapy in patients with corticosteroid-refractory chronic graft vs. host disease after allogenic stem cell transplantation	http://clinicaltrials.gov/ct2/show/NCT03112603 The purpose of this study is to assess the efficacy of ruxolitinib against best available therapy in participants with steroid-refractory chronic graft-versus-host disease (SR cGvHD).	,	Zachary Hudson 352-273-5263 zachary.hudson@medicine.ufl.edu
Infectious Disease			
<opening soon> SUP1601 Pathogen Identification in Pediatric Hematopoietic Stem Cell Transplant Patients with Suspected Lower Respiratory Tract Infection	http://clinicaltrials.gov/ct2/show/NCT02926612 Evaluate and quantify the utility of NGS in improving the diagnosis of LRTI in pediatric HCT patients.	,	

UF HEALTH CANCER CENTER ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Other Supportive Care			
UF-BMT-LDND-101 A Phase III, Randomized, Clinical Trial Comparing Two Diets in Patients undergoing Hematopoietic Stem Cell Transplant (HSCT) or Remission Induction Chemotherapy for Acute Leukemia and Myelodysplastic Syndrome	http://clinicaltrials.gov/ct2/show/NCT03016130 To determine if the incidence of major infections in patients undergoing HSCT or receiving induction chemotherapy for acute leukemia with prolonged neutropenia (>= 7 days) who are receiving Diet A (LD) is non-inferior to patients receiving Diet B (ND).	,	Zachary Hudson 352-273-5263 zachary.hudson@medicine.ufl.edu
UF-BMT-CRYO-101 Randomized controlled, open-label study on the use of cryotherapy in the prevention of chemotherapy-induced mucositis in stem cell transplant patients	http://clinicaltrials.gov/ct2/show/NCT02326675 The purpose of this study are to assess the tolerability of cryotherapy given during chemotherapy administration and to determine the efficacy of cryotherapy in reducing etoposide-induced mucositis.	,	Zachary Hudson 352-273-5263 zachary.hudson@medicine.ufl.edu
<opening soon> MDA 2013-0039 A Phase 3, Multi-Center, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Mino-Lok Therapy (MLT) in Combination with Systemic Antibiotics in the Treatment of Catheter-Related or Central Line-Associated Bloodstream Infection	http://clinicaltrials.gov/ct2/show/NCT02901717 This is a Phase 3, multi-center, randomized, double-blind study to determine the efficacy and safety of MLT, a novel antibiotic lock therapy that combines minocycline with edetate disodium in 25% ethanol solution.	,	Denise Praither 352-265-0680 Ext. 87669 dpraithe@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Correlative			
Dendritic Cell (DC) and Tumor-Specific Cytotoxic T Cell (CTL) Generation Protocol from Healthy Volunteers and Patients with Malignant Brain Tumors	The purpose of this project is to perform a series of studies aimed at developing a dendritic cell-based vaccine for patients with malignant brain tumors. In preparation for a Phase I clinical trial, we wish to validate our ability: (1) To generate and phenotypically and functionally characterize large numbers of DCs generated from patients with malignant brain tumors; (2) To optimize the efficiency of transfection of DCs with tumor RNA, and; (3) To generate cytotoxic T lymphocyte reactivity to the tumor-specific antigens with these DCs.	,	Nina McGrew 352-273-5519 nina.mcgrew@neurosurgery.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
High-Grade Glioma			
Newly Diagnosed			
<opening soon> 2-THE-TOP Phase 2, Single Arm, Historically Controlled Study Testing The Safety and Efficacy Adjuvant Temozolomide Plus Optune Plus Pembrolizumab in Patients with Newly Diagnosed Glioblastoma (2-THE-TOP)	Primary To determine whether the addition of pembrolizumab to the combination of TTFields and adjuvant temozolomide (Triple Combination) increases progression-free survival in patients with newly diagnosed GBM as compared to historical control data in EF-14 study. Secondary To determine toxicity and tolerability of the triple combination in newly diagnosed GBM patients. To determine OS and RR of the triple combination in newly diagnosed GBM as compared to historical data in the EF14 study. To determine whether pembrolizumab augments TTFields-initiated glioma-specific immune reaction.	,	
<opening soon> 18752 ACTION Trial Adoptive Cellular Therapy following Dose-Intensified Temozolomide in Newly-diagnosed Pediatric High-grade Gliomas (Phase I).	Primary To determine the safety of adoptive cellular therapy in pediatric patients with HGG receiving dose intensified TMZ and DC+xALT therapy with and without HSCs. Secondary Examine feasibility of completing treatment in enrolled subjects; Comparison of baseline to post-immunotherapy functional anti-tumor immune responses; and Analysis of progression-free survival and overall survival after treatment with DC + xALT therapy with and without HSCs.	,	
NRG-BN001 Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy versus Conventional	http://clinicaltrials.gov/ct2/show/NCT02179086 To determine if dose-escalated and -intensified photon IMRT or Proton beam therapy (using a dose-per-fraction escalation with simultaneous integrated boost) with concomitant and adjuvant temozolomide improves overall survival, as compared to standard-	,	

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
High-Grade Glioma			
Newly Diagnosed			
Photon Irradiation with Concomitant and adjuvant Temozolomide in Patients with Newly Diagnosed Glioblastoma.	dose photon irradiation with concomitant and adjuvant temozolomide.		
N0577 Phase III Intergroup Study of Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma	http://clinicaltrials.gov/ct2/show/NCT00887146 To determine whether patients who receive radiotherapy with concomitant temozolomide followed by adjuvant temozolomide (RT + TMZ ¨ TMZ) (ARM B) have a marginally better progression free survival (PFS) as compared with patients who receive radiotherapy followed by adjuvant PCV chemotherapy (RT ¨ PCV) (ARM A).	,	Sarah Andrews Sarah.Andrews@neurosurgery.ufl.edu
A Phase II Randomized, Blinded, and Placebo-controlled Trial of CMV RNA-Pulsed Dendritic Cells with Tetanus-Diphtheria Toxoid Vaccine in Patients with Newly-Diagnosed Glioblastoma	http://clinicaltrials.gov/ct2/show/NCT02465268 Primary Objective: To determine whether the addition of pp65-LAMP mRNA DC vaccine plus GM-CSF to dose-intensified TMZ treatment is worthy of investigation in a large phase III study based on impact on overall survival. Secondary Objectives: 1. Evaluate the impact of CMV pp65-LAMP RNA-pulsed DC vaccines on progression-free survival in patients with newly-diagnosed GBM. 2. Determine the immunologic effects of vaccination with pp65 RNA fusion constructs incorporating full-length LAMP vs short LAMP sequences.	,	Hoai Deleyrolle 352-273-5529 pdeleyrolle@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Recurrent			
OT-15-001 A Phase 3, Randomized, Open-Label Study To Evaluate the Efficacy and Safety of Eflornithine with Lomustine Compared to Lomustine Alone in Patients with Anaplastic Astrocytoma That Progress/Recur After Irradiation and Adjuvant Temozolomide Chemotherapy	http://clinicaltrials.gov/ct2/show/NCT02796261 The primary objectives of this study are to demonstrate superiority in OS and comparable safety when eflornithine is added to lomustine compared to lomustine alone in patients with AA that progress/recur after irradiation and adjuvant temozolomide chemotherapy. The secondary objectives of this study are PFS, objective response rate (ORR), clinical benefit response (CBR) based on magnetic resonance imaging (MRI) criteria, and OS rate at 18 months.	,	Sonisha Warren 352-294-8737 sonisha.warren@neurosurgery.ufl.edu
201501072 A Phase I and Open Label, Randomized, Controlled Phase II Study Testing the Safety, Toxicities, and Efficacy of MK-3475 in Combination with MRI-guided Laser Ablation in Recurrent Malignant Gliomas	http://clinicaltrials.gov/ct2/show/NCT02311582 Primary Objectives: Phase I: To determine the maximal tolerated dose of MK-3475 when combined with MLA for the treatment of recurrent malignant gliomas. Phase II: To determine the progression-free survival of patients with recurrent GBM, WHO grade 4 being treated with MK-3475 alone versus those being treated with MK-3475 plus MLA.	,	Sarah Andrews Sarah.Andrews@neurosurgery.ufl.edu
A Phase II Study of the Optune System, Enhanced by Genomic Analysis to Identify the Genetic Signature of Response in the Treatment of Recurrent Glioblastoma Multiforme	http://clinicaltrials.gov/ct2/show/NCT01954576 The study's primary objectives are: (1) To determine the overall response rate at 6 months for patients with bevacizumab-naïve recurrent glioblastoma being treated with Optune. (2) To determine the overall response rate at 4 months for patients with bevacizumab-refractory recurrent glioblastoma being treated with Optune.	,	Sonisha Warren 352-294-8737 sonisha.warren@neurosurgery.ufl.edu
201600074 A Phase 2, Multi-center, Single arm, Histologically Controlled Study Testing the Combination of TTFields and Pulsed Bevacizumab Treatment in Patients with Bevacizumab-refractory Recurrent Glioblastoma	http://clinicaltrials.gov/ct2/show/NCT02663271 The primary study objective is to determine whether or not TTFields combined with pulsed bevacizumab treatment increases overall survival in patients with bevacizumab-refractory GBM compared to historical controls treated with continuous bevacizumab alone or in combination with other chemotherapy. The secondary study objectives are (1) to determine whether or not TTFields combined with pulsed bevacizumab treatment re-	,	Sarah Andrews Sarah.Andrews@neurosurgery.ufl.edu

Study Title	Study Summary	Study Physician	Study Contact
High-Grade Glioma			
Recurrent			
	sensitizes bevacizumab-refractory GBM to bevacizumab re-challenge; and (2) to determine whether or not TTFields combined with pulsed bevacizumab treatment is safe in patients with bevacizumab-refractory GBM.		
CA209-908 Phase Ib /II Clinical Trial of Nivolumab Monotherapy and Nivolumab in Combination with Ipilimumab in Pediatric Subjects with High Grade Primary CNS Malignancies	http://clinicaltrials.gov/ct2/show/NCT03130959 Primary - Safety Lead In To estimate the safety and tolerability of study treatment in pediatric participants with primary high- grade CNS tumors. Secondary - Safety Lead In To describe any observed anti-tumor activity of study treatment in pediatric primary high grade CNS tumors.	,	Jennifer King 352-294-8374 Jennifer.King@neurosurgery.ufl.edu
CC-4047-BRN-001 A Phase 2 Clinical Study of Pomalidomide (CC-4047) Monotherapy for Children and Young Adults with Recurrent or Progressive Primary Brain Tumors	http://clinicaltrials.gov/ct2/show/NCT03257631 The primary objective of the study is: To identify potential tumor type(s) for further development by establishing the preliminary efficacy of pomalidomide in children and young adults with recurrent or progressive primary brain tumors within four distinct tumor types. The secondary objectives are: To evaluate the safety (type and rate of treatment-related toxicity) of pomalidomide within the study populations. To estimate the long-term efficacy of pomalidomide treatment. The exploratory objectives are: To characterize the PK of pomalidomide in children and young adults with recurrent or progressive primary brain tumors.	,	Jennifer King 352-294-8374 Jennifer.King@neurosurgery.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Low-Grade Glioma			
Newly Diagnosed			
N0577 Phase III Intergroup Study of Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma	http://clinicaltrials.gov/ct2/show/NCT00887146 To determine whether patients who receive radiotherapy with concomitant temozolomide followed by adjuvant temozolomide (RT + TMZ ¨ TMZ) (ARM B) have a marginally better progression free survival (PFS) as compared with patients who receive radiotherapy followed by adjuvant PCV chemotherapy (RT ¨ PCV) (ARM A).	,	Sarah Andrews Sarah.Andrews@neurosurgery.ufl.edu
Recurrent			
A071401 Phase II Trial Of SMO/AKT/NF2 Inhibitors in Progressive Meningiomas with SMO/AKT/NF2 Mutations	http://clinicaltrials.gov/ct2/show/NCT02523014 Primary objectives: To determine the activity of a SMO inhibitor in patients with meningiomas harboring SMO mutations as measured by 6-month PFS and response rate. To determine the activity of a FAK inhibitor in patients with meningiomas harboring NF2 mutations as measured by 6-month PFS and response rate. Secondary objectives To determine overall survival and progression-free survival of SMO and FAK inhibitors in patients with meningioma. To determine adverse event rates of SMO and FAK inhibitors in patients with meningioma.	,	Sarah Andrews Sarah.Andrews@neurosurgery.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Medulloblastoma			
Newly Diagnosed			
SJMB12 A Clinical and Molecular Risk-Directed Therapy for Newly Diagnosed Medulloblastoma	http://clinicaltrials.gov/ct2/show/NCT01878617 PRIMARY THERAPEUTIC OBJECTIVES To estimate the progression free survival distribution of WNTmedulloblastoma patients treated on Stratum W1 with reduced-dose craniospinal irradiation and reduced-dose cyclophosphamide. To estimate progression-free survival distribution of Non-WNT Non-SHH medulloblastoma patients treated on Stratum N1 with reduced dose cyclophosphamide. PRIMARY CANCER CONTROL OBJECTIVES To evaluate the effect of an aerobic training intervention, delivered during the radiation therapy period and at home, prior to the start of chemotherapy, on cardiopulmonary fitness, as measured by change in VO2 peak at 12 weeks post randomization. To assess the impact of a computer-based working memory intervention (administered prophylactically at the end of chemotherapy), relative to standard of care, on a performance-based measure of working memory.	,	Jennifer King 352-294-8374 Jennifer.King@neurosurgery.ufl.edu
HeadStart4 Newly Diagnosed Children (Less than 10 Years Old) With Medulloblastoma and Other Central Nervous System Primitive Neuro-Ectodermal Tumors: Clinical and Molecular Risk-Tailored Intensive and Compressed Induction Chemotherapy Followed by	http://clinicaltrials.gov/ct2/show/NCT02875314 Primary Specific Aims: To determine, in a prospective randomized clinical trial, whether dose-intensive tandem Consolidation, in a randomized comparison with singe cycle Consolidation, provides an event-free survival (EFS) and overall survival (OS) benefit for high-risk patients (non-Wnt and non-Shh sub-groups) with medulloblastoma, and for all patients with central nervous system (CNS) primitive neuro-ectodermal tumors (PNET) completing Head Start 4 Induction, and	,	Jennifer King 352-294-8374 Jennifer.King@neurosurgery.ufl.edu

Study Title	Study Summary	Study Physician	Study Contact
Medulloblastoma			
Newly Diagnosed			
Consolidation with Either Single-Cycle (Low Risk Patients) or Randomization (High Risk Patients) to either Single-Cycle or to Three Tandem Cycles of Marrow-Ablative Chemotherapy with Autologous Hematopoietic Progenitor Cell Rescue	if so, to further determine whether the additional labor-intensity (duration of hospitalizations and short-term and long-term morbidities) associated with the tandem treatment is justified by the improvement in outcome. We hypothesize that the tandem (3 cycles) Consolidation regimen will produce a superior outcome compared to the single cycle Consolidation, given the substantially higher dose-intensity of the tandem regimen, without significant addition of either short-term or long-term morbidities. Secondary Specific Aims: To determine if reduction in the number of Induction chemotherapy cycles from five to three for molecularly high-risk medulloblastoma (non-Shh/non-Wnt) and CNS PNET who achieve a complete response (CR) after three cycles of Induction therapy results in equivalent 3-year EFS. Outcome will be analyzed irrespective of Consolidation assignment (Primary Aim) and compared to historical controls. We hypothesize that the population of patients treated with this risk-adapted approach will not experience an inferior outcome but will experience lower population rates of long-term morbidity, especially ototoxicity. To determine molecular subtypes of medulloblastoma at diagnosis and determine whether dose-intensive and dose-compressed Induction chemotherapy, risk-adapted based upon the absence of detectable residual disease (after 3 Induction chemotherapy cycles) and low risk medulloblastoma biology(Shh or Wnt sub-groups) results in equivalent patient outcomes (3-year EFS and OS) with subsequent Single cycle marrow-ablative chemotherapy Consolidation regimen (compared to historical controls from Head Start II and Head Start III and other studies). We hypothesize that the population of patients treated with this risk-adapted approach will not experience an inferior outcome but will experience lower population rates of long-term morbidity, especially ototoxicity. To assess the rate of response to sequential dose-intensive and dose-compressed Induction chemotherapy followed by marrow-ablative chemotherapy and autologous hematopoietic progenitor cell rescue (AuHPCR) for children with medulloblastoma and other CNS PNET enrolled on the Head Start 4 study utilizing a uniform treatment regimen.		

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Medulloblastoma			
Newly Diagnosed			
	To determine the proportion of patients with each histopathological disease type of CNS embryonal tumor (desmoplastic/nodular medulloblastoma, classic medulloblastoma, anaplastic/large cell medulloblastoma; pineal region PNET or pineoblastoma, non-pineal region supratentorial-PNET and other CNS PNET) cured without the need of CNS irradiation. To determine the prevalence and severity of therapy-related hearing loss between study arms as a function of cumulative dosing of cisplatin (three versus five cycles during Induction) and AuHPCR (one versus three tandem transplants in Consolidation) and to evaluate Distortion-Product Oto-acoustic Emissions (DPOAE) as an early predictor of hearing loss to identified at-risk patients. To determine the long-term endocrine functions and physical growth, as well as incidence of development of second neoplasms, in children treated on this protocol. To compare the toxicity and quality of life (QoL) effects of single versus tandem HDCx cycles.		
Relapsed			
Recurrent Medulloblastoma and Primitive Neuroectodermal Tumor Adoptive T Cell Therapy During Recovery from Myeloablative Chemotherapy and Hematopoietic Stem Cell Transplantation	http://clinicaltrials.gov/ct2/show/NCT01326104 Immunotherapy is a specific approach to treating cancer that has shown promise in adult patients for the treatment of melanoma, malignant brain tumors, and other cancers. The study investigators will use the experience they have gained from these studies to try to improve the outcome for children affected by a recurrent brain tumor.	,	Marcia Hodik 352-273-6971 marcia.hodik@neurosurgery.ufl.edu

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ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
PNET			
Relapsed			
Recurrent Medulloblastoma and Primitive Neuroectodermal Tumor Adoptive T Cell Therapy During Recovery from Myeloablative Chemotherapy and Hematopoietic Stem Cell Transplantation	http://clinicaltrials.gov/ct2/show/NCT01326104 Immunotherapy is a specific approach to treating cancer that has shown promise in adult patients for the treatment of melanoma, malignant brain tumors, and other cancers. The study investigators will use the experience they have gained from these studies to try to improve the outcome for children affected by a recurrent brain tumor.	,	Marcia Hodik 352-273-6971 marcia.hodik@neurosurgery.ufl.edu
Supportive Care			
A Shortened Antiepileptic Drug (AED) Course in Surgical Brain Tumor Patients: A Randomized Trial	http://clinicaltrials.gov/ct2/show/NCT02334722 The primary study objective is to determine the difference in patient reported neurotoxicity associated with a shortened course (1 week) of levetiracetam compared to a longer course (6 weeks).	,	Jessica Smith 352-273-9000 jessica.smith@neurosurgery.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Adjuvant			
S1207 Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e3 Breast Cancer Study - evaluating everolimus with endocrine therapy	http://clinicaltrials.gov/ct2/show/NCT01674140 Estrogen can cause the growth of breast cancer cells. Hormone therapy using tamoxifen citrate, goserelin acetate, leuprolide acetate, anastrozole, letrozole, or exemestane, may fight breast cancer by lowering the amount of estrogen the body makes. Everolimus may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. It is not yet know whether hormone therapy is more effective when given with or without everolimus in treating breast cancer. This randomized phase III trial studies how well giving hormone therapy together with or without everolimus work in treating patients with breast cancer.	,	Brandi Lattinville 352-265-0680 Ext. 87665 blattinville@ufl.edu
A011502 A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: The ABC Trial	http://clinicaltrials.gov/ct2/show/NCT02927249 This randomized phase III trial studies how well aspirin works in preventing the cancer from coming back (recurrence) in patients with human epidermal growth factor receptor 2 (HER2) breast cancer after chemotherapy, surgery, and/or radiation therapy. Aspirin is a drug that reduces pain, fever, inflammation, and blood clotting. It is also being studied in cancer prevention. Giving aspirin may reduce the rate of cancer recurrence in patients with breast cancer.	,	Brandi Lattinville 352-265-0680 Ext. 87665 blattinville@ufl.edu
<opening soon> A011401; BWEL Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women With Early Breast Cancer	http://clinicaltrials.gov/ct2/show/NCT02750826 This randomized phase III trial studies whether weight loss in overweight and obese women may prevent breast cancer from coming back (recurrence). Previous studies have found that women who are overweight or obese when their breast cancer is found (diagnosed) have a greater risk of their breast cancer recurring, as compared to women who were thinner when their cancer was diagnosed. This study aims to test whether overweight or obese women who take part in a weight loss program after being diagnosed with breast cancer have a lower rate of cancer recurrence as compared to women who do not take part in the weight loss program. This study will help to show whether weight loss programs should be a part of breast cancer treatment.	,	Brandi Lattinville 352-265-0680 Ext. 87665 blattinville@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Adjuvant			
BRE12-158 A Phase II Randomized Controlled Trial of Genomically Directed Therapy After Preoperative Chemotherapy in Patients with Triple Negative Breast Cancer	http://clinicaltrials.gov/ct2/show/NCT02101385 The primary objective is to compare 2-year disease-free survival (DFS) in participants with confirmed triple negative breast cancer (TNBC) treated with a genomically directed therapy or standard of care following preoperative chemotherapy.	,	Brandi Lattinville 352-265-0680 Ext. 87665 blattinville@ufl.edu
RADCOMP Pragmatic Phase III Randomized Trial of Proton Vs. Photon Therapy for Patients with Non-Metastatic Breast Cancer Receiving Comprehensive Nodal Radiation: A Radiotherapy Comparative Effectiveness (RADCOMP) Consortium Trial	http://clinicaltrials.gov/ct2/show/NCT02603341 To assess the effectiveness of proton vs. photon therapy in reducing major cardiovascular events (MCE), defined as atherosclerotic coronary heart disease or other heart disease death, myocardial infarction, coronary revascularization, or hospitalization for major cardiovascular event (heart failure, valvular disease, arrhythmia, or unstable angina).	,	

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Correlative			
BELLE BELLE: Early Markers of Subclinical Pulmonary Vascular Radiation Toxicity in Breast Cancer	DESCRIPTION This study will use CT imaging, pulmonary function tests, and blood samples to examine the differences in pulmonary vessel radiation damage between patients treated with standard Xray therapy and those treated with proton therapy. PRIMARY -Quantify differences in extent of pulmonary vessel radiation damage in breast cancer patients receiving conventional X-ray versus proton RT using serial CT chest scans. Specifically, we will identify differences between the modalities in regards to the lower dose limits for observable vascular changes; the magnitude of effects and dose-response relationship; and the temporal patterns of recovery and vessel regeneration. -Quantify differences in temporal patterns of levels of cytokines in the blood in breast cancer patients receiving conventional X-ray versus proton RT using serial blood draws that are time-matched with the CT chest scans. -Mathematically model the causal relationship between cytokines levels and vascular damage, and quantify differences between X-ray and proton treatment methodologies in this aspect. SECONDARY -To monitor long-term (>8 year) incidence of clinical pulmonary toxicity and overall survival in these patients to identify any difference between X-ray and proton treatment methodologies. -To identify patterns of asymptomatic metastatic progression in those patients who develop recurrence to the thorax during the follow-up imaging period. ELIGIBILITY CRITERIA -Breast cancer patients who have Stage II or higher disease and who are scheduled to receive conventional X-ray RT (n=30) or proton therapy (n=25) to the breast and chest wall for the treatment of breast cancer will be enrolled in this study. -Age ¡Ý 18 years at time of consent	,	John Lybarger 352-265-0680 Ext. 87829 lybarj@shands.ufl.edu

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ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Correlative			
	-Patients must sign informed consent meeting all federal and institutional guidelines prior to any radiation treatment and/or research interventions. INELIGIBILITY CRITERIA -Patients not meeting eligibility criteria stated in 6.2.1 -Patients not willing or able to submit to repeat chest CT scans with injected vascular contrast and blood draws at the Department of Radiology at UF Shands in Gainesville, or Shands Jacksonville Hospitals. -Pregnant women are excluded because of possible radiation risk to the fetus. -Patients who have previously had radiation treatment where any portion of the lung received greater than 5 Gy of radiation exposure. -Women with bilateral breast cancer or metastatic disease to sites near the chest where additional radiation exposure to any portion of the lung of greater than 5 Gy is anticipated. -Because breast cancer is rare in men, males are excluded. -Women with adverse reaction to all common CT contrast agents.		
BR02 Prospective Pilot Study of Early Markers of Radiation-Induced Cardiac Injury in Patients with Left-Sided Breast Cancer Receiving Photon or Proton Therapy	http://clinicaltrials.gov/ct2/show/NCT02199366 To evaluate changes in cardiac function as measured by cardiac MRI within 1 year after radiotherapy for breast cancer.	,	Ashley Williams 904-588-1451 awilliams@floridaproton.org

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Metastatic			
E2112 A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Patients with Hormone Receptor-Positive Advanced Breast Cancer	http://clinicaltrials.gov/ct2/show/NCT02115282 The primary objective is to evaluate whether the addition of entinostat to endocrine therapy (exemestane) improves progression-free survival (PFS) and/or overall survival (OS) in patients with HR-positive, HER2-negative locally advanced or metastatic breast cancer who have previously progressed on a non-steroidal aromatase inhibitor (AI).	,	Brandi Lattinville 352-265-0680 Ext. 87665 blattinville@ufl.edu
NRG-BR002 A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer	http://clinicaltrials.gov/ct2/show/NCT02364557 Phase II-R To determine whether ablation (through SBRT and/or surgical resection of all known metastases) in oligometastatic breast cancer patients provides a sufficient signal for improved progression-free survival (PFS) to warrant full accrual to the Phase III portion of the trial Phase III To determine whether ablation (through SBRT and/or surgical resection of all known metastases) in oligometastatic breast cancer patients significantly improves overall survival (OS)	,	Brandi Lattinville 352-265-0680 Ext. 87665 blattinville@ufl.edu
EAY131, MATCH Molecular Analysis for Therapy Choice (MATCH)	http://clinicaltrials.gov/ct2/show/NCT02465060 The primary objective is to evaluate the proportion of patients with objective response (OR) to targeted study agent(s) in patients with advanced refractory cancers/lymphomas.	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu
Neoadjuvant			
B-51 A Randomized Phase III Clinical Trial Evaluating Post-mastectomy chestwall and Regional Nodal and Post-lumpectomy Regional Nodal XRT In Patients With Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert To Pathologically Negative.	http://clinicaltrials.gov/ct2/show/NCT01872975	,	John Lybarger 352-265-0680 Ext. 87829 lybarj@shands.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Screening/Prevention/Diagnostic			
Imaging the Patterns of Breast Cancer Early Metastases	The primary objectives of the research study are to: (1) determine the feasibility of the stated interventions in a multi-institutional setting; (2) document the patterns of early metastatic spread of breast cancer; (3) document the proportion of high-risk breast cancer patients that have an oligometastatic presentation within this proactive imaging protocol, and (4) provide a basis to determine how to optimize future surveillance imaging protocols with respect to the time to progression, rate of tumor growth and organs that are affected.	,	John Lybarger 352-265-0680 Ext. 87829 lybarj@shands.ufl.edu
Supportive Care			
39039039 STM4001 Efficacy and Safety of Rivaroxaban Prophylaxis Compared with Placebo in Ambulatory Cancer Patients Initiating Systemic Cancer Therapy and at High Risk for Venous Thromboembolism	http://clinicaltrials.gov/ct2/show/NCT02555878 The primary efficacy objective is to demonstrate that rivaroxaban is superior to placebo for reducing the risk of the primary composite outcome as defined by objectively confirmed symptomatic lower extremity proximal DVT, asymptomatic lower extremity proximal DVT, symptomatic upper extremity DVT, symptomatic non-fatal PE, incidental PE, and VTE-related death in ambulatory adult subjects with various cancer types receiving systemic cancer therapy who are at high risk of developing a VTE.	,	Anita Rajasekhar 352-273-8699 anita.rajasekhar@medicine.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Biliary			
INCB 54828-202 A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma Including FGFR2 Translocations Who Failed Previous Therapy	http://clinicaltrials.gov/ct2/show/NCT02924376 The primary objective of this study is to evaluate the efficacy of INCB054828 in subjects with advanced/metastatic or surgically unresectable cholangiocarcinoma with fibroblast growth factor receptor (FGFR) 2 translocation who have failed at least 1 previous treatment.	,	Margaret Veal 352-265-0680 Ext. 87656 mamcewan@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Colorectal			
Adjuvant			
ARGO; NSABP C-13 A Phase III Randomized Placebo-Controlled Study Evaluating Regorafenib Following Completion of Standard Chemotherapy for Patients with Stage III Colon Cancer (ARGO)	http://clinicaltrials.gov/ct2/show/NCT02664077 The primary aim is to determine whether treatment with regorafenib following adjuvant therapy improves disease-free survival (DFS) in patients with Stage IIIB or IIIC colon cancer.	,	Trevor Pogue 352-265-0680 Ext. 87660 tpogue@ufl.edu
First Line Metastatic			
MK-3475-177 A Phase III Study of Pembrolizumab (MK-3475) vs. Chemotherapy in Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Stage IV Colorectal Carcinoma (KEYNOTE-177)	http://clinicaltrials.gov/ct2/show/NCT02563002 The primary objective is to compare Progression Free Survival (PFS) per RECIST 1.1 criteria.	,	Trevor Pogue 352-265-0680 Ext. 87660 tpogue@ufl.edu
Neoadjuvant			
N1048 A Phase II/III Trial of Neoadjuvant FOLFOX With Selective Use of Combined Modality Chemoradiation Versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection With Total Mesorectal Excision (PROSPECT)	http://clinicaltrials.gov/ct2/show/NCT01515787 Phase II component: To assure that neoadjuvant FOLFOX followed by selective use of 5FUCMT group (Group 1) maintains the current high rate of pelvic R0 resection and is consistent with non-inferiority for time to local recurrence (TLR). Phase III component: To compare neoadjuvant FOLFOX followed by Selective use of 5FUCMT (Group 1) to standard 5FUCMT (Group 2) with respect to the proportion of patients who achieve a pathologic complete response (pCR) at the time of surgical resection.	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu
NRG-GI002 A Phase II Clinical Trial Platform of Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer	http://clinicaltrials.gov/ct2/show/NCT02921256 This randomized phase II trial studies how well veliparib works with combination chemotherapy and radiation therapy in treating patients with rectal cancer that has spread from where it started to nearby tissue or lymph nodes (locally advanced). Veliparib may stop the growth of tumor cells by blocking some of the enzymes	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Colorectal			
Neoadjuvant			
	needed for cell growth. Drugs used in chemotherapy, such as modified (m)FOLFOX6 regimen, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Radiation therapy uses high-energy x-rays to kill tumor cells and shrink tumors. Giving veliparib with combination chemotherapy and radiation therapy may kill more tumor cells and giving it before surgery may make the tumor smaller and reduce the amount of normal tissue that needs to be removed.		
Second Line Metastatic			
FC-9 A Phase II Study of the Dual Immune Checkpoint Blockade with Durvalumab (MEDI4736) plus Tremelimumab Following Palliative Hypofractionated Radiation in Patients with Microsatellite Stable (MSS) Metastatic Colorectal Cancer Progressing on Chemotherapy	http://clinicaltrials.gov/ct2/show/NCT03007407 The primary aim is to determine the efficacy of the dual immune checkpoint blockade with durvalumab plus tremelimumab following a small dose of hypofractionated palliative radiation in patients with MSS mCRC who have progressed on chemotherapy.	,	Trevor Pogue 352-265-0680 Ext. 87660 tpogue@ufl.edu
Supportive Care			
39039039 STM4001 Efficacy and Safety of Rivaroxaban Prophylaxis Compared with Placebo in Ambulatory Cancer Patients Initiating Systemic Cancer Therapy and at High Risk for Venous Thromboembolism	http://clinicaltrials.gov/ct2/show/NCT02555878 The primary efficacy objective is to demonstrate that rivaroxaban is superior to placebo for reducing the risk of the primary composite outcome as defined by objectively confirmed symptomatic lower extremity proximal DVT, asymptomatic lower extremity proximal DVT, symptomatic upper extremity DVT, symptomatic non-fatal PE, incidental PE, and VTE-related death in ambulatory adult subjects with various cancer types receiving systemic cancer therapy who are at high risk of developing a VTE.	,	Anita Rajasekhar 352-273-8699 anita.rajasekhar@medicine.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Third Line Metastatic and Beyond			
TO-TAS-102-107 A Phase 1, open-label study to evaluate the safety, tolerability, and pharmacokinetics of TAS-102 in patients with advanced solid tumors and varying degrees of renal impairment	http://clinicaltrials.gov/ct2/show/NCT02301117 Pharmacokinetic (PK) Part (Primary Objectives) (Cycle 1): To compare the plasma PK profile of TAS-102 (FTD, FTY, and TPI) in advanced solid tumor patients with varying degrees of renal impairment in order to evaluate the impact of renal impairment on the PK profile of TAS-102 (FTD and TPI) and FTY (the major metabolite of FTD). To assess the safety and tolerability of TAS-102 in advanced solid tumor patients with varying degrees of renal impairment in Cycle 1. Extension Part (Exploratory Objective) (Cycles 2 and beyond): To assess the safety and tolerability of TAS-102 in advanced solid tumor patients with varying degrees of renal impairment in Cycles 2 and beyond.	,	Twanda Robinson 352-273-9489 twanda.robinson@medicine.ufl.edu
D6070C00001; MEDI9447 A Phase 1 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of MEDI9447 Alone and in Combination with MEDI4736 in Adult Subjects with Select Advanced Solid Tumors	http://clinicaltrials.gov/ct2/show/NCT02503774 The primary objective is to assess the safety and tolerability, describe any dose-limiting toxicity (DLT), and determine the maximum tolerated dose (MTD) or the highest protocol-defined dose (in the absence of exceeding the MTD) for MEDI9447 when administered as a single agent and in combination with durvalumab in subjects with selected advanced solid tumors.	,	Marlene Sarmiento 352-265-0680 Ext. 50704 msarmien@ufl.edu
FC-9 A Phase II Study of the Dual Immune Checkpoint Blockade with Durvalumab (MEDI4736) plus Tremelimumab Following Palliative Hypofractionated Radiation in Patients with Microsatellite Stable (MSS) Metastatic Colorectal Cancer Progressing on Chemotherapy	http://clinicaltrials.gov/ct2/show/NCT03007407 The primary aim is to determine the efficacy of the dual immune checkpoint blockade with durvalumab plus tremelimumab following a small dose of hypofractionated palliative radiation in patients with MSS mCRC who have progressed on chemotherapy.	,	Trevor Pogue 352-265-0680 Ext. 87660 tpogue@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
EAY131, MATCH Molecular Analysis for Therapy Choice (MATCH)	http://clinicaltrials.gov/ct2/show/NCT02465060 The primary objective is to evaluate the proportion of patients with objective response (OR) to targeted study agent(s) in patients with advanced refractory cancers/lymphomas.	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu
General			
Miscellaneous GI Neoplasms			
16044 An open-label Phase I dose-escalation study to evaluate the safety, tolerability, maximum tolerated dose, pharmacokinetics, and pharmacodynamics of the anti-C4.4a antibody drug conjugate BAY 1129980 in subjects with advanced solid tumors known to express C4.4a	http://clinicaltrials.gov/ct2/show/NCT02134197 Primary objective: To determine the safety, tolerability and maximum tolerated dose (MTD) of BAY 1129980 Secondary objective: To evaluate the pharmacokinetics (PK), pharmacodynamics (PD), immunogenicity, biomarkers, and tumor response profile of BAY 1129980	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu
SCRX001-006 An Open-Label Study of Rovalpituzumab Tesirine in Subjects with Delta-Like Protein 3-Expressing Advanced Solid Tumors	http://clinicaltrials.gov/ct2/show/NCT02709889 The primary objective is to assess the safety and tolerability of rovalpituzumab tesirine in subjects with specific delta-like protein 3-expressing advanced solid tumors.	,	Allison Trainor 352-265-0680 Ext. 50703 awickham@ufl.edu
CA209-032 A Phase 1/2, Open-label Study of Nivolumab Monotherapy or Nivolumab combined with Ipilimumab in Subjects with Advanced or Metastatic Solid Tumors	http://clinicaltrials.gov/ct2/show/NCT01928394 The primary objective is to evaluate the objective response rate (ORR) of nivolumab monotherapy or nivolumab combined with ipilimumab in subjects with advanced or metastatic tumors. ORR will be assessed by a Blinded Independent Central Review (BICR) in selected tumor types.	,	Allison Trainor 352-265-0680 Ext. 50703 awickham@ufl.edu
EAY131, MATCH Molecular Analysis for Therapy Choice (MATCH)	http://clinicaltrials.gov/ct2/show/NCT02465060 The primary objective is to evaluate the proportion of patients with objective response (OR) to targeted study agent(s) in patients with advanced refractory cancers/lymphomas.	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu

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ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Hepatocellular			
1st Line			
JX594-HEP024 A Phase 3 Randomized, Open-Label Study Comparing Pexa-Vec (Vaccinia GM-CSF/Thymidine Kinase-Deactivated Virus) Followed by Sorafenib Versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma (HCC) Without Prior Systemic Therapy	http://clinicaltrials.gov/ct2/show/NCT02562755 The primary objective is to determine and compare the overall survival of patients with advanced HCC without prior systemic therapy, treated with Pexa-Vec followed by sorafenib (Arm A) versus sorafenib (Arm B).	,	Twanda Robinson 352-273-9489 twanda.robinson@medicine.ufl.edu
2nd Line			
XL184309 A Phase 3, Randomized, Double-blind, Controlled Study of Cabozantinib (XL184) vs Placebo in Subjects with Hepatocellular Carcinoma Who Have Received Prior Sorafenib	http://clinicaltrials.gov/ct2/show/NCT01908426 Placebo controlled Study drug,cabozantinib (XL184) to treat patients with hepatocellular carcinoma that have not responded or have progressed after treatment. XL184 is approved for use in treating medullary thyroid cancer. What will be done as part of your normal c	,	Twanda Robinson 352-273-9489 twanda.robinson@medicine.ufl.edu
Correlative			
TARGET-HCC A 5-year Longitudinal Observational Study of the Natural History and Management of Patients with Hepatocellular Carcinoma	http://clinicaltrials.gov/ct2/show/NCT02954094 TARGET-HCC is a longitudinal, observational study of patients being managed for HCC in usual clinical practice. TARGET-HCC will create a research registry of participants with HCC within academic and community real-world practices in order to assess the safety and effectiveness of the entire spectrum of current and future therapies across diverse populations.	,	Patrick Horne 352-273-9464 patrick.horne@medicine.ufl.edu
<opening soon> H3B-6527- An Open-Label Multicenter Phase 1 Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of H3B-6527 in Subjects With Advanced Hepatocellular Carcinoma or Intrahepatic Cholangiocarcinoma	http://clinicaltrials.gov/ct2/show/NCT02834780 The primary purpose of this study is to determine the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D) of H3B-6527 (Part 1), and to assess the safety and tolerability of H3B-6527 as a single agent administered orally (Part 2) in participants with advanced hepatocellular carcinoma (HCC).	,	Twanda Robinson 352-273-9489 twanda.robinson@medicine.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Hepatocellular			
EAY131, MATCH Molecular Analysis for Therapy Choice (MATCH)	http://clinicaltrials.gov/ct2/show/NCT02465060 The primary objective is to evaluate the proportion of patients with objective response (OR) to targeted study agent(s) in patients with advanced refractory cancers/lymphomas.	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Pancreatic			
Adjuvant			
RTOG-0848 A Phase II-R and a Phase III Trial Evaluating Both Erlotinib (Ph II-R) and Chemoradiation (Ph III) as Adjuvant Treatment for Patients With Resected Head of Pancreas Adenocarcinoma	http://clinicaltrials.gov/ct2/show/NCT01013649 This randomized phase II-R/III trial studies gemcitabine hydrochloride with or without erlotinib hydrochloride followed by the same chemotherapy regimen with or without radiation therapy and capecitabine or fluorouracil in treating patients with pancreatic cancer that was removed by surgery. Drugs used in chemotherapy, such as gemcitabine hydrochloride, capecitabine, and fluorouracil, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Erlotinib hydrochloride may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. Radiation therapy uses high energy x-rays to kill tumor cells. Giving chemotherapy together with or without erlotinib hydrochloride and/or radiation therapy after surgery may kill any tumor cells that remain after surgery. It is not yet known whether chemotherapy is more effective when given with or without erlotinib hydrochloride and/or radiation therapy in treating pancreatic cancer.	,	Margaret Veal 352-265-0680 Ext. 87656 mamcewan@ufl.edu
Advanced/Unresectable			
PC04 A Phase II Trial of Escalated Dose Proton Radiotherapy with Elective Nodal Irradiation and Concomitant Chemotherapy for Patients with Unresectable, Borderline Resectable or Medically inoperable Pancreatic Adenocarcinoma.	http://clinicaltrials.gov/ct2/show/NCT02598349 *Improve 12 month survival from50% to 75% *Improve local and regional disease control *Increase share of marginally resectable and unresectable patients being converted to resectable	,	Robin Toton 904-588-1460 rtoton@floridaproton.org
Second Line Metastatic			

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Pancreatic			
Second Line Metastatic			
D6070C00001; MEDI9447 A Phase 1 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of MEDI9447 Alone and in Combination with MEDI4736 in Adult Subjects with Select Advanced Solid Tumors	http://clinicaltrials.gov/ct2/show/NCT02503774 The primary objective is to assess the safety and tolerability, describe any dose-limiting toxicity (DLT), and determine the maximum tolerated dose (MTD) or the highest protocol-defined dose (in the absence of exceeding the MTD) for MEDI9447 when administered as a single agent and in combination with durvalumab in subjects with selected advanced solid tumors.	,	Marlene Sarmiento 352-265-0680 Ext. 50704 msarmien@ufl.edu
UF-STO-PANC-003 A Phase II Trial of TAS-102 (Lonsurf) in Patients With Metastatic or Locally Advanced Unresectable Pancreatic Adenocarcinoma After Progression Through First Line Chemotherapy	http://clinicaltrials.gov/ct2/show/NCT02921737 The primary objective is to evaluate the activity of TAS-102 in previously treated metastatic and locally advanced unresectable pancreatic cancer after progression through or intolerance to first line chemotherapy.	,	Allison Trainor 352-265-0680 Ext. 50703 awickham@ufl.edu
Supportive Care			
39039039 STM4001 Efficacy and Safety of Rivaroxaban Prophylaxis Compared with Placebo in Ambulatory Cancer Patients Initiating Systemic Cancer Therapy and at High Risk for Venous Thromboembolism	http://clinicaltrials.gov/ct2/show/NCT02555878 The primary efficacy objective is to demonstrate that rivaroxaban is superior to placebo for reducing the risk of the primary composite outcome as defined by objectively confirmed symptomatic lower extremity proximal DVT, asymptomatic lower extremity proximal DVT, symptomatic upper extremity DVT, symptomatic non-fatal PE, incidental PE, and VTE-related death in ambulatory adult subjects with various cancer types receiving systemic cancer therapy who are at high risk of developing a VTE.	,	Anita Rajasekhar 352-273-8699 anita.rajasekhar@medicine.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
CA209-032 A Phase 1/2, Open-label Study of Nivolumab Monotherapy or Nivolumab combined with Ipilimumab in Subjects with Advanced or Metastatic Solid Tumors	http://clinicaltrials.gov/ct2/show/NCT01928394 The primary objective is to evaluate the objective response rate (ORR) of nivolumab monotherapy or nivolumab combined with ipilimumab in subjects with advanced or metastatic tumors. ORR will be assessed by a Blinded Independent Central Review (BICR) in selected tumor types.	,	Allison Trainor 352-265-0680 Ext. 50703 awickham@ufl.edu
EAY131, MATCH Molecular Analysis for Therapy Choice (MATCH)	http://clinicaltrials.gov/ct2/show/NCT02465060 The primary objective is to evaluate the proportion of patients with objective response (OR) to targeted study agent(s) in patients with advanced refractory cancers/lymphomas.	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Bladder			
Supportive Care			
39039039 STM4001 Efficacy and Safety of Rivaroxaban Prophylaxis Compared with Placebo in Ambulatory Cancer Patients Initiating Systemic Cancer Therapy and at High Risk for Venous Thromboembolism	http://clinicaltrials.gov/ct2/show/NCT02555878 The primary efficacy objective is to demonstrate that rivaroxaban is superior to placebo for reducing the risk of the primary composite outcome as defined by objectively confirmed symptomatic lower extremity proximal DVT, asymptomatic lower extremity proximal DVT, symptomatic upper extremity DVT, symptomatic non-fatal PE, incidental PE, and VTE-related death in ambulatory adult subjects with various cancer types receiving systemic cancer therapy who are at high risk of developing a VTE.	,	Anita Rajasekhar 352-273-8699 anita.rajasekhar@medicine.ufl.edu
CA209-274 A Phase 3 Randomized, Double-blind, Multi-center Study of Adjuvant Nivolumab versus Placebo in Subjects with High Risk Invasive Urothelial Carcinoma	http://clinicaltrials.gov/ct2/show/NCT02632409 The primary objective is to compare the disease free survival for nivolumab versus placebo in subjects with tumors expressing PD-L1 and all randomized subjects	,	Amanda Slater 352-265-0680 Ext. 58127 aslater@ufl.edu
S1602 A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming With Intradermal BCG Before Intravesical Therapy for BCG-Naive High-Grade Non-muscle Invasive Bladder Cancer	http://clinicaltrials.gov/ct2/show/NCT03091660 The primary objectives of this study are to: 1. Compare whether time to high-grade recurrence (TTHGR) for patients with BCG-naïve, non-muscle invasive bladder cancer (NMIBC) receiving Tokyo-172 BCG strain (Arm 2) is non-inferior to patients receiving BCG LIVE (TICE® BCG) strain (Arm 1). 2.Test whether TTHGR for patients with BCG-naïve, NMIBC receiving intradermal Tokyo-172 BCG vaccination followed by intravesical Tokyo-172 BCG instillation (Arm 3) is superior to patients receiving intravesical Tokyo-172 BCG instillation without prior intradermal BCG vaccination (Arm 2).	,	Amanda Slater 352-265-0680 Ext. 58127 aslater@ufl.edu
GU14-182 A Randomized, Double-Blinded, Phase II Study of Maintenance Pembrolizumab versus Placebo after First-line Chemotherapy in Patients with Metastatic Urothelial Cancer	http://clinicaltrials.gov/ct2/show/NCT02500121 The primary objective will be to determine the progression-free survival as per immune-related RECIST (irRECIST) among subjects with metastatic urothelial cancer (mUC) treated with pembrolizumab versus placebo as maintenance therapy after 4-6 cycles of first-line chemotherapy.	,	Amanda Slater 352-265-0680 Ext. 58127 aslater@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Bladder			
<opening soon> rAd-IFN-CS-03 A Phase III, Open Label Study to Evaluate the Safety and Efficacy of INSTILADRIN® (rAd-Interferon (IFN)/Syn3) Administered Intravesically to Patients With High Grade, BCG Unresponsive Non-Muscle Invasive Bladder Cancer	http://clinicaltrials.gov/ct2/show/NCT02773849 Previous multi-dose Phase I and Phase II clinical studies have demonstrated that Instiladrin is a safe and effective treatment for BCG-refractory and recurrent NMIBC. This Phase III study is designed to expand those observations using a high dose of Instiladrin in patients that are "BCG Unresponsive" which refers to patients with high grade NMIBC who are unlikely to benefit from and should not receive further intravesical BCG.	,	Amanda Slater 352-265-0680 Ext. 58127 aslater@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Prostate			
Adjuvant			
PR06 UFPTI 0902-PR06: Postoperative or Salvage Radiotherapy for Node Negative Prostate Cancer Following Radical Prostatectomy	http://clinicaltrials.gov/ct2/show/NCT00969111 The purpose of this study is to see what effects, good and/or bad, proton radiation, and/or conventional radiation and hormonal therapy (if applicable), has on prostate cancer that has already returned or the risk of prostate cancer returning.	,	Judy Holland 877-686-6009 jholland@floridaproton.org
Metastatic			
17777; ARASENS A Randomized, Double-blind, Placebo Controlled Phase III Study of ODM-201 Versus Placebo in Addition to Standard Androgen Deprivation Therapy and Docetaxel in Patients With Metastatic Hormone Sensitive Prostate Cancer	http://clinicaltrials.gov/ct2/show/NCT02799602 The purpose of the study is to assess the efficacy and safety of BAY1841788 (ODM-201) in combination with standard androgen deprivation therapy (ADT) and docetaxel in patients with metastatic hormone sensitive prostate cancer.	,	Amanda Slater 352-265-0680 Ext. 58127 aslater@ufl.edu
Supportive Care			
Prostate Cancer and the LGBTQIA Community	The purpose of this study is to conduct a qualitative pilot study that will lay some of the groundwork needed to explore the knowledge of and beliefs about Prostate Cancer among transgender women and to explore if Prostate Cancer awareness needs to be increased for this population. To explore the knowledge of and beliefs about Prostate Cancer among transgender women and intersex individuals, determine how many women may be at risk for prostate cancer, and to explore whether Prostate Cancer awareness should be increased for this population.	,	Cheri Knecht 352-294-4882 cesk04@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Renal Cell			
Adjuvant			
WO39210 A Phase III, Randomized, Placebo-Controlled, Double-Blind Study of Atezolizumab (Anti-PD-L1 Antibody) as Adjuvant Therapy in Patients with Renal Cell Carcinoma at High Risk of Developing Metastasis Following Nephrectomy	http://clinicaltrials.gov/ct2/show/NCT03024996 This is a Phase III, multicenter, randomized, placebo-controlled, double-blind study (IMmotion010) to evaluate the efficacy and safety of atezolizumab versus placebo in patients with renal cell carcinoma (RCC) who are at high risk of disease recurrence following resection.	,	Amanda Slater 352-265-0680 Ext. 58127 aslater@ufl.edu
Supportive Care			
39039039 STM4001 Efficacy and Safety of Rivaroxaban Prophylaxis Compared with Placebo in Ambulatory Cancer Patients Initiating Systemic Cancer Therapy and at High Risk for Venous Thromboembolism	http://clinicaltrials.gov/ct2/show/NCT02555878 The primary efficacy objective is to demonstrate that rivaroxaban is superior to placebo for reducing the risk of the primary composite outcome as defined by objectively confirmed symptomatic lower extremity proximal DVT, asymptomatic lower extremity proximal DVT, symptomatic upper extremity DVT, symptomatic non-fatal PE, incidental PE, and VTE-related death in ambulatory adult subjects with various cancer types receiving systemic cancer therapy who are at high risk of developing a VTE.	,	Anita Rajasekhar 352-273-8699 anita.rajasekhar@medicine.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Fallopian Tube			
NRG-GY004 A Phase III study comparing single-agent olaparib or the combination of cediranib and olaparib to standard platinum-based chemotherapy in women with recurrent platinum-sensitive ovarian, fallopian tube, or primary peritoneal cancer	http://clinicaltrials.gov/ct2/show/NCT02446600 The primary objective is to assess the efficacy of either single agent olaparib or the combination of cediranib and olaparib, as measured by progression free survival, as compared to standard platinum-based chemotherapy in the setting of recurrent platinum-sensitive ovarian, primary peritoneal or fallopian tube cancer.	,	Mieniecia Black 352-265-0680 Ext. 87658 nblack@ufl.edu
Ovarian			
Supportive Care			
39039039 STM4001 Efficacy and Safety of Rivaroxaban Prophylaxis Compared with Placebo in Ambulatory Cancer Patients Initiating Systemic Cancer Therapy and at High Risk for Venous Thromboembolism	http://clinicaltrials.gov/ct2/show/NCT02555878 The primary efficacy objective is to demonstrate that rivaroxaban is superior to placebo for reducing the risk of the primary composite outcome as defined by objectively confirmed symptomatic lower extremity proximal DVT, asymptomatic lower extremity proximal DVT, symptomatic upper extremity DVT, symptomatic non-fatal PE, incidental PE, and VTE-related death in ambulatory adult subjects with various cancer types receiving systemic cancer therapy who are at high risk of developing a VTE.	,	Anita Rajasekhar 352-273-8699 anita.rajasekhar@medicine.ufl.edu
NRG-GY004 A Phase III study comparing single-agent olaparib or the combination of cediranib and olaparib to standard platinum-based chemotherapy in women with recurrent platinum-sensitive ovarian, fallopian tube, or primary peritoneal cancer	http://clinicaltrials.gov/ct2/show/NCT02446600 The primary objective is to assess the efficacy of either single agent olaparib or the combination of cediranib and olaparib, as measured by progression free survival, as compared to standard platinum-based chemotherapy in the setting of recurrent platinum-sensitive ovarian, primary peritoneal or fallopian tube cancer.	,	Mieniecia Black 352-265-0680 Ext. 87658 nblack@ufl.edu
EAY131, MATCH Molecular Analysis for Therapy Choice (MATCH)	http://clinicaltrials.gov/ct2/show/NCT02465060 The primary objective is to evaluate the proportion of patients with objective response (OR) to targeted study agent(s) in patients with advanced refractory cancers/lymphomas.	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu

Study Title	Study Summary	Study Physician	Study Contact
Nasopharyngeal Carcinoma			
16044 An open-label Phase I dose-escalation study to evaluate the safety, tolerability, maximum tolerated dose, pharmacokinetics, and pharmacodynamics of the anti-C4.4a antibody drug conjugate BAY 1129980 in subjects with advanced solid tumors known to express C4.4a	http://clinicaltrials.gov/ct2/show/NCT02134197 Primary objective: To determine the safety, tolerability and maximum tolerated dose (MTD) of BAY 1129980 Secondary objective: To evaluate the pharmacokinetics (PK), pharmacodynamics (PD), immunogenicity, biomarkers, and tumor response profile of BAY 1129980	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu

Study Title	Study Summary	Study Physician	Study Contact
Squamous Cell Carcinoma			
<opening soon> NRG-HN003 A Phase I and Expansion Cohort Study of Adjuvant Cisplatin, Intensity-Modulated Radiotherapy, and MK-3475 (Pembrolizumab) in High-risk Head and Neck Squamous Cell Carcinoma (HNSCC)	http://clinicaltrials.gov/ct2/show/NCT02775812 This phase I trial studies the side effects and best dose of pembrolizumab when given together with cisplatin and intensity-modulated radiation therapy, in treating patients with stage III-IV squamous cell carcinoma of the head and neck. Monoclonal antibodies, such as pembrolizumab, may block tumor growth in different ways by targeting certain cells. Drugs used in chemotherapy, such as cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Intensity-modulated radiation therapy uses high-energy x-rays to kill tumor cells and shrink tumors. Giving pembrolizumab with cisplatin and intensity-modulated radiation therapy may work better in treating patients with squamous cell carcinoma of the head and neck.	,	Allison Trainor 352-265-0680 Ext. 50703 awickham@ufl.edu
LCCC1413 LCCC 1413: De-intensification of Radiation and Chemotherapy for Low-Risk HPV-related Oropharyngeal Squamous Cell Carcinoma	http://clinicaltrials.gov/ct2/show/NCT02281955 The purpose of this research study is to learn about the effectiveness of using lower-intensity chemoradiation therapy to treat human papillomavirus (HPV) associated oropharyngeal and/or unknown primary squamous cell carcinomas of the head and neck.	,	John Lybarger 352-265-0680 Ext. 87829 lybarj@shands.ufl.edu
LCCC 1612 LCCC 1612: P53 mutational status and circulating free HPV DNA for the management of HPV-associated Oropharyngeal Squamous Cell Cancers	http://clinicaltrials.gov/ct2/show/NCT03077243 2.1 Primary Objective: To evaluate whether genomic based risk-stratification can be used in deciding whether to de-intensify in patients with HPV-associated OPSCC with > 10 pack years smoking history. Hypothesis: Patients with HPV-associated OPSCC, > 10 pack years smoking history, and non-mutated p53 will have similar 2 year PFS as patients with < 10 pack years smoking history. Secondary Objectives To prospectively assess if the changes in plasma circulating free HPV DNA during and after treatment are associated with clinical outcomes in patients with HPV-associated OPSCC. Hypothesis: Changes in levels of plasma circulating free HPV DNA during and after treatment will correlate with cancer control rates. To assess the 2 year clinical outcomes of local control (LC),	,	John Lybarger 352-265-0680 Ext. 87829 lybarj@shands.ufl.edu

Study Title	Study Summary	Study Physician	Study Contact
Squamous Cell Carcinoma			
	regional control (RC), local-regional control (LRC), distant metastasis free survival (DMFS), and overall survival (OS). To compare head and neck quality of life assessments before, during, and after CRT. To compare speech and swallowing function before and after CRT		

Study Title	Study Summary	Study Physician	Study Contact
Correlative			
D9902 A COG Soft Tissue Sarcoma Diagnosis, Biology and Banking Protocol	http://clinicaltrials.gov/ct2/show/NCT00919269 The purpose of this study is to collect and store tumor tissue, blood, and bone marrow samples from patients with soft tissue sarcoma that will be tested in the laboratory. Collecting and storing samples of tumor tissue, blood, and bone marrow from patients to test in the laboratory may help the study of cancer.	,	Ashley Bayne 352-294-8745 abayne@ufl.edu
Ewings Sarcoma			
AEWS1221 Randomized Phase II Trial Evaluating the Addition of the IGF-1R Monoclonal Antibody Ganitumab (AMG 479, NSC# 750008, IND# 120449) to Multiagent Chemotherapy for Patients with Newly Diagnosed Metastatic Ewing Sarcoma	http://clinicaltrials.gov/ct2/show/NCT02306161 To compare the event-free survival (EFS) in patients with newly diagnosed metastatic Ewing sarcoma treated with multiagent chemotherapy with and without the addition of ganitumab (AMG 479).	,	Ashley Bayne 352-294-8745 abayne@ufl.edu
General Soft Tissue			
ARST1321 Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (NSC# 737754, IND# 118613)	http://clinicaltrials.gov/ct2/show/NCT02180867 This randomized phase II/III trial studies how well pazopanib hydrochloride, combination chemotherapy, and radiation therapy work and compares it to radiation therapy alone or in combination with pazopanib hydrochloride or combination chemotherapy in treating patients with newly diagnosed non-rhabdomyosarcoma soft tissue sarcomas that can be removed by surgery. Radiation therapy uses high energy x rays to kill tumor cells. Drugs used in chemotherapy, such as ifosfamide and doxorubicin hydrochloride, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Pazopanib hydrochloride may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. It is not yet known whether radiation therapy works better when given with or without combination chemotherapy and/or pazopanib hydrochloride in treating patients with non-rhabdomyosarcoma soft tissue sarcomas.	,	Ashley Bayne 352-294-8745 abayne@ufl.edu

Study Title	Study Summary	Study Physician	Study Contact
Liposarcoma			
ARST1321 Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (NSC# 737754, IND# 118613)	http://clinicaltrials.gov/ct2/show/NCT02180867 This randomized phase II/III trial studies how well pazopanib hydrochloride, combination chemotherapy, and radiation therapy work and compares it to radiation therapy alone or in combination with pazopanib hydrochloride or combination chemotherapy in treating patients with newly diagnosed non-rhabdomyosarcoma soft tissue sarcomas that can be removed by surgery. Radiation therapy uses high energy x rays to kill tumor cells. Drugs used in chemotherapy, such as ifosfamide and doxorubicin hydrochloride, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Pazopanib hydrochloride may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. It is not yet known whether radiation therapy works better when given with or without combination chemotherapy and/or pazopanib hydrochloride in treating patients with non-rhabdomyosarcoma soft tissue sarcomas.	,	Ashley Bayne 352-294-8745 abayne@ufl.edu
EAY131, MATCH Molecular Analysis for Therapy Choice (MATCH)	http://clinicaltrials.gov/ct2/show/NCT02465060 The primary objective is to evaluate the proportion of patients with objective response (OR) to targeted study agent(s) in patients with advanced refractory cancers/lymphomas.	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu
Osteosarcoma			
AOST1421 A Phase II Study of Human-Mouse Chimeric Anti-Disialoganglioside Monoclonal Antibody ch14.18 (Dinutuximab, NSC# 764038, IND# 4308) in Combination with Sargramostim (GM-CSF) in Patients with Recurrent Osteosarcoma	http://clinicaltrials.gov/ct2/show/NCT02484443 To determine the disease control rate in patients with completely resected recurrent osteosarcoma treated with ch14.18 (dinutuximab) in combination with sargramostim (GM-CSF) as compared to historical COG experience.	,	Ashley Bayne 352-294-8745 abayne@ufl.edu

Study Title	Study Summary	Study Physician	Study Contact
Rhabdomyosarcoma			
<opening soon> ADVL1622 Phase 2 Trial of XL184 (Cabozantinib) an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults With Refractory Sarcomas, Wilms Tumor, and Other Rare Tumors	http://clinicaltrials.gov/ct2/show/NCT02867592 To determine the objective response rate (complete response + partial response) of XL184 in children and young adults in refractory sarcomas, Wilms Tumor and other rare tumors	,	
18613 Phase II Study of Nab-Paclitaxel in Combination With Gemcitabine for Treatment of Recurrent/Refractory Sarcoma in Teenagers and Young Adults	http://clinicaltrials.gov/ct2/show/NCT02945800 1. Response Rate [Time Frame: 13 months] Treatment response will be assessed with the most relevant imaging studies (e.g., CT or MRI) after every two cycles. Standard Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 will be used to assess responses. Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm (<1 cm). Partial Response (PR): At least a 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters. 2. Progression Free Survival (PFS) [Time Frame: 13 months] Progression-free survival (PFS) is defined as the duration of time from start of treatment to time of progression or death, whichever occurs first. Progressive Disease (PD): At least a 20% increase in the sum of the diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm (0.5 cm).	,	Ashley Bayne 352-294-8745 abayne@ufl.edu
RMS13 RMS13: Risk Adapted Focal Proton Beam Radiation and/or Surgery in Participants with Low, Intermediate and High Risk Rhabdomyosarcoma Receiving Standard or Intensified Chemotherapy	http://clinicaltrials.gov/ct2/show/NCT01871766 *To find the most effective treatment with the least amount of therapy that will still cure participants with low-risk rhabdomyosarcoma. In some low-risk participants, find out if giving less chemotherapy and less radiation using protons instead of using traditional (photon) radiation will result in fewer late side effects, but still result in a high cure rate.	,	Ashley Williams 904-588-1451 awilliams@floridaproton.org

Study Title	Study Summary	Study Physician	Study Contact
Rhabdomyosarcoma			
	Find out how many participants have their tumor come back (recurrence) and compare the recurrence to the original tumor. For some patients who receive surgery, find out if the standard procedure that is currently used to find how this cancer is spread (sentinel lymph node sampling) is effective. Learn more about RMS and how it responds to treatment by evaluating tumor tissue and blood. Learn more about the side effects of this treatment. Compare the ability of proton radiation to photon radiation to spare healthy tissue from receiving radiation.		

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Non-Small Cell Lung Cancer			
Adjuvant			
LUN005-12 A Phase I/II Study of Hypofractionated Proton Therapy for Stage II-III Non-Small Cell Lung Cancer	http://clinicaltrials.gov/ct2/show/NCT01770418 Establish the maximum tolerated dose of radiotherapy using hypofractionated proton therapy concurrently with chemotherapy and determine the percentage of patients that survive at least 12 months.	,	Samantha Sago 904-588-1529 SSago@floridaproton.org
RTOG-1308 Phase III Randomized Trial Comparing Overall Survival After Photon Versus Proton Chemoradiotherapy for Inoperable Stage II-IIIB NSCLC	http://clinicaltrials.gov/ct2/show/NCT01993810 To compare the overall survival (OS) in patients with stage II-IIIB NSCLC after image guided, motion-managed photon radiotherapy (Arm 1) or after image guided, motion-managed proton radiotherapy (Arm 2) both given with concurrent platinum- based chemotherapy.	,	David Monticalvo 904-588-1512 dmonticalvo@floridaproton.org
BR31 A Phase III Prospective Double Blind Placebo Controlled Randomized Study of Adjuvant MEDI4736 In Completely Resected Non-Small Cell Lung Cancer	http://clinicaltrials.gov/ct2/show/NCT02273375 To assess in comparison to placebo, the impact of adjuvant therapy with MEDI4736 given by intravenous infusion for one year on the disease free survival of patients with completely resected (stage IB > 4cm, stage II or IIIA), non-small cell lung cancer that is PD-L1 positive.	,	Allison Trainor 352-265-0680 Ext. 50703 awickham@ufl.edu
Early Stage			
LU03 UFPTI 0901-LU03 Hypofractionated, Image-Guided Radiation Therapy with Proton Therapy for Stage I Non-Small Cell Lung Cancer	http://clinicaltrials.gov/ct2/show/NCT00875901 This is a research study to determine if hypofractionated image guided radiation therapy (hypoIGRT) with proton therapy is a good way to treat early stage lung tumors for patients who will not have surgery. HypoIGRT delivers higher daily doses of radiation over a shorter period of time compared with conventional radiation. This is thought to deliver a more lethal dose of radiation to the tumor and is more convenient with treatment being completed within 2-3 weeks compared to the typical 7-8 week course of conventional radiotherapy.	,	Judy Holland 877-686-6009 jholland@floridaproton.org
First Line Metastatic			

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Non-Small Cell Lung Cancer			
First Line Metastatic			
UF-STO-LUNG-002 A Non-Randomized Phase Ib-II Protocol of Paclitaxel, Carboplatin and the Dual PI3K/mTOR Kinase Inhibitor, PF-05212384, for Patients with Advanced, or Metastatic Non-Small Cell Carcinoma of the Lung	http://clinicaltrials.gov/ct2/show/NCT02920450 The primary objective is to identify the maximum tolerated dose of PF-05212384 in combination with paclitaxel and carboplatin in subjects with NSCLC.	,	Allison Trainor 352-265-0680 Ext. 50703 awickham@ufl.edu
EF-25 Pivotal, open-label, randomized study of radiosurgery with or without Tumor Treating Fields (TTFields) for 1-10 brain metastases from non-small cell lung cancer (NSCLC)	http://clinicaltrials.gov/ct2/show/NCT02831959 To test the efficacy, safety and neurocognitive outcomes of advanced NSCLC patients, following stereotactic radiosurgery (SRS) for 1-10 brain metastases, treated with NovoTTF-100M compared to supportive treatment alone.	,	Sarah Andrews Sarah.Andrews@neurosurgery.ufl.edu
First Line Unresctable			
RTOG 3505 Randomized, Double Blinded Phase III Trial of Cisplatin and Etoposide Plus Thoracic Radiation Therapy Followed By Nivolumab/Placebo For Locally Advanced Non-Small Cell Lung Cancer	http://clinicaltrials.gov/ct2/show/NCT02768558 Patients with Stage III unresectable non-small cell lung cancer will receive thoracic radiation, cisplatin and etoposide followed by nivolumab or placebo given every 2 weeks for a year. The primary objectives are to assess overall survival and progression free survival in patients treated with nivolumab vs placebo.	,	Allison Trainor 352-265-0680 Ext. 50703 awickham@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Second Line Metastatic and Beyond			
16044 An open-label Phase I dose-escalation study to evaluate the safety, tolerability, maximum tolerated dose, pharmacokinetics, and pharmacodynamics of the anti-C4.4a antibody drug conjugate BAY 1129980 in subjects with advanced solid tumors known to express C4.4a	http://clinicaltrials.gov/ct2/show/NCT02134197 Primary objective: To determine the safety, tolerability and maximum tolerated dose (MTD) of BAY 1129980 Secondary objective: To evaluate the pharmacokinetics (PK), pharmacodynamics (PD), immunogenicity, biomarkers, and tumor response profile of BAY 1129980	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu
EAY131, MATCH Molecular Analysis for Therapy Choice (MATCH)	http://clinicaltrials.gov/ct2/show/NCT02465060 The primary objective is to evaluate the proportion of patients with objective response (OR) to targeted study agent(s) in patients with advanced refractory cancers/lymphomas.	,	Elena Nelson 352-265-0680 Ext. 50144 eab1109@ufl.edu
UF-STO-LUNG-003 A Phase II Trial of TAS-102 (Lonsurf) in Previously Treated Unresectable or Metastatic Squamous Cell Carcinoma of the Lung	http://clinicaltrials.gov/ct2/show/NCT02920476 The primary objective is to determine the progression-free survival, in months, of subjects receiving TAS 102 for the treatment of unresectable or metastatic recurrent squamous cell lung cancers.	,	Allison Trainor 352-265-0680 Ext. 50703 awickham@ufl.edu
D6070C00001; MEDI9447 A Phase 1 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of MEDI9447 Alone and in Combination with MEDI4736 in Adult Subjects with Select Advanced Solid Tumors	http://clinicaltrials.gov/ct2/show/NCT02503774 The primary objective is to assess the safety and tolerability, describe any dose-limiting toxicity (DLT), and determine the maximum tolerated dose (MTD) or the highest protocol-defined dose (in the absence of exceeding the MTD) for MEDI9447 when administered as a single agent and in combination with durvalumab in subjects with selected advanced solid tumors.	,	Marlene Sarmiento 352-265-0680 Ext. 50704 msarmien@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Non-Small Cell Lung Cancer			
Second Line Metastatic and Beyond			
EF-25 Pivotal, open-label, randomized study of radiosurgery with or without Tumor Treating Fields (TTFields) for 1-10 brain metastases from non-small cell lung cancer (NSCLC)	http://clinicaltrials.gov/ct2/show/NCT02831959 To test the efficacy, safety and neurocognitive outcomes of advanced NSCLC patients, following stereotactic radiosurgery (SRS) for 1-10 brain metastases, treated with NovoTTF-100M compared to supportive treatment alone.	,	Sarah Andrews Sarah.Andrews@neurosurgery.ufl.edu
Supportive Care			
39039039 STM4001 Efficacy and Safety of Rivaroxaban Prophylaxis Compared with Placebo in Ambulatory Cancer Patients Initiating Systemic Cancer Therapy and at High Risk for Venous Thromboembolism	http://clinicaltrials.gov/ct2/show/NCT02555878 The primary efficacy objective is to demonstrate that rivaroxaban is superior to placebo for reducing the risk of the primary composite outcome as defined by objectively confirmed symptomatic lower extremity proximal DVT, asymptomatic lower extremity proximal DVT, symptomatic upper extremity DVT, symptomatic non-fatal PE, incidental PE, and VTE-related death in ambulatory adult subjects with various cancer types receiving systemic cancer therapy who are at high risk of developing a VTE.	,	Anita Rajasekhar 352-273-8699 anita.rajasekhar@medicine.ufl.edu
<opening soon> CA209-9JA A Phase I Clinical Trial Combining Nivolumab and Tumor Infiltrating Lymphocytes (TIL) for Patients with Advanced Non-Small Cell Lung Cancer	http://clinicaltrials.gov/ct2/show/NCT03215810 To evaluate the safety and tolerability of TILs administered following initial progression on nivolumab therapy in combination with nivolumab in subjects with advanced non-small cell lung cancer (NSCLC).	,	Amy Yi 352-265-0702 amy.yi@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Small Cell Lung Cancer			
Extensive Stage			
SCRX001-006 An Open-Label Study of Rovalpituzumab Tesirine in Subjects with Delta-Like Protein 3-Expressing Advanced Solid Tumors	http://clinicaltrials.gov/ct2/show/NCT02709889 The primary objective is to assess the safety and tolerability of rovalpituzumab tesirine in subjects with specific delta-like protein 3-expressing advanced solid tumors.	,	Allison Trainor 352-265-0680 Ext. 50703 awickham@ufl.edu
Supportive Care			
39039039 STM4001 Efficacy and Safety of Rivaroxaban Prophylaxis Compared with Placebo in Ambulatory Cancer Patients Initiating Systemic Cancer Therapy and at High Risk for Venous Thromboembolism	http://clinicaltrials.gov/ct2/show/NCT02555878 The primary efficacy objective is to demonstrate that rivaroxaban is superior to placebo for reducing the risk of the primary composite outcome as defined by objectively confirmed symptomatic lower extremity proximal DVT, asymptomatic lower extremity proximal DVT, symptomatic upper extremity DVT, symptomatic non-fatal PE, incidental PE, and VTE-related death in ambulatory adult subjects with various cancer types receiving systemic cancer therapy who are at high risk of developing a VTE.	,	Anita Rajasekhar 352-273-8699 anita.rajasekhar@medicine.ufl.edu
CA209-032 A Phase 1/2, Open-label Study of Nivolumab Monotherapy or Nivolumab combined with Ipilimumab in Subjects with Advanced or Metastatic Solid Tumors	http://clinicaltrials.gov/ct2/show/NCT01928394 The primary objective is to evaluate the objective response rate (ORR) of nivolumab monotherapy or nivolumab combined with ipilimumab in subjects with advanced or metastatic tumors. ORR will be assessed by a Blinded Independent Central Review (BICR) in selected tumor types.	,	Allison Trainor 352-265-0680 Ext. 50703 awickham@ufl.edu
<opening soon> M16-298; Meru A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Rovalpituzumab Tesirine as Maintenance Therapy Following First-Line Platinum-Based Chemotherapy in Subjects with Extensive Stage Small Cell Lung Cancer (MERU)	http://clinicaltrials.gov/ct2/show/NCT03033511 To evaluate if rovalpituzumab tesirine improves progression-free and overall survival in subjects with extensive-stage small cell lung cancer (ED SCLC) who have ongoing clinical benefit (SD,PR, or CR) following first-line platinum-based chemotherapy (cisplatin or carboplatin plus irinotecan or etoposide) compared to placebo.	,	Allison Trainor 352-265-0680 Ext. 50703 awickham@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Brain Tumors			
Germ Cell Tumors			
A031102 A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) With High-Dose Chemotherapy Using Mobilizing Paclitaxel Plus Ifosfamide Followed by High-Dose Carboplatin and Etoposide (TI-CE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumors	http://clinicaltrials.gov/ct2/show/NCT02375204 To compare the overall survival in patients treated with conventional-dose chemotherapy using the TIP regimen with high-dose chemotherapy (HDCT) plus ASCT using the TI-CE regimen as initial salvage treatment of patients with relapsed or refractory GCT.	,	Ashley Bayne 352-294-8745 abayne@ufl.edu
Medulloblastoma			
High Risk			

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Brain Tumors			
Medulloblastoma			
High Risk			
SJMB12 A Clinical and Molecular Risk-Directed Therapy for Newly Diagnosed Medulloblastoma	http://clinicaltrials.gov/ct2/show/NCT01878617 PRIMARY THERAPEUTIC OBJECTIVES To estimate the progression free survival distribution of WNTmedulloblastoma patients treated on Stratum W1 with reduced-dose craniospinal irradiation and reduced-dose cyclophosphamide. To estimate progression-free survival distribution of Non-WNT Non-SHH medulloblastoma patients treated on Stratum N1 with reduced dose cyclophosphamide. PRIMARY CANCER CONTROL OBJECTIVES To evaluate the effect of an aerobic training intervention, delivered during the radiation therapy period and at home, prior to the start of chemotherapy, on cardiopulmonary fitness, as measured by change in VO2 peak at 12 weeks post randomization. To assess the impact of a computer-based working memory intervention (administered prophylactically at the end of chemotherapy), relative to standard of care, on a performance-based measure of working memory.	,	Jennifer King 352-294-8374 Jennifer.King@neurosurgery.ufl.edu
HeadStart4 Newly Diagnosed Children (Less than 10 Years Old) With Medulloblastoma and Other Central Nervous System Primitive Neuro-Ectodermal Tumors: Clinical and Molecular Risk-Tailored Intensive and Compressed Induction	http://clinicaltrials.gov/ct2/show/NCT02875314 Primary Specific Aims: To determine, in a prospective randomized clinical trial, whether dose-intensive tandem Consolidation, in a randomized comparison with singe cycle Consolidation, provides an event-free survival (EFS) and overall survival (OS) benefit for high-risk patients (non-Wnt and non-Shh sub-groups) with medulloblastoma, and for all patients with central nervous system (CNS) primitive neuro-	,	Jennifer King 352-294-8374 Jennifer.King@neurosurgery.ufl.edu

Study Title	Study Summary	Study Physician	Study Contact
Brain Tumors			
Medulloblastoma			
High Risk			
Chemotherapy Followed by Consolidation with Either Single-Cycle (Low Risk Patients) or Randomization (High Risk Patients) to either Single-Cycle or to Three Tandem Cycles of Marrow-Ablative Chemotherapy with Autologous Hematopoietic Progenitor Cell Rescue	ectodermal tumors (PNET) completing Head Start 4 Induction, and if so, to further determine whether the additional labor-intensity (duration of hospitalizations and short-term and long-term morbidities) associated with the tandem treatment is justified by the improvement in outcome. We hypothesize that the tandem (3 cycles) Consolidation regimen will produce a superior outcome compared to the single cycle Consolidation, given the substantially higher dose-intensity of the tandem regimen, without significant addition of either short-term or long-term morbidities. Secondary Specific Aims: To determine if reduction in the number of Induction chemotherapy cycles from five to three for molecularly high-risk medulloblastoma (non-Shh/non-Wnt) and CNS PNET who achieve a complete response (CR) after three cycles of Induction therapy results in equivalent 3-year EFS. Outcome will be analyzed irrespective of Consolidation assignment (Primary Aim) and compared to historical controls. We hypothesize that the population of patients treated with this risk-adapted approach will not experience an inferior outcome but will experience lower population rates of long-term morbidity, especially ototoxicity. To determine molecular subtypes of medulloblastoma at diagnosis and determine whether dose-intensive and dose-compressed Induction chemotherapy, risk-adapted based upon the absence of detectable residual disease (after 3 Induction chemotherapy cycles) and low risk medulloblastoma biology(Shh or Wnt sub-groups) results in equivalent patient outcomes (3-year EFS and OS) with subsequent Single cycle marrow-ablative chemotherapy Consolidation regimen (compared to historical controls from Head Start II and Head Start III and other studies). We hypothesize that the population of patients treated with this risk-adapted approach will not experience an inferior outcome but will experience lower population rates of long-term morbidity, especially ototoxicity. To assess the rate of response to sequential dose-intensive and dose-compressed Induction chemotherapy followed by marrow-ablative chemotherapy and autologous hematopoietic progenitor		

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Brain Tumors			
Medulloblastoma			
High Risk			
	cell rescue (AuHPCR) for children with medulloblastoma and other CNS PNET enrolled on the Head Start 4 study utilizing a uniform treatment regimen. To determine the proportion of patients with each histopathological disease type of CNS embryonal tumor (desmoplastic/nodular medulloblastoma, classic medulloblastoma, anaplastic/large cell medulloblastoma; pineal region PNET or pineoblastoma, non-pineal region supratentorial-PNET and other CNS PNET) cured without the need of CNS irradiation. To determine the prevalence and severity of therapy-related hearing loss between study arms as a function of cumulative dosing of cisplatin (three versus five cycles during Induction) and AuHPCR (one versus three tandem transplants in Consolidation) and to evaluate Distortion-Product Oto-acoustic Emissions (DPOAE) as an early predictor of hearing loss to identified at-risk patients. To determine the long-term endocrine functions and physical growth, as well as incidence of development of second neoplasms, in children treated on this protocol. To compare the toxicity and quality of life (QoL) effects of single versus tandem HDCx cycles.		
Recurrent Medulloblastoma and Primitive Neuroectodermal Tumor Adoptive T Cell Therapy During Recovery from Myeloablative Chemotherapy and Hematopoietic Stem Cell Transplantation	http://clinicaltrials.gov/ct2/show/NCT01326104 Immunotherapy is a specific approach to treating cancer that has shown promise in adult patients for the treatment of melanoma, malignant brain tumors, and other cancers. The study investigators will use the experience they have gained from these studies to try to improve the outcome for children affected by a recurrent brain tumor.	,	Marcia Hodik 352-273-6971 marcia.hodik@neurosurgery.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Standard Risk			
SJMB12 A Clinical and Molecular Risk-Directed Therapy for Newly Diagnosed Medulloblastoma	http://clinicaltrials.gov/ct2/show/NCT01878617 PRIMARY THERAPEUTIC OBJECTIVES To estimate the progression free survival distribution of WNTmedulloblastoma patients treated on Stratum W1 with reduced-dose craniospinal irradiation and reduced-dose cyclophosphamide. To estimate progression-free survival distribution of Non-WNT Non-SHH medulloblastoma patients treated on Stratum N1 with reduced dose cyclophosphamide. PRIMARY CANCER CONTROL OBJECTIVES To evaluate the effect of an aerobic training intervention, delivered during the radiation therapy period and at home, prior to the start of chemotherapy, on cardiopulmonary fitness, as measured by change in VO2 peak at 12 weeks post randomization. To assess the impact of a computer-based working memory intervention (administered prophylactically at the end of chemotherapy), relative to standard of care, on a performance-based measure of working memory.	,	Jennifer King 352-294-8374 Jennifer.King@neurosurgery.ufl.edu
HeadStart4 Newly Diagnosed Children (Less than 10 Years Old) With Medulloblastoma and Other Central Nervous System Primitive Neuro-Ectodermal Tumors: Clinical and Molecular Risk-Tailored Intensive and Compressed Induction Chemotherapy Followed by Consolidation with Either Single-Cycle (Low Risk Patients) or	http://clinicaltrials.gov/ct2/show/NCT02875314 Primary Specific Aims: To determine, in a prospective randomized clinical trial, whether dose-intensive tandem Consolidation, in a randomized comparison with singe cycle Consolidation, provides an event-free survival (EFS) and overall survival (OS) benefit for high-risk patients (non-Wnt and non-Shh sub-groups) with medulloblastoma, and for all patients with central nervous system (CNS) primitive neuro-ectodermal tumors (PNET) completing Head Start 4 Induction, and if so, to further determine whether the additional labor-intensity (duration of hospitalizations and short-term and long-term	,	Jennifer King 352-294-8374 Jennifer.King@neurosurgery.ufl.edu

Study Title	Study Summary	Study Physician	Study Contact
Brain Tumors			
Medulloblastoma			
Standard Risk			
Randomization (High Risk Patients) to either Single-Cycle or to Three Tandem Cycles of Marrow-Ablative Chemotherapy with Autologous Hematopoietic Progenitor Cell Rescue	morbidities) associated with the tandem treatment is justified by the improvement in outcome. We hypothesize that the tandem (3 cycles) Consolidation regimen will produce a superior outcome compared to the single cycle Consolidation, given the substantially higher dose-intensity of the tandem regimen, without significant addition of either short-term or long-term morbidities. Secondary Specific Aims: To determine if reduction in the number of Induction chemotherapy cycles from five to three for molecularly high-risk medulloblastoma (non-Shh/non-Wnt) and CNS PNET who achieve a complete response (CR) after three cycles of Induction therapy results in equivalent 3-year EFS. Outcome will be analyzed irrespective of Consolidation assignment (Primary Aim) and compared to historical controls. We hypothesize that the population of patients treated with this risk-adapted approach will not experience an inferior outcome but will experience lower population rates of long-term morbidity, especially ototoxicity. To determine molecular subtypes of medulloblastoma at diagnosis and determine whether dose-intensive and dose-compressed Induction chemotherapy, risk-adapted based upon the absence of detectable residual disease (after 3 Induction chemotherapy cycles) and low risk medulloblastoma biology(Shh or Wnt sub-groups) results in equivalent patient outcomes (3-year EFS and OS) with subsequent Single cycle marrow-ablative chemotherapy Consolidation regimen (compared to historical controls from Head Start II and Head Start III and other studies). We hypothesize that the population of patients treated with this risk-adapted approach will not experience an inferior outcome but will experience lower population rates of long-term morbidity, especially ototoxicity. To assess the rate of response to sequential dose-intensive and dose-compressed Induction chemotherapy followed by marrow-ablative chemotherapy and autologous hematopoietic progenitor cell rescue (AuHPCR) for children with medulloblastoma and other CNS PNET enrolled on the Head Start 4 study utilizing a uniform treatment regimen.		

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Brain Tumors			
Medulloblastoma			
Standard Risk			
	To determine the proportion of patients with each histopathological disease type of CNS embryonal tumor (desmoplastic/nodular medulloblastoma, classic medulloblastoma, anaplastic/large cell medulloblastoma; pineal region PNET or pineoblastoma, non-pineal region supratentorial-PNET and other CNS PNET) cured without the need of CNS irradiation. To determine the prevalence and severity of therapy-related hearing loss between study arms as a function of cumulative dosing of cisplatin (three versus five cycles during Induction) and AuHPCR (one versus three tandem transplants in Consolidation) and to evaluate Distortion-Product Oto-acoustic Emissions (DPOAE) as an early predictor of hearing loss to identified at-risk patients. To determine the long-term endocrine functions and physical growth, as well as incidence of development of second neoplasms, in children treated on this protocol. To compare the toxicity and quality of life (QoL) effects of single versus tandem HDCx cycles.		
SJMB12 A Clinical and Molecular Risk-Directed Therapy for Newly Diagnosed Medulloblastoma	http://clinicaltrials.gov/ct2/show/NCT01878617	,	
Recurrent Medulloblastoma and Primitive Neuroectodermal Tumor Adoptive T Cell Therapy During Recovery from Myeloablative Chemotherapy and Hematopoietic Stem Cell Transplantation	http://clinicaltrials.gov/ct2/show/NCT01326104 Immunotherapy is a specific approach to treating cancer that has shown promise in adult patients for the treatment of melanoma, malignant brain tumors, and other cancers. The study investigators will use the experience they have gained from these studies to try to improve the outcome for children affected by a recurrent brain tumor.	,	Marcia Hodik 352-273-6971 marcia.hodik@neurosurgery.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Brain Tumors			
PNET			
Recurrent Medulloblastoma and Primitive Neuroectodermal Tumor Adoptive T Cell Therapy During Recovery from Myeloablative Chemotherapy and Hematopoietic Stem Cell Transplantation	http://clinicaltrials.gov/ct2/show/NCT01326104 Immunotherapy is a specific approach to treating cancer that has shown promise in adult patients for the treatment of melanoma, malignant brain tumors, and other cancers. The study investigators will use the experience they have gained from these studies to try to improve the outcome for children affected by a recurrent brain tumor.	,	Marcia Hodik 352-273-6971 marcia.hodik@neurosurgery.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
<opening soon> 18752 ACTION Trial Adoptive Cellular Therapy following Dose-Intensified Temozolomide in Newly-diagnosed Pediatric High-grade Gliomas (Phase I).	Primary To determine the safety of adoptive cellular therapy in pediatric patients with HGG receiving dose intensified TMZ and DC+xALT therapy with and without HSCs. Secondary Examine feasibility of completing treatment in enrolled subjects; Comparison of baseline to post-immunotherapy functional anti-tumor immune responses; and Analysis of progression-free survival and overall survival after treatment with DC + xALT therapy with and without HSCs.	,	
CA209-908 Phase Ib /II Clinical Trial of Nivolumab Monotherapy and Nivolumab in Combination with Ipilimumab in Pediatric Subjects with High Grade Primary CNS Malignancies	http://clinicaltrials.gov/ct2/show/NCT03130959 Primary - Safety Lead In To estimate the safety and tolerability of study treatment in pediatric participants with primary high- grade CNS tumors. Secondary - Safety Lead In To describe any observed anti-tumor activity of study treatment in pediatric primary high grade CNS tumors.	,	Jennifer King 352-294-8374 Jennifer.King@neurosurgery.ufl.edu
CC-4047-BRN-001 A Phase 2 Clinical Study of Pomalidomide (CC-4047) Monotherapy for Children and Young Adults with Recurrent or Progressive Primary Brain Tumors	http://clinicaltrials.gov/ct2/show/NCT03257631 The primary objective of the study is: To identify potential tumor type(s) for further development by establishing the preliminary efficacy of pomalidomide in children and young adults with recurrent or progressive primary brain tumors within four distinct tumor types. The secondary objectives are: To evaluate the safety (type and rate of treatment-related toxicity) of pomalidomide within the study populations. To estimate the long-term efficacy of pomalidomide treatment. The exploratory objectives are: To characterize the PK of pomalidomide in children and young adults with recurrent or progressive primary brain tumors.	,	Jennifer King 352-294-8374 Jennifer.King@neurosurgery.ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Leukemias			
Acute lymphoblastic leukemia (ALL)			
B Precursor			
High Risk			
18424-269 A Phase 2 Study of the JAK1/JAK2 Inhibitor Ruxolitinib With Chemotherapy in Children With De Novo High-Risk CRLF2-Rearranged and/or JAK Pathway-Mutant Acute Lymphoblastic Leukemia	http://clinicaltrials.gov/ct2/show/NCT02723994 To evaluate intial safety and tolerability and to define the recommended Part 2 dose of ruxolitnub in combination with multi-agent chemotherapy in children and adolescents or young adults wiht de novo high-risk Philadelphia Chromosome-like (ph-like) cytokine receptor-like factor 2 rearranged and/or Janus kinase pathway-mutant B-cell ALL.	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu
AALL0932 Treatment of Patients with Newly Diagnosed Standard Risk B - Lymphoblastic Leukemia or Localized B-Lineage Lymphoblastic Lymphoma (B-LLY)	http://clinicaltrials.gov/ct2/show/NCT01190930 This partially randomized phase III clinical trial is studying different combinations of risk-adapted chemotherapy regimens and their side effects and comparing how well they work in treating younger patients with newly diagnosed standard-risk acute lymphoblastic leukemia. Drugs used in chemotherapy work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Giving more than one drug (combination chemotherapy), giving the drugs in different doses, and giving the drugs in different combinations may kill more cancer cells.	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu
Relapsed			
<opening soon> AALL1621 A Phase 2 Study of Inotuzumab Ozogamicin (NSC# 772518) in Children and Young Adults With Relapsed or Refractory CD22+ B-Acute Lymphoblastic Leukemia (B-ALL)	http://clinicaltrials.gov/ct2/show/NCT02981628 To determine the morphologic response rate (complete response [CR] + complete response with incomplete hematologic recovery [CRi]) following one cycle of treatment with inotuzumab ozogamicin (InO) in children with relapsed or refractory CD22+ B acute lymphoblastic leukemia (B-ALL).	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu
T-Cell			

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Leukemias			
Acute lymphoblastic leukemia (ALL)			
T-Cell			
AALL1231 A Phase III Randomized Trial Investigating Bortezomib (NSC# 681239; IND# 58443) on a Modified Augmented BFM (ABFM) Backbone in Newly Diagnosed T- Lymphoblastic Leukemia (T-ALL) and T-Lymphoblastic Lymphoma (T-LLy)	http://clinicaltrials.gov/ct2/show/NCT02112916 To compare EFS in patients with newly diagnosed T-ALL and T-LLy who are randomized to a modified ABFM backbone versus bortezomib plus the modified ABFM backbone.	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu
Biology Studies			
ALTE11C2 Health Effects after Anthracycline and Radiation Therapy (HEART): Dexrazoxane and Prevention of Anthracycline-related Cardiomyopathy	http://clinicaltrials.gov/ct2/show/NCT01790152 To determine whether patients randomized to the experimental DRZ arms have decreased markers of CHF compared with patients on the standard arm. To evaluate whether the cardioprotective effect of DRZ is modified by anthracycline dose, chest radiation, and demographic factors (age at cancer diagnosis, current age, sex). To determine whether patients on the DRZ arms experienced differential rates of overall-survival and event-free survival compared with the standard therapy arms. To determine whether projected quality-adjusted life years (QALY) differed by randomization status, accounting for premature cardiac disease, primary disease relapse, and 2nd cancers.	,	Beate Oltman Greer 352-294-8744 bgreer01@ufl.edu
AALL08B1 Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (ALL)	http://clinicaltrials.gov/ct2/show/NCT01142427 This research trial studies a risk-based classification system for patients with newly diagnosed acute lymphoblastic leukemia. Gathering health information about patients with acute lymphoblastic leukemia may help doctors learn more about the disease and plan the best treatment.	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Lymphomas			
Non-Hodgkin's lymphoma (NHL)			
Biology Studies			
ALTE11C2 Health Effects after Anthracycline and Radiation Therapy (HEART): Dexrazoxane and Prevention of Anthracycline-related Cardiomyopathy	http://clinicaltrials.gov/ct2/show/NCT01790152 To determine whether patients randomized to the experimental DRZ arms have decreased markers of CHF compared with patients on the standard arm. To evaluate whether the cardioprotective effect of DRZ is modified by anthracycline dose, chest radiation, and demographic factors (age at cancer diagnosis, current age, sex). To determine whether patients on the DRZ arms experienced differential rates of overall-survival and event-free survival compared with the standard therapy arms. To determine whether projected quality-adjusted life years (QALY) differed by randomization status, accounting for premature cardiac disease, primary disease relapse, and 2nd cancers.	,	Beate Oltman Greer 352-294-8744 bgreer01@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Neuroblastoma			
<opening soon> ALTE15N2 LEAHRN (Late Effects After High-Risk Neuroblastoma) Study	http://clinicaltrials.gov/ct2/show/NCT03057626 PRIMARY OBJECTIVES: I. To estimate the prevalence of organ dysfunction, subsequent malignant neoplasm (SMN), growth impairment, abnormal pubertal development, and neurobehavioral dysfunction in a large cohort of representative 5-year survivors of high-risk neuroblastoma treated with modern therapy. II. To identify the demographic, clinical and treatment-related risk factors associated with increased risk of organ dysfunction, SMN, growth impairment, abnormal pubertal development and neurobehavioral dysfunction in long-term survivors of high-risk neuroblastoma. III. To explore the impact of new biologic therapies and diagnostics including immunotherapy, immunocytokines, isotretinoin (cis-retinoic acid) and iobenguane I-131 (131 I-MIBG) on the risk of late effects. IV. To determine the impact of impaired organ function, physical growth, pubertal development, and neurobehavioral function on health-related quality of life (HRQOL) in long-term survivors of high-risk neuroblastoma.	,	
ANBL1232 Utilizing Response- and Biology-Based Risk Factors to Guide Therapy in Patients with Non-High-Risk Neuroblastoma	http://clinicaltrials.gov/ct2/show/NCT02176967 This phase III trial studies how well response and biology-based risk factor-guided therapy works in treating younger patients with non-high risk neuroblastoma. Sometimes a tumor may not need treatment until it progresses. In this case, observation may be sufficient. Measuring biomarkers in tumor cells may help plan when effective treatment is necessary and what the best treatment is. Response and biology-based risk factor-guided therapy may be effective in treating patients with non-high risk neuroblastoma and may help to avoid some of the risks and side effects related to standard treatment.	,	Ashley Bayne 352-294-8745 abayne@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Sarcomas			
Correlative			
D9902 A COG Soft Tissue Sarcoma Diagnosis, Biology and Banking Protocol	http://clinicaltrials.gov/ct2/show/NCT00919269 The purpose of this study is to collect and store tumor tissue, blood, and bone marrow samples from patients with soft tissue sarcoma that will be tested in the laboratory. Collecting and storing samples of tumor tissue, blood, and bone marrow from patients to test in the laboratory may help the study of cancer.	,	Ashley Bayne 352-294-8745 abayne@ufl.edu
Ewings			
AEWS1221 Randomized Phase II Trial Evaluating the Addition of the IGF-1R Monoclonal Antibody Ganitumab (AMG 479, NSC# 750008, IND# 120449) to Multiagent Chemotherapy for Patients with Newly Diagnosed Metastatic Ewing Sarcoma	http://clinicaltrials.gov/ct2/show/NCT02306161 To compare the event-free survival (EFS) in patients with newly diagnosed metastatic Ewing sarcoma treated with multiagent chemotherapy with and without the addition of ganitumab (AMG 479).	,	Ashley Bayne 352-294-8745 abayne@ufl.edu
Osteosarcoma			
Recurrent			
AOST1421 A Phase II Study of Human-Mouse Chimeric Anti-Disialoganglioside Monoclonal Antibody ch14.18 (Dinutuximab, NSC# 764038, IND# 4308) in Combination with Sargramostim (GM-CSF) in Patients with Recurrent Osteosarcoma	http://clinicaltrials.gov/ct2/show/NCT02484443 To determine the disease control rate in patients with completely resected recurrent osteosarcoma treated with ch14.18 (dinutuximab) in combination with sargramostim (GM-CSF) as compared to historical COG experience.	,	Ashley Bayne 352-294-8745 abayne@ufl.edu
Soft Tissue			

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Sarcomas			
Soft Tissue			
ARST1321 Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (NSC# 737754, IND# 118613)	http://clinicaltrials.gov/ct2/show/NCT02180867 This randomized phase II/III trial studies how well pazopanib hydrochloride, combination chemotherapy, and radiation therapy work and compares it to radiation therapy alone or in combination with pazopanib hydrochloride or combination chemotherapy in treating patients with newly diagnosed non-rhabdomyosarcoma soft tissue sarcomas that can be removed by surgery. Radiation therapy uses high energy x rays to kill tumor cells. Drugs used in chemotherapy, such as ifosfamide and doxorubicin hydrochloride, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Pazopanib hydrochloride may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. It is not yet known whether radiation therapy works better when given with or without combination chemotherapy and/or pazopanib hydrochloride in treating patients with non-rhabdomyosarcoma soft tissue sarcomas.	,	Ashley Bayne 352-294-8745 abayne@ufl.edu
ALTE11C2 Health Effects after Anthracycline and Radiation Therapy (HEART): Dexrazoxane and Prevention of Anthracycline-related Cardiomyopathy	http://clinicaltrials.gov/ct2/show/NCT01790152 To determine whether patients randomized to the experimental DRZ arms have decreased markers of CHF compared with patients on the standard arm. To evaluate whether the cardioprotective effect of DRZ is modified by anthracycline dose, chest radiation, and demographic factors (age at cancer diagnosis, current age, sex). To determine whether patients on the DRZ arms experienced differential rates of overall-survival and event-free survival compared with the standard therapy arms. To determine whether projected quality-adjusted life years (QALY) differed by randomization status, accounting for premature cardiac disease, primary disease relapse, and 2nd cancers.	,	Beate Oltman Greer 352-294-8744 bgreer01@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Stem Cell Transplant			
Abatacept Combined with a Calcineurin Inhibitor and Methotrexate for Graft Versus Host Disease Prophylaxis	http://clinicaltrials.gov/ct2/show/NCT01743131 The investigators are doing this study to see if a new drug, abatacept, can be used together with a calcieneurin inhibitor (cyclosporine or tacrolimus) and methotrexate to provide better protection against Acute Graft versus Host Disease (aGvHD) without causing more infections.	,	Meghan Vazquez 352-273-6843 meghanvazquez@ufl.edu
MSB-GVHD001 A Single-arm, Prospective Study of Remestemcel-L, Ex-vivo Cultured Adult Human Mesenchymal Stromal Cells, for the Treatment of Pediatric Patients Who Have Failed to Respond to Steroid Treatment for Acute GVHD	http://clinicaltrials.gov/ct2/show/NCT02336230 1.To evaluate the efficacy of remestemcel-L in pediatric subjects with Grades B-D aGVHD who have failed to respond to steroid treatment post allogeneic HSCT 2. To gather additional information on the safety of remestemcel-L in pediatric subjects with Grades B-D aGVHD that have failed to respond to steroid treatment post allogeneic HSCT	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu

UF HEALTH CANCER CENTER
ACTIVE CLINICAL TRIALS BY DISEASE TYPE

Study Title	Study Summary	Study Physician	Study Contact
Supportive Care			
ALTE1621 Pharmacologic Reversal of Ventricular Remodeling in Childhood Cancer Survivors at Risk for Heart Failure (PREVENT-HF): A Phase 2b Randomized Placebo-Controlled (Carvedilol) Trial	http://clinicaltrials.gov/ct2/show/NCT02717507 To determine the impact of a two-year course of low-dose carvedilol on surrogate echocardiographic indices of heart failure (HF) risk, including: Left Ventricular (LV) Posterior Wall Thickness-Dimension Ratio (LV T-D) a wellestablished index of early myocardial remodeling and subsequent HF risk (primary endpoint). LV systolic and diastolic function, and afterload established echocardiographic indices associated with HF risk. Natriuretic peptides, troponins, and Galectin-3 - circulating biomarkers associated with myocardial injury, and HF risk.	,	Beate Oltman Greer 352-294-8744 bgreer01@ufl.edu
CMX001-351 An Intermediate-size, Expanded Access Protocol to Provide Brincidofovir for the Treatment of Serious Adenovirus Infection or Disease	http://clinicaltrials.gov/ct2/show/NCT02596997 1. To provide patients with serious AdV infection or disease access to treatment with BCV. 2. To obtain information on the frequency of treatment discontinuations due to BCV-related AEs in patients treated for serious AdV infection or disease. 3. To collect all-cause mortality and treatment outcome data in patients treated with BCV for serious AdV infection or disease. 4. To assess the relationship between mutations associated with viral resistance to BCV and treatment response to BCV.	,	Ashley Bayne 352-294-8745 abayne@ufl.edu
MSB-GVHD001 A Single-arm, Prospective Study of Remestemcel-L, Ex-vivo Cultured Adult Human Mesenchymal Stromal Cells, for the Treatment of Pediatric Patients Who Have Failed to Respond to Steroid Treatment for Acute GVHD	http://clinicaltrials.gov/ct2/show/NCT02336230 1.To evaluate the efficacy of remestemcel-L in pediatric subjects with Grades B-D aGVHD who have failed to respond to steroid treatment post allogeneic HSCT 2. To gather additional information on the safety of remestemcel-L in pediatric subjects with Grades B-D aGVHD that have failed to respond to steroid treatment post allogeneic HSCT	,	Heather Rogers 352-294-8743 heatherrogers@ufl.edu